Sobi policy on bioethics in medical R&D

Swedish Orphan Biovitrum Group

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1 Preamble

This document describes the guiding principles of bioethics at Sobi, which are binding for all employees working on medical and scientific activities, especially clinical trials and pre-clinical research. This policy applies globally to Sobi AB and its affiliates, and all partners conducting such research on behalf of Sobi.

As a responsible rare disease biopharma company, Sobi proactively monitors and mitigates the reputational, legal and financial risks arising from its medical and scientific activities. It applies consistent standards for a culture of integrity and upholding bioethical rules to protect the people we work with from unethical medical and scientific practices.

Our main impact areas are clinical studies, the use of human biological material and gene technology, and animal welfare.

We expect the same conduct from our partners and vendors, as laid out in the Sobi Partner Code of Conduct.

2 Governance

All Sobi sponsored and co-sponsored studies and evidence generation projects are governed by the Evidence Generation Board (EGB). It ensures the scientific validity, ethical compliance, and strategic fit of studies.

The Chief Medical Officer (CMO) is accountable for the EGB. This process is applicable to all Sobi assets and all Sobi-sponsored interventional studies (including low intervention studies), non-interventional studies, Health Economic Research (HEOR), Market Research and Research Collaborations.

The R&D and Medical Affairs Leadership Team together with the Sustainability and Compliance functions review this bioethics policy regularly.

Employees and partners who become aware of potential research misconduct are encouraged to report their concerns through Sobi's internal reporting mechanisms. Sobi prohibits retaliation against individuals who report concerns in good faith.

3 Clinical studies

3.1 Applicable guidelines

All Sobi clinical and medical studies are conducted in accordance with the ethical principles set forth in the Declaration of Helsinki and in compliance with ICH E6(R2) Good Clinical Practice (GCP) guidelines and all applicable national and regional laws and regulations. All studies require prior approval from an independent ethics committee (EC) or institutional review board (IRB) before initiation.

The Declaration of Helsinki is a set of ethical principles guiding medical research involving human subjects. It emphasises the need for informed consent, the protection of participants' welfare, and the importance of ethical review by independent

committees. The declaration stresses that the wellbeing of the individual should take precedence over the interests of science and society.

Our practices comply with all applicable laws, regulations, and ethical guidelines, including Good Research Practices (GRP), Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Pharmacovigilance Practices (GVP), and Good Clinical Practices (GCP).

Sobi maintains robust pharmacovigilance systems to monitor the safety of its medicines throughout their lifecycle and to ensure that Sobi meets the regulatory safety reporting responsibilities required of study sponsors. All adverse events and safety signals are collected, evaluated, and reported in accordance with Good Pharmacovigilance Practices (GVP), applicable regulatory authority requirements, and ICH guidelines.

Sobi is committed to protecting the privacy and confidentiality of all personal data collected in the course of clinical and medical research. All data processing activities comply with applicable data protection laws, including the EU General Data Protection Regulation (GDPR), the US Health Insurance Portability and Accountability Act (HIPAA) where applicable, and other relevant national and regional requirements.

Clinical research data are collected, processed, and stored in accordance with ICH E6(R2) GCP requirements for data integrity and confidentiality. Personal data are pseudonymised or anonymised where possible, and appropriate technical and organisational safeguards are implemented to prevent unauthorised access, disclosure, or loss.

3.2 Transparency and publishing of results

Sobi conducts its own research openly. It is committed to transparently sharing the outcomes of its studies to provide scientifically founded information to guide treatment decisions.

Sobi registers clinical studies on www.clinicaltrials.gov and other applicable platforms such as CTIS for EU and EEA trials, in compliance applicable registration requirements. All clinical studies are registered and reported, and the complete and accurate results from clinical studies are shared even if they show an outcome that is not beneficial or if a study is stopped.

The website Sobi Science Library offers access for healthcare professionals to congress publications, study outcomes and other relevant information including analyses on cost effectiveness as well as the health economics data connected to Sobi medicines.

Sobi is committed to identifying, disclosing, and managing conflicts of interest that could affect the integrity of research activities. Investigators and other individuals involved in Sobi-sponsored research are required to disclose relevant financial interests in accordance with ICH GCP requirements and applicable regulations, including FDA financial disclosure requirements and EU Clinical Trials Regulation provisions.

Sobi employees involved in research governance, study design, or data analysis are subject to Sobi's internal policies on conflicts of interest and are required to disclose and manage any interests that could compromise objectivity or scientific integrity.

For clinical trials, Sobi ensures timely reporting of serious adverse events and suspected unexpected serious adverse reactions to regulatory authorities, ethics committees, and investigators in accordance with applicable requirements. Safety information is continuously evaluated and, where necessary, communicated to participants, healthcare professionals, and regulators.

