




Co-creation with research participants to inform the design of electronic informed consent

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Abstract

Objective: This study aimed to provide recommendations for a personalized electronic informed consent interface that is adapted to research participants' needs and could enable a longitudinal interaction between the participants and the research team.

Methods: The co-creation process consisted of three co-creation workshops, one focus group discussion, and four semi-structured interviews. In total, 24 participants, who had taken part in four disparate clinical studies in Belgium, were involved. Descriptive statistics and qualitative content analysis were applied to analyze the survey data and audio recordings.

Results: Varying perceptions on the type and amount of information described in an informed consent form were reported. Other findings were related to the structure and presentation of information, setting preferences for data sharing, and electronically signing new informed consent versions. Regarding the long-term interaction, most of the participants wanted to receive progress updates, including the results, of the study in which they had taken part. They proposed to receive a notification, preferably via email, in case new information is made available on the electronic informed consent interface.

Conclusions: To optimally support the design of an electronic informed consent interface, it is key to understand the research participants' needs. Study findings suggest that an electronic informed consent interface may be a promising technological application to interactively provide study-related information and to keep participants informed during and after the clinical study.

Keywords

Human-centered design, digital technology, clinical study, informed consent, user interface

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Introduction

The “*Global strategy on digital health 2020–2025*”, put forth by the World Health Organization, aims to facilitate the development and adoption of person-centric digital health technologies to promote citizen empowerment.¹ In the context of health-related research, electronic informed consent (eIC) may empower participants, by informing them according to their needs, to make a well-grounded decision on whether or not to participate in a clinical study.^{2,3} As described by the U.S. Food and Drug Administration, eIC refers to “the use of electronic systems and processes that may employ multiple electronic

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media, including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent".⁴ Moreover, eIC opens the opportunity to establish longitudinal communication between research participants and the research team.⁵ For example, participants could indicate which information they would like to receive during the course of the study.^{6,7} In recent years, there has been increasing interest in eIC applications. In 2017, TransCelerate, a nonprofit organization which aims "to collaborate across the global biopharmaceutical research and development community", issued guidance to facilitate the implementation of eIC in clinical research.^{8,9} Moreover, various for-profit and nonprofit organizations have developed or implemented such applications in clinical studies.^{5,10–13}

When developing technological applications such as eIC, it is of utmost importance to understand the end users' needs. Therefore, end users should be involved during the design process.^{14,15} Participatory design, defined as "a set of theories, practices and studies related to end users as full participants in activities leading to software and hardware computer products and computer-based activities", is considered a useful approach in the development of technological applications.^{16,17} Co-creation, a participatory design practice, refers to interactions between the end users and the researchers that aim to produce a mutually valued outcome, based upon a rich dialog. It has the potential to contribute to participant-centric technological applications by engaging participants in an innovation process.^{15,18} By focusing on the creativity, needs, and concerns of end users, an application can be co-constructed to suit its context.¹⁹

A systematic literature review and semi-structured interviews conducted with various stakeholders involved in clinical research, such as ethics committee members and investigators, revealed a general interest in eIC, as it allows for personalization of information and for ongoing communication with the research team.^{3,20} Yet, to design such a personalized and long-term eIC interface, investigating research participants' opinions would add a significant value toward a participant-centric eIC design. To this end, we used a co-creation process involving participants who had taken part in diverse clinical studies. The aim of this study was to co-create solutions regarding (i) how an eIC interface can be effectively personalized, based on the participants' needs and (ii) how such an interface can establish valuable longitudinal interactions between research participants and the research team.

Methods

General study design

To understand participants' views on how they would personalize the informed consent form (ICF) of the clinical study in which they had taken part and how they would

establish a potential long-term interaction, co-creation workshops were conducted. Each participant involved in a co-creation workshop is considered an "expert of his/her experience".¹⁵ By using tools for ideation and expression, participants are provided with an active role during the design process.^{15,21} The tools used during our co-creation workshops enabled participants to individually reflect on their needs which were then collaboratively discussed. In addition, a focus group discussion, not using the tools for ideation and expression since no individual preparation was required, and semi-structured interviews were conducted to enrich the data generated during the workshops.²² The original, paper-based ICFs of the clinical study in which the participants had taken part guided the discussion related to personalization. In doing so, participants were asked to reflect on study-related information they were already familiar with.

