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Fit–for-purpose immunogenicity assessment for theraputic antibodies in non-clinical studies

Assessing immunogenicity, the propensity of a therapeutic protein product (including antibody drugs) to generate immune responses or to induce immunologically related adverse events, is recommended during the development phase of a biotherapeutic drug. Even though immunogenicity assessment in nonclinical animal studies are not relevant in predicting potential immunogenicity in humans, it can still be very useful in assisting the interpretation of PK/PD/TK study results. This is because for non-clinical studies, immunogenicity can impact exposure (PK), response (PD & efficacy), and safety (toxicity and adverse events). Thus immunogenicity assessment, i.e. measurement of anti-drug antibodies (ADA), should be evaluated when there are evidence of altered PD activity; unexpected changes in drug exposure in the absence of a PD marker; or evidence of immune-mediated reactions (immune complex disease, vasculitis, anaphylaxis, etc.). In this presentation, several commonly used ADA assay formats and technology platforms will be reviewed. Key assay design elements and assay development procedures, including approaches that improve ADA assay drug tolerance, will be discussed in detail. We will also share ADA results from three monkey PK/PD case studies by comparing different ADA assay formats. Lastly, we will recommend fit-for-purpose strategies of ADA assay development and characterization for non-clinical animal studies.

Biography

Jerry Wang received his PhD from the Deaprtment of Biochemistry and Molecular Biology at Medical Univisity of Ohio (Toledo, OH). After post-doctoral studies at Univsersity of Michigan Medical Center, he began his industry career as a pharmacologist. He is currently a scientist in the Department of Biochemical and Cellular Pharmacology at Genentech. His group supports the therapeutic antibody programs during research and early development phases. His main responsibilities include antibody screening and characterization by *in vitro* and *in vivo* studies to select clinical candidates. He has worked in biopharmaceutical industry for more than 15 years including 10 years at Genentech for biotherapeutics R&D.

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