# Medical | Writing

# Mentorship

### Also in this issue...

- The ABCs of paediatric plain language summaries
- Presenting secondary endpoints in plain language clinical trial result summaries: Considerations for emerging practice
- AMWA-EMWA-ISMPP Joint Position Statement on Medical Publications, Preprints, and Peer Review

**EMWA** EUROPEAN MEDICAL WRITERS ASSOCIATION

# Medical Writing

## Mentorship

Mentorship is a topic very close to my heart. If it were not for the numerous mentors in both my academic and professional life, I would not be here today. The definition of mentorship is subjective and how a mentor operates is often up to those involved. Before I took on this role, my own mentor, this journal's Editor-in-Chief Raquel Billiones, and I were concocting our perspectives on mentorship – that of a mentor and a mentee from two different generations.

### What does mentorship mean to you?

*Raquel (Boomer):*
The tradition of passing on knowledge from one generation to the next goes back thousands of years, when the master craftsman took on their first apprentice to pass on the secrets of their trade. Nowadays, knowledge transfer in the professional environment comes in many different forms, the most popular of which is mentorship.

A clear definition of mentorship remains elusive. The group Catalyst tries to capture its essence by distinguishing it from other professional relationships: "A coach talks to you, a sponsor talks about you, and a mentor talks with you."[1] However, these delineations become blurred as the roles tend to overlap. I favour the quote attributed to John Crosby: "Mentoring is a brain to pick, an ear to listen, and a push in the right direction."

*Clare (Generation Y):*
I like to think of mentorship as a journey two people take together. The mentor may share their experience to help their mentee navigate their career while the mentee may provide perspectives on how a different generation or a different workforce may think and what they value so that the mentor can apply that to their work interactions too. It is a peculiar journey because both will need to work hard (especially when their lives

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have no overlaps or when they have no mutual connections or activities) to maintain the bond between them; yet it is also the lack of overlap that allows the relationship to be freeing due to minimal conflicts of interest so that the two can speak their minds (while remaining professional, of course).

As evidenced by the collection of articles in this issue of *Medical Writing*, the mentorship experience is shared among many of us. We explore personal stories from both mentors and mentees providing a glimpse of their experiences.

The point of origin into the world of mentorship, medical writing, or industry is often academia. **Selma Reguieg and Diana Ribeiro** shed light on what it is like to be a mentor in academia. **Alejandra Viviescas** then takes us on her personal journey from academia to mentorship that eventually led her into medical writing.

The definition of a mentorship is diverse and subjective. Who can be a mentor is also up for interpretation: those with connections to the mentee or mentors' career and those without. **Surayya Taranum** provides an overview of the mentorship process and how to make the most of the journey. **Jackie Raskind** dissects the anatomy of successful mentors and mentees for a successful mentoring relationship. **Sarah Tilly, Adrian Tilly, and Somsuvro Basu** focus on the human side that drives the success of the mentorship experience. Then we come to the question of the line manager or a leader's role and

**GUEST EDITOR**

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### About the Guest Editor

**Clare Chang, PhD**, is Principal Medical Communication Scientist at AstraZeneca in Shanghai, China, focussed on regulatory medical writing. She has been a proud EMWA member since 2017. She would like to thank Editor-in-Chief Raquel Billiones and Editor Emeritus Phil Leventhal for the wonderful opportunity to guest edit this issue.

how they may contribute towards their teams' successes as mentors. **Mengmeng Qiao** discusses the similarities and differences between a mentor and a line manager. **Ivana Turek** sheds light on how a great mentor can be a great leader and vice versa. **Shiri Diskin** shares her thoughts on mentoring young professionals in industry from a manager's perspective.

In essence, the success of a mentorship is in seeing the person behind the title to overcome the hierarchical relationship and thereby finding friendship. Meetup sessions are a good place to get to know each other and build rapport. Traditionally, these sessions occur face-to-face. However, with the explosion of video conferencing platforms (especially with COVID-19), virtual mentoring has become an option. **Julie Ely** discusses this modern form of mentorship – how to establish virtual relationships and the perks of virtual mentorships.

The mentor-mentee relationship may come in different forms. Formal mentorship programmes are those run by a third party such as a mentoring programme within a company or a professional organisation. There are often guidelines for those who enroll and candidates can either look for potential mentors/mentees through a self-service portal or are matched by programme administrators. **Lillian Sandø and Bjarke Stokholm Stærkind** describe their experience in a cross-functional mentorship in a company and the benefits of such a programme. **Elena Kyria and Karen Münz** describe a cross-organisational mentorship programme to help mentees grow within their specialised area of regulatory medical writing. The alternative to mentorship programmes are informal mentorships, which are relationship-based mentorships where individuals develop rapport and friendship, that lead to a mentorship.

Finally, breaking away from the traditional (one-on-one) mentoring model, other mentoring models are now growing too, including peer mentoring and having a team of mentors.

**Susanne Trillingsgaard Venø** describes her mentorship journey, which started with a university mentorship programme that later progressed to forming a team of mentors providing expertise she needed as an entrepreneur in a startup.

I would like to end my introduction with a very big thank you to all the contributors for this issue. It has been an honour to serve as the guest editor, and I have learned so much from your stories. I hope the readers will enjoy reading them as much as I have!

## References:

1. Catalyst. Coaches, mentors, and sponsors: understanding the differences.2019 [cited 2012 Dec 12]. Available from: https://www.catalyst.org/wp-content/uploads/2014/12/Mentor_Sponsor_Coach.pdf.

**Clare Chang**

# Meet & Share Session with the MedComms-SIG

Have you ever faced a situation when authors or sponsors of a publication did not want to acknowledge you as medical writer?

Have you ever been asked to add an author who has not participated in the study and the article's preparation?

Have you ever had issues with publication conclusions that are not substantiated by clinical data?

In our first Meet & Share session, we will discuss strategies and experiences when communicating with investigators and sponsors of biomedical publications.

Are there any other challenges you would like to discuss? Please email info@emwa.org and we will add it to the agenda. Please also email any other topic you would like to see in the MedComms Meet & Share Sessions.

**The session will be held on Wednesday, July 14, 2021, from 5 to 6 pm CEST.**
Email info@emwa.org to receive the Zoom link.

Want to have that paperless *Medical Writing* experience? You can opt out from receiving the paper copy by logging in your EMWA profile and unticking the hard copy checkbox under Preferences.

## From the Editor

# EMWA and *Medical Writing*
## 12 months into the pandemic

What a year! A year of corona, crisis, and challenges. But also a year of innovations, break-throughs, and opportunities. I am one to focus on silver linings and here are some to think about.

I am immensely proud of being part of an industry that stepped up to the challenge to innovate and accelerate development, testing, and approval of COVID-19 treatments and vaccines at warp speed. In parallel, we did not stop the other work we were doing. The pharma industry continued to serve other patients in need of essential medicines and medical devices.

I am also very proud of being part of a professional organisation that is resilient and robust enough to brave the pandemic and Brexit, and bounce back stronger than ever. As Magic Johnson once said, "When you face a crisis, you know who your true friends are." Amidst job hunting and lockdowns, I have seen who my true friends were. They were the EMWA Executive Committee (EC), the Education Committee, the Editorial Board, the Special Interest Groups (SIGs), the Head Office team, the volunteers, the conference attendees, and the EMWA membership. The totality of EMWA became my circle of friends in a virtual world.

In particular, I would like to call out the EC members, most especially past President Beatrix Doerr and incoming President Carola Krause. In early 2020, they were blissfully unaware of the corona clouds on the horizon that would rain on their terms. But to slightly rephrase a quote from Martin Luther King, Jr.: "The ultimate measure of a leader is not where s/he stands in the moments of comfort, but where s/he stands at times of challenge and controversy." Bea and Carola, Sarah Choudhury, Claire Hamner, Slavka Baróniková, Marian Hodges, Maria Almeida, Diarmuid De Faoite, and Phil Leventhal (who will forever be known as the "virtual" EMWA EC of 2020-2021) proved their true measure in the last 12 months. Thank you very much for keeping this organisation alive under the most challenging circumstances.

The previous EC members did not sign up for dealing with COVID-19 during their terms, but they did not have a choice. The newly elected EC members did, having seen the challenges of the past 12 months and the uncertainty of what is ahead. Yet, they did not shy away from serving the organisation. Welcome and chapeau! to Satyen Shenoy and Som Basu for their courage.

Finally, I would also like to welcome new additions to our editorial team, many of whom I have only met virtually:

- Jonathan Pitt has been co-editor since February 2021.
- Amy Whereat has been associate editor since February 2021.
- Jennifer Bell, Petal Smart, and Daniela Nakagawa are our new associate editors .
- Aurélie Gobet and Paolo Rega revived the Gained in Translation section this year.
- Kimi Uegaki is section editor of The Crofter: Sustainable Communications (launched in March 2021).
- Nicole Bezuidenhout is section editor of Digital Communication (launched in June 2021).
- Ivana Turek will be section editor of Getting Your Foot in the Door as of September 2021.
- Jennifer Bell and Louisa Marcombes will be section editors of Veterinary Writing starting September 2021.
- Tiziana von Bruchhausen will be launching the Pharmacovigilance section in September 2021.

*Thank you to all our editors, old and new. We will continue to survive and thrive due to your efforts.*

**Raquel Billiones**
Editor-in-Chief
editor@emwa.org

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### *Medical Writing* in Numbers

| Medical Writing | Medical Writing | Medical Writing | Medical Writing |
|---|---|---|---|
| The data economy | European Union regulations | Writing for patients | Social media |

**June 2020 – May 2021**
#### 4 themed issues

- Data economy ● EU regulations ● Writing for patients ● Social media
| 394 pages | 44 feature articles | 18 regular sections |
27 editorial team members from 16 countries in 4 continents

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# Presidents' Messages

## From EMWA's new President Carola Krause
### 2021–2022

A year of EMWA firsts has passed and while we are still not in a post-pandemic phase, one can see that our profession has regained its momentum.

In the past, you might have experienced the need to explain to family members and friends what "medical communications" is all about. I, at least, always received the same reaction: "People pay money for the services you provide?" Well, that perception has changed with the pandemic. Not only is there a better public understanding but actually an appreciation of professional medical writing and communications. In other words, societies associate a certain value to the services medical writers and communicators provide.

Professional, fact-checked medical communi-cations became a key element in this pandemic. However, the toolkit to com-municate medical facts has expanded and adapted to the individual audiences. Nowadays, medical communications utilise not only the written word but also audio and visual communications. Particularly, podcasts, info-graphics, and social media are becoming very popular tools to communicate medical facts.

It is interesting to see that medical communi-cation is no longer seen as unidirectional. Engaging audiences is now state of the art. I believe that our profession has benefited from the pandemic, but with the increased public aware-ness, the demands on our profession have grown. Therefore, the question arises how EMWA adapts to this ever-changing world of medical writing and communications.

Over the next few months, we aim to revisit the role of medical writers and communicators and emphasise an update of the AMWA-EMWA-ISMPP Joint Positions Statement on the Role of Professional Medical Writers.[1]

Additionally, I am very happy to announce that we will have two new Special Interest Groups (SIGs) within EMWA: the Business Develop-ment SIG (#EMWABDSIG; chaired by Allison Kirsop) and Communicating with the Public SIG (#EMWACWPSIG; chaired by Lisa Chamberlain James).

We also aim to broaden the possibilities for our newbies. We are expanding the 'Getting into Medical Writing' conference sessions to year-long activities to increase awareness of our profession. Whereas the Ambassador's Pro-gramme is an outreach initiative, the 'Getting into Medical Writing' activities (chaired by Evguenia



The EMWA Universe 2021

May Conference

November Conference

Medical Writing Journal

Special Interest Groups

PR Activities

Ambassador's Programme

Getting Into Medical Writing

Webinars

| | Educational Activities | | Networking Activities | | Other Activities | | Special Interest Groups | |
|---|---|---|---|---|---|---|---|---|
| ● Conferences | ● Workshops | ● Freelance Business Forum | ● EMWA Annual Meeting | ○ Reg. Public Disclosure | ○ Veterinary Writing |
| | ● Symposium | ● Networking Sessions | ● Nick Thomson Award | ○ Medical Communications | ○ Pharmacovigilance |
| | ● Experts Seminar Series | ● Getting Into Medical Writing | ● Geoff Hall Scholarship | ○ Medical Devices | ○ Communicating with the Public |
| | | ● Meet & Share Sessions | ● Mindfulness Session | ○ Sustainability | ○ Business Development |
| | | | ● Yoga Session | | |

1. https://www.ismpp.org/assets/docs/Inititives/amwa-emwa-ismpp%20joint%20position%20statement%20on%20the%20role%20of%20professional%20medical%20writers_january%202017.pdf )

Alechine) aims to attract people directly to EMWA activities and the educational programme. Thereby, we foresee broadening EMWA's educational offers by extending the portfolio of foundation and advanced workshops. Additionally, EMWA will launch a podcast series called 'Tab Key', initiated and run by members of the Freelance Business Group (chaired by Laura Kehoe).

Like the universe, EMWA is expanding. EMWA membership numbers have grown substantially within the last year, from 600 members in May 2020 to 1100 members in May 2021. The demand for EMWA's professional development programme (EPDP) is very high. However, it appears to me that the networking opportunities as well as the personal and cultural exchange within our community are as valuable as the EPDP. We aim to maintain EMWA's personal touch through a variety of year-long virtual and face-to-face activities. An up-to-date overview of EMWA's year-long activities can be found in the infographic 'The EMWA Universe (2021)'.

As our professional community is growing, EMWA's responsibilities are growing as well. EMWA requires a framework of good practice which we aim to develop through a Code of Conduct.

Please feel free to follow EMWA's activities on our website, social media channels, and our journal, *Medical Writing.* If you wish to actively participate in our activities, you can send us a message via info@emwa.org.

Hopefully, we will enter a post-pandemic phase within this summer which allows for future face-to-face or hybrid conference.

I am very much hoping to see you all in person in Cascais in 2021!

Carola
president@emwa.org

## From EMWA's Outgoing President Beatrix Doerr
### 2020–2021

Time to say goodbye! After having served on EMWA's Executive Committee (EC) for six years in various roles, my term ended at our Spring conference in May. These have been rewarding years, with lots of work, but also lots of unforgettable experiences and memories.

I now want to take the opportunity to share some personal words. First, I want to thank the EC members for their support in these challenging COVID-19 times. I will truly miss you! Luckily, vaccinations are speeding up so that I hope that we can see each other soon. I also want to thank our people at the EMWA Head Office, particularly Debra Cairncross and Claire Whittingham, for their continuous support. Thank you, too, to all EMWA volunteers who are the backbone of our organisation.

Lastly, I want to thank all EMWA members. Thank you for being so kind and friendly, which makes EMWA unique. And thank you for helping me keep the faith that there are still smart people out there. Particularly in these times when hate and ignorance seem to have gained the upper hand, it is a blessing to have smart and kind people like you around.

Please hold on to your kindness. One of my favourite sayings is: "In a world where you can be everything – be kind." Another credo I live by is

> We need to do our part to provide reliable information and (re)establish trust in science.

that there are two ways of enlarging your business: either take it from your competitors or expand your business opportunities. I live by the latter and this is the spirit I feel during our conferences, face-to-face or virtual. This is what makes EMWA unique. I hope that during my presidency, we have enlarged the business opportunities of medical writers/communicators. And there is more to come!

So let's aim to combat hate with kindness, and let's combat misinformation with accurate information. Continue to be kind, but be firm, and stand up when needed. Hold your ground when it comes to defending good scientific practice.

With the pandemic, misinformation grew. In the current environment, our role in science communication is more important than ever. We need to do our part to provide reliable information and to (re)establish trust in science. To adequately inform patients, lay language and virtual aids are increasingly important. With my successor Carola Krause, you have a president well-equipped and qualified to prepare EMWA for these tasks and to transform it to an even more inclusive "Medical Writers and Communicators Association 2.0."

It was an honour to serve you as president. I will continue to serve EMWA as a volunteer, but for now, I plan to take the time to travel around in our camping bus again. Over and out!

Kindly,
**Bea**

# EMWA News

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## AMWA-EMWA-ISMPP Joint Position Statement on Medical Publications, Preprints, and Peer Review

The AMWA-EMWA-ISMPP Position Statement on Medical Publications, Preprints, and Peer Review, published in *Current Medical Research and Opinion* (CMRO), provides recommendations to protect the integrity of published scientific and medical research.

The Joint Position Statement has been developed to provide practical and implementable suggestions to uphold data integrity and quality and the transparency of medical publications.

The full text of the statement is reprinted in this issue on p. 68.

## #EMWA BuzzItUP Initiative

The #EMWA-BuzzItUp initiative aims to provide one Buzzword – relevant to the Medical Writing /Communications community – every week to our EMWA members via EMWA's LinkedIn channel. After posting the Buzzword, we aim to moderate the post with additional online information such as links, comments, videos, and graphics. This way, we would like to increase awareness and proactive engagement on individual topics among our community.

## EMWA journal updates

We have two new regular journal sections for 2021:
- The Crofter: Sustainable Communications, with Kimi Uegaki as section editor
- Digital Communication, with Nicole Bezuidenhout as section editor

In addition, we have revived Gained in Translation, with Aurélie Gobet/Paolo Rega as section editors!

Do you know that we now provide the option to be completely paperless? You can opt out of receiving a paper copy of the journal by going into your membership profile.

New contents, nifty art covers, snazzy fonts! We are soliciting input, ideas, and suggestions on enhancing the "look" of our journal. Please share your thoughts and drop us a line at editor@emwa.org.

## Good news for EMWA members based in France

We are delighted to say that after a lot of hard work and dedication from two of our EMWA members, Stéphane and Marielle Romet, and assistance from our former Honorary Secretary Claire Harmer, EMWA is now Datadock-registered. In order to be accepted for Datadock registration, EMWA had to prove it met Datadock's 21 stringent criteria on the quality and variety of training offered, corresponding assessments, teaching programme, current objectives, and plans for the future. We also had to give evidence of EMWA's educational tools, techniques, and management of the available training. This is a considerable achievement which we hope will help some of our members a great deal. It means that EMWA members based in France will be able to apply for a subsidy to attend EMWA conferences and participate in training activities as part of their allocated CPD costs, provided that they are registered with an official, approved organisation in France that supports vocational training (an OPCO or 'Opérateur de Compétence'). If you are based in France and would like more information on how to apply, please contact the Opérateur de Compétence you are affiliated with.

## Scam EMWA e-mail: please be vigilant

We have been made aware of a scam e-mail purporting to come from someone connected to EMWA.

Please report anything suspicious you receive to Head Office (info@emwa.org). Do not respond with any personal or payment information.

Thank you for your vigilance on this issue.

## Bulgarian and Czech translations of the Joint Position Statement (JPS) on Predatory Journals

We are proud to announce the posting of the first JPS translations into Bulgarian and Czech.

Mariya Dobreva translated the JPS into Bulgarian with editing and review by Irina Dobreva and Ivailo Alexiev. The translation is available on the EMWA website: https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/Bulgarian/.

Marcela Covic Sr. & Marcela Covic Jr. translated the JPS into Czech. Read the Czech translation on the EMWA website: https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/czech/

We are currently looking for translators. If you would like to volunteer, please contact Head Office (info@emwa.org) or Abe Shevack (aspscientist@gmail.com).

## Certificates for webinars

If you attend a live webinar, you can now request a certificate of attendance. Simply e-mail info@emwa.org to order your certificate in exchange for an administrative fee of 20€. Please note, at present, this is only an option for live, but not for archived, webinars.
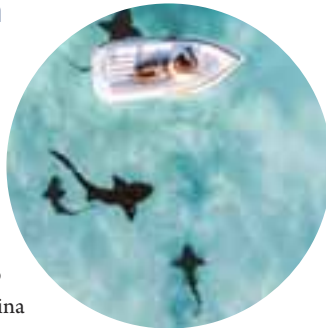
## EMWA Ambassador's Programme

The EMWA Ambassador's Programme is continuing to reach out to new audiences even in these trying times to promote medical writing and EMWA.

On February 10, 2021, Claire Gudex gave a virtual presentation on becoming a medical writer for a group of PhD candidates attending the University of Southern Denmark in Odense. The students found the presentation helpful, and Claire will be repeating this talk in the near future to interested students.

On February 26, 2021, Abe Shevack held a virtual presentation on careers in medical writing and the benefits of joining EMWA for members of the Science and Medical Writing Network in the Netherlands organised by Sally Hill. Altogether 16 participants were online for the talk. Abe spoke for half an hour, followed by an interesting and lively Q&A session

On March 11, 2021, Alison Rapley gave a well-received virtual presentation on medical writing combined with a workshop on improving writing skills to 20 attendees (40 were on the waiting list) for the University College, London (UCL) during their annual Life Sciences Career Week. The session was well organised, with questions raised through the chat function, managed by UCL, that were answered at specific points during the presentation. A recording of the session was made available to those unable to attend, and exercises were mailed out after the virtual session with a provided answer sheet.

If you are an experienced medical writer and EMWA volunteer and are interested in becoming an EMWA Ambassador, or if you know of any upcoming career events in your locality, please contact Head Office (info@emwa.org) or Abe Shevack (aspscientist@gmail.com).

## Credly badges

Have you gained a foundation or advanced certificate and want to display it more prominently as an electronic certificate on LinkedIn, your website, and e-mails? Then contact Head Office at info@emwa.org.

# Mentorship from the inside

**Selma Reguieg**[1], **Diana Ribeiro**[2]
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[2] Independent Medical Writer

## Correspondence to:
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## Abstract

In this article we interview **Jose Francisco Sanchez Herrero** from the Germán Trias i Pujol Institute in Badalona. He is Selma's tutor and gives us a glimpse of what it is like to be a mentor in an academic setting. If there is one thing we learned from the interview, it is that mentoring can help us achieve goals we might not accomplish otherwise.

Like any good race, life is so much better when you have someone cheering from the sidelines. During the rough parts they are a reminder of why you wanted to be there, and in the good parts they celebrate with you. That is why many academic programmes have a mentoring element, sometimes also called tutoring.

In this piece, we benefitted from Selma's recent involvement in a new academic pursuit to interview her new tutor, Jose Francisco Sanchez Herrero. We are thrilled to bring you this story, and we hope it will bring some insight into the life of a mentor. Enjoy!

## Tell us a bit about yourself and how you became a tutor.

I am a biologist from the University of Alicante and I have a master's degree in bioinformatics from the Pompeu Fabra University in Barcelona. I did a PhD in Genetics at the University of Barcelona on the application of bioinformatics methods in non-model organisms. Nowadays, I am a bioinformatics technician in the genomics and bioinformatics unit of the Germán Trias i Pujol Institute in Badalona.

In addition to my work as a researcher, I have participated in teaching several undergraduate and master's degree subjects and tutored several undergraduate and master's degree students in research projects.

I knew about the UOC (the Open University of Catalunya) through personal experiences of friends and family and in particular, I found out about this tutor position through LinkedIn. I went through a selection and training process and started as a tutor in October 2020.

## Have you always felt a pull towards tutoring, or did it just "fall into your lap", so to speak?

I have always enjoyed teaching and mentoring but you could say that this position just fell into my lap without thinking about it.

## Do you feel that tutoring requires a certain degree of personal involvement? Why?

It requires a significant amount of personal involvement as this is not my main job and I have to put in extra hours in the evenings, nights, or weekends.

## Did you receive any specific training to become a tutor and do you think this training was valuable?

I received a training, a short one, which could have been more specific and valuable in some aspects. It was sufficient for a first introduction to mentoring.

## Are there any prerequisites to be a tutor in certain areas?

You must be actively working in the field in which you are going to participate and have significant previous experience. It may not be necessary to be 100% linked to the same area of research but it is required to have previous experience and to hold a PhD.

## What skills do you use to explain things and motivate students?

I think my main skill is my personal experience. I try to put myself in their shoes and explain as best I can and always try to look after the student's interests.

> "Show me a successful individual and I'll show you someone who had real positive influences in his or her life. I don't care what you do for a living – if you do it well, I'm sure there was someone cheering you on or showing the way. A mentor."
>
> Denzel Washington

## How many students can you tutor at any given time and do you feel exhausted if you go beyond that number?

This is my first time as a Master's tutor and I have a high volume of students (>110). I don't usually have many cases every day as it depends on the timing (enrolment vs. teaching period), but equally the key is to be systematic and use the right tools. It is also important to prioritise the most important cases.

I can get overwhelmed if there are too many cases to be counselled on the same day, especially if they are urgent.

## Have you made friends with any of the students and do you keep in touch with them after the mentoring is over?

No. They have simply contacted me via social media but I have that information available myself. I try to maintain a professional relationship with the students.

## How do you see mentoring: as a part of your job or as an opportunity to go further?

I see it as both. It is a side job to my main job but it is also an opportunity to gain professional experience in the world of teaching.

## What is your ideal student like and are there certain characteristics that facilitate your role as a tutor?

I don't have an ideal student because at the end of the day, the teacher's job is to make everyone learn and there should be no favourites.

It is appreciated when the learner has a good look at the materials available before asking a question. Most of the time we have access to the same information, but the learner is in a hurry or not experienced enough to find the information. This is normal and we have all gone through this stage.

**Interview**

**How do you resolve conflicts or divergence of opinions?**

I have not yet had such experiences. I imagine that I must take account of both sides and look for the best solution for everyone.

**Do you think the mentoring culture is important in science? Why?**

I think it is. Many times, students are motivated and have the desire to pursue a scientific career but do not have the means or the knowledge to start it. The tutor can advise on this part and accompany the student at the beginning of his or her stage given his or her experience and knowledge.

**What are the skills and knowledge that are best acquired through tutoring, compared to the usual teaching models?**

I think the possibility of having close advice from someone experienced in the subject can help you solve problems and address concerns.

**Have you ever learned anything from your students that has had an impact on the way you work?**

I haven't had the opportunity as I have only been in this position for a short time but I'm sure the time will come when I will acquire it. The new generation is coming on strong and have a lot to contribute.

## Conflicts of interest

The authors declare no conflicts of interest.

## Author information

**Selma Reguieg, PhD**
Selma has been a medical microbiologist since 2011. After her specialisation in microbiology, she was appointed head of a laboratory department in a public hospital of Berrouaghia, Algeria. Then, she turned to the private sector and became the manager of a medical analysis laboratory. In December 2020, she enrolled at the Universitat Oberta de Catalunya UOC to study for a master's degree in Bioinformatics and Biostatistics, where she met the tutor who was interviewed.

**Diana Ribeiro, MPharm**
Diana is a freelance medical writer based in Cascais, Portugal. In 2019, she left her work in community pharmacy and began working as a medical writer, providing medical writing assistance in both medcomms and regulatory writing. When she is not working you can find her running, cooking, or reading.

# My medical writing journey:
# How I discovered self-mentoring and used it to improve my career and life

**Alejandra Viviescas**
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## Abstract

Medical writers can greatly benefit from receiving mentorship, mentoring others, and learning how to keep themselves accountable through self mentoring. Through mentorship, they can get unique advice to accelerate their career development and connect or reconnect with the reasons that led them to become medical writers in the first place. In this personal piece, I share how different kinds of mentorship have impacted my career since I left academia to pursue medical writing. I hope this inspires others in the field to explore how mentorship can help them advance their careers.

## Leaving academia and finding my first mentors

My journey into medical writing started during the third year of my PhD when I discovered that I did not want to pursue an academic career or become a college professor. This was not an easy decision; I had been trained in academia all my life and felt lost and anxious when I thought about pursuing other career options.

Luckily, around that time, I became a member of the Cheeky Scientist Association (CSA), a worldwide organisation that helps PhDs transition from academia to industry. CSA offers a lot of useful materials to help you plan your transition, but what makes it unique is that it gives members access to a private group where they can interact with other PhDs who want to transition or are already working in industry.

I found my first medical writing mentors by posting and interacting with others in the CSA private group. This cohort of mentors played a pivotal role in my transition by helping me find my path and providing personal and professional guidance.

Here are some examples of things that I discovered by interacting with my CSA mentors during the last year of my PhD:

1. **How to deal with impostor syndrome:** When I first started interacting with my mentors, I discovered that they were people just like me, instead of superheroes who achieved the impossible every day. This helped me realise that I could be valued outside of academia.

2. **Medical writing is not only for native English speakers:** From the moment I decided to leave academia, I knew I wanted to do science communication, but I felt that I couldn't become a medical writer because English wasn't my first language, and I had never lived in an English-speaking country. In the CSA private group, I found many examples of medical writers who were non-native English speakers, which gave me the courage to pursue medical writing myself.

3. **The importance of planning:** Making any dream come true takes time, and transitioning out of academia is no different. My mentors showed me the importance of figuring out what I wanted and working towards it. This was invaluable since it helped me put almost all pieces of the transition puzzle together by the time I defended my PhD.

4. **They shared their stories and encouraged me to find my path:** My mentors were always willing to share their stories and pitfalls, which helped me figure out what I wanted my career to look like and what steps I needed to take to make that happen.

5. **Where to find clients:** Once I decided I wanted to become a freelance medical writer, my mentors shared insights with me and even referred me to some of my first clients.

Some of these mentors are still in my life, some I have lost contact with, but I hold each of them in my heart as their experiences and guidance helped me through one of the most difficult times in my life. They also showed me the qualities I still value in a mentor: good communication skills, openness to talking about their past experiences, ability to give feedback, and a good dose of vulnerability.

## Self-mentoring and freelance medical writing go hand in hand

With the guidance and encouragement of my first mentors, I started doing freelance medical writing. This was a change I enjoyed, but that also took some getting used to. I went from working with a micromanaging principal investigator (PI), to having a lot of flexibility and, for the first time in my life, not having anybody pushing me and keeping me accountable. I also learned that I needed to develop a new skill set in addition to written communication, which I thought was the most important thing when it came to medical writing. I had to get better at marketing myself and managing my finances, time, and projects.

Some of the mentors I mentioned in the previous section were also freelance medical writers, and they helped me set the first stones of my freelance business. They made me realise that there is not a right way to be a freelancer. In order to have a thriving freelance business that fulfilled me as a person, I had to set goals that would work specifically for me and keep myself accountable to those goals. In short, I had to become my own mentor.

In the beginning, I didn't realise that what I was doing was self-mentoring. I didn't even know that self-mentoring was a concept.

> You need vulnerability to be able to talk about your previous experiences – good and bad – to inspire others.

Eventually, however, I realised that there were many parallels between the learning process I went through with my mentors while I was in grad school and the soul-searching process of building my freelance business. That is when I discovered self-mentoring as a formal concept.

According to Dr Marsha L. Carr, self-mentoring occurs when a person is "willing to initiate and accept responsibility for self-development by devoting time to navigate within the culture of the environment in order to make the most of the opportunity to strengthen competencies needed to enhance job performance and career progression."[1] And that is exactly what I had to do when I started freelancing.

I had to take responsibility for myself and identify the aspects I got right and the aspects I had to get better at when it came to my freelance journey. It is not always easy to be in a self-learning process. You have to assess yourself constantly and come up with strategies to improve, which can be exhausting. But the process is also gratifying. Self mentoring not only taught me a lot about myself but also made me a better freelancer and project manager.

Being your own mentor is a process of self-awareness; you have to identify your strengths, weaknesses, needs, and limitations, as well as what to expect from the process to achieve your goals.[2]

After my first three months as a freelancer, I put the self-mentoring process in place and assessed all the aspects of my freelance business to identify my strengths, weaknesses, needs, and limitations. This is what I found out:

- The writing part was a strength. I seldom had clients who were dissatisfied with my work or required a lot of edits once I delivered a project.
- I needed to improve the administrative aspects of freelancing – organising my finances and being able to compare one project to another using objective measures.
- The lack of organisation hurt my ability to make informed decisions when I was offered a project or made a pitch.
- The marketing part of freelancing was a weakness. It didn't come naturally to me, and some of the strategies I put in place to improve that part ended up yielding little result.
- Keeping myself accountable and consistent in my work was my main limitation. I went from being very hard on myself one week to cutting myself way too much slack the next. Consequently, I didn't have set work hours, which affected my work-life balance and prevented me from growing my business.

I decided to focus on fulfilling my needs and removing my limitations.

I gave myself a month to learn about time tracking apps (I ended up choosing Toggl) and started tracking how much time I spent on each task. I also set a goal to develop a system that

> I had to set goals that would work specifically for me and keep myself accountable to those goals – I had to become my own mentor.

allowed me to compare different projects, even if they took different amounts of effort and were paid based on different parameters (word count, full project, hourly, etc.).

Within a month, I was easily tracking my time and had a working system to compare projects in place. Achieving these milestones allowed me to better estimate how much time a project would take and compare projects objectively. This facilitated my decision-making process when accepting offers and provided peace of mind.

I realised that keeping myself accountable to my work hours would take longer than a month.

> We are biased when it comes to judging our path because we are the only ones who know how imperfect it actually was.

I had to work on several bad habits and do some soul searching to identify what prevented me from having a steady routine while working from home. So, I gave myself three months to come up with a system that allowed me to be more consistent.

In the end, I came up with several hours I wanted to work every day and used an adaptation of the Pomodoro Technique, the time management theory that advocates working in 25-minute increments, to achieve those hours without overworking. Each Monday, I also dedicated the first two hours to planning my week, assigning time slots to each project.

Designing the system was easy, but it took me longer than three months to master it. Life used to get in the way, and I would let it. So, I decided to break the big goal into steps to make it easier to see if I was making progress. By the time I accepted a full-time job, I would stick to my routine 80% of the time, which was not ideal but was also a significant improvement from having no routine at all.

The next goal that I set up in my self mentor process was to increase my marketing efforts and advocate for myself. I started my full-time position before I had time to achieve that goal. However, I'm going back to freelancing soon, and I'm excited to work towards this goal again.

Self-mentoring is a term that is unfamiliar for most people, yet most of us are conscious of the

benefits it can bring as we identify that successful people have systems in place to help them achieve their goals and stay accountable[2]. Self-mentoring is an ongoing process where you set goals for yourself and trace a path to achieve those goals. If you learn how to keep yourself accountable and celebrate the small victories, you can get enormous benefits from being your own mentor.

## Coming full circle: Becoming the mentor

At the beginning of 2020, I got the opportunity to become a moderator for the Medical Writing Organisation (MWO), a community of established and aspiring medical writers created by Cheeky Scientist. This was the first time I was in a position of leadership in a professional setting. As a moderator of the MWO, I inspire and advise aspiring medical writers to create a transition plan and strategy. Using my previous experience to help people who are now going through the hurdles I went through a couple of years ago is beyond rewarding. Every time one of the members thanks me for my advice or relates to something I say, I feel extremely valuable because I can see that I am making a difference.

In January 2021, I took over the role of programme leader of the MWO community, replacing the original creator of the programme and one of my dearest mentors, Evguenia Alechine. In a way, taking over as programme leader is like a rite of passage. I started as a mentee when the MWO first launched in 2019, used the resources of the community to streamline my freelance business and self-mentoring strategy, and now am in a position where I have gained enough experience where I can help others create their own paths. This does not mean I have all the answers, but I see people benefit from my experience every day, and being able to mentor them is a privilege.

I have always thought that we are biased when it comes to judging our own path because we are the only ones who know how imperfect it actually was, how many successes came close to being failures, whereas external observers can only judge based on the outcomes. The people in the MWO community remind me every day how valuable my path can be to them and how I can help them improve by mentoring them. I learn from my mentees every day. Some of them have even become mentors. I am a better person from having the opportunity to participate in and lead the MWO community.

Being a mentor, I learned that you do not have to know all the answers or have gone through the same path as your mentees to inspire them. Being a good mentor is about empathy and vulnerability. You need vulnerability to be able to talk about your previous experiences – good and bad – to inspire others. You need empathy to put yourself in the shoes of others and give advice or feedback that relates to their particular situation. In the end, everyone can be a mentor. You do not need to be an expert; you just need to be open enough to let people relate to your particular story in a way that allows them to come to answers to advance their own story.

Since leaving academia in 2018, I have experienced the benefits that mentorship can have on your career, either by being mentored, mentoring yourself or mentoring others. Each of those experiences has made me a better person and a better medical writer, and I truly encourage all readers to give any mentorship a serious chance.

## Acknowledgements
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## Disclaimers
The opinions expressed in this article are the author's own and not necessarily shared by Cheeky Scientists or any of its programmes.

## Conflicts of interest
The author was employed by Cheeky Scientist, which developed the Cheeky Scientist Association and the Medical Writing Organisation discussed in this article.

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# Setting up for success:
## An overview of why mentoring matters for aspiring medical writers

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## Abstract
The most successful people attribute their success to an effective mentoring network. Developing a great mentor network is critical to ensuring long-term professional development and growth. This article presents an overview of the mentoring process, finding the right mentors and building a lasting relationship, and making the most of the mentoring journey.

The most successful people credit their success to the guidance they received from their mentors. Great mentors can be a source of invaluable insights into career challenges and how to overcome them, building soft skills, and advancing professional networks.[1,2] Seventy-six percent of people working in industry say that mentors are important for their professional development, but only 37% of professionals have at least one mentor.[3]

PhD students and postdocs generally receive research-specific training and mentoring from their supervisors and thesis committees. However, most do not have access to a mentor outside of academia to support them in navigating their careers, or to make job transitions outside of academia.[4] Lack of information or resources, or a reluctance to seek out potential mentors outside of their primary network are some of the reasons why PhDs find their career transition journey challenging.

This article is an attempt to simplify the process of seeking out and building a relationship with a mentor.

## What is mentoring?
Mentoring is about helping people develop professionally.[5,6] It can be used for a variety of goals and at various points in a person's career, including:
- Navigating career transitions (e.g., moving from academia to industry)
- Learning new skills as part of continuous professional development
- Networking
- Working toward a promotion
- Managing various professional situations

## What is a mentor?
In Homer's *Odyssey*, a mentor is someone who provides mental strength, thereby empowering the receiver into taking positive action. The

Oxford Dictionary defines a mentor as an "experienced and trusted advisor". A good mentor aims to guide and support the mentee in their professional development goals to enable them to navigate and advance in their career. A mentor may be an expert in the role the mentee carries out (or aspires to transition into), but this is not always the case. A mentor may:

- Support the mentee by asking questions that will challenge the mentee to identify the course of action they need to take to further their development
- Help the mentee avoid common mistakes and pitfalls in their career decisions
- Transfer expert knowledge to junior professionals
- Use mentoring as part of succession planning
- Provide advice on career development
- Offer support and encouragement
- Serve as a sounding board
- Share professional contacts

There is a difference between a mentor and a coach. According to the International Coaching Federation, "Coaching is partnering with clients in a thought-provoking and creative process that inspires them to maximise their personal and professional potential."[7] A coach offers dynamic guidance to clients, and the process of coaching is goal-oriented with specific and measurable outcomes to reach within the programme. A mentor is usually an experienced and successful professional who is open to sharing insights to help the mentee make smarter decisions and grow as a professional. A coaching relationship is usually short-term (6 months to a year), while a mentoring relationship may last a year or more. A typical mentoring relationship is an informal one, however, structured mentoring

*Table 1. A sample list of structured mentoring programmes*

| | |
|---|---|
| Azur Medical Writing Programme[8] | A 'Mentor Me' programme offering 1:1 training to professionals who are looking to transition into a medical writing career. Suitable for PhDs and postdocs seeking medical writing training. |
| Cheeky Scientist Association[9] | The largest PhDs-only association in the world, the Cheeky Scientist Association provides information, training, and support to PhDs and postdocs seeking an industry career in diverse fields including medical writing. |
| Medical Writing Organisation[10] | A special programme by the Cheeky Scientist Association for PhDs interested in a medical writing career. Offers job transition support and mentoring to PhDs and postdocs. |
| Health Writer Hub[11] | A 'Build Your Portfolio Masterclass' programme offering 1:1 coaching with special focus on health writing for the web. Suitable for professionals (including freelancers) looking to polish their communication skills. |
| Elemed Mentoring Programme[12] | A structured seven-month programme for RA/QA/CL professionals in the medtech, IVD and pharma industry. Suitable for mid-career professionals seeking to advance in their careers. |
| Healthcare Businesswomen's Association Mentoring Programme[13] | A structured, 9-month, 1:1 mentoring programme to support the career development goals of mentees from diverse backgrounds. The programme places special focus on advancement of women in the healthcare industry, but is also open to men. |
| Australasian Medical Writers Association Mentoring Programme[14] | A free-of-charge mentoring programme for members of the association with focus on professionals seeking to transition to a medical writing career. |
| American Society for Cell Biology Mentor Match Programme[15] | An international programme open to members of the association. Focuses on career development goals of mentees. |
| The OPEd Project Mentoring Programme[16] | This mentor-editor programme connects young professionals seeking a career in journalism with experienced journalists. |
| The Council of Science Editors Mentorship Programme[17] | The programme aims to support editorial professionals in advancing their careers by providing a career development network, education, and resources for best practices. |
| Publishers Association Mentoring Programme[18] | A range of mentoring schemes to support professionals in various stages of their careers |

Abbreviations: RA: regulatory affairs; QA: quality assurance; IVD: in vitro devices.

To teach is to learn twice

programmes are increasingly available to support career development of professionals from diverse backgrounds (see Table 1).

## Building a relationship with your mentor

**Set goals and expectations.** Individuals enter mentoring relationships with certain expectations, and it is important to define and discuss these at the start of the mentoring journey to avoid frustration at a later point. The onus is on the mentee to drive the relationship forward, so defining goals and expectations early on will also serve to guide the mentoring journey. A simple way to get started is by listing your SMART (specific, measurable, achievable, relevant, and time-based) career goals and the obstacles you face in achieving them.[19]

**Choose a mentor**. A mentor can be from anywhere, including your own network.[20,21] A typical mentor may be a senior colleague (within or outside of the mentee's workplace), a peer, or even a family member. Mentors may also be people you have met at conferences, or were introduced to by someone. Ideally, your choice of mentor should be guided by your goals. For example, if you wish to change fields it may not be helpful to have a mentor who is an expert in your current area of work.[22,23] Once you have your goals mapped out, seek out professionals who can help you navigate the challenges you face in achieving them. You may need different mentors at various stages of your career, so be prepared to build your own network of mentors to support you in various facets of your professional development. When you approach potential mentors, make sure you convey the reason why you are approaching them. People are more willing to help when they realise you know what you require and have your goals mapped out already.

**Set up an action plan.** Once you have secured a mentor, the onus is on you to drive the relationship forward, to build trust and credibility as a professional. A simple mentoring agreement outlining what you wish to accomplish together can be helpful in guiding the relationship. Discuss your goals and plan of action with your mentor. Be open to their feedback and be willing to modify your plan of action based on their input. Create a structured accountability process that includes a follow-up schedule, plan an agenda for each meeting you have with your mentor, measure progress at every meeting, and celebrate your successes with your mentor. Continue to appreciate your mentor and follow up even after the mentoring agreement comes to a close.

> Individuals enter mentoring relationships with certain expectations, and it is important to define and discuss these at the start of the mentoring journey to avoid frustration at a later point.

