Creating educational materials about clinical research data for patients and the public: A multifaceted journey in the current digital age

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Abstract

With scientific advances during the COVID-19 pandemic and expansion of artificial intelligence (AI) in research, there has been a simultaneous increase in misinformation about data collection, privacy, and sharing in clinical trials. This increase has been compounded by general mistrust in the clinical research industry partly because of problematic practices, such as data manipulation, withholding of safety information, and inaccurate or even non-existent results reporting. All these issues contribute to the public, patients, caregivers, and even healthcare professionals being inadequately informed about clinical research and related data usage. Through transparency, clarity, and honesty, trust can be rebuilt. Recognising the clinical research landscape has changed over the last decade and that currently available information is not developed or formatted in ways that can be easily understood, we describe creating widely accessible videos and infographics to support data literacy, utilising the most recent tools and technology for content development and dissemination.

The use of, and reliance on, artificial intelligence (AI) in technologies has grown, increasing the focus on data privacy and the individual's right to their data.[1] In 2023, 81% of U.S. adults reported concern about how companies use their data, while 67% reported having little-to-no understanding about what companies do with their data.[2] Given that clinical research necessitates the collection of personal data, it is important to address this tension by promoting education and trust through data literacy initiatives.

Data literacy is a term that describes an individual's ability to read, understand, and utilise data to inform their decision-making.[3] While health and research-related information have greater data protections than other data that are collected from and about people, there justifiably exists a heightened sensitivity about data privacy and data sharing in the health and medicine context.

Beyond the challenges presented by the introduction of new technologies related to data collection and use, there is a general mistrust of clinical research. The COVID-19 pandemic escalated misconceptions and misunderstandings about clinical trials[4–6] and highlighted the importance of access to clear, understandable, and trustworthy information. Confusion and misunderstanding can introduce fear and mistrust and create barriers to participation in clinical research. Conversely, education and clear communication about data use and protections can support participation.

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Patients and participants need timely, clear information to decide whether to join, and stay in, a clinical trial; they need reassurance that their data will be used only as described in the informed consent document. Therefore, print and electronic materials that use language and imagery that is understandable and familiar, and are linguistically and culturally appropriate, are needed.

The data literacy collaboration between PHUSE and the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard, offers a series of informational videos and complementary infographics that explain, in plain language, the clinical research process, and focuses specifically on what happens to data that is collected during a research study. The collaboration shared the goal of making accessible data materials available to patients and the public, especially those being introduced to research for the first time.

PHUSE is an independent, nonprofit organisation run by a worldwide team of volunteers providing the healthcare industry with a platform for open-access knowledge sharing of ideas, tools, and standards around data, statistics, and reporting technologies. Responding to societal misinformation and misconceptions

about clinical trials during the COVID-19 pandemic,[4–6] PHUSE initiated a collaborative pilot project[7] in 2021 to produce engaging educational content, organised into logical sections, as short, animated videos of approximately 3 to 5 minutes each.

The MRCT Center is a research and policy centre dedicated to the ethics, regulatory environment, and conduct of multi-site, multinational clinical trials. One focus has been health literacy,[8,9] including a Clinical Research Glossary[10,11] that provides plain language definitions of complex clinical research terminology. The MRCT Center developed an informational brochure series, designed in plain language, to complement the PHUSE video series.

In this article we describe the process of creating an informational video series and complementary infographics designed to explain clinical trials and data collection, explicate the critical importance of data, and clarify how clinical research data are used, shared, and protected.

A patient's perspective

"Multi-modal materials are extremely important for the patient community as they cater to different ways of processing information, different literacy levels, and different target audiences. Accessibility of information is crucial for ensuring equitable opportunity to improve health literacy, as well as increasing awareness and understanding about different aspects of clinical research, such as data science. Most importantly though, these projects are co-created with patient advocates and patient groups. Creating any resource that is linked to clinical research is not only about the content, but also about using the right tone, plain language, and appropriate format, especially when addressing topics that are complex to understand. Additionally, involving patients in the development of the resources helps to widen dissemination, as they share the resources with their own communities and through their own networks."

