

Volume 29 Number 1  
March 2020

# Medical Writing



## Visual communications

### Also in this issue...

- Planting a "non-biological seed" – will this meme persist?
- Clinical trial design: Considerations for medical writers developing clinical trial protocols



EUROPEAN MEDICAL WRITERS ASSOCIATION



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**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. Members of EMWA receive *Medical Writing* as part of their membership. For more information, contact [mew@emwa.org](mailto:mew@emwa.org).

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

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# Medical Writing

## Visual communication for medical writers

Scientific information in general, and especially in health-related fields, has been increasing exponentially. At the same time, people have less time to read long texts and attempt to comprehend complex scientific information. To make this easier, different types of visuals can be used to complement the text or even replace it.

Although most medical writers are not dedicated to preparing visuals, they are frequently asked to include them in patient information leaflets, posters, conference presentations, manuscripts, and other documents.

Furthermore, medical writers are increasingly asked to help prepare interactive material and to collaborate in developing web pages or apps. Visuals and texts must work together to tell a story, and both must be clear, simple, and scientifically accurate.

**“A picture is worth a thousand words.” This quote is used so widely that it tends to lose importance, but its relevance to medical writing is unquestionable.**

In this issue of *Medical Writing*, I am honoured to present you with a collection of articles on visual communications. Not surprisingly, several of the articles cite the famous quote “A picture is worth a thousand words.” This quote is used so widely that it tends to lose importance, but its relevance to medical writing is unquestionable. Indeed, we are writers, and words are the product we sell, but we can add value to our work by including visuals.

**Caroline Erolin** introduces the applications and evolution of the classical visual material used in medicine – illustrations. Medical communications, however, now demand other types of visuals besides just illustrations. **Mariella Franker** presents a diversity of visuals, from illustrations to graphics and animations. She describes their relevance to translating data and increasing scientific credibility, and she offers tips to help produce effective visuals.

But how does visual communication work, and why is it so effective? **Ana Costa**, **Joost Bakker**, and **Gabriela**



**Plucinska** describe how perception transforms reality into unique, individual interpretations, and they present a historical perspective of visuals in biomedicine. They further explain how key aspects of visual image theory can be used to produce effective infographics.

In many instances, medical writing projects require using stock images or pre-existing images made by designers or illustrators working in the team. **Diogo Guerra** writes about how to adapt pre-existing images by adding proper callouts and labels, with practical advice and clear examples.

**Katja Martin** writes about the need for a visual approach to communication and further describes how graphical abstracts and infographics can improve medical communication materials. Her article offers numerous visual examples and provides suggestions for tools that non-designers can use to simplify creation of compelling visuals.

**Tullio Rossi**, **Flynn Slattery**, and **Katharina Richter** make the case for replacing wall-of-text posters with graphical abstract-like designs that transmit only the main message. They describe posters as a networking tool that

### GUEST EDITOR



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should be visually attractive and should stimulate conversation and help create new collaborations.

While medical communications clearly benefit from using visuals, regulatory writing might also benefit, particularly by incorporating graphics and infographics to help visualise complex data. **Leehee Navon-Perry, Jackie Raskind, and Sara Stein** provide a good example of how simple tools accessible to any medical writer can be used to create infographics to illustrate study schemas in regulatory documents. They show how this kind of image can be used as a universal tool to easily transmit the study design to all readers, regardless of their background. **Thomas Schindler, Katrin Summerer, Leonie Leithold, Kamila Sroka-Saidi, and Clive Brown** take this point further, explaining how graphical abstracts can be incorporated in lay summaries of clinical studies. They discuss how to design a graphical abstract and highlight ethical issues involved in selecting the content.

**Alexandra Sanfins and Maria João Almeida** take a different perspective, showing how visuals helped establish a professional network in Portugal. They also describe some tools that allowed them to easily create visually appealing documents without previous training in graphic design.

I hope this issue will help you understand the possibilities for producing visuals as part of your work. In many instances, you can generate an effective visual by following some simple rules and by using icons or stock images. An example is the cover image I created for this issue with the precious help of Ana Costa. For more detailed images, you may need the help of a professional illustrator or designer. In any case, your visuals should be as clear and carefully constructed as your texts.

Happy reading!

Ana Goios

## About the Guest Editor

Ana Goios is a Portugal-based medical writer with a scientific background from years of research in population health and genetics. She has complemented her academic training with courses on scientific illustration, data analysis and biostatistics, and the EMWA Professional Development Programme.

## COVID-19 forces cancellation of conference



The EMWA Executive Committee and Head Office closely monitored the rapidly evolving implications of the current COVID-19 situation and the recommendations from the World Health Organization as well as the advice from and restrictions implemented by national governments. As a result, EMWA chose the only option available and cancelled the upcoming Prague conference that had been scheduled for May 5–9, 2020.

This will be a major financial loss for EMWA, but the organisation has been careful in spending money during the past years and have a robust enough financial reserve to be able to manage its impact.

The organisation will investigate steps such as extending the length of the November 2020 conference. Stay tuned to EMWA Newsblasts for further information.

## EMWA collaboration with the German Scholars Organisation

EMWA is continuing its collaboration with the German Scholars Organization (GSO), a non-profit organisation with over 5000 members dedicated to providing career advice and networking opportunities to scientists who want to pursue careers in Germany.

As part of this collaboration, Abe Shevack was interviewed in a webinar by

Dr Anne Schreiter, the Managing Director of the GSO. The interview focused on careers in medical writing, transitioning from academia, and the role of EMWA in supporting scientists interested in medical writing.

The webinar can be viewed on YouTube: [https://www.youtube.com/watch?v=p\\_kSPCU0E3U&feature=youtu.be](https://www.youtube.com/watch?v=p_kSPCU0E3U&feature=youtu.be).

## EMWA Ambassador's Programme spreads its wings

On November 20, Abe Shevack gave a talk on EMWA and careers in medical writing at the regular meeting of Berlin medical writers at the Grand Café on Oranienburger Str. Altogether, 15 people attended, including organiser and EMWA member Paul Wafula and former EMWA President

Tiziana von Bruchhausen. There were lively discussions on the importance of EMWA training and certificates, mentorship of newbies, getting started in regulatory writing, and setting realistic timelines with clients. All present seemed to have a good time.





## AMWA-EMWA-ISMPP Joint Position Statement on Predatory Journals now available in Romanian

To raise awareness among non-English speakers about the responsibilities of medical writers and publication professionals concerning this significant issue, EMWA has initiated the translation of the joint position statement into European languages.

We are proud to announce the posting of the

Romanian translation of the joint position statement by EMWA members Georgiana Orbanu and Carmen Schmechel. The translation is available on the EMWA website: <https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/romanian/>.

We are currently looking for translators to translate the joint position statement into other European languages. If you would like to volunteer, please contact Abe Shevack ([aspscientist@gmail.com](mailto:aspscientist@gmail.com)) or EMWA Head Office ([info@emwa.org](mailto:info@emwa.org)).

## Regulatory Public Disclosure SIG update

The EMWA Regulatory Public Disclosure Special Interest Group (RPD SIG) page on the EMWA website has been updated. Please take a few minutes to read through what the RPD SIG has to offer: <https://www.emwa.org/sigs/regulatory-public-disclosure-sig/>.

On the RPD SIG webpage, you will find some great resources to help you navigate the world of regulatory public disclosure (RPD). Similar to other EMWA SIGs (<https://www.emwa.org/sigs/>), the RPD SIG provides regular updates to members at conferences. For those not able to attend the EMWA conference in Vienna, the RPD SIG presentation has been uploaded to the EMWA website: <https://www.emwa.org/media/3011/vienna-rpd-sig-slide-deck-10may19.pdf>. This presentation provides further details of the extensive RPD resources that are available to EMWA members as well as outlining the ways in which members can become involved in supporting the RPD SIG.



## Scam e-mail alert

We have been made aware of a scam email requesting payment for unpaid membership. More than one version of this email has been received by EMWA members.

Please do not respond with any sensitive personal information, such as banking details, as the email is not from EMWA.

If you have any related questions, please contact EMWA's Head Office at [info@emwa.org](mailto:info@emwa.org).

From: EUROPEAN MEDICAL WRITERS ASSOCIATION <[info2@staycentered.org](mailto:info2@staycentered.org)>  
Sent: 06 January 2020 13:28  
Subject: PAYMENT REMINDER

Dear Member,

This is to notify you to make payment as soon as possible for unpaid dues to the new association account which will be provided on request. Do reply back and notify us of which payment method best suits you.

Payments can be made via the following:

- \* Online Bank Transfer
- \* Online Credit Card Payment (E-Invoice)

If payments are not made on time, your membership will be temporarily suspended. If payment have already been made, do send payment confirmation for your account status to be updated.

Thanks,  
SYVIENGCHANH CALVIN GUY  
European Medical Writers Association  
EMWA Head Office  
Registered Office:  
Chester House, 68 Chestergate,  
Macclesfield, Cheshire, SK11 6DY

## New version of Good Publication Practice (GPP) on the way

Good Publication Practice (GPP) is an industry-leading document to guide the ethical development of medical publications. Development of a new version, **GPP4**, is now underway. A steering committee has been established and is working on revisions to the guidance. More information is available from ISMPP: <https://ismppnewsletter.com/2019/12/03/gpp4-development-is-underway/>.

## Predatory journal news

A recent comment article in *Nature*, headed up by lead authors Agnes Grudniewicz, David Moher, and Kelly D. Cobey, unveils a new consensus definition of predatory publishing and provides some suggestions of steps to take in the future to tackle the problems it causes. The 43 participants, consisting of members of industry organisations, society and commercial publishers, research institutes, libraries, policymakers, and other key academic roles, provided answers to 28 questions and engaged in 12 hours of discussion, followed by two further rounds of feedback and revision, to develop the definition. The definition put forward by the group is as

follows: "Predatory journals and publishers are entities that prioritise self-interest at the expense of scholarship and are characterised by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices." Read the article to learn more: <https://www.nature.com/articles/d41586-019-03759-y>.



## How to select the right journal

In a recent addition to their video series, Medical Publishing Insights and Practices (MPIP) provide helpful tips on "how to select the right journal". Choosing a journal can be a daunting task. The MPIP video shares useful tips and resources for journal selection, ensuring timely dissemination to the right audience. The video can be viewed on YouTube: [https://www.youtube.com/watch?v=QmHWE4Zo5tY&feature=emb\\_title](https://www.youtube.com/watch?v=QmHWE4Zo5tY&feature=emb_title).

## ICMJE Recommendations: 2019 update

The ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals received a modest annual update in December 2019.<sup>1</sup> The most significant changes are:

- The importance of disclosing financial and non-financial relationships and activities is underscored. The ICMJE has largely removed references to conflicts of interest, reasoning that is ultimately up to readers to decide whether a relationship or activity constitutes a conflict. It is recommended that authors do not cite work published in predatory journals.
- The existing recommendation that editors "engage a broad and diverse array of authors, reviewers, editorial staff, editorial board members, and readers" is given greater prominence.

## Reference

1. International Committee of Medical Journal Editors. Up-Dated ICMJE Recommendations (December 2019). 2019 [cited 2020 Jan 22]. Available from: [http://www.icmje.org/news-and-editorials/icmje-recommendations\\_annotated\\_dec19.pdf](http://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_dec19.pdf).



# President's Message

Back in January, I drafted my President's Message and was so looking forward to seeing many of you soon in Prague at what would have been our 50th conference. Then, with the pandemic spread of COVID-19, the world changed, and our conference was cancelled. I find myself greatly heartened by a wonderfully supportive Head Office and Executive Committee, all of whom stepped up to the mark – thank you!

Our conference plans may have changed, but EMWA's work continues. I would still like to provide you with an update on what EMWA has been doing in recent months.

## Dear EMWA Members,

Well, did you notice it?

Of course, you were pleased to receive this issue of *Medical Writing* and the December issue too, but what was different from previous issues? Content aside, did something else catch your eye?

As you are medical writers, I am sure you have a good eye for detail. In your haste to open the package and seize your journal, however, did you notice the packaging itself? We have changed to packaging made from potato starch that is 100% compostable. I am glad to write that after one person suggested this change, Phil Leventhal – our Editor-in-Chief – was able to quickly organise it. Do you have a suggestion for how EMWA can be more eco-friendly in its activities? We welcome your suggestions, no matter how small.

What has EMWA been doing over the last few months since I last wrote? Here are just some of the highlights:

- The Education Committee worked with EMWA Head Office to plan a diverse offering of workshops for the May conference – a mammoth logistical challenge. Their efforts are not completely lost as they will be able to build on this for subsequent conferences.
- In addition to the workshops, the Conference Director together with EMWA Head Office firmed up earlier discussions with potential symposium and seminar speakers. Again, all is not lost as sound relationships have been established and a new programme can be readily prepared.
- Each of the five special interest groups have had updates in the last few months. Check them out on the website, where each has a dedicated page:
  - Medical Communication
  - Medical Devices
  - Pharmacovigilance
  - Regulatory Public Disclosure
  - Veterinary Medical Writing

- Our ambassadors have been representing EMWA at a variety of events. We had planned to have a stand in March at the National Exhibition Centre in Birmingham, UK, for the MediWeek healthcare event, expected to have had over 3000 visitors in the one hall where we were to be located – with over 30,000 attendees overall. The organisers have rescheduled for November 2020, and we hope to attend.
- Several excellent webinars have been presented. If you didn't manage to catch them on the day, you can view past webinars through the website: look for the EMWA Webinars Programme. If like many in the world, you are currently in "lockdown", seize the opportunity, grab a coffee, then drink and listen!
- Translations continue to be made of the Joint Position Statements on both the *Role of Professional Medical Writers* and *Predatory Publishing*. These position statements were developed by representatives from the American Medical Writers Association and the International Society for Medical Publication Professionals, as well as EMWA. The translations that EMWA has organised help to spread awareness among non-English speakers about the responsibilities of medical writers.

## In closing, two reminders:

- If you have any photographs or memorabilia from previous conferences, please do scan and send them to me. Although we won't be sharing them in Prague, there will be an opportunity in the future to view some of the



Although we won't meet in May in Prague, I hope to see many of you at future conferences.

In the meantime, **STAY HEALTHY!**

highlights of the last 28 years, from the first meeting in February 1992 to date.

- If you would like to be more involved with EMWA and can spare a little time, we are always looking for more volunteers. Keep an eye on *EMWA News* on the website and the monthly *Newsblast* email for updates and opportunities. All are welcomed.

Although we won't meet in May in Prague, I hope to see many of you at future conferences. In the meantime, **STAY HEALTHY**, and I wish all of you well – you, your families, and your friends.

**Barbara Grossman**  
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# Medical illustration in the 21st century and beyond

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## Abstract

This paper provides an overview of contemporary medical illustration; the role of the modern medical illustrator is examined, including who they are likely to work for and with, as well as the range of media and technology employed. The various applications of medical illustration are described with a focus on looking at how these are likely to change and develop in the near future.

## The modern medical illustrator

*"As art reflects culture, scientific illustration reflects the findings of science and technology. Science illustrators are artists in the service of science. They use scientifically informed observation, combined with technical and aesthetic skills to accurately portray a subject. Accuracy and communication are essential."*

Guild Handbook of Science Illustration,  
©GNSI 1989, 2003

It is the role of the medical illustrator to communicate often complex scientific information and concepts to a broad range of audiences through visual media. To this end, the modern medical illustrator should be educated to an advanced level in both anatomy and visual communication. While some train first as artists and illustrators, others come from backgrounds in science and medicine, with each typically learning the other when they go on to specialise in medical illustration. While there is no legal requirement in the UK or elsewhere to undertake specialist or accredited programmes, it is generally regarded as best practice. In the UK, medical illustrators are encouraged to join the Academy for Healthcare Science (AHCS) Medical Illustrator Register, which requires the completion of an accredited degree programme. Similarly, in the US, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredits a number of medical illustration programmes in North America.

It should be noted that in the UK, medical illustration is an umbrella term for both medical photography and artistic illustration, which is also referred to as medical art. For the purposes of this article, the terms medical illustration and medical illustrator will be used in place of art and artist.

There are several professional bodies that medical illustrators can join, such as the Association of Medical Illustrators (AMI) in the US and the Institute of Medical Illustrators (IMI) and Medical Artists Association (MAA) in the UK. There are many advantages to joining a professional organisation, including the sense of community and networking that comes about through conferences and regional meetings. Such face-to-face events also provide opportunities for

continuing professional development (CPD), which is essential to those wishing to join a register such as that held by the AHCS. The registration of medical illustrators has been welcomed within the profession as it recognises and promotes the specialist skills required and thus helps to raise professional standards. In addition, such registers help to safeguard the public by allowing anyone to search them and check that practitioners are registered and meet the required standards. It is also possible for concerns to be raised against a registrant and ultimately for actions and sanctions to be taken where necessary. Most professional bodies also produce guidelines in terms of professional practice and ethics. The IMI, for example, provides a large number of guidelines to their membership on topics as diverse as; patient confidentiality, working with transgender patients, cultural diversity, and the ethical use of social media (to name just a few). These are of utmost importance as this is a profession whose members often have direct access to patients and/or their data. An understanding of the responsibilities and laws around subjects such as data protection and anatomy legislation are therefore essential.

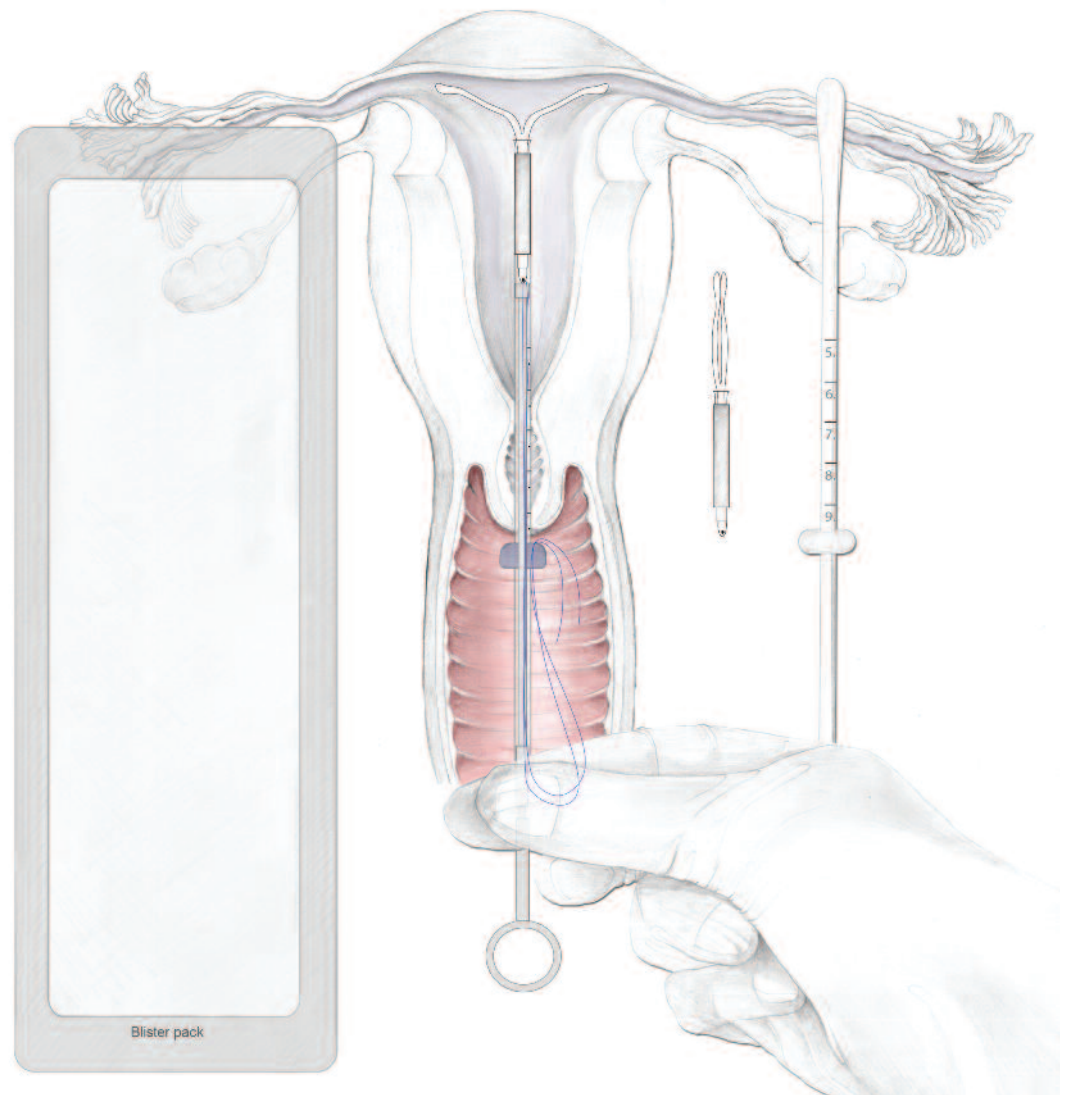
Medical illustrators work for a variety of employers including organisations such as various governmental health services, private hospitals, medical schools, research institutions, publishers, as well as specialised medical illustration companies. More recently, medical illustrators are also being employed by e-learning companies, software and app developers, and even VR developers. In addition, a sizeable proportion of the profession is self-employed, working with clients such as medical professionals and publishers directly.



## Media and technology

### Traditional media

Despite the proliferation of digital media, many medical illustrators still incorporate traditional media into their work. Those who use traditional media for all or a part of their work, often cite a preference for it because of the tactile feedback it can provide along with certain effects that can be difficult if not impossible to replicate with digital media. In addition, using a medium such as watercolours can be beneficial when depicting particularly graphic or sensitive material as it can “soften” the image and make it less disturbing, especially for a lay or patient audience. Medical illustrator Joanna Culley frequently uses both watercolour and pencil media in addition to digital. Figure 1 shows an example where the client requested the illustration be created in pencil so it could be used within an animation to “reflect a softer look and ‘feel’ to the illustrations... Graphite pencil was the preferred choice to depict the properties of the intrauterine birth control device and the insertion procedure along with the female anatomy so that it would seem more appealing to the patients watching the animation.”<sup>1</sup>



*Figure 1. Illustration by Joanna Culley, demonstrating the use of graphite pencil to depict the IUD and its insertion procedure along with the female anatomy in a style that would be more appealing to patients watching the animation*

### 2D digital illustration and animation

Two-dimensional digital illustrations are the staple work for many medical illustrators. They can be produced in a variety of styles and at different levels of realism for various target audiences. They can range from simple black and white line illustrations to full-colour realistic depictions, or even cartoons and “graphic medicine” comics.<sup>2</sup>

In addition to 2D illustrations, 2D animations are also useful for conveying information that does not require 3D spatial relationships, or for conveying complex concepts in a simpler manner. Animations (both 2D and 3D) are best combined with a voice-over (as opposed to subtitles) as this can help guide the narrative and

aid in highlighting important features.

### 3D digital modelling and animation

Over the past two decades, there has been a proliferation of 3D software enabling the creation of complex 3D models and animations. 3D models can either be based on scan data, such as magnetic resonance imaging (MRI), computed tomography (CT), and surface scans or created from scratch within the software itself. 3D digital models have a range of uses; they can be embedded as interactive models (that allow the user to rotate, zoom, and read annotations) in webpages, virtual learning environments,

e-books and iBooks, as well as in interactive PDF documents. In addition, they can be used as ‘assets’ (i.e., individual components that can be re-purposed) when creating animations or educational games and applications. They can be viewed and interacted within virtual reality (VR) and even 3D printed.

3D animations are very popular and, when done well, have the potential to convey a large amount of information in a short space of time. They are particularly useful for topics that require an understanding of 3D spatial relationships and for which a narrative or a sequence of events is important.

## Applications of medical illustration

### Medical and anatomical education

Medical and anatomical education is one of the primary applications of medical illustrations. Traditionally, medical illustrations have featured prominently in anatomy and medical textbooks. It could even be argued that some of these books (such as Vesalius's *De humani corporis fabrica*) are known more for their artwork than for the accompanying text. Such textbooks are still a mainstay of medical education, featuring modern (usually digital) 2D illustrations. However, there is a new wave of educational resources being developed, aimed at engaging students who are used to seeking information online and via apps. These include commercially available software programmes, mobile apps, e and eBooks, and websites, as well as bespoke resources made in house. Such resources tend to be more engaging for the user, often featuring 3D interactive models and animations in place of or in addition to 2D illustrations. These can be combined with touch-screen technology, "gamification" principles,<sup>3</sup> and self-testing. E-learning is a growing field as it can provide students with access to approved learning resources remotely. As such, some medical schools now employ e-learning technologists along with medical illustrators to create visual learning resources for use online; Figure 2 is an example created by the author for the University of Dundee. It is important to note, that when creating such

resources, medical illustrators work closely with subject area specialists in order to understand the key learning objectives that need to be communicated. Medical illustrators working in medical education should also have a good understanding of the research surrounding learning styles and theories in order to apply these to their work.

New technologies such as virtual and augmented reality have also made their way into medical education. These are discussed in more detail below.

### Patient information

The other primary application of medical illustration is patient information. Traditionally, this has largely consisted of illustrations and designs for 2D posters and leaflets. While these are still used, as with medical education, there is a growing demand for information to be accessible in digital formats and online. It is well documented that patients often search their symptoms or conditions in order to find out more information without the need for a doctor's appointment.<sup>4</sup> The results of such activities can be varied, largely because of the differing quality of information available online. However, research by Briggs et al. demonstrated that when patients were provided with access to high-quality digital resources (in this case, a series of three eBooks containing written information along with interactive diagrams, 3D animations, and interactive 3D models), they no longer felt the need to seek further information from external sources, such as the internet.<sup>5</sup> This demonstrates the importance of good quality and readily accessible patient information. For this reason, many organisations such as the NHS and medical charities have their own webpages where they can guarantee the quality and accuracy of the information provided. Illustrations, animations, and 3D models can enhance these online resources making them easier to understand and more accessible to a range of audiences.

When considering the best format (paper leaflet, interactive PDF, e-books and eBooks,

website, etc.) to use for patient information, the medical illustrator needs to consider who the target audience is, i.e., adults, children, the elderly, visually impaired, etc., since this may affect both the format and style chosen, as well as the level of detail provided.<sup>6</sup>

In terms of what the future holds for medical illustration, one of the major drivers will be recent and ongoing developments in technology.

### Other applications

In addition to the two primary applications described above, other types of applications also use medical illustration.

**Medico-legal exhibits**, such as Illustrations, 3D models and animations, can all be used to clarify often complex information for both

judges and juries. Such exhibits often take the form of 'body mapping' where the injuries sustained are mapped onto a digital model, both to prevent distress to the jury as well as helping them to focus on the cause and impact of the injury rather than the traumatic image. In addition, radiographs and medical scans can be enhanced with the addition of colour or the creation of an illustrated interpretation.

**Pharmaceutical and medical device** companies utilise medical illustrations in their brochures, websites and promotional materials for trade shows, etc. These tend to demonstrate, often to a specialised medical audience, what the drug or device is capable of as well as how to use it.

**Peer to peer science communication** can take many forms but typically includes illustrations, 3D models, and animations for illustrating scientific reports, journal articles, and conference presentations. In addition, visualisations can be useful when trying to engage the public in medical and life science research.

## The future of medical illustration and visualisation

### Technology

In terms of what the future holds for medical illustration, one of the major drivers will be recent and ongoing developments in technology. Imaging technologies such as medical and 3D surface scanners can capture higher resolutions of detail than ever before; likewise, modern 3D modelling software packages (such as Pixologic Zbrush, Autodesk Maya, Cinema 4D, etc.) are able to handle ever more complex models and







**Opponens Pollicis**

Nerve: Recurrent branch of the median nerve

Actions: Flexion of the thumb's metacarpal at the first carpometacarpal joint, which aids in opposition of the thumb

Figure 2. An example of a 3D interactive model (of the muscles of the hand), created by the author for use in e-learning, hosted online at Sketchfab.com (<https://skfb.ly/6GWXx>)

Created by:  
Dr Caroline Erolin



render objects with highly realistic material properties. Developments in image capture and creation technologies are already being combined with new and evolving forms of media (some of which have been described above), including e and iBooks, interactive PDFs, online 3D models, and mobile apps.

In addition to these, virtual and augmented reality technologies are being investigated by a number of medical schools as a means of further engaging students with virtual models.<sup>7-11</sup> VR refers to a fully immersive experience using a head-mounted display (HMD) where the user can interact with a digital object or environment. One of the benefits of viewing models in VR is that they are truly 3D, i.e., the user can move around them in space as

Virtual and augmented reality technologies demonstrate great promise for the future of medical and anatomical education in particular and may even find their way into other applications such as patient information and medico-legal exhibits.

opposed to viewing them on a 2D screen. Models can be displayed as life-size replicas or blown up to 100x their normal size, which can be particularly useful when exploring small structures such as those of the inner ear. In addition, not only can objects be viewed from an external perspective, but users can view a model, such as a beating heart, from within. The term augmented reality (AR) is used to describe a range of experiences, including the use of QR codes to trigger the launch of additional web-based information, such as images and models, usually on mobile devices, as well as HMDs such as the Microsoft HoloLens. Unlike the HMDs used for VR, AR HMDs show the virtual scene overlaid with reality. This has the benefit of allowing the user to interact with both

the digital and real world simultaneously.

Both technologies demonstrate great promise for the future of medical and anatomical education in particular and may even find their way into other applications such as patient information and medico-legal exhibits. Currently, however, most students don't have access to good quality VR and AR HMDs at home. This may change in the coming years as more affordable, standalone VR headsets (such as the recently released Oculus Quest) become more readily available.

**Representation**

Finally, it is worth saying something about representation in medical illustration. Parker et al.<sup>12</sup> in their 2017 paper "A visual analysis of gender bias in contemporary anatomy textbooks" explored the ratio of female and male representation in contemporary anatomy textbooks and found that out of the 17 textbooks examined (consisting of a total of 6,004 images), only 36%



of the images with an identifiable sex were female. In addition, other forms of bias were also found, including: “the visualization of stereotypical gendered emotions, roles and settings; the lack of ethnic, age, and body type diversity; and in the almost complete adherence to a sex/gender binary”. This is a major problem considering that these textbooks are used to educate our future healthcare workers. Rather, medical students (along with nurses and other allied health professionals) need to be prepared for the diverse range of patients they are likely to encounter in their working lives. It is the responsibility of everyone associated with the production of such material, including medical illustrators, to consider how to address this issue in the future.

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## Conflicts of interest

The author declares no conflicts of interest.

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# Visualisations in science communication: Friend or foe?

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## Abstract

*An image is worth a thousand words.* This saying is easily disregarded as a cliché in today's extremely visual world, but it may ring truer than ever. With the vast amounts of information reaching us every day, visualisations are increasingly important to make sense of (big) data and to aid fast decision making in science and healthcare. An effective visualisation satisfies both a scientific and a design perspective, a balancing act that requires two different skill sets. Science communicators can play a key role in translating scientific data into good visuals, but there are several common pitfalls to watch out for.

## Understanding data through visualisation

Huge amounts of information reach us every day and the speed with which we collect, and process data is rapidly increasing. Visuals are an excellent way to quickly communicate new ideas. Especially for those who are not well-versed on a particular subject, visualisation is a valuable tool to quickly assess and absorb new information. In science and healthcare, the public image is suffering, and we increasingly see that scientific information is distrusted or misinterpreted, particularly by the lay public.<sup>1,2</sup> This can have far-reaching consequences, such as the current vaccine crises in Europe and the USA.<sup>1,3</sup> Sound scientific evidence is difficult to spot among the huge amounts of information and faux news that reach us daily. Traditional news channels, which make use of trustworthy sources and thorough fact-checking, are being replaced by social media, which is often sparsely sourced and opinion-based. Hyped reports of scientific fraud in the media coupled with the (perceived) closed demeanour of scientists exacerbate the problem. To make matters worse, scientific information is often not presented in a way that aids understanding. The lack of visualisations and a storytelling approach makes it harder to

understand the value of scientific developments, both for lay audiences and those with a scientific or medical background.

As science communicators, we want our message to reach the right audience and to convey the right information. But to make an impact, our message needs to jump out from the vast amounts of information out there. Visualisations have a strong role to play in this respect. Numerous studies show that people learn more efficiently from visual input than from auditory input or written text and that short- and long-term recall improves with visual learning.<sup>4-7</sup> Creating an image (especially drawing something yourself) increases the understanding and retention of scientific concepts.<sup>8</sup> By effectively incorporating visualisation, we can increase the effectiveness of science communication, optimally exploit the potential of big data, and begin to change the negative image of science and medicine among the general public.

## A visual by any other name

For the sake of simplicity, I'll use the terms "visual" or "visualisation" as collective terms to describe a wide array of graphical representations. To name a few: Medical illustrations, infographics, animations, and data visualisations.



## 5 tips to create effective visuals in science communication



**Figure 1. Infographic: Five tips to create effective visuals in science communication**

Visualisations have a strong role to play in science communication but watch out for these common pitfalls. The pyramid grows from the bottom to the top and each of these aspects builds on top of the last. This infographic was designed using resources from Freepik.com. CC-BY Mariella Franker, Franker Medical Communications.

Think of examples such as the graphical abstract of a manuscript, the user instructions for a medical device, or the simplified scheme of a study design in a patient consent form. There is no real consensus on where one category ends, and categories will often overlap in practice. A medical or scientific illustration typically illustrates a medical or scientific principle, concept, or procedure in a single image.<sup>9</sup> An infographic combines several charts and

illustrations and minimal text to give an easy-to-understand overview of a topic.<sup>10</sup> Data visualisations are visual representations of (big) data to help people understand the significance of the data. More so than other forms of visualisation, data visualisations are used to measure and consequently steer performance.

Today, we have a plethora of tools at our disposal to create a wide variety of visualisations. Designs can be made by hand or computer

rendered in 2D or 3D and can be animated. The possibilities for creating visualisations are endless and limited only by our creativity.

### Common pitfalls of visualisations

Using visualisations in science offers a world of possibilities, but there are several pitfalls to watch out for. Creating an effective visual is a true interdisciplinary practice and marries the worlds of science and design. These two worlds require different skill sets. In the next section, I will illustrate several important features to keep an eye on when it comes to visualisations.

#### 1. Tell a story

Before you start with any piece of communication, visual or otherwise, it is essential to know where you are going. Without a clear message, the piece becomes ineffective. A good storyline is even more important when it comes to visualisations and is one of the hardest things to get right. In a visual, we often do not have the luxury to add a box or to take a detour to provide the reader with more context. Very little (or no) text is used and we need to be able to convey our message with images as much as possible.

