Observational Analysis of the eClinical Technology Landscape

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Abstract:

Background: *The clinical trials industry has been slow to adopt eClinical technology. Advancements in healthcare technology and the COVID-19 pandemic accelerated adoption and caused a rapid influx of employees, products and vendors. We determined that there is a lack of data on the eClinical technology landscape and how it aligns with the typical clinical trial lifecycle.*

The authors recognize the likelihood of human error in attempting to research and document every product and vendor in the eClinical industry. There are most likely companies that have inadvertently been overlooked. There is also an inherent challenge in consolidating and categorizing technologies with objectivity based only on the narrative each company provides. Objective reporting from vendor marketing material is inherently limited because it is based on the subjective marketing of each vendor.

Methods: *We created a map of typical tasks completed during a clinical trial. The tasks were organized by the responsible party and by study stage, and were sorted into technology categories and clinical trial operations categories. The task map was color-coded by the operational categories to show patterns in workflows and tasks.*

An extensive search of vendors in the eClinical space and their products was conducted. All products were categorized based on the product description and information provided by each vendor on their public website. A graphic display of the vendor logos supporting each category was created.

Results: *The vendor research documented 248 unique vendors offering 834 unique products in the eClinical technology market. The data was organized into a series of graphics intended to educate and explain the clinical trial process and vendor landscape in the industry.*

Conclusion: *This work provides data and information that creates a new understanding of the complex eClinical vendor landscape and of the product categories supporting the tasks and workflows in a clinical trial. These results provide an opportunity for operational teams to identify potential technology partnerships and integrations that could optimize technology usage during a study.*

Introduction

The clinical trials industry has historically been slow to adopt eClinical technology[1,2] and overall adoption remains inconsistent and complicated.[3,4,5] Even established technologies, such as electronic data capture (EDC) systems are not fully adopted for all studies.[3,6] Internal factors for this slow adoption include heavy regulations and data privacy concerns, fear of inspection findings, a complex ecosystem of sponsors, clinical research organizations (CROs), sites, and participants, and high variability in study design, complexity, and budgets.[7,8,9] External factors for the lack of adoption are that the industry is a niche market within healthcare, without well-defined career entry points, not well known by the general

public and therefore not a focus for innovative technology companies. As a result of such factors, the industry is far behind other industries and the technological landscape expected in daily life, which adds to the complexity of the clinical trial ecosystem.

Nevertheless, rapid advancements in general healthcare technology such as personal fitness wearables, compact sensor technology, and telemedicine have started to influence adoption in the clinical trial industry.[5,7,8,10,11] These technologies enable the ability to capture valuable data on a larger scale and in more new settings than ever before, which allows for evolution in protocol design.[12, 13] The COVID-19 pandemic accelerated the need for adopting operational technology as the industry had to conduct new COVID-19 vaccine trials with a large number of patients, a diverse participant population, and faster than any comparable trial had ever been conducted.[2,8,12] Technology like document sharing through portals, electronic signatures, and remote electronic health record (EHR) access for monitoring became critical for success during the pandemic.

The new demand, interest, and willingness to adopt technology led to a surge in companies creating solutions for the market.[10] Today the eClinical technology industry is a rapidly evolving landscape of vendors, services, and products. The sudden intersection of many technology and software companies with this historically paper-based industry and complex ecosystem means there is often a lack of education and awareness of industry processes, core workflows, and of the interaction of different technology used in the lifecycle of a clinical trial. This lack of knowledge leads to new technology products that are siloed, do not support the workflows they are intended to replace and are not designed for their end users. The end result is an overwhelming number of technology solutions that cause frustration and add more burden and complexity to clinical trials.[4,10,13]

The goal of this work is to provide an educational resource for the industry to fill the void in this knowledge base. This work documents the typical tasks and workflows in the clinical trial lifecycle, the users involved in those workflows, and the technology available to support those tasks. This work also analyzed the complex vendor landscape serving this industry and categorizes the products and vendors supporting the tasks and workflows. These findings can be used to learn the clinical trial process and to understand the technology available in the industry, in order to find new ways to leverage technology to evolve clinical trial operations.

