Adoption of Technology in Clinical Research Sites: Factors and Recommendations

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Title Page

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Synopsis:

Little is known about the acceptance and incorporation of technological innovations by clinical research sites, a primary entity in the clinical research enterprise in charge of conducting clinical trials. This project explores the adoption of the technological innovations that clinical research sites are presented while conducting trials A qualitative search has been conducted based on case studies about the adoption of two technologies in Danish sites and the input of several actors involved in the process, and with the contribution of innovation theories, this thesis determine the factors involved in influencing technological innovation at the clinical research site and draws a line of recommendations to overcome the obstacles facing technology adoption by the sites.

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CRA: Clinical Research Associate

CRO: Contract Research Organization

CTM: Clinical Trial Manager

CTTI: Clinical Trials Transformation Initiative

SCRS: Society of Clinical Research Sites

Executive Summary

Getting an innovation adopted even if it has many advantages is often difficult. This thesis explores this idea in the clinical research industry precisely at the investigational site level and in connection to the adoption of technological innovations. Adoption in this context is construed as the acceptance and incorporation of technological innovations into everyday practice in line with the diffusion of innovations theory by E. Rogers.

The unit of analysis in this dissertation is the investigational **site**, also called clinical research site, they are the invisible hand at the center of the clinical research enterprise. The investigational sites refers both to the locations where subjects of a clinical trial can contact health professionals (e.g., hospitals, clinics, dedicated centers) and the dedicated teams in those locations in charge of executing the study designed by the **sponsor** (i.e., pharmaceutical or biotech or research company investigating a new medical invention such a new drug in order to get it approved by the authorities for marketing). Teams are primarily composed of a **principal investigator**, often a physician, and a **study coordinator**, often a research nurse and in collaboration with the rest of the team they recruit subjects, explain the study to and obtain consent from subjects, provide the subjects with the object of the test, monitor the subjects, and collect and maintain clinical data to send to the sponsor. The sites receives a study **protocol** (a document designed by the sponsor and approved by the authorities describing in great details how the experiment to test the efficacy, safety of a clinical invention is designed and how to conduct it on the subjects) and are assigned a clinical trial associate (**CRA**) to train them in the protocol and the technologies associated with it and monitor and manage the site team throughout the trial period.

The first task in this research was to visualize the suboptimal adoption of technological innovation in the investigational site. A preliminary empirical investigation was conducted, i.e., interviews with a Danish CRA working for an international clinical research organization and in charge of managing the Danish sites conducting protocols for the organization. The issue manifests in two ways either no adoption of technology even for tasks that the site see worth technological intervention or a relatively low adoption of it by not using the technologies available optimally.

Two case studies each investigating the adoption of a particular technology among the Danish investigational sites formed the basis of the empirical investigation. The technologies in question are often used in conducting clinical trials in sites. The first is known as electronic data capture systems and is used to enter the necessary data about subjects electronically and send it

instantaneously to the sponsor instead of using copies of paper records. The second is online portals meant to connect the sites to the sponsor and assist with communication. Data about the experiences of sites staff with this technology was collected primarily from interviews with two CRAs (Each from a different clinical research organization and managing several sites all over Denmark), a CTM (A Clinical Trial Manager of a third clinical research organization) and two study coordinators (One in a site located in Aalborg Hospital and another in a site located in Rigshospitalet Denmark).

The second and third task of the research was to understand the why behind the situation by exploring the factors that influence technology adoption at the site level and providing recommendations to optimize the situation.

Five factors have identified to be particularly influential in the adoption of technological innovations the sites.

- Organizational structure
- Non-inclusion of sites
- Technology overload
- Systems interoperability.
- Design consistency.

For the third task of the report (i.e., suggestions to optimize technology adoption at the site level), a second analysis has been performed combining the organizational, human, and technological factors that has been determined and applying the theoretical concept of fit to align the potential solutions with the issues in context and it translated in this setting to collaboration between the stakeholders. Under the umbrella of collaboration, leveraging theories from business model innovation and principles from approaches to entrepreneurship, two more recommendations followed:

- Collaboration: Between sponsors, between sites, between sponsors and sites
- Rethinking the current business models
- The Scale and assessment of solutions

The study followed with a discussion reflection on the methodology and results and future actions.

Introduction

Clinical research is the foundation of modern medicine. Through outstanding inventions such as the development of antibiotics, vaccines, surgical devices and many other advances, clinical research contributes to the health and well-being of countless people around the world (Re, 2006). However, the management process of these inventions is not optimal. Clinical trials the gold standard to evaluate the safety and efficacy of clinical interventions and considered the development and implementation funnel of pharmaceutical inventions, are complex, expensive, and run over many years (DiMasi, Grabowski, & Hansen, 2016) (Califf, Robert & Rutherford, 2018) (Lauer, Gordon, Wei, & Pearson, 2017). Technological solutions are being considered a solution for the clinical research enterprise to optimize the process (Riley, Glasgow, Etheredge, & Abernethy, 2013), they present opportunities that can reduce cost, minimize complexity, and reduce the burden on staff and patients (Ali, Zibert, & Thomsen, 2020) (National Academies of Sciences, Engineering, 2019) (Steinhubl, Wolff-Hughes, Nilsen, Iturriaga, & Califf, 2019). Over the last two decades, mobile health, wearable devices, telehealth, and other innovations are on the rise and the public is increasingly welcoming those new innovations based on their reach, convenience, and advantageous contributions (Agrawal & Prabakaran, 2020) (Bhavnani, Narula, & Sengupta, 2016) (Trifan, Oliveira, & Oliveira, 2019). While the technology for conducting digital clinical trials has advanced over time, the business model supporting this technology has not changed with the transformation (Judith M. Kramer & Kevin A. Schulman, 2012). The pace for introducing digital technology into clinical trials has only picked up in the last five years (Rosa, Marsch, Winstanley, Brunner, & Campbell, 2021) and the clinical research enterprise has been slow to adopt digital substitutes to traditional practices (Rosa, Campbell, Miele, Brunner, & Winstanley, 2015) (Black et al., 2011) (Baker, Gustafson, & Shah, 2014) resulting in limited competences to successfully exploit and lead technological innovation. Transformation is a process, not a single event, it takes years and is built on many stages (Kotter, 2007). In an attempt to contribute to this transformation, this project sets for mission to study the incorporating of technology at one important institution of the clinical research enterprise: The clinical research site. It is characterized by a suboptimal

adoption of technology. Advances in IT combined with business model transformation could combine to form a critical step in achieving transformation of the clinical trial enterprise through lower cost, faster, and better data quality of clinical trials, this project leverages an innovation management perspective to examine the adoption of technology at the site level.

Two questions will lead this plan:

What factors influence technology adoption at the site level? And how could it be optimized?

Background

An overview about the clinical research enterprise is in order to provide the reader with a reference to the terminology used throughout the report and an understanding of the context of the research topic.

The clinical research enterprise also referred to as clinical trial enterprise is: *"a broad term that encompasses the full spectrum of **clinical trials** and their applications. The clinical trial enterprise includes the processes, **institutions, and individuals** including those who eventually apply clinical trial findings to patient care."* ((us), 2012)

Clinical trials

The new drug development process is complex and long and clinical trials represent the longest, most expensive, critical, and important part in the development of a new product (McGraw, George, Shearn, Hall, & Haws, 2010).

As defined by the World Health Organization (WHO), "Clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, and preventive care. Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start." (World Health Organization,). It is extremely difficult on the basis of uncontrolled observation to determine whether a new treatment or intervention makes a difference to

a patient's outcome. In addition, a true risk-versus-benefit analysis cannot be conducted outside the context of a controlled situation. Therefore, in good clinical practice, clinical trials are considered the gold standard in establishing the effects of therapeutic intervention (DeMets & Califf, 2011).

Institutions and individuals in clinical trials

Research is a complex clinical activity. Below is a definition of the actors evoked during the course of this dissertation, the connections between them and their role in the clinical trial process.

Institutions: Sponsors, Contract Research Organizations (CROs) and Clinical Research Sites.

Individuals: Clinical Trial Manager (CTM), Clinical Research Associate (CRA), Principal Investigator, Study Coordinator.

Figure 1 summarises the process of clinical trials along with the stakeholders involved.

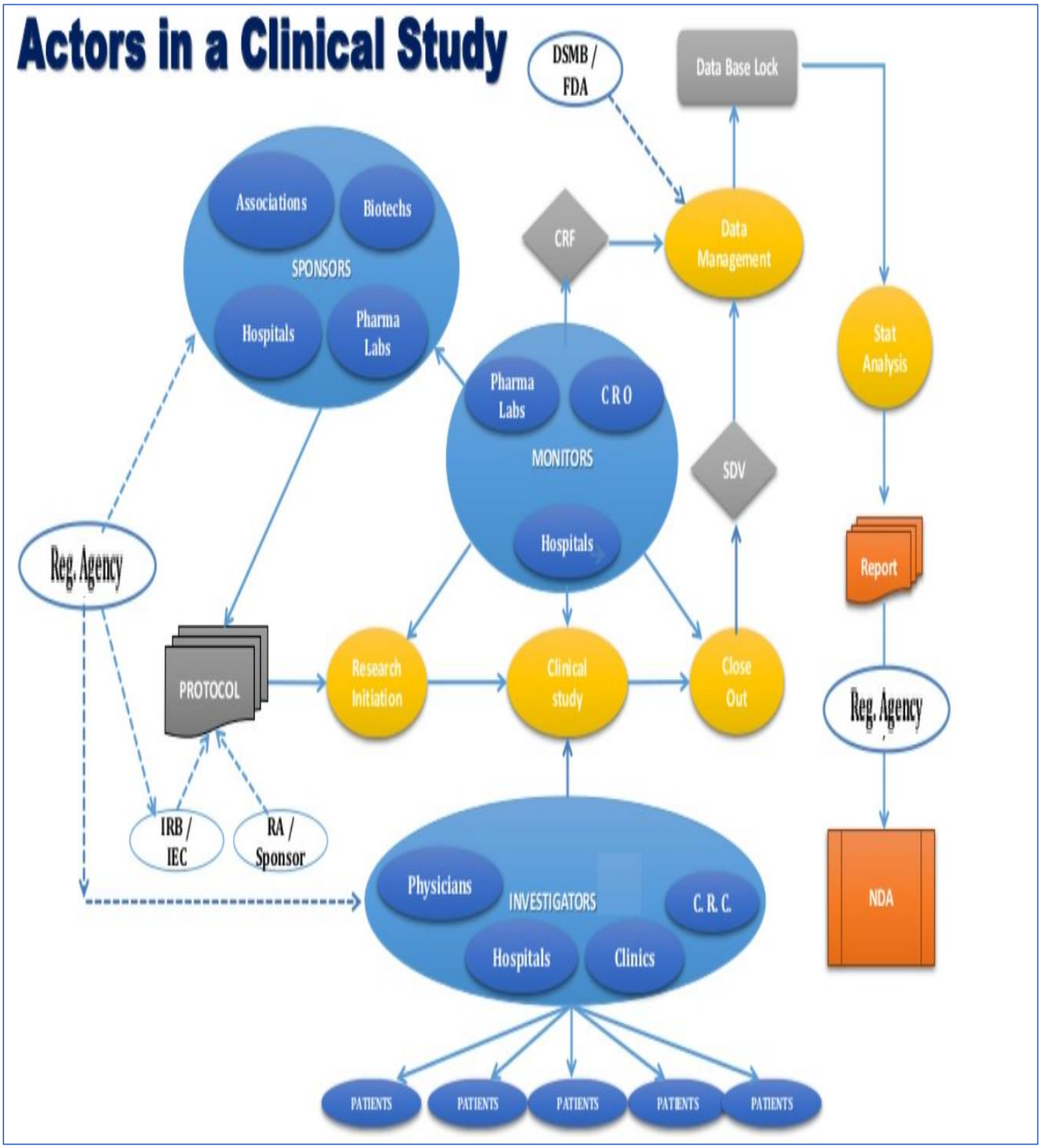

Figure 1 process of clinical trials along with the stakeholders involved

Abbreviations and frequently used terms

Table-1 provides a glossary for some of the technical terms related to clinical trials that will show up often in the report. Definitions are based on a book recommended by one the participants in the interviews. It is a guide about good clinical practices (McGraw et al., 2010).