## Become a mentor

To teach is to learn twice.[24,25] Mentoring can be a rewarding experience not only for the mentee but also for the mentor. In addition to being recognised as an expert in their field, a mentor gains improved interpersonal skills, leadership ability, and an enriched professional network.

To become a mentor, you must first be clear about your own goals: do you want to pass on your skills and expertise to junior colleagues? Or do you want to give back to the community through mentoring professionals from minority groups? How much time can you commit to mentoring? What are your expectations from the mentee? How would you define a successful mentoring relationship?

Finding the right mentor and becoming a mentor can both be a daunting process. Many mentoring relationships develop organically, for example, through networking during conferences. Structured mentoring programmes run by professional societies periodically open calls for mentors. These mentoring schemes match mentors with mentees based on the needs of the mentee and the expertise of the mentor, provide a broad framework for the mentoring relationships, as well as regular check-

ins to ensure the relationship is progressing well. Mentoring programmes within companies can facilitate transfer of knowledge and resources between employees, improve collaboration and teamwork, create a culture of learning, reduce employee turnover, and help in succession planning.

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## Conflicts of interest

Surayya Taranum is a scientific writer at 4Clinics.

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# Do you have what it takes to be a mentor or be mentored?

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## Abstract

A skilled mentor can positively impact a mentee's personal and professional development. A successful mentor-mentee relationship is contingent on mentor and mentee attributes, trust, and respect, and fit based on shared values and working style. To be mutually beneficial to both mentor and mentee, open communication with defined goals and expectations should be established. This relationship should be nurtured and revisited with the potential to evolve over the span of their careers.

The required knowledge, skills, and behaviours of a professional medical writer have been thoroughly described in the Core Competency Model.[1,2] While a mentor can use this model to guide medical writers in training, and setting goals for skills and career development, the relationship between mentor and mentee can extend beyond medical writing competencies. The mentor is a role model that can provide psychological and emotional support, career, and skills guidance, and can advocate for their mentees by recognising their achievements publicly.[3] A mentoring relationship is a sum of its parts, requiring specific attributes of the mentor and mentee to be successful. Characteristics required for an effective mentor-mentee relationship, and the way this mutually beneficial relationship can be fostered, are described.

## Characteristics of an effective mentor

The mentor should be a confident professional with interpersonal, organisational, and communication skills. The mentor should advise, guide, support, direct, challenge, encourage, and motivate, and have adequate time to dedicate to the mentor-mentee relationship. To accomplish these tasks, the mentor should engage the mentee in reflective learning leading to change. The following are suggested competencies of a mentor:[4]

1. **Interest in developing others**: Effective mentors are altruistic individuals that have an interest in achieving through others and helping others recognise and achieve their potential.
2. **Managing emotions**: Mentoring requires a high level of emotional intelligence and self-awareness to recognise and manage the mentor's own behaviour within the mentor-mentee relationship.
3. **Behavioural awareness**: Mentors must have observational and reflective skills to provide insight into behaviour patterns of individuals and their interactions with working groups.
4. **Listening and congruence**: Mentors should be attuned to what the mentee is hearing and understanding through listening, observing non-verbal signals, and adapting tone, voice, volume, pace, and language accordingly. This requires that mentors are genuine, and can share feelings, attitudes, and opinions in a way that takes ownership (for example, "I think", "I feel", … ).
5. **Communication skills**: Questions should be framed and discussed to empower the mentee to find possible answers (i.e., learn and develop). Summarising key thoughts and discussing them can provide clarity to a host of key issues.
6. **Feedback**: Mentors should provide honest feedback in a way that the mentee can process, understand, and apply it.
7. **Challenge and confrontation**: Mentors should raise consciousness in the mentee about any restriction or avoidance that blocks, distorts, or restricts learning through an appropriate challenge that raises the



The greatest good you can do for another is not just to share your riches but to reveal to him his own.

Benjamin Disraeli

mentees' awareness and help them reframe the situation.

8. **Sense of proportion/good humour**: Mentors should feel comfortable with themselves and their role within an organisation. Humour and laughter can help build relationships, ease tension, and help the mentee develop multiple perspectives.
9. **Goal clarity**: Mentors should be able to identify strengths and limitations in their mentees' development and support mentees in identifying and setting clear achievable goals.
10. **Business and/or professional savvy**: Mentors must be able to reflect critically on their own experience to develop judgement, which they can share with the mentees to address mentee issues. Mentors should be able to navigate the mentee through difficult situations, warn their mentees of potential pitfalls, and protect them from harsh interactions.

## Finding a mentor

An established mentoring programme may or may not exist in the workplace, and as such, the prospective mentee may need to identify a mentor and cultivate this relationship.

Before selecting a mentor, the mentees should clarify their needs, and define what they anticipate from the relationship (e.g., personal, professional, or other skills development).[5] Prospective mentees should also define whether they have personal preferences in a mentor (e.g., age, race, gender, personality, emotional needs, or teaching style). Mentees should set short- and long-term goals for the mentoring relationship. Mentees should be able to conduct informational interviews with potential mentors to determine if their professional experience, skills, interests, network, work style, and values are a fit for the mentee's needs. Similarly, an analogous assess-ment by the mentor of the prospective mentee to determine the success of the potential relationship is indispensable. During these interviews, the groundwork for the future relationship is laid.

> From all my teachers have I learned and from my students more than all.
>
> Rabbi Akiva

## Characteristics of an effective mentee

Once a mentor has agreed to support the mentee, the mentee should own the responsibility for establishing a communication framework. This can include scheduling meetings and their frequency, raising issues for discussion, establishing timelines for achieving goals, managing their own expectations and the mentor's expectations of the relationship, willingness to challenge and be challenged, and being open minded. Many of the competencies of the mentor and mentee are similar, and include:[4,6]

1. **Intelligence**: Mentees should be able to identify and solve problems.
2. **Ambition and enthusiasm**: Mentees should be capable and ambitious, strive for career progression, and be actively willing to seek challenges.
3. **Strong interpersonal skills**: Mentees must be able to demonstrate network ability.
4. **Feedback**: Mentees should be open to receiving feedback and be active listeners.
5. **Respectful**: Mentees should be respectful of their mentor's competing responsibilities when scheduling meetings or requesting assistance.

As the relationship develops, the mentee should reflect on the process, identify and resolve pain points, be responsible for their own develop-ment, and welcome change. The mentee should demonstrate appreciation for the mentor's commitment to the relationship.

## Characteristics of a successful mentoring relationship

A successful mentoring relationship includes the following characteristics:[6]

1. **Reciprocity**: Rewarding for mentor and mentee.
2. **Mutual respect**: Respect for the mentor and the mentee's time, effort, and qualifications.
3. **Clear expectations**: Expectations of the relationship are outlined and revisited over time. Both the mentor and mentee are held accountable to these expectations.
4. **Personal connection**: Mentor and mentee should be able to connect on a personal level and have a similar approach towards working and solving problems.
5. **Shared values**: Mentors and mentees have a shared approach to work and personal life.

## The evolution of a mentoring relationship

The mentoring relationship is dynamic, as the mentee transitions from one career stage to another, and the mentor and mentee may become colleagues. An experienced mentor will have the experience and network of colleagues to support mentee development through these transitions. The mentee should collaborate with the mentor in setting long-term career development goals and ensure that the mentee is receiving adequate support to achieve these goals. The mentor can also provide perspective on an appropriate work-life balance during life's transitions.

Finally, while face to face meetings between mentor and mentee are preferable, in the remote work environment and under restrictions imposed during the current COVID-19 pandemic, ongoing communication using video conferencing software can help facilitate communication.

## Conclusions

A successful mentor-mentee relationship can be mutually beneficial to both the mentee and mentor. A supportive mentor can nurture the mentee's personal and professional development. The mentor, in turns, gains through professional stimulation, personal enrichment, satisfaction, and giving back to their profession.

So are you ready to be a mentor or be mentored?

## Acknowledgements

## Conflicts of interest

The author declares no conflicts of interest.

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# One size doesn't fit all:
## Tailored medical writing mentoring and training

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## Abstract

While there is ultimately no "secret sauce" to mentoring, in this article I outline my non-negotiables, which, although not rocket science, often take the mentor's concerted effort to implement. Firstly, everyone is different. While hardly ground-breaking, it can be all too easy to wheel out the same experience for each mentee, because it makes *our* life easier. However, everyone's needs are different, as are their personal circumstances; "know the person to better mentor". Secondly, as a mentor, we have a parental-like responsibility to be consultant, counsellor, and cheerleader. If you are looking for a mentor to assist you with the transition to medical writing, I would prioritise this human side of the relationship more than looking for a list of what you will learn (important though that is, too).

*"The Azur mentoring programme is an incredible platform for someone wishing a career in medical writing"...*

*"The programme helped me immensely as I received training about the ins and outs of medical writing. Particularly helpful are the writing tasks through which you gain an understanding of how clinical studies are reported"...*

*"I would recommend this programme to others 100%."*

This is why I mentor. This is why I choose, some days, to help others on their journey into medical writing above doing the medical writing myself. Over the years, I have come to realise that each of us needs a mentor, each in our own way. And, that each of us can be a mentor to others. It is from this realisation that the basis of Sarah Tilly Mentoring took root. I am amazed to see how it has grown and flourished over the years, starting out as Azur Mentor Me with just two mentees and now as a fully-fledged online e-learning platform. I want to thank those first mentees for being part of the original idea and for trusting me to see them through their transition into medical writing careers of their own.

The ability to support, encourage, and teach in a nurturing environment is not something we encounter every day. Still, when we do stumble upon it, we generally don't forget the experience. It may have been a piano teacher from childhood or a tutor from university – we remember great mentors. Outside of the workplace, mentoring relationships happen fairly naturally without us really thinking about it. But in the world of work, being a mentor is often a role that is thrust upon us. Some industries have more of a culture of mentorship, others less so. To me, one thing appears to be for sure: great mentors are not born but made.

In this article, I will tell my story of mentorship and the tailored, personal style of mentoring that I find to be the key to success.

My story begins at the 2017 EMWA autumn conference in Cascais, Portugal. At this point, I had been medical writing (mostly regulatory) for 11 years at a variety of clinical research organisations and consultancies and I had, only 6 months earlier, taken the leap and set up Azur Health Science. I was asked if I would chair a roundtable discussion at the freelance business forum. I had been freelancing for only 6 months, and although hesitant, I was happy to contribute. My chosen topic for discussion was "Freelancers as Mentors to Newbies". While training and mentoring was something that I enjoyed, I proposed the topic with a certain sense of trepidation, as I by no means considered myself an authority on mentoring. But I did know that it was something about which I had strong opinions. That trepidation only increased on the evening of the forum, where, like moths to a flame, it seemed like half the room gravitated to my table. Well, that is what it felt like at the time. We ended up having a useful discussion and the evening confirmed my instinct: that there are people out there who desperately need a mentor in the medical writing industry, but who perhaps know neither how to find one nor who to approach.

> To me, one thing appears to be for sure: great mentors are not born but made.

## The art of mentoring

This mentoring instinct led me also to question how mentors in our industry receive appropriate training. Like everyone, I've had good and bad experiences being mentored. And naturally, I remember the good experiences. While some may be natural mentors, I firmly believe that being a mentor is something that can also be learnt. We can all read a "leadership" quote on LinkedIn and be inspired, but that inspiration is often only fleeting. So, soon after the Cascais conference in 2017, I designed a workshop for the mentors in the medical writing field, entitled "The Art of Mentoring".

My aim with the workshop was to offer training that is more than a quick dopamine fix, that is thought-provoking, and offers plenty of actionable, practical advice for mentors.

Mentoring is often so much more than the words we say, and our actions can speak far louder. Many of us are thrust into a mentorship role that is, by and large, an addition to our own work. As mentors, can we subtly convey to the mentee our own sense of being inconvenienced? I'm sure that my face betrays my reluctance when my daughters ask me to join in a game of make-believe!

Furthermore, as mentors, do we consider how we impart advice? It's amazing how often we frame advice in a negative way: "Don't do this, or don't do that". "The Art of Mentoring" has beenrunning at EMWA for 3 years now. We take inspiration and examples from all over the business world; we discuss learner personality types and how to deal with difficult situations, to turn an unsure mentor (and even an experienced mentor) into someone who embraces the experience. Perhaps even, at the same time, the mentor might learn a little something about themselves.

But what is a mentor without a mentee? This leads me to the next part of my mentorship journey.

## Azur Mentor Me to Sarah Tilly Mentoring

After the freelance business forum in 2017, I was approached by two of the attendees who were at the round table to see if I would mentor them. While I had only mentored colleagues who were new starts within the companies where I had worked, I realised that, having been a medical writer for more than 10 years, perhaps I did have something to offer to those outside of my small work environment.

We set up a programme structure together that combined practical writing tasks with training on some of the basics of the healthcare industry, drug development, and the different types of writing roles available. Now I didn't want this to be a simple exercise in writing for which I provided a marked assessment. This didn't sit well with me. When I perform on-the-job medical writing tasks, I am not marked, and I would hate it if I were! No, I work collaboratively with a team, I speak to them at least several

"..[the Azur mentoring] helps not only for a medical writing career but even for other career paths in the pharmaceutical or medical device industry and helped me to be more confident in my interviews. I think I successfully transitioned into the industry due to this first step."
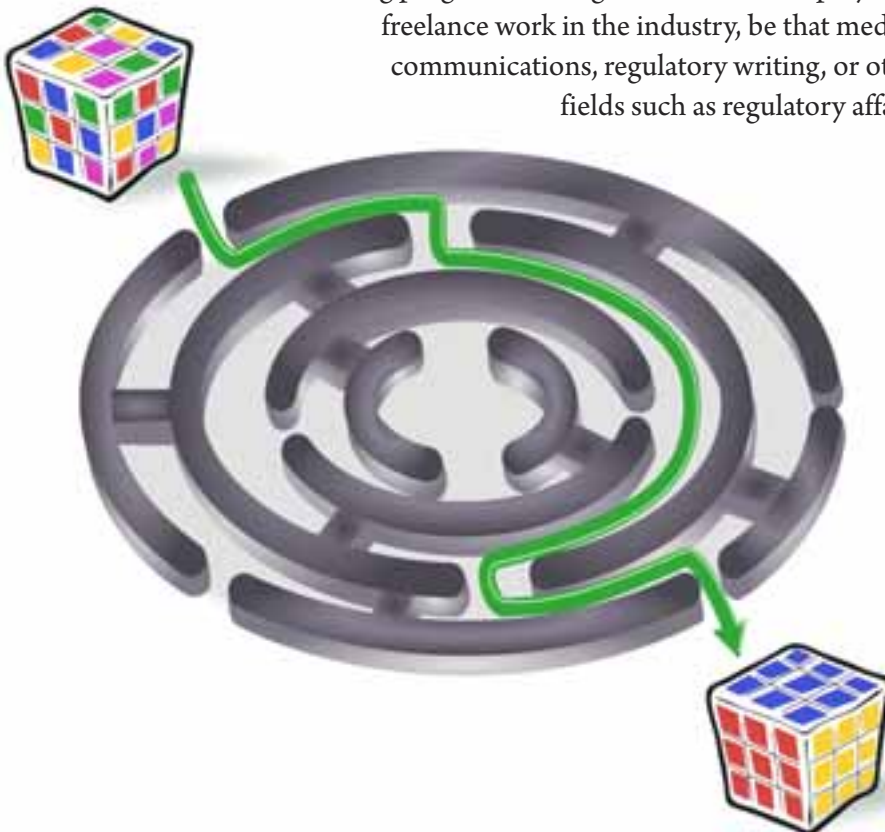
times a week during the drafting process, and I send a draft document for review so that together we can work to improve a document.

So why would I treat my mentees any differently? For the written mentoring assignments, this is just what we do: my mentees do some writing and send it to me for feedback; I take time looking through their work, I send them written comments, and we have a meeting to discuss; the mentees then have the chance to update their work for final submission. Current and past mentees have found this incredibly valuable – it gives them far more confidence in their writing skills than can be achieved from a simple score with little advice on how to improve.

I can't quite believe I can still say this, but every mentee who has been through and completed this mentoring programme has gone on to find employed or freelance work in the industry, be that medical communications, regulatory writing, or other fields such as regulatory affairs.

I am proud that our programme does not produce "mini-mes". The programme offers mentees a fantastic insight into medical writing as a whole, but it does not limit them to the regulatory writing that I do every day, and it does not even limit them to medical writing. I am proud to be part of the development of the new generation of writers who are able to get off to a confident start, who are empathetic, encouraging, and open-minded.

It has been a long process from the ad hoc mentoring with Azur Mentor Me to the point where Sarah Tilly Mentoring is an online resource available to any who have the motivation and time to commit to self-training: mentees can sign up and learn at their own pace, in their own time.

But, of course, I keep in close contact with the mentees during their online learning journey, and we have regular catch-ups. Naturally, the real review and feedback sessions are maintained. Once the main writing assignment is completed, it is only natural that we accompany mentees as they begin their search for jobs in industry.

One of the many things that I have learned on my journey from the round table in 2017 to Sarah Tilly Mentoring today, is that medical writing is a career in demand. Medical writing is a challenging, but ultimately rewarding career for which we have many motivated and talented people who need an initial helping hand to bridge the gap into the industry.

Every mentee who has been through and completed this mentoring programme has gone on to find employed or freelance work in the industry, be that medical communications, regulatory writing, or other fields such as regulatory affairs.



## From a mentee
One of the enquiring souls who flocked to Sarah's table at the EMWA freelance forum in 2017 was me, Somsuvro Basu. It was my first EMWA conference – I was itching to leave academia but still hesitant about the first moves. I believe Sarah sensed my apprehension and talked me through the possible transition paths to medical writing. The initial discussion opened up the opportunity to join her mentoring programme.

The programme started with a questionnaire and an initial call to plan a personalised programme. I provided my medical writing bucket list – helping Sarah to gauge my wishes and streamline a programme that fit my goals and filled in the gaps.

I was unsure whether regulatory writing was my true calling and was inclined to medical and science communications. Sarah used an approach where I studied a regulatory document and transformed it into an article, suiting my career intentions. I lived my fear (read: regulatory writing) and learned something new!

The task taught me two valuable lessons: first, I realised the demands and rigour required to be a regulatory writer; second, and the most crucial exercise, I learned knowledge extraction. It trained me to single out the most essential information from an astronomical clinical study report and distil it into a 3,000-word article. It provided me with a foundation to extract precise information, and to present it in a particular format for a specific audience.

In the last two years, I have been employed in a medical communications role, where I have extracted stories from the jungle of science literature out there on diverse topics, ranging from botany to nanotechnology. The training with Sarah gave me an edge to succeed in the job.

Now, it is time to give back! I am helping Sarah launch a polished mentoring programme aiming to help future medical writers. If I can do it, you can too!

## Acknowledgements

## Conflicts of interest

Sarah and Adrian Tilly are co-founders of Azur Health Science, which provides the mentoring services discussed in this article.

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**Sarah Tilly**
Sarah believes that everyone has their own, unique contribution to make to our industry and has been mentoring new medical writers since an early stage of her regulatory writing career, which began in 2006. Co-founder of Azur Health Science, she is actively involved in advising and mentoring other writers.

**Adrian Tilly**
Adrian is co-founder of Azur Health Science and a medical writer. He has been working in the industry since 2012 and brings a wealth of life experience that complements our values: respecting individuals, collaborative working, and inspiring those people looking to become future medical writers.

**Somsuvro Basu**
Somsuvro Basu, a freelance medical communi-cator, has been proudly associated with EMWA since 2017. Previously, Som acted as a science communication officer at the Central European Institute of Technology (CEITEC), a Czech research consortium. Before transitioning to medical communications, he worked in Czech Republic (PhD) and Germany (as a postdoc) as a molecular cell biologist.

# Mentor vs. line manager:
## Differences and similarities

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## Abstract

A good mentor may be a good line manager in a business setting and vice versa, but there are some key differences: mentors are more skill-oriented, while line managers are more goal-oriented. People who are both good line managers and mentors are especially valuable for an entry-level employee, but balancing the roles can be difficult, so it may be best to keep them separate. To most benefit from the line manager-direct report relationship, a medical writer should have clear career development goals and help manage their line manager's expectations. To benefit from the mentor-mentee relationship, a medical writer should communicate effectively about their knowledge gaps and concerns.

> Mentors may work for different organisations than the mentee and are more skill-oriented, whereas line managers are more goal- and business-oriented.

## Mentors vs. line managers

A mentor is someone who "practises the activity of giving a younger or less experienced person help and advice over some time, especially at work or school",[1] or in the words of Homer, "a wise and trusted counsellor."[2] A line manager is someone who is "directly responsible for managing the work of someone else in a company or business, and who is one level above that person."[3]

The key qualities of a good mentor and line manager differ (Table 1). Mentors may work for different organisations than the mentee and are more skill-oriented, whereas line managers are more goal- and business-oriented. The objective of mentors is to encourage the long-term development of their mentees; they will pay attention to skills their mentee acquires and will be rewarded by knowing that their mentee has improved as a professional. Mentors, for example, will teach a writer to produce a particular type of document or independently lead a project that requires close collaboration with experts from other disciplines such as statisticians or clinical research physicians.

By contrast, line managers focus more on tangible short-term achievements of their direct report because they need to ensure that the

*Table 1. Key qualities of good mentors vs. good line managers*

| Mentor | Line manager |
|---|---|
| Truly cares for the mentee's personal growth | Ensures projects are completed on time; therefore, business goals can be achieved |
| Selflessness – unconditional sharing of their knowledge of the industry and related skills | Hires appropriate employees best fit for the job description |
| Focuses on providing sustainable solutions to problems | Helps align the company/team goals with personal goals of the employee, so they can best perform |
| Honestly and patiently points out problems of a mentee's work | Capable of motivating employees |
| Helps with building industry connections | Provides business support when required |

***Table 2. What a medical writer can say to a mentor vs. a line manager***

| Things more appropriately said to a mentor than to a line manager | Things more appropriately said to a line manager than to a mentor |
|---|---|
| I will not be able to do this; this is not something I am good at. | Can you please find additional resources for me to complete this task? |
| I cannot finish this project on time because I do not know how to do [task]. | I can adapt to our team goal. |
| I have experienced difficulties. (Expressed at the last minute of project deadline). | I have learned enough that I am fully capable of doing [task]. |
| I don't want to do this because I'm not interested in this project at all. | I will make sure this task is completed on time. |

employee is productive and contributing to the overall business goals. Line managers will also pay more attention to existing skills a new direct report can bring to the table. Further, line managers are team leaders and are not only responsible for individuals but also for the full team and its business goals, which is why one characteristic of a good line manager is that they help their direct reports align their personal goals with the company's or team's goals. To ensure the team is achieving its goals, line managers will also have to measure each employee's performance. For example, for a regulatory medical writer, a performance metric may be the number of new drug application submissions completed in a given time, or, as I have seen, the creation of automated tools to facilitate writing and help the whole team.

**What a medical writer can say to a mentor but not to a line manager**

Medical writers need to consider different things when speaking with mentors and line managers.

The relationship between a mentor and a mentee is more casual; mentors can be more forgiving about problems, giving the mentee more opportunity to learn from mistakes and benefit from the mentor's advice. For mentees, who are permanently in learning and consulting mode, the important question to ask before communicating with a mentor is, "What more can I learn?" whereas when

communicating with a line manager, it is most important to express competence and motivation. Some examples of differences in things a medical writer can say to a mentor or line manager are provided in Table 2.

**Line managers who end up as mentors and vice versa**

It is not uncommon to think that a good mentor can be a good line manager and that a good line manager can be a good mentor because there are some overlapping qualities. For example, for a line manager to achieve goals, they may need to do some coaching. For a new medical writer, a line manager can provide particularly valuable initial coaching. Examples include helping the writer generate high-quality deliverables by teaching them about different therapeutic areas and the clinical development process, providing them with expert advice, and allowing them to gain experience through self-learning. At the same time, to help a mentee achieve personal career goals, a mentor will need to help the mentee align their goals with the company's. Of course, both mentor and line manager roles can provide industry connections for future jobs.

Having a line manager who is also a mentor is most helpful for entry-level employees. Once the writer has developed their skills and has the competence to work independently, the mentor role will become less important than the line manager. To balance these two roles, the line manager needs to fully understand their direct report's talents, capacity, and characteristics. This will allow the line manager to develop a comprehensive plan with attainable short- and long-term goals. Effectively balancing the two roles can be difficult, and it is best that they remain somewhat separate, especially because line managers are responsible for busy teams with multiple business goals. Some organisations with mentorship systems will assign a team member who is more senior to serve as a mentor but not as a line manager for new hires.
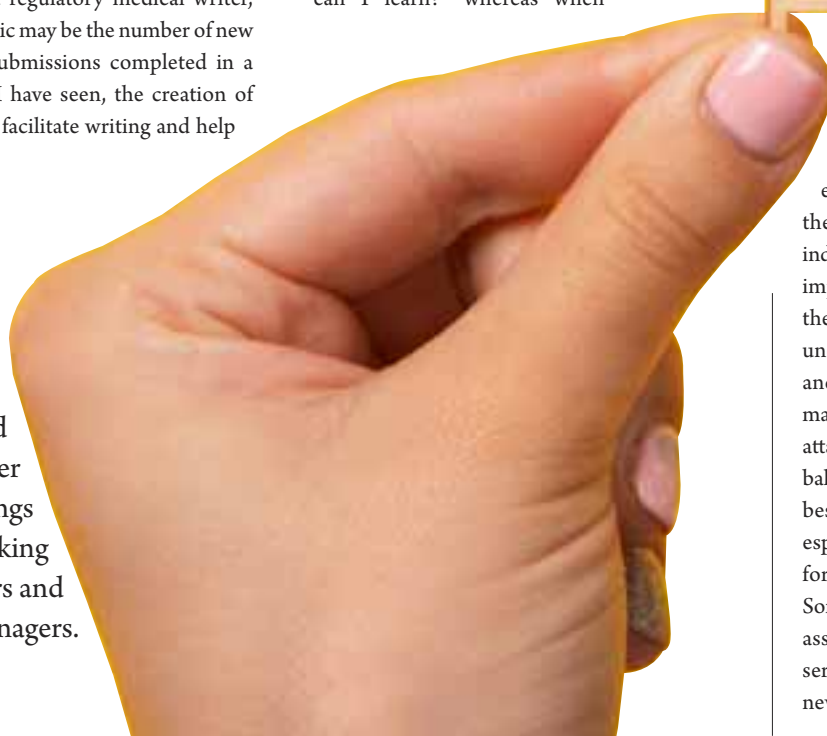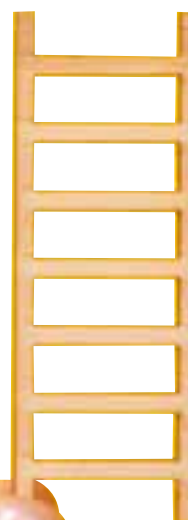
> Medical writers need to consider different things when speaking with mentors and line managers.

**How to work well with a mentor or line manager**

A good line manager is, first and foremost, a team leader, and they must value the short-term achievements of the employee over personal growth. Therefore, to best support the line manager, once an employee becomes more experienced, they should become less dependent on the line manager and focus on asking for specific resources rather than guidance or training. An employee also needs to make sure that they are working to their best ability to achieve personal goals that they have set together with their line managers. This should lead to larger responsibilities and allow the growth of professional and soft skills. For example, a writer may be given a leadership role for a document type that they have proven that they can independently develop. In this way, a positive feedback loop will form with the line manager to help a writer grow their professional skills and take on more challenges.

When working with a mentor, a medical writer needs to constantly communicate about knowledge gaps or concerns. With open communication, good mentors will use their experience to help mentees find appropriate solutions. For example, a writer may not know the key components of a particular submission dossier or may need help using Microsoft Word efficiently. Through open and frequent communication, a mentee can take full advantage of the mentor's experience while showing progress, another positive feedback loop that can form between employees and line managers.

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## Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by his employer or EMWA.

## Conflicts of interest

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# Beyond limits – *Leading at the Edge*

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## Abstract

Every member of a working group or a team has a defined role, such as that of a leader or a mentor. Although every role has its own distinct definition, a great mentor can be a great leader and vice versa. One of the finest mentor leaders, explorer Ernest Shackleton, set an example of how to lead and mentor in harsh conditions; this was laid out by Dennis NT Perkins in his book *Leading at the Edge*. Even today, in these challenging times, Shackleton teaches us that, no matter how far beyond our reach a goal might be, the key is to never give up, but rather encourage yourself and your team to take small steps, celebrate your achievements, and stand tall even when there is "no land in sight". Rest assured, beyond the horizon of our limitations lies a vast space of possibilities waiting to be explored.

## Introduction

The universe is a complicated entity whose history is still a mystery. Blocks of structures, seemingly randomised, yet organised in specific patterns, form our cosmos.[1,2] Structure formations such as galaxies, stars, webs and planets, are the organisations of the universe.[2] Similar patterns exist on our planet Earth – the Fibonacci sequence present in the flower buds of Romanesco broccoli,[3] the expanding symmetry of fractals in snowflakes, and an alpha animal in an animal pack. The universe may seem chaotic and *orderless,* but its formations give it stability. The same applies to the life of plants, animals, humans, and even molecules. Everything is interconnected, and this secures these elements' continued existence.

## What about us?

Structure formations can also be expressed in our genetic code, which is what has made our society grow and develop to its present day proportions. In ancient times, when there were no cities, a small group of people, such as a tribe, had to be well-organised to secure the food necessary for their survival and development. As the group grew larger and strived for more efficacy, villages, cities, and states were born as structures of society of the highest level of complexity, as posited by Elman R. Service in his 1962 book *Primitive Social Organization*.[4]

A complex organisation, such as those found in an industrial setting, consists of working groups and can be defined by its roles, tasks, interactions and cohesiveness.[5,6,7] A working group or a team generally consists of a leader, mentor and others.[5] A mentor is a person who advises and guides a group or an individual with their experience.[8] On the other hand, a leader is a person who leads a team towards a specific goal; they don't always have the necessary expertise, but they do have the right personality and are responsible for managing a team.[6] Leadership is commonly divided into the traditional and the modern model, which offer differing views. The traditional model is a more conservative one, where the leader is observed as a task-delegating, all-knowing autocrat.[9] The second model, known as the modern style of leadership, focuses more on the group or team members,[10] whilst the role of the leader is slightly pushed into the background. In this model, a leader acts as a symbol of empowerment, support and compassion,[9] especially when it comes to the 'mentor leadership' style.[11]

## A great mentor can be a great leader

Mentor leadership is a novel style in which a leader leads by mentoring their team members.[12] This approach creates a positive environment for the team members and encourages creativity and development.[11] One of the greatest role models

> "If you want to go fast, go alone, if you want to go far, go together."

*Ernest Shackleton*

for mentor leadership is Ernest Shackleton. He not only managed to save his crew during the dangerous expedition they had undertaken between 1914 and 1916, but he was also a great mentor to them.[13]

## A passionate leader with an indomitable spirit

Ernest Shackleton, born in 1874 during Britain's imperial century, was an explorer dedicated to reaching the shores that no one had reached before. As a teenager, he joined the Merchant Navy, which helped him become a crew member. He served as third officer on the *Discovery* in 1902 on a research expedition to Antarctica, where the new Farthest South record of 82° 17'S was set under the command of Robert Falcon Scott.[14] During that expedition, Shackleton experienced challenges typical of a polar expedition – unexpected obstacles on the route, starvation, the cold – and still, despite the discouraging circumstances, especially his health issues caused by malnutrition, he decided to lead the Nimrod Expedition in 1907.[15,16] This time, Shackleton reached 88° 23'S, setting a new Farthest South record, 97.5 geographical miles from the South Pole, approximately the distance between London and Leicester in the UK.[17] As a man thirsty for success, 7 years later, Shackleton led the Imperial Trans-Antarctic Expedition to explore the landscape of the Antarctic. After 325 days, this legendary expedition resulted in a stranded crew and a sunken ship – the *Endurance*, which has still to this day not been found under the thick layers of ice.[18] Nevertheless, the expedition was a great achievement for Shackleton and for humanity. He was able to bring his crew back home safely despite the extreme cold and starvation, even though his return initially wasn't warmly received because of the distraction of World War I. Upon his return he published *South*, a book about his expedition on the *Endurance* that was well received. Because of Shackleton's strong personality, experience in leading expeditions, and his extraordinary achievements, others attempted to keep his legacy alive. Some of the publications weren't referenced responsibly, nor published according to the original reports from the expeditions.[19] However, a publication by Alfred Lansing[16] stood out as he invested a lot of time in researching and interviewing Shackleton's crew. His work *Endurance: Shackleton's Incredible Voyage* is a

*The Endurance*

masterpiece that inspired lots of people including Dennis NT Perkins. Perkins was amazed by Shackleton's confidence, the way he managed his crew, and how he was able to get them home safely. In his book *Leading at the Edge,* Perkins reveals to us the Ten Strategies for Success™ based on the events of the Trans-Antarctic expedition; these strategies focus on how to become a better leader and how to approach personal development.

## Leading at the Edge – Ten Strategies for Success™ by DNT Perkins

Perkins's book covers 10 strategies on how to lead, as well as the philosophy of exceptional leadership, and the best approaches for becoming an exceptional leader. This perspective can also be applied to a mentor or for achieving a specific goal.

The first strategy talks about vision – to achieve a specific long-term goal, that goal should be clearly defined, and divided into smaller targets. A focus on smaller goals or achievements will give us more strength and push us towards ultimately achieving the long-term goal. After Shackleton and his crew had set off on their journey, when the ship got stranded and Shackleton realised that the ship's structural integrity would buckle, he shifted his goal toward bringing his crew home safely and succeeded in his intention. This strategy corresponds to Earl Nightingale's definition of success – "… *Success is*

*really nothing more than the progressive realisation of a worthy ideal...*" and reminds us that a person with a goal, as well as the determination to achieve that goal, reaps the rewards.

Another point the author makes is that a leader's message is strong and more powerful if it is presented in the form of symbols or memorable speeches. This second strategy is more about performance than theory. As an example, as the circumstances had become unbearable, Ernest Shackleton, who had just lost his ship, had no radio and needed to save his crew from suffering the harsh conditions from the constantly changing weather, gave several memorable speeches. He then dis-carded all of his valuables to motivate his crew to do the same, since they were traveling by foot to a research station for rescue, and traveling light would increase their chances of survival.

The third strategy reminds us that optimism can help bring us further and that we shouldn't live in denial. Challenging situations should be regarded as opportunities, not as obstacles. When Shackleton was aboard the *Discovery*, on his first voyage, his health deteriorated and the conditions of travel were harsh, yet he was still reluctant to give up, and he found the motivation to move forward. Leading or mentoring a team usually requires a lot of energy and time; if we want to do this, we must first and foremost take care of our needs to then be able to help everyone

else. Sleep deprivation, stress, and malnutrition can impact our decision making and with it our performance.

Strategies five, six and seven emphasise the importance of the modern leadership style. As mentioned above, for a team to function as a unit, a leader needs their team members as much as they need their leader. Shackleton, a historic mentor leader who was ahead of his time, shared his food with the crew and lived by the motto "*We are one, we live or die together*". He also promoted equality among his crew members and insisted on the crew sticking together, no matter how long the journey back would take. Indeed, he recognised the importance of team work, as stated in the African proverb "*If you want to go fast, go alone, if you want to go far, go together*". This brings us to strategy number seven – conflict management. Shackleton realised that conflicts should be resolved instantly to keep the crew members' resentfulness at bay. Jealousy, gossip, and ill intentions tend to disrupt a well-organised and fully functional team.

The eighth strategy is similar to the third strategy, which encourages the celebration of any achievement, no matter how small. No matter how difficult the situation is, we should be grateful for it and stay focused on our long-term vision. Aboard the *Endurance*, the men celebrated while stranded on the ice, even though their return home was uncertain. They even celebrated their last morsel of food.

The path to achieving a goal involves taking risks, but not the unnecessary kind, or any type of risk where failing is inevitable. Naturally, every risk is coupled with uncertainty; however, this is part of the process. Strategy number nine covers stepping out of one's comfort zone, which could bring a positive outlook and might prove more efficient than merely sitting around waiting for something to happen. The stranded Shackleton and his crew could have simply sat around waiting to be rescued; instead, Shackleton decided that they should move forward to reach the station on South Georgia and organise their own rescue.

The last key strategy for becoming a mentor leader such as Ernest Shackleton is to not give up – especially in the face of failure or unexpected situations. They are part of a successful journey and, therefore, we shouldn't be afraid to take a step outside of our comfort zone. Likewise, optimism alone will give us strength, but won't necessarily

"Difficulties are just things to overcome, after all".

bring us closer to the goal. Consistency in action, combined with faith and optimism, is a recipe for achieving goals. Shackleton was aware that there is a solution for every problem and he was determined to find a way home. Before calling for help, the crew set up camp on Elephant Island. Shackleton decided that contacting the station on the island of South Georgia was imperative to bring everyone home safely. After assembling a small crew of five of his strongest men, Shackleton set off on a risky voyage and saved the rest of the crew on Elephant Island four months later.

## Conclusion

The makings of a great leader or a great mentor lie not only in the learned ability to lead or mentor a team – one's virtue also plays a great role. In the words of Ralph Waldo Emerson, "*The essence of greatness is the perception that virtue is enough.*" Ernest Shackleton was remembered for his great personality and his outside-the-box thinking. His knowledge, persistence and optimism helped his crew return home safely. Other great expeditions throughout history, such as the one under the command of Robert Falcon Scott, were not as successful as Shackleton's because the crew didn't stick together. Even though the personality and managing style of the leader or a mentor is crucial for success, Shackleton chose his team members wisely, insisting on diversity. Building a diverse team where every member has an equal opportunity to use their unique skills, will significantly improve the chance to achieve any given goal.

In the challenging times we currently face in the midst of a pandemic, during which we sometimes feel like we are drifting on ice in open sea, Shackleton teaches us that we should adjust our goals, be grateful for small achievements, and not give up. Our experience will indubitably make us stronger. In the words of Shackleton himself, "*Difficulties are just things to overcome, after all*".

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## Conflicts of interest

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# Reveal, Rebalance, Release:
## Thoughts on mentoring young professionals in the industry

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### Abstract

Making the first steps as a medical writer in the pharma and biotech industry can be challenging. Three general principles can help managers foster the growth and development of their team members: **Reveal**, **Rebalance**, and **Release**. **Reveal** means that along with providing extensive professional training, a manager needs to reveal the hidden facets of the profession and the job. This includes teaching not only about regulations and writing standards but also about company culture and managing projects and clients. **Rebalance** means viewing the people you supervise as whole people, with personal lives and complex sets of commitments, and helping them maintain a full and productive life outside of work. **Release** means devising a development track for the people you supervise based on their goals rather than your own, maintaining ongoing and open communication, and being aware of how their aspirations and abilities evolve.

## My experience learning to mentor

It is April 2002, and I am standing at the door of my Cambridge, MA, house in the US. This is my first-ever "real" winter. Having spent my entire life in Israel, I have never experienced heavy snow fall before, and I am standing there, astonished at the beauty and the quiet of a cold city covered in a thick layer of snow, shimmering in the cold light of a deceptive sun.

I spend a long moment admiring the view, when suddenly, I start to panic. The profound, serene quiet all around is due to the lack of any traffic. No cars are on the roads, and how am I going to get to work?

I start walking. The subway station closest to my house is closed, and I continue my trek for 3 more kilometres to the next stop. I am relieved to finally manage to get on the Red Line and ride it to downtown Boston.

I am almost an hour late, and as I arrive panting to the door of the lab in which I am doing my doctoral thesis, I am surprised to find it empty – no one but me has come in that day. Unsure how to start the day's tasks without any of my colleagues, I am startled out of my reverie by the sharp ring of the lab telephone. On the line is my thesis advisor, and she is furious. "What are you doing there? Why did you risk traveling to work on such a day? Did you really think that I would require you to come to work on a day like this?"

This was an important and instructive moment. It is one of many in which advisors, bosses, and senior colleagues have taught me through their words and by personal example about having the right set of priorities as a supervisor when dealing with people making the first steps on their career paths. It speaks to the notion that an employee should be viewed as a whole person whose life does not start upon entering the workplace at the beginning of the workday and does not end when they leave at the end of the day.

My advisor "adopted" me into her lab after a previous advisor had left for an academic position in a different city. From the moment I started in her lab, she took on her role as an advisor and her responsibilities within it with profound earnestness. She taught me how to organise my scientific thinking in a structured and logical way, bestowed upon me her profound commitment to scientific ethical principles, and was the first to teach me how to write scientific texts.

After graduation, I said goodbye to Boston, and goodbye to life at the lab, and with my family, returned home to Israel. Upon starting my job as a medical writer at Teva Pharmaceuticals, I made my official transition from academia to industry. This transition can be overwhelming. Company culture can be quite different from what we get used to in academia. The hierarchy, social codes and – above all – the fast pace of life in clinical development can cause significant stress to newcomers. Add to that the fact that in pharma and biotech, people often start their first job at a stage in life at which they are not as flexible due to significant personal commitments, such as children or ageing parents.

In recent years, I have been managing a medical writing department within a contract research organisation. I consider the responsibility for a team member's wellbeing, advancement,

Diskin – **Reveal, rebalance, release**

and retention to be shared between the employee and the employer. In this article, I share my ideas on how supervisors can support and nurture scientists transitioning from academia to industry and foster their professional development.

## The three Rs of management: Reveal, Rebalance, and Release

Over the years, my supervisors have taught me to take a holistic approach to management and consider each employee's abilities and aspirations, as well as their complex and varied commitments. The principles of this approach can be summarised as the three R's: **Reveal**, **Rebalance**, and **Release**.

### Reveal

To foster the professional development of an employee, the first and most natural step is to provide professional training. At Teva, I was lucky to work in a very supportive and cooperative medical writing environment. Much like my thesis advisor, my boss at Teva dedicated countless hours to training her employees. I would sit shivering in her freezing office while she taught me about the drug development process, regulations, medical writing standards, how to read clinical study result outputs, and how to manage a writing project. But beyond those highly important professional training sessions, she guided me on how to work at a high level of professionalism and talked openly about the complexities of functioning and growing within a large and ever-changing organisation. The way that my boss mentored me is what I mean by "reveal": she revealed the hidden facets of the profession and the job.

In my present role, I spend many hours training my team members, but, following my former boss's example, I try to reveal to them what goes on behind the scenes in the company and with clients. I do that without fearing that nurturing a young professional will cause her to grow and develop until she overshadows me or takes my place. On the contrary, I view the development of young professionals in the workplace as a goal in and of itself. I believe that the success of each employee and the success of the whole department are the same, and that the whole is greater than the sum of its parts.