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PHUSE informational data literacy video series

Since its inception, the PHUSE pilot project[7] has united multiple stakeholders, including international representatives of the pharmaceutical industry, patient advocacy, and academia to develop videos that describe the foundational

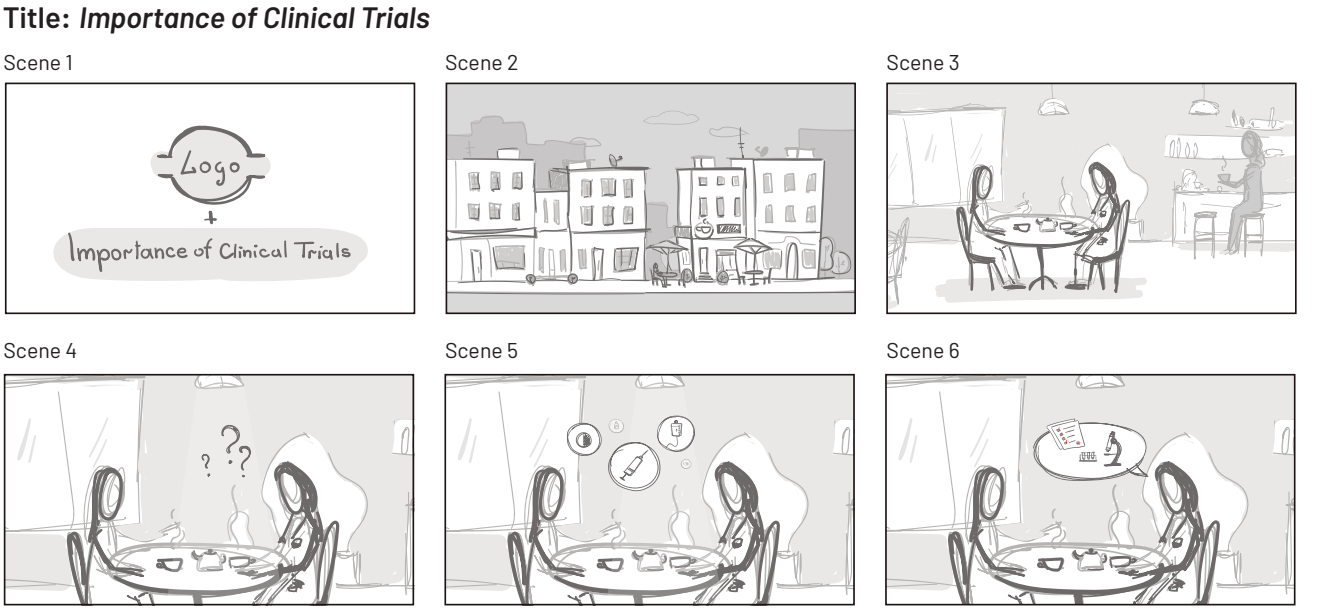

Figure 1. Example of black and white sketch drawings based on the script

concepts of clinical trials and more complex topics, such as what happens to research data.

Approaches to creating the video series

Content delivery and organisation

A video format was chosen as an engaging and accessible method for delivering content in plain language. The videos build in complexity and are intended to be watched in sequence, though each video (listed below) can also be viewed independently of the others.

- Video 0: *Introduction*
- Video 1: *Importance of Clinical Trials*
- Video 2: *What Will I Receive and When Will I Receive It?*
- Video 3: *What is Clinical Data?*
- Video 4: *Journey of a Data Point*
- Video 5: *What is Data Sharing?*
- Video 6: *What is Data Privacy?*

As of June 2024, three videos have been released (Videos 0, 1, and 2).[12]

Content and video development

The process to develop and share the content consisted of 5 steps (described below).

1. Scriptwriting
2. Audio considerations
3. Illustration and storyboard creation
4. Video animation and audio-visual integration
5. Dissemination

1. Scriptwriting

The project team started by brainstorming ideas alongside patient advocates' feedback. The script uses first-person dialogue and contractions to create a conversational tone and personable, open, and approachable setting for answering questions.

Precise word choice and concise sentences convey complex concepts clearly and technical terminology is explained within the conversation. For the videos, the project team decided to use the words "trial" and not "study" consistently and to repeat the terms "safe" and "effective" as these underpin the main objectives of clinical trials.

A draft script was reviewed by the project team, shared with PHUSE leadership, and amended based on feedback. Before sending the proofread script to the videographer, the project team highlighted part of the script for keywords to appear as bold on-screen to emphasise important words and phrases.

