Promoting equity in understanding: A cross-organisational plain language glossary for clinical research

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Abstract

Clear communication with the public and with potential clinical trial participants and their caregivers is foundational to the ethical tenets of respect, justice, and beneficence. However, health literacy, even of highly educated individuals, often declines when presented with complex content in unfamiliar contexts and in times of stress, all of which are characteristic of the types of situations people find themselves in when considering and participating in a research study. Here we describe an initiative to pilot the development of a cross-organisational plain language clinical research glossary to promote clarity, consistency, and transparency. The goal is to develop a common resource that can be used across clinical research stakeholder groups to increase understanding of clinical research and empower sound individual decision making.

Background

Clinical research is essential for the discovery of new treatments and medical interventions that advance public health and medicine. In order to participate in clinical trials, individuals voluntarily provide consent that is concordant with their personal values and intended to demonstrate that they understand and agree to be exposed to the potential risks and benefits of the proposed research. However, general understanding of medical and clinical research information is inadequate which is explained at least in part by the complexity of the information, coupled with low health literacy levels. Achieving adequate levels of health literacy is a global challenge, even in well-resourced communities: the European Health Literacy Survey found that about half (47.6%) of the respondents from eight countries have poor or inadequate health literacy.[1] In England, 42% of adults aged 16 to 65 years are unable to understand or make use of everyday health information[2] and in the USA, 36% of the population has a basic or below basic level of literacy.[3]

When health literacy is discussed and defined, it is typically presented as a problem of the recipient of the information, as opposed to a responsibility of the communicator to make themselves understood. In 2015, the World Health Organization, however, defined health literacy as "the personal characteristics *and social resources* needed for individuals and communities to access, understand, appraise, and use information and services to make decisions about health".[4] (emphasis added). This definition acknowledges that external circumstances impact understanding. Beyond an individual's health literacy level, comprehension can be impacted by the complexity of clinical research information, and the often unfamiliar and stressful contexts within which it is presented. Thus, those who are in a position to share information must ensure

they are communicating in ways that empower the recipient to make sound research decisions and take action. One resource that could support clear communication in the life sciences is a common plain language clinical research glossary that promotes clear, consistent communication with the public, potential and enrolled study participants, and their caregivers.

A number of entities, including government agencies, life sciences companies, health systems, academic institutions, non-profit organisations, insurers, and foundations, have developed health-related and disease-specific glossaries. These resources are generally designed for a more technical audience of scientific stakeholders, and even glossaries developed for the general public are focused on medicine and health, not research. While the US FDA has made an effort to use common language in providing regulatory guidance,[5] there is as yet, no common source of clinical research terminology designed for a non-research, non-scientific audience that can be used by stakeholders across the clinical development spectrum. In its absence, the public – including current and prospective research participants – may grapple with trying to comprehend similar terms that are used differently in different contexts by different research stakeholder groups leading to confusion due to the lack of consistency and clarity. For example, the terms *side effect*, *adverse event*, and *serious adverse event*, all have very specific regulatory definitions and significance; to a research participant, however, these terms all fall under the category of risks or "bad things that could happen to me" when participating in a research study. The clinical research enterprise should strive to decrease or eliminate the need for patients and participants to parse through the nuances of terminology and regulatory guidance in order to determine the personal significance of the presented information.

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Health literacy is a broad concept that includes the use of plain language and the clear presentation of numeric information (e.g., probabilities, statistics), design elements (e.g., layout, font, colours), and the use of audio-visuals (e.g., imagery, figures) to enhance clarity and re-enforce the message. These dimensions are a critical part of putting the Belmont Report's[6] ethical tenets of respect, justice, and beneficence into action and should all be considered in the development of clinical research materials for patients and participants.

Having recognised the need for a glossary, we are piloting the generation of a comprehensive, publicly available, plain language clinical research lexicon that is co-developed with patients and representative clinical research stakeholders. Envisaged to include explanations of terms and procedures frequently encountered in research – with accompanying graphical representations and descriptions, when applicable – such a resource would support the general public, including participants, to better understand clinical research.

