Michelle E Johnson. Investigating the User Experience of Electronic Data Capture Systems: Perspectives of Clinical Research Coordinators. A Master's Paper for the M.S. in I.S. degree. April, 2021. 100 pages. Advisor: Fei Yu

The purpose of this study is to explore the user experience (UX) of electronic data capture (EDC) systems from the perspective of clinical research coordinators (CRCs). Fifteen CRCs were recruited and participated in semi-structured interviews. Interview transcripts were coded and analyzed thematically. Themes were further contextualized within a theoretical framework comprised of the Technology Acceptance (TAM) Model, the Task-Technology Fit (TTF) Model, and concepts from usability theory. Themes emerging from the data included EDC usability and task-technology-fit challenges, and identification of organizational and technological barriers to EDC acceptance and performance. This study contributes to the literature by evaluating EDC systems from the perspective of a previously uninvestigated user group—CRCs—for the first time. Future work shall expand the results of this study by quantitatively evaluating EDC usability and informing the design of EDC systems.

Headings:

Human-computer interaction

User experience

Usability evaluation

Systems design

Clinical research information systems

Electronic data capture systems

Technology Acceptance Model (TAM)

Task-Technology Fit (TTF) model

User-centered design

INVESTIGATING THE USER EXPERIENCE OF ELECTRONIC DATA CAPTURE SYSTEMS: PERSPECTIVES OF CLINICAL RESEARCH COORDINATORS

by
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Approved by

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Fei Yu

Dedication

In loving memory of Mohammed Husain Jafri.

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I'm grateful to each of my study participants for their willingness to speak with me at length about their experiences with EDC systems. This study would not have been possible without them.

Finally, I would like to thank my boyfriend, my mother, and my friends, for listening to me talk about my thesis *ad nauseum* for the last six months, and for their endless support as I've made my way through graduate school.

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List of Acronyms

ACRP	Association for Clinical Research Professionals
AE	Adverse Event
API	Application Programming Interface
Con-meds	Concomitant Medications
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRI systems	Clinical Research Information systems
CRO	Contract Research Organization
CTMS	Clinical Trial Management Systems
DDC	Direct-Data Capture
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EHR	Electronic Health Record
eSource	Electronic Source Documentation
eTMF	Electronic Trial Master File
HCI	Human-Computer Interaction
HE	Heuristic Evaluation
IRT	Interactive Response Technology
IT	Information Technology
IVRS	Interactive Voice Response Systems
IWRS	Interactive Web Response Systems
IxRS	Interactive (Voice or Web) Response Systems
PEOU	Perceived Ease of Use
PU	Perceived Usefulness
Rave	Medidata Rave EDC
SAE	Significant Adverse Event
SOPs	Standard Operating Procedures
TAM	Technology Acceptance Model
TTF	Task-Technology Fit
UX	User Experience

1 Introduction

Clinical research is critical for understanding human health and disease, and for advancing potential drug treatments and other therapies. Clinical research can be broadly categorized into three types of studies: patient-oriented research, i.e., studies conducted with human subjects, epidemiological and behavioral studies, and outcomes or health services research (Embi & Payne, 2009). Clinical trials, a subtype of patient-oriented research, are clinical research studies where human subjects are "prospectively assigned to one or more interventions in order to evaluate the effects of those interventions on health outcomes ("NIH's Definition of a Clinical Trial," 2017). Clinical trials may range from smaller studies exploring tolerability of a new drug, to larger multi-institutional trials evaluating the efficacy or effectiveness of a treatment across a broad population. Patient-oriented research also includes observational studies, where data are prospectively collected from research participants in non-interventional settings to observe changes over time (National Institute on Aging, n.d.). In this study, clinical research refers to both subtypes of patient-oriented research: interventional clinical trials and observational, prospective studies of human subjects.

Multi-institutional clinical research studies are conducted at locations where eligible study participants can be identified and enrolled onto the study. This includes major academic research centers like Duke University Medical Center and

UNC Medical Center, community health centers, private clinical practices, and local health departments. These locations are commonly referred to as "sites" or "study sites." Sites are strategically identified at the beginning of the study to ensure there is an appropriate pool of potential study participants available for enrolling onto the study. Study sites are responsible for all of the participant-facing elements of the research study, from identifying potential participants, assessing participant eligibility, and conducting the study visits (Burks, 2020).

Depending on their complexity and scope, clinical research studies can be quite costly to run--especially studies that enroll participants across many study sites (Sertkaya, Wong, Jessup, & Beleche, 2016). Therefore, most clinical research studies are funded through large institutional research grants (e.g., NIH R01 awards) or through industry (pharmaceutical or biotechnology) **sponsors**. Research sponsors are responsible for overseeing the study's progress. Increasingly, industry sponsors are transferring all or part of their oversight responsibilities to a **contract research organization** (CRO), in order to reduce study costs and shorten study timelines (Wang & Motti, 2015).

Clinical research studies require a team of experienced professionals to be successful. At the site-level, clinical research teams typically include a principal investigator and one or more clinical research coordinators. More complex studies, such as multi-site clinical trials, have staff dedicated to supporting peripheral study activities, such as project management, site identification, statistical support, data quality monitoring, protocol support, billing, supply chain management, compliance

and regulatory activities, and information systems design and support. In industry-sponsored clinical research studies, many of the dedicated support staff can be found at the sponsor-level or CRO-level.

At sites, **clinical research coordinators (CRCs)** play a critical role in the planning and execution of clinical research studies. They identify potential study participants at their site, they conduct participant consent and enrollment, and they conduct all study visits with the participants. CRCs are also responsible for all research data collection activities at their site (Khan, Kukafka, Payne, Bigger, & Johnson, 2007). While many of the individuals performing these study activities have a formal job title of "Clinical Research Coordinator," the role itself, or specific elements of the role, may be performed by individuals having a variety of job titles, such as study coordinator, research assistant, research nurse, clinical research manager, research project manager, clinical trial assistant, data coordinator, and research specialist (Wessel, Tannery, & Epstein, 2006). For simplicity, the term "clinical research coordinator" or "CRC" is used throughout this paper to refer to individuals performing any of the site-level clinical research activities described above, regardless of actual job title.

CRCs face many data collection challenges in clinical research, where their study activities are often embedded into the clinical care environment, and where informed consent and patient privacy are paramount. Furthermore, the clinical research data are amassed from a variety of sources--from the study participants themselves, from participant health records, from diagnostic tools and devices at the

point of care, from medical images, from laboratory reports, and more (Nahm 2012).

A vast and growing information technology infrastructure, referred throughout this paper as **clinical research information (CRI) systems,** has formed to support the design, conduct and reporting of clinical research. Many types of CRI systems are used to support research data collection activities, including electronic data capture (EDC) systems, electronic source (eSource) and direct-data capture (DDC) systems, electronic patient-reported outcomes (ePRO) systems, and electronic clinical outcomes assessment (eCOA) systems. On the clinical care side, electronic health records (EHR) are used to abstract medical record data from study participants. There are also laboratory information management systems (LIMS) and imaging data management systems, which are used to collect and manage laboratory and imaging study data, respectively.

Electronic data capture (EDC) systems are information systems used by CRCs to capture and securely transmit accurate, auditable clinical research data from its original sources to the sponsor. EDC systems should meet basic usability goals, such as effectiveness, efficiency, and user satisfaction. The use of EDC systems in clinical research result in decreased user error, improved data quality, and increased user productivity (Dillon et al., 2014; Litchfield et al., 2005; Nahm, Pieper, & Cunningham, 2008; Rorie et al., 2017), so it follows that well-designed EDC systems may realize these benefits to an even greater extent. However, due to

organizational and technological constraints, usability principles have not been incorporated into the design of these systems (Johnson et al., 2010).

Although CRCs are critical to the success of clinical research studies, their perspectives are often not considered during the design and testing of EDC systems. While previous literature has emphasized the need for user-centered design principles to be incorporated into EDC systems (Schmier, Kane, & Halpern, 2005), and one previous study evaluated EDC system usability from the perspective of study participants (Walden, Garvin, Smerek, & Johnson, 2020), insufficient research has been done to evaluate the usability of EDC systems from the perspective of CRCs. Further, to my knowledge, no studies have used a qualitative semi-structured interview approach to evaluate the user experience of EDC systems, such as its usability and usefulness.

This purpose of this study is to extend and expand upon previous work, by qualitatively evaluating the usability and user experience (UX) of EDC systems from the perspective of CRCs--the "invisible hands of clinical research" (Davis, Hull, Grady, Wilfond, & Henderson, 2002). This work applies qualitative evaluation methods, based on models from the field of human-computer interaction to EDC systems, to analyze and contextualize the perspectives of CRCs as end users. Specific research aims include the following:

(1) Identify EDC systems that are commonly used in clinical research.

(2) Identify usability challenges impacting CRC acceptance of EDC systems.

(3) Explore the perceived degree of fit between EDC systems and CRC tasks.

(4) Propose recommendations for EDC systems design based on CRC perceptions regarding usability and task-technology fit.

(5) Identify external variables that impact EDC technology acceptance and performance.

2 Literature Review

2.1 CRCs: The Invisible Hand in Research

CRCs provide critical support for the day-to-day operations of the study. They screen for eligible patients, obtain informed consent, verify that participants meet study inclusion/exclusion criteria, collect and enter data, and follow up with patients about study visits. They are responsible for educating other staff and patients about the study, and they regularly communicate updates to the study team. They also monitor the quality of the study data, report potential study deviations, and respond to routine queries about the data (Speicher et al., 2012). Given their central role in the conduct of clinical research, and the limited amount of literature focused on this stakeholder group, CRCs have previously been described as the "invisible hand in clinical research" (Davis et al., 2002).

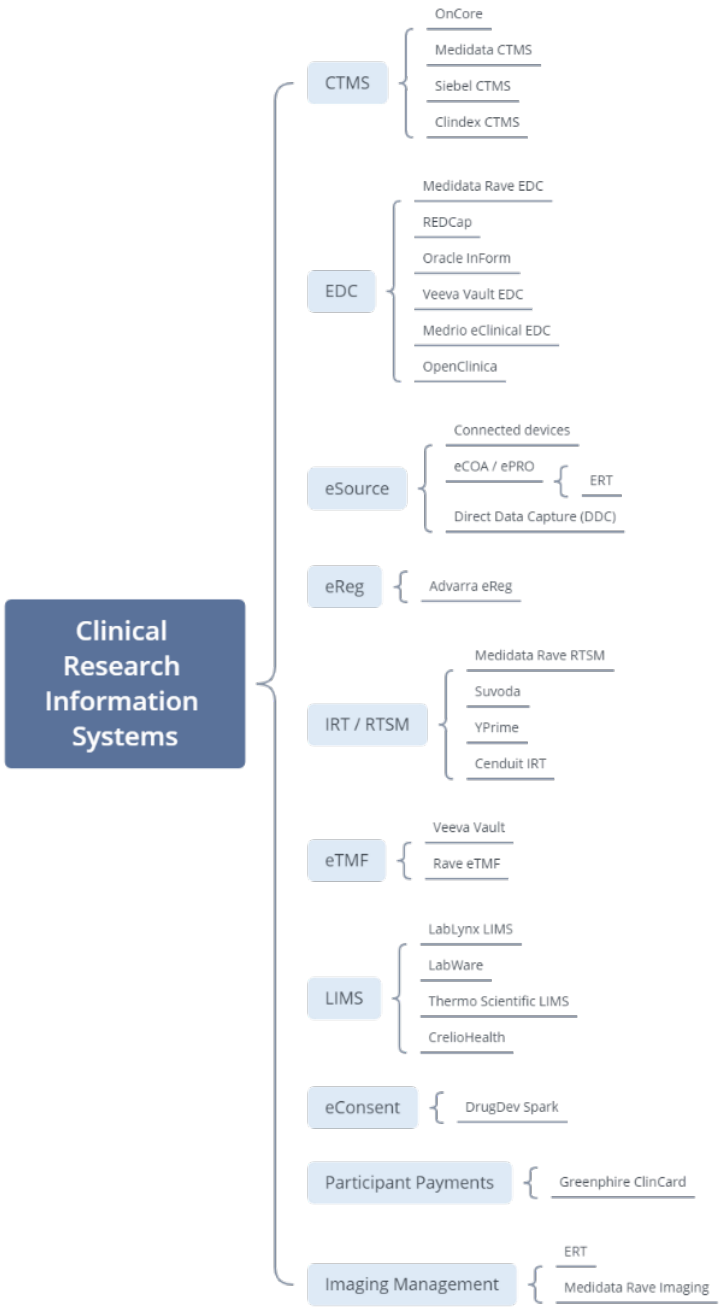
Because the individuals performing this role have many job titles, it is difficult to properly estimate the number of CRCs in the U.S. One estimate placed the number of CRCs in the U.S. workforce at just over 30,000 individuals ("Clinical Research Coordinator Demographics and Statistics - Zippia," n.d.).

Some literature has assessed the information needs of CRCs. One study performed a direct observation of CRC workflows in a community practice setting and found that there was a need for a CRC-oriented information system to enhance

collaboration, communication, and workflow efficiencies (Khan, Kukafka, Payne, Bigger, & Johnson, 2007). Another study looked at the information seeking behaviors of CRCs and found that they would benefit from enhanced training opportunities (Wessel, Tannery, & Epstein, 2006).

CRCs are primarily responsible for the data collection activities in clinical research studies. As such, CRCs are the predominant end users of most CRI systems. ***Figure 1*** on the next page illustrates the ecosystem of CRI systems that are most often used by CRCs today. CRCs are neither software developers nor data entry specialists. They often have clinical responsibilities in addition to their research role and manage multiple studies at the same time. While CRCs are likely to use a computer regularly to meet the demands of their role, they are not expected to be highly skilled in technology use (Schmier et al., 2005).

Figure 1. *CRI Systems: Subtypes and Popular Vendors*



Note: Figure developed by author using Lucidchart.com software (www.lucidchart.com)
CTMS = Clinical Trial Management Systems; EDC = Electronic Data Capture Systems; eReg = Electronic Regulatory Management Systems; IxRS = Interactive Voice/Web Response Systems; eTMF = Electronic Trial Master File Systems; LIMS = Laboratory Information Management Systems; eConsent = Electronic Consent

2.2 Description of EDC Systems

In the past two decades, clinical research data collection has transitioned from an entirely paper-based endeavor to one dominated by the use of electronic CRI systems. The move towards electronic research records was first incentivized by the Paperwork Reduction Acts in 1980 and 1995. Since then, a wide range of tools for electronic data collection have been released onto the market (Shah et al., 2010; Leroux, McBride, & Gibson, 2011).

EDC systems are a subtype of CRI systems that are designed to capture clinical research data from the original data sources, in support of data analysis. EDC systems facilitate data quality through features like edit checks, data entry constraints, derived fields, automatic and manual querying, source data verification, and audit trails (El Emam, Jonker, Sampson, Krleza-Jerić, & Neisa, 2009; Nadkarni, Marenco, & Brandt, 2012; Sahoo & Bhatt, 2003). EDC systems can also be used for remote monitoring and reporting, with features like risk-based monitoring and adverse event reports (Nadkarni et al., 2012; Sahoo & Bhatt, 2003). EDC systems are typically hosted on web servers, allowing users to access the data immediately, from any location, using an internet connection. This enables sponsors to monitor and evaluate the status of data collection in real-time, rather than waiting for sites to mail or scan paper forms (Nadkarni et al., 2012).

