



Clinical Research Integration Within the Electronic Health Record

A Literature Review

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Clinical trials have become commonplace as a treatment option. As clinical trial participants are integrated into all healthcare delivery settings, organizations are tasked with sustaining specific care regimens with appropriate documentation and maintenance of participant protections within electronic health records. Our aim was to identify the common elements necessary for electronic health record integration of clinical research for optimal trial conduct and participant management. Review of literature was conducted utilizing PubMed and CINAHL to identify relevant publications that described use of the electronic health record to directly support trial conduct, with a total of 15 publications ultimately meeting inclusion criteria. Three thematic groupings emerged that categorized common aspects of clinical research integration: functional, structural, and procedural components. These components include technological requirements (platform/system), regulatory and legal compliance, and stakeholder involvement with clinical trial procedures (recruitment of participants). Without a centralized means of providing clinicians with current treatment and adverse event management information, participant injury or likelihood of withdrawal will increase. Further research is required to develop an optimal model of research-related integration within commercial electronic health records.

KEY WORDS: Clinical trial, Electronic health record, Literature review

Clinical trials have become commonplace as a treatment option. Clinical trial participants are integrated into all aspects of healthcare delivery—from hospital, urgent, and primary care—and organizations are tasked with appropriate documentation and maintenance of human subject protections within electronic health records (EHRs). Clinical trial research information will affect EHR progress notes, provider orders, nursing

assessments, and care, along with ancillary discipline utilization, depending on the drug or device, study or observational research data capture.

Background

Clinical trials provide a unique opportunity across a spectrum of indications for access to novel therapeutics, which may or may not translate to individual benefit but will definitively advance medical science. Clinical trial protocols are designed with procedures for participant retention, which includes care management outside of research visits. The challenge facing care providers beyond the clinical trial site is managing the participant while adhering to the protocol. Few options exist for other providers to know that the patient is participating in a clinical trial and, second, to know what prescribed medications, for example, are contraindicated according to the protocol.

While EHRs were initially designated for use in capturing clinical patient procedures for billing purposes, the same core system functions of procedure tracking may also be used for clinical trial participant management.¹ Challenges are encountered when ancillary providers collect information relevant to trial conduct due to lack of data capture standardization within the EHR.² Different trial sponsors may require specific data elements to be included within the EHR that EHR platforms may not be able to incorporate. For example, one trial sponsor may require electrocardiograms to be uploaded within the EHR, whereas an EHR may accommodate only numerical measurements rather than the full visual output. Cowie et al¹ summarized the present-day abilities of EHRs to support clinical trials, namely, feasibility assessments, performance improvement, guidance adherence, safety surveillance, pharmacovigilance, and hypothesis generation, whereas emerging areas of EHR support for clinical trials include patient recruitment and point-of-care randomization.² Feasibility assessments allow the organization to review a census of the targeted patient population to evaluate its ability to conduct the trial, whereas performance improvement metrics, such as participant retention and cited deviations from the protocol, may support optimal trial conduct for present and future studies. Oversight entities, such as the US Food and Drug Administration, publish guidance to describe

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optimal trial conduct. Optimal trial conduct includes adequate informed consent of the participant, safety surveillance of participant adverse events and investigational product effects, pharmacovigilance, and evaluation of primary and secondary outcomes (hypothesis generation) that is in alignment with real-world prescription expectations.

The integration of clinical trials within a common clinical platform accessible to both clinical and research personnel has been piloted by two key, European-based projects: IntegrIT in Sweden and the five-country initiative Electronic Health Record for Clinical Research (EHR4CR). The ability to centralize communication among clinicians and researchers requires significant stakeholder engagement and technological resources to capture all pertinent aspects of trial conduct that may affect clinical care. With both IntegrIT and EHR4CR, interoperability was undertaken with standardization of data fields in mind such that any provider would be able to interpret information in a streamlined fashion within the EHR, supporting operational efficiency for both research and clinical spaces. Both projects are highlighted here for their optimal platform proposals and industry excitement surrounding initial feasibility and pilot efforts.

