Template for data management section of the study protocol

Used system: REDCap

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Please find the text for the data management section of the protocol below in case REDCap is used as the clinical data management system (CDMS). Note that blue & brown text represents instructions by the Ethics Committee and references to laws and guidelines, with at least passages marked yellow to be adapted as applicable:

1. [Clinical Protocol Template for Investigator initiated trials (IIT) with an investigational medicinal product (IMP)](#drugs)
2. [Clinical Protocol Template for ClinO, Chapter 4 “Other Clinical Trials”](#other_clinical_trial)
3. [Template for a Clinical Investigation Plan (CIP) for clinical investigations involving Medical Devices (MD)](#medical_device_MD)
4. [Template for an In vitro diagnostic (IVD) medical device Clinical Performance Study Plan (CPSP)](#in_vitro_diagnostic_MD)
5. [Project plan template: Research involving human subjects with the exception of clinical trials](#non_clinical_trial)

1. Based on swissethics protocol template “Klinische Versuche nach KlinV” (Vorlage in Englisch, Clinical Protocol template for Investigator initiated trials (IIT), V1.1, 24.02.2022)

**[Clinical Protocol Template for Investigator initiated trials (IIT) with an investigational medicinal product (IMP)](https://swissethics.ch/templates/studienprotokollvorlagen)**

**…**

# 12. QUALITY ASSURANCE AND CONTROL

(ICH/E6 6.11, 6.13; SPIRIT #19, 23, 27)

ICH: Quality Control and Quality Assurance Procedures

Describe how quality is assured and controlled. The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and Working Instructions, at all sites in case of multicentre studies. The PI is responsible for proper training of all involved study personnel.

## 12.1 Data handling and record keeping / archiving

(ClinO, Art. 18, 45, 57, 62; ICH/E6 6.13; SPIRIT #19, 27)

ICH: Data Handling and Record Keeping

Describe how data are handled and that all study related documents are archived (essential documents and site documents).

### 12.1.1 Case Report Forms

(ICH/E6 6.4.9)

ICH: The identification of any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered to be source data.

Describe how study data is recorded, e.g. with paper or electronic Case Report Forms (p-/e-CRF). For each enrolled study participant a CRF is maintained. CRFs must be kept current to reflect subject status at each phase during the course of study. Participants must not be identified in the CRF by name or initials and birth date. Appropriate coded identification, e.g. participant number in combination with year of birth, must be used.

It should be described who is authorized for which CRF entries and it must be assured that any authorised person can be identified. If paper CRFs are used, describe how data is entered into an electronic database for analysis (e.g., double data entry).

For each enrolled trial participant, an eCRF will be maintained. All data will be entered in the eCRF at the local site. eCRFs must be kept current to reflect subject status at each phase during the course of the trial. Coded identification for each participant will be as follows: [site-no]-consecutive number\*. The local trial team staff as documented on the database access list are authorized to enter data into the eCRF. The local PI is responsible for proper training and instruction of the trial personnel entering data into the eCRF.

**\**Coding/Pseudonymization (Describe how you plan to code the participants)***

*e.g. 61-1, 61-2, 61-3, … / 93-1, 93-2, 93-3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

*e.g. 1, 2, 3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

### 12.1.2 Specification of source documents

(ICH/E6 6.4.9)

ICH: The identification of any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered to be source data.

Source data must be available at the site to document the existence of the study participants. Source data must include the original documents relating to the study, as well as the medical treatment and medical history of the participant.

Describe what is considered the source documents in the respective study (e.g., demographic data, visit dates, participation in study and Informed Consent Forms, randomisation number, SAEs, AEs and concomitant medication, results of relevant examinations). Identify data that are directly recorded in the CRF, which should also be considered being source data. Also describe where source data are found at the site.

### 12.1.3 Record keeping / archiving

(ICH/E6 6.13)

ICH: Data Handling and Record Keeping

All study data must be archived for a minimum of (*time according to local legislation, see Art. 45 ClinO*) years after study termination or premature termination of the clinical trial.

Specify location of storage.

IMP: Archiving for at least 10 years (in the case of products under Article 2a paragraph 2 TPA that can be implanted, at least 15 years; for clinical trials of transplant products and for clinical trials of blood and blood products, refer to Article 40 paragraph 1 TPA)

## 12.2 Data management

(ICH/E2; SPIRIT #19)

Describe plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). In case electronic data capture systems are used, this chapter shall include a description of procedures for verification, validation and securing the database.

