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Review

Review

Key components and IT assistance of participant management in clinical research: a scoping review

Johannes Pung and Otto Rienhoff

Department of Medical Informatics, University Medical Center Göttingen, Göttingen, Germany

Corresponding Author: Johannes Pung, MSc, Department of Medical Informatics, University Medical Center Göttingen, Robert-Koch-Straße 40, 37075 Göttingen, Germany; johannes.pung@med.uni-goettingen.de

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ABSTRACT

Objectives: Managing participants and their data are fundamental for the success of a clinical trial. Our review identifies and describes processes that deal with management of trial participants and highlights information technology (IT) assistance for clinical research in the context of participant management.
Methods: A scoping literature review design, based on the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement, was used to identify literature on trial participant-related proceedings, work procedures, or workflows, and assisting electronic systems.
Results: The literature search identified 1329 articles of which 111 were included for analysis. Participant-related procedures were categorized into 4 major trial processes: recruitment, obtaining informed consent, managing identities, and managing administrative data. Our results demonstrated that management of trial participants is considered in nearly every step of clinical trials, and that IT was successfully introduced to all participant-related areas of a clinical trial to facilitate processes.
Discussion: There is no precise definition of participant management, so a broad search strategy was necessary, resulting in a high number of articles that had to be excluded. Nevertheless, this review provides a comprehensive overview of participant management-related components, which was lacking so far. The review contributes to a better understanding of how computer-assisted management of participants in clinical trials is possible.

Key words: clinical trials as topic, information systems, data management, research subjects, medical informatics

LAY SUMMARY

Clinical trials involving participants play a critical role in the development of new treatments. Management of participants and their data is fundamental for the success of a clinical trial. Information technology (IT) offers opportunities to approach clinical trial methodology in new ways, but so far there have been no comprehensive reviews of how computer-supported management of participants' data is disseminated in trial management processes. We identified 4 main process categories of participant-related management and evaluated their supporting IT systems: recruitment, administration of informed consent, management of participants' identities, and management of administrative participant data. Our results demonstrated that management of trial participants is considered in every step of clinical trials. Furthermore, we found that IT was successfully introduced to all participant-related areas of a clinical trial to facilitate processes. Our review contributes to a better understanding of how computer-assisted management of participants is possible. We anticipate our review to be a starting point for further research, providing a comprehensive overview of participant management-related components by categorizing existing literature in the field, and thereby giving an assessment of potential size and scope of available research literature.

INTRODUCTION

Clinical research is a key component of medical progress. Clinical trials are used to test efficacy and safety of drugs, new forms of treatment, medical interventions, or medical devices. After the trial planning and design phase, it is necessary to recruit volunteers as participants and inform them about the planned research with its aims, potential risks, and advantages. Tasks of the staff at a study site include the administration of contact data and obtaining informed consent of participants. Furthermore, scheduling and organization of examinations in the study context have to be managed. At many stages of the starting clinical trial, collaboration of the participants is necessary. The management of participants is, therefore, a core component of every successful person-related research project.

The organization and execution of modern clinical trials is not possible without the use of IT-assisted procedures.[1–3] Clinical Data Management Systems have become an accepted part of clinical trial data management and are considered efficient in terms of data management requirements.[4–8] For other trial management processes, such as management of participants, it is likely that new technologies to facilitate and accelerate workflows are used as well. However, to date, there have been no comprehensive reviews of how computer-supported management of participants is disseminated in trial management processes, and it is currently unknown what evidence exists to substantiate the presumed benefits of a computer-supported participant management.

This scoping review aimed to (1) identify and describe processes that deal with management of trial participants and (2) highlight IT assistance for clinical research in the context of participant management along the process chain. It provides a broad overview of published research regarding the management of participants for clinical trials, providing a basis for an in-depth analysis.

METHODS

We followed the *Preferred Reporting Items for Systematic Reviews and Meta-analyses* (PRISMA) guidelines[9] for searching and selecting relevant publications. In 4 phases, articles were first identified by a literature database search, then pre-selected based on title and abstract, checked for suitability by means of the entire text, and finally the validated publications were included in the literature analysis.

