ISR reports | Pharmaceutical Market Research

Industry Perspectives On

Clinical Technologies

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This market research is available off-the-shelf in the form of our syndicated reports, but we also frequently take on custom research projects to help drug developers and service providers make data-driven decisions with their B2B partnerships, identify new market opportunities, and stay ahead of the competition.

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ISR reports

Smarter questions ∴ Smarter answers

Using Market Research To Get Ahead In Clinical Technology Development

ELIZABETH MANN AND JOCELYN REYNOLDS Market Research Manager

Clinical technology is a fast-growing, highly competitive arena with hundreds of vendors racing to win the prize: working with sponsors to facilitate faster clinical trials and ultimately deliver lifesaving therapeutics. Clinical technologies including IRT (interactive response technology), CTMS (clinical trial management systems), and EDC (electronic data capture) are under constant pressure to keep up with evolving needs in clinical trials, including supporting decentralized trials (DCTs) and developing the next generation of software. To gain more insight, Industry Standard Research has recently conducted four studies to understand the pharmaceutical industry's experiences with clinical technology providers.

One critical component of market research on clinical technology solutions is understanding which capabilities or attributes are the most critical to sponsor organizations when selecting a technology provider. **"Considerations When Selecting An IRT Provider"** presents some key findings from our IRT Benchmarking & Market Dynamics (4th edition) study. Although cost is traditionally a relevant factor in selecting technology providers, only 17% of sponsor and CRO respondents listed *Low cost* as a "Top 5" priority when selecting an IRT vendor. On the other hand, the study reveals that *Integration with EDC, ePRO, CTMS, and other data systems* is a very important factor, among others discussed in our first article.

Today's clinical trials require sophisticated data management systems, and sponsors rely on CTMS vendors to provide industry-specific platforms. Ideally, sponsors would choose a single vendor for all their CTMS needs, but usually, they work with multiple vendors. **"Why Are Sponsor Organizations Using More Than One CTMS Solution?"** draws from our CTMS Benchmarking & Market Dynamics (3rd edition) report. Sponsors dislike the complexities of juggling multiple vendors, but most have found they are unable to meet all of their trials' needs with a single solution.

The next article focuses on respondent predictions of how EDC solutions will evolve over the next two years. In **"The Future of EDC Systems,"** based on EDC Benchmarking and Market Dynamics (5th edition), our respondents anticipate that EDC providers will advance solutions that were unimaginable just a few years ago. Our survey's respondents reported two major innovations they wish to see from EDCs regarding their functionality in decentralized trials: improved data integration with other clinical technologies and direct data capture. Data integration across multiple platforms can slow down studies when disparate systems don't communicate or data must be manually cleaned. Sponsors want dashboards with real-time reporting and automated integrations to ease clinical site staff's workload and accelerate the drug development process.

Finally, what do smartwatches have to do with clinical trials? According to our Decentralized Clinical Trials Market Outlook study, quite a lot. Smartwatches, activity trackers, wearables, and smartphone apps collect a plethora of data points on users' health and lifestyle every day. With the rise of DCTs, these data collection devices are promising for clinical trials. Likewise, the emergence of electronic clinical outcome assessments (eCOA), including patient reported outcome (ePRO) systems, opens even more possibilities for DCTs. In **"Advancing Clinical Research with Advanced Technology,"** we present the technologies sponsors currently use and how they anticipate using them in the next few years.

The arena is crowded, but the potential winners are many. Clinical technology providers that utilize market research to improve their offerings will gain an edge over their competitors. Sponsors and CROs can use market research to identify better partners for their clinical trials, ultimately improving data quality and facilitating faster clinical trials. We invite you to consider our research as your personal trainer, providing the insider information you need to win the race. ISR

About The Authors

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Jocelyn joined ISR in May of 2021 and has been conducting quantitative and qualitative research since 2016. She focuses primarily on market research in the clinical development and clinical technology service provider market. At the start of her career, Jocelyn managed several large-scale government research projects at a boutique research firm for two years, where she was honored to receive the Burns "Bud" Roper award from the American Association of Public Opinion Research in 2017. More recently, Jocelyn led numerous customer survey projects across a variety of industries at a primary research firm.

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Welcome to

Industry Standard Research

INDUSTRY PERSPECTIVES ON CLINICAL TECHNOLOGIES

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Considerations When Selecting An IRT Provider

JOCELYN REYNOLDS Market Research Manager @ISRreports

Interactive response technology (IRT) systems are used to automate supply management, randomization, and analytics for clinical trials. They ensure participants receive the correct treatment at the correct time, allow for enhanced drug supply logistics tracking, and empower users to obtain real-time data from participants throughout the study. Accordingly, selecting the right IRT system is critical to trial success.

To create Industry Standard Research's October 2022 report, IRT Benchmarking & Market Dynamics (4th edition), we asked the decision makers at sponsor organizations and CROs to discuss the criteria they consider when selecting an IRT system. While the full report covers specific provider metrics in more detail (which IRT solutions are most frequently used, how they perform in key service areas), it also can be fruitful to learn how others in the outsourcing community are evaluating IRT providers.

Integration with EDC, ePRO, CTMS and other data systems topped respondents' selection criteria by a large margin; it was selected by nearly two-thirds of respondents (61%) as one of their "Top 5" criteria (Fig. 1). This is not surprising since, within the clinical technology ecosystem, the importance of integration across platforms cannot be overstated as data quality is paramount to clinical trial success.

Ease of use, for both the clinical team and the site team, was also highly rated, included among the "Top 5" attributes by more than one-third of respondents. Several aspects of the timeline and system build customization — including *Start-up timelines, speed of build* (44%), *Configurability for study setup* (25%), and *Flexibility for mid-study design changes* (22%) — also emerged as important selection criteria.

Another highly valued attribute in the IRT selection process is the ability to support a *Complex trial experience*. While only about 24% of survey respondents listed it among their "Top 5" most important attributes, nearly 9 in 10 respondents reported selecting different vendors for less complex vs. more complex builds at least some of the time, and very few indicated that they always use the same IRT vendor regardless of the study build complexity (13%). These findings indicate that sponsors and CROs are seeking IRT service providers that can configure the IRT system to accommodate unique trial needs and support differing levels of complexity.