2. Audio considerations

The project team used a survey to reach consensus for selecting a human voiceover actor. The videographer obtained the voiceover recording from the selected actor and the project team reviewed and approved.

The project team tested AI voiceovers to reduce the financial cost of using human voice actors. AI was tested both because the videos were long and complex, making them more expensive to produce, and because of the potential benefits for choosing a character, voice, and translation in additional languages beyond English.

Through numerous rounds of review and changes to tone and empathy, using AI was proving to be more challenging than expected. Concerns included the voice sounding impersonal and robotic, and the presence of delivery issues (e.g., lack of pauses, too fast, and strange intonations and inflections).

Following discussions with patient advocacy groups and understanding the patient perspective in relation to AI, the project team

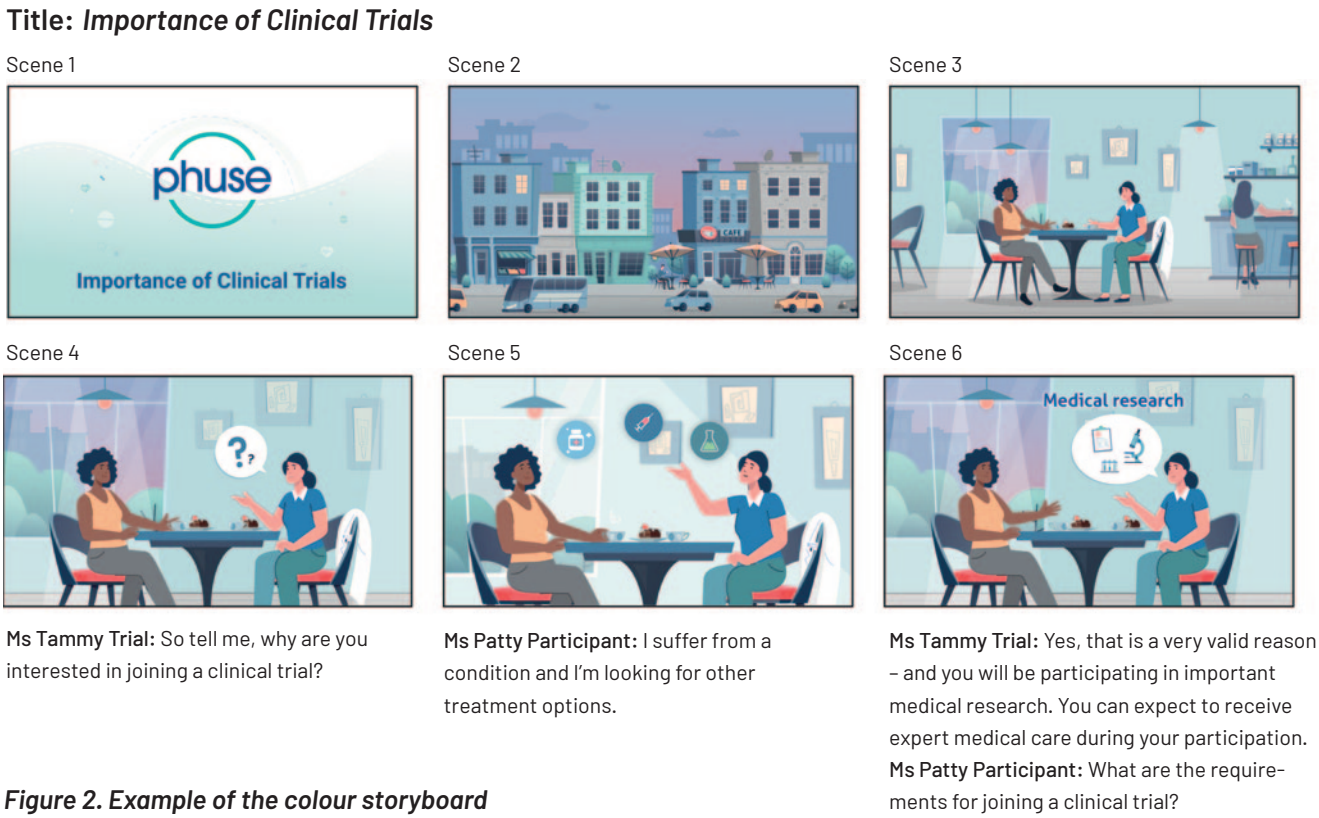

Figure 2. Example of the colour storyboard

decided to return to human voiceovers. Currently, the AI outputs do not sufficiently model the natural empathy, tone, and contextual understanding that is reflected in organic human voice speech.

