

A person wearing a white lab coat is using a handheld medical device on their hand. The device is dark blue and has a small screen or sensor at the tip. The person's hand is held out, and the device is being applied to the palm. The background is a soft, out-of-focus blue and green, suggesting a clinical or laboratory setting. A blue line graphic curves across the bottom of the image.

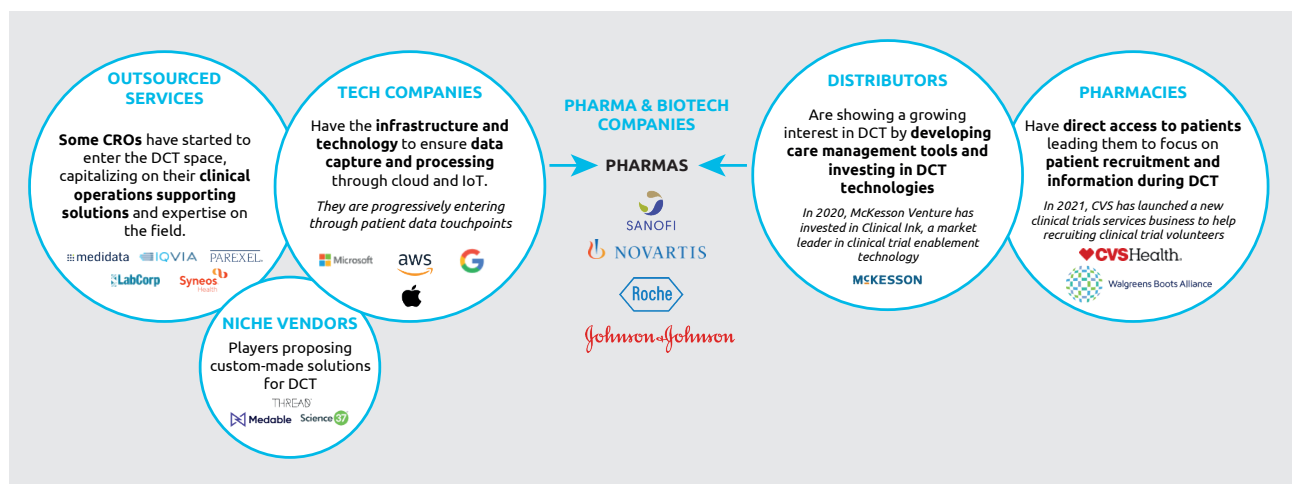
ARE DECENTRALIZED CLINICAL TRIALS THE FUTURE?

Clinical trials are "pivotal" phases of drug development. Throughout the years, they've enabled patients across the world to access innovative therapies, advanced research, and medical knowledge.

By 2025, the global spending on pharmaceutical research and development is expected to reach \$248 billion⁽¹⁾. But, clinical trials have become more complex, time consuming, and costly for sponsors, especially with the ever-increasing demand set against the limited number of patients enrolling in clinical trials. Indeed, clinical trials are facing more and more challenges, but also new levers for improvement, driven by emerging technologies, and sponsors are gaining ground in better attracting patients into their trials.

A paradigm shift is taking place through the concept of decentralized clinical trials, catalyzed by the COVID-19. Although it is a relatively small market today, decentralized clinical trials are emerging in a significant way. As a matter of fact, the FDA issued guidance to facilitate the conduct of clinical trials during the pandemic, to ensure the safety of participants and compliance with good clinical practices⁽²⁾. The guidance encourages, for instance, sponsors to evaluate the possibility of conducting virtual visits whenever feasible and to consider remote data capture through distancing technologies.

While the COVID-19 crisis has accelerated the use of decentralization, the concept is not new, and several big pharma have already taken the step, supported by tech players and consulting firms. As decentralized clinical trials are still in the early stage, the profiles of the various players are still nascent, who are jostling for a competitive advantage.



Are decentralized clinical trials a cyclical change linked to COVID-19 or a structural change that will revolutionize the clinical trials market? How do they respond to current challenges? And what are the main constraints to their deployment?

(1) <https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/>

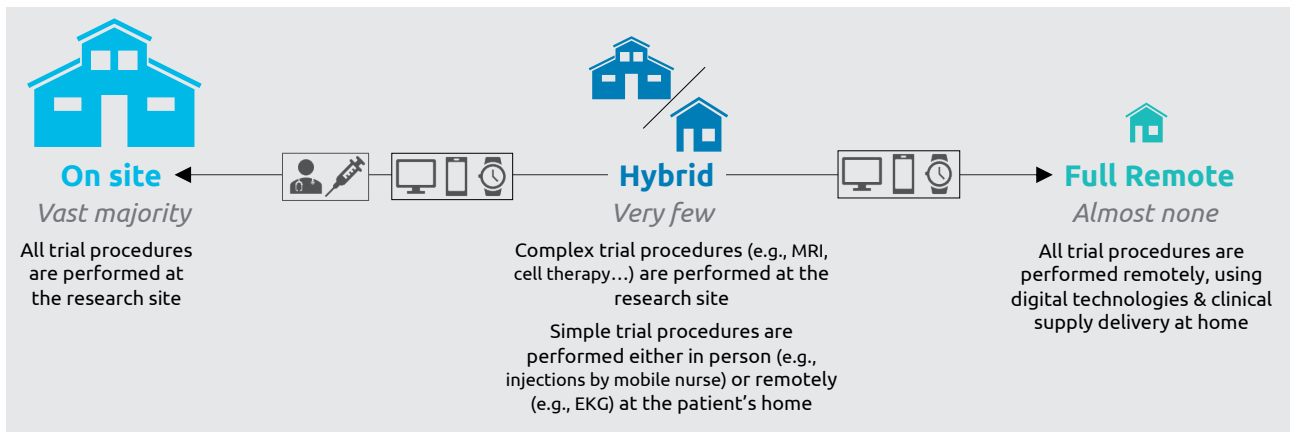
(2) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>

