DECENTRALIZED TRIALS MARKET PRIMER

May 2020

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INTRODUCTION

Drug development is a time-consuming, costly process. On average, it takes as many as 10 years and costs as much as $2.6 billion to develop a new drug that gains market approval. Because of this, there is a constant pressure in the life sciences industry to find processes that make drug development better, faster, or less expensive. Decentralized trials have been one of many processes with potential to accomplish at least one of these three goals.

Decentralized trials have been referred to by many names. Among them: at-home trials, digital trials, direct-to-patient trials, home-based trials, mobile-enabled trials, modern trials, remote trials, site-less trials, software-enabled trials, and virtual trials. While there are distinctions to be made between these terms — for example, John Reites, president of THREAD, says that "decentralized trials" is the proper way to describe these studies rather than using terms like "virtual trials" or "remote studies"[1] — what each term has in common is that they describe approaches that use technology to facilitate data collection without a site or intermediary, ideally making it easier for patients to participate in clinical trials.[2] It should be noted that the FDA refers to these types of trials as decentralized trials.

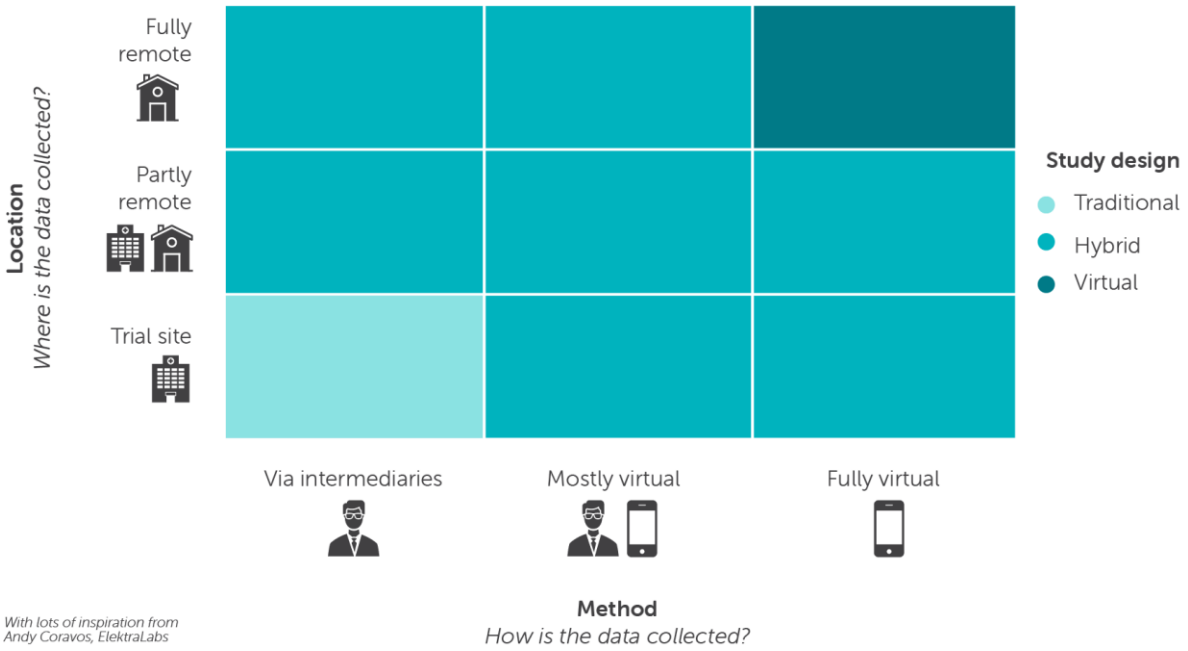
The first decentralized trial took place in 2011 when Pfizer conducted the "first-ever randomized clinical trial" using phone- and web-based technology to collect data. Since then, it has been a decade of fits and starts in the adoption of decentralized trials. The COVID-19 pandemic might be the inflection point that changes decentralized trials from a novelty to a necessity.

