Sites Speak Out on Clinical Trial Technology Overload: An SCRS Survey

Sites Share Insights on Virtual Trials, Clinical Trial Management Systems, and Risk-Based Monitoring Adoption

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SCRS WHITE PAPER
July 2020

For decades, inefficient paper-based clinical trials have inspired endless discussions in the clinical research sector, driving industry, regulatory bodies and other stakeholders to step forward in support of technological advances that could introduce meaningful change. While a myriad of technologies emerged in recent years to automate various parts of the clinical trial process, it is clear investigative sites have become overwhelmed with too many stand-alone solutions. This has led to a reality of repeated data entry into various systems, too many log-ins and passwords, and seemingly never-ending training on how to operate each system. Ironically, solutions meant to streamline clinical trials have somehow had the opposite effect, burdening sites as they attempt to perform the many tasks specified in the protocol while adhering to ever-tightening timelines.

In 2019, the Society for Clinical Research Sites (SCRS) collaborated with IQVIA to conduct a global online 30-question survey of clinical research sites on the subject of clinical trial technology. The goal of this survey was to pinpoint the challenges sites face in adopting these newer systems. The survey questions were designed to quantify which technologies sites use routinely to manage their trials (both traditional and virtual) and whether sites believe these technologies simplify study conduct. Questions were included to determine how integrated solutions have become in terms of allowing data to flow among them and reduce the need for sites to re-enter the same information multiple times. Through a combination of multiple-choice and open-ended response questions, the survey also sought to reveal which technologies are less popular with sites, especially those that create more work for little benefit.

This white paper presents key findings of the technology survey, which explored a wide range of solutions from eConsent to online payment portals. The primary focus, however, was on how sites view virtual trials, clinical trial management systems (CTMS), and risk-based monitoring (RBM) tools. These findings provide insight for sponsors and contract research organizations (CROs) who are increasingly interested in tech-savvy sites and want to understand and address how they utilize technology, especially in light of the new normal following the COVID-19 pandemic era. The paper also describes how technology has been introduced into everyday traditional clinical trials and reveals the status of newer methodologies, such as virtual or decentralized trials, artificial intelligence (AI), and machine learning (ML).

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Leading Up to the Survey

Clinical trials are widely acknowledged to be a complicated enterprise. Any number of publications on this subject have emphasized the critical importance of addressing this challenge by transforming research methodology[1, 2], starting with giving up Excel spreadsheets[3] and other siloed methods and embracing innovative technology. As digital solutions have advanced, an array of products have come to market that promise to manage more of the clinical trial steps and offer actionable insights. Research suggests that spending on clinical IT solutions is expected to reach $7.36 billion by 2022[4], with a compound annual growth rate in the 22% range between 2018 and 2023.[5]

Chart 1

Clinical Trial Technologies

- Central Recruitment
- Clinical Trial Management System (CTMS)
- e-Consent
- e-IRB
- e-Patient Reported Outcomes (ePRO)
- Electronic Data Capture (EDC)
- Electronic Trial Application
- e-Signature
- e-Source
- Interactive Response Technology (IRT)
- MobileCRA
- Online Payments Portal
- Paperless Clinical Trials (100%)
- Patient Retention
- Risk-based Monitoring
- Single Sign-on to All Applications
- Telemedicine
- Virtual Trials
- Wearables

Onboarding so many new approaches has resulted in sites being overburdened by learning, operating, and managing these systems. This notion was first hinted at nearly 20 years ago when Robert Califf, former Commissioner of the Food and Drug Administration (FDA), suggested that tremendous technological success has sometimes been poorly aligned with therapeutic principles, increasing uncertainty as to which technologies are truly effective in terms of patient treatment and cost.[6]

Since then, other studies have followed, such as the 2016 survey of 252 sites conducted by CenterWatch and the Association of Clinical Research Professionals (ACRP).[7, 8] In that research, investigators showed that sponsors and CROs overload their sites with an assortment of technologies that often do not communicate with each other, requiring entry of the same data into multiple systems. Sites claimed to be using about 10-12 different software applications to manage clinical studies in 2015. Almost half (46%) of investigators stated they believe sponsors and CROs require them to manage too many separate technologies, and 74% cited keeping track of multiple usernames and passwords as a top technology challenge.

