

Interconnectivity of Nonclinical Data Across Data Silos for Drug Discovery and Development

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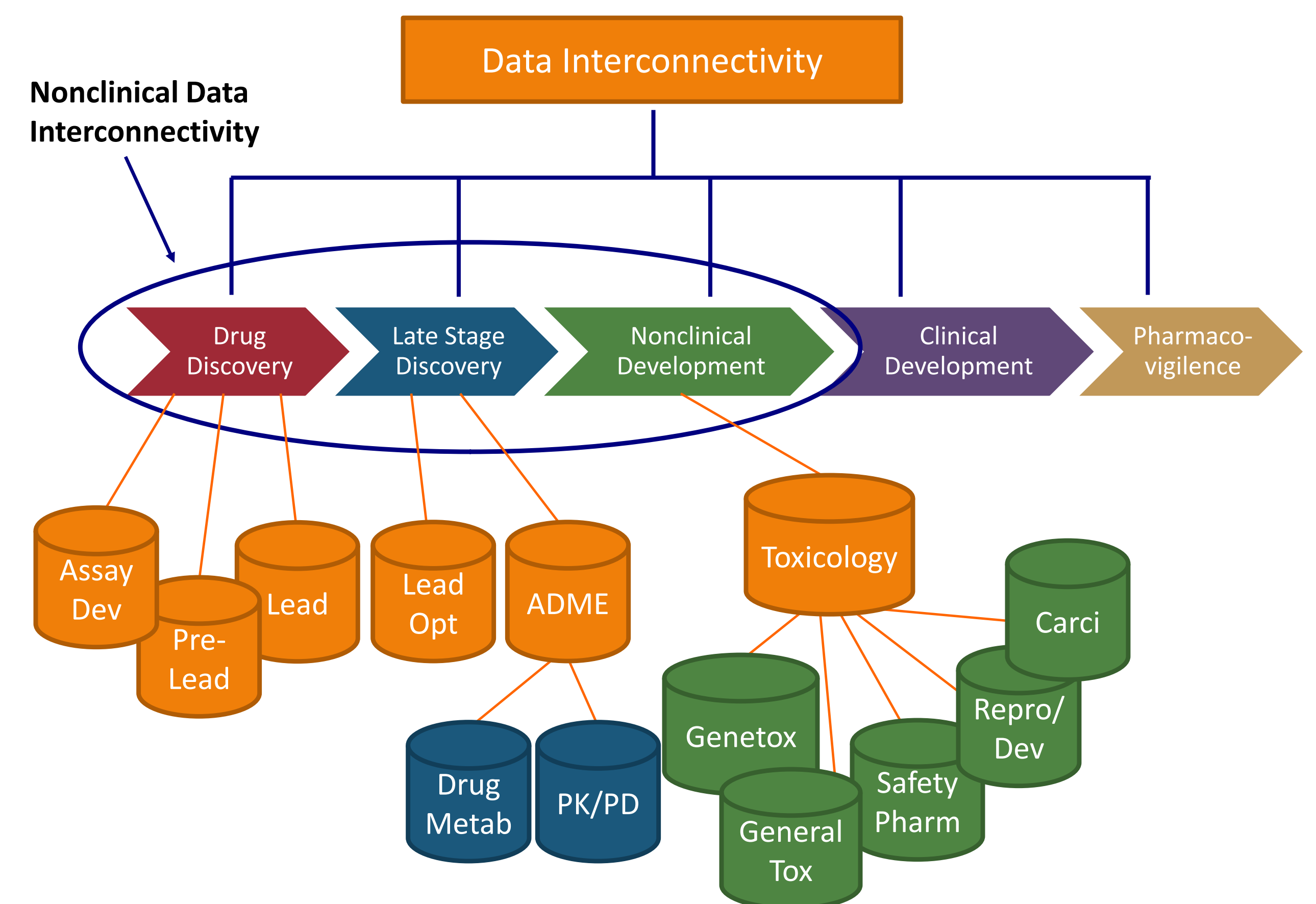
Abstract