Methods

To explain the clinical trial process we created a map of typical tasks completed during an industry-sponsored clinical trial. The tasks were organized by the responsible party (Sponsor, Sponsor/CRO, Site, Participant) and by study stage. Overlap was allowed between parties because there are many tasks that could be conducted by the Sponsor or CRO, depending on the study contract. There are also tasks that involve both the Sponsor/CRO and Site or both the Site and Participant. There is also the potential for some task crossover between study stages, depending on specific Sponsor, CRO, or site policies. For example, shipping of supplies or granting access to eClinical systems can occur before or after activation depending on the Sponsor/CRO. There is also an optional study stage for protocol updates and reconsent, which may not ever occur or may occur repeatedly, depending on the study. Within a study stage, there is a lot of variability in the task dependencies and stakeholder dependencies. It's difficult to capture and generalize even a fraction of the nuances in those dependencies, so it is better to think of the study stages as the ultimate dependency for this graphic. This task map was reviewed, edited, and updated by a group of clinical trial professionals with a range of clinical trial experience at sponsors, sites, and CROs.

It is hard to depict, but important to note, that the progression of a study is continuous, not discrete. In other words, although in general the phases are conducted sequentially, they may overlap (21CFR312.21). Due to capacity limitations and natural differences in study-site timelines, study-sites move progressively through the study stages in waves. This map represents the flow for each study-site participating in a clinical trial.

The tasks on the map were then reviewed, analyzed, and sorted by functional area and purpose into categories often corresponding to a technology available to complete the tasks. This is not to suggest that each category has 100% adoption of that technology, only that the task can be achieved by that category if technology is used. For example, an ongoing task in a clinical trial is creating, updating, and monitoring the regulatory binder. These regulatory tasks could be achieved using eRegulatory/ eISF (Electronic Investigator Site Files) software, although at many sites worldwide the regulatory binder is still maintained on paper. The categories were informed by knowledge of the industry and logical classification of tasks at a high level. There were some tasks that did not fall into a broader technology category (ex: ClinicalTrial.Gov data entry/ updates).

We then used an affinity map to find commonalities in the categories, considering the different stakeholders in each category, the tasks being accomplished, and how the categories fit into the clinical trial workflow. Five high-level clinical trial operations categories emerged as the tasks and categories were organized: Participant Management, Participant Data Collection, Site Enablement, Data Safety Management and Sponsor Operations. The task map was color-coded by the final operational categories in order to show patterns in workflows and tasks.

In parallel, our team conducted an extensive search of vendors in the eClinical space and their product offerings. The goal was to provide an objective account of the current products and vendors. We started with the list of companies on an outdated vendor graphic[14] and the data from that graphic.[15] We conducted a systematic review of vendors on the list and others advertising eClinical products by searching the internet for the tasks and technology categories already identified. Each product was documented in the technology category advertised by the vendor. Many vendors have more than one product, and many products belong to more than one category. All vendor logos were captured from their public websites. A vendor logo is displayed for each product in all categories where they offer a product, so many logos appear in more than one category and a logo may appear more than once in any category. There were technology categories with strong overlap to clinical care (EHR, Telemedicine) that were purposely not included here. IRBs were also purposely not documented here as their main focus is to assure the protection of the rights and welfare of the human subjects rather than technology services.

As the product and vendor list was created, we conducted further review of tasks and categories to iterate and update as needed. During the course of the work there was also ongoing review of vendors and products and the data was regularly updated.

