

Medical Writing



Open Science and Open Pharma

ALSO IN THIS ISSUE...

- Results of the 2021 EMWA salary and compensation survey
- Obtaining meaningful insight from publication metrics

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EUROPEAN MEDICAL WRITERS ASSOCIATION

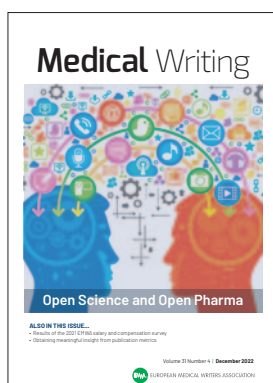


Medical Writing

is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers.

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Medical Writing



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Open Science and Open Pharma

“Medical writers and communicators have a critical role to play in helping to advance open science publication principles and best practices.”

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Open Science and Open Pharma

As well as accelerating scientific progress, open science has the potential to improve confidence in science – and trust in evidence from the pharmaceutical industry. This special issue on open science and Open Pharma brings together perspectives from medical writers, publishers, and scientists, including those with lived experience of the importance of accessibility.

Open science can best be defined as the practice of science across all STEM disciplines such that others can collaborate and contribute, and where research data and processes are freely available, under terms that enable reuse, redistribution, and reproduction. This includes peer-reviewed publications, data repositories, workflow and

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collaboration tools, and science policies and mandates.

Open access publication ensures that the highest quality, peer-reviewed evidence is available to anyone who needs it, anywhere in

the world. This issue focuses on how open access and plain language summaries improve transparency, advance medical science and ultimately improve patient care. Focus will also be given to how Open Pharma, a group of pharmaceutical companies and other research funders – alongside healthcare professionals, regulators, patients, publishers, and other stakeholders in healthcare – are driving towards this goal.

Alison Chisholm summarises the key points from a recent Open Pharma symposium held at the 2022 annual conference of the Association of Learned and Professional Society Publishers. Open access matters to the increasingly diverse range of stakeholders involved in taking new discoveries from the



Open access publication ensures that the highest quality, peer-reviewed evidence is available to anyone who needs it, anywhere in the world.

bench to the bedside. The logical next step is understandability in its broadest sense – ensuring that research findings are published in a way that can be understood as widely as possible.

In our second article, **Shalini Dwivedi** and **Vidhi Vashisht** describe open access initiatives from a range of stakeholders and review the growing importance of plain language summaries (PLSs) in improving the transparency of medical research.

The growing importance of communicating research in widely understandable language is reflected in the development of different document types for different purposes. **Sarah Griffiths** and colleagues review the varied terminology used to describe the three main types of document communicating in accessible language and change to make a case for harmonisation.

Even with immediate open access to research results in understandable language, people with disabilities face unique barriers to information access. The author **Jeffrey Ricker**, who is completely blind, explains how he faces obstacles every day owing, in part, to electronic documents designed primarily for those with vision. He also provides practical tips and resources for medical writers on writing for people with disabilities.

Data sharing is an important principle of open science that has powerful potential to increase trust in published research. For medical research, ethical considerations place important constraints on the sharing of patient data, and **Eniola Awodiya** and **Joana Osório** evaluate how pharmaceutical companies are seeking to strike the right balance between patient privacy and transparency.

Being free to access is of no value if content is not discoverable. The term grey literature is used to describe a wide range of different information that is produced outside traditional publishing and distribution channels. Typically, a lack of indexing or tagging with uniform metadata means that the grey literature is not easily discoverable. In our fifth article, **Toby Green** delivers a call to action to medical writers and communicators to engage with these rich and diverse sources of information.



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For instructions to authors, go to the journal section of EMWA's website (www.journal.emwa.org). All manuscripts should be submitted to mew@emwa.org.

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As medical communicators, we want to know that the research we are communicating has been discovered and used. Digital and social media content are a natural source of information for patients and healthcare professionals alike, but accurate and independently verified measurement of their use and value remains challenging. **Tomas Rees** critically evaluates measures of the impact of publications and how these

can generate insights to inform future publication planning.

As a takeaway message, medical writers and communicators have a critical role to play in helping to advance open science publication principles and best practices. Much progress has been made in the past 10 years, but there is much more to do.

In addition to these theme-related articles, we hope that you will enjoy other content,

including the 2021 salary survey from over 400 EMWA members. We would like to close by thanking all the authors who have contributed articles to this themed issue and the editorial team at *Medical Writing* for making it possible. We hope you enjoy these diverse perspectives on important developments for science, the pharmaceutical industry, and ultimately for the patients we are here to serve.

Author information



Martin Delahunty

Martin is a highly experienced, commercially focused, and innovative senior academic publishing executive, with global expertise gained from working with private and public scientific, technical, and medical publishing companies. He is a former Global Director at Nature Partner Journals, Past Secretary of the International Society for Medical Publication Professionals, and a Fellow of the Royal Society for the Encouragement of Arts, Manufactures, and Commerce. Martin has extensive international expertise working with universities, research organisations, and academic researchers. His core focus is the strategic and business development for open access and open science publishing.



Tanya Stezhka, MRes

Tanya Stezhka spent 7 years as a Commissioning Editor followed by work as a Senior Editor for Taylor & Francis Medical before moving to a Senior Account Manager role at Oxford PharmaGenesis in 2020. Tanya studied Biology at the University of Manchester then completed her MRes in Clinical Science at the University of Liverpool. Tanya's involvement with Open Pharma allows her to stay connected with trends in publishing and the pharmaceutical industry.



Chris Winchester, DPhil

Chris Winchester is CEO of Oxford PharmaGenesis, an award-winning HealthScience communications consultancy with over 500 employees in Europe, North America, and Asia Pacific. Chris studied Biochemistry at St Catherine's College, University of Oxford, leaving with a DPhil in 1997. He is a Co-founder of Open Pharma, a Director of Oxford Health Policy Forum, an Associate Fellow of Green Templeton College, University of Oxford, a Director of the Friends of the National Library of Medicine, and a past Chair of the International Society for Medical Publication Professionals.

THE 2021 EMWA

Salary and Freelance Rates Survey

SEE PAGES
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From the Editor

It's not "open sesame" – It's been almost 30 years



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2 022. The year EMWA turned 30. After lockdowns and closures, it took several months for the world to “re-open”. For the open access initiative, it's been almost 3 decades of trying to unlock the closed doors of publications and scientific data. Like EMWA, open access, too, has its roots in the 90s and it has been a long journey.

The list below is far from exhaustive; the dates might not be accurate. But it drives home the point that open access did not happen overnight. It is not as easy as turning the key or shouting “Open Sesame!”

Thank you to those who came before us, named and unnamed, who planted the seeds of open access, transparency, and public disclosure.

Our cohort needs to keep this growing so that future generations will fully reap the benefits.

Thank you to Tanya Stezhka, Chris Winchester, and Martin Delahunty for putting together this issue, EMWA's small contribution to the open access movement. Also thank you to our contributors, authors, editorial team, and the EMWA membership.

Wishing you all Happy Holidays and a wonderful (and open!) 2023.

Raquel

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Below is a rundown of some key milestones:¹

- 1993 Open Society Foundation (OSF, formerly Open Society Institute)²
- 1997 Scientific Electronic Library Online (SciELO)³
- 1998 Public Knowledge Project (PKP)⁴
- 2000 BioMed Central⁵
PubMed Central⁶
- 2001 Public Library of Science (PLOS)⁷
- 2002 Budapest Open Access Initiative⁸
- 2008 The National Institutes of Health (NIH) Public Access Policy⁹
- 2014 Open access as part of the European Commission's Horizon 2020 Research and Innovation programme¹⁰
- 2015 Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP3)¹¹
- 2016 OpenPharma Initiative¹²
The FAIR Guiding Principles for scientific data management and stewardship¹³
- 2018 Plan S of cOAlition S¹⁴
- 2021 Open Pharma recommendations for plain language summaries of peer-reviewed medical journal publications¹⁵
Open Research Europe¹⁶
- 2022 Good Publication Practice 2022¹⁷

President's Message

From bench to the public: Open access

Dear EMWA friends and colleagues,

At the 54th EMWA Conference in Riga in November, I couldn't help but notice the historic nature of the event. It was EMWA's last face-to-face autumn conference, keeping in line with our sustainability goals. (Going forward, EMWA will host one FTF conference a year, in the spring). The Riga conference was paired with the first Expert Seminar Series (ESS) to be offered at an autumn conference. Appropriately, the ESS was organised by EMWA's Sustainability-SIG (Special Interest Group). Also, for the first time, EMWA offered a mini-symposium at an autumn conference, the theme of which was plain language summaries (PLS).

The medical writing community has historically been involved in the production of materials with highly technical biomedical content; the consumers being scientific and medical professionals or regulatory agencies. However, there has been a steady shift in this practice in recent years with many medical writers creating content – jargon-free and easily understandable – for the general public. This is because of an increasing acceptance of the public as one of the key stakeholders in health management, and an educated and informed public is a crucial partner in the design and deployment of successful health policies. At EMWA, we have realised the importance of public education and the role medical writers play in making science understandable to the people. Our mini-symposium on PLS followed our symposium titled “Communicating with the Public: What has the COVID-19 Pandemic Taught Us?” held at the 53rd EMWA Conference in Berlin last spring. The panel at the mini-symposium comprised representatives from the pharmaceutical companies involved in publishing clinical research, publication professionals, and patient interest groups, thus giving a holistic overview on the importance of PLS. Particularly insightful was the information shared by the

patient advocates; it is vital to understand what and why exactly the public wishes to learn in order to draft an effective PLS, or for that matter, any content meant for consumption by the general public.

Every piece of communication, no matter how effective it is in conveying the message, is limited by how accessible it is.

This, however, is only half the job done when it comes to communicating science, regardless of who the end user is. Every piece of communication, no matter how effective it is in conveying the message, is limited by how accessible it is. Paywalls and subscription fees are neither new nor unheard of in scientific publishing. However, for long, these practices have been a hindrance to dissemination of research findings, especially to the scientific and medical community in the global south, due to non-affordability. This problem has been rightly recognised in the last 20 years or so and has led to the advent of “open access” publishing. Currently a number of top publishers have entire journals or certain articles within a journal available to interested consumers in the open access mode. “Pre-print” is a recently introduced concept where researchers can upload their manuscripts to pre-print servers for no fees and this allows for a wider circulation prior to peer review. Although these initiatives have curbed to some extent the problem with free accessibility to scientific information, there is more that can be done to allow 100% universal access. A few months ago, EMWA decided to make our journal *Medical Writing* fully open access, including all past issues. And once again, appropriately, the



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theme of this issue of *Medical Writing* is – open access. Lastly, EMWA is also collaborating with other associations, notably Open Pharma, to promote open access publication of clinical trial results. I must add a caveat here; although open access sounds like the solution to promote unfettered sharing of scientific information, it is not without its limitations. The open access model has been co-opted by a number of predatory publishers who in turn have flooded the scientific literature universe with low-quality research that is poorly reviewed, if at all, and is at times even fraudulent. I cannot think of a better example than the hype built around the anthelmintic ivermectin against COVID-19 on the basis of “published clinical trials”. As egregious as the instance is, one look at the real-world scenario reiterates strongly the need for effective scientific communication with the general public.

On a parting note, I think it is important to note that we are amidst an infodemic. Irrespective of which digital platform we are on, there is a vast amount of medical misinformation around us. It is available to all. And it is available for free. To counter this we need to take accurate, vetted, and up-to-date scientific information from behind pay walls and make it accessible to all without any restrictions. Open access is the need of the hour.

I wish you a happy holiday season.

A view of Riga's Old Town neighbourhood from the conference venue. In the foreground is the Riga Nativity of Christ Orthodox Cathedral (Russian Orthodox). In the background can be seen the three iconic churches of Riga (from left to right) – St. Peter's Cathedral (Lutheran), Riga Cathedral (Lutheran), and the Cathedral of St. James (Roman Catholic).

Abstracts from the EMWA Spring Conference Poster Session

Berlin May 2022

At the 2022 EMWA Spring Conference in Berlin last May, EMWA was delighted to host a poster session.

There was a wide variety of posters, all related to aspects of medical writing or of relevance to medical writers. The poster session presented an excellent way for EMWA members to see a snapshot of the latest thinking and research in their field. ICYMI, the poster abstracts are printed below.

doi: 10.56012/uqis8887

P1 Medical writing field awareness and the way forward: An online survey

Pinki Rajeev and Saurabh Shinde

Introduction

We aimed to identify awareness of medical writing professionals (MWP) regarding the medical writing field (MWF), associated growth opportunities, and the way forward.

Methods

An anonymous survey comprising 12 multiple-choice/open-ended questions was administered to MWP globally from 13 August 2021 to 6 September 2021.

Results

MWP (N=185) across 17 countries, India (93), UK (29), EU (24), Japan (11), US (9), Canada (6), and others (13), responded to the survey. Respondents were highly qualified with 87%

having an MS/PhD/equivalent degree and MWF experience of 0–5 (26%), >5–10 (29%), >10–15 (24%), and >15 years (21%).

Respondents were employed as medical writers or in MWF-associated functions across pharmaceutical industries (67%), medical writing (MW) agencies (57%), or as consultants (21%) in different domains (Regulatory/Scientific/Medico-Marketing/HEOR). They scored professional growth opportunities as high to medium (92%). Top reasons for liking MWF were skill utilisation (79%), creative thinking (75%), contribution to patients' lives (72%), and work flexibility (67%).

A majority (76%) of them were not aware of MWF during their graduation/post-graduation

with 53% learning about MWF through friends/colleagues and 7% through campus recruitment; only 9% underwent professional training before entering MWF. Similar trends emerged among developing and developed countries.

To increase MWF awareness, 86% indicated that MW should be introduced at the university level. Other suggestions included workshops by pharmaceutical companies/MW agencies, job fairs, and MW courses.

Conclusions

Although MWF offers good skill utilisation and professional growth opportunities globally, there is still limited awareness, which needs to be addressed at the university level.

P2 Utilising innovative tools to accelerate regulatory document writing

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Sara Fernandes, PhD, Early Clinical Medical Writing, ICON plc
Robert Panek, PhD, Early Clinical Medical Writing, ICON plc
Rona Grunspan, MD, Early Clinical Medical Writing, ICON plc

Introduction

Regulatory document writing requires a multidisciplinary approach which consumes time and resources. We developed a lean writing process by using innovative tools to reduce repetition, verbosity, grammar, and data errors to produce high quality documents while reducing timelines. We chose as a test case document the writing of a clinical study protocol.

Methods

Based on a 10-question survey extended to approximately 100 medical writers (MWs) and real time projects conducted over a 2-year period, we developed a process that can reduce project timelines. Our method included a

template checklist, developed by ICON MWs, PerfectIT as a proofreading tool, EndNote for management of citations, and PleaseReview for co-authoring, reviewing, and consolidating comments. Advantage was also taken of time zone differences that extend writing time and allow parallel writing and quality control.

Results

Our results indicated that timelines can be reduced by approximately 35%. The protocol checklist mitigated section prone content errors, particularly, schedule of assessments, tables, study design, and eligibility criteria resulting in better consistency across protocol sections. The different software tools efficiently identified and corrected grammar,

style and content errors, saved time by automating citation updates, and provided a window into all reviewers comments simultaneously, avoiding reviewer repetition. MWs working collaboratively proved to be able to shift workloads flexibly to break up unexpected bottlenecks.

Conclusions

Lean writing was achieved by applying innovative tools that produced high quality documents while markedly reducing timelines. These tools can be applied and tailored to other regulatory documents without sacrificing quality especially when delivery timelines are shortened.

P3 - Using audio-video abstracts to enhance the research article - A retrospective observational study

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Shruti Shah, Turacoz Healthcare Solutions Pvt Ltd, India

Introduction

With a paradigm shift of accessing research to online platforms, medical journals use audio-video (AV) abstract for post-publication knowledge dissemination on social media platforms and enhance the target audience reach. The current retrospective study was undertaken to study the incidence and impact of publications with AV abstract (pAV) in medical journals.

Methods

Research publications from high impact factor journals (New England Journal of Medicine [NEJM] and Lancet) and therapeutic area specific journals (Arthritis and Rheumatology

[A&R] and Journal of Allergy and Clinical Immunology [JACI]) were screened from Jan-2016 till date, for pAV versus those without (pWAV). Altmetrics for impact of pAV will also be studied.

Results

Of the total 6039 publications in NEJM from Jan 2016 till date, only 22% (n=1349) were pAV. Of these, 395 pAV (29%) were pharma-sponsored; 85 pAV (6%) involved medical writer. Percentage of pAV remained constant from 2016 to 2018 (16%) and increased from 2019 (19%) to 2020 (23%) and 2021 (33%). In Jan-Feb 2022, there were 37% pAV. Consistent with this, percentage of pWAV

remained constant from 2016 to 2018 (84%) but reduced considerably thereafter (81% [2019], 77% [2020], 67% [2021]). In Lancet, of 2015 publications from 2016 to 2022, only 4 were pAV (n=2 in 2019, n=1 each in 2020 and 2021). There was no pAV in JACI and A&R.

Conclusions

Preliminary results indicate that although pAV is slowly gaining popularity, it is still sub-optimally adapted by authors/researchers and medical writers. This may be attributed to lack of awareness or inadequate skill sets required for developing AV abstract.

P4 Perspectives on journal selection criteria from researchers working in a medium-sized biotech company

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b Aspire Scientific Ltd, Bollington, UK

c Oxford PharmaGenesis, London, UK

Introduction

This survey aimed to determine the most important factors for journal selection and most valuable publication enhancements from the perspective of researchers working in preclinical and early-phase programmes in a biotech company. This activity was part of a broader company programme to understand publication decisions and inform stakeholder education around good publication practice.

Methods

A questionnaire was circulated to colleagues from early-development programmes who had been invited to publications strategy and planning workshops. Respondents were asked to rank, in order of importance, ten factors

(1 being most important) they consider when selecting a journal for publication of their research, and to rank manuscript and poster publication enhancements by added value.

Results

Responses were received from 31 team members. Factors viewed as of key importance/value (ranked 1 or 2) for journal selection were: journal impact factor, n=17; immediate access (no paywall), n=9; open access, n=8; rapid online access, n=7; Citescore, n=4; Altmetrics tracked, n=3; citation indices reported, n=3; social media presence, n=2; patient involvement, n=1; option to include enhancements, n=0. Manuscript enhancements scored as follows: visual abstracts, n=21; plain

language summaries, n=14; supplementary materials, n=12; videos, n=6; podcasts, n=3. Poster enhancements scored as follows: Quick Response (QR) codes, n=20; video summaries, n=14; interactive features, n=11; plain language summaries, n=7; audio abstracts, n=2.

Conclusions

Early drug development researchers regarded impact factor as the most important consideration during journal selection, followed by immediate and open access. Visual abstracts and QR codes were ranked as the most important manuscript and poster enhancements, respectively.

P5 Landscaping the terminology of lay and plain language document types

Adeline Rosenberg¹, Sarah Griffiths¹, John Gonzalez², Slávka Baróniková²

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2 Galapagos NV, Mechelen, Belgium

This abstract was developed into a full-length feature article, which appears on p. 24.

Introduction

Regulatory Lay Language Summaries (LLS), publication-associated Plain Language Summaries (PLS) and Plain Language Summaries of Publications (PLSP) are three different document types, with distinct purposes, scope and audiences. This landscaping review outlines the variations of terms in use and aims to provide clarity on terminology.

Methods

We manually searched websites of the 38 full and affiliate corporate members of the European Federation of Pharmaceutical Industries and Associations (EFPIA, which provides good practice guidance¹ on LLS per the EU CTR no.546/2014, Annex V mandate²) for variations of LLS terminology; this search was performed on 16 February 2022.

Results

Regulatory LLS are mandated summaries of clinical study reports for study participants. LLS have limited scope, reporting on one study only, and are intended to be hosted on the central Clinical Trials Information System portal.³

Publication-associated PLS are brief jargon-free summaries, primarily of peer-reviewed publications, for non-specialist readers. Formats vary, but best practice and convention encourage text-based and concise PLS, allowing indexing on PubMed to maximise discoverability. PLS should be peer-reviewed and hosted with their associated publication.

PLSPs are full-length, standalone secondary manuscripts that “translate” previously published primary manuscripts into plain language with visual formatting, currently published by Future Science Group

journals.⁴ PLSPs may include the patient voice and patient-authors for a wider scope.

The landscaping analysis revealed that among the 38 EFPIA members, there are 18 different terms for LLS in use, including 11 instances of using the term PLS to describe LLS. Additionally, PLS and PLSP may also be used interchangeably.

Conclusions

Evidently, there is confusion regarding terminology; medical publications professionals need to be aware of these differences and ensure precision when referring to these three document types to avoid further confusion. Standardization of terminology is necessary for further clarity and to promote appropriate usage.



EMWA Membership Hardship Fund

Would you like to remain or become an EMWA member again but cannot because of financial difficulties and challenging times? If so, EMWA would like to provide some assistance.

To be considered, you must be an existing or past EMWA member. There is no limit to the number of applications. With support from the EMWA Executive Committee (EC), the Treasurer will review each application and judge them on a case-by-case basis. We ask you to tell us a little about yourself through these questions:

- What are your career aspirations? (300-word limit)
- What are your plans for any future EMWA involvement? (300-word limit)
- Why do you need this fee waiver? (300-word limit)

In return, we ask you to make whatever monetary contribution you are able to – and the rest EMWA will cover. If you cannot make any contribution at all, EMWA will not discriminate.

If you qualify, we will then review your case yearly. Hopefully, your situation will change; otherwise, we will consider supporting you through EMWA's hardship fund for a maximum of 3 consecutive years.

Details of anyone who qualifies will be kept strictly confidential by EMWA's Head Office.

This organisation's policy is to provide equal opportunities without regard to race, colour, religion, national origin, gender, sexual preference, age, or disability. EMWA, as a UN Sustainable Development Goals (SDG) partner organisation, aims to ensure inclusive and equitable quality education and promotes lifelong learning opportunities for all (UN SDG 4; <https://sdgs.un.org/goals/goal4>)

Please contact info@emwa.org and ec@emwa.org to apply.



EMWA Ambassador Programme news

The EMWA Ambassador Programme is continuing its efforts to reach out to new audiences promoting medical writing and EMWA.

On Sept. 22, 2022, during the EMWA Getting Into Medical Writing online session organised by **Evguenia Alechine** and her team, **Abe Shevack** (past EMWA President and Ambassador Programme lead) gave a short overview of the past, present, and future activities of the programme. The session was very well attended, with over 300 participants. There were presentations on medical writing, networking, writing for the public, and EMWA.

On Oct. 10, 2022, **Beatrix Doerr** (past EMWA President) presented an online webinar on conference abstracts in German to 25 young scientists who are members of the German Association for Medical Informatics, Biometry and Epidemiology (GMDS). Bea also

demonstrated the EMWA website and the resources available to the audience, highlighting the training material provided for free. Her presentation was very well received.

On Oct. 14, 2022, **Anne McDonough** was again invited to give an online presentation on science and communication at the University of Essex, Colchester, UK. The event is called "Using Science in Your Career" and was geared toward 2nd year Life Science students. There were 40 attendees who had questions about the costs of earning an EMWA certificate, how it is to be a freelance medical writer, and about social media channels for EMWA and medical writing.

On Oct. 15, 2022, **Nessie Riley** (member of the Veterinary Special Interest Group [Vet SIG]) participated in a panel discussion on freelancing during the live (London), and online Vets: Stay, Go, Diversify (VSGD) Summit. The summit showcased the career paths available to veterinary professionals and students. Over 30 people attended live and many more online: Nessie spoke about her career path to freelancing and experience to date, the different fields of technical writing, and the EMWA educational program and conferences. The panel discussion was well received, and Nessie has already been invited to participate in the next VSGD Summit.

Abe Shevack provided a prerecorded talk on medical writing and EMWA that was posted on the EMWA exhibitor page at the VSGD conference. Several new contacts have already been made, and at least one participant has joined EMWA.

A new feature on the EMWA website

Members and non-members can now view poster abstracts from the 53rd EMWA conference. From 2022, poster abstracts from all conferences will appear on the page below, and the full posters will be available to members only:

<https://emwa.org/conferences/abstracts/>

To find all poster abstracts go to the

Conferences menu tab and click on **Abstracts**.

In this issue, we are also publishing the abstracts from the 2022 Berlin conference, pp 7–10.

10% discount for referring new members to EMWA

Existing EMWA members can receive a 10% discount off their next year's EMWA subscription for referring a new member to EMWA. (A new member can be entirely new to EMWA, or they may be a lapsed EMWA member who has not been a member for a minimum period of 3 full years). This discount is only valid for a maximum of one new member per year, and the new EMWA member must pay a full year's subscription before the discount can be given to the referrer. In addition, the new member needs to include the name of their referrer on the membership application form. Please note that discounts are not cumulative, nor can they be rolled over into subsequent years – i.e., the maximum discount possible in any given year is 10%.

For more information, please contact Head Office at info@emwa.org.

Sustainability SIG News

The EMWA Sustainability Special Interest Group (SUS-SIG) organised their first ever Expert Seminar Series (ESS) at the EMWA Autumn Conference in Riga, Latvia, on Nov. 4, 2022. The hybrid ESS event was attended by more than 20 registrants, onsite and online. Summaries of the excellent presentations will be featured in upcoming MEW issues in The Crofter section.

Another update from the SUS-SIG: Carolina Rojido has taken on the leadership of the SIG; Carola Krause is staying on as core SIG member. For more information about the EMWA SUS-SIG, please contact sussig@emwa.org.

Freelance Business Group subcommittee: come join the team!



The freelance business group (FBG) focuses on all things freelance. We have a subcommittee of 3 people and are looking for new volunteers. We have several new initiatives we want to push forward this year, and we seek proactive freelancers

who can dedicate some time every month to these projects. If you are a freelancer, enthusiastic about volunteering for EMWA and having some time to spare, please contact the FBG chair, **Laura A. Kehoe**, at freelance@emwa.org

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Can access and accessibility rebuild public trust in research?

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Abstract

Trust is built gradually, and it is easily threatened, particularly in relation to pharmaceutical research. The potential for open access publishing and plain language summaries to contribute to improved trust in pharmaceutical research was discussed by experts at the Open Pharma Satellite Symposium, held at the Association of Learned and Professional Society Publishers Annual Conference and Awards 2022 in Manchester, UK. No single endeavour will win public trust overnight, but removing paywall barriers between all readers and sources of trusted information, and publishing research summaries that are written in accessible, plain English are important steps towards fostering greater trust in research. Both endeavours also have the potential to help the public make informed decisions about their health.

How can we improve trust in pharmaceutical research?

This question was the challenge posed to speakers at the Open Pharma Satellite Symposium, held at the Association of Learned and Professional Society Publishers Annual Conference and Awards 2022, held in Manchester, UK.

Despite the unprecedented successes of the COVID-19 vaccines, public trust in scientific research fell during the pandemic. Richard Smith (Symposium Chair and former editor of the *BMJ*) kicked off the symposium with a quote from Dr K. “Vish” Viswanath (Professor of Health Communication at Harvard University): “[During the pandemic], people saw the sausage



Photo: Freepik

being made, and they [didn't] like what they [saw].” Scepticism in research, he noted, is further fuelled by hyperbolic tabloid headlines, such as the *Mail on Sunday's* splash “exposé”, “The plague of fake medical trials putting lives in danger”, which claimed that “...the medical world is rife with research fraud”¹

Whether the antidote to such poisonous proclamations lies in improved systems of publishing, better public education, or something else is not yet clear. Recognising two clear opportunities for positive change, the Open Pharma Symposium focused on the role of open access publishing and plain language summaries in improving public trust in science.

Why open access matters

Richard Stephens (patient advocate and Co-Editor-in-Chief of *Research Involvement and Engagement*) explained that a preponderance of medical buzzwords has led to patients being increasingly aware that their treatment should somehow involve “precision”, “personalisation”, and “stratification”. Many patients also now expect that decisions around their care are shared and know that, beyond all else, treatment decisions should be based on evidence.

Open access publishing is the avenue through which patients can read the very evidence on

which their treatment decisions are based. Open access publishing removes an important barrier between patients and sources of trusted information. It enables peer-reviewed medical literature to sit alongside traditional patient information sources, such as the knowledge and opinions of friends and family, the information provided by patient groups, and that espoused by social media influencers.

On a more fundamental level, there is an inherent fairness in allowing patients to read the results of research to which they may have contributed data. Removing paywalls to peer-reviewed evidence not only resonates with

fundamental matters of fairness to research participants, but it also enables improved patient education, negates accusations of hiding data, and improves article impact. According to Leila Moore (Director of Open Access Policy at academic publisher Wiley), although only a small proportion of articles in Wiley journals are currently published open access, those that are receive approximately 50% more citations and three times more downloads and Altmetric attention scores than their pay-per-view counterparts.

If open access publishing improves timely communication of the latest health literature to all interested stakeholders, improves levels of

Open access publishing removes an important barrier between patients and sources of trusted information.

Box 1. Implementing an open access mandate within a pharmaceutical company

Appropriateness to act

- Recognise that pharmaceutical companies are a major funder of medical research.
- Recognise that researchers are used to restrictions/requirements from funding sources; an open access requirement is no different.

Consider strategic benefits

- Consider open access benefits in the context of core company principles (e.g., transparency; rapid access to literature for healthcare professionals and patients; potential impact on diagnostic journeys).
- Challenge attitudinal barriers and legacy thinking that associate open access publishing with inferior journal quality.

Pragmatics and implementation

- Garner broad alignment with senior leadership (medical, R&D, legal, and compliance business units).
- Incorporate open access requirement into policies, standard operating procedures, and agreements (research, author, etc.).
- Budget for open access fees, if required, with Medical Affairs.
- Conduct internal training and alignment post launch.
- Take a pragmatic approach to the definition of open access, recognising that open access publishing without embargo (a CC BY licence) may be the goal, but that it is necessary to work within the reality that currently exists in publishing until such licences are widely available.

Abbreviation: CC BY, Creative Commons Attribution [licence]

Adapted from: Rains C. Open access commitment for Takeda-supported research. *Who can we trust? Open science and pharma research*. Presented at the Open Pharma Satellite Symposium at the Association of Learned and Professional Society Publishers Annual Conference and Awards, Manchester, UK, September 14, 2022 (oral presentation).³

research impact and engagement, and diminishes data distrust, research funders should be its staunch champions. This very realisation was what Christopher Rains (Vice President of Global Medical Affairs, Global Portfolio at biopharma company Takeda) described as his “lightbulb moment”. Recognising that up to two-thirds of medical research is funded by the pharmaceutical industry, he decided that pharmaceutical companies have an important role to play in advocating wider adoption of open access publishing. In January 2018, Shire (his then employer) became the first pharmaceutical company to mandate open access publishing of their funded research.² Two years later, Takeda, which had by then acquired Shire, adopted the Shire policy and became the first top 10 pharmaceutical company to mandate open access for all globally funded research.