If data are not anonymised after statistical analysis, describe how they will be stored (e.g. coded, not deleted).

Refer to where details of data management procedures can be found, if not in the protocol.

### 12.2.1 Data Management System

Describe what system (also software) is being used and who is responsible and how it is tested before the trial (may include a description of where the system is hosted).

The CRFs used in this trial are implemented electronically using a dedicated electronic data capturing (EDC) system (REDCap, <https://www.project-redcap.org/>). The EDC system is only activated for the trial after successfully passing a formal test procedure. All data entered in the CRFs are stored on a Linux server in a dedicated mySQL database.

Responsibility for hosting the EDC system and the database lies with CTU Bern.

### 12.2.2 Data security, access and back-up

Describe who has access to data, how, where and when – and which backup systems are in place (if applicable).

The server hosting the EDC system and the database is kept in a locked server room. Only the system administrators have direct access to the server and back-up tapes. A role concept with personal passwords (site investigator, statistician, monitor, administrator etc.) regulates access to the system and database for each user as required.

All data entered into the CRFs are transferred to the database using Transport Layer Security (TLS)encryption. Each data point has attributes attached to it identifying the user who entered it with the exact time and date of entry. Retrospective alterations of data in the database are recorded in an audit table (i.e. a record of the changes made). Time/date, action, data field and altered value, as well as the person making the change are recorded (audit trail).

A multi-level back-up system is implemented. Back-ups of the whole system including the database are run internally several times per day and on external tapes once a day. The back-up tapes are stored in a secure place in a different building.

### 12.2.3 Analysis and archiving

Describe how data are extracted and where they are stored, database status recording, duration and place of storage.

At interim (if applicable) and final analyses, data files will be extracted from the database into a statistical software to be analyzed. After database lock, the status of the database is recorded in special archive tables.

The sponsor will keep the Trial Master File, the extracted data, the metadata and interim/final reports for at least 10 years (in case of products under Article 2*a* paragraph 2 TPA that can be implanted, at least 15 years; for clinical trials of transplant products and for clinical trials of blood and blood products, refer to Article 40 paragraph 1 TPA).

### 12.2.4 Electronic and central data validation

Describe how data are validated.

Data is checked by the EDC system for completeness and plausibility. If applicable: Furthermore, selected data points are cross-checked for plausibility with previously entered data for that participant. In addition, central data reviews will be performed on a regular basis to ensure completeness of the data collected and accuracy of the primary outcome data.

Before database lock, the principal investigator will validate the collected data with his signature (this happens via a dedicated form outside the database).

Template for data management section of the study protocol

Used system: REDCap

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2. Based on swissethics protocol template “Klinische Versuche nach KlinV 4. Kapitel” (Vorlage für übrige klinische Versuche, V1.4, 22.11.2022)

**[Clinical Protocol Template for ClinO, Chapter 4 “Other Clinical Trials”](https://swissethics.ch/templates/studienprotokollvorlagen)**

**[…](https://swissethics.ch/templates/studienprotokollvorlagen)**

# 8 Quality CONTROL AND Data protection

## 8.1 Quality measures

Describe measures taken for quality assurance and quality control (e.g. double data entry, study personnel trained on all important study related aspects, planned quality visits or independent data review through an independent Data- or Safety Monitoring Committee or a trial monitor, etc.).

For quality assurance purposes, the sponsor, the Ethics Committee or an independent trial monitor may visit the research sites. Direct access to the source data and all study related files is granted on such occasions. All involved parties keep the participant data strictly confidential.

## 8.2 Data recording and source data

Describe how study data is recorded (e.g. electronic Case Report Form (eCRF) such as secuTrial® or Redcap®). An audit trail is obligatory. For each participant a CRF is maintained. CRFs must not identify participants by their name or birth date, but must provide appropriate coded identification.

Please refer to www.swissethics.ch for an acceptable coding of trial subjects.

For each enrolled trial participant, an eCRF will be maintained. All data will be entered in the eCRF at the local site. eCRFs must be kept current to reflect subject status at each phase during the course of the trial.

The CRFs used in this trial are implemented electronically using a dedicated electronic data capturing (EDC) system (REDCap, <https://www.project-redcap.org/>). The EDC system is only activated for the trial after successfully passing a formal test procedure. All data entered in the CRFs are stored on a Linux server in a dedicated mySQL database.