Expanding on the role that trial complexity plays in vendor selection, respondents reported that they consider an average of three-quarters of trials to be moderately or highly complex. The reality is that even seemingly straightforward or early-phase trials might have complex randomization and trial supply management (RTSM) needs.

Therefore, providers that can accommodate highly complex studies set themselves apart from competitors. However, additional complexity often is accompanied by additional cost. While outsourcers generally value a number of selection criteria more highly than low cost (per Fig. 1, 17% of respondents selected *Low cost* as a "Top 5" concern), larger IRT providers may lose out to providers that offer a "no frills" model on the less complex studies.

Fig 1: Most Important IRT Provider Selection Criteria

"Please review the following attributes and select the five most important to you when selecting a provider for IRT services." NOTE: (n=108) Only responses included in the "Top 5" by ≥15% of respondents are shown.

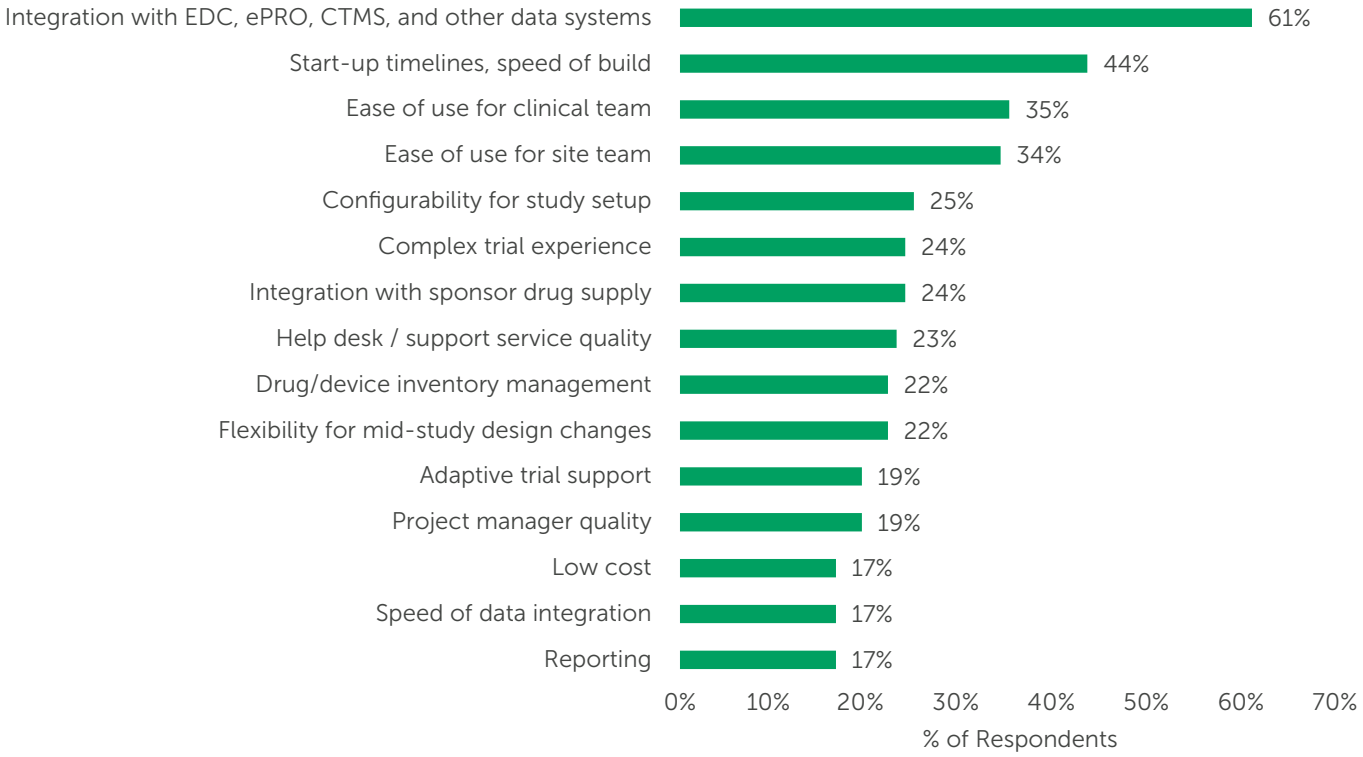
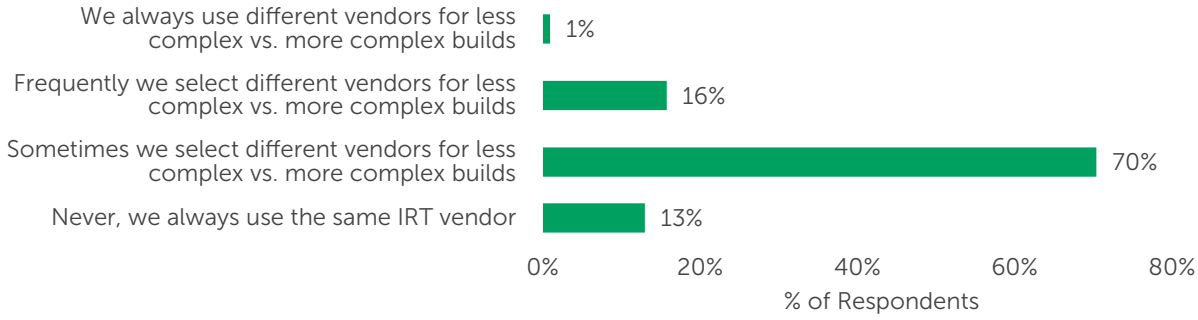


Fig 2: Role of Complexity in IRT Provider Selection

"How often do you select different IRT vendors based on the complexity of the study build?" NOTE: (n=108) On average, respondents consider 39% of trials to be moderately complex and 36% of trials to be highly complex.



