Decentralized Clinical Trials (DCTs): Fads or Future?

Campana Schott

02.02.22, NYC

DCTs or “virtual” clinical trials will continue to grow in utilization offerings within the pharmaceutical industry. In order to meet this opportunity, pharma companies must holistically view their DCT strategy. DCTs are an innovative way to achieve enhanced patient-centric clinical trials.

Traditional Clinical Trials in the Digital Age

Traditional clinical trials are a pillar of modern medicine, but they are not free of critical short comings. Central to traditional clinical trials is the need for patients to come to you in some capacity. In specific, traditional clinical trials typically centralize their storage and operational centers which can dramatically impact patient adherence, access, and inclusivity [1], [2], [3], [4].

Paired with the challenges of recruitment and retention, traditional clinical trials are increasingly out of touch with modern times and digital technology [5], [6].

Will traditional clinical trials disappear soon? Unlikely. Is a noted shift occurring towards the increased utilization of DCTs? The short answer is a **resounding yes** [7].

DCTs: Overview

DCTs strengths can be summarized into three simple concepts: **smaller, faster, and nimbler** [8], [9], [10], [11]. DCTs are smaller and can be targeted to reach underserved populations which would traditionally face significant challenges to clinical trial participation [12]. DCTs are faster due to the ability to scale quickly relative to participant enrollment, smart tools as enablers for data monitoring, paired with the limited need to physically attend a trial center [13]. DCTs are nimbler in that they can be **modified** rather easily due to the strong use of digital technology to collect, aggregate, and disseminate data to the correct parties [14].

DCTs have seen a 10-fold increase in utilization from 2014 -2019 vs. 2019-Q2 2020 [15]. Covid-19 has been the main driving force behind the explosion in popularity for DCTs [16]. For the first time, DCTs were truly seen as a viable option to clinical trials due to the forced realities that Covid-19 brought to the global community.

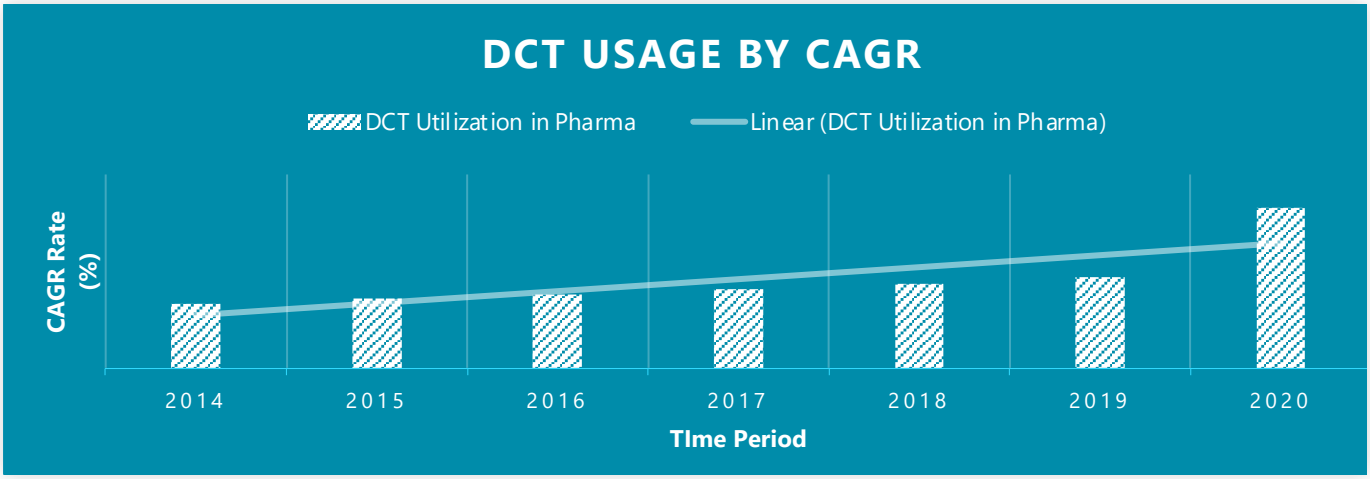


Figure 1 illustrates the explosive growth of DCTs in the last two years.

CAGR: Compounded Annual Growth Rate | Florence Health: 2021 State of Clinical Trial Technology Industry Report

DCTs: Challenges to be aware of.

DCTs hold tremendous potential but they do possess challenges which can not be ignored or overlooked.

DCTs: Weaknesses

DCTs have several advantages as denoted above but they are not a magical bullet either. DCTs require extensive levels of coordination to avoid patient burnout (e.g., redundant applications, at home data collection challenges, behavioral incentives, etc.) [17]. DCTs face shifting regulatory modalities (e.g., telemedicine, direct-to-patient product shipments, etc.) [18].