Responsibility for hosting the EDC system and the database lies with CTU Bern.

List the source data used in the study. Source data is all information in original records, certified copies of original records of clinical findings, questionnaires, observations, or other recorded activities in a clinical investigation. Clearly differentiate between source data collected on study specific documents (e.g. study CRF, study specific forms or questionnaires, etc.), and routinely collected data during the daily practice. Only routinely collected data is part of the participant file, but it may be transferred to the participant’s CRF under the condition that, in this case, the CRF will no longer be considered as source data.

## 8.3 Confidentiality and coding

Trial and participant data will be handled with uttermost discretion and is only accessible to authorised personnel who require the data to fulfil their duties within the scope of the study. On the CRFs and other study specific documents, participants are only identified by a unique participant number.

Describe who stores the participant identification list, how the data is protected from unauthorised or accidental disclosure, alteration, deletion, copying and theft. Describe the processes in place to ensure traceability (audit trail; ClinO, Art. 18). Mention password access and safety back-ups on storage media to prevent misuse.

In multicenter studies, the process can be described in an annex to cover all sites’ specificities.

Describe if uncoded or coded genetic or only non-genetic data are used.

The server hosting the EDC system and the database is kept in a locked server room. Only the system administrators have direct access to the server and back-up tapes. A role concept with personal passwords (site investigator, statistician, monitor, administrator etc.) regulates access to the system and database for each user as required. The local trial team staff as documented on the database access list are authorized to enter data into the eCRF. The local PI is responsible for proper training and instruction of the trial personnel entering data into the eCRF.

Coded identification for each participant will be as follows: [site-no]-consecutive number\*.

**\**Coding/Pseudonymization (Describe how you plan to code the participants)***

*e.g. 61-1, 61-2, 61-3, … / 93-1, 93-2, 93-3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

*e.g. 1, 2, 3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

All data entered into the CRFs are transferred to the database using Transport Layer Security (TLS)encryption. Each data point has attributes attached to it identifying the user who entered it with the exact time and date of entry. Retrospective alterations of data in the database are recorded in an audit table (i.e. a record of the changes made). Time/date, action, data field and altered value, as well as the person making the change are recorded (audit trail).

A multi-level back-up system is implemented. Back-ups of the whole system including the database are run internally several times per day and on external tapes once a day. The back-up tapes are stored in a secure place in a different building.

If applicable:

Biological material in this study is not identified by participant name but by a unique participant number. Biological material is appropriately stored in a restricted area only accessible to the authorised personnel.

Describe the measures taken to prevent unauthorised or accidental disclosure, alteration, destruction and theft of biological material.

Describe the processes in place which are essential to ensure traceability.

Describe appropriate storage and technical requirements to be met (e.g. the maintenance of a cooling system).

If biological material or data collected during the study are to be shipped outside the study site include the receiver address, the responsible person to whom the materials or data are sent, the purpose of shipment, if applicable, temperature control and how participant confidentiality is guaranteed. Biological material or genetic data can only be sent abroad in the scope of the research study, if the participant involved has given his or her consent to do so upon having been sufficiently informed. Non-genetic health-related personal data can be sent abroad for research if the requirements of the Swiss data protection law are met (FADP, Art. 6).

Please describe if applicable

## 8.4 Retention and destruction of study data and biological material

All study data are archived for 10 years (time according to local legislation; for other clinical trials usually 10 years) after study termination or premature termination of the study.

Specify time-period and location of archiving of the study data and the biological material.

If applicable, describe how biological materials will be destroyed after termination of the research study and how this will be documented.

If it is planned to further use the study data or the biological materials (e.g. for a Biobank), describe the planned use and the duration (HRA, Chapter 4).

At interim (if applicable) and final analyses, data files will be extracted from the database into a statistical software to be analyzed. After database lock, the status of the database is recorded in special archive tables.

The sponsor will keep the Trial Master File, the extracted data, the meta-data and interim/final reports for at least 10 years.

3. Based on swissethics protocol template “Klinische Versuche mit Medizinprodukten nach KlinV-Mep” (Klinischer Prüfplan für klinische Prüfungen mit Medizinprodukten, template Clinical Investigation Plan (CIP) for Investigator initiated trials (IIT), V2.0, 30.12.2022)

**[Template for a Clinical Investigation Plan (CIP) for clinical investigations involving Medical Devices (MD)](https://swissethics.ch/templates/studienprotokollvorlagen)**

**…**

# QUALITY ASSURANCE AND CONTROL

Describe how quality is assured and controlled. The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and Working Instructions, at all sites in case of multicentric investigations. Indicate the software used. The PI is responsible for proper training of all involved investigation personnel.

