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Introduction

In the years before the global coronavirus pandemic took hold in 2020, clinical development strategies and trends were already shifting towards greater globalization, digitalization, and patient centricity. This shift, while slow, could be seen in multiple arenas: regulatory guidance advising on incorporating patient perspectives in trial endpoints such as the U.S. FDA's 2021 draft guidance on the use of patient-reported outcome measures (PROMs) in oncology trials; sponsors' initiatives on including more diverse patient populations; and rapid digitalization of business processes, enabling new approaches to trial conduct and patient engagement. The onset of the pandemic only accelerated the effects of these concurrent trends and factors, facilitated by technology.

Decentralized Clinical Trials (DCTs) saw a rapid uptick as patients were unable to travel to study sites due to travel restrictions and quarantines. This model of clinical trial design and conduct allows for certain activities (as specified in the clinical trial protocol) to take place away from traditional clinical research sites. It may come as a surprise to some that this model has existed for over twenty years, long before pandemic mitigation restrictions were put in place.

While DCT technologies have enabled patients and sites to participate in novel and innovative ways, there is a lack of qualitative and quantitative data on site perspectives on the use and implementation of these initiatives. To examine how this model has impacted site experiences, Medidata partnered with the Society for Clinical Research Sites (SCRS) to survey its members on a variety of DCT topics, including scope, perceived effectiveness, and enablement. Understanding clinical research sites' experiences and perspectives on DCTs will help industry stakeholders – from sponsors and clinical research organizations (CROs) to regulatory agencies – refine trial design, operational procedures, and regulatory policy to better serve patients and sites while optimizing outcomes for the global health community.

Defining DCTs and Baseline Experience

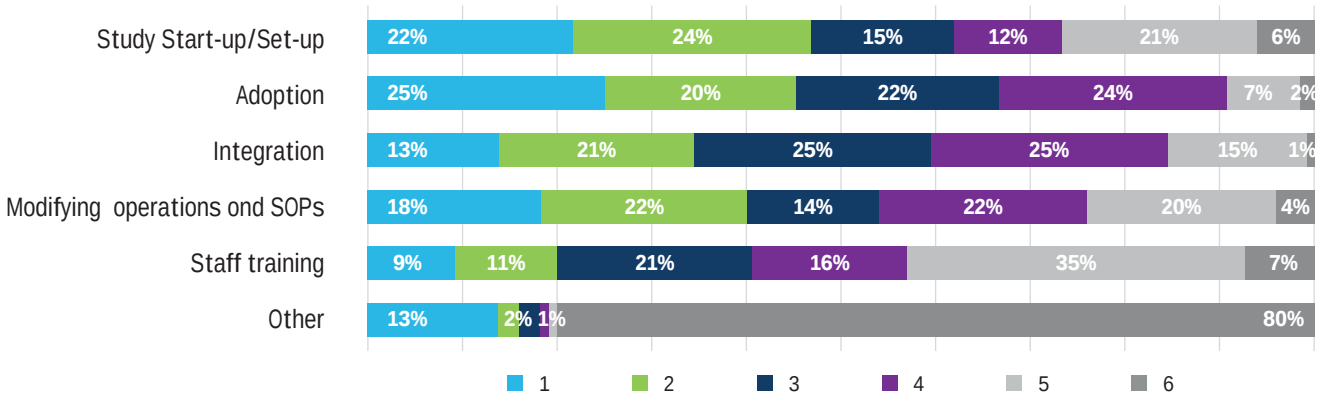
The FDA defines DCTs as a clinical investigation where some or all of the trial-related activities occur at a location separate from the investigator's location. Using technology, patients remotely engage in their trial activities, creating better patient experiences while enabling sponsors to execute faster, smarter trials driven by high-quality data, allowing for the utmost confidence in data collection and submission. Medidata DCT is an ecosystem of tools, people, and processes that allows patients, sites, and sponsors to participate, contribute, and monitor any clinical trial.

To understand if sites' definition of DCTs align with the FDA, respondents were asked to comment on their perception of a DCT. Survey participants offered a wide range of definitions. Some agreed with the definition offered, while others described the conduct or benefit of these trials, explaining that decentralized clinical trials "allow for visits to be completed at alternative locations," "take the burden off patients traveling to site," and enable "more remote visits, fewer on-site visits, [and] medications delivered to home."

Some respondents mentioned the tools or solutions that facilitate decentralized trial activities, including remote monitoring and study data collection, electronic diaries, and study visits completed at home via telemedicine, as well as tracking software to collect data on vital sign measurements. Another cohort of respondents expressed frustration with DCTs, saying that they entail "less interaction with patients," raise questions about safety or regulatory concerns, and result in more complications for sites.