Global mandates of the kind adopted by Shire, later Takeda, do not happen overnight, especially in large pharmaceutical companies. Not only are there many minds to align, but there

is also legacy thinking to contend with, a legacy that is permeated with conservatism in the pharmaceutical sector. Yet Takeda overcame these challenges because an open access mandate made strategic sense (Box 1).³

The company had already made a commitment to clinical trial transparency; a similar commitment to open access publishing was a continuation of the same principle. It also made sense from a business performance and reputational perspective, as well as from the perspective of building trust in Takeda-funded research. Importantly, it also embodied the company’s commitment to patient centricity.

Other pharmaceutical companies, including Ipsen, have since followed suit. A wide range of non-profit and publicly funded research organisations have also voiced their support of open access publishing for medical research, including the Wellcome Trust, the Bill & Melinda Gates Foundation, National Institutes of Health, and the European Commission. If there were any lingering doubts that open access is the direction

of travel for medical publishing, these were likely eradicated by the right-to-read proclamation that came from the White House this summer. On August 25, 2022, President Joe Biden’s administration announced that, beginning in 2026, federal agencies must make papers that describe taxpayer-funded work freely available to the public as soon as the final peer-reviewed manuscript is published.⁴

Access alone does not ensure accessibility

Removing the paywall barrier between interested stakeholders and medical evidence is a positive step towards improving access to timely novel evidence, but open access is not synonymous with accessibility.

Borrowing a description coined by the highly reputed medical writer Michael O’Donnell, Symposium Chair Richard Smith questioned whether scientific writing is still written in the style of “decorated municipal gothic”.⁵ O’Donnell’s elaboration of this description is that academic writing is frequently “long, tortuous, opaque, uninteresting, and possess[es] a ‘built-in quality of unreadability’”. Its main purpose, he argued, is to ennoble the writer rather than to inform the reader.⁵ Yet writer ennoblement is not a solid foundation for reader trust. Step forward the plain language (or plain English) campaigners.

As medicine strives to move away from paternalistic approaches to patient care and didactic prescribing, the patient voice can and should be factored into clinical decision-making. If that voice is to be intelligent and informed, patients need to have access to intelligible information. Quoting David Schley (Deputy Director of Sense about Science), Adeline Rosenberg (Senior Medical Writer at Oxford PharmaGenesis and Open Pharma) explained that “we have a better chance of having a well-informed public making critical decisions if they’ve got access to plain language summaries”.⁶

As an advocate for plain language summaries, Adeline also shared the view of Brian Southwell, an expert in communication and human behaviour, who explained that during the pandemic, “Part of the reason people turn[ed] to convenient, accessible, and ubiquitous information sources [was] because they [were] convenient, accessible, and ubiquitous ... We need to worry less about stamping out misinformation and worry more about providing people with a steady diet of information that serves their needs”.⁷

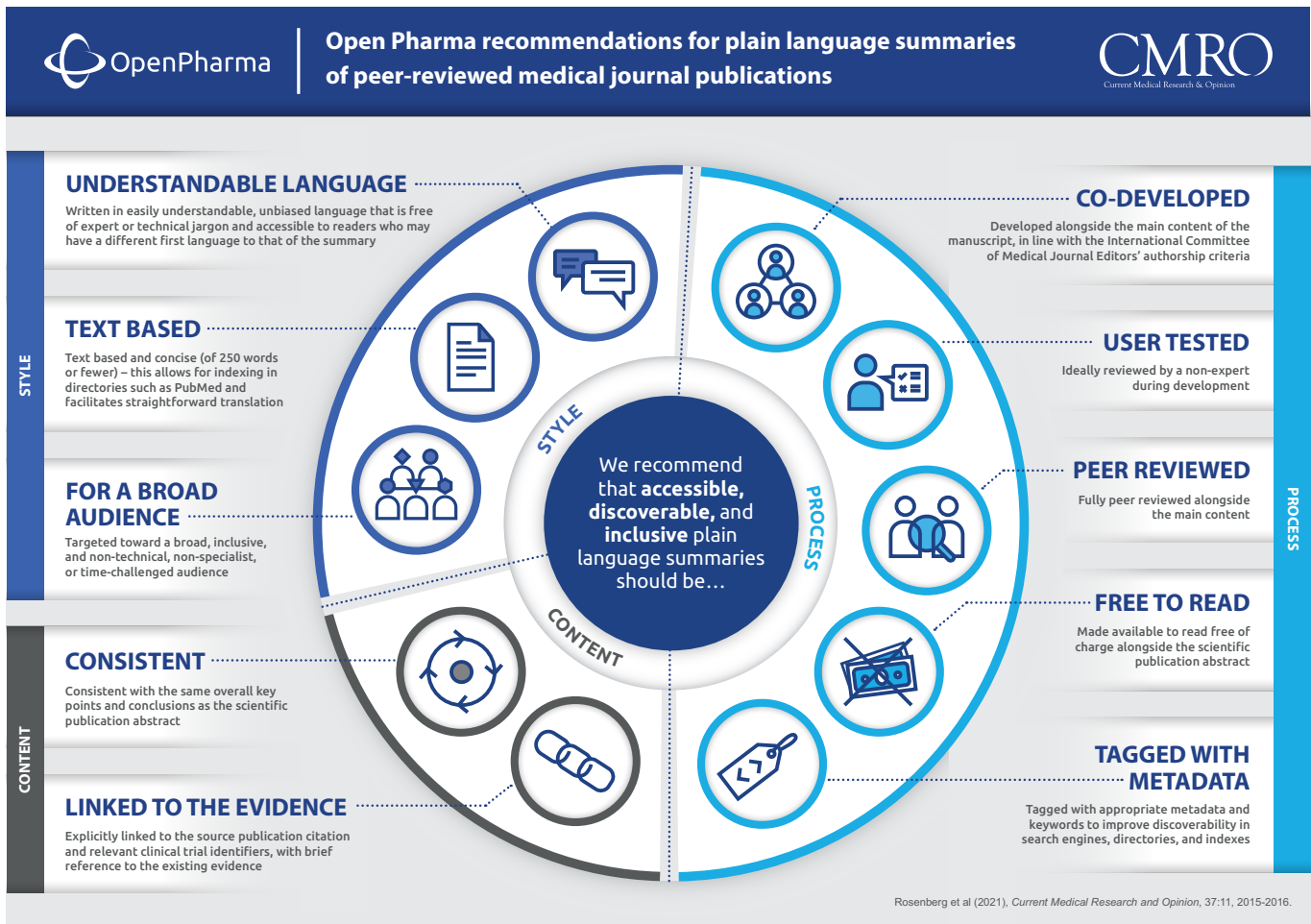


Figure 1. Open Pharma recommendations for plain language summaries of peer-reviewed medical journal publications

Reproduced from: Rosenberg A, Baróniková S, Feighery L, et al. Open Pharma recommendations for plain language summaries of peer-reviewed medical journal publications.

Curr Med Res Opin. 2021;37(11):2015–16. Update in: Curr Med Res Opin. 2022;38(6):881–2. With permission from the authors and the publisher Informa UK Limited, trading as Taylor & Francis.⁸

Motivated by this principle, the Open Pharma collaboration brought together representatives from the medical communications and pharmaceutical sectors at an expert round-table event and focused public consultation in 2021 to discuss and develop key recommendations for plain language summaries. The resultant set of recommendations is not a formal guideline for plain language summary development; rather, it is a proposed foundational standard.⁸ Appropriately, the recommendations were published open access (subject to an unrestricted Creative Commons Attribution licence) and included a plain language summary, an explanatory author video, and an accessible infographic summary of the 10 core tenets (Figure 1).⁸

Ipsen were represented among the stakeholders involved in the development of the Open Pharma plain language summary recommendations. In another clear break from pharmaceutical

company legacy thinking, Ipsen subsequently announced a commitment (starting in July 2022) to publish a plain language summary for all company-sponsored journal publications that include data from human studies.⁹ These publications will, as a minimum, be accompanied by a 250-word plain language summary. The mandate does not preclude other formats; it is a minimal commitment to ensuring content accessibility. Box 2 summarises some of the steps involved thus far in Ipsen's implementation of their mandate.¹⁰

Journal publishers are also increasingly supportive of accessible summary article enhancements. Caroline Halford (Development Director for Medical Education at Springer

Healthcare) spoke of the myriad accessible summary formats that are now on offer. These range from simple text summaries that can be indexed alongside the article abstract on PubMed to full-text plain language publications, more visual (infographic) formats, or multimedia (video, animation, and/or podcast) formats.

The inciting spark for the rapid growth in accessible summary formats may have come from author and reader demand, but it has been fuelled by regulatory mandates¹¹ and further accelerated by publisher analytics. According to Springer Healthcare data, accessible summaries not only improve article comprehension, but also bring new readers, increase article downloads, and facilitate content sharing (especially

We have a better chance of having a well-informed public making critical decisions if they've got access to plain language summaries.

Box 2. Implementing a plain language summary mandate within a pharmaceutical company

- Define a mandate with clear minimum requirements.
- Communicate the mandate internally and externally.
- Develop a plain language summary lexicon to facilitate consistent language use.
- Develop a plain language summary review process.
 - Develop briefing materials and checklists.
 - Identify non-expert reviewers and/or patient reviewers (the gold standard).
- Build plain language summary development into publication SOPs.

Abbreviation: SOP, standard operating procedure

Adapted from: Thomas S. Ipsen commitment on plain language summaries. *Who can we trust? Open science and pharma research*.

Presented at the Open Pharma Satellite Symposium at the Association of Learned and Professional Society Publishers Annual Conference and Awards, Manchester, UK, September 14, 2022 (oral presentation).¹⁰

graphical summaries). Further, from a medical education perspective, Halford explained that accessible summaries can help to equip health-care professionals with the correct language to discuss research data with their patients.

Embracing open access publishing and shunning decorated municipal gothic writing are clear and admirable breaks with legacy thinking, across the pharmaceutical, publishing, and medical communication sectors. Trust is built gradually, and it is easily threatened. No single endeavour will win public trust in research, but an important and achievable step towards improving public confidence in research is reporting it in a way that is both accessible and easier to understand.

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Disclosures and conflicts of interest

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Science for all: Is it all about the publication of data, or beyond?

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Abstract

This article presents an overview of open access initiatives by researchers, journals, government bodies, and regulatory authorities. Open access initiatives are valuable to the scientific community and have increased the amount of clinical research information available to the general public. Sharing this information in a manner that is understood by those without scientific training is important. This article discusses plain language summaries, their requirements and benefits, and what additional steps should be taken to improve transparency in clinical research.

Background

"None of the main issues which humanity is facing will be resolved without access to information," Christophe Deloire (Secretary-General of Reporters Without Borders) stated during a presentation at the International Programme for the Development of Communication.¹ Although his statement is related to improving access to information across countries for sustainable development, it also applies to scientific research.

Open access initiatives (Table 1) increase transparency, enhance access to scientific information, and expand the utility of research beyond what is possible within conventional peer-reviewed, subscription-based journals. Open access initiatives:

- Promote transparency in experimental methodology, observation, and collection of data, which in turn improves scientific collaboration.

- Increase the value to society of fundamental scientific research.
- Enhance public confidence in research.
- Increase patient participation in clinical research.²

Open access also benefits researchers in publishing their work. It allows authors to retain more control over and rights to their work, meet publication mandates from funding partners, collaborators, or research institutions, and increases the likelihood of funding for future research projects.

Despite the benefits, there are also some challenges with open access. First, there is no clearly defined quality mechanism or rigorous peer-review process for open access publishing³ as there is for a conventional, subscription-based journal. Secondly, as journals accept a publication fee from authors, open access may create a potential conflict of interest where publishers may want to maximise revenue by accepting a publication fee for anything and everything, and thereby unprofessionally exploit the "author-pay" model of open access publishing.⁴ Therefore, it is important that authors select a legitimate open access journal for their publication.

In contrast, the open access movement is supported by regulatory authorities in their drive to make more information on clinical research publicly available (Table 2). This has resulted in new regulatory requirements for sponsors to publish summary results of clinical trials (e.g., on clinicaltrials.gov, EudraCT, and other regional registries) and clinical trial documents (e.g., protocols, statistical analysis plans, clinical study reports, clinical overviews, and summaries). This approach includes robust validation and controls, where the information is reviewed either by a regulatory reviewer or validated through automated system controls. Study sponsors have the opportunity to redact confidential business information before publishing. To help preserve the scientific utility of the documents, regulatory authorities require a justification for information that is to be redacted.

Further open access initiatives within clinical research are driven by pharmaceutical

companies, universities, and non-government organisations (Table 3). These allow researchers to request individual patient data from clinical studies in order to conduct secondary, independent analyses.

A relatively recent step forward has been a drive to communicate clinical trial results to patients in an understandable format. These plain language summaries (PLS) have been mandated in Article 37 of the EU CTR 536/2014. This new requirement is accelerating the need to write more documents in plain language and supports greater transparency (e.g., plain language protocol synopses and plain language summaries of publications [PLSPs]). These documents are another step forward for the open access movement by providing clinical research information in a format that is understandable to a wider audience.

Open access initiatives in publications and clinical trial data

Open access has received growing attention and recognition globally.⁵ Several methodologies for





open access to publications have also been discussed:

- **Green open access:** The authors self-archive the pre- and post-prints of their publication
- **Gold open access:** Publications are fully accessible through open access journals
- **Hybrid access:** Payment of a publication fee (as an article processing charge) to the publisher to publish an article as open access in an otherwise subscription-based journals.

Through these methodologies, the number of open access journals and publications is increasing.

The objective of open access initiatives is not limited to publications. To improve transparency, regulatory health authorities of various countries have also mandated the publication of clinical documents. These documents provide detailed information about the design, conduct, and analysis of clinical trials, and more compre-

hensive information on trial results than more traditional publicly available sources such as journal manuscripts. Publication of clinical data enables a comprehensive and independent analysis of clinical trial results. In addition, the availability of such information offers new perspectives and ideas that may lead to innovative insights that can bring additional learning opportunities and better serve humanity.

Tables 1, 2, and 3 provide a comprehensive overview of various initiatives taken for open access for publications, public release of clinical trial documents by regulatory authorities, and

data sharing by pharmaceutical companies and industry groups, respectively.

Global pattern of international collaboration and open access

In the digital era, academicians and researchers can easily publish their work, which in turn

brings them more recognition. However, open access also has certain limitations, such as the author-pay model, no or less quality control,³ predatory publishing,³ and providing less incentive for academic researchers.⁶ Financial stability, reputation, and resources are important to academic researchers, however, there is no clear mechanism to incentivise open access publications coming from original research. In a blog, Dan Gezelter delivers a harsh verdict on open access, “... *Scientific productivity is measured by the number of papers in traditional journals with high impact factors, and the importance of a scientist’s work is measured by citation count. Both these measures help determine funding and promotions at most institutions, and doing open science is either neutral or damaging by these measures...*”.⁶

Despite these issues, open access offers mutual benefits: it permits researchers in developing countries to participate in international collaborative research projects, while researchers from developed countries get to know about local/regional research.⁷ The executive summary

There is no clear mechanism to incentivise open access publications coming from original research.

Table 1. Open access (OA) initiatives for publications

Initiatives	Date	Implementation date	Aspects covered/Comments	Website/ Reference link
arXiv.org		August 1991	<ul style="list-style-type: none"> ● Curated research-sharing platform open to all ● Hosts more than two million scholarly articles in eight subject areas (physics, mathematics, computer science, quantitative biology, quantitative finance, statistics, electrical engineering and systems science, and economics) 	https://arxiv.org/
Budapest Open Access Initiative (BOAI)		December 2001	<ul style="list-style-type: none"> ● Provides a statement of principle, a statement of strategy, and a statement of commitment to OA ● Includes research articles in all academic fields. Recommends two strategies – self-archiving and OA journals 	www.budapestopenaccessinitiative.org
Directory of Open Access Journals (DOAJ)		2003	<ul style="list-style-type: none"> ● Covers all areas of science, technology, medicine, social sciences, arts, and humanities ● Open access journals from all countries and in all languages are accepted for indexing 	www.DOAJ.org
Registry of Open Access Repositories (ROAR)		2003	<ul style="list-style-type: none"> ● Promotes the development of OA by providing timely information about the growth and status of repositories throughout the world 	www.roar.eprints.org
Bethesda Statement on Open Access Publishing		June 2003	<ul style="list-style-type: none"> ● Builds on the BOAI by saying how OA would be enacted ● Indicates that OA is a property of individual works, not necessarily journals or publishers ● Provides statements from three working groups: Institutions and Funding Agencies Working Group, Libraries and Publishers Working Group, and Scientists and Scientific Societies Working Group 	Bethesda Statement on Open Access Publishing (earlham.edu)
Berlin Declaration on Open Access		October 2003	<ul style="list-style-type: none"> ● Outlines concrete steps to promote internet as a medium for disseminating global knowledge ● Has been signed by over 750 research institutions, libraries, archives, museums, funding agencies, and governments from around the world (as on Aug 25, 2022) 	www.berlin9.org/about/declaration
SHERPA Fact SHERPA/RoMEO SHERPA/Juliet OpenDOAR		February 2004	<ul style="list-style-type: none"> ● SHERPA Fact checks the compliance of funder OA policies with a particular journal ● SHERPA/RoMEO gives a summary of publishers' OA archiving conditions for individual journals ● SHERPA/Juliet enables researchers and librarians to see funders' conditions for open access publication ● OpenDOAR enables the identification, browsing, and search for repositories within SHERPA services 	About Sherpa Romeo – v2.sherpa
The Registry of Open Access Repositories Mandatory Archiving Policies (ROARMAP)		2005	<ul style="list-style-type: none"> ● A searchable international registry charting the growth of OA mandates adopted by universities, research institutions, and research funders that require their researchers to provide open access to their peer-reviewed research article output 	http://roarmap.eprints.org
Open Access Scholarly Publishing Association (OASPA)		October 2008	<ul style="list-style-type: none"> ● Develops and disseminates solutions that advance OA and ensure a diverse, vibrant, and healthy open access community 	https://oaspa.org

Initiatives Date	Implementation date	Aspects covered/Comments	Website/ Reference link
OA2020	2015	Aims to: <ul style="list-style-type: none"> ● Transform scholarly journals from subscription to OA publishing ● Practice this transformation process by converting resources spent on journal subscriptions into funds to support sustainable OA business models ● Engage all parties involved in scholarly publishing to achieve an efficient transition 	https://oa2020.us/oa2020-the-eoi
PlanS	September 2018	<ul style="list-style-type: none"> ● Supported by cOAlition S, an international consortium of research funding and performing organisation working under the European Commission ● Suggests that scientific publications that result from research funded by public grants must be published in compliant OA journals or platforms without embargo 	www.coalition-s.org

of the National Science Foundation (2019) indicates that international collaborations have increased over the last 10 years. A review of scientific literature published in 2018 showed that one out of every five publications has co-authors from multiple countries (23%),⁸ indicating a 7.4% increase from 2020.⁹ The main reason for this increasing collaboration is that authors in countries that have limited scientific publications have accelerated their global publication output in the last 10 years.⁸

A recent study by Lee and Haupt (2020)¹⁰ evaluated the nature of international collaborations during the COVID-19 pandemic when researchers across the world worked towards a common objective (scientific globalism). This study concluded that scientific globalism improved due to an increase in international collaboration and open access publications during the pandemic. Countries that were impacted more by COVID-19 and had lower GDPs, participated more in scientific globalism than their counterparts in developed countries.

The above findings were confirmed by Moskovin et al. (2021),¹¹ who conducted a systematic quantitative analysis to evaluate open access instruments and initiatives and developed a methodology for calculating the involvement of countries in the open access movement. They concluded that scientists from low-income countries are more motivated than those from high-income countries to publish their articles in open access journals or platforms partially because their articles may be poorly cited, if not accessible publicly. Countries with the most records in nine open access registries (SHERPA/RoMEO, DOAJ, ROAR, OPEN DOAR, ROARMAP, Berlin Declaration, BOAI,

SHERPA/Juliet, OA2020 Initiative) included developed countries (USA, UK, Germany, etc.), developing countries (Indonesia, Brazil, India, Turkey, etc.), and countries with transition economies (Russia, Ukraine, Poland, etc.). Furthermore, based on the selection of 25 countries by the total number of records in open access registers, this study also concluded that developed countries, and developing plus transition economy countries (grouped together), are approximately equivalent in their degree of involvement in the open access movement.

There have also been several initiatives to enhance open access to research by governments and international bodies. In November 2021, UNESCO released its recommendation for Open Science and indicated that by making science more transparent and more accessible, research would be more equitable and inclusive.¹² In August 2022, the US government announced that starting in 2026, any scientific publication that receives federal funding will need to be openly accessible on the day it is published.¹³

Are we doing enough? Value of open science for trial participants

Over the last few years, effort has been focussed on making scientific information not just more available but also more readable. While several clinical documents, including clinical study reports (CSRs), are now published in the public domain (e.g., EMA Policy 0070, HC PRCI), these documents contain scientific jargon that

can be impenetrable to a non-scientific audience. More patients want to be fully involved in their health decisions and are eager to learn about the advancements in science and the latest treatments.^{14,15} This was highlighted during the COVID-19 pandemic when the latest updates on the COVID-19 drug and vaccine development became living room discussion topics.

Even before the pandemic, patient advocates have consistently voiced a need to access information on clinical research in easy-to-understand language and in an easy-to-follow format. These voices are being heard by the regulatory bodies and we are seeing increasing regulatory requirements and/or recommendations for plain language documents of clinical trials (e.g., informed consent forms [ICFs], plain language summaries [PLSs] of clinical trial results, and plain language protocol synopses)

across regions and countries, such as Europe, UK, and Turkey. More scientific journals are encouraging plain language summaries of publications (PLSPs) to be submitted as a supplement to a manuscript or as a stand-alone publication. Certain publishers, like Future Medicine, are going the extra mile by providing a dedicated platform for PLSPs with the aim of making scientific and medical research more accessible. They also provide several resources to help scientists and medical writers write high-quality PLSPs.¹⁶

Some sponsors are making plain language documents available in different formats, for example, traditional PDFs, infographics, comics,

Effort has been focussed on making scientific information not just more available but also more readable.

Table 2. Initiatives for improved transparency and open access of clinical trial data by regulatory authorities

Regulatory authority	Policy/Initiative/ Rule/ Database	Publication date	Aspects covered and current status	Website links
Pharmaceutical and Medical Devices Agency (Japan)	Disclosure of Information	November 1999	<ul style="list-style-type: none"> All Module 2 documents of Common Technical Documents, clinical study report synopses and mini-narratives for serious adverse events Full clinical study reports are out of scope 	Pharmaceuticals and Medical Devices Agency (pmda.go.jp) https://www.jpma.or.jp/english/about/parj/eki4g600000078c0-att/2020.pdf
European Medicines Agency (EMA)	European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) through EU Clinical Trial Register	September 2011	<ul style="list-style-type: none"> Publication of protocol and results information on interventional clinical trials 	EudraCT Public website - Home page (europa.eu)
EMA	EU Clinical Trial Regulation 536/2014	April 2014	<ul style="list-style-type: none"> Harmonisation of the processes for assessment and supervision of clinical trials throughout the EU Information-sharing and collective decision-making on clinical trials Transparency of information on clinical trials High standards of safety for all participants in EU clinical trials Implemented on Jan 31, 2022 	Clinical Trials Regulation European Medicines Agency (europa.eu)
EMA	EMA Policy 0070	October 2014	<ul style="list-style-type: none"> Public scrutiny and secondary analysis of clinical trials Protection of personal data (PPD) and company confidential information (CCI) Respect for the boundaries of patients' informed consent Consequences of inappropriate secondary data analysis, and that such analysis results should also be published Protecting the Agency's and the European Commission's deliberations and decision-making process On-halt since September 2018, except for COVID-19 studies 	0070 Policy - Publication and access to clinical-trial data (europa.eu)
National Institute of Health (NIH)	Final Rule (42 CFR Part 11)	January 2017	<ul style="list-style-type: none"> Protocol registration of applicable clinical trials (ACT) Disclosure of trial results Disclosure of full protocol and statistical analysis plan (SAP), after appropriate redactions Consequences of non-compliance 	ClinicalTrials.gov Final Rule (42 CFR Part 11) Information
Food and Drug Administration (US FDA)	Clinical Data Summary Pilot Programme	January 2018	<ul style="list-style-type: none"> Pivotal Phase III clinical study reports Pilot programme was run on a single clinical study report which was completed and learnings from this were shared – further information awaited 	Clinical Data Summary Pilot Program FDA
Health Canada	Public Release of Clinical Information	March 2019	<ul style="list-style-type: none"> Anonymised clinical information in drug submissions and medical device applications to be publicly available for non-commercial purposes Protection of personal information (PI) and confidential business information (CBI) Secondary and independent analysis of clinical data 	Public Release of Clinical Information: guidance document - Canada.ca

Table 3. Data sharing initiatives by pharma companies and industry groups

Initiative	Originator	Implementation date	What it is about?	Website link
Clinical Study Data Request (CSDR)	GlaxoSmithKline	May 2013	<ul style="list-style-type: none"> • A consortium of clinical study sponsors • Offers facilitation of the responsible sharing of patient-level data from a range of clinical study sponsors through a researcher-friendly platform, including an independent review of proposals, and protection of patient privacy and confidentiality 	ClinicalStudyDataRequest.com
The Yale University Open Data Access (YODA) Project	Yale University	October 2014	<ul style="list-style-type: none"> • Offers responsible sharing of clinical research data, open science, and research transparency • Committed to support research focused on improving the health of patients and informing science and public health 	The YODA Project (yale.edu)
Vivli	Multi-Regional Clinical Trials (MRCT) Centre of Brigham and Women's Hospital and Harvard	November 2016	<ul style="list-style-type: none"> • Includes an independent data repository, in-depth search engine, and a secure research environment • Users can search listed studies, request data sets from data contributors, aggregate data, or share data of their own 	https://vivli.org

and videos. With the intention to design these documents with purpose, they are constantly innovating and improving their delivery methods to provide the best experience to their audiences.

While sponsors are producing PLSs and PLSPs that are intended to be easy-to-understand and engaging, there remains a need to measure the impact these documents have on patients and the public. More effort is needed to raise awareness of the availability of plain language information about clinical research. A co-ordinated effort to raise awareness and making these documents available on shared platforms would advance open access and science for all. However, to do this effectively we may need to develop metrics to further evaluate:

- If the information about clinical trials is useful and understandable to the public
- If and how data are being shared and/or reused
- If the patient community and public can contribute to and track the scientific value of generated clinical trial data

Conclusion

Open access offers more transparency and accessibility to research data and drives global collaboration in clinical research. Clinical trial information is currently made public in different formats: research publications in scientific journals; synopses of individual studies on

pharmaceutical companies' websites, or through private and controlled portals such as CSDR and Vivli; availability of clinical summaries and clinical documents through a regulatory-driven, easy to understand approach on regulatory authority's dedicated websites (e.g., EMA, Health Canada, PMDA); and plain language documents shared with clinical trial participants. Although these documents are developed for a diverse audience, they serve a common objective – bringing more transparency to clinical research. However, in addition to making more information available to the public, we need to measure understanding and improve awareness amongst the public about the availability of this information. In the coming years, further advances driven by regulatory requirements, publication practices, and global scientific coalitions/ alliances are expected towards open access to research and public availability of data.

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The March 2023 edition



Clinical trials

Medical writers and communicators are involved in clinical trials, from writing the trial protocol to reporting and publishing the trial results. This issue will focus on our roles, responsibilities, the documents we create, and our audience. Furthermore, we will also cover the regulations and best working practices governing documentations for clinical trials.

Guest Editors: Raquel Billiones and Ivana Turek

Landscaping the terminology of accessible language document types

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Abstract

There are three main types of accessible language documents that medical writers and medical publications professionals may work on. These are regulatory lay summaries, publication-associated plain language summaries (PLS), and standalone plain language summaries of publications (PLSPs). Although these document types have different purposes and audiences, they are often confused because of the similar names. Here, we outline the main differences between the three document types and present the different names used to refer to lay summaries across 58 pharmaceutical companies, totalling 22 names. We also show examples of the different literacy levels used in lay summaries and publication-associated PLS. Medical publications professionals need to be aware of the differences between these accessible language document types and the importance of being precise when discussing these. Standardisation of terminology could potentially help to avoid confusion.

Introduction

Accessible language document types are central to achieving improved transparency in reporting clinical trial data in regulatory documents and publications. Efforts for improved transparency come as the pharmaceutical industry and adjacent industries are increasingly recognising the value of patient and public involvement and non-expert engagement, as well as the role accessible language plays in

enabling dialogue between stakeholders.¹ With this in mind, there are three main types of accessible language documents, among others, that medical writers and medical publication professionals may generally work on. These are:

- Regulatory lay summaries²
- Publication-associated plain language summaries (PLS)³
- Standalone plain language summaries of publications (PLSPs).⁴

These three different document types each have their own distinct purpose, scope, and audience; however, there is limited clarity regarding the terminology used when referring to these documents.

Regulatory lay summaries: a deep dive

Accessible disclosure of clinical trial results to trial participants through the regulatory sharing of Lay Summaries – either direct to participants or through posting to online portals – is of great value to participants and those involved in medical decision-making as well as pharmaceutical companies and other research sponsors.⁵ Previous work highlights the demand from participants for the timely and accessible communication of clinical trial results.⁶⁻⁸ This is a move that has the potential to improve health literacy, empower patients, and build public trust, particularly in the pharmaceutical industry.^{9,10} Simultaneously, communication with patients in this way may promote participant engagement, recruitment, enrolment, and retention in clinical trials.¹¹ The development of lay summaries is mandated by Article 37 of the EU Clinical Trials Regulation 2014/536, which indicates that “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... accompanied by a

summary written in a manner that is understandable to laypersons.”² Although this regulation was released in 2014, it came into effect in January 2022 after the launch of the EMA’s Clinical Trials Information System, an online portal designed to aid the dissemination of such summaries.¹² Official Good Lay Summary Practice (GLSP)¹³ was published in 2021, by the GLSP Roadmap Initiative,^{14,15} co-led by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Forum for Good Clinical Practice. Despite recognition of the development of lay summaries as best practice, explicit legislation has not yet been introduced beyond the EU. For instance, although the inclusion of lay summaries is not specified in the FDA Amendments Act,¹⁶ which legislates the disclosure of clinical trial results in the USA, the FDA encourages the production of “plain language summaries” of aggregate results and has provided draft guidance for voluntary development.¹⁷ In the UK, the Health Research Authority, a division of the National Health

Service, “asks” research sponsors to submit “plain language summaries” as part of final research reports that are published on the Health Research Authority website.¹⁸ Additionally, the UK’s National Institute of Health and Care Research requires “plain English summaries”, in the style of publication-associated PLS, to be submitted alongside research proposals.¹⁹ Despite legislation and guidance from these regulatory bodies, previous research has indicated that the accessibility of lay summaries to patients is lacking and initial compliance with the EU Clinical Trials Regulation has been low, though this may improve with the legislation now in effect.^{7,20} Furthermore, lay summaries have been referred to using varying

terminology across the industry, leading to a lack of consistency in official communications and potentially to confusion among lay and non-

Regulatory lay summaries have been referred to using varying terminology across the pharmaceutical industry, leading to a lack of consistency in official communications and potentially to confusion among lay and non-expert readers.