Decentralized Trials Timeline	
Year	**Event and Link**
June 2011	Pfizer Conducts First Virtual Trial
2012 to 2015	Enthusiasm for Decentralized Trials Builds
Feb 2015	Sanofi Conducts First Fully Remote Trial in Europe
Nov 2015	FDA Solicits mHealth, Wearable Tech Info for Clinical Trials
June 2016	eClinical Health Announces Successful Results for Entirely Remote Study
Dec 2016	Center Point Clinical Services Launches "World's First Site-Less Tech CRO"
2017-2019	Increased Adoption, Continued Resistance
Apr 2020	COVID-19 Stalls Clinical Trials for Everything but COVID-19

This primer is an overview of decentralized trials. Starting with definitions of decentralized trials and then continuing with immediate market prospects, we provide a review of the literature that details the benefits of and barriers to decentralized trial deployment and discuss how COVID-19 might reorient how clinical trials are conducted. We conclude with an introductory examination of companies in the decentralized trial space and an overview of the future prospects of decentralized trials.

DEFINITIONS

Decentralized clinical trials are defined and made distinct from traditional clinical trials by where and how their data are collected. For traditional trials, data are often collected at research sites by intermediaries (e.g., clinicians). Some or all data from decentralized trials are collected via virtual methods such as a device or wearable.



Source: "COVID-19 Pandemic Pushes Clinical Trials to Go Virtual," (Medium/LEO Innovation Lab – 3/26/20)

According THREAD President Reites, what makes decentralized trials unique is more their flexible approach rather than whether all data is collected using a virtual location or remote method. For Reites, decentralized studies encompass "[tools] that make a study more centric to patients and sites … that augment patients and sites." Among the tools are virtual visits and wearables. The main point is not that all parts of the "where" and "how" of data collection need to be virtual so much as there is flexibility to do so if it would benefit the patient.

Hybrid trials are studies where *either* the "where" or the "how" of data collection is not exclusively traditional or virtual. For example, data could be initially collected at a research site but subsequently collected remotely via smartphone. As hybrid trials have proven popular among sponsors and sites, they might serve as a transitional step from a purely traditional model to a completely decentralized one, or they may be the best case scenario for most trials that still require at least some in-person interaction.[3]

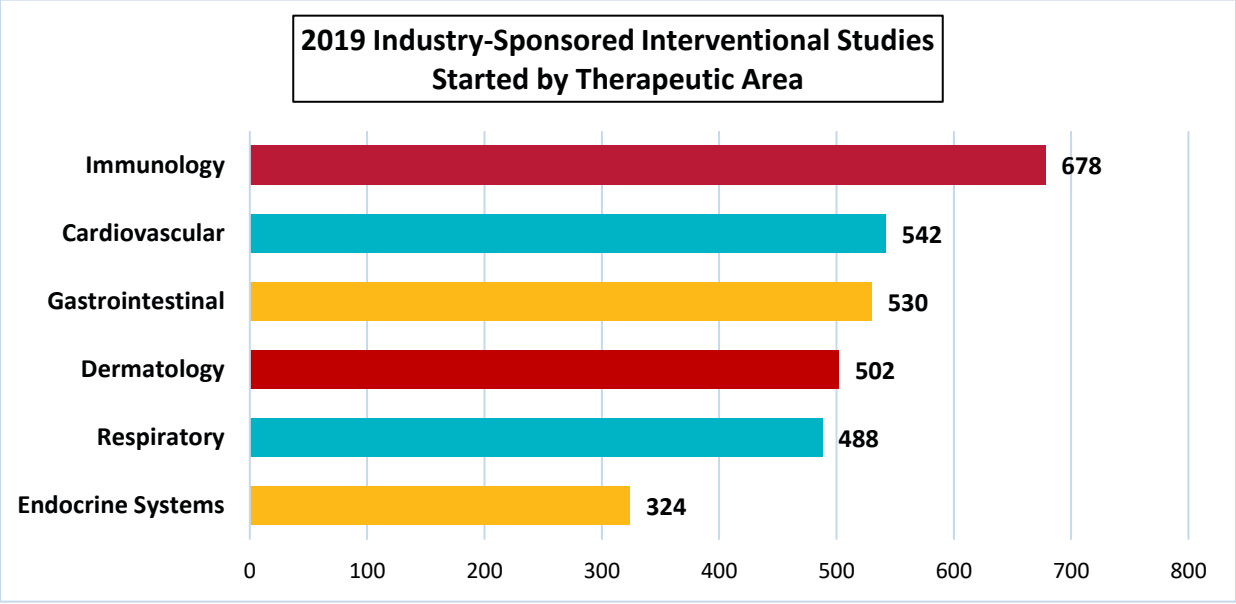
MARKET OVERVIEW

The clinical trials market is huge, estimated to be as large as $47 billion in 2019 with a forecast compound annual growth rate of 5.1%.[4] According to data from clinicaltrials.gov there were about 6,900 industry-sponsored clinical trials started per year from 2017 to 2019. Some companies focusing on a "fully virtual approach" believe that as many as 25 percent of all current studies could be conducted with a completely decentralized protocol.[5]