Participants and recruitment

Research participants were eligible to participate if they had taken part in a clinical study, ranging from a qualitative to an interventional design, and were at least 18 years old. Moreover, participants needed to be Dutch-speaking to allow for in-depth discussions during the co-creation workshops, focus group discussion, or semi-structured interviews. Participants were recruited by the research teams responsible for the clinical study. More concretely, recruitment was undertaken at Leuven, Belgium, by the KU Leuven Academic Center for General Practice, the KU Leuven Clinical Pharmacology and Pharmacotherapy unit, and the Center for Clinical Pharmacology at the University Hospitals Leuven. The recruiting parties provided an invitation letter to potential participants. Those who were interested in participating contacted the researcher (EDS). Informed consent (IC) was obtained from all participants prior to participation in the co-creation workshop, focus group discussion, or semi-structured interview. Afterward, the participants received a gift voucher. Recruitment continued until theoretical saturation was achieved, meaning that no new insights were emerging during data analysis.²³

Conduct and data collection

The co-creation workshops, focus group discussion, and semi-structured interviews took place between May and December 2021 and were conducted in Dutch via Microsoft Teams. The co-creation workshops and focus group discussion were about 3 h long whereas the semi-structured interviews lasted for 30–45 min. The conduct of these qualitative methods was moderated by the same researcher (EDS). In each focus group discussion and co-creation workshop, participants who had taken part in the same clinical study were involved. Moreover, all

semi-structured interviews were conducted with participants involved in the same study.

Prior to the co-creation workshop, focus group discussion, and semi-structured interview, participants received a survey by email. This survey aimed to sensitize the participants to the paper-based ICF of the clinical study in which they had taken part. By sensitizing the participants, we implicitly encouraged and motivated them to reflect on the content of the ICF in the light of their personal context.²⁴ This survey included a five-point Likert scale to evaluate the importance of each topic (e.g. the course of the study, study procedures, and potential benefits and risks) mentioned in the ICF. Participants were asked to score the information on the following scale: not at all important—not important—neutral—important—very important. In addition, the survey comprised questions regarding the participants' demographics (i.e. age, gender, and highest education level) and regarding whether the participant felt adequately informed for participation in the clinical study. The completed survey was returned to the researcher in the days leading up to the conduct of the workshop, focus group discussion, or semi-structured interview. At the start of each interaction, the researcher introduced herself, described the aims of the study, and emphasized that participants should not be concerned with technical or legal limitations, or limitations related to the paper-based format when suggesting new ideas or solutions.

Co-creation workshops. The co-creation workshops proceeded in two stages: the first stage focused on the personalization of the IC whereas the second stage focused on the long-term interaction between participants and the research team. In the days leading up to the workshop, participants were provided via email with the tools for ideation and expression, in the form of two worksheets (i.e. on personalization and on the long-term interaction). The worksheet related to personalization, used during the first stage of the workshop, included two questions for each topic mentioned in the ICF of the study in which the participants had taken part: (i) “How would the ICF better suit your needs?” and (ii) “Which additional information would you have required at the beginning or during the clinical study?”. During the workshops, participants were first asked to individually write their ideas or perspectives down, using the worksheet, after each topic described in the ICF. Subsequently, participants were prompted to share their ideas in group, which provided the opportunity to generate new ideas and to exchange experiences. As the paper-based ICFs discussed during the co-creation workshops were 12–27 pages long, the forms were divided into three or four parts. Hence, multiple iterations of the individual reflection and group discussions were performed. The second stage of the co-creation workshop focused on the long-term interaction between research participants and the research team. Using the second worksheet (Figure 1), participants were given an individual

Instructions

1. Choose and describe an aspect
2. Describe why you have chosen this aspect
3. Make a proposal of how you would integrate this aspect in an electronic informed consent interface