Given there are many sources of original study data across many study sites, EDC systems serve to centralize study data into a single location. Most commonly, original study data are captured by CRCs during study visits or phone calls via paper

forms or handwritten notes. Other sources of original study data include paper surveys, forms, or diaries directly filled out by study participants, or original paper copies of lab and diagnostic test results. Increasingly, there are electronic sources of original study data (sometimes referred to as "eSource"), such as study notes recorded directly into the participant's electronic health record (EHR), data from wearable fitness trackers and digital medical devices, and data collected electronically from participants through electronic patient-reported outcomes (ePRO) and electronic clinical outcomes assessments (eCOA) systems. Collectively, these original sources of study data are referred to as source documentation (Parab et al., 2020). To ensure the integrity of the data collection, sponsors assign a study monitor to conduct source data verification (SDV), a process whereby source documentation is compared against data in the EDC to ensure the data are consistent.

"Case report forms" (CRFs) are central to the design of EDC systems. CRFs are forms that are designed to capture data elements from the original study data that are critical for data analysis, such as demographic information about the participant, study visit dates, concomitant medications, lab and test results, comorbidities, etc.

While many EDC vendor systems are standalone products, some vendors provide for EDC integration with other CRI systems, such as randomization and supply management systems, electronic patient-reported outcomes (ePRO) systems,

laboratory information management systems (LIMS), imaging systems, among others.

In order to facilitate FDA submissions for new drug and new device applications, most EDC systems are compliant with 21 CFR Part 11 of the U.S. Code of Federal Regulations, which defines the criteria by which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records ("Part 11, Electronic Records; Electronic Signatures - Scope and Application | FDA," n.d.).

2.3 Evaluation of EDC Systems

After clinical research studies are funded, EDC systems are configured to match the data needs of the sponsor and to adhere to the requirements of the study protocol. EDC system configuration is performed by the sponsor, or by representatives contracted on behalf of the sponsor, such as contract research organizations (CROs) or EDC vendors. Sponsors and CROs often have internal departments dedicated to EDC system configuration, testing, deployment, and maintenance.

Schmier et al. (2005) argued that EDC systems have typically been viewed as secondary priorities by study sponsors and investigators, after supply chain logistics and enrollment/recruitment. EDC systems are often assembled as an afterthought to the trial startup process, and as such, they often have not received an appropriate degree of validation and testing. In addition, the individuals responsible for testing and approving the systems for use typically do not have

extensive training in information technology or usability (Schmier et al., 2005). Furthermore, user testing of CRI systems prior to study start-up is not included as a best practice in the good clinical data management practices guide (GCDMP), a key reference in clinical research data management (Johnson et al., 2010).

Prior to EDC system deployment, user acceptance testing is performed by representatives of the sponsor to ensure that the EDC system works correctly and that it captures the needs of the protocol. However, the term "user" in "user acceptance testing" is a bit of a misnomer, as this does not refer to true end users at the study sites.

Sites are typically "activated" onto clinical research studies closer to the targeted date of initial patient enrollment. By the time sites are brought onto a study, EDC systems have already been tested and deployed (Schmier 2005). Consequently, sites are activated onto studies after EDC systems have already been tested and deployed. Due to the pressure to begin enrolling patients as soon as possible, user acceptance testing is rarely performed by actual site users.

To date, literature evaluating the use of EDC systems in clinical research has predominantly focused on gains in research efficiency and improvements in data accuracy, as compared to paper-based systems. For example, a 2005 multicenter randomized clinical trial found that use of a web-based EDC resulted in faster data entry, query resolution, and release of data for analysis, when compared with a paper-based system (Litchfield et al., 2005). A randomized crossover trial in 1999 found that use of a touchscreen electronic questionnaire resulted in acceptable data

quality and reliability of the results, and the technology was generally well received by cancer patients (Velikova et al., 1999). Another article found that "properly validated EDC software [can] virtually eliminate post-capture data errors" (Helms, 2001).

Barriers to the successful use of EDC systems have also been described in the literature. A 2007 study by Welker et al. found that differences in user motivations, regulatory requirements, availability of economic and personnel resources, and the user-friendliness of the system's graphical user interface served as barriers to EDC acceptance and use (Welker, 2007). Another study found that successful implementation of EDCs in clinical research requires adjustment of clinical research processes, and reallocation of resources to training of study staff (Walther et al., 2011). Another study identified areas of dissonance (inefficient processes) between clinical and research workflows using Lean Six Sigma evaluation methods. This study found that the use of different tools for different purposes led to fragmented flows of information, duplication of efforts, and inefficiencies in conducting research (Cofiel, Bassi, Ray, Pietrobon, & Brentani, 2013).

Literature regarding the usability of and user satisfaction with EDC systems is scarce. Schmier et al. described the importance of evaluating EDC system usability (Schmier et al., 2005). In 2010, C.M. Johnson et al. evaluated the use of heuristic evaluation (HE) as a method to independently and prospectively identify data collection form questions associated with data entry errors. This observational study conducted HE with two independent usability experts, assessing online data

entry forms for 14 different usability heuristics. The study revealed a number of minor and major usability issues with the data entry forms, concluding that application of HE is feasible and useful as a method for examining the usability of electronic data entry systems (Johnson et al., 2010). Johnson's work established the feasibility of applying HE methods to EDC systems.

A recent study in 2020 evaluated whether clinical study tools would benefit from the incorporation of user-centered design principles. The investigators conducted usability testing on patient-facing forms within the EDC. Importantly, this research used study participants as the targeted end users, rather than CRCs (Walden, Garvin, Smerek, & Johnson, 2020). The authors concluded that "usability testing done directly by participants identifies issues that may affect the user experience of clinical study tools" and that "user-centered design can reduce the need for extensive user training, decrease potential errors, and ensure that the electronic system is easy to understand and use." The authors note that additional research should be conducted to compare different methods of usability testing and user acceptance testing to determine how such results can be better integrated into the software development life cycle (SDLC) (Walden et al., 2020).

Some case studies have quantitatively evaluated user satisfaction of research staff after implementing specific EDC systems in their departments or units to replace legacy systems or spreadsheets. Dunn et. al developed an application programming interface (API) to push legacy clinical research data from Excel spreadsheets into REDCap, in order to generate summary-level data across

members of the Alzheimer's Disease Research Centers (Dunn, Cobb, Levey, & Gutman, 2016). After conducting a user survey with a mix of principal investigators, study coordinators, and other research staff, they found that most users reported medium to high satisfaction with the system, but also found that there was a substantial initial learning curve for new users of the system (Dunn et al., 2016). However, these studies were limited in scope to single EDC systems and were limited to user satisfaction rather than overall usability assessments.

2.4 Gap in the Literature

The gap in current literature is two-fold: (1) CRCs haven't been included in the study, design, and evaluation of EDC systems; and (2) User experience with EDC systems have not been evaluated or investigated substantively. In addition, to my knowledge, no studies have employed a qualitative semi-structured interview approach to evaluate the usability and usefulness of EDC systems.

2.5 Evaluation Methods in Human-Computer Interaction

Evaluation methods in the field of Human-Computer Interaction (HCI) are used to identify strong and weak elements of a system's design. Such methods can be broadly categorized into four types: (1) empirical approaches with end users, such as controlled usability testing and user satisfaction questionnaires (2) analytical approaches with end users, such as contextual inquiry, focus groups, and interviews , (3) model-based approaches such as GOMS (Goals, Operators, Methods, and Selection), and (4) inspection-based approaches, such as HE and cognitive

walkthroughs (Sharp, Preece, & Rogers, 2019). Depending on the approach selected, the analytical output of the evaluation may consist of more objective measures of the technology's performance, more subjective measures of user perceptions regarding the technology, or a combination of both objective and subjective measures.

2.5.1 Usability and User Experience

ISO9241-11 defines usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" (*ISO 9241-11:1998*, 1998). In 1994, Nielsen defined usability as a quality attribute that assesses five key quality components of the user interface: **efficiency** (how quickly users can perform tasks using the interface), **satisfaction** (how pleasant users find the interface), **learnability** (how quickly users can learn how to use the interface), **memorability** (how well users can retain what they have learned about the interface), and **error tolerance** (how well the interface prevents or supports recovery from user errors) (Nielsen, 1994). The ISO usability criteria of efficiency and satisfaction overlap with Nielsen's usability components but include **effectiveness** (how well the interface allows the user to achieve specified tasks). These usability goals are summarized in ***Table 1*** on the next page.

Table 1. *Usability Goals (ISO 9241-11:1998, 1998; Nielsen, 1994)*

Effectiveness	how well the interface allows the user to achieve specified tasks
Efficiency	how quickly users can perform tasks using the interface
Satisfaction	how pleasant users find the interface
Learnability	how easy the interface is to learn
Memorability	how well users can retain what they have learned about the interface
Errors	how well the interface prevents or supports recovery from user errors; how well the interface supports users in recovering from errors or reversing actions

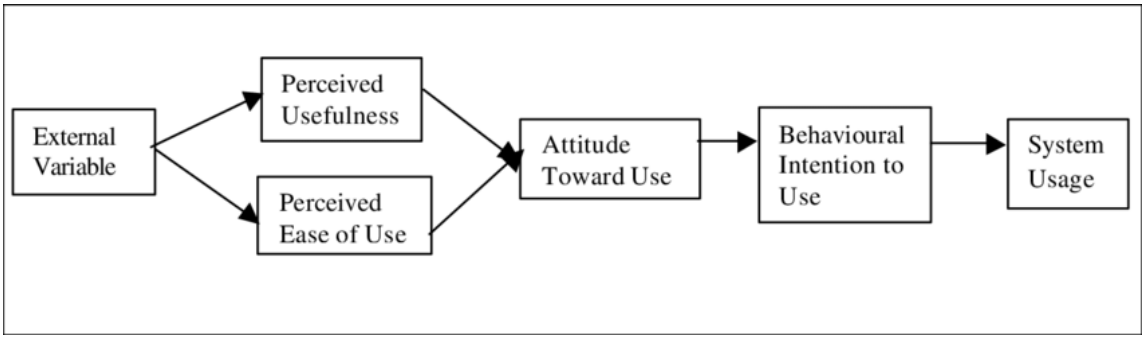
2.5.2 HCI Evaluation Models

To facilitate interpretation of the qualitative data analysis, I examined several models commonly used for evaluation in the field of human-computer interaction (HCI).

Technology Acceptance Model

The Technology Acceptance Model (TAM) is a highly cited and influential theory of information technology acceptance, accounting for nearly 40% of IT acceptance literature (Lee, Kozar, & Larsen, 2003). Introduced in 1986 by Davis, the TAM model aims to explain and predict end user acceptance of information technology through the interplay between two major constructs: Perceived Ease of Use (PEOU) and Perceived Usefulness (PU) (Fred, 1985). The first major construct, Perceived Ease of Use, is defined as an individual's perception that using an information technology system will be free from effort (Holden & Karsh, 2010). The second major construct, Perceived Usefulness, is defined as an individual's perception that using an information system will enhance job performance (Holden & Karsh, 2010). ***Figure 2*** on the next page is the TAM, as reproduced from Davis (1985).

Figure 2. *Technology Acceptance Model (Reproduced from Davis, 1985)*



Although TAM has been validated as a reliable model of information technology acceptance, it has also been criticized as being overly reductive and failing to consider the impact of external variables on technology acceptance. Consequently, many studies have sought to extend the TAM by identifying and evaluating the impact of various external factors on PU and PEOU. To date, studies have found significant correlations between PEOU and the system's usability, the system's accessibility, the user's attitudes towards the system, the user's beliefs about self-efficacy, the perceived enjoyment of using the system, among others (Lee et al., 2003). Likewise, studies have found significant correlations between PU and external factors such as job relevance, result demonstrability, system complexity, subjective norms, etc. Some studies have looked at the relationship between PEOU on PU and found that the perceived ease of use of a system has a significant impact on the perceived usefulness of the system (Lee et al., 2003).

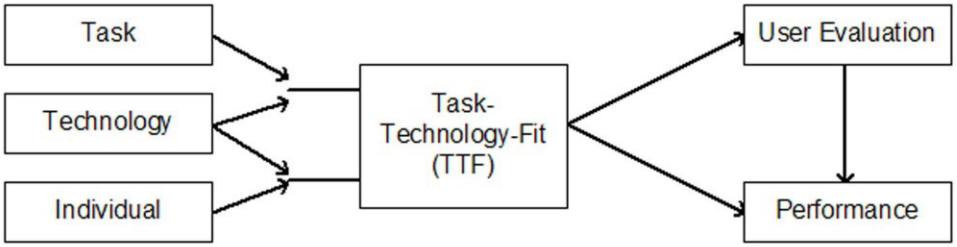
In 2007, following a review of literature on physician technology acceptance, Yarbrough proposed that external barriers, such as organizational issues and interruption of traditional clinical workflows, may have a significant impact on

technology acceptance for physician users of clinical information systems, such as electronic health records (Yarbrough & Smith, 2007). More recent literature has called for further exploration into the organizational factors impacting health information technology implementation (Cresswell & Sheikh, 2013) and the need for theoretical frameworks to guide implementation and evaluation of technology in healthcare settings (Cresswell & Sheikh, 2013).

Task-Technology Fit Model

Another significant model within HCI evaluation is the Task-Technology Fit model (TTF). The TTF model explores the impact of task characteristics and technology characteristics on an information system's ability to support a task (Goodhue, Klein, & March, 2000). The TTF model theorizes that information technology will be used only if the technology's functions support the activities of the user. Furthermore, the model suggests that users will select the technologies that most enable them to complete their tasks. A later publication by Goodhue found that user evaluation has a strong link to system performance, and therefore, that user evaluation of the system is an acceptable surrogate for measuring the degree of TTF (Goodhue et al., 2000). ***Figure 3*** on the next page is the TTF Model, as reproduced from Goodhue et al. (2000).

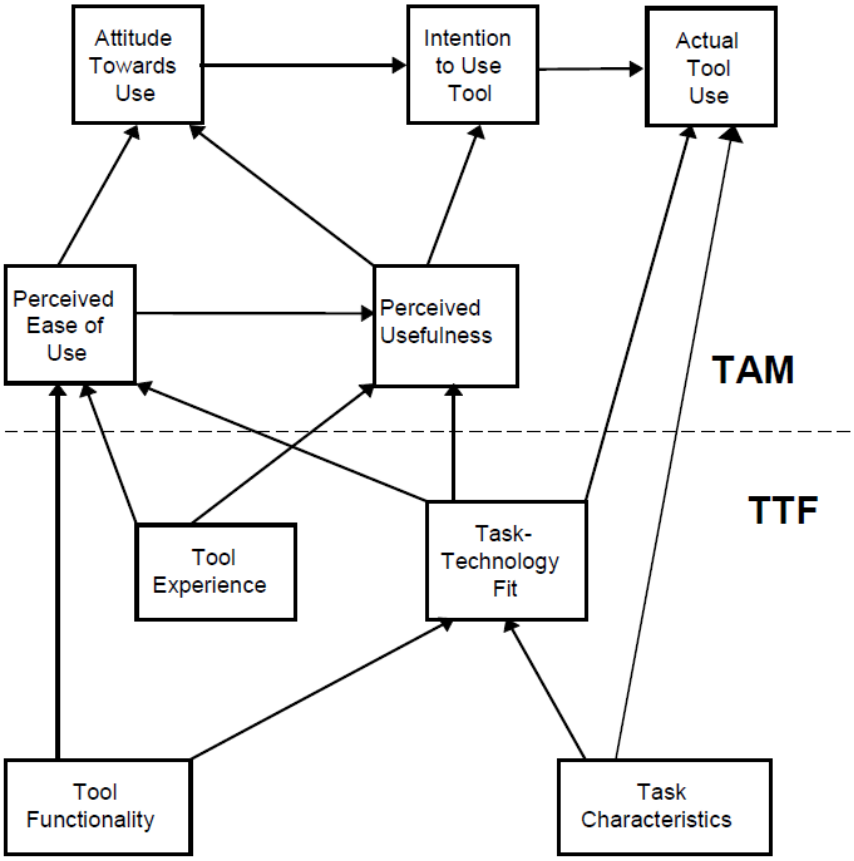
Figure 3. *Task-Technology Fit Model (Goodhue and Thompson, 1995)*



Combining TAM and TTF Models

The TAM provides a theoretical basis for evaluating the attitudes and behaviors of end users towards a particular technology (which are based on the technology's perceived usefulness and ease of use), while the TTF model provides a theoretical basis for evaluating the fit between the technology's capabilities and users' task needs. Dishaw and Strong proposed a combined TAM-TTF model as an improved representation of the relationship between information technology and its utilization by end users, after noting that integration of constructs across the two models could offer better explanatory power of technology use compared to either model alone (Dishaw & Strong, 1999). ***Figure 4*** on the next page is the combined TAM-TTF, reproduced from Dishaw and Strong (1999).

