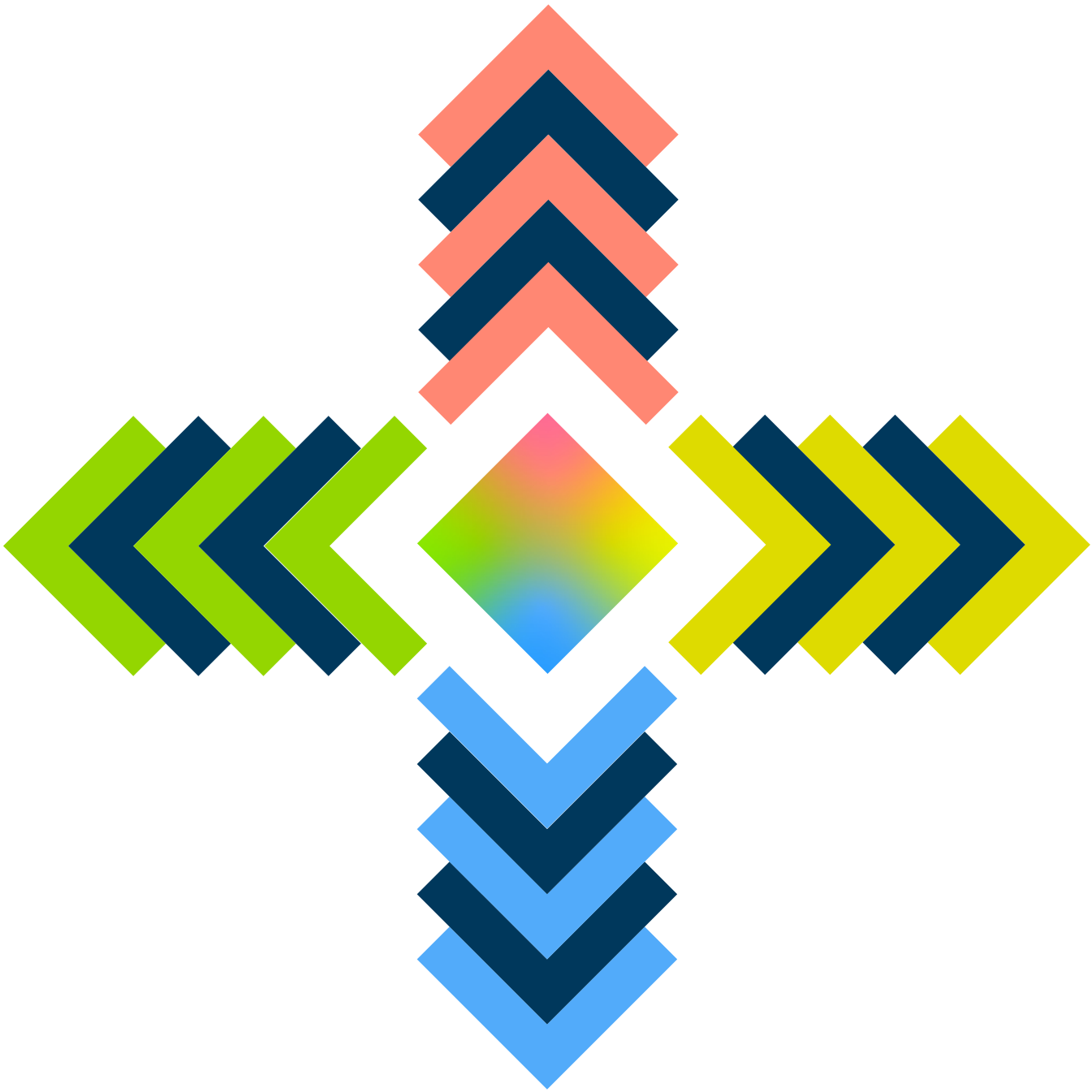
Delivering on the Promise of Decentralized Trials: Unexpected Perspectives from Clinical Research Professionals



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INTRODUCTION

There has been plenty of fanfare around decentralized clinical trials (DCTs), and it seems everyone has a view about their performance. But there has been a startling lack of inclusion of the perspectives from the clinical research professional workforce at the site level—the very people who implement the trials and are the stewards for patient interactions and study quality.

There are guidances for sponsors and clinical research organizations (CROs) and guardrails for use of digital health technologies with trial participants. However, between these trial initiators and study participants are site-based clinical research study management experts, who make trials work—and work well—on a day-to-day basis. These experts have essential roles from recruiting patients and protecting their safety to capturing data and ensuring its integrity to preparing study reports.

