

Perceptions and Use of Decentralized Clinical Trials

Prepared for:

ORACLE
Health Sciences

August 2020

Avoca[®]
THE AVOCA GROUP

Table of Contents

Background	3 0
Detailed Findings 0	
Utilization of Decentralized Clinical Trials	8 0
Benefits & Challenges	16 0
Change Management	26 0
Key Findings	29 0
Appendix	35 0

Background

Research Objectives

- Understand utilization and perceptions of decentralized clinical trials (DCTs)
- Characterize perceptions of benefits and challenges associated with conducting decentralized clinical trials
- Understand thoughts on change management, and adjustments that will be needed in order to effectively conduct decentralized clinical trials

Methodology

- A total of 121 respondents participated in this survey between March and July of 2020.
- All survey communications – invites and reminders – were distributed by Oracle.
- Respondents participated in a blinded fashion, and only provided identifying information if they selected to receive a copy of the executive summary of this research. As such, it is possible that there is more than one participant from a single company.
- Results are reported at the total sample level, as well as by Sponsors and Providers to understand any potential differences in utilization and/or perceptions of decentralized clinical trials (DCTs).
- Importantly, data collection began at the precipice of the COVID-19 pandemic. Given the worldwide focus on limiting physical interaction in order to avoid continued spread, many businesses were driven to online modes of conducting operations. As such, it is expected that the presence of COVID-19 impacted reports of usage and perceptions of decentralized clinical trials.

Company Characteristics

Sponsor Company

Top 20 Biopharma (\$10+ billion sales)	27%
Top 50/Mid-sized Biopharma (\$2.0 - \$9.9 billion sales)	16%
Other Mid-sized Biopharma (\$500 million - \$1.9 billion sales)	9%
Small/Specialty Biopharma (<\$500 million sales) \$	13%
Pre-Revenue Biopharma (\$0 sales)	24% \$
Medical Device Company	7% \$
Other	4% \$

Sponsor Location

North America	68%
Europe	20%
Asia Pacific	12%

Provider Company

Large CRO (\$500+ million sales)	36%
Mid-sized CRO (\$50 - \$500 million sales)	17%
Small/Specialty CRO (<\$50 million sales) \$	11%
Non-CRO Clinical Service Provider	5% \$
Consulting Company	17% \$
Academic Research Organization (ARO)	4% \$
Other	11% \$

Provider Location

North America	46% \$
Europe	27% \$
Asia Pacific	14% \$
Other	13% \$

Note: It is possible that more than one respondent participated per company.
 Base for Company Type: Sponsor=45, Provider=76
 Base for Location: Sponsor=41, Provider=71

Respondent Characteristics &

Sponsor Functional Area

Clinical Operations	51%
Quality	20%
Executive Management	13%
Data Management	4%
Information Technology/Management	2%
Other	9%

Sponsor Years in Industry

Mean	18
Up to 15	41%
16 to 20	24%
21 to 25	20%
26 or more	15%

Provider Functional Area

Clinical Operations	38%	\$
Regulatory	18%	\$
Executive Management	9%	\$
Data Management	9%	\$
Quality	7%	\$
Information Technology/Management	5%	\$
Other	13%	\$

Provider Years in Industry

Mean	15
Up to 5	28%
6 to 10	17%
11 to 15	14%
16 to 20	14%
More than 20	27%

Base for Functional Area: Sponsor=45, Provider=76
 Base for Years in Industry: Sponsor=41, Provider=71

Detailed Findings

Utilization of
Decentralized
Clinical Trials (DCTs)

Methodological Note

Before answering questions related to use and perceptions of decentralized clinical trials, all respondents were exposed to the description below.

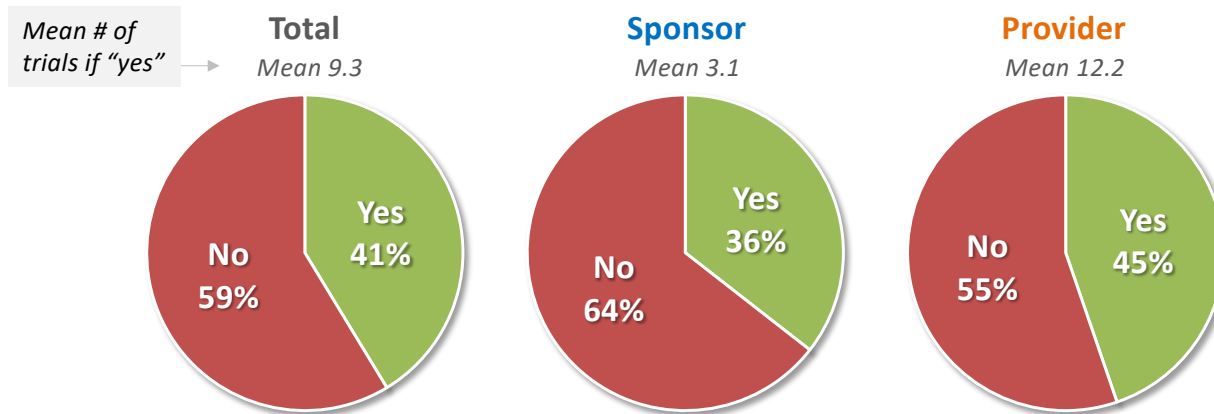
Description of Decentralized Clinical Trials

Decentralized clinical trials (DCTs) deploy a wide range of digital technologies to collect safety and efficacy data from study participants, normally from the comfort of the patient's own home. The specific digital technologies used for data collection vary by study but can include telemedicine, wearable/sensor devices, eConsent, electronic clinical outcome assessments (eCOA), and electronic health (eHealth) records.

Utilization

About 40% of respondents indicate that their organizations have participated in DCT pilot or proof of concept studies; Providers are somewhat more likely to have participated than are Sponsors.