<div style="background-color: #d95319; color: white; text-align: center; padding: 2px 5px; margin-bottom: 5px;">1. Description of the aspect</div> <div style="border: 1px solid #4a7ebb; height: 30px; margin-bottom: 10px;"></div> <div style="background-color: #d95319; color: white; text-align: center; padding: 2px 5px; margin-bottom: 5px;">2. The reason for choosing this aspect</div> <div style="border: 1px solid #4a7ebb; height: 30px; margin-bottom: 10px;"></div> <div style="background-color: #d95319; color: white; text-align: center; padding: 2px 5px; margin-bottom: 5px;">3. Practical integration of this aspect</div> <div style="border: 1px solid #4a7ebb; height: 30px;"></div>	<div style="background-color: #d95319; color: white; text-align: center; padding: 2px 5px; margin-bottom: 5px;">Examples of aspects</div> <div style="border: 1px solid #4a7ebb; padding: 5px;"> <div style="display: flex; align-items: center; margin-bottom: 10px;"> Receive study results </div> <div style="display: flex; align-items: center; margin-bottom: 10px;"> Receive information on studies for which participants are recruited </div> <div style="display: flex; align-items: center;"> Indicate the research groups with whom your personal data can be shared </div> </div>
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Figure 1. Worksheet regarding the long-term interaction.

exercise to reflect on (i) the aspect(s) for which they would like to maintain contact with the research team during or after the clinical study, (ii) why they selected these aspects, and (iii) how they would integrate their suggestion(s) in an eIC interface. To clarify what a long-term interaction could entail, some suggestions, identified using the available literature, were provided in the worksheet (Figure 1).^{3,20} Participants were encouraged to come up with as many ideas as possible. Hereafter, their ideas were discussed in a group discussion. All group discussions were digitally audio recorded.

Focus group discussion and semi-structured interviews.

Similarly, during the semi-structured interviews and the focus group discussion, participants were asked to reflect on how the ICF of the clinical study in which they had taken part could be adapted to their needs and how they would like to establish a long-term interaction. Hence, similar to the co-creation workshops, participants were asked the following questions about personalization: (i) “How would the ICF better suit your needs?” and (ii) “Which additional information would you have required at the beginning or during the clinical study?”. Related to the long-term interaction, participants were asked to reflect on the tasks listed in the worksheet displayed in Figure 1. The ICFs discussed during the semi-structured interviews and the focus group discussion were those of qualitative studies and were two and nine pages long, respectively. The conduct of the semi-structured interviews was similar to the co-creation workshops, except for the group discussions. During the focus group discussion, participants did not make use of the worksheets as they did not individually prepare the tasks regarding personalization and the long-term interaction. The interviews and the focus group discussion were digitally audio recorded.

Data analysis

The data were obtained from the answers to the survey and from the audio recordings. Descriptive statistics were used to summarize participants’ answers to the survey questions. The audio recordings were analyzed according to the framework method.²⁵ The researcher (EDS) familiarized herself with the data by conducting the co-creation workshops, the focus group discussion, and the semi-structured interviews, and by transcribing the audio recordings verbatim. A combined deductive/inductive approach was used to code the first two transcripts. The worksheets related to personalization and the long-term interaction, as well as available research, informed the creation of deductive codes.³ Inductive codes were created based on observed patterns. Both deductive and inductive codes were grouped and subsequently, a preliminary coding tree was created (Appendix). This coding tree was applied to the other transcripts by using NVivo (released in March 2020) and was further refined. Afterward, the coded data were summarized into a

framework matrix and were then interpreted. Quotes were translated to English upon inclusion in this manuscript.

Results

Recruitment resulted in 24 individuals volunteering for the study. We organized three co-creation workshops ($n = 15$, of three, four, and eight participants each), one focus group discussion ($n = 5$), and four semi-structured interviews. Participants were recruited from four clinical studies, of which one was sponsored by a pharmaceutical company. The co-creation workshops included participants (i.e. healthy volunteers) who had taken part in an interventional clinical study about COVID-19 ($n = 12$) or migraine ($n = 3$). The focus group discussion and semi-structured interviews involved participants of a qualitative study about insomnia (i.e. healthy volunteers; $n = 4$) or inflammatory bowel disease (i.e. patients; $n = 5$). Participant demographics are displayed in Table 1.

Sensitizing survey

The survey, used as a sensitizing tool, enabled us to gain insights into the importance participants give to the information described in the ICF of the clinical study in which they had taken part. Overall, the majority of participants rated the information as (very) important. All participants considered information related to the course of the clinical study and what is expected from them (very) important. In

Table 1. Participant demographics.