The latest technology is trending away from stand-alone point solutions and toward more unified, integrated offerings.[9] Solutions are often cloud-based, providing stakeholders with access to information in real time as voluminous data are stored in a central location.[10] These clinical trial platforms facilitate collaboration among sponsors, CROs, and investigators as these data can be gathered, shared and managed quickly and securely.

Decentralized or "Virtual" Clinical Trials

Decentralized clinical trials (DCTs) are becoming part of this trend. As described by the Clinical Trials Transformation Initiative (CTTI), the term decentralized clinical trials refers to trial visits that are "executed through telemedicine and mobile/local healthcare providers (HCPs), using procedures that vary from the traditional clinical trial model (e.g., the investigational medical product [IMP] is shipped directly to the trial participant)."[11] This description of DCTs is included in a comprehensive set of recommendations and resources that CTTI released in 2018 to drive the appropriate use of mobile technologies in clinical trials and guide DCT conduct.[12] DCTs may also be referred to known as "virtual trials", remote trials, direct-to-patient trials, and hybrid trials, with this last term referring to studies with both virtual and traditional study visits.[13]

With the advent of COVID-19, most site visits have been eliminated, creating the need for more visits to take place in the home, in a pharmacy or retail environment, or over a smart phone or computer. Decentralized trials moved from an industry idea to a necessity in early 2020. Virtual trials required less burdensome protocols for patients and by default decreased the number of procedures performed by clinics, lowering the risk of infection for caregivers and patients alike. Out of necessity for care continuity, new technology needs surrounding decentralized trials and remote monitoring adoption are being reviewed. This paper hopes to shed light on the current state of the industry, and the forward-thinking actions to address the health and welfare needs of the populations under care.

Currently, life science organizations are responding with the ability to accurately gather information about COVID-19, including epidemiology, local and global guidelines, and stakeholders affected. They are also working to minimize risk and exposure for employees, patients, and partners. SCRS and IQVIA have seen a rapid response to the pandemic followed by business continuity plans to execute short-term, high-impact actions that address operational stability and financial solvency. Proactive changes to create leadership and improve strategies for human health as an outcome of the pandemic will be top of mind in addition to efficient technology adoption.

The Survey

With this swirl of technologies making up the background, SCRS launched a global online survey between September and November 2019. The survey, which contained 30 questions, sought to a) identify the problem(s), b) determine how to reduce site burden, and c) determine whether available technology provides transparency, which refers to the site having visibility into processes and data throughout the trial. Nineteen (19) of the questions were multiple choice only, and 11 were either multiple choice including an "other" category or open-ended response questions to

which respondents could freely express their opinions. The questions were intended to identify opportunities to improve daily site performance by means of enabling technologies and gain a better understanding of the challenges sites face in using current and adopting future digital solutions. The key findings are presented in this white paper.

Who Participated?

A total of 377 survey respondents from an experienced group of site professionals, with 84.8% reporting involvement in more than 10 trials in the preceding five years.

Table 1

How Many Study Coordinators Do You Employ at Your Site?

Number of Study Coordinators	Percentage
1	7.7%
2	13.5%
3	15.6%
4	15.4%
5	7.7%
6	5.8%
7	2.4%
8	5.1%
9	0.0%
10	2.9%
>10	23.9%
Total	100%

n = 377

The size of the responding sites varied substantially: more than half (52.2%) reported employing only one to four study coordinators, and at the other end of the spectrum, more than one-quarter of respondents (26.8%) had 10 study coordinators or more (Table 1). At the time of the survey, a large number of participants (59.4%) were working at sites that were conducting 10 or more studies (Table 2).

Key Findings

Understanding how sites perceive clinical trial technologies starts with finding out where we are now. For example, what are sites currently using and what they are not using? Not surprisingly, electronic data capture (EDC) was named the most-used technology, with 87.7% of respondents claiming to use this tool in 75% or more of their clinical trials. The least-used technologies were those directly associated with virtual or DCTs and telemedicine, with less than 1% using each of them in 75% or more of their studies.