Storytelling is the most effective way to communicate because people are wired to think in stories. An increasing number of studies support the use of storytelling and narrative in science communication.<sup>11–14</sup> **Stories engage us and make it much easier to comprehend and remember** concepts (think plots), facts (think events), and players (think characters).<sup>15</sup> It is an invaluable tool that is widely used in fields like business and marketing but not yet fully utilised in science.

#### 2. Cater to your audience

The storyline and the target audience tie in closely together. The target audience will define how to present the message, which story we can use to do so and what type of visual or even colours to use. Is this a novice audience or does the audience already have a lot of background knowledge? For a medical specialist, a comprehensive graph may be appropriate, whereas a patient will gain more from a well-designed infographic. Remember that **most audiences will take the path of least resistance**, so the information must be tailored for that audience and presented in a clear, simple way. This is true

for lay audiences who are unfamiliar with the concepts and for busy scientists and doctors who don't always have time to decipher a complicated visual. A few things to consider when investigating your target audience: How accustomed are they to seeing data, i.e., numbers? Where will the audience see the visual, for example, in a presentation or in print? How much time will they typically spend to understand a visual? How will the visual add to the information that your target audience already has?

### 3. Accuracy above all

This next topic may be one of the reasons why many are still suspicious of visualisations in science: maintaining scientific accuracy. It is a common fear that **scientific concepts become oversimplified in visualisations and that accuracy will always suffer**. These concerns should not be taken lightly. In an improperly structured or oversimplified visualisation, the message can get lost or the data is taken out of context. It can confuse the audience, or worse, cause (huge) misconceptions.<sup>16,17</sup> There must be a balance between presenting a conclusion to the audience on one hand and presenting facts so that the audience can draw its own conclusion on the other.<sup>18,19</sup> Although design and accuracy seem contradictory at first, they go hand in hand. To achieve the right balance, an adequate understanding of the science by the designer is needed and close collaboration between scientist and designer is essential.

### 4. Choose the right visual

There are infinite possibilities when it comes to choosing which visualisation to use and each will influence how the message is perceived. The elements of the visualisation must fit the data and are not merely decorative. Specifically, graphs should be treated with great care. When choosing a graph type, ask yourself **what you want your audience to learn from the graph**. Imagine looking at the graph as if you have never seen this type of graph before. Is your message still clear? For example, pie charts are excellent for simple data that breaks down into percentages but are useless for pretty much any other data set. Again, your audience will dictate, for a large part, how the data is presented. More complicated graphs can be used for audiences with a lot of background knowledge. But be careful: Even seasoned audiences will often not spend time to



“decipher” a complicated graph, so stick to a single, clear message.

### 5. When it comes to design: Less is more

Think of the early PowerPoint days when slides were overloaded with flashing texts, items flying from various angles and a different transition after every slide, and you will know exactly what to avoid. From a design perspective, scientific visualisations are often overcrowded with information and not enticing to look at. This causes them to miss the mark with their intended audience. **When it comes to design: less is more**. It can be tempting to create flashy designs, but this will ultimately distract from your message. By now, we should have a clear idea of the main message and the target audience, and these will be leading for the design. An educational poster for kids about hand hygiene will require a different design approach than a poster for medical students showing the stages of ovarian cancer. General design rules of thumb exist. For example, use no more than four distinct colours in a single visual and think of complementary colour choices. The Gestalt principles of visual similarity and grouping also provide some guidance: “The whole is different than the sum of its parts.”<sup>20</sup> There are, however, no one-size-fits-all solutions. Close collaboration with a designer is thus invaluable to strike the delicate balance between a creative design that will be

noticed and a design that serves your message.

Finally, also when it comes to text, less is more. Text should support a visual, not the other way around. Constantly ask yourself if the visual can be understood without any text.

### 6. Bonus tip: Be aware of cognitive bias

The five pitfalls mentioned above are common and are easily controlled for with a well-thought-out design. Another aspect that is harder to control for is cognitive bias. We are often unaware of its effects, but we have undoubtedly all fallen victim to it. Cognitive bias is when our established thinking patterns influence our judgements and decisions. There are different types of cognitive bias e.g. confirmation bias – when people tend to search for or interpret information in a way that confirms their beliefs – or familiarity bias – when people tend to estimate something as more likely or true if they are already familiar with it.<sup>21,22</sup> I deem cognitive bias the sixth pitfall, and it can affect the person creating the visualisation and the person viewing the visualisation. Since visualisations rely so heavily on imagery, interpretation of a visual is subjective. As the one designing the visual or choosing the data to include, we must be careful not to select just the data that agrees with our own viewpoint. In this way, we can create a bias or a misleading conclusion without meaning to. On the flip side, every person that sees our



visualisation also has his or her subjective interpretation. We cannot, of course, correct for each individual's potential cognitive bias, but **by looking closely at the target audience and taking into account their background, we can adjust the visualisation to minimise bias.**

### Friend or foe ... or both?

To answer the question: Are visualisations in science communication friend or foe? I say friend. Visualisation is a vital communication tool that is becoming increasingly important to make sense of the huge amount of data that is collected in science and healthcare today. Presenting data in a visual way helps us to make connections and easily recognise patterns within

data sets. The importance of visuals is underlined by publishers and regulators. Elsevier, Cell Press, and *Journal of Cell Biology* call for graphical abstracts when submitting manuscripts and offer some brief guidelines.<sup>23–25</sup> Lay summaries are now mandatory in clinical trial reports and visuals are encouraged to make the information more accessible to this audience. The EU clinical trial regulation includes some general instructions.<sup>26,27</sup> It is, however, the responsibility of the trial sponsor to develop a lay summary and science communicators who can make this translation will be an important asset.

Although visualisations offer a world of possibilities, improperly designed visuals can cause huge blunders and become a big foe.

While aspects such as maintaining accuracy and catering to the right audience may be obvious, others such as storytelling and design aspects may come a bit less natural to science communicators and medical writers. However, the need for skilled people who can combine these two worlds is increasing. There is a lot of opportunity in this area, and I would argue that every science communicator should know the basics about graphic design and how to create an effective visual.

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### Fun initiatives on the topic of science visualisation

- The Picturing to Learn programme<sup>28</sup> features hand drawings made by science students and faculty from Harvard, MIT, Duke University, and Roxbury Community College, along with design students and faculty from the School of Visual Arts, New York. Students were asked to create a freehand drawing to explain various scientific phenomena to a high school senior.
- Science and Engineering Visualisation Challenge in USA co-sponsored by National Science Foundation and *Science* magazine.<sup>29</sup>
- “The Sackler colloquia: The science of science communication”<sup>30</sup> advocate the science of science communication as a unique discipline and includes topics such as “Communicating uncertainty in policy

analysis” and “Science audiences, misinformation, and fake news”. Organised by the National Academy of Sciences and published in a special issue of the *Proceedings of the National Academy of Sciences*.<sup>31</sup>

- The Health Care Foundation offers a nice collection of tips and guidelines on how to implement storytelling in healthcare. The Health Care Foundation is an independent charity committed to bringing about better health and health care in the UK.<sup>32</sup>
- A guideline from Arts and Humanities Research Council (AHRC) and University of Leeds with many excellent tips for health care infographic designs for the lay public.<sup>33</sup>



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# How and why it works: The principles and history behind visual communication

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## Abstract

“A picture is worth a thousand words” – a familiar adage, and the reason why newspaper articles are commonly accompanied by photographs and infographics. Scientific publications are no different, so medical writers are frequently asked to contribute to the design of figures and visuals. There is therefore a growing need for medical writers to expand their skills to include designing graphical abstracts, scientific figures, and infographics. This article explains the basis of visual perception and information architecture, provides some examples of biomedical information design, and explains how aspects of design theory can be applied to create effective infographics and other visuals.

## Visual perception and the power of imagery

Light – either emitted by objects or reflected from their surfaces – enters the human eye where it is converted into electrochemical signals. The rods and cones that populate the retina are tuned to respond to sets of visual attributes to different extents.<sup>1</sup> Signals from the retina are then transmitted via the optical nerve to the brain and converted into meaningful information based on previous experiences and information. Perception has a physiological and a psychological basis and – while there may be only one reality – perception is unique to the individual.



Figure 1. Lascaux cave paintings

This individual aspect of information processing makes perception a subjective process; it is a deformation of reality, in which part of the existing world is captured and the rest is discarded. In short, although our sensors detect stimuli, it is the brain that makes sense of it. Surprisingly, an estimated 50–80% of the human brain is dedicated to visual processing, including vision, visual memory, shape discrimination, spatial awareness, and image recollection.<sup>2</sup>

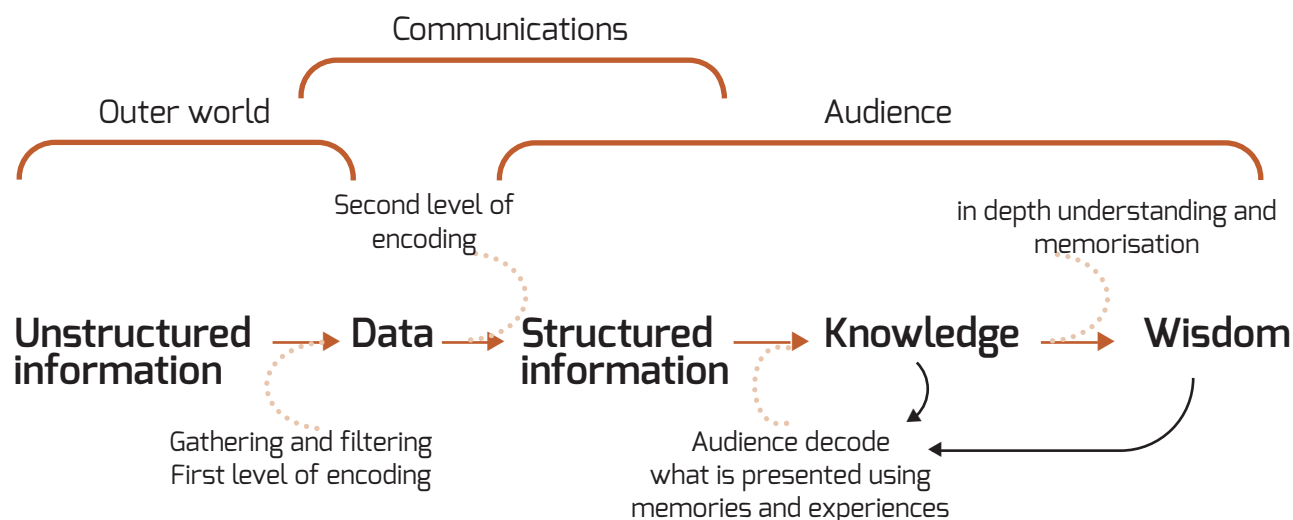
Humans are constantly drawing from previously acquired knowledge and experiences when processing visual information, thus can be considered pattern recognition machines.<sup>3</sup> To put this into

perspective, consider that our brains do not differ greatly from our ancestors'. In the early days of humankind, perception was vital for functions such as hunting (motion detection), food collection (colour recognition), and tool construction (shape recognition). It is therefore not surprising that images have been used to communicate since prehistoric times. The cave paintings in Altamira and Lascaux (Figure 1) were made 20,000 to 40,000 years ago, and by 3,000 BC, Egyptian hieroglyphs had been developed as a language. In the last two millennia,

powerful imagery has been used in church paintings and in Bible illustrations to spread the Christian message.

Perception has, thus, a physiological and a psychological basis and while there may be only one reality, perception is unique to the individual





**Figure 2. The Data-Information-Knowledge-Wisdom cascade**

This scheme illustrates the process by which communicators organise data into multiple structural levels, so that information can be transmitted and assimilated by an audience. The progression is accompanied by a decrease in the entropy of information and increments in its value.

## Infographics and information architecture

Visual communication is the norm rather than the exception. However, in an increasingly complex world, it has become a challenge to convey the essence of highly complex data in compelling visualisation that summarises all of the relevant information. One of the most widely used approaches to this challenge is to use infographics, which have been applied in many fields.<sup>4</sup>

Infographics are graphic elements that combine data visualisation (visual representation of numerical values), illustrations, text, and images in a format that tells a full and captivating story. Infographics are effective tools for communicating because they employ three key characteristics: pattern recognition (visual perception), the language of context (multiple variables shown in comparison to each other, allowing the magnitude of the effect to be conveyed), and picture superiority (pictures are remembered better than words).<sup>3</sup>

Although infographics are an old concept, their popularity increased during the 20th century because of their use in newspapers and magazines.<sup>4</sup> Thanks to the enormous increase in data available due to computing and the demand to create easily digestible visuals, the use of

infographics by classic and modern media has exploded.<sup>5</sup>

When developing infographics, many designers make use of *information architecture* – a term coined in 1975 by Richard Wurman – to describe the art and science of design solutions for unstructured information.<sup>6</sup> His ideas for structuring information are illustrated in the so-called Data-Information-Knowledge-Wisdom cascade (Figure 2). In the first step of the cascade, also referred to as the information encoding level, unstructured information (i.e. reality) is organised into a collection of observations represented by numbers and words. In research terms, this is referred to as data generation. At the second encoding level of, data is further structured using visual elements to reveal patterns or, in other words, to create meaningful content.

Information consumption by the receiver is not a passive process: when people see, read, or listen, they assimilate content by relating it to their memories and experiences. The goal, however, is to gain wisdom – the deep understanding of acquired information – and apply it to other situations.<sup>7</sup>

Information architects are thus facilitators of knowledge construction: they convey information in a simple way through words, visuals, or

both, simultaneously. The same might be said about medical writers, who also make complex information accessible to a broader readership. However, conveying information in a simple way does not imply losing information. As illustrated by the iceberg analogy: while just the tip of a visual design (e.g. visual elements, colours, fonts) is seen, a lot of work remains under the surface. The majority of a designer's and medical writer's work lies in understanding the needs of the audience, and the aim is to make life easier for the information consumer.

## Visual information in biomedicine

Data visualisation is of course a key part of communication in biomedicine. Visuals such as line plots and bar graphs are employed to rapidly convey information. These and other simple types of data visualisation were first invented by William Playfair (1759–1823) to support his economic and political activities. Over the years, they have become essential for communicating in many different fields, including biomedicine. For example, in 1854, by combining graphs with conventional maps, the renowned English physician John Snow was able to summarise reported cases of cholera in the Soho area of London (Figure 3). This allowed him to trace the



**Figure 3.** Map taken from a report by Dr John Snow, showing the spread of cholera-induced deaths from a contaminated water pump in Broad Street, London

pattern of the disease and convince the local authorities to disable a water pump that was the source of contamination. Thanks to this innovation, he became known as one of the fathers of epidemiology.

The diagrams used by Florence Nightingale in the 1850s further illustrate the importance to biomedicine of expressing data visually. She was a nurse and invented the “rose” chart while examining the causes of death of soldiers in the Crimean War. The charts revealed that, due to poor sanitary conditions, more people were dying from preventable diseases than from war injuries (Figure 4). Using these charts, it was possible to visualise matters affecting the health of British Army soldiers and inform the hospital administration of the problem, helping to lay the foundation of modern nursing.

**Information design is nothing more than learning how to make use of the magic of communication through images.**

### The impact of visuals in scientific communications

The increasing number of scientific publications and information generated have led to new trends in publishing, including the emergence of new scientific publishers and novel platforms for communicating science. Scientists also need new ways of attracting attention to their research and must help their readers wade through the massive amount of information available.<sup>8-10</sup> Infographics are well suited to this role because they can be more effective and attractive than traditional graphics for presenting information. For example, several publishing groups have introduced the concept of a *graphical abstract*, which is an infographic summarising the paper in a single image or cartoon-like visual.<sup>11</sup> Graphical abstracts are excellent tools for disseminating research on social media platforms and can be used

by both scientists and non-specialists. According to some authors, visual design improves the perception of intellectual and scientific proficiency.<sup>12</sup> They can also be used to effectively convey the benefits and real impact of science to fellow scientists and society, which is important for obtaining research funding. In recent years, graphical abstracts have become popular, and publications that include graphical abstracts and visuals have attracted more readers and generated more citations than those that did not.<sup>13-15</sup>

### Applying Gestalt theory for publications: What medical writers can do

Just like a language is made up of letters, words, spelling, grammar, and syntax, visuals are also made up of several basic components: dot, line, shape, direction, value, hue, saturation, texture, scale, dimension, and motion.<sup>16</sup> Researchers and medical writers can combine these elements to build a strong and clear message by showing



Image source: Florence Nightingale (1820–1910) [Public domain]

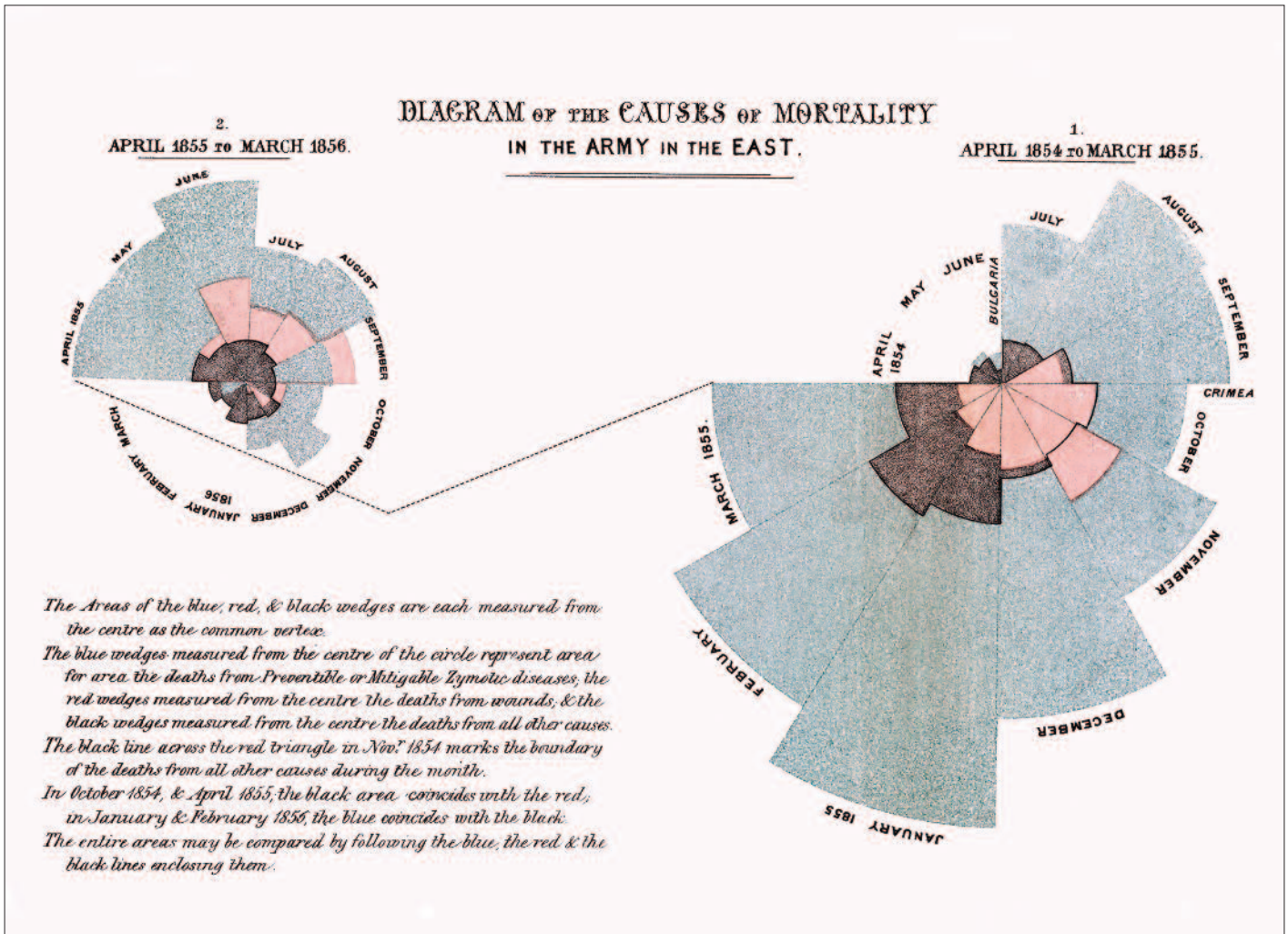


Figure 4. Rose chart originally drawn by Florence Nightingale during the Crimean War showing the proportion of deaths caused by preventable diseases (blue), by wounds (red) and due to other causes (black)

comparisons, trends, or proportions. Understanding can be further strengthened by organising these elements in terms of sequence, proximity, and hierarchy in the overall composition. But when doing so, what is known about the optimal way to arrange the elements in such visuals should be taken into account.

In the 1920s, the psychologists Max

Wertheimer, Wolfgang Kohler, and Kurt Koffka made key contributions to this field, leading to the foundations of the Gestalt theory. This theory postulates that the human brain tends to organise visual elements into groups. This led to the premise that “the whole is other than the sum of the parts”, whereby the emergent entity is distinct (not greater or lesser) than the sum of the parts.<sup>17</sup>

The processes of subtraction and simplification in visual compositions, although counter-intuitive, are essential for easing interpretation of visual information and keeping the focus on the main message.<sup>18</sup> Arranging elements properly in space according to specific principles such as similarity, continuity, and proximity, can add additional layers of meaning without having to

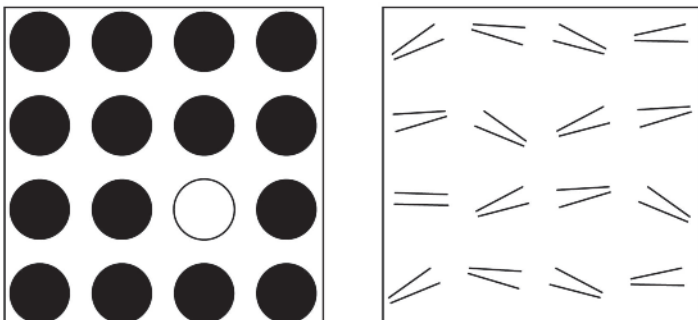


Figure 5. Visual compositions that trigger different mental processes: pre-attentive and attentive processing

Both panels contain a single element that is distinguishable from the others in the group. The speed at which the element is recognisable relies on the fact that certain graphic cues are stronger than others. As such, colour (on the left) triggers a pre-attentive, and faster, recognition process, while direction (on the right) requires an attentive and concentration-demanding recognition process.





turn everything explicit (e.g., objects that are close together are recognised as a group).

Gestalt theory can be used in many different sorts of visualisations, also when developing images for research papers. By making good use of the theory, a collection of graphs and panels from a research paper can be optimised into a more powerful and intuitive depiction of a story (Figure 5). Smart use of colour and layout can make the whole figure look more balanced and distinctive to a reader's eye.

Another way of making visual perception more effective is to exploit so-called pre-attentive processing. This mental process is extremely fast and enables us to recognise a large number of basic visual traits simultaneously. It is done in parallel (as fast as 200–250 ms), in contrast to attentive processing, which is done serially and engages the conscious part of perception and is therefore much slower.<sup>2</sup> In other words, engaging pre-attentive processing allows one to see something before *really* seeing it. Again, this can be triggered by making good use of the basic elements of visual communication.

Pre-attentive processing should therefore always be used in infographics and data figures to quickly guide the reader to the most important information. Moreover, because pre-attentive processing works so effectively, it is useful to

identify the basic visual elements of an infographic in a separate, early phase of the design process.

### Conclusion

Information architecture aims to attract and inspire so that the viewer can reflect on the underlying data and use it further. To ensure the message reaches the target audience, authors should combine appealing aesthetics and knowledge of how information is perceived with the expectations of the viewer. A successful communication process therefore relies heavily on user-centred design, pre-attentive attributes, and Gestalt principles. Following these rules will inevitably lead to clear, effective, beautiful graphics that will inspire the audience.

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### Conflicts of interest

The authors declare no conflicts of interest.

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# Get your (visual) act together: Optimising the design of labels and arrows in medical illustrations

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## Abstract

There is an enhanced communicating power of text when associated with visuals. This is a compelling argument for furnishing medical writers with basic knowledge on how to adapt and create simple figures. This article discusses tips on adding labels and arrows to pre-existing illustrations. These elements are fundamental components of scientific figures and should be consistent and designed from the start. By properly adjusting the alignment, style, and negative space of labels and arrows it is possible to convey further meaning and enhance the reading flow of figures.

## The role of image in medical communication

Written and visual contents are synergetic vehicles for knowledge transmission.<sup>1</sup> A number of studies on medical communication and patient education have demonstrated the role of images, when in combination with text, as aids to:

- Preference and attention:** Readers are more likely to focus, choose to read, and spend more time reading written pieces that include related visuals.<sup>2-5</sup>
- Comprehension:** Readers, especially with lower education levels, are more likely to correctly answer questions about the content of a text that is illustrated with figures.<sup>1</sup>
- Scientific credibility:** The presence of an appropriate image has been associated with a

higher number of readers agreeing with the conclusion of an article.<sup>6</sup>

Therefore, visuals should not be regarded as nice-to-have additions, but rather as pivotal components in communicating with all types of readers and across all platforms – from data-heavy, hard to digest materials, such as review articles for specialist audiences, to post-operative instruction leaflets that require compliance from lay patients.

For these reasons, even though visual communication is not the main focus of medical writers, there is a strong point in advocating for visual literacy as part of their basic and continuing education. The ability to develop engaging deliverables will ultimately translate into more competent and competitive professionals.

The visual literacy of a medical writer should range from the ability to properly use already-created images (such as stock illustrations), to being comfortable with visual concepts in order to work closely with medical illustrators to create tailor-made, scientifically accurate, and didactic figures.

The goal of this article is to furnish medical writers with easy tools that will allow them to independently adapt pre-existing images and create their own figures. The focus will be on simple, common, graphical elements, such as labels and arrows, which are the backbones of most medical visuals. Since figures should stand as intuitive as possible on their own, labels and arrows arise as essential components to convey further meaning; however, if poorly designed, they can greatly undermine the message of even the best quality illustrations.

## Getting started

The content of this article is presented in the form of four case studies, covering simplified scenarios with different initial challenges. A sequential reading is recommended since topics complement each other.

### Editing tools and previous considerations

In order to edit pre-existing images (e.g., illustrations, graphs, icons, diagrams, etc.), you can use vector graphics editing software, such as

Adobe Illustrator, or an open-source option such as Inkscape. These programs, which may entail a steep learning curve, are not always a feasible option. Alternatively, Microsoft PowerPoint or Keynote, despite being not so user-friendly for this type of work, are accessible alternatives to consider.

Before starting to edit any pre-existing visual, make sure that you have the permission to do so. If the image is not from a public domain, and therefore is copyright protected, you will need to obtain permission to share it and adapt it – for example, check if the image is available under any Creative Commons licence.<sup>7</sup> In all cases, contact the author/owner of the image, whether the image is from an external source or created by an internal team member. Do not forget to formally acknowledge the original author in the final production.

### Decoding the nomenclature

Throughout these four case studies, we will discuss several concepts related to labelling. A **call-out**, or **annotation**, is a label connected to the illustration by a line.<sup>8</sup> This line is called the **leader line**, and its ending is the **anchor point** (Figure 1).<sup>8,9</sup>

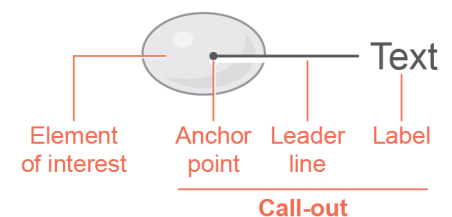


Figure 1. General structure of call-outs

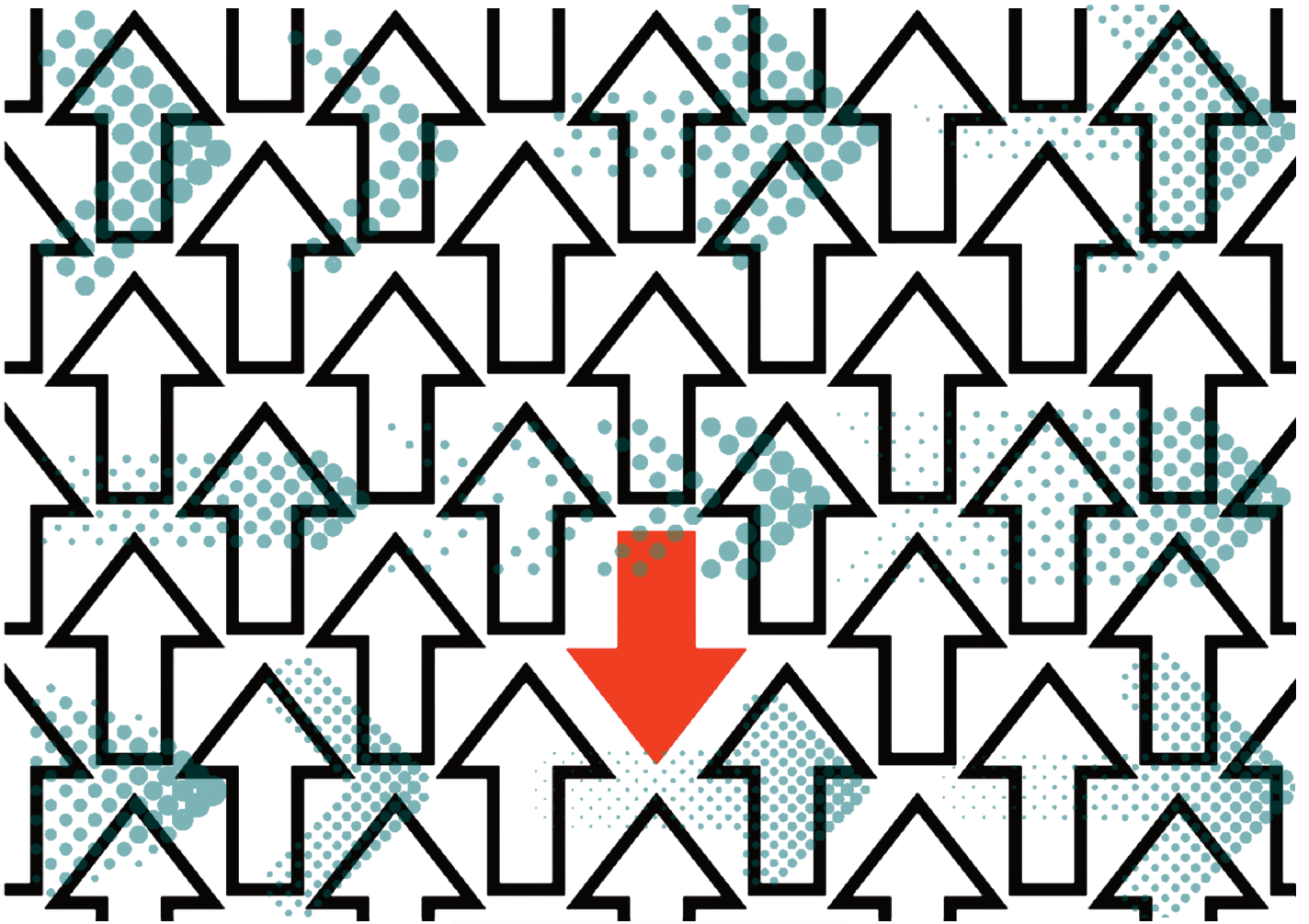
## General considerations about call-outs

Knowing labeling best practices is an important starting point to ensure a streamlined figure creation process.<sup>8-11</sup>

- Ideally, labels should be designed from the start of the illustration work:
  - If you are collaborating with a medical illustrator, make sure you inform them

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about the exact structures to label. This will allow them to design and place regions of interest to better accommodate call-outs.

- b. In the case of pre-existing images, create a text box for each label needed, so you can have an overview of the space they take collectively; then move them around until you reach an optimal organisation.
2. Avoid unnecessary labels. While it may be tempting to create figures as complete as possible, excessive information may be distracting to the readers. This holds true especially for non-specialist audiences who have less capacity to focus on the topic.<sup>1</sup> Furthermore, do not forget to pay attention to possible compliance requirements for specific labels.
3. Leader lines should be straight and solid. Lines with angles may apply in certain conditions (see Case study 2).
4. Leader lines must not cross, and labels must not overlap.
5. The typeface of the labels should be the same one used in the body copy. If the figure you

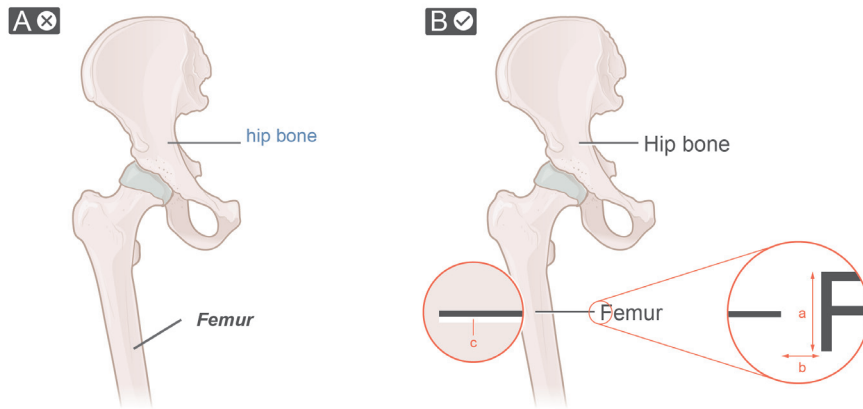


Simple, common graphical elements, such as labels and arrows, are the backbones of most medical visuals.

are creating is part of a branded document for a specific client (e.g., a pharmaceutical company), make sure the style of the label (colour, width, typeface, etc.) follows the client's branding guidelines.

6. Design dark-coloured call-outs for white/lighter backgrounds, and white/light-coloured ones for darker backgrounds. Check to determine if the contrast between call-outs and background is strong enough. Temporarily converting your image into grayscale mode is a good way to evaluate this. Labels should usually have a neutral colour (e.g., dark grey, or white) unless guidelines express otherwise, or if using a neutral colour is confusing (e.g., Figure 1 has two labelling systems, so I decided to use an orange colour on the second system to emphasise that it is not part of the illustration).
7. Place final figures as close as possible to the text they relate to. Just as with labels, do not develop figures as afterthoughts; decide where they should be placed and make sure all text can be read at their final publication size.