Figure 1.
Clinical Trial Task Map

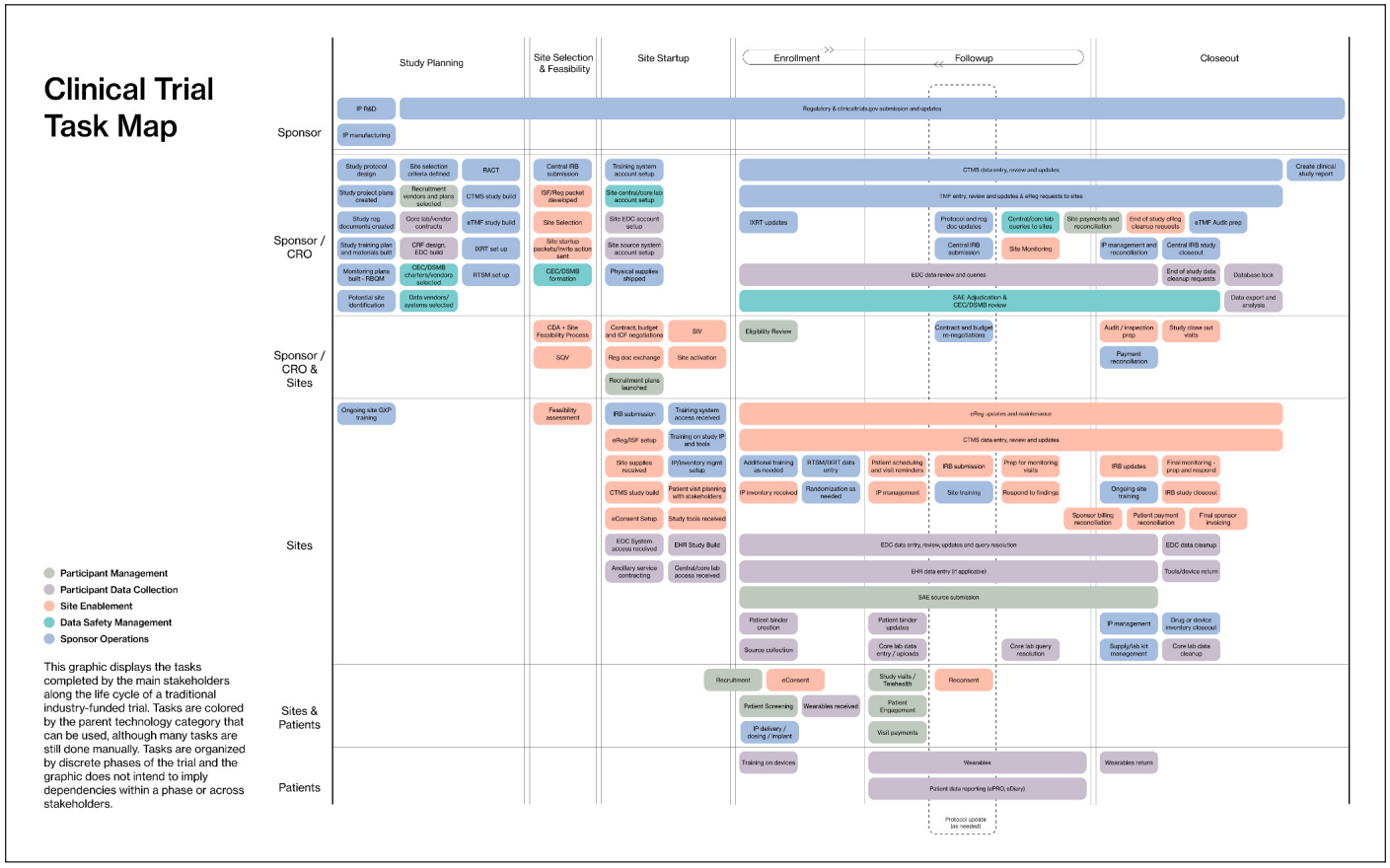

Figure 1: Clinical Trial Task Map. This figure shows typical tasks completed in an industry-sponsored clinical trial, organized by the responsible party and by the study stage. The tasks are color-coded according to their high-level categories in clinical trial operations.

Results

The result of this work is a series of informative graphics and vendor data intended to educate and explain the clinical trial process and vendor landscape in the industry.

The first output is the clinical trial task map (Figure 1), which shows typical tasks completed in an industry-sponsored clinical trial, organized by the responsible party and by the study stage. The tasks are color-coded according to the high-level categories in clinical trial operations. The figure represents the tasks for a single site participating in a clinical trial. All participating sites may be at different stages at any given point in time. For many tasks there is collaboration or there can be overlap in the responsible parties, which depends on many factors.