Table 1. Document distinctions

	Regulatory lay summaries	Publication-associated PLS	Standalone PLSPs
Purpose and audience	Mandated summaries of clinical study reports for study participants (typically a target reading age of approximately 9–13 years)	Brief, jargon-free summaries, primarily of peer-reviewed publications and occasionally congress materials, for broad non-specialist readers (typically a target reading age of approximately 14–18 years)	Full-length, standalone secondary manuscripts that “translate” previously published primary manuscripts into plain language with visual formatting, often targeted at a patient audience (typically of variable reading ages)
Scope	Reports on one study only, with a focus on primary endpoints and safety	Summarises the content of the associated manuscript	“Translates” one primary manuscript and may include the patient voice and patient authors for a wider scope
Location	Intended to be hosted on the central CTIS portal, ¹² but are currently hosted in a variety of places including sponsor websites and other portals	Hosted with the associated publication, either embedded within the manuscript or in the supplementary materials. Text-based and concise PLS can be indexed on PubMed alongside the abstract when tagged correctly	Currently published only by Future Science Group and Becaris Publishing journals
Guidelines and criteria	Outline mandated in Annex V of the EU CTR 2014/546, ² with official guidance in the Good Lay Summary Practice ¹³	Formats vary with author and journal preferences, but best practice and convention encourage text-based and concise PLS that are peer reviewed alongside the manuscript, at a minimum ^{3,24–26}	Author guidelines available from Future Science Group ^{4,27}

Abbreviations: CTIS = Clinical Trials Information System; EU CTR = European Union Clinical Trials Regulation ; PLS = plain language summaries; PLSP = plain language summary of publication

expert readers. In this article, we have chosen to align with the terminology used in the official GLSP guidance.¹³

Objective

The aim of this landscaping analysis was to outline the variation in terms used specifically to refer to lay summaries across a selection of pharmaceutical companies, with consideration given to geographic region, and to provide clarity on terminology and distinctions between the three accessible language document types.

Methods

As a sample selection of the pharmaceutical industry, we performed a landscaping analysis by identifying 38 full and affiliate corporate members of EFPIA²¹ and 43 pharmaceutical companies that were ranked in the Bioethics International 2021 Good Pharma Scorecard for transparency and data sharing.^{22,23} Accounting for overlap of pharmaceutical companies listed in

both sources, this gave a final sample size of 58. We then conducted a manual search of official company websites for mentions of lay summaries and recorded the variations of terminologies in use. This search was performed on August 10, 2022.

To aid in clarifying distinctions between accessible language document types, we used readabilityformulas.com to compare the readability of similar-length excerpts of an example lay summary and an example PLS for comparison. These two examples were selected from within oncology, based on the authors’ involvement in the drafting and development of the documents.

Results

Document distinctions and example readability comparisons

Clarification of document distinctions is provided in Table 1.^{2–4,12,13,24–27} As an example of the differences in readability and target reading

ages between lay summaries and PLS, selected excerpts^{28,29} showed the readability consensus was 12–14 years old for the lay summaries and 18–19 years old for the PLS (Figure 1,²⁸ Figure 2²⁹).

Regulatory lay summary terminology landscaping

The landscaping analysis revealed that among the 58 pharmaceutical companies whose websites were searched, 56.9% (n = 33) had information on lay summaries publicly available on official websites, whereas 43.1% (n = 25) did not. Of those with publicly available information, there were 22 different terms for lay summaries in use, with 15 companies using two or more different terms for the same document type (Table 2). The two most common terms in use were “plain language summary”, with 12 instances of companies using the term to refer to lay summaries, followed by “Lay Summary”, with eight instances of use. Additionally, the terms

PLS and standalone PLSP may be used interchangeably.

When considering the geographic region of each pharmaceutical company’s global headquarters, there appeared to be greater online transparency of lay summary practices among European companies (regardless of EU membership status) and Asian companies, compared with North American companies. There were also differences in terminology preferences, with “plain language summary” being the term most commonly used by North American and Asian companies, “lay summary” by European companies in EU member countries, and “clinical trial results” by European companies in non-EU member countries. European companies in EU member countries exhibited the greatest variation in terms used for lay summaries (Table 3).

Discussion

Our results reveal a considerable lack of clarity and precision in terminology relating to communications around lay summaries, demonstrating a need for standardisation. The lack of definition and precise description may be particularly problematic and lead to confusion for patients, participants, and non-expert readers when trying to find lay summaries online. Additionally, many of the individual company websites, portals, and databases for indexing their lay summaries were not user-friendly. Some were not clearly labelled and some took multiple clicks to reach the final documents, creating a long and

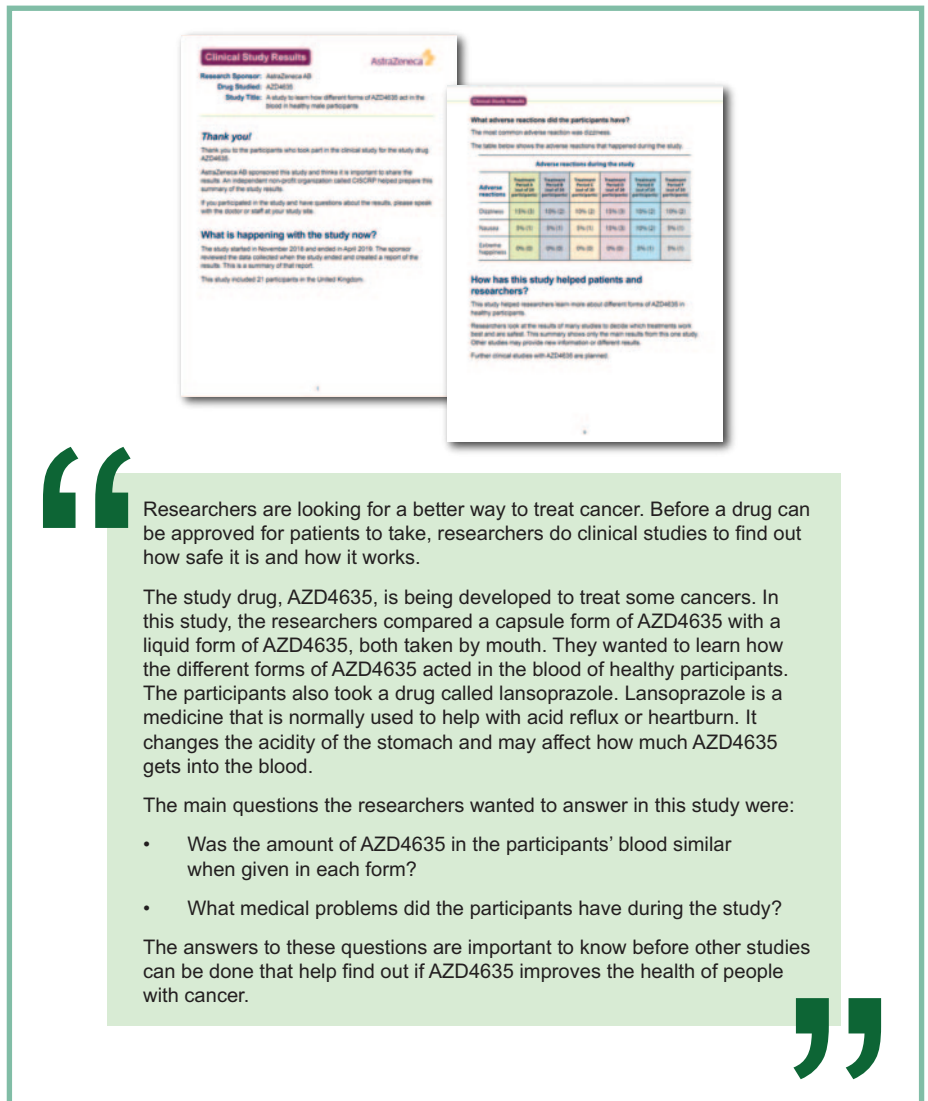


Figure 1. Visual example and excerpt of a lay summary²⁸

Table 2. Terms for lay summary in use

Term for lay summary	Number of pharmaceutical companies using the term	Term for lay summary	Number of pharmaceutical companies using the term
Plain language summary	12	Study results summary	1
Lay summary	8	Plain language summary of trial results	1
Layperson summary	3	Plain language summary of clinical trial results	1
Clinical trial results	3	Plain language summary of results	1
Clinical trials results summaries	2	Plain language study results summary	1
Clinical study results	2	Plain language clinical result summary	1
Trial results summary	2	Lay language summary	1
Lay summary results	2	Clinical trial summary	1
Summary of clinical trial results for laypersons	2	Plain language results	1
Lay readable summary	1	Clinical results summary	1
Trial summaries for patients	1	Summary of clinical study results	1
Summary results in plain language	1	Lay patient summary	1
Summary of clinical trial results	1		



Figure 2. Visual example and excerpt of a PLS²⁹

sometimes complicated process to find the relevant information. Although the manual searches of company websites yielded 43.1% (n = 25) with no mention of lay summaries (or related terms) publicly available online, we are

personally aware of at least two of these companies that are distributing lay summaries directly to their clinical trial participants. This indicates unclear online transparency policies that do not necessarily reflect real-life practices;

The official Good Lay Summary Practice guidelines acknowledge this confusion in terminology and advise sponsors to distinguish between these document types, indicating that “plain language summary” refers specifically to publication-associated PLS and not regulatory lay summaries.

it is unknown how many of the other companies with no publicly available information online fall into this same category. With regard to variations by geographic region, we believe some of these may possibly be attributable to cultural differences in the connotations of the words “lay” and “plain” and to potential interpretations of “lay” being considered condescending or patronising; we are anecdotally aware of examples of this.³⁰ Such variation may also be related to only one geographic region (European, EU member countries) having explicit legislation that requires and outlines Lay Summaries, whereas others have only guidance or even no input from regulatory bodies.

The limitations of our analysis firstly include the manual aspect of the search, which may have introduced human error. Although automation would have systematised the methods, the lack of consistent language referring to Lay Summaries and the different locations across pharmaceutical company websites meant that human interpretation was needed in the search. Secondly, the selection of the methods of the sample cohort likely introduced biases and may not be representative of the wider industry; EFPIA member organisations are known to have improved rates of results reporting compared with the industry as a whole.³¹ Further, results reporting of unregistered epidemiological and observational studies and medical devices are also not represented by this cohort. Thirdly, the limited global representation of the sample selection did not allow for robust conclusions to be drawn for geographic regions beyond Europe and North America and focused on English language lay summaries. Future analyses should include a larger sample size with greater

Table 3. Variation in terminology by geographic region

Geographic region	Number of pharmaceutical companies	Number of pharmaceutical companies with lay summary information publicly available	Number of different terms for lay summaries in use	Most common term for lay summaries in use (count)
North America	24	10 (41.7%)	11	Plain language summary (4)
Europe (EU member countries)	18	12 (66.7%)	13	Lay summary (5)
Asia	8	6 (75.0%)	6	Plain language summary (4)
Europe (non-EU member countries)	6	4 (66.7%)	7	Clinical trial results (2)
Middle East	1	1 (100%)	1	Plain language summary (1)

representation from outside Europe and North America, as well potentially as broadening the scope of the sponsors to include biotech companies and academic funding bodies.

Overall, due to the sheer range of terminology in current usage, there is likely substantial confusion regarding accessible language document types, leading to overlapping and ambiguous language to refer to different, non-interchangeable documents. The official GLSP guidelines acknowledge this confusion in terminology and advise sponsors to distinguish between these document types, indicating that “plain language summary” refers specifically to publication-associated PLS and not regulatory Lay Summaries. It is also acknowledged that these distinctions only exist in reference to document types, whereas the adjectives “lay” and “plain” as they relate to the level of accessibility of language are considered to be synonymous.¹³ Medical writers and medical publications professionals need to be aware of these differences and ensure precision when referring to regulatory lay summaries, publication-associated PLS, and standalone PLSPs to avoid further confusion. The medical writing and medical publications profession – including EMWA and other medical writing and publication professional societies, organisations, regulators, and pharmaceutical trade groups – is in a strong position to educate,

Medical writers and medical publications professionals need to be aware of these differences and ensure precision when referring to regulatory Lay Summaries, publication-associated PLS, and standalone PLSPs to avoid further confusion.

explain, and encourage accuracy of terminology. Regulatory bodies such as the EMA could also provide more explicit guidance and communications to streamline terminology. Ultimately, we believe collaborative efforts from across the pharmaceutical industry and adjacent industries, such as medical communications and medical devices, are needed to standardise terminology in order to aid clarity and comprehension and to promote appropriate usage.

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Data availability statement

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

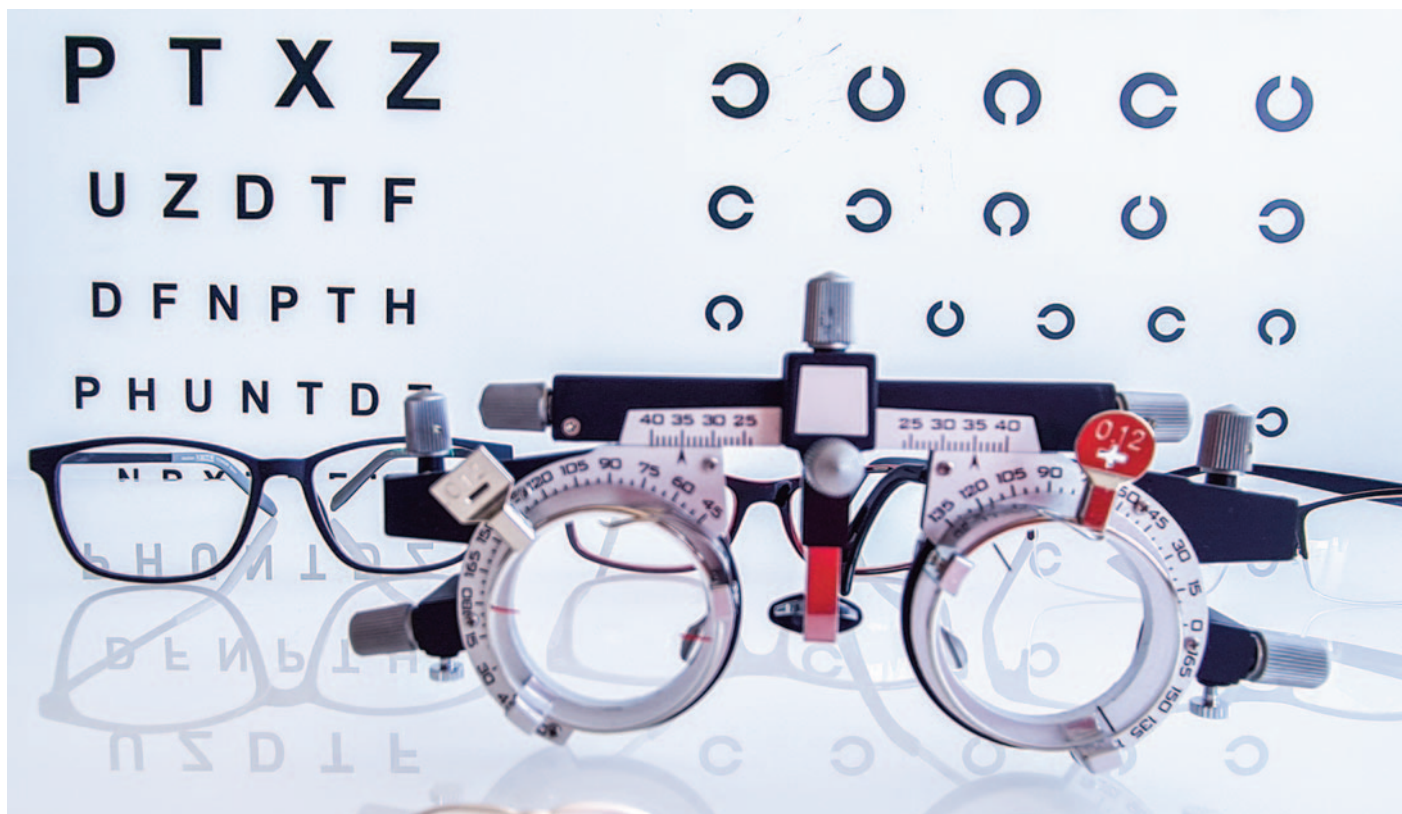
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Enabling people with disabilities:

Creating accessible electronic documents

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Abstract

Rather than equating disability with personal identity, we can better understand disability as the consequence of disabling environments. This alternative view suggests that changing the environment can enable people with sensory, motor, and cognitive/learning impairments to participate more fully in everyday life. This view is also consistent with the goal of medical writers to be aware of their audience (i.e. their relevant abilities/skills, cultural beliefs, and knowledge base). To achieve this goal, we must strive to create electronic documents that can be perceived and understood by people with a variety of impairments.

The main objectives of this article are:

- to increase awareness of the difficulties caused by inaccessible electronic documents
- to describe guidelines for creating accessible electronic documents
- to provide resources for continuing education

I am completely blind. I face obstacles every day owing, in part, to electronic documents designed primarily for those with vision. For example, I cannot use charts that convey information through colour. I cannot participate in conferences when session links are not clearly identifiable with screen readers.

People with other sensory, motor, cognitive, and learning impairments often face similar obstacles caused by electronic documents (e.g. text files, videos, podcasts, web pages, etc.) designed for those without impairments. Some



people cannot use a mouse because they cannot control their movements. Others cannot hear the sound on a video. Still, others cannot hold a lengthy sentence in mind long enough to make sense of it. Creating accessible electronic documents permits people with disabilities to participate more fully in everyday life.

The goal of creating accessible electronic documents may seem daunting. But by following some simple guidelines, your work can help to improve the lives of people that you might not be reaching as effectively now.

What is a disability?

To develop guidelines for creating accessible electronic documents, we must be clear about

what counts as a disability. According to the International Labour Organization:¹

“Virtually every existing definition of disability ... mirrors a legal system and draws its meaning from this system. A definition of disability that can be applied universally is impossible, since every country, and practically every administrative body, works with different concepts of disability.”

This conclusion seems justified when we consider the many questionably related conditions that have been called disabilities, such as paraplegia, blindness, autism, diabetes, HIV, arteriosclerosis, dyscalculia, and schizophrenia.²

“Disability results from impairments of body



- **Auditory:**⁶ Deafness and hearing loss
- **Motor:**⁷ Any condition affecting movement (e.g. spinal cord injuries).

In this article, I describe guidelines for creating accessible electronic documents. Unfortunately, I do not have the space to discuss the development of accessible websites. But at the end, I list resources that provide additional guidelines, examples, and educational opportunities.

Creating accessible text documents

This section focuses on documents created with Microsoft Office.⁸ I discuss here only a few sets of guidelines. Please see the references and resources at the end for links to additional information.

Creating accessible headings

Headings are essential to creating accessible text documents: people often scan headings to get an idea of the topics to be addressed.⁹ Headings are organized hierarchically into levels, with each level having its own distinct visual appearance.

Writers often create headings manually by altering font size, font colour, indentation and other characteristics to give the heading a distinct appearance. Headings made in this way, however, create difficulties for people like me who use screen reader software, which converts text or images into speech output. I use keyboard commands to display a list of headings on a page. When I do this for headings created manually, I get the following message: “There are no headings in this document.” My screen reader does not recognise headings created manually.

Screen readers can read headings created with the Styles Gallery in Microsoft Office.⁹ To create a heading, place the cursor in the text to be formatted, go to the Styles Gallery in the Home tab, and click the desired header (see Figure 1).

You should not skip heading levels (unless the style guide you are using requires you to do so). For example, don't skip past Heading 2 just because you prefer the look of Heading 3. Changing the appearance of a heading is a simple matter (see instructions in Reference 9).

Headings are essential to creating accessible text documents.

Creating accessible links

Links should be easily identifiable. The default style for links is underlined blue text on a white background. Even people with low vision can see these links. But screen reader users cannot.

To be identifiable with screen readers, links need to be labelled with hypertext.¹⁰ Hypertext is needed because screen reader users often call up a list of links on a page. If the links are not labelled or if they are labelled with “click here” or “link”, screen reader users cannot quickly find the links they need.

The links should be labelled with hypertext that clearly indicates the purpose of the link. For example:

- Hypertext Example 1: Article on Links and Hypertext
- Hypertext Example 2: Article on Contrast and Colour Accessibility.

The hypertext labels in these examples are:

- Concise (i.e. brief yet comprehensive)
- Descriptive (i.e. summarise the specific purpose of the link)
- Distinctive (i.e. unique, not repeated in other links).

Lastly, links should not be labelled with URLs – these are not brief or descriptive. They can also be difficult to understand with screen readers.¹⁰

Creating accessible images

Images are helpful to most users. But they can create difficulties for people with visual impairments unless the content of images is fully described in alternative text (alt text).¹¹ Alt text should be included for any image in an electronic document, such as a blog post, pdf, Powerpoint slide, etc. Figure legends in journal articles might include a description that would meet the requirements of alt text.

To write appropriate alt text, two questions need to be answered:

1. What is the purpose of the image?
2. Given this purpose, what is the best way to describe its content fully and accurately?

To answer these questions, we need to look at the document text introducing the image. Let's look at an example.

A human karyotype is an image showing the

or mind that negatively impact social functioning.”

One feature shared by many definitions is the notion that disability results from impairments of body or mind that negatively impact social functioning (e.g. occupational functioning).¹ The impairments usually addressed in the accessibility literature include the following:³

- **Cognitive/learning:**⁴ Difficulties with cognitive functions such as memory, attention, reading, and numeracy
- **Visual:**⁵ Blindness, low vision, and colour blindness

Disability results from impairments of body or mind that negatively impact social functioning.

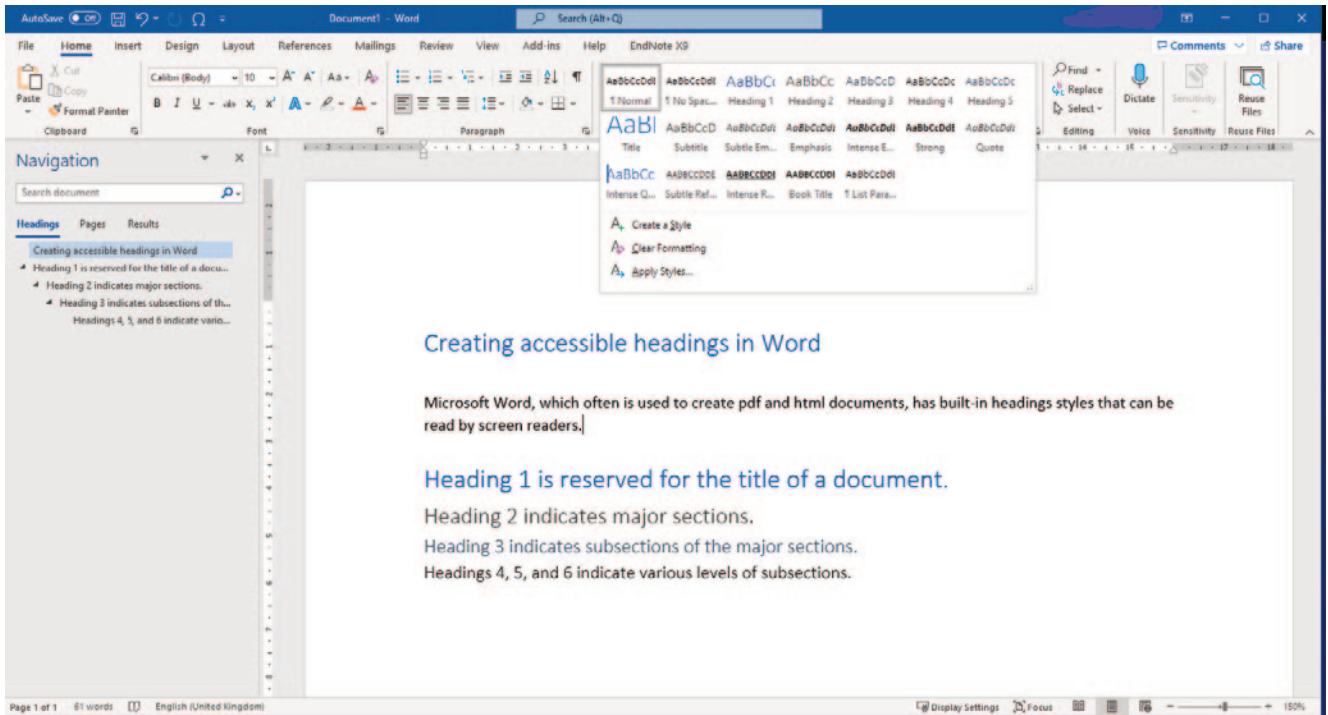


Figure 1. A screenshot of the headings style gallery in Microsoft Word

complete set of 23 pairs of replicated chromosomes during cell division. The 23rd pair is associated with sex development: females have two large X chromosomes and males have an X and a tiny Y chromosome. Some “disorders of sex development” are caused by inheriting an atypical number of sex chromosomes (see Figure 2).

Which of the following would be the best alt text for Figure 2?

- **Option 1:** A karyotype of a male with an extra X chromosome
- **Option 2:** An image of an XXY male
- **Option 3:** A karyotype of a male with Klinefelter’s syndrome (47, XXY)
- **Option 4:** A karyotype of a male with a disorder of sex development (an XXY male).

Alt-text should describe an image briefly, but also fully and accurately.

I chose the first option. To see why, let’s look at some guidelines for creating alt text.

- Alt text should describe an image briefly but also fully and accurately. In most cases, a short sentence or less is sufficient. All four options meet this guideline.
- Do not include words like “image of” or “graphic of”. By default, the words “image” or “graphic” are included in alt text. The second option – “an image of an XXY male”– would

have been a good choice if it hadn’t included the words “image of”.

- Alt text should describe the appearance of objects in the image. The third option includes novel information the name of the syndrome, which cannot be inferred by non-experts from the image alone.
- Alt text needs to be brief so that screen reader users do not have many images with long alt text to read through. Thus, alt text should describe the contents of an image without repeating any document text near the image.

The fourth option fails to meet this guideline because it includes the words “a disorder of sex development”.

I chose the first option because it briefly describes the image fully and accurately without adding novel information or repeating information presented in the document text.

Although simple images can be described in a few words, complex images contain more information than can be described in the alt-text field.¹² Examples of complex images are bar charts summarizing data, graphs, and maps. To make the information in a complex image available to people who cannot see it, the alt text needs to be presented in other ways. For instance, the data

presented in a bar chart can also be presented in a simple data table at the end of an article. A link to the data table could be placed next to the bar chart.

Depending on its purpose, a photograph may be a complex image. For example, NASA is including lengthy alt text for the images taken by the James Webb Telescope.¹³

Creating accessible tables

Screen readers are able to read simple data tables that have no merged, split, or empty cells. Tables with multiple row or column headers should be avoided as they cannot easily be read with screen readers.¹⁴

Creating accessible video and audio documents

Presentations that include audio or video components (e.g. conferences, podcasts, YouTube videos) can create challenges for people with auditory and cognitive/learning impairments. To accommodate people facing these challenges, spoken content should be converted to textual narratives. The textual narratives can take one of two forms:

- A caption is text that describes what is being said in a video presentation. The text appears at the top or bottom of a screen (i.e. computer, mobile device, television, or movie screen)
- A transcript is the entire textual narrative of an



A karyotype of a male with an extra X chromosome.

Cell No: 003

Figure 2. An example of a simple image.

The alt text for a simple image should be no more than a short sentence.

audio/video presentation. The text appears in a separate document.

Creating captions

Captions for live presentations can be created with “voice writing” (respeaking) or communication access real-time translation (CART).

In voice writing (respeaking), the person producing the captions (the voice writer) listens to a presentation and quickly repeats a block of words,¹⁵ along with punctuation, to create a recording that is processed by speech recognition software. The software produces the captions. While listening to the next block of spoken words, the voice writer tries to correct any errors in the captions. For each block of spoken words, this process takes about 4 to 10 seconds. The length of time it takes to produce corrected captions is called the ‘latency’.

The greater the focus on correcting errors, the longer the latency. Long latencies can be distracting to users. One way to avoid long latencies is to have a time delay on the presentation, so that the voice writer hears the presentation’s audio track before the audience

does. Another way is to use paraphrasing, which, of course, reduces accuracy.

CART captioners convert spoken language into text by using a stenotype machine.¹⁶ The text is generated by specialised software. The CART captioner uploads a database of words that the programme uses to create the captions. The goal of captioners is to achieve at least a 98% accuracy rate.

Creating transcripts

Voice writers and CART captioners can create transcripts. But you can create transcripts yourself. For example, with Microsoft Word 365, you can dictate directly into a microphone and the speech recognition software will transcribe the spoken words.¹⁷ You will need to proof the transcript to correct errors. You also can transcribe an audio file by uploading the file to Microsoft Office 365 Online. Again, the transcript needs to be proofed.

Conclusions

Accurately estimating the number of people in a population who have a disability is not possible

because no universal definition of ‘disability’ exists and people often must self-identify as disabled.¹

It seems clear, however, that a significant proportion of the general population has one or more sensory, motor, or cognitive/learning impairments, especially in older age groups. Thus, to include the widest possible audience, medical writers need to focus on creating accessible electronic documents. This goal may be especially important in the area of patient education.

The guidelines discussed in this article are a good start. But these guidelines are just a beginning. The resources listed below provide more information.

Resources

- **Make your Word documents accessible to people with disabilities**

This page contains information about creating accessible headings, images, tables, links, lists, and colour contrast.⁸ It also contains directions for using the Word Accessibility Checker.

● **WebAIM Articles**

<https://webaim.org/articles/>

This page has links to articles about creating accessible headings, links, lists, and much more. It also contains information about creating accessible web pages. The articles are very informative.

● **WebAIM Accessible Documents Course: Word, PowerPoint and, & Acrobat**

<https://webaim.org/training/docs/>

This online, 5-week course will teach you the fundamentals of creating accessible Word, PowerPoint, Excel and Adobe Acrobat (PDF) documents. WebAIM also has other training events. You can learn more about these events by going to their website.

● **Digital Accessibility Foundations Free Online Course**

<https://www.w3.org/WAI/fundamentals/foundations-course/>

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The June 2023 edition



Freelancing

Freelancing is becoming an increasingly popular option for medical writers and communicators, but it's not as straightforward as finding a few clients and getting paid. There's so much more involved. Freelancers are mini business owners and to be successful, you need a plethora of skills, be self-motivated, driven, and adaptable and take the highs with the lows. In this issue, the authors will discuss what options are out there for freelancers, how to get started, and all the challenges that you may come across. Freelancing can be a lucrative business but addressing all the factors is key to being successful.

Guest Editors: Laura Kehoe and Satyen Shenoy

How FAIR are pharma publication data?

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Abstract

Sharing research data increases reusability, reduces waste, supports reproducibility and promotes innovation. In medical research, sharing data also promotes transparency and access to information relevant to patient care.

While important advancements have been made in data sharing by regulators, the pharmaceutical industry and academic publishers, several barriers remain. Some of these barriers stem from concerns about data privacy and patient safety, but others are related to the need for confidence in sharing, which can be improved through agreed standards and systems for reuse of research data, including the application of FAIR (findable, accessible, interoperable, and reusable) principles and the overarching principle of “as open as possible, as closed as necessary”.