Pharmaceutical research generates enormous amounts of disparate types of nonclinical and clinical data related to safety and efficacy, and the ability to leverage this disparate data into knowledge is valuable for developing new drugs. Information systems are being implemented to collect, store, search for, develop and analyze the data to detect relationships between seemingly disparate or unrelated data sets (i.e., data silos). However, to fully utilize the potential of these systems, it is necessary to enrich metadata from the data and develop concepts regarding “interconnectivity” or relationships between disparate data sets. The FDA/PhUSE Nonclinical Working Group Data Interconnectivity Sub-Group was therefore chartered to undertake this process. A definition of data interconnectivity was developed; nonclinical data types were identified, and challenges and opportunities for interconnectivity explored. Specific use cases are described to provide examples for interconnecting data across silos, and the scientific and business values for interconnectivity will be demonstrated. The work presented in this poster is through the collaborative discussions of the Sub-Group participants with varying expertise in Toxicology, Informatics, Data Management and Statistics representing various aspects of the Pharmaceutical industry including CROs, Sponsors and Regulatory Agencies.

What is Data Interconnectivity?

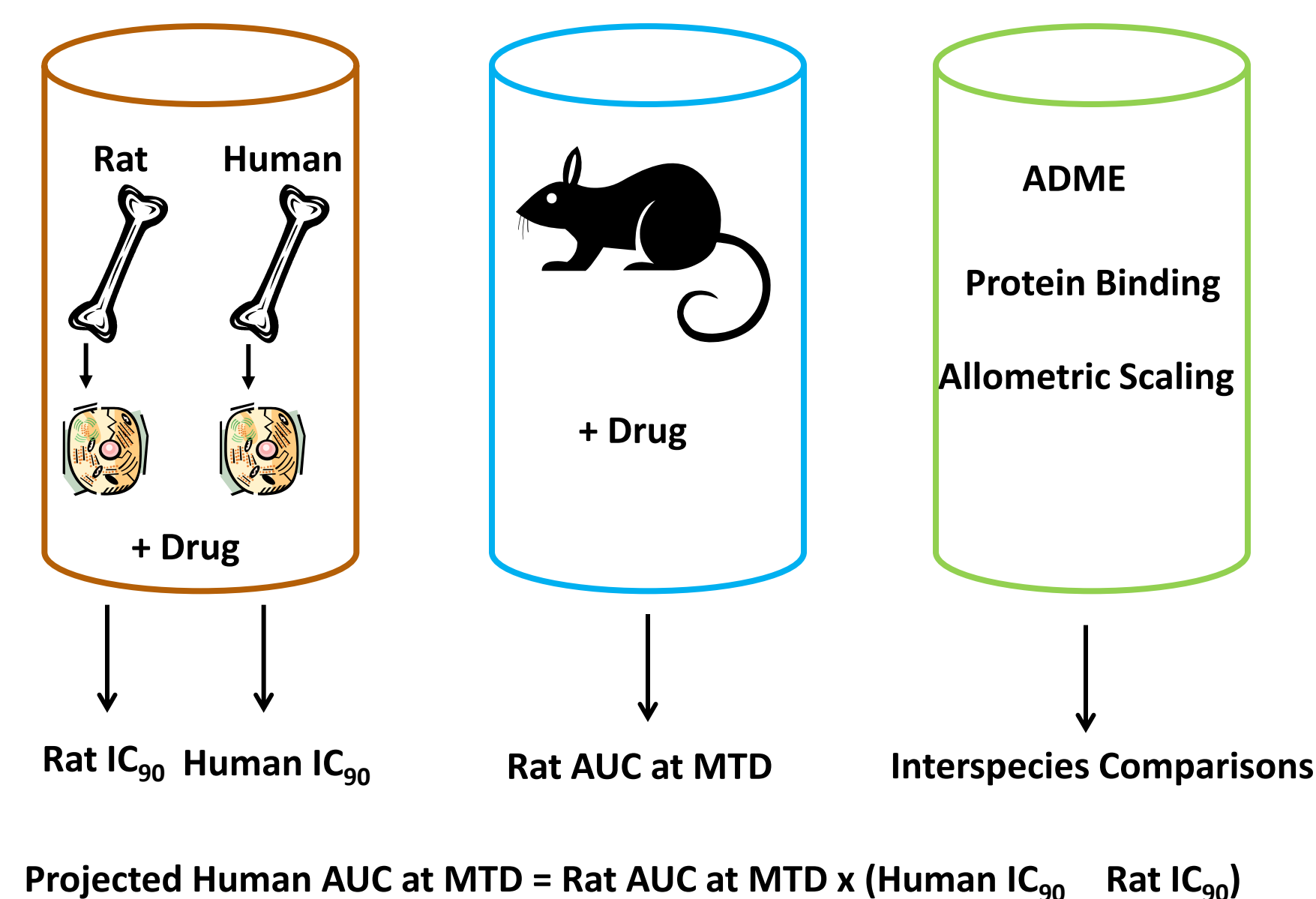
The Sub-Group considered the meaning of interconnectivity in several different contexts:

- ❑ Access to multiple data silos from an application simply by making it possible to connect to the data source from one or more applications or portals: In this context, there is no expectation that the data in each silo can be combined, or will provide an integrated experience.
- ❑ Integrating data from multiple silos where an application is able to select data from one silo and apply it in combination with data from another silo in a mathematical model, formula or algorithm to create an integrated data set or model.
- ❑ Interoperation using data from multiple silos where higher-level analysis calls for the use of data from disparate silos.

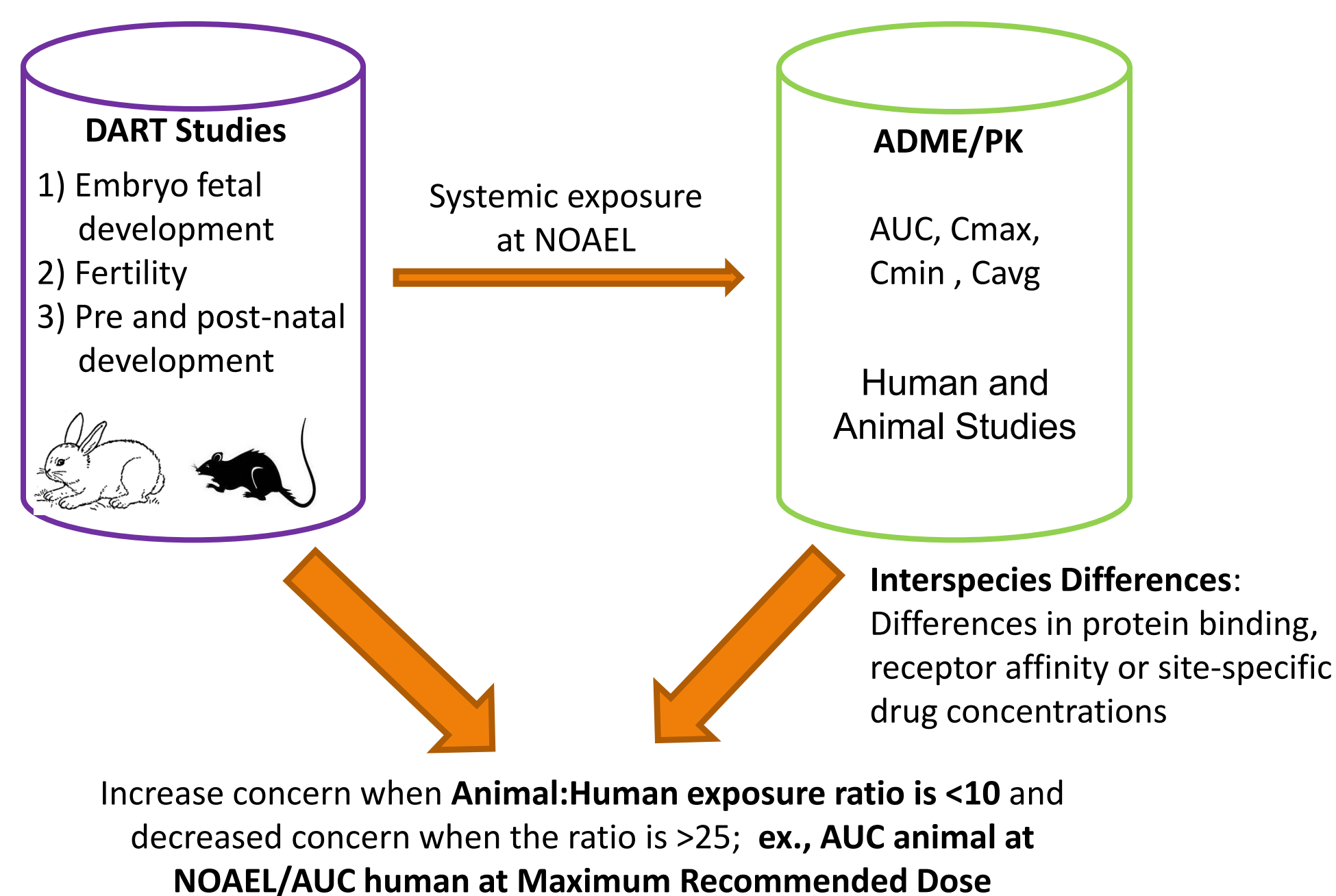


This figure is a representation of the typical nonclinical data silos collected during various phases of drug development. (as discussed by this Sub-Group)