TRENDS MOVING FORWARD

We expect IRT providers (including CROs that offer IRT services, dedicated IRT providers, and large integrated technology service providers) to continue focusing on integration with other clinical technologies — one of the industry's greatest challenges. Although integration certainly has improved, the outsourcing community continues to experience pain points managing multiple systems and thus prioritizes integration over many other selection criteria. This trend is exacerbated by clinical trials' ever-increasing complexity. ISR

Why Are Sponsor Organizations Using More Than One CTMS Solution?

JOCELYN REYNOLDS Market Research Manager @ISRreports

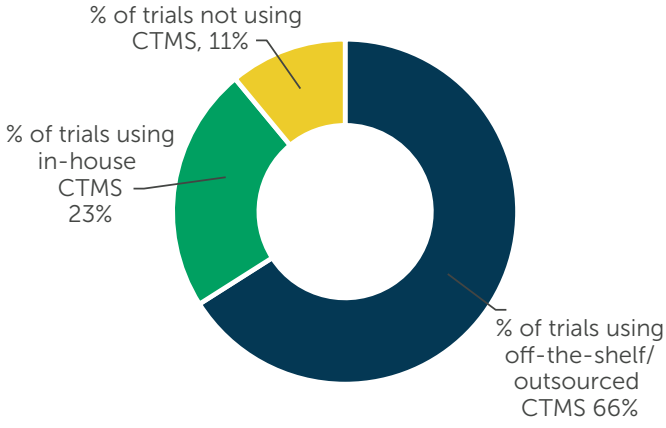
In our recent report on clinical trial management systems, CTMS Benchmarking & Market Dynamics (3rd edition)*, Industry Standard Research explores the evolution of the eClinical market and usage of CTMS in the outsourcing community. Amidst this rapid growth, it can be difficult to keep up with the requirements that sponsor organizations, CROs, and clinical trial sites have for their CTMS solutions.*

ISR has been conducting follow-up interviews with survey participants from our CTMS report to learn more about the nuances of the CTMS outsourcing landscape. Not unlike the dynamics of the broader clinical services ecosystem, we found that although some sponsor organizations would prefer to use only one CTMS provider, most research participants reported utilizing multiple providers. There are various reasons for this: CROs may require sponsors to use their own CTMS or a specific CTMS provider when working together on clinical trials; there isn't one tech provider that can satisfy all of their requirements; or certain CTMS solutions don't integrate well with in-house systems or other eClinical technologies.

Interviewee on using multiple CTMS providers:
"When you're running a big global study... we try to put as much of this onto the CRO, who we view as responsible for executing the trial, ... [including selecting] the various vendors which support the trial through them. Because then we can hold them clearly accountable and responsible for when something doesn't work. And as a small biopharma company, if [the CRO] is not happy with [CTMS provider], they have a lot more clout with those folks than we do." **- Small Pharma**

Interviewee on using a single CTMS provider:
"[We use one CTMS provider] just for consistency. We do use a number of CROs, so it's easier to bring their data into one system rather than trying to have their CTMS systems speak with a number of different ones that we are using." **- Top 10 Pharma**

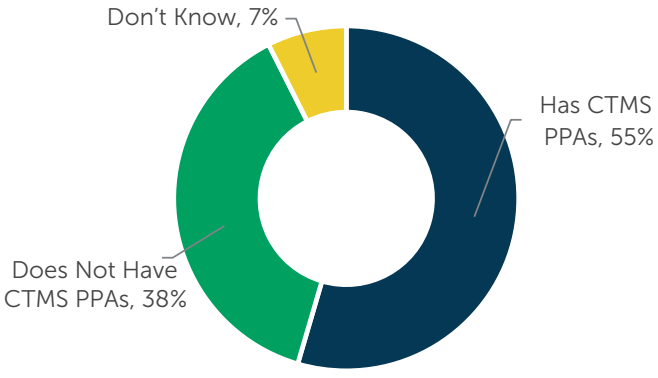
In the quantitative survey, we found that around two-thirds (66%) of clinical trials are currently managed with *off-the-shelf/outsourced CTMS solutions,* and a little under one-quarter (23%) are managed with *in-house CTMS.* Respondents expect these proportions to remain steady over the next two years.



These findings align with the qualitative interviews, where participants described that the capabilities of in-house systems are often limited and need to be supplemented with third-party CTMS solutions.

On average, 71% of respondents reported currently using three or fewer CTMS providers, and 29% used four or more providers. Only around one-quarter of respondents were currently using a single provider. Official preferred provider agreements also play a role in the selection of CTMS providers. Over one-half of respondents in the 2021 quantitative research indicate using PPAs to contract CTMS providers with an average of just under three preferred providers. However, these agreements are not without problems, as described by the interviewee below.

> *"So, the preference always is that we would like to go with one vendor, not multiple. But what happened is that we had to go [with a specific CTMS provider because of its capabilities], ...but we weren't satisfied with their other technologies. And then the sites ran into some difficulties... but [we're] continuing to use [that CTMS provider] because it's a preferred vendor of the company and the studies were ongoing at that time. It is difficult to discontinue or go to a new vendor and set up the process all over again."* – **Top 25 Pharma**



While reflecting on their current CTMS provider(s) and provisioning models, participants from sponsor organizations in both the quantitative survey and the qualitative interviews expressed myriad pain points in managing multiple providers as well as some of their unmet needs in working with single providers.