Use of Decentralized Clinical Trial Pilot or Proof of Concept Study



Note: It is possible that more than one respondent participated per company.

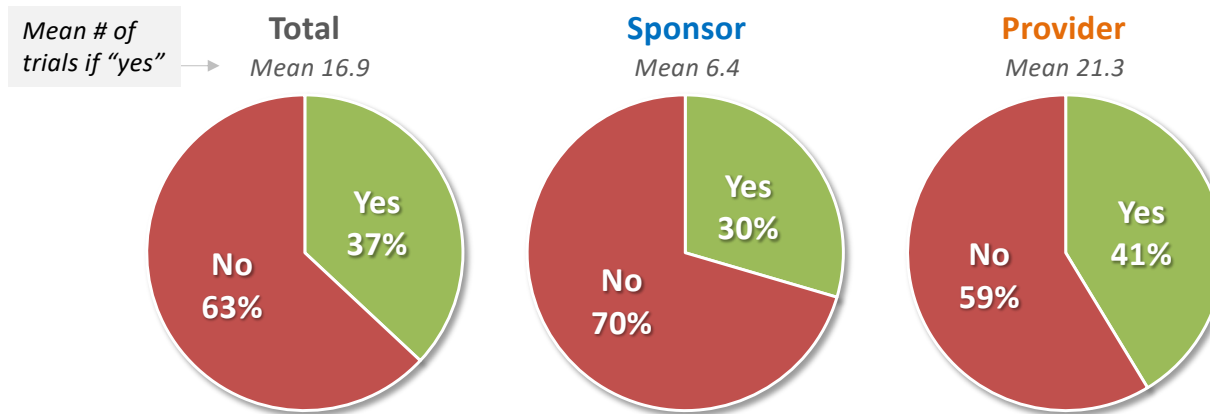
Base: Total=121, Sponsor=45, Provider=76

Q. Has your organization ever sponsored and/or run or supported in some way through services you offer a decentralized clinical trial pilot or proof of concept study?

Utilization

About one-third have used a DCT in place of a traditional trial in the past year; again, Providers were more likely to have done this than were Sponsors, and on average also reported more instances.

Use of Decentralized Clinical Trial in Place of Traditional Trial



Note: It is possible that more than one respondent participated per company¹

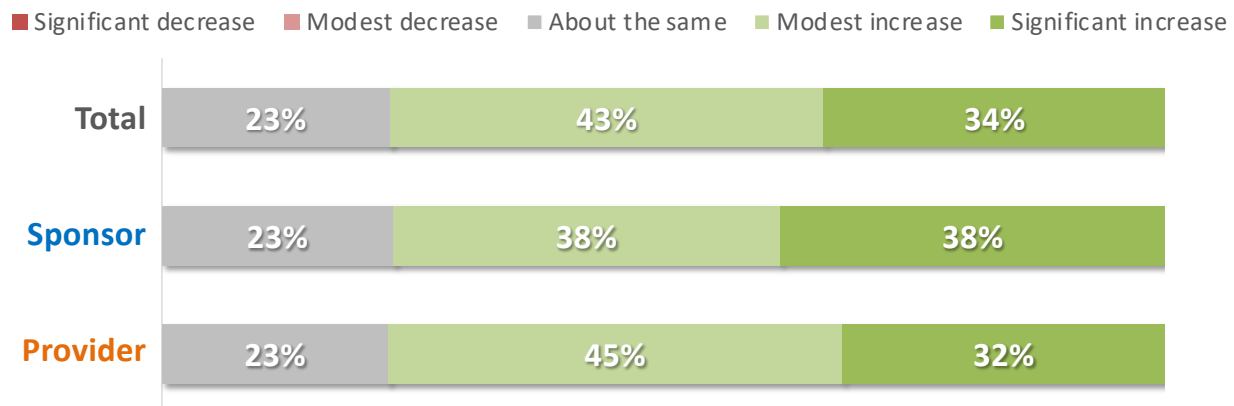
Base: Total=119, Sponsor=44, Provider=75 (among those who have run trials in past year)¹

Q. Thinking about the past year, has your organization sponsored and/or run or supported in some way through services you offer a decentralized clinical trial (in place of a traditional trial approach)?

Utilization

Three-quarters of respondents reported an increase in use of decentralized clinical trials in the past year relative to the prior year.

Trend in Usage of Decentralized Clinical Trials in Past Year



Note: It is possible that more than one respondent participated per company¹

Base: Total=119, Sponsor=44, Provider=75 (among those who have run trials in past year)¹

Q. You indicated that (#) of your organization's trials over the past year have used a decentralized approach. Does this represent...

Utilization

COVID-19 was the top reason for increased utilization, followed by greater Sponsor interest and demand.

Select Comments on Increased Usage of DCT

*“Two main drivers, first is the Sponsors’ focus on * becoming increasingly patient centric in individuals with complex/rare diseases and the second is managing the * impact of COVID and post COVID environment.” [Provider] &*