Though data on adoption levels of decentralized trials is sparse, a 2018 Avoca Clinical Innovation and Technology study reported that 25% of sponsors and 14% of service providers had utilized virtual and telehealth technologies in their clinical trials.[6] However, these adoption numbers may be slightly inflated in that some respondents may be counting mobile health studies with eCOA/ePRO or sensors in those studies when they weren't fully decentralized in moving visits from a clinic to a home.[7]

Of course, not every clinical trial can be completely decentralized. Some studies require an intermediary to perform functions such as a blood draw or a CT scan.

Decentralized trials might be best suited for less interventional studies in certain therapeutic areas such as immunology and cardiovascular. The number of 2019 industry-sponsored interventional studies in these and other therapeutic areas ranged in the hundreds. These would be the types of trials where decentralized protocols would most easily be adopted.



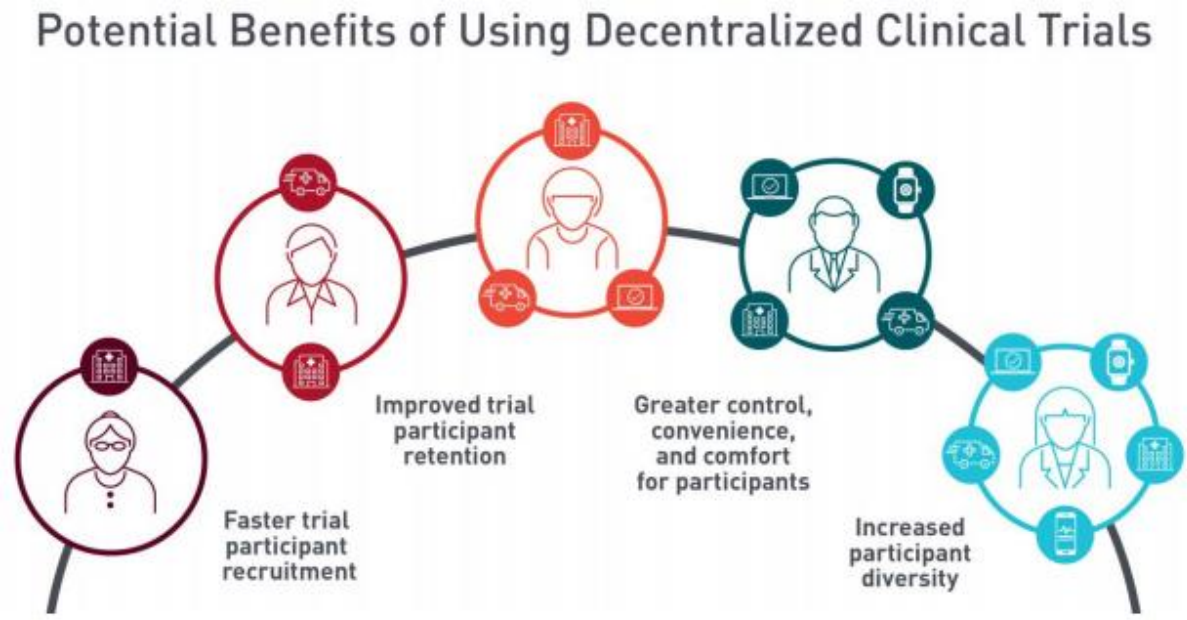
Source: clinicaltrials.gov

BENEFITS

As stated earlier, there is a constant pressure in the life sciences industry to find ways to make drug development better, faster, or less expensive.