Figure 2.
Clinical Trial Technology Categories

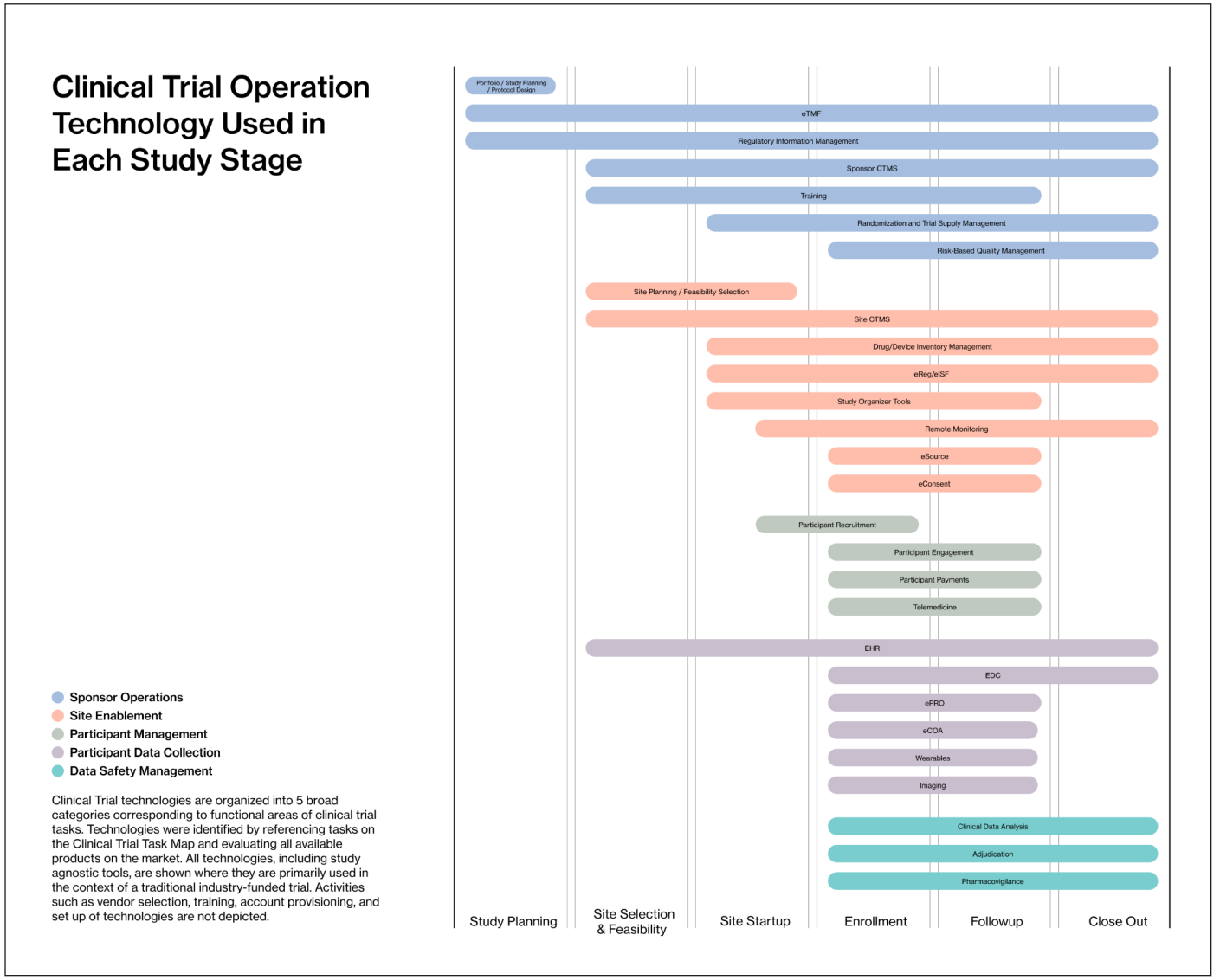

Figure 2: Clinical Trial Technology Categories. This figure shows the technology categories used at each study stage. These categories were derived from the clinical trial task map. Many categories correspond to technology types, but not all tasks for all studies are completed using technology - many tasks still rely on manual processes. The categories are depicted in the study stages where they are actively used, not including vendor contracting and setup time.