The COVID-19 pandemic has created an environment where sponsor companies need to determine how to keep their patients safer. Their options include decreasing required visits, replacing site visits with virtual visits or lab visits, and more remote monitoring. The challenge that sponsors have now is to understand how demand is changing, how to forecast for a trial, which supplies are at risk and even whether launch strategies should change. Sites must grapple with similar questions about how to ensure that staff and physicians are safe and trials can continue. Patients must remain at the center of the journey, with concern for trial participation and risk, limited hands-on patient care, and the determination

Table 2

How Many Active Trials Do You Have at Your Site Right Now? (trials enrolling or in follow-up)

Number of Trials	Percentage
0	2.1%
1-3	8.7%
4-6	14.9%
7-9	14.9%
10-14	14.3%
>15	45.1%
Total	100%

n = 377

Table 3

Most Commonly Used Technologies
(As Measured by Percentage of Trials Using the Technology)

Technology	0%	1% - 24%	25% - 49%	50% - 74%	75% +	Total
Electronic Data Capture	1.2%	2.2%	1.5%	7.4%	87.7%	263
Clinical Trial Management System	17.5%	21.7%	9.1%	13.3%	38.4%	263
Risk-based Monitoring	12.0%	24.8%	27.1%	25.2%	10.9%	266
Electronic Trial Application	16.8%	27.5%	19.4%	16.8%	19.5%	262
e-Signature	22.9%	27.1%	16.5%	15.1%	18.4%	266
Online Payments Portal	24.1%	29.8%	21.9%	15.5%	8.7%	265
Central Recruitment	29.3%	27.1%	25.9%	10.9%	6.8%	266

Most Infrequently Used Technologies
(As Measured by Percentage of Trials Using the Technology)

Technology	0%	1% - 24%	25% - 49%	50% - 74%	75% +	Total
Virtual Trials	86.4%	11.7%	1.1%	0.8%	0.0%	265
Telemedicine	79.7%	15.8%	3.8%	0%	0.7%	266
Paperless Clinical Trials (100%)	78.9%	10.5%	5.3%	3.0%	2.3%	266
Wearables	50.8%	40.2%	7.1%	1.1%	0.8%	266
eConsent	62.3%	30.9%	3.4%	1.9%	1.5%	265
Mobile CRA	67.2%	19.8%	6.1%	3.8%	3.1%	262
Single Sign-On	55.3%	29.5%	5.7%	3.8%	5.7%	264
eSource	55.4%	23.2%	6.4%	4.5%	10.5%	267

of whether systems – and patients – are ready to go virtual. Table 3 shows the most and least commonly used technologies.

Clinical Trial Management System (CTMS)

The CTMS manages and tracks the many activities that span the clinical trial continuum from protocol development, site selection, site initiation, patient recruitment, and study conduct, through to study close-out.[14] For the purposes of this survey, CTMS was defined as "the system that manages documents and practices throughout the clinical trial". This technology is generally cloud-based and facilitates collaboration among the study team in a shared environment. With this functionality, CTMS attempts to break down siloes and offers near real-time actionable information

for faster decision-making.

CTMS is widely used at the site level during study conduct, coming in second behind EDC with 71.3% of respondents reporting using this technology. Specifically, 52% of respondents claimed to use CTMS in at least 50% of their studies, and 60% stated that CTMS had an "extremely" or "very positive" impact on site efficiency.

The survey featured more than a dozen questions that addressed numerous aspects of CTMS used at the site level, such as how satisfied sites are with their current CTMS, what functions and systems sites most commonly use, what factors might inspire sites to switch to a new CTMS, and so forth. Survey results indicate that sites like their CTMS systems: nearly three-quarters (74%) reported that they are "extremely" or "somewhat" satisfied with their current system. The most commonly used functions of this popular technology were payment/receivable tracking and invoicing, site visit and planning, and managing study finances. Table 4 gives more detail.