Making Drug Development Better

Some overlapping and mutually reinforcing ways in which decentralized trials can make drug development better are: (1) faster recruitment and improved retention; (2) better patient experience; and (3) increased patient diversity.[8]



Source: "CTTI Recommendations: Decentralized Clinical Trials," (Clinical Trials Transformation Initiative – September 2018)

Patient recruitment and retention are recurring issues. A 2014 study reported that 19% of evaluated trials were either terminated or completed with less than 85% of expected enrollment.[9] A 2018 study reported that as many as 86% of clinical trials do not reach recruitment within their specified timelines.[10] And an oft-cited (but perhaps apocryphal) statistic has the average patient dropout rate at 30%.[11] The promise of decentralized trials improves recruitment by reducing patient burden, using technology to meet them where they are: in their homes. Additionally, use of social media and other digital recruitment efforts can provide a higher rate of return because of their lower costs.

Additionally, supporting sponsors in adoption of decentralized studies can improve patient recruitment. Patients can be recruited from larger geolocations around a research site, may spend less time in participation, and may see benefit in this approach when they understand how it compares to a traditional study. John Reites advises that "[Sponsors should] emphasize with patients the differences in this model to a traditional study schedule of events. For example, instead of coming into the office 16

times, you will come in eight times and meet via telehealth or with a home health nurse that will come to you."[12]

Patient centricity has been both an industry buzzword and an actual goal, designed to improve patient experience and outcomes along with clinical trial efficiency. Decentralized trials are more patient-centric in that they require less travel and time investment of patients and provide patients greater access to physicians and study staff.

Whether racial or gender-based, a lack of patient diversity has been a longstanding problem in clinical trial participant pools. In June 2019, the FDA issued draft guidance on the topic to encourage greater diversity in clinical trial populations.[13] Clinical trials have been less accessible to under-represented groups. Decentralized trials improve patient accessibility, and should theoretically also improve patient diversity.[14] More efficient trial management should also increase patient diversity.

Making Drug Development Less Expensive and Faster

The promise of decentralized trials is that their adoption can help the drug development process save money and time.

Two direct ways decentralized trials can reduce clinical trial costs are through (1) investigator fees and (2) site monitoring and management.[15] Investigator fees make up 40–60% of a total clinical budget; much of this cost comes from costs incurred from the research site and clinicians paid to staff them. Site monitoring typically makes up 25–30% of clinical trial cost; the remote monitoring utilized in decentralized trials is less costly than on-site monitoring at a research site.

Three indirect ways in which decentralized trials can reduce study costs are (1) reduction of recruitment time; (2) increased retention (and reduced need to address cost of dropped patients); and (3) increased patient adherence (which saves money that otherwise would have to be used to address noncompliance).[16]

All of these theoretical cost savings and improved processes come with assumptions of two related benefits: reduced trial complexity and shortened trial timelines. The argument behind this is that as each stage (e.g., recruitment, retention, engagement, adherence) is run more efficiently, the time required for each stage will be reduced, as well.

BARRIERS AND CONCERNS

Institutional resistance to change is prevalent in many industries. The life sciences industry is no exception regarding its reluctant embrace of decentralized trials.

Barriers to decentralized trials include cost, culture, lack of technological familiarity, and integration. Data security is another potential obstacle considering the vast amount of patient data that needs to be transmitted electronically. Four of these concerns were raised by survey respondents when asked to identify reasons for the lack of implementation of eClinical technologies.[17] Culture, or resistance to change, is a persistent issue as "stakeholders continue to be wary of such radical change in the clinical research process … Change can equate to risk and uncertainty, which makes sponsors and regulators nervous."[18] Each of these obstacles applies not only to decentralized trials but for most issues related to data collection in drug development.

Obstacles to Implementation of eClinical Solutions	
Rank	**Obstacle**
#1	Cost
#2	Fear of change
#3	Data integrity/security
#4	Insufficient collaboration
#5	Lack of resources
#6	Lack of internal support/training

Source: "Technology and eClinical Solutions," (ACT-SCORR Marketing – December 2018)

There are also patient barriers. Many patients might not have the necessary equipment, app, or wearable needed to participate in a decentralized trial. However, more patients have the necessary devices now than ever before and they are more digitally savvy. And according to a 2019 CISCRP survey of patients, one-third of them said it was very important that there be mobile/electronic applications.[19]

Additional concerns that accompany implementation of trial technologies include the following:

- New patient responsibilities – While patients no longer need to worry about travel, they have become default technology troubleshooters.
- Regulatory barriers – While the FDA has provided guidance to encourage the appropriate use of remote technology in clinical trials, pharmaceutical companies still have regulatory concerns such as good clinical practice (GCP)-related issues and HIPAA compliance.
- Reduced physician involvement – If physicians become less involved in the clinical development process, they might also be less likely to play an active role in other parts of drug development such as recommending the use of some drugs to patients.

