



INDICATIVE TOPICS
FOR THE
IMI 3RD CALL FOR PROPOSALS (2010)

SAFETY

Assessment of drug induced toxicity in relevant organs / surrogates for early drug failure

- **Improved early prediction of Drug Induced Liver Injury (DILI) in man**

DILI is one of the major safety reasons for delays or termination of drug development. The project aims at the identification of a panel of new in vitro assays and in vivo models that allow the early identification of compounds likely to cause DILI in humans. It includes approaches for an improved sharing of data and knowledge and the building of a biobank (tissue and body fluid samples).

- **Cardiovascular safety**

The aim of the project is the identification of novel biomarkers and models that could help to assess the effects of novel treatments on the heart more efficiently.

Immunological Safety of Biopharmaceuticals

- **Immunogenicity: Assessing the Clinical Relevance and Risk Minimization of Antibodies to Biopharmaceuticals**

In this project different technologies will be evaluated which can be used to detect Anti-Drug-Antibodies (ADA). It is planned to establish a comprehensive database of drug and patient data and to identify early activation biomarkers.

- **Immunosafety of vaccines – New biomarkers associated with adverse events (early inflammation and autoimmune disease)**

This project aims at the identification of validated preclinical and clinical biomarkers for early inflammation and autoimmunity and a better understanding of the incidence and epidemiology of these events in the general population.





Innovative Medicines Initiative

EFFICACY

Improve infrastructure for Tuberculosis medicines

- **Improve the scientific and preclinical models and tools for Tuberculosis medicines research**

The project aims at the identification of validated preclinical and clinical biomarkers to speed up the evaluation process, to develop models better reflecting human pathology and to improve preclinical and early clinical models with pharmacokinetic-pharmacodynamic assessment that optimizes clinical development.

Enhancing translation in neurological disease

- **Translational endpoints in autism**

The project aims to take advantage of recent progress in the understanding of the underlying neurobiology of Autism Spectrum Disorders (ASD), and to foster the development and validation of in vitro models, in vivo models and translational biomarkers enabling drug discovery. Another key objective of the project is to establish a network of clinical centres of excellence across Europe, that serves as an interactive platform for ASD specialists and clinical trials.

Development of personalized medicine approaches in diabetes

- **Personalized Medicine in Diabetes treatment**

The project aims at the identification of novel predictive tools for type 2 diabetes patients, better patient stratification and more specific clinical trials.

EDUCATION & TRAINING

Fostering a broader understanding of pharmaceutical R&D in the broader public

- **Training programs for the informed patient**

The project aims at the establishment of a pan-European Industry – Patient Organisation network and the joint development of training programs for patients and the broader public.

All information above is indicative and subject to change. Further details about the IMI 3rd Call topics will be communicated after approval by the IMI Governing Board.



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