All published studies include demographic characteristics, at least showing the gender distribution of participants. Ethnicity is tracked in local trials for some countries, for instance Japan and China. Sobi works to include patients from different ethnic backgrounds that are affected by the condition in its global trials from the beginning.

Sobi publishes lay summaries of its clinical studies, drafted with the help of patient experts.

3.3 Inclusion of patients in study design

Sobi recognises that early engagement of the patient voice is vital. It ensures well-designed clinical studies and minimises study burden. By actively involving patient experts, Sobi paves the way for future medicines that truly meet patient needs. Sobi engages patient experts during the study design phase.

In phases of clinical research not directly or fully owned by Sobi, we commit to putting our efforts into making information available and driving connections to foster inclusion of patients in existing clinical research.

Patient experts provide valuable input on the clinical design, with a specific emphasis on patient-relevant (patient related) outcomes. Their insights help shape the study protocols and end points. Sobi's clinical patient councils play a pivotal role in shaping clinical research and development. They bring together Patient Organisations worldwide, along with cross-functional Sobi teams. Together, they collaboratively plan, execute and close disease awareness activities and clinical studies. Patient councils provide insight into lived experience while Sobi retains full responsibility for scientific and regulatory decisions.

3.4 Access to investigational medicines following clinical trial participation

We recognise that patients who participate in clinical trials may derive clinical benefit from an investigational medicine but may not have access to that treatment following completion of the trial, particularly where the medicine is not yet approved or commercially available.

In such circumstances, and for patients with serious or life-threatening conditions who have no satisfactory therapeutic alternatives, access to investigational medicines may be considered following trial participation ("post-trial access") prior to commercial availability through managed or compassionate access programmes.

Post-trial access may be considered for patients who have participated in and successfully completed a clinical study and, in the opinion of the treating physician and based on available evidence, have experienced clinical benefit and for whom continued treatment represents an appropriate medical option.

All access decisions are made on a case-by-case or defined cohort basis and are subject to:

- A favourable benefit-risk assessment based on available data
- Availability of adequate product supply
- Compliance with applicable laws and regulatory requirements
- Confirmation by the treating physician that continued treatment is clinically appropriate
- Patient agreement to participate
- Consideration of alternative treatment options and ongoing clinical trial availability

Access to investigational medicines is exceptional and is not intended to replace participation in clinical trials. Provision of access does not imply or guarantee regulatory approval, commercial availability, reimbursement, or continued supply.

Access may be modified or discontinued in response to new scientific or safety information, changes in the patient's clinical condition, product availability, or the availability of approved therapies.

We recognize that responsibility for post-trial access may be shared among sponsors, investigators, healthcare providers, and healthcare systems, and we are committed to acting responsibly and ethically in balancing patient need with safety, scientific integrity, and sustainability.

4 Use of human biologic material and gene technology

At Sobi, we are guided by a commitment to science, patients, and society. The responsible use of human biological materials is essential to advancing our understanding of rare diseases and developing innovative therapies. At the same time, we recognise that such use raises important ethical considerations and requires respect for individuals, transparency, and robust governance.

Sobi applies a cautious and principled approach to the use of human biological materials, including stem cells, foetal tissue, and established human cell lines. Any such research must have a clear scientific and medical rationale. It must be conducted in full compliance with applicable laws, regulations, and internationally recognised ethical standards, and be subject to the Sobi governance by the EGB.

Sobi ensures that all clinical research participants provide voluntary informed consent prior to enrolment, based on clear and comprehensive information about the study's purpose, procedures, risks, benefits, and alternatives. Informed consent processes comply with ICH E6(R2) GCP requirements, applicable data protection laws, and local regulatory requirements.

Where study protocols are amended in ways that may affect participants' willingness to continue, Sobi ensures that participants are informed and given the opportunity to provide renewed consent.

Through these commitments, Sobi seeks to ensure that the use of human biological materials contributes to scientific progress while respecting the dignity, rights, and expectations of individuals and society.

At Sobi, we recognise that gene editing and gene therapies are promising technologies with the potential to address the underlying causes of many rare diseases, which are often genetic in origin and associated with high unmet medical need.

Sobi supports the use of gene technology in research, development and manufacturing. Any such use at Sobi must have a clear scientific, medical or patient benefit and be conducted with scientific rigour, in compliance with applicable legal, regulatory, biosafety and ethical requirements.

5 Animal welfare

Animal studies are only considered when the current state of scientific knowledge and applicable guidelines does not provide acceptable alternatives to accomplish the purpose of a study, and with application of the 3R principles of replacement, reduction and refinement.

Sobi does not perform in-house animal studies and only contracts from validated suppliers. Where animal testing is necessary, it is carefully considered and justified. From its partners, Sobi expects adherence to the principles of research ethics as stated in the Sobi Partner Code of Conduct.

Supplier agreements include references to international norms for animal studies and animal care, and each individual study needs to be justified and further framed by protocols on animal welfare.