### Rebalance

I believe that managers have the responsibility of helping their team members reach a balance between their commitments to allow them to grow and develop in all aspects of life. I try to divide their workload and tasks so that they can conduct a fruitful life outside the office. Even before the COVID-19 pandemic, all of my team members knew that they do not have to have "face time" with me – they do not need to sit at the office just for the sake of being present. Rather, team members are given tasks and are responsible for completing them on time, but they can do that on a flexible schedule, which can include working from home as needed. During the pandemic, we have all had to be home-school teachers, cooks, and information technology managers on top of our regular jobs, so flexibility has become crucial. Based on the solid professional expertise that they acquire through training and practice, I feel confident in allowing them to manage their own work.

I practice what I preach. In my personal conduct I try to convey the message that one's personal life and work are of equal importance. Starting even before the COVID-19 pandemic, I have worked a few days a week from home, and I do not hide when my work schedule is impacted by family constraints. I try to create a nurturing workplace with shared goals that each team member strives for without sacrificing their personal lives.

### Release

The last and most difficult principle is "release". Charting a career path for a team member that recreates our own or aligns with our aspirations for that person is easy; taking a back seat and helping them to define their own path and attain their goals is more difficult, but it is the principle that I try to implement. This can be achieved through open discourse, continuous listening, and trying to understand where each employee is striving to get to and how their goals develop over time. I believe that providing room for growth to team members will grow the department and the organisation so that all stakeholders will benefit.

## Disclaimers

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## Conflicts of interest

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# Modern mentorship: Developing medical writing mentor-mentee relationships in the virtual world

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## Abstract

Mentorship is often viewed as a traditional personal relationship model, where the mentor meets face-to-face with a mentee within the same organisation or group. However, I have been mentoring medical writers successfully for many years using virtual technology to connect and advise, long before the COVID-19 pandemic forced many of us to work virtually from home. Virtual mentorships may take more time and effort to build, but they provide new medical writers with unprecedented global access to mentors. Creating a successful virtual mentorship starts by identifying the right mentor, followed by setting appropriate and achievable mentee goals. These goals and the strategies to attain them are documented in a virtual mentoring plan. The plan provides a roadmap for both the mentor and mentee to keep the virtual mentorship on track in a professional and transparent manner, no matter where in the world they may work and live.

The COVID-19 pandemic has fundamentally changed the way many of us now work and interact with our colleagues. Although medical writers were early adopters of the virtual office, given the nature of their work, the pandemic has created a "perfect storm," forcing most office-based employees to work virtually from home. So many of us have had to adapt to this new way of working and somehow cope with the many unintended stressors of having to live and work 24/7 at home, often under less-than-ideal conditions. Despite the potential downsides of working from home, recent surveys conducted during the pandemic predict that anywhere from 16% to 55% of employees would prefer to continue to work remotely once the pandemic situation improves.[1,2] Clearly, the virtual workplace is here to stay.

I have been fortunate in that the pandemic has had relatively little impact on my working life as a medical writer, as I have always worked remotely from home. However, so many people in the workforce have been on a steep learning curve adjusting to a workday filled with virtual meetings, lack of face-to-face contact with colleagues, and working in isolation.

Certainly, being mentored in a virtual environment has been an entirely new experience for so many during this past year, particularly as most of us have had to overcome the initial awkwardness of using online virtual meeting platforms. The need for virtual mentoring has become so critical that mentoring strategies for scientists and medical students are now emerging in the peer-reviewed biomedical literature as a result of the pandemic.[3,4]

New and inexperienced medical writers may find working remotely particularly challenging. Medical writing can be a lonely profession, and often high-pressure, with shifting timelines and short deadlines. Thus, supporting and assisting new medical writers with their professional and personal development can make all the difference to ensure they have a successful start.

Based on my 17 years of experience working remotely as a medical writer in an entirely virtual medical writing company and then in my own freelance medical writing business, I have acquired many successful strategies to mentor and support new medical writers. In this article, I will share some of those strategies that have been most effective when mentoring medical writers virtually.

> The virtual workplace is here to stay.

## Finding a virtual mentor

Mentees looking for the right mentor have many more options available to them in a virtual mentoring model, as the mentor and mentee can live anywhere in the world. Finding a medical writing mentor does require time and effort.

Mentees can join professional organisations such as EMWA (the European Medical Writers Association) or social media

networks like LinkedIn to facilitate virtual interactions with experienced medical writers who may be working in the mentee's area of interest.

Once a mentee has identified appropriate medical writers with expertise, the next step is to reach out and enquire if the medical writer is willing to be a mentor or has a colleague interested in mentoring a newbie medical writer. I realise this step takes a bit of courage, but it is well worth the effort. Think globally. Since many medical writers work entirely remotely, highly successful medical writers can live anywhere in the world as long as they have a stable internet connection – so don't limit your search to your immediate area. Most medical writers under-stand how difficult it can be to break into our field, and the challenges involved, and are happy to provide advice.

## Creating a strong mentor-mentee relationship

Once you have found a willing virtual mentor, it is important that the mentor and mentee develop a strong and trusting relationship. A key step in developing such a relationship is getting to know each other. If you have a mentor in a different part of the world or another location in your country, this is a great conversation starter that provides opportunities for casual conversations and relationship building. Language is typically not a barrier either, as many medical writers who come from non-English speaking backgrounds are very adept at speaking and writing in English.

Communicating well is an absolute necessity, and many different virtual meeting platforms are now available to help with these virtual inter-actions.[3] Where possible, try to use video conferencing to ensure direct eye contact and effective listening. The mentor and mentee should have some knowledge of each other's personal background – this helps with understanding each other's point of view and how they came to medical writing. Medical writing is a unique career with no standard career development pathway, so knowing the mentor's story can provide a lot of insight for a mentee. As a mentor, being open about your successes

and failures along your career pathway can be invaluable because the road to becoming a medical writer can be bumpy and filled with detours. One of the most frequently asked questions I get from those who want to pursue a career in medical writing is, "How did you become a medical writer"? Understanding the details of how to navigate this career path is often a major concern for newbies. Awareness that there are many roads to becoming a competent medical writer often encourages new writers to consider different strategies and help them work with their mentor to find an appropriate career pathway.

Being honest and open about your strengths and weaknesses is critical for mentees if they want to develop a strong and trusting virtual relationship with their mentor. Explain to your mentor why you want to be a medical writer, what attracts you to the profession, and where you see your career in five or ten years. If you are unsure whether medical writing is for you, be clear that you are exploring this career path and highlight other interests you might have. Sometimes the best advice you can get as a mentee is to know when a career consideration might not be a good fit.

## Developing a virtual mentoring plan

Setting specific goals and expectations for a virtual mentorship is fundamental for a successful alliance, so I suggest creating a virtual mentoring plan. To help identify and refine the mentoring goals, the mentor should have an in-depth virtual discussion with the mentee.

What specific support and advice is the mentee seeking? Do they want assistance to improve their writing skills, enhance their knowledge about writing specific documents, further their pharma industry or drug development knowledge, find employment with a certain company, or develop career networks? These discussions will inform the content of the mentoring plan. Importantly, the role of the mentor is to review these goals with the mentee and determine if they are sufficiently specific and achievable, based on the experience and knowledge of the mentor and their preliminary assessment of the mentee.

When developing the mentoring plan, the

mentor and mentee should agree on how often to meet virtually, the aims of each meeting, and what sort of activities and discussions are planned (I suggest preparing a meeting agenda for every meeting). Preparation and forethought are critical to maintaining the professionalism of the mentorship. Further, it is also important that the mentor and mentee develop a timeline for the mentoring plan – is the aim of the virtual mentorship to be short-term or long-term?

## Ideas and strategies for a virtual mentoring plan

Developing a robust mentoring plan takes time and effort, but making this a priority early in the mentor-mentee relationship is an important step to success. Here, I've highlighted some strategies that, based on my practical experience, have worked well.

### Assessing and developing mentee core competencies

New medical writers often ask me about the core competencies they will need to be a successful medical writer. Hence, many of my mentoring plans for medical writers often include an assessment of these core competencies.[5,6] These competencies can be assessed via writing exercises, discussion, review, and critical analysis of documents that can be

*Setting specific goals and expectations for a virtual mentorship is fundamental for a successful alliance.*

shared, as well as assessment of the mentee's editing skills. An in-depth discussion with mentees regarding their knowledge and understanding of specific competencies such as data analytical skills, statistics, medical and scientific knowledge, as well as drug development knowledge, can help pinpoint knowledge gaps.

Mentors can provide new medical writers with advice regarding involvement in organisations like EMWA, the American Medical Writing Association (AMWA), and the Drug Information Association (DIA). These professional organisations provide wonderful opportunities to meet other medical writers and offer extensive education and training programmes for new writers. Annual meetings for these organisations are ideal places to find a mentor and speak with experts who have a wealth of experience. These are all resources mentees may use to help fill knowledge gaps.

Discussion of successful medical writers' behaviours is another aspect that I often spend extra time covering with budding medical writers. These include such behaviours as the ability to communicate effectively, manage time well, pay attention to detail, demonstrate learning agility, embrace change and shifting goalposts, integrate scientific and thinking skills, accept critical feedback, and act with the highest ethical standards.[6] Awareness of these important attributes is vital for potential medical writers. In this regard, mentors are well-positioned to provide mentees with concrete examples of how these behaviours will support the skills needed to work successfully as a regulatory or publications writer or in other areas of medical communications.

These assessments and discussions between mentor and mentee can easily take place virtually and often involve email correspondence, virtual meetings, or sometimes phone calls. Sharing articles and social media posts about medical writing issues is another way a mentor can support their mentee, including alerting them to webinars that might be of interest. If a mentor and mentee both attend a webinar, it can serve as an excellent discussion point at a later time, where the mentee might feel more comfortable asking questions or discussing specific points raised in the webinar.

Many virtual online meeting platforms also have the option to record the mentor-mentee meetings, including the information shared on screen such as documents or slides. This frees

attendees from worrying about taking copious notes during the meeting, and attendees can be fully present and meaningfully participate in the discussion. The recordings are also an excellent way to prepare for upcoming mentorship meetings and review how the mentee is progressing. If meetings are to be recorded, this can also be documented in the mentoring plan.

**Introducing the mentee to other experts**

Other options to consider in a mentoring plan are strategies to help the mentee liaise with other subject-matter experts who can further assist with the mentorship. For example, is there a statistician, pharmacokinetics expert, or clinical investigator who can speak to the mentee? I have found that mentees benefit greatly from interacting with other people who may work with medical writing teams. Using virtual mentoring, it is much easier for mentees to gain valuable connections with experts from around the world. These early contacts with subject-matter experts often lead to long-term working relationships throughout a medical writer's career.

**Supporting the mentee in their job search**

Getting your first job as a medical writer can be a challenging step. Companies usually look for writers with experience, so finding a medical writing role takes time and patience if you have no job experience. The virtual mentor can be very helpful in guiding mentees towards specific strategies to find their first medical writing job. Mentors who are experienced with the remote workplace often have a lot of connections globally. They are frequently aware of positions that might be available or companies who may consider taking on new medical writers, often under the recommendation by the mentor.

Further, mentors can suggest roles that might provide a bridge to a full-fledged medical writing job. For example, working in other areas such as clinical research, clinical data management, medical information, pharmacovigilance, or academic biomedical research projects can be ideal stepping stones to help medical writers move into full-time medical writing. Mentors can help their mentees think laterally about navigating their career path and providing introductions to potential employers worldwide.

**Providing guidelines for mentor-mentee communications**

The mentor and mentee should be transparent about their expectations and limitations of the mentorship. Busy professional medical writers often may feel they don't have the time or inclination to mentor; however, with a structured mentoring plan, a mentor can be more confident and better understand the scope of their mentor role. Mentors also need to be clear about their availability to assist the mentee. Mentors should set up specific communication policies/plans and advise the mentee of any limits on the mentor's availability. This information should then be incorporated into the mentoring plan. By openly discussing these issues, both the mentor and mentee eliminate the potential for misunderstandings, minimise assumptions by either party, and maximise the potential for the success of the mentorship.

## Ensuring the success of the mentorship

Successful mentorships are based on mutual respect and trust. Mentees should always keep in mind that their mentors are volunteers, so acknowledging your gratitude often goes a long way to make your mentor feel valued and appreciated. Mentees should also recognise their mentor's limitations – mentors cannot ensure you get the exact job you want, answer all your questions, or resolve your career dilemmas. If they can't help you with a specific issue, ask if they can recommend someone who can and thank them for the advice. Mentors are also not substitutes for the hard work needed to develop your medical writing skills.

I believe it is important to acknowledge the feeling of accomplishment and pride mentors often have when we see our proteges develop their skills and then get their dream medical writing job. Mentoring can be an incredibly rewarding experience, as there are so many opportunities to learn and grow. If you love what you do, there is nothing more rewarding

*Mentoring can be an incredibly rewarding experience, as there are so many opportunities to learn and grow.*

than having a former mentee become a friend and esteemed colleague.

## Conflicts of interest

The author declares no conflicts of interest.

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# Someone in your corner:
# Musings of a mentor and mentee

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## Abstract
What is a modern mentorship, how do you make it work, and what does gardening have to do with it? Let us take you on a tour of the growing garden of our own modern mentorship, showing how we as a medical writer (Lillian Sandø; mentor) and a clinical operations lead for devices, platforms, automation, and data analytics (Bjarke Stokholm Stærkind; mentee) can learn from each other across different functional business areas. Based on our experiences, we describe the structure and some tools that we think are key to making a formal mentorship work, helping both parties develop in a continuous cycle of growth.

In a corner of the garden stands a plant with scraggly leaves and drooping stems. For passers-by, it's hard to tell what kind of plant it is, if they notice it at all. One day, an observant soul sees the plant, recognising its species. Giving the wilting plant some water and fertiliser, this person starts coming by regularly. She loosens the soil around the plant's roots, pulls up weeds, adds mulch. Sometimes she prunes it, learning along the way the best method, figuring out how much and how often the plant needs pruning, water, and fertiliser to thrive – and to blossom.

At some stage in our growth cycle, we all need a gardener. Someone who *sees* us, sees past whatever is holding us back, sees who we can become with the right nurturing and stimulation. Someone who can help us grow and blossom, season after season. We all need to have someone in our corner: a mentor.

But how can we find this mentor; how do they wind up in our corner? What's in it for them? And what are the mentor's equivalents of the gardener's pruning tools and fertiliser? These are some of the questions we will muse on in this article, while exploring our own budding mentorship.

## Mentorship structures
Mentorships come in many shapes, and they may form by chance or by design. You may be fortunate enough to cross paths with someone, in your career or in your personal life, who is on the same wavelength as you and takes an interest in helping you fulfil your potential. You might find such an ally in your graduate supervisor, the manager hiring you because they see something special in you, or the medical writer you share an office with. Perhaps your dance coach, or the neighbour who shares your passion for birdwatching, will be that ally. The relationship might be one between peers. It might fine-tune your existing skills and knowledge, or transform you in a more profound way, changing your perception of yourself and others.

But what if your boss is a self-serving tyrant, you don't have any peers in your office, and your neighbour is a lone wolf? Perhaps you admire and click with someone in a different department or area, but it might feel awkward to reach out and ask them to be your mentor. So, relying on serendipity for a mentor relationship to develop organically does not always work.

However, just as a wonderful garden can evolve naturally or be designed by a landscaper,

We all need someone who *sees* us, sees past whatever is holding us back, sees who we can become.

so can a mentorship. In a formal mentorship programme, mentors and mentees are assigned to one another by a facilitator within a company or organisation, typically also providing training and tools to the participants. This is the kind of mentorship that we are engaged in and will focus on below.

**Pilot programme in LEO Pharma**

In 2020, our employer, LEO Pharma, launched a mentorship programme for staff in the R&D functional areas of Medical Sciences and Global Clinical Operations. Organised in collaboration with a consulting firm, a member of the European Mentoring & Coaching Council, the programme is based on the concept of modern mentoring (see inset, *The historical versus the modern mentor*). Rather than being a cloning factory, it aims to accelerate the personal and professional development of mentors and mentees alike. Through a structured learning partnership, mentors and mentees are meant to reach beyond "lean wisdom" or expert knowledge within a specific area, to broad wisdom and even "meta wisdom" – integrating knowledge, understanding, and experience from multiple disciplines, ideas, and contexts.

Intended to run for eight to ten months, the LEO Pharma pilot programme started in October 2020 with a kick-off meeting for participants, including 25 people at the company headquarters in Denmark plus a handful of staff members in the US, UK, and Germany. Following plenary and breakout discussions, the kick-off culminated in the pairing of mentors and mentees.

Each pair was matched by programme organisers based on the participants' functional areas, length of employment in the company, experience, expectations, and wishes. The spearhead for the LEO Pharma programme, Mette Theodora Bomhold, says a key tactic was to match employees from different functional areas, focusing on personal development. "We aimed to make each pair as diverse as possible in terms of extrinsic factors such as their department, position, and experience", she says. "At the same time, we aimed to match their personalities and expectations as best we could, based on their responses to our matching questionnaire".

Besides Bomhold, two colleagues from Medical Sciences and two from Global Clinical Operations were involved in the matching, also weighing in with any personal knowledge of the applicants. "So far, we have received very positive feedback from our mentor–mentee pairs", Bomhold says. Pending final evaluation of the pilot, the programme may be rolled out across LEO Pharma R&D.

After the kick-off, mentor–mentee pairs started their collaboration, being advised to meet every three to six weeks. The development of this new "learning alliance" is aided by a workbook packed with guidance and tools. The workbook provides structure for aligning expectations, agreeing on ground rules, setting learning goals, preparing for meetings, documenting actions and experiences, and evaluating progress throughout a cycle of eight to twelve meetings. The book also contains guidance on different situational roles the mentor can adopt, along with various tools to aid

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> A key tactic was to match employees from different functional areas, focusing on personal development.



## The historical versus the modern mentor

Named after a character in Homer's *Odyssey*, a mentor was historically seen as a teacher, or an older person in a senior position, who provides expert guidance to a student or novice.[1] Just as Mentor, king Odysseus' trusted friend (right), was asked to advise and teach the king's son Telemachus (left) so "historical" mentoring has been focused on the mentee's learning. This model does not necessarily provide a high incentive for the mentor. Conversely, "modern" mentoring can be seen as a learning partnership between two people with different levels of experience, where both can achieve new insights and personal growth.

reflection and analysis, for instance SCORE (symptoms, causes, outcomes, resources, and effects) and SWOT (strengths/weaknesses – opportunities/threats) analyses,[2] and SMART (specific, measurable, achievable, relevant, and time-bound) goals.[3]

At the time of writing this, we are halfway through the programme and soon to participate in a workshop with the other mentors and mentees, aimed at supporting and guiding our partnership. When the formal programme ends, each pair will evaluate their learning and their relationship and will end or redefine it, depending on whether they wish to continue collaborating or prefer to explore new learning opportunities.

## Benefits of cross-functional mentorship

Spanning functional business areas within our company, our mentorship is not aimed at

developing role-specific subject matter expertise. Bjarke, who works to establish innovative IT systems and devices for use in clinical trials, does not need mentoring in the nuts and bolts of medical writing. Being relatively new to drug development, however, he can benefit from having a mentor with the diverse experience of the product lifecycle gained through medical writing, from early clinical development planning through trial conduct to marketing application and beyond. Furthermore, the soft skills that a medical writer needs to succeed are transferable to other roles, and vice versa, as is knowledge of the company's structure, culture, and projects.

> The soft skills that a medical writer needs to succeed are transferable to other roles, and vice versa.

Thus, we could easily set learning goals for our mentorship that transcend our individual subject matter expertise. Besides this learning, a cross-functional mentorship – by its very nature – brings greater understanding of other departments and roles, along with their deliverables, challenges, and opportunities. Such knowledge will make us better collaborators, and for some it might even inspire a career move.

A cross-functional mentorship also has the advantage that it provides a neutral and "safe" environment for sharing work-related or personal matters with someone who does not have a stake in the matter – an impartial sounding board.

From an organisational perspective, cross-functional mentorship has the added value – besides the participants' own development – of connecting business areas, creating cultural awareness, and helping break down functional silos. This can, at least in theory, promote enterprise thinking – the coveted concept of considering the entire enterprise and aligning plans across all relevant areas before making strategic decisions, supporting a lean, agile, and efficient organisation.

## Our mentorship experience

### Why we joined the programme
**Lillian (mentor):** Leading various types of writing teams, which is part of a medical writer's job, often involves coaching of some kind. This can be helping a new medical writer or another colleague who is new to a task or team. Acting and thriving in this role, I appreciate how crucial it is for a high-performing team that the members

lift each other up. I also find it personally meaningful if I can use my strengths to help someone else be their best – or help them find a way to achieve their aspirations, even awaken their subconscious aspirations. I wish to explore and develop my ability to inspire and help unlock people's potential, although without pursuing the people management track. To that end, becoming a mentor is a great learning opportunity.

**Bjarke (mentee):** I have a profound belief that goal-setting is key to consciously ensuring progress, and I strive to write goals for myself on an ongoing basis. But it can be difficult to set goals that are both achievable and ambitious. To me, a mentorship was therefore a chance to get support and a sparring partner for both defining my goals and discussing my ensuing development. An added value was to widen my network in LEO Pharma, where I started last year, as the pandemic slimmed my chances of getting to know colleagues across the company.

**Lillian:** I have received some great mentoring in my career, which I now feel ready to "pay forward". Besides medical writing, I can help cultivate more general and transferable skills such as stakeholder and project management, handling pressure, and using feedback constructively.

### Our expectations
**Bjarke:** A mentorship to me is a private sharing space, where both parties deposit thoughts, ideas, and feelings. My expectation before entering the programme was to share my thoughts and problems and receive honest and direct feedback. I enjoy a frank approach and I don't take things personally but rather, appreciate any constructive feedback that will help me develop.

**Lillian:** Ditto! I expected both of us to come with an open mindset and readiness to meet in a sincere way. And we do; our collaboration is very much a two-way street.

**Bjarke:** Before joining the programme, I had some vague ideas about certain goals and skills

that I wanted to work on. But my three concrete learning goals came to life through my ideas, our conversations, and using the SMART[3] method in our meetings. This underlines the value of having a mentor to discuss goal-setting with.

**Lillian:** I aim to become better at listening and at *seeing* people. I expect that by consciously practicing different mentor roles, such as the coach, adviser, critic, or storyteller, I will become more aware of which role I adopt in which situation and how I can do this deliberately, not just intuitively. I hope to internalise these roles and put them to good use outside this programme as well.

## What we are getting out of it (so far)?
**Bjarke:** I really appreciate our equally dedicated approach to the collaboration and that we both enjoy a structured approach. This structure helps me build actionable tactics to accelerate my personal development, and I can already see some practical and tangible outcomes.

**Lillian:** For my part, I relish this opportunity to immerse myself in mentoring for a few hours each month. I find it gratifying, especially seeing the great effort you put into achieving your goals. I enjoy hearing about your challenges and your learning, and I learn from trying to home in on what might help you shine your brightest. I'm delighted that you are so open to self-reflection and exploring potential development areas.

> The structure helps me build actionable tactics to accelerate my personal development.

**Bjarke:** I value our open and direct communication and the questions that come up in our conversations. For instance, you typically ask a lot of questions to help clarify my understanding of the problem we are discussing, to help me explore the theme from different perspectives, and to challenge my perceptions.

**Lillian:** Sometimes, I also give you specific advice or share some knowledge or a story from my own experience. But you give me new perspectives, too, making our conversations reciprocal, inspiring discussions where we bounce ideas off each other.

**Bjarke:** Besides your advice and stories, I gain

from the discussion-oriented approach, which supports ideas, thoughts, and counterarguments that I like to test out. In relation to the different mentor roles, a discussion partner and adviser is not the only, or always the best, way to maximise my learning, though. I also benefit from you acting as a critic.

**Lillian:** Going back to the gardening analogy, I would say that the mentor's role as discussion partner and adviser provides different types of fertiliser, whereas the mentor's role as critic corresponds to the gardener's pruning shears. The latter involves giving constructive feedback that others may find uncomfortable to give and therefore tend to hold back. As a mentor with no personal stake in your behaviour and performance, I can provide feedback from a neutral position. I can represent other people present in a challenging situation, helping to interpret the situation from different angles and explore how it might have been handled better.

**Bjarke:** The different means of mentoring also present a set of intertwined paths to growth for both parties. For instance, when the mentor uses the "pruning shears", they also put themselves in a challenging situation with development potential: while you want to give constructive feedback, I might be reluctant to receive the feedback if I take it to be misplaced or shared in a wrongful tone. This emphasises the importance of having a mentoring agreement with ground rules for the collaboration and aligned expectations for the structure and methods of learning together.

## Putting it all together

We believe that having sufficient structure, the right tools, and mutual commitment are key to making a formal mentorship work – just as structure, tools, and commitment are key to creating and maintaining a landscaped garden. It's a case of "value in, value out" – a positive spin on the "garbage in, garbage out" principle known from computer science.

Furthermore, we reject the notion of a mentor being some kind of guru. Rather, we see a gardener who, after investing time and effort in nurturing a special plant, is in turn nurtured by the garden's produce. We think this circular nature of mentoring makes a more fluid boundary between the mentor and mentee, helping both parties to transition from one role to the other at the right times during their career, hopefully in a continuous cycle of growth. That way, we should not need to fear being annual plants, blossoming only once – but can enjoy life as hardy perennials, thriving year after year.

> The mentor's role as discussion partner and adviser provides different types of fertiliser, whereas the mentor's role as a critic corresponds to the gardener's pruning shears.

> We should not need to fear being annual plants, blossoming only once.

## Disclaimers

The opinions expressed in this article are the authors' own and are not necessarily shared by their employer or EMWA.

## Conflicts of interest

The authors declare no conflicts of interest.

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# How mentorship has created a special community and helped people develop their careers

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## Abstract

Mentorship is an extremely rewarding relationship between two people with the goal of professional and personal development. Elemed's Mentoring Academy in partnership with the Regulatory Affairs Professional Society (RAPS) combines three pillars – mentoring, training, and networking – to give our community the best possible solution to fast track their development, which would usually take years of trial and error. By creating a great mentoring community within the areas of regulatory, quality, and clinical, we were able to see our current mentees grow and expand their boundaries. This article shares the journey, experiences, and results we have seen from Elemed's Mentoring Academy.

2020 will always be remembered as the year COVID-19 impacted the world. This article captures Elemed's journey through the crisis, focusing on how the idea of a mentoring programme created a fantastic community of supportive mentors and mentees. Elemed is a niche recruitment agency specialised in helping people find their dream job in the areas of regulatory, quality, and clinical in the medtech and diagnostics industry.

In Spring 2020 the COVID-19 pandemic had the world in its control. Many of our clients put their hiring plans for 2020 on hold or decided to cancel them totally. What to do when you're a recruitment company and recruitment stops? We took the opportunity to really spend time talking to our talent community and our network of hiring companies about skill set shortages and talent trends. We learnt that common deficiencies found amongst candidates were in the areas of: business acumen, emotional intelligence, business curiosity, influencing, and project management skills. We noticed that there was a lot of training available for technical skills, but not enough for soft skills which are critical to progress in a career in regulatory, quality, and clinical.

The idea of Elemed's Mentoring Academy was born to add value to our community by using the power of the Elemed network to create mentoring relationships with a view to fast track skill acquisition and approaches that would otherwise take years to develop or learn through trial and error.

We were approached by the Regulatory Affairs Professional Society (RAPS), after launching the programme, to join forces. A great collaboration was born, supporting our mentees with some great speakers from the RAPS network who brought in industry insights from a regulatory perspective. All participants (mentees, mentors, and even speakers) were entitled to a certain amount of regulatory affairs certification (RAC) credits for recertification which was found very valuable, especially by our mentees.

Elemed Mentoring Academy is the first ever hybrid mentoring programme targeted at regulatory, quality, and clinical professionals within the medtech, in-vitro diagnostics, and pharmaceutical industries. The programme is conducted completely virtually and consists of three main pillars which makes it so much more than just a mentoring programme.

The first pillar of the programme is the *mentoring* component. In a highly personalised matching process we hand select each mentor-mentee pair. The advantage of this personalised approach as opposed to software is that we are able to make a high quality match taking all the information gathered from both parties into consideration. This means that we try to pay special attention to the requests and challenges of the mentees and match them with the mentor that meets their needs best. Here is what some of our mentees say about the matches we've made:

- *"The mentor I am paired with is great! She has been through a lot of what I am going through now and is able to commiserate and give valuable advice. Her perspective has helped me to see some of the challenges I faced from a different viewpoint and alter my strategy."*
- *"Elemed has made a match made in heaven."*
- *"I am glad that the mentor I was matched with fit my exact expectation when I joined the academy."*
- *"I greatly benefit from the exceptional match making of mentee and mentor that enables me to learn from my mentor how to define and reach my goals."*

The second pillar of our hybrid mentoring programme is *training*. As soft skills are the key to every career, we also offer at least one training session per month on a variety of soft skills topics. In order to ensure these sessions are valuable for the mentees, we invite experts to deliver the workshops and training sessions. All training sessions are recorded for those who cannot make the live event. We have found that our mentees greatly value combined mentoring and training as it supports their continuous learning and enables them to grow personally and professionally. Here is some feedback our mentees have provided on the training they get in the programme:

- *"The speakers have been excellent [...] I have already taken away so many tips and tricks for networking, managing up, and making better connections with people."*
- *"The live sessions, focusing on different topics such as career development or business skills, are presented by reputable speakers within the medtech and regulatory industry:"*
- *"The programme stimulates me to learn more, and read more."*

The third pillar of Elemed Mentoring Academy is the *community*. Too often mentoring is a solo development journey for mentees. But we wondered what would happen if we could bring all mentees together to create a support hub; to

share challenges and celebrate successes with each other. As we wanted to promote a culture of continuous learning, we also created a support hub for our mentors, in addition to our mentees. At the support hub we conduct regular mentee and mentor roundtables. This forum allows mentees and mentors to meet new people, strengthen existing relationships, and support each other throughout their journey. After receiving the feedback from our mentees, most of them value this community part of the programme:

- *"It has been so fun to meet the other mentees and engage with them in roundtables and workshops! There are mentees from all over the world and hearing their experiences has made me feel like a part of a community, especially with the increased isolation measures from COVID-19."*
- *"[...] it gives me also good contacts for effective networking, and I like the exchange with the other mentees [...]"*
- *"The regular meetings with other mentees are a great way to exchange experiences and to share knowledge."*
- *"It is nice to network with the other mentees and see how they are dealing with certain situations and how their mentee-mentor relationship is. I really appreciate how helpful everyone is. That impressed me a lot."*

The last component to our mentoring programme is our online learning platform for mentors and mentees. This is the place where we add some useful resources to start the programme such as tips on goal setting and a first meeting checklist. Apart from the recommended reading we suggest for our mentees and mentors,

we have built a great list with their own recommendations to share within our mentoring community. There is constantly new content added to the platform to engage our mentees in between their one-on-one mentoring sessions and group training sessions.

Seven months on, what are some of the results? We've seen huge personal and professional growth amongst all of our mentees, greater self-awareness around strengths and weaknesses, more confidence in their professional and technical abilities, and also more willingness to experiment with new things such as leadership methods, communication styles, etc.

We've also seen some mentees who were very unhappy in their roles who started to approach their managers with some constructive ideas on how to make their working environment more effective. Solutions improved internal structure but also made the workplace a more enjoyable place to be, a place the team looked forward to coming to every morning. Their line managers

were very happy about their proactive approaches and honesty and helped them to implement these changes within the company.

When it comes to the actual careers of our mentees, we have seen internal promotions, the chance to lead significant projects, as well as mentees navigating career change and transformation.

Due to COVID-19, some of our mentees have been made redundant or were unhappy in their current roles. Due to the support of our Elemed Mentoring Academy, they were able to find their next challenge and get some security back in these uncertain times.

*"I cannot say enough positive things about this programme, I am so happy I found it! I 100% recommend the Elemed Mentoring Academy to anyone looking to find a role model and make more connections in their career."*

*"There is much to be gained from the programme, independent of career stage."*

*"Overall, Elemed's mentoring programme provides a fantastic opportunity to grow."*

We are currently recruiting for mentees to join our 2021 programme. If you want to find out more about the programme, visit our mentoring website, sign up, and benefit your career!

## Acknowledgements

## Conflicts of interest

The authors are both part of Elemed, the company that facilitates the program discussed in this article.

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**Elena Kyria** is an award winning talent acquisition specialist in the medtech industry. She has worked with many professionals in regulatory, quality and clinical roles in Europe, over the last 9 years. In 2018, Elena was named one of the year's top Millennial Shepreneurs by *Insights Success* magazine.

# Growing the top and bottom line of your mind – an entrepreneurial journey as a joint venture with mentors

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## Abstract

Having spent more than a decade in academia, it has been almost inherent to me to think of learning as exercising your IQ, thereby improving you practical and technical knowledge. It is quantifiable and can easily be described on your CV. The mentor experience opened a whole new world of education I had neglected: studying my own emotional intelligence (EI) and boosting my self-awareness. Fully balanced growth requires exercising both IQ and EI. This is my account of several very different mentorships, all of which have contributed to the speed of my personal entrepreneurial journey.

## Introduction

This is a story about the development of a start-up company finding a place for itself in the market and how different mentors played a role. My journey into entrepreneurship was not planned; yet here I am, a partner in a spinout and start-up company from Aarhus University, Omiics. Coming from academia, the unique combination of expert knowledge and skills that you gain there is highly valuable, but many may not know where they fit in outside of academia. Therefore, self-awareness is instrumental to discovering what makes you special and how you fit in. According to Daniel Goleman, self-awareness is defined as an honest image of one's strengths, weaknesses, values, and drives; it is also one of the key skills for people to maximise

performance.[1] The right mentor can contribute to one's self-awareness and self-development. To me, anyone who takes an interest in helping you grow can be a mentor (from boosting one's technical skills to emotional intelligence). A mentor's support may come in many forms, knowledge, networks, feedback and discussions, and it is up to you to make the message significant. For medical writers who may want to start up their own companies or start freelancing, the stories here may help you navigate the turbulent early stages of starting out. The main lessons here are:

1. openness to seizing unplanned opportunities and
2. the ability to identify knowledge gaps and seek out said expertise.

## My first mentorship

While still a postdoc at Aarhus University, I enrolled in the university's mentorship programme to get an outside opinion on whether to aim my efforts towards staying in academia or going to industry. The coordinator of the program matched my profile with three candidates and presented me with their profiles. All three candidates had an academic career and moved to industry in their forties so I could discuss the pros and cons with them. I chose the one who had a reputation for focussing mostly on mindsets and soft-skills because I felt the questions I had were about emotional components in addition to professional and technical ones. I expected him to

help me improve my CV and build a career plan; instead, the mentorship exceeded my expectations and I found my Yoda (the sage *Star Wars* guru) in my first mentor: Meredin Stoltenberg.

My conversations with Yoda were my first taste of how a mentor can help one become more self-aware. At the industry-academia crossroads, he helped me realise my reluctance to leave academia was due to my passion for solving the puzzles that came from research. He asked if I could find other ways to quench this thirst. He also introduced me to "The Alchemist"[2] (a story about journeys), which helped me see that academia was like a safety net and that it would be alright to venture out into the unknown. So, I took a leap of faith and quit.

Another pivotal event came from a job interview aptitude test that separated an individual's ability into three main categories: verbal (derives knowledge from reading a text), numerical (from graphs and diagrams), and

> ❝ I consider myself a mentor and coach on soft skills, personal awareness and development, job advice and business aspects are not my interest.
>
> My two cents on mentoring:
> Agree on a "contract" that respects boundaries for both parties, be willing to discuss and adjust that contract again and again. Being a mentor is about listening and containing, and ideally never give specific advices or recommendations; but potentially, during dialogue, open the mentee's awareness of the multiple opportunities that are (always) there. ❞
>
> **Meredine Stoltenberg, MD, PhD**
> Safety Lead at UCB, Brussels

diagrammatic analysis (pattern recognition).3 IQ is the average of the three tests. This showed me that intelligence is not the same for people with the same IQ value; rather, it is the sum of different traits. I was surprised to learn Yoda's strengths and weaknesses were the exact opposite of mine. We have so much in common, yet our brains operated very differently. The concept that ideas can be conceived in different ways extended my understanding and appreciation of how different minds work.

Our mentorship grew from a mechanically mandated programme to one that is more organic with traits of a friendship. From Meredin, I learnt of a world beyond performance and scores, and about life between tasks. His value for authenticity encouraged me to check my gut-feelings and speak honestly even when it is hard. He does this by validating what I say even when he does not agree. He is always honest about what he hears me say even when it is difficult for me to hear. This helped me identify my method of communication so that I learnt how to be perceived the way I really intended.

## The seeds of my entrepreneurial journey

My journey with Yoda started my mental transformation away from academia, which led

to me networking and job hunting. At the same time, Omiics Aps was born from a lab where I had done a postdoc. Little did I know that the company's journey would eventually merge with mine.

Morten Venø (my husband), Yan Yan, and I all worked in Professor Jørgen Kjems' lab at one point or another in our postgraduate careers. Morten and Yan pioneered RNA Next Generation Sequencing (NGS) in Jørgen's lab and the two had many successes over a decade, attracting other scientists to collaborate with them and starting a company, Omiic, in 2018. However, shortly after Yan realised she was pregnant and a few months after this, Morten broke his collarbone doing sports. As Mortens wife, I followed their journey from the side lines. While I was amazed at their achievements, I never considered joining them. However, since I found myself between jobs, I decided to help Morten and Yan get a good start on Omiics while finding my own path. The rest, as they say, is history.

## Finding business mentors in a start-up company

As I found myself in a start-up environment with only a few days' notice, I was very conscious about the immediate challenge: the lack of the

knowledge and experience that we needed to be successful. My job interview experience thus far all indicated that an experienced colleague often guided their junior counterparts. Now, with no real superiors or senior colleagues to support me, I had to think outside the box. A constant question I had was "How can I get this another way?" I realised I needed a business mentor and went to a seminar at my union to learn about their mentorship programme. At one point the speaker said, "If you have a specific person in mind, go ask them because then you do not need us." That comment stuck with me and before I got around to applying for the programme, I met Otto.

**Business and biotech acumen in one**
At a networking session of a public seminar on "Fundraising for Entrepreneurs", people mingled and pitched ideas. I quickly developed an elevator pitch: *"We are a biotech spinout, selling NGS (next-generation sequencing) and analyses services to academic institutions, industries, and hospitals across Europe…".* I highlighted our customer track record, as this was the bestseller to this audience. Out of nowhere, an investment manager responded to my pitch with "Oh, I have always had an interest in NGS". We chatted a bit, and while he was an investment-manager by

trade, he clearly understood the central elements of the academic research community. He was open and patient with every start-upper who spoke to him and I made sure to write down his name: Otto Bjerg Hausgaard.

It turned out that he had been a chief financial officer in a biotech venture and later became an investment manager handling a biotech portfolio. I set up a coffee meeting after the event. He may have expected me to come through the door with a strong pitch to apply for funding; instead, I came in with my honest concerns looking for advice. There was no doubt that this guy was brilliant, having both technical experience and strong interpersonal skills. I asked if he would be my mentor after the meeting. He declined, but said we could always have a cup of coffee now and then. So, I kept coming back drinking his coffee for a couple of times a year and he kept replying to my emails. Although not officially labelled a mentor, his role surely fit the title.

Being experienced in establishing a bio-technology-based company, he helped me filter and analyse events and tasks that were relevant for the business. For example, he suggested to do a "pull", which was to offer seminars on the technology. People with an interest in our technology (potential customers) would be "pulled" in by their interest and then we could connect. Additionally, sometimes when Omiics was approached by investors or invited to

meetings (where I did not know what to expect), I would always consult him. He has a talent for keeping things simple and I would leave the meeting less confused and more focused. Within Omiics, we repeatedly were told that our team did not contain a strong extro-vert (we are all intro-verts to some degree). After I shared my thoughts about this and concerns about acquir-ing new profiles, he simply said, "Let us decide now that this *is* the right team!"

### Lost in translation and finding common ground

As things progressed after joining Omiics, I found myself taking on the official Omiics mentor, Thomas Lundgaard, to learn about expert sales and business management. Thomas was introduced as a mentor to Omiics during its inception. He gave a kind of business world wake-up call to the academic scholar. He pushed for organisation, strict deadlines, and effici-ency measurements. As opposed to Yoda, we did not have much in common, but I knew the value of his know-ledge. Admittedly, the first few times we met, I left the meetings very annoyed. With time, however, I grew to enjoy our discussions and I learned a lot from him. He knew the ways of the business world and the jargon and I was eager to understand it.

During one session, we reviewed a draft of a business model for a grant application I had made. After reading it,

he said it was unclear to him and asked me to explain (step by step) the idea to him. As I went through my ideas and reasoning, he repeated them back to me using the appropriate business terms, which I used to revise the application. It was very educational for me. And we got the grant! The more we talked, the more we understood each other's language. I learnt that although it is sometimes hard to find the right words, it does not mean that there is no common ground – we are just struggling with translation.

### Community of practicing marketing and management communication

To increase my business acumen, I attended a mix of seminars, workshops, and a few minor courses. The major breakthrough happened when a professor, Constance Kampf, from the local business school asked Omiics to serve as a case study. She wanted her students to work on a "real life" company so Omiics and I became the focus of 150 students for a semester. This unique opportunity provided an intensive exercise in the "language of business" together with beginners who did not mind my broken grammar. The learning curve was steep because the topics taught during the course were new to me and the feedback from the students taught me important lessons on how to communicate across audiences. A classic example is when they interpreted DNA in the figurative sense (e.g.

> Working with a startup is super interesting!
>
> I always enjoy mentoring meetings, and find it both challenging and intellectually stimulating to establish a common understanding – a map of the landscape - that can help mentees navigate their business successfully.
>
> Further, it is really motivating to see how mentees manage to translate input into action, fast feedback and learning. As a mentor, this allows you to feel that you are contributing to their well-deserved success.

**Thomas Lundgaard, MBA**
Strategic Project Management

> As a seasoned investment professional I find it very rewarding meeting new technologies and young teams with yet undiscovered potentials.
>
> I strongly believe that some of the solutions that will save the world will come from such paths. New discoveries and new business are emerging, but it needs time and it needs to be talked through. I find talking with Susanne and the team gives me the opportunity to listen in on such talks and I appreciate the opportunity.

**Otto Bjerg Hausgaard**
Senior Relationship Manager at the Growth Fond, Denmark

I learnt that although it is sometimes hard to find the right words, it does not mean that there is no common ground – we are just struggling with translation.

business DNA) when I spoke of it in the literal sense (e.g. the biological molecule). Throughout the course, Constance patiently guided me through the feedback and extended my business jargon. At the end of the semester, the winning

team used the Knowledge Intensive Business Service theory to clarify our value as a business[4]. In short, "knowledge becomes implicit when working as a specialist in a focused environment. Being able to translate inherent knowledge into explicit information is one of the main challenges specialists face in a new environment. It requires you to practice telling what you do to strangers again and again."