Still, there is room for improvement in CTMS, as several factors were cited as causes for switching to another product (Table 5).

Responses to the "Other" category provided additional insight. Participants gave the following other reasons for switching:

- Quality and better interface with EDC
- Better financial analytics
- Easier builds
- Robust analytics reporting
- More EU-focused

Reflecting the growing interest in more integrated tools among clinical trial stakeholders, SCRS questioned respondents about whether they would value the capability for data entered into the EDC system to flow automatically into the CTMS. This would eliminate the need to enter the same information more than once, a tedious step that can introduce error. A strong 71.7% reported that this would be a significant benefit, and 17.6% viewed this capability as "somewhat of a benefit".

How many systems are currently integrated? According to the survey results, integrations

Table 4

Most Commonly Used Functions	Percentage
Payment/receivables tracking and invoicing	25.8%
Site visit planning/ reporting	23.7%
Managing study finances	23.5%
Study document storage including protocol, informed consent, and amendment updates	16.8%
Communication with CRO/Sponsor	4.7%
Other	5.5%

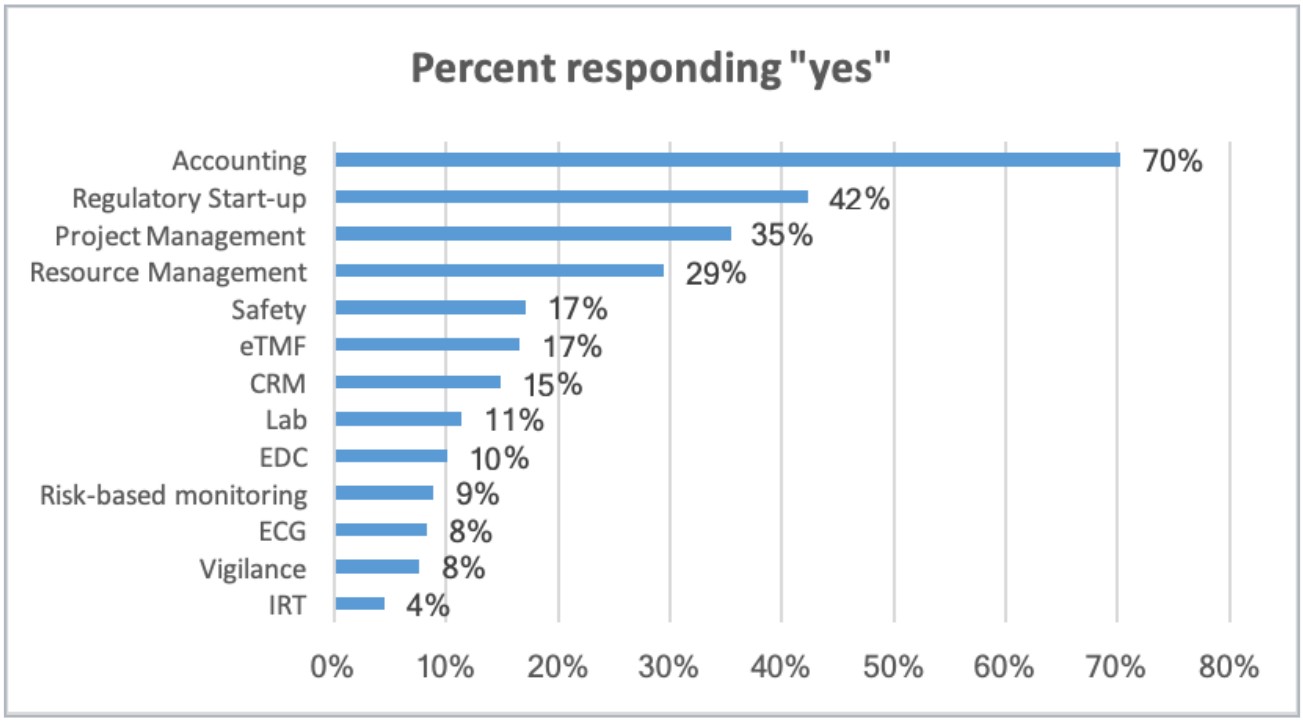
n = 489

Table 5

Features That Might Encourage Switching	Percentage
Ease of Use	27.3%
Features	27.0%
Price	19.6%
Support	17.0%
Other	9.1%