IntegrIT Project

The IntegrIT project was conducted in Sweden as a means of facilitating clinical research across health systems, EHRs, and providers throughout the country via the Health Information Exchange (HIE) platform.³ Through redirection of requests between separate health information systems, such as EHRs, the HIE platform acts as the “Grand Central Station” of information, a conduit of centralized communication.³ Clinical research processes, such as contacts, informed consent, and clinical trial information, would be made available to providers while facilitating a more efficient means of recruitment across participating centers. A 2-year project, usability testing of IntegrIT has been completed and the next stage is testing in a clinical research environment.³

Electronic Health Record for Clinical Research Project

A pan-European initiative, EHR4CR, shares the desire to increase awareness of clinical research information and usability of research-related tools within the EHR. Faced with limitations, such as language barriers, differing national regulations, and inconsistency in documentation practices, the EHR4CR team developed a scalable, platform-based approach to interoperability between EHR systems and clinical research systems.⁴ An unprecedented display of stakeholder engagement backed this initiative, with 34 academic and private industry partners across five European countries.⁴ Via this project, key commonalities between systems were extrapolated (standardization of documentation, data capture, and security requirements) to not only support integration of clinical

research within the EHR but ultimately enhance trial conduct through the availability of data regardless of institution.

While clinical management is the routine function of the EHR, structuring EHRs to include research-related information will support optimal patient care to incorporate protocol limitations and prevent research participant withdrawal from trials. Lack of appropriate capture of information can result in protocol deviations, participant injury, and federal or research sponsor citations for noncompliance. In a survey of US-based health centers, only 8% of respondents affirmed integration of clinical and research-related data within the EHR.^{4,5} Our aim is to identify the common elements necessary for EHR integration of clinical research, including structural, functional, and procedural core requirements for optimal trial conduct and participant management.

METHODS

Review of literature was conducted from May 3, 2018, to July 25, 2018, utilizing PubMed and CINAHL, to identify relevant publications that described use of the EHR to directly support conduct of a research trial. Search restrictions included human subject research, English language, peer-reviewed publications, and randomized controlled trials (RCTs). Date range was not initially limited to encompass early EHR integration perspectives; however, relevance was thoroughly examined if the date of publication was older than 10 years. Reference lists of pivotal literature were reviewed for additional publications. Search terms included “integration” AND “EHR” AND “RCT,” “EHR” AND “RCT” AND “organization and administration” OR “management” OR “disease management” OR “disease” AND “management” OR “disease management.”

The PubMed search yielded 150 initial articles, while CINAHL yielded two articles. Discarded articles included case studies, abstracts, and articles that were solely based on clinical pathway support or clinical decision making that were non-research related.

Inclusion and Exclusion Criteria

The following inclusion and exclusion criterion were used to guide this review of literature. Inclusion criteria for the review of literature were as follows: direct alignment to research-related EHR applications including global clinical trials, randomized clinical trials, human subject research, all populations (pediatric and adult), peer reviews, drug and device protocols, all indications, and full-text publications. Papers were excluded if they were case studies, clinical pathway support literature that did not have direct EHR research utilization, clinical decision frameworks that did not have direct EHR research utilization, abstract only, editorial publications with no tie-in to trial-related data, and preclinical or animal research.

Selection of Studies

As part of inclusion criteria review, publication titles and abstracts were screened for relevance; the full text of articles was reviewed for research questions, methods, findings, and research setting. Thirty-five publications were initially identified for a thorough inclusion criteria review, with 15 publications ultimately selected (Table 1).

RESULTS

Fifteen papers were reviewed and organized by thematic groupings. These groupings were then reviewed with 100% agreement by the authors. Common themes arose as to the integration of EHRs: structural components, functional necessities, and procedural requirements. Articles in the structural grouping focused on the technological foundation required to support clinical trials within the EHR, whereas articles in the functional and procedural groups highlighted the financial considerations, legal obligations, and stakeholder engagement that are necessary for optimal integration (Figure 1).

Structural Grouping

One of the key technological needs in support of clinical trials is a means of alerting the system user to clinical trial information, whether patient eligibility or active screening status. Schreiweis et al⁶ reviewed five hospital sites in Germany, observing variability in use of system notifications (visually conveyed as red flags) for clinical trial participation and separate workflow for documentation of recruitment status. The system notifications (flags) allowed the end user to distinguish trial management from clinical management. Sites ranged from data input via demographic or status assessment forms to relying on nursing dialogue or Excel tables.⁶ None of the EHR systems supported the management of trials within standard installation parameters or provided a way to determine patient recruitment.⁶

A common limitation of current EHR systems includes the inability to reuse clinical data to screen potential clinical trial participants. Similar to the Schreiweis et al⁶ review of German university hospitals, Girardeau et al⁷ reviewed the EHR4CR platform—an attempt at sharing data and interoperability among European network users—and found lack of foundation for clinical trial information within current platforms. As part of the EHR4CR initiative, investigators first defined a base set of terminologies that would standardize data in the hope that eligibility criteria could then be normalized.⁷

