



BIOBANK SQAN

FAQ

VERSION 1.0

I. GENERAL INFORMATION

In which language should I answer the biobankSQAN?

It is recommended to enter the answers in English to allow for a uniform directory and summary for all of Switzerland.

Who do I contact if I need help?

For any questions regarding the biobankSQAN, there is a contact link in the navigation bar, or you can send an email to bbsqan@swissbiobanking.ch

In order to improve, feedback is always welcome. Do not hesitate to contact us.

How can I access the biobankSQAN?

Each user can access the biobankSQAN via the link: www.biobanksqan.ch

Before starting, the user must register in the upper right corner.

Once the user has his own access, he can log in in the upper right corner.

Does the biobankSQAN work on any Internet browser?

For the biobankSQAN to work optimally, the user shall use a browser such as Chrome, Firefox or Safari (avoid using a version prior to 11 for Internet explorer).

How much time do I need to answer all the questions?

The pilot tests indicated that it takes less than two hours to complete the entire questionnaire, if all the required information is available at the time of completing the questionnaire.

Do I have to answer all the questions at once?

The 250 questions can be answered in one or more sessions. Your data are securely stored under your profile. You can access and modify your answers at any time.

Do I need to inform my current practice or the one I would like to introduce?

Your answers should reflect current practices that have already been implemented, not practices that you will implement in the future. At any time, once the new practices are in place, it is possible to update the information in the biobankSQAN. It is recommended to update the information at least once a year. SBP will send a reminder when the user needs it.

Are there different access rights?

The first «creator» of the biobank/infrastructure automatically becomes «administrator» of the structure. He can therefore manage access to his biobank/infrastructure alone. He can invite other users to have the role of editor (read & write) or guest (read-only). He may also propose to assign the role of administrator to another person via the admin tab.

What are the use cases of the biobankSQAN?

When entering the biobankSQAN, the user can choose from the following three actions:

- a. **FIND** a biobank or a biobank infrastructure
This browser allows the user to search for a biobank, a sample type or a biobank infrastructure and services. Several filters can be applied to facilitate the search
- b. **REGISTER** a new biobank or a new biobank infrastructure.

If “**Register a new biobank/new biobank infrastructure**” has been selected, the registration process begins. The user can access a form of 250 questions to complete the registration process.

- c. **VIEW** my biobank(s) or my biobank infrastructure(s)
If “**View my biobank(s)/my biobank infrastructure(s)**” has been selected, the user is directed to the profile of his biobanks/biobank infrastructures, which have already been registered.

Three tabs are available in your biobank / biobank infrastructure profile:

- > **Summary**: this is a summary of the characteristics of the biobank/biobank infrastructure
- > **Dashboard**: this is a graph representing the activity indicators of the structure (only available for biobanks, and currently under development)
- > **Quality indicators**: this is the score of the biobank/biobank infrastructure, according to SBP’s quality criteria.
- > **Admin**: this tab appears if you are the administrator of the selected biobank or biobank infrastructure.

For a simple visitor (accessible to the public), only the summary is visible.

How can I change my data?

There are two options:

- 1) Click on «view my biobank/infrastructure» and select your biobank/infrastructure. Once you are in your summary, you will find a «Edit» button in the right corner. Click on it, you will be redirected to the questionnaire.
- 2) Click on “find a biobank/infrastructure”. In the right corner, you can select «Show only my affiliations», select the biobank/infrastructure of your choice and edit the questionnaire by clicking in the right corner on «Edit».

How can I save my data?

It is not mandatory to complete the questionnaire at one time and there is no imposed order. The user must save the data each time he leaves the page by clicking on the «save» button in the upper right corner. We recommend that the user wait for a «message in a green box» indicating that the data have been correctly recorded. Due to the calculation of the score, it may take a few seconds.

Do I have to answer all the questions?

No, there is no obligation and only few fields are required. Mandatory fields are marked with a red star and the field is framed in red.

What do the different colored symbols in the questionnaire represent?

The following symbols are used throughout the questionnaire, indicating the purpose for which the question will be used or considered:

- R** Questions used for generating the biobank regulation
- V** Questions used for the legal and ethical scoring (governance) corresponding to SBP Vita label
- N** Questions used for the process management scoring, corresponding to SBP Norma label
- O** Questions used for the quality assurance management scoring, corresponding to SBP Optima label

If you are interested in one of these evaluations, you must at least answer the questions with the corresponding symbols.