n = 341

Chart 2



with CTMS are only moderately commonplace, with a handful of functions leading the way, most notably accounting (70.2%), regulatory startup (42.3%), and project management (35.4%). Stragglers include interactive response technology ([IRT] 4.4%), vigilance (7.6%), and ECG (8.2%). Chart 2 shows the range of integration.

Given that EDC is the most widely used technology, it is surprising that only 10% of respondents claim that it is integrated with their CTMS. Offering this integration would be an opportunity for providers of clinical trial solutions to increase the value of the CTMS to sites and ease site burden.

Risk-based Monitoring (RBM)

RBM is a complex subject that has emerged from the growing consensus that risk-based approaches to monitoring are more likely than routine visits to all sites and 100% source data verification (SDV) to ensure subject protection and data quality.[15] As described in the 2013 FDA guidance[16] on the topic, RBM is an adaptive approach to monitoring that focuses on identifying the risks to the most critical data elements and processes needed to achieve study objectives. Similarly, a 2013 European Medicines Agency Reflection Paper describes RBM as enabling the identification of study risks on a continuous basis, starting with study design, followed by study conduct and analysis.[17] According to the International Conference on Harmonization (ICH) E6(R2), "The sponsor should develop a systematic, prioritized, risk-based approach to monitoring clinical trials."[18] The literature, however, suggests that an industry-wide definition and standardized way to implement this function are lacking.[19] So, for the purposes of this survey, RBM was defined as "tailoring the frequency and type (on-site, remote) of monitoring activities using risk assessments based on data analytics."

RBM has been the subject of industry-wide efforts to quantify the status of its acceptance. The seminal survey on monitoring approaches was conducted in 2009 by CTTI and included questions about the status of RBM at that time.[20] In 2013, Metrics Champion Consortium

deployed a 20-question survey[21] to gather data on various types of RBM techniques. TransCelerate BioPharma released a position paper on RBM,[22] detailing the methodology for shifting monitoring from an excessive concentration on SDV toward risk-driven monitoring. The pressing need to move to less risk during the COVID-19 environment and studies has further fueled interest in remote or RBM, reducing physical contact, and easing the burden on doctors while still keeping them informed.

In the context of this background and a growing body of literature on the subject, our survey posed seven questions about sites' views of RBM. These questions gathered information on topics such as how many active trials are using RBM, whether analytics reports are being used, and more. Some of the others are:

- In your experience, what impact (if any) does RBM have on communication between sites and clinical research associate (CRAs)/ monitors when compared to standard monitoring studies?
- How much time do you spend resolving queries using RBM vs. traditional approaches?
- How often are sponsors sharing RBM metrics about site success?

Results show that RBM is used in a range of trials (Table 6), with most sites using it in 1-3 active studies (38.4%). In addition, a modest number of respondents (19.3%) claim to receive reports detailing analytics used to evaluate study risk. In comparison, approximately two-thirds (65.0%) do not receive reports, and the remaining 15.6% were unsure.

Survey participants mostly held negative views of RBM, with 58% reporting that it somewhat or significantly worsened communication among sites, CRAs, and other stakeholders versus traditional monitoring methods (Chart 3). Moreover, 51% of sites reported spending much more or a little bit more time resolving queries using RBM as compared to traditional approaches (Chart 4).

