US CHINESE ANTI-CANCER ASSOCIATION
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Chinese Society of Clinical Oncology
Beijing Xisike Clinical Oncology Research Foundation

Early phase clinical trials methodology for drug development in oncology

Principles-Design-Methodology of Early phase trials

- From pre-clinical data to 1st-in human trials
  - Key points and critical review of preclinical data package – MOA, ADME, toxicology, PK/PD modelling, biomarkers
- How to build-up an early phase clinical trial unit in the clinic with integrated translational medicine capability
- 1st time-in-human trials
  - Phase 1 trials – Overview of a Ph1 study protocol; safety measures; key objectives and endpoints;
  - Basic principles of pharmacokinetics/pharmacodynamics (PK/PD relationship, potential drug-drug interactions, etc)

- Medical statistics for early phase trials
  - Dose escalation models
  - Maximum Tolerated Dose (MTD) Definition and Selection of Recommended Phase 2 Dose (RP2D)
  - Endpoints
- **Practice of Ph1 Trial Design**
  - Case study 1 – small molecule ALK inhibitor
  - Case study 2 – large molecule anti-PD1 antibody