## 12.1 Data handling and record keeping / archiving

Describe how data are handled and that all investigation related documents are archived. A list of the essential clinical investigation documents which should be maintained in the investigation site and sponsor file is given in ISO14155 Annex E.

### 12.1.1 Case Report Forms

Describe how the investigation data is recorded, e.g. with paper or electronic Case Report Forms (p-/e-CRF). A CRF is maintained for each enrolled subject. CRFs must be kept current to reflect subject status at each phase during the course of the investigation. Subjects must not be identified in the CRF by name or initials and birth date. Describe the coding used for the investigation, e.g. subject number in combination with year of birth (see the guidance document published on swissethics.ch “coding of trial subject accepted by swissethics and secure storage of subject identification list” <https://swissethics.ch/assets/Themen/akzeptierte_verschluesselung_e.pdf>)

If paper-CRFs are used, describe how data is entered into an electronic database for analysis (e.g., double data entry).

Note: The person(s) authorized by the PI to enter the data in the CRF must be listed on the delegation log.

For each enrolled participant, an eCRF will be maintained. All data will be entered in the eCRF at the local site. eCRFs must be kept current to reflect subject status at each phase during the course of the trial. Coded identification for each participant will be as follows: [site-no]-consecutive number\*. The local trial team staff as documented on the database access list are authorized to enter data into the eCRF. The local PI is responsible for proper training and instruction of the trial personnel entering data into the eCRF.

**\**Coding/Pseudonymization (Describe how you plan to code the participants)***

*e.g. 61-1, 61-2, 61-3, … / 93-1, 93-2, 93-3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

*e.g. 1, 2, 3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

### 12.1.2 Specification of source data and source documents

Source data should be available at the site to document the existence of the investigation subjects. Source data must include the original documents relating to the investigation, as well as the medical treatment and medical history of the subject. In case of electronic source data (e.g. from apps or from automatic recording devices), describe how the data is handled, transferred, stored and accessed by the PI and authorised staff.

Describe what are considered the source documents in the investigation (specify what is the source document for each data collected in the CRF, e.g., demographic data, visit dates, participation in investigation and ICFs, randomisation codes, SAEs, SADEs, USADEs, and concomitant medication, results of relevant examinations). Identify data that are directly recorded in the CRF, which should also be considered source data. Also describe where original source data are kept at the site. You can also refer to a separate document in the appendices (‘source data description and source data location’).

### 12.1.3 Archiving of essential clinical investigation documents

All the documents of the investigation must be archived for a minimum of (*time according to local legislation*) years after regular or premature termination of the investigation.

Describe Sponsor (Art. 40 Abs 1 ClinO-MD) and PI (Art. 40 Abs 2 ClinO-MD) responsibilities. Specify location and length of storage. Archiving for 10 years, in the case of an implantable device 15 years in Switzerland (Art. 40 ClinO-MD).

## 12.2 Data management

Describe plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). In case electronic data capture systems are used, this chapter shall include a description of procedures for verification, validation and securing the database.

If data will not be anonymised after the statistical analysis, describe in which form they will be stored (e.g. coded). If the data is anonymised, describe how this is done.

Reference to where details of data management procedures can be found, if not in the CIP.

### 12.2.1 Data Management System

Describe what system (including cloud services and software) is being used and who is responsible and how it is tested before the investigation begins (may include a description of where the system is hosted).

The CRFs used in this trial are implemented electronically using a dedicated electronic data capturing (EDC) system (REDCap, <https://www.project-redcap.org/>). The EDC system is only activated for the trial after successfully passing a formal test procedure. All data entered in the CRFs are stored on a Linux server in a dedicated mySQL database.

Responsibility for hosting the EDC system and the database lies with CTU Bern.

### 12.2.2 Data security, access and back-up

Describe who has access to data, how, where and when – and which backup systems are in place (if applicable).

The server hosting the EDC system and the database is kept in a locked server-room. Only the system administrators have direct access to the server and back-up tapes. A role concept with personal passwords (site investigator, statistician, monitor, administrator etc.) regulates access to the system and database for each user as required.

