

Curebase Pioneers Completely Virtual Site to Meet Patients Where They Are

Curebase Applies CTTI's Decentralized Clinical Trials Recommendations

SUMMARY

Curebase started as a company highly focused on building software technology to optimize decentralized clinical trials (DCTs), but quickly decided to expand into providing services for operationalizing and conducting these trials. It used CTTI's recommendations to navigate the ever-changing legal and logistical waters of DCTs, successfully launching itself as a specialized DCT software platform and virtual research site.

GOAL(S)

Upon its founding in 2017, Curebase was known primarily for its eClinical software platform, an all-in-one patient, provider, and remote monitoring solution built for decentralized studies. The San Francisco-based startup was doing well, but its Chief Executive Officer (CEO) quickly realized there was an opportunity to add specialized services to compliment the software platform. Curebase wanted to offer researchers a one-stop-shop for DCTs, which are executed through telemedicine and mobile/local healthcare providers using processes and technologies that differ from the traditional clinical trial model. DCTs are conducted outside a traditional site setting, with subjects remaining at home during a significant portion, or all, of the study.

CHALLENGES

The concept of DCTs is relatively new, so there was limited information available to understand logistical and regulatory challenges specific to these trials. The Curebase team also had to start shifting their mindset from software-focused to trial operations-focused. One leader joked that prior to the expansion, most of the team thought of "API" as an "application programming interface" rather than an "active pharmaceutical ingredient," the term most frequently used by sponsors and Clinical Research Organizations (CROs).

SOLUTION(S)

CTTI has worked to address the legal and regulatory challenges that come with conducting DCTs through telemedicine and mobile healthcare providers. They have [created recommendations](#) that explore several topics--including telemedicine state licensing issues, FDA review division reception, and Good Clinical Practice-related issue--to help advance widespread use of mobile technologies in DCTs. One Curebase employee connected to CTTI stakeholders heard of the recommendations and brought them into Curebase, and those recommendations became the basis for the organization's efforts to combine its proprietary software platform with its proposed suite of services to operationalize DCTs.

TAKING ACTION

Curebase relied on CTTI's DCT recommendations to better understand the landscape of legal and regulatory barriers to DCTs. Curebase specifically looked at CTTI's work discussing state licensing and direct-to-patient shipping. For example, the DCT recommendations suggest that DCTs that operate across multiple states can manage state-by-state medical licensure concerns through maintaining an investigator in each state where services are anticipated, utilizing investigators licensed in multiple states, or contracting with companies providing licensed mobile health care provider research services across all U.S. states (or at least in those states in which the trial will be conducted). The recommendations also note the ever-changing legal landscape around DCTs and encourage an investment in legal counsel to help understand them. Curebase took that advice, which later proved to be an important and critical investment that was key to their success. CTTI's recommendations were also instrumental in Curebase's ability to determine when particular studies require aligning sites with an investigator in each state to represent its DCTs. In this way, Curebase is working to combat "dead zones" in the United States where there is not a large institution for miles, making patient participation low and affecting the representativeness of research. Achieving principal investigator oversight might seem impossible in a virtual trial, but Curebase has developed detailed plans to combat this challenge. Those include 1) live meetings with principal investigators at scheduled times with staff; 2) giving staff access to reports so they can see high-level information and drill down as needed; and 3) setting up alerts and other triggers for safety events. Having a defined plan is something sponsors and CROs are very receptive to, and this approach has helped differentiate Curebase from its competitors.

IMPACT

Today, Curebase is thriving as a specialized DCT software platform for virtual research, using its pioneering software platform to run clinical studies that reach patients and physicians everywhere. When the COVID-19 pandemic hit in March 2020, Curebase was ahead of the curve and ready to offer the digital solutions the industry suddenly needed urgently. Curebase's leadership believes the digital approaches to clinical trials will continue to grow, even after the pandemic subsides. In November 2020, the U.S. Food and Drug Administration released [new recommendations](#) around diversity in clinical research. With Curebase's established focus to target rural areas, the organization was already well aligned.

ADVICE


From Curebase's perspective, the best lesson they have learned to date is that trials don't have to be all decentralized or all traditional. The original idea Curebase had in 2017 was to separate itself as a truly "decentralized" (versus a "virtual") solution. Curebase is grounded on the principle of flexibility in study settings, whether that be at large institutions, private clinics, mobile providers, or virtually at home. Some patients WANT to go to the clinic or must, but they don't want to travel hundreds of miles each time. The organization implemented this flexibility to its model toward true patient centricity by partnering with local and community health care providers as sites to offer patients a convenient choice in the care setting. Curebase also recommends putting in the time to go outside your company's knowledge base--the speed of change in the industry requires that now, its leaders say. In addition, researchers should engage in those discussions early during protocol development to save headache on the back end. Have a good process for vetting the technology solutions

you choose for your digital trial--there are a lot of options out there, and not all of them are created equal. Use CTTI's recommendations to ensure your technology is in compliance with regulatory requirements.

ORGANIZATION

Curebase

CONTACT

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ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2018

TOPIC

Decentralized Clinical Trials

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