The standardization of language will support not only the identification of potential clinical trial participants but also the completeness of data for clinical trial capture, specifically for industry-funded trials. Healthcare systems could maximize the use of normalized clinical terminologies and common data elements, thus building efficiencies within the

EHR to perform clinical trial procedures such as adverse event reporting, prescreening, and feasibility assessment. Bruland et al⁸ stated that industry sponsors have a bank of forms and data sets that are similar among clinical trials, which could be a launching point for EHR platform design with clinical trials as a focal point. A platform design would require attention to standardization of data input by the user, rather than the free text capabilities currently seen with EHR technology. As Bruland et al⁸ report, 133 data elements were identified that were most frequently used in clinical trials, ranging from vital signs to demographic information. Expanding the volume of common data elements, standardizing terminology, and supportive documentation design within the EHR are all critical technological, structural components to optimal clinical trial integration.

Functional Grouping

The articles in the functional grouping highlight the need for fiscal feasibility objectives and clinical trial duties that would be best served via integration within the EHR. The European EHR4CR project targeted the fiscal feasibility via cost-benefit assessment of common clinical trial scenarios: protocol feasibility assessment, patient identification for recruitment, and clinical study execution.⁹ While theoretical in nature, given that the EHR4CR is not in use at the time of writing, EHR4CR tackled cost-benefit analysis of oncology clinical trial integration in the EHR, one of the costlier therapeutic areas for patient care. Beresniak et al⁹ estimated the cost-benefit of the EHR4CR platform for late-phase oncology trials to be 110.9 million euros, including potential fees for service and reduction of cycle time (commercial benefits). Overall, a platform such as EHR4CR has the potential to reduce time from study design to enrollment opening, identify potential patients to accelerate recruitment, and reduce resources required for data entry.⁹

Much of the literature surrounding EHR integration of clinical trials is produced in Europe, such as the work of Gulliford et al,¹² who examined the process by which clinical trials could be conducted using the EHR. Based in the United Kingdom, the authors reviewed cluster trial performance using EHRs with primary care practices that were operating via the Clinical Practice Research Datalink.¹² While conducting clinical trials is possible from a functional standpoint (standardized eligibility criteria, database, or connected sites), the authors noted the process was time-consuming from a legal aspect with research governance approvals.¹²

Legal implications of clinical trial integration were thoroughly discussed, as well as a point of generalized concern regarding integration of clinical trial participant information and allowing a wider distribution of data. One survey noted that privacy, legal implications, and public relations ramifications were stated as concerns by more than 80% of

Table 1. Summary of Included Studies Highlighting Clinical Trial Integration Within the EHR

Publication	Database	Research Method	Research Question/Aims
Structural thematic grouping			
Schreweis et al, ⁶ 2014	PubMed	Surveys, personnel interviews, and EHR data review	Participant recruitment feasibility with commercial EHR modules
Hagglund et al, ³ 2017	PubMed	EHR data review	Feasibility and ease of use with national HIE system integrating research
Girardeau et al, ⁷ 2017	PubMed	EHR data review	Process development and identification of issues implementing EHR4CR
Bruland et al, ⁸ 2016	PubMed	Case report form data review	Determine most commonly used data elements in clinical trials and availability in EHRs
Functional thematic grouping			
Beresniak et al, ⁹ 2016	PubMed	Cost-benefit assessment, advanced prospective modeling	Assess value of EHR4CR compared to current clinical trial sponsor practices
De Moor et al, ⁴ 2015	PubMed	EHR data review	To demonstrate a scalable, widely acceptable, and efficient approach to interoperability between EHR systems and clinical research systems
Doods et al, ¹⁰ 2014	PubMed	Platform program querying	Assessment of EHR4CR as a protocol feasibility platform aligning to technology and governance stipulations between sites
Andersen et al, ¹¹ 2015	PubMed	EHR and database review	Empirical evaluation of source data verification and data integrity
Gulliford et al, ¹² 2014	PubMed	Trial data sets and author experiential narrative review	Issue identification with designing and performing randomized, controlled clinical trials within EHRs
Procedural thematic grouping			
Ni et al, ¹³ 2015	PubMed	Retrospective	Participant identification via EHR algorithm
Effoe et al, ¹⁴ 2016	PubMed	RCT	Participant conversion analysis, direct cost review, and impact of exclusion criteria on minority enrollment
Vawdrey et al, ¹⁵ 2011	PubMed	Retrospective EHR data	Care provider identification approaches employed within a commercial EHR
Mojca et al, ¹⁶ 2016	PubMed	RCT	Effectiveness of provider point-of-care reminders on quality care
Benthin et al, ¹⁷ 2016	PubMed	Survey questionnaires to investigators	Feasibility of e-alert standardization in multicenter research
Chute et al, ¹⁸ 2010	PubMed	Data warehouse process review	Data and analytical capabilities of an enterprise data trust to integrate intersite practice, research, education, and administration

