How Shall We Analyze Change From Baseline in COA Endpoints? Is MMRM Bowing Out?

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Introduction

This panel will discuss the suitability of Mixed Model Repeated Measures (MMRM) to evaluate change from baseline in COA data

COA data typically collected at multiple timepoints during a clinical trial

Often, MMRM is considered to analyze COA data for change from baseline endpoints



Introduction

MMRM limitations must be considered alongside research objectives and context of use

- Assumes missing at random
- Consider intercurrent events, e.g., treatment discontinuation or death

Speakers will discuss considerations for evaluating whether MMRM is an appropriate method to use, including threats to interpretability of the data, and when not appropriate, what alternative methods might be considered



Speakers

Ashley F. Slagle, PhD

- Moderator
- COA / Endpoint Scientific and Regulatory Advisor
- Aspen Consulting, LLC

Andrew Potter, PhD

- Speaker/Panelist
- Senior Mathematical Statistician
- Office of Biostatistics, FDA-CDER

James Bell, PhD

- Speaker/Panelist
- Biostatistician and Pharmaceutical Scientist
- Elderbrook Solutions GmbH

Konstantina Skaltsa, PhD

- Speaker/Panelist
- Director, Statistics
- Patient Centered Solutions, IQVIA



Panel Discussion