DCTS also require a new skillset relative to design, operations, and execution of the trial itself. Gone is the ability to house all your resources under “one-roof”. Rather for a DCT to be successful you need a strong master data management (MDM) strategy, industry leading data security mechanisms, sophisticated data analytics, solid distribution operations, and hands on partnerships with experienced global project management firms to handle the hundreds of intricacies which arise from at-home clinical trials [19], [20], [21], [22].

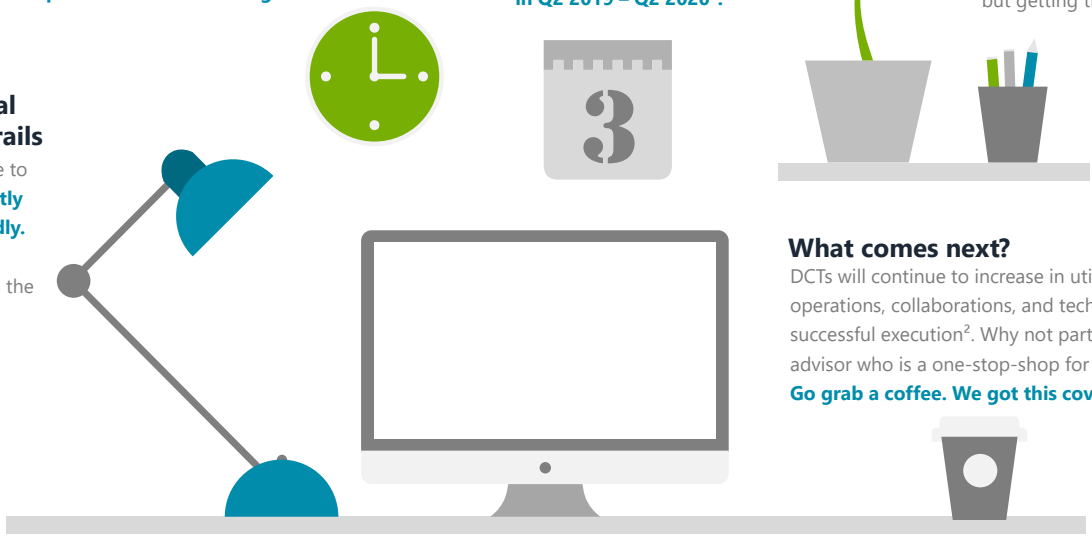
Decentralized Clinical Trials (DCTs)
The way of the future.

DCTs : Strengths
Smaller, faster, and fleeter **patient-centric modeling**[1].

Why now?
DCTs modelling went from a 7% CAGR in 2014-2019 to a **77% CAGR in Q2 2019 – Q2 2020**[2].

DCTs are easy right?
No. DCTs are the way of the future but getting there is another matter.

Traditional Clinical Trails
Patients come to you. **Frequently and repeatedly.** This is not sustainable in the digital age.



What comes next?
DCTs will continue to increase in utilization, future ready operations, collaborations, and technology services for successful execution[2]. Why not partner with a global advisor who is a one-stop-shop for all the above?
Go grab a coffee. We got this covered.

> Managing the risks and opportunities of DCTs will be the principal driver for the pharma industry.

DCTs: What Comes Next?

DCTs will continue to increase in utilization, future ready operations, collaborations, and technology services [15]. DCTs are well accepted by patients, showing up to a 20% increase in patient-adherence against traditional models [23]. Up to 80% of medical studies are non-reproducible due to data collection errors and interpretation misalignments [24]. The possibility to mitigate this reproducibility crisis may soon be achievable via DCTs and blockchain. Any pharma firm making operational and or strategic shifts towards DCTs must take a holistic approach to this surging trial design methodology. Managing the risks and opportunities of DCTS will be the principal driver for the pharma industry in the near-to-medium term. With 30 years of global industry experience Campana & Schott is ready to support you on your journey to successful DCT implementation. Whether you are in the ideation, pre-clinical, clinical, or simply looking for a sparring partner phase, Campana & Schott is here for you. **Go grab a coffee, we got you covered.** Campana & Schott | USA.

References

[1] e. a. Inan, „Digitizing Clinical Trials," NPJ, p. 101, 2020.

[2] S. &. C. A. Khozin, „Decentralized Trials in the Age of Real-World Evidence and Inclusivity in Clinical Investigations," Clinical Pharmacology & Therapeutics, pp. 1-3, 2019.

[3] NIH, „The NIH Collaboratory Launches a New Reseource on Methods and Best Practices for Pragmatic Clinical Trials," 2020.

[4] J. e. a. Unger, „Systematic Review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trail participation.," Journal of National Cancer Institute, vol. 111, pp. 245-255, 2019.

