

# Modernizing Clinical Trials Through Decentralization and Digitization



Amid the turmoil of the COVID-19 pandemic, an unexpected benefit has been the accelerated exploration of methods to modernize clinical trials. Medtech companies, in particular, now have new opportunities to conduct clinical research faster, more effectively, and at a lower cost than traditional methods.

## Shortcomings of traditional clinical trials

Clinical research is the first step to introducing medical device and diagnostic innovations to the public and requires the highest levels of safety, compliance, and data quality. Achieving those benchmarks comes with common challenges and pitfalls, including:

**Time.** It takes significant time to get systems up and running to generate the necessary trial data to validate a device's safety and effectiveness. However, sponsors historically have struggled to keep up with technological innovations that could overcome procedural hurdles and accelerate trials.

**Enrollment.** Clinical research enrollment never goes as quickly as sponsors would like, which can seriously affect the timing of a trial. The number of patients in a trial also is critical. Without enough patients, the data will not have statistical significance and cannot be validated. Finally, it often involves paper-based processes, physical travel, time commitments, and the associated financial burden, which can limit the number and diversity of subjects.

**Infrastructure.** Documentation can be a challenge. Clinical trials involve various processes that have been slow to modernize. Developing documentation, setting up data capture systems, and ensuring compliance — especially when using paper-based processes — takes a significant amount of time and resources, slowing the pace of a study.

Medtech companies, in particular, now have new opportunities to conduct clinical research faster, more effectively, and at a lower cost than traditional methods.



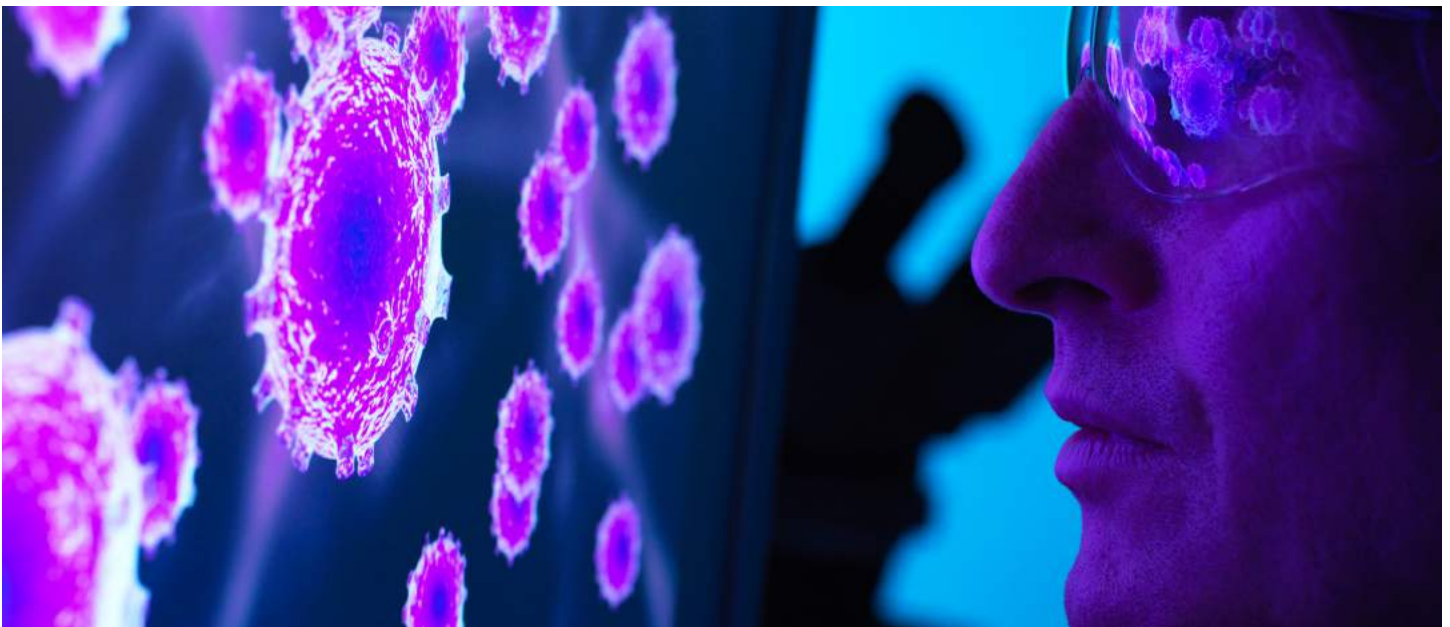
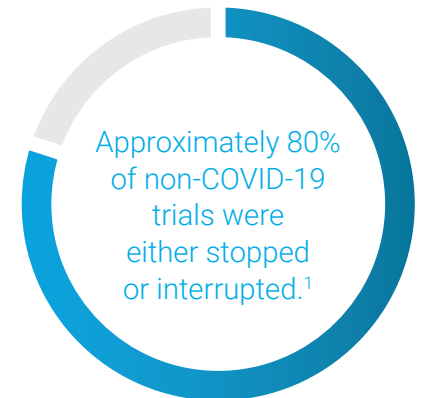
## How the pandemic has exacerbated current challenges