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**Figure 2. Anatomy of the hip joint**

Image A. non-optimised figure; Image B. optimised figure; a. height of the text; b. distance between the leader line and the label; c. leader line highlight.

### Case study 1: General figure with a limited number of independent labels

In this first example, the goal is to label two bones in an anatomic illustration (Figure 2).

An important rule of thumb in illustration and design is that what is equal should stay equal. Hence, unless there is a reason to highlight a specific structure, all call-outs should be as cohesive as possible. You should use the same typeface, font size, font weight (e.g., thin, regular or bold), case (e.g., sentence or lower case), and colour in labels, and the same line thickness, colour and anchor point style in leader lines (Figure 2B). Start by designing a template call-out, and use it to recreate all others.

You should also ensure constancy in more subtle variables, such as the direction of leader lines and the spatial relationship between the start of the leader lines and the annotations. In Figure 2A, the two leader lines have different directions; Figure 2B was optimised by making these lines run parallel. This adjustment grants the image a flow that is very useful in guiding the eye from the illustration to the labels, and vice-versa. This effect is much more evident in images with a high number of labels that may overcrowd the image. In Case study 2, possible exceptions are discussed.

In Figure 2B, both leader lines start at the middle of the height of the label (a), and the distance between the leader lines and the labels is constant (b).

In images with few labels, if the organisation allows, it is advisable to place all call-outs on the same side; this will also reduce the space needed for the figure. Usually, I prefer to place the call-outs on the right side of the illustration, so readers can study the visuals first.

A final trick to ensure clear readability of leader lines throughout all its length is adding a small highlight just below it, in the same colour of the background.<sup>12</sup> In Figure 2B, we can witness how the addition of this highlight in white (label c) creates a visible contrast between the leader line and the bone underneath.

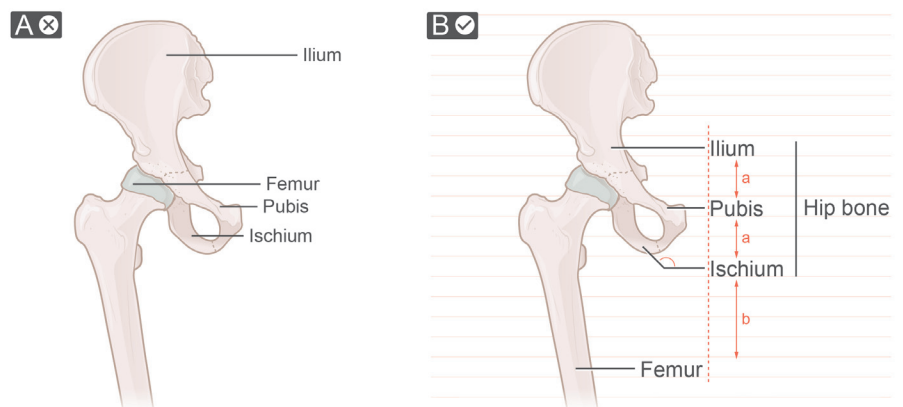
### Case study 2: Detailed figure with a high number of related labels

This second example features the same illustration from the previous case study; however, the goal here is to label a higher number of structures, including some that are related (see the three bones that make up the hip). For the sake of simplification, the actual number of labels displayed is not high; in real scenarios, this could correspond to 15 or more labels in this type of illustrations.

Leader lines should cover as little as possible of the illustration and, whenever possible, end near the central point of the labelled region. In Figure 3A, the labels of *Femur* and *Ischium* cross several structures, and could easily be shifted to avoid overlapping important details. The label of *Femur* can be easily moved down; it could even be placed on the left side if we had a true higher density of call-outs, which would require more than one label to switch sides.

The leader line of *Ischium*, as a straight line, does not exhibit a placement where it is not crossing the pubis. A possible compromise solution would be to have the leader line arise as a straight horizontal line, and break it, after its central point, at a specific angle (135°, in this case) (Figure 3B). These angular leader lines should always have the same obtuse or right angle (e.g., 150°, 135°, 120° or 90°) to avoid disturbing the figure flow as much as possible.

Call-outs that stand close to each other



**Figure 3. Bones of the hip joint**

Image A. non-optimised figure; Image B. optimised figure; a. distance between labels of the same group; b. distance between labels of different groups.

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should be aligned to a vertical axis that runs along the start of their leader lines (Figure 3B) – this creates a more obvious organisation, guiding the eye through the listed labels. Labels further apart from each other do not need to be aligned, as this would create unnecessarily long leader lines (e.g., that would have happened with the label of *Femur* in Figure 3B). In those cases, you can opt for creating alignment groups based on location and eventually on relationships – in Figure 3B, all three parts of the hip bone are aligned with each other, but not with the label of *Femur*, thus reinforcing their different nature. If it is important to name the group of some labels, you can create a heading label (e.g., the label *Hip bone* in Figure 3B).

A final suggestion for figures with a high number of labels is to add a baseline grid along which you can place text (this grid will not show up in the final version). The equal spacings between labels create a certain rhythm and a cleaner and more appealing visual. You can make use of this grid to further emphasise the relationships between different groups (e.g., in Figure 3B, the distance *a* is shorter than *b*).<sup>13</sup> The drawback of a grid is that you are less flexible with the distribution of labels, therefore its need should be evaluated case by case. Nevertheless, clusters of labels that are close to each other, even if not related, should be spaced evenly.

### Case study 3: Figure depicting a pathway/sequence of actions

In this third example, the goal is to label several elements in a depiction of the replication cycle of the hepatitis A virus.

In these types of figures, which have a precise directionality, arrows should guide readers through several steps. Therefore, opt for thicker, curved arrows that convey the movement/reading direction and are well integrated in the illustration. Make sure the end of an arrow is aligned with the start of the next one (e.g., in Figure 4B, it feels like it is almost a single arrow flowing from start to end).<sup>14</sup> Always assess if an arrow is needed and if you can merge several arrows together without compromising the message. Reducing the number of extra elements will make the image cleaner (e.g., in Figure 4B, there is no need for an arrow for each of the four

Labels and arrows arise as essential components to convey further meaning; however, if poorly designed, they can greatly undermine the message of even the best quality illustrations.

elements that make up the virion). For the same reason, avoid very bright and colourful arrows, which compete with the salience of the illustration. Choose neutral colors such as dark grey for the arrows; alternatively, use background colours as shown in Figure 4B, where I used a dark blue that recedes against the warmer tones of the virus. Lastly, arrows should follow similar rules as leader lines, in terms of consistency and highlight (e.g., in Figure 4A, arrows with very different sizes and colours are not read as a single entity).

In visuals depicting sequences, you should also label relevant elements the first time they appear (e.g., in Figure 4A, it does not make sense to label *Virion* only at the last steps of the cycle).

In more complex illustrations, where individual elements are clearly discriminated or within an environment (e.g., inside a cell, tissue, or organ), leader lines may simply add excessive noise. In some cases, these are redundant, and you can omit them altogether without losing

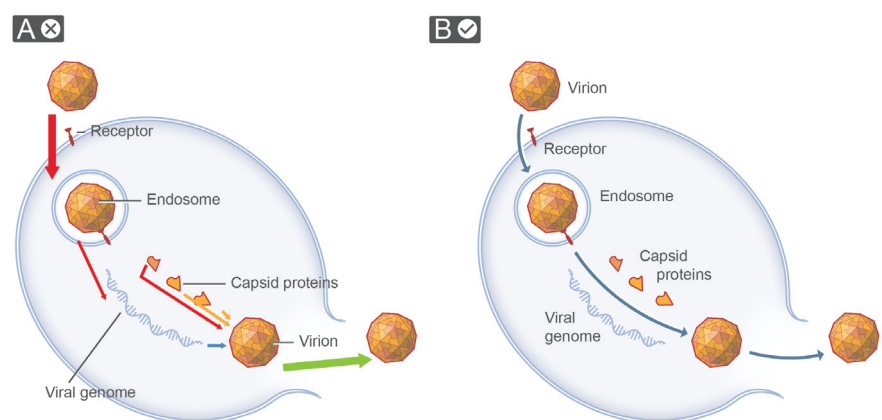
meaning (Figure 4B). When doing this, make sure legibility of the text is not compromised by a dark-coloured or busy background (e.g., the label of *Receptor* in Figure 4A), or by the text crossing multiple backgrounds (e.g., the label of *Viral genome* in the same figure).

### Case study 4: Anchor points and coloured labels

This last case deals with the need to use different styles of anchor points and coloured labels.

In general, anchor points can be blunt (Figure 2B), or circular-shaped (Figure 5A overleaf). Circular bullet anchor points are especially useful if you are naming a specific small element (Figure 5A). When labelling two small elements that are slightly separated from each other, you may opt for a branched leader line with two anchor points (Figure 5B). When labelling three or more elements in close proximity, a single, wider circular anchor point without colour fill (more accurately, an anchor region) is an effective solution (Figure 5C). These approaches guarantee that all individual elements are included. Avoid arrowheads as anchor points, reserving them to convey movement only.

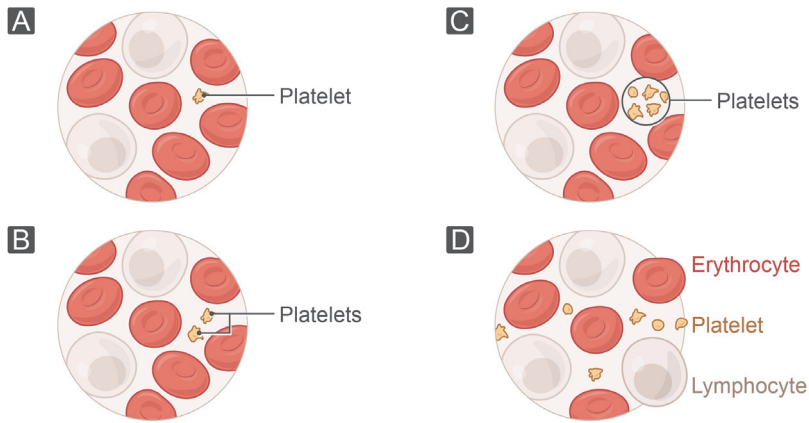
If the elements of interest are scattered throughout the illustration and have a specific main colour not present elsewhere, it may be easier to add a label in that same colour next to one of those elements (Figure 5D). This is particularly helpful when there is not a lot of space to add leader lines, so colour is used to create that connection. Make sure the coloured



**Figure 4. Generic replication cycle of hepatitis A virus (Picornavirus)**

Image A. non-optimised figure; Image B. optimised figure





**Figure 5. Different styles of anchor points and labels**

A. leader line with circular/bullet anchor point; B. branched leader line with two anchor points; C. leader line with anchor region; D. coloured labels.

text is legible. A good rule of thumb is to always colour the call-out in a shade darker than that of the labelled element, to guarantee enough contrast with the background. This colour-labelling approach is not recommended if you need to label more than three structures.

## Conclusion

This article aims to be a short introduction to image creation. Although it should not be required for medical writers to also be proficient illustrators or graphic designers, learning basic visual concepts may ease their work with images. It is in the best interest of medical communication that text and visuals be more and more consistently used in tandem.

Finally, the discussed case studies only included examples of medical illustrations. However, these tips can be applied to all sorts of visual materials such as graphs, diagrams, or flowcharts. Naturally, none of the above recommendations is set in stone. These tips should be adapted to each situation and, more often than not, a compromise is the best solution, especially in more complex figures.

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## Conflicts of interest

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**Guest Editors: Raquel Billiones and Sam Hamilton**

# A picture is worth a thousand words

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## Abstract

As modern medical writers, we face a changing communication landscape greatly altered by the arrival of the internet and the rise of social media. This article provides insights on how to keep pace and what options you have to make your written content more visually attractive. Graphical abstracts or infographics are effective visuals to capture attention, enhance comprehension, and increase information recall. Online tools like Mind the Graph or Piktochart provide a great base to get you started in the creation of your own powerful visuals without having to involve a graphic designer. The importance of promoting content, e.g., through social media, is highlighted, as this will help you to attract and reach your target audience in the crowded online space packed with information competing for attention.

It's no secret that humans are visual creatures. Since the dawn of time, we have communicated visually – drawing cave paintings to tell stories, using symbols to share knowledge, and painting pictures to express beliefs.

The human brain thinks in pictures. Unlike text, which must be scanned and decoded character by character, our visual system can process multiple images simultaneously. Information presented in pictures and images can be absorbed and understood better, a phenomenon known as the Picture Superiority Effect.<sup>1</sup> Recognition tests have shown that the human brain can remember more than 2000 pictures with at least 90% accuracy, even with short periods of presentation times.<sup>2</sup>

As medical writers, communicators, and

marketers, we have a limited time in which to convey our message to our audience. Understanding the way humans process information can be the key to ensuring our messages are absorbed and understood.

Additionally, over the last few decades, a new phenomenon has been impacting the way the brain recognises and interprets data: the internet. It has not only revolutionised the way we find information, but it has also altered the way we learn.

## The internet has reshaped how we seek, process, and retain information

Over the past two decades, a substantial body of work has investigated the impact of the internet on our brains and cognitive processes. Study after study has shown that the internet has

unequivocally reshaped human cognition.<sup>3</sup>

Carr (2011) stated, that in terms of information processing, we are shifting towards a shallow mode of learning characterised by quick scanning, reduced contemplation, and decreased information retention.<sup>4</sup> Today's multifaceted stream of incoming information triggers and demands attention switching and multi-tasking rather than a sustained focus.<sup>5</sup> These fundamental changes to cognition and information processing have accelerated the need for a more visual approach to communication. The scientific and medical communication landscape are no exception, your content has to stand out – visually – to cut through the noise.

Medical writers have many options to visually adapt their content accordingly. Examples could be to use more bullet points to break up the text and to present more data in clear tables and charts. Text could also be replaced through

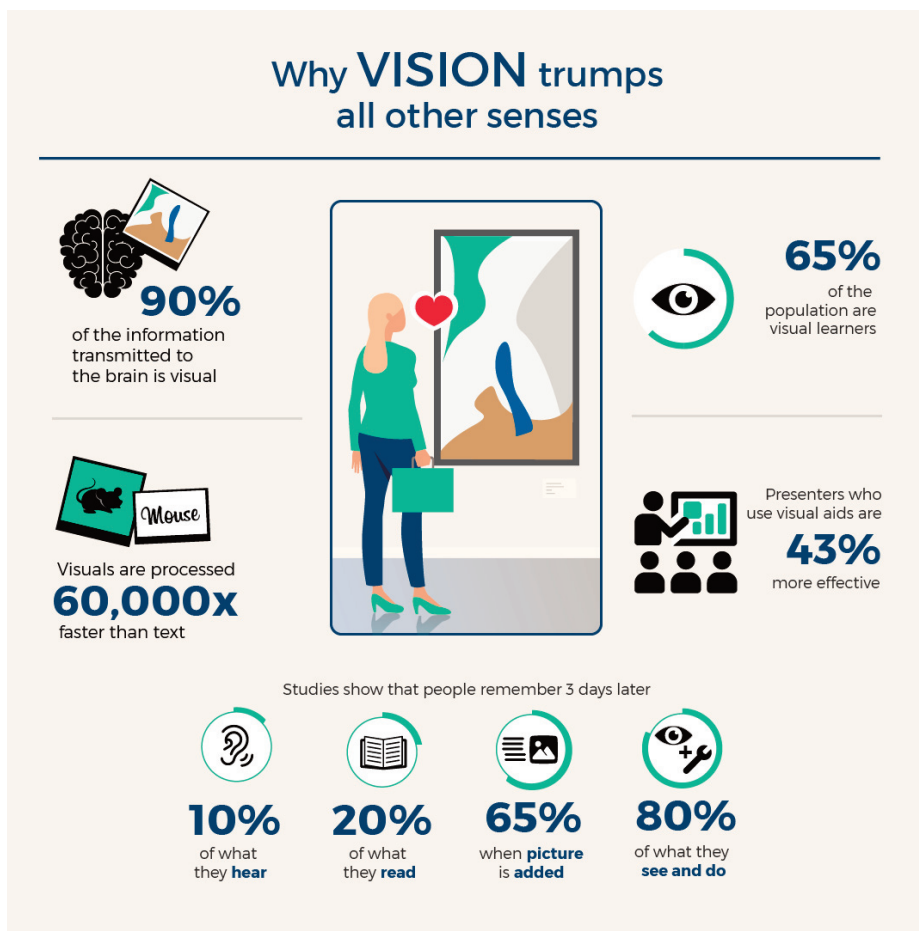


Figure 1. Visualisation of key facts on how our brain reacts to visuals





illustrated graphical summaries. Where appropriate, the use of symbols or icons can render content more visually attractive and also facilitate information retention.

Comprehensive documents that mostly comprise of text (e.g., regulatory documents) can also be complemented with graphical outlines or other visualisations to provide better orientation to the reader. However, in many cases, this may require authorities to make official adaptations of guidelines and instructions on how to prepare such documents.

### The scientific communications marketplace is changing

Because of its open-source nature, the world wide web fosters exponential “scientific information proliferation”. Without being held to any measure of scientific scrutiny, such as peer review or empirical data, online publishers are able to create digital journals that are freely accessible to the public. Not only does this lead to a crowded information landscape with higher competition for audience interest, but it also becomes challenging for consumers to find credible information on the topic of interest. At the same time, promotion and marketing become vital to the success of online journals and libraries, as they can only survive if they are growing their audience and reputation.

New digital channels such as LinkedIn, Facebook, and Twitter have emerged as attractive communication and promotion vehicles. However, and this is not to be neglected, these channels are subject to algorithms that make particular content available based on previous user activity. This reinforces the need to capture attention, stand out from the noise, and prompt engagement.

In today’s digital landscape, how scientists communicate and display their work will determine, to a significant extent, how their findings are received. It is no longer enough to generate new insights or produce ground-breaking research and to publish it. Today’s medical

findings and healthcare content must be packaged in an engaging and attention-grabbing format. This is where visuals become paramount.

### The visual toolbox

When we think about suitable visualisations it is important to remember that there are different types of visual communication. Scientific writers may already be familiar with the concept of data visualisation, but a growing trend taking over today’s marketplace is visual storytelling.

Data visualisation refers to the practice of designing complex data or processes into clear, aesthetically pleasing diagrams, charts, or maps to help the audience better understand and analyse the information presented. The idea of visual storytelling is to guide the viewer to a conclusion based on an introductory statement or thesis. The world of visual storytelling offers a plethora of creative options including videos, quirky GIFs, memes, interactive quizzes, and much more. Each has its benefits, drawbacks and anticipated outcomes to suit various objectives.

For scientific medical content, two visual storytelling formats are especially attractive: graphical abstracts and infographics.

### Graphical abstracts

The goal of a graphical abstract, a relatively new section to many publication formats, is to provide a single, concise, pictorial summary of the main findings. More and more publishers now require graphical abstracts to make primary scientific findings easier to understand and accessible for in- and out-of-domain researchers, as well as wider audiences such as students, journalists, or members of the public. Importantly, graphical abstracts are thought to be an addition to and not a replacement for the classical way of publishing research.

Elsevier outlines, that graphical abstracts should “allow readers to quickly gain an understanding of the main take-home message of the paper and are intended to encourage browsing, promote interdisciplinary scholarship, and help

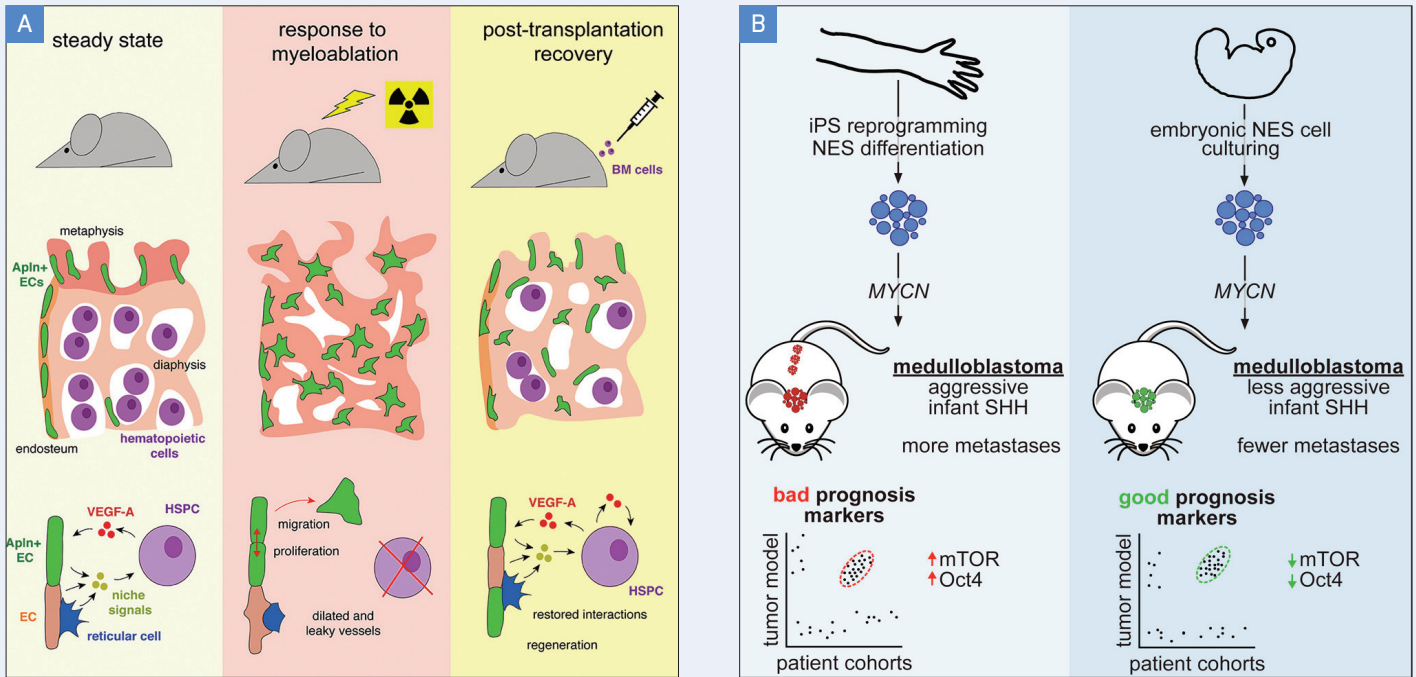
readers identify more quickly which papers are most relevant to their research interests”.<sup>6</sup> With CellPress, Elsevier introduced a new approach to structuring the traditional linear sections of a printed research article into an online format that is integrated, linked, and easy to navigate through tabs. The landing page of each article is complemented with a graphical abstract that provides a quickly reviewable visual summary, bullet-pointed article highlights, and keywords, all with the goal of enhancing article presentation.

For some writers, graphical abstracts may initially seem like extra work for little reward. Consequently, many solely consist of extended figures from a paper or display a summary of a conclusion. However, graphical abstracts have myriad benefits when they have been created as a compelling visual summary of the research and main findings. When searching for topics online, they are displayed in the search results pages (e.g., in an image search in Google) or appear beside the title of the paper (e.g., Science Direct), capturing the attention of the reader. This helps increase visibility and can drive web traffic to an author’s research. Moreover, graphical abstracts are perfect to share on social media to promote research. Ultimately, their use may lead to more interest in an author’s work, more citations in other publications, and possibly greater recognition. Their effective, strategic use may even encompass new funding possibilities and new collaborations.

### Three examples of good graphical abstracts:

Great examples of clear, self-explanatory graphical summaries of research papers are presented in Figure 2. Each chosen illustration is able to perfectly summarise the topic of research and materials and methods used, as well as outline the core findings. The information given adheres to the principles of good design, guiding the eye through the data in a clear and logical order.

In the future, one hopes that graphical abstracts and meaningful visuals will become



**Figure 2. Examples of compelling, clear graphical abstracts from Elsevier CellPress**

Figure 2A shows how hematopoietic cells, lost in response to irradiation and other treatments, trigger vessel dilation, permeability, and endothelial cell (EC) proliferation. It further shows transplanting hematopoietic stem and progenitor cells (HSPCs) increases the fraction of ApIn<sup>+</sup> ECs and promotes normalisation of the bone vasculature in response to VEGF-A. The abstract clearly depicts all elements of the process and findings and is nearly self-explanatory.

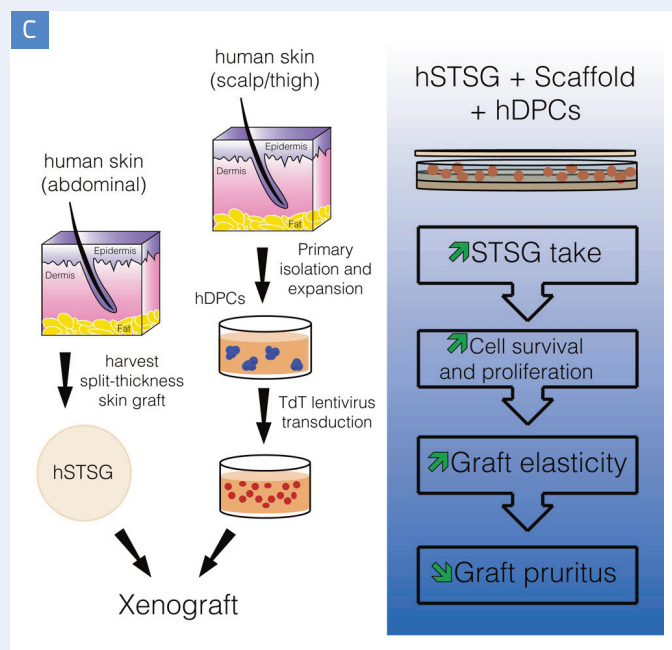
Reproduced with permission from [https://www.cell.com/cell-stem-cell/fulltext/S1934-5909\(19\)30427-8](https://www.cell.com/cell-stem-cell/fulltext/S1934-5909(19)30427-8).

Figure 2B demonstrates the underlying mechanisms of how human iPSC-derived or primary neuroepithelial stem cells can be transformed by MYCN and how that drives infant SHH medulloblastoma. It shows a suitable model (embryonic NES cell culturing) and that mTOR and Oct4 inhibition is efficient resulting in fewer metastases in just one image.

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Figure 2C shows the complete process and detailed outcome of in-vitro isolation and expansion of dermal progenitor cells (DPC) from human skin.

A DPC transplant graft combined with a scaffold improves split-thickness skin grafting (STSG), cell survival and proliferation, graft elasticity and limits graft pruritus. Reproduced with permission from [https://www.cell.com/stem-cell-reports/fulltext/S2213-6711\(19\)30372-8](https://www.cell.com/stem-cell-reports/fulltext/S2213-6711(19)30372-8).





more and more prominent in a publication environment still dominated by traditional print. This includes adapting text-based search tools like PubMed and Google Scholar to show visuals in search results. It is important to leverage the potential of online dissemination of research results for all life science disciplines by adapting publication practices to an already changed communication landscape.

## Infographics

Another compelling option to disseminate scientific medical information is an infographic. According to the *Oxford English Dictionary*, an infographic (or information graphic) is “a visual representation of information or data”.

In contrast to graphical abstracts, which aim to summarise the full content of a study or research paper, infographics focus on painting a more in-depth picture of a complex topic or fact. They can be used to help capture attention, enhance comprehension, and increase information recall.

Infographics have many digital benefits and have maintained their popularity over the last few years. They can contain links or backlinks and can be optimised for search engines to improve website rankings. They are easily shareable on social media and can be repurposed across different communication channels.

### Infographics applied in healthcare

In addition to presenting scientific research and data, infographics can be used in many healthcare communications:

- Patient information and education – disease information/management, disease prevention campaigns, health behaviour change campaigns
- Procedural explanations – patient information explaining hospital entry and exit, treatment procedures, post-treatment recommendations, rehabilitation schemes, medication adherence, etc.
- Educational materials for care settings – for students, nurses, physicians, pharmacists, physical therapists, etc.
- Industry information – product explanations, procedures, and product instructions for med tech, pharma, or laboratories
- Wider use – information about patient organisations, non-profits, health insurance

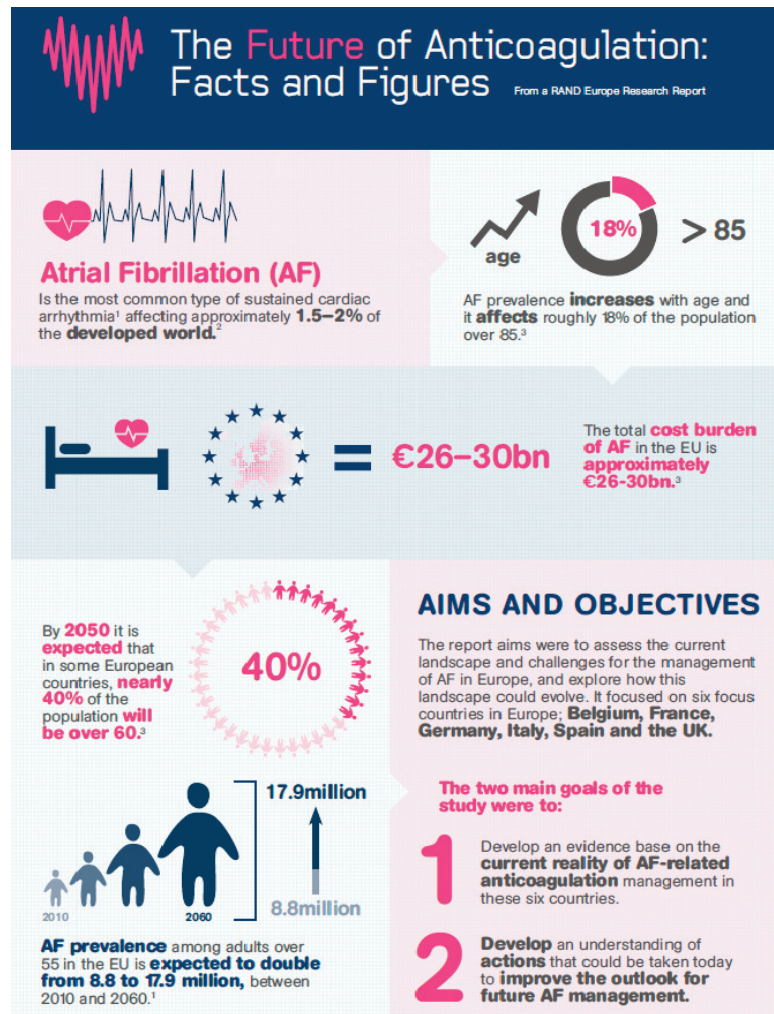


Figure 3. Screenshot of *The Future of Anticoagulation: Fact and Figures*

Reproduced with permission from RAND. Find the complete infographic here:

<https://www.rand.org/pubs/infographics/IG122.html>

### Three examples of good infographics

The examples selected in Figures 3, 4, and 5 break down a comprehensive topic into an easy-to-follow overview that a viewer can understand and retain at first sight. Importantly, only a few contrasting colours and fonts are used to support grouped information blocks.

### Creating compelling visuals

Before you start designing visuals, several important factors should be considered. Below are listed some tips that will help you to get started.

- Begin by consulting the instructions of your target journal for specifications or other guidance.
- Understand your target audience. Will they be familiar with any terminology used? Will they understand your reference points?
- Craft your story. Choose the most meaningful and relevant data to focus on. Include all important information, from hypothesis to results.

- Use popular keywords and phrases to grab attention.
- Select the right design software for your needs and skill level, or work with a design professional.
- Pay attention to image quality and readability. Be mindful of text size and include ample whitespace to avoid crowding.
- Keep the design simple and easy to understand.
- Employ a text hierarchy for headings, subheadings, and body text. Use a maximum of three fonts.
- Avoid too many colours as this can distract the reader away from the main message; use one or two contrasting colours/shades instead
- Always use the principles of good design.

A great source of principles of good design is *Picturing Science: Design Patterns in Graphical Abstracts* from Jessica Hullmann.<sup>7</sup> The full text is available at <https://www.researchgate.net/>.