Figure 4. *Integrated TAM/TTF Model (Dishaw & Strong, 1999)*



3 Methods

3.1 Methodological Approach

To explore CRC user experiences with EDC systems, I used semi-structured interviews to collect qualitative data from study participants and thematic analysis to iteratively code, categorize, and construct themes from the data. I followed a qualitative methodological approach modeled after Blandford's description of semi-structured qualitative studies (Blandford, Furniss, & Makri, 2016). This study design allowed me to obtain a "thick" description from participants regarding their experiences with and perceptions with EDC systems. The semi-structured nature of the interviews also allowed me more flexibility to probe interesting lines of inquiry when potential patterns or connections emerged. Given the exploratory nature of the research aims and the intent to evaluate EDC systems from a subjective end user perspective, I chose to approach this study from an interpretive theoretical lens.

3.2 Participant Recruitment and Enrollment

Prior to the initiation of study activities, this study was reviewed and determined to be exempt by the UNC Institutional Review Board (IRB #20-2620).

Participants were eligible to participate in the study if they were 18+ years of age, if they had current or recent (within the last two years) clinical research

responsibilities, and if they had experience using at least one EDC system. Clinical research responsibilities were defined as screening and enrolling patients, scheduling and conducting study visits, following up with participants in clinic or by phone, entering data into forms, transcribing data into EDC systems, and resolving questions from data managers.

Participants for this study were identified through a combination of snowball sampling (starting with former colleagues at UNC Chapel Hill) and convenience sampling (by posting recruitment messages to several listservs and forums frequented by clinical research professionals).

Once initial contact was established, eligibility was assessed, and eligible participants were provided with additional information about the study via email. Participants who were still interested in participating were provided with a URL to an electronic consent form created using UNC REDCap. In the consent form, individuals were asked to provide consent to participate in the interview, and they were also asked to consent to either an audio-only recording and/or an audiovisual recording of the interview.

3.3 Data Collection

Qualitative interview data was collected using semi-structured interviews held over Zoom videoconferencing software. An interview guide was developed (see Section 9. Appendices - Interview Guide) to guide discussions with the

participants.[1] Interview questions and probes were designed to explore the study aims by asking participants to reflect on their recent experiences using EDC systems, to describe how they use EDCs to accomplish study tasks, to examine their perceived satisfaction with EDC systems, and to identify potential ways EDC systems can be improved. Most of the questions were intentionally open-ended, to allow more flexibility for exploring areas of interest in depth. A list of interview questions and associated research aims can be found in ***Table 2*** on the next page.

[1] I am grateful to Dr. Todd R. Johnson and Ram Dixit (University of Texas Health Science Center) for providing a copy of the protocol and appendices used in their study evaluating user needs and usability of a biomedical data discovery index tool (Dixit et al., 2018), The interview questions were used as a starting point for developing the interview guide for this study.

Table 2. *Interview Questions and Associated Research Aims*

Aim1: Identify EDCs	Aim 2: Usability Challenges	Aim 3: Task-Technology Fit	Aim 4: Recommendations	Aim 5: External Variables	
				✓	Tell me about your role at your company.
				✓	What is your work environment like? (Note: Ask about COVID-19-related changes.)
				✓	Please tell me about a clinical research study that you are currently involved in (or were involved in within the past two years).
		✓			What tasks are you responsible for?
		✓		✓	Do you share these tasks with other colleagues in your study team?
		✓		✓	What does the overall study workflow look like for you?
✓		✓		✓	What sort of information do you need to keep track of? How do you keep track of it?
✓		✓		✓	What sort of information do you regularly need to look up? How do you find it?
✓		✓		✓	Where do you enter study data? Do you ever record study information in supplementary locations (such as Excel spreadsheets)?
✓					Do you use REDCap, Oracle Health Sciences InForm, Oracle Clinical One, OpenClinica, Medidata Rave, etc. in your studies? How familiar would you say you are with [EDC name]?
	✓			✓	Did you receive training on how to use it?
				✓	When the study first started, were you included in meetings or discussions regarding the setup of this system? • If yes, please tell me more about the input you provided on the system design. • If no, do you wish that you had been able to provide input regarding the system design?
	✓	✓			I'd like you to think back to the last time you used [EDC name]. Can you walk me through how you might use this system, starting for example with enrolling a new patient, up through the end of patient follow-up? • How do you currently go about [task]? • What kind of device do you tend to use in completing [task]? • How much time do you typically spend on [task]? • What is the biggest pain point related to [task]? • Do you use any workarounds or shortcuts related to [task]?
	✓	✓	✓		What do you like about [EDC]?
	✓	✓	✓		What is the hardest part about using [EDC] in your studies?
	✓	✓	✓		What could be done to improve [EDC]?
	✓	✓			Does [EDC] have any features that you really like? Describe.
	✓	✓			Is [EDC] missing any features that you really need to do your work? Does [EDC] have any features that you find particularly frustrating or unhelpful? Describe.
✓	✓	✓			Have you used other EDCs? • How do they differ? • How are they similar? • What do you like or dislike about these other products or tools?
✓	✓	✓		✓	Is there anything else that you think would be helpful to know regarding your information needs as a [role], that we have not talked about yet?

Secure web-based Zoom meeting invitations were emailed to consented study participants in advance of the interview. At the onset of the interview, participants were asked if they had any questions about the consent form or about the study. Participants were also asked to reconfirm their comfort in having the interview recorded. Interviews were audio-recorded and automatically transcribed using Zoom's live transcription feature. Due to the poor quality of the Zoom transcriptions, transcripts were supplemented using manual transcription.

Interviews ranged from 37 minutes to 59 minutes long, with an average duration of 46 minutes. At the conclusion of the interview, participants were emailed a $20 Amazon.com gift card in appreciation of their time.

3.4 Data Management

All study data, including Zoom audio recordings, interview transcripts, and collected participant information, was stored in a secure, HIPAA-approved Microsoft Teams location. Interview transcripts were redacted of identifying information prior to analysis.

To minimize the risk of breach of confidentiality, personally identifying information about the participants was stored separately from the study transcripts and audio recordings. A unique Subject ID was assigned to each consented participant and used to link the transcripts and audio recordings back to the participant information. Transcribed interviews were pseudonymized with the Subject ID, and any instances of identifying information contained within the interview transcripts were redacted prior to analysis.

3.5 Data Analysis

Transcript data from the interviews were analyzed using thematic analysis. Thematic analysis is a method of data analysis in which ideas and concepts that emerge from the data are iteratively grouped, coded, and organized into higher-level concepts and themes. NVivo, a computer-assisted qualitative data analysis software (CAQDAS) was used to support consistency and organization of identified codes, categories, and themes[2]. In accordance with the Braun and Clarke six-phase framework for thematic analysis, codes were first collated into potential themes, and then themes and codes were reviewed iteratively until a thematic map could be identified, defined, and refined (Braun & Clarke, 2006). The six-phase framework is illustrated in ***Table 3*** below (Braun & Clarke, 2006). The thematic analysis process occurred over a period of several weeks, with several deliberate pauses in the analysis to support consistency in the themes identified.

Table 3. *Six-Step Data Analysis Process (Braun & Clarke, 2006)*

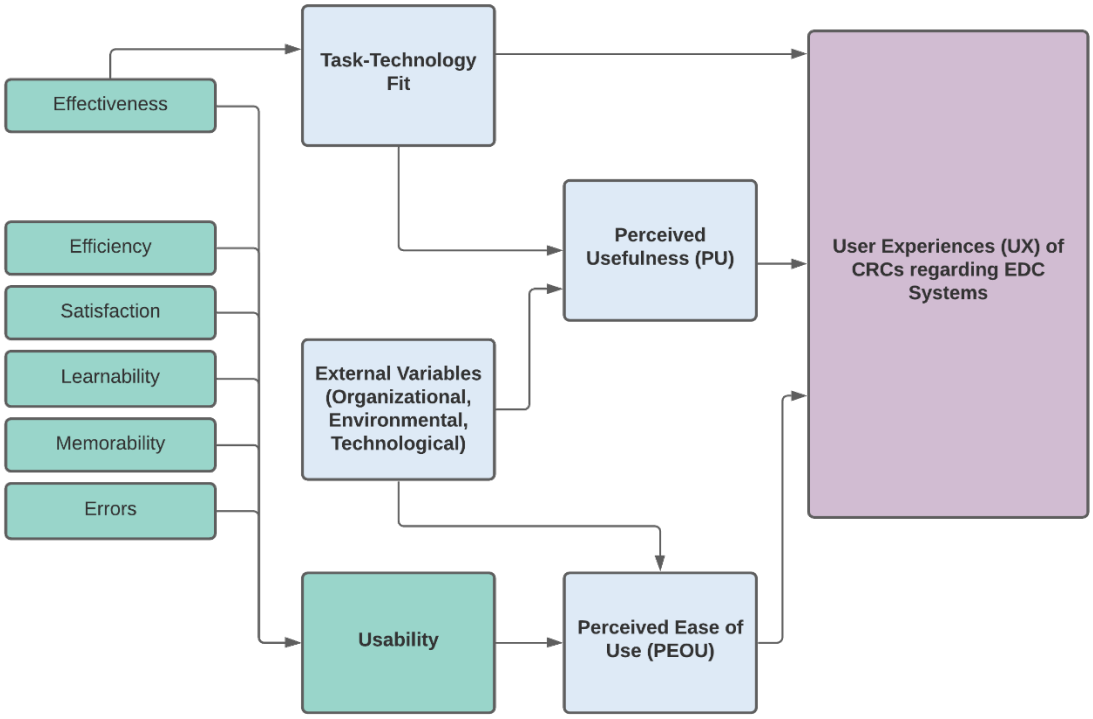
Phase	Examples of procedure for each step
1. Familiarising oneself with the data	Transcribing data; reading and re-reading; noting down initial codes
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the data-set, collating data relevant to each code
3. Searching for the themes	Collating codes into potential themes, gathering all data relevant to each potential theme
4. Involved reviewing the themes	Checking if the themes work in relation to the coded extracts and the entire data-set; generate a thematic 'map'
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme; generation of clear names for each theme
6. Producing the report	Final opportunity for analysis selecting appropriate extracts; discussion of the analysis; relate back to research question or literature; produce report

QSR International Pty Ltd (2021). NVivo [Computer Software]. Retrieved from www.qsrinternational.com .

Thematic analysis is a highly flexible qualitative research method; however, this flexibility can lead to inconsistency, concerns about validity, and lack of coherence. As such, thematic analysis was conducted in accordance with the approach set forth by Nowell et al. (2017) to demonstrate that "data analysis has been conducted in a precise, consistent, and exhaustive manner through recording, systematizing, and disclosing the methods of analysis with enough detail to enable the reader to determine whether the process is credible" (Nowell, Norris, White, & Moules, 2017).

While initial coding and identification of themes followed an inductive process driven directly by the interview data (Anderson, Burford, & Emmerton, 2016), further refinement of the themes was driven by concepts from existing literature. An analytical framework (***Figure 5*** on the next page) was developed for this study using constructs from usability theory, TAM, and TTF to contextualize and interpret the initial findings of the qualitative analysis. Identified codes and themes were iteratively re-reviewed against the analytical framework to determine how they fit existing constructs.

Figure 5. *Analytical Framework for Qualitative Data Analysis*



Based on the definition of effectiveness (how well the interface allows a user to achieve specified tasks), I connected this element of usability to the Task-Technology Fit model (which explores the fit between the user's tasks and the technology's ability to support those tasks) and corresponds indirectly with Perceived Usefulness (the user's perception that using a technology will enhance job performance.) The other usability goals (efficiency, satisfaction, learnability, memorability, errors) could be mapped directly to the concept of usability, which has been described in the literature as an antecedent to Perceived Ease of Use.

4 Results

4.1 Participants

Fifteen semi-structured interviews were held with CRC participants via Zoom. Interviews ranged from 37 minutes to 59 minutes long, with an average duration of 46 minutes. A summary of participant characteristics is included in ***Table 4*** on the next page.

Table 4. *Description of Participants*

	# Participants	% Participants
Years' relevant work experience*		
<2 years	3	20%
2 to 5 years	6	40%
6 to 10 years	3	20%
11 - 19 years	0	0%
20+ years	2	13%
Unknown	1	7%
Employer		
Academic medical center	10	67%
Not-for-profit health organization	2	13%
Contract Research Organization (CRO)	2	13%
Specialty medical practice	1	7%
Region		
Southeast	10	67%
South Central	2	13%
Midwest	1	7%
Northeast	1	7%
Mid-Atlantic	1	7%
Current Job Title		
Clinical Research Coordinator (CRC)	8	53%
Clinical Research Nurse	3	20%
Other	3	20%
Clinical Research Associate	1	7%

4.2 Identification of Common EDC Systems

Participants discussed a total of 14 EDC systems. Nearly all participants interviewed (14 of 15) used Medidata Rave EDC[3] in one or more of their studies. Many participants also reported using REDCap[4] and Oracle InForm[5] (7 and 5

[3] Medidata Rave EDC. [Computer Software]. Retrieved from https://www.medidata.com/
[4]REDCap. [Computer Software]. Retrieved from https://www.project-redcap.org/software/
[5]Oracle InForm. [Computer Software]. Retrieved from https://www.oracle.com/

participants, respectively). The remaining EDC systems identified during the interviews were discussed by one participant each, including Advarra EDC[6], BioClinica EDC[7]; Captivate EDC[8]; Dacima[9]; DATATRAK EDC[10]; eCaseLink EDC[11]; Clindex EDC[12]; IBM Clinical Development EDC[13]; ClinTrak EDC[14]; Medrio eClinical EDC[15], and REDCap Cloud[16]. Between two to five EDC systems were discussed at each interview, with a median of three EDC systems discussed. Fifteen additional EDCs were identified through the literature review, but these systems were not discussed by any participants.