**Professional entrepreneurial schooling**

In the spring of 2020, the Omiics team was invited to give a talk on creating a spinout from academia at an entrepreneurial class for academics. The course was organised by Mashauri[5], an online entrepreneurial education

platform whose CEO Simon Gifford, had spent the last decade consulting in the entrepreneurial space and launching a few of his own ventures. In preparation for our talk, Simon and I had several email correspondences on agenda suggestions and presentation techniques. Based on this positive experience, I asked him to help me grow my entrepreneurial mindset. During our first mentor meeting, I mentioned that I learned by doing, but I still lacked the basic foundation needed to build an overview. He enrolled me in one of his online classes and we discussed my results monthly. I identified with his core-philosophy that *you don't need to be born with the entrepreneurial mindset; with the right stimuli it is something you can grow*.

**The full package – experience in building a successful company from an academic spinout**

Meanwhile, I just got a new mentor. This time around, I was not looking. Otto suggested I look into the business model of the local IT company Mjolner Informatics, as they also started as a university spinout offering expert counselling. Their homepage did not offer the information I was looking for, so I decided to get creative. The

> It is inspiring to work with someone open, curious, and interested in learning about new perspectives.
>
> Susanne's engagement as our class client in Project Management was really strong, and our students also benefitted from sparring with her about their project ideas and plans.
>
> **Constance Kampf, PhD**
> Associate Professor at Business and Social Sciences, Aarhus University

> **Crossing the bridge between the academic world into the commercial world is a road with many tumbling rocks. The focus and strategies are very different. The talents trying to cross this bridge are heroes, that we (as country and as individuals) must support during their travel.**
>
> **Personally, I find energy and inspiration in working with startups on that journey. Guiding them as a translator between the worlds and giving them a strong commercial focus is my aim. Together, the goal is to establish Omiics as a successful and sustainable business.**

**Jørgen Lindskov Knudsen, PhD**
Investor, business advisor and
professional board member

Omiics office is located in a start-up incubator known as INCUBA,[6] which offers support for start-ups including a website of local business people who are interested in mentoring. There I found the co-founder of Mjølner, Jørgen Lindskov Knudsen, and proceeded to ask him for coffee. Jørgen is currently a business angel (an individual who provides capital for the development of a business). He was the co-founder of Mjølner about 30 years ago but after being CEO for 25 years (and looking at his timeslips), he decided he had worked enough, retired, and pulled his money out of the company. Since then he has spent part of his time mentoring, providing capital to startups, and acting on advisory and professional boards. Our meeting ended, but there was still so much to discuss. As with Otto, I was not looking for money, but experience and advice, and Jørgen was happy to share his knowledge so he offered to take me on as a mentee and I was very happy to accept.

## Concluding remarks

In the beginning of my mentorships journey, I approached mentorships very formally. When entering a mentorship through a programme, guidelines are usually provided as best practices on how to conduct the sessions. Nowadays, I have discovered mentors more organically. My main decree is that it should be done completely on the mentor's terms, which sometimes mean that they want me to lead. In a way, my mentors are my senior co-workers in my self-assembled fictional organisation (my husband calls it my personal advisory board). If I have sales-related questions, I go to Lundgaard. If I have financial questions or want information on a business profile, I would email Otto. If I need to reflect on how I managed a situation, I go to Yoda. People have asked me how I found all these wonderful people. From the story they all sound like serendipitous events and the relationships grew from there; however, part of the answer is quantity. When I started at Omiics, I aimed to meet at least one new person per week since I had to grow not only my own but a full company's business network from basically nothing. I did not always meet my quota but I have seen a lot of new faces. I still consider myself an introvert, which means that even during the most agreeable sessions, it is an active decision which consumes energy. Yet "taking a leap" into a room of new people is a muscle that grows with exercise. I do consider myself very lucky that my first experiences with mentorships have been so positive. If your first try doesn't turn out well, keep trying.

## Acknowledgements

## Conflicts of interest

The author is employed by Omiics ApS, whose services are discussed in this article.

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> **When and why do I offer to mentor?**
>
> 1. There are times when I see that I can really be of value to someone who needs it
>
> 2. When I can, I try to help - if I can make a difference, I will, if I feel I cannot, then I do not (but it is not always a criterion)
>
> 3. My philosophy: if you "give" to the world, it tends to come back (often double!)

**Simon Gifford**
CEO of Mashauri and Professor of
strategy & entrepreneurship at IE
business school, Madrid

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**Susanne Trillingsgaard Venø, PhD**, has acquired multi-disciplinary competencies within strategy, leadership, operations, project management, technology, and business development. She has disseminated science, through scientific papers, lectures, popular-science articles, and TV interviews. In 2019 she joined the entrepreneurship Omiics. In 2021 she was awarded a scholarship to the Instituto de Empresa business school Executive Programme.

# EMWA's Special Interest Groups



Veterinary Medical Writing (VET SIG)

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Sustainability (SUS SIG)

# The ABCs of paediatric plain language summaries

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## Abstract

Plain language summaries need to be written at a proficiency level of 2 to 3, which roughly corresponds to a 6th grade to 8th grade reading level. Writing these for paediatric audiences brings even greater challenges.

For communication to be effective, the needs of the target audience should be the foremost consideration. A document written for a child needs to be different from a document written for an adult reader.

In an attempt to understand preferences among the paediatric participants, the authors tested 3 different formats of plain language summaries with 30 paediatric volunteers. This article discusses insights gained from this exercise.

## Plain language summary (PLS)

Plain language summaries (also called layperson summaries, lay summaries, lay language summaries, simple summaries, and trial results summaries) are summaries of the aggregate results of clinical trials written in plain language. They are required by the European Medicines Agency (EMA) through the EU Clinical Trials Regulation 536/2014 (Article 37).[1] The main goal of writing a PLS is to help the study participants and the public understand clinical study results while keeping scientific integrity intact.

## Writing a PLS for a paediatric audience

In general, PLSs need to be written at a proficiency level of 2 to 3, which roughly corresponds to a 6th grade to 8th grade reading level. Writing PLSs for a paediatric audience brings greater challenges.

For communication to be effective, the needs of the target audience should be the foremost consideration. A document written for a child needs to be different from a document written for an adult reader. While the specific requirements vary by age group, a document written for a child often has:

- Shorter sentences and simpler words
- More white spaces
- More graphics.

These are not just cosmetic aspects of a document, but fundamental requirements to help children understand the content and to hold their attention. Therefore, it is important to apply these principles while writing PLSs for children and/or adolescents.

The recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use[2] mentions that sponsors of paediatric studies should consider developing a child-focused version of the PLS that may differ in terms of presentation and style (more illustrations or graphics) to assist children in understanding trial results, over and above what is required under the EU CT Regulation.

While considering the appropriate format, the sponsor must ensure that the information presented is non-promotional, non-misleading, and factually correct, while still being easy to understand.

## Different PLS formats

To better understand the impact of format and graphics on the readability of a paediatric PLS, 3 different formats of a PLS on pollen allergy were created:
1. Standard PLS
2. Infographic version
3. Illustrated version

### Standard PLS

The standard PLS was a basic version that met the minimum requirements of a PLS:
- Text was suitable for people with low to average levels of literacy.
- Simple words and sentence structure were used.

- Basic graphics, e.g., diagrams explaining the study design, simple bar graphs for the primary endpoint results were used.
- Simple tables were used to report the safety results.

Figure 1 includes examples of the key components of the paediatric PLS. The full PLS for study CIGE025F1301 can be found at www.novartisclinicaltrials.com.[3]

### Infographic PLS

The infographic PLS used a combination of text, icons, and charts to improve the readability and presentation of the document for a paediatric audience:
- All the readability elements of the standard PLS, described above, were retained in this version.
- Where possible, relevant icons or info-graphics were added to support the text, shortening the paragraphs of information. This also helped to add more white space in the document:
- A glossary of terms was included at the beginning of the PLS to familiarise the reader with the scientific terms used in the PLS.
- Previous testing suggested that bar graphs for primary endpoint results are easy to comprehend and thus were retained in this version.
- The tables to explain the safety results were changed into an infographic format.

> These are not just cosmetic aspects of a document, but fundamental requirements to help children understand the content and to hold their attention.

Figure 2 shows examples of key differences from the standard PLS. The full infographic PLS for study CIGE025F1301 can be found at www.novartisclinicaltrials.com.[3]

### Illustrated PLS

An illustrated version was created using the standard PLS as the starting point. The simple graphics and tables of the standard version were replaced with comic-style graphics. The text of the PLS was edited to make it more concise, so as not to overwhelm the children and adolescents.

Figure 3 shows examples of key differences from the standard and illustrated PLS.

## Feedback from user testing on the 3 PLS formats

Children between the ages of 9 and 16 were asked to provide feedback on all 3 versions of the anonymised PLS. The children were asked to read the PLSs and provide their feedback either face-to-face or online. Their feedback was

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## Why was the research needed?

1 Researchers are looking for a better way to treat severe Japanese cedar pollinosis that is not completely controlled by the currently available treatments. Japanese cedar pollinosis is a type of seasonal allergy caused by Japanese cedar pollen. This allergy affects around 30% of the people living in Japan. A majority of the people affected have severe symptoms that impact their daily activities. Symptoms include sneezing, runny nose, stuffy nose, and itchy and watery eyes. Even with the available treatments, some patients still report symptoms during the cedar pollen season.

2 **Most Common Non-Serious Adverse Events**

| | Drug X | Placebo |
|---|---|---|
| Total number of participants | 161 | 175 |
| Total participants affected with the most common events | 16% (26) | 12% (21) |
| Common cold | 9% (15) | 5% (8) |
| Sore throat | 4% (7) | 3% (5) |
| Flu | 3% (4) | 5% (8) |

*Figure 1. Examples from the standard PLS format*

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*Figure 2. Examples from the infographic PLS*
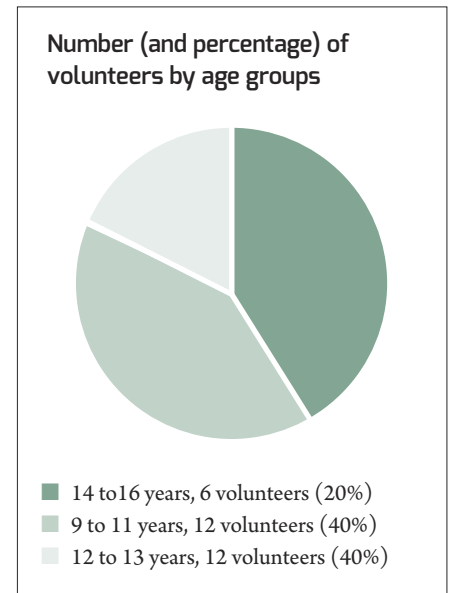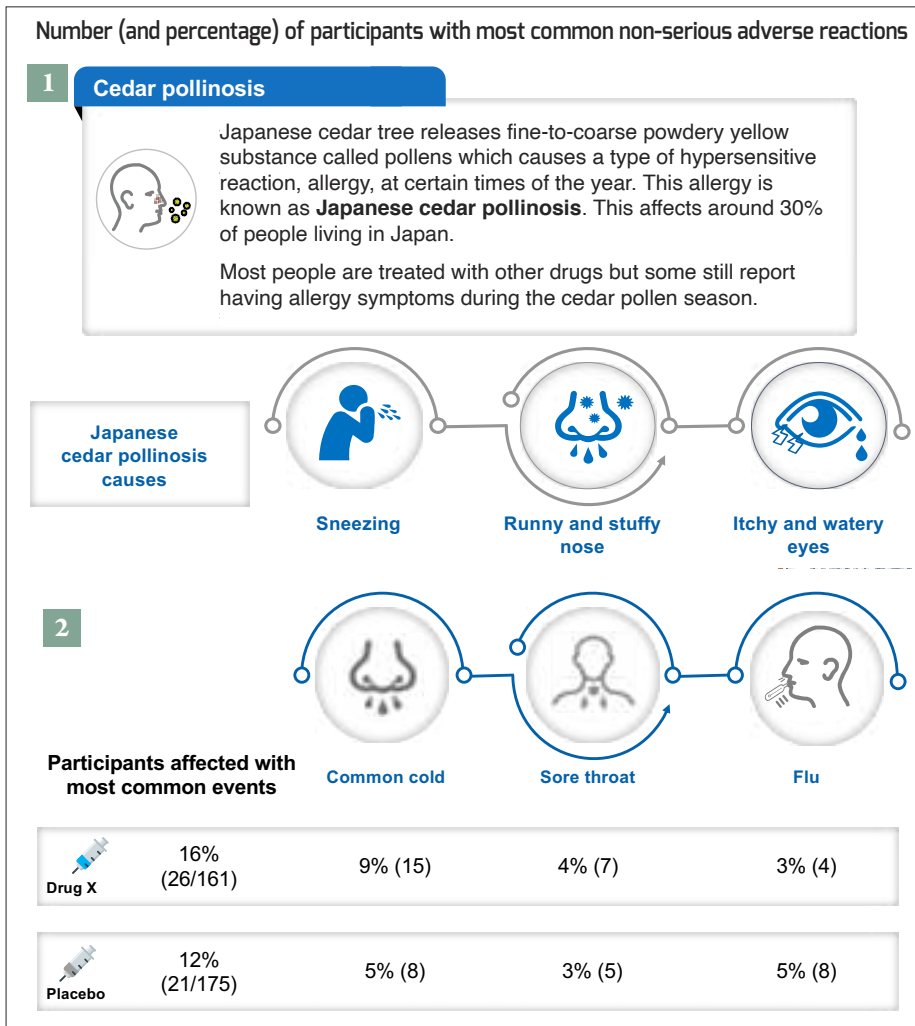


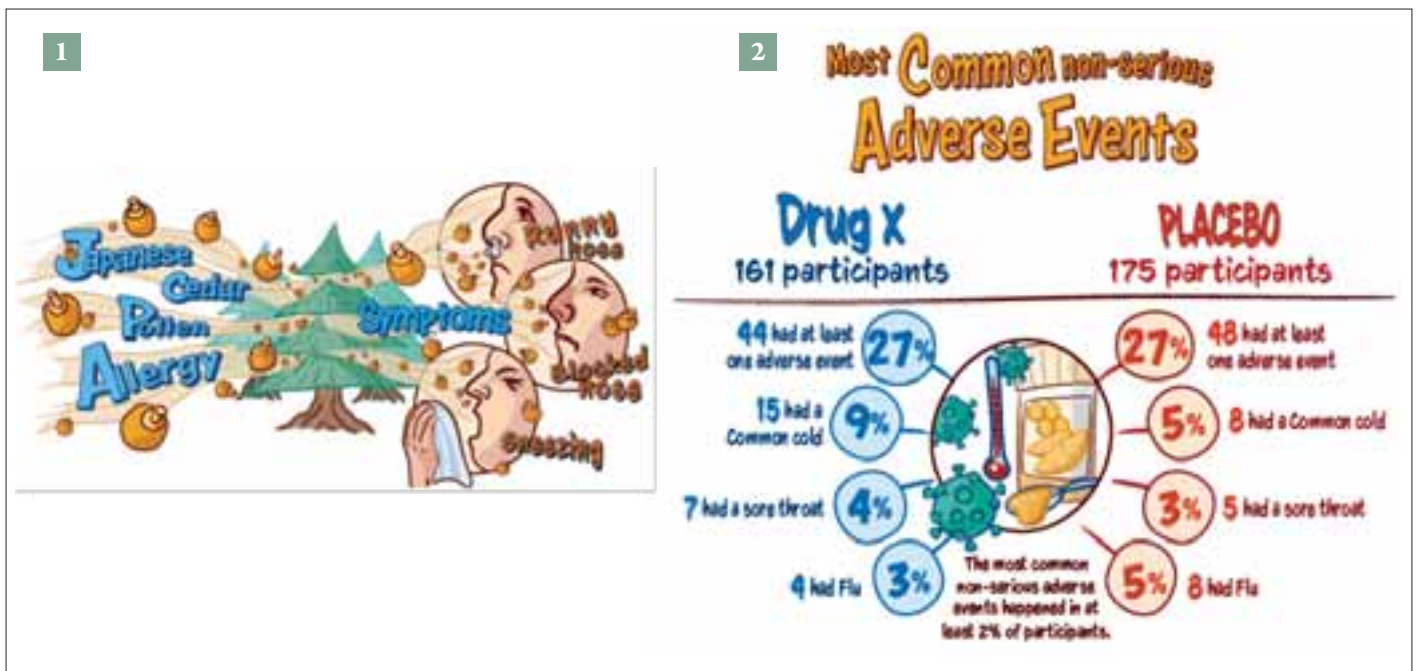*Figure 4. Number of volunteers by age group*



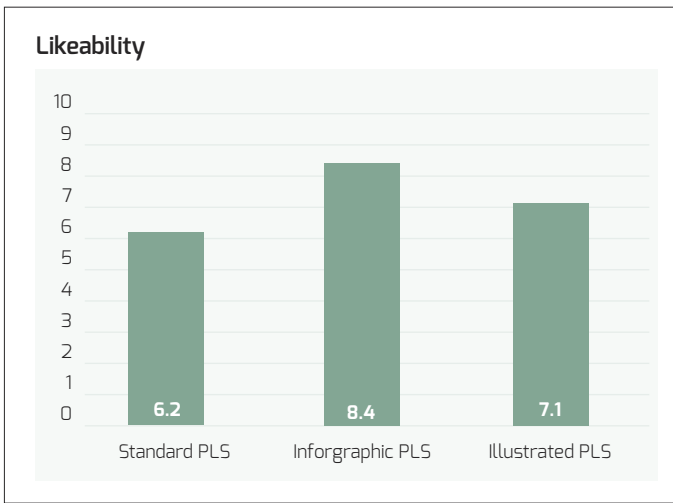*Figure 3. Examples from the illustrated version*
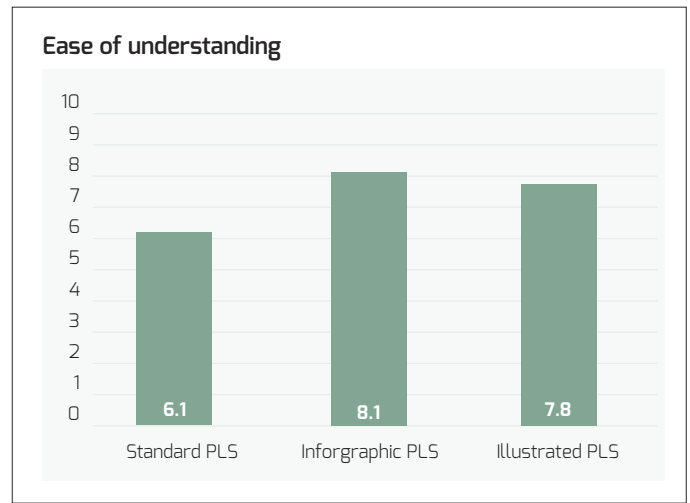
*Figure 5. Likeability by PLS format*



*Figure 6. Ease of understanding by PLS format*

recorded and analysed to identify preferences and trends.

Thirty volunteers (15 male, 15 female) between the ages of 9 and 16 provided feedback on the 3 PLS versions. Figure 4 shows the distribution of volunteers by age group.

The volunteers were from 3 countries: two in the US, 12 in India, and 16 in the UK.

**Likeability of the PLS based on format**
All volunteers were asked to rate the likeability of each PLS format on a scale of 1 to 10.

How much do you like the summary? Rate it on a scale of 1 (don't like it at all) to 10 (it is perfect).

The infographic and illustrated versions were preferred over the standard version. The average scores for likeability are presented in Figure 5.

When asked which of the versions was their favourite, 19 (63%) volunteers chose the infographic version, 7 (23%) volunteers chose the illustrated version, and 4 (14%) volunteers chose the standard version. The preference for a particular version did not differ based on the volunteers' age. The majority of volunteers (including the ones who were between 14 and 16 years old), acknowledged that the illustrated PLS was engaging and appropriate for their age group.

The main reasons shared by volunteers for preferring the infographic and illustrated versions over the standard format were:
- Inclusion of relatable and meaningful graphics
- Good balance of text and graphics
- More white spaces

When asked what they would like to change in the infographic version, which was the most liked, 4 volunteers recommended using more colours than just blue and black.

**Ease of understanding**
Volunteers were asked to rate their ease of understanding of each format of the PLS on a scale of 1 to 10.

How easy is it to understand the summary? Rate it on a scale of 1 (too difficult) to 10 (really easy to understand).

According to the volunteers, the infographic and illustrated versions were easier to understand than the standard version. The average scores for ease of understanding are presented in Figure 6.

The main factors that seemed to help volunteers understand the PLS were:
- Appropriate graphics that increase comprehension
- More white spaces between different sections
- A glossary of terms at the start of the summary (specific to infographic version)

**Length of the document**
The length of a PLS is believed to be an important factor related to the readability of the document. More so, for a paediatric PLS considering the shorter attention span of children. Table 1 presents the number of pages in each of the PLS formats tested.

When asked about the length of the document, 12 (40%) volunteers commented that the PLS should not be too long, as otherwise,

*Table 1. PLS Page Length*

| PLS Format | Pages |
|---|---|
| Standard PLS | 8 |
| Infographic PLS | 12 |
| Illustrated PLS | 8 |

they could lose interest. All of these participants were between the ages of 10 to 14 years. Fourteen (47%) volunteers said that the length did not matter to them as long as the PLSs are easy to understand.

Interestingly, 13 (43%) of the volunteers felt that comparatively, the standard version was too long and boring. Considering that the standard and illustrated versions were of the same length and the infographic version was even longer, this finding indicated that the use of white spaces, use of graphics, and format of the PLS influenced the perceived length of the PLS. This suggests that design and layout of the document are more important than the length of the PLS for these readers.

While sponsors should be cautious not to write very lengthy PLSs, they should not compromise on including the graphics and white spaces just to remain within a certain page limit.

**Trust towards the sponsor**
When asked whether they trust the sponsor of the clinical trial based on the PLSs they have read, all volunteers confirmed that they trusted the sponsor.

When asked if their feelings towards the sponsor changed based on the format of the PLS, 19 (63%) responded that the format did not change their trust and feelings towards the sponsor. For the remaining volunteers, 8 (27%) felt most trust reading the format they liked the most, which showed that their trust was directly linked with their preference for the PLS format.

This suggested that readers' feelings of trust towards the sponsor are dependent on multiple factors, including ease of understanding of the document and perceived reliability of findings, and may not be directly influenced by the format.

## Conclusions

While creating PLSs for paediatric audiences, sponsors should not restrict themselves to a single template and should tailor the PLS content by:

- Applying the fundamental communication strategies for the different age groups within the paediatric audience
- Creating a good balance between text and engaging graphics
- Providing tools like a glossary at the beginning of the PLS.

Sponsors should consider incorporating user testing in the PLS writing process, especially for paediatric PLSs. This will allow sponsors to develop a stronger understanding of their audience to create better PLSs.

## Acknowledgements

## Disclaimers

## Conflicts of interest

The authors declare no conflicts of interest.

## Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

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# The December 2021 edition



## Medical Journalism

We are living at a time when the general public is increasingly interested in scientific and medical advances. Hence, for medical writers, understanding our audiences and how to efficiently reach them is key.

This issue will cover those insights.

Guest Editors:

Evguenia Alechine and Phil Leventhal

# Presenting secondary endpoints in plain language clinical trial result summaries:
## Considerations for emerging practice

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## Abstract

**Background:** The European Union Clinical Trials Regulation 536/2014 (EU CTR) requires sponsors to submit summaries of clinical trial results in plain/lay language (Plain Language Trial Summaries [PLTS]). A multidisciplinary working group developed recommendations for defining, selecting, and summarising patient-relevant secondary endpoints in the PLTS.

**Considerations:** For sponsors who elect to include more than the primary endpoint, emerging practice is to include patient-relevant secondary endpoints, defined as those that were prespecified as secondary endpoints in the protocol, their analysis being described in the protocol or statistical analysis plan, and represent something of particular importance or value to patients. The summarisation of patient-relevant secondary endpoints should reflect the statistical rigour applied to the analysis. Patient-relevant secondary endpoints should be clearly distinguished from primary endpoints in the PLTS, and they should refer to information that exists in the public domain.

**Conclusions**: For sponsors who elect to include patient-relevant secondary endpoints in the PLTS, emerging practice is to apply a systematic approach for selection and summarisation so that meaningful information is provided to patients in a fair and balanced way.

## Introduction

Research has shown that clinical trial participants want to know the results of trials in which they participated. This information recognises participants' contributions, can help them better understand the facts about the clinical trial in which they participated,[1–3] and may affect their willingness to participate in future trials.[4–6] While sponsors are required to post technical/scientific result summaries of completed trials on public registries (e.g., EU Clinical Trials Register, ClinicalTrials.gov),[7,8] the language and format used is not understandable to most trial participants.[9,10]

Article 37 of EU Clinical Trials Regulation 536/2014,[11] once in application, will require sponsors to submit summaries of clinical trial results "written in a manner that is understandable to laypersons" (herein referred to as Plain Language Trial Summary[ies], or PLTS). In their recommendations,[12] the EU Expert Group that convened to provide guidance on the design and writing of PLTS indicates the results section should describe the outcome of the trial, including "the primary endpoint(s) and results by trial arm which were prespecified by the statistical analysis plan (SAP) as a primary endpoint, and additional safety data important to the overall results of the trial" and "should reference the complete list of outcomes based on all endpoints available in the technical results summary for each clinical trial in the EU database including patient relevant secondary endpoints." In a Question & Answer (Q&A) document, the European Commission (EC) on Health and Food Safety Directorate-General indicates that the PLTS should include "the main objectives of the clinical trial and should therefore reflect at a minimum the primary endpoints, and patient-relevant secondary endpoints."[13] No definition of patient-relevant secondary endpoint is provided by either the Expert Group or the EC.

While the requirement to include the primary endpoint(s) is clear, the guidance for nonprimary endpoints is ambiguous, leaving trial sponsors to decide which, if any, nonprimary endpoints may be appropriate for inclusion in the PLTS and how to select them.

## Methods

The multidisciplinary working group that developed these considerations met in the context of contributing to the European Forum for Good Clinical Practice (EFGCP) Good Lay Summary Practice Guidelines,[14] sponsored by the European Federation of Pharmaceutical Industries and Associations (EFPIA). In a series of meetings over 8 months in 2020 and 2021, the working group developed the criteria that sponsors can apply in identifying patient-relevant secondary endpoints and a framework for how to evaluate, select, and summarise these endpoints in the PLTS. This article is an independent publication by this working group and was not developed under the auspices of EFGCP or EFPIA. The following questions were explored:

(a) Should secondary endpoints be included in the PLTS?
(b) How can patient-relevant secondary endpoints be defined or determined?
(c) What are the considerations for selecting and including patient-relevant secondary endpoints in the PLTS?
(d) Should additional endpoints (e.g., tertiary, exploratory) be included in the PLTS?
(e) When and how should patient input be obtained?
(f) What are the considerations for summarising patient-relevant secondary endpoints in the PLTS?

## Results

The working group proposes a framework, based on emerging practice, to systematically evaluate, select, and summarise patient-relevant secondary endpoints in PLTS, with the goal of producing a PLTS with fair, balanced, and relevant content.

### Should secondary endpoints be included in the PLTS?

Considerations for deciding if more than the primary endpoint(s) may be disclosed in a PLTS include: whether the endpoint results have been publicly described elsewhere (e.g., trial documents on public registries), whether the endpoint represents something of particular importance or value to patients, and whether providing the additional information to patients creates the risk of the information being misinterpreted.

### How can patient-relevant secondary endpoints be defined or determined?

We acknowledge that the term "patient relevant" cannot be defined in any narrow or strict sense.

For the purposes of this article, patient-relevant secondary endpoints were defined as those that were prespecified as secondary endpoints in the protocol, had the statistical analysis described in the protocol or SAP, and represent something of particular importance or value to patients. Endpoints considered of interest to patients are those that reflect their experiences, perspectives, needs, and priorities related to symptoms of their condition and its natural history, the impact on their functioning and quality of life, or their experience with treatments.[15,16]

### What are the considerations for selecting and including patient-relevant secondary endpoints in the PLTS?

A PLTS is meant to be a brief, clear, easy-to-read, and understandable summary of trial results for participants and the public. The addition of patient-relevant secondary endpoint results could potentially lead to misinterpretation or confusion of the results from the primary endpoint and cause the reader to give more weight than appropriate to the secondary results.[17] The importance of the secondary endpoints relative to the primary endpoint should not be overstated. In addition, the results should be meaningful to patients. Sponsors are encouraged to consider seeking input from patients, patient advocacy groups, and/or clinical team members. When including only a subset of patient-relevant secondary endpoints in the PLTS, the selection of endpoints should be undertaken and clearly documented prior to knowing the trial results. All endpoints included in the PLTS should be supported by data in the clinical study report (CSR) and described in technical/scientific results summary(ies) posted on public registries, such as ClinicalTrials.gov. To help address these points, emerging practice suggests a predefined, systematic approach for selecting and summarising patient-relevant secondary endpoints as outlined below.

1. Only patient-relevant secondary endpoints should be summarised in the PLTS.
2. To reduce the appearance of selection bias, decisions about which patient-relevant secondary endpoints to include in the PLTS should be made and documented prior to database lock and before any knowledge of trial results,

> The importance of the secondary endpoints relative to the primary endpoint should not be overstated.

including results of interim analyses. Results of posthoc analyses should not be included. Sponsors may consider identifying PLTS endpoints already at the time of protocol development.

3. Develop a PLTS endpoint selection process that can be consistently and transparently applied across trials and therapeutic areas.

4. While it is the sponsor's responsibility to determine final PLTS content, it is suggested that the decision about patient-relevant secondary PLTS endpoints be made with input from other patient-centric sources. Some suggestions for gathering input are listed:

   a. Patient feedback is the most direct method for gathering patient-relevant information. Patient feedback may be obtained through mechanisms available within the sponsor's institution, e.g., ongoing patient engagement activities, market research, or from other sources for investigating patient relevance.[18–22]

   b. Other reasonable alternatives that could supplement direct patient feedback are input from patient advocacy groups,

carers, and health care providers.

   c. Input from clinical team members with experience in the disease area and direct involvement in protocol development and execution is another method.[23] Consider including at least one contributor with detailed knowledge of trial-specific statistics to advise on the summarisation of data. Clinical team input can be a valuable way of identifying secondary endpoints that are potentially patient relevant; this may be corroborated through patient-centric sources.

**Should additional endpoints be included in the PLTS?**

Due to their inherent exploratory nature, emerging practice is not to include tertiary or exploratory endpoints or secondary endpoints that are not considered as patient relevant in the PLTS. Doing so may result in misinterpretation and potentially confuse readers without providing valuable information. In situations where such endpoints are considered important to patients, in lieu of providing results, the sponsor may acknowledge that the endpoints

were assessed and comment on next steps or indicate where additional information may be found.

**When and how should patient input be obtained?**

Direct patient input may be obtained in a number of ways throughout the clinical development process, including, but not limited to the following three different stages:

1. initial creation of research objectives,
2. defining protocol endpoints and their hierarchy for a clinical trial, and
3. selecting patient-relevant secondary endpoints for the PLTS. For the purpose of this article, we focus on Stage 3. Additional information on patient engagement can be found elsewhere.[24–27]

The selection of patient-relevant secondary PLTS endpoints can be done using qualitative and quantitative preference research methods.[28,29] Patients selected to provide input are usually not participants in the trial of interest but should be familiar with the concept of study endpoints and be able to suggest how to describe them in plain

language. To provide the appropriate context, the primary and all secondary study endpoints should be presented to patients to clarify the trial objectives and define expectations for patients' contributions, including that other criteria will be applied to determine final endpoint selection for the PLTS.

For each patient-relevant preference exercise, a list of endpoints and their attributes should be developed. Attributes are features, such as efficacy, safety, duration of effect, duration of use, lifestyle aspects, and other benefit-risk considerations that the endpoints are designed to assess. The endpoints can then be presented to patients for ranking in terms of preference. This will demonstrate their preference for one endpoint relative to the other endpoints.

**What are the considerations for summarising patient-relevant secondary endpoints in the PLTS?**

All information in the PLTS, including patient-relevant secondary endpoints should be summarised using plain language that is simple, clear, fair, balanced, and non-technical without diluting or changing the meaning or importance of the

data. Health literacy and numeracy principles should be followed.[30–32] Further guidance for summarising trial data in lay language may be found at the Multi-Regional Clinical Trials Center[32] and in the TransCelerate Recommendations.[33] In general, consider how meaningful numerical data may be to patients (e.g., number of hospitalisations, number of blood transfusions, survival in months) versus something more abstract (e.g., decimal changes in a clinical index) for which absolute changes may be less meaningful without a lengthy explanation or training in the scientific discipline.

Emerging practice for summarising and presenting patient-relevant secondary endpoints in PLTS involves several important considerations that are outlined below.

Maintain the appropriate context with respect to the primary endpoint(s): Patient-relevant secondary endpoints should be clearly separated and distinguished from the primary endpoint(s) in the PLTS. One way to do this is to place the results for primary endpoint(s) and patient-relevant secondary endpoint(s) in separate sections and name them differently (e.g., "main aim of the trial" versus "other trial results"). Use of visual icons may also help draw readers' attention to the important or main messages (primary endpoint) of the PLTS. Language should be provided that indicates the patient-relevant secondary endpoints were not the main focus of the trial.

Consider how patient-relevant secondary endpoints may have been described in other publicly disclosed trial-related technical/ scientific results summaries or patient communications: The summary of patient-relevant secondary endpoints in the PLTS should be consistent with other information that has been publicly disclosed (e.g., trial-related documents posted on public registries, scientific publications, etc.). Although presenting information the same way in all cases may not be possible, the suggestion is to convey information in the PLTS that is consistent with information that has been presented in other trial related patient and public communications.

Maintain statistical rigour with which the endpoint was analysed and include appropriate level of detail: Tailor the summary of results to the data that are available, the statistical rigour

applied to the analysis, and how valuable the numerical results might be to a patient. This can range from simply describing the endpoint with no mention of results to a presentation of numerical results with figures, tables, and graphs. Figure 1 shows an algorithm for deciding how results in a PLTS may be summarised.

When results of non-statistically powered patient-relevant secondary endpoints are presented, these should be accompanied by a clear explanation that the results are preliminary, non-confirmatory, may reflect chance findings, and that no conclusions can be drawn from them (adjust the statement to fit the data). To reduce the risk of readers overlooking these types of disclaimer statements, emerging practice suggests keeping them concise and limiting their use throughout the document. Finally, consider including a statement (and corresponding link) indicating where further information about the endpoint can be found (e.g., link to technical/ scientific results summaries on public registries or scientific publications).

Table 1 lays out possible approaches for summarising patient-relevant secondary endpoints in the PLTS and is meant as a guide to help sponsors think through the most appropriate way to describe the data. The examples shown are for illustrative purposes only. The approaches are classified into tiers, ranging from a presentation of numerical results with health-literate graphics (Tier 1, Quantitative Summary) to merely a description of the endpoints with no mention of results (Tier 4, Aggregate Description). The Tiers are not absolute, and there may be more than one way to represent the same data. In all cases, the text in the PLTS should reflect the statistical rigour applied to the analysis and the data and conclusions in the CSR. Avoid using comparative statements (e.g., stating that results in one group were better/worse than in another group).[33] This is particularly important in cases where no numerical results are presented.

*All information in the PLTS should be summarised in a fair, balanced, and non-technical way.*

## Discussion

As noted in the introduction of this article, there is a lack of clarity in guidance between the Expert Group on Clinical Trials and the EU Q&A. Although the recommendation in the Expert

*Table 1. Approaches for summarising patient-relevant secondary endpoints in plain language trial summaries*

| Levels of Summarisation | | |
|---|---|---|
| | **Tier 1 – Quantitative** | **Tier 2 – Semi-quantitative** |
| **Secondary endpoint attribute** | • Statistically powered endpoint predefined to confirm a hypothesis or one that was considered in determining sample size of the study. | • Endpoint was not statistically powered to confirm a hypothesis but was statistically analysed to investigate differences (e.g. between groups or from baseline). |
| **Results available** | • Statistical results (e.g. p values, 95% CI) provided.<br>• Conclusions can be drawn from the data due to statistical rigour applied to the analysis. | • Statistical results may have been provided. However, conclusions should not be drawn from the data as the study was not designed for this. |
| **Considerations for summarising results** | • Consider presenting numerical results (e.g. average, range) including figures, tables, or graphs that meet health literacy principles.<br>• Comparative statements (e.g. more patients had an outcome in one group versus another) may be included if supported by the results and statistical rigour of the analysis (e.g. p value; 95% CI). | • Consider presenting numerical results, but avoid graphical displays (figures, tables, graphs) that could be read in isolation and misinterpreted without appropriate context.<br>• Avoid statements that suggest a conclusive finding. |

| Examples of endpoint summaries by tier for hypothetical study endpoints | | |
|---|---|---|
| | **Tier 1 – Quantitative** | **Tier 2 – Semi-quantitative** |
| Pain score defined as a reduction from baseline in pain of ≥50% at Week X<br><br>Plasma concentrations of Treatments A and B | • "At Week X, more patients taking Treatment A (50 of 100 patients, 50%) had a lower pain score than patients taking Treatment B (35 of 100 patients, 35%)."<br><br>*[Note: statistical rigour allows making a* **comparison** *between groups, supported by the data.]* | • "At Week X, 50 of 100 patients (50%) taking Treatment A and 35 of 100 patients (35%) taking Treatment B had lower pain scores."<br><br>**Sample disclaimers:**<br>In the case where results (e.g. p value/CI) suggest a potential difference:<br>• "The results suggest there could be a difference between the 2 groups. Researchers cannot be certain whether the difference between the 2 groups was due to chance or due to the treatment. These results should be confirmed in another study."<br>In the case where the results (e.g. a, p value/ CI) suggest no potential difference:<br>• "The results suggest there may be no difference between the 2 groups. These results should be confirmed in another study."<br>*[Note:* **numerical** *results are presented, but* **no comparison** *is made between group – the study was not powered to confirm this – and a* **disclaimer** *is added about the limitations of the study.]* |

Notes: In all cases, text presented in the PLTS should be consistent with the data and conclusions in the clinical study report (CSR).

Endpoints in the results section should have been previously explained/defined, in plain language

*Table 1 (continued)*

| Tier 3 – Qualitative | Tier 4 – Aggregate Description |
|---|---|
| • Endpoint was not statistically powered or analysed.<br>• For example, secondary endpoints may have been evaluated to assess their potential use as outcome measures in future studies, or they may represent procedures that were particularly burdensome for patients (hence, they are included in PLTS for the patients' benefit). | • Endpoints for which results would not be considered meaningful to patients. For example, PK parameters, disease scores. |
| • Summary results may have been provided, although, the data may be considered difficult for patients to understand without a lengthy explanation. | • Statistical or descriptive statistics may have been provided, and the data may or may not be considered conclusive (based on statistical rigor applied).<br>• Data are likely not understandable to patients without training in the scientific discipline. |
| • Do not present any results in any format (textual, numerical, or graphical).<br>• Qualitatively describe the endpoint and indicate why it was measured, and if applicable, what information was learned from it. | • Do not present any results in any format.<br>• Acknowledge (in aggregate) that other patient-relevant secondary endpoints were evaluated (i.e. rather than listing/describing each one separately), briefly describe how the data were used (in aggregate). |

| Tier 3 – Qualitative | Tier 4 – Aggregate Description |
|---|---|
| • "At Week X, both groups had lower pain scores."<br><br>**Sample disclaimers:**<br>• "This study was not designed to provide firm evidence of an effect on pain."<br>• "This study was not designed to confirm if there was a true difference in pain reduction between patients receiving Treatment A or Treatment B. These results should be confirmed in another study."<br>• Instead of summarising the results, another option could be to indicate why the endpoint was assessed and what information may have been gained:<br>• "The researchers learned that measuring pain may be useful for studying drugs to treat X disease. These results should be confirmed in another study."<br><br>*[Note: **no numerical results** are presented, but rather, a **textual description** of what was observed in each treatment arm/information learned is given along with a **disclaimer** about the limitations of the study.]* | • Researchers also measured the level of drug in patients' blood. Further details can be found at (source)."<br><br><br>*[Note: this acknowledges that PK endpoints were assessed but gives **no results**. A statement indicating where **additional information** can be found is included.]* |

Abbreviations: CI=confidence interval; PK=pharmacokinetic; PLTS=plain language trial summary
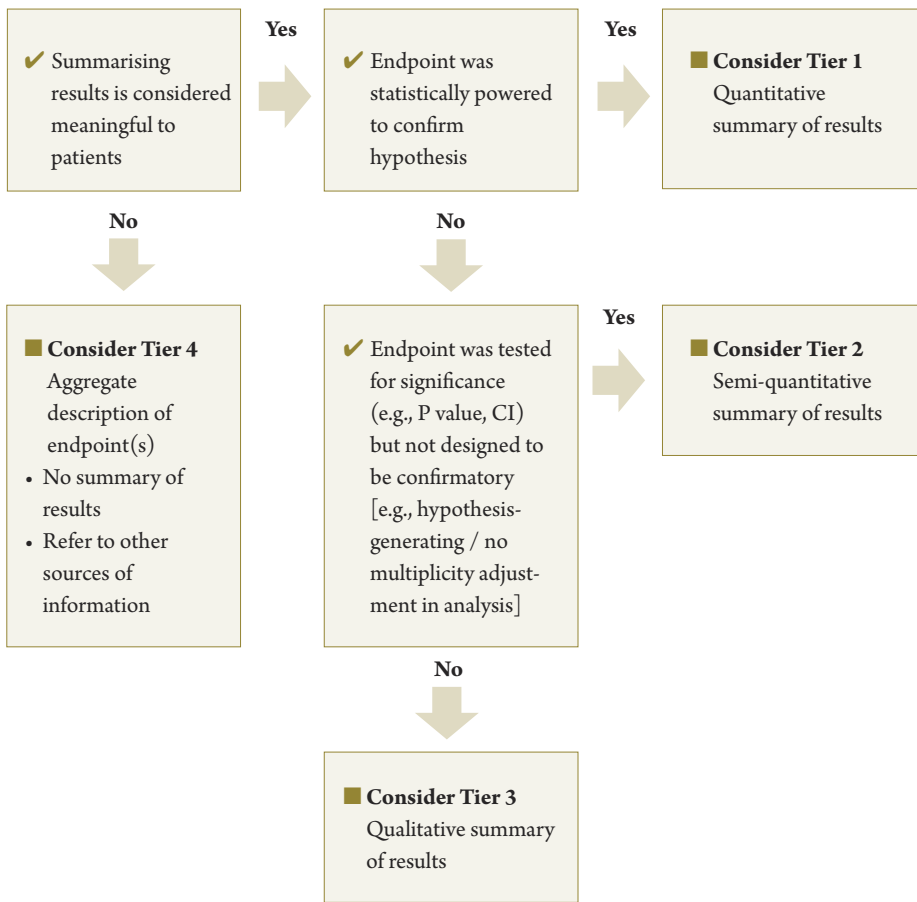
*Figure 1. Algorithm for summarising patient-relevant secondary endpoints in plain language trial summaries*

Group on Clinical Trials is to include only primary endpoint results in the PLTS, trial participants may want to know more. While some sponsors will include only results of the primary endpoint in the PLTS, others may elect to also include secondary endpoints. Including more than primary endpoint in the PLTS, or a subset of secondary endpoints, presents the challenge of conveying the additional information concisely in a non-biased, fair and balanced way that patients can easily understand. The working group did not seek to resolve these issues, but rather, to acknowledge they exist and offer considerations for addressing them, based on emerging practice. It is each sponsor's

> Sponsors should predefine a systematic, transparent approach toward the selection of endpoints in PLTS that can be applied across all clinical trials within their organisation.

responsibility to interpret and apply the regulatory guidance and determine which endpoints will be included in PLTS and how they will be presented.