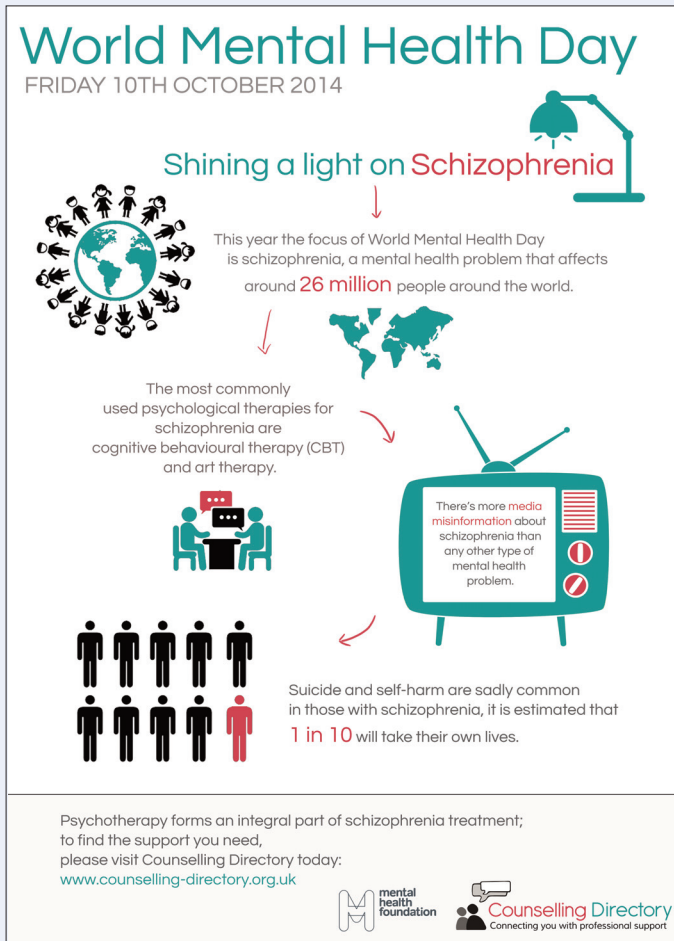


Figure 4. Screenshot of infographic designed by Counselling Directory addressing the World Mental Health Day 2014

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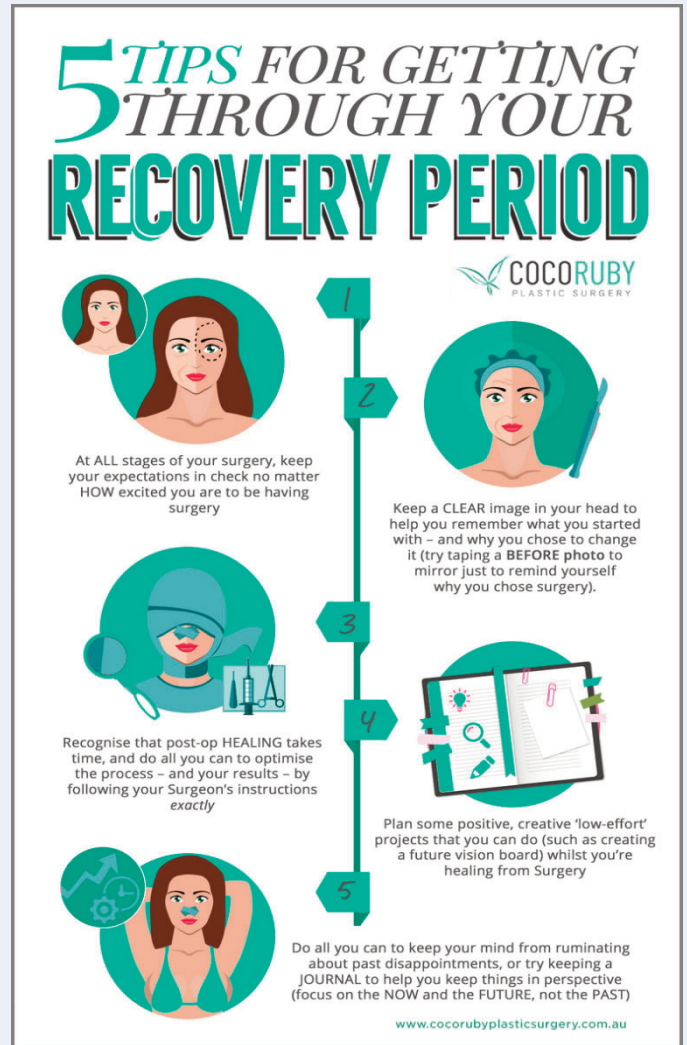


Figure 5. Post-treatment tips from Coco Ruby Plastic Surgery

Reproduced with permission from <https://cocorubyplasticsurgery.com.au/emotions-after-cosmetic-surgery/>

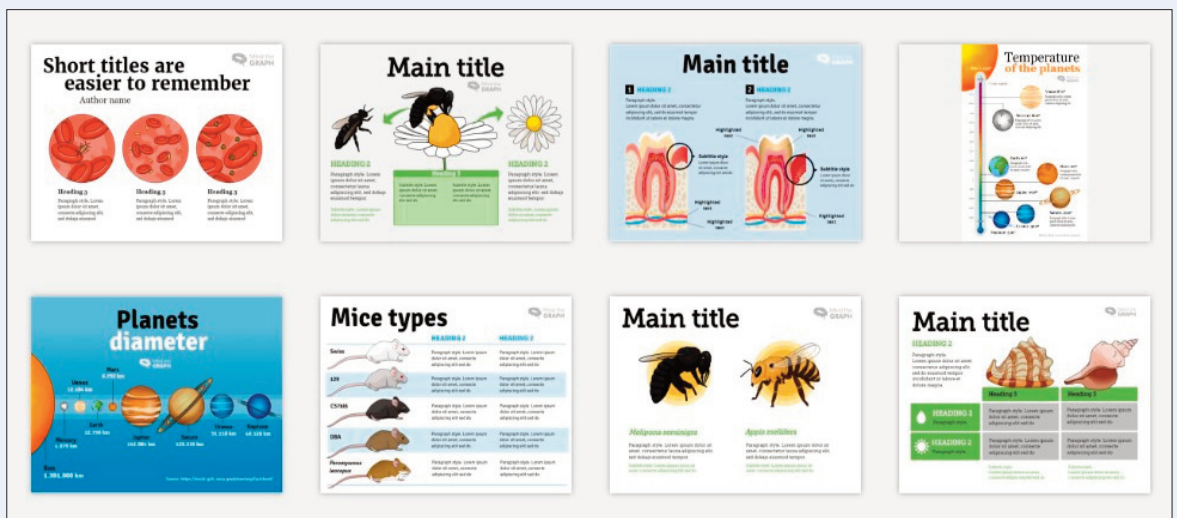


Figure 6. Screenshot of template section of Mind the Graph website<sup>8</sup>



Table 1: Comparison of various online design tools best suited to create infographics and graphical abstracts






	CANVA <sup>9</sup> 	VISME <sup>10</sup> 	VENNGAGE <sup>11</sup> 	PIKTOCHART <sup>12</sup> 	EASEL.LY <sup>13</sup> 
<b>Overview</b>	All-in-one visual communication design tool for design needs, infographics included	All-in-one visual communication design tool for marketers, focus on infographics	All-in-one visual communication design tool, focus on infographics	Comprehensive design tool for infographics and visual presentation styles (presentation, poster, banner, report, flyer, social media)	All-in-one visual communication design tool, for educators and students, small business owners, focus on infographic design
	Free plan gives access to most functions Possibility to purchase on demands User-friendly	Interactive with links, integration of animation and pop-ups Integrated analytics	Browse infographic templates by 8 different types, including statistical, informational, comparison and geographic	Includes graph and chart maker	Free design sand box; support options: articles, webinars, videos, direct customer support 6 Mio+ infographics
<b>Templates</b>	50,000+ (total) 126 (infographics) categories: education, process, business, timeline, charity not searchable by categories	500+ (infographics)	100+ (infographics)	600+	732 searchable
<b>Editor</b>	Drag and drop	Drag and drop	Drag and drop	Drag and drop	Drag and drop top bar menu
<b>Icons</b>	2,000+, scaleable	1,000+, fully customisable	1,000+, fully customisable	4,000+ free	4,000+ free
<b>Fonts upload</b>	✓	✓	✓	✓	✓
<b>Images library upload</b>	1 Million+ API (Unsplash, Pexels, Pixabay)	1 Million+	1 Million+	1 Million+	681,982
		API (Unsplash) ✓	API (Unsplash) ✓	API (Unsplash) ✓	✓
<b>Animation</b>	✓	✓	No	✓	✓
<b>Interactivity</b>	Video, GIFs, sound media embed possible	Can link between blocks and to outside sources; can embed video and third-party content	Can link to outside sources; can embed video	Video, charts, map visualisation; animated icons embed possible	Video embed possible
<b>Smart resize</b>	✓	✓	✓	✓	
<b>Download</b>	JPEG, PNG, PDF	JPEG, PNG, PDF, HTML5	PNG, PNG HD, PDF and interactive pdf	PNG, JPEG	JPEG, PDF
<b>Social sharing</b>	✓	✓	✓	✓	JPEG, PDF

Table created with the information available in December 2019.

Abbreviation: API: application program interface

publication/325186940\_Picturing\_Science\_Design\_Patterns\_in\_Graphical\_Abstracts.

## No designer required

If you don't have a professional design team at your disposal, consider the following online tools to create your own detailed visuals in under 30 minutes, no experience needed. Most tools offer a free trial to assess their capabilities and come with affordable subscription options should you wish to invest.

### Mind the Graph

Mind the Graph<sup>8</sup> is an easy-to-use, comprehensive online graphic software that is specifically designed to cater to the design needs of the scientific community. It includes medical content like medical images, icons, and symbols and is my recommended tool for medical writers.

Mind the Graph provides a library of over 6000 scientific illustrations and ready-to-work template layouts for both graphical abstracts and infographics (Figure 6).

### Other design tools

If you are new to designing and creating visual content, it's important to test various software tools and find the solution that best fits your needs. Begin your research with the handy chart in Table 1.

Other tools, not covered in the table, are Infogram,<sup>14</sup> Vizualize.me,<sup>15</sup> and Snappa.<sup>16</sup> Creately<sup>17</sup> is a chart maker tool that currently provides about 40 types of diagrams and over 100,000 diagram examples.

All online graphic design tools come with

tutorials on their websites, blogs, or on YouTube.

If you are more advanced and want to create your own illustrations from scratch, there are also plenty of easy-to-use, free graphic design desktop software options to choose from, e.g. Krita,<sup>18</sup> Gravit Designer,<sup>19</sup> and GIMP.<sup>20</sup>

## Don't forget to promote

In today's digital communications landscape, authors must adapt to the changing digital communications landscape to stand out. Not only do scientists, medical writers, and marketers need to create visually compelling content, but they also must market that content effectively. Study after study has proven the power of visual storytelling, but even the most compelling visuals are powerless if nobody sees them.

Therefore, once you have created your visuals, be sure to choose the right strategy for distribution. Your plan may include sharing on your own website or social media channels, reaching out individually to your network by email or even submitting your infographics to directories (Daily Infographic,<sup>21</sup> Flickr,<sup>22</sup> Infographic journal<sup>23</sup>).

## Visuals are vital, today and tomorrow

Recent years have seen a significant shift towards visual content in academia and medical communications, for example, easy-to-grasp infographics that break down complex information, attractive, scribed animations like whiteboard explainers and engaging video.

Graphical abstracts and infographics present new opportunities for promoting scientific research. They help to increase visibility and establish online credibility in a crowded content landscape. They are great assets that can be easily re-used as a whole or as parts and shared across different online channels such as social media, websites, and email event announcements.

Creating compelling visuals doesn't have to mean reinventing the wheel. Armed with the right online software and basic design principles, even the least digitally minded writer can produce visual accompaniments to their work.

Use the principles outlined above to create and disseminate visual content for your next publication project. Take note of the impact it has, not only on the initial interest in your findings but on how well the information has been digested, understood, and retained by your readers.

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## Disclaimer

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

## Conflicts of interest

The author is self-employed and declares no conflicts of interest.

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- Add some prestige to your CV
- Improve your knowledge of medical writing and related topics

# The evolution of the scientific poster: From eye-sore to eye-catcher

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## Abstract

Despite the rise of social media, high-speed internet, and teleconference software, conferences seem to be here to stay. But what is their purpose? Networking. So why then do we design conference posters in a way that makes people run away from us?

In this article you will learn why a scientific poster should be an eye-catcher and a conversation starter and how to design effective posters with the reader in mind. A poster should be a visual abstract of your research, not a wall-of-text. Beyond the conference, graphical abstracts can be effective tools for broadening the reach of research and are becoming more commonplace in scientific publishing. When it comes to effectively engaging with your audience, it is time to break the status quo. Let us bury the wall-of-text posters and embrace graphical abstracts.

Conferences. Despite the rise of social media, high-speed internet, and teleconference software, they seem to be here to stay.

Have you ever asked yourself why? There is one thing that technology cannot replace –

human interactions.

Shaking hands, smiling, bonding over shared interests and struggles, and of course, the late nights out eating and drinking with fellow researchers, that's where the best networking happens, and long-lasting collaborations are forged!

So if conferences are all about connecting with new people, why do we design conference posters in a way that makes people run away from us? Traditionally, the academic poster has looked something like depicted in Figure 1.

Let's reflect for a moment on the user experience that this format of poster creates. First, this is a poster that is hard to notice in the crowd because it is not eye-catching. Second, it overwhelms the reader with a wall of text, which ensures that the take-home message is well-concealed deep within a long paragraph. Third, it is hard to navigate because the structure is unclear, and there is simply stuff everywhere. The result? People will pretend that the researcher and the poster are not even there.

## Why did the “wall-of-text” poster become the status quo?

WHY and HOW has this become the norm? Where is it written that conference posters need to be designed in a way that goes against every principle of effective communication?

Unfortunately, we don't have the gift of travelling back in time to find the evolutionary origin of the conference poster. But *somehow* the “wall-of-text” poster became the generally accepted norm, just like it became the norm to write our research papers in a stale and impenetrable way.<sup>1</sup>

The fundamental problem is that we are not designing posters with the reader in mind. We are preparing posters to show-off all



of the data and text because they give the presenter a sense of comfort and security. We are selfishly designing our posters without even considering that most people at conferences might not be interested in all of those eight plots

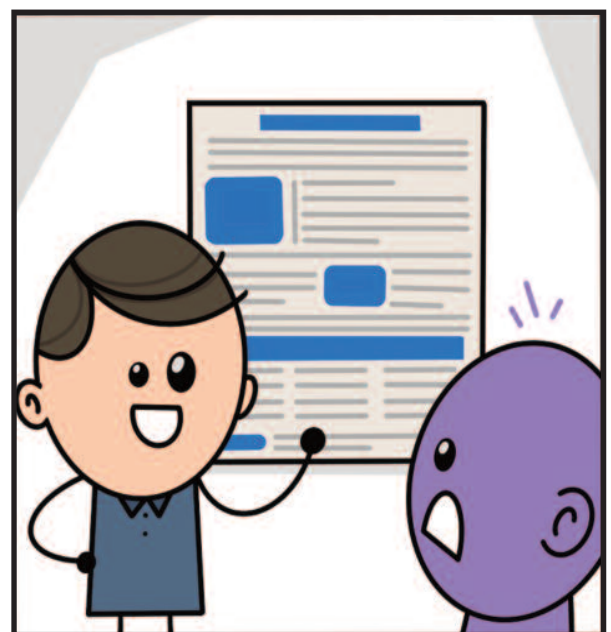


Figure 1. The wall-of-text poster – the dark ages of networking





and tables full of highly significant p-values. People at a poster session just want to have a chat! They don't want to read and they want the scientist to tell the story of their research.

### Back to the basics – why do we design conference posters?

Now please put all of your pre-existing ideas about conference posters into a mental box, seal it with double-strength duct tape, and throw it away.

We need to start afresh.

If we go to conferences to meet people and network, then posters should be networking tools above all. How? Simple, we need to make sure that posters work as an eye-catcher and conversation starter.

Here is where things get interesting. Our brain can process images in about 150 milliseconds,<sup>2</sup> and you can use this to your advantage making sure that your poster acts as an eye-grabber. All you need is a large and easily recognisable graphic, which can relate to the research even loosely. Its role is to get noticed and trigger people's curiosity so that they walk towards the poster and start an interaction with the presenter. This is how to get the attention of that superstar professor!

Now imagine being the researcher. You dressed up to look professional, you even ironed your clothes, and you feel ready to perform at the conference poster session. Thanks to the eye-catching visuals you've made people curious, so they come to you saying something like "cool poster, can you tell me about your research?" Bingo! Now you want to give your one-minute spiel about your research, while pointing to graphs and images on the poster as needed. You MUST contain your excitement and speak for only one minute because at this point you still don't know who you are talking to and you cannot assume that they want to know about all the little details. Your objective is to understand your audience, their interest and needs, and start a two-way conversation. Ask them open questions like: "What is your field of work?" Let them do the talking and try to understand how your work relates to theirs. Once you know that, your next objective is to give value: basically, try to help them in some way. Do you know someone they should meet? Make the

introduction. Do you master a statistical analysis that would interest them? Offer them help. Do you have samples this person would be interested in studying? Offer them your samples. The important thing is that before you even think about what you might *take* from this person, try to *give* value in some way. Giving is the best possible foundation to a great relationship.<sup>3</sup> This is how you use a poster as a networking tool.

### A poster should be a graphical abstract

We have clarified that a conference poster should be an eye-catcher and a conversation starter. So how much should be put on it?

Unfortunately, most conference posters are overloaded with far too much content. But some conference organising committees understand that such posters don't work.

In the past few years, we have observed various conferences abandoning posters all together and replacing them with graphical abstracts in printed or digital form (example 1: Natural Resource Management Science Conference 2018,

If we go to conferences to meet people and network, then our posters should be networking tools above all. How? Simple, we need to make sure that our posters work as an eye-catcher and conversation starter.

<https://www.environment.sa.gov.au/the-weekly/articles/nrm-science-conference>, example 2: Australian Society for Fish Biology Conference 2019, <http://asfbconference.org/abstracts/graphical-abstracts/>).

As science communication specialists, we welcome this change. Although we think that posters can be a very efficient communication tool, the problem is HOW we design posters. If we followed a few basic principles of graphic design and communication, posters could give researchers the visibility and attention they always desired.

And what about e-posters? E-posters are essentially a slideshow of posters that are displayed on a screen without the author being present. Therefore, as each poster is visible for only a short time it is even more crucial to be succinct and visually appealing.

So let's do it. As a general principle, you should think about a poster as something closer to the abstract of your paper than the actual paper. It should be a visual abstract (Figure 2).

A poster should not tell the whole story of the research in detail; that is what papers are for. We understand that, after many years of conditioning, it is hard to let go, but it is crucial to realise: less is more for poster design. As a rule of thumb: limit your word count to 250, possibly 150; limit your graphs to a maximum of 2 or 3; and definitely do not use tables. Just extract the key numbers and highlight them by placing them in a shape (see Figure 3 for an example). Good

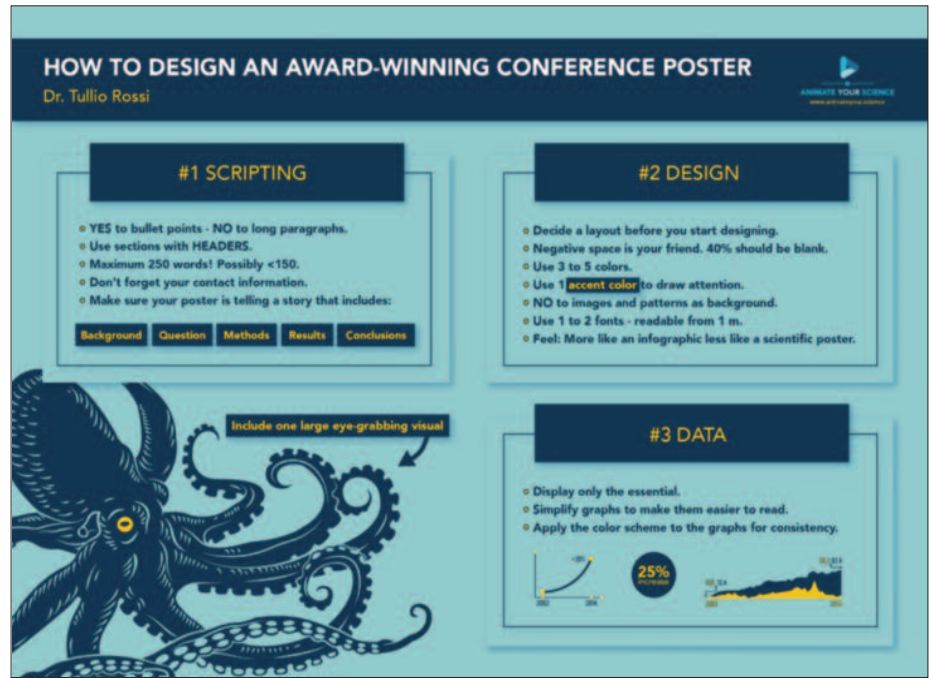


Figure 3. The essential elements to an effective conference poster

See <https://www.animateyour.science/post/how-to-design-an-award-winning-conference-poster>

communication is all about simplicity and clarity, and so your poster should reflect that.

Once you've successfully limited the amount of content in the poster, something amazing will happen. You will have unused space! Most people think about unused space as wasted space, designers instead call it negative space and appreciate its power. You can see negative space as a superpower that enables you to control what people look at on your poster. With negative space you can guide the viewer's eyes to the key message you want them to take home. Without it, they will get lost, feel overwhelmed, and lose

interest. For an excellent example of negative space simply go to [www.google.com](http://www.google.com) and admire how clean the interface is. It is all negative space except what matters – the search bar.

### The rise of social media for science communication

For better or worse, social media has become a key vehicle of science communication: either within the scientific community, or to the broader public.

However, social media is a noisy ecosystem, and for something to be seen, it needs to be *seen*. This means simply posting the URL link to a published paper may not be sufficient to capture attention. Here is where a well-designed graphic can help. It is akin to standing out to passers-by in a conference poster hall and there is emerging evidence of its benefits in improving the reach of new scientific publications. One study used Twitter to quantify the effect of including a graphical abstract in the promotion of new publications.<sup>4</sup> The researchers compared Twitter posts with and without graphical abstracts over one year, using each post as its own control. They found that the reach of posts with graphical abstracts were substantially greater than those without. Tweets with graphical abstracts received a 7.7-fold increase in Twitter impressions, a 8.4-fold increase in retweets, and a 2.7-fold increase in article visits.



Figure 2. A poster is not a manuscript but rather a visual abstract of your research

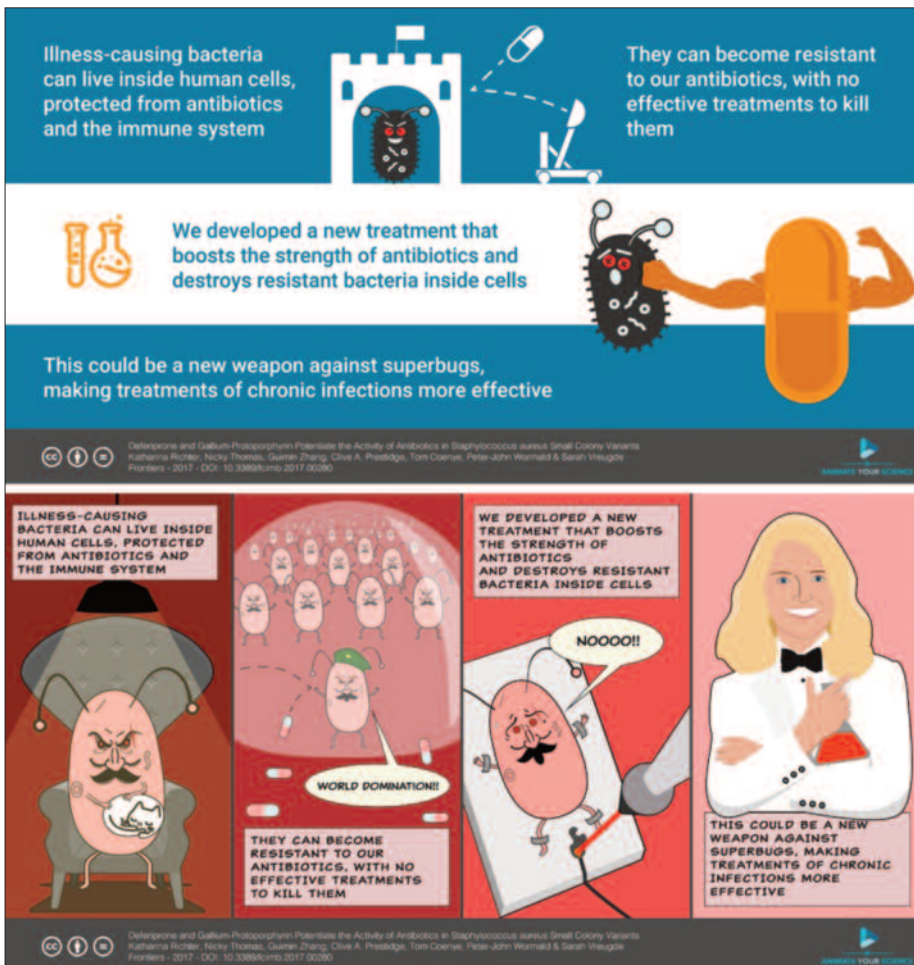


Figure 4. Examples of two approaches to a graphical abstract for the same paper<sup>12</sup>  
Upper panel = Infographic Style. Lower panel = Comic Style<sup>11</sup>

## Where to use a graphical abstract

As graphical abstracts are effective in capturing attention on social media, more and more journals demand a graphical abstract for publishing manuscripts.<sup>5,6</sup> This can be as a key figure at the beginning of an online publication,<sup>7,8</sup> or in a graphical table of contents.<sup>9,10</sup> After all, the graphical abstract is a tool to guide you towards papers of interest.

A graphical abstract does not have to be limited to online use. We believe that a graphical abstract is effective as a conference poster in its own right, especially if you are there to provide more information to the viewer. Graphical abstracts have even been embedded directly into conference posters. This gives an opportunity to include a rapid “take-home summary” to the viewer, while still providing more detailed information as well.

## Styles of graphical abstracts

So how *should* a graphical abstract look?

Firstly, we should follow the same design principles as when creating a beautiful poster. This means “less is more”, so choose one key message/finding to summarise your work. Remember, the goal is not to replace the paper, but rather to bring more eyes to it.

The second thing to carefully consider is the target audience. Is the graphical abstract for networking purposes at a conference? Or is it to engage with the general public on social media? This will influence your choice of style.

Consider the *Infographic Style* (Figure 4, upper panel). This is a clear and effective style that offers great flexibility and can be tailored to your target audience. Provide *some* detail to inform a scientific audience or stick to the broader context to relate to the general public. A graphical abstract is not the place for figures or charts, rather key points should be graphically supported by pertinent visuals and icons.

As always, include an eye-catching visual to stand out.

Alternatively, the *Comic Style* (Figure 4, lower panel) is an excellent way to engage with the general public and scientific community alike. It does not lend itself to presenting precise findings but is a powerful and fun way to communicate the broader research impact.

## From regular microbiologist to James Bond (Katharina's experience)

When attending conferences many junior researchers compete for visibility, but how can you stand out from the crowd?

For me, trying a new thing – putting a *Comic Style* graphical abstract<sup>11,12</sup> (Figure 4, lower panel) on a poster – felt like being a scientific rebel. I worried about being ignored, being laughed at, and diminishing my reputation as a scientist.

But being brave enough to deliberately be different and challenge the status quo on wall-of-text posters worked out! After putting up the poster in the morning of the conference, it only took until lunchtime to receive enquiries of attendees asking if I was the female James Bond. Wow, this was unexpected, in particular as there were 400 posters pinned up. During the poster presentation in the evening many people came along and wanted to know more about my research. I almost lost my voice as I was talking for 2 hours straight, I got connected to various researchers from around the world and suddenly felt myself being on the radar of high-profile investigators. Even months later, one of the conference organisers contacted me, remembering my unique poster, and enquired if I was keen to write a book with her. On top of that, I was invited to an international visit at a prestigious laboratory, where I had access to state-of-the-art facilities to boost my research and write a joint paper. All of this because of a poster!

If done right, a poster can be a powerful tool to increase a researcher's visibility, and a conversation starter that can open pathways that you never imagined were possible.

So, give it a try, change your poster design, and leave a unique impression.



## Let's bury the wall-of-text poster once and for all

It's clear. Conference posters are traditionally designed to do the opposite of their objective: to spark a conversation. But posters are not a data dumpster. It's time to break the status quo and use the right tool for the job. Let us *bury the wall-of-text posters and embrace graphical abstracts*. It will make researchers stand out, increase their visibility, enhance their networking opportunities, and it will give a better experience to readers. Win-win.

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## Conflict of interest

Tullio Rossi is the founder and director at Animate Your Science. Flynn Slattery works as a science communication officer for Animate Your Science. Katharina Richter has no conflicts of interest to report.

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**Don't miss!**

**The September 2020 edition**



## **European Union regulations**

This issue will focus on new EU regulations and their impact on medical writing. Key topics will include changes to centralised procedures, effects of Brexit on the EMA, and new regulations on medical devices, drug-device combinations, and veterinary medicines.

**Guest Editor: Ana Madani**

# Leveraging infographics in study schemas

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## Abstract

Data disclosure requirements of the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) mandate that protocols be shared on designated clinical trial websites. As a visual medium, the internet is transforming the way these protocols are communicated to a global audience.

Medical writers can use data visualisation to represent study schemas in protocols as infographics and in this way help readers to better understand multiple layers of complex information. Study schemas can be designed using standard tools such as Microsoft PowerPoint. Medical writers can use visual elements such as colour, shapes, and icons to portray timelines, dosage regimens, treatment arms, study periods, and procedures. This article describes key concepts in data visualisation and demonstrates how those concepts can be applied in designing creative, effective, and informative study schemas.

## What is data visualisation?

In recent years, data visualisation (#dataviz) has become a common sight. We see it in news articles, social media, and almost every industry that produces digital content, including scientific communication and medical writing. Data visualisation represents information in the form of graphs, tables, charts, maps, infographics, and dashboards, and allows readers to quickly grasp trends and patterns in data.

In 2020, it is estimated that the digital universe of data will expand to 44 zettabytes (one zettabyte =  $10^{21}$  bytes).<sup>1</sup> As data growth accelerates exponentially, it becomes more difficult to manage, use, and interpret data. Advanced tools, such as artificial intelligence and machine learning algorithms, are becoming increasingly important for data collection and analysis. In the sea of information surrounding us, data visualisation helps readers to make sense of complex information by simplifying it and presenting it visually.

## Visual info gets priority

Visual information is generally much easier to process and understand than chunks of text. There are several cognitive reasons for this:

### 1. We scan images faster than text

Neuroscientists at the Massachusetts Institute of Technology (MIT) discovered that the brain can identify images seen for as little as 13 milliseconds (ms).<sup>2</sup> This is super fast compared to the average time taken to process a letter of the alphabet (476 ms) or a word (441 ms). This rapid processing of images means that readers can identify and start to understand a graphic before reading any text.

### 2. Images attract more attention than text

Using eye-tracking equipment that produces heat maps, the search-engine optimisation company Moz studied users as they viewed Google search results.<sup>3</sup> The aggregated heat map shows that a search result with an image attracted much more attention (yellow area) than a search result without an image (red area). The application of this concept in the context of medical documentation is that readers are more likely to focus on visuals – and not text – as their anchor.



### 3. We remember images better than text

Most people can remember images better than words, a phenomenon known as the picture superiority effect.<sup>4</sup> Researchers presented subjects with either words (as text or audio recordings) or as images with text labels. After 3 days, subjects exposed to words alone could recall only 10% of the words presented to them. However, people exposed to images together with text could recall 65% of the words (Figure 1). This result demonstrates that people remember information much better when text is combined with a relevant image.

Infographics visually represent data, processes, or concepts. Since visuals are processed faster than text and are easier to understand, infographics should be used to communicate complex information whenever possible. By breaking down a complex mass of information into its components and relationships, essential data can be conveyed to the reader in a clear and understandable format.

## Visualising study schemas

The content of clinical regulatory documents is usually governed by health agency guidelines that stipulate the type of information to include and the format in which it is to be presented. Most of the information in clinical regulatory documents is not necessarily suited for visualisation, and may

All authors contributed equally to this work.





sometimes be difficult to translate into a visual figure other than a table or graph.

A significant exception is the study schema, which appears in clinical study protocols and may subsequently be included in the corresponding

clinical study report or publication. The study schema is a graphical description of the study design detailed in the text, and provides an opportunity for the medical writer to be creative. Specialised graphic design abilities and expensive

software are not necessary. Study schemas that adhere to the company brand and standards of professional publication can be designed using standard tools such as Microsoft PowerPoint.

The study schema allows writers to visualise complicated study designs, such as first-in-human Phase 1 studies (which often involve sequential dosing of several cohorts, either single or multiple doses and/or multiple strengths of the study treatment) and studies with several treatment periods. Adaptive study designs, which are becoming more common in the pharmaceutical industry, can also be depicted using schematic diagrams.

The audience for clinical regulatory documents includes not only regulatory agencies, health authorities, and investigators, but also the wider public of potential study participants and their caregivers, who may access protocols on regulatory websites due to the data disclosure requirements of the EMA and FDA. Visualising the study schema as an infographic helps an international audience to understand the study design at a glance.

Furthermore, if the study is later presented as a poster or presentation at a scientific conference, a well-prepared study schema will provide the reader with a rapid grasp of the study design while saving valuable space in a slide deck or poster.

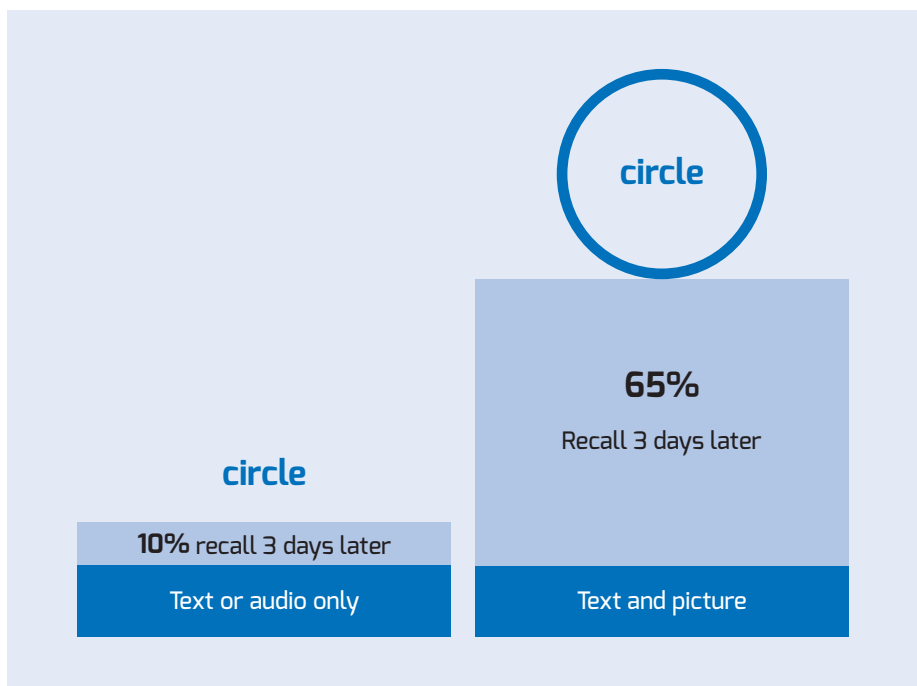


Figure 1. Picture superiority effect: images are recalled better than text or audio alone

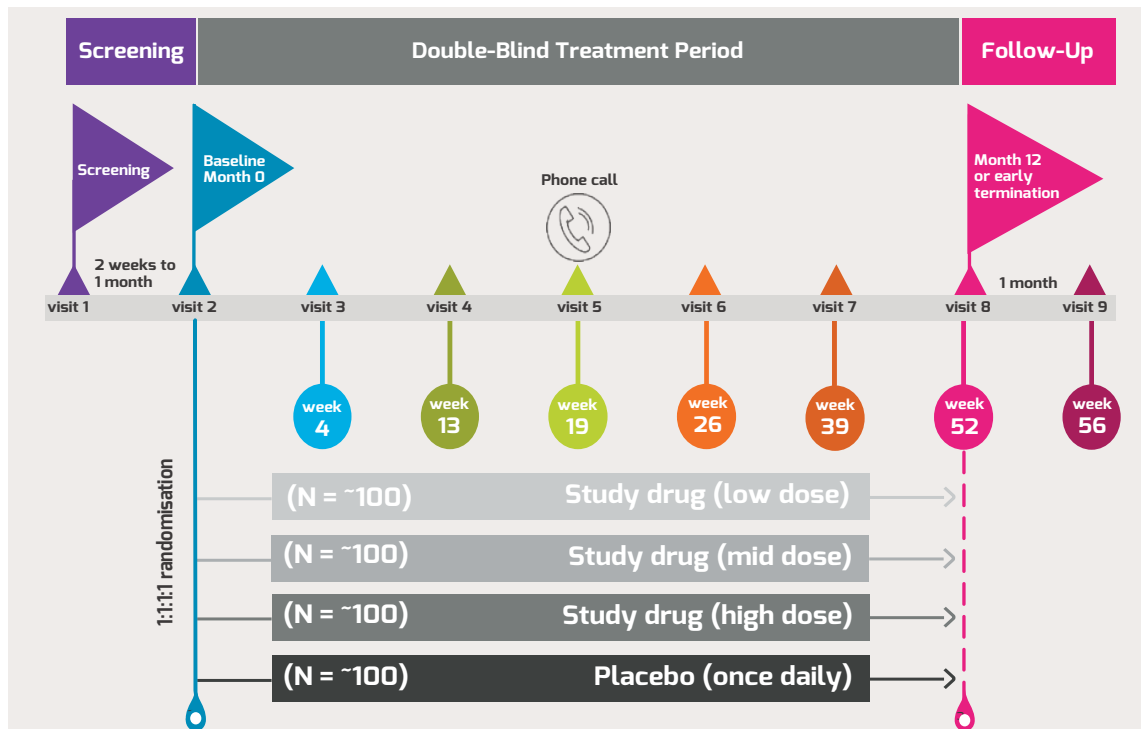


Figure 2. Study schema of a fixed-duration, double-blind placebo-controlled study

### The study schema as a timeline

With a defined start point, and usually an end point, a timeline infographic is the most suitable way of representing a study schema. The timeline simultaneously conveys processes that occur sequentially and in parallel.

