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WEBINAR

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Prolonger the life of a New Chemical Entity, The advantage and clinical development strategy of 505 (b)(2) program

The 505 (b) (2) is a NDA pathway when one wants to market a new drug with enough evidence on drug's safety and efficacy. The candidates for a 505(b)(2) application include:

- New indication from approved drug
- New combination of approved drugs or new active ingredients
- Changes in dosage form, strength, route of administration of approved drug on the market, such as: oral extended-release, injectables, inhalation, transdermal patches, etc.

The 505 (b)(2) program can rely on safety and efficacy studies that were not conducted by applicant. The applicant(s) conduct clinical pharmacokinetic (PK)/Pharmacodynamic (PD) studies in their applications. It usually starts with relative bioavailability of new product to marketed drug under fasting condition. There will be dose finding either parallel or ascending dose depends on safety profiles of the new product. Once the desirable bioavailability is obtained, the food effect of the new product should be tested. The comparative steady-state PK assessment should be carried out to investigate the accumulation of new product relative to marketed drug. The gender and age effect, drug interaction, and active metabolite(s) should be explored as early as possible. Chronopharmacokinetics, dose-proportionality, special population (renal and hepatic) PK studies are added value to 505 (b) (2) program(s). Such studies usually are crossover design with healthy subjects, except for special population studies, and relatively easy to handle from conduct practice and data anaysis perspectives. This speech will present case studies of our experince and strategy of clinical studies for 505 (b)(2) program for our sponsor's new product development.

Biography

Juan He has completed her MSc of Pharmacy from University of Toronto and had over 25 years of experience working in the field of clinical study design and conduct. She is currently VP of Pharmacometrics at a global early phase CRO called BioPharma Services Inc, focus on Phase 1 and BA/BE trials. Juan has set up and managed the sceintific/biopharmaceutical department inlcuding PK/Stats/Medical writing/Data Management in past 20 years for two CROs. She also represents company in medicine for EU and other regulatory/pharma industry associations including Asian such as Chinese market with NMPA submission.