### **IMMUNE SAFETY AVATAR**

# Nonclinical mimicking of the immune system effects of immunomodulatory therapies



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

The development of immunomodulatory agents and therapies has received fresh impetus following the latest successes in immuno-oncology. And cancer medicine is not the only area where cell and gene therapies are increasingly taking hold as alternatives or complementary to classic, low-molecular drugs and biologicals.

A significant challenge facing the development of new therapies, however, is and remains their preclinical evaluation in terms of efficacy and safety. The greatest problem is the complexity of the human immune system. When a person is ill, for example in the case of cancer, autoimmune or inflammatory diseases, the cells of the immune system interact differently to when a person is healthy. Preclinical tests have so far mainly focused on the basic toxicity of a new therapeutic agent in terms of the (healthy) immune system. Consequently, there is a lack of non-clinical models accurately capturing the individual interactions of the human immune system in the pathogenic state.



"With the imSAVAR project we aim to tackle the challenge of a better understanding of the complexity of the human immune system." Ulrike Köhl, Coordinator



The imSAVAR team plans to characterise [...] models and biomarkers [that] ultimately lead to the development of safer efficacious medicines for patients."

Jonathan Moggs, Coordinator

The EU consortium imSAVAR (*Immune Safety Avatar: nonclinical mimicking of the immune system effects of immunomodulatory therapies*) is addressing this shortfall by inventing and testing new ways of examining immunomodulatory therapies. The aim is to improve existing model systems and develop new ones in order to:

- Identify adverse side effects of new therapies affecting the immune system,
- Develop new biomarkers for diagnosing and predicting immune-mediated pharmacology and toxicities,
   and
- Further explore toxicity mechanisms and the potential for their mitigation via therapeutic interventions.

The project hopes to lay the foundations for new Europe-wide standards in drug development.

The interdisciplinary imSAVAR consortium is made up of 28 international partners from 11 nations and is being coordinated by the Fraunhofer Institute for Cell Therapy and Immunology and Novartis. Partners include university and non-university research facilities, pharmaceutical and biotechnology companies, as well as regulatory authorities.



For more information about the imSAVAR project, the stakeholder community, recent publications, and news please visit our <u>website</u>, subscribe to our <u>newsletter</u>, or follow us on <u>Twitter</u> and <u>LinkedIn</u>.









### PATIENT INVOLVEMENT

## Become part of the imSAVAR project!



imSAVAR aims at engaging patient stakeholders in an ongoing dialogue among all partners of the project. Their valuable perspective will contribute to the progress of the work and optimize/shape the outcomes.

How Patient Stakeholders will be involved:

- Patient stakeholders will take part in the project team meetings as well as the general assembly to share their view on on-going activities and future planning.
- Patient stakeholders will work alongside the project participants to provide a lay summary of the progress report following each General Assembly.
- Patient stakeholders will conduct short interviews to convey the patient perspective to the consortium members
- Patient stakeholders will work with the researchers to develop lay summaries to accompany the publications produced within the project. These lay abstracts along with the publications themselves will be used for social media and a project overview.

Let us know if you would like to become part of the team!

#### **GET IN TOUCH WITH US!**

Either write an email to our imSAVAR Project Management Office via <a href="imsavar@izi.fraunhofer.de">imsavar@izi.fraunhofer.de</a>
or contact our project partner in charge of stakeholder engagement Scott Wagers from BioSci Consulting directly via <a href="mailto:scottwagers@biosciconsulting.com">scottwagers@biosciconsulting.com</a>.



© Fraunhofer IZI Kick-off Meeting, ImSAVAR Consortium, 2 December 2019.







