eTRANSAFE

eTRANSAFE, a New Player in Translational Safety Assessment

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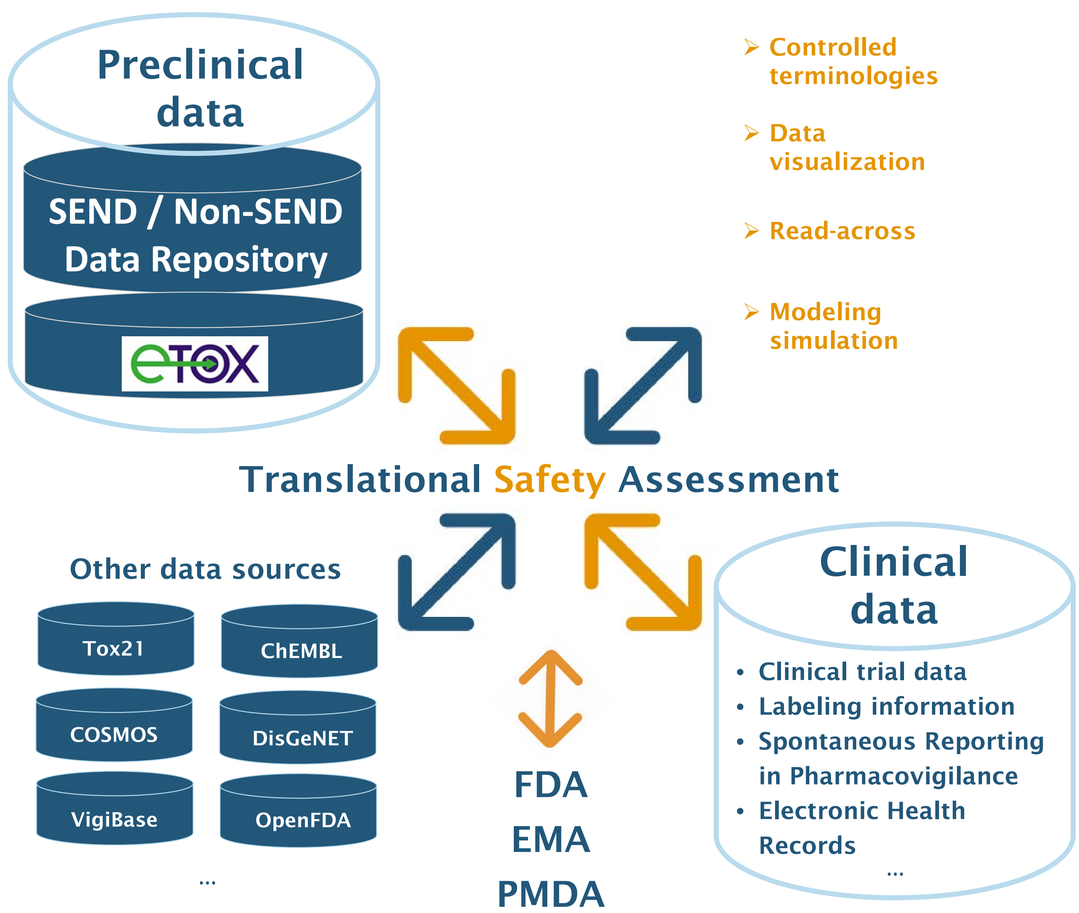
Abstract: PP32

The Innovative Medicines Initiative eTRANSAFE project develops an integrative data infrastructure and innovative computational tools that aim to improve predictivity and reliability of translational safety assessment during the drug development process. The project will leverage existing scientific data (biological, pharmacological, toxicological and clinical from public sources and EFPIA companies of the Consortium) which will be curated, harmonized and made accessible to the project partners via an integrated software platform designed to support translational analyses.

The planned focus on the SEND format will foster this standard as the de facto global standard for nonclinical data exchange, and will enhance the cross industry/academia experience on managing and utilising SEND datasets within Europe. The Consortium works to convert legacy toxicological data (non-SEND) into a SEND compatible format allowing a broader analysis of nonclinical data across pharma archives.

The eTRANSAFE outcomes will ensure improved decision-support to the project participants and related stakeholders (i.e. scientific community, regulators, other industry sectors).



eTRANSAFE project

Enhancing TRANslational SAFEty Assessment through Integrative Knowledge Management is a five-year project, starting from 1st September of 2017, funded by the **Innovative Medicines Initiative 2 Joint Undertaking** (IMI 2) together with the pharmaceutical industry. The **eTRANSAFE** project aims to develop an **integrated data infrastructure** and **innovative computational methods and tools** to significantly improve the predictivity and reliability of translational safety assessment during the drug development process.

The eTRANSAFE consortium is working to:

- Pioneer guidelines for data sharing and precompetitive collaborations.
- Create and maintain the most complete and highest quality preclinical database, including a specialised SEND data management system.
- Link legacy data (non-SEND) and SEND data using ontologies developed within the eTOX project.
- Gather, organise and normalise as much human/clinical data as possible.
- Produce *in silico* predictive modules accepted by the scientific and regulatory communities.
- Exhaustive assessment of the validity of preclinical data to human safety.
- Correlate preclinical and clinical biomarkers to discover translational and reverse-translational biomarkers.
- Together with health authorities, revise and optimise our approaches to animal-based human safety assessment, potentially impacting ICH guidelines.
- Assess optimization in how preclinical studies are run and how industry designs these studies.

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References

IMI https://www.imi.europa.eu/
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Legacy data sharing to improve drug safety assessment: the eTOX project. Nat Rev Drug Discov. 2017 Dec;16(12):811-812.

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