> *"I wish the systems would be able to talk [to each other] better. I don't have the behind-the-scenes [information] on how to make everything connect, but it just seems that we're collecting the same information. Why is it so difficult that two [different] systems can't talk to each other and have that seamless flow of data coming through, like for instance, number of sites activated, or number of sites closed? There always seems to be a lag or somebody always has to go in and manually correct it."* - **Top 10 Pharma**

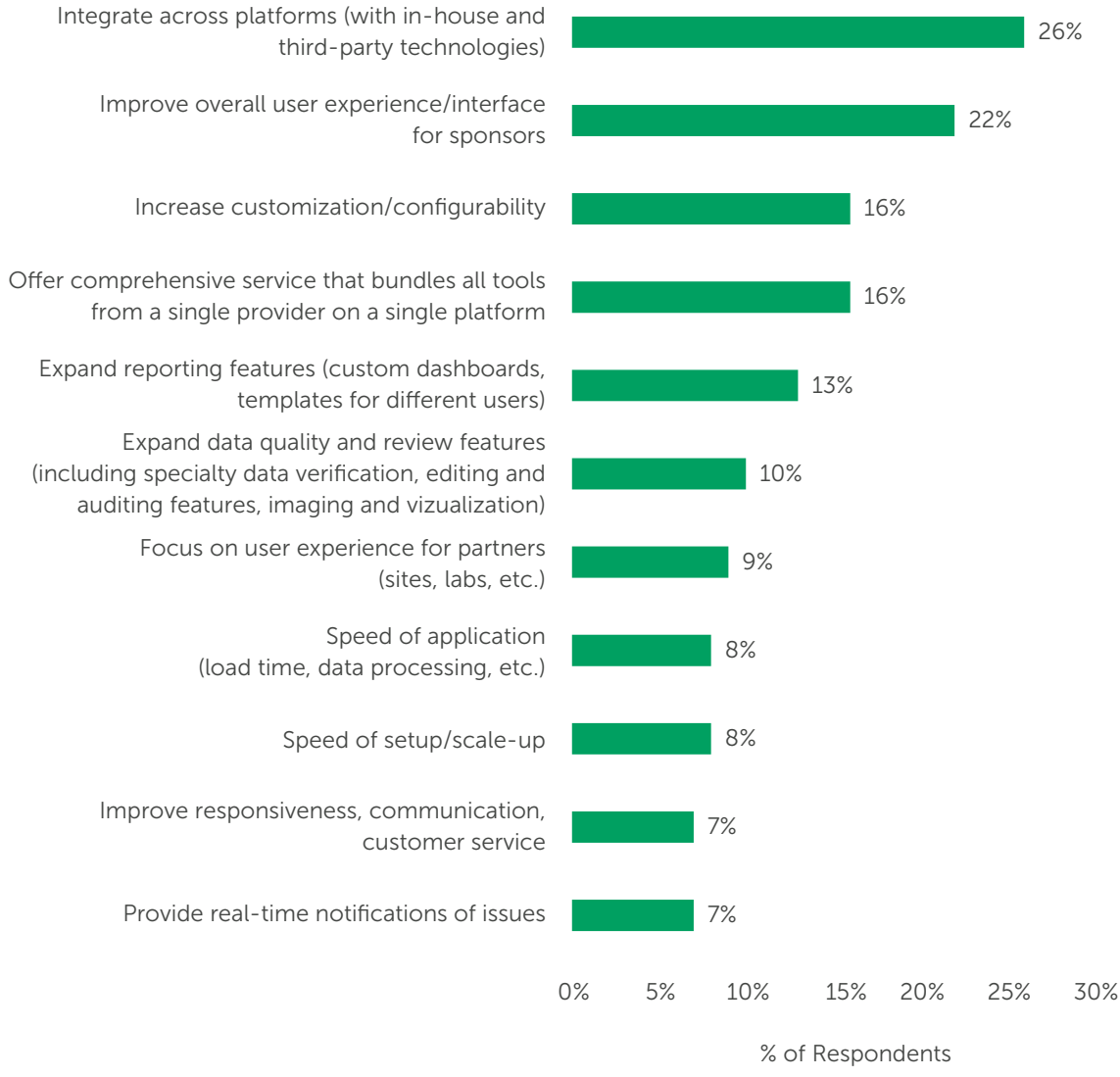
> *"The ease of the start-up is always much better with a single provider versus managing multiple [eClinical technology] providers and then integrating the data into one platform for the submission purposes. ...One headache we face all the time is the reconciliation integration. We have a couple of labs in Japan and in Egypt, and their reporting is not different. But the uploading of the data into the system is very challenging. And then we had to find some mitigation measures to get that information in a single platform."* – **Top 25 Pharma**

When asked what improvements they would request for the next generation of CTMS software solutions, survey respondents provided a wide range of detailed suggestions for CTMS providers. Over one-quarter of respondents felt that CTMS solutions needed to be better integrated with in-house systems and other eClinical technologies. As suggested by the interviewee below, improving user experience (including at the site level) and configurability of the solution are also very important for sponsor organizations.

> *"[That provider] is just not mature enough yet, but... has a lot more user-friendliness, including friendliness on the part of the person at the site. ...The easier you can make things at the site level, the more likely your study's going to get the attention above someone else's. Because when it's all said and done, the site personnel are the ones who control the site enrollment, how much emphasis they put behind getting patients to return for subsequent visits, all that other kind of stuff. And the easier you can make their lives, the more they're going to appreciate you as a company over somebody else."* – **Small Pharma**

Fig 1: Desired CTMS Improvements

"If you were in charge of developing the next generation of CTMS software solutions, what improvements would you make to existing products/ services?" (n=117, open-ended responses have been themed)



These high-level suggestions for improvement are well aligned with the provider-level feedback that respondents shared both in the quantitative survey and qualitative interviews. At present, although some sponsor organizations may prefer to work with a single CTMS provider or fewer CTMS providers in the long term, it seems that individual CTMS solutions may not currently be able to satisfy all of their clinical trial management needs. Not all of the CTMS solutions offer the same features or have the same strengths, which represents an area of opportunity for CTMS providers to differentiate themselves. By focusing on the capabilities that are the most important to customers, CTMS providers may be able to close the gap on unmet needs and emerge with solutions that fit for most – if not all – clinical trials rather than only some. ISR

The Future Of EDC Systems

JOCELYN REYNOLDS Market Research Manager @ISRreports

Electronic data capture (EDC) systems have been a part of the clinical trial ecosystem for several decades and are now one of the most mature clinical technologies on the market. However, there are constant pressures to evolve to support decentralized trials in a changing environment for data collection and data quality.

In our recent survey, *EDC Benchmarking & Market Dynamics (5th edition)*, ISR asked EDC users at sponsor organizations and CROs about the trends they expect to see over the next two years. Survey participants provided valuable suggestions for how EDC systems could keep up with decentralized clinical trials and expressed the importance of direct data capture.

