Immune Safety Avatar

Nonclinical mimicking of the immune system effects of immunomodulatory therapies

imSAVAR

www.imsavar.eu

imSAVAR develops innovative model systems for the evaluation of immunomodulatory therapeutics.

The imSAVAR is an Innovative Medicines Initiative funded project that aims to develop a standard for integrated nonclinical safety overviews for immune-modulatory investigational new drugs (IND) and clinical trial applications (CTA).

The Challenge

Models used up to now are too basic and incomplete, species-specific and reflect only limited areas of the human immune system, which often lead to wrong predictions of human adversities.

- Current models do not adequately represent the complexity of the human immune system
- Current models are too species-dependent
- Current models do not accurately reflect the diversity of human response to new immunomodulatory therapies (healthy human donors vs. diversity of patients with diseases).

Our Vision

The vision of imSAVAR is to develop a platform for integrated nonclinical assessments of immunomodulatory therapy safety and efficacy.

imSAVAR aims to develop:

- Models that represent complexity of diseases and have been shown to be predictive of clinical responses
- Novel biomarkers and analysis approaches
- IT infrastructure for data management and integration
- Network of sample resources

"Within imSAVAR we aim to tackle the challenge of a better understanding of the complex human immune system. We plan to characterise a range of innovative human-relevant models and biomarkers that ultimately lead to the development of safer efficacious medicines for patients."
Ulrike Köhl and Jonathan Moggs, Coordinators

Our Objectives

Gain early insights and experience into translational safety assessment with R&D pipeline-relevant therapeutic modes of action.

A cost-effective way to evaluate the potential utility of sophisticated non-clinical tools:

- Human immune cell-derived microphysiologic systems
- Engineered/humanized animals
- Novel molecular and cellular biomarkers of immunomodulation

Influence optimal safety assessment strategies for immunomodulatory therapeutics:

- Benchmarking of new models/biomarkers against current First-In-Human (FIH)-enabling non-clinical experience
- Consortium-facilitated stakeholder engagement with Regulators, Pharma-industry working groups and Patient organisations

imSAVAR Consortium

Formed to provide a diversity of expertise on the ambition to deliver a sustainable platform of non-clinical tests that can more accurately reflect disease states.

28 partners from 11 countries provide expertise in:

- Safety of immunotherapeutics, their mode of action and adverse events including development of novel biomarkers
- Experimental assay systems (in vitro, in vivo, microphysiological systems and organ-on-chip models)
- Management of data, data privacy and biological samples including a network of sampling providing centres
- Knowledge and innovation management, bioinformatics solutions
- Patient stakeholder involvement

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Contact

imsavar.eu
www.imi.Europa.eu

www.twitter.com/ImSavar

www.linkedin.com/company/imsavar

imsavar@izi.fraunhofer.de

www.imsavar.eu

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 853988. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and JDRF INTERNATIONAL.