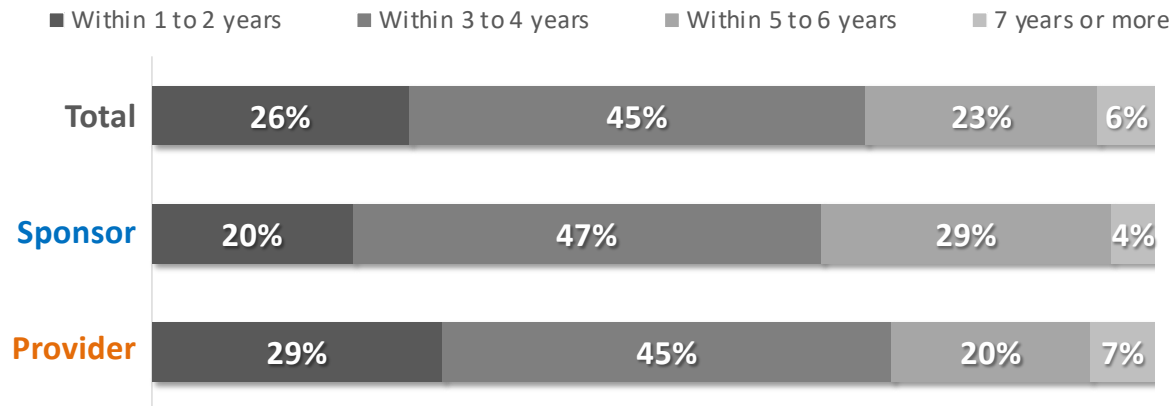
“The COVID-19 pandemic has forced the industry to adapt to minimize, if not eliminate in-person site visits. I have been collaborating with an adaptive ePRO vendor in developing a platform ideally suited to this type of trial.” [Provider]

“Attempting to make collection of data easier on patients and sites; it is important for our company to ensure our patients and sites remain engaged, feel supported, and enjoy participating in clinical research.” [Sponsor]

Utilization

Nearly half of respondents feel that DCTs will be available at scale within the next 3 to 4 years; about one-quarter feel that this will happen sooner.

When do you think DCTs will be at scale?



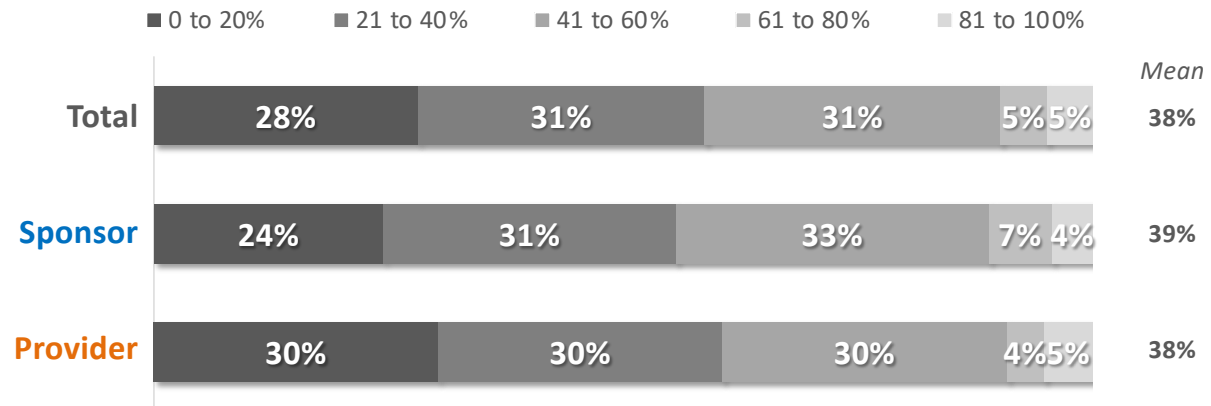
Base: Total=121, Sponsor=45, Provider=76

Q. In your personal opinion, in how many years from now do you feel decentralized clinical trials will be available at scale?

Utilization

Once DCTs are available at scale, most respondents still foresee that 40% of trials or less will move to this format; only 10% foresee that a clear majority of trials will move to this format.

When Available At Scale, Estimated Percentage of Trials via DCT



Note: It is possible that more than one respondent participated per company¹

Base: Total=119, Sponsor=44, Provider=75 (among those who have run trials in past year)¹

Q. Thinking ahead to when you foresee decentralized clinical trials to be available at scale, please estimate the percentage of your organization's trials that will be decentralized?

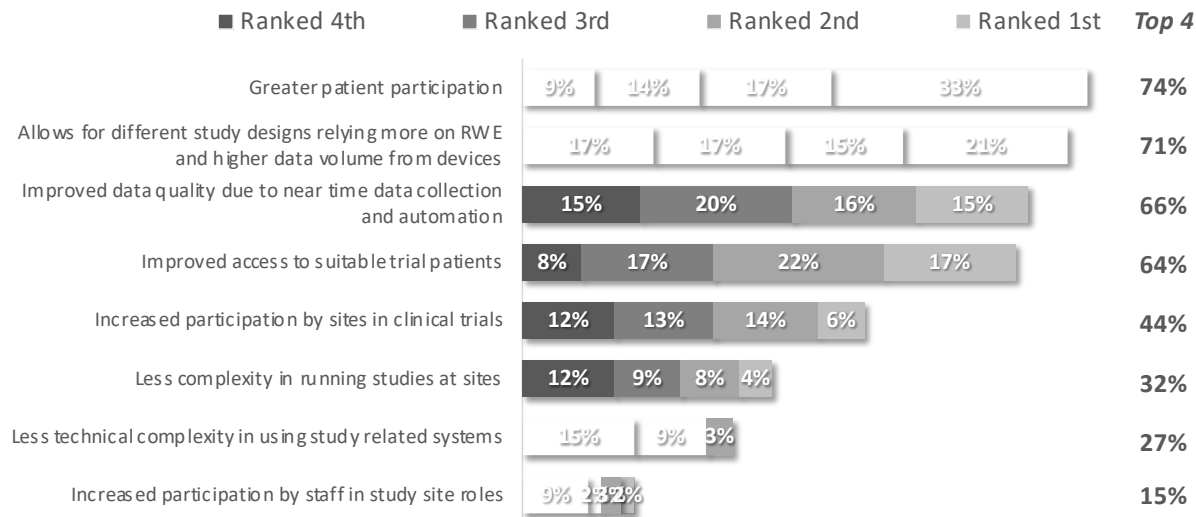
Detailed Findings

Benefits & Challenges
Associated with DCTs

Benefits & Challenges

Increased patient participation, flexibility in study design, improved data quality, and improved access to suitable patients are seen as top benefits of DCTs.