DECENTRALIZED TRIAL SUPPORT

For the purposes of this research, we described decentralized trials as trials in which patients participate outside of a traditional clinical site (e.g., from home) for some visits/activities rather than exclusively in a clinical setting. When asked how well current EDC systems have met their needs to successfully execute a decentralized trial, roughly 9 out of 10 respondents (89%) indicated that their EDC systems did not completely meet their needs.

In describing their unmet needs related to EDC use in decentralized trials, approximately one-quarter of respondents mentioned that they would like to see better data integration with eCOA/ePRO, IRT, and eConsent systems (26%) and improved direct data capture from remote patients (26%). Respondents also suggested improving remote monitoring capabilities (11%), data quality (10%), and ease of use for sites (9%). As described in the verbatim responses below, EDC users value flexibility and improvements that reduce the burden on patients and sites.

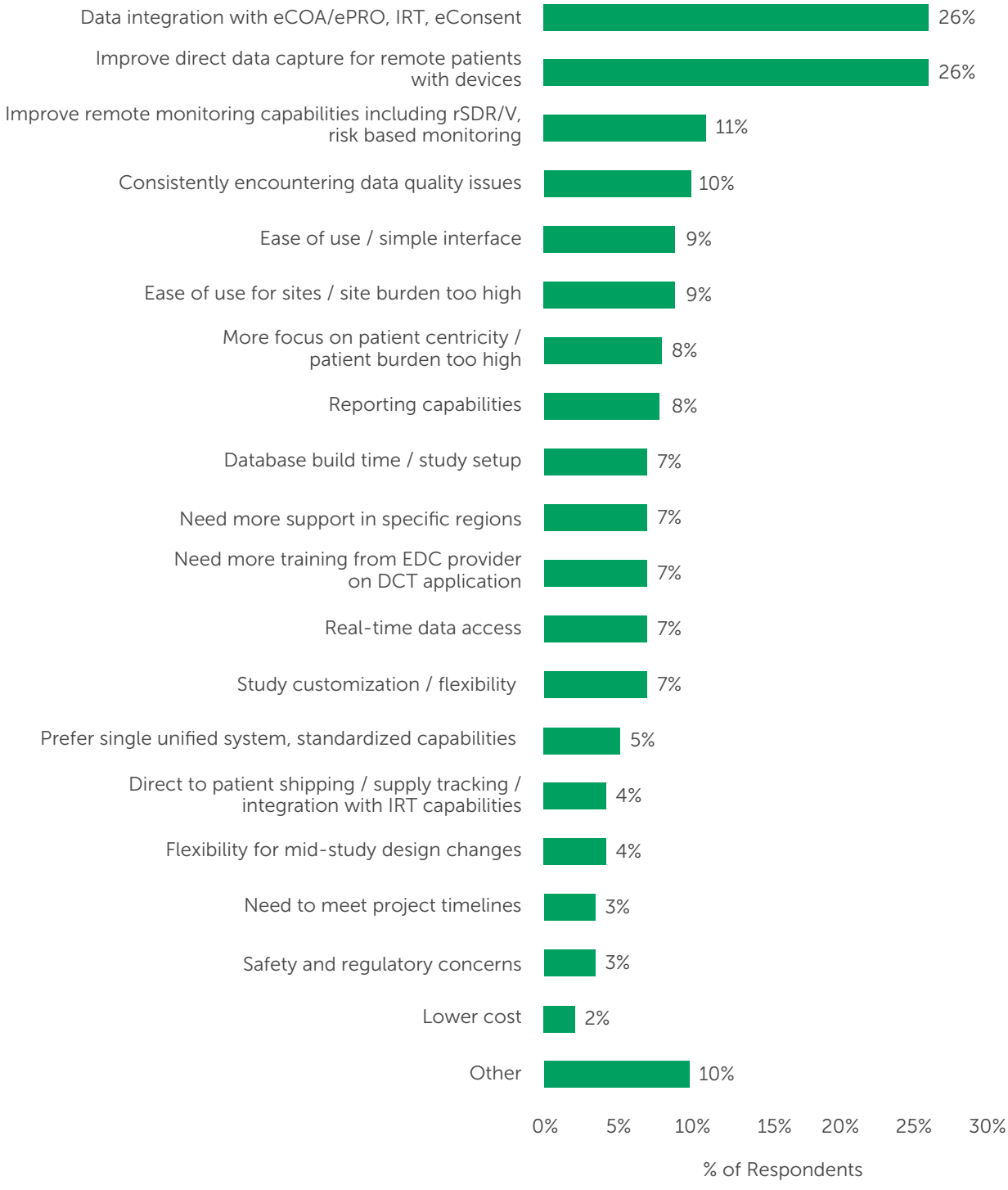
> *"Flexibility to have the possibility to record on-site visits and remote visits. Better dynamics to accommodate different situations and avoid missing data. Better accommodation for risk-based monitoring options. Better integration of external data and easier validation/reconciliation processes."*
>
> **–Small Sponsor, Clinical Operations**

> *"Better development of remote data entry options (e.g., smartphones, tablets) and integration with eCOA and wearables."*
>
> **–Large Sponsor, Clinical Operations**

> *"Input of data — site staff need more training. Site staff need more incentive to input data, e.g., easy interface."*
>
> **–Midsize Sponsor, Medical Director**

Fig 1 - Unmet Needs in Decentralized Trials – Themed

"What are your unmet needs related to EDC usage in decentralized trials?" (n=92, only asked of respondents with experience with decentralized trials and some level of unmet needs, open-ended responses have been themed)



