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eTRANSAFE

enhancing TRANSLATIONAL SAFETY ASSESSMENT
through integrative knowledge management

The eTRANSAFE project develops

an integrative data infrastructure

and innovative computational methods

and tools that aim to remarkably

improve the feasibility and reliability

of translational safety assessment

during the drug development process

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777365. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

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→ Our Vision

To improve the efficiency of translational safety assessment in the drug discovery and development process.

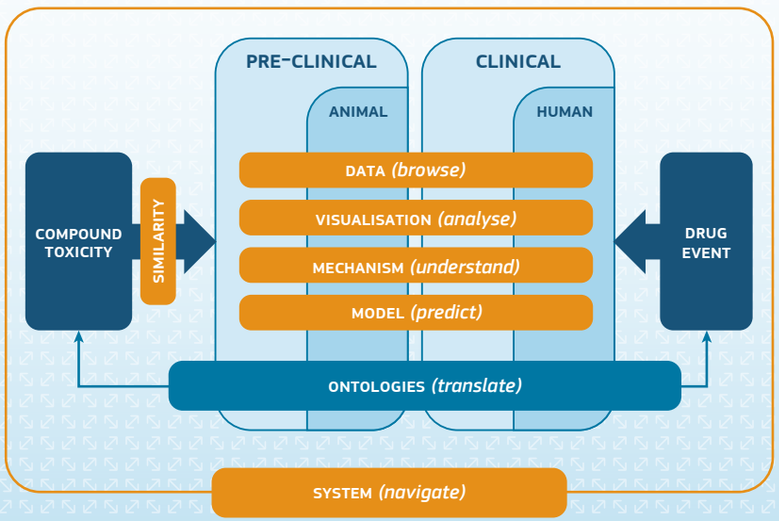
→ Our Mission

To develop a state-of-the-art, powerful and flexible strategy and technological architecture for data sharing, data integration and data exploitation.

→ Highlights

- Public and proprietary resources united
- Comprehensive analysis of the concordance of preclinical safety data to human safety
- Discovery of translational and reverse-translational biomarkers
- Optimisation of preclinical study programmes
- Development of guidelines for data sharing

→ eTRANSAFE Translational Safety Assessment



→ Approach

Key elements of the **eTRANSAFE** architecture will be a specialised SEND data management system, a database of shared proprietary data managed by an honest broker, a Knowledge Hub providing seamless access to all the databases and data sources, and an ecosystem of data exploitation modules.

The intended use of this architecture will establish overarching policies and guidelines for data sharing, secondary use of human safety data and use of pooled data and models in drug safety assessment.

An ambitious and flexible IT architecture capable of efficiently integrating and managing a proprietary and public data framework, allowing its exploitation for the development of a platform of useful software applications.

→ Action

Establishment of a preclinical and clinical data warehouse.

Development of the data sharing guidelines and policies necessary for industry and other organisations to share drug safety related data with the aim to improve the feasibility and reliability of translational safety assessment during the drug development process.

Development of protocols for predictive model development that describe how models have to be created and documented in order to facilitate their industrial acceptance and approval by regulatory bodies.