All data entered into the CRFs are transferred to the database using Transport Layer Security (TLS)encryption. Each data point has attributes attached to it identifying the user who entered it with the exact time and date of entry. Retrospective alterations of data in the database are recorded in an audit table (i.e. a record of the changes made). Time/date, action, data field and altered value, as well as the person making the change are recorded (audit trail).

A multi-level back-up system is implemented. Back-ups of the whole system including the database are run internally several times per day and on external tapes once a day. The back-up tapes are stored in a secure place in a different building.

### 12.2.3 Analysis and archiving

Describe how data are extracted and where they are stored, database status recording, duration and place of storage.

At interim (if applicable) and final analyses, data files will be extracted from the database into a statistical software to be analyzed. After database lock, the status of the database is recorded in special archive tables.

The sponsor will keep the Trial Master File, the extracted data, the metadata and interim/final reports for at least 10 years (15 in case of implantable devices).

### 12.2.4 Electronic and central data validation

Describe how data are validated.

Data is checked by the EDC system for completeness and plausibility. If applicable: Furthermore, selected data points are cross-checked for plausibility with previously entered data for that participant. In addition, central data reviews will be performed on a regular basis to ensure completeness of the data collected and accuracy of the primary outcome data.

Before database lock, the principal investigator will validate the collected data with his signature (this happens via a dedicated form outside the database).

4. Based on swissethics protocol template “Klinische Versuche mit Medizinprodukten nach KlinV-Mep” (Klinischer Leistungsstudienplan für IVD Leistungstudien, template Clinical Performance Study Plan (CPSP) for Investigator initiated trials (IIT), V1.0, 29.06.2022)

**[Template for an In vitro diagnostic (IVD) medical device Clinical Performance Study Plan (CPSP)](https://swissethics.ch/templates/studienprotokollvorlagen)**

**[…](https://swissethics.ch/templates/studienprotokollvorlagen)**

# QUALITY ASSURANCE AND CONTROL

Describe how quality is assured and controlled. The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and Working Instructions, at all study sites in case of multicentric investigations. Indicate the software used.

The PI is responsible that all people participating in the study are properly trained.

The PI ensures that experience and scientific or clinical knowledge is guaranteed and documented for all members of the study team at the study site in order to adequately conduct the performance study, including specific training, as applicable to each role. All members of the study team receive specific training on the performance study and such training is documented in the Study Site File.

## 12.1 Study documentation

Note: Due to the specific nature of IVD medical devices, in order to demonstrate good clinical performance study practices, distinct and separate sets of documentation to that required for other medical devices (such as that described in ISO 14155) are required.

ISO 20916 Annex H describes the type of documentation that should be compiled and maintained in the Investigator’s file and Sponsor’s file in order to demonstrate good clinical performance study practices. The type of documentation differs according to the type of performance study.

* studies using left-over / archived specimens or studies where specimens are primarily collected for the purposes of the study and for which the collection procedure poses no additional risks to the subject.
* interventional studies or studies where the specimens are primarily collected for the purposes of the study and for which the collection procedure poses additional risks to the subject.

Describe how the documentation is handled throughout the course of the performance study and at study termination.

For any of the documents, source documents should be maintained throughout the duration of the performance study.

### 12.1.1 Source data and source documents

Note: Source data is all information in original records, certified copies of original records of clinical findings, observations, device results or other activities in the performance study, necessary for the traceability and evaluation of the clinical performance study (Art 3.45, ISO 20916).

Note: A source document is a printed or electronic document or other media containing source data (example: Hospital records, laboratory notes, test results, patient’s surveys, device accountability records, photographic evidence, records kept at the study site, at the laboratories and at the medico-technical departments involved in the clinical performance study (Art. 3.46, ISO 20916)).

Describe precisely what are considered the source documents in the performance study and specify what the source document for each data collected in the CRF is, e.g., Hospital records, laboratory notes, test results, patient’s surveys, device accountability records, photographic evidence, records kept at the study site, at the laboratories and at the medico-technical departments involved in the clinical performance study.

In case of electronic source data (e.g., from apps or from automatic recording devices), describe how the data is handled, transferred, stored and accessed by the PI and authorised staff.

Identify data that are directly recorded in the CRF, which is also considered source data.

Indicate where source data are kept at the study site.

You can also refer to a separate document (‘source data description and source data location’) in chapter 18.