Search strategy

A systematic search of literature regarding *participant management in clinical research* is challenging, due to a lack of consistently used standard terms. Medical Subject Headings, which is the controlled vocabulary thesaurus of the United States National Library of Medicine (NLM), defines "Persons who are enrolled in research studies or who are otherwise the subjects of research" as *human subjects* or as its preferred term *research subjects*.[10] On the other hand, the website ClinicalTrials.gov, a database for clinical studies conducted around the world, and also provided by NLM, defines in their protocol registration data element definitions, that the term *participant* is used to refer to *human subjects*.[11] When we started with a broad internet search to identify further keywords and indexing terms, we have seen the use of the terms *subject*, *study-*, *trial-*, *research-participant* or *-patient*, and *-volunteer* to describe someone who enrolls in a clinical research study. Which term is most appropriate will not be discussed here, but it shows that many keywords have to be included in the search strategy.

From the keywords we identified, we developed a database search strategy (Table 1). Databases were searched using a combination of (1) keywords for process flows in the management of participants, (2) *participant* and similar search terms, and lastly (3) *clinical trial* and synonyms. Additionally, we included keywords for electronic workflows that we already assigned to the topic of participant management, like *electronic informed consent*, *recruitment system*, or *pseudonymization services*. The challenge was to include all relevant keywords but avoid generic search terms such as *informatics* or *data management*, which yielded a too massive result as also off-topic literature was included. We searched a medical and a multidisciplinary science database to find relevant articles for this study: PubMed and Web of Science. The search strategy was mapped to the respective search query syntax and rules of the databases (Supplementary Appendix SA). As search categories, [Title/Abstract] in PubMed and [TS=Topic] in Web of Science were chosen to keep the search broad and include all relevant literature. The search was conducted at the end of July 2019.

In addition, we looked for practice guidelines and available software products, and searched sources of gray literature. The gray literature search was based on the methodology outlined by Godin et al[12] for which the same keywords were used as for the systematic literature search, but the search was customized to the syntax of the Google search engine.

Selection of articles and synthesis of results

The literature selection process according to PRISMA is shown in Figure 1. Web of Science and PubMed searches identified the potentially relevant articles. A reference management software was used to manage the results of the literature search and the subsequent selection process of relevant articles. After removing duplicates from the results, the articles were screened by titles and abstracts. Articles were kept for further analysis, if they met one or more of the following 3 inclusion criteria:

- Processes: We included articles that described processes, work procedures, or workflows from clinical trials that are trial participant-related. We excluded studies that only mentioned the use of participant management but did not describe how it was conducted. Processes in clinical trials vary depending on the design and aim of the study. Therefore, only procedures common across trials are taken into account.
- IT assistance: We were interested in articles that described or evaluated electronic systems used in an administrative context with trial participants. This included systems that were either standalone systems or software as part of a bundled system.
- Publication type: We were looking for systematic reviews and original articles in English.

Articles that did not meet the inclusion criteria were excluded. Articles meeting the inclusion criteria and, thereby, considered relevant for this review, were read and tagged with key terms of content to classify articles regarding the clinical trial processes that were covered. This classification was used to identify the main trial processes. In addition, gray literature allowed us to identify topics that are not covered by scientific publications.

