

Clinical Trial Data and Document Sharing Request by External Researcher



Instructions:

- ▶ Complete this form electronically and save it on your computer
- ▶ Send the completed form and CVs to medical.info@sobi.com
- ▶ If any field is not applicable for your request, enter N/A
- ▶ Please read the information in the end of this form explaining how Sobi will process personal data submitted as part of this request

General Information

Lead Requestor Name:
E-mail:
Telephone:
Institution/Affiliation:
Address:
**Name of All Researchers
Involved in Project:**
**Name all individuals who will
have access to the requested
data/documents**

Date of Request:
Sobi Product(s):
Study:
(if more than one, list all)

Suggested Titel:
Objectives:
Endpoints:
Hypothesis (if applicable):

Request Reason and/or Intended Use

Briefly describe the reason for requesting the data, the intended use and background information:

Data and/or Document Sharing Request Details	
Data and/or Document Specify Data and/or document(s) being requested	
Variables Description If a dataset is requested, specify which variables	
Data Analysis Plan Indicate whether a data analysis plan exists	Yes <input type="checkbox"/> If "Yes", attach plan when sending the completed form No <input type="checkbox"/> If "No" provide details on Data Analysis Method Section here below
Data Analysis Method(s) Describe the main data analysis methods	
Publication Plan Provide details of plan(s), including planned date(s) or approximate timeframe to publish the research results. If there are no plans to publish, provide justification	

Expertise	
Curriculum Vitae(s) CVs of all members of the research team to this request are attached	Yes <input type="checkbox"/>

Data Sharing Agreement	
Is there an existing Agreement with Sobi related to this data sharing request?	Yes <input type="checkbox"/> No <input type="checkbox"/> If "Yes", attach a copy of the agreement with request
Does the existing Contract/Agreement include data or document sharing provisions?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Data Privacy Policy

By submitting this request form to Swedish Orphan Biovitrum AB (“Sobi”) you will provide personal data to Sobi, e.g. name, contact information and CV information. This policy explains how such data will be processed as well as your data privacy rights.

Data Controller

Swedish Orphan Biovitrum AB (publ) (“Sobi”), with registered offices at SE-112 76 Stockholm, Sweden, e-mail address privacy@sobi.com, will collect and process the information you provide through the registration process.

Legal basis for processing and how we will use personal data provided by you

The personal data you provide will be processed by Sobi for the purpose of our legitimate interest in order to manage the request and, if applicable, the subsequent sharing of clinical data.

How we may share your personal data

Sobi will not share the personal data provided with third parties, unless you have explicitly given your consent to such disclosure or if it is required by law or industry standards.

Transfer of data outside the EEA

The personal data you provide may be accessible or transferred to our affiliates or government authorities, if required by law or industry standards, including countries outside the European Economic Area (“EEA”). The level of legal protection for personal data is not the same in all countries and may not provide the same level of protection as the data protection laws in the EEA or of the country in which you live. In case of such transfer, Sobi will take reasonable efforts and security measures in an effort to keep your information secure, and Sobi is responsible to ensure that the transfer takes place in accordance with this Privacy Policy and applicable laws. You may contact us at privacy@sobi.com if you have any questions about the methods we use to safeguard any personal information transferred outside the EEA.

Retention and erasure of personal information

We will retain your information only for the period necessary to manage the request. If your request is rejected all personal data submitted will be deleted. If the request is approved the personal data submitted will be retained for as long as needed in order to manage the data sharing and to comply with legal requirements and industry standards.

Information regarding your rights

You will at any time have the right to access your personal information, to have it rectified, erased or to transfer it to other organizations at your request. You also have the right to object or to restrict some processing. If you have any questions, requests or complaints about how we process your personal information, simply write to us using the email address: privacy@sobi.com. If you have any comments or complaints regarding the way your personal data is being handled, you have the right to contact the supervisory authority in Sweden (Swedish: Datainspektionen, see this link) or in the country where you live, to lodge a complaint.

Contact

We welcome any questions, requests, comments and complaints that you may have regarding this Privacy Policy. Please do not hesitate to reach out to us by writing an e-mail to privacy@sobi.com.