Term	Other terminologies	Definition
Clinical Trial	Clinical Study	Any investigation in human subjects intended to discover or verify the clinical, pharmaceutical and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Clinical Research Associate **(CRA)**	Monitor	The person overseeing the progress of the clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures, good clinical practice, and the applicable regulatory requirements. The CRA may work directly with the sponsor company of a clinical trial, as an independent freelancer or for a contract research organization (CRO).
Contract Research Organization (**CRO**)		A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of sponsor's trial-related duties and functions.
Investigational Product		A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial.
Medical Institution		Any public or private or agency or medical or dental facility where clinical trials are conducted.
Multicenter Trial		A clinical trial conducted according to a single protocol but at more than one site.
Investigator		The responsible leader of the team conducting a clinical trial at a trial site.
Protocol		A document that describes the objective (s), design, methodology, statistical considerations, and organization of a trial.

		The protocol usually also gives the background and rationale for the trial, but there could be provided in other protocol-referenced documents.
Regulatory Authorities		Bodies having the power to regulate. Regulatory authorities include the authorities that review submitted clinical data and those that conduct inspections.
Sponsor		An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Study Coordinator		A person responsible for the conduct of the clinical trial at a trial site and lead by a principal investigator.
Subject/Trial subject		An individual who participates in a clinical trial, either as a recipient of the investigational product, or as a control.
Trial Site	Investigational site, Clinical research site, Clinical site, Research site, Trial site, Site	The location where trial related activities are actually conducted and the team of people conducting the activities.

Table 1 Glossary for Some of the Technical Terms Related to Clinical Trials

Preliminary Investigation

Empirical research

With the COVID-19 pandemic, I was curious about the innovation model for developing new drugs by pharmaceutical companies. In my line of investigation, I narrowed my focus to integrating technological innovations into clinical trials and the issues surrounding the subject and how in return it impacts the overall performance of the clinical research enterprise. Through my network, I reached out to a Clinical Trial Associate (CRA), to get the version of events from the industry. The CRA in question works for Multinational Contract Research Organization (CRO) and monitors studies of pharmaceutical companies contracted with the CRO and having those studies run in several Danish clinical research sites. The discussion started about technology input and challenges in the clinical trials on the high level, such as decentralized or digital trials, and the technology status from her personal experience in her workplace but a major part of the narrative was dedicated to the technological challenges faced by those that she monitors: the clinical research sites conducting the studies she is in charge of. Intrigued about the situation, I conducted a research based on industry reports namely those from the society of clinical research sites[1], an association of investigational sites around the world and having for mission to unify the voice of the global clinical research site. Some of the reports they conducted among their members revealed that the clinical research site is struggling with technology, there is a technological burden on the sites caused by the amount of systems they have to use and how they have to keep up between all of them. Scheduling an official interview with my CRA, I shared my findings with her, and she contributed with her input answering two main questions I had, an overview of the technologies her sites use and how the non-adoption of the technologies show as they are still supposed to use these systems and conduct the trials they are in charge with to the best of their abilities. Below is a summary of this journey.

[1] https://myscrs.org/

Interview 1 notes

Technology involvement in clinical trials
CRA (KM)
25/01/2021
It seems that technology involvement in the clinical trial process indeed faces many challenges. According to the CRI, their workflow and productivity could be optimized with the introduction of better IT systems, more user friendly and modern interfaces or putting in place technologies that adapt to the current COVID-19 situation and promote remote monitoring for example. Obvious factors such as regulations, and how they could be bureaucratic and strict in connection to the nature of clinical trials, shortcomings such as the lack of involvement of the end users were mentioned. Another idea was to focus on problems that need technological involvement rather than starting from technologies and forcing them upon the users to solve unnecessary or secondary problems.

Interview 2 notes

Protocol Deviations at Site Level and Technology
CRA (KM)
30/01/2021
Currently the work process at the research site level is relying on manual practices which leaves room to errors. The work could be optimized to avoid protocol deviations through a technological solution. The systems in use by sites. Sites typically use around 10 different systems (EDC: Electronic data captures, systems for reporting adverse events, electronic case report form (like EDC), clinic web portal, CTMs…) with 8 to 9 sponsors running studies at the same time. A range of tactics to avoid using a system, not doing it, asking for assistance to do it, doing it wrong,

The preliminary investigation described above revealed a suboptimal adoption of technology manifesting in two ways. First, a low incorporation by the site staff into their workflow of many of the technological solutions that they are presented with. Second, while site staff have at their disposal many technologies, there are still many aspects lacking technology and multiple examples of how site staff spend study related activities that could be saved by adopting current and simple technological solutions were identified. Table groups these examples.

Need technology but no incorporation of a solution	Presented with technology but low incorporation
Cognitive technologies to generate actions items from study protocols to assist with scheduling patient visits and related tasks instead of the current manual and paper process.	Leaving it for other nurses or until CRA is present.
A database to record training for recurrent systems and certify the user instead of spending time redoing training for each sponsor with every new study.	Minimal use of a system.
	Significant need for assistance using a system.
	Avoiding the use of a solution or delaying the task related to it.

Table 2 Manifestations of the Suboptimal Adoption of Technology in Sites

Literature research

The first step in this academic investigation is to get a clear understanding of the concepts forming the search topic. While the definition of clinical research site has been determined in earlier sections, the concepts of adoption and technological innovation need clarification to set the right base for the discussion. Afterwards, there will be a review of the literature's answer to the adoption of technological innovation by clinical research sites. Finally, the literature research will be concluded with an examination of the theories to consider for the remaining of the research.

The concept of adoption

The purpose of this dissertation could be lost, and the progress hindered by the use of inter-related terms that sometimes are employed interchangeably in connection to the processes by which innovations are presented and then established (or not) into the habits of social structures. Consequently, a review of the differences and nuances between the concepts is necessary. Table defines these concepts.

Diffusion	The study of how, why, and rate new ideas and technology spread in organizations (Rogers, 2010).
Adoption	The acceptance and incorporation of innovations into everyday practice (Rogers, 2010).
Infusion	The degree of comprehensiveness or sophistication of use of an innovation (Zmud & Apple, 1992).
Implementation	The consideration and the introduction of innovations (Rogers, 2010).
Integration	The process where technology becomes incorporated in organizational practices (Stead, Miller, Musen, & Hersh, 2000).
Deployment	The process where technology is put into use in the organization. (A. Dearle, 2007)
Normalization	The process by which an innovation becomes routine (May et al., 2007)

Table 3 Adoption and Closer Concept

The concept of adoption is the one of interest in this project. The sense of accepting and incorporation of innovation into practice as defined by the theory of diffusion of innovations (Rogers, 2010) *in combination with the concept of adoption as described by one of the authors in the sense of the assimilation of innovations in the subject's environment* (Robert, 2009)*. The nuance adopted in this dissertation is closer to the notion of infusion as defined in table but with the adoption there is a highlight of individual perspective by the mention of* ***acceptance*** *and the organizational aspect is added by considering if the* ***full potential of the innovation has been embedded within the workplace.***

The concept of technological innovation

Three conceptions of technological innovation have been identified through the research.

1-Technological innovation as another term for innovation. A view of innovation and technological innovation that was popular among the authors in the 70s and 80s and earlier. In a study about the origins and development of the concept of innovation, Godin explains that "After World War II, various groups appropriated the concept of innovation, each for their own purpose. Governments, engineer-managers, and academics adopted it

and made it a strictly technological matter" (Godin, 2016). Technology plays a big role in creating a competitive advantage and influencing a firm's performance ((Barney, 1991), (Lin, Lin, & Lin, 2010), (Porter, 1985)) but perhaps this tight association between innovation and technology could also be linked to the role technology played in changing the negative connotation about innovation to a positive beneficial concept: "…innovation gradually starts to receive a positive connotation…The Industrial Revolution and the rise of mainstream economics ultimately led to the current dominance of technological innovation, a concept that intrinsically relates technology with the market" (Schomberg & Blok, 2019).

2-Technological innovation for some authors is specific to product and production processes innovation. Governments and international organizations paved the way for this view. "Many scholars borrowed a definition of technological innovation from government sources. In the 1960s, governments and international organizations produced some of the first titles on technological innovation" (Godin, 2016). The Oslo Manual (A collaboration between the Organization for Economic Co-operation and Development (OECD) and the Commission of the European Communities (CEC) to inform innovation policy), in its second edition in 1997, links technological innovation to products and processes: "Technological innovations comprise new products and processes and significant technological changes of products and processes" (Oslo manual 1997: Proposed guidelines for collecting and interpreting technological innovation data, 2nd edition.1997) as opposed to non-technological innovations compromised of organizational and marketing innovations further defined in the third edition (Oslo manual 2005: Guidelines for collecting and interpreting innovation data, 3rd edition.2005). The growing research on the dynamics between technology and a business model in general ((Chesbrough, 2007), (Chesbrough, Di Minin, & Piccaluga, 2013)), made the exclusivity of technological innovation to product and production processes innovations obsolete, the latest version of the Oslo Manual no longer focuses on technological innovation and the distinction between technological and non-technological innovation are completely omitted from this new edition (Oslo manual 2018: Guidelines for collecting, reporting and using data on innovation, 4th edition.2018).

3- Technological innovation is associated by several authors with the introduction of new technological knowledge in a firm in order to do things better or differently. Technological innovation in this context is not exclusive to production processes or products but rather recognizes the various variations in how efficient organizations are at turning new technological knowledge into output ((Dosi, 1982), (Heij, 2015)).

For a proper interpretation of the literature findings, and to build on a sound theoretical foundation, it was important to determine the different connotations of technological innovation. While the first and second meanings are still present in the literature, the historical or governmental policy dimensions in which they were conceived no longer hold the same weight. Within this dissertation, the research embraces the third meaning of technological innovation (i.e., an innovation in which new technological knowledge is embodied) which is in line with the aim of this research in studying the diffusion of technology-based innovations in clinical trials and also earlier research in the same context (Allen, 2000). Follows are the attributes adopted in this dissertation in connection to technological innovation:

- Presence of a technology or a combination of technologies. The research focus is on the diffusion of that technology in the sector of clinical trials.
- The technologies in question could be at any level of maturity (e.g., information systems, block chain or artificial intelligence technologies). Technology is understood in the context of contemporary technology as an applied science ((Dusek, 2006), (Scharff, 2009)).
- The focus is not on the technologies themselves as inventions but in connection to innovation (Innovation = invention + exploitation (Roberts, 1988)). Technology is discussed through the contributions of innovation studies (e.g., adoption, impact of and on business model innovation…).

Review of literature about technology adoption by sites

Technological innovations adoption by clinical research sites is not in depth covered by the literature. The literature review resulted in two articles treating similar dimensions of this dissertation: manifestations of low adoption of technological innovations and

challenges facing the adoption. The first article is a study of the use technological innovations by research nurses from 2009 to 2013 and aiming to study the reasons behind a better and quicker use of technological innovations. It points out at the time the lack of academic intervention to study the issue: "*Few studies have acknowledged explicitly that nurses influence the adoption, implementation and assimilation of technological innovations*" (Robert, 2009). Many years later, and with the same issue still present in the industry, a second articles studying the investigator sites preferences about technologies involved in clinical trials and the advantages and challenges facing them about it, makes the same observation: "*information is sparse on how site investigators feel about the potential value and challenges of embedding digital health technologies within clinical trials."* (McKenna et al., 2021).

