Data sharing policy

Sobi is committed to responsible and ethical sharing of data from clinical studies and supports the continuous efforts of the European Medicines Agency (EMA), the European Commission and the Food and Drug Administration (FDA) to further increase the transparency of data from clinical studies. As a pioneer in rare diseases, Sobi also advocates sharing of data from studies while protecting individual patient integrity and compliance with applicable legislation.

Public disclosure of clinical study information

Sobi follows the policy to register and disclose information for all Sobi-sponsored clinical studies (both interventional and non-interventional) on the publically available website www.ClinicalTrials.gov and other public domains as applicable to local laws and regulations. Study registration is completed before recruitment of the first study participant.

Public disclosure of clinical study results

Sobi follows EMA and FDA regulations and/or other applicable local laws and regulations for public posting of clinical study results. At a minimum, results of all interventional studies of approved and available medicinal products, regardless of study outcome, will be posted on ClinicalTrials.gov and/or other domains as applicable within 12 months (6 months for paediatric studies) of study completion.

Moreover, as per Good Publication Practice 3 (GPP3) Sobi intends to make the results from all Sobi-sponsored studies (both interventional and non-interventional studies) publically available to the scientific community, ideally in peer-reviewed journals, regardless of outcome.

Sharing of anonymised clinical study data with qualified researchers

Sobi commits to sharing clinical study data on participant level and summary data for medicines and indications approved by EMA and/or FDA. Data access will be granted in response to qualified research requests. All requests are evaluated by a cross functional panel of experts within Sobi. A decision on sharing will be based on the following:

- The scientific merit of the proposal – i.e. the proposal should be scientifically sound, ethical, and have the potential to contribute to the advancement of public health.
- The feasibility of the research proposal – i.e. the requesting research team must be scientifically qualified and have the resources to conduct the proposed project.
- Maintenance of personal integrity – i.e. Sobi will not consider sharing individual data if there is a risk of re-identification of individuals despite a proper anonymisation. Moreover, the patients' informed consent will always be respected. Sobi reserves the right to reject the proposal if the anonymisation process will render unusable data.
- Publication of results – the applicants should commit to submit their findings to a peer-reviewed scientific journal, alternatively to present the results at a congress (poster or similar), regardless of the research outcome.

Data sharing requests

To request access to clinical study data, please complete the data sharing request form and send together with any additional attachments to medical.info@sobi.com. Only duly completed data sharing request forms will be considered.

Related Documents
Data sharing request form