

Are we misinterpreting FDA guidance?

Objective

“Enabling physicians to offer clinical trials as a care option is the holy grail of participant enrollment.”



Craig Lipset

MEDVECTOR Advisor, Founder & Co-Chair of DTRA.org, Former Head of Clinical Innovation at Pfizer, Founder Clinical Innovation Partners, and Adjunct Professor at Rutgers University

Design

From an FDA compliance perspective, when engaging a participant using telemedicine, **is the patient-location relevant to the source data?**

DCT

Brings the study to the patient



MEDVECTOR

A site utility that brings the patient to the site (virtually).



FDA Guidance for Industry

Electronic Source Data in Clinical Investigations

Many data elements (e.g., blood pressure, weight, temperature, pill count, etc.) in a clinical investigation ... can be entered directly into the eCRF by an authorized data originator. For these data elements, the eCRF is the source.

The FDA does not recognize a difference between a participant who is...

PHYSICALLY PRESENT

VS

VIRTUALLY PRESENT

at a clinical trial site.

Scott Stout
CO-FOUNDER / CEO



Ted Barduson
CO-FOUNDER / COO

Results

The FDA has established that the source data remains unchanged when utilizing an alternative patient-location, because the patient is **at the clinical trial site (virtually)**.

“Using technology to connect patients from alternate locations to a PI site does not trigger any new clinical sites or clinical investigators. The FDA is open to new technologies that make it easier for patients to participate in clinical research, whether it be from their home, a local clinic, or a provider’s office.”



Jonathan Helfgott

MEDVECTOR Advisor, Former FDA Associate Office Director, and Author of the FDA eSource Guidance.

Conclusion

Clinical trial sponsors are missing opportunities by misinterpreting FDA guidance.

Encouraging participation through alternative locations aligns incentives between treating physicians and investigator teams, finally enabling “clinical trials as a care option.” This middle ground between DCT and the traditional clinical trial model, creates immediate access to the missing-majority trapped behind physicians who don’t refer to clinical trials.

Presenters

Scott Stout, Ted Barduson, Craig Lipset (DTRA), Jonathan Helfgott (Former FDA)

Affiliations

MEDVECTOR, Johns Hopkins University, Healthcare Innovation Catalysts, FDA, DTRA, Clinical Innovations Partners, Rutgers University

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Beyond Clinical Trial Sites