The study schema in Figure 2 consists of a relatively simple fixed duration, parallel-group design, where three dosages of a drug were tested in comparison to a placebo. The study schema depicts the timepoints of the in-clinic visits and the telephone contact during the course of the study. An example of a sequential process is the visits that occur from enrollment throughout the duration of the study; administration of study drug to patients in the different treatments is a parallel process. It is easy to simultaneously understand different processes when they are visually presented as separate bars on a timeline, since our minds already have built-in assumptions about how to read and parse visual information:

- We read English from left-to-right, so the timeline begins on the left and proceeds to the right.
- We parse information from top-to-bottom, so the main stages of the study are described at the top.

The timeline in Figure 2 provides a visual representation of all the significant milestones in the study schema:

- Main study periods – Appear as top-level headings in the infographic: Screening, Double-Blind Treatment Period, and Follow-Up. All elements in the infographic are placed under one of these three main headings.
- Periodic visits – Indicated by small triangles, starting from the first visit (visit 1) to the last (visit 9). Each visit in the Double-Blind Treatment and Follow-Up periods is anchored to the specific week in which it occurs. Unique colours are used to link each visit with the week in which it occurs. Different colours can be used to depict the visits, even though the assessments and procedures performed at some visits may be similar.
- Visits of particular importance – Indicated by flags. Examples include visit 2 (Baseline) and visit 8 (end of the treatment period or, for patients who withdraw from the study, the early termination visit).
- Number and type of treatment arms – If a treatment arm is discontinued for any reason, this can be indicated (for example, by an “X” on the specific arm). The approximate number of planned enrolled patients can also be included.
- Start and end dates of treatment – Vertical

lines indicate the start and end of the treatment period.

### Icons in study schemas

In the 20th century, Otto Neurath and Gerd Arntz developed 4,000 symbols for Isotype – the International System of Typographic Picture Education. Pictograms were then designed for the 1964 Summer Olympics in Tokyo as a universally intelligible way of communicating different sports, services, and modes of transport to international visitors.<sup>5</sup> Today, icons are used for road signs, software interfaces, and instruction manuals, and can be seen in every public space from hospitals to airports. They are a global visual language that transcends linguistic and cultural barriers.

When infographics include icons, their value as an effective communicating tool increases. This is particularly important in the clinical study setting, in which many late-phase studies are conducted globally in several countries and might require translation to the local language. By leveraging icons in medical infographics, writers can convey concepts in a visual language that everyone understands.

Some companies have their own brand of icons, which are consistent with their brand and

A well-prepared study schema will provide the reader with a rapid grasp of the study design while saving valuable space in a slide deck or poster.



Figure 3. A sample collection of medical icons

Source: SVG Repo<sup>6</sup>

patient perceptions. However, writers can also find collections of medical icons on the internet, on sites such as SVG Repo, Dry Icons, and Freepik (Figure 3). Many of these icons are open source files so they can be used in commercial projects without payment of royalties. The icon file will state if the source must be acknowledged.

Icons can be used in study schemas to depict important or repeating elements in the study clearly and consistently. In the study schema in Figure 4, the study has a complex structure consisting of multiple checkpoints, patient interfaces (in-clinic visits and phone calls), and treatments. An oral treatment period is followed

by randomisation to one of the three treatment arms. The patients are monitored with monthly in-clinic visits, and weekly telephone calls are made in the weeks between visits to enquire about adverse events and concomitant medications.

Icons are used to symbolise the main types of

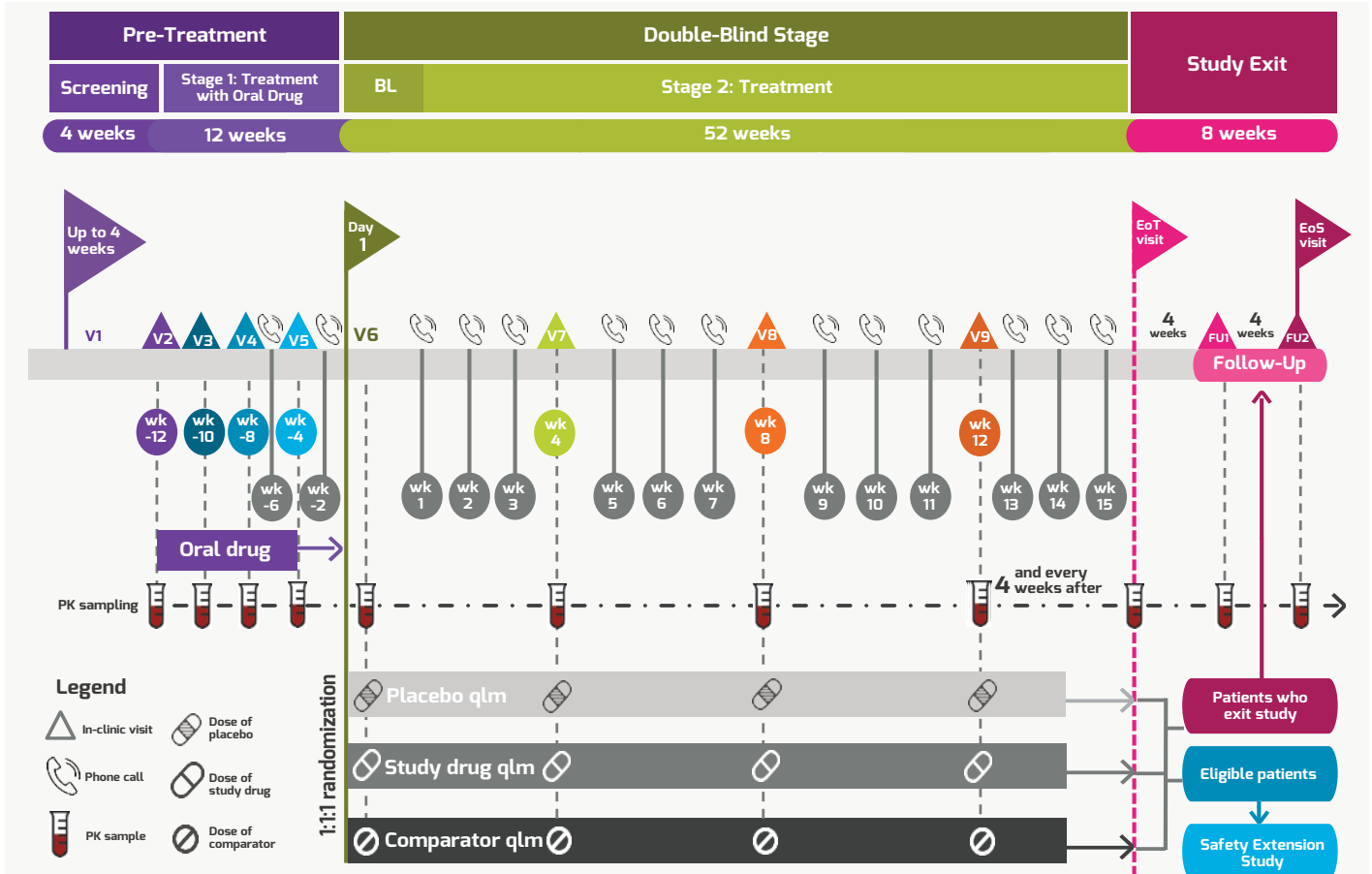


Figure 4. Study schema of a double-blind, placebo-controlled study evaluating the study drug vs placebo and a comparator after initial treatment with oral drug

BL = baseline, FU = follow-up, EoT = end of treatment, EoS = end of study, V = visit, wk = week, PK = pharmacokinetic, q1m = once-monthly



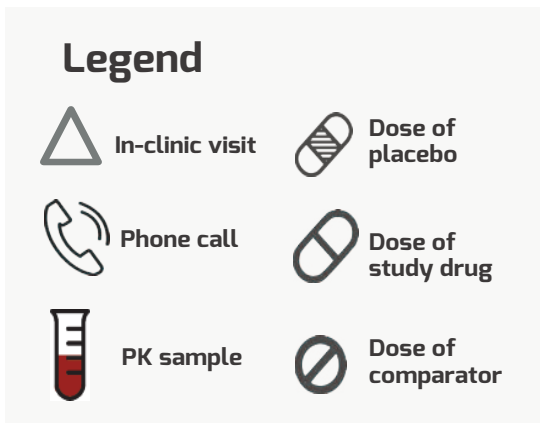


Figure 5. Double-encoding: labelling the icon makes it less ambiguous

assessments or treatments. For example, an icon of a tablet can depict an oral drug, whereas a syringe depicts an injection. Icons can also be

used to represent inpatient and outpatient periods, which are especially critical in Phase 1/2a studies.

When icons are used in an infographic, they should be described or labelled to avoid ambiguity in interpretation. Using text together with a visual icon enables double encoding – where readers can process the concept according to its label and image. Double encoding facilitates memory, so readers are more likely to recall the icon when it is accompanied by text. Icons used repeatedly in an infographic

should be labelled in a legend (Figure 5).

The study schema in Figure 6 depicts a phase 1 study with an oral treatment period, washout,

and randomisation of patients to two treatment arms investigating different study drug formulations. The important elements of the study are depicted with icons:

- Inpatient and outpatient periods
- Pharmacokinetic assessments
- Pharmacodynamic assessments
- Electrocardiograms

A brief look at the infographic in Figure 6 enables readers to quickly see, for example, whether a treatment was administered in a clinical trial unit, or on an outpatient basis, and whether there were specific visits of particular importance (at which several key assessments were performed).

**Using Gestalt to organise infographics**

According to Gestalt theory, “All things exist in

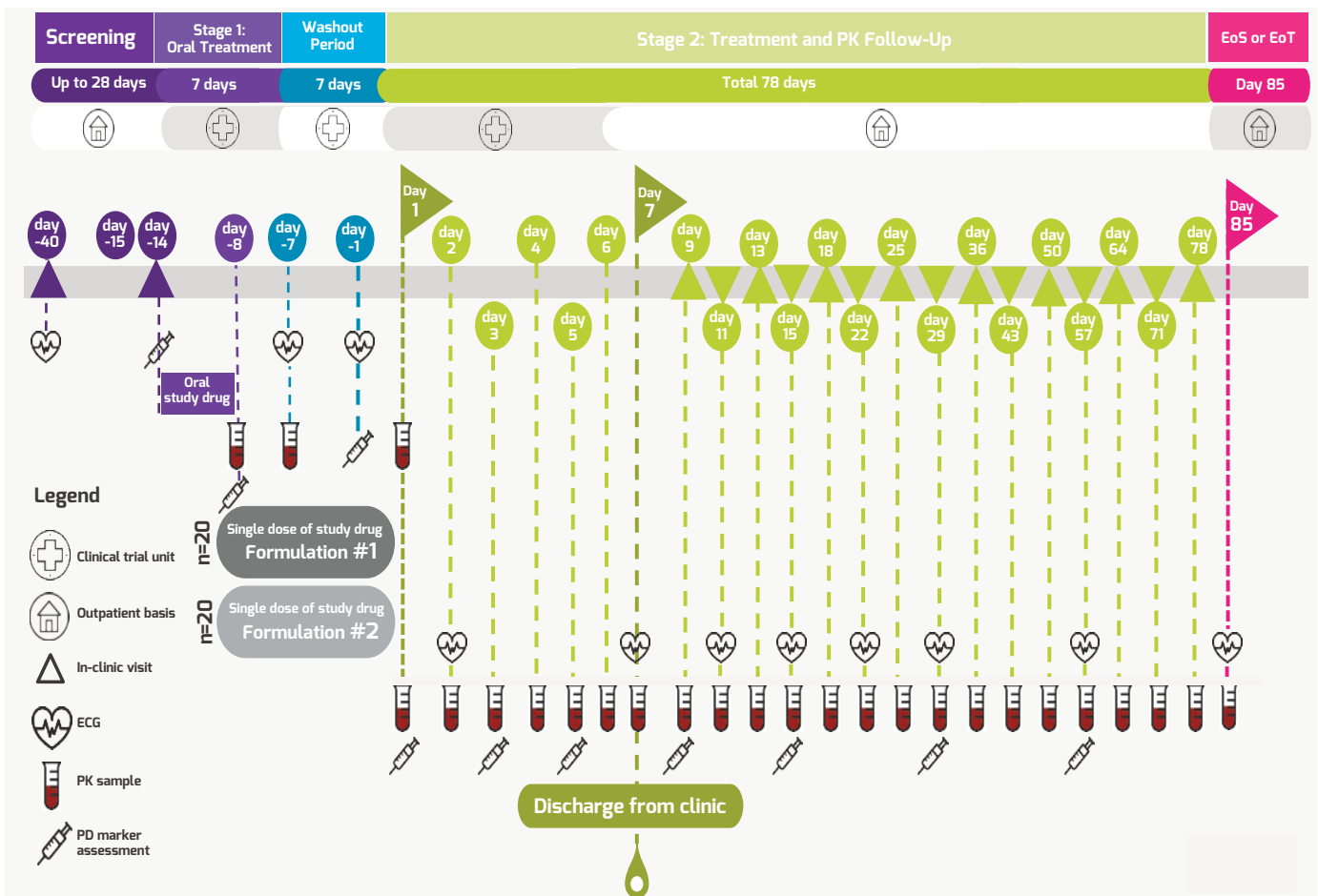


Figure 6. Study schema of a phase 1 study with an oral treatment period, washout, and randomisation of patients to two treatment arms investigating two different study drug formulations

PK = pharmacokinetic, EoT = end of treatment, EoS = end of study, ECG = electrocardiogram, PD = pharmacodynamic

interaction with other things” and “the whole is other than the sum of its parts”.<sup>7,8</sup> The principles of Gestalt explain how the mind perceives forms. When leveraged in infographics, writers can use Gestalt to attain a balanced visual representation of data. The main principles of Gestalt include:<sup>9</sup>

- **Similarity** – When objects look similar, people perceive them as a group or pattern.
- **Continuation** – Points that are connected by straight or curving lines are seen in a way that follows the smoothest path.
- **Closure** – If something is missing in an otherwise complete figure, we tend to add to it to complete it.
- **Proximity** – Objects near each other tend to be viewed as a group.
- **Figure-ground** – One aspect of an event is perceived as the figure or foreground, and the other aspect as the background.

In the study schema examples in Figures 4 and 6, the similarity of form and colour is used to group similar elements:

- **Similarity of form** – Circles are used to represent weeks, while triangles are used to represent in-clinic visits. Oblongs represent treatment arms. The numerous visits and weeks in the study are recognisable by their unique shapes and hence are easily grouped.
- **Similarity of colour** – Visits and weeks are paired using colour so that each visit is linked

to its respective week by the same colour. The flags that indicate milestones in the study schema are colour-coded according to their respective stage. At a glance, readers can tell which study period a milestone flag belongs to based on its colour and position.

**Recognising  
the ways that the mind  
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context.**

### Conclusion

The role of the medical writer is to present complex medical and scientific data in the most clear, concise, and accurate manner possible. In a world where increasing amounts of data and visual messages demand the audience’s attention, this task becomes increasingly challenging. Recognising the ways that the mind processes information enables medical writers to better understand how best to present data to their readers, depending on the document type and its purpose, while providing readers with the necessary context. In the world of clinical regulatory documents, the study schema within the protocol represents a specific example of how to depict various study designs in a creative yet efficient manner.

### Conflicts of interest

The authors declare no conflicts of interest.

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# Enhancing accessibility of study data: The development of a graphical abstract for lay summaries of clinical trial results

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## Abstract

We describe the development of a graphical abstract for lay summaries of clinical trial results. The new graphical summary serves the same purpose for a lay summary as an abstract does for a scientific publication. Lay summaries are intended to inform the general public about the results of clinical studies. Consequently, they need to be understandable to people without specific knowledge of the disease or knowledge of the clinical research process. Visual displays have been shown to greatly support the understanding of complex data. With the support of patient organisations, we first determined the information items that were to be included in the graphical abstract and then transformed them into visual representations on a single page preceding the lay summary. Review and feedback from stakeholders and patient representatives helped derive a final graphical abstract template for all lay summaries across therapeutic areas. The generally positive feedback from patient representatives emphasises the usefulness of the graphical abstract in conveying key information of clinical trials.



## Introduction

Lay summaries are short documents summarising the results of a clinical trial in a way that is understandable to the lay public. They are a new requirement introduced by the European Clinical Trial Regulation 536/2014 (EU-CTR) in 2014. According to the EU-CTR, a lay summary is to be provided for all clinical trials regardless of the clinical phase and therapeutic area, and irrespective of whether the trial was successful. The requirements regarding content of lay summaries are provided in Annex V of the EU-CTR in the form of a list comprising 10 items.<sup>1</sup>

Some aspects of the EU-CTR such as the central approval of clinical trials were intensively discussed with stakeholders before becoming part of the regulation. Conversely, the requirement for lay summaries was only included in the EU-CTR at a later stage and without broad consultation. A central component of the EU-CTR is a web portal that will facilitate the handling of all aspects of clinical trial application, review, and approval. In addition, this web portal will serve as a database for information on clinical trials. The idea is that the scientific summary, the lay summary, the protocol, and the clinical study report of one clinical trial are made available at a





single web location (§67 of the EU-CTR).<sup>1</sup> The central portal establishes a new interaction among sponsors, ethics committees, and regulatory authorities, i.e., for those that had also previously been part of the clinical research process. Lay summaries are the one new aspect of the regulation that is directly linked to patients and the general public.

For an innovative document such as the lay summary, the EU-CTR does not provide sufficient guidance for a successful and compliant implementation.<sup>2,3</sup> Many stakeholders, including sponsors of clinical studies and patient organisations, raised the need for more comprehensive guidance. Therefore soon after the publication of the EU-CTR, the Health Research Authority, a part of the National Health Service in the United Kingdom, was asked to coordinate the development of further guidance on the writing of lay summaries. A large stakeholder group was formed that developed detailed recommendations on the structure and content of lay summaries. The final version of the guidance became available as the “Recommendations of the Expert Group” in February 2018 (referred to as “expert recommendations” in the subsequent text).<sup>4</sup> The document consists of a section with general principles and two annexes with detailed guidance for the different parts of lay summaries. It provides clarifications on many aspects of the writing and design of lay summaries. Very importantly, the recommendations state that the primary audience of lay summaries is the general public. Consequently, lay summaries need to be

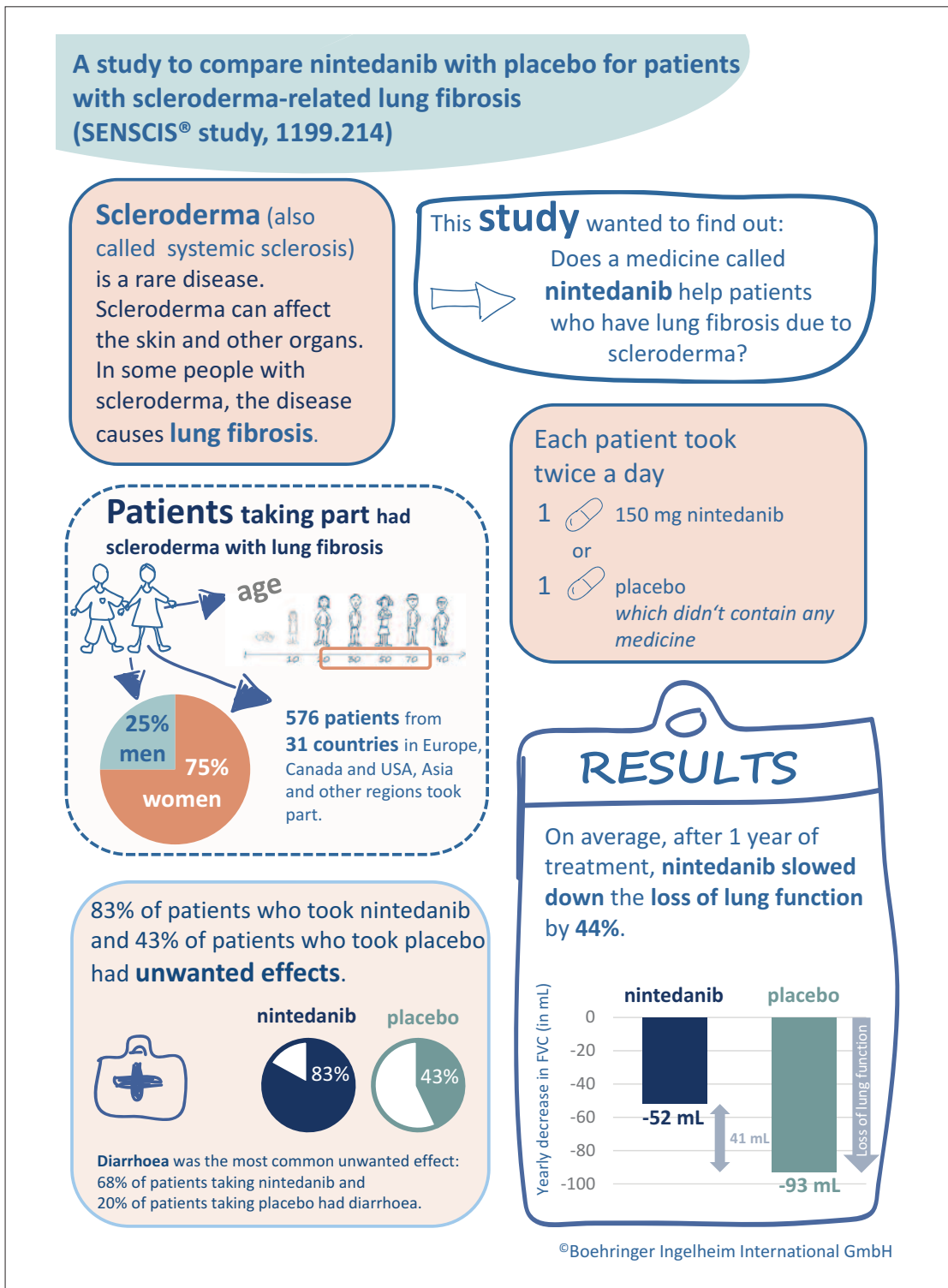
written in a way that they are understandable to people without specific knowledge of the disease, the indication, or knowledge of the clinical research process. International surveys of adult literacy have demonstrated that average literacy levels are generally low. Across Europe, the average literacy level is 2 to 3 based on the International Adult Literacy Survey (on a scale from 1 to 5); level 3 roughly corresponds to a level attained after completing secondary school.<sup>5-7</sup> The stipulation that lay summaries need to be understandable to people with low literacy skills dominates all aspects of the guidance, particularly the sections on writing style, language, and use of numbers.

The expert recommendations also touch on the use of visuals and graphics in lay summaries. The use of “well-chosen and clearly designed visual aids” is encouraged.<sup>4</sup> This is in line with the understanding that the general public is the primary audience for lay summaries. People with low literacy levels find the processing of text challenging and their understanding is greatly helped by graphic displays. Research on medical instructions for patients has underlined the importance and helpfulness of visual aids.<sup>8-11</sup>

Going beyond the provisions of Annex V of the EU-CTR, the expert recommendations propose that a lay summary should have an abstract<sup>4</sup> to help readers decide whether they want to read the entire lay summary. The abstract should describe the purpose of the study, what was tested, the people who participated, the main results, and give information on safety (Annex 1

**Box 1. Content of lay summaries as provided in Annex V of the EU-Clinical Trial Regulation.**<sup>1</sup> (Reprinted under Creative Commons).

1.	Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers);
2.	Name and contact details of the sponsor;
3.	General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it);
4.	Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria);
5.	Investigational medicinal products used;
6.	Description of adverse reactions and their frequency;
7.	Overall results of the clinical trial;
8.	Comments on the outcome of the clinical trial;
9.	Indication if follow-up clinical trials are foreseen;
10.	Indication where additional information could be found.



tion items into graphical representations. Our idea was to create a graphical abstract that serves the same purpose for a lay summary as an abstract does for a scientific publication. This entails a limitation of the content of the graphical abstract to highly aggregated data and statements. To ensure a harmonised format across different trials and therapeutic areas, we developed a template for the graphical abstract. The initial template was used to create the first version of a graphical abstract, which was then reviewed by representatives

**Figure 1. Example of a graphical abstract preceding a lay summary.** (Reprinted with permission.)

NB: The full lay summary is available at the Boehringer Ingelheim trial results website ([https://trials.boehringer-ingelheim.com/trial\\_results/clinical\\_trials\\_overview.html](https://trials.boehringer-ingelheim.com/trial_results/clinical_trials_overview.html))

of the Expert Recommendations).

Using the expert recommendations as a basis, we first identified those items that constitute the key information of a study for a general audience. The next step was the determination of the

appropriate level of data aggregation. We fine-tuned our conclusions in discussions with internal stakeholders, patient representatives, and patient organisations.

Subsequently, we transferred these informa-

of different patient organisations. Their feedback and input helped us to make improvements and shaped the development of the final template so that it aligned with the needs of patients.

### Design principles for the graphical abstract

In line with the expert recommendations and the requirements of the EU-CTR,<sup>4</sup> we based our



development on the notion that a graphical abstract must be strictly non-promotional. That also meant that the overall appearance, the “feel”, and the content of the graphical abstract should be distinctly different from any marketing material used for the medicine under study. We consciously aimed at a sketchy, non-glossy appearance of the graphical abstract; something a clinical investigator might draw to illustrate the results of a study in a conversation with a patient or study participant.

The graphical abstract is intended both to invite readers and to provide them with a high-level summary of the study. Therefore, we limited it to one page and placed it at the beginning of the lay summary, i.e., where an abstract of a publication is also located. After having viewed the graphical abstract, the readers should be able to decide whether they want to continue reading the full lay summary.

The graphical abstract should not only be visually appealing to attract readers but also be able to hold their attention. To achieve this, we decided to present the content information in several distinct panels, leaving as much white space as possible. Each panel presents a single aspect of the lay summary content such as demographics, disease information, study aim, efficacy, and safety. They are independent so that each panel can be understood without reference

to others. The panels are arranged in a logical order but we did not introduce a fixed sequence. The readers should be free to go through the content at their discretion.

We varied the shapes, line styles, and background colours of the different panels to enhance the visual appeal. However, we were mindful that too much playfulness might be associated with a non-serious, non-scientific intention.

Since the information is to be conveyed graphically, the amount of text was reduced to a minimum. Variations in font features (style, size, colour, and highlight forms) make certain words stand out from the rest of the text. These words serve as visual focal points and “headings” for the different panels. They enable readers to skim the graphical abstract and focus on the content area that they are most interested in.

### Content of the graphical abstract

Since the graphical abstract was to be the first page of the lay summary, we decided to start it with the lay title of the clinical study. We routinely develop lay titles for all clinical studies based on the full scientific title and the final study protocol. The lay titles are also used for other study-related documents such as Informed Consent Forms and for the posting on ClinicalTrials.gov.<sup>12</sup> Having the lay title as the

first element on the page allows the reader to judge quickly whether the study is relevant for them. Encompassing the suggestions of the expert recommendations,<sup>4</sup> we include the following elements in a graphical abstract:

- Disease description: a short description of the disease under study. This panel provides the reader with high-level information on the disease and complements the information provided in the lay title.
- Study aim: a short description of the study objective
- Demographics: a depiction of key inclusion criteria, age range, gender distribution, and location of study participants. We use a pie chart for the depiction of the gender distribution and sketches of human age characteristics to depict the age requirements.
- Information on the medicines that are studied: name and dose, mode of administration.
- Information on safety outcomes: adverse reactions as required by Annex V of the EU-CTR. Since the term adverse reaction is not familiar to lay readers, we chose “unwanted effect” instead. The frequencies of the unwanted effects in all treatment groups are visualised by pie charts.
- Information on the outcome of the protocol-specified primary endpoint: the results of all





treatment groups are shown graphically by bar charts.

We write all texts in plain language using short, simple, and neutral sentences. Since abbreviations are usually not known to lay readers, we avoid using them in the graphical abstract.

#### Other considerations

The information in lay summaries and in graphical abstracts needs to be presented objectively. To retain the credibility of lay summaries for the general public, anything promotional must be strictly avoided. This notion is strongly emphasised in the expert recommendations.<sup>4</sup> To ensure objective scientific content, we have developed internal guidance documents for the writing of lay summaries and graphical abstracts. The key elements are:

- The content of the graphical abstract is strictly factual.
- In line with the expert recommendations, we limit the presentation of efficacy results to the protocol-specified primary endpoint.
- We provide numeric data for the primary endpoint and for the key safety observations to enable the readers to link the information provided in the graphical abstract to the scientific summary or the results posted on ClinicalTrials.gov.
- The standards of ethical publishing are

observed in the graphical representations of the results, e.g., the axes of bar charts and pie charts are appropriately labelled and the results of all treatment groups are shown.

- All statements are made in neutral language; emotional words and expressions as well as superlatives are avoided.
- The different content elements such as efficacy results and safety results are presented in a balanced way.

For people with limited numeracy skills, decimal numbers are difficult to understand. Therefore, we only present full numbers in the graphical abstract, i.e., we apply conventional rounding rules wherever possible. Numerical data are supported by graphical presentations.

We consider the graphical abstract and the full lay summary as forming one document. Both are contained in a single file and are posted as one pdf-file (examples are available at [https://trials.boehringer-ingenelheim.com/trial\\_results/clinical\\_trials\\_overview.html](https://trials.boehringer-ingenelheim.com/trial_results/clinical_trials_overview.html)). The highly aggregated data in the graphical abstract are complemented by more detailed data and descriptions in the lay summary. The single file format is also important because our lay summaries comprise a disclaimer called “Important notice” that also applies to the graphical abstract. The disclaimer states that the lay summary presents only the

results of a single study and that it cannot represent the entire knowledge about a drug. Other studies may have different results. In addition, the disclaimer alerts the readers that they should not change their therapy on reading the lay summary and that they should always consult with their physician.

### Challenges

One of the challenges in designing and writing graphical abstracts is the choice of the appropriate level of aggregation. To be useful for the general public, lay summaries are limited in the amount and depth of information that can be provided and this applies even more to the graphical abstract. We try to meet the challenge of describing objective scientific information for lay audiences within a limited space by following clear rules (see above) and by involving patient representatives in the review of lay summaries. The use of the template in conjunction with following clear instructions ensures high-quality graphical abstracts. For complex trials and trials with unclear results, the graphical abstract may need to deviate from the template.

Scientifically and ethically, it is most appropriate to present the results of the primary endpoint as the key efficacy outcome. The primary endpoint is the assessment for which the study was designed and for which it was powered to show differences in a confirmatory way. Therefore, the expert recommendations require that the primary endpoint data are always shown.<sup>4</sup> Secondary endpoints are evaluated in an exploratory way and studies commonly evaluate large numbers of secondary endpoints. Given the space limitations of a graphical abstract, the inclusion of secondary or even tertiary endpoints amounts to a selection and may lead to presenting only those results that are favourable for the drug. This is ethically and scientifically questionable, as studies are usually not powered to show differences in secondary endpoints. In addition, the issue of multiple testing and adjustment of the significance levels needs to be considered before reporting them. However, sometimes, secondary endpoints capture patient-relevant observations. A solution to this would be the inclusion of secondary endpoint data in a lay summary but under a separate heading and with a statement that no firm conclusions can be drawn.

## Conclusions

We have developed a new graphic format to present the key information of a study to patients. The graphical abstract summarises the data in a lay summary similar to what an abstract does for a scientific publication in a visually appealing way. We have tested the graphical abstract with patient representatives from various disease areas. The feedback to the overall idea of an abstract preceding the lay summary has been positive and patient reviewers have found the graphical display helpful and attractive. We therefore believe that this new format can increase the attractiveness of lay summaries and thus help to more adequately inform the general public about the results of clinical studies.

## Disclaimers

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

## Conflicts of interest

The authors declare no conflicts of interest.

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# Connecting medical writers in Portugal through visual communication

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Portugal, the westernmost country in mainland Europe, still experiences a lack of awareness of the medical writing profession.<sup>1</sup> Most medical writers work for contract research organisations (CROs) or in the few pharmaceutical companies that exist in the country. The lack of medical/health communication agencies is another

limitation for medical writers, which is compounded by the fact that these agencies mostly outsource work to freelancers. On top of these constraints, the absence of communication between experts creates additional barriers for emerging opportunities. Thus, there is an urgent need for national communication between medical writing professionals in Portugal. A collaborative group of Portuguese medical writers could tackle these difficulties together through education and networking, thereby developing better specialists and advancing the medical writing profession in Portugal.

We want to share our experience in establishing a Portuguese medical writer group and how visual communications helped us during this process.