Theoretical background for project

Identifying a gap in the academic evidence regarding the clinical sites and adoption of technologies. The following dissertation will attempt to help fill this gap through a study of the adoption of technological innovations by clinical research sites. Based on the previous theoretical findings reached about the concept of adoption and the concept of technological innovations, two aspects to the study uncover. The adoption part about the technology and the management part of the process as technological innovation as it has been established earlier, is not only about the invention part, but also the process of successfully getting the invention to an audience who will take advantage of it. The management part of the process will be covered through innovation theories from the background of the entrepreneurial engineering program based on the outcome of the adoption part the right tools will present themselves. The adoption part in the other hand could be decided from this point in the conversation. Many options could be employed, during the literature research about adoption and related the concepts, a predominant theory in innovation came across several times, the theory of diffusion of innovations by E. Rogers and the studies that followed the book from 1983. The theory focus on how innovations spread in and across social structures over time and one the most interesting part of the theory to this discussion is the characteristics or attributes that make an innovation desirable, that raises it adoption rate.

Innovation attribute	Description by the theory
Relative Advantage	"Relative advantage is the degree to which an innovation is perceived as being better than the idea it supersedes. The degree of relative advantage is often expressed as economic profitability, as conveying social prestige, or in other ways. The nature of the innovation determines what specific type of relative advantage (economic, social, and the like) is important to adopters"
Compatibility	"Compatibility is the degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential adopters. An idea that is more compatible is less uncertain to the potential adopter and fits more closely with the individual's situation. Such compatibility helps the individual give meaning to the new idea so that it is regarded as more familiar."
Complexity	"Complexity is the degree to which an innovation is perceived as relatively difficult to understand and use. Any new idea may be classified on the complexity-simplicity continuum. Some innovations are clear in their meaning to potential adopters while others are not."
Triability	"Trialability is the degree to which an innovation may be experimented with on a limited basis. New ideas that can be tried on the installment plan are generally adopted more rapidly than innovations that are not divisible. Some innovations are more difficult to divide for trial than are others. The personal trying out of an innovation is one way for an individual to give meaning to an innovation and to find out how it works under one's own conditions."
Observability	"Observability is the degree to which the results of an innovation are visible to others. Some ideas are easily observed and communicated to other people, whereas other innovations are difficult to observe or to describe to others."

Table 4 Attributes of Technologies in the diffusion of Innovations Theory ***(Rogers, 2010)***

These attributes could be used to evaluate the technologies used by the sites to examine how adoptable are they from there perspective.

A second theoretical approach that could conceptualize the interaction between human, structure and technology and assist with first one could be from more targeted towards the area of this subject and stemming from studies about healthcare and technology or as

referred to by Health Information Technology (HIT). A new evaluation framework, human, organization, and technology-fit (HOT-fit) was developed based on previous findings of existing HIT studies such as the IS Success Model and the IT-Organization Fit Model. In line with its building models on the concept of fit that emphasizes that social, technological, and work factors should align with each other and not to consider them individually in building solutions. The better the fit the higher levels of adoption are supposed to be (Yusof, Kuljis, Papazafeiropoulou, & Stergioulas, 2008). The interesting aspect of this framework in particular compared to others is that the authors have compiled a long list of factors to evaluate technology and its perception by the user and how it is applied in the organizational setting they are in. Table 5 groups this list of factors.

Human		Organization		Technology		
System use	User satisfaction	Structure	Environment	System quality	Information quality	Service quality
*Amount (amount of connect time, frequency, number of functions used, number of data accessed, number of data generated) *Use by whom? (direct vs. chauffeured use) * Actual use (actual & reported) *Nature of use (intended purpose, appropriate use) * Level of use (general vs. specific) *Motivation to use * Attitude (expectations, belief, acceptance, resistance, voluntaries of use, Results acceptance) *Expertise *Training	*Satisfaction with specific functions *Overall satisfaction *Perceived usefulness *Software satisfaction *Decision making satisfaction	*Nature (type, size) *Culture *Planning *Strategy Management *Clinical process *Autonomy *Communication *Leadership *Top management *Support *Medical sponsorship, champion, mediator *Teamwork	*Financing source *Government *Politics *Localization, *Competition, *Inter-organizational relationship, *Population served, *External communication	*Data accuracy *Data currency *Database contents *Ease of use, ease of learning *Availability *Usefulness of system features and functions *Flexibility, reliability *Technical support *Security *Efficiency, resource utilization *Response time *Turnaround time	*Importance *Relevance *Usefulness *Legibility *Format *Accuracy *Conciseness *Completeness *Reliability *Timeliness *Data entry methods	*Quick response *Assurance *Empathy *Follow up service *Technical support

Table 5 Evaluation Factors for a New Technology in the Healthcare based on HOT-fit framework (Yusof et al., 2008)]

Problem Statement

For a new drug to be approved, it needs to be studied rigorously through clinical trials on human subjects to ensure the drug's safety and efficacy (World Health Organization,). A fundamental actor in the clinical research enterprise is the investigational site, the responsible unit for applying the steps of a trial (Califf, Robert M., 2009) (Buchanan et al., 2020). Research about this institution lead to the assumption that despite the site's willingness to use technology, technology is not effectively adopted when it comes to the investigational site. The preliminary investigation described in the previous section revealed that this suboptimal adoption of technology manifests in two ways a low incorporation by the site staff into their workflow of the solutions offered or lack of technological solutions to optimize redundant work processes. This is less than an ideal situation. Technology plays a significant role in clinical trials by reducing study duration, cutting costs and accurately obtaining data (Hirsch et al., 2017) and its impact has been well documented and proven and the covid 19 pandemic is a recent example of the potential of technology-driven clinical trials (Asaad, Habibullah, & Butler, 2020), therefore there has been increasing efforts of the clinical research industry's to introduce technological innovation into all clinical trials operations (Rosa et al., 2021) and fully engaging sites to acclimate to this technophile vision is a big component. Consequently, identifying the key factors influencing a greater adopting of technology by sites is a primordial task that unfortunately did not receive much exploration in the academia. While current literature is abundant on the study of all aspects of innovation at the level of clinical trials as a whole and healthcare in general, similar investigations at the site level are lacking. Enabling innovation in organizations at all stages and helping individuals understand, commit to, accept, and embrace changes in a business environment is at the heart of the entrepreneurial engineering program. In fact, two aspects could be identified: the adoption aspect and the aspect of technology. What makes a technology desirable and when talking about the desirability it is relative to the recipient of the technology and that leads us to value proposition and a match between the offer and the needs, or through a marketing perspective of value creation and capture. It is important to study the audience and **the factors that influence their desirability** of the technology

for them. In order to enlarge this study and catch as many factors as possible, a wider theoretical perspective could be used such as adoption of innovation theories and also one specific to the context of clinical research such as Rogers and Fit models. The second aspect in connection to the case is the process, the natural question that comes is how to make it desirable how to utilize those extracted factors into bringing the desired effect. Levering tools from innovation studies core processes aimed at managing innovation at the corporate level (tools to adapt and promote innovation at the corporate environment or business model innovation) and support processes (change management, risk management) could be valuable into bringing **solutions towards the optimization of technology adoption**. Leveraging these aspects to examine technology adoption at the site level and provide suggestions to optimize the situation is the objective of this thesis which addresses to the two following questions:

what factors influence technology adoption in clinical research sites? and how could it be optimized?

Research Design

The first question to consider in the design of the study is whether to employ a qualitative approach or quantitative one. Given the nature of the research aiming to understand what is happening at the level of the research site and the lack of knowledge about the complex situation, a qualitative approach made sense.

The empirical basis for this dissertation is two case studies, each investigating the adoption of a particular technology among the Danish investigational sites. The technologies in question are a staple in the conduction of clinical trials and have been around for a few years but each is adopted at a different level (i.e., the degree of embracing and incorporating into practice to reach the full potential behind a technology).

First Technology: EDC Systems	Second Technology: Investigators Portals
The EDC stands for Electronic Data Capture, replaced the process of entering patient data on paper and sending copies to the sponsors. The process now is done online, allowing for an instance reception of the data.	Investigational portals provide a mean of communication between the site and the sponsor through which documents exchange can happen such as training materials, protocols.
There are a few versions (products) of EDC systems, the market consolidated by now for this relatively mature technology and most of the market's offer is dominated by a few big vendors.	There are many investigational site portals to choose from, they are most of the time designed by the sponsor.

Table 6 Technologies Subject of the Case Studies

Study design logic (gathering, analysis, validation)

The data collection and presentation has been approached from two perspectives:

- From the diffusion of innovation theory, specifically the characteristics of innovations (i.e., relative advantage, compatibility, trialability, complexity, observability). Each characteristic has been used as a dimension to gather data about a technological solution (e.g., how a characteristic is expressed at the site level, its drivers, or challenges…). Later on the data gathered in that way will witness a cross analysis of the cases at each dimension in attempt to extract

whenever possible the common factors that influence complexity, compatibility… and it's known from diffusion of innovations theory that the higher the complexity for example the less desirable the technology is (all other characteristics constant), by gathering factors that influence the characteristics of innovation at the site level, we are gathering factors that could influence technological innovation adoption at that level.

- From the HOT-fit framework, in an attempt to compare the data gathered by the first approach and enlarge the investigation angle. The human, organization, and technology dimensions of the HOT-fit framework are used to direct the investigation and presentation and the evaluation criteria proposed by the framework within each dimension have been used for inspiration for questions and guidance in the collection of data about each dimension for each technology.

Bellow is the process followed in gathering and verifying data:

1- Interview the principal informant, first discussion to just listen and get an understanding of the situation, they can guide the situation,

2- Plug in as much data in the 5 characteristics of innovation, and make note of,

3- Listen again to discussion and look for additional information missed in the first attempt,

4- Prepare questions for second round of discussion with principle informant based on:

Reflecting on the data gathered, prepare questions about specific characteristics,

Using HOT-Fit factors for inspirations to look into the intervention of other factors,

5- Interview the principal informant again, this time guided with questions and more knowledge,

6- Repeat step 2, 3, but this time also populate the HOT-fit framework dimensions (human, organizational, technological) with remaining elements that did not fit in the diffusion of innovations approach (technology characteristics),

7- Reflect on the data gathered and prepare to interview informants 2, 3 and 4,

8- Conduct semi structured interviews with informants 2, 3 and 4,

9- Compare their answers and compare them to gathered data from informant 1 and whatever industry reports available and academic studies about technology 1 and technology 2,

10- If results non-consistent: consider additional informants and/or replacing some informants, else if results consistent in general: discuss possible differences, or new findings with informant 1,

11- Adjust first lot of gathered data under new light and plug in the additional data,

12- Reflect on data gathered, perform a first analysis and if need be, try to get an insight from the point view of an upper management from a CRO or sponsor.

Figure 2 is an alternative explanation to the process.

Below are the three steps designed for analyzing data, figure 3 provides a larger view.