Characteristics	Participants ($n = 24$)	
	<i>N</i>	%
Age range (years)		
21–39	13	54
40–59	4	17
60–75	7	29
Sex		
Male	15	63
Female	9	38
Education		
High school	3	13
Bachelor’s degree	8	33
Master’s degree	13	54

addition, the results indicate that all but one participant were sufficiently informed about the aspects of the study. The latter participant argued that the ICF, more than 10 pages in length, was too long to read and understand, and advised to include concise and well-structured information.

Personalization

During the co-creation workshops, focus group discussion, and semi-structured interviews, participants were asked to describe how they would tailor the ICF of the clinical study in which they had taken part to their needs. Their answers related to the type and amount of information, the structure and presentation of information, signing new IC versions, and data sharing and sample reuse.

Type and amount of information. Many participants mentioned that the ICF presented clinical information in an understandable manner. Nevertheless, some participants raised that the ICF was too lengthy, containing redundant information, and was not attractive to read. In addition, a few participants admitted that they did not fully read the ICF before signing it because of the trust they have in the research team. They were of the opinion that an ICF is primarily a legal document that must contain all study-related information, and thus, seemed to be an attorney's contract. As a result, it required efforts to read and to understand the (non-medical) information mentioned in the ICF. For example, each ICF contained information about data protection. The majority of participants indicated they did not pore over this type of information and mentioned that it would be mainly participants with a legal background who are able to understand this. Moreover, some participants mentioned that the legal information, for example, related to data protection, is not important to them.

The importance of information is dependent on the type of study in which I am taking part. If my blood samples would be collected, as part of an interventional study, I would pay more attention to information related to data protection. (P24)

Varying perceptions were reported on the amount of information required in an ICF. Various participants raised that some information was already well-known, and therefore, may be omitted from the body of the ICF. Examples of such information are definitions of the terms "randomization" or "double-blinded". Nevertheless, additional information was required by some participants. They, for instance, preferred a more detailed explanation of the health condition for which the intervention is investigated in the clinical study. These participants suggested that, in an eIC interface, additional information could be provided when hovering over specific words or they advised to include a hyperlink, allowing research participants to access updated and detailed information about this health condition.

Structure and presentation of information. To create a user-friendly (electronic) ICF, the participants raised several suggestions. First, the implementation of a scheme or a table was considered an added value to notice important information (e.g. information related to the course of the clinical study and what is expected from the participants) at a glance. Second, it was suggested to present necessary and additional information in the first and second layers, respectively. A layered approach could solve the issue of flooding the participants with information and could help them to differentiate essential from explanatory information. For example, it was proposed to list the definitions of the terms "randomized" or "placebo-controlled" as explanatory information. Third, it was advised to format the text using font options (e.g. italic and bold font) and bullet points, in order to enable participants to screen the information. Fourth, in some ICFs discussed during our qualitative study, a summary was included which was considered valuable. Similarly, a participant who had taken part in another clinical study, of which the ICF did not include a summary, argued that one page that summarizes the most important points must be included.

If you read a lengthy document, it is not always clear what the most important information is. (P3)

Fifth, it was suggested to integrate visuals, such as a figure or a video fragment, to clarify study-related information.

Information could be conveyed via multimedia formats, which would be mainly interesting for participants who are visually oriented. (P6)

Finally, some participants advised to implement a decision tree for information related to pregnancy, contraception, and interaction with other drugs. Such a decision tree could allow the integration of information reflecting the participants' medical history and demographics, such as their gender or age. These participants raised that, based upon the implementation of such a decision tree, they would be able to receive personalized information. For example, only women of childbearing potential would receive information about pregnancy.

Signing new informed consent versions. Some participants had to reconsent several times to reaffirm their decision to participate upon study amendments. It was considered burdensome to make additional visits to the research site to sign new ICFs. As a result, these participants suggested signing these ICFs electronically. One participant raised that the COVID-19 pandemic had accelerated the digitalization process, and therefore, did not understand why it was not possible to make use of electronic signatures in the context of health-related research.

It requires some efforts to provide the research team with a signed IC version. Therefore, I would prefer to sign it electronically. (P15)

Some participants considered it important to easily notice the changes in the new IC version and advised to highlight these. Moreover, they were of the opinion that it was confusing to receive different paper-based IC versions and raised the point that it would be helpful if the research team could store the previous versions at the research site. It was also mentioned that if participants would be informed about new IC versions electronically, it would be sufficient to receive the changes only.