RESULTS

The searches from Web of Science and PubMed yielded 1321 potentially relevant articles. Of those, 175 were selected for full-text screening, resulting in a total of 103 articles to be finally included in

Table 1. Database search strategy

1 ("participant management" OR "trial patient management" OR "study patient management" OR "volunteer management" OR "subject management" OR "trial management" OR "research management" OR "study management" OR "workflow management" OR "task management" OR "project management" OR "identity management" OR "pseudonymization service*" OR "pseudonymisation service*" OR "trusted third party" OR "consent management" OR "electronic consent" OR "electronic informed consent" OR "digital consent" OR "digital informed consent" OR "econsent" OR "e-consent" OR "participant management system*" OR "patient management system*" OR "recruitment system*" OR "enrollment system*" OR "eClinical")
AND (
2 (participant* AND ("clinical study" OR "clinical studies" OR "clinical trial*" OR "clinical research") OR patient* AND (study OR studies OR trial* OR research)) OR volunteer* AND ("clinical study" OR "clinical studies" OR "clinical trial*" OR "clinical research") OR "human subject*" OR "research subject*")
3 OR ("clinical trial*" OR "clinical research" OR "clinical study" OR "clinical studies")
)

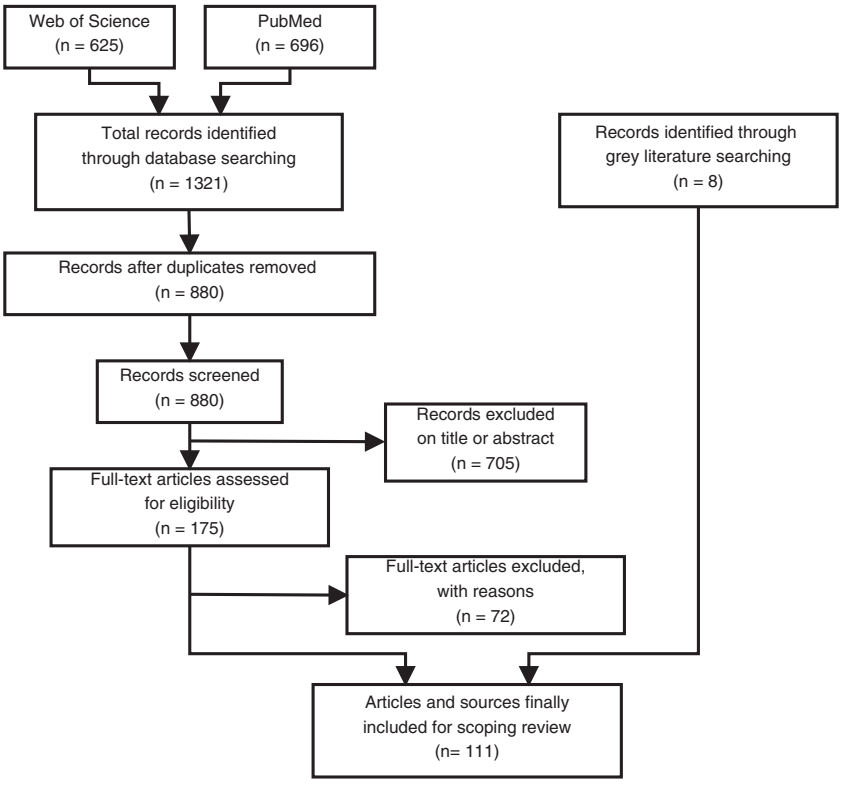

Figure 1. Flow diagram of the literature selection process.

the review. Most of the excluded articles were not within our scope, did not describe the process of a clinical study but routine care, or described managing of patients or participants in an unrelated context for this review. In addition, 8 results of the gray literature search were included in the review,[13–20] which provided information that were not accessible via scientific publications.

The screened articles were grouped into categories that represent the processes related to management of trial participants throughout a clinical trial execution, from concept development to trial result reporting. In Figure 2, we summarized these processes and highlight possible IT assistance for clinical research in the context of participant management along the process chain. Management of trial participants needs to be considered in nearly every step of the clinical trial—from recruitment of eligible participants and obtaining informed consent, to planning their participation by scheduling tasks and exams, to managing their contact data to inform them about study results and possible follow-up periods.

The characteristics of the reviewed articles are presented in Table 2. Out of the 103 selected articles, 36 concerned recruitment workflows, 36 dealt with informed consent processes during enrollment, 12 described pseudonymization workflows during enrollment, and 19 articles dealt with processes during trial participation. As shown in Table 2, articles considered different types of IT assistance: for example, recruitment support system, digital consent management, and identity management.