The clinical trial operations categories can be divided into more detailed clinical trial technology categories shown in Figure 2, organized by the study stage where they are used. These categories were derived from the tasks in the clinical trial task map. Many categories correspond to technology types, but not all tasks for all studies are completed using technology; many tasks still rely on manual processes. The categories are depicted in the study stages where they are actively used, not including vendor contracting and setup time.

Figure 3. Clinical Trial Technology Landscape Categories and Subcategories

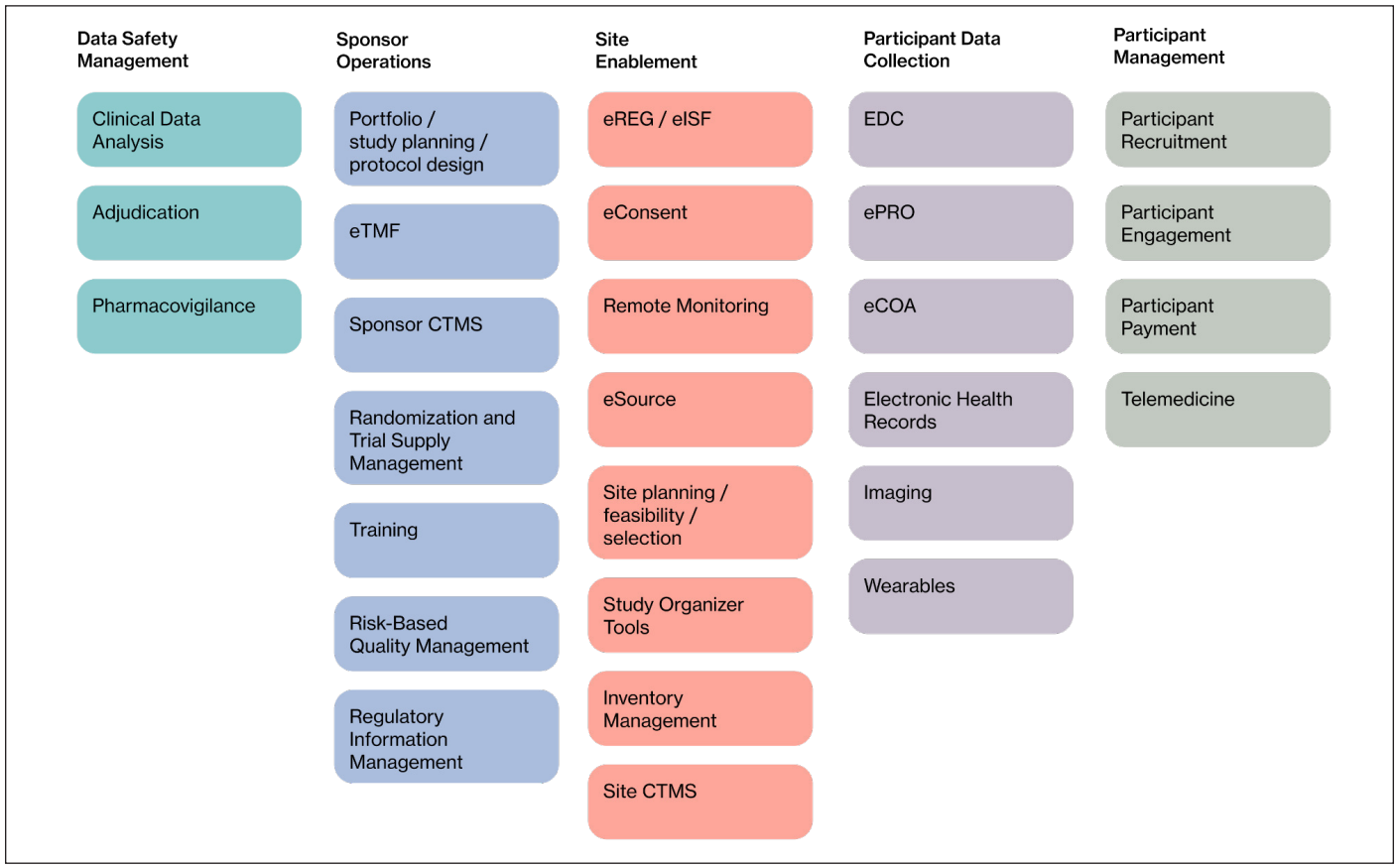

Figure 3: Clinical Trial Technology Landscape Categories and Subcategories. This figure shows the technology categories and subcategories. These categories were derived from the clinical trial task map.