I need to be informed about the changes only and do not need to receive the full IC document. (P7)

Data sharing and sample reuse. The ICF of a particular clinical study described that in case the study would reveal information clinically relevant to the participant's health, this information would be shared with his/her general practitioner. Participants who had taken part in this study mentioned that it is important to keep their general practitioner informed. Nevertheless, they suggested receiving a notification when such information would be shared. In another ICF, participants could tick boxes to indicate their preferences regarding data sharing, which was considered valuable.

The consent form states that participants should be aware that any clinically relevant data obtained during the study will be shared with their general practitioner. I would prefer to tick a box to explicitly consent for my personal data to be shared with my general practitioner. In addition, I would like to be informed about what type of data is shared exactly. (P2)

Moreover, this ICF listed that the participants' samples could be used for the purposes of genetic research in the context of the health condition investigated in this particular study. According to one participant, it was unclear if there would be sufficient control, for example, by the government, on what happens with these samples. This participant was surprised that his initial consent to participate in the study was also valid to use his samples in further genetic research. Some other individuals commented that a research participant should have trust in the research team to handle his/her personal samples correctly.

The researcher signs the IC in good conscience. Therefore, it is important to hold trust in the researcher that he/she handles participants' personal data properly. (P12)

Long-term interaction

All but one participant showed a positive attitude toward a longitudinal relationship with the research team. This particular participant (P11) mentioned that the information

described in the ICF sufficed to be truly informed about the study. Many participants stated that they would like to be able to indicate if, how, for which reasons, and for which duration they would like to establish this longitudinal relationship. It was raised that an eIC interface, enabling a long-term interaction, offers a largely untapped opportunity to bring science closer to research participants. Nevertheless, some participants thought that the type of information shared longitudinally would be impacted by legal or scientific restrictions.

Progress updates and study results. A longitudinal aspect suggested by almost all participants related to updates concerning the progress of the clinical study and the results. It was acknowledged that, although it may take several years, it would be interesting to receive the final study results. Some participants raised that they had taken part in the clinical study because of their interest in the field and to advance scientific research rather than for the financial compensation. Therefore, they considered it an opportunity to receive the study results. Nevertheless, some participants also raised concerns about how the results would be presented. They voiced the opinion that if they would receive an academic journal article, the results may not be understandable.

It was also considered valuable to receive individual test results, such as results of scans or biochemical tests conducted on the participant's samples, or in particular the results of the genetic test (if performed). A particular participant (P2) mentioned that returning individual test results could offer lessons for participants in their health management.

I think that the results of a baseline scan or test can be shared with the participant, and this information may be interesting if one of the participants would suffer from health problems later on. (P2)

However, another participant disagreed and stated that it is not necessary to be kept informed about these individual investigations and considered it to be burdensome for the research team.

It would be a huge cost and would place time demands on the research team if they have to keep participants informed about additional research conducted on our samples. (P16)

Some participants, who had taken part in an international clinical study, raised that they would like to be informed about adverse events, related to the investigational medicinal product, that take place in other countries. One participant mentioned that, during the course of the study, he was actively looking for updates about the investigational medicinal product in scientific journals.

If there is important news related to the investigational medicinal product, I would like to be informed via email or text message. (P10)

Nevertheless, several other participants advocated that it would not be useful to receive information about events that occur in another setting, and considered it important to have trust in the research team to inform the participants about important events. Another participant added that if there were any questions, they could always be posed to the research team.

Overview of studies. Participants suggested a couple of more aspects they would like to be informed about. Several participants would like to establish a longitudinal relationship to receive information about new clinical studies for which participants are being sought. Nevertheless, it was considered valuable if they could indicate for which type of studies, for example, related to a specific health condition, they would like to be informed.

I am interested in clinical studies related to a specific health condition, and therefore, it would be useful to have an oversight of these studies for which participants are being recruited. (P18)

Some participants mentioned that they already received invitations to participate in clinical studies via email, which was considered useful. Nevertheless, they raised the point that these invitations often referred to studies including participants of a specific sex or age category. They advised to receive invitations for studies they are eligible for only, which may be done automatically based upon the participants' personal data. In this way, the research site could immediately target the eligible population when recruiting.