> *"Clinical research professionals who conduct trials are crucial for high-quality implementation of DCTs. Their perspectives are critical."*
>
> **SUSAN LANDIS**
> **Executive Director, ACRP**

While a rapid increase in studies using DCT elements was a practical response to the COVID-19 pandemic, it is clear that these new approaches to data collection and study designs would have lasting effects throughout the clinical trial enterprise. The long-term impact of COVID-19 on the research workforce, decentralized data collection, and many traditional clinical trial functions remains to be seen. However, it is clear that clinical research professionals at the site will have to adapt to the requirements of these decentralized approaches.

To assess the realities faced by clinical research professionals at clinical research sites in adopting DCTs, the Association of Clinical Research Professionals (ACRP) partnered with Medable Inc., the leading software provider for patient-centered clinical trials, and Advanced Clinical, a clinical development organization managing decentralized trials, to conduct a survey to document the perspectives of the professional workforce that helps to make DCTs work. The survey was carried out by Continuum Clinical (Northbrook, Illinois).

The ACRP DCT Membership Survey supplements findings from an ACRP DCT Think Tank, sponsored by Medable, Advanced Clinical, and Syneos Health, the only fully integrated biopharmaceutical solutions organization. Entitled *"Empowering the clinical research workforce to transform clinical research,"* the think tank was held on October 20, 2022, and included 42 participants from multiple clinical trial stakeholder groups, including sites, clinical research organizations, academic research organizations, healthcare providers, pharmaceutical companies, and regulators. ACRP will publish a white paper on the findings of the think tank, including the leading barriers to adopting DCTs at the site level and proposals to address them.

"Now is the time to build on the progress we made over the past few years to ensure we truly transform how clinical research is implemented. Innovative solutions that are informed by all stakeholders help to build trust and ensure that new ways of doing things are readily and quickly adopted."

MOHAMMED ALI
Chief Domain Expert, Medable

"The adoption of DCT components allows us to cascade productive and positive change throughout many areas for the sites and their patients, including ease of participation, process improvements, revised budget models, and review of regulatory requirements. This is a real opportunity to make systemic improvements."

CAROLINE REDEKER
SVP, Corporate Development, Advanced Clinical

RESEARCH METHODOLOGY

The ACRP DCT Membership Survey was conducted from August 24 to September 14, 2022, with a total of three survey deployments. The survey, conducted by Continuum Clinical, was sent to study coordinators and other site personnel in the ACRP membership database in the United States. To qualify, survey respondents had to work at a site that conducts clinical trials. Job titles for those who received the survey include clinical research coordinators (CRC) or study coordinators (SC), research managers/directors, Principal Investigators (PI), research or data analysts, and other roles.

SURVEY RESPONDENTS PROFILE

- 745 respondents entered the survey and 291 qualified and completed it.
- Among the total sample of respondents, 47% were clinical research coordinators or study coordinators, 29% were research managers/directors, 6% were Principal Investigators and 3% were research or data analysts. A wide variety of other site staff roles (16% in total) completed the survey, including regulatory affairs, pharmacists, various nursing roles, sub-investigators, research assistants, quality managers, clinical research educators, and directors of operations.
- 59% say their research staff only conducts activities onsite, and 38% say their research staff does both onsite and offsite activities (hybrid model). There was extremely low offsite-only representation, and very few respondents had access to non-research staff to conduct offsite activities.
- 44% of respondents work at an academic institution, 21% work at a private practice/clinic, while another 21% work at a research-only site.
- The vast majority of respondents (96%) say their site works with more than one sponsor at the same time.
- 44% say their site is currently conducting 10 clinical trials or less, while 41% say their site is currently conducting 21 clinical trials or more. 57% of sites are running more than 10 trials at once.
- On average, respondents report spending most of their time conducting study visits and managing study documentation/updates. They spend the least time managing payments.
- 58% of sites use at least three technology platforms as part of running DCTs.

DATA INTERPRETATION

Throughout the report, data interpretation for areas with statistically significant difference at a 95% confidence level is indicated in red upper-case letters. Directional differences at a 90% confidence level are indicated by red lower-case letters.

DEFINING DCTs

For the purpose of this survey, DCTs are defined as studies "executed through telemedicine and mobile/local healthcare providers, direct-to-patient shipments, and using processes and technologies differing from the traditional clinical trial model only at the site."

