CSRC Think Tank: Detection, Assessment and Risk Mitigation of Cardiac Safety Signals in Oncology Drug Development

Session I: Translational Medicine and Non-clinical Signals of Potential Cardiac Toxicity
Translational Medicine Group Members

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TRANSLATIONAL MEDICINE: Dependent on Multiple Factors (i.e. Biomarkers)

**Definition:** A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions

**Types:** Molecular, histologic, radiographic, or physiologic characteristics
BIOMARKERS IN DRUG DEVELOPMENT

- MECHANISM OF ACTION
- DRUG TARGET SELECTION

- STRATIFICATION
- PATIENT SELECTION
- DOSE SELECTION

- SAFETY ASSESSMENT
- ENRICHMENT
- EFFICACY ASSESSMENT

MOLECULAR PATHWAYS LEADING TO DISEASE

- PRECLINICAL SAFETY ASSESSMENT
- MECHANISM OF ACTION
- DOSE SELECTION

BASIC RESEARCH

PROTOTYPE DESIGN OR DISCOVERY

PRECLINICAL DEVELOPMENT

PHASE 1

PHASE 2

PHASE 3

CLINICAL DEVELOPMENT

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