SERVICE PROVIDERS

While some CROs explicitly demonstrate expertise in decentralized trials, most currently do not. Below are a selection of CROs that present some level of decentralized trial expertise or thought leadership on their websites.

Selected CROs and How They Demonstrate Decentralized Trials Expertise or Provide Decentralized Trials Content	
CRO	**Web Page Heading and Link**
Avania	[Blog] How to Successfully Perform Remote Monitoring During the COVID-19 Pandemic
Biorasi	[Content Tagged with "Virtual Trials"]
Covance	Decentralized Clinical Trials
ICON	Decentralised and Hybrid Trials
IQVIA	Trials Designed Around the Patient
Medpace	Minimizing Disruption to Clinical Trials During COVID-19
Parexel	[Press Release] Parexel Advances Patient-Centric Drug Development
PPD	[Blog] Responding to COVID-19 Continuity Challenges
PRA	Wearables and Virtual Trials
Syneos	Deployment Solutions: Our Commitment During the COVID-19 Pandemic
Synteract	[Blog Post on Recruitment] 14 Ways to Increase Recruitment in Rare & Orphan Disease Clinical Trials
Worldwide	[Article] Boldly Going Where Few Have Gone Before: Key Considerations for 'Siteless' Clinical Trials

Below and on the next page are some pharmaceutical, technology, and wearables companies that have played or might play a role in the execution of decentralized trials. Note: These are not exhaustive lists.