The working group's recommendation for sponsors who elect to include more than primary endpoint results in the PLTS is to select only patient-relevant secondary endpoints that have been otherwise publicly disclosed. The working group members acknowledge the process of selecting a subset of patient-relevant endpoints is subjective even with patient input. Therefore, to reduce the risk of perceived bias, sponsors should predefine a systematic, transparent approach toward the selection of endpoints in

PLTS that can be applied across clinical trials within their organisation and select and document endpoint selection prior to knowing the study results. Results of patient-relevant secondary endpoints should be clearly distinguished from the primary endpoint results in the PLTS and presented in the appropriate context based upon the level of rigour applied to the statistical analysis.

## Conclusion

There are important considerations for determining whether to include more than primary endpoints in a PLTS. For sponsors who elect to include patient-relevant secondary endpoints in PLTS, emerging practice is to apply a systematic approach toward the selection and summarisation of patient-relevant secondary endpoints in order to consistently produce PLTS that are meaningful to patients with fair, clear, and

**REGULATION (EU) No 536/2014**

**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014**

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

Article 37

End of a clinical trial, temporary halt and early termination of a clinical trial and submission of the results

4. Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV.

It shall be accompanied by a summary written in a manner that is understandable to laypersons. The content of that summary is set out in Annex V.

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL FOR LAYPERSONS

balanced content. It is recognised that adjustments to the considerations described in this paper may be needed if the guidance is clarified and/or new instructions are provided on how sponsors could include patient-relevant secondary endpoints.

## Disclaimers

The views and opinions expressed herein are those of the individual contributors and should not be attributed to any organisation or institution with which the contributors are employed or affiliated, or to EMWA.

## Conflicts of interest

The authors declare no conflicts of interest.

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# AMWA-EMWA-ISMPP

## Joint Position Statement on Medical Publications, Preprints, and Peer Review



## Background

In medical publications, just as in research and development, quality depends on the expertise and integrity of researchers/authors as well as qualified peer reviewers and journal editors. However, the laborious and time-consuming process of the traditional peer review[1] can be compromised by the pressure to publish quickly – particularly during a health crisis, when timely

distribution of credible medical information can make a substantial difference.[2] Recent examples of negative consequences are two articles on COVID-19 that were hastily published in high-profile medical journals and subsequently retracted.[3,4]

Traditional peer review, although not perfect, remains the most frequently used process for vetting scientific publications. However, it has become more common for manuscripts to be released without prior review, which raises new concerns.

The potential value of rapid publication should be weighed against the potential harm of inadequate validation of the final output. There is a danger that lowering the threshold of publication oversight sets a precedent that cannot be easily reversed, potentially eroding standards and public trust in medical science.[2]

We have joined in a multi-party consortium

among three eminent professional organisations for medical communication professionals – AMWA, EMWA, and ISMPP – to advocate for the adoption of standards by all stakeholders to better ensure the integrity of published scientific and medical information. Thus, the following Joint Position Statement has been developed to provide practical and implementable suggestions to uphold data integrity and quality, and the transparency of medical publications.

Note: We use the term "medical writer" to represent the spectrum of professionals who prepare documents either for submission to regulatory authorities or for publication in peer-reviewed journals.[5]

Contact: amwa@amwa.org; info@emwa.org; ismpp@ismpp.org

# Communication of research: issues and suggested solutions

## Preprints

Preprints are preliminary scientific reports that are made publicly available online for anyone to read, comment on, and discuss before they have been peer reviewed. Some preprint servers scrutinize submissions for scope and for basic quality standards before making them publicly available.[6–8] Once the preprint is posted, most reputable preprint servers assign a unique digital object identifier (DOI) to aid traceability. Authors can revise preprints according to readers' comments and post iterative versions. Preprints are often not indexed on mainstream bibliographic services, although Europe PMC now indexes preprints,[9] and there are standalone tools for searching named preprint servers to improve discoverability.[10]

Preprints have been rapidly adopted by physicians and scientists, their obvious benefits being the immediate availability to their peers and the public, avoiding lengthy peer-review processes prior to release, and the option of readers to leave comments. However, there are issues associated with preprints that ideally should be addressed by standards jointly developed by a convened body of all stakeholders.

### Issues with preprints:

- While preprints enable rapid release and discussion of data, many are never revised, and only about a third to a half are ever fully published.[11,12]
- "Once the toothpaste is out of the tube, it cannot (easily) be stuffed back in."[13] Provocative or poor quality research results could be reported by the media, or posted and discussed on social media, with little regard to the preliminary nature of the findings.[14,15] No amount of retrospective "tagging" will have much effect. Misinformation or deliberately misleading or sloppy science can be freely circulated, cited, and believed ad infinitum, regardless of whether it is ultimately debunked and retracted.

### Our suggested solutions:

- Preprints should not be used as references in any medical publication unless these are cited in the manner of a personal communication, that is, as an in-text reference (using the preprint link, DOI, or both) rather than as bibliographic references. It should be clearly disclosed that the source is a preprint.
- Clearly distinguishing preprints from peer-reviewed articles might help to reduce the tendency of readers to view the work as fully vetted.[14,15] This should be done by
  - Watermarking the article, as is done, for example, by medRxiv and bioRxiv, with the information that it has not been peer reviewed.
  - Placing a clearly-worded disclosure in the body of the article highlighting that the findings have *not* been formally peer reviewed.
- Pre-publication vetting:
  - Pre-publication checks by server hosts. MedRxiv performs a basic screening process for plagiarism, nonscientific content, and material that might pose a health risk, including material that might compromise existing public health measures.[7] However, these checks should be more extensive and consistent across server hosts, and a comprehensive checklist should be used (Appendix I)
  - Encouraging authors to ensure that preprints that have been subsequently fully published be marked as such on the preprint server and linked via DOI to the fully published article.

## Post-publication peer review

In post-publication peer review, an article is published in its original form, then subjected to informal (as with preprints) as well as invited peer review. For instance, with the model used by the F1000 publishing platform,[16] articles are posted online after passing pre-publication checks and after an article processing charge (APC) is paid. When posted, articles are assigned a DOI and opened to comment from registered users. Expert peer reviewers are invited to review in the usual way. All comments, peer review reports, and article revisions are available with the article, and once the article receives two favorable peer review reports, the final, peer-reviewed version is indexed in external bibliographic databases and becomes fully discoverable. The benefits of this model are similar to those of preprints – rapid access to the readers and the option for readers to comment.

### Issues with post-publication peer review:

- The issues with post-publication peer review are basically identical to those of preprints, but it should be noted that the requirement for an APC would potentially discourage casual or low-quality submissions. Articles are clearly marked as "under peer review," and the progress of that review is accessible to readers.
- As with preprints, articles undergoing post-publication peer review should not be used as references in any medical publication until the peer review process is completed and the article is approved for publication. If the article is cited, we suggest the citation be made in the same manner suggested for preprints.
- Issues associated with traditional peer review also apply and are addressed in Section 2.3, below.

### Our suggested solutions:

- Our suggested solutions include those proposed for preprints; however, we suggest that the publication be indexed by mainstream bibliographic databases (if applicable) once it has been fully peer reviewed, as is done on the F1000 platform.

## Traditional peer review

Traditional peer review occurs after a submitted article is accepted for consideration by a journal, then passed to expert peer reviewers. The reviewers' comments are sent to the authors to use in revising their article, or else the article is rejected after review. For rejected articles, authors can start the process again with another journal. If an article is revised to the peer reviewers' satisfaction, the article is published and assigned a DOI, after which the article is indexed in mainstream bibliographic databases. Peer review reports and revisions may or may not be available with the final article, depending on the peer review model the journal uses. The benefit of traditional peer review is that information is released to the readers only after there has been quality control applied by subject matter experts.

### Issues with traditional peer review

- Lengthy review process, which may impede the timely release of valuable information – particularly in a pandemic or public health-crisis
- Inadequate time for high-quality peer review
- Inconsistency among reviewers

- Difficulty in "recruiting" qualified reviewers, given time commitment, particularly in times of health crises when the most appropriate reviewers are likely to have a high clinical workload

**Our suggested solutions:**
- Authors:
  - Submit rejection comments to second-choice journals, with itemized rebuttals and updates to the manuscript (portable peer-review).[17,18]
  - Be more accepting of editor referrals to cascade journals.[19]
- Journal editors:
  - Accept, request, or require portable peer review as described above, thereby reducing the need for additional review cycles.
  - Consider commercial back-end services that expedite peer review (eg, Research-Square [https://www.researchsquare.com/], as used by the BMC journals and others).
  - Form a rapid response team of reviewers, with appropriate expertise, who can provide peer review with a quick turnaround time.
- Publishers:
  - Standardise formatting requirements to expedite resubmission.[20]
  - Offer fast-track options for potentially practice-changing work.
  - Consider incentives for reviewers.[21]

## Suggested solutions for all formats

### Quality control
- Make use of existing publication guidelines[22–24] and available checklists[25] to ensure high-quality publication development.
- Include Clinical Trial Protocols and Statistical Analysis Plans (SAPs) as supplementary material.
- Ask all authors to sign an author form confirming that they had full access to the relevant data reported in their article, along with acceptance of responsibility for submitting the article for publication. Furthermore, the contributor statement should name the authors (at least 2) who have accessed and verified the underlying data, as suggested in the revised *Lancet* publication guidelines.[26]
- Journals should clearly explain the initial quality review that editors perform on newly submitted manuscripts.

### Training in peer review
- Authors, peer reviewers, and editors should be adequately trained in the nature and technical aspects of peer review.
- Guidelines should be used, such as those created by the Committee on Publication Ethics (COPE),[25] along with the reviewers' checklist in Appendix I.
- Medical journalists and the public should be educated on how preprints and pre-publications differ from peer-reviewed literature.
- The role of professional medical writers and scientific communicators in expediting the publication process
- Evidence suggests that the use of professional medical writers enhances publication quality and speed,[27–33] and such assistance has been associated with a reduced risk for retractions due to misconduct.[34] If a qualified medical writer is part of the team, they should be involved in the process as early as possible.[5] The medical writer should have access to the clinical study report (if available), source data, and related documents, including statistical outputs and patient narratives, to the extent that data-protection regulations allow.
- Professional medical writers should have an active role in ensuring the high quality of publications, including their development, editing, and referencing,[22,24,35] and the use of appropriate publication checklists.[36] Medical writers and statisticians should be actively involved in peer review, during which the medical writer will critically assess the quality of the manuscript according to common appraisal criteria, thereby augmenting the traditional subject-matter-expert review (Appendix I).
- Medical writers could also be involved in pre-publication vetting, act as trainers, or both (see Training in Peer Review section).

As professional medical writers and communicators, we have identified areas that could benefit from increased quality assurance. We have suggested some processes that we believe would better ensure effective oversight of scientific and medical publications, whether in the context of a health emergency or not. To maintain confidence in published science, each involved party (including the reader) must take responsibility for exercising their best judgment and selecting information from sources with good publishing practices that are rigorous and transparent.

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# Appendix I. Reviewers' checklist

This checklist is intended to be used by journals. However, it can also guide authors and medical writers in their review of manuscripts before submission.

The checks should be performed by a suitably qualified team, preferably consisting of editors, subject matter experts (i.e., peer reviewers; not required for preprints), medical writers, statisticians, and trained researchers. The review team should comprise at least two reviewers.

Not every reviewer is required to complete all fields, but all items need to be checked by at least one accountable reviewer.

| Item | Medical Writer Reviewer | Clinical Reviewer | Biostatistical Reviewer | Peer Reviewer A | Peer Reviewer B |
|---|---|---|---|---|---|
| **Source documents (if available and required by journal)** | | | | | |
| Clinical Study Protocol | | | | | |
| Redacted Clinical Study Report Synopsis | | | | | |
| Statistical Analysis Plan | | | | | |
| Tables/Listings/Graphs | | | | | |
| **Attestations** | | | | | |
| Data sharing statement (ICMJE template) | | | | | |
| Author contribution form[a] | | | | | |
| Signed author forms confirming that the authors had full access to the data reported in the article and accept responsibility for submitting the article [b] | | | | | |
| Author confirmation that verified data were used to develop the manuscript | | | | | |
| Conflict of interest statement (ICMJE template recommended) | | | | | |
| List of sources of funding for the study and any supporting activities | | | | | |

| Item | Medical Writer Reviewer | Clinical Reviewer | Biostatistical Reviewer | Peer Reviewer A | Peer Reviewer B |
|------|------------------------|-------------------|-------------------------|-----------------|-----------------|
| **Suggested Checks for Preprint Editorial Review** | | | | | |
| Manuscript contains no offensive or nonscientific content | | | | | |
| No material is plagiarised | | | | | |
| Basics of the statistical methods are sound (e.g., adequacy of analysis population, adequate handling of missing data) | | | | | |
| Endpoints and inclusion/exclusion criteria are in alignment with the study registration on a publicly available registry (e.g., ClinicalTrials.gov), provided this is required. For primary reports of clinical trials, all end points are mentioned in the results section. | | | | | |
| Content is consistent and clear across each section of the manuscript (e.g., information in abstract matches results, hypothesis posed in introduction is addressed in discussion) | | | | | |
| Discussion points and conclusions are supported by the reported data | | | | | |
| Adherence to guidelines (e.g., CONSORT, STROBE, PRISMA, SPIRIT, CARE) Specify guideline(s):_____ | | | | | |
| No ethical concerns | | | | | |
| **Additional Checks for Peer Review** | | | | | |
| **Further statistical considerations**: <br> • adequacy of sample size calculation (e.g., adequate comparator) <br> • adequacy of statistical methods <br> • check for random errors <br> • sources of bias addressed | | | | | |
| **Methodological quality** [c] <br> • confounding influences (e.g., concomitant treatments) <br> • inadequate disclosure of information <br> • misinterpretation | | | | | |
| **Study design** [b] <br> • adequacy and relevance of endpoints <br> • adequacy of inclusion/exclusion criteria <br> • blinding <br> • adequacy of follow-up period <br> • adequacy of reporting of complications <br> • adequacy of data presentation | | | | | |

[a] Should include a question if medical writing support was used.

[b] May be merged with author contribution form.

[c] Adapted from MEDDEV 2.7/1; alternatively, other criteria can be used to appraise the manuscript (eg, https://libguides.napier.ac.uk/litrev/critapp).

Additional columns and signature lines can be added as needed.

Reviewer: _____     Signature: _____

Reviewer: _____     Signature: _____

# Winners of the
# Geoff Hall Scholarship
# Essay Competition

**Dear all,**

When I wrote the editorial for this issue last year, I never dreamed that a year later we would still be dealing with global lockdowns and quarantines. I hope and pray that you and your loved ones are staying safe (and sane!).

The Geoff Hall Scholarships (GHSs) are given in honour of a former President of EMWA. Geoff was a very special person, an extremely valued member of EMWA, and a very good friend to many EMWA members. He firmly believed that the future of EMWA lies in our new and potential members, and so it's a very fitting legacy that we have the scholarship awards in his memory. The scholarships are awarded annually on the basis of an essay competition, and the title of this year's essay was "**Do you have what it takes to be a medical writer? Discuss three**

**FOR CORRESPONDENCE**

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**attributes or skills that best qualify one to be a medical writer**". This year's scholarship winners were Johanna Svanberg Larsson and Alexandra Smith.

Johanna has a DPhil in physical chemistry and has worked as a scientific editor. She was inspired by her editing work related to improving human health to transition to medical materials and pharmaceuticals. She is now a freelance medical writer specialising in the medical communications area.

Having completed her undergraduate in biochemistry in 2015, Alexandra stayed in academia and gained her PhD in molecular biology from the University of Manchester, UK, in 2019. Knowing it was time to leave the lab behind, she then moved into med comms and started a new career as a trainee medical writer at Mudskipper, an AMICULUM agency.

Johanna's and Alexandra's winning essays are presented here, and we wish them the very best at the start of their very promising medical writing careers.

For those of you inspired to pick up your laptop, and looking for something to fill your time during quarantine, this year's essay title is "The ethics of medical writing".

Hope to read your essays soon, and stay safe all, until we see each other at the next EMWA conference.

Bestest,
**Lisa**

# Curiosity, creativity and tenacity:
## The core attributes of a medical writer

Medical writing involves drafting and reviewing a multitude of documents as diverse as clinical trial protocols to be submitted to health authorities, research manuscripts for peer review, and patient information leaflets. Other activities include creating conference presentations as well as educational and promotional materials.[1] In order to perform these tasks, medical writers must be able to convert complex information into a clear, concise, audience-appropriate format.[2] So, what three attributes best qualify someone to be a medical writer?

### Curiosity

When starting a project, a medical writer needs to understand the data to be presented and know what the take-home message should be. This implies that the medical writer must know of current advances in interventions or diagnostic tools in the particular therapeutic area, grasp the relevance of the project to the field, and be able to determine the main features to be presented. If a medical writer is to enjoy learning and staying up to date in relevant therapeutic areas, they must be curious. A "desire to know, an interest leading to inquiry"[3] is paramount if a medical writer is to be effective in their background research and consideration of the information to be presented.

The information itself is only half the message – to be effective, the message needs to be comprehensible to the audience. A patient is not necessarily interested in the same study features as an ethics committee; the general public does not have the same level of scientific knowledge as a medical journal peer reviewer. A medical writer must be cognisant of who the audience is and enquire into the audience's needs and ability to understand in order to be able to present the information appropriately. Again, interest leading to enquiry: a medical writer must be curious.

A curious medical writer will have a genuine interest in and look into all aspects of the project, including any background information, the specific audience needs as well as the regulatory, ethical and publishing guidelines, that a person lacking in curiosity may overlook.

### Creativity

In order to convert medical data into a suitably pitched message, a medical writer needs to be creative. Journals often limit the number of figures and tables that can be included, and it can be difficult to fit all the relevant data into shorter formats such as posters or patient leaflets.

Presenting information concisely, illustratively and accurately requires creativity. This type of creativity applies equally to the structure and wording of text as to the design of figures. Although a medical writer must take care that they do not distort data when the format is brief or when combining different data into one figure, creativity is fundamental to conveying data in graphical form, as exemplified by John Snow's 1854 map of cholera spread in London.[4]

## Tenacity

Curiosity and creativity allow a medical writer to produce a first draft; one or more review rounds are often necessary before all team members and/or the client are happy with the final product. Given the nature of reviews, the outcome is often as much a question of taste as of fact, and a medical writer must be tenacious in ensuring that data is accurately presented and not degraded from partial changes by multiple reviewers. Furthermore, as a medical writer moves on to other projects, a tenacious memory enables them to build and maintain singular knowledge and expertise, making them more efficient in future projects.

## Why does this list not include language skills, analytical thinking, or integrity?

Language skills, analytical thinking, and integrity are crucial to medical writing, but they are not

*Analytical thinking, a characteristic that all medical writers must also have in order to process data, is perhaps less easily gained than language skills.*

core attributes. Rather, language skills and analytical thinking are both attributes that can be obtained from, or are implied by, the core attributes discussed above. For example, a curious person would make an effort to fill any gaps in their knowledge, including gaps in language skills. Language is an inherent part of medical writing, and a curious medical writer would seek the requisite language skills. A tenacious medical writer would then keep working on their language skills until they become proficient. Language skills are therefore not a core attribute of medical writers as they can be derived from curiosity and tenacity.

Analytical thinking, a characteristic that all medical writers must also have in order to process data, is perhaps less easily gained than language skills. However, analytical thinking is still not a core attribute. A curious medical writer knows which questions to ask and therefore which areas to research when starting their project, and a creative medical writer can present information in an engaging and relevant manner. Taken together, a medical writer who is both curious and creative is capable of critically appraising data, lifting important aspects, and discerning any shortcomings. Analytical thinking is therefore implied by the pairing of curiosity with creativity.

Finally, lacking integrity should absolutely be grounds for disqualification as a medical writer, but integrity is not an attribute that qualifies

someone to be a medical writer; integrity does not enable a person to perform the tasks of a medical writer. A person with high integrity would not necessarily be capable of distilling multifaceted information into understandable, audience-appropriate communications, but a curious, creative and tenacious person would be able to do so.

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# Collaboration, precision, and resilience:

So, you want to be a medical writer? Me too. Less than a year into my PhD, I was certain that academic research was not for me, and so the search for a rewarding alternative career began. Fast forward a few years and I find myself writing this essay from the perspective of being a trainee medical writer for just under a year. I by no means claim to be an expert, but I do believe that by being on the lower rungs of the medical writing career ladder, I'm in an optimal position to reach out a helping hand to those looking to start the same climb. Here, I offer my advice to aspiring medical writers on the three key skills I regard as essential to succeed as a medical writer: collaboration, precision, and resilience.

## What are your thoughts?
### Skill #1: Collaboration
Regardless of who it's with, a successful medical writer is comfortable with collaborating in a variety of different contexts. Medical communication is often referred to as the metaphorical bridge between those who are making new medicines and medical devices (pharma and biotech), and the end-users of those products (healthcare professionals and patients). To bridge that gap effectively, collaboration with

colleagues, clients and healthcare experts alike is vital.

Whilst there are many skills and attributes that define a strong collaborator (such as empathy, active-listening, time-management), there are some that can hinder effective teamwork. It is just as important to consider these as it is to hone and build the positive attributes required. In his TED$^X$ talk, Jim Tamm elegantly explains how defensiveness is the greatest inhibitor of collaboration.[1] Appreciating this and managing your own defensiveness in response to feedback from your team is a desired attribute of a good medical writer (albeit one that is not typically highlighted). After all, the result will be better collaboration that benefits all.

So, ask yourself these questions: would you be comfortable receiving multiple rounds of feedback and criticism on your work? Are you happy not to take full ownership on a project, but instead support others' ideas, even when it's not how you would have done it? Would you actively flag any mistakes you have made, so the team can respond accordingly? If you answered an honest 'yes' to each of those questions, then maybe you do have the collaboration skills it takes to be a medical writer. Ultimately, a strong collaborator

has the confidence to ask 'What are your thoughts?' and the ability to listen and respond in a non-defensive, productive manner.

## Be clear. Be concise. Be correct
### Skill #2: Precision
Medical writing is not science journalism. It is not about providing perspectives or swaying opinion. Medical writing '*is about clearly communicating clinical and scientific data and information in written form.*'[2] Communication is all about intended and received messages. Clear communication is achieved when the received message is the same as the intended message. Clear medical writing is no different. Often, clear communication is also concise; communicating only what needs to be said in as few words as possible. Furthermore, any medical writer needs the ability to understand and analyse scientific data and information accurately, and only communicate ideas that can be supported by the available data. The ability to be clear, concise and correct is an obvious necessity when communicating information about new medicines to the health care professionals and patients who will eventually prescribe and use such products.

As a medical writer, what does being precise

# Do you have what it takes to be a medical writer?

mean in practice? The short answer is that you need to be a pedant. Would you know when to describe a result as 'significant' versus 'substantial'? Would you know when to use 'compared to' rather than 'compared with'? Do you know what hanging comparators and dangling participles are and how to avoid them? Precision allows for clear communication of complex clinical information and eliminates the possibility of misinterpretation. As such, precision is a key ingredient in producing medical writing of the highest quality.

## Seriously, do you have what it takes?

### Skill #3: Resilience

Medical writing is a rewarding career that combines your passion for science with an interest in communicating that science. But don't be fooled – it may be rewarding but it is definitely not easy! Cue the final skill I consider to be of most importance to make it as a medical writer: resilience.

In my opinion, the real reason a PhD is preferred on applications for new medical writers is because a PhD demonstrates resilience. Let's

face it, the specifics of your PhD project are unlikely to be of use as a medical writer. Nevertheless, by completing a PhD you have demonstrated your ability to stick at something despite things going wrong as well as your capacity to problem solve under time pressure. This resilience will definitely put you at an advantage as you move into medical writing.

As a trainee medical writer, most of the learning is done 'on the job'. After review, your work will be returned to you covered in comments and suggestions for improvements (all of which, rather annoyingly, make perfect sense). Don't be intimidated by this, instead use it as the opportunity to hone your craft and learn from others. Don't be disheartened when a client changes their mind on what they want, despite having invested so much of your time already on their original request. Be calm when relentlessly chasing authors who seem to have disappeared off the face of the earth. Despite all these challenges (and more) you've just got to keep going. Be resilient.

The inspiration for this essay has come not only from my own personal experience as a trainee medical writer, but also from all the many wonderfully supportive colleagues I have the

pleasure of working with. Just as I have learnt from them, this essay is my way of helping others at the very beginning of what I believe will be a very rewarding, life-long career. Just remember to collaborate, be precise and be resilient. Good luck and enjoy!

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# News from the EMA

**SECTION EDITOR**

Section Editor:
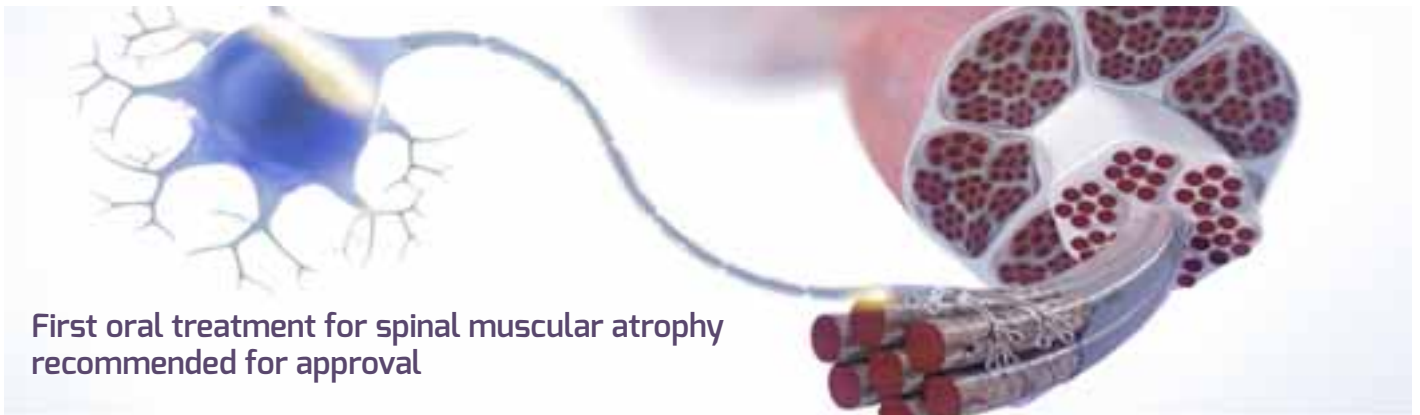**Anuradha Alahari**
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## First oral treatment for spinal muscular atrophy recommended for approval

**February 26, 2021** – EMA has recommended granting a marketing authorisation in the European Union (EU) for the first treatment that can be given orally to patients with certain types of spinal muscular atrophy (SMA), a rare and often fatal genetic disease that causes muscle weakness and progressive loss of movement.

Spinal muscular atrophy is an inherited disease usually diagnosed in the first year of life that affects the motor neurons (neurons from the brain and spinal cord that control muscle movements). Patients with the disease lack a protein called 'survival motor neuron' (SMN), which causes the motor neurons to deteriorate and eventually die. This is a long-term debilitating and life-threatening disease because it causes breathing problems and muscle wasting that worsens over time.

The SMN protein can be made by two genes, SMN1 and SMN2. Patients with SMA lack a working SMN1 gene but have at least one copy of the SMN2 gene, which mostly produces a short SMN protein that does not work as well as a full-length protein.

Risdiplam, the active substance of Evrysdi, has shown that it can enable the SMN2 gene to produce a full-length SMN protein, which is able to work normally. This is expected to increase survival of motor neurons and reduce symptoms of the disease. Evrysdi is indicated for the treatment of 5q SMA in patients 2 months of age and older, with a clinical diagnosis of Type 1, Type 2 or Type 3 SMA or with one to four SMN2 copies.

Although a number of treatment options have become available over recent years, they all require frequent clinic visits or invasive procedures. During the COVID-19 pandemic these treatments have become more difficult to access due to measures to promote physical distancing and changes in hospital priorities that have postponed elective procedures. New therapies with easier routes of administration are needed to help patients with this life-long chronic disease to adhere to their treatment and get the full benefit from it.

Evrysdi has been developed as a non-invasive oral treatment that can be used at home. It was accepted into PRIME, a support scheme EMA developed for promising new medicines that address an unmet medical need. Representatives of patient organisations were also consulted during the assessment of benefits and risks of Evrysdi to bring their unique real-life perspective and ensure that patients' needs are taken into account in the regulatory decision-making process. EMA's human medicines committee (CHMP) reviewed the application for marketing authorisation under an accelerated timetable to enable faster patient access to this medicine.

EMA's recommendation is based on two clinical studies, one investigating the effects of Evrysdi on patients with infantile-onset SMA and the other on later-onset SMA. The results from the trials show beneficial effects in very young patients in terms of their motor development and survival at 12 months, compared to data on the natural course of the disease in these patients. The positive effect in later-onset SMA (Type 2 and 3) has been demonstrated in a double-blind placebo-controlled trial, including patients between 2 and 25 years of age. The main adverse reactions observed in trials were headaches, mouth ulcerations and aphthous ulcers, urinary tract infections including cystitis, arthralgia nausea, pyrexia, and dizziness/vertigo.

As part of its recommendation for marketing authorisation, the CHMP requested that the company performs a post-authorisation efficacy study (PAES): a long-term prospective, observational study to further evaluate disease progression in SMA patients (both pre-symptomatic and symptomatic) with 1 to 4 SMN2 copies treated with risdiplam, in comparison to natural history data in untreated patients.

As for all medicines, a risk management plan (RMP) will ensure rigorous safety monitoring of the medicine once authorised across the EU. Further efficacy and safety data will be collected through ongoing studies and post-marketing reports and will be regularly reviewed by the CHMP and EMA's safety committee (PRAC).

The opinion adopted by the CHMP is an intermediary step on Evrysdi's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

## EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials

**March 22, 2021** – EMA has reviewed the latest evidence on the use of ivermectin for the prevention and treatment of COVID-19 and concluded that the available data do not support its use for COVID-19 outside well-designed clinical trials.

In the EU, ivermectin tablets are approved for treating some parasitic worm infestations while ivermectin skin preparations are approved for treating skin conditions such as rosacea. Ivermectin is also authorised for veterinary use for a wide range of animal species for internal and external parasites.

Following recent media reports and publications on the use of ivermectin, EMA reviewed the latest published evidence from laboratory studies, observational studies, clinical trials, and meta-analyses. Laboratory studies found that ivermectin could block replication of SARS-CoV-2 (the virus that causes COVID-19), but at much higher ivermectin concentrations than those achieved with the currently authorised doses.

Results from clinical studies were varied, with some studies showing no benefit and others reporting a potential benefit. Most studies EMA reviewed were small and had additional limitations, including different dosing regimens and use of concomitant medications. EMA therefore concluded that the currently available evidence is not sufficient to support the use of ivermectin in COVID-19 outside clinical trials.

Although ivermectin is generally well tolerated at doses authorised for other indications, side effects could increase with the much higher doses that would be needed to obtain concentrations of ivermectin in the lungs that are effective against the virus. Toxicity when ivermectin is used at higher than approved doses therefore cannot be excluded.

EMA therefore concluded that use of ivermectin for prevention or treatment of COVID-19 cannot currently be recommended outside controlled clinical trials. Further well-designed, randomised studies are needed to draw conclusions as to whether the product is effective and safe in the prevention and treatment of COVID-19. This EMA public health statement has been endorsed by the COVID-19 EMA pandemic Task Force (COVID-ETF), in light of the ongoing discussions on the use of ivermectin in the prevention and treatment of COVID-19.

# EMA reviewing data on use of monoclonal antibodies for treating COVID-19: casirivimab, imdevimab, bamlanivimab, etesevimab, and regdanvimab

**March 5, 11 and 26, 2021** – EMA's human medicines committee (CHMP) has completed its review of data on the use of the monoclonal antibody to treat patients with COVID-19, namely, regdanvimab (also known as CT-P59) being developed by Celltrion Healthcare, REGN-COV2 monoclonal antibody combination of casirivimab and imdevimab; combination of bamlanivimab and etesevimab which are being developed by Eli Lilly to be used in combination. The reviews were undertaken to provide a harmonised scientific opinion at EU level to support national decision-making on the possible use of these antibodies prior to marketing authorisation.

These five monoclonal antibodies have shown activity against SARS-CoV-2, the virus that causes COVID-19. The antibodies have been designed to attach to the spike protein of SARS-CoV-2, and thereby reduce the ability of the virus to enter the body's cells. Casirivimab and imdevimab attach to the spike protein of SARS-CoV-2 at two different sites. Similarly, bamlanivimab and etesevimab antibodies also attach to different parts of the spike protein. Using the antibody combinations, REGN-COV2 (casirivimab + imdevimab) or bamlanivimab + etesevimab is expected to have a greater effect than using a single antibody.

The Agency concluded that the combinations REGN-COV2 and bamlanivimab + etesevimab can be used for the treatment of confirmed COVID-19 in patients who do not require supplemental oxygen and who are at high risk of progressing to severe COVID-19. Preliminary results indicate that the REGN-COV2 combination reduced the viral load (amount of virus in the back of the nose and throat) more than placebo (a dummy treatment) and led to fewer COVID-19-related medical visits. In terms of safety, most side effects reported were mild or moderate, however reactions related to the infusion (including allergic reactions) have been seen and should be monitored for. In case of bamlanivimab + etesevimab EMA has not yet evaluated the full dataset and it is too early to draw any conclusions regarding the benefit-risk balance of the medicines. The Agency also looked at the use of bamlanivimab alone and concluded that, despite uncertainties around the benefits of monotherapy, it can be considered a treatment option.

EMA reviewed data from an ongoing study looking into the effects of regdanvimab in adult outpatients with COVID-19 symptoms described as mild to moderate who do not need supplemental oxygen. Results from the first part of the study indicate that regdanvimab may lower the rate of hospitalisation. However, the results were not robust enough to reach a firm conclusion on the medicine's benefits at this time. In terms of safety, most side effects were mild or moderate. The Agency concluded that regdanvimab can be used for the treatment of confirmed COVID-19 in adult patients who do not require supplemental oxygen therapy and who are at high risk of progressing to severe COVID-19.

The Agency has started rolling reviews on these monoclonal antibodies based on the preliminary results.

EMA will evaluate all data on these medicines, including evidence from clinical trials as they become available. The rolling reviews will continue until enough evidence is available to support formal marketing authorisation applications. EMA will assess the medicine's compliance with the usual standards for effectiveness, safety, and quality. While the overall review timeline cannot be forecast yet, the process should be quicker than a regular evaluation due to the time gained during the rolling review.
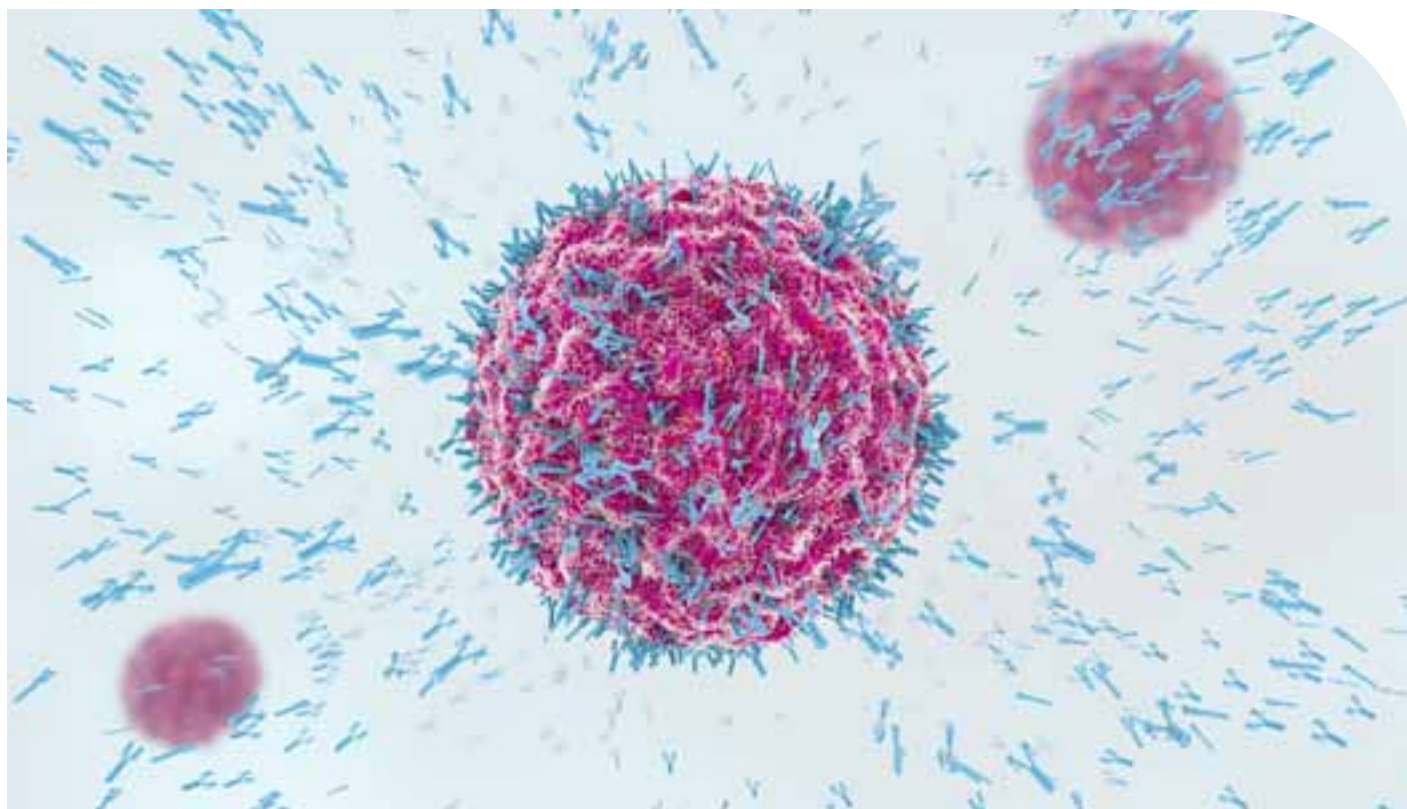
# AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets;  and confirms that overall benefit-risk remains positive

**April 07, 2021** – EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded today that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria (formerly COVID-19 Vaccine AstraZeneca). In reaching its conclusion, the committee took into consideration all currently available evidence, including the advice from an ad hoc expert group.

EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed.

The PRAC noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) and in arteries, together with low levels of blood platelets and sometimes bleeding. The Committee carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance) as of March 22, 2021, 18 of which were fatal. The cases came mainly from spontaneous reporting systems of the European Economic Area (EEA) and the UK, where around 25 million people had received the vaccine. As of April 4, 2021, a total of 169 cases of CVST and 53 cases of splanchnic vein thrombosis were reported to EudraVigilance. Around 34 million people had been vaccinated in the EEA and UK by this date.

At present the review has not identified any specific risk factors, such as age, gender or a pre-vious medical history of clotting disorders, for these very rare events. One plausible explanation for the combination of blood clots and low blood platelets is an immune response, leading to a condition similar to that sometimes seen in patients treated with heparin (heparin induced thrombocytopenia, HIT). The PRAC has requested new studies and amendments to ongoing ones to provide more information and will take any further actions necessary.

The PRAC stresses the importance of prompt specialist medical treatment. By recognising the signs of bloods clots and low blood platelets and treating them early, healthcare professionals can help those affected in their recovery and avoid complications.

EMA's scientific assessment underpins the safe and effective use of COVID-19 vaccines. COVID-19 is associated with a risk of hospitalisation and death. The reported combination of blood clots and low blood platelets is very rare, and the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.

# Medical Devices

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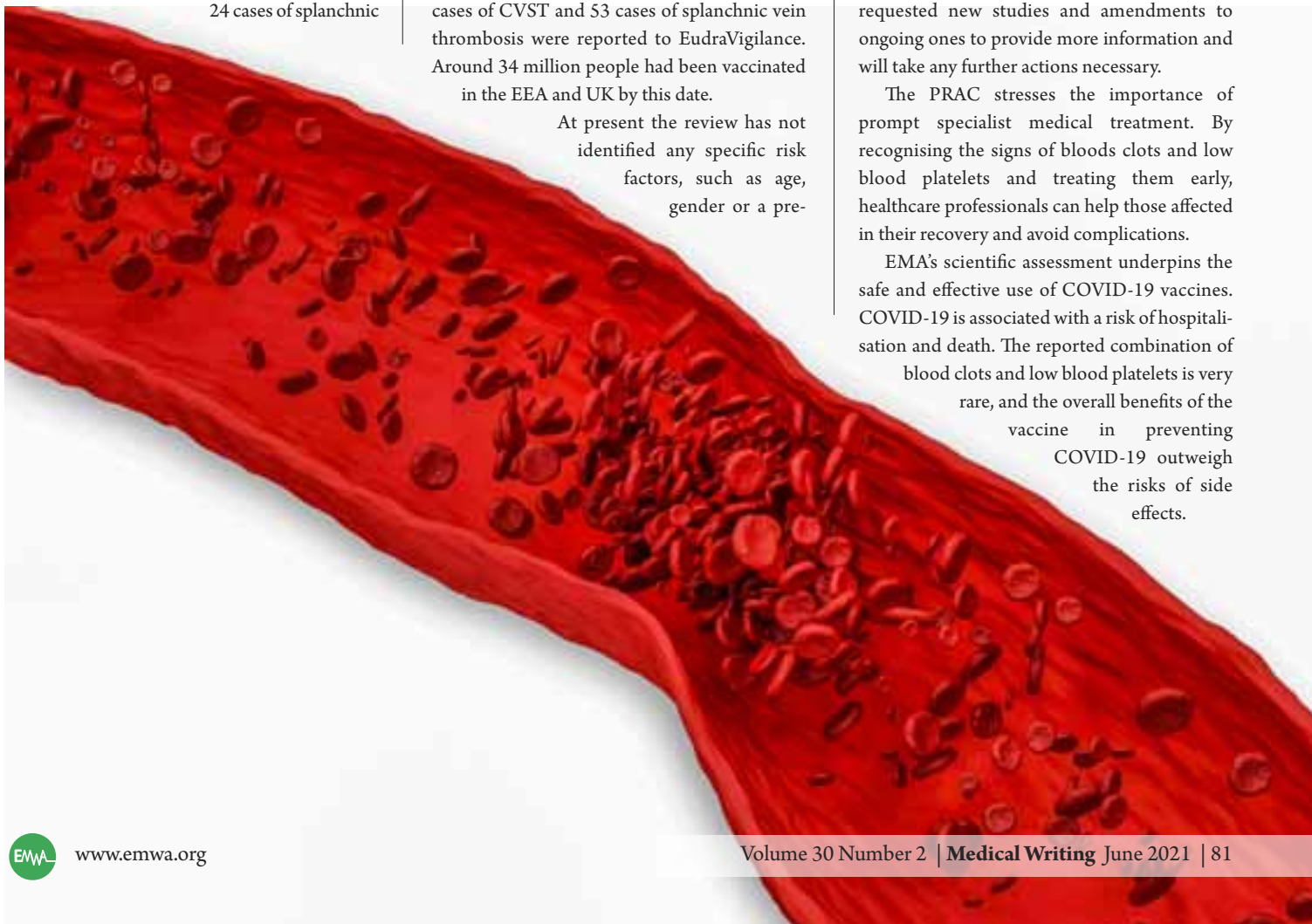
### Editorial

ISO 14155 is an asset for every professional working in the medical device industry. With the new update to this standard, we see improved harmonisation and a clearer guidance to medical device manufacturers who are amidst transition to the newly implemented Medical Device Regulation (MDR). This article, by Diana Nogueira, helps introduce the essential updates done to ISO 14155 from its previous version and how it may facilitate manufacturers to implement the requirements for clinical investigations for medical devices.