Total: Top Benefits of Decentralized Clinical Trials



One Sponsor respondent and three Provider respondents indicated they do not believe there to be *any* benefits associated with DCTs.

Base: Total=117 (among those who did not select "no benefit")

Q. From your perspective, what are the biggest potential benefits from decentralized clinical trials? Please rank the top four (4) benefits you see as being most important, where "1" indicates the biggest potential benefit..

Benefits & Challenges

Sponsor and Provider respondents are generally aligned on the approximate ranking of perceived benefits of DCTs, except in the case of “increased site participation,” which Providers are more likely to recognize as a top benefit.

Top Benefits of Decentralized Clinical Trials

% of respondents indicating this as a most important benefit

	Total	Sponsor Respondents	Provider Respondents
Greater patient participation	74%	80%	70%
Allows for different study designs relying more on RWE and higher data volume from devices	71%	73%	70%
Improved data quality due to near time data collection and automation	66%	70%	63%
Improved access to suitable trial patients	64%	64%	64%
Increased participation by sites in clinical trials	44%	34%	51%
Less complexity in running studies at sites	32%	34%	32%
Less technical complexity in using study related systems	27%	30%	26%
Increased participation by staff in study site roles	15%	14%	15%

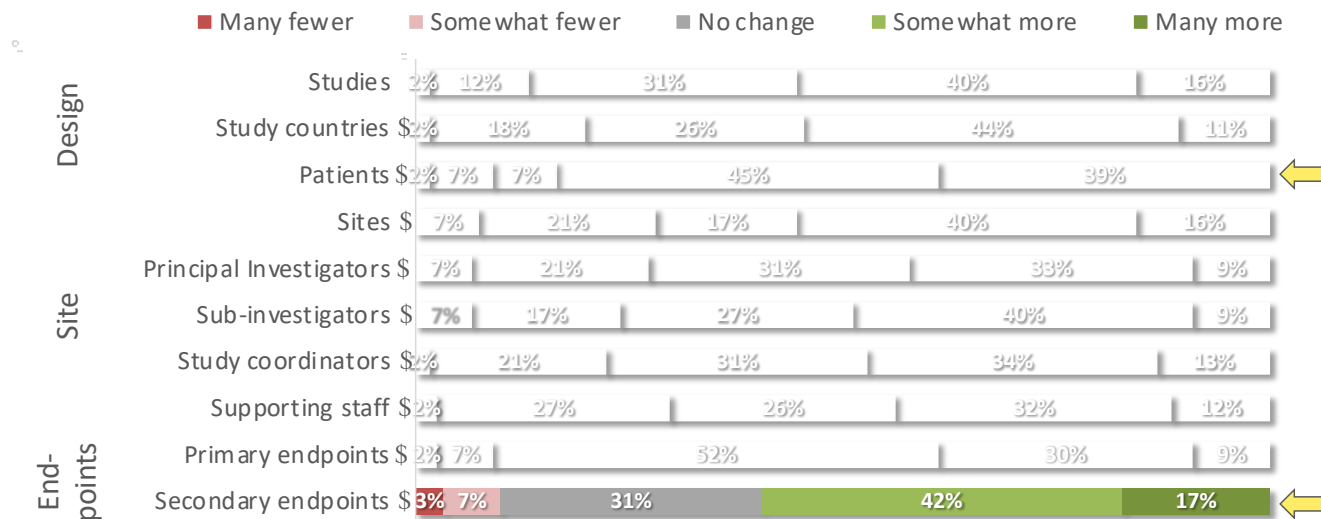
Base: Total=117, Sponsor=44, Provider=73 (among those who did not select “no benefit”)

Q. From your perspective, what are the biggest potential benefits from decentralized clinical trials? Please rank the top four (4) benefits you see as being most important, where “1” indicates the biggest potential benefit.

Benefits & Challenges

In terms of dimensions of study design, there is strong consensus around the idea that DCTs will result in both more patients as well as more secondary endpoints.

Total: Impact of DCTs on Study Design Attributes...



Studies, study countries, and sites are also expected to show significant increases.

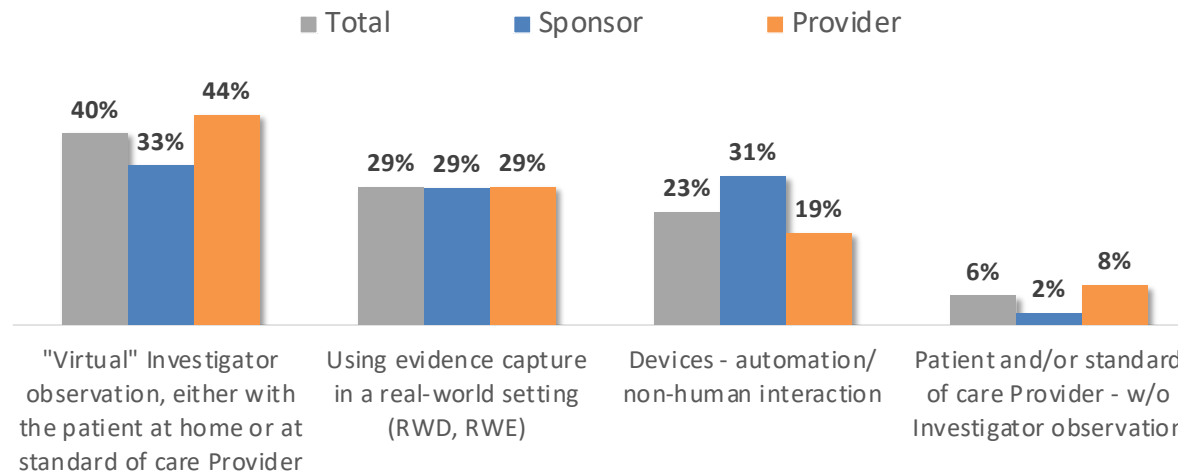
Base: Total=121

Q. In your personal opinion, how will decentralized clinical trials impact the following?

Benefits & Challenges

Reported outcomes via “virtual” Investigator observation and sources of real-world data are considered the optimal modes of collecting such data within DCTs.

