Question 1: When population pharmacokinetics (PPK) models are used for generating model-integrated evidence (MIE) for bioequivalence (BE), what would be the appropriate model validation strategy? What are the basic elements for MIE to be considered suitable to demonstrate BE?

Question 2: What are the pros and cons of the two main types of MIE approaches:

1) Virtual BE that model built on a small sample size is used to simulate results for a larger population;
2) Continuation of “in silico” dosing to the exact same group of individuals.

Question 3: What are other innovative study designs that can control the Type-1 error and maintain the study power with the most efficient sample size/study duration?