*Namrata*

## Good Clinical Practice applied to medical devices: The new ISO 14155:2020

After many years of preparation, the International Organization for Standardisation (ISO) published the ISO 14155:2020 (3rd version) in July 2020, which replaces the second version from 2011. Analogous to the International Conference on Harmonisation (ICH) Guideline E6 (R2) for Good Clinical Practice (GCP), ISO 14155 regulates the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance and safety of medical devices. In alignment with the Declaration of Helsinki (DoH), the utmost purpose of ISO 14155 is to protect the rights, safety and well-being of human subjects in clinical research.

### Essential updates

The main changes in comparison to the previous version are:

- Inclusion of a summary section of GCP principles (aligned with ICH E6)
- Reference to registration of clinical investigations in a publicly accessible database (aligned with DoH)
- Inclusion of clinical quality management
- Inclusion of risk-based monitoring
- Inclusion of statistical considerations in Annex A (Clinical Investigation Plan, or CIP)
- Inclusion of guidance for ethics committees (ECs) in Annex G (EC responsibilities)
- Reinforcement of risk management throughout the process of a clinical investigation, including Annex H (application of ISO 14971 to clinical investigations and interaction between ISO 14971 and ISO 14155)
- Clarification of applicability of requirements to different clinical development stages in Annex I
- Inclusion of guidance on clinical investigation audits in Annex J.

### GCP principles

The GCP principles summarised in ISO 14155 are aligned with the DoH and ICH E6, as follows:

1. Clinical investigations shall be conducted in accordance with the ethical principles that have their origin in the DoH, and that are consistent with this document.
2. Before a clinical investigation is initiated, foreseeable risks and inconveniences shall be weighed against the anticipated benefit for the individual subject and society. A clinical investigation shall be initiated and continued only if the anticipated benefits outweigh the risks.
3. The rights, safety, and well-being of human subjects are the most important considerations and prevail over interests of science and society.
4. The available non-clinical and clinical information on the investigational device shall be adequate to support the proposed clinical investigation.
5. Clinical investigations shall be scientifically sound and described in a clearly detailed CIP.
6. A clinical investigation shall be conducted in compliance with the CIP that has received prior EC approval/favourable opinion and, where applicable, approval/non-objection of regulatory authorities.
7. The medical care given to, and medical decisions made on behalf of subjects shall always be the responsibility of a qualified healthcare professional.
8. Each individual involved in designing, conducting, recording, and reporting a clinical investigation shall be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent shall be obtained from every subject prior to the participation in the clinical investigation.
10. All clinical investigation-related information shall be recorded, handled, and securely stored in a way that allows its accurate reporting, interpretation, monitoring, auditing, and verification.
11. The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules.
12. Investigational devices shall be designed, manufactured, handled, and stored in accordance with the essential principles. They shall be used in accordance with the approved CIP, the investigator's brochure (IB) and manufacturer's instructions for use (IFU).
13. Systems with procedures that ensure the quality of every aspect of the clinical investigation shall be implemented.

### Clinical quality management

The inclusion of clinical quality management is a new requirement that obliges the use of quality management principles in alignment with ISO 13485:2016. This is to ensure that the clinical investigation is designed, conducted, monitored,

> The inclusion of a clinical quality management is a new requirement that obliges the use of quality management principles in alignment with ISO 13485:2016.

and that the data generated is documented, evaluated, and reported in accordance with regulatory requirements and in compliance with the ISO 14155, the CIP and other applicable standards. The sponsor shall document the implementation of these clinical quality procedures in writing.

## Risk-based monitoring

Another new aspect of ISO 14155 is a risk-based approach to study monitoring. Results of the device risk assessment shall be used to develop a risk-based monitoring plan, in which the extent and nature of the monitoring shall be based on the objective, design, complexity, size, critical data points, and endpoints of the clinical investigation and the degree of deviation from normal clinical practice. In particular, the sponsor shall ensure that unanticipated adverse device effects are identified and investigated rapidly, so that additional risk control measures can be implemented where necessary.

The application of ISO 14971:2019 to clinical investigations is described in detail in Annex H of ISO 14155. The risk management process associated with a clinical investigation allows the hazards and hazardous situations associated with the investigational device to be identified. The associated risks are first identified and estimated (risk analysis), then evaluated (benefit-risk analysis), followed by a reduction of these risks to an acceptable level where necessary (risk control). The effectiveness of risk control is

evaluated throughout the product's lifecycle and during clinical investigations. As soon as the risks are no longer acceptable, any clinical investigation should be terminated. Information on acceptable and anticipated risks should be part of the CIP, IB, IFU and informed consent forms. Risks should be monitored against risk acceptability thresholds throughout the clinical investigation. In case an unanticipated safety concern is identified, a thorough risk assessment should be conducted to determine risk acceptability.

## Types of clinical investigations

Annex I of ISO 14155 provides a general indication of the possible types of clinical investigations. It is categorised based on different clinical development stages (pilot, pivotal or post-market stage) and in relation to the regulatory status (pre-market or post-market stage) including exploratory, confirmatory or observational studies (registry or post-market

clinical follow-up studies), interventional or non-interventional studies. This overview is helpful in face of the expected increase in rate of clinical investigations brought about by the European Medical Device Regulation (MDR) 2017/745. According to this regulation, clinical investigations should be conducted in line with international guidelines, such as ISO 1415 5 on good clinical practice and the DoH.

## Overall considerations

Altogether, the new ISO 14155 underpins the importance of risk management in all phases of product development, including clinical investigations, and the beneficial interplay with other ISO guidance documents (i.e ISO 13485 and ISO 14971). Adherence to ISO 14155:2020 is important for complying with ethical aspects in clinical research and human rights. In addition, it contributes to the generation of high-quality clinical data, regulatory compliance and acceptance of study conduct, and outcomes across countries.

## Conflicts of interest

The author declares no conflicts of interest.

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# Lingua Franca and Beyond

### Our mentors

It is my great pleasure to introduce this article written by Julia Bates from Australia, who in a very personal way describes her journey to becoming a very professional and experienced medical writer – a journey that often went across oceans and continents. What I particularly like in Julia's article is the breadth of her experience of mentorship. In other words, she found mentors all over the place; she did not limit herself to looking for guidance only in typical professional settings. She just had her eyes wide open and was prepared to grasp lessons wherever she could.

Yes, indeed – the moment we are born, we start learning, and we never know when a particular skill gained deliberately or by chance turns out to be life-saving.

A typical mentorship implies professional, friendly, long-lasting, and personal guidance towards a successful career for a young and inexperienced person. On the other hand, according to the Merriam-Webster dictionary, the term *mentor* is "anyone who is a positive, guiding influence in another (usually younger) person's life."[1]

Looking back at my life, I can easily name quite a few people who made a remarkable impact on my life and helped me grow and develop personally and professionally. Maybe not all fall under the strict definition of mentorship, but all definitely had a guiding influence on my life. I will mention just one of them – my friend's mother. Around 50 years ago, during an extremely tough time for my family, she said: "Maria, as long as one is alive, there is still

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hope." I still hear her voice, even though she passed away many years ago, and this sentence still sits in my head. I just want to share its simple, supportive power with you. We all need it nowadays.

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1. https://www.merriam-webster.com/dictionary/mentor from Merriam-Webster [accessed 2021 March 13].

Maria Kołtowska-Häggström

## Finding mentors: A freelancer's search

*"… good medical writing is more than just a particular skill set, it is a craft, which means that it takes time to learn and hone."*

Julia Forjanic Klapproth and
Lisa Chamberlain James[1]

As I embarked on my freelance career 5 years ago, I was faced with a dilemma: where could I get support on a daily basis? If I was working on my own, who would help me hone my writing skills?

Besides medical writing, I also needed guidance on accounting, quoting, website development, marketing, and navigating legal requirements. How could I become proficient in all these areas? I soon realised that the guidance I was looking for could not be provided by a single *mentor*; instead, I would have to draw on the expertise of many. And so, I began my search.

### Family members as mentors

Perhaps not surprisingly, some of the biggest mentors in my career have been my parents. They taught me my core values: the importance of education, self-motivation, hard work, and maintaining a work-life balance. I remember one important piece of advice they gave me: "Do what you love, and the money will follow." This lesson gave me the confidence I needed to



risk leaving my academic research career to pursue a career as a freelance writer.

My parents have always run their own business. And so, from a young age, I was well aware of the perks (e.g., flexibility in working hours) and drawbacks (e.g., irregular income) of self-employment. As a bonus, they were able to provide me with practical advice on setting up a

business. My parents also taught me valuable lessons that they had learned over decades of self-employment, including the importance of written contracts or agreements.

My older brother and my husband (both contractors who established their own companies) were also invaluable when setting up my business. They provided me with knowledge

and guidance on business plans, tax matters, writing contracts, and client interactions. Even now, I often go to them for advice on how to run my freelance business. It is definitely handy having a husband who is also my mentor, as I can meet with him whenever I need to, and he is always invested in me and my success!

## Looking back to move forward

In my former academic career, I had two remarkable mentors who were instrumental in my success as a researcher. And when I first began freelancing, these people remained some of my biggest champions. Not only did they provide me with paid work (in the form of editing journal articles or grants), but they also offered glowing recommendations to pass on to new clients (as they were already aware of my skills and abilities in the work-place). Even though they are on very different career paths to me, to this day, they provide me with valuable psychosocial support and advice.

## Support from professional societies

Early on in my freelance career, I joined EMWA and the Australasian Medical Writers Association (AMWA). At first, I was a bit apprehensive about getting involved in these professional associ-ations, as I felt I was not a true *medical writer* but more of a *science writer*. However, I eventually built up the courage to join the organising committee for the annual AMWA conference. After seeing first-hand how inclusive and friendly the members were, I decided to start organising

local networking events in my city. These events were a great way to meet more senior medical writers and learn about the diverse careers people have under the umbrella of *medical writing*. These local mentors have since helped me to expand my skill set and find new clients.

On a side note, AMWA has a Mentoring Programme[2] that runs for approximately 3 months; it involves nine experienced medical writers and editors who volunteer their time to offer general writing, editing, and career advice to those who want to enter the profession or would like to be freelancers.

## "With a little help from my friends"

The final place I found mentors was through my colleagues and friends. I was fortuitously introduced to an experienced and highly regarded medical writer through an academic colleague. We were at a party, and I told her that I was about to start my writing and editing business. She exclaimed, "Oh, my mother runs a company like that based in Europe!" and immediately set up an introduction. My friend's mother took a chance on me as a writer with only limited medical writing experience. Not only did she provide me with regular paid work, but she guided me in areas that were new to me (e.g., regulatory writing), gave me opportunities (like writing articles for this journal!), and helped develop my writing skills. Whenever she made the long-haul flight to Australia to visit her daughter, she always took the time to meet with me and provide me

with further advice and knowledge. This mentoring relationship has been vital to my success as a freelance writer.
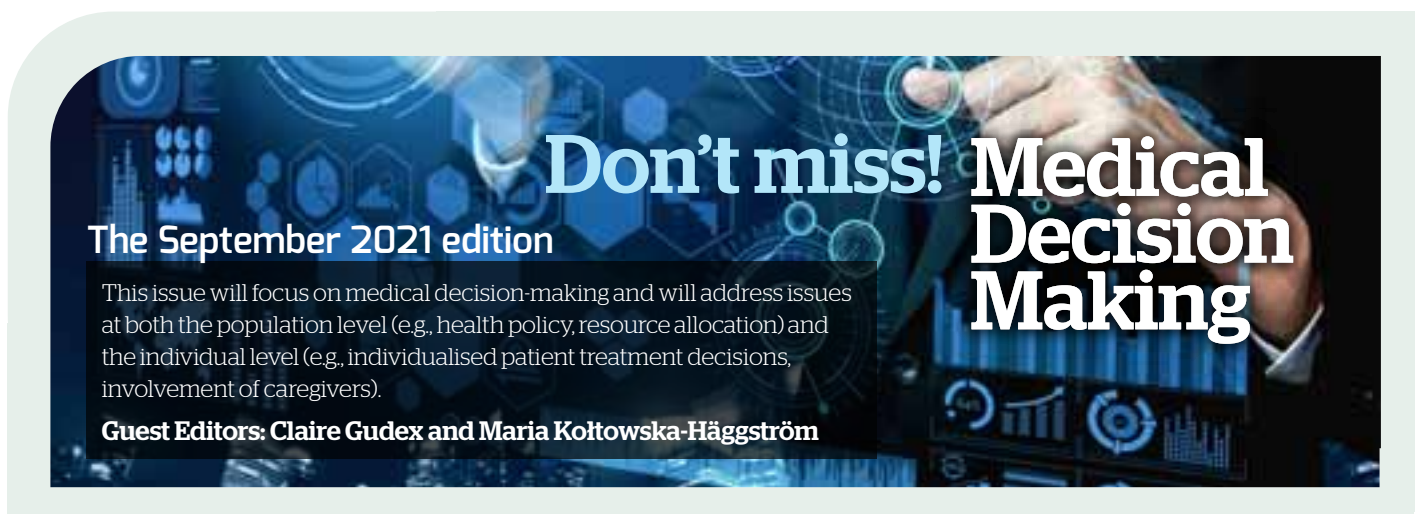
I also found a great peer mentor through another friend from academia. She gave me the name of someone who had left the bench and was now working as a freelance medical writer in my city. We connected over LinkedIn and met up for a coffee (sort of like a blind date). This peer-to-peer mentoring relationship was key in the early stages of our freelance careers, as we could bounce ideas off each other without feeling intimidated.

In summary, there are many benefits to having multiple mentors, especially as a freelancer, and they can be found in many places and forms. All of my mentors, past and present, have helped me "hone my craft", build my confidence, and shaped me into the medical writer I am today. I sincerely thank each and every one of them.

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> It is definitely handy having a husband who is also my mentor, as I can meet with him whenever I need to, and he is always invested in me and my success!

## Don't miss! Medical Decision Making

### The September 2021 edition

This issue will focus on medical decision-making and will address issues at both the population level (e.g., health policy, resource allocation) and the individual level (e.g., individualised patient treatment decisions, involvement of caregivers).

**Guest Editors: Claire Gudex and Maria Kołtowska-Häggström**

# Getting Your Foot in the Door

**Editorial**

Below, two young colleagues share their experiences as mentees and the benefits they gained from such programmes. First, Geneviève Laumen tells it from the perspective of being part of an organised, structured mentorship. Next, Ivana Turek shares her experiences from a combination of internship and self-organised mentorship. Despite the different paths they travelled, it is heart-warming to read about their journey of transitioning from academia to industry.

Raquel

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## A Tale of Two Mentees

### How mentoring got me where I am today

When Raquel Billiones asked me if I would like to contribute to this section, my first thought was: "Yes, of course what a great opportunity for me." My second thought was: "Oh my gosh. What can I say? I am just a fledgling and completely new to the field of medical writing." I hope that sharing my experience will be an incentive for others to break from the classical academical route and be open to the versatile options out there.

### Classical academic career

I was always intrigued by the processes of life and nature around me, therefore I decided to study biology. After a few years I ended up sitting dispirited in a lab, asking myself how I should proceed. Reaching the end of my PhD, I was sure that I did not want to stay in academia. However, I was unsure what else was out there. I was surrounded by researchers with a straight academic path, and I pondered what else could I do with my knowledge and skills.

### New inputs

It was by coincidence that my doctoral programme offered mentorships for PhD students and postdocs. It was a one-year programme with regular mentor-mentee meetings and accompanying workshops on topics such as career planning or conflict management. During the regular monthly meetings with my mentor, we discussed not only typically PhD-related topics, like time management and coping with failure, but also career planning. I remember looking at different job advertisements during one of our meetings. For me, it was reassuring how many opportunities are out there where I could use my skills and knowledge.

However, I was not aware of medical writing until I attended the career day in neuroscience at my university. One of the presenters was a science journalist who gave an enthusiastic talk about medical writing. During my studies, I practised classical scientific writing by drafting my thesis and manuscripts for publication. I enjoyed analysing, summarising, and presenting data. In the laboratory, one sometimes loses the bigger picture of one's research while working on tiny bits and pieces. Therefore, writing a paper or giving a talk to put data in context brought me joy.

### I needed a break

Shortly after the mentoring programme, I finished my PhD and decided to take a year off to take a deep breath. So I travelled, together with my fiancée, around the world. We had a wonderful year with unforgettable memories, like watching the lights in the trees in Singapore's Gardens by the Bay, snorkelling with turtles in Australia's Ningaloo Reef on Christmas Day, observing stunning waterfalls in New Zealand's Milford Sounds, enjoying a relaxing Thai massage on Koh Phangan, or driving with our old VW T3 van across Europe.

### Unexpected turn

An unexpected disruption of our trip due to a broken oil pipe in our van forced us to stay at home for two weeks waiting for a spare part. Since I knew that our travel would not continue forever, I used our break to take a quick look at open positions that would fit my skills and interests. To narrow down my search, I looked for positions where I could use my scientific knowledge in auditory research. I checked the websites of manufacturers for implantable hearing solutions since some former colleagues found positions in this medical device area. Two manufacturers had vacancies for a medical writing position in scientific publishing. This directly caught my attention since the job description dovetails with all I love about science. I applied for both positions as we continued our travel.

### Failure and success

After a few days, I got a rejection from one manufacturer, which was disappointing, but I was

invited for a job interview by the other manufacturer. This happened while travelling, so there I was, sitting in a hotel room in Southern France, having a job interview and taking a writing test. In the end I didn't get the job; however, they offered me another position as a clinical evaluation manager that fits my background better.

Meanwhile back in Germany (after escaping heavy snow in Spain), I had a second phone interview and was invited to Innsbruck, Austria. At first, I felt a bit overwhelmed by so many new faces. However, the atmosphere in the office was very welcoming and all the interviews went well. The next day, I got a call offering me the job. I was unbelievably happy although this meant a huge change for me. After a few weeks in Germany, we packed up our things to move from one of the flattest parts of Germany (Oldenburger Land) to the Alps. It was a big step for us, but it was worth it. I am fortunate to work with such a professional team and colleagues that helped me to settle in quickly. My main responsibility is to conduct systematic literature searches, appraisal and summaries of literature, and the writing of clinical evaluation reports for medical devices. My background in hearing research definitely helps me with these tasks.

## Mentoring: A two-way street

The first two years have been an exciting journey with a steep learning curve. Last year the head of my department asked me if I wanted to take part in Elemed's mentorship programme. Since I had such good memories and benefits from the previous programme, I immediately accepted it and did not regret it. My mentor is such an inspiring person and gives me so much insight into the field of medical writing. I can definitely recommend mentorship to everyone. A mentor can give you career advice, emotional support, or help you learn specific skills. It feels like a safe space where you can ask all your questions and talk about your concerns, fears, and hopes. You will learn from the experience of your mentor, while they get new insights from your perspective. It is a bilateral engagement with a long-lasting relationship as the best outcome.

It is advantageous to structure your mentorship time. Documents like session logs and development plans give you a structure and ensure that you keep your goals in mind. Therefore, it helps to define what you expect from your mentorship, discuss how you can achieve your goals with your mentor, and check your progress regularly.

One of the benefits of a professionally organised mentorship programme is the regular exchange with other mentees and the accom-panying webinars about diverse topics. However, an informal and self-organised mentorship is also fruitful.

## Summary

Mentorship definitely helped me progress in my career and pursue my passion. I can recommend it to everyone. Regardless if it is a structured programmed or self-organised, you will benefit from it in many ways.

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# The path of professional self-fulfilment

## A few facts to start

After cosily floating around in warm darkness for approximately nine months, a sudden flash of light hits the baby's eyes and pulls it into a new, noisy world.

This world brimming with novelty is quite different from the mother's womb and demands various changes. As time passes, children familiarise themselves with the environment, growing into it, and suddenly, a few years have gone by and everybody is keen to know and understand who we want to become.

When children are asked about their plans for the future, most of them say they want to be a superhero, a veterinarian or a pilot, or that they just don't know yet. An answer which relates to working on one's personal improvement is not valid in adults' eyes and children are expected to express their career goals with certainty even if they are far too young to do so.[1]

Eventually, every person will choose a professional path to follow, and after finishing compulsory education, he or she will decide to either pursue higher education or find a job. According to Rose and Ortiz-Ostina,[2] North America has the highest percentage of students enrolling in college education at approximately 84%; followed by Europe and Central Asia at 62%, and 43% in Latin America and the Caribbean. Even though at a first glance, a higher education may seem the doorway to the promised land for any job seeker, the actual statistics are in stark contrast to this belief.

In the US, 41% of recent graduates are employed in roles that don't require a degree, according to data published by the Federal Reserve Bank in New York in 2020.[3] This is especially the case for this current year, 2021, as with the ongoing COVID-19 pandemic, the number of entry level jobs for graduates has fallen by 45%.[4] The situation on the European market isn't much better; the unemployment rate rose by 3 percentage points within just a few months at the beginning of the pandemic.[5] Nevertheless, this data shouldn't discourage us, it is just a reference point for gaining a better understanding of the market and it serves as proof that having a degree isn't a guarantee for landing a job. Regardless of the latter, higher education should be made available to anyone who is hungry for more knowledge and wants to specialise in a specific field.

## From a passionate learner to a higher calling

If there is no instant solution for landing a dream job, then why even study? How should one go about pursuing their goals?

I was raised to adhere to the motto *Scientia potentia est* (Latin for *knowledge is power*), and was taught that, by applying these words to your daily life, success is just a step away. However, in my experience, besides knowledge, there are many factors that can help bring you forward. Speaking broadly, when pursuing a goal or a dream job, some of the following ideas may help: find a mentor, get the necessary experience, network, and be persistent.

## My experience

In the last year of my PhD programme, I did my internship at a company, in a role that involved having direct contact with customers, but was still laboratory-based. For the first time, my performance with respect to the outcome of the assigned project also impacted sales. Even though this was only a three-month internship, this experience was instrumental for me in landing a job in the marketing department of a pharmaceutical company. Knowing that this role was not my dream goal, I found myself a mentor who gave me well thought-out insights on how to pursue my real professional goal. In my case, I was advised to network and to pursue an additional training certificate in my desired field. I learned that every person you meet or any experience you get along the way is a step closer to the intended goal. I ended up getting a training certificate in clinical research and showed great interest in regulatory affairs within my company. I was interested in understanding the key skills required for that position, and I worked on improving them. After a few months

of other successful people, finding a mentor, and staying on track, you are sure to make it to the top; just don't get discouraged by diverse challenges on your path to achievement. The obstacles are here to make you a better version of yourself.

## Acknowledgements

## Disclaimers and disclosures

The author is employed at a pharmaceutical company. The opinions expressed in this article are the author's own opinions and not necessarily shared by her employer or by EMWA. The article was written voluntarily.

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of intense job hunting, I got a job in regulatory affairs.

## Realisation

If you want to achieve a specific goal, whether in your career or in personal development, you probably already have a vision of it. Three main attributes can help you achieve your goal, such as action, determination, and networking.

To have a vision and to work on a specific goal is essential. This has been known to mankind for the last 2,700 years – as the Bible says: "*Faith without works is dead*" (James 2:26 NKJV). Believing is just a part of it, the action is, however, the driving force that will bring you towards your goal.

The second ingredient of the recipe for success is determination: *"Pain is temporary. It may last a minute, or an hour, or a day, or a year, but eventually it will subside and something else will take its place. If I quit, however, it lasts forever"* (Lance Armstrong).

When you are getting one step closer toward your goal, don't forget about people. Networking, as a third component, can help you share your ideas and experience, and deliver you important information for your goal.

If we compare our abilities and achievements to those of others, there will always be those who are inferior or superior to us. There are personalities, abilities, and achievements of all colours of the rainbow, and we shouldn't be afraid to learn from them. You can save yourself a lot of time and resources if you let somebody share reliable experience or advice with you. So, by understanding the journey

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# Teaching Medical Writing

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### Editorial

One of the most challenging aspects of the COVID-19 pandemic has been remote education. Instructors and students, from primary grades to university level to professional training forums, have struggled to teach and learn synchronously online. Here, *Medical Writing* Associate Editor Joselita T. Salita explores challenges – and solutions – in tackling this problem by considering the pedagogical importance of interaction, inclusion of participants, and diversity of activities. It is a timely and valuable article for medical writers who deliver courses, seminars, or workshops in the online environment.

**Claire**

## Handling the challenges of online teaching

The COVID-19 pandemic created a new type of normality. Many governments attempted to keep the pandemic under control by introducing lockdown measures, forcing educators and trainers to move the "classroom" into a totally different place – the virtual space – in a short time. Not only universities and schools have been challenged by this unusual situation, but companies and organisations providing training through seminars or workshops have been as well. Medical writers who work as adjunct faculty are fully aware of the challenges of a virtual learning environment, but not all of them obtain enough support from the faculty where they teach. Medical writers who hold workshops for their company or for EMWA's educational programme have a different "clientele" composed of professionals and highly motivated individuals, but the attention span of even these participants wanes after hours of video conferencing.[1,2,3] Teachers and workshop leaders have the same aim, i.e. to reach out and effectively pass their message on to their course participants to promote learning. Therefore, although this article shares insights and experience made by educators in a university setting, these insights are likely to be applicable in other setups such as company webinars and workshops.

## Synchronous vs. asynchronous learning

There are two types of online education: (a) synchronous, in which the educator and the students/workshop participants meet in real time by using video or teleconference tools (such as Zoom, Adobe Connect, BigBlueButton, GoToMeeting, etc.) and (b) asynchronous, in which educators prepare their materials for learning and distribute these through online

means, for example, by direct email contact or uploading of materials onto a common digital learning platform (e.g., *Moodle, AULIS, STudIP*). Depending on the length and purpose of the teaching, courses can be purely synchronous or asynchronous, or a hybrid of these two approaches.

Asynchronous education uses the model applied in correspondence or long-distance learning, which had its beginnings in the early 1900s.[4] Some students find asynchronous learning better than the traditional face-to-face learning as they can work at their own pace, e.g. they can skip concepts they already know and re-read new information as often as they want. However, the success of asynchronous learning is dependent on the learner's age, self-discipline, and motivation, and how well the materials have been prepared by the educators.[5] The challenge for educators engaging in asynchronous learning is the increased time and effort spent on preparing the instruction materials and following up on student progress with assignments and exams. In asynchronous education, the teacher checks and comments on the activities submitted by each student individually, making it almost a one-to-one environment. Therefore, the challenges faced in asynchronous teaching are quite different from those in synchronous teaching, from the point of view of both students[6] and teachers. This article focuses on the challenges faced by educators and learners in a synchronous online educational setting and offers concrete measures that educators or workshop leaders can use to create a stimulating learning environment. Most of the measures mentioned come from a combination of the author's own teaching experiences and strategies learned from various webinars attended such as that of *Orbium Seminare*, a German organisation that "trains trainers" (www.orbium.de). Workshop leaders may find these methods especially useful if they are preparing workshops held over a whole day or several hours over the course of a week.

## The challenges of synchronous online teaching

As Zoom is the most widely used video conferencing tool, this article describes the functions available in Zoom and uses the words "host" instead of "teacher" or "workshop leader", and "participants" instead of "students".

The obvious difficulties that hosts must overcome are the technological aspects of multitasking in an online environment. These include stopping and starting screen-sharing during a Zoom meeting while maintaining awareness of their participants' reactions through facial expressions and messages in the chat box. Another is the noise caused by simultaneous speaking and speaker feedback which may happen if all microphones are active. Therefore, hosts usually mute their participants' microphones – but then have to cope with the difficulty of not being able to easily recognise response from their participants. It takes time for a participant to verbally respond (due to the necessity of unmuting the microphone first) or to write a reply in the chat box. These lags in interaction plus an inherent 1.2-second delay in conferencing systems may make hosts perceive participants as uncooperative.[7]

More difficult to cope with is the lack of genuine interaction in an online environment, especially if the group has more than 10 members. Gestures are an important part of interaction[8] but are absent in online communication as conference hosts can only see the faces of their course participants. Hosts thus rely on facial expressions, but faces are reduced in size (or cannot be viewed simultaneously) if there are many participants and are lost while the host is screen-sharing on *Full Screen* mode. Eye contact can also be lost in a Zoom interaction, depending on the location of a participant's computer camera.[9] Eye contact provides cues that help us assess other people's understanding and is especially important in the absence of gestures.[10] In a genuine classroom, the instructor can see all the participants in the room and is more easily aware of individual or group reactions through verbal means, facial expressions, or body language. Even when instructors are writing on the board or showing slides, they always have the opportunity to look at their audience.

Meaningful online interactions are more obviously absent when participants' webcams are turned off. At most universities, instructors cannot require their students to have their cameras on during class[11] due to the students' right to privacy.[12] While some participants have their cameras off to maintain privacy, others may be engaging in non-course related activities such as answering their *WhatsApp* messages or sending emails (one survey showed that even adult business people do other tasks while video conferencing[3]). Most educators complain and find this problematic, but some believe this is no different from the doodling activities done in traditional classrooms.[13]

> More difficult to cope with is the lack of genuine interaction in an online environment, especially if the group has more than 10 members.

The short attention spans of participants in an online environment is well known. This is due to distractions and competing interests of participants as well as a new phenomenon called "Zoom-fatigue".[2,12] Frequent video conferencing lowers one's capacity to concentrate because it requires more focus in the absence of non-verbal cues and thus drains one's energy.[7] The current lockdown situation with few social contacts and lack of variety in activities adds to negative feelings that cause exhaustion among participants.[7] For these reasons, online participants easily lose interest and may leave the Zoom meeting without notice; something that would not happen in a face-to-face classroom. These aspects can make online teaching frustrating as the educator may find themselves almost talking alone in front of a black box.[11]

Learning and constantly listening in an online environment is understandably challenging. Apart from "Zoom fatigue", participants can find learning online difficult when they do not interact with each other[14] but only with their teacher. Interaction of learners with each other can enhance learning,[15] and the host needs to create a perception of connectedness,[16] especially if participants do not know each other prior to the course.

## Strategies for meeting these challenges

After considering the reasons why online teaching can be challenging, let's consider potential solutions based on pedagogic principles using functions available in Zoom and other digital learning systems. Whenever possible, you as the instructor or conference host should make sure that participants' webcams are on. This should be included as a course requirement (along with other minimum technological standards) or agreed upon with participants as meeting rules. If this is not possible for whatever reason,[12] however, you can still encourage reaction from the participants.[11]

1. Design the course so that it is personal and social. Firstly, make sure that your participants write the names they would like to be called by on their screens. Zoom has a function (in menu bar: *Participants –> Rename*) so that meeting participants can give their own screen names. This will help you identify participants during an activity. (In a traditional setting, the instructor can catch the

*Figure 1. A padlet link showing participants' entries about themselves and the arrows they have drawn to indicate common interests*

attention of a participant by going up to them and establishing eye-to-eye contact, or by describing them or the person sitting next to them; these options are not available online.) Moreover, social presence online can be enhanced by addressing participants personally.[16]

2. Build connections between you and your participants, and among the participants themselves, at the beginning of the course. This connection is important as social interaction contributes to higher motivation and learning success (see above) and can be enhanced by sharing of personal stories.[16] If you have a small group, you can give instructions for linking with each other during the course's getting-to-know-you phase, instead of asking each one to introduce themselves while the others passively listen. For example, the instuctor can have one person talk about themselves, while listeners show a sign (e.g. crossing their fingers in front of the camera) when they find something in common with the person speaking. When the speaker sees this sign, they should give the floor to that listener. The host sets an example by introducing themselves and talks, for example, about a hobby such as watching football. A participant who is passionate about watching football may then show their crossed fingers in front of the camera and can then introduce themselves, and the ball keeps rolling. This type of exercise indicates to listeners that they are not isolated entities but have shared experiences with the other participants. In a large group or when some participants opt to have their cameras off, you can establish connections by building smaller groups (of 3-5 individuals) using the Zoom function *Breakout Rooms*. You should give clear instructions that the participants are to talk to each other and, for example, find three things they have in common in three minutes, and that they are to report these to the following plenary session.[17] (The numbers are arbitrary, but for the purposes of clarity in instruction, these values should be given). This activity acts as an ice-breaker and gives a sense of belonging. It is also recommended that you ask participants to exchange email addresses or phone numbers so that they can contact each other after the day's session. In writing classes, you can use the application *padlet* (www.padlet.com) where participants write something about themselves and then read what fellow participants have written. In *padlet*, participants can draw arrows to other participants they have something in common with (Figure 1). People connected by lines can then be grouped so that they work together for the rest of the course (see no. 3 below).

3. Initiate group activities as often as possible. Zoom's *Breakout Rooms* function is very useful for this purpose. Groups can be manually organised (especially when formed before the meeting) or randomly formed in Zoom during the meeting itself. These smaller groups help participants interact and share what they do and do not know. The host can join any group at will or send chat messages to guide participants in their activities. It is important to give time limits and clear instructions on what should be accomplished in these group sessions. Group activities can also be held after the main online session has ended, where the group participants independently decide when to "meet". Activities can include discussing one's opinions on a controversial topic, summarising the day's lecture, outlining the best solutions to a particular programme, or reading an article aloud while paying attention to each other's pronunciation. Participants are more likely to participate actively in smaller groups during breakout sessions – and also to turn their webcams on.[11]

*Figure. 2. Zoom icons that participants can use to express themselves during the session or a screen share. They allow participants to respond faster when their microphones are muted.*
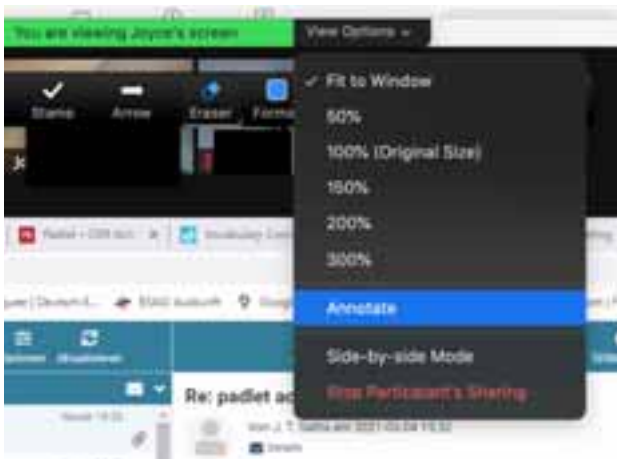


*Figure 3. The menu bar that participants can see during a screen share. The Annotate option allows participants to draw, write, or stamp something on the slide being shared.*
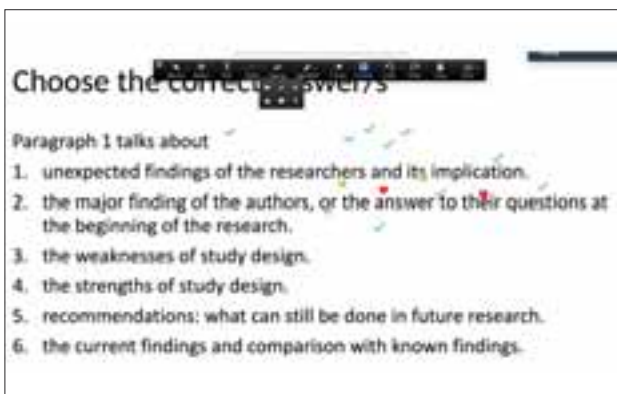


*Figure 4. A multiple choice question that the host is showing on a PowerPoint slide. Participants can "stamp" in the form of arrows, ticks, stars, and hearts to indicate their chosen answer. The host can decide whether these responses are anonymous or not.*
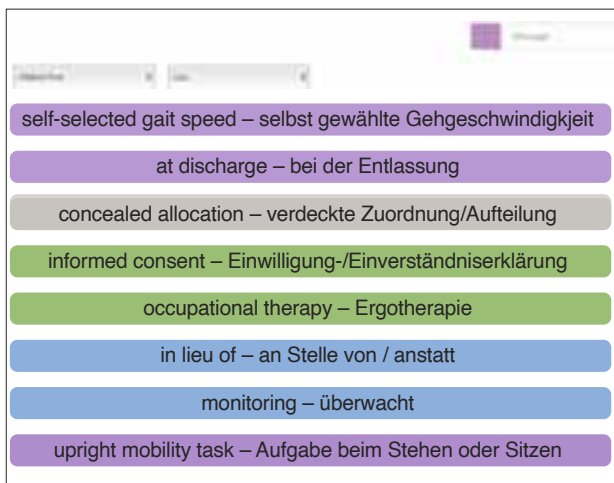
4.  Prepare slide presentations (e.g., *PowerPoint*) for screen sharing that include more visual cues than words. Engaging your participants during your slide presentation keeps them attentive. Before you start the presentation, tell the participants they can just speak, or write in the chat box, or use the *raise hand* icon found in the option *Reactions* in Zoom's menu bar whenever they have questions or comments (Figure 2). Better still, design your course so that you actively formulate questions for the students to answer. If the question is answerable by "yes" or "no", give instructions to click the thumbs-up icon or use the tick or cross ($x$) icons. You will see these "reactions" appear on their screens and can respond to them. During slide presentation or screen sharing, however, it might be difficult for you to see all your participants' screens simultaneously. You can remedy this while sharing your screen by asking participants to click on the menu bar saying *View Options* and then to choose *Annotate*, which then shows *Stamp* (Figure 3). There are several icons that participants can choose from under *Stamp* (e.g., a tick or a heart) to indicate their answers to the question you posted in your slide. Figure 4 shows an example of a multiple-choice question where participants marked their answers with a tick or an arrow. This function of Zoom also allows the participants to write texts or draw something on whatever you share on the screen. In this way, they participate and do not just listen. As host, you can access the *Annotate* option while screen sharing, so you can write text or draw with your students while you share the slide (Figure 5).

5.  Most importantly, give enough time for participants to respond when you ask questions. Most hosts interpret a time lag as a lack of reaction from participants even if participants are willing to react. Repeat your question and instruction, e.g. to use the *Reaction* option. Enforce this by saying that you are waiting for their answers.

6.  Encourage active participation by using the *White Board* option on Zoom's *Share Screen*. This function is like a blackboard in the physical classroom as it allows participants to write text, add symbols, or draw on the board during Zoom sessions. Thus, both host and participants can write on the board, and they have the same access to the tools in the *Annotate* option under *View Options* (see no. 4 above, and Figure 5). Activities in which participants have to write their ideas on this white



*Figure 5. A slide shared by the host showing the menu bar available during a screen share. The host and the participants can enter text or other symbols at the same time during the slide presentation.*

*Figure 6. A flinga link that allows interactive activity. Anyone with access to the link can drag prepared anatomical adjectives in boxes to the corresponding human body part and can write or edit a box.*



self-selected gait speed – selbst gewählte Gehgeschwindigkeit

at discharge – bei der Entlassung

concealed allocation – verdeckte Zuordnung/Aufteilung

informed consent – Einwilligung-/Einverständniserklärung

occupational therapy – Ergotherapie

in lieu of – an Stelle von / anstatt

monitoring – überwacht

upright mobility task – Aufgabe beim Stehen oder Sitzen

*Figure 7. A vocabulary list prepared by the participants during a course using flinga. Colour codes indicate the section of the reading text where the word or phrase occurs.*

board or share their own screens (which you as host may or may not allow) makes students think while listening. Interactive tools such as *padlet* (see no. 2 above) or *flinga* (see https//flinga.fi) also encourage participants to be active. These free applications act as a virtual notice board. As host, you just go to the application website and give your email address. Once in the application, you can prepare an activity by laying out appropriate formats, and you will be given a link or QR code that can later be sent to the course participants, who access the activity by clicking into the link or QR code (they do not need to register). For example, in Figure 6, participants can drag the jumbled labels of a human body to the correct place or re-label them correctly in real time. Anyone who is in this link can move and/or write the labels, and this is seen by everyone in the link. These actions can be made anonymous if desired so that no one risks feeling embarrassed due to imperfect answers or worries about offending someone when correcting the work of other participants. Another example that makes participants interact and work as a team digitally is in producing a vocabulary collection. A group of participants can be assigned to read a particular paragraph, and in a *flinga* link they enter words or phrases new to them and their meanings. After a few minutes, the class has a collection of vocabulary for that topic (see Figure 7) that can be saved in *Excel* or as PDF for later retrieval. Such interactive applications are also powerful for teaching writing skills. Figure 8 shows a *padlet* link in which students write a summary of a selected section of a pre-assigned scientific article, either during or outside of class. Anyone in this link sees what is written and can correct or improve entries anonymously. In a genuine classroom situation, students do not necessarily stand up and go to the board to write their summaries, but these interactive tools allow students to write freely without risking the consequences of incorrect answers. As host, you can also pick an entry to use as an example for class discussion.