The selected literature addresses the various aspects of participant involvement in clinical trial processes. In the following chapters, we will reflect each process within the clinical trial workflow taken from the grouped articles with background information on the execution and how IT assistance can contribute.

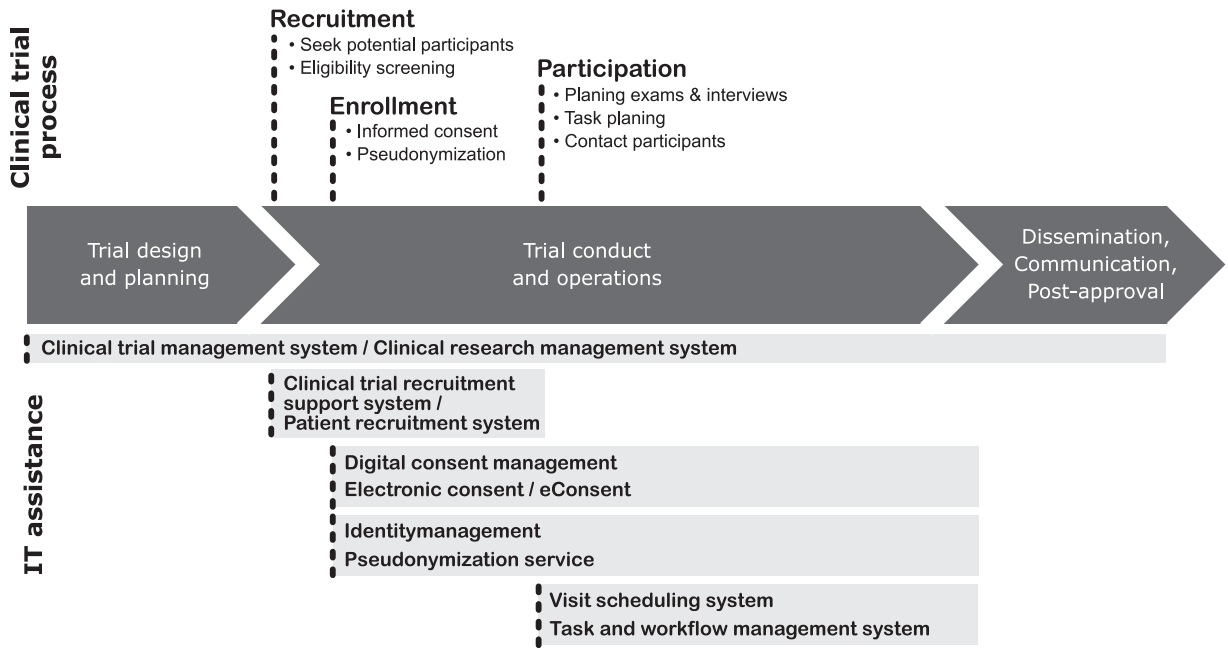

Figure 2. Clinical trial management process from start to finish, highlighting processes with trial participant involvement over time. IT systems provide support for the corresponding processes.

