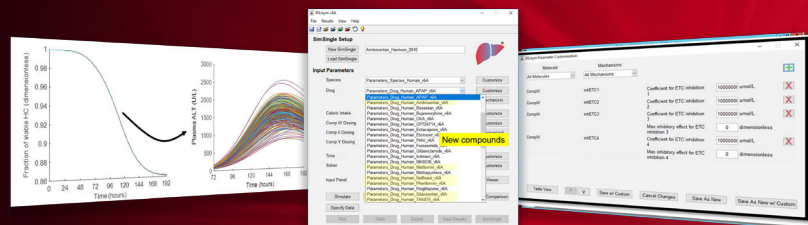




**DILIsym**



**DILIsym is Quantitative Systems Toxicology (QST) software capable of predicting and explaining Drug-Induced Liver Injury (DILI)**

**Sound Science**

- Developed through The DILI-sim Initiative, a consortium supported by 17 pharmaceutical companies and the FDA; regularly updated to include leading edge science
- Includes interacting sub-models such as: PBPK sub-model of drug disposition; bile acid representation of homeostasis and disruption by transporter inhibition; mitochondrial function and dysfunction sub-model including lipid metabolism and lipotoxicity; sub-model of oxidative stress generation and clearance; cell death representation of hepatocyte apoptosis, necrosis, and regeneration; representations of many well-accepted and novel biomarkers of liver injury
- Many publications released describing design and applications

**Capable**

- Utilizes compound-specific *in vitro* data to enable predictions
- Humans, rats, mice and dogs included
- SimPops™ incorporate inter-individual physiological variability
- User-friendly GUI for *in silico* experiments and visualization of results

**Application Driven**

- Rank candidates for DILI potential
- Extrapolate from animal and *in vitro* findings to humans
- Optimize clinical dose (risk versus presumed benefit)
- Infer magnitude of injury based on measured biomarkers
- Extrapolate from healthy volunteers to patient groups
- Guide incorporation of emerging biomarker measurements in clinical trials
- Analyze mechanisms underlying observed liver signals
- Inform choice and timing of biomarker measurements
- Aid identification of risk factors leading to precision medicine approaches