3. Illustration and storyboard creation

This process started with the videographer developing black and white sketch drawings based on the script to support understanding (see Figure 1).

After project team review, the storyboard was provided as colour images, showing how the characters and images should look in the video when paired with the approved script (see Figure 2). The industry-standard animations were suitable for use in public-facing healthcare materials to cover a wide range of audiences and age groups.

Project team amendments were implemented by the videographer. For example, facial expressions were added for each character to reflect a range of emotions, as a common concern for patients is that many digital materials do not reflect the complex emotions and concerns people have about clinical trials. For Video 2 onwards, the "Ms" titles were removed from all character name labels following project team feedback around less prescriptive gender identity.

4. Video animation and audio-visual integration

For the animation, character movements and background images were prepared first, together with the integration of voiceover. The project team assessed if additional pauses needed to be included in the speech given the complexity of the information being presented and to provide the videographer with specific timepoints for where these should be included. Facial movements were added to the animation before finalisation of video together with patient advocate feedback. A running transcript was provided alongside the video while both characters were talking, and key words appear as prompt boxes.

5. Dissemination

PHUSE uploaded the approved video to YouTube, created social media posts, and e-mailed communications to the wider PHUSE Community.

Additional considerations

As of the writing of this article, the first three videos are complete, feature two primary characters that present as female, one black and the other white. As the project has evolved, there has been increased focus on ensuring the videos are representative of different populations, especially those who have been historically minoritised. Future videos will introduce new characters with other diverse backgrounds and ethnicities.

MRCT Center data literacy infographics

The MRCT Center joined the PHUSE project team in 2023 to collaborate on creating simple one-page printable infographics about research data collection, management, and use. These are complementary to the PHUSE video series and can be downloaded, saved, and printed for easy in-person access and dissemination, where technology may be limited. An infographic can deliver memorable and concentrated information on one specific topic in a digestible way using simple text, graphics, and a diversity of characters to promote engagement, comprehension, and retention.

The creation of the data literacy infographics was informed by the MRCT Center's experience developing a related resource, the Clinical Research Glossary[11], which provides measured

amounts of focused and accessible information. The infographics explain what data are, why a participant's data are important in clinical research, and how data are protected. Like the PHUSE videos, the series is intended as an educational tool to inform the public of the significance of research, while also empowering and destigmatising participation in clinical research.

Approaches to creating the data literacy infographics

Content delivery and organisation

Since PHUSE was creating videos, the MRCT Center led the production of educational materials that could be used in settings where video use may not be possible or appropriate, and a printable infographic could be helpful.

Five infographics cover key questions about research and data:

- *Infographic 1: Your Data, Your Information:* defines data and provides an elementary overview of the significance of data to research.
- *Infographic 2: What happens to data during a research study?* reviews the life cycle of data during a clinical trial, from data collection to data analysis.
- *Infographic 3: What happens to data after a research study?* explains the importance of saving data and how that is accomplished.
- *Infographic 4: What is a data repository*? defines data repositories and their role in advancing science through aggregate data collection.
- *Infographic 5: What happens to your data when you leave a study early?* provides an overview of what can happen to data after withdrawal of consent, discontinuation of interventions, or termination of a study.

Content and infographic development

The process to develop and share the infographic content consists of 4 steps (below), each of which will be further described.

1. Scriptwriting
2. Graphic design
3. Translation
4. Dissemination

1. Scriptwriting

An infographic was developed whenever a concept mentioned in the PHUSE video series was not only complex but critical for participants to understand. The infographic content was developed to be clear, simple, and in plain language, and reviewed extensively by the project team, including subject matter experts, patients, and participants. The first goal was to immediately engage the reader, making use of the human tendency to process most efficiently the first half of the page when viewing information and help encourage reading further down the page.[13,14]

Each infographic addresses its topic through informative subheadings and bullet points. Sentences are constructed to be clear and concise, using an active voice to decrease ambiguity, and using a second person to directly address the reader. As is customary in infographics, sections are short so the reader can absorb the information without trawling through dense text.