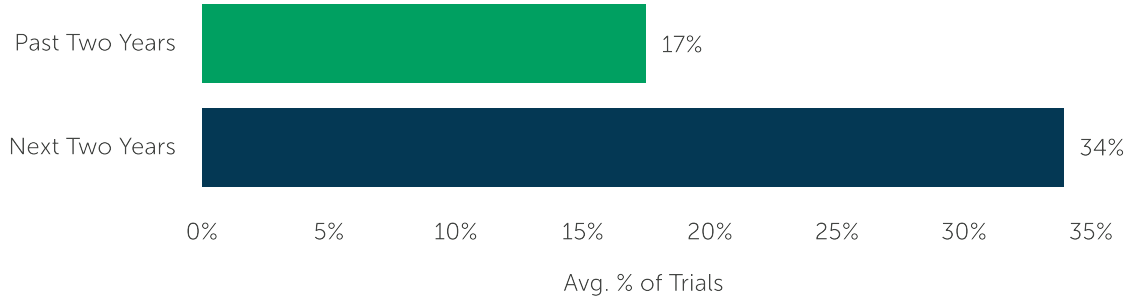
**Additional suggestions available in the report for purchase.*

DIRECT DATA CAPTURE

Industry experts and survey participants alike are excited about direct data capture, a method of capturing electronic data directly from patient devices and other systems. When asked about the proportion of clinical trials that collect patient data transmitted from sensors and/or wearables directly into the EDC system, respondents predicted a significant increase, from an average of 17% of their EDC trials over the last two years to an average of 34% over the next two years.

Fig 2 - Direct Data Capture from Devices

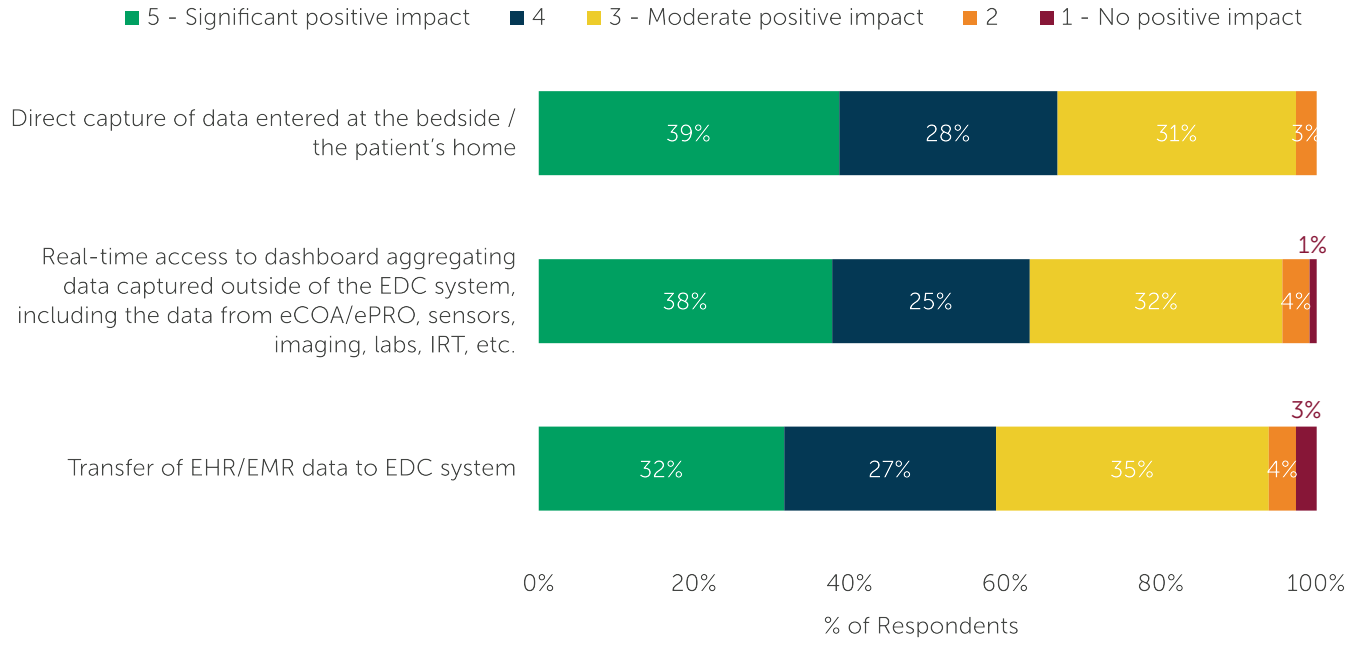
"What percentage of your EDC trials collected and will collect patient data transmitted from sensors and/or wearables (e.g., glucose meter, spirometer, activity meter) directly into the EDC system?" (n=114)



The direct data capture approach eliminates the need to download data from patient devices or transcribe documents; it also enables real-time access to data captured remotely. Underscoring the importance of patient centricity and ease of use for sites, the majority of respondents agreed that each of the trends described in the chart below would have a positive impact on the conduct of their clinical trials over the next two years.

Fig 3 - Expected Impact of EDC Trends on Trial Conduct

"How would the following EDC trends related to reducing site burden and improving patient oversight impact your clinical trials over the next two years? Please evaluate each trend on a scale of 1 to 5 where: 1=this would have no positive impact on the conduct of our trials and 5=this would have a significant positive impact on the conduct of our trials." (n=114)



**Responses sum to more than 100% due to rounding.*

For clinical technology providers looking to differentiate their offerings, it's important to note that EDC users will value capabilities related to real-time data integration. Looking to other industries, consumers of cloud-based technologies take for granted the seamless and instant integration of data between our smartphones and other devices, on our favorite online shopping sites, on our business platforms that automate day-to-day processes and track data, and the list goes on. Therefore, it's not surprising that sponsors and CROs expect the same of clinical trial technology providers.

In our research on various clinical trial software systems, we at ISR consistently hear that waiting for data to be communicated to other systems and dealing with data reconciliation are major issues. As seen in Figure 3, enabling clinical trial site staff to enter data from a patient's bedside or remotely at their homes and push data from electronic health records to an EDC system is likely to have a very positive impact on patient outcomes. Additionally, respondents expect the data entered in patient diaries, captured on biometric devices/sensors, gathered in labs, and managed by drug supply software to be available in real-time to facilitate faster clinical trials.

Although the road to developing and improving these capabilities is anything but easy, we anticipate that the next generation of EDC will focus on decentralized trials and direct data capture. Early adopters rejoice and luddites beware; updates to the traditional EDC systems are on the way. ISR

Advancing Clinical Research With Advanced Technology

LAURA MCWHINNEY Market Research Manager @ISRreports

Technology advances so rapidly, it seems that adapting to innovative technology takes more time than it does to actually develop the technology.