These varied responses suggest that definitions of decentralized or hybrid clinical trials are ever evolving and dependent on one's role in clinical research, while also underscoring that a single, unified definition has yet to coalesce across the industry. What is clear from sites' perspectives is that decentralized clinical trials leverage technology to capture data and replace activities traditionally done at sites, but that they also require greater safety and adherence oversight, reduce site staff interactions with patients, and often add uncompensated work for sites.

Figure 2. Please rank the following challenges your site has faced as it pertains to the adoption of DCTs from most challenging to least challenging.



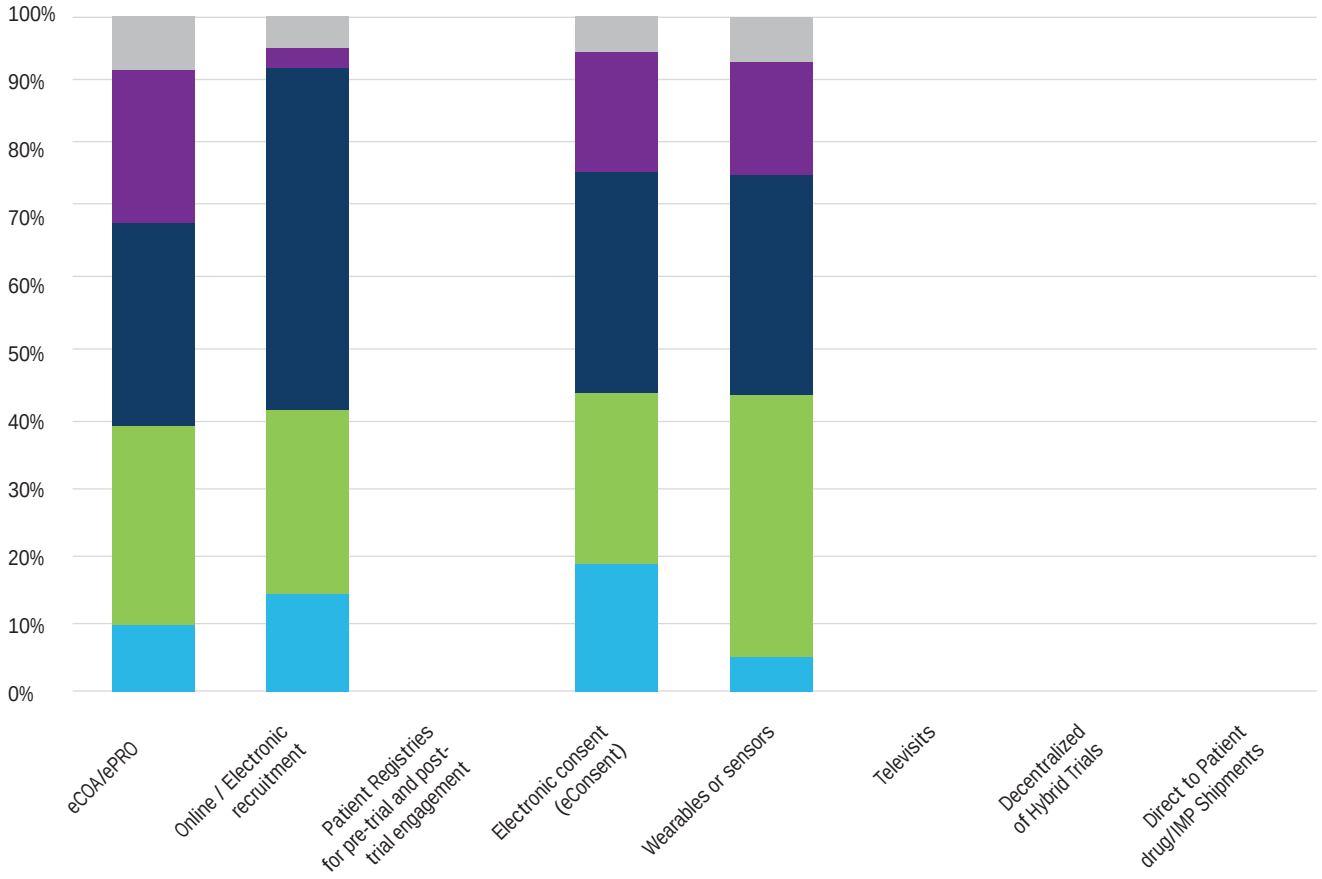
To understand what drives these perspectives, the survey asked respondents about their experiences and challenges with respect to conducting DCTs (Figure 2). Nearly two thirds of survey participants said they had participated in hybrid or decentralized trials, reporting that their top challenges in adopting this trial model included overall adoption and study startup activities. Integration, as well as modification of operations and standard operating procedures, ranked closely after that, suggesting that new technologies and processes introduced complications. However, despite such challenges, sites recognize the benefits that DCTs offer in terms of offering access to broader patient populations, as well as improvements to patient experience, diversity, and retention.

