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.

All authors contributed equally to this work.

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).[1] 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).[2] 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.[3] 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.[4] 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

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.

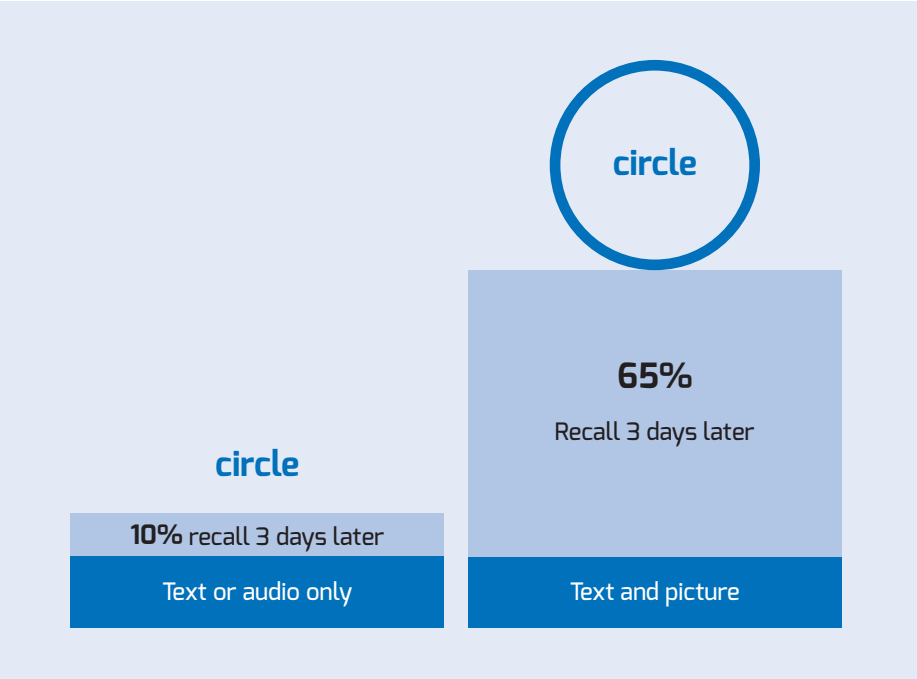

Figure 1. Picture superiority effect: images are recalled better than text or audio alone

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.

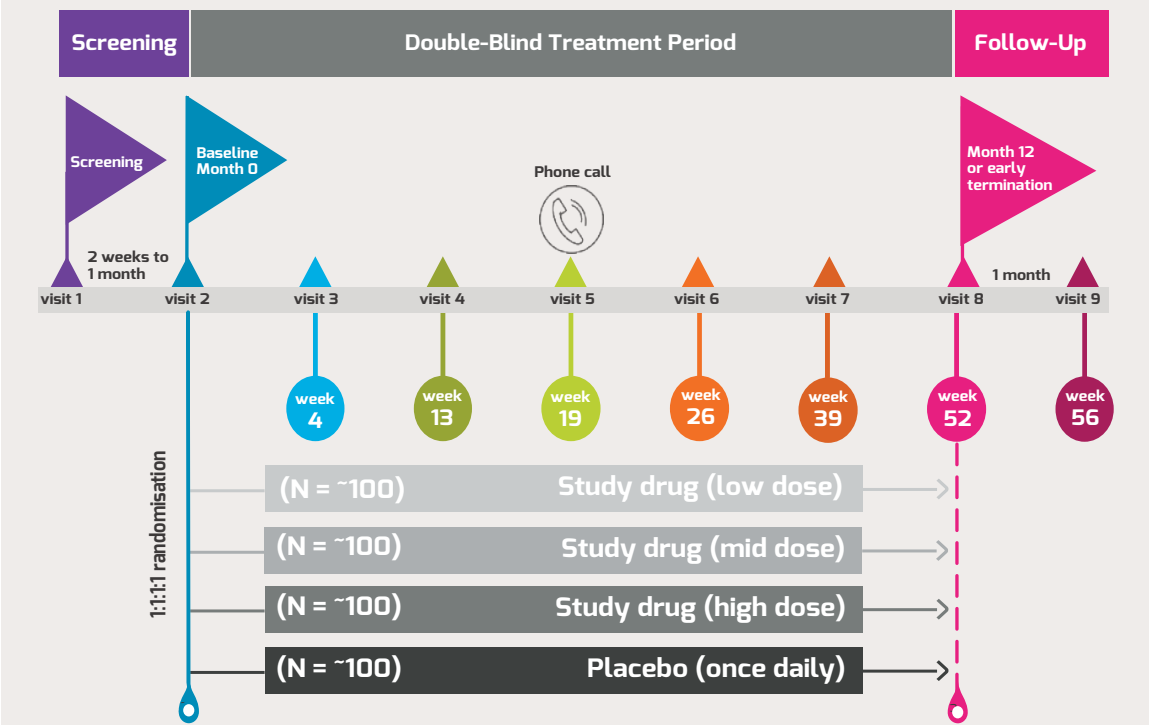

Figure 2. Study schema of a fixed-duration, double-blind placebo-controlled study

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.[5] 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.

