Cutting-Edge Approaches to Support Studies in the COVID-19 Era

The world is very different than it was just a few short months ago as the COVID-19 pandemic threatens the conduct and completion of clinical studies, including real-world evidence (RWE) generation studies and randomized clinical trials (RCTs). This webinar explored two areas that offer solutions to mitigate the impacts studies face in light of COVID-19, and highlighted the pressing need for innovative and flexible approaches in the collection and analysis of data, ensuring that patient safety remains the focus.

"While the wave of the COVID-19 pandemic has some parts of the world working to get back to normal, others are initiating lockdown and dictating shelter-in-place orders. At the same time, we need to collect study-dictated data as much as possible."

Mariah Baltezegar, MBA, Executive Director, Head of Peri- and Post-Approval Virtual Trials, Evidera

Baltezegar is a senior leader responsible for virtual and digitally enabled trial approaches and associated, integrated solutions. She has over 20 years of experience, many in the complex space of rare diseases, and has established herself as a results-oriented, motivating leader of global, interdisciplinary teams that develop innovative solutions to meet client needs.

Decentralizing the Collection of Real-World Data with the Integration of Virtual and Digital Enablement Into Development and Execution Strategies

As patient centricity is at the heart of what must be the current paradigm of data collection in clinical research, regulators and ethics boards are advising stakeholders to employ strategies to bring studies to the patient safely, as access to study sites is restricted. Strategies such as televisits, remote consent, and direct-to-patient supplies can be used to solve several key challenges. While each of these tactics can be leveraged individually, researchers can also bring solutions together in a metasite or decentralized model through a digitally enabled platform.

CHALLENGE	Televisit	eSignature Consent	Remote consent + eSignature	eCOA/ ePRO	Devices/ Wearables	Home nurse/ phlebotomist visits	Direct-to-patient supplies	Metasite or decentralized/ virtual model
Patients **cannot visit HCPs** to have SOC or protocol-defined safety assessments performed	✓							✓
Patients **do not have appropriate consent** in place to perform a televisit		✓						✓
Patients **cannot visit sites to be consented** or consented to perform procedures not detailed in the current consent form			✓					✓
Patient cannot visit sites for clinical or **patient-reported outcome assessments**				✓	✓	✓		✓
Patient is running **low on clinical supplies** and cannot visit a site							✓	
Decrease in patient recruitment and retention rates are putting a study at risk								✓

"We think that simulation is a very powerful tool that helps overcome difficulties in completing clinical and real-world studies or randomizing sufficient patients. It helps us fix the broken studies and by the same token, offers a means to speed up COVID-19 treatment trials because it allows us to focus power on the experimental arm."

J. Jaime Caro, MDCM, FRCPC, FACP, Chief Scientist, Evidera

Caro focuses on advancing Evidera's leadership in developing and applying novel techniques in modeling, health economics, comparative effectiveness, epidemiology, and outcomes research. He is a pioneer of new methodologies and is dedicated to advancing the industry through his positions as an adjunct professor of medicine, epidemiology and biostatistics, at McGill University, and a professor in practice at the London School of Economics.

Leveraging Simulation to Rescue Clinical Trials Affected by COVID-19

Some clinical trials are having difficulty recruiting or randomizing patients because of patient inability to visit sites, study personnel not available to carry out activities, etc., preventing the necessary collection of data to keep those trials moving forward. One solution is the use of clinical trial simulations to project outcomes. This novel approach uses a multitude of existing data sources to make detailed predictions of outcomes for enrolled patients assigned to control arms had they completed the study. It also offers a potential means to speed up COVID-19 treatment trials because it allows us to focus power on the experimental arm. Simulation is a very powerful tool that can help overcome these trial challenges and fix broken studies.

As COVID-19 threatens the conduct and completion of clinical studies, the virtual, digital, and simulation strategies discussed can facilitate decentralized, real-world data collection to support patient safety and provide streamlined approaches to rapid, automated, and repeatable access to data. As the situation continues to evolve so will guidance to meet new and unique challenges as they present. Consult with ethics committees and regulatory agencies to see if these tactics are a fit for your trial.

View recorded webinar: Cutting-Edge Approaches to Support Studies in the COVID-19 Era

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