*Maria João: I started my career as a medical writer just after I gave up being an exclusive distributor for certain pharmacy products, where I would spend my days sending overdue invoices to my clients. I felt that what I needed was to work for myself, doing something science-related. I started with translations and then moved on to building content and campaigns for a comms agency. At this point, someone told me about EMWA. I quickly became a*

*member, registered in the freelance listing, and started attending conferences and workshops for credits.*

*Alexandra: As I was trying to learn more about the scope of being a medical writer, I realised that in my country, Portugal, there were no organised groups of medical writing professionals. I then met Maria João, who introduced me to EMWA.*

*Maria João: In the meantime, after volunteering with EMWA for a while, I joined the Executive Committee as Public Relations Officer. And then, one day, I met Alexandra.*

*Alexandra: I became an EMWA member in December 2018. Being new in the field, I was anxious to learn from medical writers already settled in the professional arena. But, apart from the EMWA conferences, how could I connect with these professionals and learn from them? I believe networks are a valuable tool for learning and keeping people with the same interests connected. So then Maria João and I decided to create a group of Portuguese medical writers and used visual communications along with social media networks to attract and gather people interested in this career.*



Figure 1. Examples of images produced using Canva and posted on Facebook, Instagram, and LinkedIn to promote the Medical Writers of Portugal (MWP) group





# Clinical trial design: Considerations for medical writers developing clinical trial protocols

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## Abstract

Clinical trial protocols must provide a clear trial design to meet the study objectives. Medical writers must understand and be ready to review and discuss aspects of the trial design with the protocol development team, in order to write a clear and accurate protocol. This article reviews some of the main trial design concepts medical writers should expect to find when writing protocols.

## Introduction

Clinical trial protocols for trials evaluating pharmacological products are complex documents that describe the medical, ethical, and regulatory foundations of the trial. Medical writers work together with protocol development teams of subject matter experts (including medical experts, statisticians, regulatory experts, operational experts, and pharmacokineticists) to write clear protocols that will address the proposed medical questions and protect participant safety and rights. To accomplish this, writers must understand and be able to communicate clinical trial design concepts that are often complex. Moreover, although International Council for Harmonisation (ICH) Good Clinical Practice (GCP)<sup>1</sup> provides recommendations on what a trial protocol should include, and efforts

have been made to harmonise the structure of trial protocols (e.g., TransCelerate Common Protocol Template<sup>2</sup> and SPIRIT Statement<sup>3</sup>), a standard similar to ICH E3<sup>4</sup> for trial reports, defining what information to present and how is

not available. This creates an additional challenge for writers.

This article reviews the main concepts affecting trial designs presented in protocols and how to address them from a medical writing

**Table 1. Protocol writing tips and considerations for key sections**

### Introduction

- The introduction section should include a literature review covering the indication, available therapeutic options, and test treatment(s)
- Present the scientific rationale of the trial, identifying its primary purpose, what it aims to achieve, and its importance

### Objectives

- Confirm consistency between the rationale and objectives
- Write SMART objectives (see Table 2 opposite)

### Population

- Define the target population and present a list of inclusion/exclusion criteria
- Confirm that the inclusion/exclusion criteria are consistent with the objectives

### Endpoints

- Write short descriptions of the endpoints, which should be measurable
- Confirm consistency between the objectives and endpoints
- Confirm that all variables are captured in the schedule of assessments
- Confirm consistency between the defined estimands, objectives, endpoints, and analyses

### Trial design

- Confirm that the trial design is clear and consistent with the objectives, endpoints, and schedule of assessments
- Confirm that bias minimisation methods are presented. If randomisation and/or blinding are not used in a comparative trial, this should be justified

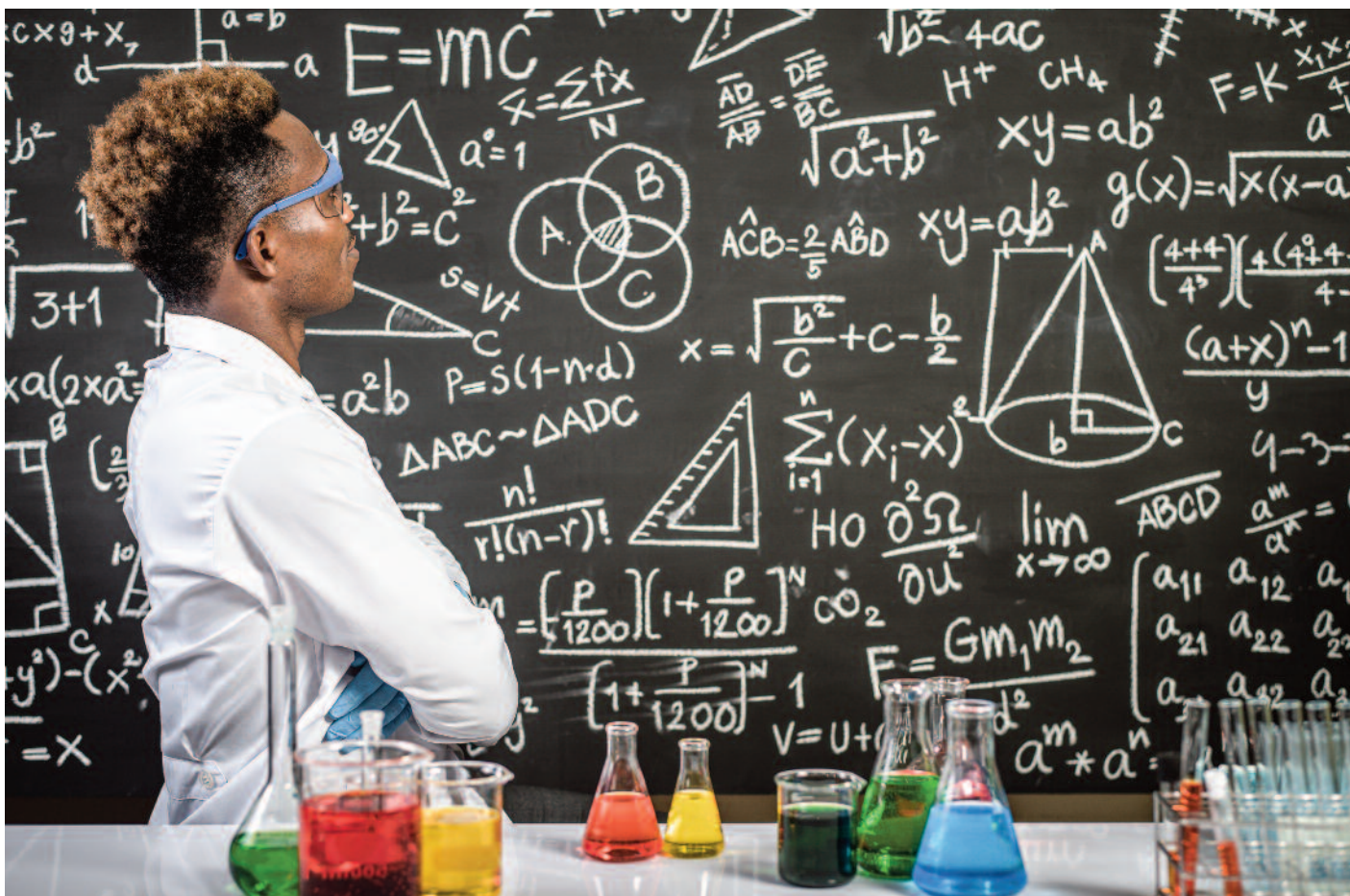
### Control groups

- Confirm that the control group is clearly identified and justified
- Confirm that the control group is aligned with the design and objectives
- Confirm that all test treatments (including placebo) are clearly identified and characterised

### Statistical considerations

- Confirm consistency between statistical considerations and trial endpoints
- Confirm that all variables analysed are collected at the appropriate times in the schedule of assessments
- Avoid too much detail when presenting the statistical analysis methods, referring to the statistical analysis plan when appropriate





perspective while ensuring compliance with ICH GCP. Operational, regulatory, and ethical concepts are not discussed.

Table 1 summarises some writing tips for each key section of the protocol.

## Rationale

Clinical trials assess the efficacy, safety, and/or pharmacological characteristics of medicinal products in human participants. The protocol must present a rationale that identifies the primary purpose of the trial, usually in the “Introduction” section (Table 1). At trial conception, the protocol development team should consider:

- If the rationale is clear
- If the trial is clinically relevant and feasible
- If an unnecessary risk/burden will be posed to trial participants

## Objectives

Trial objectives are the actions proposed to fulfil the trial’s rationale. The objectives should be conceived by the protocol development team and written by the medical writer according to the SMART principles (Table 2).<sup>5,6</sup>

Objectives in clinical trials can be divided into three categories:<sup>7</sup>

- **Primary** (typically one): aims to directly answer the primary purpose of the clinical trial
- **Secondary**: other actions relevant to and/or indirectly associated with the rationale
- **Exploratory**: hypothesis-generating objectives that can be confirmed in dedicated studies

## Population

Protocols should briefly define the **target population** (i.e., the set of people throughout the world for which the trial results may be generalised).<sup>8</sup> A detailed **list of inclusion and exclusion criteria** should follow, specifying:<sup>8,9</sup>

- Demographic characteristics (e.g., age, sex, body mass index)
- The medical indication under study,

**Table 2. Example of a SMART written objective**

To assess the efficacy of paracetamol 1000 mg per os versus placebo in adult patients with fever of unknown origin (body temperature >37.5°C) 2 hours after administration.

**Specific:** identifies the action (to assess efficacy), medication(s) (paracetamol and placebo), population (adults), and indication (fever of unknown origin)

**Measurable:** temperature is a measurable variable

**Achievable:** feasible and not burdensome to the participant (to be confirmed by the trial medical expert)

**Relevant:** objectives should be clinically relevant (to be confirmed by the trial medical expert)

**Time based:** in this example, a 2 hour timeframe is specified



acceptable/prohibited comorbidities, and acceptable/prohibited concomitant medications

- Ethical requirements for participation (e.g., informed consent)
- Exclusion criteria that may bias result interpretation or pose an unnecessary risk to the participant

## Endpoints

In clinical trials, variables are the parameters (sociodemographic, clinical efficacy and safety, laboratory/imaging-related, etc.) that will be measured. Variables can be independent (variables that potentially influence health outcomes, e.g., treatment, age, sex, smoking history) or dependent (health outcomes, e.g., vital signs, laboratory parameters).<sup>8</sup>

An **endpoint** is defined by Spilker as “an indicator measured in a patient or biological sample to assess safety, efficacy or another trial objective.”<sup>10</sup> Each objective must be matched with at least one endpoint, to ensure that the right variables will be captured and that all questions posed by the trial will be addressed. As an example, let’s consider the following objective:

- To assess the efficacy of paracetamol 1,000 mg per os versus placebo in adult patients with fever of unknown origin (body temperature >37.5°C) 2 hours after administration of the test treatment

Two possibilities for the corresponding endpoint can be proposed (the best possibility should be selected with the protocol development team based on clinical relevance and feasibility):

- Proportion of patients with a body temperature higher than 37.5°C 2 hours after test treatment administration

- Mean body temperature 2 hours after test treatment administration

The protocol development team is responsible for defining the endpoints, while the medical writer should ensure that they are clearly written (Table 1).

Endpoints are classified in accordance with the corresponding objectives (primary, secondary, exploratory). The primary endpoint should provide the most clinically relevant and convincing evidence directly related to the primary objective of the trial and its selection should reflect the accepted norms and standards in the relevant field of research.<sup>11</sup>

Endpoints should be measurable and should be concisely described in the protocol, while details of how the endpoints will be captured can be provided in one or more dedicated protocol sections. All endpoints and variables must also be captured in a schedule of assessments that identifies which variables will be measured at each trial visit and that provides summarised procedural information for quick reference to the trial site teams.

**Estimands** were recently introduced in ICH E9 (R1) and describe the treatment effect with consideration of specified post-randomisation events and whether the outcome would be under different conditions.<sup>12</sup> Four interrelated attributes are considered for this purpose:<sup>12,13</sup>

- Population: participants targeted by the trial
- Variable/endpoint
- Post-randomisation events: events that happen to participants that may affect results (e.g., death, treatment discontinuation, use of rescue medications)

The protocol defines the procedures by which a clinical trial is conducted, and its writing requires careful assessment of all concepts surrounding trial design for accuracy and consistency.



- Population-level summary statistics for the endpoint: the basis for treatment comparisons

A summary of the use of estimands in clinical trials can be found in a publication by Bridge and Schindler.<sup>13</sup>

## Trial design

The trial design will dictate participant treatment and follow-up, the number of treatment groups, and data collection, among other aspects.

### Single group design

In single group trials, variables are compared in the same participant before and a certain time after exposure to the test treatment (intra-participant analysis).<sup>8</sup> These are typically early phase trials or are conducted where limited participant pools are available. Results are usually preliminary since it is not possible to blind the treatment.<sup>14</sup>

### Comparative design

In comparative trials, two or more test treatments

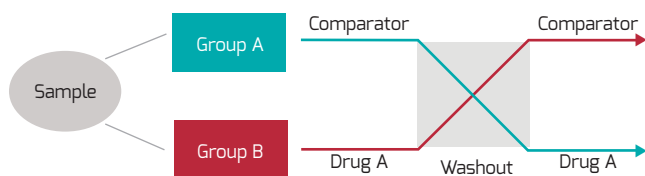


Figure 1. Crossover design

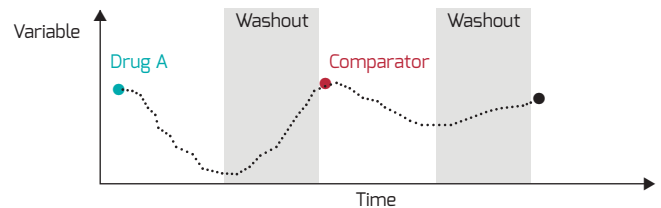


Figure 2. Ideal crossover trial variable



are compared. In a **parallel design**, participants will keep the same treatment until trial completion or discontinuation. At defined time points, variables are compared between groups (interparticipant analysis).<sup>15</sup>

In a **crossover design**, participants receive all treatments in a randomised sequence. Administration of different treatments is separated by a washout period, where no active treatment is given. This is done to prevent the effect of the previous treatment from biasing the new treatment, i.e., carryover effects (Figure 1).<sup>8,15</sup> Because the same participant receives different test treatments, intraparticipant analyses are possible.

Crossover trials are useful when assessing stable variables and conditions that produce a response during treatment and return to near-baseline levels during washout (Figure 2).<sup>8,14</sup>

**Factorial designs** compare different treatments given as monotherapy or in combination, creating groups for each possibility (Table 3). These trials assess various possible interactions

Table 3. Factorial design (2<sup>2</sup>)

Product A	Product B	
	Yes (+)	No (-)
Yes (+)	Group 1 ++	Group 3 +-
No (-)	Group 2 -+	Group 4 --

and complementary effects. However, they can be complex if a high number of groups is required.<sup>14</sup>

**Minimising bias in comparative trials**

Comparative trials typically include measures to minimise bias and ensure groups are comparable.

**Randomisation**, in which trial participants are randomly assigned to the different study treatments, is the standard method to obtain treatment groups with similar baseline characteristics (e.g., age, sex). Randomisation increases the likelihood that baseline characteristics that could confound treatment effects will be distributed equally among treatment groups.<sup>8</sup> Randomisation lists with the participant codes and respective treatment allocations are informatically generated by different methods:

- Simple randomisation: based on a single sequence of random assignments (like tossing a coin), it is useful for large samples, but can create unequal treatment groups in smaller samples.<sup>15-17</sup>
- Block randomisation: blocks of equal size are defined with all possible treatment orders and are picked randomly to generate the randomisation list (Figure 3).<sup>8,16,17</sup>
- Stratified randomisation: the sample is stratified by key baseline characteristics (e.g., sex, age). Participants are randomised so that these characteristics are distributed equally between treatment groups.<sup>8,16,17</sup>

Another allocation method is adaptive randomisation, where the first participant is randomised, while subsequent participants are allocated non-randomly to minimise group imbalances

regarding key baseline variables.<sup>16,17</sup>

After ensuring that all treatment groups are comparable, it is important to confirm that participant follow-up and outcome assessments are not biased.<sup>8</sup> The key trial procedure here is **blinding** (or masking): the process of ensuring that the Investigator and/or participant is unaware of the treatment assigned. The main types of blinding include:<sup>15</sup>

- Double blinding: both the Investigator and the participant are unaware of the treatment given. This is the preferred type of blinding as it avoids biased assessment of outcomes by both the Investigator and the participant
- Single blinding: only the Investigator or the participant is aware of the treatment given
- Open label: both the Investigator and the participant are aware of the treatment given

Double blinding requires test treatments to be indistinguishable (shape, colour, smell, taste), which is sometimes not possible (e.g., comparing two active treatments with different formulations). One way to overcome this is to perform a **double dummy trial**, where each treatment has a matched placebo (dummy), so each participant receives one active treatment and the placebo version of the comparator.<sup>15</sup>

**Control groups**

The choice of the control group in comparative trials should consider the rationale and objectives, along with regulatory, operational, and ethical aspects.

**Placebo**

Placebos are formulations without any active pharmaceutical ingredient used in double blind trials.<sup>15</sup> These must be indistinguishable from the test treatment in terms of packaging, labelling, size, shape, opacity, coatings, viscosity, colour, smell, flavour, and route of administration.<sup>18</sup> Placebos are useful to minimise bias and distinguish the real effects of the test treatment and “noise” effects, such as:<sup>15</sup>

- Normal physiology and spontaneous disease fluctuations
- External factors that can alter the participant response (e.g., increases in liver transaminase levels after a long period of hospitalisation in a clinical trial unit due to a strict diet, lack of exercise, or other lifestyle changes)

On the other hand, placebo groups may not be appropriate in some settings, such as serious

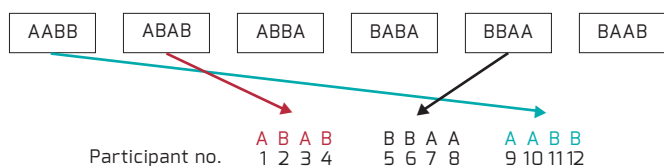
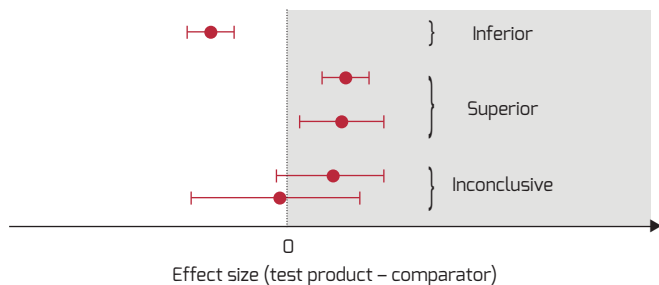
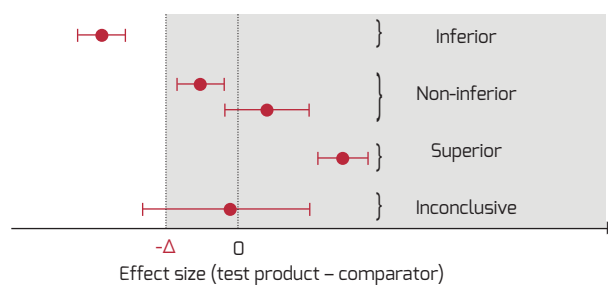


Figure 3. Block randomisation for treatments A and B

Twelve participants are randomly allocated to treatment A or treatment B using three randomly selected blocks of 4, each containing a unique sequence of treatment options.



**Figure 4. Possible outcomes of a superiority trial**  
Data are shown as the point estimate and 95% confidence interval.



**Figure 5. Possible outcomes of a non-inferiority trial**  
Data are shown as the point estimate and 95% confidence interval.

diseases with available therapeutic alternatives (e.g., oncology, infectious diseases).<sup>15</sup>

**Active comparator**

When comparing a test treatment against an active comparator, different trials can be considered.

**Superiority trials** aim to demonstrate the superiority of the test treatment against the active comparator regarding the primary endpoint. If the difference between the test treatment and comparator and 95% confidence interval (CI) are higher than 0 for the primary endpoint, the test treatment is considered superior (Figure 4).<sup>19</sup>

Sometimes, a different test treatment may not be superior in terms of efficacy but may offer other advantages (e.g., a better toxicity profile, more convenient administration).<sup>15</sup> Here, **non-inferiority trials** can be considered. These trials evaluate whether the test treatment is as good as or worse to an acceptable degree compared to the reference. Here, a non-inferiority margin ( $-\Delta$  in Figure 5) is defined.<sup>8,20,21</sup> If the difference between the test treatment and comparator and 95% CI for the primary endpoint is higher than  $-\Delta$ , the test treatment is considered non-inferior

(Figure 5).<sup>19</sup> If the 95% CI lies entirely above 0, there is evidence of superiority at the two-sided 5% significance level ( $p < 0.05$ ).

A justification for the non-inferiority margin, typically provided by the trial statistician, should be included in the protocol.

**Bioequivalence trials** compare two products with the same active pharmaceutical ingredient (i.e., different formulations of the same product or generic versus comparator).<sup>22</sup> Two products are considered bioequivalent if they produce the same plasma concentration-time profiles, i.e., if the 90% CIs for the geometric mean ratios for the area under the curve from time 0 to last measurable concentration ( $AUC_{0-t}$ ) and maximum plasma concentration ( $C_{max}$ ) for the test and reference products lie entirely within the interval 80% to 125%.<sup>22,23</sup> Examples are shown in Figure 6.

**Other control groups**

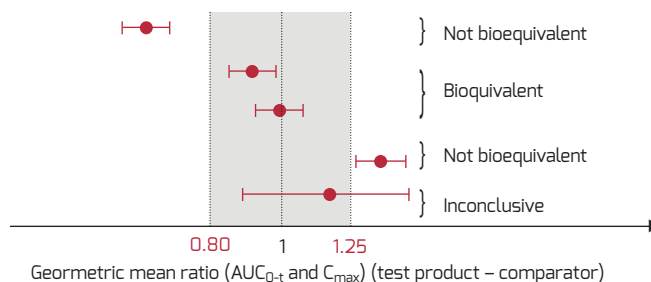
Other potential control groups include:

- **No treatment:** this method is not blinding and can be unethical unless it is confirmed that participants will not be subjected to an unacceptable risk<sup>24</sup>

- **Standard of care** (treatment as usual, routine care): this can be employed to compare the test treatment with existing practice. However, “standard of care” can vary between study sites and countries, hampering an objective definition<sup>25</sup>
- **Active placebo:** a placebo that mimics the adverse effects of the test treatment. This can be useful when the risk of unblinding due to characteristic adverse events is high<sup>26</sup>

**Statistical considerations**

Statistician support is needed when developing the statistical sections of the protocol. When applicable, other experts should also be consulted (e.g., a pharmacokinetics/pharmacodynamics expert, quality of life expert). The protocol should present a **rationale for the calculated sample size** with the necessary statistical and clinical assumptions (based on the primary endpoint). In addition, the **statistical analysis methods** should be summarised for all endpoints, with full details being provided in a separate statistical analysis plan.



**Figure 6. Possible outcomes of a bioequivalence trial**  
Data are shown as the geometric mean ratio and 90% confidence interval for the area under the curve from time 0 to last measurable concentration ( $AUC_{0-t}$ ) and maximum plasma concentration ( $C_{max}$ ).



## Final remarks

The protocol defines the procedures by which a clinical trial is conducted, and its writing requires an assessment of all concepts surrounding trial design. Medical writers must understand these concepts and work with the protocol development team to communicate them clearly. This will protect the scientific integrity of the trial and the safety of the participants.

## Acknowledgements

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## Disclaimers

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

## Conflicts of interest

The author declares no conflicts of interest.

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# Planting a “non-biological” seed – will this meme persist?

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## Abstract

Some word uses persist and some do not. Part of what makes use of a word stick is how catchy it is. This word is already used on our supermarket shelves. This proposed new use illuminates a small way in which language evolves. And it helps to compartmentalise differences between chemical and biological manufacture of pharmaceuticals. The question is, will this word use persist enough to enter common vocabulary? The word is *non-biological*.

*Survival of the fittest* was coined in 1864 by Herbert Spencer in *Principles of Biology*. He did this after he read *On the Origin of the Species* by Charles Darwin.<sup>1,2</sup> *Survival of the fittest* describes biological evolution through natural selection. *Meme* was coined by Richard Dawkins in 1976 in his book *The Selfish Gene*.<sup>3</sup> A meme transmits by natural selection analogous to that of biological evolution. Yet, a meme is an element of a culture or system of behaviour passed from one individual to another by imitation or other non-genetic means. It is a play on the word *gene*. New words and meanings enter the language as memes. They persist if they are catchy enough to enter common vocabulary.<sup>4</sup> In 1993, Mike Godwin proposed *internet meme*.<sup>5</sup> Richard Dawkins characterised *internet meme* as something deliberately altered by human creativity that goes viral on the internet.<sup>5</sup>

I have met scientists who coined phrases that stayed in their laboratories. For example, my PhD supervisor, Chris French, coined the phrase *bactin*.<sup>6</sup> It means any bacterial actin-like protein. To us *bactin* is an efficient word that conveys a great volume of meaning. Today, Bactin® is a



registered trademark of an antibiotic.<sup>7</sup> This is similar to convergent evolution. Convergent evolution is the independent evolution of similar characteristics in a separate line. Like flight evolving independently in birds, bats, flying fish, and flying frogs. The word *bactin* originated in two places independently.

The motivation for coining *bactin* was to avoid saying the “bacterial actin-like protein” mouthful. At the time coining *bactin* was fun and witty. It was also a relief to have a shorter more practical word to describe the topic of my research. *Bactin* was catchy to us and I suppose the antibiotic marketers thought it was catchy too. They registered Bactin® as a trademark.

More practical word usage appears in the

pharmaceutical industry. A common trait among these words and phrases is that they are less of a mouthful to say – *pharma* being one. Some of these words and phrases convey a great volume of meaning. They include *big data* to describe the extremely large data sets generated during drug development; *KOL* short for key opinion leader; *vax* for vaccine or vaccination; and *mAb* for monoclonal antibody. Enter *pharma buzzword bingo* into your favourite search engine and see what you come up with.

## A case for using the term *non-biological drug*

This article presents a case for wider pharmaceutical industry use of *non-biological*. *Non-*





*biological* is self-explanatory. Something that is non-biological does not involve a biological system.

In the pharmaceutical industry, a biological is any drug manufactured from a biological source, e.g., vaccines, blood products, cells, allergens, genes, tissues and recombinant proteins (Table 1). Generally, *biological*, *biologic*, and *biopharmaceutical* are collective interchangeable terms meaning the same thing.<sup>8</sup> A biopharmaceutical is not any drug (chemical or biological) with an intended use in humans or animals.

The larger proportion of drugs manufactured

use chemical means (Table 1). At times chemically manufactured drugs are referred to as *small molecule* drugs. This term is arbitrary.

It refers to molecules below a range of 500 to 1000 Daltons depending on the reference.<sup>9,10</sup> Plus, some biological drugs are below this cutoff.

For example, cerliponase alfa is a biological drug that is 59 Daltons.<sup>11</sup>

Chemically manufactured drugs are also referred to as *more traditionally manufactured chemical* drugs. *Non-biological* is more practical to say.

Using *non-biological* is not being irreverent towards the scientific discipline of chemistry. Chemistry is in a less stable and more

I imagine some are saying “poppycock!”

unpredictable higher order within biology. Various scientific disciplines mould molecular biology into a fascinating study to improve lives.

It is important to acquaint industry with the use of *non-biological*. The US FDA has a Non-Biological Complex Drugs (NBCDs) Working Group.<sup>12,13</sup> Non-biological complex drugs are nanotechnologies unable to receive comprehensive characterisation through physicochemical analysis (Table 1). Most traditionally manufactured chemical drugs (*non-biological drugs*) can receive comprehensive characterisation through physicochemical analysis. Yet, *non-biological* is not widely used to refer to the more traditional manufacture of chemical drugs.



### Biological and non-biological drugs differ at molecular level

Biological drugs contain chemicals from the table of elements. Everything around us contains chemical elements. In routine life, we see chemistry in the animate that reproduce and in inanimate objects. (Figure 1).

Biological drugs consist of many more atoms compared to non-biological pharmaceuticals (Figure 2). They contain thousands of carbon atoms and have a higher molecular weight compared to a few carbon atoms and a lower molecular weight in non-biologicals. Biological molecules are generally larger than non-biological molecules and this alone makes them less rigid. Lower molecular rigidity has stability profile consequences to consider.<sup>14</sup>

Often, non-biological drug names contain a reference to chemical elements and functional groups. For example, acetylsalicylic acid (aspirin).

### Where do biological drugs come from?

Recombinant biologicals are the highest proportion of biological drugs approved worldwide.<sup>8</sup> This classification includes monoclonal antibodies, hormones, clotting factors, enzymes, vaccines, nucleic acid-based products, and engineered cell-based products.<sup>8</sup> Indications are for cancer, inflammation-related diseases, haemophilia, diabetes, asthma, migraine, HIV, and inhalational anthrax.<sup>8</sup> Of 71 genuinely new biological active ingredients that came to market between January 2014 and July 2018, 62 were recombinant proteins.

The trend is to identify the genetic code of a natural source biological drug, whatever it is, and to create a recombinant form in the laboratory.<sup>15</sup> This is a more sustainable approach to using the natural source. The natural source is not depleted and controls are engineered in the clone. Product purification is easier using a model organism and higher product yields are gained.

### Recombinant protein example

#### A wild-type molecule is deemed beneficial as a therapeutic protein

Therapeutic proteins represent biological drugs. The therapeutic protein is concentrated and purified from a biological source. The biological source occurs in nature. One example includes human chorionic gonadotrophin (hCG) which represents a natural source.

hCG was first purified from human urine. Pregnant women produce hCG as their placenta grows. They excrete hCG in their urine. It causes the positive pregnancy line to appear on a home pregnancy test. Concentrated hCG is used to treat women who have less success in getting pregnant.

Or, the gene coding the protein might be recombined by a manufacturer. Genetic recombination bypasses the natural source to produce concentrated and purified protein.

Table 1. Lists representing biological and non-biological medicines<sup>13</sup>

Non-biological <sup>a</sup>	Non-biological complex drugs (NBCD)	Biological
Functional group names <ul style="list-style-type: none"> <li>● Acetyl</li> <li>● Alcohol</li> <li>● Aldehyde</li> <li>● Alkane</li> <li>● Alkene</li> <li>● Alkyl halide</li> <li>● Alkyne</li> <li>● Amide</li> <li>● Amine</li> <li>● Benzene ring (phenyl)</li> <li>● Carboxylic acid</li> <li>● Ester</li> <li>● Ether</li> <li>● Ketone</li> <li>● Thiol</li> </ul>	<ul style="list-style-type: none"> <li>● Swelling cross-linked polymers</li> <li>● Liposomes, dendrimers and polymeric micelles</li> <li>● Iron carbohydrate complexes</li> <li>● Glatiramoids</li> <li>● Ocular emulsions</li> </ul> Worldwide classification varies <sup>b</sup> <ul style="list-style-type: none"> <li>● Albumin-bound nano-particles</li> <li>● Low molecular weight heparins</li> </ul>	Recombinant <ul style="list-style-type: none"> <li>● Bone morphogenetic proteins</li> <li>● Enzymes</li> <li>● Growth factors</li> <li>● Hormones</li> <li>● Interferons, interleukins, and tumour necrosis factor</li> <li>● Monoclonal antibodies</li> <li>● Recombinant vaccines</li> <li>● Toxin and anti-toxin</li> </ul> Blood, blood component or derivative Allergens for immunotherapy Vaccines Advanced therapeutic medicinal products <ul style="list-style-type: none"> <li>● Gene therapies</li> <li>● Somatic cells</li> <li>● Tissues engineered therapy</li> </ul>

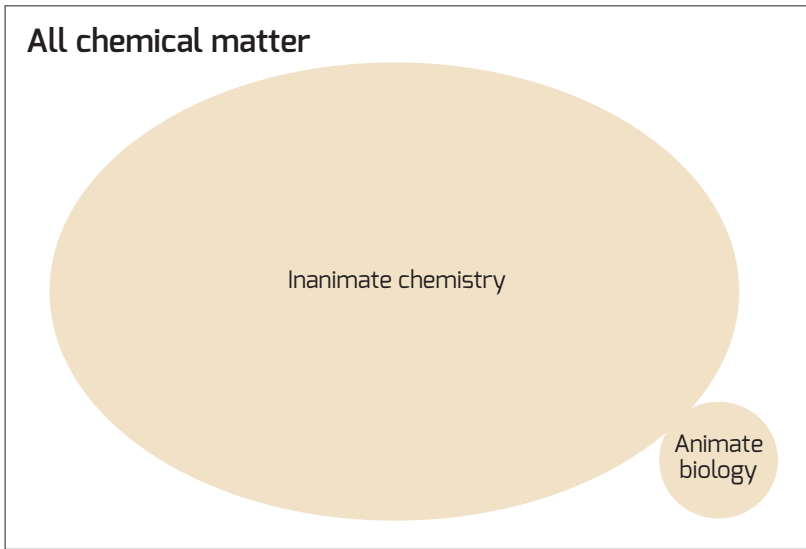
Non-biological chemically manufactured drugs are represented by examples of functional groups often specified in drug names. The allowable word count of this article does not do justice to the number of classifications.

<sup>a</sup> In this instance ‘non-biological’ is an informal term.

Non-biological complex drugs (NBCD) are nanotechnologies unable to receive comprehensive characterisation through physicochemical analysis.

<sup>b</sup> Worldwide classification varies where some NBCDs are considered biological.<sup>13,18</sup>

Biological medicines listed based on USA and EU definitions.<sup>13</sup>



**Figure 1. A Venn diagram representing how biology is animated and chemistry is not**

The chemical composition of all things in the universe is represented. Out of all chemical things a small proportion is considered under the scientific discipline of biology. Biology is self-animated and chemistry is not. The inanimate and the animate complement each other (A<sup>c</sup>).



**Recombinant forms are manufactured using biological source genetic code.**

Understanding the genetic code for hCG has allowed the development of recombinant hCG. This means hCG does not always come from the urine of pregnant women these days. Molecular biology techniques allow high concentrated volumes of hCG manufacture without urine. Today women receive the recombinant form.

Other biological drugs may utilise transplant or transfusion technology like stem cells, tissue, and blood products. Examples of biological allergens are pollens that cause hay fever and

bee stings that cause anaphylaxis. Allergens might be used by your doctor to identify sensitivities that you might suffer from.