[5] N. e. al., „Overcoming barriers to clinical trail enrollment.," Soc. Clin. Oncol. Educ., vol. 39, pp. 105-114, 2019.

[6] K. e. al., „Broadening eligibility criteria to make clinical trials more representative: American Society of Clinical Oncology and Fiends of Cancer Research Joint Research Statement," Journal of Clinical Oncology, vol. 35, p. 3737, 2017.

[7] Florence Healthcare, „2021 State of Clinical Trial Technology: Industry Report," 2021. [Online]. Available: https://florencehc.com/downloads/2021-state-of-clinical-trial-technology-industry-report/. [Accessed 6 Feb 2022].

[8] G. e. al., „Clinical trials in the era of digital engagement: A SWOG call to action," JCO Clin. Cancer Infromat, vol. 4, pp. 254-258, 2020.

[9] S. e. al., „Building clinical trials around patients: Evaluation and comparison of dencentralized and conventional site models in patients with low back pain," Contemporary Clinical Trails Communications, vol. 11, pp. 120-126, 2018.

[10] D. A. A. &. S. M. Plana, „Re-Envisioning Clinical Trials During the Covid-19 Pandemic," Health Affairs, 2020.

[11] W. e. a. De Brouwer, „Empowering clinical research in a decentralized world," Digital Medicine, vol. 4, p. 102, 2021.

[12] J. e. a. Concato, „Randomized, controlled trials, observational studies, and the hierarchy of research design," New England Journal of Medicine, vol. 342, pp. 1887-1892, 2000.

[13] B. M.A., „Core Concept: In the wake of COVID-19, decentralized clinicial trials move to center stage," PNAS, 2021.

[14] Pfizer, „Pfizer conducts first „virtual" clinical trial allowing patients to participate regardless of geography," 2021.

[15] Plumlogix Inc, „The Promise of Decentralized Clinical Trials," 2020.

[16] K. e. a. Flaherty, „Rethinking cancer clinical trial conduct induced by Covid-19: An academic center, industry, government, and regulatory perpective," Cancer Discovery, vol. 11, pp. 1881-1885, 2021.

[17] G. e. al., „Why Decentralized Clinical Trails are the Way of the Future," Applied Clinical Trials, no. 1, 2021.

[18] „FDA Appropriations Bill 2021," 2 Feb 2022. [Online]. Available: https://www.appropriations.senate.gov/imo/media/doc/AGRept.pdf. [Accessed 2 Feb 2022].

[19] e. a. Khin, „Tackling Challenging Data Integrity Topics in 2020: Update on Good Clinical Practice Perspectives from the US FDA and MHRA UK," ASCPT, 2021.

[20] K. Morovat, „Verifying Integrity of Big Data in Cloud Databases," in International Conference on Computational Science & Computational Intelligence (CSCI), 2017.

[21] A. S. Ozalp, „Unlawful data access and abuse of metadata for mass persecution of dissidents in Turkey: The Bylock Case," Amsterdam, Institute of Network Cultures, 2019.

[22] U.S. Food & Drug Administration, „What is Digital Health?," 2020.

[23] S. e. al., „Building Clinical Trials around Patients: Evaluation and Comparison of Decentralized and Conventional Site Models in pateints with Low Back Pain," Contemporary Clinical Trials Communications, vol. 11, pp. 120-126, 2018.

[24] I. e. a. Omar, „Applications of Blockchain Technology in Clinical Trials: Review & Open Challenges," Review-Computer Engineering & Computer Science, vol. 46, pp. 3001-3015, 2021.

[25] G. e. al., „Digital technologies as biomarkers, clinical outcomes assessment, and recruitment tools in Alzheimer's disease clinical trials," Alzheimer's Dement, vol. 4, pp. 234-242, 2018.

Our Experts

Benjamin Figueroa

Campana & Schott Inc.
1460 Broadway
New York City, NY 10036
M +1 201 736 3412
benjamin.figueroa@campana-schott.com

Amber Evans

Campana & Schott Inc.
1460 Broadway
New York City, NY 10036
M +1 561 222 5186
kayla.evans@campana-schott.com

Grayson Mick

Campana & Schott Inc.
1460 Broadway
New York City, NY 10036
M +1 214 998 9042
grayson.mick@campana-schott.com

Campana & Schott

Campana & Schott is an international management and technology consultancy with more than 400 employees at locations in Europe and the US.
We shape the digital future of our customers and for more than 25 years have ensured the success of technological, organizational or entrepreneurial transformation projects – using an integrated and passionate approach.

Our customer base includes numerous companies as well as large mid-size sector companies. We can draw on more than 7,000 best practice projects at over 1,000 customers worldwide, and a follow-up contracting rate of over 90%.

Additional information:
www.campana-schott.com

CS Campana Schott