Optimal Approach to Capturing Reported Outcomes in DCTs



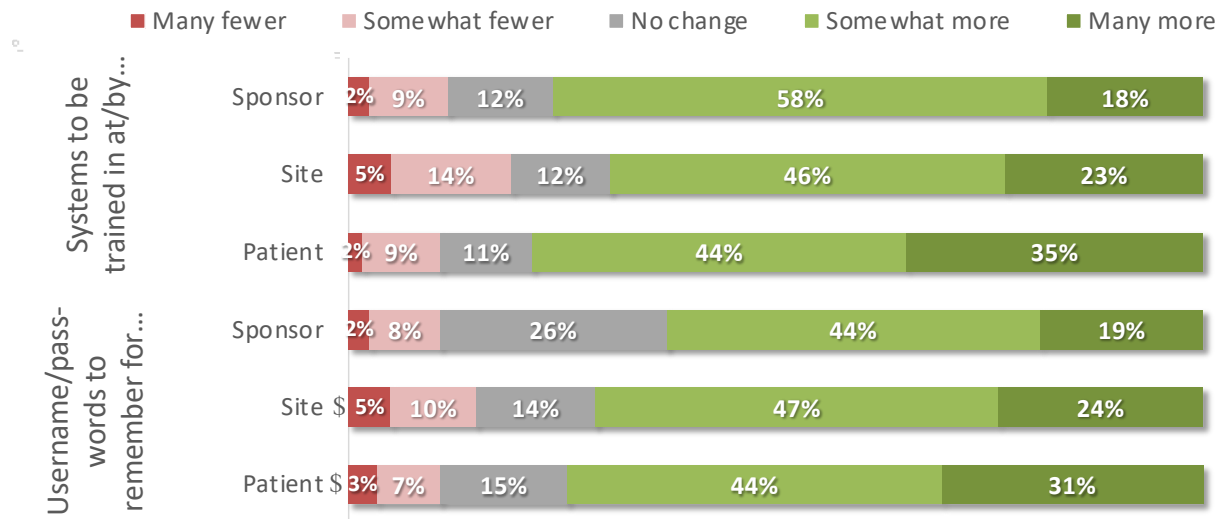
Base: Total=115, Sponsor=42, Provider=73

Q. With respect to capturing reported outcomes, which of the following do you feel will be the optimal approach once decentralized clinical trials are available at scale?

Benefits & Challenges

Regarding systems to be trained on and technology passwords to remember, most respondents foresee that DCT will impose a higher burden on Sponsors, sites, and patients. Of these three parties, respondents are more likely to anticipate higher burdens for patients.

Total: Impact of DCTs on Technology Attributes...



Base: Total=121

Q. In your personal opinion, how will decentralized clinical trials impact the following?

Benefits & Challenges

Some differences are observed between Sponsor and Provider perceptions, namely, Sponsors are more likely to see an increase in technology burden, and less likely to see an increase in site-related attributes.

Impact of DCTs on Attributes...

% indicating much/somewhat more

	Total	Sponsor Respondents	Provider Respondents	PPT Difference
Studies	55%	47%	61%	-14
Patients	83%	87%	82%	5
Study countries	55%	51%	57%	-5
Sites	55%	49%	59%	-10
Principal Investigators	42%	44%	41%	4
Sub-investigators	49%	38%	55%	-17
Study coordinators	47%	33%	55%	-22
Supporting staff	44%	38%	47%	-10
Primary endpoints	39%	36%	41%	-5
Secondary endpoints	60%	58%	61%	-3
Systems to be trained in at sponsor	76%	89%	68%	20
Systems to be trained in at site	69%	71%	68%	3
Systems to be trained in by patient	79%	82%	76%	6
Username and passwords to remember by sponsor	63%	69%	59%	10
Username and passwords to remember by site staff	71%	78%	67%	11
Username and passwords to remember by patient	74%	71%	76%	-5

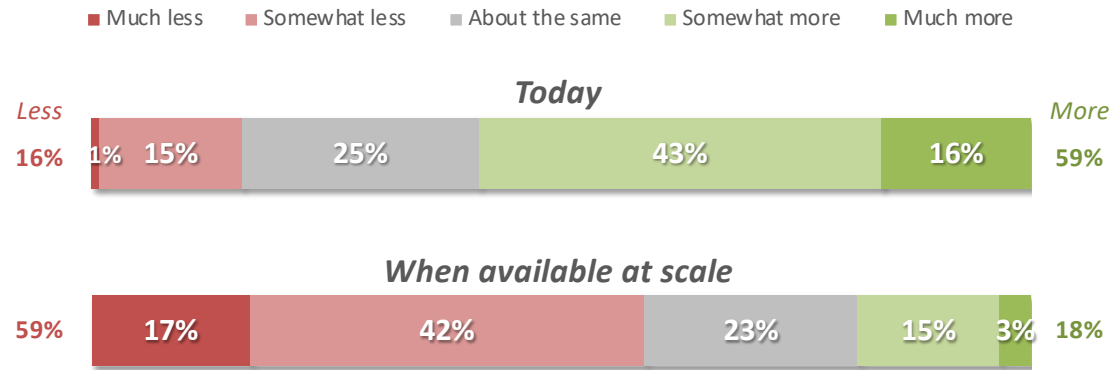
Base: Total=121, Sponsor=45, Provider=76

Q. In your personal opinion, how will decentralized clinical trials impact the following?

Benefits & Challenges

Today, a slight majority of respondents believe that DCTs cost more than “traditional” trials; however, most anticipate that as use scales up, costs will decrease to the point that DCTs are less expensive than “traditional” trials.