RESEARCH KEY FINDINGS

The ACRP DCT Membership Survey revealed valuable insights from clinical research professionals who work at sites:

DCT technology utilization lags behind other trial technologies

- Less than half of sites say they have clinical trials that use DCT components/services
- Remote technologies, with potential to help patients and sites, are rarely used

Sites that use DCT elements spend more time on trial delivery activities than sites that do not

- Some sites need frequent support and experience issues collaborating with stakeholders

Site perceptions strongly influence DCT acceptance

- Many technologies are not single sign-on (SSO)-enabled
- Sites lack the training and budget necessary to implement DCTs effectively

What percentage of your site's clinical trials use decentralized clinical trial (DCT) components/services?

DCTs are not a daily reality for sites. Nearly half of sites (47%) surveyed say that 1-25% of their clinical trials use DCT components/services, while 41% of sites say that none of their trials use them. Only 12% of sites indicate that more than a quarter of their clinical trials use DCT components/services.

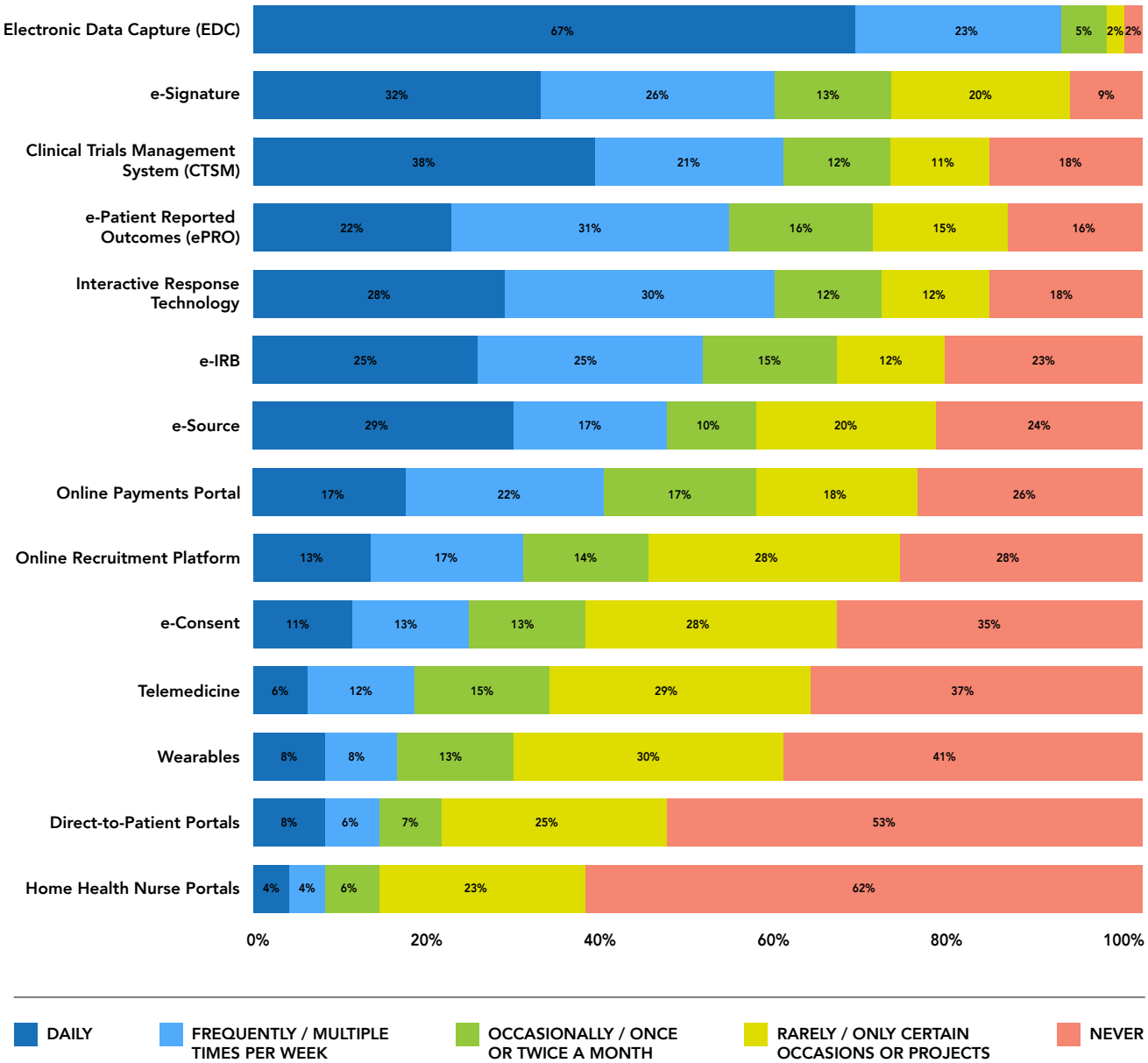
Total	N=291
0%	41%
1-25%	47%
26-50%	7%
51-75%	3%
76-100%	2%

Estimate how often your site uses each of the following technologies.