### 12.1.2 Case Report Forms

Case report forms (CRFs) shall be developed to capture the data for each enrolled subject/specimen as required by the CPSP. The CRFs shall include information on each subject/specimen at commencement, and during the course of the clinical performance study, use of the IVD device and any other relevant information.

Describe how the study data is recorded, e.g., with paper or electronic CRF (p-/e-CRF).

If a paper-CRF is used, describe how data is entered into an electronic database for analysis (e.g., double data entry).

No subject’s personally identifiable information shall be included within the CRF.

Describe the coding used for the performance study, e.g., subject number in combination with year of birth (see the guidance document published on swissethics.ch “coding of trial subject accepted by swissethics and secure storage of subject identification list”).

Note: The person(s) authorized by the PI to enter the data in the CRF must be listed on the delegation log.

If applicable, describe which study data is not recorded in the CRF but recorded by other means (e.g., instrument printouts, etc.).

When it is necessary to amend the CPSP, the Sponsor shall review the CRFs to determine if an amendment of these forms is also necessary.

The CRF is annexed to the CPSP chapter 18.

For each enrolled participant, an eCRF will be maintained. All data will be entered in the eCRF at the local site. eCRFs must be kept current to reflect subject status at each phase during the course of the trial. Coded identification for each participant will be as follows: [site-no]-consecutive number\*. The local trial team staff as documented on the database access list are authorized to enter data into the eCRF. The local PI is responsible for proper training and instruction of the trial personnel entering data into the eCRF.

**\**Coding/Pseudonymization (Describe how you plan to code the participants)***

*e.g. 61-1, 61-2, 61-3, … / 93-1, 93-2, 93-3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

*e.g. 1, 2, 3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

### 12.1.3 Storage of biological material and related health data

In the event the subjects’ personal data of the performance study is stored in a data-registry: add here that the coded data of the subjects who consented for the further use of their data (independently of the study specific consent) will be stored in a registry for an undetermined length of time, and the data could be re-used for other research projects (provided previous approval by the CEC).

If applicable, describe for how long and where the specimens and personal data are stored, or state that specimens are destroyed and data anonymised after the end of the storage period. You can refer to chapter 12.3. In any case, the information provided here must match the information given in chapters 9.2.4 and 12.3.

In the event the specimens are stored in a Biobank, confirm that coded specimens and associated personal data are stored only if the subjects’ consent for further use has been obtained. This consent is given (or withheld) independently of the participation in the investigation (Art. 17. ClinO).

### 12.1.4 Archiving of essential clinical investigation documents

All the documents of the performance study must be archived for a minimum of 10 years after regular or premature termination of the performance study.

Describe Sponsor (Art. 40 Abs 1 ClinO-MD) and PI (Art. 40 Abs 2 ClinO-MD) responsibilities.

Indicate location and process for archiving, secure access, etc.

You can refer to Sponsor / study site written Standard Operating Procedures.

## 12.3 Data management

Give procedures used for data review, database cleaning, and issuing and resolving data queries.

Give Procedures for verification, validation, and securing of electronic clinical data systems, when applicable.

Give procedures for data retention.

Describe in which form the data is retained after the termination of the performance study (e.g., retained in coded form). If the data is anonymised, describe the procedure of anonymization of the data.

Specify data retention period.

Specify other aspects of quality assurance, as appropriate.

When electronic databases or remote electronic data systems are used, implement written procedures to:

1. establish and document requirements for the electronic data system to receive, transfer and process data – information/data transferred to the Sponsor shall be without personal individual identifiers,
2. verify and validate that the requirements for the electronic data system can be consistently met,
3. ensure traceability, completeness, reliability, consistency and logic of data entered,
4. ensure accuracy of reports,
5. ensure that data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail),
6. maintain a security system that prevents unauthorized access to the data, both internally and externally,
7. maintain a list of individuals who have access to the electronic data system as well as the dates of access and privileges granted to each user,
8. ensure that all completed documents are signed by the Principal Investigator or authorized designee,
9. maintain adequate backup, retention and retrievability of the data, and
10. provide documented training of users on proper use of the system.

It is possible to provide a detailed plan for data management separate from the CPSP. The plan for data management must be annexed to the CPSP chapter 18 (Annex XIII, art. 2.3.3, IVDR).

The CRFs used in this trial are implemented electronically using a dedicated electronic data capturing (EDC) system (REDCap, <https://www.project-redcap.org/>). The EDC system is only activated for the trial after successfully passing a formal test procedure. All data entered in the CRFs are stored on a Linux server in a dedicated mySQL database.