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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

Figure 3. A sample collection of medical icons

Source: SVG Repo[6]

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

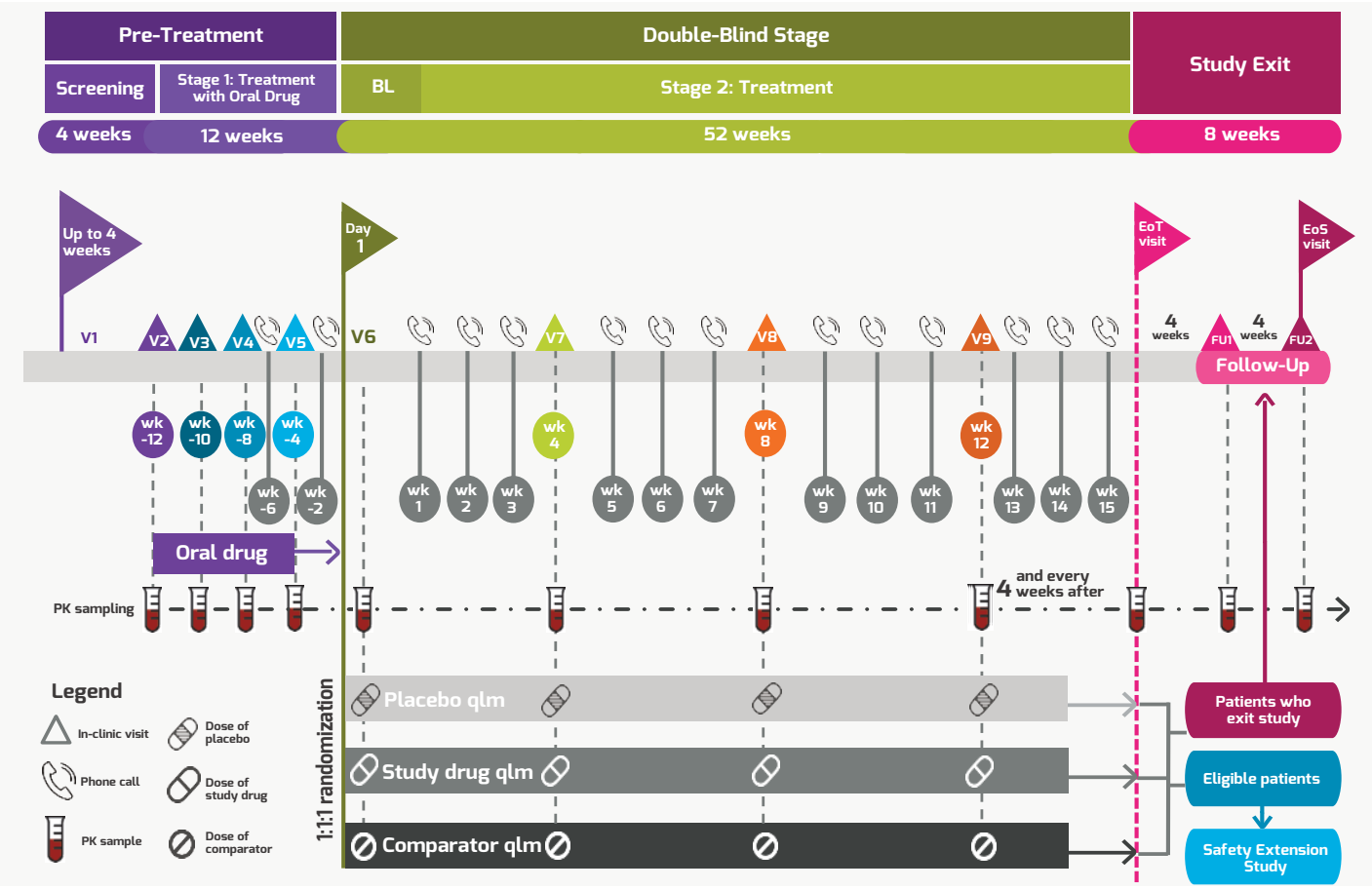

Figure 4. Study schema of a double-blind, placebo-controlled study evaluating the study drug vs placebo and a comparator after initial treatment with oral drug