Finally, according to respondents, RBM offers little transparency to sites, as

Table 6

Active Trials Using RBM

Number of Active Trials Using RBM	Percentage
1 - 3	38.4%
4 – 6	23.2%
7 – 10	15.1%
>10	14.1%
Unsure	9.2%

n = 185

Chart 3

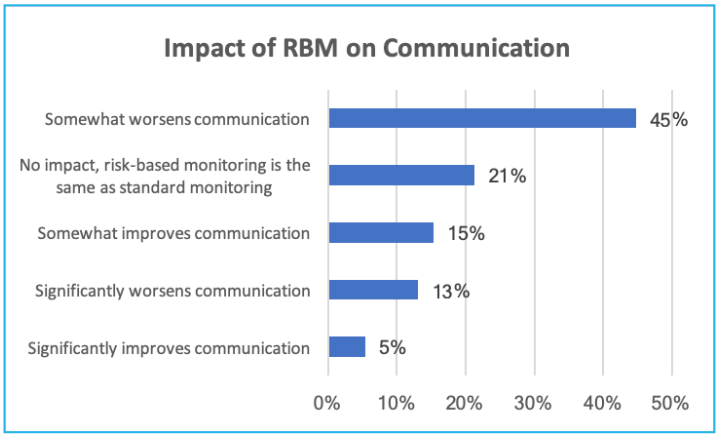
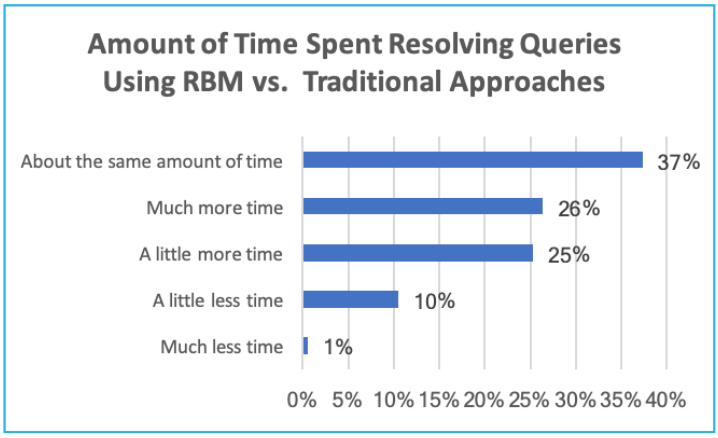


Chart 4



sponsors generally fail to share RBM metrics about site success (61.4%) or only sometimes share them (21.7%). However, the answer to the question of whether it would be helpful for sponsors to share this information with sites was a resounding yes (89.7%).

A Word about RBM

Sites are clearly interested in a simpler technology landscape, but the survey results indicate that RBM is not helping them achieve this goal. In light of the reported negative impact on communication among stakeholders and the need for more time to resolve queries, the question arises as to how sponsors and CROs can make RBM less burdensome on sites and also provide them with metrics that help improve study quality.

So far, RBM remains focused on sponsors who, in recent years, have been using analytics to identify risk more quickly. However, there seems to be a lack of widespread agreement as to how RBM can be best implemented, leading to wide variations in tools and methodologies. According to Agrafiotis et al.,[23] the non-prescriptive style of regulatory guidance plus limitations in technology and integration, issues in operationalization, and limited evidence of superior outcomes have hindered widespread RBM adoption. However, a system designed with quality-by-design principles, central monitoring, and triggered adaptive on-site and remote monitoring makes it possible to improve monitoring by shifting resources from higher-performing sites to those that underperform. Taking this approach in their studies from 2013 to 2017, Agrafiotis et al. found that RBM resulted in 28% fewer critical and major findings per clinical quality control visit as compared to conventional monitoring, 10% fewer critical and major findings per investigator site audit, and 29.3% lower median query resolution time.

Despite these findings, it remains unclear how RBM can reduce sites' burdens. Chart 2 shows that only 9% of respondents reported that their CTMS was integrated with RBM, suggesting that it is a standalone function at most sites. More research is needed to understand how sites can be brought into the discussion to determine what is needed for a well-designed, integrated RBM tool that can offer improved data quality and timelines for sites.

Looking Ahead to Artificial Intelligence and Machine Learning

For the most part, newer technologies such as artificial intelligence (AI) and machine learning (ML) are the domain of the sponsor and CRO. This is apparent in our survey, as respondents—all site-based—make virtually no mention of AI or ML in any of the open-ended questions.