1. Cross case analysis looking for patterns promoting technology adoption
2. Evaluating the patterns if they can be influential factors in adopting technology
3. Check connection between potential factors

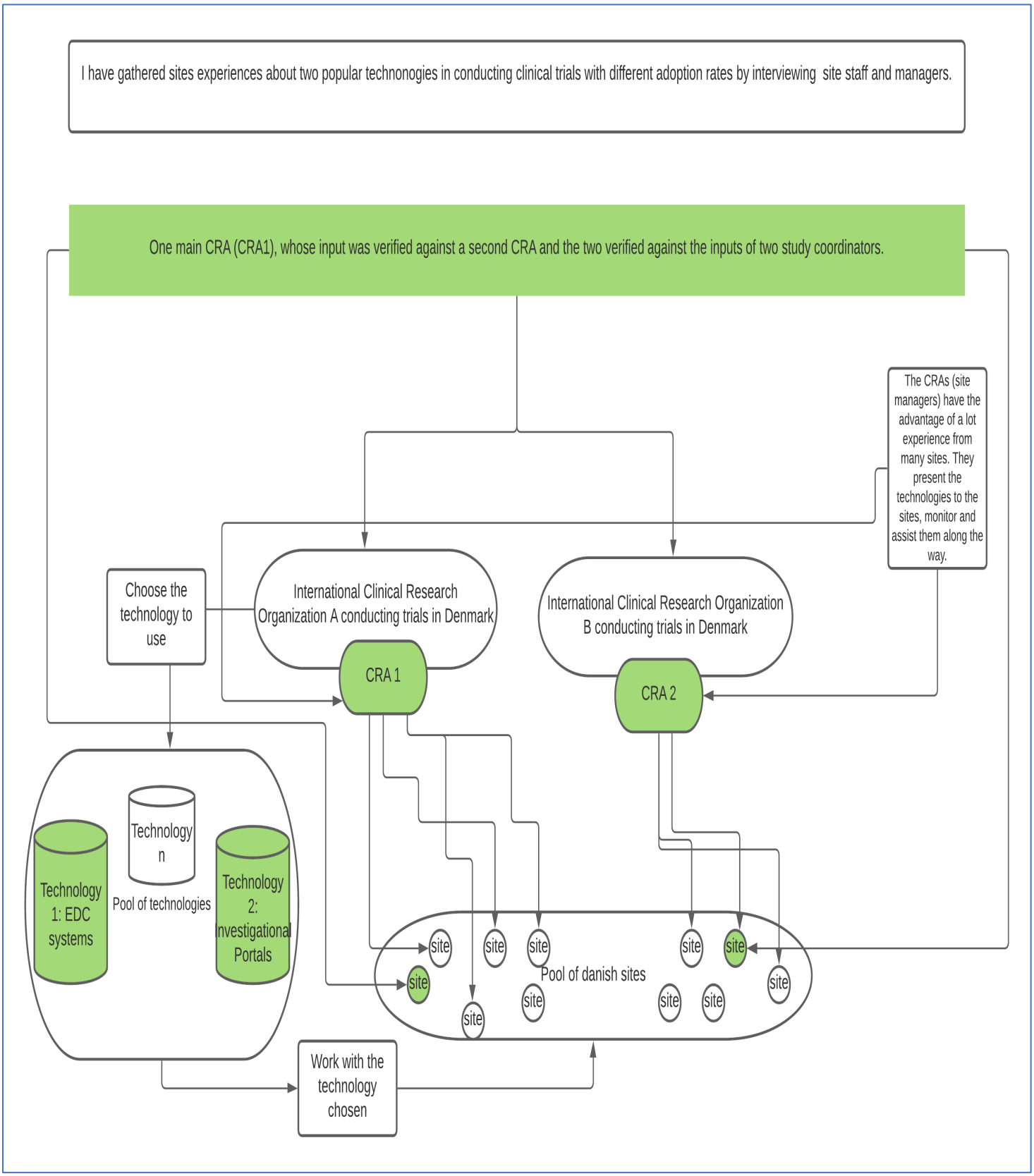

Figure 2 Data gathering and Verification

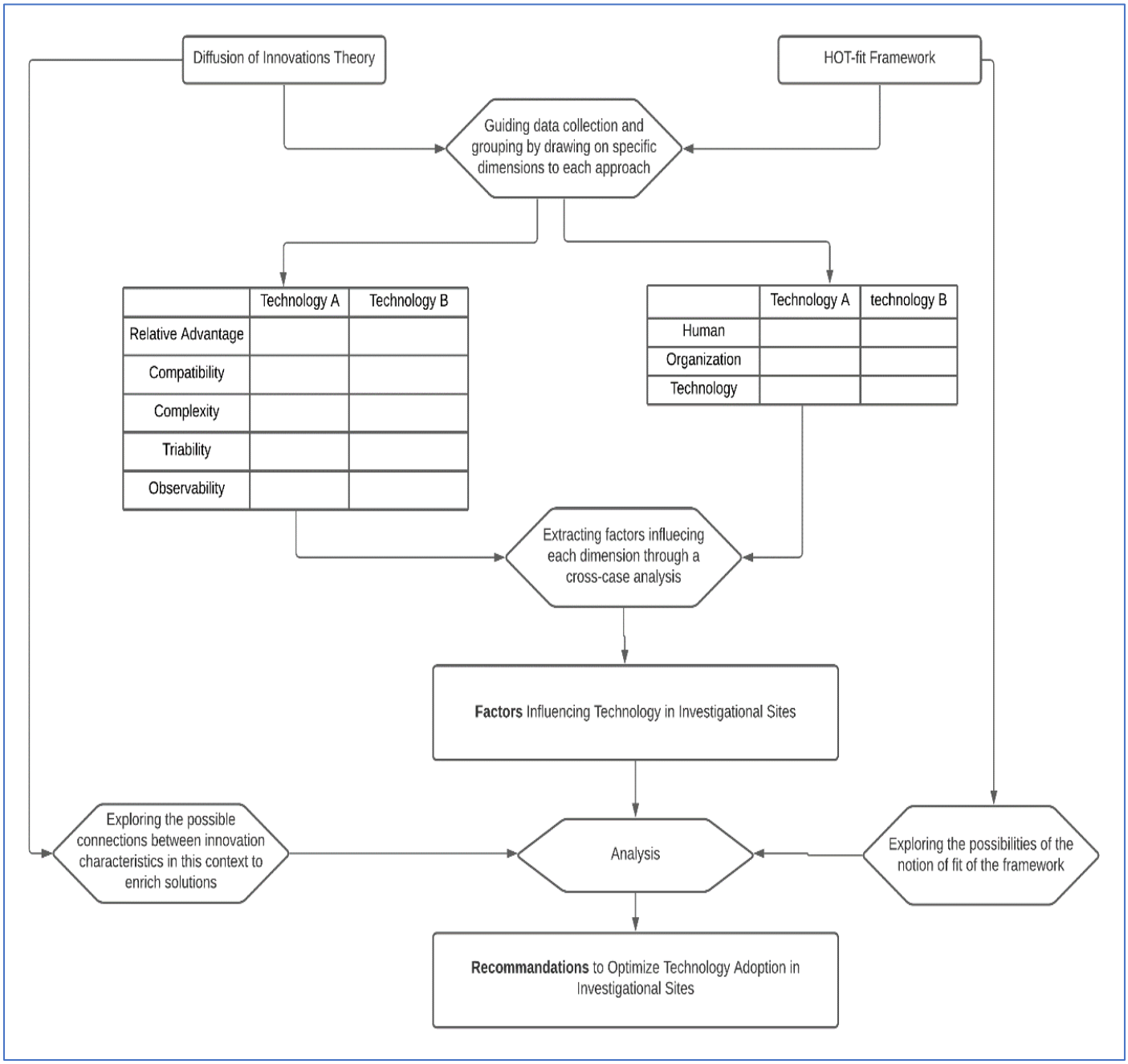

Figure 3 Data Analysis

Research Results

Data

This section offers a presentation of the data gathered as set by the research design. It is important to mention some events that occurred or did not occur while conducting the research and held the potential to diverge from the initial design plan or the best-case scenario.

- The data from the diverse informants has been consistent, there was no odd input that did not match the narration of the others.
- After the reflection on the data gathered through the first analysis, a correspondence with an upper management was considered helpful to get the side of those proposing the technologies to the sites and making the decisions about it. A two emails correspondence has been conducted with a clinical trial manager (CTM) from an international CRO operating in Denmark (i.e., conducting a clinical trial in Danish sites and hiring Danish based CRAs and CTMs to manage the process). The performed correspondence aimed to give more insight to the solutions.
- Additional data unaccounted for in the design, has been added. It is in connection to the solutions; it is a desktop research of two cases helpful in examining the line of solutions.
- There was no data related to the technological and human dimensions of HOT-fit that could not fit in innovation characteristics table, therefore the framework only grouped the remaining dimensions (i.e., organizational). The organizational dimension is common and applicable the same to both cases, so no cross-case analysis is going to be performed on the findings. (Both technologies are examined in the same organizational setting, the same people are working in under the same structure are being asked about the two technologies).

The data about the two cases gathered and presented through the approach of diffusion of innovation is under first set of data and the one with the HOT-fit framework is under

second set of data and the remaining data (i.e., summary from correspondence with a CTM and an overview of 2 relevant cases) employed in the second analysis is presented under third set of data.

First set of data

	First Technology: EDC Systems	Second Technology: Investigators Portals
Relative Advantage	*Seen as offering an easier communication with the sponsors. Replacing the traditional entry of data on paper and having physical copies of it. There is less work both in recording the data and archiving it and also and especially when it comes to answering queries about the data, where all of it is presented electronically. *There is the disadvantage of having to initially enter data the first time on paper as demanded by regulatory authorities and then copying it into the electronic system but still for the site staff the overall advantage of the workflow through an EDC system out weights a purely paper based one.	*Avoided unless obliged to use it *Perceived as redundant, the main function intended to be covered by the system can be achieved through other systems: the principal objective is document exchange but there are different systems specific in handling the process related to a good number of the documents meant to be exchanged through the portal. *Too many versions: almost each sponsor has its own version of the product which create several issues: passwords management, training for different products, several system updates to maintain, several process and styles to try and keep in mind
Compatibility	*High Interoperability, in popular commercial versions especially with the electronic case report forms (eCRF) systems, the difference between the two sources is seamless	*Low Interoperability, products often developed in house by CROs and are basic. *If an information or a document is needed it has to be copied manually from source system and moved to the destination one.
	* In popular commercial versions, there is standard workflow between	* Each sponsor offers its own system and with its own design patterns and

	the products and similar design styles and patterns	workflow, hard to keep up with all the different logics
	* Products that support and complement the work process such as predictive data entry and errors detection on the user's side are appreciated, favored, and demanded by site staff given the chance.	
Complexity	* Some users handle the systems better than others, depends on the user skills and preferences. There was not a single answer or pattern about what is complex or hard about the systems or between them.	* Using a system on itself is different from user to user and there too many systems to get a straight answer about it and from the interviews assessing user friendliness.
	* No complexity in connection to the number of versions. The number of versions at disposal has consolidate over the years. Every now and then a sponsor will insist on using a certain version and it is usually met with resistance	* The complexity seen as how hard it is to use the system is attributed to the multitude of versions and the nonstandard design/workflow between them.
	* Short videos as training or answering common answers were mentioned as a nice way of quickly assimilating the functionality instead of written guides or slides.	* Training material and support is often only in English and that could be less favorable by some study staff, and they will call the CRA for help.
Triability	* There was not enough comments about it, most versions are previously tried by the site staff from a previous trial. * If it is a new version for the site, it is a plus by the CRA to present the system in person and assist the staff	* Usually, the CRA assist the first time with the login and executing some of the functions, it seems to optimize according to the CRAs the learning of the system.

	login the first time and locate the training material progress.	
	* In a kick start of a new study where site staff from all over the locations where the studies are to be conducted, meet with the sponsor and the CRO staff and have a few days of introduction to the study. Stands by vendors of EDC system are in place to promote for new features or products and the site stuff get a chance to try them and see them in action and understand the potential of them and that is met a positive attitude and nice feedback from the site members.	* Positive feedback about if the system is introduced in a sponsor-investigational meeting when kick starting a study.
Observability	* Easy to conclude even when factoring training time that it will save time. * Also, given that not all the sponsors offered the use of an EDC system at the start, it was easy to observe its advantages by comparing the workload associated to the sponsors with or without an EDC. * When asked if there was any metrics or feedback set in connection to the use of the EDC systems, there was not any to the knowledge of the participants in the interviews.	* It was hard to see how the system could be helpful, and it is still the case. *There is no feedback from sponsors on how beneficial it is or the presence of some metrics to track the use.