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

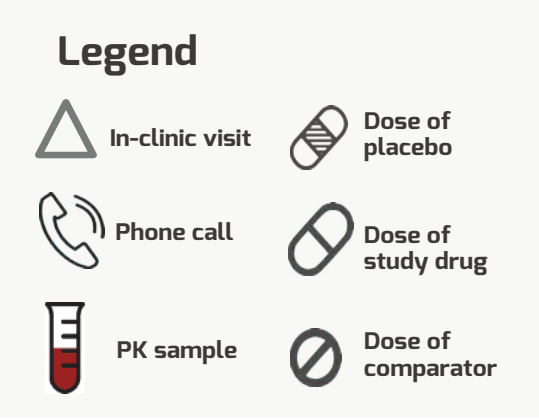

Figure 5. Double-encoding: labelling the icon makes it less ambiguous

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

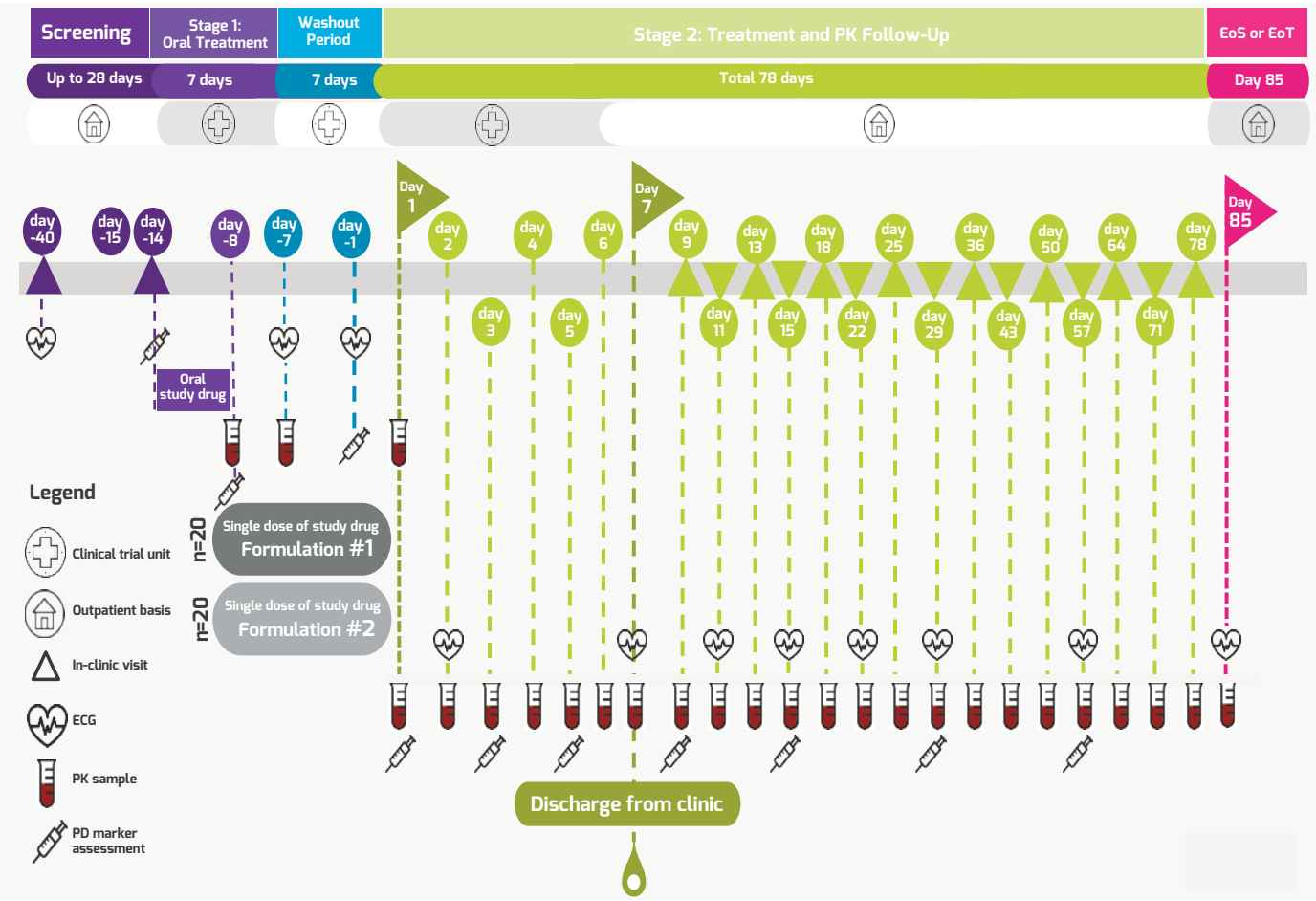

Figure 6. Study schema of a phase 1 study with an oral treatment period, washout, and randomisation of patients to two treatment arms investigating two different study drug formulations

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".[7,8] 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:[9]

- **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 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.

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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