



40 Million EUR European project for new **drug safety assessment** and **integrative data analysis** research.

The five-year project, Enhancing Translational Safety Assessment through Integrative Knowledge Management (eTRANSAFE), aims to develop an advanced **data integration infrastructure** together with **innovative computational methods** to improve the **security in drug development process** and is funded by the Innovative Medicines Initiative 2 Joint Undertaking (IMI 2) together with the pharmaceutical industry.

The eTRANSAFE consortium is a private and public partnership of 8 academic institutions, 6 SMEs and 12 pharmaceutical companies, and is coordinated by the Fundació Institut Mar d'Investigacions Mèdiques (IMIM) and led by the pharmaceutical company Novartis.

The eTRANSAFE project aims at improving the **safety assessment** across the drug discovery and development process by applying bioinformatics approaches to shared preclinical and clinical data to systematically analyse the translatability of effects. Thus, enabling the optimisation of resources and the development of safer medicines.

*"The safety of new drug candidates in first clinical trials is extrapolated based on preclinical animal data. These extrapolations are made using solely the data generated for the project at hand, since a global and systematic analysis of predictivity of the entire collective historical data pool has never been made",* said Project leader Francois Pognan from Novartis. *"It is often poorly known to what extent and frequency an observed effect in an animal species may translate into a human effect",* adds deputy leader Thomas Steger-Hartmann from Bayer.

Based on the experience gained in the previous eTOX project, the eTRANSAFE project will carry out key efforts in the field of data standardisation and quality control, promoting the development and implementation of relevant data sharing policies and procedures that will have a great global impact in the community. eTRANSAFE will catalyse the transformation of drug safety modelling from monolithic applications and isolated data repositories to an open innovation ecosystem based on open standards, modular components and data integration services.

Professor Ferran Sanz, coordinator of the project said: *"eTRANSAFE will improve translational safety assessment and contribute to the key scientific policies, such as the reduce, **replace**, **refine** (3Rs) one and the FAIR principles for data sharing."*

The main specific objectives of the eTRANSAFE project are:

- The development of a state-of-the-art, powerful and flexible strategy and technological architecture for data sharing (diverse sources of nonclinical and clinical data), data integration and data exploitation.
- The implementation of the following key elements for this architecture: a specialised SEND ("standards for the exchange of non-clinical data") 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 establishment of overarching policies and guidelines for safeguarded data sharing, secondary use of human safety data and use of pooled data and models in drug safety assessment .
- Optimising how preclinical studies are run and how the industry designs these studies.

For more information about eTRANSafe project please visit: <http://www.etransafe.eu/>

The project is coordinated and led by:

Fundació Institut Mar d'Investigacions Mèdiques (Coordinator)

Novartis Pharma AG (Leader)

Synapse Research Management Partners SL (Co-coordinator)

Bayer AG (Deputy Leader)

The eTRANSafe partners are:

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| 1. Fundació Institut Mar d'Investigacions Mèdiques (IMIM)                 | 13. PDS Computer Software Limited                  |
| 2. Synapse Research Management Partners S.L.                              | 14. Universitat Pompeu Fabra                       |
| 3. Lhasa Limited  | 15. Novartis Pharma AG                             |
| 4. European Molecular Biology Laboratory (for ELIXIR)                     | 16. Bayer AG                                       |
| 5. Erasmus Universitair Medisch Centrum Rotterdam                         | 17. Sanofi-Aventis Deutschland GmbH                |
| 6. Universiteit Leiden  | 18. F. Hoffmann-La Roche AG                        |
| 7. Universität Wien   | 19. Merck KGaA                                     |
| 8. Simcyp Limited   | 20. Janssen Pharmaceutica NV                       |
| 9. Molecular Networks GmbH – Computerchemie                               | 21. Institute de Recherche Internationales Servier |
| 10. Optibrium Limited   | 22. AbbVie Inc                                     |
| 11. Liverpool John Moores University                                      | 23. AstraZeneca AB                                 |
| 12. Fraunhofer-Gesellschaft zur Foerderung der Angewandten Forschung e.V. | 24. Boehringer Ingelheim International GmbH        |
|   | 25. Clarivate Analytics                            |
|   | 26. IPSEN Innovation SAS                           |

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