MEDICAL UNIVERSITY OF VIENNA

Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

Please join the Biometric Colloquium

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ESTIMANDS: THE NEW BEDROCK OF DRUG DEVELOPMENT?

November 20th, 2024 at 16:00

Schulungsraum Center for Medical Data Science (previously CeMSIIS),
Spitalgasse 23, Room 88.03.512
Medical University of Vienna, 1090 Wien
Host: Martin Posch and Franz König

Abstract:

The release of the ICH E9(R1) addendum has led to a significant shift in clinical trial methodology by emphasizing the importance of clearly defining the questions a trial intends to answer through the use of the estimand framework. By introducing a common language, the clinical questions of interest and associated estimands are specified at the initial stages of planning a clinical trial, leading to a better alignment of trial objectives, trial design, data collection, and analysis methods. In this presentation, we will share our experiences with using the estimand framework in drug development. Following a brief overview of the E9 Addendum, we will present anonymized and simplified case studies to share our learnings and highlight some common themes that have emerged when applying the estimand framework. We will then identify areas that require further attention and education. Finally, we will conclude with some open questions and reflect on the five years since the E9 Addendum's release.

Links to ICH E9 Statistical principles for clinical trials and E9(R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials:
https://www.ema.europa.eu/en/ich-e9-statistical-principles-clinical-trials-scientific-guideline