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[6] Advarra. Advarra EDC [Computer Software]. Retrieved from: http://www.advarra.com/
[7] Bioclinica EDC [Computer Software]. Retrieved from: http://www.bioclinica.com/
[8] Capitvate EDC [Computer Software]. Retrieved from: http://www.clincapture.com/
[9] Dacima [Computer Software]. Retrieved from: http://www.dacimasoftware.com/
[10] DATATRAK EDC [Computer Software]. Retrieved from: http://www.datatrak.com/
[11] eCaseLink EDC [Computer Software]. Retrieved from: http://www.dsg-us.com/
[12] Clindex EDC [Computer Software]. Retrieved from: http://www.fortressmedical.com/
[13] IBM Clinical Development EDC [Computer Software]. Retrieved from: http://www.ibm.com/
[14] ClinTrak EDC [Computer Software]. Retrieved from: http://www.medpace.com/
[15] Medrio eClinical EDC [Computer Software]. Retrieved from: http://www.medrio.com/
[16] REDCap Cloud [Computer Software]. Retrieved from: http://www.redcapcloud.com/

Table 5 on the next page lists the EDC systems identified through participant interviews. Appendix 9.2List of Popular EDC Systems and Vendors lists all EDC systems identified through both the participant interviews and the literature review.

Table 5. *EDC System Vendors Discussed*

EDC Name	Vendor Website	Pricing Strategy	# Participants using EDC
Rave EDC	www.medidata.com	Proprietary	14
REDCap	www.projectredcap.org	No cost for REDCap Consortium Partners	7
InForm	www.oracle.com	Proprietary	5
Advarra EDC	www.advarra.com	Proprietary	1
BioClinica EDC	www.bioclinica.com	Proprietary	1
Captivate EDC	www.clincapture.com	No cost for COVID-19 research, otherwise proprietary	1
Dacima	www.dacimasoftware.com	Proprietary	1
DATATRAK EDC	www.datatrak.com	Proprietary	1
eCaseLink EDC	www.dsg-us.com	Proprietary	1
Clindex EDC	www.fortressmedical.com	Proprietary	1
IBM Clinical Development EDC	www.ibm.com	Proprietary	1
ClinTrak EDC	www.medpace.com	Proprietary	1
Medrio eClinical EDC	www.medrio.com	Proprietary	1
REDCap Cloud	www.redcapcloud.com	Proprietary	1

4.3 Themes Identified

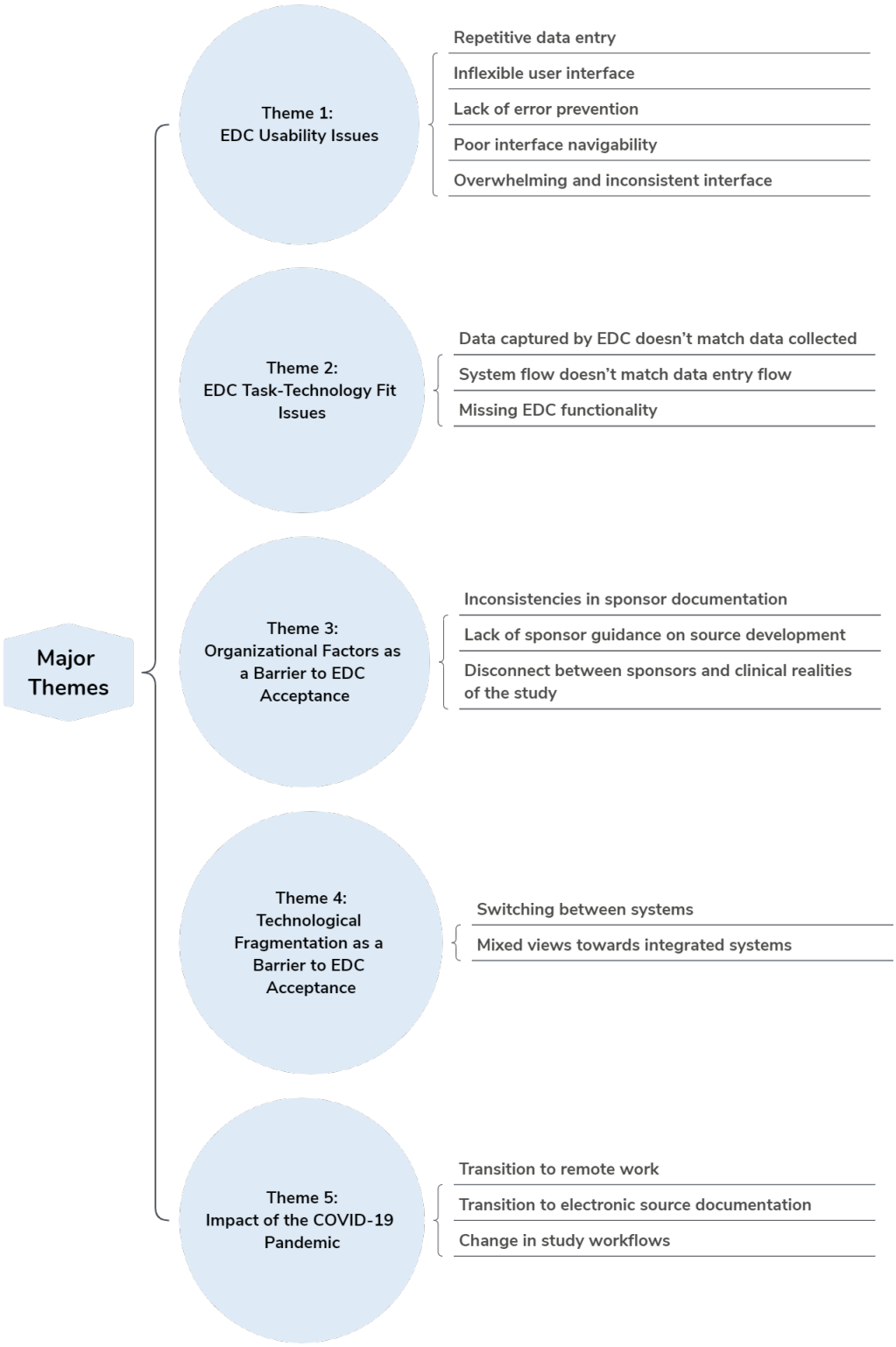
Table 6 highlights the five major themes that were revealed during the iterative process of coding, categorizing, and examining the codes within the context of the analytical framework. Major themes were identified based on the number of interviews containing the theme, a full count of the number of times the theme emerged across all interviews, and the perceived level of emphasis by the interviewees. Themes identified were consistent across all EDCs discussed. Major themes and sub-themes are also illustrated in ***Figure 6*** on the following page.

Table 6. *Major Themes Identified*

	# Interviews*	# References*
Theme 1 – EDC Usability Challenges	14	84
Theme 2 – EDC Task-Technology Fit Issues	13	39
Theme 3 – Organizational Factors as a Barrier to EDC Acceptance	15	82
Theme 4 - Technological Fragmentation as a Barrier to EDC Acceptance	15	87
Theme 5 – Impact of the COVID-19 Pandemic	9	16

Note:
 # Interviews = Total number of interviews that had relevant discussion pertaining to the theme (out of 15 interviews).
 # References = Full count of the number of times a theme was discussed across all interviews. One interview could contain multiple discussion segments regarding the same theme.

Figure 6. *Thematic Map*



4.4 Theme 1 – EDC Usability Challenges

The first theme encompasses the range of comments made by participants regarding their user experiences with EDC systems. Sub-themes were identified and contextualized according to the usability criteria identified in the analytical framework, as described in ***Table 7*** below. Due to their impact on usability, identified sub-themes also confirmed the construct of Perceived Ease of Use within the TAM model.

Table 7. *EDC Usability Challenges and Relevant Usability Goals*

Sub-themes	Usability Goals Impacted	Constructs Confirmed
Repetitive data entry	Efficiency, Satisfaction	Perceived Ease of Use (TAM)
Inflexible user interface	Efficiency, Satisfaction	Perceived Ease of Use (TAM)
Lack of error prevention	Errors, Satisfaction	Perceived Ease of Use (TAM)
Poor interface navigability	Efficiency, Satisfaction	Perceived Ease of Use (TAM)
Overwhelming and inconsistent interface	Learnability, Satisfaction	Perceived Ease of Use (TAM)

4.4.1 Repetitive data entry

Many study participants described frustration with what they perceived to be redundant data entry tasks in the EDC. A common source of frustration was the process for adding individual entries to EDC forms intended to capture one-to-many relationships, such as Adverse Events and Significant Adverse Events, Concomitant Medications, and Labs:

> *"You would have to put every singular administration during an SAE hospital visit. In a previous study, it was every singular administration of a drug, if it was not a regularly scheduled drug … So we would have to either type or copy / paste the full compound name for the drug. It wouldn't accept market names. And put in all of the dosage information. A new line for each administration. And when a subject is in the hospital for a month, that is an obscene amount of work." Participant 03*

> *"For example, we have to enter very many labs. But the labs are usually drawn the same time, but [EDC] requires us to enter the date and time for every single lab we enter. For whatever reason, they have not been able to track our lab ranges. So those have to be entered for every single individual lab. …We all hate entering labs, because it seems so repetitive." Participant 04*

> *"It's super frustrating to keep having to put the same date, like when labs are drawn…. you put in the subject date, and then the next page will auto-populate, and it will have labs or PK's that are drawn. And you put in the date again, for every single thing, and that's frustrating. But that's just because it has the date 15,000 times." Participant 04*

> *"They are not healthy people. And there are a ton of medications. And every time they are in the hospital, you have to put in every medication that they receive in the hospital. So I had this one patient who had been probably a half dozen to a dozen times in the hospital. He had probably around 200-to-300-line items of medications..." Participant 09*

4.4.2 Inflexible user interface

Some participants commented on the inflexibility of EDC systems, where design constraints force users to progress through the forms in a very specific order or enter data in a very specific way. Participants described this system rigidity as causing unnecessary delays during subject visits, data entry inefficiencies, and inability to complete tasks in the order desired by the CRC:

> *"[For] a number of different EDCs, it's rather difficult to create a patient. Some of the proprietary EDCs that I've worked with require you to put a patient and their documentation into your CTMS before adding them into the EDC. And so, when the randomization was through the EDC and not the CTMS system, it was an extra five minutes of work that I was making the patient wait up for." Participant 03*

> *"Until you fill out all of the forms for your current visit, you can't go on to the next visit, which is a bit of a bummer when we're reporting AEs. I get why they're doing it, because they want you to enter all of your data [for your current visit first]. But sometimes it's not the best, because you just want to get certain data [entered] for certain visits." Participant 04*

> *"When you have a piece of paper and you make a mistake, you just initial and date it. But when you have electronic, it won't let you move*

> *forward, it won't let you move back. It freezes if you don't put something in exactly the way they want it." Participant 12*

4.4.3 Lack of error prevention

One component of good usability is interfaces that support error prevention or recovery from errors. One participant mentioned concern about the fact that Significant Adverse Event (SAE) reports could be added to the EDC system, but there were no subsequent notifications, warnings, or reminders to select the 'Transmit' button after a new SAE event had been entered:

> *"The studies I work on now have electronic SAE reporting within EDC. It's basically how you would add anything else in EDC. You just add the event. And then you have to transmit it. You click another box and you hit Transmit. And that's how information goes to the safety team. I hate it. I think it's awful… I'd rather have a physical form in front of me, where I'm like, "Look, I did it." … I've definitely updated data on [the form], and then forgotten to transmit it." Participant 14*

Another participant noted difficulty visually distinguishing between required fields and non-required fields in the EDC:

> *"It's sometimes it's hard to distinguish between things that are definitive and required versus things that you can leave blank. … Visually, it's not distinct from some of the other [fields]." Participant 15*

4.4.4 Poor interface navigability

Poor EDC navigability was a common point of discussion, with CRCs noting that "too many clicks" are required to complete certain tasks. Several CRCs indicated a desire to navigate between fewer forms in the EDC, with more information located on a single page:

> *"On [EDC system], if there was a query, then you click on the query, it brings you to a whole different page… there's multiple clicks to just answer one query. And when we are very busy, nitty gritty, trying to get*

> *down and do the work, I need everything to be in one spot, because it makes it so much more efficient." Participant 06*
>
> *"For some studies, if it requires dose changes for study medication, that's a separate form to go to. I feel like it would've been easier to do it on that same visit form. I don't want to go into a different form to do that." Participant 01*
>
> *"I work on the concomitant medication pages and there's three separate pages, depending on what type of medication it is. We really couldn't just put this all on one page? One folder, one log?" Participant 14*

Related to poor navigation, several CRCs noted issues related to lengthy horizontal data entry forms, the inability to view all data in the forms in a single view without scrolling or zooming out, and inability to visually differentiate between different rows of data:

> ***"****I don't love the views of [EDC]. I don't think it's very conducive to entering data. You have to get it from two different views. I prefer the landscape view versus the portrait." Participant 04*
>
> *"That entry was captured horizontally. …by the time you [got to the last field in the form], you no longer could even see what medication you were putting in. Something as simple as a page lock makes a big deal. … it's a big deal when you can see all of your information in one glimpse." Participant 06*
>
> *"I have a pretty big monitor, and I don't have my web page zoomed into 150%. The log is too long, or the way they formatted it is too long to see in one view. You have to scroll over to the side." Participant 14*
>
> *"There's no delineation as you look across a horizontal line of information. So it makes it really difficult when you have 10 patients all on the same page with all this information. I worry that there [could be] a transcription error. … it's hard to see what line belongs to who, when there's a lot of patients and a lot of information. Without having things that Excel has, like an option to make every other line a light color. Just so that at a quick glance, you can tell what information belongs to who. If a patient passed away, we would gray out the entire row [in Excel], just so that we know this person is no longer technically on study and doesn't need anything done for them. That is helpful. And you can't do that in EDC systems." Participant 07*

There were also discussions about confusing, poorly organized EDC interfaces, and EDCs presenting the users with either too much --or not enough-- information:

> *"The layout and the flow of everything doesn't make sense to me. And the way the tabs work is very confusing. There are tabs along the top of the page. There are tabs along the left side of the page. And it doesn't make sense to me what is actually nested in what…. Or, if all the information is on one page, and then you go to another page--then, you either have everything you need there, or none of it is there, and then you have to go back and copy it down, and then move to the next page and re-copy it down." Participant 07*

> *"On the homepage, on the right-hand side, it has all these options to go to queries, and also has options to randomize. There's too much stuff on the homepage, that there's multiple other ways to get to …There's just so many different ways to do everything." Participant 09*

> *"Yeah, just the amount of clicks and just how it's all organized. It's all very jumbled. It's just not organized very well." Participant 09*

Nevertheless, some EDC systems have elements that support easier navigation, such as grids on the subject's home page displaying all study visits and queries for that subject in one place, or the ability to click from the home screen and go directly to a query:

> *"For the [EDC] that's nice, it gives you a grid on the homepage, and you can enter [data] visit by visit. Whereas, the one that I'm not the biggest fan of has it by patient number. So you click on the patient number, and then you have to add each visit. As opposed to seeing where you are [up-front]. If there's queries, you have to enter into the patient's file, and then you have to click this, click that, as opposed to the one with a nice grid, where you can see the queries on the main page." Participant 13*

> *"It's helpful that [EDC system] has a link that you can click on that takes you right to the query. Or it has the question mark system. So, you can see that somewhere in this folder, there's a query. That's helpful for me." Participant 07*

4.4.5 Overwhelming and inconsistent interface

In general, the CRCs I spoke with found EDC systems to be relatively straightforward to learn, due to the way they are conceptually modeled after paper-based binders and case report forms. However, this sentiment was not universal, and some CRCs described feelings of confusion and overwhelm when using EDCs:

> *"[EDC name] is harder to learn. Complicated. Too broad." Participant 10*

> *"It's not very user friendly to me. It looks like it is. … It was just a very confusing system. And I struggled a lot with it. To be completely honest. I think it's an internally built system. And I'm sure it was built very quickly to accommodate for the growing needs of the COVID trials. But I did not like it at all." Participant 07"*

> *"It [should not] take a PhD to try to figure out how to how to use it." Participant 12*

> *"I think it was a little bit overwhelming at first, because looking at it, never have having done research before, it just looked like a whole lot of information. And in a very small space. But after doing it for a couple of days, it got to be straightforward." Participant 09*

One participant described frustration with the length of the EDC documentation (eCRF guidelines) provided by the sponsor:

> *"They gave me 125-page document for [EDC] guidelines … which was not helpful at all… it was totally unmanageable." Participant 04*

Another participant described the importance of having on-site trainers to assist when new systems are implemented:

> *"We had these people come to do training with us. And it seems so easy when they're doing it. But when you start doing it, it's not as easy as it looks. It's nice to have what I call "elbow people." When you're setting up these systems, they are [on site] for a month-- while you're trying to work with [the system.]" Participant 12*

CRCs also noted inconsistencies in the way that EDC systems present forms and functions differently across studies, and difficulty finding features that were moved after system updates:

> *"Queries show up differently [on some EDC systems]. Some sponsors, some studies, they show up very easily. You can see the query directly, but some studies...you really have to look very hard to find the query." Participant 10*

> *"They constantly change it, so as soon as you get used to one way, they completely change everything. … next thing you know, something that you use all the time is gone. You don't know where it went, you don't know what happened to it." Participant 12*

4.5 Theme 2 – EDC Task-Technology Fit Issues

Another major theme identified from the interview data was a described mismatch between the tasks performed by the CRC and the design of the EDC. Three sub-themes were identified in support of this theme and confirmed the importance of the Task-Technology Fit model, as described in ***Table 8*** below.