Table 2. Characteristics of reviewed articles

Article	Trial process	IT assistance
Afrin et al,[21] Ahmad et al,[22] Breitfeld et al,[23] Butte et al,[24] Cuggia et al,[25] Dowling et al,[26] Dugas et al,[27,28] Ferranti et al,[29] Fink et al,[30] Grundmeier et al,[31] Harris et al,[32] Heinemann et al,[33] Khosropour et al,[34] Kost et al,[35] Kotoulas et al,[36] Köpcke et al,[37] Lagor et al,[38] McDonald et al,[39,40] Mattingly et al,[41] Nielsen et al,[42] Rollman et al,[43] Schmickl et al,[44] Schreiweis et al,[45–47] Straube et al,[48] Sully et al,[49] Thadani et al,[50] Thompson et al,[51] Trinczek et al,[52,53] Treweek et al,[54] Walters et al,[55] Zimmerman et al[56]	Recruitment	Recruitment support system
Bergmann et al,[57] Bethune et al,[58] Bialke et al,[59] Boutin et al,[60] Buckley et al,[61] Chen et al,[62] Chhin et al,[63] Doerr et al,[64] Fink et al,[65] Grady et al,[66] Greenhalgh et al,[67] Harle et al,[68,69] Haussen et al,[70] Iafrate et al,[71] Kim et al,[72] Kondylakis et al,[73] Nijhawan et al,[74] Phillippi et al,[75] Ramos,[76] Rothwell et al,[77] Schreiweis et al,[78] Shelton,[79] Simon et al,[80–82] Sommer et al,[83] Soni et al,[84] St John et al,[85] Stevens et al,[86] Suarez et al,[87] Vanaken,[88] Vanaken and Masand,[89] Warriner et al,[90] Welch et al,[91] Wilbanks[92]	Enrollment	Electronic informed consent, digital consent management
Aamot et al,[93] Bialke et al,[94] Bruland et al,[95] Chevrier et al,[96] Deserno et al,[97] Ebner et al,[98] Jonas et al,[99] Lablans et al,[100] Lautenschläger et al,[101] Nurmi et al,[102] Sahi et al,[103] Schwaneberg et al[104]	Enrollment	Identity management, pseudonymization service
Abshire et al,[105] Almeida et al,[106] Berard et al,[107] Bose and Das,[108] Campion et al,[109] Cramon et al,[110] Durkalski et al,[111] Geyer et al,[112] Gupta et al,[113] Leroux et al,[114] Müller et al,[115] Nadkarni et al,[116] Park et al,[117] Raptis et al,[118] Schobel et al,[119] Schwanke et al,[120] Solomon et al,[121] Weng et al,[122] Zhao and Pauls[123]	Participation—managing administrative data	Task- and workflow management system, visit scheduling system, clinical trial management system, clinical research management system

Recruitment

Patient recruitment describes the process of finding suitable participants for clinical trials. Potential trial participants are usually identified by the treating physician, the study nurse, or the principal investigator. Conventional clinical trials often occur within the confines of health care settings, through the identification of participants during their clinical encounters, or prior to visits via electronic and paper healthcare records. Other channels to recruit participants are used as well such as advertisements, phone calls, use of third-party data, processing information from clinical trial registries or patient registries. Prior to formal enrollment in clinical trials, patients, interested in participating, will go through a screening process. The eligibility criteria, defined in the study protocol, describe characteristics that must be met by all participants.

A common problem with clinical trials is the achievement of the recruitment target. Trials often fail to achieve the required recruitment numbers or to recruit the necessary number of patients within the planned recruitment time.[39] Between 50% and 60% of random-

Table 3. e-Consent management divided into 3 levels, describing the options of collecting and using structured data in e-consent

Level	Type	Structure	Explanation
Level I	Paper consent form	No structured data	Consent on a paper form, which is scanned and kept electronically
Level II	Paper and e-consent form	Some structured data	Consent on a paper form, which is transferred into an electronic format (manually or by automatic parsing of paper-based consent scans)
Level III	e-consent form	Structured data	Consent in an electronic form. IT systems can interpret and process participants consent decisions from structured data

Note: In accordance with ref.[20]

ized clinical trials do not meet their original recruitment targets or face significant delays.[49,55] Poor recruitment can lead to the prolongation of trials, increasing the costs, and can lead to an underpowered study from which wrong conclusions may be drawn. Several potential limiting factors have been identified in the literature, including organizational, financial, or trial management-related difficulties.[40,48] Barriers to patients' involvement include lack of knowledge, general lack of trust in trials, and disagreement with the assignment to a certain treatment group.[40] There are several proposals how to increase recruitment rates in trials. A recent systematic review of methods to improve recruitment numbers in randomized controlled trials compared 68 recruitment strategies.[54]

IT assistance offers the potential to improve the recruiting processes and meet the recruitment target. Clinical Trial Recruitment Support Systems (CTRSS), or sometimes called Patient Recruitment Systems, have been designed to support the patient recruitment process by suggesting potentially suitable study participants. These CTRSS use electronic patient data, typically from electronic health records, to assess patient eligibility for a clinical trial. The system alerts of a patients' study eligibility or provides a list of potential trial participants to a study investigator. Our search provided a total of 30 relevant articles on CTRSS,[21–38,41–47,50–53,56] which indicates that CTRSS are potentially beneficial in managing trial participants.