Pharma

abbvie

AstraZeneca

Bristol Myers Squibb™

GILEAD
Creating Possible

gsk

Johnson & Johnson

MERCK

NOVARTIS

Pfizer

Roche

teva

Technology

aparito

Clinical Ink
Confident Decisions, Faster

CLINPAL

ELLIGO
HEALTH RESEARCH

EmpiraMed

evidation

MEDABLE

Sage

Science 37

THREAD

transparency life sciences

VIRTRIAL
The Future of Decentralized Clinical Trials

Wearables

ActiGraph

AliveCor

WATCH

BioSensics

empatica

fitbit

GARMIN

mc10

SAMSUNG

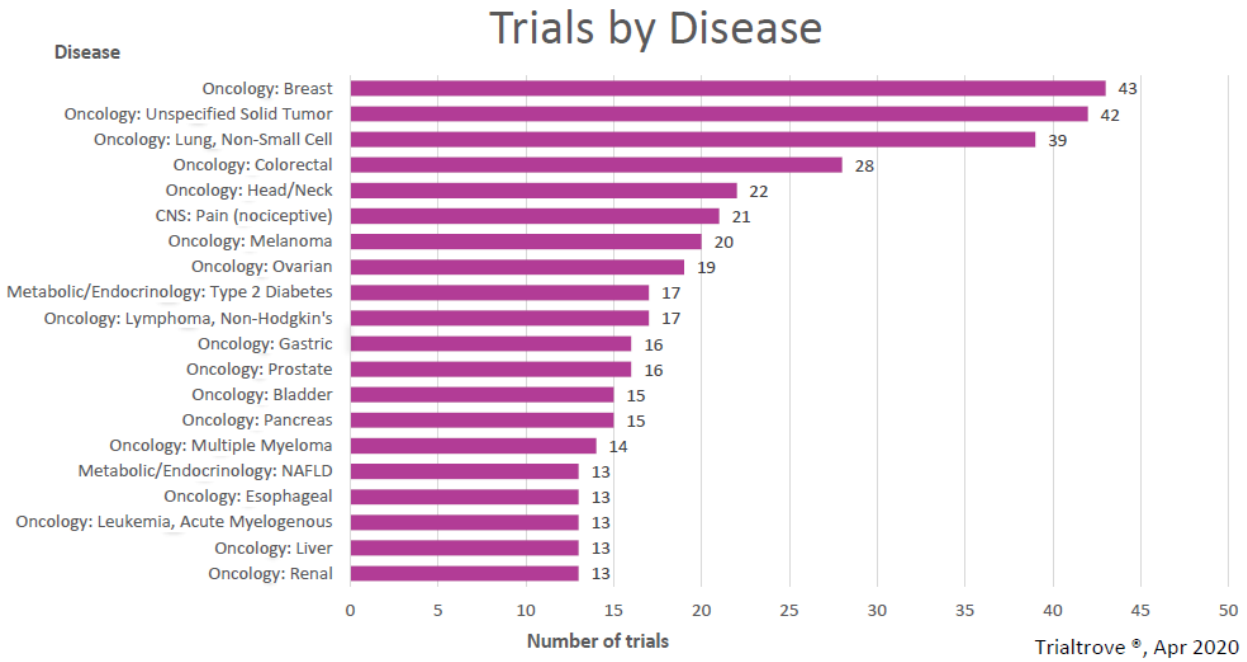
THE IMPACT OF COVID-19

As stated earlier, traditional clinical trials are defined by data collection at research sites and collected by intermediaries such as on-site clinicians. Pre-COVID-19, the time and travel required for patients to participate in clinical trials had already resulted in a level of patient burden that made it prohibitive for many potential patients to join studies and for others to stay in them.

Pause/Slowdown

The introduction and then steep increase of COVID-19 cases led to resulting public health measures such as shelter-in-place orders and quickly formed norms such as voluntary social distancing. This, in turn, significantly increased the level of patient burden for trial participation. By mid-March, the increase in trial delays became apparent. COVID-19 had shut down drug trials for a number of diseases. In a survey of clinical sites, nearly one-third of them feared total closure and more than three-quarters of them believe ongoing trials have been impacted.[20]

According to Trialtrove, more than 500 trials had been delayed and around 400 had been officially suspended by the end of April — a disproportionate amount of them were oncology trials.[21]



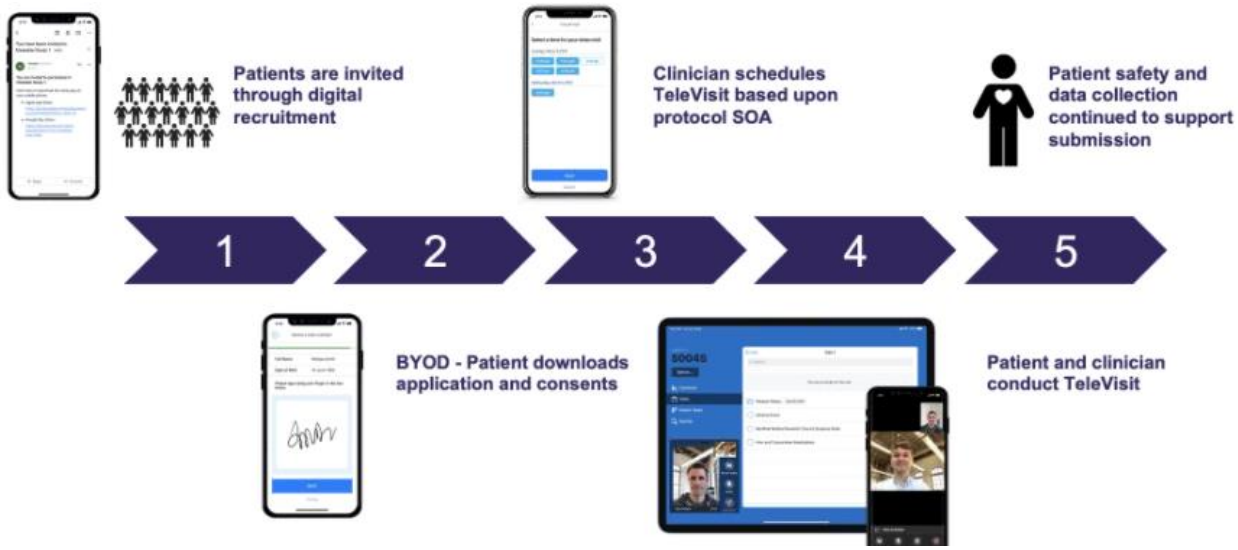
Source: "Pharma R&D Review: What Changed in 2019, What to Look Out for in 2020," (PharmaIntelligence/Informa webinar – 4-28-20)

Pivot to Decentralized Trials

Decentralized trials have been around for almost a decade. The promise of decentralized trials — the application of the most up-to-date technologies to reduce patient burden and in turn improve processes such as trial recruitment, retention, and diversity — are not new. But the COVID-19 pandemic made them more popular as traditional trials have become logistically less viable.