Table 7 Summary of First Set of Data Gathered

Second set of data

	First Technology: EDC Systems	Second Technology: Investigators Portals
Human	Covered in the first set of data	Covered in the first set of data
Organization	Research centers are under the Danish institutions Regions but to a certain extent are managed for the duration of a trial by the trial owner or its representative (sponsor or CRO) which translates in the assignment of a CRA to lead, monitor and assist the site team in conducting the trial. This organization applies in particular to technology decisions. Unless it is a regional or national initiative to introduce a new information system by the Region and which usually does not target specific problems to the clinical research site in particular but addresses health practitioners in general and provides the basic IT infrastructure needed (computers, network infrastructure and access…) the information systems or technologies meant for conducting a study are proposed by the owner of the study (i.e., sponsor) or an organization acting on their behalf (i.e., CRO).	
	Technological choices are made based on the sponsors/CRO assessment of the best conditions to conduct their study. The decisions do not take in consideration the opinion of the investigational site. Two to three steps relatively involve the site side in the process: • A site evaluation step, conducted as a physical visit to the site location by a representative of the sponsor/CRO to assess the IT infrastructure of the site and see if they meet the IT criteria need to optimally conduct the trial. • Sometimes a sponsor-investigational study kick start seminar where there are opportunities to be introduced to new systems. • A second classic step is called an initiation visit, conducted by the CRA most of the time in person unless extra circumstances are involved (like the COVID-19 pandemic). Among the tasks in the agenda of the initiation visit is to talk about the systems used and make sure the site has accessed	

	to the training and can access the systems and they are running properly. After those two steps the sites are supposed to adjust to the systems proposed by the sponsor.	
Technology	Covered in the first set of data	Covered in the first set of data

Table 8 Summary of Second Set of Data Gathered

Third set of data

	Main points of Correspondence
CTM Correspondence	*Partnerships are at the center of their digital strategy; they need talents with different skills set like ones coming from the vendors side (software developers). *There are some good initiatives that are leading the wave for working together, TransCelerate is a good one and also the American movement of clinical trials transformation. There is also a very helpful portal easing collaboration with sites in Denmark, trialnation.dk. *Full collaborations with sites as a global unit are a long shot, we are embracing a site centric view, there many obstacles in the way, geography, complexity of structures, number, and commitment of sites, it will drive up costs, a radical change have to happen starting by the sites themselves, we need to cultivate more assertive sites.

Table 9 Summary of Correspondence with CTM

	Overview	Source
TransCelerate	*An association of clinical trial sponsors. * Ccollaboration of 20+ biopharmaceutical organizations such as AstraZeneca, Bayer, Johnson & Johnson, Novo Nordisk, Roche, Pfizer * "There are over 1,000 people from TransCelerate Member Companies, spanning more than 30 countries"	https://www.transceleratebiopharmainc.com/ (Vicky Aguiar, 2017) (Minisman et al., 2012)
Society of Clinical Research Sites (SCRS)	*A global clinical research association *SCRS currently represents over 9,500 research sites in 47 countries.	https://myscrs.org/ (Veeva, 2019)

Table 10 Cases of Collaboration in the Clinical Research Enterprise

	Overview	Impact, how does it impact tech adopt in sites
TransCelerate	"An industry association comprised of clinical trial sponsors formed to resolve common problems and thereby drive innovation in clinical trials at an industry level."	* Collaborate with academic research to study issues in the industry. * Rise awareness about issues and provide sponsors with an overview. * Proposes solutions. Either in the forms of standardized procedures and frameworks of action or as software solutions by collaborating with technology providers. * Interaction with clinical research sites: • "A strategic priority for TransCelerate is to deliver solutions that will reduce the administrative burden of clinical trials and increase the time of actual patient care. To achieve this,

		understanding the pain points from those directly impacted…and their perspectives on how to solve them." • Notable attributions in connection to adoption of technology by sites: Shared Investigator Platform. * *"In just four years, TransCelerate has demonstrated what we're capable of, if we work together,"* TransCelerate CEO Dalvir Gill (2017)
Society of Clinical Research Sites (SCRS)	"A representative organization of the needs of clinical research sites globally."	* Advocate for, educate, mentor, and connect clinical research sites. * Conduct large scale Industry reports and summit international events between industry stakeholders. * Lead site advocacy groups: *"The Site Advocacy Group (SAG) is a landmark industry initiative begun by SCRS that facilitates meaningful dialogue between site professionals and industry leaders on a variety of topics"* * Attributions in connection to adoption of technology by sites: • In depth reports to expose sites' points of view and raise awareness about challenges faced. Among them technology adoption burdens. • The SCRS Digital Innovation Initiative: *"an avenue for industry partners to work closely with sites to bring the clinical research*

		industry to the forefront of digital innovation and ensure site needs are heard and addressed": Representing the needs of sites and at the same time preparing sites to integrate technological innovations into their practice. Initiative started in 2020 and it is still going through meetings between stakeholders to collaborate on solutions.

Table 11 Summary of Desktop Research about Cases of Collaboration

First Analysis

Analysis of the first set of data

Cross-case analysis

Relative Advantage

The relative advantage for the EDC systems is reducing the burden of the paper based manual work to a more efficient automated process, a need that was already highlighted in the preliminary investigation, mentioning the site longing and enthusiasm for technologies that could help optimize some of the current manual processes they are doing. Given the amount of manual processes that the sites deal with in conducting the trials, as already explored in the preliminary data, **replacing a manual task** or related tasks could be a welcome change among the site staff and therefore a driver for adopting an innovation as it will be seen more advantageous. In the case of the second technology, the site could not reach an advantage about the innovation, it simply replaced a task from a software with another software and the burden of the multitude of systems did not get optimized but got worse as their amount grew even more. The system might be advantageous for the sponsor in centralizing their documents exchange platform, but it was done at the expense of the sites. For the sites from this case, an additional software is additional work unless it is helping with the redundancies and replacing numerous

systems at once and not a single software (or more precisely in this case just the one task: exchange of documents) because that will **reduce the technological overload** on their shoulders, which is the second issue they deal with besides the manual processes. The intended use of it as a single point for exchanging all documents even though it is helpful, it is not worth the trouble from switching from system to system for each sponsor, keeping up with passwords, training, and updates, it adds to the problem.

To conclude, a pattern emerged in relation to holding a high relative advantage in the context of investigational sites. As lead by the analysis, it is one that will hold a good value proposition and address the current needs experienced by sites in connection to technology and that is **replacing manual tasks or reducing the technological overload**.

Compatibility

The first aspect of compatibility expressed at the site level is the **interoperability**[2] of the systems. It was cited for both technologies and there was a clear appreciation for a timely and seamless compatibility of a system with the other systems it needs data from or can provide data for. The EDC systems, and more precisely the popular versions possess enough sophistication to assist with the many layers of interconnectivity. While there are inherent issues from the health sector in connection to interoperability based on several legal and technical considerations (Rosa et al., 2021) (Nordo et al., 2019), including fundamental, structural, and semantic levels and taking advantage of the capabilities present in the overall infrastructure is a clear advantage. In house versions by sponsors or CROs of EDC systems lacking this ability are much less appreciated and avoided when given the chance.

The second aspect of compatibility documented at the site level is in connection to the **consistency of design and workflow logic** between the versions of a technology and between technological systems in general. Designers strive to optimize the graphical interfaces of their systems for users and enhance the logic of transactions with software and an ecosystem is established around software usage, there are universal rules and

[2] "Interoperability is the ability of a product or system to interface successfully with other products or systems in order to exchange and make use of information".

standards that are common to all designs (e.g., a green button or bright colour compared to a low opacity one is usually intended to encourage or guide proceeding forward or agreeing). While the user friendliness and intuitiveness of the system has been filed under the complexity characteristic and will be discussed in the next section. The facet discussed here is about design compatibilities between the systems and supporting the work of the site team. Less popular versions of the first technology or most versions of the second technology fail to share common design manifestations or matching workflows and that a major drawback in the second technology in the eyes of sites. Several examples have been mentioned or shared

"In one EDC queries are populated by the default in the front page but in another from another study they have to be filtered to see them, so we always when using the second system we forget to filter first and we think that there is no work to do because we see no queries. In another example, switching between the investigational portals is maddening, in one system you have to select the study name and the pages shows the missing data fields for the study and fill out the required information and press update and it's done, in another you have to enter the study name and press update to refresh the page for any missing information, fill the form and then confirm changes, confused between the two styles, I always click update in the wrong time and end up having to re-enter the data, I don't have a preference for one style or the other, I just want it to be the same."

The third aspect of compatibility had been only identified in connection to the first technology, systems that offer **smart assistance** with the workflow and succeed to do so are valued among the EDC systems, one particular commercial version is successful in making the data entry easier on the sites and more efficient by checking smartly for common errors uncaught by site staff before sending the data to the datacentres and get it sent back, flag it by a query and then having solve the query and correct it. Given that this aspect has only been mentioned in the first technology, there was no mention of it in the second technology even when asked directly about it and therefore it could not be established if it is a strong enough driver for influencing adopting a technology and more precisely influencing the non-adoption of a technology and therefore it will not be included in the list of extracted factors.

To conclude on compatibility of an innovation for investigational sites, two influencing aspects have been retained. The first one is the interoperability of the system, the more interpretable the more it makes its use efficient and the more it is wanted to be used. The second aspect is the design and workflow logic. Site staff would prefer and will use a system whose design is matching the design of the majority of the systems and share common design standards.

Complexity

The data that went under the complexity dimension is in connection to the perceived complexity by the individuals from a perspective of human-technology interaction. The technologies under investigation could be classified as very complex from a pure technological point view and what level of abstraction is used or also complex in a different way for other entities. While this is true for all the characteristics as it has been mentioned in the previous section[3], it is particularly important for this characteristic in the light of the research findings connected to this characteristic. Three aspects have identified in relation to the complexity of the two case studies from the perspective of the investigational site: user IT expertise, training material and support quality and finally the amount of the systems to use but only the last one could be described as currently having a good potential to impact complexity of a technology for sites.

The **user's IT skills** or expertise was the common link between a few perspectives of the site staff about the user friendliness of the first and second technology. There are mixed views about the complexity of these technologies in regard to ease of use, different aspects are mentioned (e.g., bulkiness because of too many functions, not very intuitive, too little customization possibilities) and different or opposite opinions are present, therefore the pattern that could emerge from these findings is the user's IT skills. It is so common and could influence all information systems for all populations, it is almost at the level of the analysis dimensions in here, for example what could be said about the

[3] It is the relativity subjectivity of the characteristics and their combination that influence the adoption rate and intensity of innovation from one social structure to the other.

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relative advantage (i.e., the higher the advantage the better the potential of adoption) could be said about the IT skills: the better the IT skills, the easier is to use technology and the better chances of accepting it. It is too generic and the aim in here is to extract factors that are particular to the investigational site, that hold a good chance of deterring from or accepting a technology. To describe it as a driver for technology adoption at the sites level requires more investigation for example to see if there is a very high rate of poor IT skills among the site staff, requiring special considerations in the design of information systems.

The **training quality and support** was identified as the second aspect of complexity at the site level, as the outcome of a good training could potentially reduce the complexity or the perception of it. However, at the site level there were mixed results about training between the two cases. In the first technology, it has been mentioned that watching a video of how a task in executed in the system is easier that reading a training manual so that indicates that maybe training has a positive outcome on reducing the complexity of a system but in the results from the second case did not confirm this conclusion as training of all kinds did not influence one way or another the adoption of technology. Maybe it is a particular case for that technology, it needs further investigation. It will not be added as an influencing factor at this stage.

The last aspect is the number of versions of a technology, many vendors contribute to this market by bringing a new product serving the same purpose and each sponsor present the site with the version they see fit for the technology, also from technology to technology, the harmony between the tasks is lacking which leaves site staff with redundancies between systems, **technology overload** will be the term used to refer to these observations. As observed by the two technologies, the multitude of systems and the implications related to it as it has been mentioned earlier (passwords, training, updates, workflow…) make technology overload the main driver of complexity at the site level. The systems themselves if they were single by themselves have not been linked to any particular high degree of complexity but as a big group (a group resulting from duplicates of the same technology and the nature of work needing many technological functionalities) with overlapping tasks from the members sometimes and interconnected

some other times, keeping up with systems is hard. Both technology one and two have an element of technology overload, just at different degrees the EDC systems have fewer coexisting products because the product choices consolidated over time, but the second technology is experiencing a much harder effect of the technology overload to the point where the site staff forget what the systems are for. The technology overload drives complexity because it becomes harder to clearly see what system is applicable between the sea of systems.