2. Graphic design

Graphic designers were utilised in the graphics development phase and were asked to follow the same general style as the PHUSE videos. Characters were created to represent a diverse range of audiences to reiterate that clinical research is for all people and not just one group. The text was distributed evenly across the layout from left to right and top to bottom to reflect the reading direction of English speakers. Bold font and italics were used to highlight key terms and concepts and blank space was introduced to ease the reading experience.

Text was divided into 3–4 digestible sections, and imagery was designed to complement the infographics' objectives to aid understanding and support viewing either online or as a printout.

The MRCT Center's graphic designers objectively developed the materials for varying visual ability levels by testing for colour contrast, using legible fonts, and ensuring suitable font sizes. Imagery was developed with the intention of depicting research as a positive social good, with the purposeful focus on using diverse characters and avoiding any potentially fear-inducing or dehumanising icons (e.g., drills, needles, test tubes, etc).

3. Translation

The infographics were initially developed in English. Prior to translation, a multi-variable assessment was conducted that focused on the target audience and intended reach. Latin American Spanish was chosen, and additional languages will be considered in the future. The English-to-Spanish infographic text translation process begins when the text is first exported and translated using an online instant translation platform (Google Translate). The English text and its Spanish translation are then sent to an MRCT Center bilingual translation partner who back-translates the text, edits, and confirms the accuracy of the translations. The edited and confirmed translated text is then used to produce the translated infographic.

4. Dissemination

The infographics will be available on the MRCT Center and PHUSE websites. A QR code will be included to facilitate access to all materials in one location. Disseminated file formats will include PDF to allow for text search function, PNG to optimise image quality for electronic sharing, and JPG to optimise image quality for printed infographics.

Video and infographic feedback collection and user testing

A process involving feedback collection, response documentation, and comment resolution has been implemented for both the data literacy videos and infographics (see Figure 3).

An important consideration was to ensure the audience remained engaged. The audience can pause and repeat sections of a video to support learning, particularly when complex and sensitive topics are discussed. As a result, the project team included a variety of images, highlighted key words, and added short pauses between concepts to allow the audience to digest and assimilate words, audio, and visuals. After the release of the two pilot videos, strategic user testing[7] was conducted through the PHUSE Community Forum as a live comment and feedback discussion, to ensure future video content aligns with audience needs and to determine the direction of subsequent videos.

It was important to engage with key partners who represent a range of knowledge of clinical trials and data literacy when the MRCT Center team determined which topics should become infographics, what information to share on the topics, and how that information should be described and depicted graphically. Brainstorming the infographic content was collaborative and involved significant participant review. Formal feedback was collected three times throughout development:

1. After initial text content generation
2. After the initial graphic layout was produced

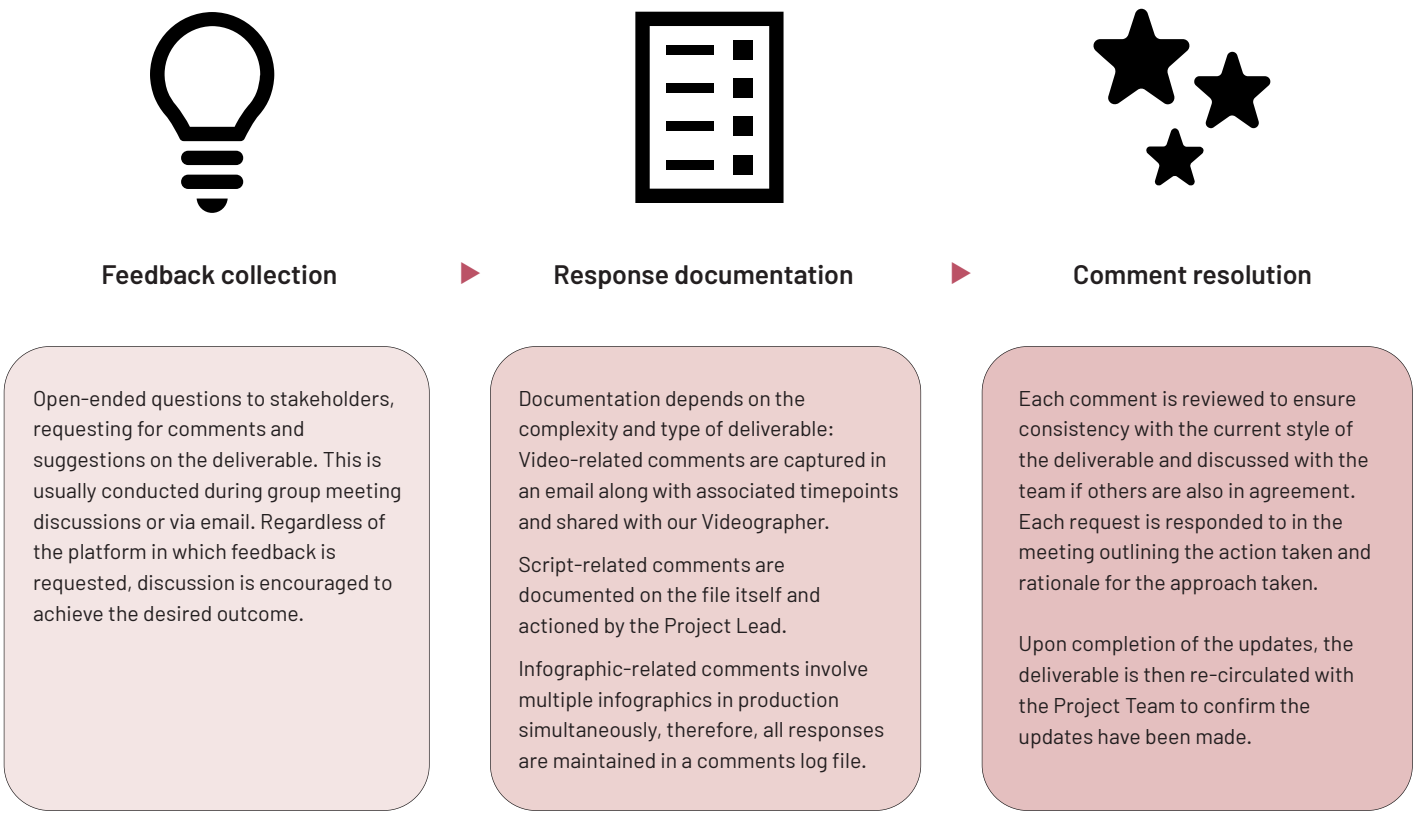

Figure 3. Feedback process for videos and infographics

3. After all the feedback has been reconciled and the infographic is considered complete

Our recommendations

Our efforts to create data literacy videos and infographics have reiterated the importance of engaging key stakeholders and performing user testing early in development, to gain feedback and understand what the audience already knows, the questions they may have, and how to convey these points in effective, patient-centric ways. Although integrating essential changes have at times lengthened the development timeline, the investment is worthwhile, as the content cannot be easily altered once released into the public domain. It is also necessary to balance the tendency to continuously edit, which has time and cost implications. Current plans are to include periodic updates into future deliverables as an evolutionary process of this project.

Finally, it is valuable to obtain feedback from different audiences across different contexts and different geographies. Having a wide range of perspectives allowed the project team to consider how to incorporate linguistic and cultural differences. For example, various options to depict travel to a research site that would resonate with the intended audience were discussed.

The limitations of this project include no language translation, a lack of low-and-middle-income country representation on the project team, and a focus that is predominantly northern/western hemisphere and high-income-centric. These factors are being continuously considered as the project evolves.

Conclusion

PHUSE and MRCT Center's journey to create easily accessible information through videos and infographics highlights the importance of clear communication, plain language, tone, and empathy, while honouring the fact that participants' data comes from individuals who care about participating, understanding what happens to their data, and protecting their privacy. In rejecting AI voiceovers, the human elements of patient-friendly materials were emphasised. Transparency, flexibility, and openness to collaboration with different stakeholders, particularly patients and their caregivers, help to ensure that content development is suitable, appropriate, and relevant for its intended audience. The videos and infographics are two examples of trustworthy resources designed with and for patients and trial participants. Both PHUSE and the MRCT Center welcome readers to share the content and contribute to this project going forward.

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Disclaimers

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

Disclosures and conflicts of interest

Trishna Bharadia is the owner of The Spark Global, a patient engagement and advocacy consultancy that undertakes paid work with multiple stakeholders in the life sciences industry, including pharmaceutical companies and CROs. She also holds a voluntary position on the Advisory Board for the Patient Information Forum. The author declares no conflict of interest.

The remaining authors declare no conflicts of interest.

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