Responsibility for hosting the EDC system and the database lies with CTU Bern.

The server hosting the EDC system and the database is kept in a locked server-room. Only the system administrators have direct access to the server and back-up tapes. A role concept with personal passwords (site investigator, statistician, monitor, administrator etc.) regulates access to the system and database for each user as required.

All data entered into the CRFs are transferred to the database using Transport Layer Security (TLS)encryption. Each data point has attributes attached to it identifying the user who entered it with the exact time and date of entry. Retrospective alterations of data in the database are recorded in an audit table (i.e. a record of the changes made). Time/date, action, data field and altered value, as well as the person making the change are recorded (audit trail).

A multi-level back-up system is implemented. Back-ups of the whole system including the database are run internally several times per day and on external tapes once a day. The back-up tapes are stored in a secure place in a different building.

At interim (if applicable) and final analyses, data files will be extracted from the database into a statistical software to be analyzed. After database lock, the status of the database is recorded in special archive tables.

The sponsor will keep the Trial Master File, the extracted data, the metadata and interim/final reports for at least 10 years.

Data is checked by the EDC system for completeness and plausibility. If applicable: Furthermore, selected data points are cross-checked for plausibility with previously entered data for that participant. In addition, central data reviews will be performed on a regular basis to ensure completeness of the data collected and accuracy of the primary outcome data.

Before database lock, the principal investigator will validate the collected data with his signature (this happens via a dedicated form outside the database). .

# Confidentiality, Data Protection

The Sponsor and the PI affirm and uphold the principle of the subject’s right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the subjects shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. Individual subject medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited.

Specify here how the subjects’ confidentiality is guaranteed (for example: the assignment to each subject of a unique subject identification number ensures subject confidentiality).

Describe how the unique identification number is generated.

For data verification purposes (monitoring) the PI or institution provide direct access to source data during and after the performance study to the Sponsor’s personnel, or to other personnel designated and authorized by the Sponsor.

The PI or institution provide direct access to source data during and after the performance study for Sponsor audits, CEC review and RA inspections.

Refer to chapter 12.1.1 for description of source data and source documents.

Refer to chapter 14 for publication and communication policy of the results of the study.

5. Based on swissethics protocol template “Forschungsprojekte mit Personen” (HFV Kapitel 2, Nicht-klinische Versuche, Project plan template: Research involving human subjects with the exception of clinical trials, V2.5, 05.02.2024)

**[Project plan template:](https://swissethics.ch/templates/studienprotokollvorlagen)**

**[Research involving human subjects with the exception of clinical trials](https://swissethics.ch/templates/studienprotokollvorlagen)**

**[…](https://swissethics.ch/templates/studienprotokollvorlagen)**

# 7 Quality CONTROL AND Data protection

## 7.1 Quality measures

Describe measures taken for quality assurance and quality control: e.g. double data entry, project personnel trained on all important project related aspects, planned quality visits or independent data review, etc. For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

## 7.2 Data recording and source data

Describe how project data is recorded, e.g. with paper Case Report Forms (CRF) or an electronic Case Report Form (eCRF) such as secuTrial® or Redcap®. Efforts should be made not to use any software, like Microsoft Office software’s (e.g. Excel), that do not have an audit trail and do not guarantee data privacy and data reliability, as changes can be made in an uncontrolled manner. If a software without audit trail is used nonetheless, describe how data quality and data traceability throughout the research project is guaranteed.

If Microsoft Excel is used, a system must be put in place to improve data privacy and data reliability. That is with a protected cloud system that combines controlled access and user rights with tracking of changes at file / document level, and using the feature “Track changes” (see instruction for use of this functionality [here](https://support.microsoft.com/en-us/office/track-changes-in-a-shared-workbook-22aea671-cac7-4fa3-845d-eeb23725bd15). Training videos on how to use this feature are available on the YouTube channel, e.g.: <https://www.youtube.com/watch?v=Itz8v_z7ha4>).

If paper CRFs are used, describe how data is transferred to an electronic database for later analysis. An electronic database is recommended.
List the source data used in the project. Source data is all information in original records, certified copies of original records of clinical findings, questionnaires, observations, or other recorded activities in a clinical investigation. Clearly differentiate between source data collected on project specific documents (e.g. project CRF, project specific forms or questionnaires, not part of participant file), and routinely collected data during the daily practice. The routinely collected data is part of the participant file but can also be transferred to the participant CRF.