The situation described by one of the CRAs:

"Just for Electronic Data Capture, a site usually is using at least three different products each from a sponsor, for example: Rave Medidata, Datalab, Omnicom…and a site staff member works with 7-9 sponsors at the same time… because of the many systems included in a clinical trial and made worse with the number of concurrent sponsors, the staff of the site forgets how to use them or even what they are for, it's out of control they don't have a clear overview of the technologies at their disposal."

To conclude, technology overload (referring in the dissertation to the situation resulting from duplicates of the same technology and the nature of work needing many technological functionalities) is an important factor driving the complexity of using a technology at the site level by obscuring the technological choices available for a site and reducing the chances of keeping up to easily navigate them.

Triability

At its essence, the triability characteristic is about how easy it is to try a new innovation to the potential adopter. In the of investigational sites, data that went under the category of triability did not stem from the classical scenario of the possibility of trying an innovation and then deciding to committee or not, it translated differently. Site staff are presented with the technologies they have to use, there is no process of trying them before hand, that would be job done by the sponsor or the CRO, which moves the dynamics of triability and decision making about the adoption. From the research data, the closer they get to the concept of trying a new technology is from its presentation by the CRA when assigned a new study (and hence a set of recommended technologies to

use with it) and therefore the common factor stemming from the study cases and that seems to influence triability at the site level is the amount of **effort and time put into the introduction of the system** by the CRA. Also, it seems that getting introduced to the technologies in seminars held by the sponsors to introduce the study in general and focus on the activities related to its conduction such technology has a positive impact on the site stuff, they could remember clear instances of the systems they were presented with and how the vendors offered them the possibility to try them. *"It was nice to try Teckro[4] and have it uploaded on my phone with a protocol by the developer and see how it worked in practice"*

To conclude, the promotion of the ease of triability at the site level, based on the input of the staff, is driven by the settings of introducing the technology, the more effort put into the introduction by giving the staff a chance to see the technology at work and assisting them in person with the first login and tour the better the impact they hold about the system.

Observability

Observability is linked to the ease of observing the advantages of a technology, both the study cases did not offer any visible patterns in connection to drivers or challenges to observability. The only common point observed is that it was easy to observe, in the first case it was because of the use after a certain period of time and simultaneously comparing it to the studies where it is not used. For the second case, it was easy to observe the non-advantage because it did not work for them in short while and there is no **communication** part from the sponsors or CROs to share any feedback about the advantages of its usage after a while, after that could have maybe motivated the sites to put more effort into the adoption of the second technology but that is in the realm of speculation as the first case even though it has the same observation about the lack of feedback and usage metrics from upper management, it does not seem to hold an effect on the adoption.

[4] An application offering easy access to protocols and helping navigate and search them. (https://teckro.com/)

To conclude, there a slight indication that communication through feedback or usage metric might have an impact on the observability of an innovation at the site level but it is pending a definitive confirmation.

Conclusion

Table 12 is a summary of the cross-case analysis results from the first set of data: The patterns observed from the cross-case analysis and a conclusion in considering them as influencing factors at the site level for adopting technological innovation or not.

Dimensions	Potential element of pattern in the first technology (EDC Systems)	Potential element of pattern in the second technology (Investigators Portals)	Pattern Between the Cases	Could the pattern qualify to be a driver or barrier to adoption?
Relative Advantage	Less work all in all by avoiding the manual process and also, technology consolidation: a few dominant products in the market.	Redundant with other systems and too many versions.	Technology overload (Avoiding technology overload by reducing number of systems in use is considered advantage in both cases)	Could be established a factor, because systems with the potential to avoid technology overload presented an advantage in both cases.
Compatibility	Good interoperability.	Limited interoperability.	Interoperability	Could be established as a factor because from cases there is evidence for a particularly high the amount of data needed to be moved around between systems and databases in conducting clinical trials.
	Consistent design and logic between systems.	Different design styles from system to system.	Consistency of design	Could be established as a factor because from cases there is

	Smart features to assist with working better.			evidence for issues of with design inconsistences.
Complexity	Too customizable, not user friendly sometimes...	Too many functions, bulky…	IT expertise	was not considered a factor influencing technology adoption at the site level, it is too generic and requires more investigation to see if it is an issue for site staff. (Statistics about their IT skills)
	Videos and online presence technical support.	Training does not seem to help, often forgotten.	Training quality and support	have a mixed impact in the cases and was not considered as a factor.
	Complexity driven by the too many systems in general.		Technology overload	Has been considered a a factor influencing the adoption of technology at the investigational site level as it drives complexity, it has been deduced before in another characteristic (relative advantage) just presenting another aspect here, the number of systems in general needed to conduct a trial.
Triability	Site stuff introduction and setup help and initial time.	Introduction in kick starting studies is good	Introducing technologies	could be a factor influencing the adoption of technology at the investigational site level, in both cases
	Stands of EDC vendors in meetings	Presentation in meetings and		

	left a positive impact.	chance to try has a positive impact.		positive adoptive results issued from putting an effort into introducing systems.
Observability	Easy to conclude even when factoring training time that it will save time, there was a lot of talk about the advantage of EDCs at the start of the technology.	Hard to see the advantage, no feedback, or metrics from /by sponsor.	Communication: advantages, and feedback	Have the potential to be a factor influencing the adoption of technology at the investigational site level, but the results are undecisive.
	Absence of feedback but no influence.	Absence of feedback could have an influence.		

Table 12 Summary of Cross-Case Analysis of First Set of Data

Analysis of the second set of data

The second set of data conducted through the HOT-fit framework was gathered by examining points mentioned under the organizational dimension in the framework, elements such as organizational structure, hierarchy, communication, culture were the elements that the interviewees had an input about. The overall input has been grouped in two categories. The first category includes data about the organizational structure that investigational sites run under. The second category is in connection to communication and decision-making style.

Organizational structure

Investigational sites are operating under a unique **structure**, it has many similarities to a matrix organizational structure (A functional manager from the side of the Region hierarchy and a project manager or project managers from the side of the sponsor/CRO and portrayed by the CRAs) but the major difference in this case is that the functional and product manager entities do not belong to a common organization, each stem from a different organization. The two organizations (Region and sponsors/CROs) are completely independent organizations that are not linked in any way.

Operating under many organizations means the absence of a unique vision and a long-term strategy. Therefore, long term investments in technology to conduct trials with a site centric vision will be hard to achieve; systems to promote better workflows for investigational sites are hard to achieve between the Regions general purposes policies for improving digital health on a large scale and the short cycles of contact between the sponsors and sites where the purpose is to conduct a trial quickly and at minimum costs. In the absence of long-term plans, the sponsors/CROs have to consider original implementation strategies for technology to meet the original situation where it will be implemented. Based on the data gathered, it is hard to describe the current practices as implementation plans. They consist of making assumptions about the sites, introducing the choices either in seminars or often by the CRA responsible for the trial and expecting the site to adjust to the technologies and fulfil the intended expectations from it. Successful implementation plans include many considerations in order to materialize the anticipated benefits from the technology, user feedback, tracking system performance,

proper communication plans, are just a few examples of considerations missing from than the current practice (Cresswell, Bates, & Sheikh, 2013).

To conclude, the nature of the organizational structure of the investigational sites, in one hand under the Region and in the other hand under the management of many sponsors/CROs is a major obstacle in setting proper implementation plans and structures for a successful adoption of technology.

Communication and decision-making style

Based on the data in connection to this category, the communication and decision-making around the technologies are marked by a one-way communication channel in a top-down approach. The value of an information system is based on an interpretation of the sponsor/CRO of what could be valuable for the site. The decisions are made at the higher level and the lower level in this case the sites are informed by them and expected to use them. The decisions made at the upper level are not based on an assessment of the sites' situation but rather assumptions of the sponsors/CROs of what may work or not, because as expressed earlier in the data section, "The decisions do not take in consideration the opinion of the investigational site". In all the steps including the sites' introduction to technologies, none of them include the feedback of the site or including the site earlier in the process.

The **non-inclusion of the site** in the decision process is a fundamental design issue. The absence of a space to ensure a fit between the actual situation and people in the situation and the final product is problematic to the adoption of the technologies. The jobs that need to be fulfilled by technology at the site level might be missed, the pains and gains from a technology are ignored and the result is a mismatch between need and offer.

To conclude, not including sites in the process of technological decisions and adopting a one-way communication style from top-down has the high potential of introducing unvaluable technologies to conduct a trial from the perspective of the site staff.

Second Analysis

The second analysis is a reflection about the factors extracted from the first round of analysis and an examination of potential connections between them and how could that reflect on the outcome. After an establishment of the factors, an exploration for potential solutions is conducted building on these factors and additional data (third set of data).

Analysis for Factors

Below is a review compiling the factors reached from the analysis of the first two sets of data.

Factors influencing technology adoption at the site level, reached **from the second set of data**	
Organizational structure	The Danish institution Region and many sponsors at the same time
Non-inclusion of the site	One way, top-down decision making about technology
Factors influencing technology adoption at the site level, reached **from the first set of data**	
Technology overload	The use of many systems by the nature of work and many available products or versions from the same system
Interoperability	Interface communication between systems
Design consistency	No standard design and workflow logic between systems and products
Introducing technologies	Effort and time put in introducing technologies
Communicating advantages and feedback	Not completely established as a factor but not enough evidence to discard it.

Table 13 Factors Influencing Innovation Adoption in Sites as Extracted from First Analysis

Connections between the factors come in display when looking at the list, some of the factors seem to be an effect of other factors. Below a map of all the possible connections between the factors has been established. Based on this map, a rethinking of the factors to keep will take place.

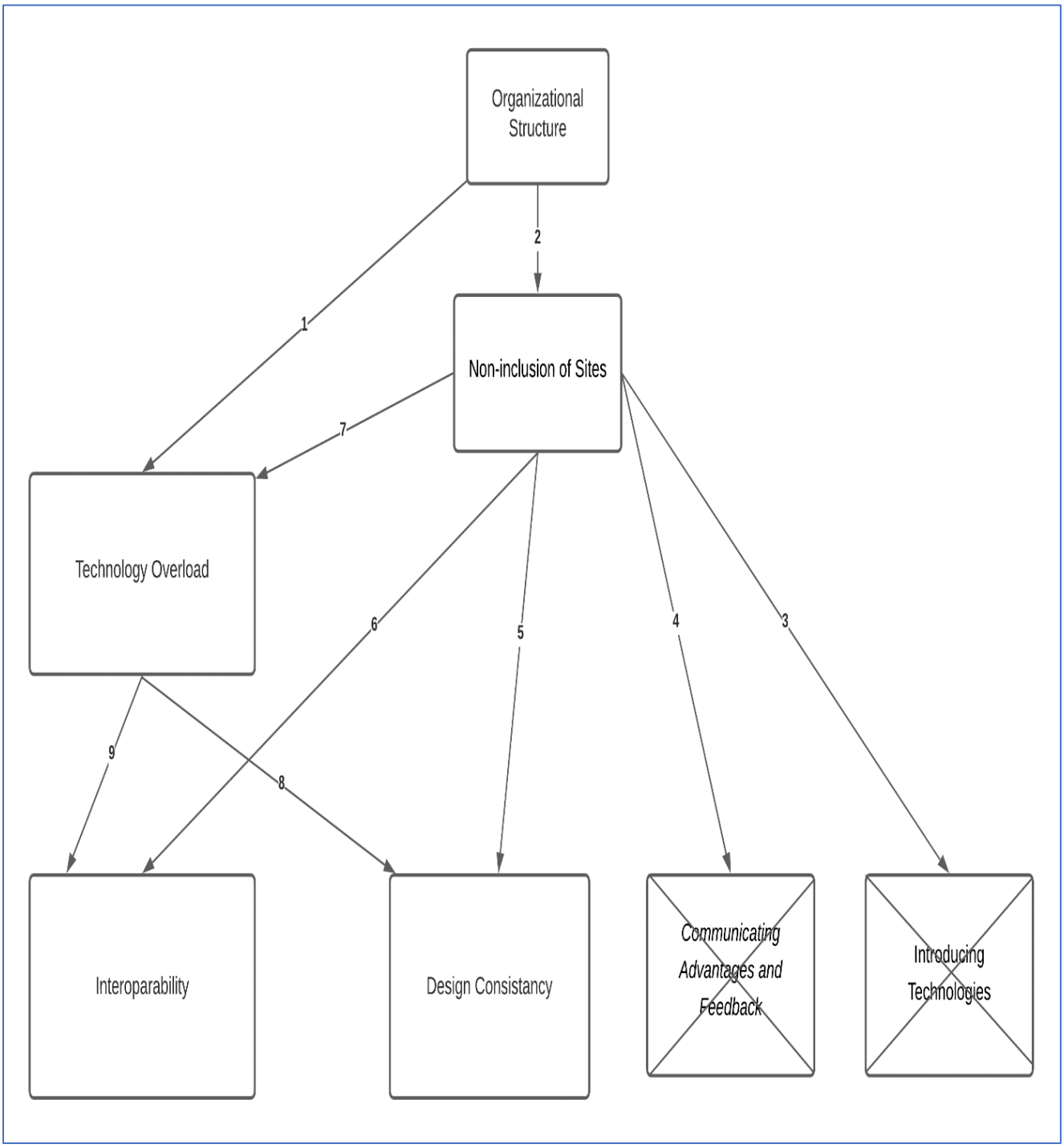

Figure 4 Connections Between the Factors Influencing Technology Adoption at the Site Level