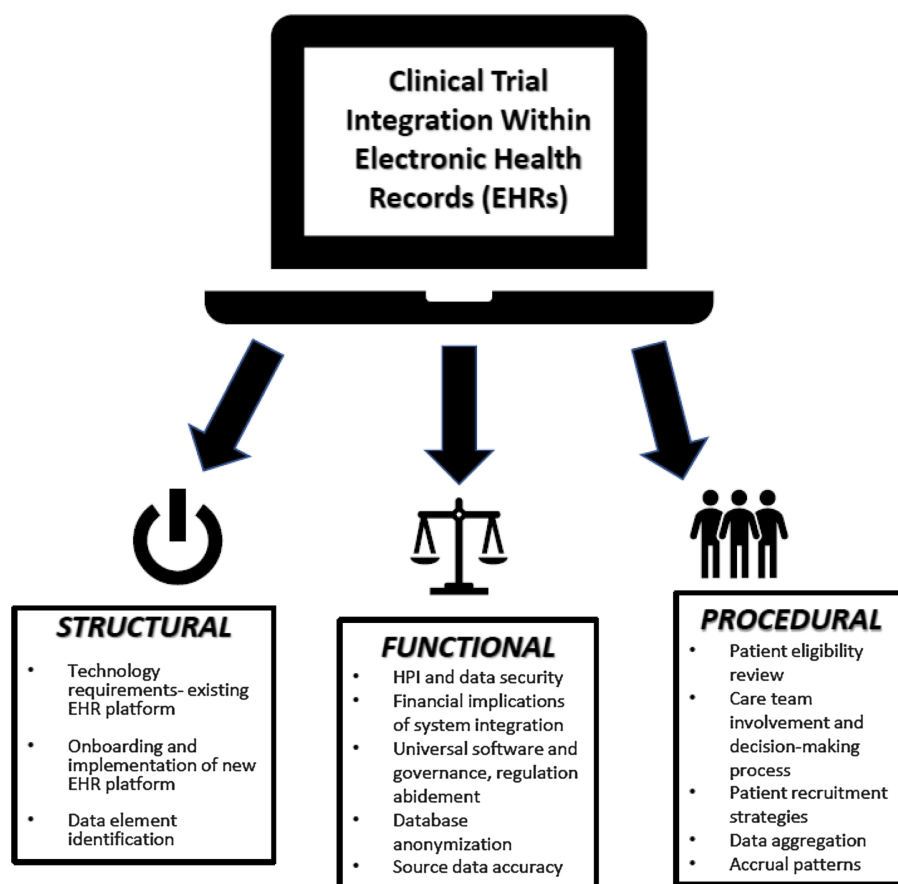


FIGURE 1. Thematic groupings referencing integration aspects for clinical trial management within EHRs.

respondents.¹⁹ The EHR4CR project addressed this aspect of healthcare informatics integration via Doods et al,¹⁰ who stated it was possible to use a uniform platform, such as EHR4CR, while complying with local data protection regulations. Permission was obtained by ethics committees and varying data controllers associated with 11 university hospitals to support use of de-identified EHR data.¹⁰

Source data verification (SDV) and overall monitoring of clinical data is another aspect of the functionality of the EHR as it pertains to trial conduct. Source data verification can account for almost one-quarter of an industry trial study budget.¹¹ Industry is presently divided in its use of 100% SDV versus risk-based monitoring, which is structured to verify data by specific triggers (such as volume or data critical to endpoint analysis). Andersen et al¹¹ found, after surveying 3 million data fields with 100% SDV, it would take a review of 370 data points to find one unspecified error. This finding further supports the shift to remote monitoring or risk-based models, leaning on the data from EHRs to be accurate and review to be efficient. The potential cost savings to industry and at the site (time and effort required to host monitors

on-site) align with other articles in the review as to the benefit of EHR—clinical trial integration.

Procedural Grouping

Although the focus of EHR integration is on the technology, institution staff and clinicians will be the daily users and thus must be at the forefront of integration discussion. An average of 30 separate clinicians may view the patient chart within the EHR per patient stay (3 to 5 days).¹⁵ Issues such as usability, necessary functionality, and workflow assimilation are all discussed by articles in the procedural grouping. Efficiencies for the management of clinical trial information and conduct of studies equate to maximization of participant recruitment potential. With many clinicians and specialists viewing information about a patient—and potential clinical trial participant—integration of clinical trial information may be another tool for collaboration among providers.