DCT MOVES THE TRIAL TO THE PATIENT'S HOME

Decentralized Clinical Trials (DCTs) make it possible to monitor clinical trials participants at home in near real-time. An overview of the main activities of clinical trials enable us to better understand the differences between an on-site and a decentralized clinical trial:

On site Clinical Trial	Activities during Trial Conduct	Full remote Clinical Trial (DCT)
Mainly from sites	Recruitment	Mainly online
In person	Consent & Enrollment	Electronic
Primarily in clinic	Study visit location	Primarily at home
Via investigator	Access to study drug	Via courier or visiting nurse
In person	Method of assessing participants	By phone or video
Often investigator-derived	End points	Patient-reported or device-captured
On-site monitoring	Study oversights	Remote/central monitoring
Flexibility viewed as risk	Sponsor culture	Flexibility viewed as strength
High	Participant burden	Moderate
Low and late	Participant involvement	High and early

Enabled by a combination of **digital technologies** and **at-home services**, DCTs can partially or fully move clinical trial activities to the patient's home.



A clinical trial can be considered as a **decentralized clinical trial if is one or all these 3 pillars are in place:**

- **Remote interactions* with the patient** – the patient does not need to come to the investigator site and can stay at home.
- **Patient information can be accessed later** – the patient does not need to be available at the same time as the physician.
- **Data push from the patient** – no data pull from trial assistant; the data is directly and/or automatically pushed by the patient with a potential feedback loop.

(*): administrative, information collection, medical data collection...

DCT ADDRESSES KEY UNSOLVED ISSUES OF CURRENT RANDOMIZED CLINICAL TRIALS

Through a patient-centered approach, DCT can help drive drug development, decrease time-to-market and improve patients' quality of life.

Focus on patient	Improve data quality	Reduce overall trial cost
<ul style="list-style-type: none">At-home delivery increases participationDirect-to-patient approach accelerates recruitmentPersonalized interaction maximizes retention and foster better medical adherenceVirtual study team facilitates patient journey	<ul style="list-style-type: none">Mobile, connected devices enhance data gatheringCentralized collection reduces variabilityNear real-time access enhances safety signal detectionIncreased data completeness and accuracyBetter study results with greater Patient diversity	<ul style="list-style-type: none">Streamlined engagement, enrollment, trial managementFewer physical site visit costsCentrally managed workflows, monitoring and communications improve efficiency

THERE ARE 3 KEY ELEMENTS TO CONSIDER WHEN DEPLOYING A DCT

First and foremost, deploy a user-centric approach (patients and HCPs)

DCT allows patients to overcome geographical barriers and reduce the burden of actively going onsite. To improve patient engagement, sponsors need to work closely with patients to **understand their needs** and **improve their experiences**. It is not only a matter of moving the data collection activity to home but also a need to provide a convenient experience that adapts to the patients' needs⁽³⁾. But DCT should also consider the impact on the physician's day to day activities.

(3) <https://www.appliedclinicaltrials.com/view/why-decentralized-clinical-trials-are-the-way-of-the-future>

Feasibility assessment as a prerequisite

All clinical trials cannot be candidates for decentralization. For instance, DCTs are less prone to be implemented in phase I as the assessment of safety and dosage require a more active observation and an early detection of adverse events.

Still, there is a need to assess **protocols** that are more suitable for DCT: consider the existing protocols and assess those eligible for decentralization; or revisit the entire protocol from the design phase in order to make them compatible with decentralization. In addition, sponsors should evaluate the target **therapeutic area**, the **clinical trial phase**, **study endpoints**, the **type of assessment procedures** or the **administration route** that can be adapted to decentralization.

As a matter of fact, there are still significant differences between the therapeutic areas. Indeed, Oncology seems to be lagging behind, as sponsors are still reluctant to monitor remotely critical elements such as the follow-up of adverse events.

A critical need for a robust technological infrastructure

Decentralization requires the use of **new digital data capture**, through wearable medical devices, telemedicine, electronic clinical outcomes assessment (eCOA), electronic Patient Recorded Outcomes (ePRO) platforms, and other distancing technologies. Sponsors must ensure they are well equipped to collect and integrate accurate and qualitative data into their IT infrastructure. New tech providers are gaining ground and big pharma players are building strategic partnerships to integrate DCTs in efficient and agile ways.

EMPOWERING CLINICAL RESEARCH IN A DECENTRALIZED WORLD

As of 2020, only 0.5% of clinical trials conducted worldwide were decentralized (~1,000 to 2,000 DCTs). While **drug-based interventional DCTs** only experienced a 7% CAGR between 2014 and 2019, most of the trials turned into DCT in the course of 2020, due to the obvious constraints. The **COVID-19 pandemic significantly accelerated the adoption of DCTs**, with an increase in trial activities conducted remotely and in participants' homes.

The global DCTs market size is projected to reach **Bn 9,1 USD in 2026**, from Bn 1,8 USD in 2021, at a **CAGR of 38.5% during 2021-2026**⁽⁴⁾.

Nonetheless, **fully decentralized trials are more likely to remain limited** to a defined set of therapeutic areas and set-ups, due to the amount of invasive data collection sometimes required by protocol design.

(4) <https://research2guidance.com/product/the-digital-decentralized-clinical-trial-solutions-market-2018-2026/>

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