This paragraph will be referring to the connection numbers (1-9) drawn in figure 4. The connections can be divided in two groups:

- First, connections between factor a and factor b, where factor b is a total effect of factor a. Factor b is included in factor a and by having factor a, factor b will be covered. Connections 3 and 4 falls in this scenario. The non-inclusion of sites factor (One way, top-down decision making about technology) among its effects will be a bad introduction of technologies and no communication or feedback considerations about these technologies supposed to be used by the site. In the case of an inclusion of the site in the process of implementing technologies, the lack of communication and proper presentations will not happen. Therefor the factors "Introducing technologies" and "communicating advantages and feedback" will not be removed from the list of the factors extracted as they are totally the effects of the "non-inclusion of the sites".
- Second, partial connections between factors. Factor b is in some cases an effect of factor a, but factor b is also sometimes not connected to factor a. For example, the non-inclusion of sites could have for affect the technology overload (not asking the sites and not taking in consideration the whole systems at the site disposition and what versions are already in use and hence adding another system to the pile with one single useful function) but technology overload could also be simply from the by default need for many systems to conduct a clinical trial and communicate successfully with all the stakeholders .Even with the presence of the non-inclusion of sites factor technology overload has to stay in the list to cover the scenario of the nature of conducting clinical trials that needs a lot technology involvement. Similar logic apply for remaining connections 1, 2, 5, 6, 8 and 9. And therefore the final versions of the factors influencing technological adoption by clinical research sites, all connections considered and acted upon (only no connection or partial connections were added) is presented in table.14.

Organizational structure	The Danish institution Region and many sponsors at the same time
Non-inclusion of the site	One way, top-down decision making about technology
Technology overload	The use of many systems by the nature of work and many available products or versions from the same system
Interoperability	Interface communication between systems
Design consistency	No standard design and workflow logic between systems and products

Table 14 Final Versions of the Factors Influencing Technological Adoption by Clinical Research Sites

Analysis for Solutions

Nourishing collaboration

Five factors influencing the adoption of technological innovations at the site level have been identified from the previous analysis. The question is how to optimize the situation based on these factors, according to the HOT-fit framework and the fit concept in general presented in the literature review section, the process of identifying solutions to challenges in adopting technology is not only about the solutions in themselves but it is in their fit together to form a whole solution where there is room for all the partial solutions to develop and integrate more factors. In this context, the findings reached points towards a key opportunity for collaboration between several stakeholders of the clinical research enterprise. Because whatever partial solution for a factor is reached, who in ecosystem will drive the change, given the constraints that each stakeholder might have it might be unfeasible for one player to succeed independently. Not only the execution of solutions depend on the collaboration but also finding them in the first place as a collaborative model can include the preservative of many stakeholder sponsors/CROs, sites, patients, regulators…Under this line of thought, collaboration can address many aspects of the factors identified. The organizational structure and non-inclusion of sites can be covered completely under the umbrella of collaboration and given the connections with the remaining factors; they will help partially addressed as well.

From the third set of data, the communication conducted with a clinical trial manager (CTM) in connection to the impact of collaboration on the adoption of technological innovations at the clinical research sites, points towards a fruitful impact. Putting collaboration at the center of their digital strategy, one plan is combat the shortage of technological talents and expertise in the domain in general and work closely with technology vendors to develop more professional technologies to meet their digital needs. It is a positive step towards better technological input by the sponsors instead of their in-house solutions that often not reach market standards and fail to blend with the workflow as seen from the data sets 1 and 2 and reflected from the factors of consistency of design and interoperability.

Another successful impact not only on the site but also for the sponsors, patients, and the clinical trials enterprise as whole could be deduced from Pfizer (Sponsor) collaborative approach to conduct the first virtual trial in the history of the industry in 2011, allowing subjects to participate over the internet (Pfizer Inc. Media, 2011). The sponsor, the regulatory authorities, and a principal investigator (representing a site) worked very closely to design and test this new approach. For the site part such studies mean leveraging technologies through other channel to provide alternatives to conducting trials and consequently lower their work burden and technology overload freeing more space to focus on core cases of trials and basic technologies.

Despite this attempts, the collaboration task is not obvious, and the actors will have to consider different paths and mindsets to work together. In the remaining of this section, collaboration between the main actors in the research are going to be considered and explored on how they can benefit technology adoption for clinical research sites.

Between sponsors

Given the structural problems involved in adopting technology at the site level (i.e., lack of unique functional management entity and having instead sponsors not connected in any way), presenting the site with a collective voice and ears in shaping innovation is an advantage. Collaboration between the sponsors could be influential for a better understanding of complex situations, sharing knowledge and experiences to overcome industry wide challenges such as the adoption of technology by investigational sites from a narrow perspective or rethinking the whole the technological policy of enterprise from a higher level. Addressing adoption from this level can shift the paradigm from studying individual technologies and solutions to considering technologies collectively and building the infrastructure necessary to engage in digital strategies.

Collaboration is not only in theory a sensible idea, in the last few years, the clinical trials enterprise is observing a positive increase in industry consortia. A positive case for that is TransCelerate as recommended to look into by the informant in the third data set (the clinical trial manager). A consortia composed of pioneer pharmaceutical and biotechnology companies (J&J, Pfizer, Amgen, Roche…). TransCelerate presents an

original take on collaboration between sponsors by centralizing the issues the industry is facing, finding the optimal solutions through cross industry collaborations, and bringing the solutions back to the sponsors to access centrally. The solutions range from different domain related to clinical trials and include assistance to many actors in the process. In connection to the clinical research site, many contributions have seen the day offering targeted solutions based on pains lived by the sites. The most relevant proposition by TransCelerate is their collaboration with a third party to develop a shared investigator platform instead of each sponsor offering their own portal (The technology of the second case study), it a game changer for sites which can relieve them from a big aspect of the technological burden they face. It is a new platform but in just four years, 100 000 sites have joined the platforms from 97 countries[5]. The initiative would not have been possible without the collaboration efforts between the sponsors in the form of TransCelerate.

However as exciting as TransCelerate as an interface between the sponsors and the sites, centralizing the many aspects of the process and solutions in one place through their website and partners. It is missing the actioning power to implement the interesting solutions they create which begs the questions in the study of optimal collaboration solutions between sponsors is it the lack of the solutions or is the implementation process by the sponsor itself that need to be revised.

Between sites

The second possible aspect of collaboration in this context is for sites to work together through association of sites or networks. It can target the non-inclusion of sites aspect by having a unified mouth and a pair of hands to act as a single entity interacting with the sponsors. Many benefits could potential be achieved from such arrangement. First, there could be a better decentralization of data about sites to offer the sponsor better and easier criteria to select the right sites to work that could be a better match for the technological package they are offering along with the study protocol. Another benefit could be the creation of an infrastructure to handle technological innovations better and share or optimize adaptive mechanisms. Through networks there could be also the

[5] https://www.sharedinvestigator.com/sipwsstatic//documents/newsletter/newsletter-latest.pdf

advantage of accessing quality training for the technologies to be used through the network and scaling down the costs of quality training compared to training a single site at the time.

The second and last case in the third set of data is the case about the society of clinical research sites, a representative organization of the needs of clinical research sites globally. The society of clinical research sites is an example of the potential of sites collaboration in practice. In connection to technological innovation input they conducted industry depth studies examining the needs, the pains, and potentials of investigational sites by running studies through their fast network of member sites. The results of their reports in connection to technology at the sites is in line with the findings of this report, the technology overload, the multi sponsors environment…A series of workshops has been conducted between representative of sites and sponsors to work towards a unified vision and targeted solutions. The workshops are a first step towards bringing the voice of sites closer to the source and offering the knowledge necessary to orient the technological attempt of sponsors.

Between sponsors and sites

The third aspect of collaboration could be between the sites and sponsors. Depending on what form it will take, it could target both the organizational structure issues from the investigational site perspective and also those related to the non-inclusion of sites. It has the potential to improve the managerial decision-making process in implementing new technologies at the site by exchanging knowledge between both actors: Knowledge from the site's perspective and knowledge to the sites about the technologies. Examine a closer level how receptive the site to the potential of a new technology and work on it concepts from the start.

The input from the empirical data in the third set is not sufficient to explore the possibilities or benefits in practice of the sites sponsors collaboration. From the point of view of the clinical trial manager in question in the third set of data, it might be too early to turn into reality a fully operational collaboration. At the moment the leading

perspective from sponsors is a site and patient centric approach and even achieving that is lead with many challenges.

Rethinking the business models

The collaborative line of solutions discussed earlier, while they proved necessary and effective from the cases studied to optimize the structural and communication issues challenging the adoption of technology by sites, they are not sufficient to drive the execution of the solutions. The TransCelerate initiative for example while providing a multitude of solutions it is missing the actioning power and their proposition however powerful they are stay on the real of suggestions that yet have to be considered and fit into the organizational infrastructure and decision making process of the sponsors. The same goes for the collaboration between the sites. The society of clinical research sites with all the powerful conclusions that it draws it still reliant on the sponsors to consider the sites input and act. Without a deeper change to the business infrastructure itself the collaborative solutions will not effectively and massively see the light in the industry. Therefore, a revaluation of the business model of each institution is a necessary condition to reach full results. Both business model suggestions for sponsors and sites will follow.

Table 15is a compact view of the nine blocks of the business model proposed by A. Osterwalder (AG,), which will be referred to during the analysis.

Value Propositions		
Partners	Cost structure	Customer relationships
Activities	Revenue stream	Channels
Resources		Customer segments

Table 15 The Nine Blocks of Business Model Canvas

The following of analysis is built on the business model process configurations framework (Taran, Nielsen, Thomsen, Montemari, & Paolone, June 23, 2015).

Sponsors Business Model Potentials

Considering what aspects of the business model of sponsor would be interesting to exploit under the light of the context of this dissertation, two blocks from the business model rise to the attention: The value proposition, the partners, and the channels.

Depending on the sponsors priorities and vision. Modification to each of the blocks will result in a different business model and possible a different value proposition.

Reconsidering the channels for example could open the door for other possibilities to reach the subjects of the trials through other channels than sites which will in return lessen the burden on the sites, and they can focus on more tasks and studies that need them as a channel. Under this changes, subsequent modifications to the whole business model have to happen in connection to the value configuration and value proposition.

In the other hand, if the sites are considered as partners, then new configurations to the model present themselves and while it is the case in the current model, sites are partners, and the sponsors hold a patients and sites centric view as discovered from the data findings. The extent to which is translated in the current business model is narrow. Focussing on configuration that highlight this vision could be more consistent and would deliver better results. In connection to the technology adoption aspect, it will improve aspects of site inclusion in the process and develop common solutions reflecting to the partnership decided on.