Regulatory bodies began advocating for increased use of decentralized trials. The FDA issued guidance pushing for clinical researchers to utilize virtual technologies.[22] And in Europe, the EC and MHRA both encouraged the substitution of decentralized trial data collection where possible.[23]

The industry has increasingly embraced decentralized trials as the existing traditional method of data collection has become, for the time being, impractical.[24] There has been an urgency to utilize decentralized trials to help clinical research continue.



Source: "Rapid Deployment of Remote Trials During Containment," (EndPoints/Medable webinar – 4/23/20)

THE FUTURE OF DECENTRALIZED TRIALS

The COVID-19 pandemic has pushed the adoption of decentralized trials to the forefront … for now. But is it the beginning of a longer-term change or is it a temporary uptick that will recede once the pandemic is over?

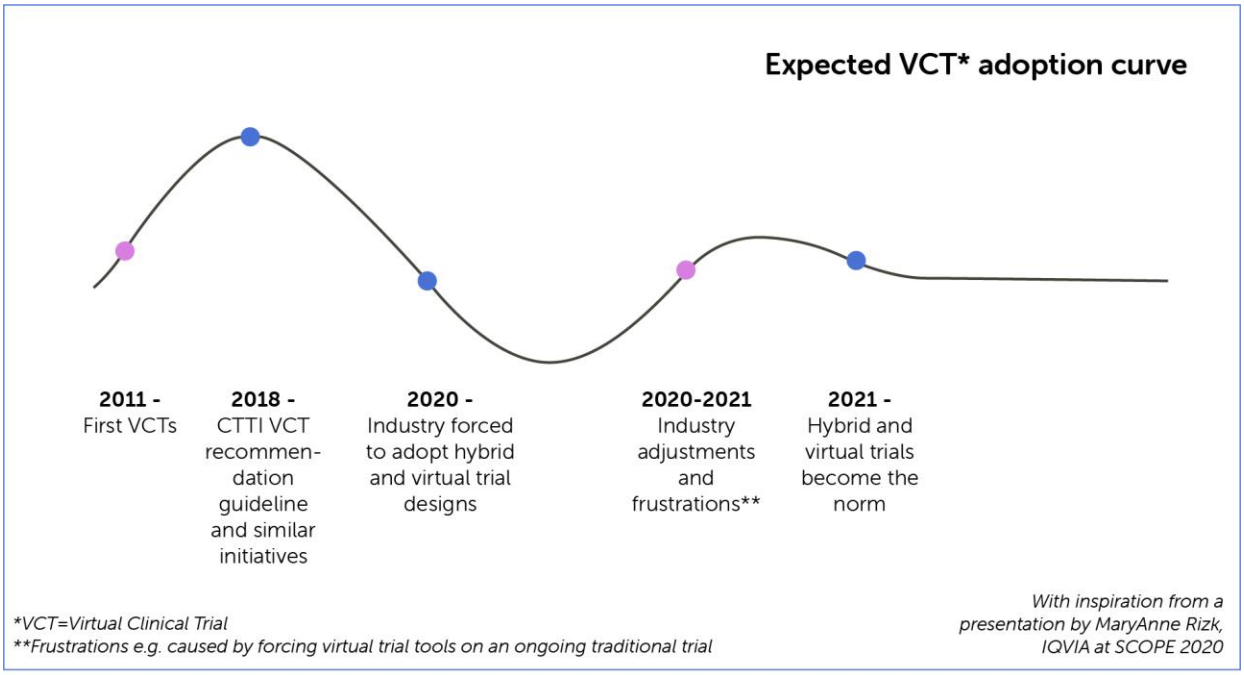
A number of industry players are bullish about the future of decentralized trials:

- John Reites, president of THREAD: "We have all recently learned new habits in working and living more virtually. Our sites and patients have begun to form the same habits while getting more comfortable with technology, video meetings and doing things without going to a physical location. I believe this will continue to catapult the use of decentralized study approaches as a new paradigm in clinical research."[25]
- John Potthoff, CEO of Elligo Health Research: "While devastating for so many, the COVID-19 pandemic has reinforced our industry's focus on patient centricity. During the pandemic, many new clinical trial models and technologies have been successfully employed that bring clinical trials closer to the natural patient-physician relationship, including decentralized and other healthcare-based models. These have been so successful that I think their adoption will be accelerated going forward."[26]
- Ed Seguine, CEO of Clinical Ink: "In an emergency like the current pandemic, operational issues are more acute, monitoring is more complicated, and risk is higher because of the potential spread of disease. Longer term, events like this are a catalyst for pragmatic innovations such as decentralized trials. The crux of a decentralized approach is "execution optionality": built-in protocol options allowing trials to be conducted to suit site and patient preferences while ensuring rigorous, controlled data collection. For example, within the same trial, patients might engage in remote visits or attend the clinic; sites might adopt eSource or use EDC. Executing such optionality requires a broadly flexible underlying technology platform with the full spectrum of direct data capture, such as BYOD ePRO — and the undeniable benefits of cleaner data, reduced cost, improved patient engagement, and accelerated results."[27]
- Jeff Kasher, president of Patients Can't Wait: "If one good thing emerges from this pandemic, it will be the use or remote/centralized monitoring in all clinical trials … We can't keep conducting trials the way we have in the past. Going forward, we need to see a new normal emerge for clinical trials."[28]
- Bruce Hellman, CEO of uMotif: "The fact that coronavirus is so contagious and has caused countries the world over to close business and schools and implement social distancing demonstrates the need for more virtual and hybrid trials. The world will be a changed place post COVID-19 and clinical trials will be, too."[29]

Some others are more reserved:

- Vivienne van de Walle, co-founder and owner of PreCare Trial & Recruitment: "In the past, I would have been concerned about the patient not being home [and] ensuring patient compliance, drug accountability and reliability of the process by monitoring at a distance. Right now, however … virtual visits and [direct-to-patient] trials are no longer [just] a nice [thing] to have. We have to do what we can to help patients and continue research."[30]
- Ida Kløvgaard, virtual clinical trial manager, LEO Innovation Lab: "No doubt, we are going through a major change in the way the industry looks at virtual clinical trials, switching quickly

from 'nice-to-have' to 'need-to-have' … However, [there could be] frustrations from the adopters modifying virtual tools as a band-aid solution for already ongoing traditional trials … Nonetheless, it is certain the market adoption curve for virtual clinical trials has been shortened by up to several years."[31]



Source: "COVID-19 Pandemic Pushes Clinical Trials to Go Virtual," (Medium/LEO Innovation Lab – 3/26/20)

As reviewed in the Barriers and Concerns section, there has been plenty of institutional inertia that has, up until COVID-19, acted as a brake on the widespread adoption of decentralized trials. We do know the following:

- Decentralized trials will have been more widely adopted than ever before.
- The levels of adoption for technologies such as telehealth and wearables that support decentralized trials are projected to grow.[32,33]
- Post-COVID-19, there will still be a need for drug development including both new clinical trials and a backlog of delayed clinical trials.
- Patients will still be interested in participating in clinical trials.[34]

SUMMARY

The first decentralized clinical trial took place less than a decade ago. Since then, there have been many more such trials but not as many as advocates for decentralized trials would have hoped.

- **Benefits** – The promise of decentralized trials is that they can help make drug development better, faster, and less expensive. This would be achieved through better patient recruitment and retention, better patient experience, improved patient diversity, shortened timelines, and savings in investigator fees, site monitoring, and management.

- **Barriers & Concerns** – The largest barriers to decentralized trials — cost, cultural resistance to change, and data integrity — are also recurring obstacles to most change. Other concerns are additional patient responsibilities, regulatory barriers, and reduced physician involvement.

- **The Impact of COVID-19** – The pandemic has resulted in a pause or delay of ongoing trials that has driven, as a matter of necessity, greater adoption of decentralized aspects of trials. Decentralized trials have gone from a niche type of trial to into something much more widespread.

- **The Future of Decentralized Trials** – The big question is whether the increased situational adoption of decentralized trials that has occurred as a result of COVID-19 is a temporary phenomenon or the beginning of a permanent, longer term evolution. Review of a handful of industry players points to a consensus that there will be greater decentralized trial adoption in the new normal than pre-COVID-19. Some analysts are quite bullish and believe a markedly higher adoption rate will be the norm. Others believe there very well could be some fallback as sponsors and CROs, when given the option, revert to processes with which they are more comfortable.

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