Sites report using emerging DCT technologies much less frequently than "operational" technologies. Among the total sample, sites use Electronic Data Capture (EDC) more often than any other technology by a significant margin. Most sites use EDC either daily or frequently/multiple times per week.

E-Signature, Clinical Trial Management Systems (CTMS), e-Patient Reported Outcomes, and Interactive Response Technology are the next most frequently used DCT technologies. More than half of sites say they use these technologies daily or multiple times per week.

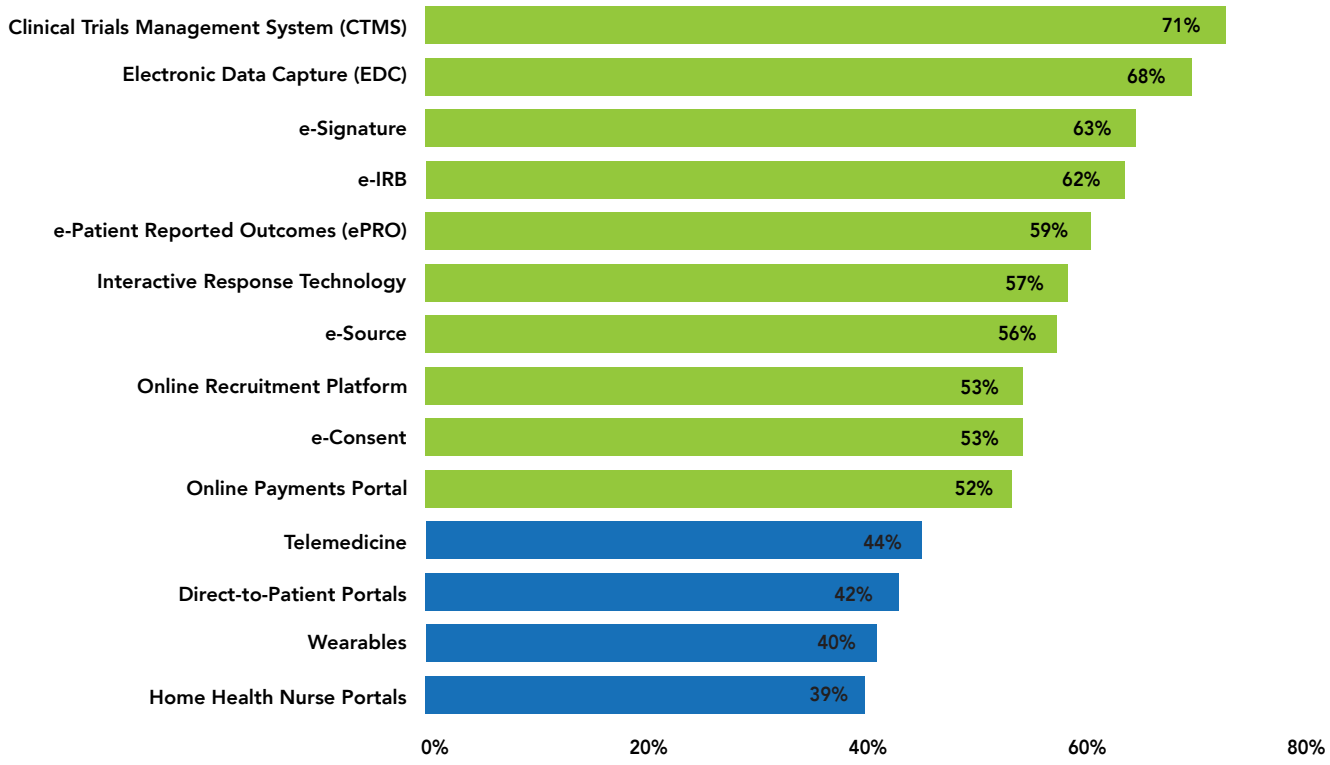
Emerging technologies like telemedicine, wearables, direct-to-patient portals, and home health nurse portals are used far less often (most sites say they use them rarely or only on certain occasions or projects).



Of the technologies listed, please indicate whether the ones you work with are SSO-enabled.

SSO is a common tech feature that improves ease of use and facilitates adoption, but the emerging DCT technologies that are less frequently used often lack this as standard.