Table 8. *EDC Task-Technology Fit Issues*

Sub-theme	Constructs Confirmed
Data captured by EDC doesn't match data collected	Task-Technology Fit, Perceived Usefulness (TAM)
System flow doesn't match data entry flow	Task-Technology Fit, Perceived Usefulness (TAM)
Missing EDC functionality and workarounds	Task-Technology Fit, Perceived Usefulness (TAM)

4.5.1 Data captured by EDC doesn't match data collected

Participants described numerous situations where the data collected at study visits did not align with the data entry requirements of the EDC. Participants described cases of EDCs firing automatic queries on "out of range" values, despite the data being reasonable and entered correctly:

> *"With a lot of studies, whatever parameters they put for auto-queries…they're always kind of 'off.' I get really annoyed. I've got one study where for every single visit, you have to document [the patient's] weight. And for every visit, in this two-year long study, I have to answer the auto-query of "Yes… weight is correct." …The weight is out of window when it's not even that big of a person." Participant 14*

> *"There are some things that just don't make sense. For instance, some ranges…I had a patient whose weight was over the expected range. … [It is] frustrating, because [the system] queries that and [the queries] bounce back and forth. And I like my queries to be nice and resolved. And it's not able to be resolved." Participant 05*

Many participants described situations where EDC systems required data entry at a level of granularity that did not match the data that was collected during the study visit:

> *"A pretty common one is, for a specific form, it might ask for the collection date and collection time for specific samples for blood draws. And we'll have to enter the collection time for each individual item, and one of them might not be applicable, because they're not collecting it for that specific arm, or they're no longer collecting [the data point] as of a certain amendment to the protocol. Or it might be for a sub-study that the subject has not enrolled in. And then it will query 'Why is this blank?' And we will have to say, 'Not required per protocol.'" Participant 15*

> *"[The paper forms ask] patients to enter medications that they're taking. And they'll have a separate row for each medication that they can fill in. But it only asks how often [the medication is] being taken. In the EDC, it asks far more granular data than that. Like start date, stop date, that sort of thing. It asks if [the medication is] related to something that we recorded previously on their medical history. It's a little bit tough to go back and forth. And a lot of times, we end up just putting our best guess." Participant 14*

> *"Sometimes not all the values for the row are taken for a particular time point. For each value, they're requesting temperature, respiration, rate, height, weight, that kind of stuff. Sometimes the highest temperature would be taken at a time when no other values were taken. If I had to mark the time that the temperature was taken, it would query that I left all of the other fields blank. …Not all vital signs are taken at the same time. …And if there weren't other values taken at that same time, I would leave them blank…but then [the EDC] would query and be really mad at me. And that's frustrating." Participant 05*

> *"It was data that just wouldn't 'fit,' if that makes sense. For instance, in this study, they had to use a swab of some sort, to test for something. And in the protocol, it never really stated that you had to say what type of swab you used. But in the [EDC], it asks you to pick a type of swab. And so with the data that I had, I was like, 'I don't know what this swab is.'" Participant 02*

> *"Sometimes I would have to change what I was doing, because the EDC was asking for something in a different way. But that wouldn't really mess with my flow so much as it would mess with what I was actually collecting." Participant 02*

Participants also described situations where EDCs limited the amount of detail they were able to provide, constraining their ability to record and convey useful contextual information:

> *"I would sometimes have gigantic half page worth of Progress Notes, talking about the reasons some things might be off, or something that might have happened. And that is nowhere in the EDC. And so, the only person that saw that was the monitor when they came, so that way it could explain discrepancies anywhere. Like, let's say a vital sign was five minutes out of window because the patient went to the bathroom. There's no way for me to put that in the EDC unless somebody queries me on it." Participant 02*

> *"When you are having to explain something like queries, you're only allowed like 60 letters. But what I have to say might be more than 60 letters. So, I feel like [the sponsor is] not getting the information [they need]." Participant 12*

4.5.2 System flow doesn't match data entry flow

There was a strong sense that the flow of forms required by various EDC systems did not consistently follow the most logical flow of forms for CRC data entry. This mismatch between the EDC design and the CRC workflow results in inefficient data entry, such as requiring CRCs to flip back and forth between forms or to create visit forms for data elements that are not actually visits:

> *"When you do data entry, it takes so long. The way it's set up … you can't really get a good flow." Participant 13*

> *"It populates the page before the initial page you did entry on, but you have to put in the date. So it's not flowing. I have to go back and put the date in, and then click somewhere else and continue the visit. I'm like, "Why is the date not the first thing I put in?" Participant 14*

> *"For instance, for a study I'm on right now, the vitals is normally one of the first things that occurs [during a visit], but it's actually the last thing listed in our EDC system currently. So it makes a lot of flipping back and forth and trying to follow what the EDC system has, but also follow the subject's chart." Participant 11*

> *"I get really annoyed when I'm doing something that makes no sense. There's a page we have to create every time they're hospitalized. … There's a section where if [the subject is] hospitalized for [an AE], you have to associate it to [another form]. Except, it's just a blank field, and they want a number … It's so annoying that there's no way I know [the form's record number], unless I'm in the EDC system and go and look at that page." Participant 14*

> *"Say we're on Visit 30 now and [the patient] has an adverse event. Why is there a separate form that I have to go back to on the home screen, if I say in Visit 30 that they have an AE? It should naturally go to [the AE form], versus me having to go to [the home screen] and having to manually create it. … It's impossible to keep going form by form by form to answer all this information when vitals and AE should be in the same place." Participant 01*

> *"For whatever reason, there's a Procedures folder. But the X-ray doesn't go there. I have to create an 'Unplanned Visit,' which has nothing to do with the study. [The sponsor] decided that the way to document [the X-ray] is to create an 'Unplanned Visit.' That makes absolutely no sense." Participant 14*

Notably, one participant indicated that the EDC required them to confirm eligibility at the onset of data entry, before source documentation would typically be reviewed to establish eligibility:

> *"A lot of times, they'll make you confirm eligibility before you look at any source. So you're confirming eligibility on a subject and saying that they're eligible for a study, but you haven't looked at any of the results. So, they'll have eligibility as one of the first few questions. But if the subject isn't eligible, you don't know until you actually start getting into the data." Participant 11*

4.5.3 Missing EDC functionality and workarounds

CRCs also noted specific examples of CRC tasks that could not be performed in the EDC, such as linking adverse event records to visit records, and being able to filter queries by specific roles in order to prioritize work:

> *"We don't have the capacity to see who queried us. I have to look at all of [the queries]. Sometimes I just want to see what my monitor queried me on in the last visit, so I can address those first." Participant 04*

> *"I would say absolutely you have to fix your query system. I think - importance- really matters about what you want answered, and how long it's overdue. And right now, [EDC system] just doesn't really have that capability. So, to be quite honest, we've just been entering missing data as we're able to. Versus in other systems, because they could flag high priority queries, or they could flag how long it's been overdue, so I would answer those first. But [EDC system] doesn't seem to have that capacity." Participant 02*

> *"A lot of times, in regards to AEs, or con-meds, or medical history, the sponsor will request certain information, and the site's not always able to make the system work in that sense. A subject may have two AEs and use the same medication for both AEs. … You have to put [both AEs], even though it's only one medication. And these are the kind of issues that we run into on a regular basis." Participant 11*

CRCs noted that EDC systems are insufficient for tracking their own day-to-day activities. Instead, CRCs develop workarounds to support their work:

> *"I would say, like, if I had my perfect world, an EDC would have the ability to do everything that I do in Excel, as well. So, for instance, scheduling … when all of the next visits are due… I have to do that in Excel. Even tracking participant payments -- you've got to have a log to reconcile payments. And that has to be separate, because the EDC just doesn't have that capability. So as an industry-sponsored trial, especially, they don't care. That's not what they're there for." Participant 02*

> *"I've developed my own checklist that basically might not be in the same order as the EDC. But it's in the way in the like. It's in the order that my brain wants to do things to make sure that all the boxes are checked before we consent, enroll and randomize." Participant 07*

> *"I could in theory I guess pull [the EDC systems] up on the computer and be able to maneuver back through … in real time. The difference is, everything is on my ONE Post-It note, but in the EDC, I have to make 15 clicks to get to all the pieces of information I would need. So, yes, I could go and look at that. But, would it make it easier to have one place where it's all listed out? Yes." Participant 06*

Due to their flexibility and ease of use, Excel spreadsheets continue to be extremely popular with CRCs as a method for tracking disparate information:

> *"We have one [spreadsheet] for invoicing. We have one [spreadsheet] for a screening log. We have one [spreadsheet] internally. And then we also have one where the sponsor asks that we provide deidentified [information] to let them know why we enrolled this person or why we didn't. And then we have one [spreadsheet] that is tracking follow-up visits. We have one [spreadsheet] that is tracking participant payments. We have one [spreadsheet] that is tracking blood draws. We did have one [spreadsheet] in the beginning to track start-up effort, but we don't use it anymore." Participant 04*

> *"So for recruitment, I will admit that I tend to like to use Excel sheets. I know that's not the way that we should technically be doing it. But, for recruitment, I use Excel sheets for the tracking, because it's just a lot easier…From a privacy standpoint, I'm sure the privacy office would prefer us not having the stuff in Excel sheets… and [would rather it's] in a more secure application. But the problem is, [the systems are] just not built for that." Participant 02*

> *"I think our internal Excel spreadsheets are just easier for us to see data in a way that makes more sense to us. Like it has all the information we need. But it might not be set up in a way that makes our job easier. And it might not make the information that we want or need, as accessible or visible as we want it to be." Participant 07*

4.6 Theme 3 – Organizational Factors as a Barrier to EDC Acceptance

As the interviews progressed, it became increasingly evident that organizational factors have a significant impact on CRC satisfaction with EDC systems. In this study, "organization" refers to the sponsor of the clinical research study and/or the clinical research organization (CRO) supporting the study on

behalf of the sponsor. Organizational factors serving as a barrier to EDC acceptance are listed in ***Table 9*** below.

Table 9. *Organizational Factors as a Barrier to EDC Acceptance*

Sub-theme	Constructs Confirmed
Inconsistencies in sponsor documentation	External Variables (TAM)
Lack of sponsor guidance on source development	External Variables (TAM)
Disconnect between sponsors and clinical realities of the study	External Variables (TAM)

4.6.1 Inconsistencies in sponsor documentation

One major organizational factor impacting EDC acceptance pertains to sponsor documentation. Through interviews, it was learned that the IRB protocol, rather than the EDC system, is typically the first and primary source of information for CRCs when designing the study's standard operating procedures (SOPs) and source documentation. Consequently, any inconsistencies or ambiguity in the protocol can lead to similar inconsistencies and ambiguity in the study SOPs and source documentation. These inconsistencies are often discovered by CRCs at the time they enter data into the EDC, leading to frustrations with the system itself.

> *"Depending on how detailed your source documentation is, I find that a lot of times, EDCs ask for information that isn't necessarily like spelled out in the protocol. So if you are following the protocol, you wouldn't know to collect that data point. …I find that happens a lot. And I will say it's mostly a time thing. Like, "What time was this done?" And I'm like, I have no idea. I didn't know I needed that." Participant 14*

> *"My study requires patients to be exposed to COVID. And [the protocol] says eight days from exposure. But it didn't specify, what we could consider as exposure. Is it the most recent exposure to someone with a confirmed positive case? Is it based on the person's swab date? Is it based on the person's result date?" Participant 02*

One CRC described a situation where the IRB protocol did not include visit windows (windows of time during which a study visit can occur, e.g., Day 14 plus or

minus two days). The lack of visit windows in the protocol caused follow-on queries and deviations via the EDC system:

> *"There were no windows built in the protocol, meaning that we take chemo dynamic assessments and do blood draws, and everything, but they didn't give us a window of time. And so if it's not exactly on the right minute, then it's a protocol deviation. In Medrio, unfortunately, it comes up as a query from the system first. And then when you fix the query, it is now a protocol deviation, because you know, it's out of the protocol. Since there were no windows worked into the protocol." Participant 05*

Another CRC wished for better sponsor documentation, due to the complexity of the protocols:

> *"We're always directed back to the protocol. Yes, it's all in there. But protocols are so long and difficult to work through. It'd be nice if there was separate clear cut, better communication through documentation." Participant 09*

4.6.2 Lack of sponsor guidance on source development

Almost every CRC interviewed noted a lack of sponsor guidance in developing source documentation, and this lack of guidance could be traced to follow-on issues with the EDC. CRCs described how lack of source documentation guidance led to reworking SOPs and task-technology fit issues with the EDC:

> *"I have a study right now that you can't see the [EDC forms] until you actually have a patient. So they told us you have to do your own source documents. Well, I have no idea how the [forms] look. …It makes it hard when you can't see what they're talking about." Participant 11*

> *"Yeah, we do access the EDC, but some of the forms are not activated until you enter data. And we don't necessarily know what's going to be in there until we've entered something that creates that …once it's populated creates a new form for us to enter." Participant 15*

> *"The sponsor will sometimes send you printouts of the EDC to show you what it's going to look like. But sometimes they don't do that. So your first interaction with the EDC is when you're actually putting in participant data. And there's usually these little things that aren't clear*