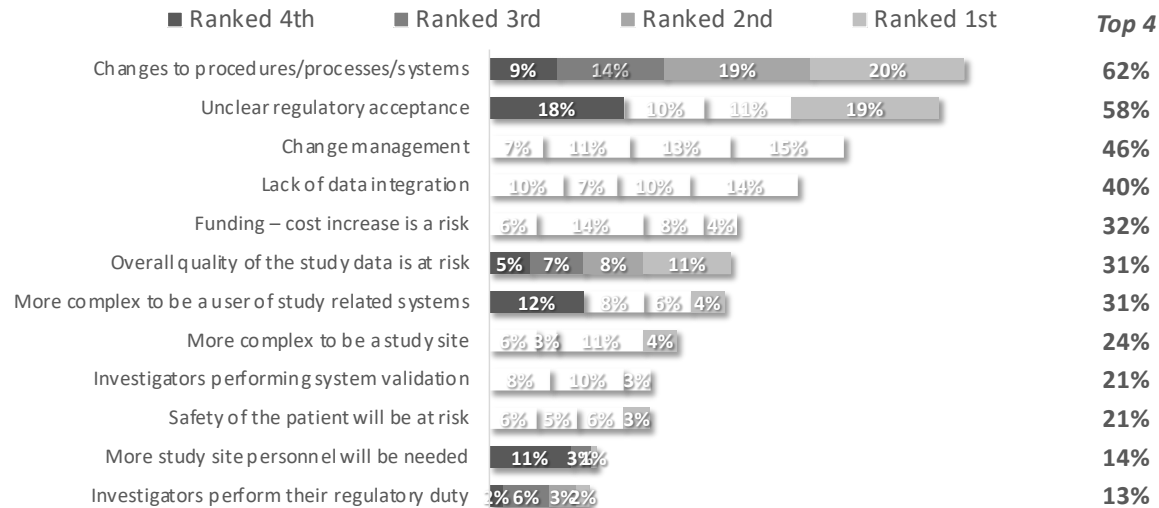
Total: Estimated Cost of DCT Relative to Traditional Trial...



Benefits & Challenges

Change, particularly related to processes and systems, unclear regulatory acceptance, and data integration issues are most likely to rank among respondents' greatest challenges with respect to DCTs.

Total: Top Challenges of Decentralized Clinical Trials



Importantly, perceptions of issues with data quality and patient safety are seen as less of a challenge.

Base: Total=115 (among those who did not select "no challenges")

Q. From your perspective, what are the biggest challenges facing decentralized clinical trials? Please rank the top four (4) challenges you see as being most important, & where "1" indicates the biggest potential challenge. &

Benefits & Challenges

Provider respondents are more likely than Sponsor respondents to rank change management among their top challenges, while Sponsors are more likely than Providers to rank data integration among theirs.

Top Challenges of Decentralized Clinical Trials

% of respondents indicating this as a most important challenge

	Total	Sponsor Respondents	Provider Respondents
Changes to procedures/processes/systems	62%	64%	60%
Unclear regulatory acceptance	58%	64%	55%
Change management	46%	31%	55%
Lack of data integration	40%	52%	33%
Funding – cost increase is a risk	32%	38%	29%
Overall quality of the study data is at risk	31%	29%	33%
More complex to be a user of study related systems	31%	29%	32%
More complex to be a study site	24%	24%	25%
Investigators performing system validation	21%	7%	29%
Safety of the patient will be at risk	21%	19%	22%
More study site personnel will be needed	14%	17%	12%
Investigators perform their regulatory duty	13%	19%	10%

Base: Total=115, Sponsor=42, Provider=73

Q. From your perspective, what are the biggest challenges facing decentralized clinical trials? Please rank the top four (4) challenges you see as being most important, where "1" indicates the biggest potential challenge.

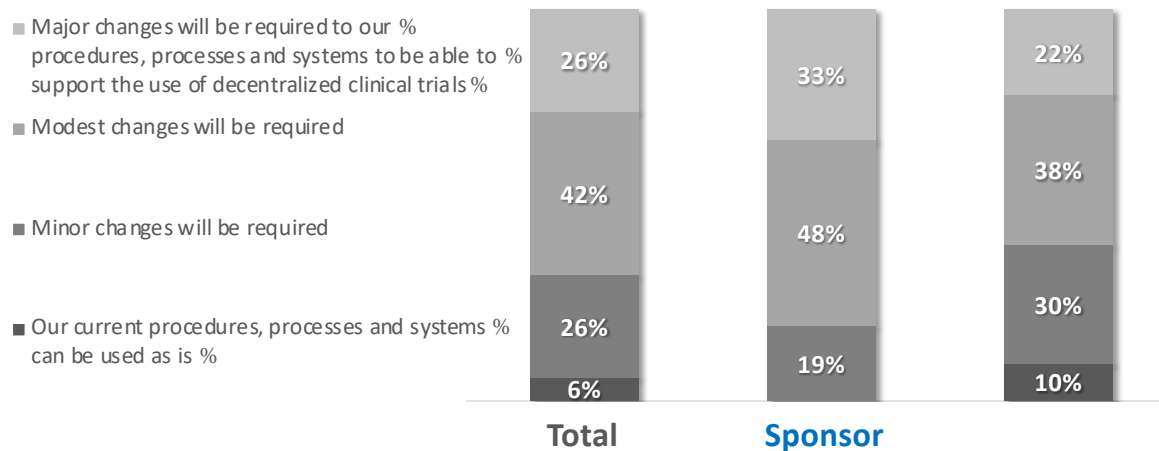
Detailed Findings

Change Management

Change Management

Nearly all respondents feel that at least some changes will be required to procedures, processes, and systems to support DCTs; Sponsors are more likely than Providers to foresee the need for modest to major changes.