There are a number of potential benefits of a common glossary for clinical research (See Table 1). First, as previously mentioned, the resource would be valuable to patients and the public because it would support understanding via consistent explanations that can support decision making. Second, it would improve accuracy and precision when generating public-facing research communications within and across organisations. Third, a reference plain-language lexicon would minimise barriers and increase the efficiency of creating understandable research communications that, in turn, would increase the likelihood of these documents fulfilling their intended purpose by reducing the waste associated with such issues as extended recruitment periods and participant attrition. Fourth, having common terms and usage can simplify the translation process and results in more consistent and understandable presentation of complex clinical research information in other languages. Fifth, the use of common terms would render natural language processing easier and support electronic interoperability. Lastly, demonstrably prioritising participant comprehension would increase transparency of research and contribute to building the trustworthiness of the entire clinical research enterprise, hopefully leading to increased access and, ultimately, better health outcomes.

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We turn now to a summary of the work that preceded the proposal for the creation of a clinical research glossary pilot and a description of the pilot project itself.

The proposed pilot

In 2017, the Multi-Regional Clinical Trials (MRCT) Center, a research and policy centre in Boston, released a guidance and a toolkit on the individual[7,8] and summary[9,10] research results. These projects identified the need for understandable communications, especially in the dissemination of study findings. Further, patient and participant feedback on prototype plain language summary examples demonstrated that written materials – even those created by individuals attentive to health literacy principles – required specific skills and experience. Subsequently, in 2018, a multi-stakeholder workgroup developed a comprehensive web-based resource on the integration of health literacy principles into the clinical development process that expanded clear communication best practices, beyond results communications, to include participant-facing materials used throughout the continuum of the clinical research life cycle. The resulting website, Health Literacy in Clinical Research,[11] was launched in the autumn of 2019. This work highlighted the need to create a common clinical research glossary of terms, described in plain language, that could be adopted by stakeholders across the research spectrum. While the website included a sample translation of several terms used in clinical research, the table was acknowledged to be incomplete. In the process of further developing a more robust set of terms, explanations, examples, and images, we learned of other groups within the life sciences industry, non-profit organisations, and data standards organisations that were either initiating, or interested in leading the creation of a comprehensive lexicon.

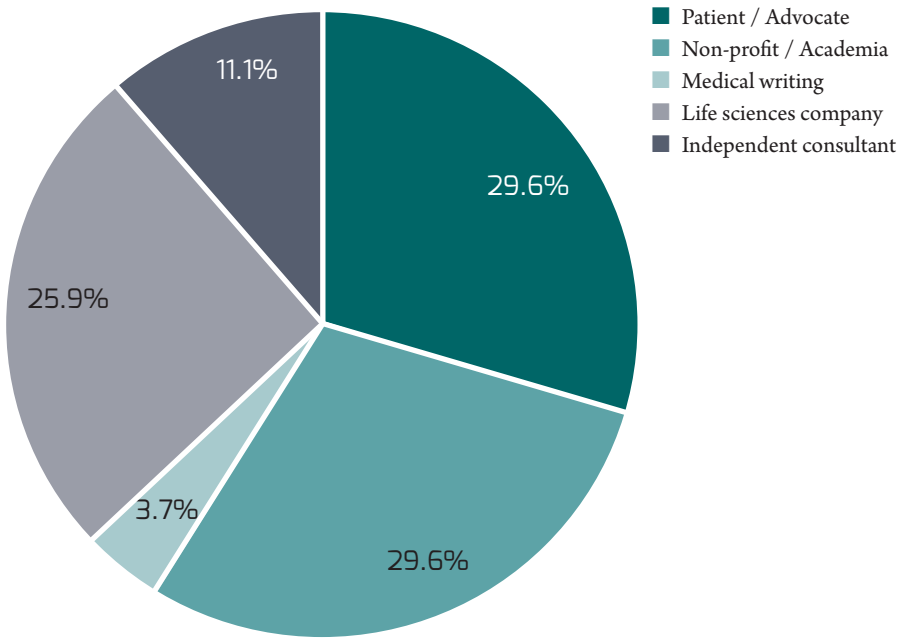

Figure 1. Distribution of clinical research representation (N=27)

Collectively, we realised the value of collaboration and that a common resource used within and across organisations would be most beneficial for the public.