A comprehensive review of employing IT for the recruitment for clinical trials was done by Köpcke and Prokosch.[37] Compared to a previous review paper by Cuggia et al,[25] which analyzed 28 CTRSS from articles published before October 2009, Köpcke and Prokosch reviewed 101 papers on 79 different systems and created an overview of all CTRSS reported until the end of 2013. They distinguished between 3 types of CTRSS: (1) systems for the retrospective identification of trial participants based on existing clinical data, (2) systems that monitored the appearance of a key event of an existing health IT component in which the occurrence of the event triggered an eligibility test of a patient, and (3) independent systems that required a user to enter patient data into an interface to trigger an eligibility assessment.

While in scientific publications the non-commercial part of clinical research is mainly considered, there is also an industrial view of patient recruitment. For profit-oriented companies—such as pharmaceutical and medical device enterprises—a short time to market is crucial. Accelerating patient recruitment for clinical trials with CTRSSs can be one effective component to reduce time until revenues are generated. The patient recruitment industry is valued at a total of $19 billion per year.[15] Some companies outsource their patient recruitment-related needs to specialty service providers.[14] IT has impacted this branch as well. Several companies have built proprietary software for a range of activities that rely on patient recruitment. The website capterra.com, an online peer-review site that aims to help businesses find software solutions, lists 36 products for *Recruiting Management* in the category *Clinical Trial Software*.[13]

Enrollment—informed consent

Before a participant can enroll in a clinical trial, they must be recruited, screened, and must give their informed consent.[16] Informed consent is one of the founding principles of modern research ethics. It is a process by which "a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate," as stated in the International Council for Harmonisation's (ICH) Good Clinical Practice guidelines (GCP).[17] Informed consent is not only required for clinical trials, but is an essential prerequisite before enrolling a participant in any type of research involving human subjects.[74] The process of obtaining informed consent is tightly regulated. Requirements are defined in federal laws and regulations as well as in a worldwide harmonization approach, the ICH-GCP guidelines, and the guidelines for Data Protection of the Organisation for Economic Co-operation and Development.[17,18] Informed consent is documented by means of a written, signed, and dated informed consent form (ICF). In accordance with GCP, the signed ICF has to be stored in an Investigator Site File.[17]

In recent years, there has been a greater use of electronic methods to gain informed consent (called eIC or e-consent) in research studies.[57–65,67–92] The New England Journal of Medicine published in "The Changing Face of Informed Consent" innovative approaches to improve and expand the electronic informed consent process for researchers and participants.[66] e-Consents can include multimedia information (graphics or videos) and interactive components to increase the understanding of the study purpose and is less focused on signing legal documents. e-Consents can be divided into 3 levels of consent management maturity; from plain paper-based consent to combining paper and electronic means to solely relying on e-consent (Table 3).[20] e-Consent management solutions enable to manage a large number and variety of research projects in a hospital due to process automation.[59]

Positive results using e-consent are increasingly reported by clinical studies, in which electronic management is perceived by, both, participants and staff members as straightforward, efficient, and simplifying workflows.[77,88] As a reaction to the increasing use, the Food and Drug Administration and the Office of Human Research Protections published a joint guidance for the use of e-consent for institutional review boards, investigators, and sponsors in December 2016.[19] e-Consent has been accepted by central institutional review boards in the United States and some other countries. However, launching of e-consent is challenging in international trials as each country has different legal requirements for the use of e-consent.[89]