The clinical trial operations categories can also be displayed by category and subcategory, as shown in Figure 3. This format allows the vendor information to be displayed for each subcategory and facilitates sorting and filtering vendors without the added complexity of the study stage.

Our detailed eClinical product and vendor research documented 248 unique vendors offering 834 unique products in the eClinical technology market. Table 1 shows the count of eClinical products by operations category. Table 2 (on following page) shows the count of eClinical Products by the more detailed technology categories.

TABLE 1 - eClinical Products by Operations Category

Clinical Trial Operations Category	Count of Products
Data Safety Management	68
Participant Data Collection	204
Participant Management	150
Site Enablement	145
Sponsor Operations	267
TOTAL	**834**

Table 1: eClinical Products by Operations Category. This table shows the count of technology products in each high level clinical trial operations category.

TABLE 2 - Clinical Trial Technology Subcategory

Clinical Trial Operations Category	Count of Products
Participant Recruitment	72
EDC Electronic Data Capture	68
Portfolio/Study Planning/Protocol Design	65
RTSM/IRT Randomization and Trial Supply Management/Interactive Response Technology	58
Participant Engagement	47
ePRO electronic patient-reported outcome	45
eConsent	42
eCOA Electronic Clinical Outcome Assessment	38
Sponsor CTMS Clinical Trial Management System	37
eTMF Electronic Trial Master File	36
RBQM Risk Based Quality Management	32
eSource	28
Clinical Data Analysis	26
Adjudication	26
Training	24
Wearables	23
Remote Site Access/Remote Monitoring	19
Imaging	17
Pharmacovigilance	16
Participant Payments	16
eREG/eISF eRegulatory Management System/ Electronic Investigative Site Files	16
Telemedicine	15
Site Planning/Feasibility/Selection	15
Regulatory Information Management	15
EHR Electronic Health Record	13
Study Organizer Tools	12
Site CTMS Clinical Trial Management System	11
Drug/Device Inventory Management	2

Table 2: eClinical Products by Technology Category. This table shows the number of products offered in each subcategory. The data highlights that even in mature product categories (ex. EDC), there has not been vendor consolidation.

The vendor data can also be analyzed by the number of vendors offering different numbers of products (Figure 4). This representation shows there are many vendors in the industry offering only one product, which highlights the fractionation and complex vendor landscape.

Finally, vendor information found on the Internet by our team is represented visually in Figure 5, a clinical trial vendor map. Vendors' publicly available logos are displayed in each category where we found advertising of a product offering. A logo may appear more than once in a single category if that vendor offers multiple products in that category. These data are simply intended to demonstrate the fragmentation and complexity of the eClinical technology landscape. We also have an updated version with the logos that is published live online in an interactive format at https://researchrevolution.com/tech-vendor-map/.
The authors apologize to any vendor that may not have been included in our discovery and presentation of a vendor map. Changes (additions/edits) to the vendor map may be requested via the link on https://researchrevolution.com/tech-vendor-map/.

