

## MEMBERSHIP TERMS OF REFERENCE imSAVAR Stakeholder Community

### Background

imSAVAR is an Innovative Medicines Initiative funded project—composed of academia, private sector, pharma, regulators, and technology providers—to address the current limitations of non-clinical assessment of immunomodulatory therapies. To expand effectiveness of these advanced therapies, better prediction of the transferability of safety and efficacy from pre-clinical models to first-in-human studies is vital. Vision: develop a platform for integrated nonclinical assessments of immunomodulatory therapy safety and efficacy.

Mission: to enhance translational safety assessment of immunomodulatory therapeutics and ultimately lead to the development of safer efficacious medicines for patients.

Through the following 4 objectives, the imSAVAR project will aim to enhance prediction of adverse immune-related toxicities and establish a standard approach to immune safety assessment:

- Identification of immunomodulatory modes of action (MoAs) that have insufficient methods for predicting human toxicities so that resources can be focused where they are most likely to lead to real differences in predicting immunosafety.
- Refine existing models, develop new models, and identify biomarkers for preclinical assessment of efficacy and safety for immunoncology and immuno-inflammatory therapeutics so that development of unsafe immunomodulatory therapies can be stopped early in the development process.
- Establish a platform that combines models with a network of biosample resource providers that can carry out immune safety assessment strategies in an efficient manner and continually to progress the field.
- Creation of immune safety stakeholder community and business models that can maintain and extend the vision of imSAVAR beyond the funding period.

More information about imSAVAR can be found at [www.imsavar.eu](http://www.imsavar.eu).

### Stakeholder Community

This document establishes the process for an organisation or individual to become a member of the imSAVAR stakeholder community.

A member of the stakeholder community is not an imSAVAR project partner. Only imSAVAR partners possess specific rights and responsibilities related to the imSAVAR project. imSAVAR partners establish and govern its stakeholder community and participate in related activities with members.

The imSAVAR stakeholder community can include: partners, organisational members (through organisational representatives) and individual members.

### Governance

The imSAVAR Executive Committee manages the stakeholder community. Partner BioSci Consulting is the dedicated point of contact for members.

All requests or recommendations by members are welcome and should be sent to the point of contact. Adoption of requests or recommendations lies at the discretion of the imSAVAR Executive Committee.

Members that act in such a way as to damage the interests or reputation of the imSAVAR project, may be removed from membership of the imSAVAR stakeholder community by the imSAVAR Executive Committee.

A member may resign at any time by sending a written notice to the point of contact. The same process applies to any changes in membership.

The membership terms of reference are subject to change. Members will be informed of changes in a timely manner by the point of contact.

This document is not intended to and does not create any legally binding financial or other obligation on the part of the member

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(organization/individual), the imSAVAR project or between the member and the imSAVAR project.

### Roles & Responsibilities of Members

Members can be organisations, either not-for-profit or for-profit, or individuals in fields—such as healthcare, public health, biomedical and other research, information and life sciences, oncology, and patient advocacy—that subscribe to the goals of the imSAVAR project.

Organisational Members may designate representatives, from its organisation, to represent itself in imSAVAR stakeholder community activities.

Member benefits include:

- access to a member only platform and tools;
- networking opportunities;
- awareness of the project (updates, seminars, dissemination activities);
- consultations;
- multistakeholder interactions (e.g. roundtables, focus groups);
- member only events;
- member developed sub-projects in alignment with imSAVAR roadmap;
- and collaboration on project incubators.

Members agree to receive communication related to the imSAVAR project and its stakeholder community.

Participation in stakeholder community activities is voluntary. Activities will be effected progressively when deemed feasible by the imSAVAR Executive Committee.

### Consent Process

Membership to the imSAVAR stakeholder community (organisational or individual) will be confirmed upon completion of the online [consent form](#) (by each organisational representative or individual member) which is required for GDPR compliance.

Following completion of the consent form, access will be granted to the imSAVAR stakeholder community platform. One organisational representative is required to provide a short profile of their organisation (~1 paragraph).

For queries please contact BioSci Consulting ([sapnasheth@biosciconsulting.com](mailto:sapnasheth@biosciconsulting.com))