Research Areas

- Tool Development
  - Prediction
- Data-Sharing Enabler

At a Glance

- Status: Active Consortium
- Year Launched: 2010
- Initiating Organization: Innovative Medicines Initiative
  - Initiator Type: Government
  - Location: Europe

Abstract

A project of the European Union’s Innovative Medicines Initiative (IMI), eTOX (http://www.etoxproject.eu) aims to develop computer models that can predict toxicity of new molecular entities in humans. It hopes to achieve this goal by creating a pharmaco-toxicological database integrating publicly available data with proprietary data from pharmaceutical partners of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Mission

The eTOX project is creating this pharmaco-toxicological database containing public and private data with an aim to

- Reduce the number of animal tests
- Decrease the attrition rates of new drug candidates
- Increase the success rate of new molecular entities becoming drugs
- Improve the safety of drugs on the market

The project consists of three different systems:

- eTOX VITIC Database: a unified database containing all confidential and nonconfidential data collected in eTOX (historical data from the pharmaceutical industry)
- ChOX Database: a unified database containing public data (literature and public database)
- eTOXsys Query and Prediction System: an interface providing a uniform access to the two databases (VITIC and ChOX) and to all developed prediction models and systems

Anticipated use-cases and advantages of eTOX are as follows:

- Allow researchers to modify, early in the discovery process, the chemical backbone of molecules to keep the pharmacology and other desirable parameters such as solubility, distribution, etc. and to reduce unwanted side effects
- Consider impurities or metabolite, which are not amenable to in vivo toxicity testing because of the low available amount
- Provide mechanistic insights for demonstrated in vivo toxicities
- Bring into animal studies only those compounds that would have been optimized as much as possible for their safety, reducing the overall number of animals used for drug development

**Consortium History**

eTOX was launched in 2010 for a duration of five years. It was formed as a partnership between 13 companies, seven academic institutions, and six small to medium-sized enterprises (SMEs). In 2013, eTOX received approval for its ENSO (Explore New Scientific Opportunities) application from IMI to
extend the project for another two years until end of 2016 and include four new partners.

Structure & Governance

eTOX is an initiative of IMI, a public-private partnership between the European Union, represented by the European Commission, and EFPIA.

The eTOX Steering Committee consists of representatives from each partner and is supported by a Scientific Advisory Board, which includes outside experts in toxicology and pharmacology. The eTOX Steering Committee reports to the IMI Executive Office and provides oversight to the eTOX Executive Committee.

The Executive Committee members are chosen from participating EFPIA companies. It consists of a leader, a deputy head, leader of the public partners, and a project management leader.

The positions are currently held as follows:

- Leader, Novartis
- Deputy, Bayer HealthC
- Leader of the public partners, FIMIM
- Project management office, Synapse

Financing

eTOX is funded by IMI, a unique partnership between the European Union and EFPIA. The original eTOX budget totals €13.9 million, which includes €4.7 million from the IMI, €7.9 million in-kind contributions from EFPIA, and €1.3 million from SMEs and academia. The ENSO extension will increase the project budget by an additional €4.4 million, which includes a €2.2 million contribution from IMI and €2.2 million in-kind contribution from EFPIA.
Intellectual Property

Any intellectual property (IP) generated by eTOX follows IMI’s general principles for IP management.

- Each participant retains its rights to any IP brought into the collaboration (background information).
- IP rights of any inventions created during the consortium belong to the researchers and their institutions.
- All access rights are part of the project agreement.
- During and after completion of the project, the participants and their institutions have access rights to the background IP from the other participants, but only to the extent reasonably required for and only for the purpose of the collaboration.

Data Sharing

eTOX’s primary objective is to compile data from different sources to create a database that improves drug safety assessment and accelerates drug development. eTOX includes the participation of experts in toxicology, knowledge management, bioinformatics, chemoinformatics, biostatistics, and software development from industry and academia. Teams share and analyze the archived results of steadily increasing and currently more than 3,000 toxicological studies from pharmaceutical partners and public sources.

The database is hosted and maintained by a third party and is accessible to consortium partners. Technical and legal agreements are used to protect IP of each contributing partner. It is hoped that new data will be continuously added to the database after the end of the project to increase the impact of the collaborative effort.

eTOX conducts an annual assessment of its collaboration, in addition to the overall IMI-wise assessments. It is currently top-ranked among all IMI consortia, in regard to its publication output.
Links/Social Media Feed

Consortium homepage
IMI homepage on eTOX
Twitter
YouTube
LinkedIn

http://www.etoxproject.eu/
http://www.imi.europa.eu/content/etox
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Updated: 05/24/2016