Next to future studies, some participants highlighted that they would like to have an overview of the studies in which they had previously taken part. They suggested that an eIC interface would enable them to navigate throughout their studies, accompanied by the study results.

Practical integration. When participants were asked how they would practically integrate the aspects in an eIC interface, almost all of them stated that they would like to receive a notification when new information is available, preferably via email. Several participants mentioned that they would not always think about logging in to an eIC application, and therefore, wanted to receive notifications. Another suggestion made by some participants was to receive a newsletter of the study on a regular basis. This newsletter could also inform participants that new information had been made available on the eIC interface. Moreover, it was suggested to integrate a chat feature into an eIC interface which participants could use to contact the research team directly in case of questions about the information.

According to some participants, it should be avoided to create a new account to access the eIC interface. They

preferred that such an eIC interface would be integrated into established systems because of their professional and security properties. For example, these participants mentioned that they were already using systems that store medical information and inform them about updates.

If you would integrate eIC in an existing application, I would directly associate it with professionalism and security. (P1)

Discussion

This study aimed to explore how an eIC interface could be personalized and could establish longitudinal interactions, based on the research participants' needs. The combination of co-creation workshops, a focus group discussion, and semi-structured interviews allowed us to facilitate data richness regarding participants' experiences related to their study participation, and more specifically the ICF. The qualitative methods provided participants with the opportunity to discuss how they would tailor the (electronic) IC process to their needs. We further identified that almost all participants would like to maintain a longitudinal relationship with the research team, mainly to receive the (final) study results. Options to personalize an eIC interface ranged from customizing the information mentioned in an ICF to signing new IC versions electronically. Through the provision of various qualitative methods, we made a series of suggestions that may be considered when designing an eIC interface.

First, several participants, especially subjects who had taken part in interventional clinical studies, were of the opinion that the ICF of the study is very long and complex to understand. The IC process in clinical research is tightly regulated. The information that must be conveyed to participants is laid down in ethical codes and regulations, such as the Declaration of Helsinki and the Clinical Trials Regulation.^{26,27} Nevertheless, existing literature showed for example that the length of ICFs used in some of the major COVID-19 vaccine trials could be reduced by at least 50% while still complying with the applicable legislation.²⁸ In this respect, the results obtained in the present study also show that a lengthy, static ICF may not be the best approach to truly inform the participants about a study, according to their needs. Similarly, a cross-sectional study conducted at study sites in seven Asia-Pacific countries showed that research participants wanted to be informed about most topics of the ICF content required. Some of these participants required more information about particular topics. Nevertheless, this cross-sectional study found that participants preferred to read an ICF no longer than 12 pages.²⁹ Some advantages could be found in an eIC interface that presents tailored information, fortified by using simplified and concise language, which may reduce the length of the eIC.^{28,30} In addition, a personalized

eIC can be considered an added value to the verbal elucidation provided by the research team. According to stakeholders involved in clinical research, a personalized eIC interface could result in more focused conversations with the research team.³

Second, participants expressed the need to better structure the information. According to Schneiderman et al., one of the eight golden rules of interface design is to strive for consistency.³¹ Therefore, it is advised to standardize the formats and colors used in the eIC interface. Moreover, structured information could shorten the ICFs. For example, if multiple study drugs are used, it is suggested to list duplicative side effects of these drugs only once, by adding a statement describing that all drugs can cause side effects such as fever, instead of listing them for each drug separately.³² This idea also highlights that special attention must be paid to the creation of an information architecture in which the information is structured and categorized in a coherent and usable way. For example, key concepts may be illustrated by using graphics.³³ The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), defined as “a network of independently established regional fora for ethical review committees, health researchers and invited partner organizations from the Asia and Western Pacific region, former Russian states, Latin America, Africa, and North America”, defined three principles to assist researchers in developing an enhanced ICF.^{34,35} One of these principles is to convey information to participants in a simple format; for example by using illustrations, by placing the core information into boxes, or by highlighting keywords in color.³⁵ Moreover, also the user experience must be investigated.³⁶ During usability testing, end users perform tasks that represent the user activity, and thus, will be performed during the course of using an eIC application in practice.³⁷ Based on the results generated during usability testing, potential issues of an information architecture, including structured and categorized information, can be uncovered before implementing the application in clinical research.³⁸

Third, all but one participant favored establishing a longitudinal interaction with the research team during and after the clinical study, mainly to receive study results. An eIC interface could allow participants to set their preferences regarding the type of information they would like to receive electronically. The Clinical Trials Regulation already specifies that the sponsor must include a summary of the clinical trial results, understandable to a lay person, in the EU database in order to make them publicly available.^{27,39} Similarly, in the United States, the Food and Drug Administration Amendments Act requires the submission of results to the ClinicalTrials.gov trial registry for certain types of clinical trials.^{40,41} Yet, based on the results of our study, it seems that the majority of participants is not aware of these databases or would prefer to be notified when new information becomes available.