Enrollment—identity management and pseudonymization service

Preserving participants' privacy is crucial in clinical research.[102] *De-identification* and *anonymization* are the 2 most common terms

used to refer to the technical approaches that protect privacy.[96] However, anonymous data collection are only possible in very few clinical trials. Many clinical study designs require to capture and integrate data from heterogeneous data sources or from different locations, which requires the identification of participants. Here, one of the most important requirements is keeping acquired clinical data and personal information of participants apart to ensure confidentiality and data protection.[98,100,101] Therefore, an identification code (pseudonym) is assigned to each participant upon enrollment. The identification code is saved in a confidential list [subject identification code list (ICL)], also including the name of the participant, the date informed consent was obtained, and all additional information needed to relate a participant to their identification code (eg, gender, date of birth). Clinical data, documented in case report forms, are encoded with the identification code and cannot be directly related to the participant's identity. Only by means of the ICL can the acquired clinical data be connected to identifying information. Linking data and identity, however, is a necessity, as stated in the GCP guidelines,[17] to allow contacting participants in case medical irregularities during a trial emerge.

The described workflow is often conducted paper-based, especially in local (ie, single site) and small trials. However, the procedure quickly reaches its limits when dealing with larger projects or greater technical requirements. Technical requirements increase, for example, for collaborative acquisition of data (eg, in multi-site studies), which has become a core element of biomedical research over the last years. To advance data management and improve data quality in clinical trials, electronic data capture (EDC) systems are increasingly used.[4–8] Integrating pseudonymization services into EDC systems is, therefore, a chance to improve and facilitate the described procedure by making use of IT infrastructures.[95,97,104] In this context, digital solutions that are compliant with data protection legislation are needed to ensure (1) that participants who appear in multiple institutions obtain the same pseudonym across sites and are not handled as 2 different individuals (identity management) and that (2) unambiguous pseudonyms are assigned for each participant and each separate system (pseudonymization service). A comprehensive overview of current methods and applications for pseudonymization services can be found in the literature.[93,103] For identity management and pseudonymization services, a trusted third party (TTP) is often assigned to handle the ICLs.[94] Participants can then only be identified by the person in charge of the identifying data. A recent study has investigated a novel approach to pseudonymization without the necessary use of a TTP, but requires a higher accountability of the participant.[99]

Managing administrative participant data

Commitment of study participants is essential to ensure the power and internal validity of longitudinal research. One of the most commonly used strategies to avoid losing participants are reminder, contact, and regular scheduling methods.[105] The participant's contact information is securely stored at each clinical site for internal use during the study. The information is collected on a so-called *locator form*—a working document of all contact information that can possibly help the researcher team find the participant when needed.[121] At the end of the study, all records will be kept in a secure location for as long as dictated by local regulations. The clinical research staff is in charge of scheduling appointments for trial visits and may send reminders to participants. Depending on the trial protocol, the trial visits could include lab tests, X-rays, computed tomography scans, physical exams, etc.

Using a task and workflow management system for clinical studies, all the processes associated with a health research study can be simplified.[106] These systems support the setup of clinical trials, the management of participants, as well as the overall governance process. Electronic clinical research visit scheduling systems provide the potential of coordinating trial visits with patient care visits. Thereby, the efficiency at clinical sites as well as the likelihood of participants keeping their trial appointments can be increased.[122] Unnecessary or redundant visits or tests for patients, and a considerable administrative burden for involved institutions can, thus, be avoided. The ability to manage participant schedules displayed in calendar form can be a feature of a Clinical Trial Management System (CTMS).[117] Managing administrative participant data in software systems is often not a standalone application. CTMS[107,108,110–112,114,117–119,123] or Clinical Research Management Systems (CRMS)[109,115,116] support the whole clinical trial process. Although the functional scope of a CTMS or a CRMS is larger and varies from product to product, these systems also manage trial participants and support tasks in the administration of study participants. Systems that were intended for a different purpose, however, can be used for the management of study participants as well, such as custom-build case management systems for participant data[113] or customer relationship management systems for the management of study participants.[120]