% Always or Mostly Single Sign-On Enabled



Here are the full data for each item (sample size per column is respondents that use each technology):

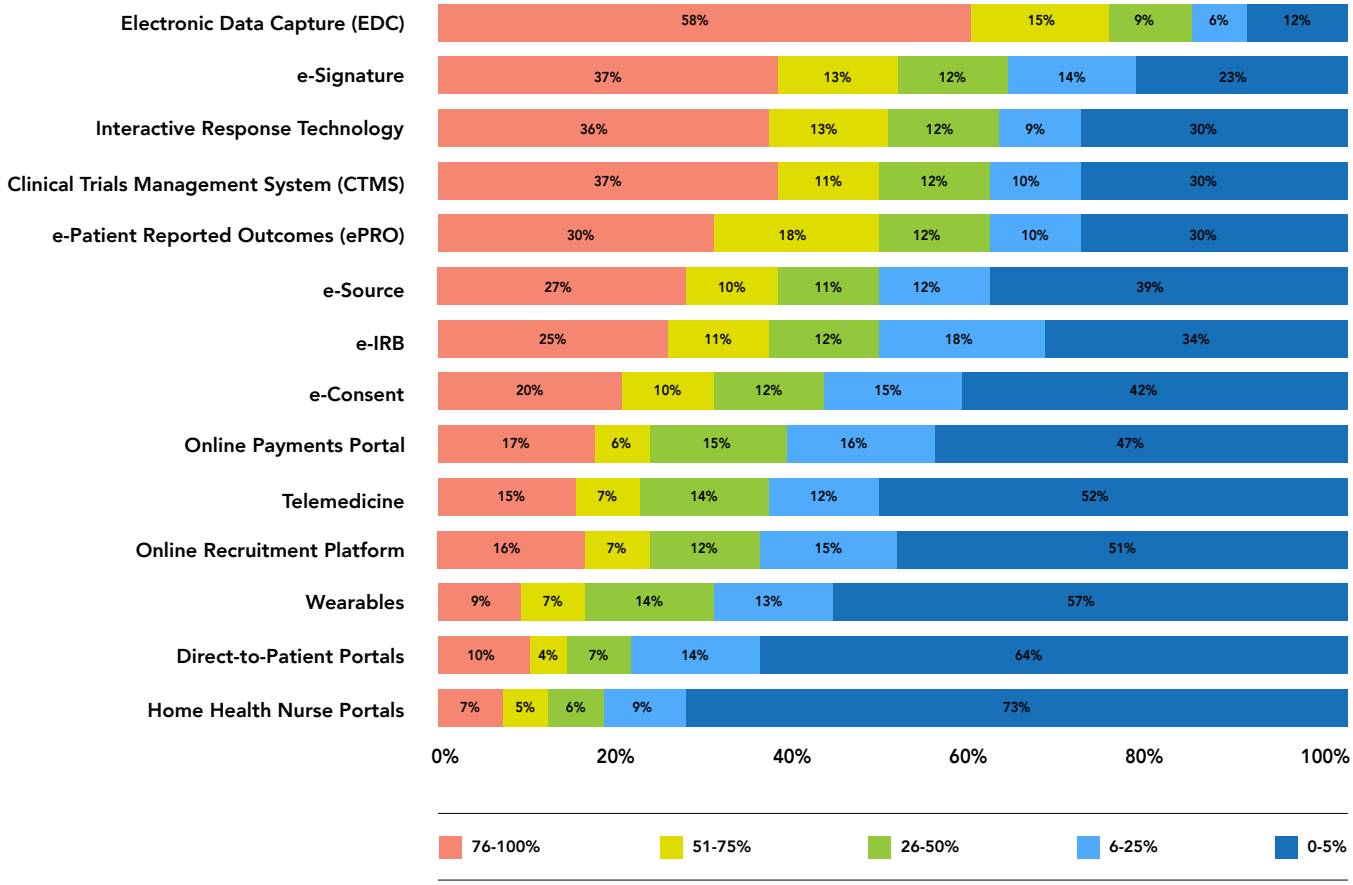
	Online Recruitment Platform A	Clinical Trial Management System (CTMS) B	e-Consent C	e-IRB D	e-Patient Reported Outcomes (ePRO) E	Electronic Data Capture (EDC) F	e-Signature G	e-Source H	Interactive Response Technology I	Online Payments Portal J	Telemedicine K	Home Health Nurse Portals L	Direct to Patient Portals M	Wearables N
Total	100% 164	100% 220	100% 154	100% 205	100% 213	100% 263	100% 236	100% 186	100% 211	100% 174	100% 137	100% 80 *	100% 113	100% 128
[1] Always SSO Enabled	29% n 47	47% ACEhIJKLMN 103	33% KLmN 51	41% AjKLMN 85	34% KLMN 73	44% ACEJKLMN 115	42% AcjKLMN 98	38% aKLMN 71	37% aKLMN 78	32% KLmN 56	22% 30	20% 16	23% 26	20% 25
[2] Mostly SSO Enabled	24% 39	24% 52	20% 31	21% 44	25% h 53	24% 62	21% 50	18% 33	20% 42	20% 34	22% 30	19% 15	19% 21	20% 25
[3] Occasionally/Rarely SSO Enabled	25% BD 41	17% 37	26% BD 40	16% 32	22% 46	19% 51	20% 48	27% BDFg 51	26% BD 54	28% BDFg 49	24% bd 33	29% BDf 23	28% BDfg 32	30% BDeFG 38
[4] Never SSO Enabled	23% BF 37	13% 28	21% BF 32	21% BF 44	19% bf 41	13% 35	17% 40	17% 31	18% 37	20% Bf 35	32% aBCDEFGHIJ 44	33% aBcdEFGHIJ 26	30% BcdEFGHIj 34	31% aBCDEFGHIJ 40