With a team of committed cross-organisational stakeholders, the MRCT Center volunteered to lead a pilot initiative to determine the feasibility of co-creating a common, plain language clinical research glossary and research procedure resource. The pilot was thought to be a necessary first step to determine the feasibility of establishing a replicable process for the development of definitions and contextual explanations as a proof-of-concept before dedicating effort to a larger initiative. Further, a pilot would allow the team to determine the effort required, and assess the resulting resource's potential utility, before expanding the scope of the project.

To date, the preliminary work has consisted of an early landscape analysis of existing initiatives and glossary resources, refinement of the pilot scope, estimation of the necessary resources to accomplish the pilot, and, importantly, creation of partnerships with other individuals and organisations committed to the vision. The current pilot team includes representatives of the broader clinical research community, including patients and advocates, non-profit and academic organisations, life sciences companies, medical writers, and independent consultants (See Figure 1). Certain members of the group plan to develop the model terms while others will then serve as critical reviewers. The plan is to engage in iterative, rapid-cycle development until consensus is reached. The following stages are planned (see Figure 2):

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1. Build consensus

The pilot team will determine the feasibility of developing a process for defining terms (e.g., randomisation, blinding, placebo) and drafting research procedure descriptions (e.g., magnetic resonance imaging; pharmacokinetic study), considering that stakeholders may use different terms and explanations, and often have their own reasons for doing so.

This stage will include determining a process for reaching consensus and finalising the choice of terms and their definitions. The analysis will include an assessment of the challenges (including when consensus cannot be achieved) and methods that will contribute to successful completion of the pilot phase. In addition, the pilot team will determine how best to consolidate and harmonise terms that may have unique and/or technical regulatory definitions, but not necessarily a practical difference to study participants. The group will also discuss whether certain technical differences are important for or irrelevant to the participant (e.g., are there important, salient differences between an "event" and a "reaction"?). In addition, technical aspects, such as the format of the glossary, nomenclature, a research procedures guide, style of definitions, as well as inclusion of icons, imagery, and audio-video content (as applicable) will be discussed.

2. Establish governance processes

The pilot team will develop an initial draft of governance principles and a model for the glossary and research procedure resource, with respect to distribution, comment, approval, updates, and use of terms and explanations. Such a governance document will consider:

- Project management resources needed;
- Review of terms and existing definitions, descriptions, and graphics, if available;
- Allowance for adaptations or modifications of existing terms and their associated definitions and media;
- Creation and evaluation of plain language definitions;
- Timely curatorial oversight to coordinate and control future changes, including ongoing maintenance and updates;
- Attribution for use, if any;
- Copyright and other legal/licensing issues (e.g., how access will be provided, links to other websites, independent website, Creative Commons https://creativecommons.org/licenses/by-sa/4.0/).

The governance draft will then be reviewed and finalised by additional external stakeholders who will convene to oversee transition from and possible expansion of the project to a larger initiative.

