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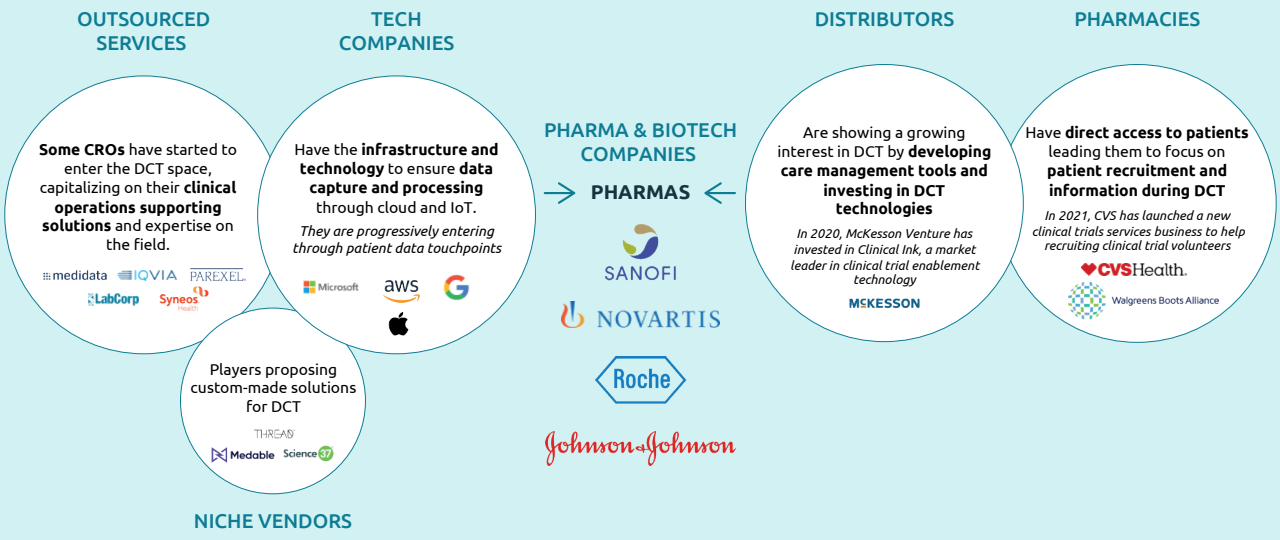
ARE DECENTRALIZED CLINICAL TRIALS THE FUTURE?

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 the improved ability of sponsors to attract patients to their trials.

A paradigm shift is taking place through the concept of Decentralized Clinical Trials (DCTs), 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. This was done 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 companies 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, all 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 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

- Mainly from sites
- In person
- Primarily in clinic
- Via investigator
- In person
- Often investigator-derived
- On-site monitoring
- Flexibility viewed as risk
- High
- Low and late

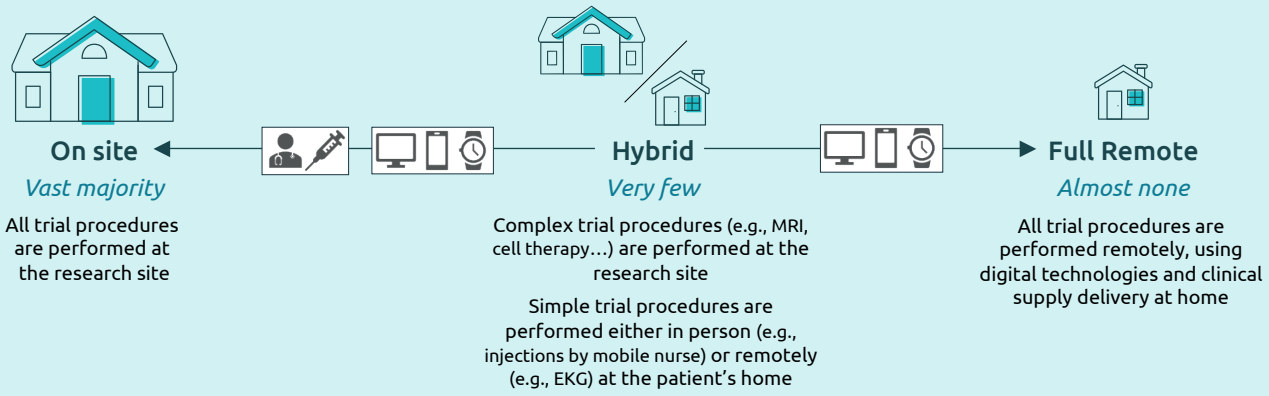
Activities during Trial Conduct

- Recruitment
- Consent and Enrollment
- Study visit location
- Access to study drug
- Method of assessing participants
- End points
- Study oversights
- Sponsor culture
- Participant burden
- Participant involvement

Full remote Clinical Trial (DCT)

- Mainly online
- Electronic
- Primarily at home
- Via courier or visiting nurse
- By phone or video
- Patient-reported or device-captured
- Remote/central monitoring
- Flexibility viewed as strength
- Moderate
- 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 a **decentralized clinical trial if 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

- At-home delivery increases participation
- Direct-to-patient approach accelerates recruitment
- Personalized interaction maximizes retention and foster better medical adherence
- Virtual study team facilitates patient journey

Improve data quality

- Mobile, connected devices enhance data gathering
- Centralized collection reduces variability
- Near real-time access enhances safety signal detection
- Increased data completeness and accuracy
- Better study results with greater Patient diversity

Reduce overall trial cost

- Streamlined engagement, enrollment, trial management
- Fewer physical site visit costs
- Centrally 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 Healthcare Proxies (HCPs)

DCT allows patients to overcome geographical barriers and reduce the burden of actively going on-site.
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.appliedclinicaltrialsonline.com/view/why-decentralized-clinical-trials-are-the-way-of-the-future

Feasibility assessment as a prerequisite

Not all clinical trials can be candidates for decentralization. For instance, DCTs are less prone to be implemented in phase I. This is because 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. Additionally, 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 critical elements remotely, 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 **USD 9,1 bln in 2026**, from USD 1,8 bln 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/

Authors:

Damien Vossion

Head of Industry & Life Sciences
Capgemini Invent France

damien.vossion@capgemini.com

Aéthalie Chabriol

Senior Managing Consultant & DCT expert
Capgemini Invent France

Aethalie.chabriol@capgemini.com

Barnabé Lecouteux

Director AI & Data services
Capgemini Invent France

barnabe.lecouteux@capgemini.com

Salma Benchekroun

Pharm. D & Consultant
Capgemini Invent France

salma.benchekroun@capgemini.com

If any queries, do reach out to our Life Sciences Country Leads.

Pesanello, Michele
michele.pesanello@capgemini.com

Balachandran, Arry
arry.balachandran@capgemini.com

Sinner, Axel
axel.sinner@capgemini.com

Stich, Christoph
christoph.stich@capgemini.com

Dobles, Ivania
ivania.dobles@frog.co

VOSSION, Damien
damien.vossion@capgemini.com

MADELON, Camille
camille.madelon@capgemini.com

Roudil, Guillaume
guillaume.roudil@capgemini.com

Diana, Chiara
chiara.diana@frog.co

Karkera, Suday
suday.karkera@capgemini.com

Shirke, Poonam Prakash
poonam-prakash.shirke@capgemini.com

Jones, Broderick
broderick.jones@capgemini.com

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