Translational Safety Strategies that Accelerate Drug Development

PSTC brings together 18 pharmaceutical companies to share and validate innovative safety testing methods under advisement of the FDA, EMA, and PMDA.

Safety Biomarker Working Groups

- CARDIAC HYPERTROPHY
- SKELETAL MUSCLE INJURY
- NEPHROTOXICITY
- HEPATOTOXICITY
- VASCULAR INJURY
- TESTICULAR TOXICITY

Qualification Pathway

Translational Biomarkers

Letter of Support ➔ Clinical Qualification (1) ➔ Clinical Qualification (2)

Nonclinical
- Context of Use
- Exploratory Studies
- Confirmatory Studies
- Data Package
- Publications

Clinical