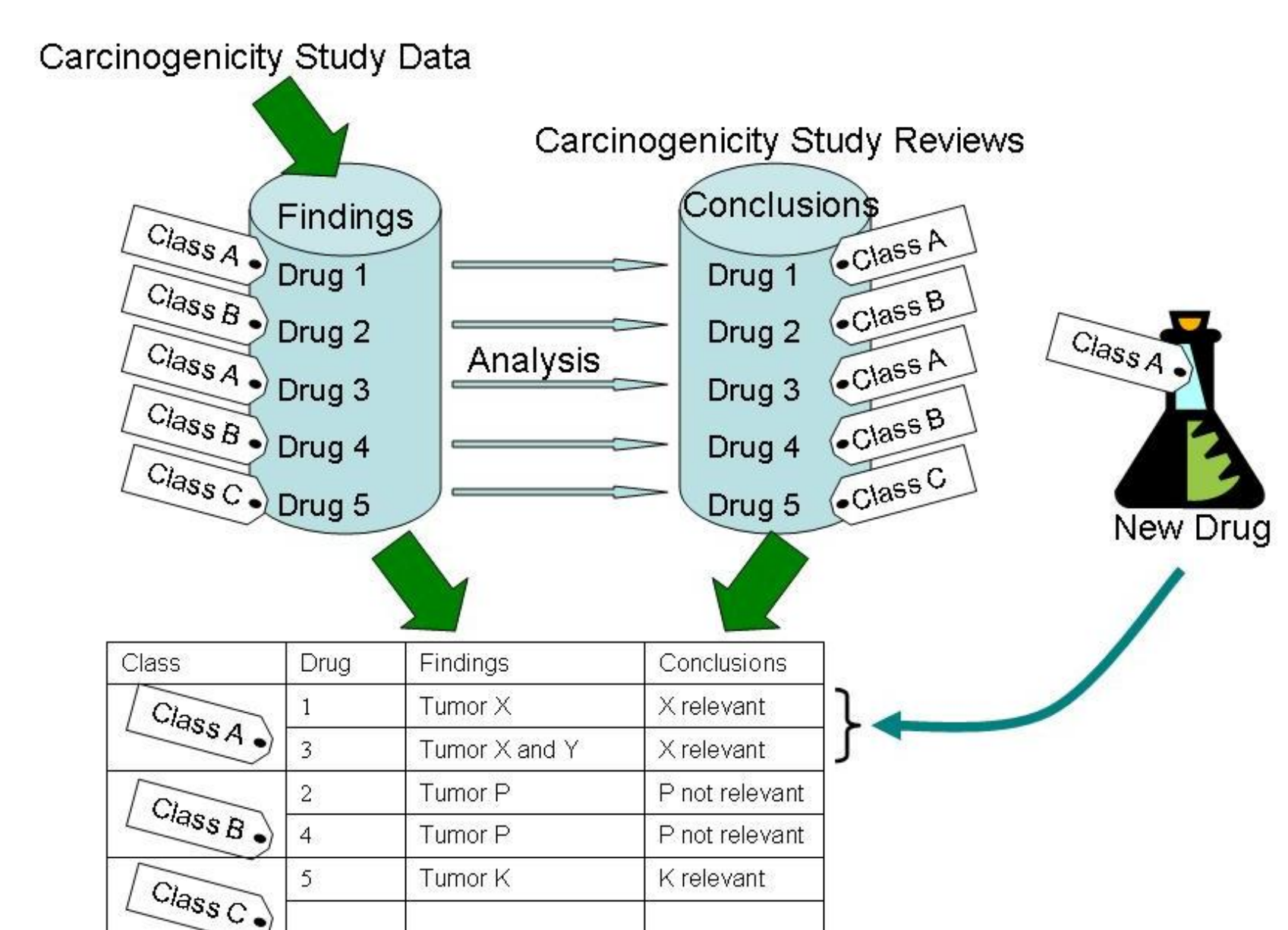
Use Case: In Vitro + In Vivo + ADME



Use Case: Reproductive and Development Toxicology + ADME

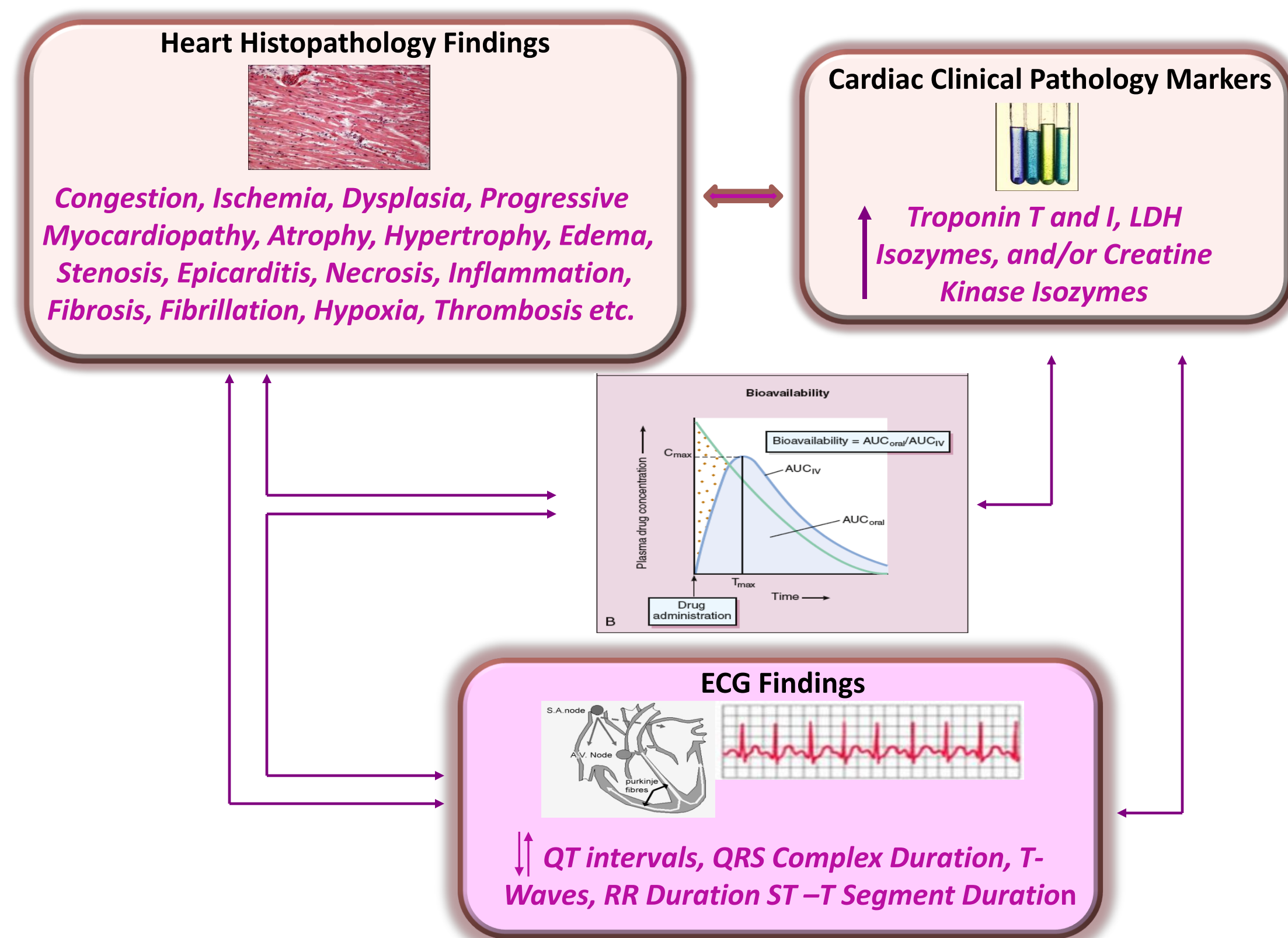


Use Case: Carcinogenicity + Pharmacological Classes

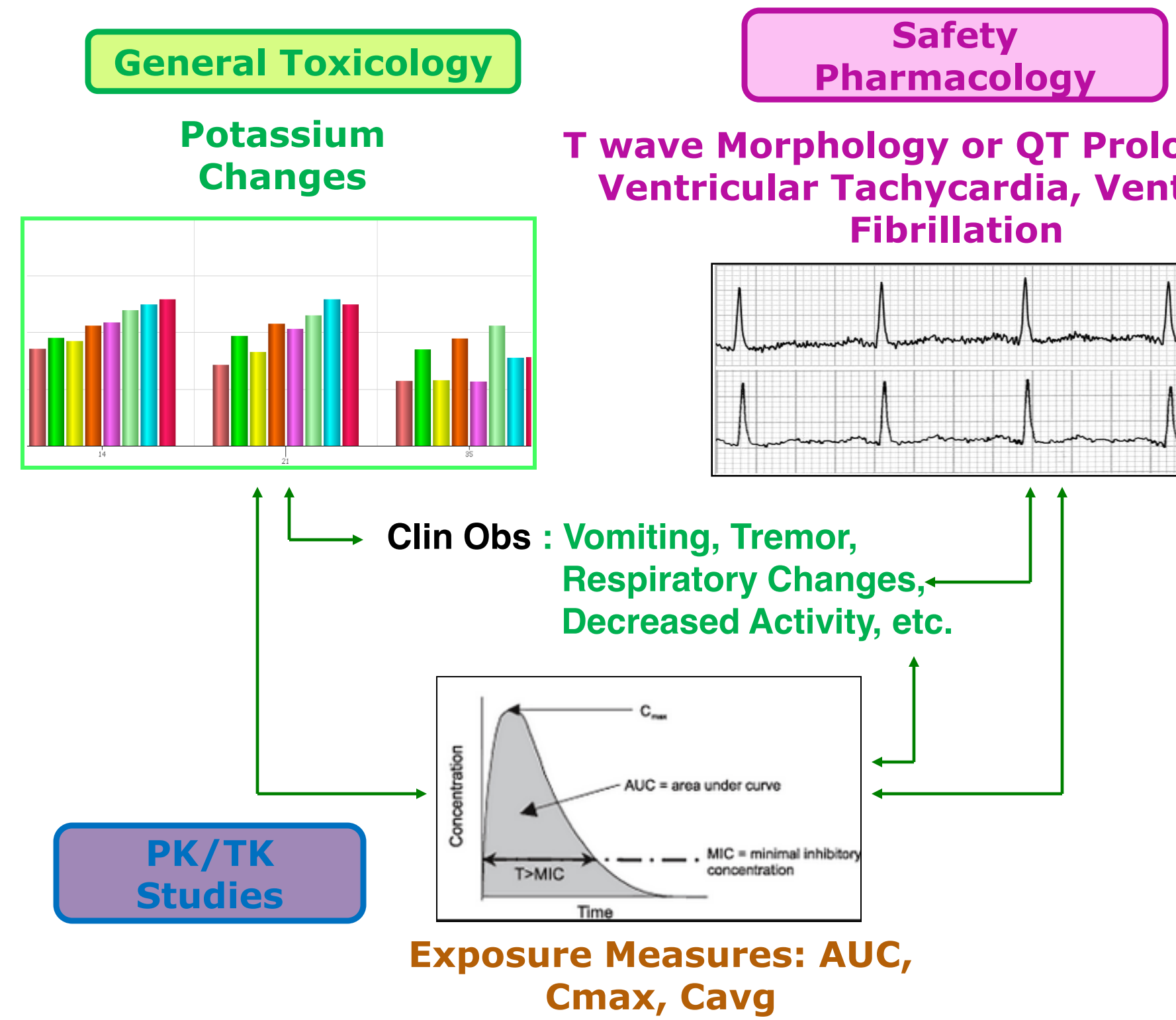


Use Case: Safety Pharmacology + Toxicology + ADME

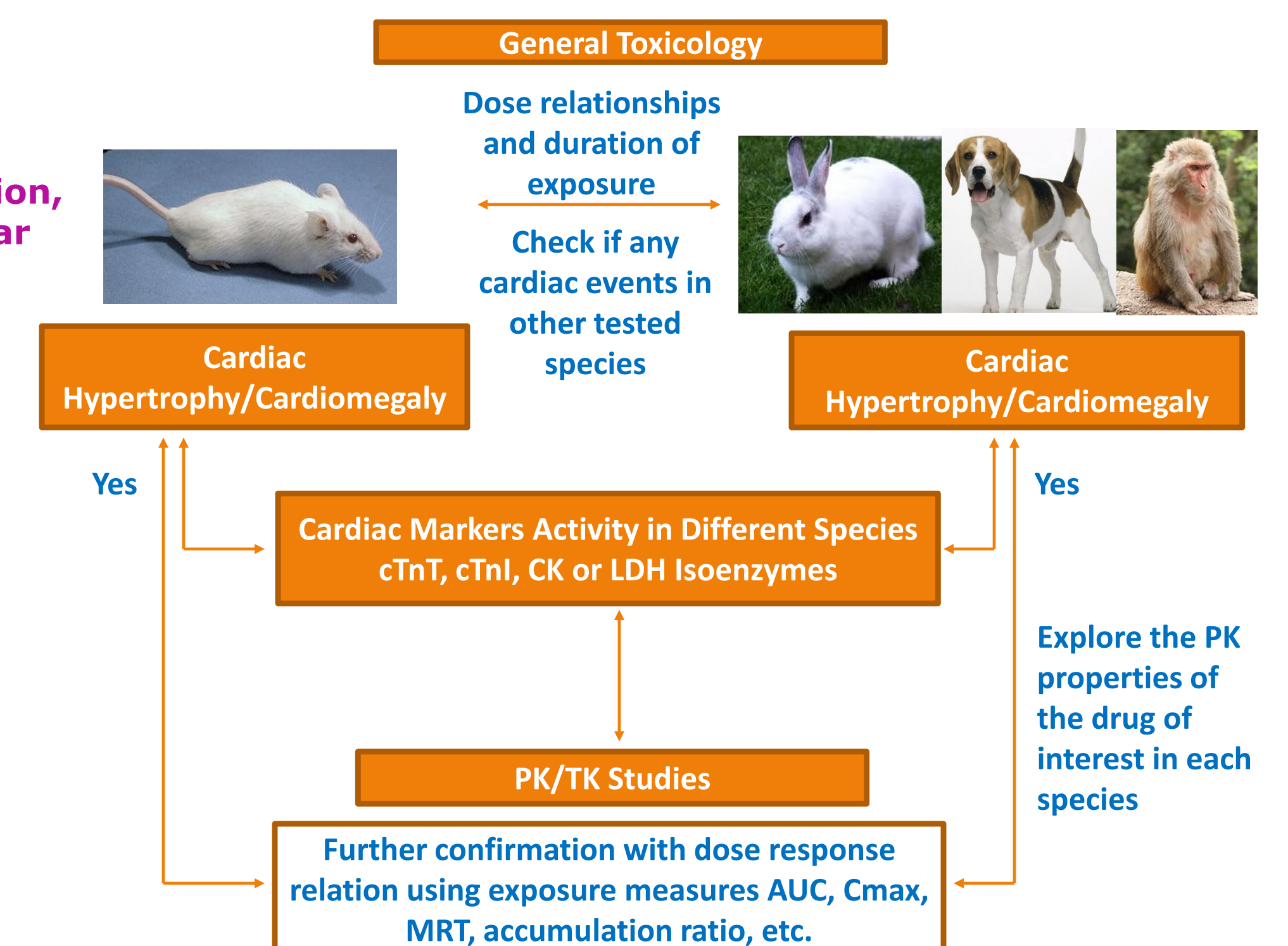
Relationship Between Histomorphologic Changes and Cardiac Biomarkers of Drug Induced Myocardial Cell Injury



Potassium Changes, ECG Findings and Cardiotoxicity



Cross-Species Comparison of Cardiobiomarkers



Challenges and Limitations

- ❑ Significant challenges exist with collection, transmission, storage, retrieval and utilization of the large amount of data generated during drug development.
- ❑ Disparate data collection and sources, varying data formats and complexity.
- ❑ Varying definitions and terminology.
- ❑ Limited access to publicly available data causes difficulty in testing new interconnectivity hypotheses and methods.

Conclusions

- ❑ There are several definitions of data interconnectivity.
- ❑ Connecting data can occur at several levels.
- ❑ Utility of the resulting relationships should drive the connections made.
- ❑ Standards and systems should facilitate data interconnectivity.
- ❑ Making predictions requires data interconnectivity.

NOTE: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their representative organizations.