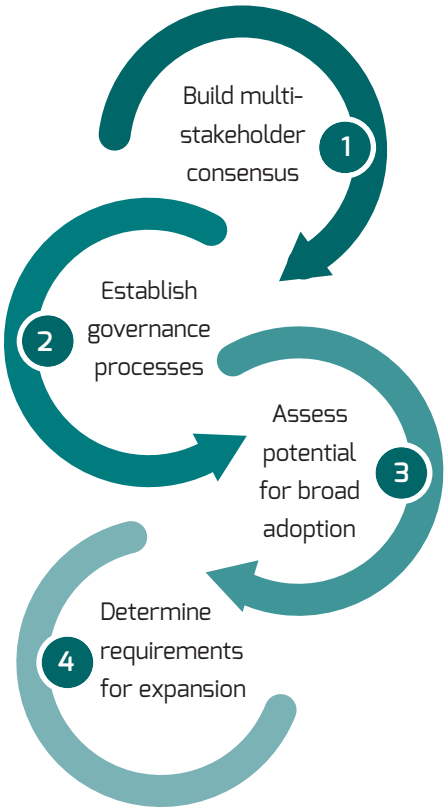

Figure 2. The four planned stages of the clinical research glossary pilot

3. Investigate the potential for broad adoption

The pilot team will explore receptivity for adoption of the proposed clinical research glossary within their organisations, as well as develop use cases for its integration into existing and newly-created policies and procedures. They will prepare recommendations for the need for, or benefit of, endorsement from advocacy organisations, foundations, regulatory, and professional groups in order to increase the likelihood of cross-organisation uptake of the glossary and research procedure guide. A plan for outreach will be developed if indicated. In addition, the pilot team will determine the anticipated format(s) and method(s) for communication and dissemination.

4. Determine the possibility for expansion

Finally, taking into account the lessons and conclusions from the preceding steps, the pilot

Table 1. Benefits realised through the availability of a harmonised plain language clinical research glossary

Benefit	Rationale
Consistency	A common lexicon will improve intra- and extra-organisational consistency throughout the communication process. It will also increase understanding/comprehension for patients and study participants who are comparing multiple trials from different sponsors.
Accuracy	Identical words are used in different ways at different times, and the explanations are not always correct, succinct, or understandable, leading to confusion or misconception. Information being presented to potential research participants and their families must be accurate and precise. This is best achieved through the adoption of definitions that have been co-created, reviewed, and user-tested by multiple different stakeholder groups including patients, resulting in a common understanding of the information presented.
Efficiency	Stakeholders currently define terms independently and differently, leading to inefficiencies and confusion. A common resource will improve efficiency in developing health-literate communications. These range from pre-study communications and those received at consent and enrolment, to those received at the end of a study and after commercialisation.
Ease of Translation	Having multiple terms for the same concept can negatively impact how well a term or concept can be translated into another language, and limit the development of accurate translation via artificial intelligence (e.g., Google Translate, Microsoft Translator) that must account for context. This is relevant not only to global clinical research studies, but also to diverse populations within countries, and to individuals for whom English is not their primary language.
Electronic Interoperability	A curated and coded glossary allows retention of the technical aspects and context of the explanation, will promote machine readable technologies, and expands the utility and interoperability of data.
Transparency	A common clinical research glossary supports clear communications, allowing potential and enrolled study participants to access information and to trust that information is complete and truthful.
Trustworthiness	Clear communications and working towards understanding and comprehension by the public, patients, and participants help support the trustworthiness of the research enterprise. Co-creation of a lexicon with patients and participants will assist in that regard.

team will determine the feasibility and resource needs of expanding the pilot to a comprehensive glossary that would include additional terms, research procedures, related images, and audio-visual formats. Again additional external stakeholders will review the summary recommendations and suggestions for refining the process and deliverables, and advise on scaling the project, including any necessary adaptations, and eventual dissemination.

Conclusion

Clear communication and understanding can potentially improve health outcomes. The development of a clinical research glossary and procedure guide using health literacy principles is needed to optimise public and participant understanding of complex terms in the context of low health literacy. We describe the planned pilot effort to test the development of such a resource. Collaborating as a clinical research community, we can communicate more effectively with patients and participants using shared terminology and visuals to describe common research concepts and procedures. Cross-organisational cooperation can promote transparency and, thus, increase the perceived trustworthiness of the clinical research enterprise. The results of the pilot will inform whether and how to expand the work beyond the initial scope of the pilot project to a larger, more comprehensive set of terms and procedures. The clinical research community must champion the creation of resources that provide the public – and research participants – with the opportunity to better understand the information they need to support values-concordant decision making.

Conflicts of interest

The authors declare no conflicts of interest relevant to this publication.

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