The CRFs used in this trial are implemented electronically using a dedicated electronic data capturing (EDC) system (REDCap, <https://www.project-redcap.org/>). The EDC system is only activated for the trial after successfully passing a formal test procedure. All data entered in the CRFs are stored on a Linux server in a dedicated mySQL database.

Responsibility for hosting the EDC system and the database lies with CTU Bern.

## 7.3 Confidentiality and coding

**Project data** will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number.

Describe if uncoded or coded (genetic or non-genetic) data is used. Describe who stores the participant identification list, how the data is protected from unauthorized or accidental disclosure, from alteration, deletion, copying and theft. Describe the processes in place, which are essential to ensure traceability (audit trail). Mention password access and safety back-ups on storage media to prevent misuse. If applicable for multicentric trials: the process can be described in an annex to cover all sites’ specificities.

The server hosting the EDC system and the database Is kept in a locked server-room. Only the system administrators have direct access to the server and back-up tapes. A role concept with personal passwords (site investigator, statistician, monitor, administrator etc.) regulates access to the system and database for each user as required. The local trial team staff as documented on the database access list are authorized to enter data into the eCRF. The local PI is responsible for proper training and instruction of the trial personnel entering data into the eCRF.

Coded identification for each participant will be as follow: [site-no]-consecutive number\*.

**\**Coding/Pseudonymization (Describe how you plan to code the participants)***

*e.g. 61-1, 61-2, 61-3, … / 93-1, 93-2, 93-3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

*e.g. 1, 2, 3, …*

Study-related data of the participants will be collected in a coded manner. The names of the participants will not be disclosed. A code (unique and consecutively numbered per site) will be attributed to each participant registered.

All data entered into the CRFs are transferred to the database using Transport Layer Security (TLS)encryption. Each data point has attributes attached to it identifying the user who entered it with the exact time and date of entry. Retrospective alterations of data in the database are recorded in an audit table (i.e. a record of the changes made). Time/date, action, data field and altered value, as well as the person making the change are recorded (audit trail).

A multi-level back-up system is implemented. Back-ups of the whole system including the database are run internally several times per day and on external tapes once a day. The back-up tapes are stored in a secure place in a different building.

If applicable: **Biological material** in this project is not identified by participant name but by a unique participant number. Biological material is appropriately stored in a restricted area only accessible to authorized personnel. Describe the measures taken to prevent unauthorized or accidental disclosure and to prevent the biological material to be altered, destroyed or stolen. Describe the processes in place, which are essential to ensure traceability of the biological material.

Describe appropriate storage and technical requirements to be met, i.e. maintenance of the cooling system. If biological material or data collected during the research project are to be shipped outside the research site, include: receiver address, responsible person to whom materials or data are sent, purpose of shipment, temperature control if applicable and how participant confidentiality is guaranteed. Biological material or genetic data can only be sent abroad in the scope of the research project, if the participant involved has given his/her consent to do so upon having been sufficiently informed (HRO, Section 2).]

Please describe if applicable

## 7.4 Retention and destruction of project data and biological material

Specify time-period and location of archiving of the project data and the biological material; e.g. health related data are stored for x (for example 10) years after publication of the research project (in clinical trials the data is archived for at least 10 years after project end). If applicable, describe how biological materials will be destroyed after termination of the research project and how this will be documented.

If it is planned to further use the data and/or the biological materials, such as for biobanking, describe the planned use and the duration.

At interim (if applicable) and final analyses, data files will be extracted from the database into a statistical software to be analyzed. After database lock, the status of the database is recorded in special archive tables.

The sponsor will keep the Trial Master File, the extracted data, the meta-data and interim/final reports for at least 10 years.

Template for data management section of the study protocol

Used system: REDCap

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6. Based on swissethics protocol template “Weiterverwendung mit Einwilligung (HFV Kapitel 3)” or “Weiterverwendung ohne Einwilligung (HFV Kapitel 3)”

**[Vorlage für die Einreichung eines Projekts «Weiterverwendung mit Einwilligung (HFV Kapitel 3)» / «Weiterverwendung ohne Einwilligung (HFV Kapitel 3)» gemäss HFG/HFV](https://swissethics.ch/templates/studienprotokollvorlagen)**

**Please refer to the examples provided in the template.**