It was fewer than 30 years ago that we first heard those grating sounds of dial-up internet, connecting just long enough to send an email (electronic mail! How cool, we said). Fast-forward to today, and the streets have self-driving cars, we carry little computers in our pockets that can search the internet in seconds, and there are even robot hostesses that will lead you to your table when you dine out with family or friends. There is no question of the rapid advancement of technology.

When it comes to clinical trials for drug development, Industry Standard Research (ISR) wanted to understand the utilization of some of these technologies – such as patient-facing smartphone apps and wearables. We also wondered about the uptake in using and/or adapting to newer technology in the face of a global pandemic. Our *Decentralized Clinical Trials Market Outlook* study provides a larger overview, beyond the scope of technology. Understanding the utilization of, challenges with, and improvements needed for the technology in decentralized trials is just one aspect.

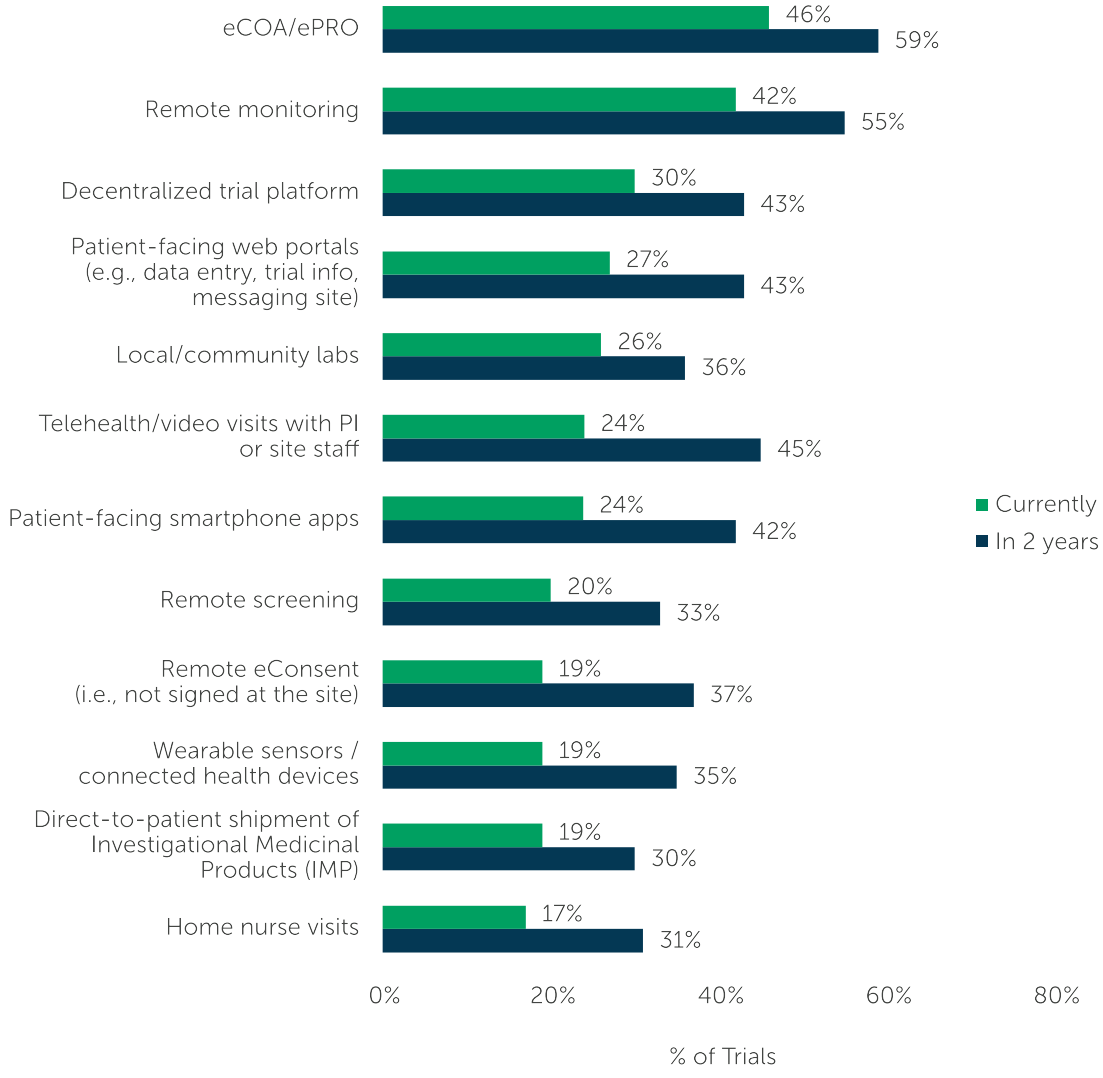
Decentralized clinical trials, also sometimes known as virtual or remote trials, have emerged as a promising approach to improve the efficiency, patient experience, demographic diversity, and cost-effectiveness of clinical research. These trials leverage innovative technologies to allow patients to participate in clinical trial activities from the comfort of their homes. During the third quarter of 2022, ISR collected data from biopharmaceutical professionals who were involved in at least one decentralized clinical trial within the past 12 months. Respondents in this study estimate, on average, that their companies are currently conducting 38% of trials using the decentralized model. They expect this to rise to 50% in the next two years.

Among the various technologies used in decentralized trials, electronic clinical outcome assessments (eCOA) and electronic patient reported outcomes (ePRO), as well as wearable devices, are examples of technologies that have been gaining attention as potential game-changers in the field.

eCOA/ePRO technologies refer to electronic systems that allow patients to report their outcomes, symptoms, and other relevant data remotely, using smartphones, tablets, or computers. These technologies offer several advantages over traditional paper-based methods, including increased accuracy, real-time data capture, and reduced burden on patients and site staff. In decentralized trials, eCOA/ePRO technologies can help to ensure that patients stay engaged and comply with study require-

Fig 1: Utilization of Decentralized Components

"What percentage of your company's current clinical trials utilize the following components? What percentage of your company's clinical trials will utilize these components in two years? Your best estimates are fine." (n=114)



ments, even if they are not physically present at a study site. Respondents in our research reported use of eCOA/ePRO most often in recent decentralized trials (46% of their company's trials, on average), and they expect increased use over the next two years (see Figure 1).