Opinions on Current Operational Processes



Note: It is possible that more than one respondent participated per company.

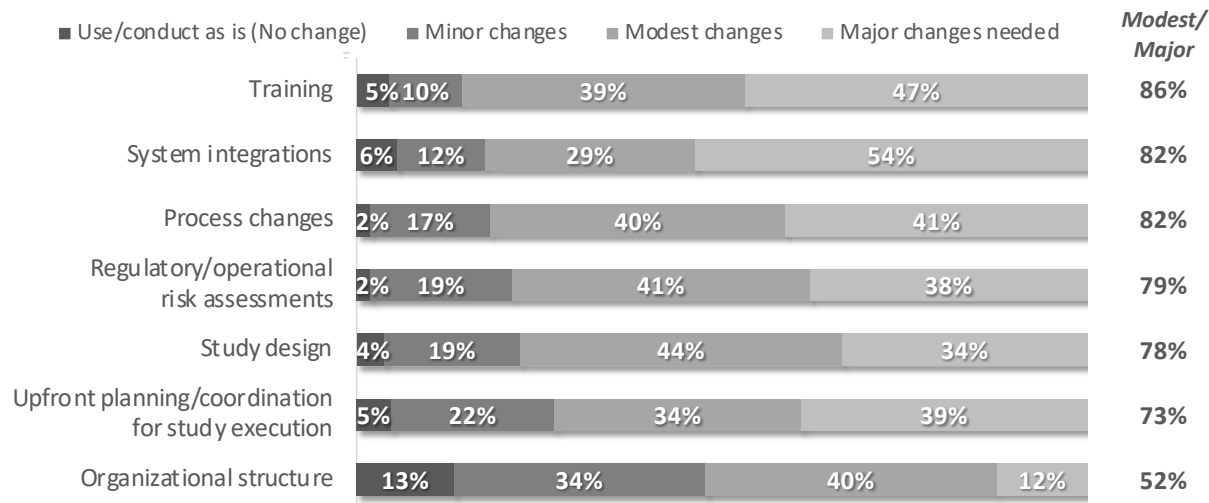
Base: Total=115, Sponsor=42, Provider=73

Q. Which of the following comes closest to your opinion with respect to your organization's current operational procedures, processes and systems?

Change Management

Most respondents foresee that modest to major changes will be needed across many areas (training, system integrations, processes, etc.) to support DCTs. Though change is also anticipated in organizational structure, the impact is expected to be less substantial relative to more tactical changes.

Total: Degree of Change Required to Implement DCTs



Results were similar for Sponsors and Providers.

Note: It is possible that more than one respondent participated per company.

Base: Total=105-111

Q. In order to implement decentralized clinical trials, to what degree, if any, do you feel the following aspects of studies will require change from traditional clinical trials & at your organization with respect to...? &

Summary of Key Findings

Key Findings: Utilization of DCTs

- Though utilization of decentralized clinical trials (DCT) appears to be in the earlier stages of adoption, usage has increased substantially in the past year, primarily due to changes brought on because of the COVID-19 pandemic.
 - About 40% have indicated piloting and/or using a DCT in place of a traditional trial – with the fraction higher among provider than sponsor respondents.
 - Three-quarters indicate an increase in usage of DCTs in past year.
- A majority of respondents feel that DCTs will be available at-scale (or more regularly used) within the next four years and foresee approximately 40% of trials being run in this manner at that time.
 - Provider respondents, who are somewhat ahead on the adoption curve, are also slightly more likely to say that DCTs will be at-scale within the very near future – 1 to 2 years from now.

Key Findings: Benefits & Challenges

- Increased patient participation and flexibility in study design are two key benefits that respondents foresee coming out of the utilization of DCTs.
 - Nearly three-quarters of respondents see ‘increased patient participation’ as a top benefit, and it is the top benefit among Sponsors and Providers alike.
- Virtual observation and real-world data are seen as the optimal approaches to capturing outcomes in the DCT setting.
 - Among Providers, the use of devices to record outcomes is a close second to virtual investigator observation, which, again, may be attributable to this audience being a bit further along on the adoption curve.

Key Findings: Benefits & Challenges

- In terms of top perceived challenges related to DCTs...
 - Required changes to processes and procedures as well as adapting to those changes were highly reported challenges among both Sponsors and Providers as a potential challenge.
 - Regulatory acceptance – specifically a lack of clarity around this – is another area where & respondents cite potential challenges. &
 - Data integration and alignment of systems.
- The technological burden on all parties – Sponsors, Providers, Sites – in terms of systems training and account info, is expected to increase, with patients expected to bear most of the burden.
- Costs of DCTs are perceived to be higher than those of traditional trials today, though respondents anticipate that once DCTs are at-scale, the reverse will be true.
- Importantly, perceptions of quality and safety are less likely to be reported as strong concerns for – rather, it is the more tactical side of trials that presents potential challenge.

Key Findings: Change Management

- With change management being perceived as a top challenge, it is not surprising that nearly all respondents expect at least some changes to be required in order to support DCTs appropriately.
 - Sponsors, in particular, are more likely to anticipate the need for moderate to major change to systems and processes in order to accommodate this approach.
- As it relates to specific aspects of trial conduct, DCTs are perceived to demand changes across several dimensions:
 - First and foremost, training, systems integration, and process change are most likely to be & perceived as requiring modest to major adaptation. &
 - In close second position, regulatory assessments and study planning/design, will also require attention.
 - Organizational structure is seen as being least impacted by DCT implementation, with only 12% indicating this will need “major” adjustment.