Therefore, if an eIC application could send automated alerts to inform participants about new information, it would be valuable to also include these lay summaries in an eIC application. However, it would be important to inform research participants that it can take years before study results are made public. For example, in the case of phase I trials, it can take up to 30 months from the end of the trial before the lay summary is made public.⁴² In addition, a longitudinal interaction may be used to electronically remind participants about study visits or to provide them with certain types of questionnaires they have to complete.⁴³

Finally, participants of one particular study needed to re-consent several times. Although the Belgian informed consent template for interventional clinical trials in adult patients suggests including a table with the revision history, it was not clear to some participants what exactly had been changed in the ICF.⁴⁴ Therefore, an eIC interface could provide a clear overview of all IC versions signed by the participant, while clearly indicating the changes. Moreover, teleconsultations could be integrated into an eIC interface, allowing the researcher to remotely video conference with the participant to explain these changes and to answer potential questions.⁴⁵

Strengths and limitations

One of the main strengths of this study is the involvement of participants, who had taken part in a clinical study, in a co-creation process. The limited number of participants in each co-creation workshop and focus group discussion allowed us to pay attention to each individual while still having the opportunity to discuss the participants' ideas in a group.²⁴ Another strength relates to the diversity of the participants included, given that they had taken part in clinical studies with a different design, sponsored by academia and the pharmaceutical industry. Finally, the multidisciplinary team that was involved in the design of this qualitative study is an important additional asset. Nevertheless, a limitation of this study is that it included participants who had taken part in a clinical study in Belgium only. It may be that ICFs are designed differently in other countries. Moreover, our study involved a small, relatively well-educated sample of participants, and thus, the results may not be generalizable. A lack of generalizability has become inherently associated with qualitative research. However, the main objective of qualitative research is to gain in-depth insights into participants' opinions in order to formulate suggestions rather than to make statements with universal validity.

Next, the group nature of the co-creation workshops and the focus group discussion may have hampered certain participants from freely expressing their experiences. However, this limitation was mitigated by additional individual interviews. Finally, it should be noted that the analysis of

the qualitative data was conducted by one researcher as opposed to multiple researchers, meaning that no cross-check was performed.²⁵ Nevertheless, the use of the other stages of the framework method, described by Gale et al., and the availability of existing literature to inform the coding process minimized subjective interpretation of the data.^{3,25}

Future perspectives

This study presents the views of participants who had taken part in four clinical studies. To gain more knowledge about the feasibility of participants' suggestions in daily practice, follow-up studies should be conducted. For example, the perspectives of data infrastructure organizations and health-care professionals involved in clinical research could be explored.

Conclusions

This co-creation approach enabled us to understand how research participants, who had taken part in a clinical study, would adapt the ICF of this study to better suit their needs and how they would establish a longitudinal interaction with the study team. As a result, this qualitative study offers a set of key considerations for the design of a participant-centric eIC interface. We identified varying perceptions related to the personalization of the ICFs, suggesting the need for a tailored interface. In addition, an eIC interface could allow participants to indicate which information they would like to be longitudinally informed about, such as the study results. Future research opportunities lie in the design and usability testing of such an eIC interface.

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Appendix

See Appendix Table 2.

Table 2. Coding tree.

Code	Sub-code level 1	Sub-code level 2	Sub-code level 3	Description
Personalization				How can (electronic) IC be personalized?
	Structure			
	Signing			
	Type of information			
		Additional information required		
		Less information required		
	Understandability			
Long-term interaction				How and for which reasons can eIC establish long-term interactions?
	Aspects			
		Study results		
			Individual	
			General	
		Study status		
		Other research studies		
	Practical integration			
		Notification		
		Newsletter		