The early weeks of the COVID-19 pandemic added to these ongoing challenges — and had a devastatingly disruptive effect on clinical trials. Approximately 80% of non-COVID-19 trials were either stopped or interrupted. As of January, COVID-19 had stopped more than 2,000 clinical trials.<sup>1,2</sup> One study, which examined more than 62,000 trials that started before and during the pandemic, found that the number of studies initiated in the US from February to May last year was only 57% of what would have been expected had the pandemic not occurred.<sup>3,4</sup>

Thankfully, this slowdown did not apply universally. In some instances, particularly for COVID-19 diagnostics and vaccines, trials were unaffected or even accelerated.

But even as the US begins to move forward, the trial industry still isn't fully operating as before. Sponsors are still facing challenges enrolling patients because physicians and sites that typically participate in studies are prioritizing other medical visits and treatments for patients that were delayed by the pandemic.

Although the pandemic has disrupted the clinical trial community, it also has brought greater attention to potential new solutions, including a paradigm called decentralized clinical trials, or DCTs.



## How decentralized clinical trials work

In 2015, the Clinical Trials Transformation Initiative defined DCTs simply as trials executed through telemedicine and mobile/local health care providers. The institution then recommended that trial sponsors give greater consideration to fully or partially decentralized clinical trials.<sup>2</sup>

More recently, McKinsey defined a DCT as a “trial centered around patient needs that improves the patient experience. The focus of such a trial is on making it more convenient, closer to the patients, or both by using a combination of virtual and physical elements to conduct the required trial procedures. It involves bringing an increasing proportion of a trial’s activities to the patients rather than using the traditional paradigm of bringing patients to a trial site.”<sup>5</sup>

This type of modernized trial paradigm has been discussed for years but was not commonly used until the pandemic lockdown in March 2020, leading medical device and diagnostics organizations to actively explore logistical alternatives. Medtech companies rapidly implemented digital clinical trials to ensure continued innovation.





## Characteristics of DCTs

Three key characteristics of DCTs are:

- **Virtual data collection**
- **Reduced on-site activity**
- **Digitization**

DCTs employ methods for virtual data collection and patient assessments, including virtual/telehealth visits and remote patient monitoring.

In the traditional trial model, the physical site is the central location of all the action. This is where patients are enrolled and treated, where their data is collected, and where sponsors go to train and monitor the research sites. DCTs, on the other hand, aim to reduce on-site visits as much as possible.

Digitization offers sponsors new levels of efficiency. Examples include online forms for patients to report health outcomes and paperless methods for collecting and documenting trial information in a compliant and audit-ready manner.



## Benefits of DCTs

Now, medtech companies are realizing the many benefits of DCTs.

**Improved speed and data quality:** Digitization and decentralization can improve the speed of trials while maintaining, or even improving, data quality. This can be achieved by collaborating on documentation using online tools, rather than physically sending paper documents back and forth. In addition, subjects are able to report their health status more quickly when they would otherwise have waited until seeing a provider or going to the site for a follow-up visit.

**Fewer obstacles to patient enrollment and participation:**

The top causes of trial delays or terminations are because of patients having to be at physical locations and time commitments that are eliminated or reduced with DCTs. Being able to recruit outside certain ZIP codes also expands access to patients who fit the trial criteria.