Medical writers, who are key links between the pharmaceutical and publishing industries, can contribute to making pharma publication data FAIRer. They also have an important role in educating others about the path to more findable, accessible, interoperable, and reusable data.

Introduction

Good data management is essential in a healthy research ecosystem. Greater access to appropriately shared data increases reusability, reduces waste of resources, supports reproducibility, and promotes innovation.

The landscape of healthcare data sharing has changed considerably over the past decade. Registration of clinical trials and disclosure of the results of many types of trials are mandatory in

the US, the EU, UK and other countries.^{1–2} Publicly available lay language summaries of clinical trials are also mandatory in the EU.² The data sharing policies of most pharma companies adhere to the principles and positions developed by industry bodies such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).^{3–5} These commitments include publishing all human trial results, including “negative” results, in appropriate peer-reviewed journals.

While the principles of registering and disclosing clinical trial results are now widely accepted, even if incompletely adopted,⁶ sharing individual patient

data is more complex. The principles of open science and open data championed by many funders, regulators, and national and international policy organisations have to be balanced with responsibilities towards patient privacy, legal consent, data ownership, and intellectual property.^{7–21}

The use of repositories that meet data sharing requirements while protecting individual privacy can help ensure that research data are “as open as possible, as closed as necessary”. This statement is often associated with the FAIR principles, which state that research data should be findable, accessible, interoperable, and reusable by both humans and machines (Table 1).^{22–23} The FAIR principles

Repositories that meet data sharing requirements while protecting individual privacy [ensure] data are “as open as possible, as closed as necessary”.



seek to address the rising need to strengthen the infrastructure supporting the reuse of scholarly data, so that data use can be automated and standardised. Importantly, FAIR principles apply to both the raw data and to their associated metadata – the data that enable discovery, linkage, and reuse across multiple systems.

The FAIR principles are domain-agnostic, and can be applied to many types of data including clinical trial and healthcare data.²⁴ As medical writers have key roles in communicating research findings, and preparing data to be shared, they are well placed to influence data sharing best practice in publications and promote FAIR data sharing efforts where possible.

FAIR principles in medical publishing

Most medical publishers have endorsed the International Committee of Medical Journal Editors (ICMJE) recommendations on data sharing.^{25–26} Authors of articles that report clinical trials must submit a data sharing

statement with their manuscript and, for all trials that began enrolment after January 1, 2019, they must also include a data sharing plan when registering the trial.

Some publishers have also endorsed the FAIR principles, at least for a subset of their journals (Table 2), and more journals may join them as the support for FAIRer data grows.

How findable are pharma publication data?

Findability refers to how easily identifiable published data are. Table 1 highlights the four aspects of this principle.

Aggregated and summary data produced by pharma companies are fairly easy to discover through platforms such as ClinicalTrials.gov³¹ and publications. The link to the raw data used to produce these summary outputs, however, is not always obvious.

Pharma companies often deposit patient-level data from clinical trials on repositories that

are used by multiple companies or institutions. These repositories include Vivli,³² ClinicalStudyDataRequest.com,³³ and the Yale University Open Data Access (YODA) Project.³⁴

On Vivli, for example, all data sets are assigned a unique digital object identifier (DOI), in line with the F1 criterion. Furthermore, Vivli uses patient population, intervention, comparison and outcomes (PICO) searches designed to yield more precise search results from broader clinical questions to optimise findability. Vivli has a process to extract and curate metadata from source documents and other indexing platforms, although the current catalogue does not yet enable highly precise search and browse functionality.

Some pharma companies also use company-specific databases to hold and share some types of data, such as non-interventional trial data. In these cases, it is often unclear whether F1–F4 criteria are being met.

Journals with more stringent data sharing



Table 1. The FAIR principles²²

Findable

- F1. (Meta)data are assigned a globally unique and persistent identifier.
- F2. Data are described with rich metadata (defined by R1 below).
- F3. Metadata clearly and explicitly include the identifier of the data they describe.
- F4. (Meta)data are registered or indexed in a searchable resource.

Accessible

- A1. (Meta)data are retrievable by their identifier using a standardised communications protocol.
 - A1.1 The protocol is open, free, and universally implementable.
 - A1.2 The protocol allows for an authentication and authorisation procedure, where necessary.
- A2. Metadata are accessible, even when the data are no longer available.

Interoperable

- I1. (Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
- I2. (Meta)data use vocabularies that follow FAIR principles.
- I3. (Meta)data include qualified references to other (meta)data.

Reusable

- R1. (Meta)data are richly described with a plurality of accurate and relevant attributes.
 - R1.1. (Meta)data are released with a clear and accessible data usage license.
 - R1.2. (Meta)data are associated with detailed provenance.
 - R1.3. (Meta)data meet domain-relevant community standards.

policies (Table 2) require data to have a persistent identifier, meeting FAIR criterion F1. They also recommend that data are properly labelled and described, and that they are associated with the appropriate metadata for the kind of data being shared, supporting criteria F2–F3. Many of these journals also recommend data deposition in a searchable repository, supporting criterion F4.

A key role of medical writers is to prepare the metadata and documentation needed by secondary users of research data. They may also be asked to advise on the choice of repository for specific, less common types of data. By understanding that FAIR requirements also extend to metadata and by understanding the characteristics of a FAIR-compliant repository, writers are instrumental in increasing the FAIR findability of data associated with publications.

How accessible are pharma publication data?

Accessibility supports data reuse and integration. Importantly, accessible data are not the same as

open data. Data that are not in the public domain but that are accessible to qualified researchers, after evaluation by a review panel, are not open but can be FAIR. Two FAIR criteria address the principle of accessibility (Table 1).

Criterion A1 refers to the ability of retrieving data or metadata using an open, free, and standardised protocol that also includes an authorisation and authentication process when necessary. Following regulatory and industry guidelines, pharma companies have committed to deposit summary results for eligible trials conducted in the US on the ClinicalTrials.gov platform³¹ and for all trials conducted in the EU on the EudraCT platform,³⁵ within specified time frames. The next step towards accessibility is to continue to increase the rates of clinical trial data sharing on these platforms by both pharma and academic researchers.

Increasing the accessibility of patient-level data is a harder issue to tackle. Pharma companies have justifiable concerns about data privacy and patient safety. They must also overcome hurdles associated with the costs of data management and curation, and the potential delays in publication timelines that may result from preparing data to be shared in appropriate formats and deposited in specific platforms.

However, even heavily protected and private data can be FAIR, if the metadata clearly states the data privacy requirements restricting access to data.²² The YODA repository provides detailed information on frequent reasons data access requests may be denied, such as restrictions arising from informed consent agreements with patients.³⁶

Vivli stores data for up to 10 years and maintains the persistent DOI associated with the description of a data set even after the data set is

Unusual or complex data sets might be more difficult to standardise owing to the time and costs involved in data curation.

Table 2. Publishers' data sharing policies

Policy type	Data sharing	Data citation	Data availability statement	Peer review of data	Licence applied to data set	FAIR standards for data
Encourages data sharing	Encouraged	Encouraged	Optional	Optional	Author's choice	Optional
Encourages data sharing with evidence	Encouraged	Encouraged	Encouraged	Optional	Author's choice	Optional
Expects data sharing	Encouraged	Encouraged	Required	Optional	Author's choice	Optional
Mandates data sharing	Encouraged	Required	Required	Optional	Author's choice	Optional
Mandates data sharing and peer review of data	Required	Required	Required	Required	Author's choice	Optional
Mandates data sharing and peer review of data, which must be open	Required	Required	Required	Required	CC0, CC BY or equivalent (open data)	Optional
Mandates data sharing and peer review of data, which must be open and fully FAIR	Required	Required	Required	Required	CC0, CC BY or equivalent (open data)	Required

The table shows an overview of data sharing policies, combining information from four publishers: Taylor & Francis,²⁷ Springer Nature,²⁸ Wiley,²⁹ and the Public Library of Science (PLOS).³⁰ Springer Nature and Wiley have four tiers of data sharing for different journals, whereas Taylor & Francis has five tiers. PLOS has a single data sharing policy for all its journals.

CC0, Creative Commons Zero; CC BY, Creative Commons Attribution.

no longer accessible,³⁷ supporting the A2 criterion. Whether metadata are accessible after the data are no longer available in other repositories is less clear. Unification and standardisation of repository accessibility criteria could help to increase FAIRness.

Journals that mandate data sharing often recommend authors use an external repository, which can help meet A1.1 and A1.2 criteria. Journals do not typically require publication-associated data to meet criterion A2, although publications in some Taylor & Francis journals must meet fully FAIR criteria.²⁷

At the bridge between pharma research and publishers, medical writers are uniquely positioned to help pharma companies prepare even protected data in the most accessible way possible and support authors with information they may need to overcome data accessibility barriers.

How interoperable are pharma publication data?

Interoperable data can be integrated with other data, applications, or workflows for analysis, storage, and processing. Table 1 shows the three criteria within this principle.

Pharma companies are making increasing efforts to structure and annotate their data in a way that enables and facilitates interoperability and reuse.³⁸ Enabling interoperability of data from multiple sources is also one of the main stated goals of the Vivli platform.³² Despite these advances, it is often difficult to reuse and reanalyse data across different systems, even when the data are accessible. The COVID-19 pandemic, which highlighted the healthcare benefits of data sharing at scale, spurred several pharma voices to call for greater efforts to increase interoperability of data across the industry.³⁹

Medical writers can advance this FAIR principle by helping to produce data and metadata in standardised formats and with controlled vocabularies that make them easy to integrate in multiple workflows, users and systems. Using standard file types, machine-readable text rather than PDFs and open-source software rather than proprietary software for storing data (for example, .csv rather than Excel) can help, as well as clearly annotating table headings, scales and other elements that make the data easy to reuse across systems. In addition to preparing data for publications, medical writers can also help to promote repositories that favour interoperable data.



Photo: Freepik

How reusable are pharma publication data?

Publishing (meta)data in a manner that increases its use (ability) for the community is the primary objective of FAIRness.²² This FAIR principle has one criterion with three components.

Criterion R1.1 states that (meta)data are released with a clear and accessible data usage licence. The extent to which this criterion is being met across all pharma publication data is unclear, but the Pistoia Alliance, an industry collaboration, does recommend that there are always human-readable and machine-readable pointers in the metadata to the data owner or license.³⁸

Several journals, including the most prestigious medical journals, request that protocols and statistical analysis plans are available for clinical trial publications, and there is evidence that researchers, including pharma companies, are complying with this requirement.⁴⁰ In addition, many publishers require data citations (Table 2), in alignment with the Joint Declaration of Data Citation Principles.⁴¹ These efforts support criterion R1.2, which recommends that data and metadata are associated with their provenance.

The data sets published as part of a pharma publication typically adhere to domain-relevant community standards, in line with criterion R1.3.

Those data sets that are submitted to a known repository do so as well, as the requirements for data submission and entry into these platforms encourage standardisation. However, unusual or complex data sets might be more difficult to standardise owing to the time and costs involved in data curation. Recognition of the value of data curation and an appropriate set of incentives for this type of work could promote further adherence to R1.3.

Conclusion

Open Pharma exists to improve the transparency, accountability, accessibility, and discoverability of pharma publications;⁴² this ultimately has an impact on patient care. Responsible data sharing supports all of these goals and can increase trust in the pharma industry and its research outputs.

Responsible data sharing recognises the public health benefits of access to reusable data, but also the rights of patients and other people involved in clinical research. To make data available while protecting the personal information of research participants, researchers may need to anonymise or randomise data, and even omit data that, when shared, would be likely to reveal a patient's identity. Any data sharing increases transparency, but not all data sharing enables reproducibility and reuse.

While pharma publication data cannot always be open, for legal, privacy and safety reasons, there's an opportunity to make them FAIRer. Improvements are in progress but there is still much to be done, including: standardisation of data structure, metadata and systems to enable interoperability; unification of policies across regulators, publishers, pharma companies, and other research data producers; clearer guidance about metadata that advances all four FAIR principles while decreasing the burden of data management; and education of authors on the benefits of FAIRer data for their research.

Medical writers, linking academic authors, pharma companies, and publishers, are in an influential position to drive these changes.

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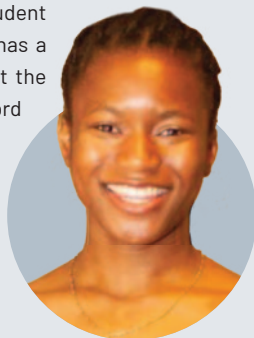
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Wait! What? There's stuff missing from the scholarly record?

Why more needs to be done to include grey literature

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Abstract

The scholarly record is an ever-evolving network – or graph – of truth assertions on which each discipline bases its discussions, and against which each discipline measures its progress. But what if the scholarly record is missing a significant number of truths? In this article, you will learn about the scholarly record, what it comprises, and what's missing. You'll discover that the volume – and value – of what's missing, called grey literature, has been. Grey literature is a costly asset that's going to waste.

1 *I have seen further it is by standing on the shoulders (sic) of Giants.*"

So wrote Isaac Newton to his rival, Hooke, in 1675. Newton wasn't the first to notice the importance of building on the works of others. Five hundred years earlier, Bernard of Chartres is quoted as saying "We see more and farther than our predecessors, not because we have keener vision of greater height, but because we are lifted up and borne aloft on their gigantic stature". It seems to me that the collective noun for giants' shoulders should be a "scholarly record" since this comprises "an ever-evolving network – or graph – of truth

Grey literature is a costly asset that's going to waste.

assertions"¹ "upon which each discipline bases its discussions, and against which each discipline measures its progress."² Some go further to suggest the scholarly record can even frame the identity of an institution.³

If we agree that a giant's shoulder is worth standing upon, how do we ensure that their truth assertions are collected and preserved to ensure that we can indeed see further than our predecessors and measure progress? In short, how do we ensure that all giants are included in the scholarly record?

To qualify for inclusion in the scholarly record, Dougherty proposed that an item must advance or summarise knowledge, have an identifiable author, be issued through an academic publisher, be catalogued by a university library, appear in curated research databases, and belong to a recognised discipline.⁴ OCLC, a global library organisation, defines the scholarly record as "published outcomes of scholarly enquiry" such as "journal articles and monographs",⁵ even though others recognise that it has, of late, become much more diverse, encompassing protocols, code, and data.⁶

Let's put these definitions to the test. Let's start with the first published output on Covid-19.

On December 31, 2019, the Wuhan Municipal Health Commission published a briefing on "a pneumonia epidemic situation" and informed the WHO China Country Office. On January 5, 2020, WHO published a briefing on its website.⁷ These publications marked the start of the Covid-19 pandemic and future generations of scholars and students might well want to study them. Yet, according to the definitions above, they fail to qualify for the scholarly record because they were

not issued by a scholarly publisher nor did they appear in the form of a journal article or monograph. Today, the link to the Wuhan briefing returns a message of "404 – page not found". I don't know if this content is simply offline or whether it is now lost. Either way, it is no longer easily accessible and, if it's lost, shows why maintaining the scholarly record matters.

A similar story can be told about the beginning of HIV-AIDS. On June 5, 1981, the US CDC published an article in its *Morbidity and Mortality Weekly Report* (MMWR) describing rare lung infections in five young men in Los Angeles.⁸ The CDC isn't an academic publisher and MMWR isn't a journal – so, again, in theory, this report doesn't qualify for the scholarly record.

Let's tack away from medicine for a moment. In 2019, two professors from University College London and King's College London published a podcast that discussed two working papers authored by economists from the Bank of England, University College London, Cambridge University, London School of Economics, and University of Warwick. The papers had made headlines in the UK press, including the *Financial Times*, and were cited in a blog run by a professor from University of London's Royal Holloway. This blog has a larger following than most journals. None of these items, including these high-impact papers, passed through the hands of an academic publisher. Hunting for them in journals, subject databases, and library catalogues will be in vain because, as with the previous examples, this is content that was released into the wild without any thought as to how it might be captured for the scholarly record.⁹

These examples lead me to conclude that Dougherty and OCLC's criteria for what should

Criteria for what should be included in the scholarly record needs to be updated...



Bernard of Chartres on the shoulders of a giant

Wikimedia: Library of Congress, Rosenwald 4, Bl. 5r. Unattributed

be included in the scholarly record needs to be updated, not least to take into account how digital and Web 2.0 tools are changing the ways in which knowledge is being published, as the 2019 example illustrates.

In the analogue era, authors had little choice but to find a publisher for their works: the cost of self-publishing and dissemination in print was beyond the means of most. Equally, the cost of organising and maintaining archives meant that only institutional libraries could offer readers meaningful and useful collections of previously published materials. It's no surprise that publishers and libraries were central to the creation and maintenance of the scholarly record.

Behind the scenes, publishers worked with booksellers and agents to develop an efficient, near-global, supply chain that carried their publications to libraries around the world. To reduce administration costs and speed delivery, publishers, booksellers agents, and librarians co-developed processes (e.g. ICEDIS) and metadata standards with unique identifiers (ISBNs in 1969, ISSNs in 1975). In parallel, secondary services and catalogue systems emerged to tackle

(Grey literature) is hard to source and is missing from secondary discovery services.

the challenge of discoverability.

Since 2000, and with the transition to a digital era, both the supply chain and discovery services have been totally re-engineered. Today's standards include new persistent identifiers (PIDs) for content (DOIs) as well as for authors (ORCiDs) and their institutions (Ringgold).

This is not to say that all scholarly publications exist inside this publisher-secondary services-library "complex". They don't. Some institutions choose to self-publish because doing so has advantages, such as control over branding, timing, and pricing. Whilst some institutions, such as OECD and Brookings Institution, mimic

mainstream publishers, using the same metadata standards and supply chains to channel their publications to libraries, others, especially smaller organisations, don't. In eschewing publishing norms and supply chains, their content is hard to source and is missing from secondary discovery services – frustrating for librarians and readers alike. Their content is known as "grey literature".

Grey literature

In 1984, Wood coined the term grey literature to describe material "which is not available through normal bookselling channels ... leading to problems for the producers of secondary services, for librarians who wish to collect it, and for end users." Whilst noting that grey literature had a number of other distinguishing

Box 1: Prague definition of grey literature¹²

Grey literature stands for manifold document types produced on all levels of government, academics, business, and industry in print and electronic formats, that are protected by intellectual property rights, of sufficient quality to be collected and preserved by library holdings or institutional repositories, but not controlled by commercial publishers, i.e., where publishing is not the primary activity of the producing body.

Number of organisations founded per year 1946 - 2015

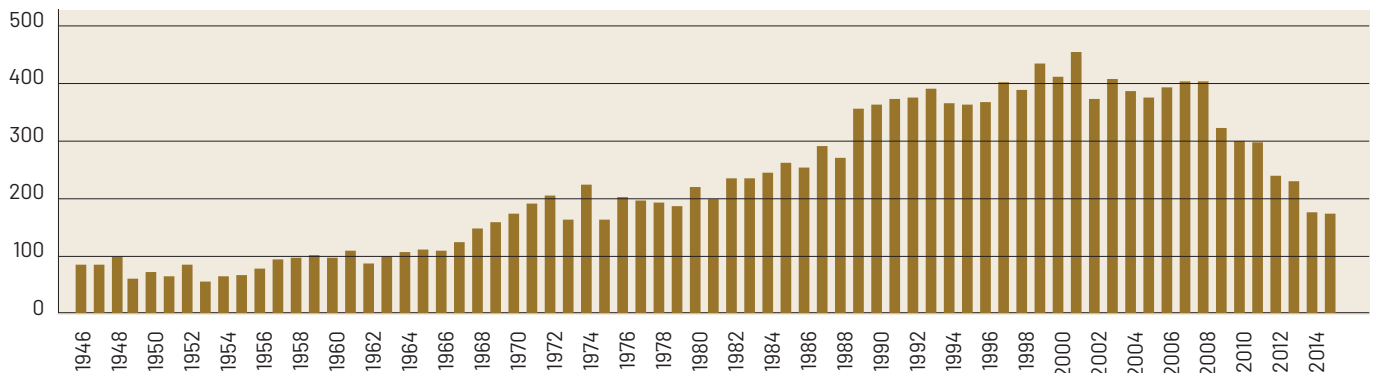


Figure 1. Number of NGOs and think tanks founded per year 1946–2015. Source: Policy Commons

characteristics – “variable standards of editing and production, poor publicity, poor bibliographic control, and poor availability in libraries”, Wood rejected as “mistaken” the belief that grey literature was “essentially ephemeral and of local interest only” because “it contains information likely to be of use to a considerable number of people”.¹⁰ It is often thought that, while useful, grey literature hasn’t been peer-reviewed. This is a big misunderstanding because, at least in policy, more than 60% is reviewed by experts prior to release.¹¹ So, no wonder that Wood reckoned grey literature “a costly public asset going largely to waste”. How costly? One estimate puts it at \$33BN a year.¹¹

Wood’s definition captured the essence of the challenge grey literature poses information professionals and readers: that this content is hard to find, capture, and use.

In 2010, the Prague definition (see Box 1) attempted to build on Wood – but the additions, to my mind, simply muddy the waters. Prague lists some producers (“government, academics, business, and industry”) but excludes others (e.g., third-sector organisations and NGOs). It adds the qualifier “commercial” to publishers, which fails to understand that any publisher, for profit or not, must behave in a commercial manner if it is – as Dickens’ Mr Micawber elegantly put it – to avoid financial misery. Moreover, the Prague definition is wrong to suggest that producing bodies where publishing “is not the primary activity” necessarily produce grey literature. Many universities and, as noted above, some IGOs and NGOs, run professional

publishing “presses” that publish in a manner identical to houses like Elsevier and Springer and their publications are as easily found in secondary services and obtained by libraries and users alike via standard supply chains.

Wood was right in 1984 and, as I will show, his definition is just as valid in today’s digital era. However, he would probably be shocked by the scale of today’s public asset going to waste. That’s because there is a growing amount of scholarly and professional content being published outside mainstream supply chains, which – as Wood would recognise – leads to problems for the producers of secondary services, for librarians, and for end users. The scholarly record is missing many shoulders from today’s *bone fide* giants. One example is the Intergovernmental Panel on Climate Change (IPCC) who actually switched from working with publishers to self-publishing on their websites: what was formally published is now grey literature.

The core problem is the same one as Wood identified in 1984: poor bibliographic control. What compounds it is the significant increase in the supply of grey literature over the past decade. Let’s look at these two issues, starting with supply.

Supply

The supply of scholarly content strongly correlates with the number of researchers.¹³ So, has the supply of researchers been growing? In the 1980s, just under a third of those emerging from education systems in OECD countries did so with first degrees. Of these, roughly a quarter

went on to do a masters or doctorate, so around 8% of this cohort emerged as “research capable”.

In the 2000s, the proportion leaving education systems with degrees in OECD countries was up to half, of whom half went on to get postgraduate qualifications. So, 25% of the 2000s cohort emerged “research capable”, a sizable increase over the 8% seen in the 1980s.^{14,15} Yet, the number of jobs in academia barely changed. In the 1980s, around 15% of freshly-minted PhDs in the UK could expect to work in academia. By the 2000s, this had fallen to around 3%. So, if not into academia, where did this growing number of highly-trained, research capable people go? Some went into industry and government, but some must have joined the booming services and third sectors. (The third sector is that part of an economy or society comprising non-governmental and non-profit-making organisations or associations, including charities, voluntary and community groups, cooperatives, etc.) As the graph above shows, there has been strong growth in the number of new third sector organisations since the end of WWII, with many employing researchers to support their mission. But here’s the kicker. Unlike their cousins in academia, researchers in government, industry, and third and service sectors don’t have to publish in books and journals to further their careers. They are free to work with their employers to self-publish their research as reports, working papers, and other digital-first formats – and they are increasingly doing so. An analysis of the Policy Commons database, which indexes grey literature from over

8,500 IGOs, NGOs, think tanks, and research centres from around the world, shows 55% more grey literature was released in 2020 compared with 2010 (287,545 items and 184,514, respectively). In the field of policy alone, I estimate that each year sees around 400,000 newly published items of grey literature – that's 10% of the world's journal output.

Poor bibliographic control

Today, desktop publishing, web 2.0 tools, and websites make it easy for anyone to self-publish. As Clay Shirky, an early internet "guru" and Professor at the Interactive Telecommunications Program at New York University said in a 2012 interview: "Publishing is not evolving. Publishing is going away. Because the word 'publishing' means a cadre of professionals who are taking on the incredible difficulty and complexity and expense of making something public. That's not a job anymore. That's a button. There's a button that says 'publish', and when you press it, it's done."¹⁶ Shirky was half right. It is indeed easy to press a button and publish something online. The problem is that most people who press that button are not from that cadre of professionals who understand the incredible complexity of preparing content so it's discoverable and useful for its readers. They don't know how to wrap it in the metadata that's needed to make it discoverable and easily and reliably citable. They don't know how to ensure it is included in specialist discovery services. Nor do they understand, and more than Shirky's interviewer did, that it isn't "done" until the work has been safely preserved in the scholarly record. It's ironic that links to Shirky's interview, published in the blog *Findings*, returned a "404-page not found" within months of its publication when the blog closed and went offline.

Worse, like *Findings'* publisher, most organisations have no strategy to prevent link rot¹¹ and it's hardly a surprise that 75% of links in scholarly journals to "web at large" items lead to the wrong content.¹⁷

Plainly, it is still incredibly difficult and complex to prepare content and metadata to the standards needed to ensure that it's discoverable by users and easily available to librarians for their collections. Despite the advances in digital publishing, gathering a scholarly record of giants' shoulders is still as challenging as herding cats.



If I have seen further it is by
standing on the shoulders (sic)
of Giants."

SIR ISAAC NEWTON

Conclusion

In 1990, I met a professor who ran a laboratory in France. He told me that the door to the library was open 24/7 but the key to the lab was given only to those who had first used the library to complete a thorough literature review of the topic they wished to investigate. At that time, when practical and financial hurdles meant there was little grey literature, the policy made sense. The professor could be confident that the library's access to the scholarly record was such that valuable lab time would only be spent looking further than was possible from the shoulders of giants who had gone before.

Today, in a world where "a button" has removed the practical and financial barriers to posting research findings on employers' websites, that policy would be increasingly undermined. Valuable lab time might be wasted because an increasing volume of giants' truth assertions are missing from the library's collection.

Now, you might imagine that what's missing can be quickly found via public search engines than scan open websites, like Google. The trouble with public search engines is that they deprecate content with poor metadata on low-traffic websites – most grey literature will be crowded out by content from "optimised" websites run by digital marketers.¹⁸ Besides, public search engines seek to tailor results to each users' "bubble" of preferences, attitudes, and even location and results can change from day-to-day as algorithms evolve.^{19,20} This is why most scholars and students still turn to the specialist search engines where, of course, grey literature is largely absent.²¹

Over the past two decades, publishers and librarians have been focussed on capturing research findings from the academy – mainly in books and journals – to create a digital scholarly record that's overlaid with sophisticated discovery systems for use by the academy. At the same time, they are attempting to pivot a \$25BN industry to open access so the scholarly record becomes an asset not just for the academy but also for society at large.²²

In parallel, and largely ignored, a growing number of researchers at non-academic institutions and organisations have been using digital publishing tools to post their research findings – as reports and papers – openly, via their websites. This is also a \$25BN information industry, but, as I've shown, this grey literature is missing both from specialist discovery systems and library collections and is still woefully under-used. Grey literature is still a costly asset that's going to waste.

Disclosures and conflicts of interest

The author is a co-founder of Coherent Digital LLC., whose mission is to tame wild content.

Some of the references and data used in this article come from services provided by Coherent Digital.

Researchers
in
government,
industry, and
third and
service
sectors don't
have to
publish in
books and
journals to
further their
careers.

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Don't miss!

The September 2023 edition



Automation/Software

Streamlined complex medical report writing supported by artificial intelligence/machine learning is making its way into clinical regulatory writing. The medical writing automation's goal is to speed up and ease clinical development processes by reducing the time and cost involved in creating and keeping regulatory documents up to date. This issue will examine current issues, challenges, and opportunities towards human guided medical writing automation systems.

Guest Editors: Shiri Diskin and Daniela Kamir

Obtaining meaningful insights from publication metrics

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Abstract

Altmetrics and other article-level metrics offer new opportunities to understand the impact of medical publications and, indeed, clinical trial programmes. For example, we can learn whether the publication has been viewed, shared, engaged with, or cited on different platforms. These metrics have limitations, but new tools and techniques for aggregating and summarising different metrics are making it easier for publication planners to understand the impact of their publications.

So, great news! After weeks, or perhaps months, of effort and work by the authors, publication team, and the writer, your pivotal study has finally been published. Traditionally, this would pretty much mean the end of the story. You move on to the next project.

Nowadays, this is not where the story ends. In the Internet Age, we can gain insight into how the audience has interacted with the publication. We can find out if anyone read or talked about it and even if it has been used to inform clinical practice. This and other information about published articles is critically important for optimising publication planning.

For example, we can learn whether the publication has been communicated effectively. From the perspective of the full clinical programme, we can gather insight into whether the right studies were conducted, the right publications were developed, and which topics attract the greatest interest. We can also look at all of these in comparison to competitor

publications. Fundamentally, we can learn whether the effort to develop the publication and publication plan was invested productively or if alternative strategies might be more effective.

Many publication teams still use the journal impact factor (JIF) as a measure of the success of their publications. However, as its name implies, the JIF is a journal-level metric that only provides a rough indication of the impact of individual publications. The JIF is an average score and is highly skewed because most publications receive fewer citations than the mean. Further, the JIF is unidimensional because it is based solely on citations. As a result, it does not take into account the many other forms of impact that can now be assessed.