What percentage of your site staff is trained on each of the following DCT technologies or capabilities?

Sites report that significantly more of their staff are trained on "operational" technologies than emerging DCT technologies (telemedicine, home health nurse portals, wearables, direct-to-patient portals). 73% of respondents reported more than half of their staff being trained on EDC.

Roughly half of respondents indicate that at least half of their staff is trained on e-Signature, Interactive Response Technology, CTMS, and ePRO.

For nine DCT technologies/capabilities, more than half of sites indicate that 25% or less of their staff is trained on them. These include home health nurse portals, direct-to-patient portals, wearables, online recruitment platforms, telemedicine, online payments portals, eConsent, electronic institutional review board (e-IRB), and eSource.



Indicate what percentage of time you and your site staff spend conducting each of the following clinical trial delivery activities.

Whether sites have adopted DCT components/ services or not, they are likely to spend most of their time conducting study visits or managing study documents/updates.

On average, sites that report using DCT components/ services consistently spend more time on almost all clinical trial delivery activities than sites that do not.

Key for Averages	
5% or less	1
6-10%	2
11-25%	3
26-50%	4
51-75%	5
76% or more	6

	Total (A)	0% Trials use DCT (B)	Some trials use DCT (C)
Total	**N=291**	**N=118**	**N=173**
Conducting study visits	4.27	4.30	4.25
Study documentation and study update management	4.05	3.92	4.14
Sponsor communication and outreach	3.29	3.10	3.41 b
Site visit planning/reporting	3.21	3.17	3.24
Query resolution	3.05	2.86	3.18 b
Remote monitoring support	2.79 B	2.40	3.06 aB
Managing study financial planning	2.49	2.34	2.59
Working with sponsor vendors for tech support	2.20 b	1.96	2.37 B
Managing of third party resources (HHN, DTP, etc.)	2.20 B	1.87	2.42 B
Payments/AR	2.15	1.95	2.28 B
Patient payments	1.86	1.79	1.90

How often is your site utilizing these DCT capabilities/services for clinical trial delivery?

On average, sites use these DCT capabilities/services for clinical trial delivery occasionally (once or twice a month) or less often (average of three or higher). Many are used rarely or only on certain occasions or projects (average of four).

Key for Averages	
Daily	1
Frequently/Multiple Times Per Week	2
Occasionally/Once or Twice a Month	3
Rarely/Only on Certain Occasions or Projects	4
Never	5
76% or More	6

Total	N=291
Digital Engagement with Sponsor (i.e., dashboards and trial analytics)	3.46
Patient Retention	3.66
eConsent Delivery	3.98
Patient Shipments and Management	4.02
Telemedicine	4.02
Decentralized/Virtual Site Set Up (regional models)	4.03
Decentralized Patient Diagnostics	4.22
At-home Nursing	4.47

How easy or difficult has it been to adopt each of the following DCT capabilities/ services?

More than two-thirds of sites who use each service indicated that eConsent delivery, telemedicine, patient retention, digital engagement with sponsor, and patient shipments and management were very or somewhat easy to adopt.

For the other three services (decentralized patient diagnostics, decentralized/virtual site set-up [regional models], at-home nursing) nearly half of sites found these to be very or somewhat difficult to adopt.