> *in the protocol that you need to collect, that you don't collect." Participant 02*
>
> *"But the FDA doesn't like for sponsors to send out templates anymore for their source. So our source wasn't necessarily built off of the way to EDC looks, which was a challenge, because it was a high enrolling study. We just had to get going. So we're editing our source as we go to match what the EDC wants." – Participant 04*
>
> *"Especially for industry-sponsored trials, that data system's already been built by the time that they even select us as a site. So [the issues identified] will be things that potentially have to be edited later on, because it's already built" Participant 02*

Relatedly, many of the CRCs interviewed mentioned the difficulty in figuring out study processes for the "first patient." Some of these difficulties could be ameliorated by more sponsor guidance on source documentation:

> *"I would say for every industry-sponsored trial that I worked on that used [an EDC], I had to go back after the first patient and rework my checklist" Participant 02*
>
> *"The question is if you [made the source forms] wrong the first time. Later on, you may have a lot of trouble with the data entry, because you needed the data, but you didn't make the choice to put it in the form. So you have to start all over sometimes." Participant 10*
>
> *"[It's challenging] just knowing what you need for the first patient. Knowing the order of events, knowing which CRFs need to be fill out how they want the data done. What this process is going to look like, or what the sponsor wants the workflow to look like. A lot of times we make the workflow up according to the protocol and just kind of wing it. But it you know, it would just be nice to have more clearly defined expectations and a better outline, and what the day to day is going to look like for this study." Participant 09*
>
> *"I think source documentation is challenging, and I think it opens up a lot of room for errors and for missing information. Because we have no way of really knowing of all the pages that truly exist in the EDC until we use those pages. … I personally feel they should provide us with source documentation so that we have a less chance of missing things. Participant 06*

One CRC noted that sponsors will provide "eCRF Guidelines" to support study startup, but that the purpose of this document is to provide guidance on data entry, and does not facilitate source documentation creation:

> *"eCRF completion guidelines are more telling you what [the sponsor] mean[s] by this question, or when to fill [the forms] out. Not really, "This is what the source looks like. And this is what we want your source to look like." So we had to do a lot of combing through that to get our source correct." Participant 04*

Furthermore, the guidelines were unmanageably long and complex:

> *"They gave me a 125-page document for eSource guidelines for [EDC system] which was not helpful at all whatsoever." Participant 04*

> *"I like it when they have a training [EDC] where you can go in there and play in and put [data] in. And see what happens. … It seems like a lot of people nowadays aren't doing that. They just think that they can give you a book that tells you how to do it. But it doesn't really tell you everything you need to know, so then you have to start calling your monitor." Participant 11*

Finally, multiple CRCs noted frustration with the way that the sponsors continue to make changes to the EDC forms after the study has started. Sometimes, this causes CRCs to have to go back and modify their source documentation. Sometimes, the EDC changes are significant enough that CRCs need to go back and collect additional data from study participants. In some cases, the sponsor doesn't notify CRCs of the changes, and discrepancies are later discovered during data entry:

> *"So we had to do a lot of combing through that to get our source correct. And honestly, we're still editing it as we go. Because even as we're making changes the source, the sponsor is making changes to [EDC system]. We're already on our second database update. So it's definitely a work in progress." Participant 04*

> *"I had a particular study, where we were very quick out of the gate, because we had a lot of really sick people on this drug was going to save their lives. And the sponsor was wanting it to move fast, but the CRO wasn't finished with making changes to their electronic eCRF. And so*

> *they kept on changing it. They'd add all these new pages. Something like that is particularly irritating" Participant 07*
>
> *"[The sponsor adds pages constantly. I have a study right now that's been going on for three and a half years. And they have JUST NOW added more pages. There's not been any amendment. They're just like, all of a sudden, here are additional pages… I personally feel they should provide us with source documentation so that we have a less chance of missing things." Participant 06*

4.6.3 Disconnect between sponsors and clinical realities of the study

Two CRCs I spoke with described a disconnect between the sponsor and the realities of the study, and viewed this disconnect as the cause of some of the technological issues encountered in the role:

> *"I definitely think that as technology gets the kinks worked out, like anything else, it makes some things easier. But we're not at that stage yet. Because there are a lot of kinks and with clinical trials. Sponsors get what they think might work. Might work in the ivory tower, but it doesn't work with patients. So they can be very grandiose." Participant 07*
>
> *"Research in general, especially with study startup…it's just such a disconnect, from the data coordinating center, down to the coordinators. There's never any direct communication or questions to the coordinators and what they prefer, and there's no input opportunities." Participant 09*
>
> *"There's just so many, there's so many levels in between a coordinator, and the people who are managing the study startup. It makes it really difficult to do study startup as a coordinator, because I feel like you're left in the dark most of the time. And you've got to figure it out as you go. And you really don't figure things out and actually get your feet under you until you get through the first patient. So the first patient is always quite a stumble." Participant 09*

Similar frustrations were noted in CRCs' interactions with those building the EDC systems and those issuing queries from the EDC, and their lack of clinical background:

"It's not even a problem with the system itself. It's a problem with the way that they build it… It's always an issue at the beginning of trials, because they build the system in a very specific way, and then you have data that you're trying to put in it. And it's not letting you put it in, or this certain form is not popping up for this visit, but you did it. That's one of the bad things actually about these big companies having these more complex systems…the problem with these companies is they have a separate person that really doesn't have anything to do with the study building the study databases, so they're doing the best they can, but they just don't understand the inner workings of it. And so it just takes some trial and error to figure it out." Participant 02

"A lot of data management people are just that. They're data management, and they have no medical background." Participant 12

"There are a lot of people who are data managers or data analysts who have no clinical experience. That is why [the EDC is] so rigid. They have little understanding of the clinical day-to-day. They're just creating forms that answer the questions and capture the correct data. …There's a heavy, heavy workforce that can create the [EDC], but a lot of them are not experienced in the clinical side. They've never worked with patients or EMRs." Participant 01

"One thing is just kind of the overarching topic that data manager type roles in the industry-sponsored world are so far removed, I think, from the just the protocol and stuff like that, like the day-to-day that they can just be so annoying to coordinators, because it's just like, why are they asking me for this? But it's really because they just don't even know what they're asking for. I think they just see like, this isn't conforming to what we need it to be. So I'm going to ask them. You know, I think that's a common joke for coordinators is just how much they get frustrated with the people giving them queries." Participant 02

4.7 Theme 4 - Technological Fragmentation as a Barrier to EDC Acceptance

Technological fragmentation also presented as a common theme across the interviews, as described in ***Table 10*** below.

Table 10. *Technological Fragmentation as a Barrier to EDC Acceptance*

Sub-theme	Construct Confirmed
Switching between systems	External Variables (TAM)
Mixed views regarding integrated systems	External Variables (TAM)

4.7.1 Switching between systems

Each study sponsor has a unique set of systems required for managing study data. Consequently, CRCs are required to switch between a variety of different systems, sources, and tools during the study. Participants described the impact of switching frequently between different systems and tools:

> *"In the last few years, we've had to have not just one electronic vendor …it's now like four or five vendors you have with each study … Now you have a lot of studies with multiple vendors, and it makes it very difficult, because you have to remember all the things that each of these vendors require. I mean, you do training, but when you have more than one study, that's complicated… I have to keep a little notebook here with all my passwords and usernames because you have to change them all the time." Participant 12*

> *"It would be so nice if it was just all in one place, because there's a lot of studies that you have to ... pre-screening logs to figure out how your screening process is going. And then you have to go to another website to randomize the subject and dispense their medication. And then you have go to the EDC to do all the data entry. If there's ever diaries or handheld devices that you're giving these subjects, that's another portal to go to, to register them in that portal, and then to keep up with all that data too. So there's still so much planning going on being a coordinator. And even though we have all these systems and calendars and everything, the systems are not all connected." Participant 05*

> *"That's an extra additional platform you have to remember to go into. You have to remember your username and password, you have to remember that if there are changes, you have to go in and update those. And that's just one extra place where someone is looking behind you. At some point, there's too many platforms that you have to access. If they're all-in-one, that might be a little bit different. But every study has like, between five to eight platforms you have to have access to and that is just unreal, in my opinion." Participant 05*

> *"I wish there was a link inside of Veeva Vault that would just direct me to [EDC system], or at least they could talk to each other and say, "Oh, well, she already filled out these forms, so why do I have to go through both?" It'd get queried both ways for one item." Participant 01*

As one participant noted, using multiple systems presents a risk to the study's data integrity and leads to inconsistent data across platforms:

> *"I feel like we all have a lot of different pieces of the puzzle-- a lot of different pieces that weren't really intended for us. So [the systems don't] really capture the things that we need. … I just don't think when you're trying to protect your data integrity and make sure everything is cohesive, I don't think that's always the best. Because anytime that you have a lot of systems, you have to make sure that everybody closes the loop and checks all those systems, which is where I think things can get missed sometimes." Participant 04*

4.7.2 Mixed views regarding integrated systems

Some CRCs had used centralized, "all-in-one" clinical research platforms in their studies. Perceptions regarding these systems were mixed:

> *"We tried using [a centralized clinical trial system] years and years ago, and we spent countless hours trying to learn that system. And to me, it made triple the work for us, because you have your source document that you're putting information into, and then you're putting it into the eCRF. And then we had to put in all that information into [the centralized system]. So it's like three places that you're having to put information in. …But I know places use it, and they swear by it. You know, I have yet to see one that works. And if we ever get one, I'll be more than happy to use it." Participant 12*

> *"It was supposed to have every single thing encompassed in [the system]. It was a platform, which was supposed to have all these different things in this one platform, and you were supposed to be able to have one sign in. …So it was it was given to us at the investigator meeting in this package that this was going to be the greatest thing. Well, by the time they gave us the platform, they didn't have the kinks out. And each of those platforms had their own password and username. Which was okay, because that's what we're used to… … But it was touted like it was something that it wasn't." Participant 08*

> *"I'm thinking of all the things that you need to collect. And not even just data, but also specimens. People have to put effort into making sure they have the right kits, they have the right source, they've confirmed with the patient. So I think consolidating that into less systems would be really nice. Instead of "Hey, let me go check my protocol. And let me go check the system where I enter the data." It would be nice if you had*

> *something that prompted you for everything you need, versus study teams having to make their own checklists. And with each site making a different checklist there might be different data collected." Participant 04*

4.8 Theme 5 – Impact of the COVID-19 Pandemic

The COVID-19 pandemic had a substantial impact on the role of CRCs, as described in ***Table 11*** below.

Table 11. *Impact of the COVID-19 Pandemic*

Sub-theme	Constructs Confirmed
Transition to remote work	External Variables (TAM), Task-Technology Fit
Transition to electronic source documentation	External Variables (TAM), Task-Technology Fit
Change in study workflows	External Variables (TAM), Task-Technology Fit

4.8.1 Transition to remote work

Since the start of the COVID-19 pandemic, CRCs have largely transitioned the non-clinical aspects of their roles to remote work. However, CRCs noted limitations in their ability to conduct remote data entry into the EDC, due to the requirement that paper source documentation remain on-site:

> *"We are encouraged to work from home as much as possible. Being a coordinator, that's difficult, because our role is primarily patient-facing. And also, the other part of our role that requires us to be on site is that we are entering in data. Our source documents--all of our case report forms…they're housed on-site in a secure location. And so, it's really hard to do that sort of data entry from home because you need to keep those source docs on site where they can be locked up in a secure place. And so we have to come on-site to be able to do a good deal of our data entry. It makes it hard when asked to do it remotely. What we can do remotely is-- when we have access to the EMR, if we have data that we are entering directly from there, then we can do that from home. But primarily, our data is on our paper source docs." Participant 06*

> *"I have tried to document more things in our EMR … With the pandemic, we have structured it to be on-site when you have to see your patients, but then working from home if you don't have any patients scheduled. And so I've come to find out … there's a lot of stuff that I can't do data entry on from home, because I don't have access to it. Because you know,*

> *it's a paper form that's sitting in my office. … Vitals and things like that are easy to document in EMR, but a lot of studies require logs that the PI has to sign off on. I don't really know how well those things would translate electronically." Participant 14*

4.8.2 Transition to electronic source documentation

The COVID-19 pandemic encouraged rapid adoption of electronic source documentation at sites. Early COVID-19 guidelines warned that the virus could be transmitted via paper surfaces, pushing sites to move away from paper source documentation:

> *"It's been tough, because when we're in-person, we still try to follow COVID guidelines. So, we try not to have much paper, which is why we were leaning towards eSource." Participant 04*

Some sponsors have temporarily permitted data capture straight from the EDC, without using paper source as an intermediary:

> *"Most [sponsors] are allowing the EDC to be the data capture. So there isn't technically source, because we're pulling because we're pulling straight from the EMR." Participant 05*

Participants also noted the way that electronic source documentation permitted the continuation of (remote) monitoring visits:

> *"With COVID, a lot of the sites that have invested in [electronic source documentation] were able to continue monitoring visits more easily, because it's all electronic. So, we could review from home." Participant 11*

> *"There's a lot more technology that's come out because of the pandemic, and a lot more need for remote monitoring just because [the monitors] can't come here on-site to do source document verification." Participant 01*

The move to electronic source documentation has not been without challenges. For example, one CRC found that electronic consent was difficult to obtain if study participants did not have access to email:

> *"For consent forms we've been using Adobe Sign, which I have found is super useful. But of course, we run into populations that don't use email. So we still have to sometimes take in paper source and then take pictures of it, but we have to leave it in the room because nothing comes out in the room for COVID units." Participant 04*

Largely, the participants I spoke with emphasized that the COVID-19 has profoundly changed their work and that they believe sponsors will continue to use electronic source in the future:

> *"What's frustrating is now that COVID has changed everything. Now, sponsors are leaning away from paper source, because that has to be in office all the time. And that's frankly not happening." Participant 05"I think the pandemic has really kicked us into the modern era, when I think a lot of us were hanging on to it by a straw. …. I think a lot of studies that don't have to have face-to-face contact, whether that's questionnaire-based studies, interview-based studies… and even drug trials where every visit doesn't involve a drug administration … I think [sponsors] are going find ways to move towards [electronic source] because it's cheaper. It doesn't make any sense to … pay staff to be somewhere when you can just do it over Zoom." Participant 02*

However, the transition to electronic documentation could be a temporary phase. One CRC indicated that their site has already started to go back to paper source, now that on-site work has resumed:

> *"We transferred over the summer with the COVID studies to electronic data sources only. Now that we're back to in person, on-site work is more normalized, and we are going back to paper source." Participant 08*

4.8.3 Change in study workflows

In addition to moving sites to electronic source documentation, the COVID-19 pandemic has made CRC study workflows more complex. SOPs needed to be rewritten to accommodate things like longer visit windows, in-home and virtual

visits, and COVID-19 prescreening before allowing participants to come on-site for their visits:

> *"Pre-COVID, it was a lot easier. Our studies were very cut and dry, black and white. You know, you get a protocol. And you're told this is how you consent. And so, I'd study the protocol, build source, and then we would have subject visits. Before COVID, all that was very normal. Very easy to complete those tasks. But since COVID, we had to rewrite all of our SOPs." Participant 05*

> *"For non-COVID studies, we had to come up with an SOP in case our subjects don't pass screening to come into the visits. And we have to pre-screen them before they even get here. We call them and ask them a couple questions. And we stress to a lot of the sponsors that we need bigger windows of days." Participant 05*

> *"Most of our protocols have been amended to add in-home visits. There's a lot of sponsors that are going to virtual visits, which is very helpful." Participant 05*

One CRC noted that the rapid pace of procedural changes at the onset of the pandemic made it difficult for her to plan study visits:

> *"In some ways, it's been easier because some people aren't participating in trials...but when we got caught with some people in trials... it just made everything harder because [employer was] changing [the processes] daily. I think it was a great effort on [employer's] part to try to get it right. But in doing so, it made doing our jobs with both hands tied behind our backs. …It was really difficult planning appointment times when you really didn't know where you could see them." Participant 08*

With more CRCs encouraged to work from home, some sites had providers collect data at in-person study visits on behalf of the CRCs and enter this data into the EHR. However, one participant found that provider-entered notes were less detailed and less easy to follow compared to her own notes:

> *"We're having providers seeing the patients, and the providers are writing the notes. So the provider might write something like, "She came in complaining of headache for the last few days." Whereas I go in and say, "What day?" "When did this start?" "What did you take for it?"*

“What days did you take for it?” “How did you take it?” “Did you take Tylenol as needed, or once a day?" … [The data I record is] more concise and easy to follow.” – Participant 14

5 Discussion

5.1 Aim 1: Identify EDC systems that are commonly used in clinical research.

As described in Section 4.2, participants discussed a total of 14 EDC systems, with Medidata Rave EDC, REDCap and Oracle InForm discussed most often. Fifteen additional EDCs were identified from the literature review. Appendix 9.2List of Popular EDC Systems and Vendors lists all EDC systems identified through both the participant interviews and the literature review.