As described in the literature, many sponsors view AI as transformative for operating models and stemming the decline in return on investment and R&D productivity.[24] There is discussion on how AI and machine learning can change this scenario by re-imagining the way clinical trials are designed and conducted. For example, machine learning models at M.I.T. were deployed to assist with COVID-19 modeling during the pandemic to predict cases.[25] Specifically, these technologies can help automate processes, make efficient use of big data, and improve early decision-making with predictive analytics – functions needed to boost the low volume of drug candidates who successfully complete the clinical trial process.

Researchers in the pharmaceutical industry and academia are embracing AI. Fueled by the massive volume of medical data available to researchers, including those provided by electronic health records and wearable devices, sophisticated ML algorithms have the potential to speed up medical advances and expand access to experimental treatments while saving billions of dollars.[26] As part of this effort, a branch of AI known as natural language processing (NLP) enables computers to analyze the written and spoken word. In the medical field, such techniques could allow algorithms to search doctors' notes and pathology reports for people who would be eligible to participate in specific clinical trials.

ML is promising as it can be used to review patterns in data and notify data managers if irregularities are found or if data are missing.[27] Furthermore, data from prior studies are available for ML algorithms and are a source of learning. For example, ML models can be trained to determine how long it will take to reach the enrollment target. They can also help determine whether a clinical trial is ready to reach a certain milestone and identify bottlenecks.

To date, AI and ML have barely translated to site

use, but that may change if there are more studies that utilize wearable or ingestible devices with the ability to send clinical data and adherence information to sponsors or CROs.[28] If this happens, both of these methodologies may eventually become part of sites' daily work as they seek to improve communications among stakeholders and improve their level of tech know-how.

Opportunities for Sponsors and CROs

As this survey reveals, sites want to be tech-savvy. But as they transition to a slew of digital technologies, sites want and need simpler ways to engage with them so they actually streamline work rather than create burdens. Answers to questions about the impact of technology on efficiency and the barriers sites encounter to adopting virtual trial applications highlight that sites are deluged with numerous standalone systems, each with its own portal, sign-on, and password. This reflects today's reality in which many solutions remain siloed and un-integrated with other functions even as sites make the move to cloud-based systems. As a result, data cannot flow across the clinical trial enterprise, meaning sites must enter the information multiple times in multiple systems.

This is where sponsors and CROs can take the lead. By adopting technologies that enable cloud-based, seamless trial management, they can share that experience with sites to simplify their efforts, starting with the application of an integrated Clinical Trial Management System. Interest in this functionality was one of the key findings of the survey, with 52% of respondents claiming to use CTMS in at least 50% of their studies, and 60% stating that CTMS had an "extremely" or "very positive" impact on site efficiency. CTMS came in second only to the widely-used EDC technology as being more prolific. Sites want to see CTMS provide more integration. Accounting and study start-up functions are frequently integrated, but EDC is not. In fact, according to respondents, it was only integrated with their CTMS 10% of the time.

RBM holds promise for sponsors in terms of providing actionable insights in real time compared to traditional methods of monitoring. In its current form, however, it holds little attraction for sites. However, the recent pandemic may have shifted how the industry moves forward. In deploying resources and capabilities to help all healthcare workers as they work to support patients, providers, communities, and health systems around the world, sponsors can share with sites the insight they gain from RBM. This action will provide specifically faster query resolution and fewer critical and major findings per visit, enabling a transparency that may go a long way toward improving how sites view RBM.

Looking ahead, sponsors are implementing AI and ML to manage big data in an effort to build more predictive and prescriptive algorithms. The survey showed that these intelligent automation solutions have yet to impact sites' daily work, but as COVID-19 modeling has shown, this may change going forward, as these tools can alleviate classic bottlenecks such as data modeling, patient recruitment, and study startup.

Technology has made an enormous improvement in the clinical trial process, including a fast turn toward "virtual" or decentralized trials. However, the survey clearly indicates that work is needed to create a seamless experience for the site, the sponsor, and (most importantly) for patients who are awaiting much-needed new therapies.

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