Session Title:

How Synthetic Control Arms offer a new future for working in life-threatening diseases

Speaker(s):

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11:00 AM - 11:30 AM

Abstract:

Clinical development teams working in rare or life-threatening diseases may face unique challenges for generating adequate evidence to demonstrate safety and effectiveness from a clinical trial alone. In part, this may be because existing standards-of-care are deemed unappealing and the risk of being selected for a control group could dissuade patients from enrolling or completing the expected follow-up in trials.

Hear from industry experts about how and why the use of external control arms like Medidata's Synthetic Control Arms offering hope to patients and clinical developers alike, by:

- Minimizing the number of patients required for a control group, easing recruitment challenges and giving more patients earlier access to potentially life-saving treatments.
- Allowing clinical development teams to run trials more efficiently and with lower costs, while still generating scientifically rigorous data.
- Aiding regulatory conversations with the application of historical clinical trial data to bolster findings and prove safety and effectiveness.