5.2 Aim 2: Identify usability challenges impacting CRC acceptance of EDC systems

A range of positive, negative, and neutral views regarding EDC usability were expressed by participants; however, negative and neutral views predominated many of the conversations due to the improvement-based orientation of the interview questions. A summary of design recommendations related to usability challenges is found in ***Table 12*** below.

Many CRCs interviewed described highly repetitive data entry tasks in EDC systems. Human-computer interfaces should seek to minimize user input (1) by making it easy for the user to provide the input, (2) by reducing required input to only what is necessary, and (3) by not asking users to provide the same input more than once (Lacey, 2018). Repetitive EDC data entry tasks can be made easier by

incorporating keyboard shortcuts, autocomplete suggestions, selection-based fields instead of free-text, and auto-advancing through fields with fixed lengths (Lacey, 2018). Required input can be reduced by limiting required data entry fields to only those that are essential for the study's data analysis. Finally, input duplication can be reduced by incorporating more auto-calculations, prepopulated or default values, and typing alternatives in the form design, such as buttons that copy existing data to a new record (Lacey, 2018).

Several CRCs described challenges concerning EDC interface rigidity, such as restrictions on their ability to edit/view forms in a flexible order, constraints on the data entry itself, and inability to save partial form data to return to it later. When implemented correctly, interface design constraints can minimize user error. However, too many constraints can cause frustration by reducing the user's sense of control and freedom during interface interactions (Lacey, 2018). A balanced approach is needed for EDC systems, where the user goals of CRCs (navigational flexibility and ability to control the order that they enter data into forms) are balanced with the system constraints necessary to ensure a quality interaction (Jill Butler William Lidwell, 2020).

Closely related to the topic of system constraints, error prevention was identified as a key EDC usability challenge. A simple design recommendation pertaining to this usability challenge is to ensure that required fields are always clearly distinguishable from non-required fields. In addition, many EDC systems require CRCs to submit form data before the system will display data validation

failures and error messages, necessitating time-consuming query resolution. Instead, wherever possible, EDC systems should automatically check for potential issues during user input, to allow for issue identification and correction in real-time (Lacey, 2018). Finally, one participant suggested that EDC systems administrators should routinely collect and evaluate the error logs, to identify frequently re-occurring data entry issues that can be addressed via simple design updates. This closely matches recommendations by usability experts (Lacey, 2018).

Regarding poor navigability, participants provided a number of direct suggestions, such as reducing the degree of form "nesting" (i.e., forms within forms), ensuring that related fields are grouped and presented on a single page rather than split across multiple pages, and displaying all pertinent information on the first page. Similarly, regarding issues related to scrolling and page views, participants suggested use of page locks (i.e., freezing a view so that certain data can be displayed during scrolling), better visual delineation between rows of data, and adding features to resemble Excel spreadsheets more closely, such as sorting/filtering rows and hiding/displaying columns.

Some CRCs perceived EDC system interfaces to be visually overwhelming, complicated, and confusing. EDC systems should be simplified by maximizing the signal-to-noise ratio in the design , by minimizing the amount of irrelevant information displayed on each page, removing unnecessary elements, and by minimizing the expression of the necessary elements without compromising function (Jill Butler William Lidwell, 2020). EDC systems should not require 125-

page guidelines or long training sessions for CRCs to be able to use them. Instead, they should be designed in a manner that is intuitive and simple, incorporating mental models, affordances, and other design principles wherever possible. Finally, EDC systems should strive to use consistent form layouts and field arrangements across studies and sponsors, and any updates made during the course of the study should avoid fundamentally relocating key forms and fields.

Of the five usability challenges identified, all five relate to the usability goal of "satisfaction" and three relate to the usability goal of "efficiency," highlighting a general perception by study participants that EDC systems are inefficient and unsatisfying to use. In addition to confirming Perceived Ease of Use as a construct impacting EDC acceptance, this study demonstrates that EDC systems designers should prioritize efficiency and satisfaction as key usability goals for supporting CRC acceptance of EDC systems.

5.3 Aim 3: Explore the perceived degree of fit between EDC systems and CRC tasks

Interviews also revealed key mismatches between the data entry required by the EDC, and CRCs' expectations for the data entry based on source documentation. Furthermore, EDC systems constrain the data entry process to a specific sequence of forms, causing frustration when this sequence is perceived to be out of step with the CRC's actual research workflow. These observations confirm the Task-Technology Fit model, by identifying areas of poor fit between CRC tasks and EDC systems design. Furthermore, CRC frustrations caused by mismatched expectations can be

linked to the TAM construct of Perceived Usefulness, and therefore may also impact CRC acceptance of EDCs. Design recommendations relating to the Task-Technology Fit issues identified can be found in ***Table 13*** below.

5.4 Aim 4: Propose recommendations for EDC systems design based on CRC perceptions regarding usability and task-technology fit.

Table 12 proposes design recommendations for EDC systems pertaining to usability challenges identified in this study.

Table 12. *Design Recommendations Related to Usability Challenges*

Sub-Theme	Design Recommendations
Repetitive data entry	Streamline and minimize data entry. E.g., keyboard shortcuts; autocomplete suggestions; pre-populated values; drop-down menus/radio buttons/checkboxes in lieu of free text
Inflexible user interface	Balance system constraints with user needs for control and flexibility. E.g., allow partially completed forms to be saved and returned to.
Lack of error prevention	Visually distinguish between required and optional fields. Anticipate and prevent user errors through clear visual cues, reminders, and warnings.
Inefficient to navigate and poorly organized	Reduce navigational complexity and nested forms (forms within forms). Display more fields across fewer forms. Simplify layout and provide navigational shortcuts. Display all pertinent information for the subject on the first page. Structure form fields so that scrolling is not required. Provide page locks for wide data entry grids. Visually delineate rows of information. Provide Excel-like functionality, i.e., ability to hide/display columns, resize columns, filter rows. Retain user page view preferences across sessions.
Overwhelming and inconsistent	Minimize cognitive load by reducing complexity, increasing use of mental models, and offloading tasks. Present system features consistently across studies. Provide clear guidance when system features are updated or moved.

Table 13 proposes design recommendations for EDC systems pertaining to task-technology fit issues identified in this study.

Table 13. *Design Recommendations Related to Task-Technology Fit Issues*

Sub-Theme	Design Recommendations
Data captured by EDC does not match data collected	Ensure that form fields, automatic queries, and data validations are "reality checked" by experts with familiarity in the conduct of clinical research. Ideally, involve site CRCs in the user acceptance testing process. Provide CRCs with ability to view, download, and print forms from the EDC for direct use as source documentation.
System flow does not match data entry flow	Ensure that the flow of forms follows a reasonable clinical research workflow, by having the system "reality checked" by experts with familiarity in the conduct of clinical research. Ideally, involve site CRCs in the user acceptance testing process. Remove system constraints that restrict CRC ability to move to different areas of the EDC. Allow CRCs to save and return to incomplete forms.
Missing EDC functionality and workarounds	Support searching and filtering of queries. Support flagging of high priority queries. Provide Excel functionality i.e., ability to hide/display columns, resize columns, filter rows. Support custom views and custom reports for individual users. Enhance system flexibility to support unique one-to-many and many-to-many relationships between data points.

5.5 Aim 5: Identify external variables that impact EDC technology acceptance and performance.

Several of task-technology fit issues identified in Theme 2 appear to be preceded by the organizational and technological factors identified in Themes 3 and 4. For example, mismatches between the data collected and data captured, and

between the EDC form flows and CRC's preferred workflows, can be attributed to the organizational barriers identified in Theme 3: inconsistencies in the sponsor-provided documentation, a lack of sponsor guidance on the development of source documentation, and an overall disconnect perceived between the CRCs and the sponsors. These organizational barriers are likely influenced by various external variables, such as the unique relationships between sponsors and sites, by the sponsor's willingness to take on certain types of risk (i.e. some clinical data standards indicate that the investigator, not the sponsor, should retain control over source documentation (Wilsher, 2009) by the study funding and amount of time available to support EDC system design and testing, by the involvement of clinical research experts in the protocol and systems design decision-making, and by the degree of resources and training available to the sites and CRCs. As noted above, one recommendation to mitigate the task-technology fit issues identified in Theme 2 is for the sponsor to involve clinical research experts earlier in the EDC system design and user acceptance testing process, to ensure that the EDC reflects the needs of its true end users (CRCs).

Technological fragmentation was also identified through the interviews as a cause of poor task-technology fit and a barrier to EDC acceptance. Participants described inefficiencies caused by switching between various CRI systems while conducting study activities. For example, one interviewee described the way that newly enrolled participants needed to first be added to the CTMS system before being added to the EDC system, and that led to a several minute delay during the

study visit. Another interviewee described switching from the EDC system over to the randomization system in order to get information about the assigned study drug, and then switching back over to the EDC system to record the remainder of the study visit. Context switching is recognized in the literature as a cause of work fragmentation, leading to increased cognitive load and time spent reorienting to the tasks (Mark, Gonzalez, & Harris, 2005). To reduce instances of technology fragmentation and mitigate the negative impact of context switching by CRCs, efforts should be made to centralize CRI systems into a single platform, with study data integrated between individual systems.

One limitation observed in the Task-Technology Fit model is its failure to consider the impact of external variables on the degree of fit between the user tasks and the system. Because organizational factors and technological fragmentation are seen as contributing to poor fit between CRC tasks and EDC systems, organizational factors should be examined in future research as a potential antecedent variable to the Task-Technology Fit model.

5.6 Impact of the Pandemic

The COVID-19 pandemic had a profound impact on the roles of CRCs in clinical research and on their interactions with EDC systems. Most of the CRCs interviewed indicated that they had engaged in some form of remote work in the past year, with the exception of CRCs working exclusively on COVID-19 trials or in-patient studies considered essential for patient care. This transition to remote work highlights the need for EDC systems to be designed to facilitate and support remote

work. For example, with more CRCs working from home, there is a greater need for EDC systems to accommodate technical challenges, such as VPN connectivity problems and internet outages. Where previously it may have been acceptable to save entered data at the time of form submission, it is now necessary to allow for frequent, automatic data saving throughout the process of data entry, and ability for CRCs to conduct data entry while offline.

In addition, many CRCs found that their ability to perform EDC tasks was hampered by the location of study source documentation. When source documentation could be accessed remotely online, such as through EHR portals, CRCs were able to conduct EDC tasks from home. Due to the privacy and security requirements of the site, CRCs could not conduct EDC tasks from home if the study source documentation was stored in paper at the site. Sites that employed electronic source documentation were also able to transition to remote monitoring visits, whereas sites using paper source documentation were required to postpone monitoring visits or file deviations for missed or delayed monitoring visits.

Decentralized (a.k.a. site less, or virtual) trials—trials where study participants are not tied to sites, where study drugs can be shipped directly to participants' homes, and where study visit data can be captured directly from the participant through the web – were already becoming more common prior to the events of 2020 (Hirsch et al., 2017). However, COVID-19 forced sites, sponsors, and EDC vendors to test the feasibility of this approach in practice. In the future, EDC systems may be adapted to better accommodate the needs of decentralized trials,

and this will require rethinking the role of CRCs and their relationship to study data collection activities.

5.7 The future of EDCs and the rise of eSource DDC systems

Although it did not rise to the level of a theme, several participants described having very positive experiences using eSource Direct Data Capture (DDC) systems. DDC systems are a new subtype of CRI system that are designed to allow CRCs to directly capture original study data into electronic format (Parab et al., 2020). A major benefit of DDC systems is their ability to validate the data as it is being entered, reducing data entry errors, resulting in fewer queries, and minimizing the need for source data verification (because the DDC system is considered the original source of data) (Parab et al., 2020).

While the intention of existing eSource DDC systems vendors is to eliminate the need for EDC systems entirely, in most cases it is not feasible for DDC systems to integrate across all potential sources of original study data, such as EHR and device data. In addition, the clinical research industry has been slow to adopt DDC systems (Parab et al., 2020). One participant noted that his CRO implemented an eSource DDC at the sites, but the study sponsor still preferred to retain its EDC system. Therefore, he continued to transcribe source data into the EDC. Despite this, he found that using the DDC made the transcription process "*at least 10 times easier, more efficient, more reliable, more easily auditable, clear, concise. Better in every way, by an order of magnitude than doing it on paper*." He further emphasized that he could not imagine voluntarily planning a study with paper source after using the

DDC, and that "*if [eSource] doesn't become industry standard, [he] would be shocked.*" (Participant 03)

With virtual and decentralized clinical trials coming to the forefront as a result of the COVID-19 pandemic, it seems likely that future clinical research studies will make use of DDC systems to capture some data directly from study participants from the convenience of their own homes, rather than requiring participants to come to sites for all study visits. In addition, efforts to integrate original sources of research data with CRI systems have increased in recent years (Bruland, Doods, Brix, Dugas, & Storck, 2018; Bruland & Dugas, 2017; Parab et al., 2020). Therefore, the EDC systems will either fall out of style in favor of new DDC systems, or DDC and EDC systems will merge over time into a type of data collection platform that is capable of handling both direct capture of source data as well as centralization of data capture across all sites, data sources, and CRI systems.

6 Limitations and Future Work

This study has a number of inherent limitations, which can be addressed in future research. First, selection bias may limit the significance of the study results, as individuals who volunteered to participate in this study may have been motivated by personal interest in the topic or may possess more passionate viewpoints regarding EDCs. Future work might consider a probability-based sampling strategy to guard against potential sampling bias.

In addition, participants were predominantly employed by two major academic medical centers in the southeast. Consequently, the CRC user experiences identified in this study are situated in academia, and these experiences may not be transferrable to CRCs in other site settings, such as community health centers or private clinical practices. Future studies may be needed to evaluate CRC perceptions regarding EDC systems within other settings.

Due to time constraints and limited access to data, I was unable to enhance the validity of the results through data or methodological triangulation. I originally intended to conduct content analysis on a secondary source of data (relevant forum posts from the Association of Clinical Research Professionals), however, I learned that ACRP forum data is not considered to be publicly available, and therefore would require informed consent from each individual post author prior to conducting any analysis. I also hoped to triangulate my research methods by using the results of the

qualitative analysis to inform the design of a large quantitative survey on EDC satisfaction. However, due to time limitations, a mixed methods study was not feasible. Future studies could use the findings from this study to inform the design of future quantitative or mixed methods studies.