While not a new concept, automation of participant eligibility is discussed as a facet of clinical trial integration within the EHR. Manual review of potential participants is time-intensive and limits the breadth of patients who may be reviewed. Ni et al¹³

reviewed the eligibility criteria of 55 oncology clinical trials while comparing EHR clinical information and, using an eligibility screening (ES) algorithm, found that automating the ES reduced clinician workload by 90%. Standardization of nomenclature for the Ni et al¹³ ES algorithm was achieved with the support of medical dictionaries and codes for clinical terms. When tested against an oncologist chart review, the physician identified 29 potential participants, whereas the ES algorithm identified 34 participants.¹³ Harnessing the potential of adaptive ES algorithms within the EHR makes it possible to reach more potential participants while reducing burden on providers.

The LIFT Diabetes trial, as described by Effoe et al,¹⁴ demonstrates the game-changing difference between conventional recruitment methods (eg, mass mailings) versus EHR-led recruitment. With early, brisk-paced recruitment as a reliable indicator of overall clinical trial enrollment success, employing the EHR (and, in that study, referrals) as a way to recruit participants resulted in improved identification and retention of participants compared to laborious methods such as mass mailings and community health screening events.¹⁴

Reducing burden and effort in identifying clinical trial participants can save money. Industry-sponsored trials do not reimburse sites for time and effort in the participant identification process, highlighting the need to identify participants via EHR. As Penberthy et al²⁰ found at Virginia Commonwealth University, research personnel may spend from 3.4 to 8.8 hours per participant on identifying, screening, and enrolling a patient in a clinical trial. The time and effort convert to approximately \$129 USD per patient for an observational trial versus \$336 USD for a phase I enrollment.²⁰

As clinical trial participants become increasingly common and RCT protocol design includes ancillary discipline support (ophthalmology, surgery, dentistry), the need to capture participant information in the EHR will increase. Without a centralized means of providing clinicians with current therapies, adverse event information, concomitant medications, and impending procedures, participant injury or withdrawal will be a greater possibility. The American Society of Clinical Oncology stressed that, regardless of the EHR selected for use in oncology RCTs, the system must be interoperable to allow information exchange between departments and providers, preventing missing information that can lead to costly errors and participant safety lapses.² The first step may very well be data normalization and shared vocabulary management, as implemented by the Mayo Clinic.¹⁸ Data comparability and consistency support accuracy and facilitate integration of clinical trial data within the EHR or data warehouses.¹⁸

Discussion centered on clinician alerts pertaining to clinical trial participants, either concerning recruitment or

practice-related information. Benthin et al¹⁷ noted the variability in the use of alerts within EHRs. Of 38 institutions surveyed as part of the National Institute of Health-funded Clinical Trial Network for the Prevention and Early Treatment of Acute Lung Injury, 57% of the sites noted use of alerts, but only 59% of these sites evaluated the alerts for accuracy or validity.¹⁷ Furthermore, only 41% of sites used alerts for both clinical decision support and research; 29% used them only for research-related purposes.¹⁷ Query cycle time was reported as less than 1 hour, but still not immediate.¹⁷ Computerized decision support systems are similar to alert systems, while already integrated in most EHRs. Moja et al¹⁶ have launched an RCT assessing the use of MediDSS to improve care of oncology patients. Based on the rationale that data aggregation can support more sophisticated care plans and thus optimize patient outcomes, the use of this technology pertains to clinical trials, for example to manage adverse events and identify trends.¹⁶

CONCLUSIONS

While literature focusing on clinical trial integration within the EHR is limited in nature, work is in progress on solutions for interoperability and clinical trial support within the EHR. Articles in this review provided a full view of the issues at hand with integration, such as technological limitations, legal implications, and stakeholder feedback. Standardization of data capture and presence of clinical trial information within EHRs enhance trial conduct and support institution efficiencies just as with routine clinical operations. Clinical trial participants provide their time, effort, and course of treatment to advance scientific understanding of a disease or affliction. As a population, these participants deserve recognition in EHRs to ensure the same protections as nonclinical trial participants. Likewise, patients within a system should be provided the opportunity to participate in clinical trials regardless of whether their provider is research focused, through the use of identification alerts within the EHR. Establishing clinical trial information within EHRs sends a message: these participants are invaluable, assisting the progress of medicine and, with their data, the ability to improve therapeutics.

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