Thank You

The Avoca Group

www.theavocagroup.com

info@theavocagroup.com

(609) 252-9020

179 Nassau Street, Suite 3A

Princeton, NJ 08542



Appendix

Clinical Trials

Sponsor

Clinical Trials in Past Year	
Mean	58
0 to 5	18%
6 to 10	31%
11 to 20	13%
21 to 50	18%
More than 50	20%

Outsourcing Rate	
Mean	68%
0 to 20%	20%
21 to 50%	18%
51 to 99%	18%
100%	43%

Provider

Clinical Trials in Past Year	
Mean	110
0 to 5	21%
6 to 10	16%
11 to 20	11%
21 to 50	16%
More than 50	37%

Base: Sponsor=45/44, Provider=76

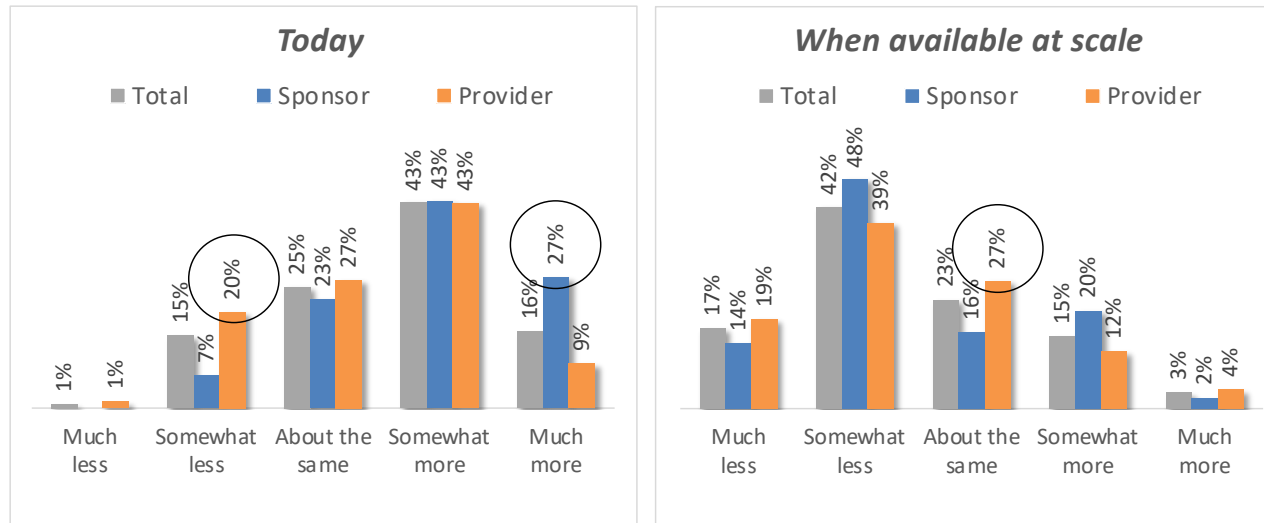
[Sponsor] Q. In the past year, approximately how many clinical trials did your organization sponsor? &

[Sponsor] Q. In the past year, approximately what percentage of trials that your organization sponsored were outsourced? &

[Provider] Q. In the past year, approximately how many clinical trials did your organization run or support in some way through services you offer? &

Benefits & Challenges

Estimated Cost of DCT Relative to Traditional Trial...



Base: Total=119, Sponsor=44, Provider=75

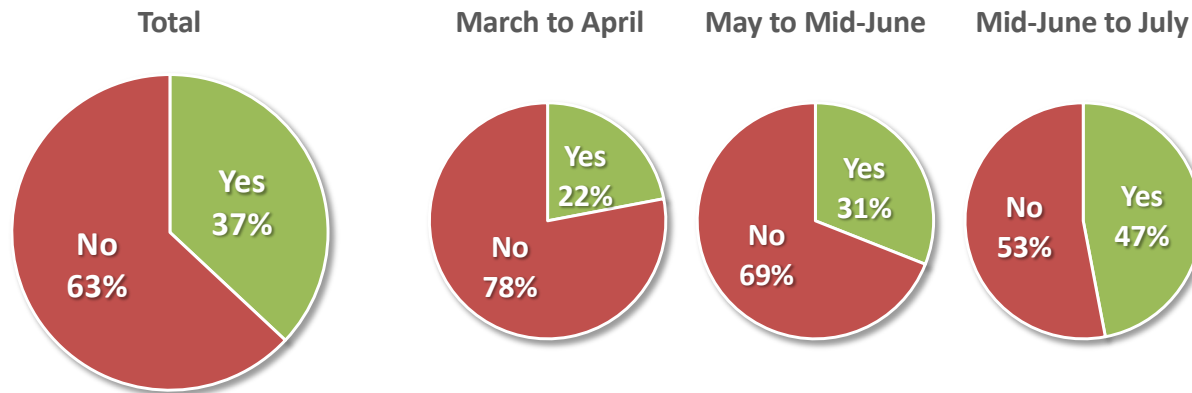
Q. In your personal opinion, what are your thoughts on the cost of decentralized clinical trials vs. traditional trial research...

Ad Hoc Analysis of Results by Timeframe

Analysis by Timeframe

Utilization of a decentralized approach increased over 2020.

Use of Decentralized Clinical Trial in Place of Traditional Trial



Note: It is possible that more than one respondent participated per company¹

Base: Total=119, **March-April=23**, **May-Mid-June=36**, Mid-June-July=60 (among those who have run trials in past year, aggregated across Sponsors and Providers)¹

Q. Thinking about the past year, has your organization sponsored and/or run or supported in some way through services you offer a decentralized clinical trial (in place of a traditional trial approach)?