	% Very or somewhat easy	% Very or somewhat difficult
eConsent Delivery	73%	27%
Telemedicine	73%	27%
Patient Retention	67%	33%
Digital Engagement with Sponsor (i.e., dashboards and trial analytics)	66%	34%
Patient Shipments and Management	66%	34%
Decentralized Patient Diagnostics	55%	45%
Decentralized/Virtual Site Set Up (regional models)	53%	47%
At-home Nursing	53%	47%

Sample Sizes (number of respondents that use each DCT capability/service): At-home nursing N=100; Patient shipments and management N=170; Telemedicine N=159; eConsent delivery N=150; Digital engagement with sponsor (i.e., dashboards and trial analytics) N=203; Decentralized/virtual trial setup (regional models) N=146; Patient retention N=179; Decentralized patient diagnostics N=128

Thinking about each of the following DCT capabilities/services that your site utilizes, does your site manage it directly or do you work with a provider that manages it for you?

More than 70% of sites say they manage eConsent delivery, telemedicine, and patient retention directly. Roughly half of sites say they manage the other DCT capabilities/services directly, while the other half say they work with a provider that manages these services for them.

	Our site manages it directly	We work with a provider that manages it for us
eConsent Delivery	76%	24%
Telemedicine	74%	26%
Patient Retention	70%	30%
Patient Shipments and Management	58%	42%
Decentralized/Virtual Site Set Up (regional models)	55%	45%
Digital Engagement with Sponsor (i.e., dashboards and trial analytics)	53%	47%
Decentralized Patient Diagnostics	48%	52%
At-home Nursing	41%	59%

Sample Sizes (number of respondents that use each DCT capability/service): At-home nursing N=100; Patient shipments and management N=170; Telemedicine N=159; eConsent delivery N=150; Digital engagement with sponsor (i.e., dashboards and trial analytics) N=203; Decentralized/virtual trial setup (regional models) N=146; Patient retention N=179; Decentralized patient diagnostics N=128

Thinking about each of the following DCT capabilities/services that your site utilizes, does your site manage it directly or do you work with a provider that manages it for you? How easy or difficult has it been to adopt each of the following DCT capabilities/services?

Sites tend to view DCT technology and services that they manage directly as easier to adopt than services managed by an external provider.

	% Site manages it directly	% Very or somewhat easy to adopt
eConsent Delivery	76%	73%
Telemedicine	74%	73%
Patient Retention	70%	67%
Patient Shipments and Management	58%	66%
Decentralized/Virtual Site Set Up (regional models)	55%	53%
Digital Engagement with Sponsor (i.e., dashboards and trial analytics)	53%	66%
Decentralized Patient Diagnostics	48%	55%
At-home Nursing	41%	53%

When implementing DCTs, how often have you had to seek support for each of the following issues?

30% or more of sites have to seek support for each issue every other week or more often when implementing DCTs. System access and CRA issues/access are the two areas where support is needed the most often.

% Every Other Week or More Often

Total	N=291
System Access	39%
CRA Issues/Access	39%
Protocol Understanding	33%
Patient Outreach and Communication	32%
User Interface/User Experience (UI/UX) Navigation Issues of System Operations	31%
Drug Access and Accountability	30%

Full data for this question are here:

	Protocol Understanding A	System Access B	UI/UX navigation issues of system operations C	Drug access and accountability D	Patient outreach and communication E	CRA Issues/Access F
Total	100% 291	100% 291	100% 291	100% 291	100% 291	100% 291
Daily	8% 23	11% C 31	6% 17	10% c 28	10% C 30	8% 23
Multiple times per week	7% 21	10% d 28	8% 23	5% 16	8% 22	12% aDe 34
Once a week	9% 27	9% 27	8% 22	10% 28	6% 18	10% e 29
Every other week	9% d 27	9% 26	9% d 27	5% 16	8% 24	9% d 27
Once a month	13% 38	19% adEf 55	14% 41	13% 39	10% 30	13% 39
Rarely (only on certain projects)	35% 101	30% 88	33% 96	37% b 107	32% 94	32% 92
Never	19% B 54	12% 36	22% Bf 65	20% B 57	25% aBF 73	16% 47
Mean	4.91 B	4.56	5.06 BF	4.96 Bf	4.98 Bf	4.68

Thinking about each of the following issues when implementing DCTs, which of the following groups do you have the most trouble collaborating with?

When implementing DCTs, some sites have trouble collaborating with CROs when addressing issues around CRA access (32%), protocol understanding (20%), and drug access and accountability (18%).