**Reduced rates of participant dropouts:** Dropout rates rose from 15% in 2012 to 19% in late-stage studies globally during the pandemic.<sup>2</sup> Digital trials are more convenient for patients, and both sponsors and investigators say they can speed enrollment and reduce dropout rates.<sup>2</sup>

**Higher-quality results:** Replacement of manual and paper-based processes with digital and virtual methods drives higher-quality study results and patient satisfaction.<sup>6</sup>

**Increased collaboration:** Use of collaborative technologies across clinical operations and data management streamline the process for trial sponsors and research sites, speeding the overall process.

Digitization and decentralization can improve the speed of trials while maintaining, or even improving, data quality.



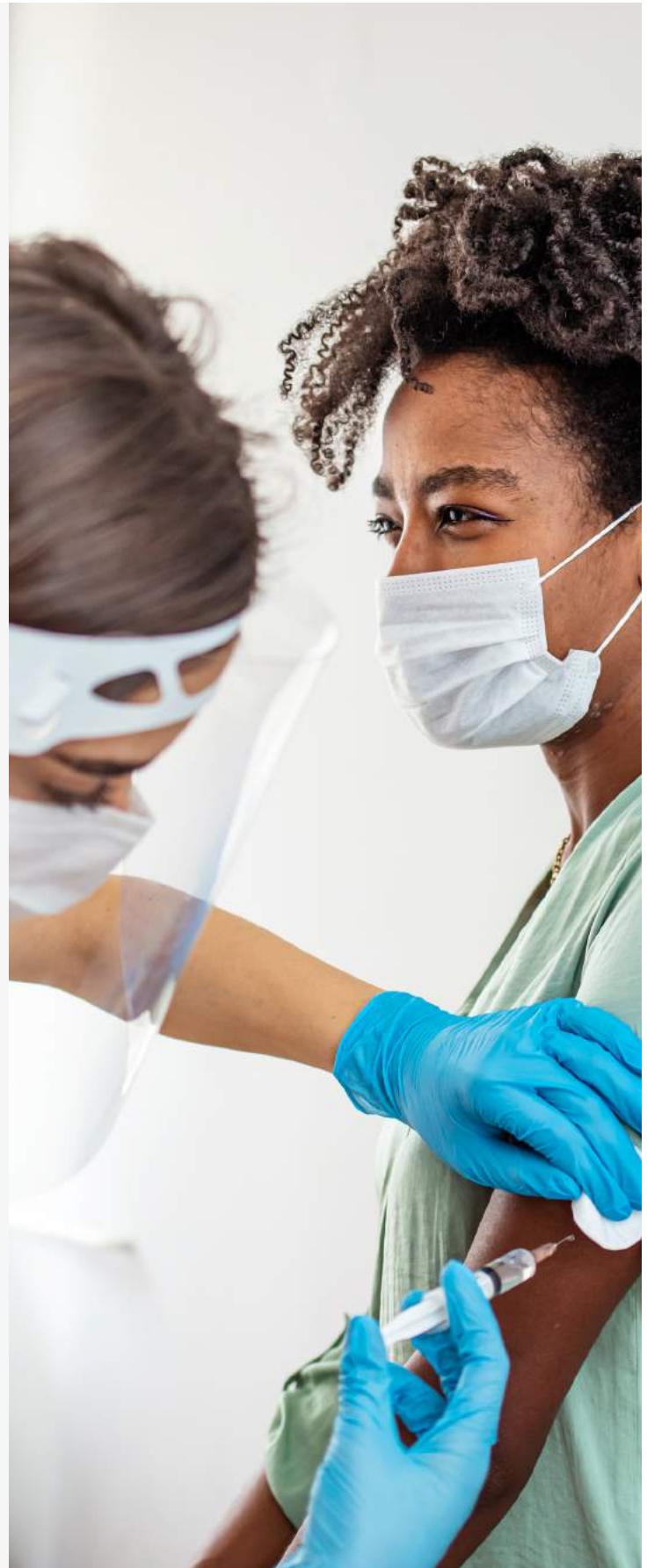
## A key benefit: DCTs can broaden the pool of patients

One of the most notable benefits of digitizing and decentralizing clinical trials is that this can broaden the pool of patients, both geographically and demographically.