Altmetrics

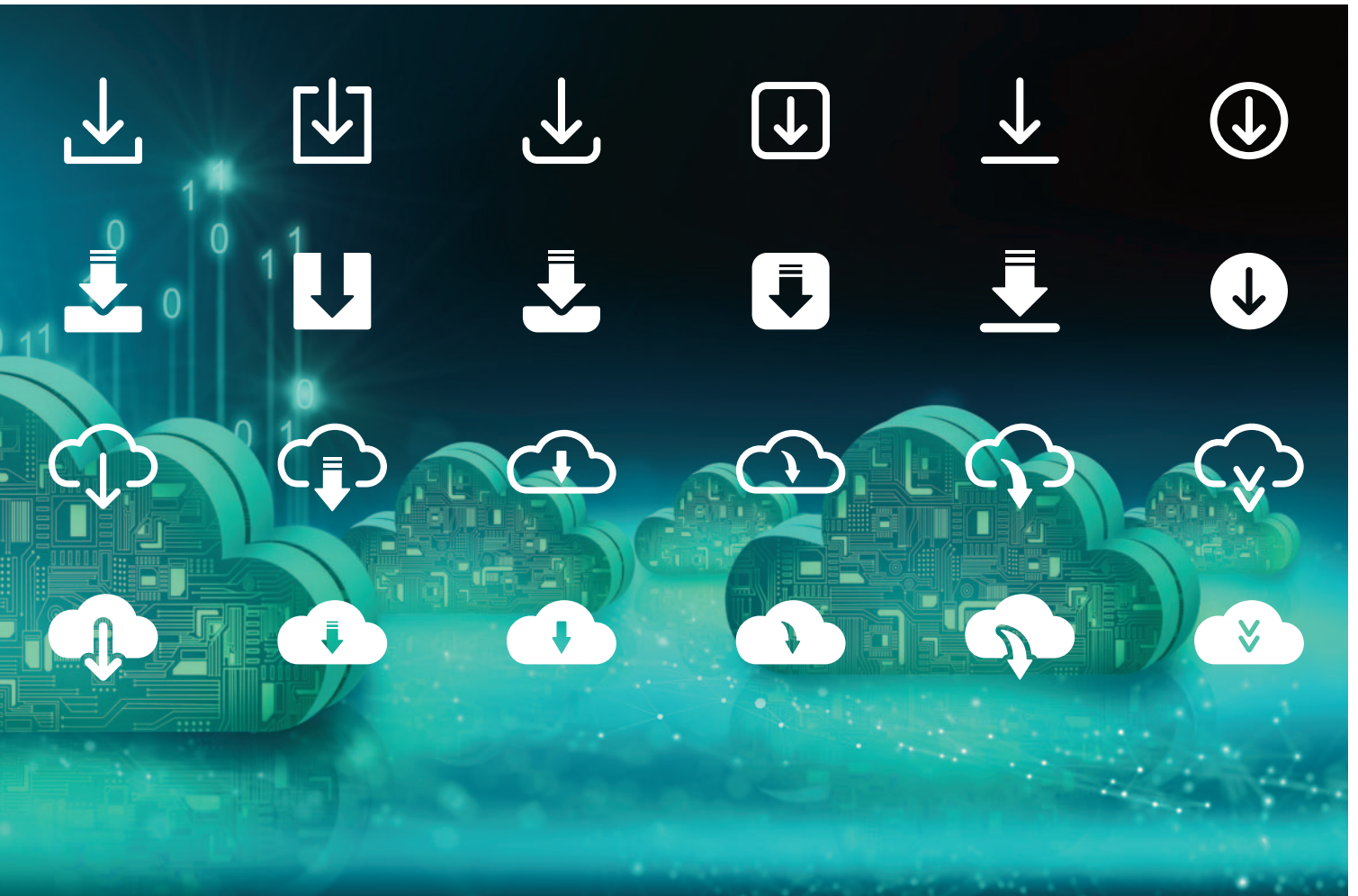
It is far better to look at the actual impact of each individual publication using article-level metrics than by using the JIF. Article-level metrics have been transformed in recent years with the development of the so-called “alternative metrics” (altmetrics), which provide an alternative to citations for measuring article-level impact. Altmetrics are a product of the internet, which has provided new avenues for interacting with journal articles. At the most basic level, publishers can track each time an article is viewed or downloaded. There is a lot more that goes on with a publication, however, which was previously entirely opaque. It is now possible to monitor a wide variety of news sources and to be alerted in real time whenever a news article discusses a journal article. Social media platforms make it possible to identify when individuals share or discuss publications. We can also track when individuals save a publication to their reference library or when an article is cited both in the peer-reviewed and in the grey literature, such as in blog posts, on open peer-review sites, and in governmental and non-governmental evidence syntheses, policy

Article-level metrics have been transformed in recent years with the development of the so-called “alternative metrics” (altmetrics), which provide an alternative to citations for measuring article-level impact.

documents, and guidelines.

All of these altmetrics have limitations in their coverage. For example, different publishers track article views slightly differently, and they often do not share the data, making it difficult to compare article views across a wide range of publications. Also, social media engagement can only be tracked on platforms that allow machine access to the content, which means that platforms such as LinkedIn are excluded. Similarly, some providers of guidelines (e.g. National Comprehensive Cancer Network) do not allow automated systems to read their reference lists. Only one reference manager (Mendeley) provides anonymised usage data, so the data





from individuals using other reference managers are hidden. Altmetrics providers have to decide which news sources to monitor: do you go broad and inclusive (and potentially pick up a lot of noise) or stick to the more widely read outlets only? And none of these services can capture discussions about a publication when it is not named or referenced in some way.

The value of altmetrics comes from their ability to record different types of interactions with the publication. That means that altmetrics can provide greater insight than simple citation counts, despite limitations in their coverage. For example, the act of posting a link on social media is very different from citing an article in a peer-reviewed publication and is usually done for quite different reasons. People may save an article into their reference manager with the clear intention of citing it later, but it is often simply because they found the article interesting and

want to bookmark it. News outlets tend to focus on newsworthy studies that could be of interest to the wider public and are less likely to pick up studies that are scientifically interesting but less immediately relevant to the public.

How to digest the vast amount of data available from altmetrics

Because they represent different actions, correlations between different metrics can vary. This can help us address another issue with altmetrics – how to digest the vast amount of data we now have access to. For example, the company Altmetric.com tracks 21 different metric sources, while their main rival, PlumX, tracks over 40 (although not all of these are relevant to journal articles).

To try to make sense of all these numbers, Altmetric.com collapses many of the metrics it captures into a single headline number – the Altmetric Attention Score (AAS). To minimise the problem of combining divergent metrics, the AAS simply excludes certain key article-level metrics (reference manager saves and citations in peer-reviewed publications), and to account for the fact that some metrics are more prevalent than others, they are weighted differently; a news article, for example, carries around 30 times the weight of a tweet. Even so, the AAS is almost entirely driven by mentions in news articles and tweets – it really is simply an “attention score”.

The value of altmetrics comes from their ability to record different types of interactions with the publication.

The **Total Value** score represents a weighted average of the Social, Scholarly, and Societal scores
 A **Total Value** score of 100 is equivalent to the average scores of phase 3 articles published in the NEJM in 2016

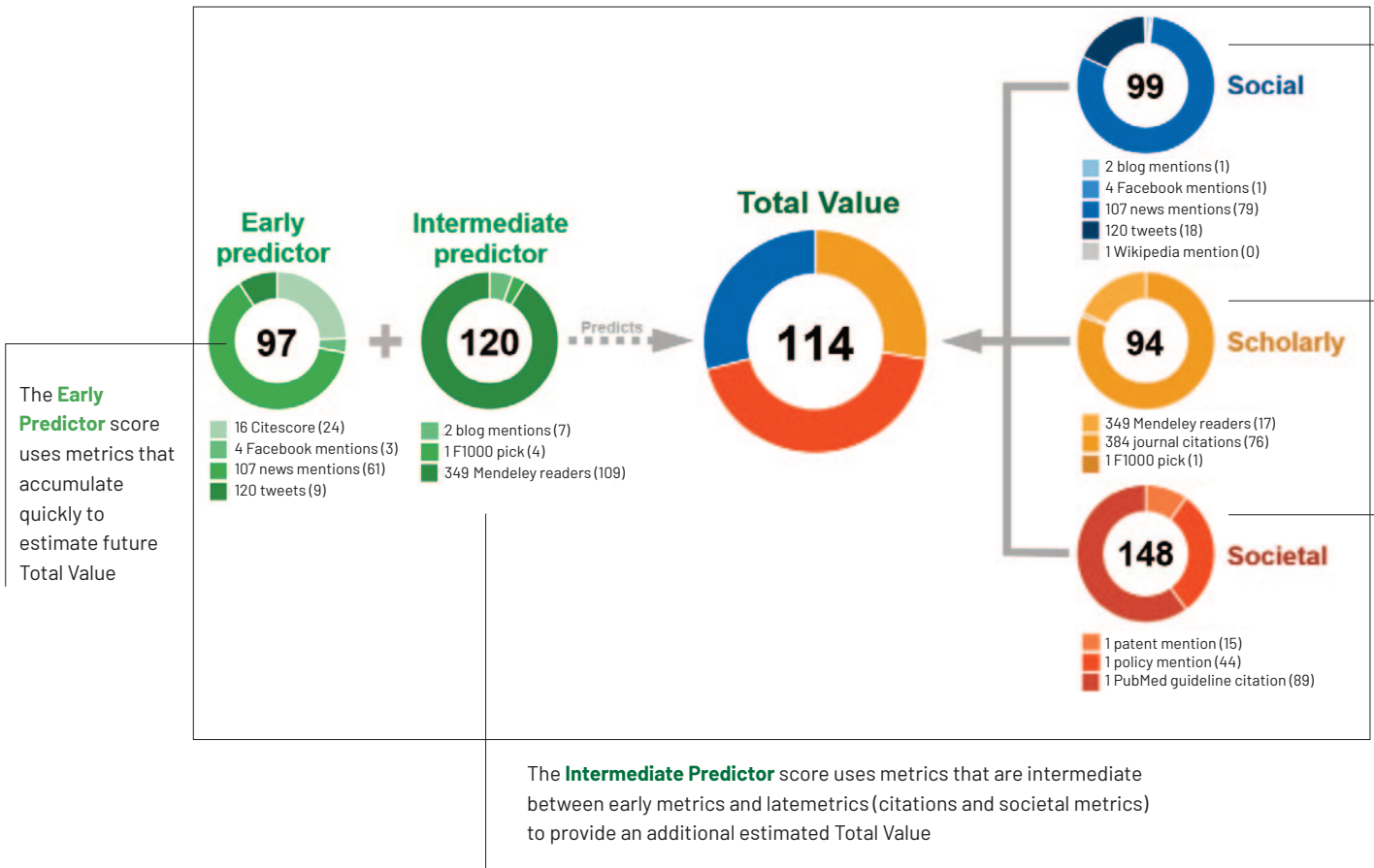


Figure 1. Example of the EMPIRE Index score for a single publication.
 HCP, healthcare provider; NEJM, New England Journal of Medicine

The EMPIRE Index

Although article-level metrics cannot be reduced to a single dimension, this general approach is helpful in making sense from publication metrics. Using a statistical technique (factor analysis), Avishek Pal and I explored the metrics of nearly 3000 publications of phase 3 studies. We found that, rather than trying to create a single score, the different metrics could be reliably placed in one of three groups, which we have named:

- Social Impact (Twitter, Facebook, news, blog mentions, and Wikipedia citations);
- Scholarly Impact (Mendeley saves, citations in peer-review publications, and citations in the Faculty Opinions service); and
- Societal Impact (citations in guidelines, policy documents and patents).

By appropriately weighting the metrics in these three separate scores, we were able to balance them so that the typical Social Impact would be similar to the typical Scholarly Impact and the typical Societal Impact. As a result, the scoring system, which we called the EMPIRE Index, captures the key different types of interaction that can be measured with article-level metrics in a way that makes it easy to compare across different articles (Figure 1). The EMPIRE Index is fully open for anyone to use and is described more fully in a publication in PLOS One.¹

The EMPIRE Index can help understand which publications have greater or lesser impact

and which can be used as a starting point for deeper insight; metrics can help you understand what and when, but they cannot tell you how or why. Knowing that your publication has been cited is good, but knowing the context in which it has been cited is even better. This applies just as much to social media as it does to citations in peer-reviewed publications. Fortunately, platforms that gather altmetrics also allow you to dive in and see the sources, where these are available.

As artificial intelligence advances, automating insight-gathering from unstructured text sources will become easier.

The future: artificial intelligence and natural language processing

As artificial intelligence advances, automating insight-gathering from unstructured text sources

The **Social** score represents the impact of the article in public domains such as social media and news

Audience: HCPs, non-specialists, healthcare support staff, patients and other members of the public

The **Scholarly** score represents the impact of the article in academic domains such as journal citations and scholarly reference libraries

Audience: Specialists, experts, scientists, and academics

The **Societal** score represents the impact of the article in treatment guidelines, policy documents, and patents

Audience: Healthcare and policy decision makers, disease management bodies

will become easier. Sentiment analysis is a widely used approach that attempts to classify statements as either emotionally positive or negative. However, sentiment analysis is easily confused by medical discussions (with all their talk of death and pain).² Although the lexicons that define the emotional valency of different words can be tweaked, sentiment analysis is fundamentally not suited to understanding publication impact. At the end of the day, we are not really that interested in knowing whether people are happy or sad about the publication.

This is where more advanced natural language processing comes in. By understanding the language used when discussing a publication, we can get rapid insight into the readers' perspectives. We are already seeing the first examples of this in services such as Scite – (<https://scite.ai>), which assesses whether a citation supports or contrasts with the original publication. This is a fast-moving area that has the potential to provide a second transformation in

our ability to understand the true impact of publications we develop.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

Data availability statement

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

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Tomas James Rees has over 20 years of experience in medical communications and publications planning and delivery. He has a longstanding interest in the transformation of scientific publications in the digital environment, including all aspects of open science, increasing reach and engagement across broad stakeholder audiences, and article metrics.



Results of the 2021 EMWA salary and compensation survey

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Abstract

In 2021, EMWA members were asked to participate in a survey about their current salary and compensation. The survey included questions on some of the factors that typically influence earnings, such as education, geographic location, level of experience, and type of employer. Four hundred EMWA members responded. The aim of this article is to provide salary and compensation information for company employees and freelancers who are medical writers and communicators based on the responses of the EMWA members who completed the survey.

Introduction

In 2006, EMWA conducted its first survey of members' salaries targeting both company employees and freelancers.¹ Subsequent salary surveys of EMWA members were fielded in 2012² and 2017.³ Here, we present the results of the 2021 salary and compensation survey. This edition of the survey was largely based on the previous surveys. However,

modifications were made to capture hybrid working modes combining employment by a company and freelance work and to evaluate the impact of the COVID-19 pandemic.

The primary objective of the 2021 survey was to provide up-to-date salary and compensation information for professional medical writers and communicators. We also explored differences in salary and compensation across geographic regions. Finally, we tried to understand whether salaries and compensation varied according to satisfaction with remuneration and job satisfaction, level of experience, and characteristics of work.

Methods

Survey details

The present survey (see Appendix 1) used many questions from the 2017 survey to allow for comparisons between the two surveys. EMWA members were invited to participate in two separate windows: September 29 to October 15, 2021 and November 4 to December 1, 2021. An email reminder was sent shortly before the end of each survey period. The survey was only open to EMWA members. It could be completed only once on a given device (e.g., laptop, mobile phone), but there was no way to check whether multiple devices were used by the same respondent. Moreover, respondents were

Nearly half (46%) of employees reported COVID-19-related workplace disruptions, such as having to work from home.



able to submit incomplete survey responses. As the survey was anonymous, it was not possible to query missing or inconsistent data.

Statistical analyses

Summary statistics were calculated for demographics, background, employment type, other job characteristics, and job/salary satisfaction. For salaries and compensation rates, the mean, median, interquartile range, and range were calculated. In analysing salaries and compensation rates, respondents were divided into two full analysis sets (FAS) based on their employment type: the employee FAS and the freelance FAS. Small business owners and participants with “hybrid” employment in which their time was divided between working as a company employee and as a freelancer were not included in the employee FAS or the freelance FAS. Because they were few in number,

data for respondents who chose “small business owner” or “hybrid” as their employment type were not analysed separately. The analyses of salary/compensation by geographic region only included countries where at least five respondents in the given FAS provided analysable data.

When asked to give reasons for dissatisfaction with their current work or salary, employees most frequently cited high workload (26%), low salary (22%), and being undervalued (18%).

Germany),² and 2017 (30% from the UK and 27% from Germany).³ As in previous surveys,¹⁻³

most respondents (80%) were women. Sixty-one percent of respondents were non-native English speakers.

The employee FAS comprised 266 respondents, and the freelance FAS comprised 103 respondents (Table 1). The remaining respondents were either small business owners or had a hybrid employment type.

Employees

Most company employees were female (77%) and most worked 31 to 40 hours per week (57%) (Table 1). Half of the employees had worked as medical writers or communicators for more than 5 years. Two-thirds (67%) of employees reported project management responsibilities. Almost half (48%) of them provided mentoring, and a fifth (21%) had line management responsibilities.

A third of employees (34%) spoke English as their native language. Some 86% of employees had a degree in life sciences and 18% had a degree in a healthcare discipline. Seventy-three percent of employees had an advanced degree (BBS, MD, PhD, PharmD, or equivalent). Thirty-five percent of employees had an EMWA Professional

Results and discussion

Characteristics of the overall survey sample

A total of 400 EMWA members (approximately 30% of the membership) responded to the survey, a response rate similar to that of the 2017 survey (31%).³ Just over half of the respondents were from the UK or Germany (25% from the UK and 26% from Germany), consistent with the surveys from 2006 (32% from the UK and 20% from Germany),¹ 2012 (29% from the UK and 27% from Germany),² and 2017 (30% from the UK and 27% from Germany).³ As in previous surveys,¹⁻³

Table 1. Demographics and work characteristics

Characteristic	Employees (N=266)	Freelancers (N=103)
Gender, n (%)		
Female	204 (77)	88 (85)
Male	60 (23)	15 (15)
Missing	2	0
Hours worked per week, n (%)		
11-20	2 (1)	9 (9)
21-30	26 (10)	34 (35)
31-40	149 (57)	38 (39)
41-50	75 (29)	9 (9)
>50	8 (3)	7 (7)
Missing	6	6
Years worked as a medical writer or communicator, n (%)		
≤5	131 (50)	30 (30)
>5	133 (50)	69 (70)
Missing	2	4
Responsibilities, n (%)		
Project management ^a	178 (67)	47 (46)
Mentoring	128 (48)	21 (20)
Line management	56 (21)	8 (8)

^a No line management



Development Programme (EPDP) certificate, and 13% had other formal training or certification in medical writing (e.g. AMWA or Drug Information Association certificate). Sixty-three percent of employees primarily worked as regulatory writers and 26% mainly worked as medical communications writers.

The overall mean gross annual income of employees was €67,205. The corresponding values from previous surveys were €54,924 in 2006,¹ €61,505 in 2012,² and €62,793 in 2017.³ It is unclear whether the increase in average incomes over time simply reflects inflationary

trends or whether increasing job value or other unknown factors also played a part.

The median income was the same (€49,000) for employees with 2 years or less, 3 to 5 years, or 6 to 10 years of experience as a medical writer or communicator (Table 2). Median incomes were higher for employees with 11 to 15 years (€69,500) or more than 15 years of experience (€90,000). Associate medical writers were at the lower end of the income spectrum, with a median income of €41,500 (Table 3). Directors/owners of medical writing companies were at the opposite end, with a median income of €186,000.

Median incomes were higher for writers with additional responsibilities of project management (€55,000 vs. €43,000 for those without this responsibility), mentoring (€63,000 vs. €46,000), or line management (€98,800 vs. €49,500) (Table 3). Similarly, in the 2017 survey, respondents with supervisory (€69,045 vs. €52,459) or line management responsibilities (€79,224 vs. €58,161) had higher average salaries than those without these responsibilities.³

Median incomes were highest in Switzerland (€138,000, n=26), France (€69,500, n=27), and Sweden (€61,220, n=16), and lowest in Spain

Table 2. Gross annual income (€) of employees by years of experience (n=264)

Years worked as a medical writer or communicator

	n (%)	Median	Range
≤2	54 (20)	49,000	3,600–87,000
3–5	77 (29)	49,000	2,200–126,000
6–10	52 (20)	49,000	5,000–118,000
11–15	36 (14)	69,500	20,000–186,000
>15	45 (17)	90,000	39,000–220,000

Table 3. Gross annual income (€) of employees by job title and responsibilities (n=266)

Job title/responsibility

Job title	n (%)	Median	Range
Junior medical writer	45 (17)	55,000	2,200–91,000
Associate medical writer	21 (8)	41,500	3,600–79,663
Senior medical writer	81 (30)	55,000	3,600–190,000
Principal medical writer	31 (12)	77,000	3,840–145,000
Publishing specialist	2 (1)	47,000	39,000–55,000
Medical writing manager	34 (13)	68,000	5,000–105,000
Communication lead/head of medical writing	19 (7)	84,365	55,000–172,000
Director/owner of medical writing company	7 (3)	186,000	150,000–220,000

Project management

Yes ^a	178 (67)	55,000	3,600–186,000
No	86 (33)	43,000	2,200–220,000
Missing	2	–	–

Mentoring

Yes	128 (48)	63,000	2,200–220,000
No	136 (52)	46,000	3,600–172,000
Missing	2	–	–

Line management

Yes	56 (21)	98,800	44,000–220,000
No	210 (79)	49,500	2,200–172,000

^a No line management

(€31,000, n=16) and Portugal (€33,600, n=12) (Figure 1). In the 2017 survey, median incomes were highest for medical writers and communicators from Switzerland (€120,000), Scandinavia (Denmark, Finland, and Sweden: €72,000), and Germany (€63,250), and lowest for those in Spain (€40,500) and Austria (€41,000).

Employees working for biotech companies (€80,000) and pharmaceutical companies (€76,700) had the highest median incomes. Median incomes were lower for employees of medical communications/advertising agencies/consultancies (€48,000), academic institutions/government agencies/not-for-profit organisations (€52,500), medical device companies (€54,000), and contract research organisations (€55,000).

Office-based employees had the lowest median income (€43,800), and those who were mainly home-based but worked some days in the office had the highest median income (€58,500) (Table 4). Working arrangements were not captured in previous surveys, presumably because it was assumed that most employees would be office-based. The 2021 survey was conducted during the COVID-19 pandemic, and only 4% of employee respondents were solely office-based. When probed on how the pandemic had changed their work, 58% of respondents mentioned the lack of face-to-face interactions at work, conferences, and other occasions. Nearly

Table 4. Gross annual income (€) of employees by working arrangement (n=261)

Working arrangement	n (%)	Median	Range
Home-based	86 (33)	50,000	24,000–101,000
Home-based with some days in the office	68 (26)	58,500	28,000–220,000
Office-based with some days at home	97 (37)	51,500	2,200–126,000
Office-based	10 (4)	43,800	14,000–150,000

Table 5. Gross annual income (€) of employees by hours worked per week (n=260)

Hours worked per week	n (%)	Median	Range
11–20	2 (1)	39,500	24,000–55,000
21–30	26 (10)	46,000	3,840–90,000
31–40	149 (57)	49,000	3,600–120,000
41–50	75 (29)	73,000	2,200–172,000
>50	8 (3)	186,000	101,000–220,000

half (46%) of employees reported COVID-19-related workplace disruptions, such as having to work from home, while 27% reported increased activity. Only 17% of employees felt that COVID-19 had not disrupted their work. It will be interesting to see whether these changes, particularly opportunities to work partly or fully from home, will persist beyond the end of the pandemic.

Median income increased with an increasing number of hours worked per week, from €39,500

for employees who worked 11 to 20 hours per week to €186,000 for those who worked more than 50 hours per week (Table 5). The fact that 11% of employees worked 30 hours or less per week suggests opportunities exist for at least some company-employed medical writers and communicators to reduce their work commitments and achieve a healthier work-life balance.

Most employees were satisfied or very satisfied with their current salary. Employees who were satisfied (€59,000) or very satisfied

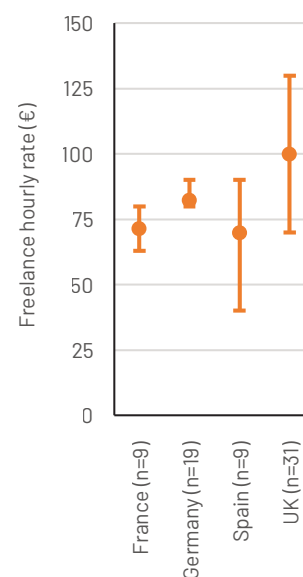
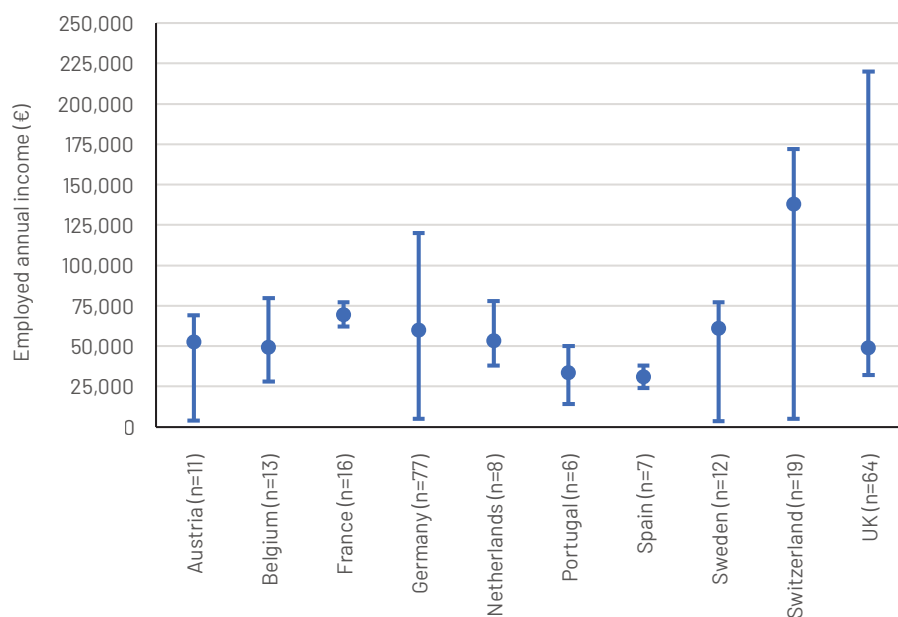


Figure 1. Gross annual income of employees and hourly rates for freelancers by country where they were based for tax purposes (data collected September 29 to October 15, 2021, and November 4 to December 1, 2021)

Data are the median and range. The analyses only included countries where at least five respondents in the given analysis set provided analysable data.

Table 6. Gross annual income (€) of employees by satisfaction with current salary (n=251)

Level of satisfaction	n (%)	Median	Range
Very unsatisfied	5 (2)	44,000	14,000–46,000
Unsatisfied	32 (13)	47,500	24,000–78,000
Neutral	63 (25)	45,900	2,200–150,000
Satisfied	109 (43)	59,000	3,600–220,000
Very satisfied	42 (17)	55,000	33,600–172,000

Table 7. Gross annual income (€) of employees by satisfaction with current work (n=262)

Level of satisfaction	n (%)	Median	Range
Very unsatisfied	3 (1)	74,000	46,000–149,000
Unsatisfied	9 (3)	39,000	22,500–57,000
Neutral	31 (12)	60,000	2,200–155,000
Satisfied	125 (48)	60,000	3,600–200,000
Very satisfied	94 (36)	58,000	3,600–330,000

(€55,000) with their salaries had slightly higher median incomes than those who were neutral (€45,900), unsatisfied (€47,500), or very unsatisfied (€44,000) (Table 6). However, satisfaction with current work was not predictive of employee incomes (Table 7): median salaries were similar for respondents who were neutral about or satisfied/very satisfied with their current work, and the three respondents who were very unsatisfied with their current work had the highest median salary (€74,000). When asked to give reasons for dissatisfaction with their current work or salary, employees most frequently cited high workload (26%), low salary (22%), and being undervalued (18%).

Freelancers

In addition to the 2006,¹ 2012,² and 2017³ salary surveys for employees and freelancers, other EMWA surveys of remuneration rates for freelance medical writers and communicators were held in 2003,⁴ 2007,⁵ 2010,⁶ 2013,⁷ 2015,⁸ and 2018–2019 (unpublished). The 2021 salary survey is, therefore, the tenth EMWA salary/compensation survey to include freelancers.

The proportion of freelancers who were women was 85% (Table 1), an increase from 75% in the 2017 survey.³ Forty-four percent of freelancers worked 30 hours or less per week – a higher proportion than for employees. Over

two thirds (70%) of freelancers had worked as a medical writer or communicator for more than 5 years. While almost half (46%) of freelancers reported project management responsibilities, very few of them (8%) worked as line managers.

Forty-seven percent of freelancers were native English speakers, a higher proportion than for employees. Just under two-thirds of freelancers had a life sciences degree (65%) and just over two-thirds had an advanced degree (69%). A third (33%) of freelancers had an EPDP certificate and 23% had other formal training or certification in medical writing. Considerably more freelancers worked primarily as medical communications writers (59%) than as regulatory writers (27%).

Satisfaction with current work was not predictive of employee incomes.

Median hourly rates increased with increasing satisfaction with current earnings and with increasing job satisfaction.

When asked to classify their main type of client, 43% of freelancers reported providing services to medical communications agencies, 26% to pharmaceutical companies, and 13% to contract research organisations. As expected, the overwhelming majority of freelancers (96%) worked exclusively from home.

The overall mean hourly rate of freelancers was €78, slightly down on the €81 reported in the 2017 survey.³ The median hourly rate did not increase steadily with increasing experience as a medical writer or communicator, being higher for freelancers with 3 to 5 years of experience (€90) than for those with 6 to 10 years (€63) or more than 15 years of experience (€80) (Table 8). However, respondents with 2 years or less of experience (€30) had the lowest hourly rate, and the median hourly rate was higher for freelancers with 11 to 15 years of experience (€110) than for those with 10 years or less of experience.

Among countries included in the analysis of freelance compensation by geographic region, freelancers based in the United Kingdom (€100) reported the highest median rate and those in Spain (€70) the lowest (Figure 1).

Eighty-one percent of freelancers were satisfied or very satisfied with their current earnings, and 91% were satisfied or very satisfied with their current work. Similarly, in the 2017 survey, most freelancers were satisfied with their current salary (77%) and work (91%).³ Overall, median hourly rates increased with increasing satisfaction with current earnings (Table 9) and

with increasing job satisfaction (Table 10). Again, these findings mirror similar trends in the 2017 survey, which found that the average hourly rate was significantly higher among freelancers who were satisfied (€88) than those who were dissatisfied (€59).³ The most frequently reported reasons for freelancer dissatisfaction with current work

Table 8. Hourly rate (€) of freelancers by years of experience (n=99)

Years worked as a medical writer or communicator	n (%)	Median	Range
≤2	10 (10)	30	15–65
3–5	20 (20)	90	70–100
6–10	28 (28)	63	40–90
11–15	12 (12)	110	40–140
>15	29 (29)	80	70–150

Table 9. Hourly rate (€) of freelancers by satisfaction with current earnings (n=99)

Level of satisfaction	n (%)	Median	Range
Very unsatisfied	1(1)	75	N/A
Unsatisfied	5(5)	40	15–100
Neutral	13(13)	70	60–80
Satisfied	57(58)	80	40–140
Very satisfied	23(23)	95	70–150

Table 10. Hourly rate (€) of freelancers by satisfaction with current work (n=98)

Level of satisfaction	n (%)	Median	Range
Very unsatisfied	1(1)	75	N/A
Unsatisfied	1(1)	40	N/A
Neutral	7(7)	60	23–82
Satisfied	44(45)	80	40–140
Very satisfied	45(46)	90	40–150

or salary were high workload (24%), difficulties finding regular clients (13%), and low salary (11%). Impacts of COVID-19 on freelancers included increased activity (39%), lack of face-to-face interaction with colleagues (29%), and workload fluctuations (17%). Only 4% of freelancers experienced COVID-19-related workplace disruptions, presumably because most of them were already working from home. Compared to employees, almost twice as many freelancers (30%) reported no impact on their work as a result of the pandemic.

Conclusions

In many instances, the results of the 2021 salary and compensation survey are consistent with those of the 2017 survey. However, novel findings are the differences in employee salaries according to working arrangements and respondents' experiences of COVID-19-related work disruptions, which were more frequent for employees than for freelancers. For employees, income levels did not always reflect satisfaction with their current work. The reasons for this apparent disconnect should be explored in future surveys.

