10 YEARS OF BREAKTHROUGHS A HEALTHIER FUTURE

eTRANSAFE

39

Translational Safety Assessment in Pharma: eTRANSAFE

R.Bueters[1], A. Kreuchwig[2], J. Wichard[2], T. Steger-Hartmann[2].

[1.] Janssen R&D, Beerse, Belgium. [2.] Bayer AG, Berlin, Germany.

Facts & Figures

Start date:	01/09/2017
End date:	31/08/2022
IMI funding:	20 000 000 €
EFPIA in kind:	1 700 050 €
Total cost:	21 700 050 €
Project website:	www.etransafe.eu
Social media:	@etransafe

Ambitions - The eTRANSAFE project aims to:

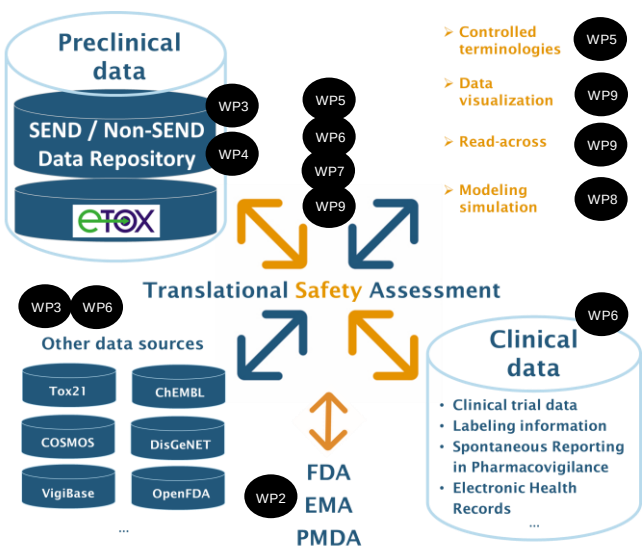
- Create and maintain the most complete and highest quality preclinical database.
- Gather, organise and normalise as many human/clinical data as possible.
- Exhaustive assessment of the validity of preclinical data to human safety.
- Correlate preclinical-clinical biomarkers and unearth new ones.
- Together with health agencies, revise and optimise our approaches to animal-based human safety assessment, potentially impacting ICH guidelines.
- Produce in silico predictive modules accepted by the scientific and regulatory communities.
- Pioneer guidelines for data sharing and precompetitive collaborations.

Challenges

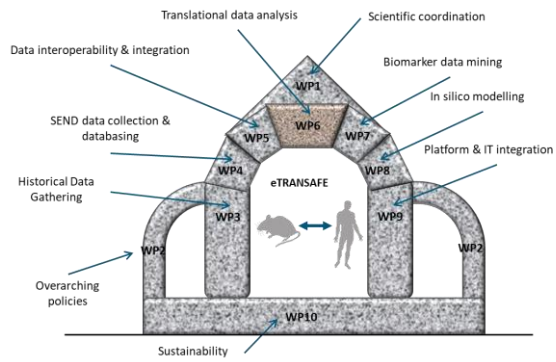
- Get sufficient preclinical and clinical EFPIA data for meta-analysis and predictive modelling.
- Generate ontologies and interface data between databases.
- Keep modelling work packages progressing even though there are dependencies on data donation.

Approach & Methodology

A knowledge hub will be constructed to act as a crossroad of data from the public and private domain using an “honest broker concept”, using advanced computational tools and methods to improve preclinical to clinical translation.



Our challenges are adressed by allocating tasks to work packages which can support each other and having participants in multiple work packages to secure alignment.



Results – 1 year in

- Main design for the knowledge hub has been completed and a first prototype is underway.
- First preclinical data donations are in (about 3500 studies), but many more are needed.
- Agreements were made on how to approach clinical data donation.
- Ontology mapping and curation of databases is progressing.
- eTOX IMI members endorsed the use of its data for eTRANSAFE, enabling modelers to start building user workflows and experiment with new tools.
- Proof of principle of some computational tools was shown and additional tools are being explored.

Value of IMI collaboration

- Construction of an extensive and integrated knowledge hub such as eTRANSAFE not likely possible without collaboration.
- Development of high quality predictive models trained on datasets of multiple EFPIA companies.
- Integration of EFPIA and public datasets will accelerate research of academic partners.

Impact & take home message

eTRANSAFE aims to optimize the use of resources and to improve development of safer medicines for patients by combining preclinical and clinical data sources to systematically analyze the translatability of observed preclinical observations to clinical adverse drug reactions in humans.

This work has received support from the EU/EFPIA/[Associated Partner] Innovative Medicines Initiative [2] Joint Undertaking ([eTRANSAFE] grant no [777365]’.