Nearly a third of sites have trouble collaborating with technology providers when managing issues around system access (31%) and user interface/user experience (UI/UX) system navigation (29%).

	Protocol Understanding (A)	System Access (B)	UI/UX navigation issues of system operations (C)	Drug access and accountability (D)	Patient outreach and communication (E)	CRA Issues/ Access (F)
Total	**N=291**	**N=291**	**N=291**	**N=291**	**N=291**	**N=291**
Sponsor	12% CE	8%	7%	13% bCE	7%	10%
CRO	20% CE	16%	14%	18%	14%	32% ABCDE
Technology Provider	6%	31% ADEF	29% ADEF	13% AF	12% Af	8%
Home Health Provider	4% BCF	1%	1%	2%	3%	1%
Other	2%	3%	4%	3%	8% ABCDF	4%
N/A or no trouble/ issues collaborating	56% BCF	40%	46%	51% B	55% BCF	45%

In your opinion, are the budgets that you receive reflective of the work you are doing in DCTs?

More than half of sites (55%) say the budgets that they receive are not reflective of the work they are doing in DCTs.

Total	N=291
Yes	45%
No	55%

CONCLUSION

This survey provides a much-needed window into the perspectives of clinical research professionals from the site level on the challenges of implementing decentralized trial elements. The survey highlights the fact that clinical sites are busy, with 80% working on more than six trials at a given time, yet 41% of sites are not using any DCT elements.

These insights provide a new, broader perspective of the many challenges that must be addressed at the site level—where day-to-day trial activities take place—to accelerate DCT adoption. While technology adoption is demanding, with a significant burden relating to technological support and integration, this in itself is not a primary barrier. The human element is key, with a need for implementation of processes that allow for the successful conduct of clinical trials leveraging the available solutions.

Other barriers include ongoing site staffing issues, a need to minimize the number of platforms used and increase single sign-on enablement, requirement for additional training on DCT capabilities, freedom for sites to choose between using vendors or in-house management of trial delivery, and the need for optimized support capabilities for sites. Added to this, the clinical trial budget process urgently needs to be updated to reflect the demands of DCT elements.

This lack of budget flexibility and issues with managing third-party vendors were also raised at the think tank, which highlighted the need for regulatory clarity in this area. The role of the PI when patient home visits are managed by vendors was a major concern; this could be addressed by regulators revisiting the definition of a site.

To transform clinical research, a web of multiple challenges faced by sites must be tackled by involving all trial stakeholders in decision-making—rather than having "solutions" imposed on the sites. Action is needed if sites are to build on learnings during the COVID-19 pandemic and adapt in a sustainable way to DCT elements and realize their potential in high-priority areas such as improving enrollment diversity by easing the participation of underserved populations.

ABOUT ACRP

With more than 12,000 members, the Association of Clinical Research Professionals (ACRP) is the only non-profit organization solely dedicated to representing, supporting, and advocating for clinical research professionals in every phase of their careers and contributions to improving public health. ACRP provides a wide range of educational programs for individuals and life science companies globally, as well as a vibrant community for the networking needs of its members and other stakeholders in the clinical research enterprise. The affiliated Academy of Clinical Research Professionals' (The Academy) certification programs for clinical research coordinators (CCRC), clinical research associates (CCRA), and Principal Investigators (CPI) are accredited by the National Commission for Certifying Agencies/Institute for Credentialing Excellence. The Academy has certified more than 35,000 individuals since 1992.
acrpnet.org

ABOUT MEDABLE

Medable is on a mission to get effective therapies to patients faster by transforming clinical drug development with disruptive technologies. The company's digital platform streamlines design, recruitment, retention, and data quality for decentralized trials, replacing siloed systems with integrated digital tools, data, and interfaces to accelerate trial execution. Medabe connects patients, sites, and clinical trial teams to improve patient access, experience, and outcomes. Medable is a privately held, venture-backed company headquartered in Palo Alto, California.
medable.com

ABOUT ADVANCED CLINICAL

Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research—approaching each opportunity with foresight, character, resilience, and innovation. Based on decades of experience, we help our clients achieve better outcomes by conducting candid conversations and anticipating potential issues through our customized solutions.
advancedclinical.com

ABOUT CONTINUUM CLINICAL

Continuum Clinical is a global clinical trial enrollment company that has been providing fact-based patient recruitment solutions since 1993. We have built and maintained long-standing relationships with pharmaceutical and biotech companies around the world, including 10 of the top 20 global sponsors. This experience led Continuum Clinical to become the industry's most trusted partner for clinical trial engagement, recruitment, retention, and analytics.
continuumclinical.com