Pink Sheet
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New Global Alliance To Drive Momentum On Decentralized Trials

The Coronavirus Pandemic Is Forcing A Shift In Attitude

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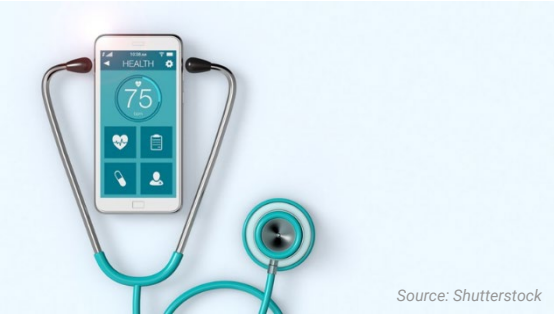
Executive Summary
A new multi-stakeholder alliance wants to improve the adoption of decentralized clinical trials that have already drawn much attention during the COVID-19 pandemic. There are plans to aggregate best practices, share evidence and information, and identify and address key barriers.



DECENTRALIZED TRIALS CAN BE EXECUTED THROUGH TELEMEDICINE AND MOBILE/LOCAL HEALTHCARE PROVIDERS

A new international alliance has been launched to address the "significant barriers" that stakeholders from across the research community continue to face in the meaningful adoption of decentralized trials.

The Decentralized Trials & Research Alliance (DTRA) was launched on 10 December with more than 50 organizations as its members, including the US Food and Drug Administration, several contract research organizations, patient advocacy groups and other members of the research community.

A key concern with conventional clinical trials is that they are inaccessible to many potential participants due to the time and cost required for visits to investigator sites. One of DTRA's aims is to "democratize clinical trial participation" through the use of decentralized approaches. This can enable greater access for all to participate.

COVID-19 Impact
Travel and social distancing-related restrictions during the COVID-19 pandemic have drawn renewed attention to the potential advantages of decentralized trials over conventional trials. (Also see "COVID-19 Clinical Trial Disruptions: A Real-World Test Of De-Centralized Techniques" - Pink Sheet, 5 Aug, 2020.) (Also see "EU Remote Trials Project Gets Moving" - Pink Sheet, 29 Jun, 2020.) (Also see "COVID-19 Trial Changes Are "Propulsive Force" For Digital Adoption" - Pink Sheet, 9 Apr, 2020.)

There is more appetite for innovative decentralized approaches. Several organizations and industry associations are already making efforts to keep this momentum going. "There was a significant belief that [a new] collaboration can address many shared challenges," said DTRA founding conveners and life science executives Amir Kalali and Craig Lipset.

Current initiatives on promoting decentralized trials are either focused on addressing a diverse range of issues or comprise of a limited group of

stakeholders. “DTRA is the only organization that convenes the diverse community to focus exclusively on addressing the barriers to decentralized trials,” Kalali and Lipset told the *Pink Sheet*.

To coordinate efforts, DTRA has opened dialogue with all existing collaborations/consortia that have workstreams relating to decentralized trials. “We will be working closely with these complimentary organizations to advance the field of decentralized trials,” they said.

To improve the adoption of decentralized trials, DTRA leaders are currently completing a prioritization process.

This involves identifying specific topics that will lead better definitions, sharing of best practices, improving knowledge sharing, and addressing remaining barriers. “Together this will improve information and knowledge among the research community on the feasibility and reality of decentralized research,” they said.

Fiona Maini of Medidata, a US-based technology company that develops and markets software as a service for clinical trials, said it was great to see collaborations like DTRA come together to further advance innovation in clinical research.

The adoption of decentralized clinical trials operational processes requires “collaboration between stakeholders, training… and a shift in cultural mindsets to change to a new model where patients are at the heart,” said Maini who also chairs the Decentralised Clinical Trials Working Party at the Association of Clinical Research Organizations.

This requires greater engagement with regulators regarding remote strategies, controls and governance, and ensuring these approaches are “infused into the modernization and renovation of good clinical practice,” said Maini.

“Greater and faster adoption of solutions like electronic informed consent and remote source data verification in the EU along with other innovations can help support these objectives.” (Also see "EU Makes Only Limited Use Of Remote Clinical Trial Monitoring" - Pink Sheet, 7 Dec, 2020.)

FDA – The Lone Regulator

On the FDA being the only regulatory member of DTRA, Kalali and Lipset explained that as the US regulator has been providing guidance on decentralized area, it became part of the alliance at its launch. (Also see "Decentralized Trials Guidance May Reflect US FDA’s Lessons Learned During COVID-19" - Pink Sheet, 25 Jun, 2020.) (Also see "US FDA Outlines Wishlist For Decentralized Clinical Trials" - Pink Sheet, 13 Mar, 2020.)

“We will be actively engaging with additional regulatory agencies” to expand membership, they added.

Democratizing Clinical Trials

Coronavirus-19-related restrictions have caused major disruptions to conventional trials. Experts estimate that COVID-19 may set back non-pandemic clinical trials by several years due to prospective patients’ inability or reluctance to schedule visits at physical research locations.

Inclusion of representative patient populations in clinical trials by race, age, and geographic location has long been an operational challenge. “COVID-19 has amplified the disparities and inclusion biases that have become hurdles for potential trial participants,” DTRA said.

“Making it possible for any patient, anywhere, to access trials with convenience and safety, during the pandemic and beyond” is also a key focus of DTRA member Stand Up To Cancer, a fundraising campaign of Cancer Research UK. Ensuring “equal access to clinical trials… supports our mission to make every cancer patient a long-term survivor,” said Stand Up To Cancer’s CEO Sung Poblete.

This article was updated on 15 December 2020 with quotes from Fiona Maini of Medidata.