Figure 4. Vendor and Product Data

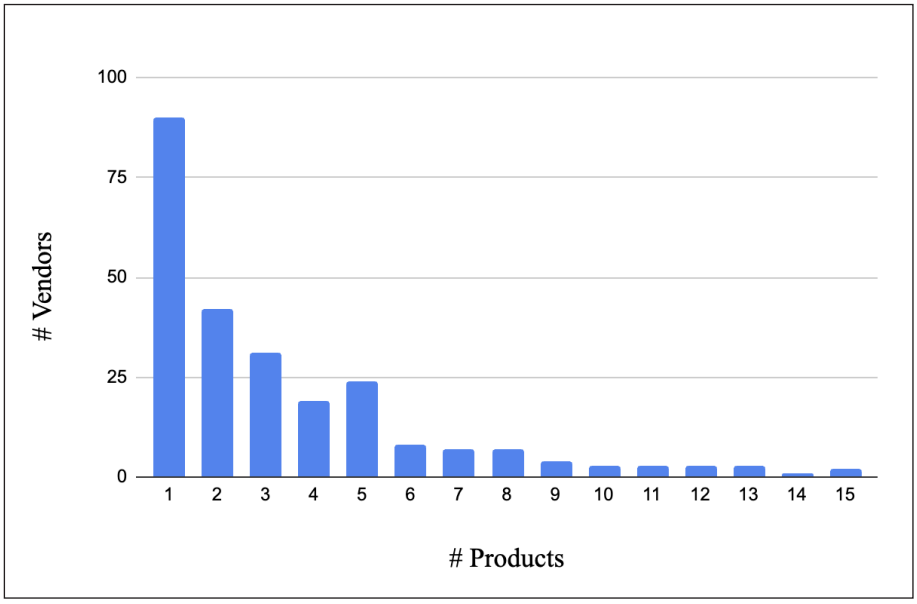

Figure 4: Vendor and Product Data. This graph shows the number of vendors by the count of products they offer in the eClinical technology space. The data highlights the large number of vendors that offer just one product, indicating the vendor landscape is complex and ripe for consolidation.

Figure 5. Clinical Trial Vendor Map

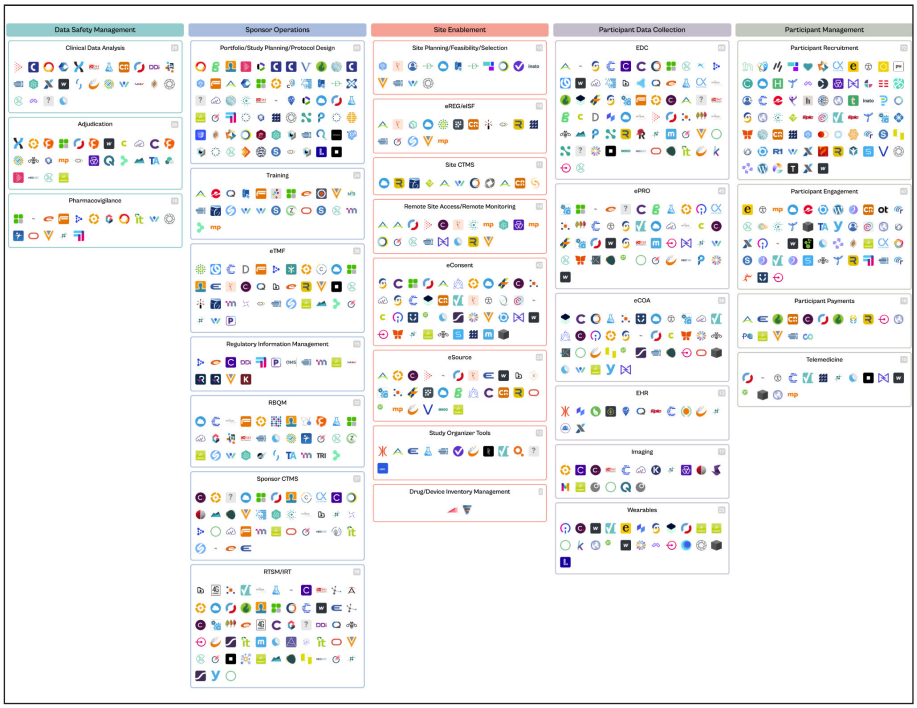

Figure 5: Clinical Trial Vendor Map. This figure shows technology vendors serving each category. Vendors are displayed in each category where they offer a product, and may appear more than once in a single category if they sell multiple products in that category.

Static Image generated January 29, 2024 from the live map at https://researchrevolution.com/tech-vendor-map/.

Discussion

We found that there is a lack of consolidated information, especially peer-reviewed information, available on the teams, tasks and technology needed to navigate a clinical trial. The information available tends to be marketing material or online publications. The vendor landscape diagram that we found is outdated, published in 2018[14], and uses product categories that are not comprehensive in today's industry landscape. This information is critical to understanding the industry, for people starting a career in the industry as well as for vendors designing products to serve the industry.