7. Make people move during online courses. This is one of the most neglected aspects of online teaching. Although studies have shown that physical activity activates the brain and stimulates learning,[18] hosts forget to make their participants move in between activities. This is as easy as instructing participants to stand up and do some stretching[19] or assigning participants to suggest some stretching exercises. In language courses, this is a creative means of making learners practise imperative sentences and enrich their vocabulary. Physical movement acts both as a "brain break" and an ice-breaker.[18] You can also design a task in which participants have to get up and walk. For example, match pairs of participants and ask them to exchange phone numbers, so they can call each other and discuss an issue while walking around.[17]

8. Give quizzes in the middle or at the end of each meeting. This can be announced at the start of the class to encourage participants to listen. The quizzes do not have to evaluated nor do they have to be long or difficult (e.g. they can be trivia quizzes), especially if your purpose is only to shorten the participants' listening/passive phase and to introduce diversity or avoid monotony. Course-related quizzes give participants the opportunity to check their understanding and ask questions about anything that was not clear. Quizzes based on reading assignments pave the way to start a discussion. Many learning platforms provide the option to make quizzes (e.g. *Moodle, Learning-Snack*[17]) where participants receive feedback straightaway and can access the quizzes even after the course, thus providing a chance to review what was learned. Such platforms also allow the host to gauge participant understanding as a group or individually. However, learning platforms are not necessary to design quizzes; Zoom's *Polling* function can also be used and is recommended if anonymity is required. The host will not know which students answered correctly but sees the class performance through poll results (although this is only available if the host is a licensed user). Quizzes also can be produced by the participants themselves for fellow participants, a useful activity for learners as they need to actively review the lesson to formulate sensible questions. The application *Quizlet Live* (www.quizlet.com) lets you make game-like quizzes that foster competition between individuals or teams.

9. Get feedback from participants at the end of the day's session (and not necessarily at the end of the course) to improve teaching strategies during the course. For example, the host can use Zoom's *Polling* function or show a *PowerPoint* slide with a picture of a scale and ask participants to rate the lesson by using an icon to *Annotate* their perceived speed of the lesson (Figure 9; see also no. 4 above).

10. Reserve time after the Zoom meeting – there are always participants who have issues to discuss or requests to make. It is helpful if the

*Figure 8. An interactive activity in which participants had to summarise an assigned paragraph based on key words at the topmost square of each column. The entries can be corrected or commented on by anyone in the link.*

host takes the initiative and offers to stay online after the meeting so that participants with special concerns can take this opportunity. Giving feedback straightaway to participants' concerns and being available one-on-one enhance personalisation and social interaction.[16]

## Other issues

### Assessment

In courses which involve formal education, students have to be assessed at the end of the course. Identifying a fair means of assessing work can be a serious challenge for online educators. Cheating during exams is more obvious in the virtual classroom. Although teachers can require two working cameras positioned at different angles to the student during written exams, this does not guarantee that the student will not access other online resources. Most educators resort to an open book exam that assesses analytical, critical, or interpretative skills, but it is not easy to develop effective exam questions of this type and to assess its answers objectively. An alternative is portfolio assessment, in which students submit a collection of completed written assignments, presentations, and other activities as proof of their competence.

## Data protection and copyright issues

Teachers and workshop leaders should be aware of the strict regulations in each country regarding data sharing and the privacy of their participants. It is always useful to inform course participants that slides used for presentation should not be reproduced and the meeting not recorded. Make sure that pictures you use as visual aids are not protected by copyright. You can opt for Google

to search only images under Creative Commons license (in Google, click *Settings* → *Advanced Search* → *Usage rights*). Some instructional materials are also free on the internet, and you can provide the links in lectures or during a presentation. However, not all materials that are downloadable are free for distribution. If you download materials, you have to ask its owner if you can freely distribute it online. This also holds for any material that was photocopied



*Figure 9. Participants give feedback by rating the speed of the lesson through using icons available in Zoom during screen sharing.*

and uploaded onto the internet for use by your course participants. As a rule, you cannot photocopy and distribute more than 15% of the contents of a book (i.e. from the title page until the last page of the bibliography or appendix) for teaching purposes. Most academic papers with open access can be used and distributed freely as long as they are distributed as individual articles. This means you cannot download or photocopy one whole issue of a journal and distribute it online.

## Conclusion

This article has outlined some of the challenges faced by instructors in delivering synchronous online courses and by learners having to cope with Zoom sessions. It has then described concrete measures to meet these challenges. These measures build on pedagogical principles for creating a positive learning experience in remote settings, i.e. to provide Zoom sessions that are personalised, social, and engaging, provide diverse activities, and

> A positive learning experience leads to a positive teaching experience.

encourage physical movement. A positive learning experience leads to a positive teaching experience.

By providing opportunities for active participation and self-learning, educators cannot only achieve their own aims but also enjoy the feedback and "company" of their Zoom participants. Indeed, the role of the educator in the online environment has evolved from the classic role of simply giving information to that of facilitating learning through interaction. Medical writers giving a daylong webinar should also acknowledge this shift. If you merely aim to inform your course or webinar participants, then simply presenting slides online may work for one hour. However, if you really want your participants to take home something important after your webinar, you must enable them to actively participate. As online teaching may continue in the post-pandemic period[5] due to its flexibility and encouraging students to be responsible for their own learning, this article is not only useful for the current situation but also for meeting our educational goals in the future.

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## Conflicts of Interest

The author declares no conflicts of interest.

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# Gained in Translation

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## Medical translation basics: Translating into your native language and knowing the target audience

With 10 years of experience in medical and pharmaceutical translation, I have translated for patients, pharmaceutical companies, researchers, and students many times. Translation is the process of understanding a text in a foreign language and rewriting it in the native language of the translator. I translate patient information sheets, clinical trial presentations, clinical science papers, training material, and pharmaceutical marketing material. The target readers can be as varied as in medical writing: general practitioners, health outcome experts, nurses, patients, or a general audience. For the December 2020 issue of *Medical Writing*, the theme of which was "Writing for patients", Andrea Rossi wrote an excellent article on translation. I think that this is the perfect, although unintentional, introduction to the series of articles that the translators from the MedComms group have started to publish. Thank you, Andrea!

This is the first of a series of articles on the basics of medical translation. There surely are many common points with what medical writers deal with. After the fascinating article of Paolo Rega on the Latin and Greek roots of medical terms in the March 2021 issue of *Medical Writing*, let's get into a more topical subject.

In this article, we will start with the importance of translating into the translator's native language and knowing the target audience. But first, a short explanation of what medical translation actually involves.

### What is medical translation?

Medical translation is translating various types of documents, such as training materials for healthcare, medical device or pharmaceutical fields, marketing or clinical, journal articles, regulatory, and technical documentation.

Many doctors engage the services of medical translators for their patient records, prescriptions, medical history, and diagnoses that are written in another language.

Medical translation is not just about working with doctors, as there are several other areas where it is needed. For example, labels, package inserts, and medical devices sold locally need to be translated into the language that is commonly used. Such pharmaceutical documents are more patient-oriented. When they are translated, it is crucial that the translation contains no mistakes, because these documents are what the patients rely on to take their medicines. For example, it is particularly important not to make mistakes on the translation of posology and method of administration.

Furthermore, all the other parts of a package insert (in particular those mentioning the possible side effects and the indication) are of utmost importance. For example, a drug might have hyperthyroidism or hypertension as a side effect. So if the translator mistakenly translated it as "*hypo*thyroidism" or "*hypo*tension", the signs to be aware of will not be the same at all and the patients might disregard them and not realise they're suffering from a side effect.

Medical translators are involved in translating texts in all areas in healthcare. They are not only meant for patients and doctors, but also for clinical researchers and regulators. For these particular target readers, mistakes on dose and method of administration could have disastrous consequences on clinical trial safety and prevent authorities from granting them a marketing authorisation.

The translation of medical texts is very important for clinical trials in order for local clinicians and representatives of regulatory organisations to understand them. For example, informed consent forms have to be well understood by patients, as well as investigators brochures by researchers and Summaries of Product Characteristics (SmPCs) by clinicians.[1]

### Why do most translators translate INTO their native language?

Remember learning a language at school:

- How easy was it to read in a foreign language? It probably wasn't that difficult because some words looked familiar.
- How easy was it to understand a teacher speaking in a foreign language? This might have been a bit harder but most of the meaning was still understandable.
- Now, how difficult was it to write in a foreign language? Even though the ideas were very clear, that may have seemed so hard that going back to writing an essay in your native language felt so much less of a chore after that!

When translating, the translator has to re-invent a text from a foreign language. Some translators do translate in both directions because they have lived a significant part of their lives in two countries having different official languages. This means that most translators only translate from foreign languages into their native language. When translating into their native language, translators are indeed much more able to convey the message in a precise manner because it is the language they know best. A non-native might not be able to have such an in-depth knowledge of a foreign language. This high level of accuracy is crucial when translating.

However there are some specific situations where it may be difficult to find a native translator. Here are two brief examples:

- Multicultural societies with high immigration, like Australia, where there are many chal-

lenges for successful communication due to cultural, political and commercial interactions, and a lack of competent native speakers in all of the many different languages immigrants speak.
- Lack of native speakers of foreign languages who are competent in the language of the country, such as Finland, where many into-English translations are done by non-natives.[2]

## Knowing the target audience

Medical writers are fully aware of the utmost importance of knowing the target audience.

This also applies to medical translation.

As we saw earlier, medical translation is not just about working with doctors. Document types a medical translator deals with can range from an article published in a medical journal to an internal document for the sales department of a pharmaceutical company. This is a non-exhaustive list of the documents that a medical translator may be required to translate:
- Summaries of product characteristics (SmPCs)
- Drug leaflets
- Marketing authorisations
- Informed consent forms
- Patient questionnaires
- Investigator's brochures
- Package inserts/labels
- Clinical trial presentations
- Press releases for the pharmaceutical industry
- Medical PowerPoint presentations for conferences
- Medical articles for specialists or for a general audience
- Corporate documents
- Drug marketing material

The target readers can therefore be the following:
- Patients
- Doctors
- Health authorities
- Clinical trial investigators
- Researchers
- General audience
- Pharmaceutical company employees

As the target readers can vary, so can the purpose of the translation. For the translation of patient questionnaires, it is important to be aware of the patient's culture. For example, in a questionnaire about hand motor skills, the question might be about peeling an orange in one country and opening a milk carton in another country. For package inserts, it is of course critical for the dosage and administration sections to be error-free for the safety of patients.

In other cases, such as internal emails about a future conference between two branches of a pharmaceutical company, such a level of accuracy might not be required, and a fit-for-purpose translation might be good enough as long as the client agrees.

In English into French translations, there are many examples of the changes a translator needs to do to adapt to the target audience.

Simple things, such as the translation of "headache" will have to be adapted to the target audience. It will be translated as *maux de tête* for patients and the general audience, for example in a drug leaflet or a patient questionnaire. However, the best translation will be *céphalées* for documents written for doctors and researchers, such as SmPCs or clinical trial presentations.

Table 1 shows other examples of translations adapted to the target audience.

As a medical translator, I am not always directly in contact with the translation client. Very often, I work with translation companies. I send them my translation and they send it to their client. Of course, I can ask questions that they will send to their client and they can get instructions from their client that they will send to me. There are similar validation steps between writers and authors in medical writing to make sure that the right message is conveyed.

## Translating for patients
### Example 1
Under the influence of English, German texts use the personal pronoun *du* more often than they used to, assigning it the same meaning as "you" in English, i.e., to speak to an adult person, even though *du* is the second-person singular pronoun and *Sie* is the formal pronoun in German. The pronoun that should be used to address an adult person in German should therefore be *Sie*.

In French these pronouns are *tu* (second person singular, but only for children and familiar people) and *vous* (second person plural and formal pronoun for an adult person). For example, one would never say *tu* to an unknown adult because that might seem rude. But once they become familiar, especially if they're in the same age group, it becomes socially accepted to say *tu* to them, most of the time after asking if they agree to use *tu*. In French, *vous* is the formal pronoun that is used to address an adult person.

To sum that up, the translation of the English *you* when used for an adult person in a formal context should be *Sie* in German and *vous* in French, but in some German texts, I see *du*. However, it would be inappropriate to translate it as *tu* in French because the French language is not under the influence of English in this specific case and reading *tu* would seem weird to the French adult readers.

One of the only cases in which it is advised to use *tu* in a French medical text is for medical trial consent forms and informative medical documents written for children. Therefore, it is very important to know if the French translation is intended for adults or children.

### Example 2
Also, when translating for patients, a translator has to make sure that the wording doesn't convey

*Table 1. Medical terms translated differently to adapt to the target readers*

| English medical term | French translation for patients/general audience | French translation for doctors/scientists/health authorities |
| --- | --- | --- |
| Headache | maux de tête | céphalées |
| Dry skin | peau sèche | sécheresse cutanée |
| Weight gain | prise de poids | gain pondéral |
| Kidney function | fonctionnement des reins | fonction rénale |
| Blistering | formation de cloques | formation de vésicules |
| Chest tightness | serrement dans la poitrine | oppression thoracique |
| Life-threatening | potentiellement mortel | pouvant menacer le pronostic vital |
| Wheezing | respiration sifflante | sibilances |
| Sputum | crachats | expectorations |
| Brain MRI | IRM du cerveau | IRM cérébrale |

*Table 2. Preferred terms for English-into-French medical translations for patients*

| English medical term | Preferred French translation for patients | Do not use |
|---|---|---|
| Patients with cancer / diabetes / depression | patients présentant un cancer / un diabète / une dépression | cancéreux / diabétiques / dépressifs |
| Elderly patients | patients âgés | vieux patients |
| Transgender | transgenre/trans | transsexuel |

anything pejorative or discriminatory. For example, when translating "cancer patients" or "patients with cancer" into French, it is advised not to use terms such as *cancéreux*. Using *patients présentant un cancer* or *patients atteints de cancer* are better options because they sound more neutral.

Of course, it is also very important to be aware of gender considerations. I recently translated a text dealing with breast cancer screening. It mentioned that patients having breasts could benefit from breast cancer screening. It involved cisgender women assigned female at birth as well as transgender women assigned male at birth and taking feminising hormones.

Table 2 shows other examples of preferred terms when translating into French for patients.

It's important to take the evolution of our society into account when writing and translating medical texts for patients. Recognising patient preferences, differences or conditions gives them a sense of inclusion, which is one of the tools we can use to make them feel more involved in their treatment or trial participation. For example, data protection has gained importance since the

General Data Protection Regulation was applied in the EU in May 2018. Therefore, in patient consent forms, it is compulsory to explain in a very detailed manner how the patient's health data are going to be used and stored.

## Conclusion

In this article, we have moved from theory to practice with concrete examples to understand the reality of medical translation. We have summed up what medical translation involves and focused on two main points: the importance of translating into the native language and why translators should know their target audience and their culture well. These are only two of the many aspects medical translators have to be aware of and experienced in. Medical translation requires many different capacities, some of them overlapping with medical writing. I hope that this article raised the interest of medical writers for medical translation and that those of you who are also translators will find that it truly reflects the reality of their practice. If not, I'm always open to discussion! Please contact me if you have

comments or questions. I hope to hear from you. Watch this space for future articles on medical translation.

## Acknowledgments

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# Regulatory Matters

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## Real-world by design: Considerations for designing clinical trials that include real-world evidence

The complexity of modern-day clinical trials has propelled trial design from being a consideration to now becoming what some experts believe is a science in and of itself. The United States Food and Drug Administration (FDA) sees immense potential in utilising real-world data in designing clinical trials. This article introduces real-world data and presents a few considerations for designing nonrandomised single-arm clinical trials and observational studies that include this design element.[1,2]

The FDA's Food, Drug and Cosmetics Act defines real-world data as data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources, including data derived from electronic health records, medical claims and billing data, data from product and disease registries, patient-generated data, data from in-home-use settings, and data gathered from mobile devices.[2]

**In a nonrandomised, single-arm trial setting,** the following are some opportunities for the incorporation of real-world data:
1. external controls for studies wherein the disease evaluation criteria is well established;
2. historical records of vital signs, either as a pooled dataset or stratified according to any prespecified participant characteristic, collected from trial participants residing in different geographies; and
3. comparison datasets for those trials wherein a placebo or non-treatment arm is either not ethical or feasible.[2-4]

**In an observational study setting,** the following are some opportunities for the incorporation of real-world data:
1. because certain types of real-world data such as data from mobile health monitoring and wearable devices are captured in a noninterventional, purely observational, uncontrolled and 'natural' setting, they may be utilised to

test hypotheses based on physical activity, caffeine consumption, and a variety of other lifestyle characteristics; and
2. postmarketing surveillance data and real-world data derived from medical claims, administrative claims, and electronic health records may be used not only to gain a deeper understanding of treatment-emergent adverse events in the long term, but also to validate safety and efficacy claims from randomised controlled trials.[3,4]

Despite the value that real-world data can offer, it may not be applicable to all types of trial designs. As a design element, the incorporation of real-world data in a clinical study often begins with a multifaceted discussion focusing on many considerations, including the following:
1. whether the treatment methodology is routine enough and the therapeutic area is established enough to gather sufficient real-world data before study initiation;
2. whether the available real-world data is of sufficient quality to lend itself to statistical comparisons against data gathered in a more traditional longitudinal study;
3. in trials focused on rare and ultra-rare

diseases, whether the volume of available real-world data is sufficient for its utilisation as a trial design element; and
4. in cases where historical controls are being used as real-world evidence, whether clinical practice guidelines and data collection methods have remained consistent for the data to be useable as an accurate comparator dataset.[2]

In conclusion, the incorporation of real-world data as a design element in clinical trials can broaden our perspective, allow us to see the invisible, and potentially improve regulatory decision making.

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# Regulatory Public Disclosure

## COVID-19: Out there in all its glory

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**Editorial**

In the first half of 2021, keeping up with the regional regulators' activities on COVID-19 medicines became a competitive sport. FDA's Emergency Use Authorizations (EUAs), EMA's Conditional Marketing Authorisations, and Health Canada's Interim Orders kept us all busy – if not doing, then reading. By late May 2021, the EU had approved remdesivir; conditionally approved two mRNA vaccines (Pfizer-BioNTech's and Moderna's) and two adenovirus vector vaccines (AstraZeneca's and Janssen's); had publicly disclosed the clinical documentation for the Moderna and Pfizer-BioNTech vaccines; and had endorsed dexamethasone. The EU had a further four vaccines under rolling review. The FDA had authorised the Moderna, J&J, and Pfizer-BioNTech vaccines under emergency use, as well as several medicines including monoclonal antibodies and remdesivir. Health Canada had "authorised with conditions" the Moderna and Pfizer-BioNTech vaccines under an Interim Order and had publicly disclosed the associated clinical documentation. Exhausted? Yes, weren't we all? Then some country agencies expedited access for their citizens even ahead of the regional regulators making their decisions. More COVID-19 vaccines and medicines are in development, and regulatory rolling review is now a commonly employed tool. All of this speaks of a highly regulated pharmaceutical industry, being pragmatic, responsive, and committed to finding operational and regulatory solutions to fast-track COVID-19 prophylactics and therapeutics in impossibly short timeframes! With the ability to use CRISPR technology to modify and re-code RNA vaccines in response to emerging viral variants, customised vaccines may be developed in a matter of weeks, scaled-up, and deployed. This can be considered conceptually similar to minor modifications in drug formulation, as would be represented in an Amendment to the New Drug Application for an already-approved drug. Regulators will need to maintain creativity and impetus to authorise vaccine variants as fast as we need them. All of this is playing out in a very public arena. Everyone has an opinion on what we do and how we do it. The source clinical study documentation provides the most objective information available; at least some is publicly accessible at EMA's Treatments and vaccines for COVID-19 pages (https://www.ema.europa.eu/ en/human-regulatory/marketing-authorisation/ conditional-marketing-authorisation) and at Health Canada's Clinical Information Portal (https://clinical-information.canada.ca/ search/ci-rc). A dedicated page titled "Transparency: exceptional measures for COVID-19 medicines" (https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats-coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines) clarifies how the transparency measures for a standard practice (i.e. non-COVID medicine) regulatory activity – such as scientific advice, rolling review, etc – stack up with that of the transparency measures for the same activity for a COVID-19 medicine. So for example, although publication of clinical trial data remains suspended for non-COVID medicines, COVID-19 data are published on the Clinical Data website: https://clinicaldata.ema.europa.eu/web/cdp/home. By the time you are reading this in print, there will undoubtedly be further updates – so the best advice is to watch this space and check these sites regularly. Through this pandemic, we are also really beginning to understand the value of real-world data when combined with data collected through pre-approval pathways. Read more on this below.

This pandemic has also increased awareness of the importance of well-prepared and presented patient-facing documents. If we consent to participate in trials or receive a COVID-19 vaccine, we read some of this material as adult participants or patients ourselves. Children also need appropriately presented clinical trial documents – as Vidhi Vashisht and colleagues describe in their article on p. 52, "The ABCs of paediatric plain language summaries". This article provides guidance on plain language summary formats that appeal to children. All this reminds us of the need to keep patients centre-stage, as the UK Medicines and Healthcare Regulatory Agency (MHRA) plan to do in piloting a project that includes greater patient involvement in clinical trials and medicine development (https://www.gov.uk/government/news/mhra-pilots-patient-involvement-in-new-applications). Although at an exploratory stage, this initiative should serve patients better and increase transparency within clinical trials. It is certainly one to watch.

Sam Hamilton

## Regulatory Public Disclosure Special Interest Group (RPD SIG) News

Visit the revamped RPD SIG page at: https://www.emwa.org/sigs/regulatory-public-disclosure-sig/#

Our current co-chairs are Holly Hanson and Tracy Farrow. A big "thank you" to Christopher Marshallsay for co-chairing with Tracy since the RPD SIG came into being in 2016; and a warm welcome to Holly who has kindly stepped up. We are delighted to introduce our newest committee member, Amanda Hunn. Amanda is a freelance consultant and subject matter expert on patient-facing documents, including the Patient Lay Summary (PLS), and brings valuable expertise through her previous experience as Head of Policy and Public Affairs at the Health Research Authority in the UK, where she led the EU-wide taskforce responsible for drafting the guidelines on writing lay summaries of clinical trial results on behalf of the European Commission and developing policy on informed consent including publishing joint guidance with the MHRA on eConsent. She sat on a national research ethics committee for 6 years and has co-authored a number of papers including "Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension". Amanda shares her knowledge on the latest development in lay summaries. See the update on the next page on good lay summary practice.

EMWA's RPD SIG is interacting with Statisticians in the Pharmaceutical Industry (PSI) Data Transparency SIG (https://www.psiweb.org/sigs-special-interest-groups/data-sharing-working-group). This group shares experiences and challenges of external patient level data sharing, with particular focus on data privacy and anonymisation processes. Janice Branson and her colleagues first published their article "Secondary use of data – Unleashing Data Assets to Create Value" in the PSI publication *SPIN* in Spring 2021. In the article, which we are republishing here on p. 105 to share with the medical writing community, the authors describe the wider picture of data sharing in the pharma industry using examples of internal data re-use programmes. Please do not hesitate to provide feedback on this article, as the authors are keen to hear our perspectives.

## COVID-19 real-world data

ICH regulators emphasised the importance of international collaboration on observational studies of real-world data in facilitating regulatory decision-making on vaccines and treatments for COVID-19. The January 25, 2021, workshop convened under the International Coalition of Medicines Regulatory Authorities (ICMRA) (http://www.icmra.info/drupal/en/home) and co-chaired by Health Canada and the EMA, allowed participants to share information on ongoing initiatives on observational studies derived from real-world data. Key learnings from these activities and opportunities for international collaboration were identified. Regulators also discussed international cohort building; pregnancy studies; and vaccine surveillance and vigilance (https://www.ema.europa.eu/en/news/ema-preparing-guidance-tackle-covid-19-variants)

As COVID-19 vaccines are being authorised and rolled out across the world, regulators must ensure the continuous monitoring of their safety and effectiveness, especially when used by special populations. Real-world evidence from observational research is critical to understanding the benefits and risks of medicines in everyday use for the prevention and treatment of COVID-19. The main findings are summarised in this ICMRA report (published February 8, 2021) (http://www.icmra.info/drupal/covid-19/25january2021). It is also heartening that non-ICH Regulators have been contributing to the EMA's COVID-19 Pandemic Task Force since December 2020 (https://www.ema.europa.eu/en/documents/other/questions-answers-pilot-project-open_en.pdf) and support these assessments.

## EMA Clinical Trials Information System news

Due to technical difficulties, EMA has postponed the launch of the Clinical Trials Information System (CTIS) to January 31, 2022. Full details are on the CTIS page (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation). This EMA webpage is dedicated to the CTIS training programme (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation/clinical-trials-information-system-ctis-training-programme). Most training is online, but there a few virtual training sessions in classroom format aimed at Sponsors. Full functionality of CTIS is linked to full application of the European Clinical Trials Regulation EU No 536/2014 (https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf). There will be an 8-year gap between the CTR being adopted and entered into force (2014) and it being fully applicable (2022 – as currently planned), plus a pandemic and the associated innovations in clinical trial design, conduct, reporting, and authorisation that have taken place in between. Outcomes will be interesting to follow.

## Good Lay Summary Practice update

When the EU's Clinical Trial Regulation (CTR) comes into force, it will require the preparation of a summary of trial results in lay language in addition to a technical summary. Whilst the EU has produced guidelines on the content of lay summaries (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf), questions remain around their collaborative planning, preparation, and dissemination. The European Forum for Good Clinical Practice and the European Federation of Pharmaceutical Industries and Associations have collaborated in leading a Roadmap Initiative for Good Lay Summary Practice with input from over 60 international patient organisations, pharmaceutical companies, academia, not-for-profit organisations, and clinical research organisations. A public consultation on the recommendations was held in 2020 and further revisions are being considered. The Good Lay Summary Practice recommenda-tions will provide a wealth of useful detail including considerations in planning and design of lay summaries, guidance on writing paediatric lay summaries, and the tricky issue of translation, together with links to glossaries of lay terminology.

## Resources

1. "The Impacts of COVID-19 on Clinical Trial Transparency and Document Disclosure PHUSE CTT Project" (https://phuse.global/Communications/PHUSE_Blog/the-impacts-of-covid-19-on-clinical-trial-transparency-and-document-disclosure-phuse-ctt-project) is a December 2020 update (https://phuse.global/Communications/PHUSE_Blog/phuse-covid-19-impact-on-ctt-update) that explains some of the initiatives that have changed since the initial PHUSE Clinical Trial Transparency project launched.
2. EMA's Medical Terms Simplifier (https://www.ema.europa.eu/en/documents/other/ema-medical-terms-simplifier_ en.pdf) – a plain-language description of medical terms related to medicines use – is a boon for medical writers preparing patient-facing texts, including the PLS and Patient Information Sheet/Informed Consent Form (PIS/ICF). The resource is housed on the patient pages of the EMA website (https://www.ema.europa.eu en/about-us/about-website/glossary).
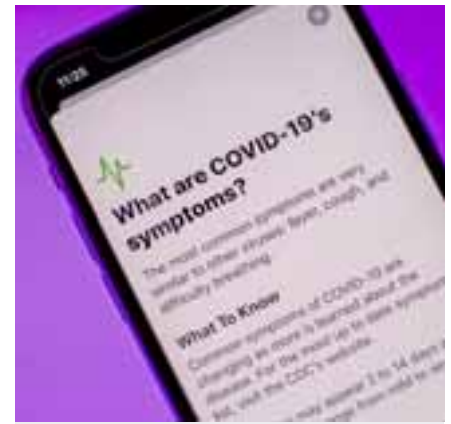
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You can review the same information as monthly summaries at:
- https://www.core-reference.org/news-summaries/
- https://www.emwa.org/sigs/regulatory-public-disclosure-sig
- View it in the monthly EMWA NewsBlast.

If you have news for this RPD Section or any of the aforementioned resources please get in touch and I will gladly share.

> EMA's Medical Terms Simplifier is a boon for medical writers preparing patient-facing texts.

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**#** This is called the hash, pound, or number character. A hashtag is a keyword or set of keywords that is preceded by the # character. It is used in social media to create a thread of conversations around a specific theme or topic conveyed in short texts or microblogs. It is commonly used in Twitter, Instagram, YouTube, Pinterest, etc.
A dictionary of most common hashtags can be found at https://www.hashtags.org/definition/~h/.
For your info, EMWA is compiling a list of standarised hashtags for our social media use.

**@** This is called the "at" sign or symbol. The @ sign is part of email addresses and social media user names ("handles"). Our EMWA handles are as follows: **@Official_EMWA** (Twitter), **@EMWA** (LinkedIn), and **@europeanmedicalwritersassociation** (Facebook)

## The two most important keys on your keyboard

# Secondary use of data
## unleashing data assets to create value

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## Introduction

Over the last decade, there has been increasing recognition in the value of secondary use of clinical trial data. The data may in fact be valuable for other scientific investigations beyond the initial purposes and objectives of the protocol. Across the pharma industry and academia, huge amounts of clinical trial data have accumulated over many years. Within pharma companies as we plan new programmes and investigate emerging and evolving scientific areas, we seek to understand how we can utilise this already collected data. In 2020 with the urgency of a pandemic situation, we also saw a huge interest in collaboration and intentions to share data across companies and academia. What can we learn from the pandemic experience and how can some of these ideas be incorporated into drug development in order to make drug development cycles shorter and more cost effective? Figure 1 highlights some of the key milestones in the evolution of data sharing and access that we have experienced since 2008.

There are four main areas to consider as we embark on re-use of data: ethical considerations, legal and data privacy considerations, good data science practice, and business sensitivity. In terms of ethical considerations, it is important to utilise

> It is important to utilise personal data in line with patients' original expectations.

personal data in line with patients' original expectations e.g., aligned with secondary use language in the informed consent form. However, the best practice for secondary data use may be to utilise anonymised or synthetic data where possible. Data privacy elements are covered in more detail below. In terms of good data science, how do we ensure reproducible research and avoid the reproducibility crisis – can we always ensure analyses plans, data and results follow FAIR (Findable, Accessible, Interoperable and Reproducible) principles? Finally in terms of business sensitivity, re-use of data should be from locked studies only (or those having reached primary endpoint). Depending on the stage of the programme development lifecycle, the project team should be made aware or involved and any commercially confidential information needs to be accounted for. In addition, if the re-use of data is for the actual organisation that generated the data in the first place, then some of
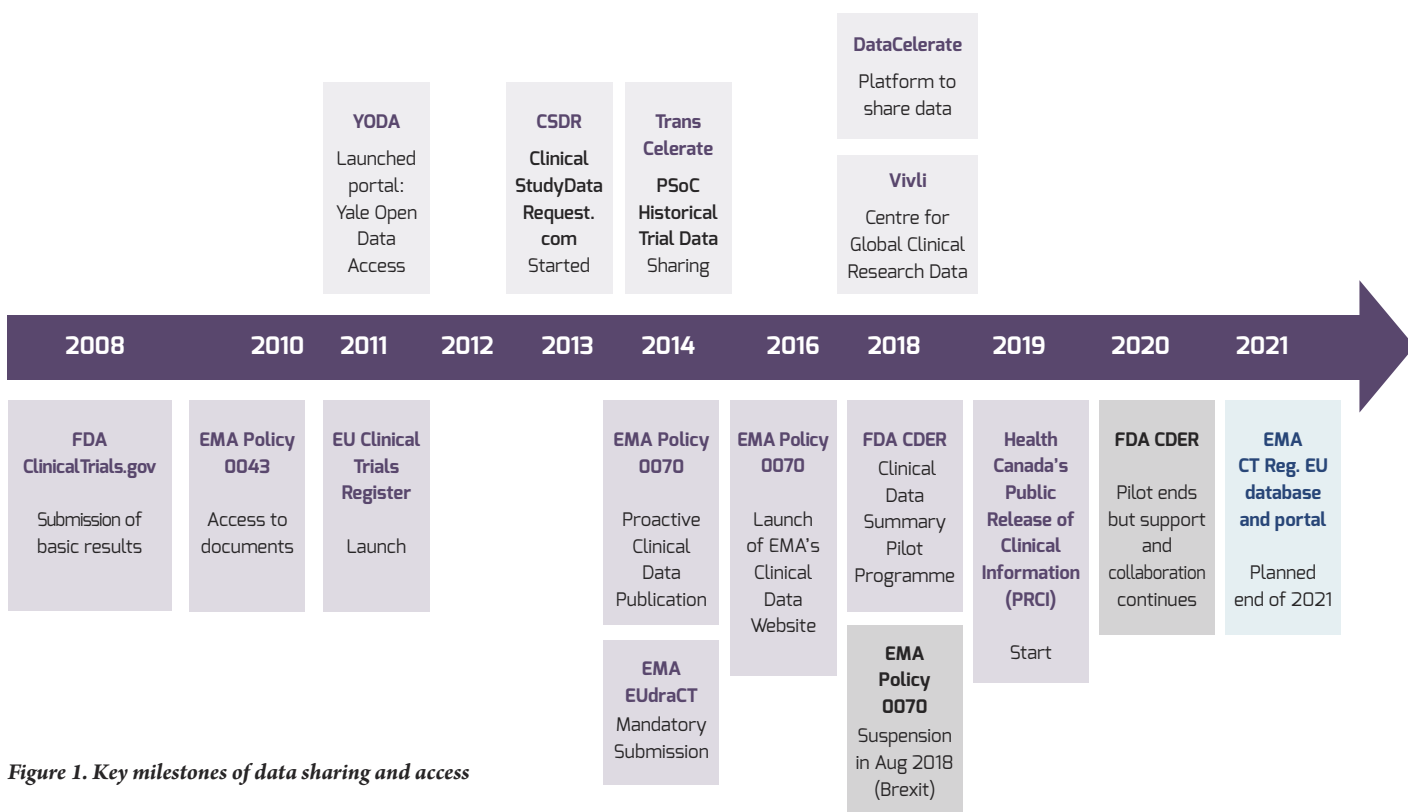


*Figure 1. Key milestones of data sharing and access*

these considerations may differ slightly compared to external re-use of data. It is true that the external re-use of data has been triggered by public and regulatory pressure on transparency, but there is a growing realisation that internal re-use of data and the considerations that need to be taken into account are still relatively immature within the industry.

## Secondary data re-use programmes internally in an organisation

Many larger pharmaceutical companies have multi-year internal data re-use programmes, such as Novartis "data42", Roche "Enhanced Data and Insights Sharing" and AstraZeneca internal Data Access Policy (iDAP). The aims of such programmes are to bring early and "frictionless" access to R&D data across the broader organisation, including making data "FAIR" (Findable Accessible Interoperable Reusable).

Clinical trial data has value beyond the initial purposes and objectives of the protocol. Data can be used to inform understanding of patient populations and disease, validate new targets, develop new methodologies, endpoints, biomarkers, tools, and other scientific research thus helping develop more "personalised healthcare", and ultimately deliver greater benefits to patients.

Data re-use programmes should be underpinned with a comprehensive data governance strategy. Such a strategy ensures responsible data re-use in order to maximise scientific insights, at the same time as minimising risks, for example those related to data privacy. Responsible re-use could advance science in the interest of patient

care, ensure data are used maximally for the public good, bring benefits to society, and increase trust in organisations and ethics.

Examples of data re-use objectives include – new insights to characterise the drivers of response to cancer immunotherapy; better understanding the properties of assessment scales used in autism studies (resulting in a change of approach for new studies); enabling clinical and biomarker related questions in a broad breast cancer population, including relationship between certain gene expressions and disease prognosis, thereby informing better designed future studies; identifying groups of super or non-responders.

## Data privacy laws and clinical trials

So how do data privacy laws impact our ability to re-use data to answer new scientific questions? "Data privacy" (US) or "data protection" laws (EU) cover the fair and proper use of data about people ("personal data" under the EU general Data Protection Regulation or GDPR). Numerous other counties have their own laws, which may diverge from one another and today there are 100+ country specific data privacy laws. So for a late-stage clinical trial conducted in countries across the globe, this can make a clear assessment of privacy guardrails very challenging.

A pragmatic approach would be to focus on the GDPR as a good starting point. This is true,

even with Brexit since the EU currently recognises the "adequacy" of UK privacy laws, which align with GDPR, at least in the short-term. Under GDPR, clinical trial data is considered as "personal data" and "pseudonymised" (i.e., labelled with a pseudonym). All processing of personal data under GDPR comes with a whole host of obligations on the company, institution or other body including a "legal basis". In 2019, the EDPB (European Data Protection Board) issued guidance to clarify this for the clinical trials context. It split activities into "primary use" (and further into "reliability and safety purposes" and "research activities") and "secondary use". Options for secondary use included analyses deemed "compatible" to the original trial objective, for scientific research purposes and anonymising data.

## Data anonymisation

A challenge of anonymisation in the context of global clinical trials are varying data privacy laws and definitions across different jurisdictions. There is no single definition of anonymisation or de-identification (or even terminology). Once data are anonymised, they fall out of the scope of the GDPR (i.e., they are no longer personal data). However, whilst the GDPR does provide a brief definition of anonymisation ("with all means reasonably likely to be used, data subjects are no longer identifiable"), in practice it is challenging to interpret what this actually means. The GDPR definition lends itself to a more "context-driven" approach. That is, considering the overall context and risks of the data sharing scenario as well as the identifiers present within the data.

However, there are now numerous pragmatic frameworks and materials available to work through anonymisation approaches, some developed by industry organisations such as EFSPI/ PSI, PHUSE, TransCelerate, guidance as part of more formal routes such as EMA policy 0070, Health Canada PRCI (Public Release of Clinical Information) and publications such as the recently updated UKAN ADF (UK Anonymisation Network – Anonymisation Decision-making Framework) and those by Prof. Khaled El Emam. For example, the EFSPI/PSI Data Transparency Special Interest Group (SIG) aims to publish this year on "Anonymising Clinical Data for Secondary Use" and both Transcelerate and PHUSE are working on common definitions

> Statisticians have a deep understanding of the context, trial design and risks associated with a particular trial or molecule and knowledge of the nuances of the data itself.

including anonymisation. There is also hope that the EFPIA GDPR Code of Conduct on Scientific Research will provide some harmonised industry definition when published later in 2021.

Aside from a choice between personal or anonymised data, a third option to consider is generation of synthetic data. Synthetic data are initially generated from actual personal data but ultimately they do not relate to individuals. However, they retain the same statistical properties of the original data, making them a valuable low-privacy risk alternative for certain secondary use purposes.

## Putting it all together: Balancing the demands in an evolving landscape

We have covered the bigger picture of data sharing in the pharma industry as some examples of internal data re-use programmes. We also focused on considerations related to data privacy and anonymisation of data. Aside from these, there are numerous other considerations to take into account when building an internal re-use strategy. Ideally, it should be framed within a comprehensive data and information governance strategy and related policies. Some considerations are outlined in Box 1. For example, it is important to consider the flow of data across the entire lifecycle of a clinical trial and when and how in that lifecycle can data be made more broadly available for secondary use (beyond the original objectives of the trial). Development of such a strategy needs to take a truly cross-functional approach to enable detailed evaluation of opportunities and risks.

What can statisticians do to contribute to this discussion? Statisticians are strongly positioned to take a lead in these discussions, both in identifying where secondary use of data may be beneficial within drug development programmes and in ensuring data is collected in a way that will facilitate future data sharing. Statisticians have a deep understanding of the context, trial design and risks associated with a particular trial or molecule and knowledge of the nuances of the data itself. All of these elements are important to inform when data can be made available for secondary use and also in providing this knowledge in the form of associated metadata for the downstream data user.

To conclude, we have seen that external data sharing and collaboration involving the pharmaceutical industry has seen a huge increase in the last 6–7 years via platforms such as CSDR (ClincalStudyDataRequest.com) /Vivli, TransCelerate, and others. The COVID-19 pandemic saw a massive influx in discussions

*Box 1: Considerations when developing an internal data re-use strategy*

### Use original (personal) data

- The purpose of the re-use is a key consideration
- Definitions – primary and secondary use, wider regulatory activities, compatible use, scientific research
- Role of ICF and its language regarding data re-use
- GDPR legal basis for data processing
- Ability to respond to Subject Access Request
- Dealing with patient consent withdrawals
- How to match planned re-use purpose vs. original protocol objectives and ICF language
- Decision-making

### Use anonymised/synthetic data

- How to define anonymisation in an internal context
- Definition of acceptable risk threshold
- Automation via application of standard rulesets to data
- Balancing privacy vs. utility
- How to define "TOMs" (technical and organisational measures)
- Complexity across modalities, 'linkability'
- Limits on what anon data can be used for (scientific research)
- Processes and assumptions for generation of synthetic data

### Other considerations as part of a data governance strategy

- Develop "secondary use" data privacy strategy – philosophy, principles, definitions, ethical considerations, flow diagram, decision-making etc.
- Making data "FAIR"
- Dealing with global studies with patients across multiple countries, implications of different privacy laws
- Defining good data science practices – planning and reporting, reproducibility etc.
- Defining appropriate internal data access rules
- Data flow across study lifecycle, privacy by design
- Systems, processes, infrastructure
- Aspects such as reporting/regulatory status e.g., business sensitivity, use of data pre-database lock; safety signal reporting; restrictions due to co-developments, divestments etc.
- Other laws and regulations e.g., cybersecurity, use of samples, country specific laws, e.g., China "HGRAC"
- Data citizenship and culture, codes of conduct
- Staff awareness, training, knowledge
- Adapting to changes to external guidance

Abbreviations: FAIR, Findable, Accessible, Interoperable, and Reproducible; GDPR, General Data Protection Regulation; I CF, International Classification of Functioning, Disability and Health;
HGRAC, Human Genetic Resources Administration of China

across industry on expedited data sharing and dedicated platforms such as Covid19 Data Platform as well as organisations like Vivli and Transcelerate committed platforms to facilitate this. We can learn a lot from the pandemic situation and see how the open and collaborative approach can be applied more generally. It is fair to say many companies have been turning their attention to data as a valuable asset within their own companies and developing internal secondary use policies and programmes. Such a strategy requires a broad cross-functional approach with numerous "dimensions" to be

considered and stakeholders to be included. Such programmes are complex and will develop over many years. Companies need to start thinking about such topics sooner rather than later.

The PSI/EFSPI SIG for Data Transparency considers many of the topics covered in this article: external and internal data sharing and re-use, data anonymisation/data privacy in the context of clinical trial data use. If you are interested in finding out more and contributing to the SIG, *please visit the PSI Data Transparency SIG website,* also for some links to the references in this article.

# Good Writing Practice

## Grammatical misagreement in tense

### II – Present Participle, Progressive Verb

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## Introduction

In this regular feature, the misagreement in tense is extended from present and present perfect tense (discussed in the previous edition of MEW) to an analysis of the frequently used present participle (of the participial phrase) and the infrequently used progressive verb (of the progressive phrase), each of which contains an *ing* syntactic unit.

The present participle component of the participial phrase functions primarily adjectivally but as a verbal retains verb-like qualities such as tense. The present progressive verb phrase is infrequently (if at all) used in research writing, possibly because of its informal narrative pattern (characterised by agent- and action-focused sentence constituents).

The following examples are analysed according to (1) the context of a conceptual component in a journal article section, (2) the type of syntactic unit (participle, progressive verb), and (3) the type of misagreement (time, certainty).