Of the 33% of sites who had not conducted hybrid or decentralized trials, most responded that they lacked the finances, patient population, staff, or technology required. Some suggested that they preferred and continued to see patients in person, or that they had concerns about oversight and regulatory or legal issues.

User Experience

Building on this understanding of sites' technology usage, the survey asked participants to report on their satisfaction with these solutions or groups of solutions. More than 50% of sites reported a somewhat or extremely positive experience with eCOA, electronic recruitment solutions, patient registries, eConsent, televisits, and direct-to-patient supply solutions. However, 29% reported somewhat or extremely negative satisfaction levels with eCOA, and 30% said the same for eConsent and decentralized clinical trial solutions. Interestingly, most respondents reported positive, very positive, or neutral levels of satisfaction with all eight categories of solutions, suggesting these technologies do add value to clinical trial operations for sites.

Figure 5. Please rate your patients' experience using these solutions or groups of solutions



To gauge the impact of technology on clinical trial participants, the survey also asked sites to rate their patients' experiences with the same technologies. More than half of sites reported that televisits (56%) and DtP drug/IMP shipments (50%) were extremely or somewhat positive experiences for their patients, while decentralized or hybrid trials and patient registries (27% each) were the lowest rated under positive experiences. Of the responses for somewhat

Considerations and Factors Impacting Technology Adoption

With this clearer picture of sites' and patients' experiences, expectations, and satisfaction regarding digital enablement solutions, we can now look at the factors both driving and preventing technology adoption. Of the sites which currently use the aforementioned technologies, 18% cited staff workload and technology complexity as the top two factors limiting their utilization of eCOA solutions, while 15% cited training requirements as a top limiting factor (Table 1). For sensors and wearable technologies, the most significant factor is training requirements, followed by time and technology complexity.

Table 1. Based on the solutions you selected, what factors, if any, currently limit your usage of these solutions or groups of solutions?

eCOA/ePRO	
Online / Electronic recruitment	
Patient Registries for pre-trial	

In terms of future utilization, a significant cohort of respondents said staff workload and time are the primary impediments to employing electronic patient registries, while infrastructure upgrades and revisions to standard operating procedures are noted as the top two limiting factors for the usage of televisits (Table 2).

Notably, "nothing is limiting our use of this tool" was cited as a top-tier response for both current and expected solution utilization. Although sites have reported in this survey and others that decentralized clinical trials result in additional uncompensated costs and significant changes in process, they only marked "cost" as one of the top impediments in one instance for both current and future technology adoption. This suggests that the benefits of technology and of decentralized clinical trials, in general, outweigh the costs, and it provides insight for sponsors and clinical research organizations who may be looking for specific ways they can support sites conducting hybrid or decentralized trials. Some sites responded that they would prefer their own in-house solutions over a sponsor's, CRO's, or third-party vendor's solutions; this response may prompt dialogues among stakeholders about investing in, implementing, and managing technology infrastructure that fulfills their sites' needs.

Table 2. For the solutions or groups of solutions, you do NOT currently use, what factors, if any, would limit your usage of these solutions in the future?

eCOA/ePRO	**13%**	**19%**	**13%**	**13%**	6%	6%	6%
Online / Electronic recruitment	0%	6%	**17%**	**17%**	**17%**	11%	11%
Patient Registries for pre-trial and post-trial engagement	**18%**	8%	**28%**	**15%**	5%	5%	5%
Electronic consent (eConsent)	7%	7%	10%	0%	10%	**12%**	**20%**
Wearables or sensors	3%	7%	3%	3%	**14%**	**17%**	7%
Televisits	0%	0%	4%	0%	**27%**	**19%**	**27%**
Decentralized of Hybrid Trials	5%	8%	8%	18%	8%	**13%**	**21%**
Direct to Patient drug/IMP Shipments	4%	4%	9%	4%	6%	**20%**	**24%**

Other DCT Technology: Remote Monitoring Solutions for Source Data Verification and Reviews

Another technology solution that enables remote trial conduct, off-site clinical trial monitoring systems, are increasingly utilized to enable remote source data verification (SDV) and source data review (SDR). More than half of sites believe this technology to be a viable solution for data quality and patient safety oversight. Of the 43% interviewed in this survey who do not currently use this solution, most said it is because sites are not compensated for the additional activity and costs associated with it. They also reported that the lack of integration between EHR, EMR, imaging, and EDC systems makes this solution impractical for SDV/SDR. Others suggested that their technology or processes are not prepared to support remote monitoring for SDV/SDR or described concerns about increased risks, complications, and reduced communication among stakeholders.

Sites that utilize remote monitoring solutions for SDV and SDR reported that it facilitates efficient engagement with clinical research associates (CRAs), reduces inspection findings, and helps remediate issues cited in inspection findings.

The most challenging aspects of utilizing remote monitoring for source data verification and reviews are related to document management (e.g., scanning, uploading, or exporting documents), lack of integration between systems, and managing CRA access to EHR/EMR systems.