Finally, although this study identifies perceived challenges regarding EDC systems design, it does not investigate whether there is a relationship between CRC perceptions and actual EDC use. In addition, since this study used qualitative methods to evaluate CRC's user experience with EDCs, the results cannot be generalized to all CRCs. Therefore, quantitative evaluation studies are recommended in the future to validate and quantify the relationships between identified challenges/barriers and actual EDC use.

7 Conclusion

This study investigated the user experience of CRCs with EDC systems through semi-structured interviews and thematic analysis. The findings demonstrated that usability and task-technology fit challenges impacted the acceptance and use of EDC systems commonly used in academic clinical research settings. In addition, external variables, such as organizational factors and technological fragmentation, led to poor task-technology fit of EDC systems and associated CRC workarounds. This study confirms the utility of combining the Technology Acceptance Model (TAM), the Task-Technology Fit (TTF) model, and concepts from usability theory into an analytical framework to guide a qualitative, user-focused evaluation of EDC systems. In addition, this study provides a long-ignored user group–CRCs—with a voice in the development of EDC systems, and proposes a set of design recommendations to improve the usability and TTF of EDC systems. Finally, this study contributes to the literature by evaluating user experiences with EDC systems using a qualitative, semi-structured interview approach. Future work shall build on the results and experience of this study and expand the evaluation by conducting quantitative evaluations of EDC systems.

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9 Appendices

9.1 Definitions

Clinical research coordinators (CRCs): Individuals responsible for participant-facing clinical research activities at sites, including consenting and enrolling new participants, conducting study visits, and collecting research data.

Clinical research information (CRI) systems: Information technology applications that support the design, conduct and reporting of clinical research studies.

Contract Research Organizations (CROs): Organizations that conduct some or all of the oversight responsibilities on behalf of the study sponsor.

Electronic Data Capture (EDC) systems: Clinical research information systems used to capture and securely transmit accurate, auditable clinical research data from its original source at the site to the sponsor.

eSource Direct Data Capture (DDC) systems: A subtype of CRI systems that allows CRCs to directly capture original study data into electronic format.

Sites: Locations where eligible study participants can be identified and enrolled onto the study.

Standard Operating Procedures (SOPs): Step-by-step instructions developed (usually by CRCs) to guide the site's conduct of the clinical research study.

Sponsors: Organizational entities that are responsible for overseeing the progress of clinical research studies. A sponsor may be an academic or industry organization. Many industry sponsors transfer their oversight responsibilities to contract research organizations (CRO).

9.2 List of Popular EDC Systems and Vendors

EDC Name	Vendor Website	Pricing Strategy
Advarra EDC	www.advarra.com	Proprietary
BioClinica EDC	www.bioclinica.com	Proprietary
Captivate EDC	www.clincapture.com	No cost for COVID-19 research, otherwise proprietary
Castor EDC	www.castoredc.com	No cost for COVID-19 research, otherwise proprietary
Clindex EDC	www.fortressmedical.com	Proprietary
ClinTrak EDC	www.medpace.com	Proprietary
Dacima	www.dacimasoftware.com	Proprietary
DADOS	www.dadosproject.com	Proprietary
DataFax	www.dfnetresearch.com	Proprietary
DataLabs EDC	www.parexel.com	Proprietary
DATATRAK EDC	www.datatrak.com	Proprietary
eCaseLink EDC	www.dsg-us.com	Proprietary
Fusion eClinical	www.axiommetrics.com	Proprietary
IBM Clinical Development EDC	www.ibm.com	Proprietary
InForm	www.oracle.com	Proprietary
Main EDC	www.datamangement365.com	Proprietary
Matrix EDC	www.datamatrix.com	No cost for COVID-19 research, otherwise proprietary
Medrio eClinical EDC	www.medrio.com	Proprietary
OnlineCRF	www.OnlineCRF.com	Proprietary
OpenClinica EDC	www.openclinica.com	No cost and proprietary versions available
Rave EDC	www.medidata.com	Proprietary
REDCap	www.projectredcap.org	No cost for REDCap Consortium Partners
REDCap Cloud	www.redcapcloud.com	Proprietary
TrialKit	www.crucialdatasolutions.com	Proprietary
TrialMaster	www.anjusoftware.com	Proprietary
TrialStat EDC	www.trialstat.com	Proprietary
Veeva Vault EDC	www.veeva.com	Proprietary
Veridata EDC	www.elsevier.com	No cost for COVID-19 research, otherwise proprietary

9.3 Interview Guide

This document describes the semi-structured user needs analysis interview guide. The interview goal is to understand the information needs of clinical research staff, specifically as they pertain to electronic data capture.

[Introduction]

Hi, my name is Michelle Erin Johnson, and the purpose of this interview is to learn more about your information needs as a [role]. In particular, I'd like to know more about your experiences with common clinical research data collection tools like REDCap, Oracle Health Sciences InForm/Clinical One, Open Clinica, Medidata Rave.

We'll do that by going through a series of questions, which will take approximately 30 to 45 minutes. During the interview, please imagine that you are describing your role and the systems you use to someone who isn't familiar with clinical research.

Before we get started, there are a few things that you should know. First, when I write up my thesis, I may want to quote some of the things that you have said, but I will not include your name or any other information that might identify who you are. If there is anything in particular that you really don't want to be quoted, please let me know.

Also, this interview is completely voluntary – if for any reason you want to stop, please just let me know. We can end the interview at that point with no negative consequences for you. I can also discard anything you've told me up to that point.

Third, if you would like, I can provide you with a copy of my final paper, once it is completed.

Finally, would it be okay if I record this interview? This is just so I don't miss anything – no one else will have access to the recording, and I will de-identify the transcripts so that your confidentiality should be preserved.

Do you have any questions for me? Okay, let's get started.

[Role and Tasks]

- Tell me about your role at your company.
- What is your work environment like? (Note: Ask about COVID-19-related changes)
- Please tell me about a clinical research study that you are currently involved in (or were involved in within the past two years).
    - What tasks are you responsible for?
    - Do you share these tasks with other colleagues in your study team?
    - What does the overall study workflow look like for you?
    - What sort of information do you need to keep track of? How do you keep track of it?
    - What sort of information do you regularly need to look up? How do you find it?
    - Where do you enter study data?

- Do you ever record study information in supplementary locations (such as Excel spreadsheets)?

[EDC Overview]

- Do you use REDCap, Oracle Health Sciences InForm, Oracle Clinical One, Open Clinica, Medidata Rave, etc. in your studies?
    - **NOTE**: Pick one EDC that the participant is most familiar with. If time allows, probe Task Analysis and Sentiment questions for additional EDCs.
- How familiar would you say you are with [EDC name]? Did you receive training on how to use it?
- **When the study first started, were you included in meetings or discussions regarding the setup of this system?**
    - **If yes, please tell me more about the input you provided on the system design.**
    - **If no, do you wish that you had been able to provide input regarding the system design?**
- **Do you feel the [EDC name] is currently designed in such a way that it meets the needs of the study protocol?**

[Task Analysis]

- **I'd like you to think back to the last time you used [EDC name]. Can you walk me through how you might use this system, starting for example with enrolling a new patient, up through the end of patient follow-up?**
    - For each task: How do you currently go about [task]?
    - For each task: What kind of device do you tend to use in completing [task]?
    - For each task: How much time do you typically spend on [task]?
    - For each task: What is the biggest pain point related to [task]?
    - For each task: Do you use any workarounds or shortcuts related to [task]?

[EDC - Sentiment]

- What do you like about [EDC]?
- What is the hardest part about using [EDC] in your studies?
- What could be done to improve [EDC]?
- Do you believe that [EDC] helps you carry out your tasks effectively?
- Overall, would you rate this system "excellent," "good," "fair," or "poor." And why**?**
- Does [EDC] have any features that you really like? Describe.
- Is [EDC] missing any features that you really need to do your work? Does [EDC] have any features that you find particularly frustrating or unhelpful? Describe.

[EDC – Comparisons]

- Have you used other EDCs?
    - How do they differ?
    - How are they similar?
- What do you like or dislike about these other products or tools?

[Conclusion]

- Is there anything else that you think would be helpful to know regarding your information needs as a [role], that we haven't talked about yet?

[after any response they provide]

Thank you, that's all of my questions. Do you have any questions you'd like to ask me?

[after their questions are answered]

Thank you again. If there's anything you'd like to follow up on down the road, you have my e-mail address. Please don't hesitate to reach out.

9.4 Study Information Sheet and Consent Form

University of N*orth Carolin*a at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 11/17/2020
IRB Study # 20-2620
Title of Study: Electronic Data Capture (EDC) Systems: Analyzing the Information Needs of Clinical Study Staff
Principal Investigator: Michelle Erin Johnson
Principal Investigator Department: UNC School of Information and Library Science
Principal Investigator Phone number: (617) 945-6822
Principal Investigator Email Address: mej@unc.edu
Faculty Advisor: Fei Yue
Faculty Advisor Contact Information: feifei@unc.edu

What are some general things you should know about research studies?
You are being asked to take part in a research study. Being in this research study is completely voluntary. You can choose not to be in this research study. You can also say yes now and change your mind later.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above about any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to identify the information needs of clinical research study staff and to evaluate their experiences with common clinical research data collection tools. You are being asked to take part in a research study because you have indicated that you are currently a clinical research coordinator, clinical research associate, clinical research nurse, or similar role.

Are there any reasons you should not be in this study?
You should not be in this study if you are under 18 years old. You should not be in this study if you lack access to a personal computer capable of running Zoom or a stable internet connection.

How many people will take part in this study?
Up to 15 clinical research study staff members will be interviewed for this study.

How long will your part in this study last?
The study will require approximately 30 to 45 minutes of your time.

What will happen if you take part in the study?
If you agree to take part in this research, you will be asked to participate in an interview. This interview will be conducted over Zoom at a convenient time. It will last approximately 30 to 45 minutes.
You will be asked if we have your permission to record your interview. Your interview will be audio-recorded to ensure accurate and complete answers are collected. You must agree to have your interview audio-recorded in order to participate in this study.

Additionally, in this study, your interview may be video-recorded to ensure accurate and complete data are collected. It is optional to have your interview video-recorded.

You can choose not to answer any question you do not wish to answer. You can also choose to stop taking the survey at any time.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
There is minimal risk or possible discomfort involved in this study.

- Fatigue: You may feel mentally fatigued or time-constrained during the study. You may reschedule the interview at any time, and you may request to conduct the interview over multiple sessions as needed.

- Breach of Confidentiality: There is a minimal risk for any breach of confidentiality. All information that could be used to identify you, as the research participant, will be stored in a password-protected, secure UNC server. All records will be kept completely confidential.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will information about you be protected?
- You will not be identified in any report or publication about this study
- Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be

reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

- During the study, all information about you will be kept in a secure location that only approved study staff can access.
- ID numbers will be used to help keep your study data anonymous. The link between your personally identifying information and your study ID number will be stored on secure UNC servers, separate from the study data.
- Personally identifying information, including audio and video recordings of the interviews, will be destroyed at the end of the study.
- Study data without any personally identifying information will be stored securely for at least three years.

In this study, your interview will be audio-recorded to ensure accurate and complete answers are collected. You must agree to have your interview audio-recorded in order to participate in this study.

Please <u>check</u> the line that best matches your choice:

_____ OK to audio record me during the study

_____ Not OK to audio record me during the study

Additionally, in this study, your interview may be video recorded to ensure accurate and complete data are collected. It is optional to have your interview video recorded.

Please <u>check</u> the line that best matches your choice:

_____ OK to video record me during the study

_____ Not OK to video record me during the study

Who is sponsoring this study?
This study is unfunded. Michelle Johnson, the principal investigator on this study, is a graduate student at UNC School of Information and Library Science and an employee at UNC Lineberger Comprehensive Cancer Center. She is conducting this research in her role as a master's student.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigator also has the right to stop your participation at any time. This could be because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive a $20 gift card for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, or concerns, you should contact the researchers listed on this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have any questions about this research, please contact the Investigator named at the top of this form by calling (617) 945-6822 or emailing mej@unc.edu. If you have questions or concerns about your rights as a research subject, you may contact the UNC Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Name of Research Participant

9.5 Recruitment Scripts

RECRUITMENT EMAIL

SUBJECT LINE: Invitation to participate in a study on clinical research data collection

Hello,

My name is Michelle Erin Johnson, and I am a graduate student at UNC-Chapel Hill in the School of Information and Library Science. I am conducting a research study to identify the information needs of clinical research study staff and to evaluate their experiences with common clinical research data collection tools like REDCap, Oracle Health Sciences InForm/Clinical One, Open Clinica, Medidata Rave, among others.

I would like to interview individuals who are involved in the day-to-day conduct of clinical research, with roles such as clinical research associate (CRA), clinical research coordinator (CRC), clinical research nurse, etc. Individuals should have recent (i.e. past two years) or current clinical research responsibilities, including screening, enrolling, and consenting patients; scheduling and conducting study visits; following-up with study participants in clinic and by phone, entering data into case report forms, and resolving questions from data managers. Specifically, I am looking for individuals who are directly intervening/interacting with study participants.

I am interested in speaking with individuals who work in academic research groups and individuals who work for contract research organizations (CRO).

What will I be asked?
You will also be asked general questions about your role and responsibilities, followed by a series of questions about your information needs and your experience with clinical data collection.

How long is a session? The study will consist of a single interview that is between 30 – 45 minutes long.

When and where?
I will reach out to schedule a Zoom call with eligible participants. No traveling is required.

Interested in participating?
Please reply to this email with your contact information.

If you have any questions, please contact me at mej@unc.edu.

Thank you for interest,

Michelle Erin Johnson
UNC Chapel Hill
School of Information and Library Science
mej@unc.edu

CONFIRMATION EMAIL

SUBJECT LINE: Confirmation: Your participation in a study about clinical research data collection

Dear [PARTICIPANT NAME]:

Thank you for agreeing to participate in my study to identify the information needs of clinical research study staff and to evaluate their experiences with common clinical research data collection tools. As I mentioned, you will be asked general questions about your research role and responsibilities, followed by a series of questions about your information needs and experiences with clinical data collection.
You won't need to prepare anything before the session.

You are scheduled to participate as follows:

DATE: [DAY, DATE]
TIME: [TIME]
PLACE: Zoom Conference Call

As soon as possible, please do the following:

1. **Verify your ability to participate in a Zoom call**

   The study will be conducted remotely over Zoom. Please verify that you can use Zoom and perform any necessary installations or updates before the time listed above. If you have never used Zoom before, please contact me and we can schedule a time to try it out together before the session.

2. **Read the Understanding Your Participation document (attached)**

   With your permission, the audio and video of the Zoom session will be recorded. You will be asked to verbally consent to video recording at the beginning of your session. We will only use the recording for note-taking and transcript purposes. Your name will not be used for any purpose beyond this session.

A few key reminders:

- During the study, I will ask you to answer some interview questions about your role in clinical research, and the systems you have used.
- Please reserve a quiet space where you will not be disturbed or interrupted during our session.

Also, if you find that you cannot participate on your scheduled day, please contact me as soon as possible so I can reschedule your interview.

Thanks again!

[INTERVIEWER NAME AND CONTACT INFORMATION]