The results of the present survey should be interpreted with caution. Because the survey was only open to EMWA members, the findings cannot be generalised to the global or even European medical writing community. Also, the analysis did not consider the cost of living in respondents' countries of residence. Moreover, the fact that respondents participated voluntarily, rather than being randomly selected, may be a source of selection bias. Finally, the way the survey was presented enabled respondents to select multiple response options for certain questions, even when this was illogical.

At the time of the 2021 survey, EMWA decided to establish a dedicated Salary and Compensation Team to conduct surveys every 4 to 6 years and to publish the results in *Medical Writing*. The team will look to improve the way future surveys are designed and conducted to leverage salary and compensation information that is more robust and more useful for medical writers and communicators. To help us in this endeavour, we welcome feedback on the 2021 survey and on this article.

Acknowledgements

The authors thank EMWA Head Office for organising the 2021 salary and compensation survey and for collecting the results. We also thank the EMWA Executive Committee for supporting the creation of the Salary and Compensation Team, providing input into the



The most frequently reported reasons for freelancer dissatisfaction with current work or salary were high workload (24%), difficulties finding regular clients (13%), and low salary (11%).

survey questions, and reviewing this article before publication.

Disclaimers

The ideas expressed in this article are the authors' own and are not necessarily shared by their employers (as applicable) or EMWA.

Disclosures and conflicts of interest

Sarah Choudhury is an employee of AstraZeneca, Cambridge, UK. She is a Director in Clinical Regulatory Writing. The other authors declare no conflicts of interest.

Data availability statement

The data collected in this survey are the property of EMWA. The original data are available for purposes of further research, upon reasonable request to EMWA Head Office. For inquiries about data and other supplemental information, please contact the corresponding author.

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Appendix 1. Survey questions

EMWA Salary and Rates Survey

The aim of this survey is to gather data on the salaries and freelance compensation of medical communicators. EMWA would also like to collate data on additional factors that typically influence income levels, such as education, work experience, location of work, and type of employer.

For the purpose of this survey, a salaried employee is defined as anyone employed by a company, institution, or individual (either full-time, part-time, or fixed-term contract work where taxes are paid on your behalf), and paid a salary or hourly wage. An update summarising the responses to this survey will be prepared for the November 2021 Congress and for a 2022 issue of *Medical Writing*.

This survey is anonymous, and we will not identify names or other sensitive information. If you are concerned that a particular question may compromise confidentiality (e.g., if you know you are the only EMWA member working in a particular country), feel free not to answer it. However, to enable the data to be analysed per country, we would appreciate responses to all questions, if possible. Individual responses to questions will not be reported when the results are published.

Demographics

1. Are you...?

- Male
- Female
- Non-binary
- Prefer not to say

2. In which country are you based for tax purposes?

(list of countries, with option "Prefer not to say" in the end)

3. Is English your native language?

- Yes
- No
- Prefer not to say

Education

4. What is the highest academic degree that you hold?

- Associate's degree or below (i.e., an academic degree for a programme of 2 years or less)
- Bachelor's degree or equivalent
- Master's degree (MSc, MBA) or equivalent
- Advanced (MBBS, MD, PhD, PharmD, or equivalent)

5. In what field of study did you obtain your highest academic degree?

- Life sciences (Biology, Biochemistry, Chemistry etc.)
- Healthcare (Medicine, Pharmacy, Public Health, Epidemiology, Nursing, etc.)
- Applied sciences (Mathematics, Physics, Engineering, etc.)
- Humanities (English, History, Journalism, Communications, Technical Writing, etc.)
- Languages, Translation, etc.
- Other (please specify)

6. Have you obtained an EMWA professional development programme (EPDP) certificate?

- Yes
- No

7. Have you completed any other formal training or certification in medical writing (e.g., AMWA certificate, Drug Information Association, other online courses)?

- Yes (please specify)
- No

Work Experience

8. How many years of experience do you have as a medical communicator?

- ≤2 years
- 3–5 years
- 6–10 years
- 11–15 years
- >15 years

9. Did you work in science before working as a medical communicator?

- Yes
- No

Employment Information

10. How would you classify your employment type? (Tick all that apply)

- Employed
- Freelance/independent contractor
- Hybrid (a mix of employed and freelance)
- Small business owner (<10 salaried or subcontracted team members)

11. For employed and hybrid, how would you classify your employer?

- Pharmaceutical company
- Veterinary company
- Medical device company
- Biotech company
- Medical communications/advertising agency/consultancy company
- Contract research organisation (CRO)
- Academia/government agency/not-for-profit
- Other (please specify)

12. For freelancers, how would you classify your main client?

- Pharmaceutical company
- Veterinary company
- Medical device company
- Biotech company
- Medical communications/advertising agency/consultancy company
- Contract research organisation (CRO)
- Academia/government agency/not-for-profit
- Other (please specify)

Job information

13. Which of the following best describes your job title? (Tick all that apply)

- a. Associate medical writer
- b. Junior medical writer
- c. Senior medical writer
- d. Principal medical writer
- e. Manager, medical writer
- f. Communication lead/ Head of medical writing
- g. Publishing specialist
- h. Director/owner of medical writing company
- i. Freelance
- j. Other (please specify)

14. Do you have project management responsibilities? (e.g., oversight of a project but not line management)

- a. Yes
- b. No

15. Do you have mentoring responsibilities?

- a. Yes
- b. No

16. Do you have line management responsibilities?

- a. Yes
- b. No

17. On average, approximately how many hours per week do you work?

(For freelancers: please enter an average number of hours across all projects in a typical week)

- a. 1–10
- b. 11–20
- c. 21–30
- d. 31–40
- e. 41–50
- f. >50

18. Where is your activity located?

- a. Full office activity
- b. Fully remote (working from home)
- c. Office based with some days working from home
- d. Remotely based with some days in office

19. How would you categorise your primary role?

(Note: if you are a team leader or manager but also work alongside your team, please select the category of your team)

- a. Writing, medical communications
- b. Writing, regulatory
- c. Writing, other (please specify)
- d. Editing
- e. Translation
- f. Manager
- g. Other (please specify)

Salary information

20. For members in employed work only: What is your yearly income before tax deductions?

Please specify to the nearest 1,000 Euros using the valid exchange rate for your local currency

21. For members in freelance work only: What is your hourly rate before tax deductions?

Please specify to the nearest 10 Euros using the valid exchange rate for your local currency

22. For members in hybrid work (a mix of employed plus freelance): What is your yearly income before tax deductions?

Please specify to the nearest 1,000 Euros using the valid exchange rate for your local currency

23. Considering your typical weekly workload, what percentage of your time is spent working on the following:

- a. Documents for clinical and nonclinical drug development __%
- b. Documents for clinical and nonclinical development of medical devices __%
- c. Articles for scientific journals and the scientific press __%
- d. Marketing materials, including congress materials and proceedings __%
- e. Educational materials for patients and/or health professionals, including audiovisual media __%
- f. Grant writing __%
- g. Translations __%
- h. Social media/electronic publishing __%
- i. Other (please specify) __%

Job and Salary Satisfaction

24. How satisfied are you with your current work?

- a. Very satisfied
- b. Satisfied
- c. Neutral
- d. Unsatisfied
- e. Very unsatisfied

25. How satisfied are you with your current salary?

- a. Very satisfied
- b. Satisfied
- c. Neutral
- d. Unsatisfied
- e. Very unsatisfied

26. Which of the following best describes your satisfaction level with your current work or salary? (Tick all that apply.)

- a. My workload is too high
- b. The work is not interesting or challenging enough
- c. Unsupportive work environment
- d. I feel discriminated on the basis of gender, nationality, age, or other
- e. My role is undervalued
- f. Salary is too low
- g. I have difficulty finding regular clients
- h. None of the above/Other (please specify)

Impact of COVID-19

27. How has the COVID-19 pandemic changed your work (tick all that apply)?

- a. Workload fluctuations
- b. Tighter deadlines
- c. Workspace disruption (e.g., having to work from home)
- d. Unemployment/fewer clients
- e. Inability to work due to health issues/family assistance, etc.
- g. No disruptions
- h. Increased activity
- i. Lack of face-to-face interaction with colleagues at work, conferences, etc.
- j. Other (please specify)

Thank you for your answers. This survey is anonymous and we will not share any data that could compromise confidentiality.

EMWA NEEDS YOU

EMWA is a member-run organisation

When you volunteer to assist EMWA in any capacity, you are furthering the development of our association.

You can choose how you want to get involved: in a very limited way or as part of a larger project. The choice is yours, and everyone shares the benefits.

EMWA members can volunteer in the following areas:

Conference

- Planning Committee
- Advertising

Finance

Journal

- Submitting articles
- Editorial board

Website

- Contributions
- Web team

Freelance Business Group

Social Media Team

Training

- Leading workshops
- Professional development
- Webinar contributions
- Webinar team



Special Interest Groups

- Business Development
- Communicating with the Public
- Medical Communications
- Medical Devices
- Pharmacovigilance
- Regulatory Disclosure
- Sustainability
- Veterinary Medical Writing

Ambassador programme

Getting Into Medical Writing Group

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- President
- Vice President
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- Public Relations Chair
- Conference Chair
- Honorary Secretary
- Professional Development Programme Committee Chair
- Treasurer
- EMWA Web Manager

WHY VOLUNTEER?

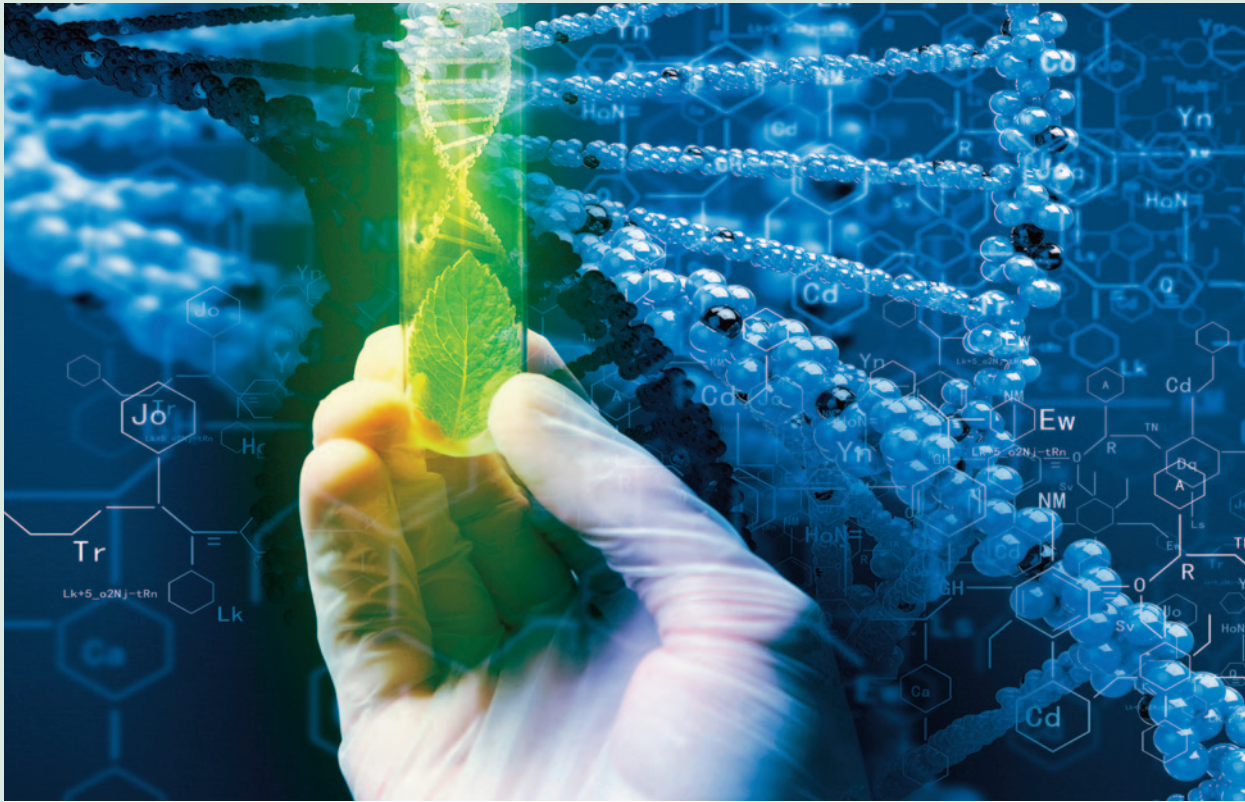
- Help promote the role of medical writers and strengthen our association
- Help to raise standards in our field
- Increase your visibility and communication opportunities within the medical writing community
- Add some prestige to your CV
- Improve your knowledge of medical writing and related topics

TO FIND OUT MORE

If you are a member of EMWA and eager to support ongoing initiatives, please contact info@emwa.org.

Don't miss!

The December 2023 edition



Biotechnology

Biotechnology uses biological systems and living organisms in R&D and production processes. Biotechnologies include biologic and biosimilar pharmaceuticals like monoclonal antibodies, vaccines and advanced therapy medicinal products, for example, gene and cell therapies and tissue engineered products. In addition, biotechnologies support the product lifecycle, for instance, in non-clinical work using in silico, in vitro, and animal testing methods. Also, support services personnel like those in biobanks and supply chains require an understanding of biotechnology. This issue focuses on the crucial role of writing and communications in biotechnology and product development.

Guest editor: Jennifer Bell

The deadline for feature articles is September 1, 2023.

News from the EMA

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The articles included in this section are a selection from the European Medicines Agency (EMA)'s News and Press Releases archive. More information can be found on the Agency's website: www.ema.europa.eu.



Global regulators call for international collaboration to integrate real-world evidence into regulatory decision-making

July 22, 2022

EMA has endorsed a joint statement calling for international collaboration to enable the generation and use of real-world evidence for regulatory decision-making published today by the International Coalition of Medicines Regulatory Authorities (ICMRA).

The use of real-world data and real-world evidence in the development, authorisation and monitoring of medicines to support regulatory decision-making is rapidly increasing. Although real-world evidence can play an important role in bridging knowledge gaps, there are still challenges that need to be addressed, such as heterogeneous data sources across the globe and different levels of quality of the data. Interested parties also need to deal with various processes for data sharing and access.

During the COVID-19 pandemic, international medicines regulators and researchers

have worked together to establish or reinforce collaboration allowing efficient sharing of data and experience in relation to real-world evidence. They agreed to further such collaboration beyond the pandemic.

In their statement, ICMRA members pledge to foster global efforts and further enable the integration of real-world evidence into regulatory decision-making. They identify four focus areas for regulatory cooperation:

- harmonisation of terminologies for real-world data and real-world evidence;
- regulatory convergence on real-world data and real-world evidence guidance and best practice;
- readiness to address public health challenges and emerging health threats; and transparency.

Global regulators emphasise their commitment to steer the work in these areas which could be taken forward through a variety of existing fora, including the International Conference on Harmonization (ICH), international standardisation bodies, and clusters of interested regulators.

The joint statement was developed following an ICMRA workshop on real-world evidence co-organised by EMA, US FDA and Health Canada, held in Amsterdam in June 2022. Participants from more than 40 countries, representing medicines regulatory authorities globally as well as representatives from the World Health Organization (WHO), shared their accomplishments and challenges in generating real-world evidence to support the evaluation of medicines. As a next step, international medicines regulators will discuss concrete actions to implement the above-mentioned four areas of collaboration.

New medicine for multiple myeloma patients with limited treatment options

July 22, 2022

EMA has recommended a conditional marketing authorisation in the European Union (EU) for Tecvayli (teclistamab) for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and whose cancer has worsened since receiving the last treatment.

Multiple myeloma is a rare cancer of a type of white blood cells called plasma cells. Normal plasma cells are found in the bone marrow and are an important part of the immune system. Plasma cells make the antibodies that enable the body to recognise and attack germs, such as viruses or bacteria. In multiple myeloma, the division of plasma cells becomes uncontrolled, resulting in abnormal, immature plasma cells multiplying and filling up the bone marrow. When plasma cells become cancerous, they no longer protect the body from infections and produce abnormal proteins that can cause problems affecting the kidneys, bones, or blood.

A range of new medicines for the treatment of multiple myeloma have been developed and approved in recent years, leading to a steady overall improvement in patient survival. However, for patients who have already been treated with three major classes of drugs (immunomodulatory agents, proteasome inhibitors and monoclonal antibodies) and no longer respond to these drugs, the outlook is still bleak. Therefore, new medicines are needed for these patients.

Tecvayli is a monoclonal antibody that targets two proteins at the same time: a protein called

B-cell maturation antigen (BCMA), which is present on the surface of the multiple myeloma cells, and CD3, a protein that is present on T cells (cells of the immune system responsible for destroying abnormal cells). By attaching to BCMA and CD3 at the same time, the medicine activates the T cells to kill the multiple myeloma cells.

Tecvayli was supported through EMA's PRiority MEDicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs. EMA's human medicines committee (CHMP) reviewed the application for marketing authorisation under an accelerated timetable to enable faster patient access to this medicine.

The CHMP based its recommendation for a conditional marketing authorisation on a phase 1/2, multicentre, open label, single-arm clinical trial. The study investigated the efficacy and safety of Tecvayli in 165 patients with relapsed or refractory multiple myeloma who had received at least three prior therapies (including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody) and who didn't respond to the last treatment regimen. 63% of patients enrolled in the study responded to the treatment with Tecvayli and lived without their disease getting worse for about 18 months on average. The most common side effects reported in the clinical trial for Tecvayli were hypogammaglobulinaemia (a condition in which the level of immunoglobulins (antibodies) in the blood is low and the risk of infection is high), cytokine

release syndrome (CRS) (i.e. a condition causing fever, vomiting, shortness of breath, headache and low blood pressure), and neutropenia (low levels of neutrophils, a type of white blood cell).

Tecvayli is recommended for a conditional marketing authorisation, one of the EU regulatory mechanisms to facilitate early access to medicines that fulfil an unmet medical need. This type of approval allows the Agency to recommend a medicine for marketing authorisation with less complete data than normally expected, if the benefit of a medicine's immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available.

In order to better characterise the safety and effectiveness of the medicine, the company will have to submit data from a randomised phase 3 confirmatory study comparing the efficacy of teclistamab in combination with daratumumab SC with the treatment regimen daratumumab SC, pomalidomide, and dexamethasone (DPd) or daratumumab SC, bortezomib, and dexamethasone (DVd) in adults with relapsed or refractory multiple myeloma. The company is also required to submit the final results of the pivotal study.

The opinion adopted by the CHMP is an intermediary step on Tecvayli'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 or use of this medicine in the context of the national health system of that country.





Big data use for public health: Publication of Big Data Steering Group workplan 2022-25

July 28, 2022

The Big Data Steering Group set up by EMA and the Heads of Medicines Agencies (HMA) has published its PDF icon third workplan that sets key actions to be delivered between 2022–25.

The new workplan will allow to further enhance the efficient integration of data analysis into the evaluation of medicinal products by regulators. Using novel technologies and the evidence generated from big data will benefit public health by accelerating medicine development, improving treatment outcomes, and facilitating earlier patient access to new treatments.

The former Big Data Task Force carried out a thorough assessment of the challenges and opportunities posed by big data in medicines regulation, which culminated in 2020 in the publication of priority recommendations for regulators on the best approaches to use and generate data. The joint HMA-EMA Big Data Workplan 2022–2025 follows the key recommendations and includes mainly activities related to medicines for human use. However, the scope

of some activities covers veterinary aspects, and a separate section in the workplan is fully dedicated to veterinary medicines.

The workplan lays out deliverables and timelines including for the following areas:

- The Data Analysis and Real World Interrogation Network (DARWIN EU), EMA's network of data and services in Europe for a better use of real-world evidence when assessing medicines: the workplan foresees more than one hundred DARWIN EU studies per year by 2025.
- Data quality: a data quality framework for the EU regulatory network is to be delivered by the end of 2022, following the analysis and exchanges on data quality with a wide range of stakeholders including patients, healthcare professionals, regulators, pharmaceutical industry and academia.
- Data discoverability: the workplan foresees the publication of a good practice guide on real-world metadata and a public catalogue of European real-world data. In addition, search-

ing for information from regulatory documents will be enhanced through the development of analytics tools and the development of standardised clinical trial protocols.

- EU network skills: the workplan includes the delivery of training on biostatistics, pharmacoepidemiology and data science for regulators with targeted access for patients, healthcare professionals and academics.

Big data are extremely large, rapidly accumulating datasets captured across multiple settings and devices, for example through wearable devices and electronic health records. Coupled with rapidly developing technology, big data can complement the evidence from clinical trials by filling knowledge gaps on a medicine, and can help to better characterise diseases, treatments, and the performance of medicines in individual healthcare systems.

The work carried out by the Big Data Steering Group builds on the Regulatory Science Strategy to 2025, published in March 2020, and will support the European Medicines Agencies Network Strategy to 2025.

New medicine to protect babies and infants from respiratory syncytial virus (RSV) infection

September 16, 2022

EMA has recommended a marketing authorisation in the EU for Beyfortus (nirsevimab; from AstraZeneca AB) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in newborn babies and infants during their first RSV season (when there is a risk of RSV infection in the community).

RSV is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover within one to two weeks, but RSV can be serious, especially in infants. It is the most common cause of lower respiratory tract infections, such as bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) that may lead to hospitalisation or even death in newborn babies and young infants. For instance, in 2015, RSV caused an estimated 33 million lower respiratory tract infections in children younger than five years globally; 3.2 million of them required hospitalisation. Approximately 59,600 children died, the vast majority (43,600) in low- and middle-income countries. Despite a decrease in the number of RSV infections during the pandemic in 2020 and 2021, a resurgence in infections is expected following the easing of COVID-19 mitigation measures. In the EU, the virus is usually more common during the winter.

Nirsevimab, the active substance in

Beyfortus, is an antiviral monoclonal antibody (a type of protein), which has been designed to attach to the F (fusion) protein that RSV needs to infect the body. When nirsevimab is attached to this protein, the virus becomes unable to enter the body's cells. This helps to prevent RSV infection. Because the medicine is removed slowly from the body, over a period of several months, a single dose of Beyfortus protects infants against RSV disease during the entire RSV season. Beyfortus should be given before the RSV season (when there is a risk of RSV infection in the community) or as soon as possible after birth for infants born during the RSV season. In the northern hemisphere, this is from December to March.

Beyfortus was accepted into EMA's PRIME scheme on January 31, 2019 scheme. This scheme provides early and enhanced scientific and regulatory support to promising new medicines that address unmet medical needs. Beyfortus was also evaluated under EMA's accelerated assessment mechanism because prevention of RSV infection in all infants is considered to be of major public health interest.

The opinion by EMA's CHMP is based on data from two randomised, double-blind, placebo-controlled multicentre clinical trials that investigated the efficacy and safety of nirsevimab in healthy preterm (premature) and full-term

infants entering their first RSV season. These studies demonstrated that Beyfortus prevents lower respiratory tract infection caused by RSV requiring medical attention (such as bronchiolitis and pneumonia) in term and preterm infants during their first RSV season.

The safety of nirsevimab was also evaluated in a phase II/III, randomised, double-blind, multicentre trial in infants who were born five or more weeks prematurely (less than 35 weeks gestation) at higher risk for severe RSV disease and infants with chronic lung disease of prematurity (i.e. long-term respiratory problems faced by babies born prematurely) or congenital heart disease. The results of this study showed that Beyfortus had a similar safety profile compared to Synagis (palivizumab). The most common side effects reported for Beyfortus were rash, pyrexia (fever) and injection site reactions (such as redness, swelling, and pain where the injection is given).

The opinion adopted by the CHMP is an intermediary step on Beyfortus' 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 pilot offers enhanced support to academic and non-profit developers of advanced therapy medicinal products

September 29, 2022

EMA is launching a pilot to support the translation of basic research developments into medicines that could make a difference in patients' lives in the European Economic Area (EEA). The pilot is open to academic sponsors and non-profit organisations who are developing advanced therapy medicinal products (ATMPs). These medicines for human use are based on genes, tissues, or cells and might offer groundbreaking treatment options to patients.

The pilot will focus on the needs of non-profit academic developers. They are a major contributor to the development of ATMPs and diagnostic and delivery devices, but experience has shown that navigating regulatory requirements can be challenging.

During the pilot, EMA will provide enhanced regulatory support for up to five selected ATMPs

that address unmet clinical needs and are solely developed by academic and non-profit developers in Europe. EMA will guide the participants through the regulatory process with the aim to optimise the development of the ATMPs, starting from best practice principles for manufacturing to planning clinical development that meets regulatory standards.

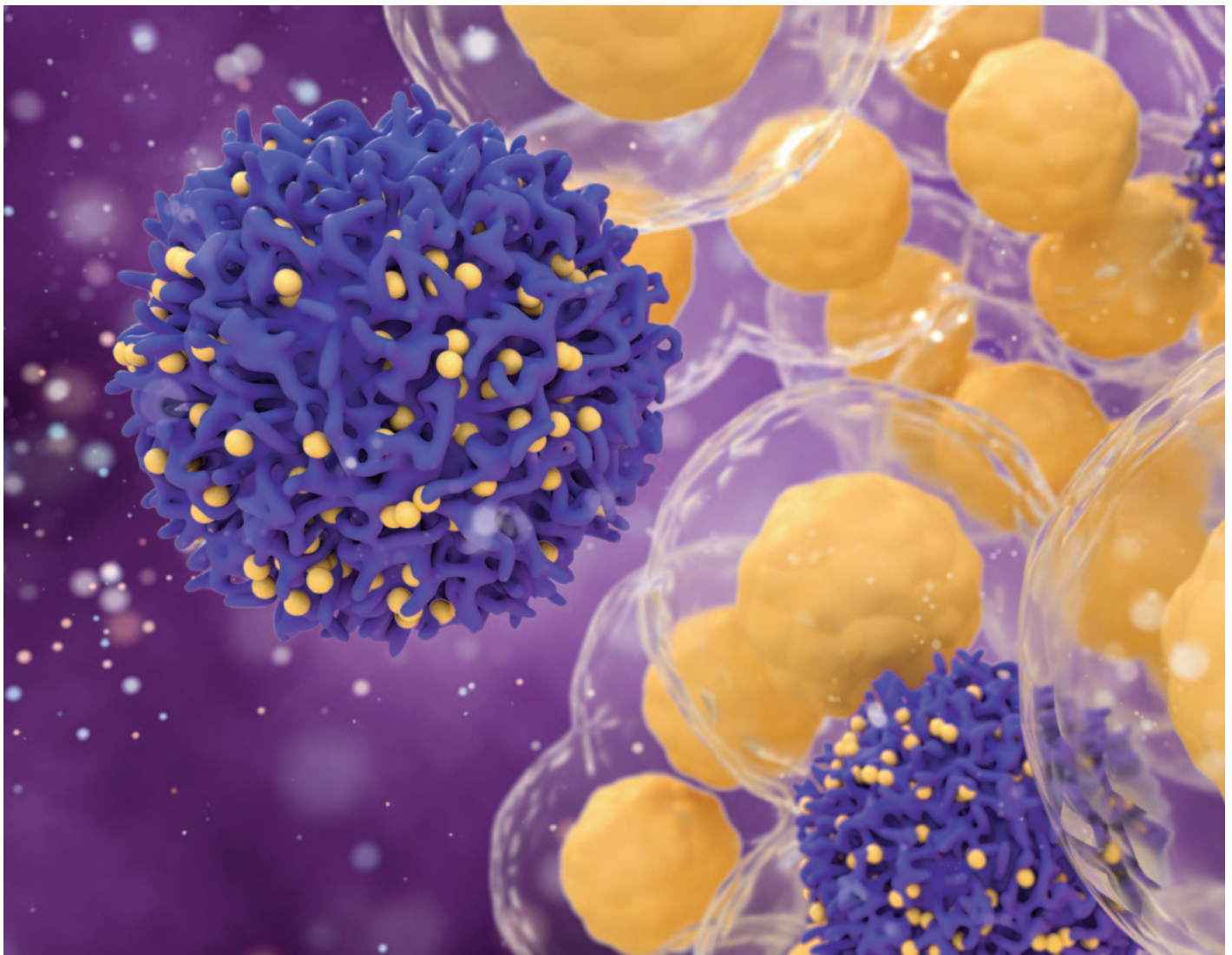
The pilot's first participant has already been selected. This ATMP is ARI-0001, a chimeric antigen receptor (CAR) product based on patients' own T-cells, that is developed by the Hospital Clínic Barcelona. In December 2021, the product was granted eligibility to PRIME, EMA's scheme to support the development of medicines that target an unmet medical need.

Importantly, no new regulatory tool will be introduced as part of this pilot. However, the aim

is to assess what further support or regulatory tool may be provided to enhance the number of ATMPs reaching patients in the EEA. In the process, EMA is keen to learn how to better interact with and support academic developers.

The pilot participants will benefit from all the available regulatory flexibilities and development support measures, such as fee reductions and waivers. The progress will be closely monitored, and initial results of the pilot are expected to be available in 3-4 years. Upon completion, a report will be published and a workshop with relevant stakeholders may be organised to discuss the learnings.

Potential developer candidates can contact their national competent authority or EMA via advancedtherapies@ema.europa.eu to express their interest in participating in the pilot or to receive more information.



Digital Communication

SECTION EDITOR



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Open science provides faster, easier access to data, technologies, and tools that can be used to drive innovation and accelerate research and solutions to ongoing or future social crises. When combined with the myriad of digital communication tools and platforms available today, the effects of open science can be amplified even further. This article explores how open science has evolved in the digital age and gives a closer look at the role digital communication, mainly social media, has played in pushing forward the open science movement within the scientific community and beyond its borders.

Open science

To some, open science may seem like a novel, modern-day concept, given its fitness to the digital age. But open science dates back to the late 1600s, around the time of the first scientific journal. During this time, scientific theories were openly questioned and experiments frequently repeated to test the reproducibility of results. As many of us will recognise, this practice has faced challenges in the not-so-distant past, primarily due to more and more elements of scientific research being closed, including access to data, methodology, and publications. Such a lack of openness in research impedes not only the scientific process but also the scientific discourse needed to produce scientifically sound, reproducible, and relevant results. It furthermore unfairly limits certain members of society, like the general public, from learning about and being a part of conversations around the latest research and discoveries.

As the Age of Information began, more advanced technology became available to share information and build networks, bringing digital communication to the forefront and alongside it the open science movement. In 2017, Bradley Voytek from the Department of Cognitive Science at the University of California argued that open science, data science, and social media

Open science in the digital age



are all inextricably linked, sharing underlying social and technological transformations that have in one way or another influenced the practice of science in recent years.¹ Some of these events include:

1. The launch of *PLOS Biology* in 2003, an open access pioneer which boosted open-access publishing
2. The critical article by John Ioannidis in 2005, “Why most published research findings are false”
3. The launch of *PLOS One* in 2006 to facilitate post-publication peer review
4. The launch of GitHub in 2008 to make scientific version control easier.¹

Of course, the Budapest Open Access Initiative (BOAI), developed in December 2001, played, perhaps, the most important role in rebooting the open science movement. The initiative was created by people from around the world and from different academic disciplines. It called for

the old tradition of researchers publishing their findings (free of charge) in scientific journals to be combined with the new technology of the Internet – removing access barriers to accelerate research, enrich education, and connect humanity in a common intellectual conversation and quest for knowledge.² Two subsequent initiatives, inspired by the BOAI, were critical in broadening and strengthening the support base for open science, namely the Bethesda Statement (April 2003) from Howard Hughes Medical Institute and the Berlin Declaration (October 2003) from the Max Planck Society.