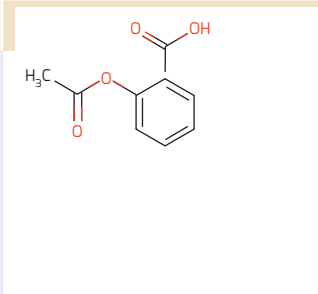

**Their differences determine their regulatory pathways**

The term *reference originator biological* is used for the first drug of its kind licensed by a regulatory agency – a *biosimilar* follows on.<sup>16</sup>

*Reference originator biological* and *biosimilar* compare to *originator* and *generic* of *non-biological drugs*. The terms are comparable and not interchangeable, i.e., biosimilars are not generics.

Biosimilar drugs are often in different suspensions compared to the reference originator biological. Generics could have variation in functional group placement compared to the originator product.

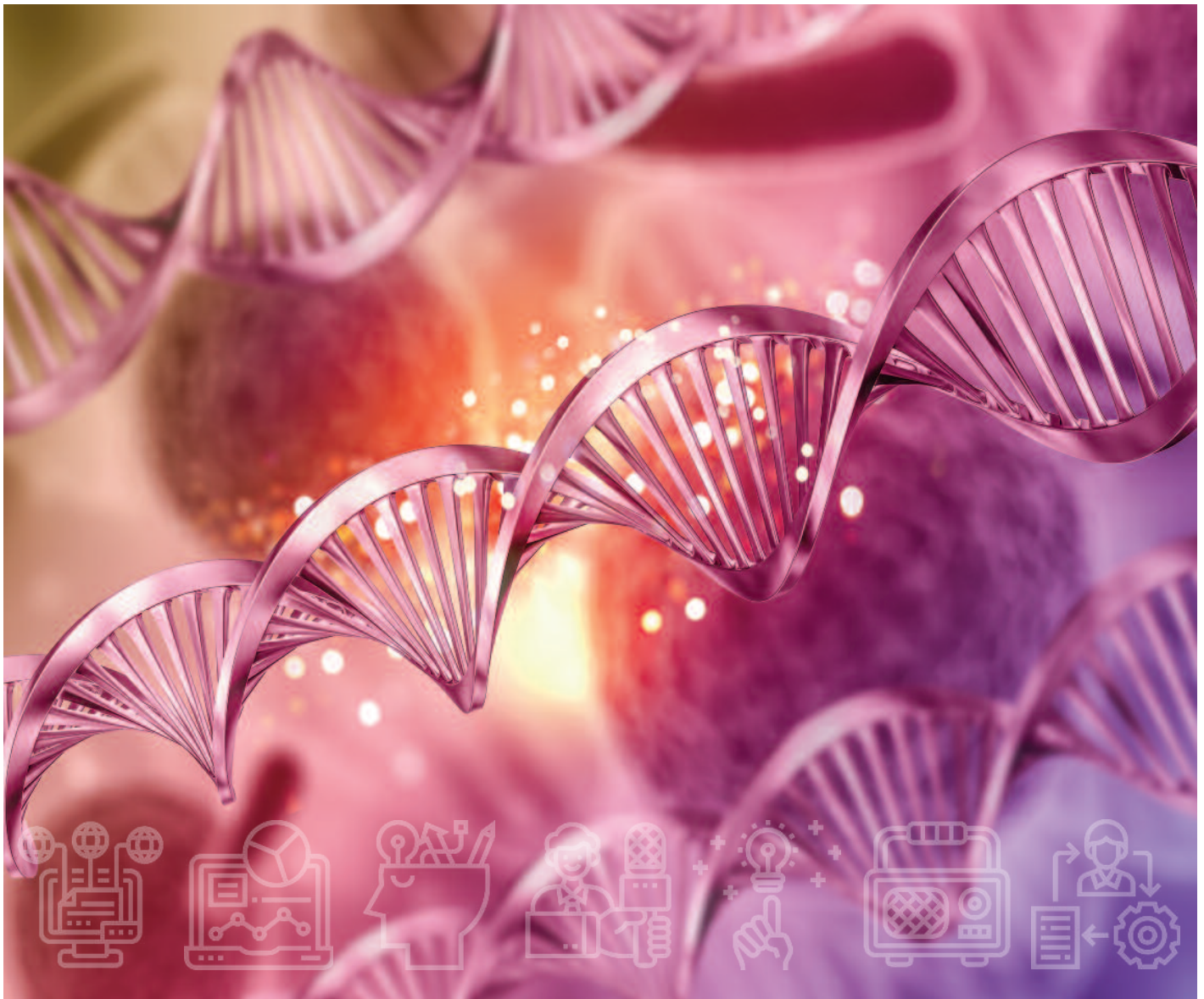
Biologicals and non-biologicals follow different regulatory pathways to the marketplace. The US FDA regulates biologicals through the Center for Biologics Evaluation and Research. It regulates non-biologicals through the Center for Drug Evaluation and Research. In the EU, biologicals market authorisation follows the EMA Centralised Procedure. Non-biologicals

Name	Aspirin (Acetylsalicylic acid)	Abciximab
Synthesis	Non-biological	Biological
Chemical formula	C <sub>9</sub> H <sub>8</sub> O <sub>4</sub>	C <sub>6462</sub> H <sub>9964</sub> N <sub>1690</sub> O <sub>2049</sub> S <sub>48</sub>
Molecular weight	180.157 Daltons	145651.1 Daltons
Chemical structure		

<https://www.drugbank.ca/>

**Figure 2. An illustrative comparison between a non-biological and a biological drug**

Generally, chemically manufactured non-biological drug molecules are smaller and less complex compared to biologically manufactured drug molecules. The molecular weight cut off for a chemically manufactured drug is from 500 to 1,000 Daltons. Aspirin and abciximab are blood thinners. Aspirin is a chemically manufactured drug with nine carbon atoms and a total molecular weight of 180.157 Daltons. Abciximab has 6,462 carbon atoms and a total molecular weight of 145,651.1 Daltons. Information in this figure is from Drugbank.<sup>11</sup>



follow the Centralised Procedure, Decentralised Procedure, Mutual Recognition Procedure, or National Procedure. Regulatory pathways reflect differences in the molecules, their manufacture, their administration, and their risk-benefit profiles. Yet for many, it is difficult to imagine differences in things that are invisible to the eye. So, the importance of their differences is not always appreciated.

The June 2019 issue of *Medical Writing* has articles cover-to-cover on generics and biosimilars. It highlights clinical and regulatory considerations for drug development of these types of medicinal products.<sup>17</sup> It is a very

interesting and insightful read and partly inspired this article.

### An outlier at first glance

Regional dossiers have a section for BCS data. BCS is an acronym for Biopharmaceutics Classification System which can be applied to non-biological drugs.<sup>18</sup> The Biopharmaceutics Drug Disposition Classification System (BDDCS) is also important in drug development.<sup>19</sup> Biopharmaceutics is the study of physical and chemical properties of drugs, their bioavailability, and therapeutic effects. The Biopharmaceutics Classification System (BCS) developed from

bioavailability work by Gregory Amidon.<sup>20,21</sup> All drugs whether biological or non-biological have various levels of bioavailability as they are metabolised by their patients.

Amidon published his work in 1995.<sup>20,21</sup> BCS and BDDCS developed after that.<sup>20,21</sup> In these systems *biopharmaceutics* refers to any drug with an intended use in humans or animals. This is an understandable cause of confusion among laypeople and uninitiated industry personnel when differentiating between biological and non-biological drugs.



## Will non-biological persist?

The use of biological drugs is becoming more accepted and commonplace. Non-biological drugs are sometimes referred to as *normal* drugs. Once biological drugs are thought of as normal, this differentiation will be obsolete.

Year on year, the number of biological drugs sold on the market is increasing. Terms to make a clear distinction between biological drugs and non-biological drugs are increasingly necessary.

Drug definitions become rigid by necessity as they are used in regulatory frameworks.<sup>21</sup> *Non-biological, non-biologic, and non-biopharmaceutical* are descriptively agreeable and contain more intuitive meaning when compared to *biological, biologic, and biopharmaceutical*. Also, *non-biological, non-biologic, and non-biopharmaceutical* do not have formal designations, and they are appropriate in describing all drug products that have not been manufactured biologically.

To me, *biological* and *non-biological* as drug descriptors are synonymous with biological and non-biological washing powder found on supermarket shelves. Biological drugs are not traditional chemical drugs – and they should not be treated as such.<sup>22</sup>

In fact, Hussaarts *et al* 2017 does refer to *biological* medicines compared to *non-biological* medicines.<sup>13</sup>

Will this meme gain popularity? Time will tell if this meaning persists and is used more widely in industry.

## Disclaimers

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

## Conflicts of interest

The author declares no conflicts of interest.

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# Regulatory Matters

## Anonymisation and data privacy:

A medical writer's perspective on the relationship between EMA Policy 0070 and the General Data Protection Regulation



Over the last few years, the call for anonymisation has been increasing – both in frequency and volume – and like snoozing the alarm, resistance, eventually, is futile. From the perspective of a medical writer, especially one within a contract research organisation (CRO) or other types of vendors, what can we do to make sure it's performed correctly, whilst protecting data privacy and retaining the data's scientific value? In this article, we look at how the two concurrent pieces of EU legislation, EMA Policy 0070 and the General Data Protection Regulation (GDPR), need to be addressed from the perspective of the medical writer. Rather than going into detail on either, we will focus on the tensions between the two, drawing on experience from the medical writing team of a CRO.

### EMA Policy 0070

Policy 0070, which was implemented in January 2015, makes it legally binding to make public the clinical information included in a marketing authorisation application. Although publicising clinical research information builds faith in the

pharmaceutical industry and aids further research, a side effect is the unwitting publication of personal or proprietary data. So, as part of the submission process under Policy 0070, any "sensitive" information needs to be protected or removed.

Policy 0070 is being rolled out in two phases. The first phase specifies that all "clinical reports" included in the submission will be made publicly available by the EMA. Clinical reports include clinical overviews (Module 2.5), clinical summaries (Module 2.7), and the clinical study reports (Module 5), plus certain clinical study report appendices: 16.1.1 (protocol and protocol amendments), 16.1.2 (sample case report form), and 16.1.9 (documentation of statistical methods). The second phase, with an unknown implementation date, will include the public disclosure of individual patient data included in the submission. In December 2018, the EMA temporarily suspended all Policy 0070 activities and the resumption date is yet to be announced. However, 131 submissions had already been authorised and are now in the public domain.<sup>1</sup>

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The protection or removal of sensitive information from clinical reports is achieved by anonymisation, and this is where the medical writer plays a role. The anonymisation can be done either proactively or post hoc, using redacting/masking techniques or more sophisticated, automated anonymisation techniques. More on this topic below.

Policy 0070 defines two different categories of sensitive information: commercially confidential information (CCI) and protected personal data (PPD). The CCI includes any information that isn't already publicly available and may have a financial impact on the Market Authorisation Holder if it were made publicly available. The PPD includes information relating to an identifiable person. Definitions and limits of each are detailed in Policy 0070, but the job is to identify what actually falls into the scope of each definition; this needs to be agreed upon with the key stakeholders in advance, to create a redaction strategy for the submission. It may be more likely that a CRO/vendor medical writer would be involved in helping the sponsor define this strategy than would a medical writer in the sponsor company itself.

Medical writers will need to work with biostatisticians, regulatory advisers, privacy/intellectual property associates, as well as key members of clinical and nonclinical teams, to create a strong cross-functional team. The objective is to build a predefined strategy for anonymisation of clinical data.

Policy 0070 also specifies that an Anonymisation Report is generated as part of the submission package. Among other topics, this report includes details on the anonymisation methodology and how the risk of re-identification is measured and managed. We'll look at this in more detail later, but it's quite likely that medical writers will be involved in generating this report.

## The EU's General Data Protection Regulation (GDPR)

Our attention to the thorny issue of data privacy and public disclosure became more focussed after the thought-provoking presentation on Policy 0070 and the EU's GDPR, given by Elizabeth Youngkin and Raquel Billiones as part of the EMWA Expert Seminar Series, in May 2018. One of the points discussed during the presentation was the eye-watering cost of the fines that could be imposed if a data breach were to occur (4% of the annual company turnover or 20 million Euros – *whichever is greater*). The GDPR has been in force since May 2018, and a glance at Wikipedia shows us that the highest fine for any single company so far has been 183 million pounds, sterling,<sup>2</sup> just in case there was any doubt that this is serious business.

So, as medical writers, what do we need to know about anonymisation within the framework of Policy 0070 and the GDPR? A key part of the GDPR is the legal requirement to protect an individual's private data, **by design** (i.e., using built-in systems to ensure compliance) and **by default** (i.e., the minimisation of data collection, processing, and reporting). This means we need to have predefined processes and systems to ensure that:

- Only necessary data are collected and processed.
- Data are anonymised appropriately.

Also, the risk of re-identifying data needs to be assessed. As noted above, Policy 0070 provides guidance on what needs to be anonymised, as well as how to address the risk of re-identification. Privacy by design and default brings us back to the use of proactive anonymisation. Medical writing departments and medical writers will need to reconsider how to present data so that only the most clinically meaningful information is presented, whilst aiming to reduce the presence of CCI and PPD in the reports. One of the purposes of the Clarity and Openness in Reporting: E3-based (CORE) Reference is to address the need for proactive anonymisation. The objective is to think ahead to what would need to be protected to reduce the need for later redaction or masking. This can help the medical writer approach report writing with a "data protection by design and default" mindset and help comply with the GDPR. Medical writers are very familiar with the deliverables that are included under Policy 0070, are well-placed to approach the writing with "protection by design" in mind, and can perform the redaction and masking. We therefore have a very valuable role in the overall process.

Although Policy 0070 provides definitions and limits for the anonymisation, it does not mandate any particular method to achieve it. However, feedback from the first phase of Policy 0070, as well as the review process, is leading to a consensus on what needs to be anonymised. The suspension of all Policy 0070 activities offers an opportunity to fine-tune internal strategies and processes and reinforce best practices.

### A risky business?

As we know, the Anonymisation Report should address the risk of re-identification. This is defined as the probability of re-identifying trial participants once they have been anonymised. Just think about how investigative journalists can uncover information about an individual by making connections through seemingly unrelated pieces of data, or how artificial intelligence is evolving and can be used to make these connections. These are so-called adversary attacks on the data – a deliberate attempt to "crack the code". Equally, re-identification can occur through unintentional discovery of an individual's identity.

Risk of re-identification can be assessed either quantitatively or qualitatively. Qualitative risk is calculated by a subjective assessment of the risk of re-identification, usually as either low, medium, or high. Quantitative risk is calculated using data to produce a numerical value, which is then used to predict the probability of re-identification. Policy 0070 recommends a threshold of 0.09 for quantitative risk of re-identification. In an informative article on the topic, Raquel Billiones<sup>3</sup> analysed the anonymisation methodology used for the redaction packages submitted as of December 2017. Of 45 redaction packages that identified a risk of re-identification methodology, 39 used a qualitative method. So, for now, the qualitative method is the most commonly used, which fits with the use of redaction and masking. This will likely change to a predominance of quantitative methodologies in the future.

### Who's responsible?

Two roles are clearly defined in the GDPR: data controller and data processor. The data controller is responsible for determining the purposes and the methodology for the processing of personal data. The data processor is responsible for processing personal data **on behalf of** the controller. What isn't clearly defined is how sponsors, vendors, and the individuals doing the

work are legally responsible in terms of breach of data. This is where it gets nerve-wracking for medical writers.

One way of looking at it that has been proposed is that medical writers are the data processors, taking clear instruction from the methodology defined by the data controller. It gets more complicated when we look at the role of the CRO vs that of the sponsor. This can be interpreted as the sponsor acting as the data controller and the CRO as the processor. The

discussion is still open, but the GDPR guidance recommends that these roles are very clearly defined up-front in the contract for the work, and the data controller is responsible for ensuring that the data processor has in place appropriate technical and organisational measures to meet the GDPR requirements.

So, coming back to we medical writers: GDPR compliance and Policy 0070 requirements are becoming intermeshed with our

approaches to data presentation. CRO medical writers should check responsibilities are clearly defined in the contract and consult with company privacy experts. Sponsor medical writers will need input from the appropriate group responsible for privacy within their company.

The take-home message? It's not solely a writer's role to decide what should and shouldn't be removed from a report – it will be a collaborative review and approval process, so make sure that you have the support you need.

It's not solely a writer's role to decide what should and shouldn't be removed from a report – it will be a collaborative review and approval process.

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# News from the EMA

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The articles included in this section are an edited selection from the European Medicines Agency (EMA)'s News and Press Releases archive from October 2019 to December 2019. More information can be found on the Agency's website: [www.ema.europa.eu](http://www.ema.europa.eu)



## First vaccine to protect against Ebola

**October 10, 2019** – EMA's human medicines committee (CHMP) has recommended granting a conditional marketing authorisation in the EU for Ervebo (rVSVΔG-ZEBOV-GP), the first vaccine for active immunisation of individuals aged 18 years and older at risk of infection with the Ebola virus.

Ebola virus disease is a rare but severe illness caused by the Ebola virus. Death rates in patients who have contracted the disease have varied from 25% to 90% in past outbreaks. The largest outbreak to date occurred in West Africa in 2014–2016 with more than 11,000 deaths. The 2019 outbreak in the Democratic Republic of Congo (DRC), which was caused by Ebola Zaire, had shown case fatality rates of approximately 67%. More than 3,000 people were infected with the Ebola virus during the outbreak, which was declared a public health emergency of international concern by the World Health Organization (WHO) in July 2019.

Ervebo is a genetically engineered, replication-competent, attenuated live vaccine. Data from

clinical trials and compassionate use programmes have shown that Ervebo protects against Ebola virus disease in humans following a single dose administration.

The clinical development of Ervebo was initiated in response to the 2014–2016 Ebola outbreak in cooperation with public health stakeholders, including national institutes of health, ministries of health in countries such as Guinea and DRC, WHO, the US Centers for Disease Control and Prevention, the Public Health Agency of Canada, Médecins Sans Frontières, and others. In the 2019 Ebola outbreak in DRC, the vaccine was used under an Expanded Access Protocol or 'compassionate use' to protect people at highest risk of infection such as healthcare workers, or people who have come into contact with infected patients or contacts of contacts according to a ring vaccination strategy.

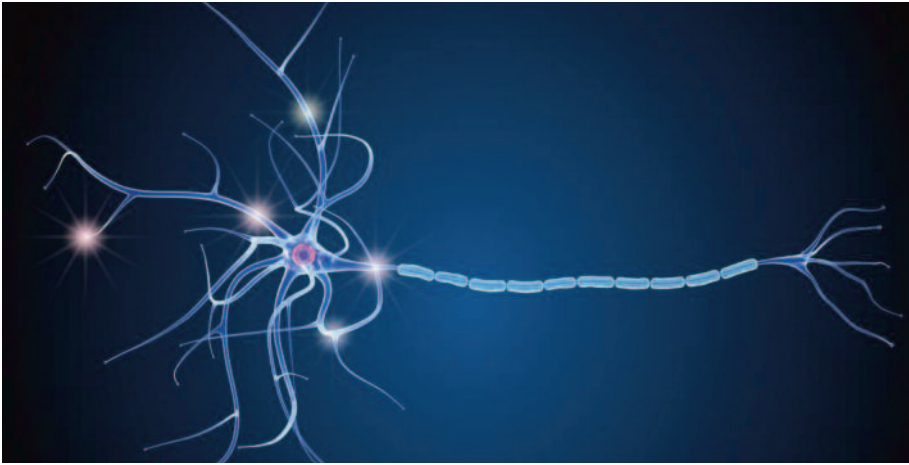
Ervebo has been tested in approximately 16,000 individuals involved in several clinical studies in Africa, Europe, and the United States where it has been proven to be safe, immuno-

genic (i.e., able to make the immune system respond to the virus) and effective against the Zaire Ebola virus that circulated in West Africa in 2014–2016. Preliminary data suggest that it is effective in the current outbreak in DRC. Additional efficacy and safety data are being collected through the Expanded Access Protocol and should be included in post-marketing safety reports, which are continuously reviewed by EMA.

Currently, there are no therapies approved for Ebola. Ervebo 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. Ervebo was granted eligibility to PRIME in June 2016 for active immunisation against Ebola.

Ervebo received a positive opinion for a conditional marketing authorisation from the CHMP. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation.

## Measures to minimise risk of serious side effects of multiple sclerosis medicine Lemtrada



**November 15, 2019** – EMA is recommending restriction of the use of the multiple sclerosis medicine Lemtrada (alemtuzumab) due to reports of rare but serious side effects, including deaths. New measures to identify and manage the serious side effects are also recommended. The side effects include cardiovascular disorders (affecting the heart, circulation and bleeding as well as stroke) and immune-related disorders (caused by the body's defence system not working properly).

Lemtrada should now only be used to treat relapsing-remitting multiple sclerosis if the disease is highly active despite treatment with at

least one disease-modifying therapy or if the disease is worsening rapidly. Lemtrada must also no longer be used in patients with certain heart, circulation, or bleeding disorders or in patients who have autoimmune disorders other than multiple sclerosis. The medicine should only be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions.

EMA has also recommended updating the physician's guide and the patient information pack with advice on minimising the risk of serious cardiovascular disorders, which may occur shortly after a Lemtrada infusion (drip),

and immune-related conditions, which may occur many months and possibly years after the last treatment.

Lemtrada was authorised in the EU in 2013. It is used to treat adults with relapsing-remitting multiple sclerosis, a disease of the nerves in which the body's immune system acts incorrectly to destroy the protective sheath surrounding the nerve cells. Relapsing-remitting means that the patient has attacks (relapses) in between periods with few or no symptoms (remissions).

The active substance in Lemtrada, alemtuzumab, is a monoclonal antibody that has been designed to recognise and attach to CD52 found on white blood cells. By attaching to CD52, alemtuzumab causes the white blood cells to die and be replaced, thereby reducing damaging activity of the immune system.

The review of Lemtrada was initiated on April 10, 2019, at the request of European Commission (EC) and was first carried out by the Pharmacovigilance Risk Assessment Committee (PRAC). While the review was ongoing, the PRAC had issued temporary recommendations restricting the use of the medicine. The PRAC issued its final recommendations on October 31 to the CHMP. The CHMP opinion will now be forwarded to the EC, which will issue a final legally binding decision applicable in all EU Member States in due course.

## EMA update on metformin diabetes medicines

**December 6, 2019** – trace amounts of an impurity, N-nitrosodimethylamine (NDMA), have been found in a small number of metformin diabetes medicines outside the EU. The levels of NDMA in the affected non-EU metformin medicines are very low and appear to be within or even below the range that people can be exposed to from other sources, including certain foods and water. At this point, there are no data indicating that EU metformin medicines are affected.

Authorities in the EU are in the process of working with companies to test EU medicines and will provide further updates as more information becomes available. Patients in the EU should continue taking their metformin medicines as normal. The risk from not having adequate diabetes treatment far outweighs possible effects of the low levels of NDMA seen in tests. Healthcare professionals should remind

patients of the importance of keeping their diabetes under control.

Metformin is widely used alone or in combination with other medicines to treat type 2 diabetes. It is usually the first-line treatment, and it works by reducing the production of glucose in the body and reducing its absorption from the gut.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) on the basis of animal studies.

It is present in some foods and in water supplies, but it is not expected to cause harm when ingested in very low levels. Last year, NDMA and other impurities of the same class (nitrosamines) were found in some blood pressure medicines known as sartans. Subsequently, EMA

started a review of ranitidine medicines and launched a procedure to request companies to take specific measures to avoid the presence of nitrosamines in human medicines, including metformin. The expedited testing of metformin medicines in the EU is part of this procedure.





## Launch of international pilot programme on inspection of manufacturers of sterile medicines

**December 17, 2019** – EMA and its European and international partners are launching a pilot programme to increase their cooperation in the inspection of manufacturers of sterile medicines for human use. This new initiative is built on the success of and experience gained from a similar collaboration, the international active pharmaceutical ingredients (APIs) inspection programme.

This collaboration will allow EMA, EU national authorities (France and the United Kingdom), the United States Food and Drug Administration, Australia's Therapeutic Goods Administration, Health Canada, the Japanese

Pharmaceuticals and Medical Devices Agency, and the WHO to share information on good manufacturing practice inspections of manufacturers of sterile medicines who are located outside the participating countries, and to organise joint inspections for manufacturing sites of common interest.

International collaboration in inspections has demonstrated its benefits in improving oversight of manufacturers and making best use of inspection resources worldwide, through mutual reliance between participating regulatory bodies, the reduction of duplication of inspections and the increase in the coverage of sites inspected

worldwide. The objectives, scope, and general principles of this new collaboration are laid out in the of reference for the programme.

The products in scope are sterile medicinal products for human use of chemical origin and certain therapeutic biotechnology-derived products (such as monoclonal antibodies and recombinant proteins). Products currently out of scope of this pilot are vaccines, cell and gene therapies, and plasma-derived pharmaceuticals.

The pilot will last for a minimum of 2 years after which the participating authorities will assess the programme and determine the next steps in the collaboration.

## Four-year overview of pharmacovigilance activities in the EU shows robust and effective medicines safety system

**December 17, 2019** – A report on the activities ensuring the safety of medicines carried out by EMA and the national competent authorities of the EU Member States, Norway, and Iceland from 2015 to 2018 shows that the EU pharmacovigilance system is strong and adaptable and has had a positive impact on public health.

The report measures the longer-term impact of the pharmacovigilance legislation, which came into effect in July 2012, in terms of simplification of pharmacovigilance processes, improved transparency and stakeholder engagement, and protection of patient health. The measurement of impact is based on a strategy and action plan for measuring the impact of pharmacovigilance activities, adopted by EMA's safety committee (PRAC) in 2017.

### Some key outcomes 2015–2018:

- More than 500 new or updated risk management plans were assessed by the PRAC each year, ensuring the safety monitoring and risk minimisation is proportionate and planned. In addition, nearly 7,000 risk management plans were assessed by the Member States for nationally authorised medicines

during the reporting period.

- Enhanced EudraVigilance database of suspected side effects, resulting in improved reporting and greater analytical power;
- Evaluation of nearly 9,000 potential signals (information about new or changing safety issues potentially caused by a medicine) by EMA's signal management team over the period covered by the report, and a similar number of potential signals assessed by Member States;
- Radical simplification and improvement of the way periodic safety update reports are handled, by establishing a common repository with a single portal for access;
- Development of criteria to determine when a public hearing on issues of medicines' safety would be of value, and the successful holding of the first such hearings, for valproate-containing medicines in 2017 and for quinolone and fluoroquinolone antibiotics in 2018;
- Continued development of the "Article 57 database", which now contains information on more than 800,000 medicinal products authorised through central, decentralised,



mutual recognition and national procedures across the European Economic Area.

The report on the impact of pharmacovigilance measures was prepared by EMA in collaboration with the national competent authorities and aims to meet the European Commission's ongoing obligation to publish information on pharmacovigilance activities carried out by the Agency and the competent authorities of the EU Member States, Norway, and Iceland. It includes quantitative data covering the period 01/01/2015 to 31/12/2018 and shows that the European regulatory network for medicines is held accountable for the implementation of the pharmacovigilance legislation.



# Journal Watch

Journal Watch is based on the French language blog, *Rédaction Médicale et Scientifique*, by Hervé Maisonneuve, available at [www.redactionmedicale.fr](http://www.redactionmedicale.fr).

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## ICMJE recommendations replace “conflicts of interests” with “relations and activities”

Each December, the International Committee of Medical Journal Editors (ICMJE) updates its influential document “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals”. The most recent changes to the document, available at [www.icmje.org](http://www.icmje.org), are limited in number but nonetheless significant.

While the definition of conflicts of interest remains unchanged, the term “conflicts of interest” has now been replaced by “relationships and activities” throughout the document. The expression – ‘financial and non-financial relationships and activities’ – has been introduced. The expression “disclosure of conflicts of interest” has been banned and replaced by “disclosure of relationships and activities”. We will see if journals change the wording accordingly in their instructions to authors and papers.

Additional information has been added to explain how to interpret the new phrase concerning relationships and activities:

*Individuals may disagree on whether an author’s relationships or activities represent conflicts. Although the presence of a relationship or activity does not always indicate a problematic influence on a paper’s content, perceptions of conflict may erode*

*trust in science as much as actual conflicts of interest. Ultimately, readers must be able to make their own judgments regarding whether an author’s relationships and activities are pertinent to a paper’s content. These judgments require transparent disclosure. An author’s complete disclosure demonstrates a commitment to transparency and helps to maintain trust in the scientific process.*

In turn a new category of scientific misconduct is introduced: “purposeful failure to report those relationships and activities”. This is likely a reaction to the many scandals in recent years, such as the Jose Baselga case in which a much-published cancer researcher failed to disclose he had direct ties to medical industries.

A close reading of the document also brings to light these evolving principles:

- Editors have no role in the choice of author listing: “The criteria used to determine the order in which authors are listed on the byline may vary, and are to be decided collectively by the author group and not the editors.”
- Authors have sole responsibility for where to publish. “Policies that dictate where authors may publish their work violate this principle of academic freedom.” This arises because

sponsors have been suspected of influencing the choice of which journal papers are submitted to.

- “Authors should avoid citing articles in predatory or pseudo-journals.”

The long section on trial registration has been completed by the idea that approval to conduct a study from a review body (ethics committee) does not fulfil the requirement for registration.

A new paragraph entitled “Diversity and Inclusion” has been added:

*To improve academic culture, editors should seek to engage a broad and diverse array of authors, reviewers, editorial staff, editorial board members, and readers.*

In previous versions, this concept was less explicit and was buried in the middle of a paragraph.

Concerning peer review, this statement appears:

*Reviewers who seek assistance from a trainee or colleague in the performance of a review should acknowledge these individuals’ contributions in the written comments submitted to the editor. These individuals must maintain the confidentiality on the manuscript.*

## What did we learn about peer review in 2019?

The peer review process has been accused of being subjective, slow, expensive, biased, poor at detecting errors, etc. Nevertheless, we don't yet have any better system to replace it with, and most researchers are generally confident in peer review, because it is shown to improve papers. On the whole, research on peer review made progress last year.

Hilda Bastian is a health care advocate, and had a professional career in Australia, Europe, and North America. She writes a blog hosted by PLOS, "Absolutely Maybe" with a subtitle "Evidence and Uncertainties about medicine

and life" (<https://blogs.plos.org/absolutely-maybe/about-hilda-bastian/>). Some of her posts concern peer review. Here are her highlights for 2019 (<https://blogs.plos.org/absolutely-maybe/2019/12/31/5-things-we-learned-about-peer-review-in-2019/>) and five messages based on topics most covered by quality publications:

1. Peer review might sometimes be a kind of academic matchmaking, increasing the chances of future scientific collaboration.
2. Peer reviewers may provide no line of defense against authors' conflicts of interest.
3. Peer reviewers sign their own names more often

when they are recommending acceptance of an article.

4. Editorial peer review may be increasing the acknowledgement of study limitations – but without reducing study spin.
5. Peer review of scientific publications is not a fairly recent development – it's even older than we realize.

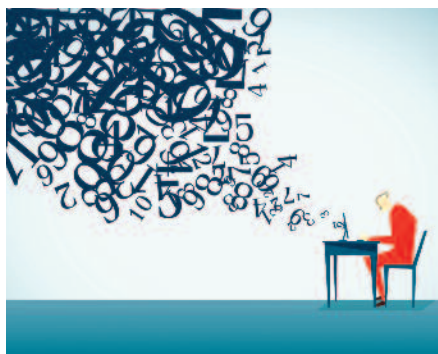
These messages are the conclusions drawn from randomised trials or observational studies. All references are cited in the post. Bastian is also a cartoonist and adds amusing images in her posts.

## Defining "predatory" journals

Finally, a definition of predatory journals has been prepared by a group of experts with good working methods. Predatory journals emerged in the early 2010's, and it has always been difficult to define and identify them. We must learn to differentiate them from scholarly society or professional journals. The Ottawa Journalology Centre, headed by David Moher, has done a great deal of work on misleading or predatory journals (<http://www.ohri.ca/journalology/>).

On December 11, 2019, *Nature* published an article that included a definition of predatory journals.<sup>1</sup> In April 2019, these researchers brought together a group of 35 experts to propose a definition of predatory journals using a structured Delphi-type method. There were 12 hours of discussion, and then two more rounds of review. In the end they decided to keep the term predatory journals, even though in previous publications, the Ottawa group was not a fan of the term and proposed "misleading journals" instead. Here is the definition finally agreed on:

*Predatory journals and publishers are entities*



*that prioritize self-interest at the expense of scholarship and are characterized by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices.*

Researchers are still being trapped by predatory journals, which have become better and more sophisticated over time. For example, they use online submission systems by dropping the

submission as an email attachment. In choosing a journal, authors must be careful and limit their search to journals indexed (Web of Science, Medline, Scopus, DOAJ), or to journals published by known learned societies and/or publishers. Additional guidance on how to choose the right journal is available on the website Think, Check, Submit (<https://thinkchecksubmit.org/>), or from one of the many journal selector sites available online. A word of caution, however: Be careful with journals you see in PubMed, because predatory journals can sometimes be found through PubMed searches that retrieve articles deposited in PubMed Central.<sup>2</sup>

### References

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2. Manca A, Moher D, Cugusi L, Dvir Z, Deriu F. How predatory journals leak into PubMed. *CMAJ*. 2018;190:E1042–5.



## Mark Your Calendar

### September 2021 International Congress on Peer Review and Scientific Publication (Chicago)

In 2020, consider performing some kind of research on peer review, with the objective of presenting a poster or a communication at the ninth International Congress on Peer Review and Scientific Publication to be held in Chicago in September 2021 (<https://peerreviewcongress.org>). The closing date for abstract submissions is January 2021.



## Gender disparities in publications are too obvious

Articles on gender differences in the research system seem to be more numerous than a few years ago. This is an area that might benefit from more action and less research. We already know that editorial boards of journals have few women, there are fewer articles with women as first authors and fewer women reviewers; women's articles are rejected more often than men's, and when two authors have contributed equally to an article, the woman is listed after the man.