## Experimental section

### Part 1 – Results section: results statement and preliminary interpretation

*Example: Present tense – misagreement in certainty*

*The band shifts and the new bands were consistent with the predicted bands, <u>indicating</u> that the plasmid pIV4Sm integrated into the chromosome at ure C.*

#### Revision 1

*The band shifts and the new bands were consistent with the predicted bands, **a consistence which indicated** that the plasmid pIV4Sm integrated into the chromosome at ure C.*

#### Revision 2

*The band shifts and the new bands were consistent with the predicted bands, **which indicated** that the plasmid pIV4Sm integrated into the chromosome at ure C.*

## Notes

In the Example, the tense of the present participle *indicating* denotes a timeless truth rather than a circumspect preliminary interpretation.

A preliminary interpretation denotes information one conceptual level above a result statement. To a traditionalist, the preliminary interpretation may seem to belong in the Discussion section; however, an even higher level of conceptualisation, such as inference (including the Conclusion and Consequence) do belong in the Discussion section. Therefore, the more depth of the Discussion section, the more appropriate placement of a preliminary interpretation in the Results section.

In Revision 1, the usage of the past tense (as a past participle) is circumspect, befitting the care with which research was performed and interpreted. To write the past participle *indicated*, a *which* is required, inexplicitly modifying more than one of the constituents or even the whole sentence. This *which* (often termed the 'vague' *which*) ostensibly justifies usage of the antecedent marker *consistence* that identifies the inexplicit antecedent (Revision 1) being modified.

Usage of the antecedent marker *consistence* may seem as a hypercorrection and redundant, so despite its vagueness an adjective clause with the inexplicit marker *which* may be the preferred option (Revision 2).

## Contextual sections

### Part 1 – Introduction section: research objective

*Example: Present participle – misagreement in time*

*Unlike the previous study <u>focusing</u> on plasma alone, in the present study the function of the erythrocyte as well as plasma was tested.*

#### Revision

*Unlike the previous study **focused** on plasma alone, in the present study the function of the erythrocyte as well as plasma was tested.*

## Notes

The present time of the present participle *focusing* is inconsistent with the past focus of the other sentence constituents (sentence orientation *previous study* and the sentence verb *were tested*). In the Revision, transformation into the past participle *focused* avoids the tense misagreement. Both the present and past participle adjectivally modify the noun *study*.

Another distraction of ***study focusing on*** is personification of an inanimate subject, which is less so in the past tense as ***study focused on***.

### Part 2 – Introduction section: research problem pertinent background and research problem

*Example: Active progressive verb – misagreement in time*

*Although many researchers are <u>looking</u> for cementum-specific markers (that differentiate cementum from bone), their existence is still uncertain.*

#### Revision

*Despite wide-spread interest, existence is still uncertain of cementum-specific markers that differentiate cementum from bone.*

## Notes

The progressive verb is just too narratively current. The narrative is a result of an ongoing present action of *are*, the agent *researchers*, and the narrative informal verb *looking*. In the Revision, the progressive tense is de-narrativised by replacement of the adverbial dependent clause (*although many researchers are looking*) with the tense-less prepositional phrase (*despite the wide-spread interest in cementum-specific markers*).

## Part 3 – Discussion section: research consequence

*Example: Passive progressive verb – misagreement in time*

*The present study may also be contributing to understanding magma transport mechanisms at mid-ocean ridges.*

**Revision**

*The present study may also **contribute** to understanding magma transport mechanisms at mid-ocean ridges.*

## Notes

The progressive verb, even in the passive voice *be*

*contributing*, indicating a present on-going action, is in misagreement to a consequence of past research. In the revision, the present tense *may also contribute* conveys a time-independent consequence in the present and even future time.

## Summary

**Rhetorical consequence:** The frequent usage of a present participle to denote a preliminary interpretation in the Results section connotes a

timeless truth – a certainty characteristic of a non-professional tone, as is the highly informal narrative progressive tense.

**Revision options:** Transformation of the present to past participle minimises the certainty in a preliminary interpretation. For replacement of the narrativism of the progressive tense, there are tenseless syntactic alternatives or the present tense.

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## Schematised misagreement in tense – distractions and preferred revisions

### Present Participle Misagreement

#### Introduction: research objective
**Transformation:**

**present → past participle**

*Unlike the previous study focusing on plasma alone, in the present study the function of the erythrocyte as well as plasma was tested.*

→ *Unlike the previous study **focused** on plasma alone, in the present study the function of the erythrocyte as well as plasma was tested.*

#### Results: results statement and preliminary interpretation
**Replacement:**

**present participle → past tense adjective clause**

*The band shifts and the new bands were consistent with the predicted bands, indicating that the*

plasmid pIV4Sm integrated into the chromosome at ure C.

→ *The band shifts and the new bands were consistent with the predicted bands, **which indicated** that the plasmid pIV4Sm integrated into the chromosome at ure C.*

### Progressive Verb Misagreement

#### Introduction: research problem pertinent background and research problem
**Replacement:**

**adverb clause → tenseless prepositional phrase**

*Although many researchers are looking for cementum-specific markers (that differentiate cementum from bone), their existence is still uncertain.*

→ ***Despite wide-spread interest, the existence is still uncertain of cementum-specific markers** that differentiate cementum from bone.*

### Discussion: research consequence
**Transformation:**

**progressive verb phrase → present tense finite verb**

*The present study may also be contributing to understanding magma transport mechanisms at mid-ocean ridges.*

→ *The present study may also **contribute** to understanding magma transport mechanisms at mid-ocean ridges.*

# Digital Communication

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## Digital communication – bringing us closer

Digital or online communication is second nature to us all – with more than half of the global population active on the internet, a world without it seems unimaginable. In recent years, digital communication has increased in popularity for, among other things, the efficiency and convenience it lends to personal as well as business undertakings. In 2020, we relied on digital communication even more, with activities like virtual conferences, video meetings, and even telehealth becoming the norm. Furthermore, digital communication tools have proved useful in facilitating collaborative authoring and learning, particularly in remote work situations. Growing use of the internet and our swift adaptation to using digital communication tools show great potential for further development in online communication and distance working moving forward. In fact, a *Forbes* article estimated that 70% of the workforce will be working remotely at least five days per month by 2025.[1] In this section, you can expect to read more about digital communication in general, as well as relevant tools and applications in medical communication and healthcare.
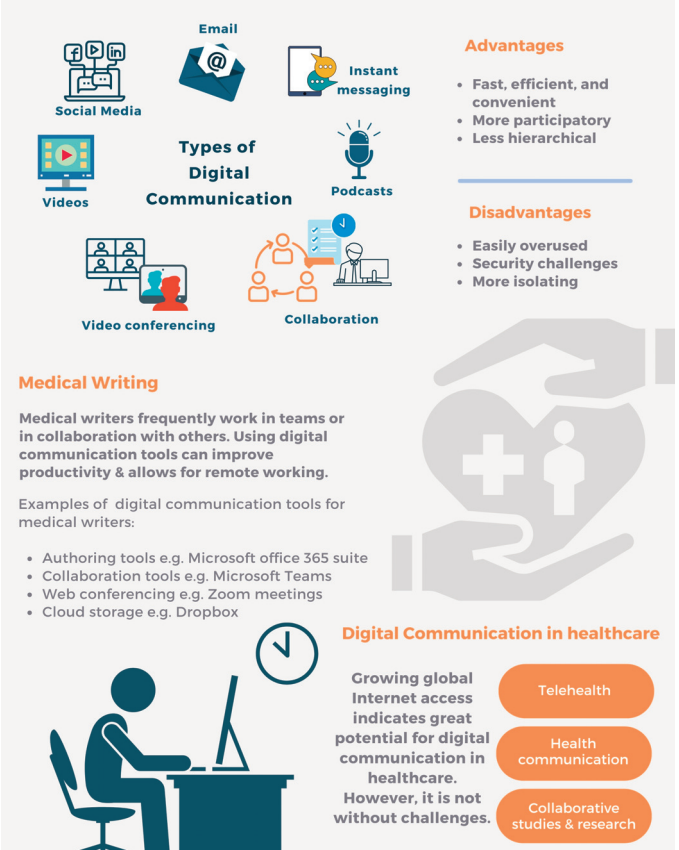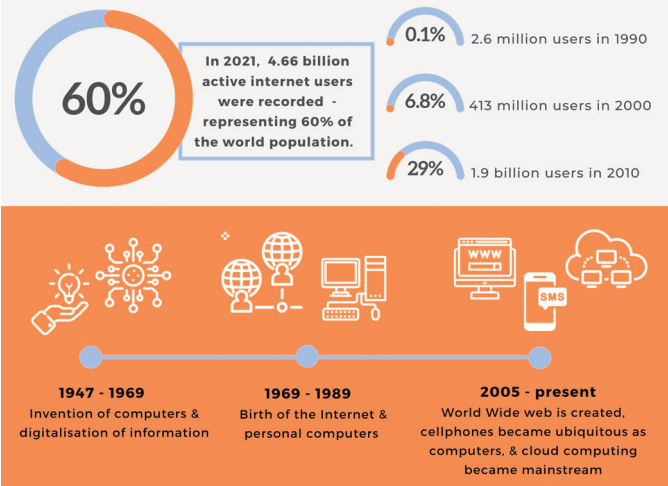
To launch this new Digital Communication section of *Medical Writing*, we illustrate an overview of the evolution of digital communication, the most commonly used tools, and some of their applications (Figure 1).

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*Figure 1. A snapshot of digital communication*
Global active internet users over the last four decades:
1990 – 2.6 million users per 5.28 billion people globally (0.05%)[2,3]
2000 – 412.8 million users per 6.114 billion people globally (6.8%)[2,3]
2010 – 1.992 billion users per 6.922 billion people globally (28.8%)[2,3]
2020 – 4.66 billion users per 7.9 billion people globally (60%)[4,5]

# Collaborative authoring – an interactive and dynamic opportunity for acceleration



Cloud-based content collaboration platforms, including Microsoft's Office 365 suite as the most widespread solution, have become standard in the industry. The main characteristics of this type of platform include collaboration workspaces, simple workflow capabilities, and more granular security features that enable team-restricted access to the workspace and documents. The cloud-based location of these authoring suites and collaboration tools enable new ways of working, and its potential is increasingly recognised and utilised. The conventional sequential way of document development, with distinct cycles of authoring, review, and revision, is evolving towards a collaborative, highly inter-active, and dynamic development process. This approach is more efficient and allows expedited execution. In this way, document development timelines can be met that are hardly feasible if based on solitary authorship.

## The collaborative approach

Using Office 365 as an example, the interplay of MS OneDrive, MS Teams, and SharePoint (all of which are bundled within the Office 365 Suite), allows remote collaborative authoring to be con-ducted in a sequential, parallel, or simultaneous manner. Authors, other stakeholders, and reviewers may work on separate sections or on a single section of the document under preparation. A sequential collaborative approach

is applied, for example, when document development follows-the-sun, i.e., if the writing is done across distinct time-zones. Most often, collaborative authoring proceeds in a parallel-working fashion where a team of writers, coordinated by a lead author, works on separate sections of the document or fulfils distinct individual tasks – a kind of coordinated piecing-together of a puzzle – by multiple players. The collaborating authoring team can be permanently or transiently expanded to allow contributions, reviews, and revisions by subject matter experts (SMEs), experts performing quality control (QC), the client team, or the business partner. The exact touchpoints or collaborative phases can be handled flexibly as mutually agreed upon and adapted at any time during the development process. As for the clarification of very specific questions, a synchronised approach is recommended where the collaboration occurs during a conference call with the work-in-progress document shared online.

Employing these collaborative authoring tools allows the authoring or document development to become agile and responsive during the writing process, rather than only at distinct stages, where there is a "handover" between authors, other SMEs, or the external business partner (e.g., the client's expert team) via a predefined schedule.

## The collaborative options

**OneDrive** utilises an individualised workspace and can be seen as a personal filing repository. A single SharePoint page is enabled for the document owner and document provision is based on a *SharePoint Document Library.*[1] Access control at the document level is managed by the document owner. OneDrive is optimally used for limited internal collaborative tasks, like the management of QCs by multiple quality reviewers or as a review tool for alignment among a smaller group of stakeholders.

**MS Teams** has proved to be a very powerful tool to accommodate all needs of an internal team of authors (medical writers), functional experts, and SMEs to drive collaborative document development efficiently and, if needed, in an accelerated fashion. Access control is at the team level and the document also resides within a *SharePoint Document Library* embedded in the team's SharePoint page. Similar to OneDrive, versioning is enabled and the central filing repository allows all information and source documents to be available within the team's SharePoint area. As a unified communication platform and in contrast to OneDrive, MS Teams allows communication by various means within the designated team space. Instant messaging can be restricted to team members, and when combined with task management, significantly promotes communication, interaction, and

alignment between all team members. Conveniently, the complete chat history is automatically stored and centrally shared with all team members. However, careful consideration should be given regarding whether to include external partners and clients in the team, because not all communication within the internal team might be appropriate for public sharing, e.g., internal alignment activities or certain decision-making.

**SharePoint** is also intended to be used by internal teams in addition to a wider audience. While the specific support capabilities for efficient team interactions are not as advanced as in MS Teams, as it is not designed for unified team communication, it allows stringent and secure access control of the central filing repository. Access is usually granted at the SharePoint page or folder level by a non-team member, such as an administrator who follows corporate security rules. Therefore, SharePoint is better for focused and controlled usage of the collaboration tools and is preferentially used when external stakeholders need to participate, e.g., clients or business partners, for collaborative editing or review of the document. These features of SharePoint are also integrated into the **Veeva Vault (VV) platform**, which combines effective and auditable document management with collaborative authoring, review, and approval capabilities. A document in progress is checked out from VV and a specific VV workflow is set up for edit/review collaboration using a specific VV workflow with a *SharePoint Shared Document Library*. The workflow allows edit permissions to be granted to internal as well as external users (e.g., the client team) via sharing settings.

All the above collaborative options support a browser-based and work with the desktop Word application respectively. The latter supports an expanded set of features and functionality and is therefore the preferred option for many collaborative authoring teams. This is relevant for using the comments and track-changes functionalities. Furthermore, if multiple authors work simultaneously in one document, it is important to see the others' changes, which happens dynamically if the auto-save functionality is on. Although this collaborative functionality enables provision of review comments and edits in a consolidated manner, there are other specifically designed collaborative review tools, like *PleaseReview*, which offer enhanced control over the entire review workflow and advanced clarity regarding review comments.

## Planning, strategy, and rules

This new way of writing requires adaption at various levels – it affects resource management (>1 medical writer (MW) needs to be assigned) and requires both a conceptual framework defining how a team should work (e.g., an upfront agreement on rules and on best-practice prior to start) and a defined project-specific strategy for collaborative authoring depending on the document type or the project state. For example, if a team develops a clinical study protocol, it is relevant whether the process starts from a comprehensive synopsis, which defines the study design fully, or from a study outline where some decisions about essential study design elements are still pending when the protocol authoring work starts. In the latter case, collaboration of and decision making by functional experts takes place in parallel to authoring of the protocol. This scenario is initially more demanding in terms of the necessary alignment of all internal and external stakeholders, and the ambiguities that accompany the initial authoring phase.

The intensity of a collaborative authoring process can be significantly higher compared to the conventional sequential preparation of a document. Multilateral communication, a pronounced need for ongoing communication and adjustment across all team members are requirements that play less of a role in solitary authoring. Therefore, an enhanced commitment by all team members is necessary to ensure that reviews, comment provisions, and responses are coordinated in time.

Medical writing management also needs to promote this different setting and line-up for successful collaborative authoring, by training and cultivating an appropriate mind-set among the team of medical writers. Some writers, especially among those who are very experienced, have reached this level by focusing on details and being able to control every aspect of the authoring process and content. However, successful collaboration requires teamwork that is based on trust in the competency of co-authors and the ability to delegate tasks.

From a learning perspective, the collaborative authoring approach also allows delegation of less critical tasks to writers who benefit from the experience of a senior writer who leads the

> Successful collaboration requires teamwork that is based on trust in the competency of co-authors and the ability to delegate tasks.

authoring team and coordinates the individual activities. In fact, depending on the document type (e.g., a clinical study protocol or a clinical study report), certain sections in these documents are less dependent on other sections and content can be broken down into separate entities. For example, the *Introduction* (rationale, background, benefit/risk assessment, etc.) can be written relatively independently from the remainder of a protocol. The three main clinical study report result sections: *Study Participants* (Disposition, Demographic/Baseline Characteristics, etc.), *Efficacy,* and *Safety* also lend themselves to division of labour. However, regardless of the respective collaboration strategy, it is crucial that one author leads the team through the document development process, to ensure consistency of content and messaging. The demands on the team leader in terms of administrative tasks and project management are higher than when with a single authorship project. Here it is the lead author who ensures that there is a common understanding of the content and the general objective(s) by the authoring team. When used effectively, the collaborative authoring process ensures there is a continuous parallel peer review of content by the other writers or SMEs involved.

## Opportunities

For scenarios under constricted timelines, collaborative authoring might be the only way to meet aggressive deadlines. Under such circumstances, it is not only the team of authors and internal experts who need to adapt to this highly interactive approach. Rapid decision making, last-minute calls for resolution of conflicting perspectives, and quick resolution of queries require increased availability and flexibility from an external client or stakeholder team too. Their corresponding expectations and involvement are often dictated by specific situational business needs or exceptional circumstances (see *Case Study* below).

As business partners might become more closely involved in the drafting of a document, e.g., in that the work-in-progress document is more or less continuously accessible to them and edits and comments can be provided any time along the process, the classical sequential approach for document development (Figure 1A) may take a back seat. This might apply in particular to cases where there is an overlap between client expert contributors working directly in the document and the client reviewers. Conventionally, the writing approach is characterised by distinct pre-defined touchpoints that dictate a sequence of drafting, QC, client review, and

comment incorporation. In a collaborative process (Figure 1B), these touchpoints shift in favour of a process of reacting and responding (i.e., continuous review and revision). As a result, QC activities might shift towards an agreed time point shortly before finalisation of the document, with a more holistic focus. In fact, some business partners may welcome this option as they prefer to follow the developing status at any time rather than waiting for the traditional defined deliverable.

## Case study – protocol development

With the advent of the COVID-19 pandemic, an immediate need for therapeutic measures became prevalent and respective clinical trials demanded accelerated start-up. Thus, the development and finalisation of respective protocols were expedited. The first COVID-19 protocol, prepared by Medical Writing Services, was finalised within approximately 2 weeks, and required a collaborative approach by a team of medical writers with full utilisation of collaborative authoring tools.

In this case, a lead author coordinated a team of three supportive writers. The team agreed upfront on the conceptual framework of their collaboration, with the lead author responsible for task allocation and management; they were also the primary contact for other stakeholders, including the client. Additional lead author responsibilities included version control of the in-progress master document, work-in-progress status updates for the internal team and the client, and authoring the critical study design elements of the protocol.

The collaboration mode of this authoring team entailed:
- Daily alignment on task completion and task allocation
- Parallel peer review of completed sections

Protocol writing commenced while other functional leads (statistics, medical, regulatory, data management) in liaison with the medical writing team worked out essential study design elements that flowed into a robust study synopsis.

The technical aspects of collaborative authoring for this protocol entailed:
- A master work-in-progress document that was maintained in **OneDrive** and was accessible to the medical writing team and quality reviewers for QC.
- At the end of each workday, a copy of the work-in-progress document was updated in the collaborative work space on **MS Teams** and made accessible to all members of the internal team to provide their contributions, review and revise drafted sections, and address queries raised by the Medical Writing team.
- The lead author directed specific tasks or questions to respective internal team members on a daily basis, using the task management functionality of MS Teams.
- Revisions and contributions made by the internal team (functional leads) in the MS Teams version were transferred to the master work-in-progress document in OneDrive.

*Note: external (client) access to a common collaborative workspace at the time of protocol preparation was not yet available, but going forward,* the Collaborative Authoring module within Veeva Vault will allow the team to benefit from the full potency of this approach.

## Final remarks

Although not previously mentioned, all these collaborative authoring activities are available under remote working conditions. While pandemic conditions have driven us to this mode of working, collaborative authoring also underscores the great potential of being able to pull together the contributions of appropriate experts at a global level.

## Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by his employer or EMWA.

## Conflicts of interest

The author declares no conflicts of interest.

## References

1. A *SharePoint Document Library* is a "place" to store, organise, and control files of various formats (e.g., Word-, Excel-, PowerPoint, Outlook-files, pictures, etc.). This "place" is an element (a library app) included in and associated with the distinct SharePoint page.
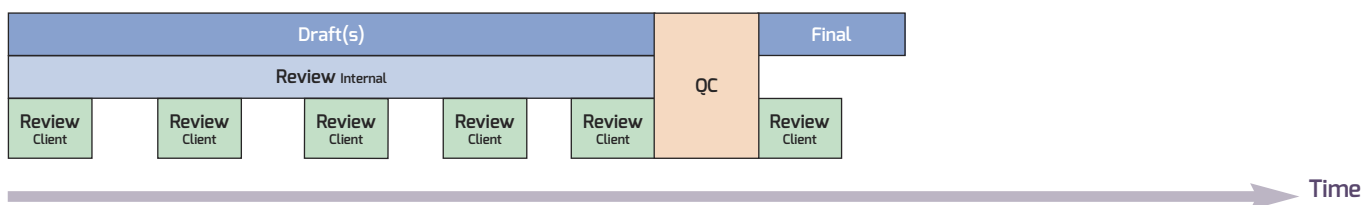
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### A. Sequential approach



### B. Collaborative approach



**Figure 1. Document development models**
The sequential approach (A) requires some interaction between stakeholders but is characterised by phases where the work-in-progress document is primarily allocated to a certain party, while the others are excluded. Communication and decision-making proceeds preferentially in a staggered fashion, although common touchpoints (e.g., comment resolution meetings) are interspersed as needed. Central to the collaborative approach (B), the work-in-progress document is almost continuously accessible by all stakeholders, who are all engaged throughout the development of the document. The team works in a highly dynamic, interactive, and reactive mode leading to joint development.

# The Crofter:
# Sustainable Communications

## SECTION EDITORS

**The EMWA Sustainability Special Interest Group**

**Kimi Uegaki**
kimi@iwrite.nu

**Greetings from the croft!**

I think it's a neat coincidence that I have the pleasure to write my first editorial to this edition of The Crofter in the *Medical Writing* special issue on mentorship. I don't have an official mentor but ever since I became a member of EMWA in 2019, I feel like I have been mentored in some way, organically, by each member I've met. In particular, my professional development has blossomed since joining the Sustainability Special Interest Group (SUS-SIG) in 2020. Now in 2021,

I am thankful to be part of such an enthusiastic SIG that supports my efforts to learn more about sustainability in research, healthcare, and our medical writing profession. Thanks to Raquel Billiones and Carola Krause's support and encouragement, here I am as The Crofter's section editor.

Here in The Crofter, we aim to share regular articles to help support your interest in learning more about sustainability. In this issue, Carola Krause and I introduce the EU Green Deal, its impact on the healthcare industry, and what

it means to us as medical writers and communicators. I learned a lot from writing this article, and I hope you do, too.

*Kimi Uegaki*

## Impact of the European Green Deal on the healthcare industry



The EU aims to become climate neutral by 2050

### The European Green Deal: A road map to sustainability

The European Green Deal (hereafter referred to as the EU Green Deal) is a road map towards sustainable development. It aims to guide the EU policymakers as they journey through the policy-making process and ensure all policy initiatives steer the EU towards the efficient use of resources and a clean, circular economy.

The EU Green Deal was adopted on December 11, 2019. This marked the moment that climate change and environmental issues

moved from the fringes into the heart of policy-making within the EU. The EU Green Deal aligns with the EU's commitment to the Paris Agreement (adopted in 2015)[1] and the UN's 17 sustainable development goals, which are at the heart of the UN's 2030 Agenda for Sustainable Development (adopted in 2015).[2,3]

*The EU Green Deal will form the basis for all policies in the healthcare, pharmaceutical and medical technology sectors*

Moving forward, the EU Green Deal will drive changes to EU laws in all economic sectors, including the health care industry, so that the EU can achieve the following goals:

- to become climate neutral (i.e., no net emissions of greenhouse gases) by 2050;
- to invest in economic growth that is decoupled

from resource use (think resource-efficient and circular economy);
- to ensure no person or place is left behind (think fair and prosperous society);
- to protect, conserve and enhance the EU's natural capital; and
- to protect the health and well-being of its citizens from environmental risks (think air, water, and chemical pollution).[4]

The changes will be driven through transformative policies and enabling pillars (Figure 1). The eight policy areas cover the following aspects:
- becoming climate neutral;
- supplying clean, affordable and secure energy;
- mobilising industries for a clean, circular economy;
- building and renovating in an energy- and resource-efficient way;
- striving for zero-pollution and a toxic-free environment;

- preserving and restoring ecosystems and biodiversity;
- implementing a farm-to-fork (F2F) strategy; and
- accelerating the shift to sustainable and smart mobility.[4]

Actualising the transformative policies will be made possible through enabling pillars such as:
- dedicated investments and financial tools to ensure that the transition is fair and inclusive across all member states;
- a commitment to mobilising research and innovation;
- a commitment to building capacity for the transition by engaging active public participation through education and training; and
- a commitment to establishing a new pact for accountability between all citizens, national/regional/local authorities, civil society, industry, and the EU's institutions and consultative bodies.[4]

This article aims to discuss what the EU Green Deal means for the healthcare, pharmaceutical and medical technology sectors, and reflect on the impact of the EU Green Deal on the medical writing and communications profession.

## What does the EU Green Deal mean for the healthcare industry?

Human health relies on the protection of communities and their environments. Within the EU Green Deal, the global healthcare principle of "do no harm" is imperative. Through new policies and regulations, the EU Green Deal paves the way for a sustainable healthcare industry. Figure 2 presents an overview of the EU Green Deal goals and their impact on selected healthcare industry segments. In the following sections, we provide a high-level overview of strategies that focus on the following:



**EU Green Deal**

Climate neutral by 2050

Clean, affordable and secure energy

Zero pollution ambition for toxic-free environment

Clean and circular energy

Transformative Policy Areas

Preserving and restoring ecosystems and biodiversity

Building and renovating in a resource efficient way

Sustainable and smart mobility

Farm-to-fork strategy

**Pillars**

| **Accountability** | **Education** | **Research** | **Finances** | |
|---|---|---|---|---|
| A green oath "do no harm" & accountability | Activating education & training | Mobilising research & innovation | Green finance & investment | Greening national budgets & right price signals |

*Figure 1. The transformative policy areas and enabling pillars that comprise the EU Green Deal.*

# EU Green Deal Goals and The Healthcare Industry



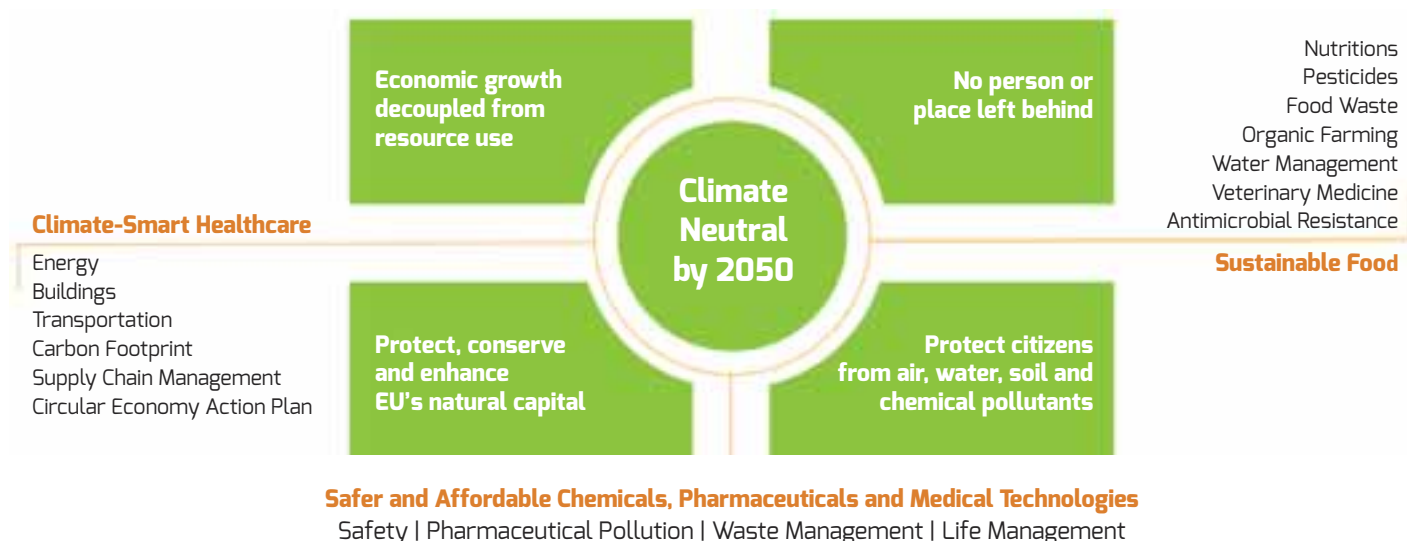**EU Green Deal Goals and**
**The Healthcare Industry**

Economic growth decoupled from resource use

No person or place left behind

**Climate Neutral by 2050**

**Climate-Smart Healthcare**
Energy
Buildings
Transportation
Carbon Footprint
Supply Chain Management
Circular Economy Action Plan

Nutritions
Pesticides
Food Waste
Organic Farming
Water Management
Veterinary Medicine
Antimicrobial Resistance

**Sustainable Food**

Protect, conserve and enhance EU's natural capital

Protect citizens from air, water, soil and chemical pollutants

**Safer and Affordable Chemicals, Pharmaceuticals and Medical Technologies**
Safety | Pharmaceutical Pollution | Waste Management | Life Management

*Figure 2. Overview of the EU Green Deal goals and their impact on selected healthcare industry segments*

- Replacing harmful chemicals with safer and greener alternatives.
- Managing healthcare waste sustainably.
- Addressing pollution caused by the pharmaceutical industry and the development of green medicines.
- Transitioning to climate-smart healthcare.
- Enabling sustainable food practices.

## Replacing harmful chemicals with safer alternatives

A substantial amount of chemicals, including those with well-documented adverse effects on health and the environment, are still used by the healthcare sector. Solutions that address the additive effects of different chemicals, nonbiodegradable chemicals, endocrine disruptors, and hazardous chemicals in all consumer products are acutely needed.[5] Therefore, the EU Green Deal includes plans to produce a Chemical Strategy for Sustainability. This strategy will be one of the steps toward a toxic-free environment and also contribute to the forthcoming Zero Pollution Action Plan (adopted by the EU in 2021).[6]

## Managing health care waste sustainably

With its toxic and infectious properties, healthcare waste is an overlooked environmental and public health threat. Hospitals generate an estimated 5 million tons of waste each year,

*The universal healthcare principle of 'do no harm' is at the core of the EU Green Deal.*

which translates to 13.2 kg of waste per bed per year.[7] The WHO and nongovernmental organisations such as Health Care Without Harm and Practice Green Health aim to transform healthcare worldwide so that the healthcare industry reduces its environmental footprint and becomes an anchor for sustainability.[8–10] Thanks to these organisations' efforts, healthcare waste management became one of the focus points within the EU Green Deal.

Under the EU Waste Framework Directive (Directive 2008/98/EC), a resource-efficient and circular economy will be promoted and an order of preference for waste management called the "waste hierarchy" will be introduced.[11] The waste hierarchy, which is based on the 3R's of reduce, reuse, recycle, categorises healthcare waste in four major types:

- general medical waste;
- infectious medical waste;
- hazardous medical waste; and
- radioactive medical waste.

Thereby, the EU Green Deal bases its approach to healthcare waste management on the WHO release guideline, "Safe management of wastes from healthcare activities".[12]

## Addressing pharmaceutical pollution and the development of green medicines

It is well recognised that pharmaceuticals, as a unique form of healthcare waste, are released into the environment with implications for human health, including antimicrobial resistance.[13] Globally, more than 600 active pharmaceutical substances (or their metabolites and transformation products), mainly antibiotics, analgesics, lipid-lowering drugs, beta-blockers, x-ray contrast media, and synthetic estrogens, have been detected in the environment in all sorts of environmental matrices.[14]

With the growing demand for pharmaceuticals around the world, the pharmaceutical industry's impact on the environment will be amplified.[13] With that in mind and in line with the EU Green Deal, the EU launched the Pharmaceutical Strategy in 2020, which aims to support innovation, competitiveness, and sustainability of the EU pharmaceutical industry. A core focus is to accelerate the development of safe, effective, and affordable "greener" medicines and medical technologies.[15] Thereby, the terminology "green" implies that the life cycles of medicines and medical technologies become relevant. The industry will be requested to evaluate, document, and report the environmental impact of a medicine or a medical technology on humans and animals. Thereby, the environmental impact, for instance, becomes a justification parameter for Biosimilar Market Authorisation Applications. Once approved, the pharmaceutical industry will be held accountable for the entire life cycle management of a medicine or medical technology.

**Transitioning to climate-smart healthcare**

That the climate crisis negatively impacts health is public knowledge; however, little is known about the healthcare sector's contribution to climate change. The healthcare sector contributes 4.7% of the total EU $CO_2$ emissions,[16] which putatively hinders achieving the EU's 2050 net-zero emission target documented in Europe's first legally binding Climate Law proposal.[17] Several initiatives such as the European Health Care Climate Council (EHCC) and Health Care Climate Challenge (HCCC) report that healthcare providers across Europe have committed to decarbonisation actions, green constructions (e.g., the use of antimicrobial wall coatings; overcrowding preventions; anti-viral ventilation systems), purchasing from circular economies, reducing hospital water consumption, using clean energy, and improving sustainable mobility options for patients and staff.[13,18] In the future, green healthcare systems will contribute to the health benefits of patients, workers, and visitors within healthcare facilities and outside them by promoting green construction and operation.[13]

**Enabling sustainable food practices**

The EU Green Deal informed the EC's Farm to Fork (F2F) Strategy to balance the impact of fair, healthy and environment-friendly food systems and farming. The F2F Strategy aims to achieve:

- a 50% reduction in the use and risk of chemical and hazardous pesticides;
- at least a 50% reduction in nutrient losses while ensuring that soil fertility is not decreased;
- at least a 20% reduction of fertiliser use;
- a 50% reduction in the sale of antimicrobials for use in farmed animals and aquaculture; and
- that 25% of total farmland is used for organic plant and animal farming by 2030.[19]

According to Health Care Without Harm, the healthcare sector, including many hospitals in Europe, have already transitioned to sustainable food systems. However, finding the balance between sustainable food systems and the ever-increasing climate crisis, with challenges such as water shortages, land and energy restrictions, and environmental pollution, is difficult.[20] Therefore, the EU aims to take the following steps to overcome these hurdles:

- Restructuring food environments so that consumers can make healthy and sustainable choices easily;
- Adding food labels so that consumers can choose healthy and sustainable foods;
- Stepping up the fight against food waste by cutting food waste by half;
- Promoting research and innovation;
- Improving animal welfare to improve animal health, which reduces the need for medication and preserves biodiversity.

Under the Horizon Europe Programme 2021-2027, the EU has earmarked €10 billion to invest in projects that aim to create innovative and secure ecosystems for plants and animals that make food healthier and greener while ensuring food security.[19–21] Additionally, the EU aims to intertwine the F2F Strategy with other healthcare initiatives such as the Europe Beating Cancer Plan in order to reduce the incidences of noncommunicable diseases through accessible and affordable healthier food.[13,20,22]

## What does the EU Green Deal mean for the medical writing and communications profession?

As the EU Green Deal now forms the basis for all policies in the healthcare, pharmaceutical, and medical technology sectors, the need to address sustainability issues in certain regulatory

documents and grant applications will likely increase and become more explicit. Medical writers and communications specialists will need to stay abreast of new developments and requirements to prepare these documents for their clients adequately.

**Regulatory documents**
Medical writers are involved in preparing EMA marketing authorisation documents such as the Investigator Medicinal Product Dossier (IMPD; Module 3 of the eCTD dossier) and the Environmental Risk Assessment (ERA; Module 1.6 of the eCTD dossier). The IMPD aims to demonstrate the impact of medicinal products on humans. Thereby, data of all required chemicals, formulations, container closure and packaging systems, labelling, and the benefit-risk assessment, are collected in the IMPD (for further information, please join EMWA's DDA28 workshop).

The ERA aims to identify potential adverse effects of medicines on the environment due to use in practice (not manufacturing, transport, or storage) and to develop methods to minimise their release into our ecosystem. Such methods may include proper labelling for correct disposal of the medicinal product by patients, healthcare professionals, and keepers of companion or production animals.

In general, an ERA is conducted using a stepwise approach. In Phase 1, the medicinal product in question is evaluated in terms of its potential for bioaccumulation and persistence in the environment, that is, its so-called environmental exposure. If significant environmental exposure is anticipated or the active compound is associated with specific risks, known as the "however clause", then the evaluation continues to Phase 2. Phase 2 involves determining what happens to the medicinal products when they enter the environments (i.e., their "fate") and the product's potential effect on the organisms living in the ecosystem. If risks are identified, then the evaluation continues to Phase 3 to refine and extend the risk assessment. A negative Phase 3 result can be cause for rejecting authorisation for veterinary medicinal products but not human ones.[23]

Examples of ERA-related resources are listed in Table 1 for reference. With regards to veterinary medical products, new EU regulations will come into effect in January 2022; forthcoming changes for the veterinary ERAs will include a shift from a product-based to substance-based approach, new guidance for aquaculture, and updates to ERA guidelines before 2005.[23]

**Nonregulatory documents**
One of the EU Green Deal enabling pillars is "financing" and with it comes the healthcare industry's obligation to justify any EU-funded research. Of particular interest to the medical communicators is that the justification in EU grant applications needs to address UN Sustainability Development Goals.[24] Last year, the EU ran, for the first time, a call under the Horizon 2020 Framework Programme that invited research-driven small and mid-sized enterprises to submit a grant proposal with a "green" approach towards (medical) research.[21]

In September 2020, the EU announced the launch of a €1 billion call to stimulate the development of innovative solutions that address the climate crisis and help protect the continent's unique ecosystems and biodiversity.[25] Under the Horizon Europe Framework Programme (the follow-up of the Horizon 2020 programme), these Green Deal calls will target research and economic concepts with a focus on long-term changes.[21] Therefore, medical communicators need to be educated on the UN Sustainability Development Goals in order to implement them into their application documents.

Lastly, another aspect that medical writers and communicators need to be aware of is the increasing attention that (inter)national funding agencies are placing on how data from research studies needs to be Findable, Accessible, Interoperable, and Reusable (FAIR).[26] This is aligned with the need to reduce and prevent research waste, such as unnecessary duplication of efforts. FAIR involves the creation of GDPR-compliant data systems in which all (meta)data are machine-readable and where real-time analyses are possible without the movement of (meta)data from their locations. FAIR data principles are advocated by organisations such as EMA and the Heads of Medicines Agencies,[27] EC,[28] and the WHO.[29]

**Sustainability interest groups**
Medical writers and communicators play a

> *The EU announced the launch of a €1 billion call for research and innovation projects that respond to the climate crisis.*

> *Medical writers and communicators play a valuable role in bringing the message of sustainability to others*

*Table 1. Examples of EU and EMA resources related to environmental risk assessments*

| Type of ERA | Resource |
|---|---|
| Human use medicinal products | • Directive 2001/83/EC – Community Code Relating to Medicinal Products for Human Use.[30]<br>• Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use. Doc. Ref. EMEA/CHMP/SWP/4447/00 Rev. 1, 15 November 2018.[31]<br>• Guideline on Environmental Risk Assessments for Medicinal Products Consisting of, or Containing, Genetically Modified Organisms (GMOs). Doc ref. EMEA/CHMP/BWP/473191/2006 – Corr.[32]<br>• Guideline on Scientific Requirements for the Environmental Risk Assessment of Gene Therapy Medicinal Products. Doc. Ref. EMEA/CHMP/GTWP/125491/2006[33] |
| Veterinary medicinal products | • Directive 2001/82/EC – Community Code Relating to Veterinary Medicinal Products[34a]<br>• VICH GL6 Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase I – Step 7. CVMP/VICH/592/98-FINAL[35]<br>• VICH GL38 Environmental Impact Assessment for Veterinary Medical Products Phase II. CVMP/VICH/790/03-FINAL[35]<br>• Assessment of Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent and Very Bioaccumulative (vPvB) Substances in Veterinary Medicinal Product, EMA/CVMP/ERA/52740/2012.[35] |

[a] Directive 2001/82/EC will be repealed when Regulation (EU) 2019/6 comes into effect on January 28, 2022.

valuable role in bringing the message of sustainability to others. Various sustainability interest groups for writers exist around the world, for instance:

- In-house sustainability groups within professional MedComms agencies.
- #GreenMedComms.
- The Environmental Writers Association (also known as turfwriters.org).
- The Society of Environmental Journalists.
- The Sustainability Special Interest Group (SUS-SIG) within EMWA (#EMWASUSSIG).

## Conclusions

The EU Green Deal brings sustainability to the forefront of all economic sectors, including the healthcare industry. Moving forward, medical writers and communicators need to remain abreast of new developments and requirements for regulatory and nonregulatory documents so that they can adequately serve their clients.

Topics introduced in this article, such as environmental risk assessments, will be addressed more deeply in future editions of The Crofter. We also invite EMWA members who are interested in joining a dialogue about the EU Green Deal and its impact on the healthcare industry to join a **SUS-SIG Meet-and-Share Session** that will be scheduled in July 2021.

## Acknowledgements

## Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

## Conflicts of interest

The authors declare no conflicts of interest.

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# Upcoming issues of **Medical Writing**



**September 2021:**

## Medical decision making and health technology assessment

This issue will focus on medical decision-making and will address issues at both the population level (e.g., health policy, resource allocation) and the individual level (e.g., individualised patient treatment decisions, involvement of caregivers). It will give medical writers a broad perspective over current issues and trends in medical decision-making and provide information and practical hints for how to describe decision-making processes and report data for health technology assessment.

Guest Editors: Claire Gudex and Maria Kołtowska-Häggström
**The deadline for feature submissions has passed.**



**December 2021:**

## Medical journalism

We are living at a time when the general public is increasingly interested in scientific and medical advances. Hence, for medical writers, understanding our audiences and how to efficiently reach them is key. This issue will cover those insights.

Guest Editors: Evguenia Alechine and Phil Leventhal
**The deadline for submitting feature articles is September 1, 2021.**



**March 2022:**

## Sustainable communications

Sustainability is a key focus area across all economic sectors, including the pharmaceutical and healthcare industry. This issue will focus on where and how scientific and medical writing can contribute to current debates on scientific and environmental problems and their impact on human health. The issue will also cover emerging career opportunities for medical writers in this area.

Guest Editors: Surayya Taranum and Elisa Sala
**The deadline for submitting feature articles is December 1, 2021.**

### CONTACT US

If you have ideas for themes or would like to discuss any other issues, please write to **mew@emwa.org**.