Wearable devices, such as smartwatches or activity trackers, have also become increasingly popular in decentralized trials. These devices can collect various types of physiological data, such as heart rate, sleep patterns, or activity levels, and transmit them to study databases in real time. This can help to provide more objective, continuous, and comprehensive data than traditional methods, as well as improve patient adherence and motivation. Respondents indicated 19% of their company's recent decentralized trials involved wearables but expect this to increase to 35% of their trials in the next two years (see Figure 1).

Wearables are among those remote components currently utilized least often, and yet, even among the least-utilized, these components are reported to be implemented in nearly one out of five decentralized trials, according to our respondents. Overall, use of each of these components is expected to increase over the next two years.

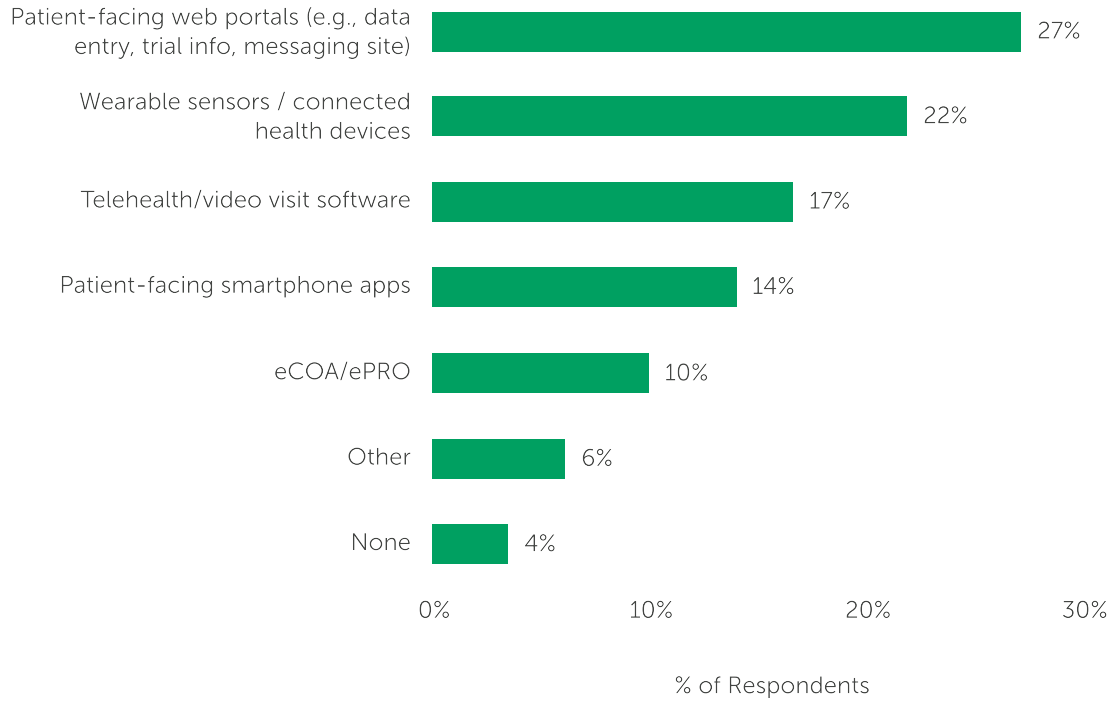
While decentralized trials offer many benefits, there are still several areas in which technology needs improvement to fully realize its potential. 66% of respondents believe that currently available clinical technologies only "somewhat", "slightly", or "not at all" meet their decentralized trial needs, leaving room for improvement in this area. The top two technologies needing improvement, according to respondents to our 2022 survey, are *Patient-facing web portals* and *Wearable sensors* (see Figure 2).

While our full report offers more detail from respondents, the key takeaways about technology improvement revolve around broader themes of ease of use and reliability. Decentralized trials generate large amounts of data that must be accurately collected, managed, and analyzed. One challenge is ensuring the validity and reliability of electronic data. Validation of the electronic devices and software used in decentralized technological components is critical to ensure that the data collected are accurate and reliable.

Another challenge is patient compliance with electronic data collection. While many of the decentralized components/technologies can help to reduce patient burden, some patients may struggle with the use of electronic devices or may have concerns about the privacy and security of their data. It is important to ensure that patients receive adequate training and support to use the electronic devices and software effectively and that patient privacy and data security protocols are in place.

Fig 2: Technologies Needing Improvement

"Which technology needs the most improvement to meet your decentralized trial needs?" (n=114)



Altogether, decentralized clinical trials offer many benefits, but there are still several areas in which technology needs improvement. Data collection and management, reliability and ease of use, and data security are just a few areas in which technology can play a vital role in improving the decentralized trial process. By addressing these challenges, technology can help facilitate the adoption of decentralized clinical trials and help to advance clinical research. ISR

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Where Did the Participants Come From?
Eliminating sample bias translates into accurate competitive information and improves service quality by ensuring your decisions are the right ones. Our Health Panel provides an array of participants from all company sizes within the pharmaceutical industry.

When Were the Data Collected?
This should be the first question you receive during a presentation and saying "I don't know" doesn't sound so good. In all our research products, we collect up-to-date data relevant to the project at hand.

Who Sponsored the Research?
We're an independent, third-party data source. We provide clean, unbiased data and clean data means you can confidently stand behind your analysis and presentations.

What is the Responsibility Profile for the Participants?
Nothing stops a presentation faster than management questioning the basis of your research. Confidently project the research knowing that we pull information from key decision makers.

What is the Background of the Analyst Who Managed the Project and Reporting?
We have experienced analysts with hands-on industry knowledge. Their insights can quickly be turned into fit-for-purpose recommendations for your organization.