Here are some additional gender-related publications, and selected quotes from their conclusions:

A study published in JAMA Network Open, was based on 72,000 comments solicited by medical journals (including editorials):<sup>1</sup>

*In this case-control study of invited commentaries published in 2,459 journals from January 1, 2013, through December 31, 2017, the odds of authoring an invited commentary were 21% lower for women compared with men who had similar fields of expertise and publication metrics among researchers who had been actively publishing for the median of 19 years.*

This paper was commented on in an interesting editorial signed by two female editors (BMJ and Headache).<sup>2</sup> The messages of this editorial are:

*Medical science thrives when there is vigorous dissent, discussion, and debate. It is vital that women experts are able to play a full and active role in this process. Women physicians should insist on being heard, and medical journal editors and other gatekeepers must work to identify and dismantle the systems that stand in the way of their full participation.*

In other words, we are not to blame for behaviours, but we are responsible for suggesting improvements and continuing to act on them over time.

A preprint was posted online January 11, 2020, by a team of researchers from University of Pennsylvania Perelman School of Medicine.<sup>3</sup> Looking just at citations, they have done some original research:

*Utilizing data from five top neuroscience journals, we indeed find that reference lists tend to include more papers with men as first and last author than would be expected if gender was not a factor in referencing. Importantly, we show that this overcitation of men and undercitation of women is driven largely by the citation practices of men, and is increasing with time despite greater diversity in the academy. We develop a co-authorship network to determine the degree to which homophily in researchers' social networks explains gendered citation practices and we find that men tend to overcite other men even when their social networks are representative of the field.*

A paper presenting a curious finding was published in the 2019 BMJ Christmas issue. The study focused on how male and female scientists present the importance of their research:<sup>4</sup>

*Articles in which the first and last authors were both women were, on average, 12.3% less likely to use positive terms to describe research findings compared with articles in which the first and/or last author was male. The gender difference in positive presentation was greatest in high impact clinical journals, with women being 21.4% less likely to present research positively. Positive presentation was, on average, associated with 9.4% higher subsequent citations.*

Accompanying this is a nice editorial written by two women from Ann Arbor and Boston.<sup>5</sup> The quote in the margin says: "We should consider the ways that women are told that their work is 'not quite good enough' as drafted."

The editors of the *Lancet* Group are moving to address these issues, and most of the *Lancet* journal editorial boards have changed accordingly over the past years.<sup>6</sup> Here is what they say about official journal policy:

*The Diversity Pledge and No All-Male Panel Policy are displayed prominently on our website. Across all 18 journals published by the Lancet Group, all commissioning letters and instructions to authors now include our preference for diversity among author teams, and all peer-reviewer invitations request that alternative reviewer suggestions consider diverse groups of colleagues.*

Other journals will undoubtedly follow this lead, but it could still be a steep hill to climb.

## References

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5. Jaggi R, Silver JK. Gender differences in research reporting. *BMJ*. 2019;367:l6692.
6. The Editors of the Lancet Group. The Lancet Group's commitments to gender equity and diversity. *Lancet*. 2019;394:452–3.



# Getting Your Foot in the Door

## Editorial

Welcome to our first edition for 2020. Looking back to the year past, there were a lot of GYFD moments to acknowledge and be thankful for. The March 2019 issue on *Medical Writing Careers* was my first stint as MEW guest editor. The experience has proven to be so addictive that I volunteered for another guest editorship this year. Watch out for the June 2020 issue.

In 2019, I also got my foot in the door of big pharma medical writing. But most importantly, it was the year when several medical writing wannabes became medical writing newbies, landing their first industry jobs and/or gigs. Congratulations to Adriana, Archana, Cherry, Gauri, Namrata, and Sanjukta. Some of these ladies have shared their stories in previous MEW issues<sup>1</sup> and EMWA webinars.<sup>2</sup>

In this edition, I want to thank Cherry for sharing her incredible GYFD journey. It brings a sense of déjà vu as I started a similar journey 14 years ago, both professionally and geographically.<sup>3,4</sup> Like Cherry, I will always be grateful for EMWA for showing me the way.

Finally, check out Brian Bass' (my co-guest editor for the *Medical Writing Careers* issue) valuable advice on breaking into the medical writing field. I especially love Brian's poultry metaphors. But much more, it's a privilege to get tips from such a seasoned writer. Thank you, Brian.

## References

1. Rocha A, Dey-Irmeler S. Getting Your Foot in the Door. *Med Writ*. 2019;28(1):82–3.
2. Oh, Vienna Impressions of my first EMWA

## SECTION EDITOR



**Raquel Billiones**

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conference. 29 Aug 2019.

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**Raquel Billiones**

## Finding balance: My path to medical writing

As plans go, or rather never did for me really, the path that led me to medical writing reflects the winding roads that litter my life. When I had originally planned to go to specialty training upon completion of my medical degree, I ended up moving to Switzerland to start a new life with my husband. When I planned to sign on full-time to a Basel-based CRO after completing my biomedical engineering master's degree, I found I was pregnant. At one point, it was clear that planning big was just a waste of time, seeing as every turn kept sending me on a side road to a destination completely off my map!

Though the first child was a surprise, the second wasn't. So after a few years of working part-time in research, the arrival of the second and our subsequent move to another region led me to take on family duties full-time (or better said, 24/7). Later, with the arrival of No.3, I had imagined that I would enjoy the house-wifing a few years more, focusing on the equally challenging science of child-rearing, while making the most of our Swiss countryside life.

But unexpectedly, 4 years into this domestic life, a growing unrest led me to late-night googling for possibilities to jump-start my sidelined career. That's when I found EMWA. And with its discovery, I read an abundance of member testimonials which left me compelled to meet these writers. So, I set my sights on the



Photo: Cherry Malonzo Marty

*The author's town in the Swiss Alps*

Vienna conference in the spring of 2019 to dive right in. It was to be my first big trip alone in years, so despite the uncertainty, I was excited to finally have 5 days of uninterrupted "me time" to saturate my head with science, for a change.

At the conference, it was a delight to strike up

conversations with scientific writers of different specialties and experiences. Though not one story was the same, writing was a shared passion in everyone's journey into this profession. Because of the hobby I had been cultivating during my years of staying home with the

children, I could easily relate (if not to the specialty, then at least to the writing).

Though a mere hopeful by the end of the week, I left Vienna quite fulfilled with a few leads to boot. Having rediscovered a part of myself I had unintentionally put away while focusing on the family, my confidence was renewed and I knew I was welcome in this community, regardless of the path I had taken to get here.

A month later, my hopes did pan out, and an acquaintance from Vienna signed me on to a regulatory consultancy he was leading. And with today's connectivity and productivity tools, I am able to work from any location, in a virtual office shared by colleagues across the globe.

A typical workday can sometimes mean having a call on my way to the morning's errands after dropping off the 2-year old. Later, I could set aside a few hours in the evening for documents without missing out on an afternoon bike ride with the 4-year old. On other days, the share-screen option connects me to other colleagues and clients, allowing me to hold a presentation as if we were all in the same room, then attend to a personal appointment afterwards. And on lazy mornings, I can take it slow and make a check-in call while preparing lunch, to gear up for writing when the toddler naps and the older boys spend their afternoon out playing with the neighbourhood children.

With the virtual office and flexible working hours, I may constantly be on the move, but with a growing family, this is inevitable. And though the reality of juggling family duties with a developing career is nothing short of challenging, working remotely is keeping me sane, without sacrificing my family.

After that fateful trip to Vienna, there isn't a day I don't feel blessed with this turn of events. Had I hesitated to go, I would not have met the people that believed in my potential and didn't discriminate against my unusual and interrupted career track or my already packed family situation.

Though clearly this is yet another one of those roads leading to an unknown destination, sharing this journey with my husband and three sons while working in a team that respects my personal obligations makes it possible and worthwhile each day.

Thank you EMWA for helping to open doors that I hadn't known existed.

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## How committed are you to breaking in?

Breaking into the field of medical writing is a conundrum. Like most, if not all other worthy professions, you can't get experience without getting a job, and you can't get that first job without having experience. It's a chicken-and-egg sort of problem. But having broken into the medical writing profession many years ago without having any discernable medical writing experience – and harder yet, breaking into the field as a freelance, I can tell you with all confidence that it can be done. The question is, how committed are you to breaking in?

To paraphrase another poultry-related saying, when it comes to making a ham and egg breakfast, the chicken is involved but the pig is committed. Fortunately, breaking into medical writing doesn't require a life-or-death commitment. But you better be all in.

Medical writers come from many walks of life. I was a professional writer for almost a decade before I broke into medical writing, with absolutely no writing experience in health, medicine, or even science. While my learning curve over the years has been steep, I don't think it's any steeper than that of a scientist or health or medical professional who needs to prove they can write.

So here's my first tip for anyone wanting to break into medical writing: be honest with yourself about what you know and don't know, then do whatever it takes to learn it. For example, I knew that I didn't know everything about health, medicine, and science. I've worked very hard at that for my entire career as a medical writer. At the speed with which medical science advances, there's always more to learn.

In my opinion, one of the greatest challenges to overcome is the perception that we know how to write. Everyone knows how to write, right? I discovered that even after years as a professional writer I could still benefit from writing courses. Surely anyone whose career to this point has not exclusively involved writing can benefit as well. Fortunately, there are excellent workshops, webinars, and other resources available through EMWA and the American Medical Writers Association (AMWA) to learn and reinforce what you already know (or think you know) about writing mechanics.

Then you need to write. A lot. Being good at the mechanics of writing does not make you a great writer. Being a great writer means being a great communicator. To achieve that kind of

greatness you need to know not just the mechanics of writing and the topic about which you're writing, both of which are expected. You need to be able to write for specific audiences, understanding and adapting to their unique and varied needs, desires, and learning styles. You need to be able to engage those audiences so they want to read what you've written. And you need to be able to communicate information clearly and accurately in a variety of media. These are all skills you learn by practice, over time.

This is my second tip: be patient. One of my undergraduate professors said you can't consider yourself a professional writer until you've written a million published words. That was a lot harder to do before the days of the internet, blogs, and self-publishing; but I suspect these days the goal post has also shifted further out. I think this is accurate because becoming a great writer doesn't happen overnight. You learn by doing, and especially by making mistakes.

This brings me to my third tip: don't be afraid to make mistakes. From very young, we're taught to be correct and admonished for making errors. But as another famous poultry-related saying goes, you can't make an omelet without breaking a few eggs. One thing I've learned is that if you can't make a mistake you can't make anything. Fear of failure makes you afraid to try anything new. As William Shakespeare put it in *Measure for Measure*:

“Our doubts are traitors,  
and make us lose the good  
we oft might win  
by fearing to attempt.”

If you want to break into medical writing, this last tip is the single most important piece of advice I can give you. If you're not afraid to fail you never will because you'll see each step backward as a learning experience, each negative as a positive, and each obstacle as a challenge along the road to your success.

For more information, I invite you to check out my blog post “How To Become a Medical Writer”. [<http://blog.amwa.org/how-to-become-a-medical-writer>]

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# Veterinary Medical Writing

SECTION EDITOR



Karim Montasser

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## Editorial

Cemile Jakupoglu of Cyton AH Biosciences GmbH and Maggie Fisher of Veterinary Research Management give the Veterinary Medical Writing section of the journal an overview of some major changes involved in the revision of the “Guideline on the conduct of bioequivalence studies for veterinary medicinal products”, EMA/CVMP/016/ 2000-Rev.3, which came into effect on July 1, 2019.<sup>1</sup> This

article is based on a more detailed article previously published.<sup>2</sup>

## References

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## Bioequivalence studies in veterinary medical writing

Bioequivalence (BE) studies are used in a variety of situations. Most often, a sponsor wishes to produce a generic version of an already approved product for which the data protection period has expired. BE studies provide pivotal data within marketing authorization applications for generic veterinary medicinal products, as they allow bridging of the safety and efficacy data associated with the reference veterinary medicinal product.

A need to update the CVMP Guideline was identified with the purpose to bring it in line with the VICH GL52 Bioequivalence: blood level bioequivalence study. Additionally, the analytical methods used in BE studies must now, according to the revised guideline, comply with standard criteria of validation as given in the Committee for Medicinal Products for Human Use guideline on bioanalytical method validation (EMA/CHMP/EWP/192217/2009-Rev.1).

The definition of BE has been updated. In Revision 2, BE was defined as: “The similarity between two products that contain the same active substance(s) and shows similar rate and extent of absorption of the active substance(s). In most cases, the rate and extent of absorption are expressed as concentration (C) and area under the curve (AUC). The aim is to show that two medicinal products are similar to such degree that their systemic effects, with respect to both efficacy and safety, will be essentially the same.” In Revision 3, the new definition of BE reflects the attention to metabolites and the site of action as following: “Absence of a difference (within predefined acceptance criteria) in the

bioavailability of the active pharmaceutical ingredient (API) or its metabolite(s) at the site of action when administered at the same molar dose under similar conditions in an appropriately designed study.”

In the updated guideline, the randomised, two-period, two-sequence, single-dose crossover study design is still recommended as a preferred first choice, where appropriate. However, alternative study designs are mentioned and in certain situations – a parallel study design might be more appropriate.

Highly Variable Drug Products (HVDPs), now defined as those for which the intra-individual variability for a parameter for the reference product is larger than 30%, might need a replicate partial crossover study or crossover with four periods

design. It is recommended scientific advice is sought before embarking on designs more complex than a simple crossover due to the nature of the animals or substances being evaluated.

The dose to be tested should normally be at the highest labelled dose approved for the reference product. This shall allow the detection of significant formulation differences more easily. Lower or higher doses must be scientifically





justified. Exceptions include where there are substances with non-linear pharmacokinetics and where the highest level is undetectable in blood (so it may be necessary to go above the highest recommended dose rate). In crossover studies, the same total dose should be administered to each animal in all study periods. The use of dose adjustments in those rare situations where large weight changes are anticipated (e.g., studies conducted in rapidly growing animals where there is a risk of differences in drug absorption, distribution, metabolism or elimination in period 1 vs 2 that could bias the within-subject comparison) will need to be considered on a case-by-case basis.

The sample size (number of subjects needed) should now be based on the pharmacokinetic parameter anticipated to have the greatest magnitude of variability and/or difference in treatment means (e.g., C). To maintain statistical

power, replacement of study animals during an ongoing study might be allowed. However, the removal criteria should be provided in the protocol.

### Conclusion

The new guideline provides considerably more guidance on the details of crossover designs, when to choose parallel studies over crossover designs, and study animals – particularly considerations on numbers to be included and doses to be tested.

Broadly, this is likely to assist those designing studies and there remains the option to seek scientific advice if the guidance fails to address a particular circumstance. As ever, care should be taken to ensure that sufficient planning is undertaken to address the specific requirements of a particular BE evaluation so that it has maximum opportunity to demonstrate BE

sufficiently, and it addresses the key recommendations made in the guideline.

### Reference

3. European Medicines Agency. Guideline on the conduct of bioequivalence studies for veterinary medicinal products. Available at: [https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-conduct-bioequivalence-studies-veterinary-medicinal-products-revision-3\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-conduct-bioequivalence-studies-veterinary-medicinal-products-revision-3_en.pdf).

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**Save the date:  
EMWA Conference in  
the United Kingdom  
LONDON**

**November 12-14, 2020**

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# Good Writing Practice

## Circumlocution: Absolute phrase

### Introduction

The absolute phrase contains a noun headword and a present participle. The noun is the reason that the phrase is termed the absolute (actually nominative absolute). Its absoluteness is the result of the phrase being relatively independent of the main clause – an independence often necessitating its initiation by a *with*. Another feature of the absolute phrase is over-emphasis resulting from its usual sentence-end position.

An absolute phrase expresses a smooth literary but wordy narrative style, which seems unconventional compared to the formal descriptive style of research writing. Contributing most to the narrative (action-focused) style is the present participle (e.g., *being*), which conveys an ongoing action, similar to that of the progressive tense. This presentness can often result in a tense mismatch between the absolute and the conceptual component being conveyed.

### Experimental sections

#### Results section: inter-data comparison

##### Example: wordy absolute phrase

*The amount of root blunting was increased for both age groups, with both groups responding similarly.*

##### Revision

*The amount of root blunting was **similarly** increased for both age groups.*

##### Notes

Although the absolute emphasises the concept of *similarly*, the revision does so succinctly without being narrative and repeating *both age groups*. The adverbial function of the absolute phrase is justified by its equivalence to the adverb *similarly*.

### Contextual sections

#### Part 1 – Introduction section: research problem pertinent background

##### Example: unconventional absolute phrase

*The ingestion of fluoride affects more than one*

*aspect of this system, with the principal effect being porous enamel.*

##### Revision

*The ingestion of fluoride affects more than one aspect of this system, **but the principal effect is enamel porosity**.*

##### Notes

The relation (an equivalence) between information in the main clause and that of the absolute is clearer when the absolute is coordinated as an independent clause in a compound sentence. Thus, revision of the circumlocution expressed by absolute phrase is not only syntactic reduction but also replacement by an equally long but conventional structure (e.g., an independent clause of a compound sentence).

#### Part 2 – Introduction section: research objective

##### Example: wordy absolute phrase

*The objective of this study was to further investigate the responsiveness of these genes with the ultimate project goal being the elucidation of the molecular mechanism associated with the BMP-2 signalling pathway for osteoblast differentiation.*

##### Revision

*The objective of this study was (1) to further investigate and confirm responsiveness of these genes and (2) **to elucidate the molecular mechanism** associated with the BMP-2 signalling pathway for osteoblast differentiation.*

##### Notes

The narrative absolute phrase can be transformed into an infinitive phrase that can be coordinated with the first infinitive phrase *to further investigate the responsiveness of these genes*. The transformation is reductive from 21 words to 14. However, because of the length of each infinitive phrase, phrase enumeration is used for clarity.

In the example, another distraction is that the present participle *being* is inconsistent with the pastness of the objective.

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### Part 3 – Discussion section: hypothesis + post-results support

##### Example: wordy absolute phrase

*A statistically significant improvement was observed for tibial length, growth plate (length, width), and body weight, with the magnitude of the improvement appearing to be dose dependent.*

##### Revision

*A statistically significant **dose-dependent** improvement was observed for tibial length, growth plate (length, width), and body weight.*

##### Notes

The reduced size and the pinpoint placement of *dose-dependent* contiguous to *improvement* clarifies meaning. The compounded noun-adjective *dose-dependent* is equivalent to the entire absolute phrase. Thus, the absolute is functioning adjectivally.

In the example, the present tense of the participle (i.e., *appearing*) is inconsistent with the pastness (i.e., *past support for hypothesis*).

### Part 4 – Discussion section: limitation

##### Example: wordy absolute phrase

*The results must be considered preliminary, with only one animal being examined.*

##### Revision

*The results **limited to only one animal** must be considered preliminary.*

##### Notes

The revision conveys with greater clarity the reason for the preliminary nature of the results and involves replacement of the absolute phrase



by an adjectival past participle phrase (participle + prepositional phrase).

## Summary

It is not unexpected that the absolute phrase is more frequent in the contextual sections (four out of five of the examples) than in the experimental sections of the journal article, because of the increased need for qualification in argument

development. Four of the revisions for circumlocution involve syntactic reduction and one, replacement by an equally long but conventional structure.

The circumlocution and end position–caused over-emphasis of an absolute phrase is further distracting by a narrative present tense structure disagreement in tense with the conceptual component. Such a distraction can range from

dissonance to nonprofessional tone. The non-professional tone also results from the usual informality of the absolute.

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## Schematised distractions and revisions

### Syntactic Reduction

#### Adverb

*The amount of root blunting was increased for both age groups, with both groups responding similarly.*

→ *The amount of root blunting was **similarly** increased for both age groups.*

#### Compound word

*A statistically significant improvement was observed for tibial length, growth plate (length and width), and body weight, with the magnitude of the improvement appearing to be dose dependent.*

→ *A statistically significant **dose-dependent** improvement was observed for tibial length, growth plate (length and width), and body weight.*

### Participial phrase

*The results must be considered preliminary, with only one animal being examined.*

→ *The results **limited to only one animal** must be considered preliminary.*

### Infinitive phrase

*The objective of this study was to further investigate the responsiveness of these genes with the ultimate project goal being the elucidation of the molecular mechanism associated with the BMP-2 signalling pathway for osteoblast differentiation.*

→ *The objective of this study was (1) to further investigate and confirm responsiveness of these genes and (2) **to elucidate the molecular mechanism***

*associated with the BMP-2 signalling pathway for osteoblast differentiation.*

### Syntactic Transformation

#### Independent clause of a compound sentence

*The ingestion of fluoride affects more than one aspect of this system, with the principal effect being porous enamel.*

→ *The ingestion of fluoride affects more than one aspect of this system, **but the principal effect is enamel porosity.***



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# Medical Writing Humour

## Cover letters and “Arctic monkeys”

We ended our recent *Intensive Medical Writing Course* at Copenhagen University with a session on cover letters.

Writing cover letters can be a hassle, and the result is often uninspiring. During the course, we do our best to provide practical tips, concrete examples, and – not least – inspiration. We show the students a sample cover letter to give them an idea of appropriate length, style, and structure, and we also present a list of useful vocabulary, standard phrases, and inspirational extras.

After providing tips and examples, we ask the class to complete the following:

“We believe our work would be of particular interest to the readers of *The International Journal of Convincing Research* because...”

First, our students write individually. Then they split into small groups, where they read out their texts. Finally, one text from each group is chosen and is read out to the whole class.

There were many excellent suggestions, but we were all agreed that Tin’s good humoured “Arctic monkeys” text beat the others into the ground. Tin successfully incorporated many of the ideas and phrases we had previously introduced:

- We are pleased to submit this manuscript to be considered for publication in ...
- We used state-of-the-art techniques ...
- This work dramatically alters our current concepts of ...
- As far as we are aware, this is the first study ...
- Unexpectedly ...
- However, we do not consider these to be “negative” data ...
- This manuscript is original work, has not been published before, and is not being considered for publication elsewhere either in printed or electronic form.

Experimental Unit  
Institute of Convincing Science  
January 23, 2020

**Dear Dr Editorian,**

We are pleased to submit this manuscript titled “Aerial Primate Experiment: APE” to be considered for publication in your journal.

We believe our work would be of particular interest to the readers of *The International Journal of Convincing Research* because we used state-of-the-art surgical techniques to transplant wings onto monkeys, finally allowing primates to soar freely through the skies. This work dramatically alters our current concepts of their preferred breeding and hunting grounds. Surprisingly, 12 monkeys migrated to the North Pole, turning the cold lands into their new habitat. This band of monkeys was later labelled the “Arctic monkeys”.

As far as we are aware, this is the first study about the migratory behaviour of aerial primates. The fact that monkeys choose to traverse oceans when given the opportunity contrasts with previously published data on their migratory behaviour.

Unexpectedly, none of our study subjects managed to leave Earth’s gravitational field and fly off into space. However, we do not consider these to be “negative” data, and we can conclude that the sky *is* indeed the limit.

This manuscript is original work, has not been published before, and is not being considered for publication elsewhere either in printed or electronic form. Thank you for considering our paper for publication.

We look forward to hearing from you.

Kind regards,

**Tin-Quoc Nguyen**

### SECTION EDITOR



**Phil Leventhal**

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- Thank you for considering our paper for publication.
- We look forward to hearing from you.

After Tin read out his text, the students went off in high spirits, eager to get back to writing (and revising) their articles and cover letters!

### Suggested reading

Møller C. New medical writing course in Copenhagen: Increasing chances of publication for non-native speakers. *The Write Stuff*. 2007;16(1):8–9.

Langdon-Neuner E. About cover letters for manuscripts submitted to biomedical journals. *The Write Stuff*. 2010;19(3):184–7.

### Acknowledgement

We thank Tin-Quoc Nguyen for allowing us to share his “Arctic monkeys” cover letter with members of EMWA.

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# Out on Our Own

## Welcome readers,

We are in an era where information is at our fingertips. If we need answers to our questions, we head straight to the internet and can come up with a search response within milliseconds. Usually, among the endless list of links, there are blogs, podcasts, videos, and YouTube channels to offer more creative explanations. At the last FBE, there was a table discussion on blogs and social media for medical writers. It soon changed into discussing YouTube channels when our author of this issue,

Dr Karim Montasser (also editor of the Veterinary Medical Writing section) who was running another table discussion, joined forces and shared his own experience on the topic.

It is more apparent than ever that podcasts, blogs, and YouTube channels can be hugely beneficial for medical writers. In one way, as Karim explains and Diana Ribeiro wrote in her article “Sound, microphone action: Podcasts for medical writers” in the December 2019 issue of *Medical Writing*, medical writers can assist others when setting up scientific podcasts and videos,

or they can set up their own channel, as Karim has done himself. On the other hand, as time is so precious, especially for freelancers working on an hourly rate, finding the information about a specific topic has never been easier with these scientific and medical channels available.

If you’re tempted by the digitalised world of communicating science then read on, follow the links, explore the podcasts that Diana lists and get yourself a YouTube channel or blog page.

Laura A. Kehoe

## How many medical writers do you need to film a video?

I promise I will give you an answer to that question and it won’t be a lame joke. But first, let’s say you quickly want to find out how to get air into your bike with a Presta valve (it’s infuriatingly hard). Or you would like to hear what a baby koala sounds like (it’s adorably cute). Chances are that your internet search will be directed to a YouTube video. If you are under 35 years old, we can delete the word “chances” and move on to certainty. I won’t bore you with numbers explaining the metrics behind YouTube’s success. Suffice to say, it is the second largest search engine in the world just behind Google, which of course both belong to Alphabet Inc., and amounts to 10% of all internet traffic.<sup>1</sup> If you are producing video content and would like a large number of people to see it, this is where you go.

more than 10 million subscribers “Kurzgesagt – In a Nutshell”<sup>2</sup> is the largest German channel. They cover scientific topics illustrated through animation. The most prominent example in the #sciencefluencer sphere is “Mailab”<sup>3</sup> with over 500,000 subscribers, in which a former chemistry scientist explains different scientific topics in the form of video essays. People seem to be genuinely interested in learning more about science. That is remarkable in itself, isn’t it?

What do these two channels have in common besides their popularity? They belong to a network called “funk” (the German word for wireless transmissions, not the funky funk), which is funded by the German government. Granted, only a few of the 75 channels of funk delve into scientific topics, still, there seems to be a rising awareness of the need for communicating science to the public in new and easily accessible ways.

science.<sup>4</sup> While specific measures are still vague there seems to be an understanding that scientists need to speak up to counteract fake news and their maimed friends. More grants for science communication seem to be close.

Meanwhile, more and more scientific publishers also want to make their papers accessible to a lay audience through video abstracts. One recent example is a paper called “Deconstructing climate misinformation to identify reasoning errors”<sup>5</sup> in which the authors deconstruct logical errors to inoculate against fake climate news. In their wonderful video abstract, a couple argues about whether climate change is real in a restaurant when the authors drop in to explain reasoning errors. You will find the link in the references or you can just google the paper title. It is worth it, and I will wait for you.

## Science channels on the rise

Video seems to be preferred over plain text. While this has been true for a decade now, only in the past couple of years one specific type of content has gained traction. Yes, the biggest channels in the world cover gaming, lifestyle or music. But in the past years, we see more and more channels that cover scientific topics among the major league. With currently a bit

## Funding is imminent

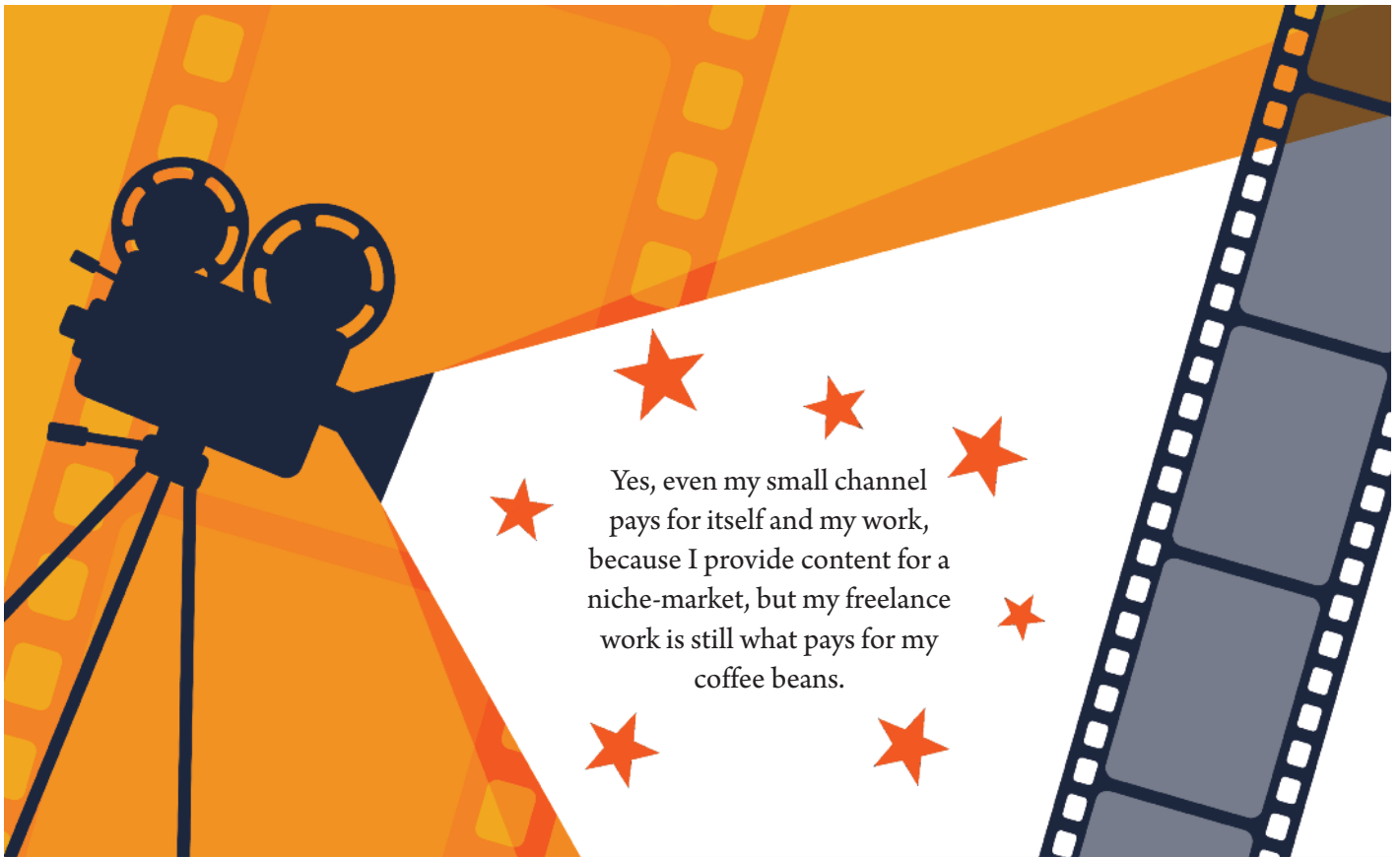
The German government not only pays for a few YouTube channels but just this year the German Federal Ministry of Education and Research released a policy paper underlining the importance of communicating

## What does it take?

Oh good, you are back. It’s a very entertaining video, isn’t it? To produce such content, we need a few things:

- A thorough understanding of videography
- Videography equipment
- An even better understanding of the topic of the paper
- A creative idea to bring the message across

I will not go into the first two points because I would run out of space quickly. Videography is



Yes, even my small channel pays for itself and my work, because I provide content for a niche-market, but my freelance work is still what pays for my coffee beans.

hard. But it is also very fun. If you want to learn more about it you can find excellent tutorials on, you guessed it, YouTube.

The third and fourth point sound familiar though. This is what medical writers in MedCom do every day the whole day. I would argue that after we get a few videography tutorials under our belt, we are perfectly equipped to bring science to the people through video. We understand medicine, we can bring key messages across in an entertaining way without distorting the facts, all we need to do is swap a keyboard for a camera.

### So, how many medical writers do you need to film a video?

The answer to my initial question is: just one. It's you.

I started a channel in 2018 about evidence-based veterinary medicine called "Der Tierarzt"<sup>6</sup> and like most YouTubers, I am a one-man show. This means I do the research on a topic like "Does dry-food kill my cat?" (no, it doesn't), write a script, do lighting-, video- and audio-setup, film and edit the footage, upload it and stay in touch with my viewers in the comment section and on Instagram and Facebook. I do a veterinary podcast called "Breaking Vet"<sup>7</sup> and am a fully booked freelance medical writer as well. This is a

lot of work, but if you are as organised as I know most medical writers are, you can do it.

Why would you do that, you ask? Well, it's certainly not for the money. Yes, even my small channel pays for itself and my work, because I provide content for a niche-market, but my freelance work is still what pays for my coffee beans. There are two reasons to get into science videos right now. First, medical writers are not only capable of communicating science to a lay audience, but I would also argue we are obliged to, we are the link between science and the public and our planet needs us to quote a famous caped hero. The second reason is a more economic one: Video abstracts will be in high demand in the very near future. Having experience in the field will be an asset for any MedCom writer and something you can put onto your résumé.

Thanks for watching, if you are interested in finding out more about video abstracts or science on YouTube, click the like button, make sure to subscribe and write a comment ... or send me an email.

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2. Kurzgesagt – In a Nutshell. Available from: <https://www.youtube.com/user/Kurzgesagt>.
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6. Der Tierarzt. Available from: <https://www.youtube.com/dertierarzt>.
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# Upcoming issues of **Medical Writing**



**June 2020:**

## **The data economy**

In an increasingly digitised world, data are economic assets that are becoming the lifeblood of the world economy. Medical writers need to know how the data economy affects the development of healthcare products and should understand which big data repositories are reliable, the specialised data analysis approaches needed, and the issues around big data protection. Guest Editors: Raquel Billiones and Sam Hamilton



**September 2020:**

## **European Union regulations**

This issue will focus on new EU regulations and their impact on medical writing. Key topics will include changes to centralised procedures, effects of Brexit on the EMA, and new regulations on medical devices, drug-device combinations, and veterinary medicines.

Guest Editor: Ana Madani

**The deadline for feature articles is June 10, 2020.**



**December 2020:**

## **Writing for patients**

This issue will feature articles from some of the key opinion leaders in the area of writing for patients. We will cover aspects such as the current state of information given to patients and how we can do this better, the role of the medical writer with patient associations, the patient voice in research publications and writing up patient-reported outcomes, writing for the internet, and how patient needs are being incorporated into traditional medical communications.

Guest Editor: Lisa Chamberlain James and Amy Whereat

**The deadline for feature articles is September 8, 2020**

### **CONTACT US**



If you have ideas for themes or would like to discuss any other issues, please write to [mew@emwa.org](mailto:mew@emwa.org)



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