Open science today embodies many different components, but at its centre, it involves open access, open methodology, open data, open source, and open peer review. It enables the critical evaluation of the major components of scientific research, facilitating collaboration in relevant networks, and sharing essential knowledge with all levels of society whether amateur or professional.

Open access

Since the milestones in the open science movement in the early 2000s, over 18,000 high-quality, peer-reviewed journals have become open access. That number grew from a mere 300 open-access journals in 2003 (see: <https://www.doaj.org/>), opening up science like never before and bringing an unprecedented level of transparency to research.

In the scientific community digital communication, especially social media, has become a research tool scientists use to leverage their work. Having a strong online and social media presence gives journals, scientists, and companies a platform to raise their profiles and promote their content. For anyone who is interested in science, social media is an ideal dissemination tool and source of information given its affordability, convenience, and ease of use. Through digital communication, users can access and share information on many different topics and from various sources, give opinions, and gain a better understanding of current events. But how have digital communication platforms like social media benefited the open science movement? And how have open access and social media combined impacted society?

A matched-pair analysis of links to open-access vs. paid scholarly articles on social media assessed the effect of open access on the reach of scientific information.³ Unsurprisingly, open-access links were found to perform better than paid content links, as measured by a higher number of post clicks. These results would suggest that combining social media with open-access features enhances the reach of scientific information, and that social media exposure to scholarly articles likely promotes the use of research outputs.³ Indeed, the use of professional social media platforms like ResearchGate, LinkedIn, and Publons have become immensely popular among scholars. Even healthcare providers and public health organisations make regular use of digital communication platforms like social media, online forums, messaging apps, websites, video conferencing, and blogs. The inherent openness of these platforms to wider audiences and the possibility to communicate bidirectionally has, among other things, helped make science more inclusive and strengthen relationships between different groups within and outside of the scientific community.⁴ In addition to improved visibility of their work, scholars can also receive informal/public reviews and blind peer reviews – the analytics of which can be used to support their professional/academic careers (e.g. job and funding applications).⁴

Spending time on social media undoubtedly allows users to acquire transferable skills to boost digital literacy that can be applied to other online environments, further enhancing the open science experience. Successfully reaching wider audiences on digital platforms requires finesse. In this way, open access has pushed scientists to broaden their expertise and improve their science communication skills to produce widely appealing and understandable communications (e.g. plain language/lay summaries, newsletters, and blogs). Favourably, numerous journals have embraced the incorporation of digital features (e.g. videos, infographics, graphical abstracts) to complement published articles, which require the use of specialised graphic design and/or video editing software, and, in some cases, social media performance tracking capabilities to assess impact (e.g. PlumX Metrics).

In many ways, the COVID-19 pandemic confirmed the scale and speed with which open science combined with social media and other digital communication channels can benefit society.⁵ Throughout the pandemic, both open science and social media played crucial roles in facilitating scientific exchange that supported diagnostic and drug/vaccine development and ameliorated the public health response.^{6,7} Reportedly, over 100 organisations, including journals and funding bodies, committed to opening access to COVID-19 research data, including articles and protocols, which were made freely available through the COVID-19 Open Research Dataset (CORD-19).⁵ In January 2020, scientists from China published the first whole-genome sequences of SARS-CoV-2 on the Global Initiative on Sharing Avian Influenza Data repository – an open-access data repository for genomic data of influenza viruses (GISAID). Australian virologist Eddie Holmes went one step further, sharing (what he referred to as) the initial genome sequence of the coronavirus on Twitter, linking to the discussion forum for the analysis and interpretation of virus molecular evolution and epidemiology Virologist.org.⁸ These, and other similar events, gave scientists around the world access to the initial data needed to understand the virus and combat its spread and associated disease. Holmes, in an interview from 2021, reiterated “the importance of global research collaboration and open sharing of findings, which makes science faster, more

efficient and more accurate”, when referencing the more than 400,000 research papers that have been written on COVID-19 since the start of the pandemic and the lightning speed at which new COVID-19 tests, treatments, and vaccines were created, saving millions of lives.⁹

Social media has also grown to be a useful source of data to answer a wide range of research questions from various disciplines, to better understand societal phenomena. For instance, social media monitoring and analytics can be used to evaluate how public health recommendations are being perceived or even how they are influencing people’s behaviour.

To this point, a German study demonstrated the effectiveness of social media in promoting COVID-19 vaccination among migrant communities.¹⁰ With their dedicated social media campaign, they reached over 1 million Facebook users within a 27-day period – 17,000 of which followed their advertisement for booking a COVID-19 vaccine appointment, with an estimated 1800 people receiving a vaccine. Overall, their findings (click-through and

conversion rates) were on par with the average user engagement rate of online advertising in healthcare. It also highlighted the usefulness of social media marketing in driving action in healthcare and social media metrics in understanding associated behavioural trends.¹⁰

It’s evident that the communication of science on digital platforms can be beneficial. But it’s not without drawbacks, and more information is not always a good thing. Keeping in mind that audiences are immensely diverse and that not all information is credible or reliable, the communication and consumption of science on social media can be tricky. This was very much the case during the COVID-19 pandemic and the associated infodemic, where an overload of information as well as copious amounts of mis- and disinformation negatively impacted public well-being and contributed to disruptions in public health efforts to control the spread of the virus and manage the disease.¹¹ Since then, tackling mis- and disinformation online has become a top priority for many organisations, including the WHO.¹²

Open data, source, and methodology

Great strides have been made toward storing and sharing data online. In the digital age, it is no surprise that much of the work done in research relies heavily on the use of computers and

Open science today embodies many different components, but at its centre, it involves open access, open methodology, open data, open source, and open peer review.

appropriate software. Technology is constantly evolving to improve and support how we analyse, simulate, calculate, and even visualise especially large sets of data. It's not enough that the data is available, the software used to view, handle, and transfer data also needs to be freely available and user-friendly, and most important of all, the data should be of high-quality. To this effect, the OpenScience Project has been creating free, easy-to-use open-source scientific software to make available to "anyone who wishes to discover or explore something new about the natural world".¹³ Furthermore, the findable, accessible, interoperable, and reusable (FAIR) guiding principles promote good data management and data stewardship practices to ensure that researchers produce high-quality data for wide dissemination and utilisation. Interestingly, a cost-benefit analysis by the European Union in 2018 showed that not having FAIR research data can be expensive, costing the European economy at least €10.2 billion every year.¹⁴ Regarding open methodology, I think we can all agree that, in certain instances, it can be incredibly difficult to replicate an experiment from the methods and materials described in an article. Open electronic lab notebooks can be a highly beneficial complement to an article by offering more insights into a particular method. It's also not uncommon for journals to request that detailed protocols of methods are made available to their readers. For clinical trials, detailed information about a trial can be found on, for example, the US clinical trial repository ClinicalTrials.gov and the EMA's website Clinical Data, and is available to anyone with access.

Despite its speedy evolution over the last two decades and many clear advantages, open science still faces significant challenges, including financial constraints, intellectual property barriers, impact on academic advancements, prestige, and more. Ultimately, all stakeholders in the open science ecosystem have a responsibility to be aware and help create awareness of the incredible benefits and the challenges of open science.¹⁵ It's also clear that digital communication is an unbelievably valuable tool in this movement. Use its power to spread the word, and share resources that ensure that open science is credible and of high quality. Together, and especially as medical/ science communication professionals, we can elevate open science even more, harnessing the expertise, data, and

Interestingly, a cost-benefit analysis by the European Union in 2018 showed that not having FAIR research data can be expensive, costing the European economy at least €10.2 billion every year.

awareness needed to optimally tackle society's most pertinent issues.

Disclaimers

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

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Author information

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EMWA Future Conference

Prague 2023 (May 9–13, 2023)



Continuing education and professional training for medical communicators

Call for **★ ABSTRACTS ★**

The EMWA spring and autumn conferences provide a medium for networking, active discussions and extensive cost-effective professional training. It is also an opportunity to benefit from the experiences of other medical writers.

The venues, facilities, and training programmes are chosen to offer the best possible learning environment. In addition to the formal training sessions, a relaxed, friendly conference atmosphere provides for ideal networking opportunities and enables all those attending to meet medical writers and communicators at all stages in their careers.

Call for Abstracts

The Scientific Organising Committee invites abstract submissions for the 55th Annual EMWA Conference in Prague, Czech Republic.

Posters based on accepted abstracts will be displayed at the conference from May 10–13, 2023.

Abstracts must be:

- based on original research, case reports or reviews and relate to any field of medical writing, communications, editing or translation
- structured (Introduction, Methodology, Results, Conclusion) and include fewer than 250 words (excluding title, authors and affiliations)
- submitted in English (UK spelling)
- submitted on the official EMWA submission form (below)
- submitted by e-mail to emwaconference@emwa.org by February 17, 2023, 17:00 GMT by the presenting author.

By submitting an abstract, the authors confirm that the data have NOT been previously published as a full paper and agree that if abstract is accepted, it will be published in the official EMWA journal, *Medical Writing* (open access, CC-BY).

Please note only presented abstracts will be published – if presenting author is unable to present at the conference, the abstract will be withdrawn.

All abstracts will be reviewed by an expert panel and may be selected for poster presentation (or rejected). Abstracts notifications will be sent to authors via email w/c March 13, 2023, together with the poster preparation guidelines (if abstract accepted).

The presenting author must:

- be registered for the conference and present the poster during indicated times
- ensure that all co-authors are aware of, contributed to and agree with the content of the abstract before submission
- state that this condition is met in the submission email

The Crofter: Sustainable Communications

SECTION EDITOR



Kimi Uegaki
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Editorial

Greetings from the croft! By the time this issue is published EMWA's Sustainability Special Interest Group (SUS-SIG) will have hosted its first Expert Series Seminar on "Sustainable Medical Communications – From Awareness to Action" during the Autumn 2022 EMWA Conference. In keeping with this theme, we are happy to share three contributions to help you put sustainability into practice at home and in the workplace. For home, to help sustain you during busy periods, Paula Pinto and Sarah Kabani each share one of their favourite plant-

based, go-to recipes. The day after I received Paula's recipe, it rescued me when I was having "one of those (work) days" and found myself under pressure to get something ready for dinner before my daughter had to leave for her acrobatic gymnastics training session, and my son was moaning that he was hungry. We all loved it! I'm looking forward to cooking Sarah's recipe next.

To help make your workplace more sustainable, Viviana Neviani shares easy-to-implement tips that were generated by a fun competition organised this past summer by Stichting Incubator Utrecht, the building where

she works. The competition was for the best ideas to create a sustainable, energy-efficient workplace, and anyone working in the building could enter by writing an idea on a green post-it and dropping it in the glass jar in the lobby. The four winning ideas, and another four from Viviana's experience as a member of the sustainability team at her employer, Merus, are presented in the infographic. If this inspires you, then please share your tip with us at The Crofter and we'll be happy to share it in the next issue.

Best,
Kimi





CHESTNUT BOURGUIGNON

Recipe adapted from *The More Veg Cookbook* by Carolyn Humphries.

UK: Dorling Kindersley Limited, Penguin Group; 2013.

INGREDIENTS

- 1 tbsp olive oil
- 30 g butter
- 2 red onions, thickly sliced
- 2 garlic cloves, crushed
- 115 g carrots, in large chunks
- 150 g mushrooms (all types work well), halved if large
- 2 tbsp flour
- 300 ml red wine
- 300 ml vegetable stock
- 1 tbsp tomato puree
- 240 g cooked peeled chestnuts
- 400 g can red kidney beans, drained
- 1 bouquet garni or a few sprigs of thyme and rosemary
- salt and pepper

PREP TIME: 25 MINS

COOK TIME: 1 HR 30 MINS

TOTAL TIME: 1 HR 45 MINS

DIRECTIONS

A fantastically warming dish for the winter. Easy to throw together in a quick break when working from home to be ready for dinner time.

1. Preheat the oven to 180°C. Heat the oil and butter in a casserole dish and fry onions until brown.

2. Add the garlic, carrots, and mushrooms and fry for 2 minutes. Add the flour and stir a further minute. Gradually add the wine, stock, and tomato puree. Continue stirring until simmering and sauce has thickened slightly.

3. Add chestnuts, beans, herbs, and seasoning. Put on lid and cook in oven for around 1.5 hours until vegetables are tender.

4. Serve with baked or mashed potatoes and seasonal greens.

Note: This keeps very well in the fridge for three days and reheats well from frozen. It makes an excellent freezer standby for those end-of-year deadlines.



Author information

Sarah Kabani, PhD, has been a medical writer for a French teaching hospital since 2016 following a career as a researcher in molecular biology. Sarah is a supporting member of the EMWA's SUS-SIG.



Pasta with mushrooms & onions

A quick, delicious meal!

SERVINGS: 2

PREPPING TIME: 10 MIN

COOKING TIME: 15 MIN

INGREDIENTS

110 g spaghetti (or other pasta)
300 g sliced mushrooms (I love
Portobello but you can choose)
1 large onion, sliced
3 tbsp olive oil
1 tsp white wine or cider
vinegar
a handful chopped parsley
salt & black pepper

NOTE:

This dish goes well with a green
salad with cherry tomatoes.
Bon appétit!

DIRECTIONS

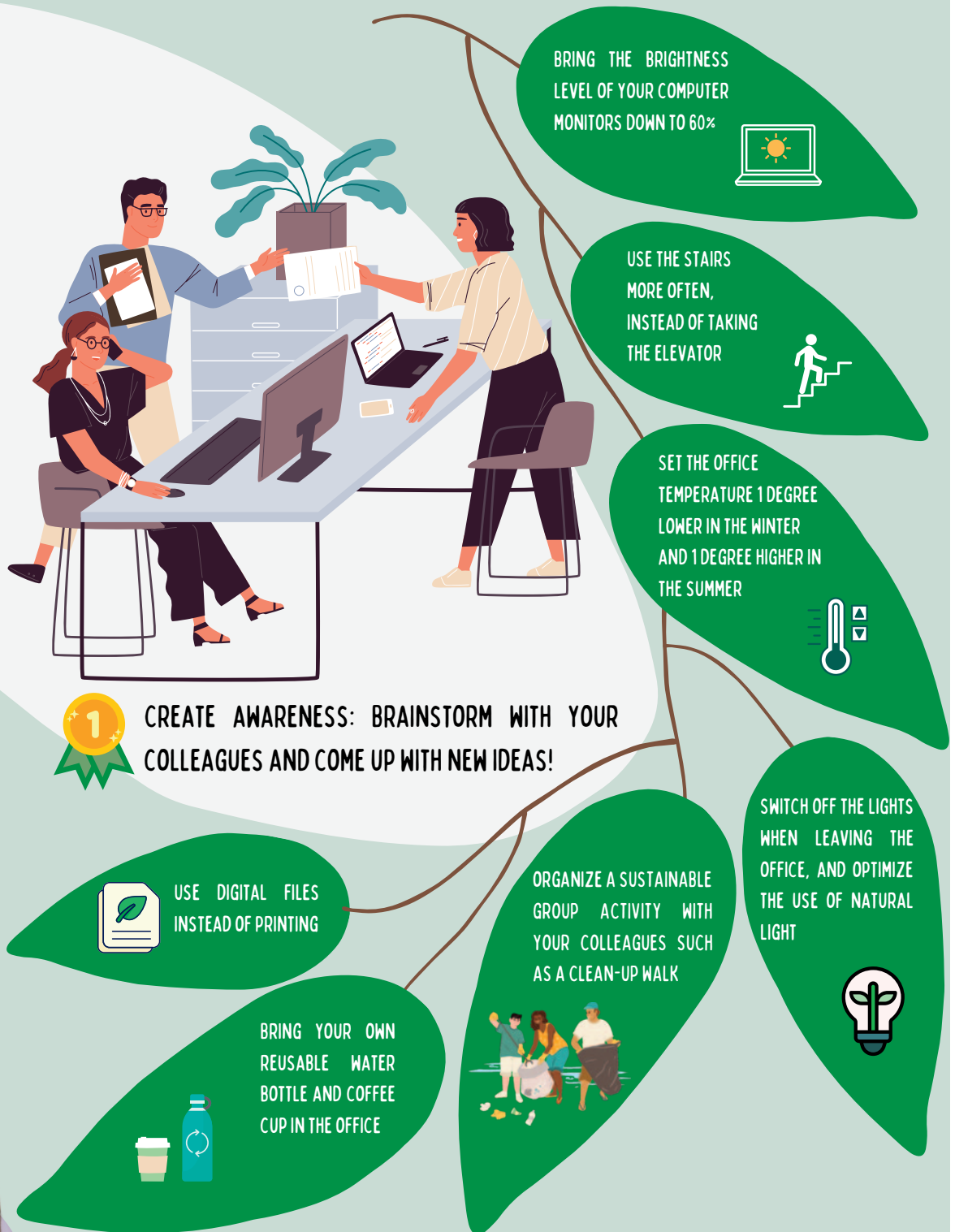
1. Cook the spaghetti *al dente* according to the package instructions. Drain and return to the pot. Add 1 tbsp of the olive oil and black pepper to your liking and stir.
2. While the spaghetti is cooking, heat 2 tbsp of the olive oil in a non-stick pan at medium-low heat. Add the sliced onion along with a sprinkle of salt and fry for 5 minutes or until the onion is soft and golden.
3. Add the sliced mushrooms and cook for another 5 minutes. If necessary, add some more olive oil. Add vinegar and season to taste with salt and pepper. Turn up the heat to high for the final minute of cooking.
4. Plate the pasta with the mushrooms and garnish with chopped parsley. (Mmm..I can smell it already!)

Author information

Paula Pinto, PhD, is a freelance medical writer based in the northern region of Portugal. Her advanced degree is in Pharmaceutical Sciences and she has over 20 years of professional experience, 15 of which have been devoted to research and teaching. Paula is a supporting member of EMWA's SUS-SIG. Paula adapted the above from a recipe that belonged to her mother, Lida.



8 tips for a sustainable workplace



Author information

Viviana Neviani, PhD, is a scientific writer at Merus N.V. in Utrecht, the Netherlands, since 2020. In her current role, she writes non-clinical study reports for the R&D department and contributes to the creation of posters, presentations, and scientific artwork. She is also a member of Merus' Sustainability Team.



Editorial

Jana Kubátová describes how biotechnology is a large field “comprised of products consisting of organisms, cells, their parts, and molecular analogues of endogenous substances”. The subject of her article represents a newly defined class of biotechnology product that falls under microbiome-based medicines.

One person’s gut microbiota weighs approximately 2 kg and contains microorganisms (bacteria, archaea, phages, protozoa, viruses), human cells, mucus, enzymes, bile acids, metabolites, and undigested food remnants.¹ Microorganism activity is key to human nutrition and immunological functions and its

composition can indicate the health of an individual. Faecal microbiota transplantation (FMT) is an innovative therapy where gut microbiota are transplanted from a healthy individual to restore the equilibrium of an unbalanced gut microbial population in an unhealthy individual – a practice that started centuries ago.

The topic of Jana’s article might be considered distasteful, but FMT is important and beneficial to those who receive it – she specifies those suffering from *Clostridioides difficile* infection (CDI). She outlines how hospitals can conduct this non-standard procedure and how regulations define FMT as a drug or a transplant depending

on the world region. She also outlines the advantages of using a medical writer for communications about FMT and how cultural differences are important to consider to avoid putting off lay people.

I want to thank Jana for discussing FMT and drawing my attention to something I had not thought about at all.

Jennifer Bell

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“All that is gold does not glitter”: Faecal microbiota transplantation

Jana Kubátová, PhD

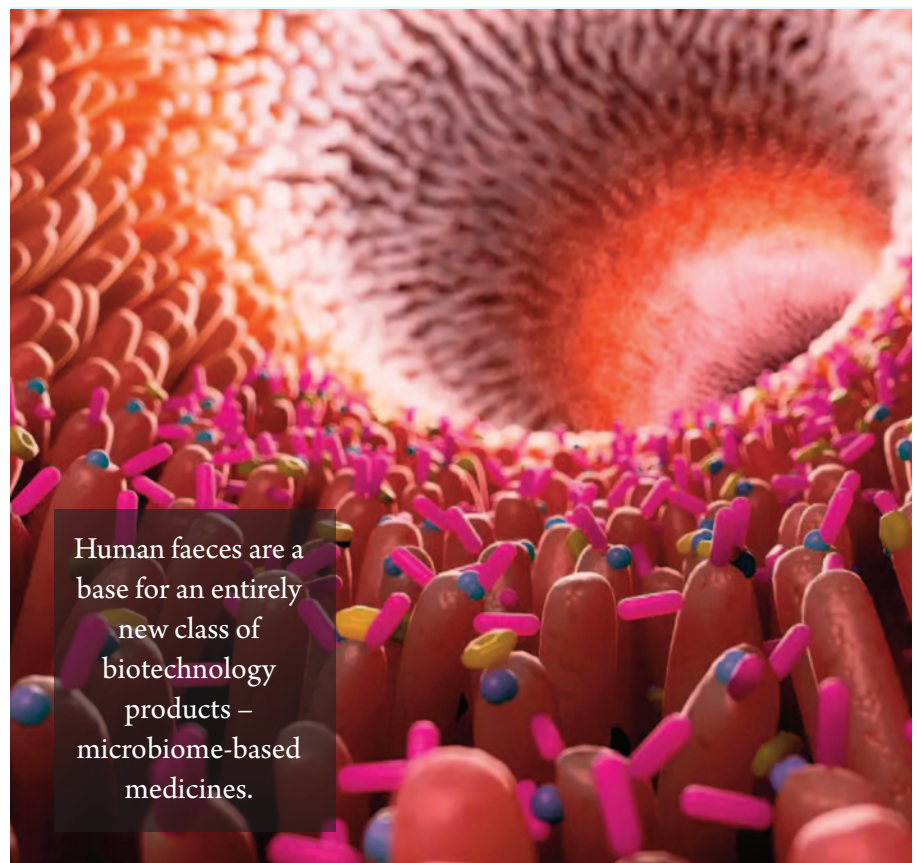
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doi: 10.56012/dawh4648

In ancient and medieval times, the therapeutic arsenal of natural healers, first physicians, and proto-pharmacists included excrement from various animal species. For instance, ancient Egyptian healers used hippopotamus and human excrement to treat gynaecological problems.¹ Ancient Chinese brought a fever down with “golden juice” from human faeces,² while ox excrement was used for the same purpose in medieval Britain.³ The mixtures were applied to skin, mucosae, or even ingested. Let us try to overcome nausea. Humankind has always used faecal matter to treat diseases. What is surprising is that we have never stopped.

Weird but mainstream

The large field of biotechnology is comprised of products consisting of organisms, cells, their parts, and molecular analogues of endogenous substances. Biotechnology products originate from the interconnection of natural and



Human faeces are a base for an entirely new class of biotechnology products – microbiome-based medicines.

Photo: Freepik.com

Table 1. Healthy stool components¹⁴

Microorganisms or cells	Number per gram of wet stool
Bacteria	10 ¹¹
Viruses	10 ⁸ -10 ⁹
Archaea	10 ⁸
Colonocytes	10 ⁷
Fungi	10 ⁶

engineering sciences and aim to improve our life, health or environment.^{4,5} Human faeces are a base for an entirely new class of biotechnology products – microbiome-based medicines.

The use of faeces is generally called “faecal microbiota transplantation” (FMT) and refers to the transfer of biological material containing faecal microorganisms from a human donor to a recipient’s gastrointestinal tract (GIT) to modify gut microbiota composition.⁶⁻⁸ Currently, FMT is used in conventional clinical practice to treat *Clostridioides difficile* infection (CDI). This bacterium causes severe nosocomial enterocolitis that could be fulminant. It frequently develops in immunocompromised patients and after the use of broad-spectrum antibiotics. Randomised controlled trials and observational studies have confirmed that FMT is highly effective in treating CDI and preventing its recurrence.⁹ According to the European and American clinical guidelines, FMT is an option in recurrent CDI or when the infection is refractory to the standard therapy.¹⁰⁻¹² Compared to the standard therapy of recurrent CDI, FMT proved to be the most cost-effective method.¹³

Table 2. The regulatory status of FMT products⁶

Country	Medicinal product (or equivalent)	Tissue and cells (or equivalent)	Therapeutic intervention	Classification undetermined / case-by-case
EU member states				
Austria				x
Belgium		x		
Croatia	x			
Czechia	x			
Denmark				x
Finland			x	
France	x			
Germany	x			
Ireland	x			
Italy		x		
Netherlands				x
Portugal	x			
Spain	x			
Sweden	x			
Non EU countries				
Australia		x		
Canada	x			
United Kingdom	x			
United States	x			

Waste is a treasure

The healthy human stool consists not only of various living or dead microorganisms (bacteria, fungi, archaea) but also bacteriophages and other viruses, human cells, mucus, enzymes, bile acids, metabolites, and undigested food remnants (Table 1).^{14,15} FMT increase microbial diversity and quantity in the recipient’s gut. However, the

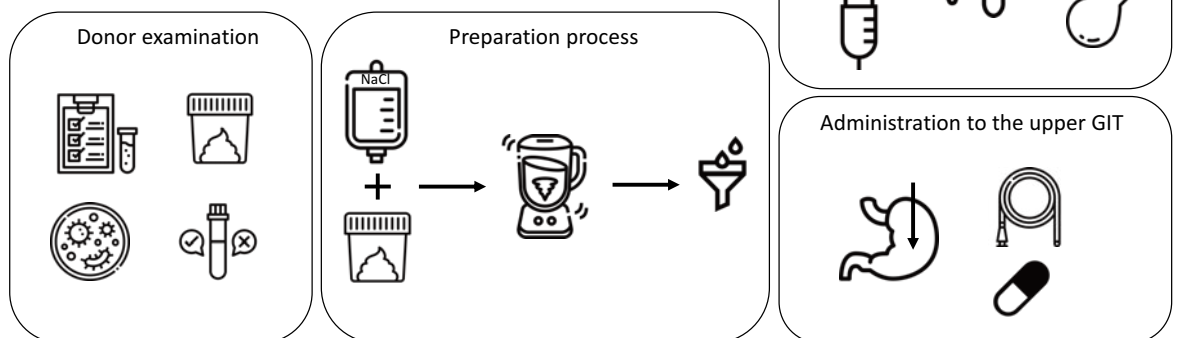
mechanism of action is more complex. FMT starts multiple interactions between the microbiota and the recipient’s intestinal environment and immunity.¹⁶

Hospital do-it-yourself

FMT product is prepared using a portion of stool from a healthy donor. The exact preparation

Figure 1. Preparation and administration of the FMT product

The biological material is mashed with sterile saline in a blender and then sieved through gauze to eliminate most of the undigested material. The resulting suspension is filled into sterile large-volume syringes or bags. A liquid product is administered to the patient’s lower GIT using an enema or endoscopic techniques or to the upper GIT via a nasogastric or nasojejunal tube. The suspension can also be freeze-dried to get a loose solid material which can be filled into conventional or acid-resistant capsules and used orally.



Abbreviations:
NaCl, sodium chloride (saline).

Figure 1 was designed using free resources from FlatIcon.com.

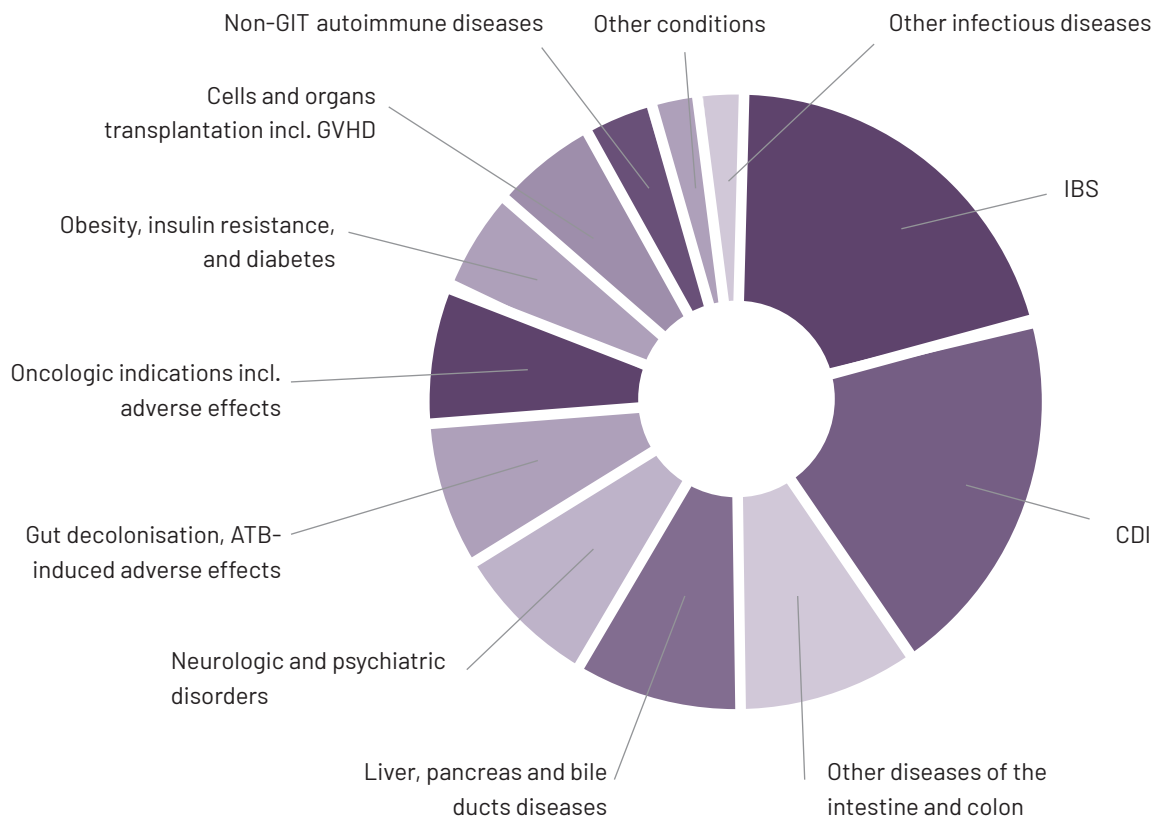


Figure 2. The spectrum of clinical trials focused on FMT

The term “fecal microbiota transplant” was searched on ClinicalTrials.gov (Beta Website), and the summary table was exported. Trials with the status “suspended” and “withdrawn” were excluded, while the indication was verified in the study description for the others. The trials were then sorted into broader indication categories. Studies focused on multiple indications were counted in more than one category.

Abbreviations: ATB, antibiotics; GVHD, graft versus host disease; IBS, irritable bowel syndrome.

method is not standardised, and facilities modify it according to their individual experience. Figure 1 gives an overview of the common way of preparation.

