

Enabling Translational Safety (ETS)

Facilitate better decision-making around compound toxicity to allow focus and agile shifting of resources to address attrition rates thereby bringing therapies to patients faster

→ Project Life Cycle Phase:

Last Update: January 2024



→ Potential Benefits:

- Reduce the patient burden of participating in clinical trials
- Strengthen the overall patient experience
- Optimize public health outcomes
- Enhance the data-driven approach to identifying safety concerns earlier in the development process to preclude costly late-stage failure or delays
- Promote agile allocation of resources to accelerate the delivery of safe and effective therapies to patients
- Optimize R&D resources to promote reusability and reliability
- Reduce animal usage and stimulate non-animal methods

→ Potential Solutions:



Proof of Concept Approach

A small-scale framework to determine if combined datasets can be leveraged to detect common signals between preclinical and clinical data (2024)



Global Ontology Framework

A proposed method of ontology development (inclusive of FDA and HA input/endorsement) that allows for the translation of preclinical and clinical terms across all ontologies to enable translational safety (2024)



New DataCelerate Module

A new module that will permit the proof of concept to be executed (2025)