It is challenging to explain the incredible variability and complexity of the clinical trial process across a dynamic ecosystem of sponsors, CROs, sites, and participants. For example, sites alone are their own complex ecosystem of large academic medical centers, independent research sites, site networks, multicenter coordinating centers, site management organizations (SMOs), and integrated research organizations (IROs). Each of these organizations has its own structure and function, and there is no standard operational model. Sponsors and CROs contribute just as much complexity, with many different models of insourcing vs. outsourcing, different organizational structures, job titles and responsibilities, and operational procedures. All of these organizations vary in size, complexity, budget, phases of research conducted, geographies served, number of trials/assets, specialty area/disease state, as well as being pharmaceutical or medical device focused. Each member of the ecosystem often runs many studies across many stages of clinical research, which results in a complicated web of interaction and overlap. Finally, vendors provide products to serve the ecosystem, as well as services and staff to participate in the ecosystem. The end result is high variability in operations and technology from study to study.

This variability makes it difficult to cover all possible scenarios in any educational content. Nevertheless, it is possible to find a balance by generalizing enough to explain the process. The task map (Figure 1) represents the most common tasks for an average high-complexity industry-sponsored clinical trial, from study planning through closeout. For a lower-complexity study design (ie. a registry), tasks would be removed from this map. For the highest-complexity study design this map may not be fully inclusive of all tasks. The map highlights tasks that can or do require interactions between the different "layers'' of people supporting the clinical trial process (sponsors, CROs, sites, and participants).

All of this variability also makes standardization of any technology category slow and difficult. This has contributed to the lag in technology adoption and the fragmented eClinical market. Many vendors seek to solve a specific workflow challenge or fill a specific process need, resulting in many vendors, products and services for different specific tasks/workflows/phases of a clinical trial. When the clinical trial tasks are aggregated into their technology categories across the phases of the study (Figure 2) it simplifies the view of technology that can be used across the study stages. This view allows us to identify what technology is isolated to a study phase or spans the entire study lifecycle. It also helps facilitate an understanding of how solutions can integrate—where point solutions should connect to each other, and where they might connect to a technology that spans the study lifecycle.

The vendor data presented here demonstrate that the industry landscape has changed dramatically in the last 5 years. The 2018 vendor map and data showed far less products offered by only 154 vendors.[14,15] The categories used in the 2018 map were no longer comprehensive of the technology landscape. Using the task map to organize and sort the technology categories provides a more operationally-focused way of explaining the industry.

The vendor map also illustrates that we have not seen much vendor consolidation even in the most mature product categories. For example, there are still 68 EDC vendors, one of the earliest and most adopted eClinical technologies. The majority of the product categories are much newer, which suggests that we may even see further expansion of vendors in these categories in the near future.

Sponsors and CROs regularly supply eClinical technology to study-sites that study-sites are required to use during their studies, resulting in a deluge of different and disjointed technology at clinical trial sites. We feel that this complexity is often discussed as a reason for the high levels of burnout and turnover across the industry. In other words, the changing industry landscape has created new payer-user dynamics, where the customer/buyer is often not the software end-user. This poses a challenge for vendors when designing and evaluating the user experience of their products. The data also shows a lot of overlap in users, with users from multiple layers on the task map accessing the same system. Theoretically, this provides an opportunity to develop collaborative products, but that result is often not achieved in today's technology.

Conclusion

The vendor data presented here quantify and validate the complexity perceived and often discussed by stakeholders in this industry. The complexity has resulted in high levels of burnout and turnover across the industry. This sustained imbalance in capacity and demand in the industry puts clinical trials at risk of delay or failure, associated with incredible cost and delays getting new therapies to market. The data presented here offer educational value for the many industry newcomers needed to fill the capacity gap. For clinical trial operations leaders, the diagrams create a new understanding of the vendor landscape and the alignment of product categories to the tasks and workflows used throughout the clinical trial lifecycle. This overarching view is often lost in the myopic focus of vendors solving the problems of an isolated task or workflow. These results provide an opportunity for operational teams to identify potential technology partnerships and integrations that could optimize technology usage during a study. The ultimate goal of using technology is to create efficiency and by taking a broader view of the landscape we can collectively work towards that goal.

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