DISCUSSION

Trial participant management in its generic concept stands for a number of processes that handle participants and their data in clinical research. However, there is no precise definition of participant management as a distinct subset of processes in clinical research. For the purposes of this review, we selected articles that either describe processes that deal with management of trial participants, or in which IT assistance for clinical research in the context of participants is used. This made a broad search strategy necessary, including many keywords (Table 1). In our opinion, using the determined terms was sufficient to provide a broad range of participant-related processes and workflows. Disadvantage of the broad search was the high number of articles ($n = 656$) that had to be excluded. Many of the excluded articles described clinical trials on specific diseases and focused on their results, but were only casually mentioning the participant managing processes. Based on the included articles, we identified the key components of participant management in clinical research, divided into 4 processes: recruitment, obtaining informed consent, managing identities, and managing administrative data. We found that IT was successfully introduced to all participant-related areas of clinical trials. However, our review is limited insofar that the processes identified are based on the literature and information publically accessible. In our experience, clinical trials use far more IT assistance than is mentioned in the available literature on clinical trials. Most medical publications, however, describe little about methods or systems that have supported the data collection in an operational context. Additionally, traditional methodologies that rely on paper-based processes are also rarely published. We intended to emphasize the benefits of using IT-based solutions and technologies, but similar to missing process descriptive literature, studies comparing paper-based and IT-assisted management are also lacking.

A good overview of research activities was found for the recruitment process of clinical trials. It shows the importance of the topic for medical research—patient recruitment is vital to the success of any trial. The use of CTRSSs dates back to the early 1990s. Since then, CTRSSs have become even more popular and numerous publi-

cations have appeared. Although CTRSSs have been established, some of the problems in recruitment still persist, which require further research.

The combination of organizational, legal, ethical, and technical approaches is necessary to protect health data. The first and most important basis is established by gaining informed consent. Working with pseudonymous data is another important element to protect privacy and confidentiality. Nevertheless, a central question that researchers have to explore is how to protect privacy and confidentiality in constantly changing clinical research practice, technical possibilities, and legislation. For instance, getting ethical approval for studies varies enormously across European countries.[124]

After conducting the literature review, we noted that few publications deal with the managing of administrative participant data in a clinical trial. This is surprising as these processes must be conducted in every clinical trial. It can be assumed that administrative patient management processes are often managed with the common office IT tools.

IT can assist clinical research in the context of participant management. However, the degree of digitalization depends on the respective clinical trial. While the biopharmaceutical industry often uses more complex software solutions to manage the whole process of a clinical trial, the non-commercial clinical study research is generally less well equipped.[8,125–127] This is also reflected in the fact that commercial software products were not mentioned at all in scientific publications, although there is a strong market for these products.

Attention has been paid to each participant-related topic individually in the literature, but a synthesis addressing all aspects of participant management in clinical research was lacking so far. This review provides a comprehensive overview of participant management-related components.

CONCLUSION

Conducting a clinical trial typically implies management processes handling participants and their data. Participant-related processes include recruitment, administration of informed consent, management participants' identities with pseudonyms, and the management of administrative participant data. Effective use of available technologies is a crucial advantage. This article categorizes existing literature in the field, and thereby gives an assessment of potential size and scope of available research literature. It contributes to a better understanding of how computer-supported management of participants is disseminated in trial management processes. Further research should focus on availability, interconnectivity, and costs of IT assistance for participant management presented here. Additionally, the comparison of various participant management methods and their impact on the trial success as well as the comparison of management in different trial types should find more attention in future studies.

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AUTHOR CONTRIBUTIONS

JP and OR developed the study design. JP was responsible for data acquisition, analysis, and interpretation, and wrote the first draft of the manuscript. OR participated in the revision and approved the final version of the manuscript.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

CONFLICT OF INTEREST STATEMENT

None declared.

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