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Considerations in innovative clinical study design for China development and registration

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ICH E5 stated that data developed in one region can be possibly extrapolated to the new region if a bridging study shows evidence that the drug will behave similarly across regions. However, “Similarity” of efficacy across regions is not clearly defined in ICH E5 guideline. There is lack of regulatory guideline on defining “consistency” in bridging study, and no commonly accepted statistical inference in demonstrating “consistency”. Our work provided statistical, regulatory, clinical considerations and guidance on design and analysis of efficacy bridging trials, and explored how the primary objective should be defined, how to select the consistency criteria, and key considerations on sample size. Other innovative study design options that could lead to China registration, such as China enrollment extension in global pivotal study, will be also discussed.

Biography

Nicole F Li is a Director of Biostatistics and the APAC site head of Biostatistics at Roche. She joined Genentech/Roche in 2001. She has over 17 years of pharmaceutical experiences and has worked on clinical development programs across multiple therapeutic areas. She has been passionate about the overall clinical drug development strategy and how innovative statistical methodology can make an impact by contributing to study design and analyses based on the best science. She received a PhD in Biostatistics from University of California, Los Angeles, and a MS in Applied Mathematics from Peking University.

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