This examples were just an exercise to prove that by aligning the business model with a vision and aligning the practices with the business model there a better potential of holistic actions that could benefit more stakeholders and in return benefit the sponsor.

Given the slim amount of data about the sponsors it is not possible to consider more implications and variations to solutions around the business modelling innovation. The sites could a more interesting case for the work of this project since greater data about the sites is present.

Sites Business Model Potentials

Site staff experience frustration not only about the technology but from a broader perspective it is linked the amount of activities that they have to conduct in the context of a clinical trial such as contracts, trainings, preparing for meetings with CRA and other taxing but necessary activities when they all would prefer is to just focus on their patients. The sites frustration with the situation could ultimately drive a change of the

business model. Instead of considering that they are in the business of healthcare, it could be considered that they are in the business of data. One way of looking at their activities is to see it as moving data from one source to the other, they gather data from subjects and send it to sponsors.

Rearranging their business model under a value proposition in these lines of thought could change the dynamic and potential of the whole clinical research enterprise. They will invest in quality delivery of data and yet providing optimal care for the study subjects. Changing their value proposition will affect all the other blocks of their business model. They could invest in more resources to build a better infrastructure that could address the current challenges they are facing. The dynamics between them and the sponsors will change towards customers relationships and a more assertive role of the site about its technological decisions, reaping first-hand the benefits from it, raising the standards, and meeting the need of their customers better. Changing the business model in this direction greatly benefits the technology adoption in the context described in this text, they might experience some other issues, but the main factors related to the organizational structure and non-inclusion of sites, will be neutralized, the site will make their own decisions, it will create an efficient workflow and reduce redundancies which in return will make the site more desirable for both working in it and with it.

Considering the scale and assessment

Changing business models or entering into collaborations are risky activities that involve a lot of uncertainty. Addressing the issue from an entrepreneurial perspective rather than a risk management act, many principles, and tools from the entrepreneurial approach of dealing with uncertainty could be utilised in this context. The Discovery, Incubation, Acceleration approach (Arteaga & Hyland, 2013) and the lean startup one (Ries, 2011), two major approaches to manage the innovation process, share common principles between them.

- Creative prototyping through quick and inexpensive iterations,
- Setting specific and measurable goals to the iterations,

- Making decisions at the end of an iteration to decide if to go for another round or cut the losses there.
- No matter the outcome of an iteration it is still a knowledge gained to build learning

Additionally, the DIA approach as it is meant for the corporate context consider the learning received from any iteration a gain for the firm driving knowledge and experience rather than a failure. Investments made in the sense are expenses well spent.

Applying these principles in looking for solutions to optimize the adoption of technological innovations at the site level and based on the factors and solutions reached so far could be beneficial in reducing risk, uncertainty, and expenditure on running big programmes to come to face some of the experienced challenges. Small scale collaborative projects or controlled experimental business models innovations built with metrics in mind can offer the best of the two worlds.

Conclusion

Through the first and second analysis the answers to the research questions have been achieved.

What factors influence technology adoption in clinical research sites?

How could it be optimized?

- Five factors influencing technological innovations adoption in clinical research sites have been identified:
    1. The particular organizational structure the clinical research sites operate under, the Danish Region and the multitude of sponsors running trials with them.
    2. The non-inclusion of the clinical research sites in technological innovations decisions.
    3. The technology overload, stemming from the nature of work and also the multitude of sponsors each providing their own version.

4. Interoperability, the ability of a system to interface with others.
5. Consistency of the design and the workflow logic.

- Three lines of recommendations been reached about optimizing technological innovations adoption in clinical research sites:
    1. Nourishing collaboration: Collaborations between a site and a sponsor to start with, collaborations between sponsors, collaborations between clinical research sites, and collaborations between networks of sites and networks of sponsors.
    2. Rethinking the business models, in order to drive any meaningful results from the collaborations, the business model of each actor have to support it.
    3. Considering the scale and assessment of the solutions, working in an iterative manner running measurable small scale pilot solutions.

Table 16 and 17 summarise the analytical process behind this factors and recommendations.

	Manifestation at the site, description (based on empirical data)	Logic, proof of it influencing adoption based on data (Cross case analysis)
Structure	Managed by the Region and a multitude of sponsors.	No cross-case analysis in this case. Case studies running under the same organization.
Non-inclusion of sites	"Top-down IT decisions making, and only one way, The decisions often do not take in consideration the opinion of the site Solutions is proposed by sponsors & sites are supposed to adjust".	No cross-case analysis in this case. Case studies running under the same organization.
Technology overload	Multitude of sponsors and often each present their own version Nature of work requires a lot of technological assistance	It drives complexity, making it harder to make sound decisions, what system and how to use it. System ends up not being used or used non-optimally with the need for a lot of assistance. Plus, systems with the potential to reduce technology overload have a high potential to be adopted.
Interoperability	The context of sites data from health sector, Data between systems Data from sponsors, labs…	The more interoperable the system is the more it will reduce manual processes of copying data and working in the background seamlessly
Design Consistency	Many systems coming from different sources with different standards	Having an odd design than the standard in a system is frustrating, hard to switch from mindset to mindset, doing the bare minim when absolutely having to, wasting time with mistakes and assistance

Table 16 Summary of Factors Influencing the Adoption of Technological Innovationat the site level

Solution	Description	Empirical or Theoretical Contribution to the solution
Collaboration	*The factors extracted could be synthesised into a solution *Collaboration with many stakeholders *Collaboration in particular between sponsors, sites, and sponsors-sites	*The factors extracted *The theoretical fit concept for HOT-fit framework *CTM opinions
Collaboration between sponsors		*CTM opinions *Case of TransCelerate
Collaboration between sites		**Case of Society of clinical research sites*
Collaboration between sponsors and sites		*CTM opinions
Rethinking the business models		Business model innovation (5 V framework)
Considering the scale and assessment		Discovery, Incubation, Acceleration approach and lean startup approach

Table 17 Recommendation to optimize the Adoption of Technological Innovation at the site level

Discussion

Reflection on methodology

In this section a reflection on the research design is conducted. The discussion will be covered through three dimensions: the data collected, the theories employed and the overall process.

Data

The main source of data in this research was of qualitative nature and a particular dilemma to working with qualitative data arose down the line, how much data of the interviews to use. While designing the study, the impression was that all data will be relevant and fill into place. Later on, in examining the interviews there was the dilemma of how much prepared codes, in my case looking for characteristics of innovation as described in the diffusion of innovations theory, should be used to make sense of the data and how much pure inductive coding should happen. As discussed by Bailey, et al., in their review about inductive coding versus theory driven coding (Bailey & Jackson, 2003), a compromise could use sensitizing concepts *("Sensitizing concepts offer ways of seeing, organizing, and understanding experience;")*. Sensitizing concepts could be used as a point of departure from which to study the data and afterwards apply pure inductive coding to stay faithful to the study the respondents' point of view. Intuitively it was the case through the use of the five characteristics of innovations in the first iteration of exploiting an interview and afterwards use themes naturally present in the interview to categorize the data and get full advantage of the input. In the other hand, the price for striving for inductive coding relatively differentiate the end results show cased in the five characteristics of innovation from the original meaning of the characteristics of innovation as defined by the theory. Nonetheless, this personal interpretation of the meaning of the original characteristics was not consequential in changing the end results. The content of each characteristic and its data stayed consistent with the main idea that the perception of the characteristics by the potential adopters will influence their decision to adopt an innovation.

A second point related to the reflection on the data gathered was the amount of empirical contribution in the third set of data used to look into solutions to optimize the situation studied. It is the contribution of a single participant and therefore it was supplemented with non-empirical data from cases of current corporations in the industry and also it relied heavily on theoretical input to drive to examine potential solutions and therefore the contribution of this dissertation in relation to providing solutions to optimize theory adoption by clinical research sites is in the line of conceptual recommendations.

Theory

Theory impact was different along the study. The analysis of the first and second set of data, relied on theory to organize, manage the data collection process, and conduct the first round of analysis, notable through the diffusion of innovations theory and the HOT-fit framework. The third set of data or the second round of analysis relied more on theory to propose solutions, notably theories stemming from the entrepreneurial engineering background.

The contribution of the diffusion of innovations theory through the characteristics of innovation proved to be useful in providing a holistic systematic overview about the perceptions of the technologies at study by in the clinical research sites. However, it was not an easy task to code the narratives of the participants into five characteristics and at times as mentioned in the previous section. Also, it did not cover the organizational factors at play but that makes sense as it looks into the human technology interaction and personal perspectives about it. It was expected that it will not help uncover all potential factors and that is one of the reasons the second approach was added.

The HOT-fit framework was very helpful and straightforward to use. It helped with the gathering of data by providing a list of potential factors specific to the health care setting that could be checked for in the study and it highlighted the organizational factors in play. Also, it highlighted the importance of the fit of individual solutions to reach a common useful one.

Process

The overall process slightly differed from the initial plan, but the results were reached as expected from the design. There was some uncertainty about major decisions such using a CRA as the main informant and studying the technologies through their different products available in the market instead of comparing two single products.

The choice of CRA met its projected value and the risks envisioned did not occur, the line of input of the CRA matched the one of the remaining participants especially the staff in the clinical research centers and therefore a wider overview of technology adoption has been reached through the CRA as a point of entry.

The choice of technology umbrella for the case studies instead of single products turned out to be more helpful than expected as it offered an additional and non-factored level of comparison of parameters influencing adoption, in getting insights of the site's perspective of the products of a single technology and what makes them adopt one over the other.

The maturity element of the EDC, is it fair to compare, is it shielding facts, it it too harsh for IP, I think the maturity is just a proof of what could be better. Is there is data about adoption rate going more with time?

Reflection on results

The core results reached are 5 factors influencing the adoption of technological innovation by clinical research sites and recommendations for 3 dimensions of collaboration aiming to drive adoption of technology at the site level.

The factors are based on analysis of empirical data from the perspective of the Danish sites; however, they are in line with global industry reports. Also, they are in line with the results of academic studies about the adoption of health information systems in the broader sector of the healthcare, the following comparison has been conducted with two recent paper reviewing challenges in connection to health information technology and adoption (Asan & Carayon, 2017) (Ratwani, Reider, & Singh, 2019).

Factors from Present Dissertation	**Paper 1** (Asan & Carayon, 2017)	**Paper 2** (Ratwani et al., 2019)
Organizational structure	Human-centered design	Create a database of usability and safety issues
Non-inclusion of the site	Systems approach in the design and implementation	Establish basic design standards
Technology overload		Addressing unintended harm
Interoperability		Simplify regulatory documentation
Design consistency		Develop measures to usability

Table 18 Results in Comparisson to HIT Results

In comparison with recent systematic reviews (Inan et al., 2020) (Rosa et al., 2021)about technology adoption in clinical trials in general, interoperability is a factor shared with the reviews. The most interesting aspect about the factors reached might be is that they portray the sites perspective, to succeed in optimal adoption of technology by sites, these factors must be taken into consideration.

Further action

Further action to develop this subject further could be:

- Enhancing the research data with quantitative data through surveys, from different stakeholders but in particular site, to build a larger database around the question and reach further insights through the benefits of quantified data.
- Another interesting course of action could be to examine the same phenomenon (i.e., technology adoption by clinical research sites) but in a different context, through private clinical research sites (institutions with healthcare practitioners with the sole responsibility of conducting clinical trials and organized and managed privately, not under the Danish Region for example) and examine the impact of organizational factors and perhaps the presence of dedicated management on success of technology adoption.

Conclusion

With patient's life in mind, adopting technologies in the sector might be a long and resource intensive process but the rewards are worth the effort. This dissertation dove into the complex clinical trials enterprise attempting to contribute through the lenses of the entrepreneurial engineer with improving the adoption of technological innovations at the level of the clinical research site.

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