2. QUALITY INDICATORS

On which criteria is the biobankSQAN quality score based?

The assessment of a biobank or a biobank infrastructure is based on criteria based on ethical and legal requirements and on Good Biobanking Practices.

Criteria based on ethical and legal requirements concerns the Governance scoring and are based on four legal and ethical documents:

- > Human Research Act (HRA), 30 September 2011
- > Human Research Ordinance (HRO), 20 September 2013
- > Declaration of Taipei (WMA), October 2016
- > European Recommendation on research on biological materials of human origin (CM/Rec(2016)6) of 16 May 2016

Criteria based on Good Biobanking Practices concerns the Quality scoring and are based on the following guidelines and standards:

- > OECD guidelines for biological resources centres, 2007
- > IARC guidelines for biobanks, 2017
- > ISBER recommendations for repositories, 2018
- > NF S 96-900 standard for the management of biological resources centres, 2011
- > ISO 9001 standard for the management of quality management system, 2015

How is the evaluation structured?

The questions assessed by the biobankSQAN correspond to 47 mandatory requirements divided into four categories:

- > Governance management
- > Process management
- > Resource management
- > Quality assurance management

Can any type of biobank be evaluated by the biobankSQAN?

While any type of biobanks can evaluate their organization by completing the biobankSQAN, the scoring on «ethical and legal requirements» has been designed to evaluate human biobanks established for research

purposes, regulated by the Swiss Federal Law: the Human Research Act (HRA). Therefore, the scoring for ethical and legal requirements (Vita Label) will not appear for biobanks and biobank infrastructures that are not regulated by the HRA. To support such biobanks, the specific requirements for diagnostic biobanks or animal biobanks are explained anyway in the quality indicators tab.

How is the global score calculated?

The Governance management category assesses the degree of compliance with the law and the respect of biobank ethical considerations. It ensures a good management of regulatory affairs, the presence of a strong governance, a transparent informed consent form, an ethical biobank regulation, a harmonised Material Transfer Agreement (MTA), and the training of staff.

Process and resource management categories assesses the degree of conformity of IT infrastructure, equipment monitoring, and premises control. It ensures a good management of processes, from the consent administration to the shipment of samples, the quality controls, and the validation of methods.

Quality assurance management category assesses the degree of effectiveness of Quality Management System, including efficient documentation management system, non-conformities management, the risk management, and the implementation of appropriate preventive/corrective actions.

Is the evaluation publicly available?

No, the evaluation is confidential and is intended to help biobanks strengthen their practices by identifying areas for improvement. A personal scoring is issued with an explanation of the requirements.

Can I follow the improvement of my biobank/infrastructure over time?

Yes, through an audit trail, profile updates and changes to the biobankSQAN questionnaire can be tracked over time (QMS improvement, biobank activities). You can view it graphically in the quality indicators globally or specifically.

Do I have access to the full evaluation?

To access the full evaluation, you must be a member of SBP. Without membership, you only have access to the «governance» evaluation section. It should be noted that biobank infrastructure does not have a governance evaluation.

3. DATA SECURITY

Are my data securely archived?

The results of the questionnaires will be archived securely at Vital-IT. Upon request, SBP will be able to compile statistics on the data obtained from respondents. The confidentiality of respondents' individual responses will be strictly respected.

Which data are personal?

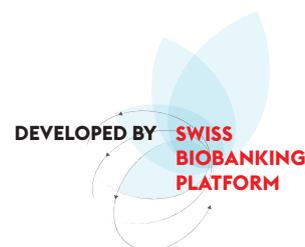
The personal login ensures confidentiality and data protection. The full questionnaire, dashboard and quality indicators (scoring related to Governance issues and Quality issues) are personal. Directory and summary of biobanks or biobank infrastructures are public data that other users can visualize.

Once my biobank is registered, which data are publicly available?

If you register your biobank/biobank infrastructure, you agree to be publicly available into the corresponding directory. Any users can search for your biobank/biobank infrastructure and see your details in the summary.

The summary data includes the following information:

- > Biobank/biobank infrastructure details (address, responsible person contact...)
- > Organisation (type of biobank, purpose, multicentricity, QMS ...)
- > Associated data (inclusion criteria, preanalytical and personal data collected, type and number of collected samples...)
- > Sample access (access policy, sharing criteria and conditions)



If you have any questions, you can contact us at bbsqan@swissbiobanking.ch