EMA distinguishes two ways of FMT product preparation. The “extemporaneous preparation” processes the stool minimally in on-site healthcare facilities. “Manufacture”, on the other hand, is carried out in dedicated facilities, and the process includes multiple steps and uses more sophisticated technologies.⁶

Physicians’ approval

FMT therapy is widespread, and more than 1800 hospital-based procedures were estimated to be performed in Europe in 2019.¹⁷ Many countries have already adopted clinical guidelines for the rational and safe use of FMT (e.g. Australia, Austria, Canada, Czechia, Denmark, Poland, Romania, South Korea, and

the United Kingdom).^{18–26} However, these guidelines are mostly an expert consensus of medical societies without the point of view of relevant regulatory authorities.

A drug or a transplant?

The regulations of products influencing human health often fall behind clinical practice. In 1958, the first modern scientific article about FMT was published.²⁷ Currently, there is still no internationally agreed classification of FMT products.

The first attempt to define the product from the regulatory point of view was made by FDA in May 2013. FMT was classified as a drug and, moreover, an Investigational New Drug. The decision generally ruled out its use outside clinical trials. A few months later, after the expert community objected to this position, FDA declared the

enforcement discretion for using FMT in CDI not responding to standard therapies.²⁸ In other indications, FMT is still perceived as the Investigational New Drug.²⁹

In 2014, the European Commission declared that FMT does not fall within the scope of the EU tissues and cells legislation or any other legislation framework. This position meant EU member states were free to regulate the use of FMT on a national level.^{6,16} Since then, a significant tendency to classify FMT as a medicinal product has emerged across the EU. Summary Table 2 outlines the regulatory status of FMT in different countries, as found by EMA during a recent survey.⁶

Stool donation

The selection of a stool donor is the most critical element of FMT. Candidates must be examined extensively, including medical history and laboratory testing. Their stool sample must be

Altogether, it is easier to donate blood than stool.

Box 1. General rules for stool donation^{7,8}

- Candidate screening: questionnaire, medical examinations, laboratory tests (blood, urine, and stool), interview with a healthcare professional
- Healthy donors, non-anonymous for the donation facility
- Altruism-driven donations, no direct payments for the donation
- Informed consent expressed by the donor and the recipient
- The donor's identity not to be revealed to the recipient
- Traceability of the material from the donation, through the preparation process, to the administration of the product
- Written or electronic records kept for an adequate time for vigilance reasons

free of GIT pathogens (including parasites) and drug-resistant bacteria to avoid transmission of undesirable germs or drug resistance genes. Healthcare professionals should not donate stool because they are often colonised with multidrug-resistant microbiota.⁷ The microbiological safety of a stool sample is fundamental, as the transmission of antibiotic-resistant *E. coli* and subsequent serious adverse reactions to FMT were reported.^{30–32} Altogether, it is easier to donate blood than stool.

Many measures typical for blood, tissues, and cells donation must be observed when performing FMT (Box 1). This similarity has led several countries to base their rules for FMT on the national tissues and cells legislation. In other countries, the classification is determined case-by-case depending on the indication, preparation process and facilities involved.^{15,16}

More questions than answers

The classification influences many practical aspects of FMT use, and particularly, the drug/medicinal product status challenges clinicians, facilities, and regulators. What is the active ingredient/drug substance? How to test its potency? Is GMP necessary if the product is prepared extemporaneously in the hospital? How can batch-to-batch similarity be achieved if stool samples even from the same healthy donor vary in composition? Many other questions arise and are not yet sufficiently answered.

Better safety and availability

The role of gut microorganisms in human health is becoming evident in many other conditions besides infectious enteritides. Microbiota composition is also altered in patients with autoimmune diseases, liver pathologies, obesity, or neurological disorders.³³ As the evidence for the efficacy of FMT in these indications is not yet strong, the treatment is considered experimental and only used in the controlled environment of

clinical trials. In the middle of July 2022, more than 400 academic or industry-sponsored trials registered at ClinicalTrials.gov declared the use of FMT (Figure 2).

The development of FMT rushes forward despite the regulatory ambiguity. Researchers are now hunting for microbial species responsible for the main effect in CDI, inflammatory bowel diseases, and other conditions. Companies are developing FMT-based “purified” products based on defined bacterial strains cultivated from the stool.^{34,35} This approach would largely reduce safety concerns associated with administering extemporaneously prepared FMT suspension. Currently, no FMT-based medicinal product has a marketing authorisation, but several are tested in Phase III trials with encouraging preliminary results.^{16,36,37}

A different opinion in the expert community suggests that the effect of FMT cannot be reduced only to living bacteria. Dead bacterial cells, bacteriophages, or metabolic products of microorganisms have biological and immunological activity as well and may contribute to the clinical effect of FMT. This “whole stool” approach will benefit from continuing development of certified non-profit stool banks and efforts to internationally standardise the method.

The right place for a medical writer

As in any other clinical research and development project, the involvement of a medical writer brings advantages. Above all, it is the quality and reliability of documents and professional communication with various stakeholders.

In the clinical research of FMT, non-commercial sponsors prevail over companies. These could be universities and university hospitals, research centres, medical societies, or patients' organisations. Many non-commercial sponsors have already established a department of clinical trials handling the trials' expert administrative and communication with the regulatory authorities. And medical writers have started to appear there; however, they often had to take on more roles in the team.

When working on FMT projects, the regulatory status of FMT is important for the medical writer to choose appropriate writing guidelines and templates for the required

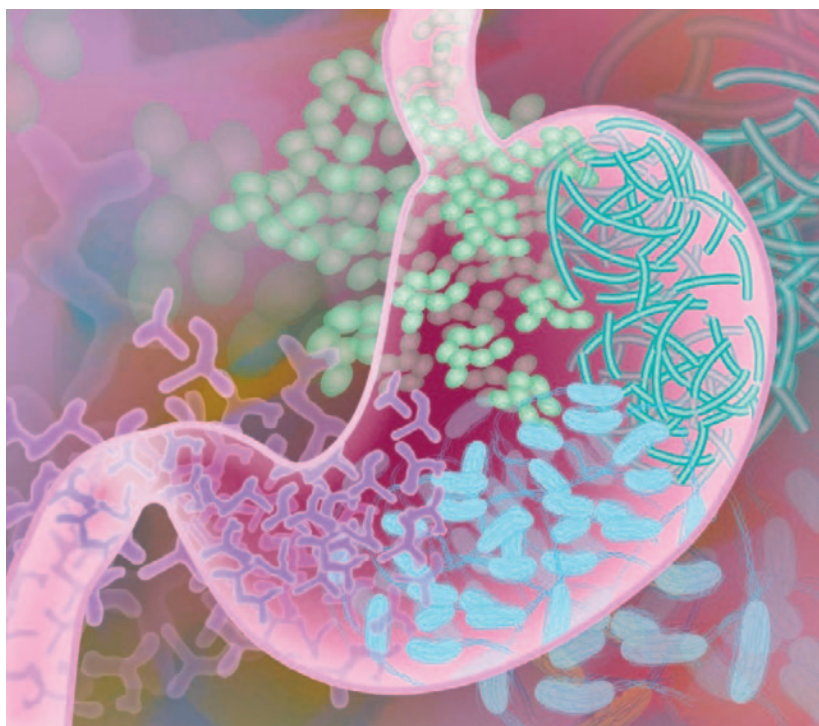


Photo: Freepik.com

regulatory documents. Consultations with the national regulatory authority are necessary and valuable, especially if there are no specific position statements regarding FMT. A medical writer well acquainted with the preparation process and facility, clinical aspects of the project, and relevant legislation can be an excellent leader in these consultations.

Last but not least, presenting FMT in a neutral, informative way to a lay audience is a challenge. It is easy to repulse potential donors and patients just by using inappropriate language or humour. The cultural differences in the approach to human waste are huge. For instance, what is acceptable for most Europeans could be totally unacceptable for the Japanese. And this is a task for a communication expert.

Conclusion

FMT is a potent tool to improve gut health and influence diseases associated with an impaired community of gut microorganisms. It is a life-saving treatment, while it can be life-threatening at the same time if not performed in a controlled way. The future should bring more profound knowledge about its mechanism of action and measures to increase the efficacy, safety, and quality of FMT as well as its availability for patients worldwide. And medical writers might take part.

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The first part of the article's title was adopted from the poem "The Riddle of Strider" by J. R. R. Tolkien.

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The author declares no conflicts of interest.

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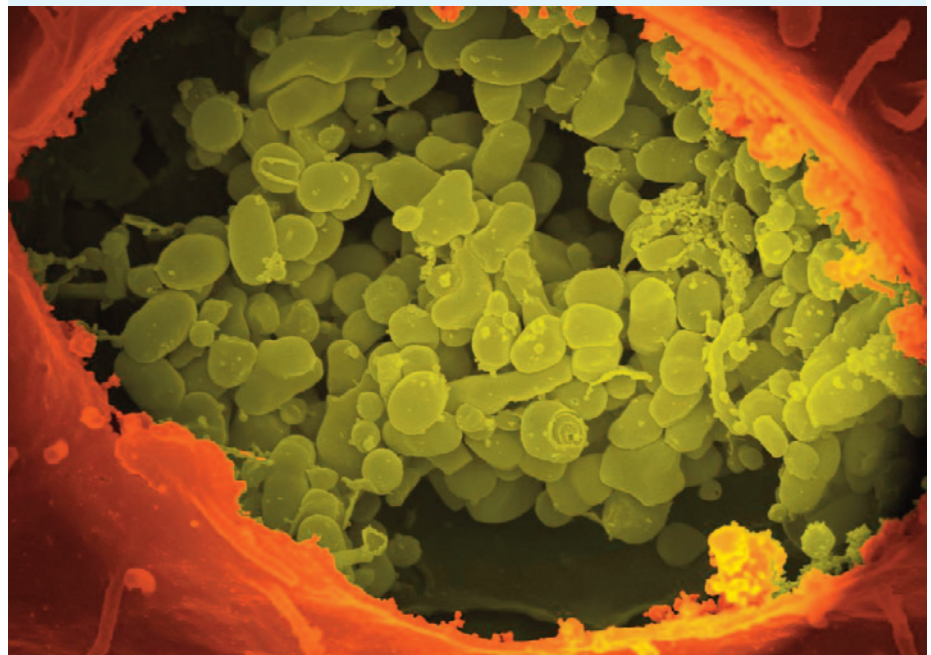


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Good Writing Practice

Syntactic punctuation distraction

Comma: Misusage

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Introduction

If the punctuation is distracting, so is the syntax. Often a comma is misused (not sufficiently explicit) for its intended function especially in the presence of another comma with a different function. Consequently, a stronger (1. semicolon, 2. colon), weaker (3. parentheses) mark of punctuation, or a lexical marker (4. direct statement) is necessary for clarity.

Stronger marks of punctuation

Example 1: Semicolon

(Material and Methods section)
Blowwhittaker, Boston, MA

Revision

Blowwhittaker; Boston, MA

Notes

At the phrase level, a semicolon is useful to separate syntactic units one of which contains an internal comma.

The semicolon, a visual hybrid of a period and a comma, is intermediate in explicitness between a comma and a period. The period marks the end of a sentence; the semicolon marks an interrelation between independent clauses of a compound sentence and between syntactic units in apposition.

Example 2: Colon

(Results section: results statement)

This sensitivity correlated with enhanced T-cell accumulation in CCL25 expression sites, the intestinal epithelium, and the intestinal lamina propria.



Revision

This sensitivity correlated with enhanced T-cell accumulation in CCL25 expression sites: the intestinal epithelium, and the intestinal lamina propria.

Notes

The pattern at first seems to be three objects (*sites, epithelium, and propria*) of the preposition *in*. However, a more explicit mark (colon) is necessary to distinguish the forecasting noun *sites* from the following two appositives. Unless the

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reader immediately knows that the intestinal epithelium and the lamina propria are CCL25 expression sites, the comma after *sites* mis-marks the first of three sites for T-cell accumulation.

A colon would be disruptive between core constituents of a sentence such as a transitive verb and direct object (*measures included: the Fugl-Meyer assessment*). Disruption is also a consequence between a present participle and its object (*several measurements including: the irregularity index*), and between a preposition and its object (*such as: approaches*).

For another perspective, a complete sentence should precede a colon. Thus, 'the following' is often added (*measurements including the following:*)

Weaker mark of punctuation

Example 3: Parentheses

(Introduction section: Research problem)

Although the complex movement in tennis depends on many factors, such as players' somatic traits, grip force, and sometimes mental status, many researchers propose to investigate a variety of scaling variables for lower limbs, such as joint laxity, soft-tissue flexibility, and power output.

Revision

Although the complex movement in tennis depends on many factors (e.g., players' somatic traits, grip force, and sometimes mental status) many researchers propose to investigate a variety of scaling variables for lower limbs (e.g., joint laxity, soft-tissue flexibility, and power output).

Notes

In the Example, the commas segregating the examples of *factors* and *scaling variables for lower*

limbs are not distinguishable from the commas between the examples. In contrast, the parentheses explicitly segregate the secondary information from the primary.

Without the *e.g.*, the list would appear complete because of the *and*.

There is a punctuational hierarchy to differentiate secondary parenthetical information: em-dash (emphasis); comma (slight emphasis); parentheses (deemphasis).

Lexical marking instead of punctuation

Example 4: Past participial phrase

(Introduction section: Research problem background)

Membrane-bound granules, which are caused by peroxidation, are composed of lipofuscin.

Revision

Membrane-bound granules, most frequently caused by peroxidation, are composed of lipofuscin.

Notes

The comma segregating the adjective clause initiated by *which* is intended to mark extra information, not to restrict the meaning to a subgroup (usually marked by a comma-less *that are*). This non-restrictiveness of the adjective clause inexplicitly indicates that all membrane-bound granules are formed by peroxidation. However, such non-restrictive marking is often unknown by readers (and even the authors) necessitating the use of an explicit lexical modifier (adverb participial phrase) to clarify meaning.

Another example of inexplicit non-restrictive meaning *My brother, Harvey, is a physician* tests the subtlety of non-restrictive marking; that is, when questioned about how many brothers the punctuation indicates, even English as first language graduate students are unsure. The commas are intended to convey that the name *Harvey* is not necessary to indicate that there is more than one brother.

It would be immediately clear to write *Harvey, my only brother, is a physician* or *Harvey, one of my two brothers, is a physician*.

Tabular Summary

The indicated replacement markers indicate that usage of either specific punctuation or a specific lexical modifier can clarify an inexplicit comma.

Misused comma	Revision	Replacement
1. Company, City, State	Company; City, State	Semicolon
2. Category, tissue, tissue	Category: tissue, tissue	Colon
3. Category, example, example, example	Category (example, example, example)	Parentheses
4. Noun, non-restrictive which-fronted adjective clause	Noun lexical modifier	Superlative adverb + past participial phrase



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 standardised 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

Getting Your Foot in the Door

SECTION EDITOR



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Editorial

What does it mean to be a medical writer? How can you start off on the right track? Good advice is very valuable and learning from others is important for our development.

Therefore, Bruna Landeira asked three experienced medical writers to share some insights on their start in medical writing. This article can help you avoid some pitfalls at the outset and advance your career. Enjoy the read!

Ivana

What piece of advice do aspiring medical writers tend to ignore?

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doi: 10.56012/quyl2082

Medical writing is a field that includes a widely diverse range of jobs and work styles. Consequently, aspiring medical writers can lose their focus and time struggling in their first steps. With this in mind, I interviewed three medical writers with different professional backgrounds to provide advice that may be helpful to beginners in this field.



Photo by Lukas Brzdek

Alejandra Viviecas, Clare Chang, and Barbara Bartolini are experienced medical writers with distinctive career trajectories. Alejandra Viviecas and Barbara Bartolini started as freelancers, even though Barbara decided to take a different career path in the end and works as a scientific editor. Clare Chang built her career in regulatory medical writing.

The three of them reflected upon their own



Photo by KOBU agency

experience to answer two questions:

1. What is a piece of obvious advice that beginners tend to ignore?
2. What is a piece of advice for beginners that may not be so obvious?

Alejandra Viviecas

What is a piece of obvious advice that beginners tend to ignore?

Focus on the lifestyle you want and the kind of deliverables you want to work on. Medical writing is a big field that offers a lot of opportunities in terms of lifestyle. This is one of the things I love the most about this career, but it requires you to think about what you want

before you start applying for jobs or projects. Sometimes, beginners are so eager to hit the road running that they forget to answer these basic questions. Do you want to do freelancing? Would you rather write or edit? Do you lean more towards medical communications or regulatory? Asking these questions beforehand will help you target the right roles, leading to higher job and personal satisfaction, and ultimately making job progression easier.

What's your piece of not-so-obvious advice for beginners?

Once you start working in medical writing, **use a time tracking tool so you know how you are**

Use a time tracking tool so you know how you are allocating your time.

allocating your time. This will help you be more efficient and plan realistically. It will also show you how you are getting faster as you gain more experience, which will give you a lot of satisfaction.

Clare Chang

What is a piece of obvious advice that beginners tend to ignore?

This piece of advice might be difficult to swallow for aspiring writers. For many beginners, there is a lot of focus on writing (e.g. grammar, creating a portfolio to showcase writing skills). My own take from this is, if you are only *starting* to refine or polish your writing skills to fit the medical writing role, then the role may not necessarily be for you. Writing well is one of the foundational skills a medical writer should have in their inventory before they start their career. It should come naturally, as drawing is natural for an artist. Of course, one can always further refine these skills. However, **throughout their medical writing career, there will be a lot of other skills they have to learn.**

What's your piece of not-so-obvious advice for beginners?

To find a job, the best way is through **networking**. Networking is not just about sharing your details and having someone in your LinkedIn network. It is also not just about connecting and asking for a job. As an aspiring writer, it's important to learn about the craft by starting a conversation. Ask about the role. Be curious about what the role entails. **Make human connections.** Give updates on what you are doing and how you're working towards getting a medical writing role. Ask questions about things that you don't understand. Most importantly, follow up!

Barbara Bartolini

What is a piece of obvious advice that beginners tend to ignore?

Take some time for yourself. To be a medical writer means that you have to like writing and thinking on your own. Indeed, many medical writing projects are based on teamwork, but the medical writer is the player who spends the most "alone" time. It may be different from the usual office life and even from an academic job, where discussion and meetings are common. As a medical writer, you have meetings and discussion with clients, authors, and stakeholders, but the



Photo by Diego PH

most precious time, in my opinion, is that spent reading and thinking, developing ideas, and metabolising the context and information to be reported in the text. The creative part happens when I am alone. Working independently in three-hour blocks, without interruptions (emails, WhatsApp, calls, coffee breaks) is extremely important in my view, and can be underrated by beginners.

What's your piece of not-so-obvious advice for beginners?

I hesitated a lot before starting. I

never had real training as a medical writer after finishing my PhD, nor during my postdoc years. I never got a certification, and I felt I was unprepared for the job. Then I just started to post short pieces on social media, more to test my writing abilities than to demonstrate that I could write. It was worth it. **Experience gained in the**

field helped me to understand what I liked to do and what I was good at, and at the same time, it gave me visibility in the market. After the first few projects I was more aware of my abilities and of my limits, so I was able to search for material focused on what I needed to know to grow as a professional. In addition, networking and talking to other medical writers has been extremely important for my growth. I believe that getting training is good, but one can learn a lot while on the job. Another thing I would like to point out is **the importance of having other skills besides writing,** i.e. data analysis, social media management, graphics,

and artwork. Different backgrounds and interests are a plus for a medical writer because there are so many different types of editorial output: manuscripts for peer review, digital output, infographics, videos, and interviews. Medical writing is a wide umbrella and in every project, there's a need for more than just writing. Being able to contribute more than one skill is a plus, while continuing to develop your qualifications as a medical writer.

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The opinions expressed in this article are the author's own and not necessarily shared by her employer or *Medical Writing*.

Conflicts of interest

The author declares no conflicts of interest.

To find a job, the best way is through networking. Networking is not just about sharing your details and having someone in your LinkedIn network. Make human connections.

The creative part happens when I am alone.



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Out On Our Own

SECTION EDITOR



Laura A. Kehoe
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Editorial

Dear readers,

To be a freelancer, you must factor in many elements to run a personal business. A topic that has raised discussion over the years I've been chair of the Freelance Business Group is whether a freelancer needs Professional Indemnity Insurance (PII) or not. In this issue,

Sara Rubio and Lucia Messi are discussing just that after they both came across the demand from a potential client to set up a PII. Unsure of what was available and the reasons why they needed one, they went into research mode. With their research and asking the EMWA LinkedIn group and attendees of the Freelance Business Forum in November 2021, here, they present their

findings, not to give a definitive answer but to let you all know what information is available on this topic. Many thanks to both of them for bringing this together. I hope it helps those faced with a similar situation.

Happy reading.

Laura A. Kehoe

Professional indemnity insurance: One of the many dilemmas of freelance medical writers

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Sooner or later in their professional journey, freelance medical writers (MWs) may be confronted with the decision of whether or not to obtain professional indemnity insurance (PII). We believe no blanket recommendation can (or should) be conveyed regarding this topic due to the many factors to consider and the variability from one freelance MW's circumstances to another's. We personally encountered the dilemma of whether we needed PII or not in 2021 upon a request by a potential client. After conducting some research, we realised this is a complex topic that is recurrently discussed among the freelance MW community.^{1,2} We, therefore, asked EMWA members to complete a short survey both on the EMWA LinkedIn group and during the November 2021 EMWA Freelance Business Forum (FBF) to gauge the current opinion among the community and to spark some debate around it. Here, we share the pooled results of these polls, some key discussion points from the FBF and beyond, and extra details/resources that we hope are useful to the community. We are by no means experts

on PII or other insurance/legal aspects, so please keep that in mind while reading this article and consult the appropriate experts if you need advice regarding PII. Of course, the survey header indicated that the questions were related to PII, so there may be a response bias as people with PII may be more inclined to respond. However, we wanted to share these general results with the community to inform those of what other freelance MWs are doing regarding this topic.

What is PII, and why would a freelance MW want to have it?

In general terms, PII is a commercial insurance that covers against claims from clients or third parties due to potential negligence, errors, breaches of contractual terms, and alike committed by a business (including freelancers) during the course of their professional activity. Below we present some reasons for/against having PII.

Reasons for having PII:

1. In some countries, it may be required so a person can be recognised as a professional MW and, thus, be able to perform the job.
2. It may be contractually required by some clients to engage in a collaboration with the freelance MW.
3. It provides protection to the freelancer, especially against financial risks and time lost from work.
4. It gives peace of mind to both the freelancer and their clients.

5. It might be seen by some as a sign of professionalism/marketing tool to attract new clients.

Reasons against having PII:

1. Its benefits may not be fully relevant to all freelance MWs (PIIs in the market are often not specific for our profession, plus activities and risks greatly vary from one MW to another).
2. Some freelance MWs argue they do not need PII as they shall not be held liable for the final content of the documents they work on.
3. Some insurance companies have difficulties understanding the day-to-day job of a MW and their potential risks and insurance needs, which might make the PII purchase process more difficult.
4. Policy clauses and jargon may be complex for non-experts and often require some research or advice before purchase, which may put some people off.
5. It is a structural cost that may be considerable in the long term.



Some PII jargon explained:

Premium: The price a professional pays for their insurance cover, which is calculated based on the risks resulting from their activities.
Limit of indemnity: The maximum amount covered by the insurance policy during the policy period.
Excess: A pre-agreed amount of money the professional has to pay to the insurer in the case of a claim; the insurer will then contribute the rest of the established limit of indemnity.

Pooled results of the surveys and key discussion points

Question 1. Do you have PII in place?

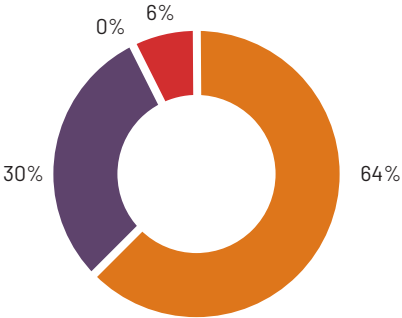


Among the interviewed professionals, there was a 1:1 distribution between MWs who have PII and those who do not.

Discussion points

- There is clearly no unanimous consensus on the topic.
- Among freelance MWs who do not have PII, some have never been asked to carry insurance, while others prefer to only engage in insurance-free collaborations.
- During the FBF discussion, it emerged that having PII in place seems to be a common practice among freelance medical translators.
- The percentage of freelance MWs with PII is slightly higher than the 43% reported among MedComms freelancers in a survey published in 2014.³

Question 2. What would you do if your new client agreement states that you must have a PII cover, but you do not have one?



Most of the interviewed freelance MWs would prefer to put PII in place rather than negotiating the removal of such clause from the agreement.

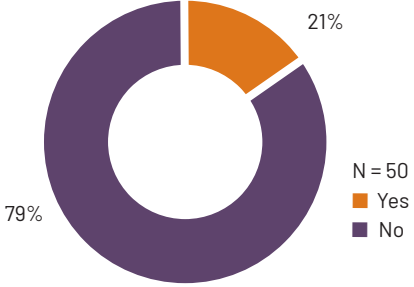
Discussion points

- One potential reason to explain these results is that refusing to get PII might mean losing the prospective business (some of the interviewees already experienced that).
- Not all clients require PII. The interviewed

freelance MWs often found this requirement coming from large clients, especially those based in the United Kingdom (e.g., contract research organisations [CROs] and MedComms agencies), or from publicly funded organisms in the US, which tend to enforce that all contractors are insured for legal reasons.

- Some clients seem to be rather flexible in finding alternative ways to work with freelancers who do not have PII and may even be willing to remove such clause from the contract (see next question).

Question 3. Have you ever asked a client to remove the PII requirement from the collaboration agreement?

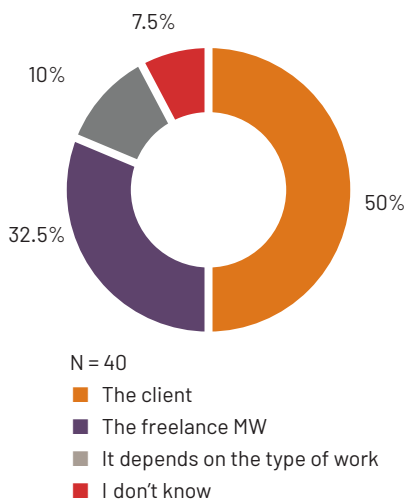


Only a minority of freelancers have asked a potential client to remove the PII requirement from the contract.

Discussion points

- Even after asking the client, removal of the PII requirement may not be possible due to legal reasons. For instance, a prospective client of a freelancer may hold a PII themselves and may be contractually required by their end client (e.g., a pharma company) that any subcontractors are also insured, to guarantee that any work is performed under appropriate cover.
- The plausibility of such a request may depend on who is considered responsible for the final document (see next question).

Question 4. Who is responsible and liable for the final content?



Half of the interviewed freelance MWs consider their client responsible for the final content of the document.

Discussion points

- Some freelance MWs argue that they do not need PII and they shall not be held liable for the final content of the documents they work on because:
 - Freelance MWs do not usually sign off on the final document
 - The final document is usually the result of a shared effort involving a team of MWs, data checkers, editors, and expert reviewers
 - Most of the time, the freelance MW does not even see the end product.
- Some situations might expose MWs to a higher responsibility, visibility, and consequent risk of exposure to legal action such as:
 - Authoring clinical study protocols, reports, or other documents
 - Acting in a consultant capacity or offering

professional expert advice to a client who does not have any expertise in the area of interest

- Being acknowledged in published articles, according to Good Publication Practice (GPP 2022) guidelines.
- Of note, a separate question on the poll showed that none of the interviewed freelance MWs have ever faced a claim. This result may make us question the real risk faced; however, we should apply some caution here because anyone who faced a claim is likely not to share that information to safeguard their reputation.

Conclusion

The need for PII continues to be a debated topic among the freelance community. In many cases, freelance MWs can perform their business activities regardless of whether they have PII or not, which means taking PII is a choice rather than an obligation. Therefore, we believe there is no blanket recommendation on whether freelance MWs should take PII. This will most likely depend on the circumstances of the business, the nature and risks of services provided, or the requirements imposed by clients, among other factors. In any case, it is worth dedicating some time to fully understand a PII policy, including the fine print, to decide whether the cover suits the particular needs of a freelancer. On a final note, we would like to acknowledge that data in this article should be taken lightly as the sample size of these polls ($N \leq 50$) is small if one considers the amount of freelance MWs in Europe, and responses may be slightly biased. However, we wanted to share what we gathered from our EMWA freelance community hoping that other peers find it useful.

Acknowledgements

A special thanks to Laura Kehoe for the opportunity to present about PII during the November 2021 EMWA FBF, and to write this article. We are also grateful to everyone who participated in the polls and/or discussions about PII.

Disclaimers

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

The authors of this article are not experts in the insurance/legal field. Therefore, they cannot provide any advice on the topic and do not intend to convey definite opinions.

This article summarises key points from discussions that took place during the November

2021 FBF, live and remote discussions among freelance colleagues, and materials available online. For these reasons, not all sentences have been referenced but the additional consulted online materials have been included in the "further reading" section.

Conflict of interest

Lucia Massi and Sara Rubio are both freelance medical writers and declare no disclosures or conflicts of interest related to this piece.

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Further reading

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Upcoming issues of **Medical Writing**



March 2023:

Clinical trials

Medical writers and communicators are involved in clinical trials, from writing the trial protocol to reporting and publishing the trial results. This issue will focus on our roles, responsibilities, the documents we create, and our audience. Furthermore, we will also cover the regulations and best working practices governing documentations for clinical trials.

Guest Editors: Raquel Billiones and Ivana Turek

The deadline for feature articles has passed.



September 2023:

Automation/software

Streamlined complex medical report writing supported by artificial intelligence/machine learning is making its way into clinical regulatory writing. The medical writing automation's goal is to speed up and ease clinical development processes by reducing the time and cost involved in creating and keeping regulatory documents up to date. This issue will examine current issues, challenges, and opportunities towards human guided medical writing automation systems.

Guest Editors: Shiri Diskin and Daniela Kamir

The deadline for feature articles is June 1, 2023.



June 2023:

Freelancing

Freelancing is becoming an increasingly popular option for medical writers and communicators, but it's not as straightforward as finding a few clients and getting paid. There's so much more involved. Freelancers are mini business owners and to be successful, you need a plethora of skills, be self-motivated, driven, and adaptable and take the highs with the lows. In this issue, the authors will discuss what options are out there for freelancers, how to get started, and all the challenges that you may come across. Freelancing can be a lucrative business but addressing all the factors is key to being successful.

Guest Editors: Laura Kehoe and Satyen Shenoy

The deadline for feature articles is March 1, 2023.



December 2023:

Biotechnology

Biotechnology uses biological systems and living organisms in R&D and production processes. Biotechnologies include biologic and biosimilar pharmaceuticals like monoclonal antibodies, vaccines and advanced therapy medicinal products, for example, gene and cell therapies and tissue engineered products. In addition, biotechnologies support the product lifecycle, for instance, in non-clinical work using in silico, in vitro, and animal testing methods. Also, support services personnel like those in biobanks and supply chains require an understanding of biotechnology. This issue focuses on the crucial role of writing and communications in biotechnology and product development.

Guest Editors: Jennifer Bell

The deadline for feature articles is September 1, 2023.



<http://journal.emwa.org/>