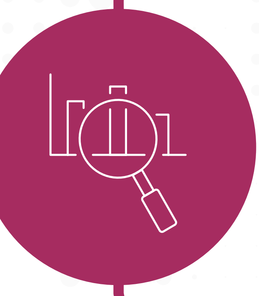
DIA

Questions to be Answered at the Biostatistics Industry and Regulator Forum

PDUFA VI New Commitments – How will the FDA Complex Innovative Design (CID) Pilot facilitate the advancement and use of complex adaptive, Bayesian, and other novel clinical trial designs? How will the Model Informed Drug Development (MIDD) Pilot aid in the development and application of models derived from preclinical and clinical data sources?

What are the issues related to trial designs and analyses that are so complex that simulations are needed in order to understand the full behavior of the model?

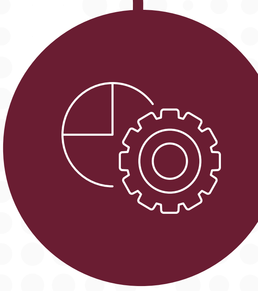


How is patient experience data developed, analyzed, and used to inform the benefit-risk assessment in the US drug approval and labeling process?

When are “Real World” studies beneficial for answering scientific and medically important questions, and should we be thinking about RWE and RCTs as an “either/or” proposition in drug development?

What are the coming changes with the implementation of the recently published ICH E9 R1 step 2b draft, the soon-to-be-published ICH E17, and the upcoming ICH E6/E8 renovation, and what factors will influence local and regional implementation experiences?

What can statisticians do to help address key challenges with Alzheimer’s disease (AD) drug development, to ultimately help bring much needed treatments to patients and their families?



Learn More at DIAglobal.org/BioStats18