Why is this important? The No. 1 challenge for trials is enrollment. Physical test sites limit the geographic area from which subjects can participate. Making it possible to participate remotely allows trials to enroll patients who have largely been excluded because of socioeconomic factors, such as not being able to take time off work to travel to the test site.

This also broadens the age group range that will participate in a trial. Trial enrollment tends to skew toward older participants who may have more schedule flexibility, while digital solutions can enable broader participation of a younger population that necessitates and prefers being able to leverage technology in their daily lives, including health care.

The ability to reach more populations can help increase clinical trial diversity and build trust at all stages of the trial.



## Looking ahead to better trials

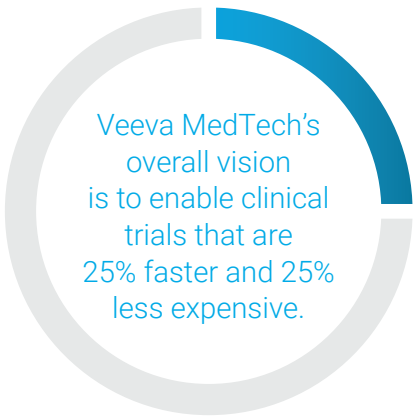
After an initially chilling effect on clinical trials, the COVID-19 pandemic has catalyzed the industry and highlighted new opportunities for the medtech industry to modernize. Sponsors are now learning on a wider scale that decentralizing and digitizing clinical trials gives them the tools to get their products to market in new, more effective ways.

DCTs can also lead to greater diversity in trials, which is a key step toward a world of true personalized medicine, where the right treatment is given to the right patient at the right time.

As companies begin the transition to digital trials, there has been a greater need for technology to help support and drive efficiency. Modern clinical operations and data management solutions are critical as we move forward. Leveraging cloud-based solutions that offer a single platform for data, content, and process management allows organizations to build and run more trials. Cloud-based solutions that streamline electronic data collection, coding, monitoring, research site document exchange, and trial management and operations oversight improve how teams work together by providing widespread access to data for study stakeholders.<sup>6</sup>

Veeva MedTech's overall vision is to enable clinical trials that are 25% faster and 25% less expensive. As sponsors continue to adopt DCTs at scale, they can expect to reach that world in a quicker, more efficient and more compliant manner than ever before.

With the right solution and the right partner, quality and regulatory teams have the information they need to get safer, higher-quality products to patients faster.



Veeva MedTech's overall vision is to enable clinical trials that are 25% faster and 25% less expensive.





## References:

1. Van Dorn, A. COVID-19 and readjusting clinical trials. The Lancet. Aug. 22, 2020. Retrieved Aug. 26, 2021, from [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31787-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31787-6/fulltext).
2. The Modernization of Clinical Trials: COVID-19's Lasting Impact. ACRP. April 20, 2021. Retrieved Aug. 28, 2021, from <https://acrpnnet.org/2021/04/20/the-modernization-of-clinical-trials-covid-19s-lasting-impact/>.
3. Ledford, H. The COVID pandemic's lingering impact on clinical trials. Nature. June 28, 2021. Retrieved Aug. 29, 2021, from <https://www.nature.com/articles/d41586-021-01569-9>.
4. Unger, J., and Xiao, H. The COVID-19 pandemic and new clinical trial activations. PubMed. Retrieved Aug. 28, 2021, from <https://pubmed.ncbi.nlm.nih.gov/33832534/>.
5. Agrawal, G. No place like home? Stepping up the decentralization of clinical trials. McKinsey & Co. Retrieved Sept. 12, 2021, from <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials>.
6. Goldenberg, S., and Liang, K. MedTech's Path Towards Patient-Centric, Paperless Trials. Veeva. Retrieved Aug. 27, 2021, from <https://www.veeva.com/resources/medtechs-path-towards-patient-centric-paperless-trials/>.



### About Veeva Systems

Veeva Systems Inc. is the leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 975 customers, ranging from the world's largest pharmaceutical and medical device & diagnostics companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. For more information, visit [veeva.com/medtech](https://veeva.com/medtech).