

# **Sponsor Site File template**

Clinical Investigations with Medical Devices

**Detta dokument är framtaget och kvalitetssäkrat av Kliniska Studier Sverige.**

Vi utvecklar och erbjuder stöd för kliniska studier i hälso- och sjukvården.

Stödet vi erbjuder ger goda förutsättningar för kliniska studier av hög kvalitet.

## About the document

Sponsor Site File template was first published 2022-01-17. This is version 1.0.

The Sponsor File is the sponsor’s folder and contains all essential documents for the clinical investigation. The Sponsor File template may need to be adapted to the current clinical investigation.

The table of contents is applicable to clinical investigations on medical devices only, it is not applicable to clinical investigations on combinations of medical devices and medicinal products. For combination trials, this table of contents can be combined with the table of contents created for clinical trials on medicinal products by the QA working group within the Clinical Studies Sweden node collaboration.

Several documents should be available both in the Investigation Site File and in the Sponsor File. A common recommendation is that the document is saved in original where it was created.

It is the sponsor’s responsibility to:

* keep the Sponsor File complete and updated during the ongoing clinical investigation.
* store the Sponsor File in a safe way while the clinical investigation is ongoing and during the retention time.
* ensure that archiving occurs in accordance with current legislation.
* provide a reference if any document is stored elsewhere than in the Sponsor File.

For more information on the contents of the Sponsor File please refer to Annex E of SS-EN ISO 14155:2020.

| **Index** | | **Contents** | **Comments**  *Help text (in Italics) column to be removed when using the index* |
| --- | --- | --- | --- |
|  | **Clinical investigation team** | * List of investigation sites (with names and addresses) * Contact information for monitor/s/monitoring function * Address and telephone list for important parties | *Contact information for important parties such as the clinical investigation management, site personnel, external parties e.g., laboratories.* |
|  | **Signed Clinical Investigation Plan (CIP) and amendment(s)** | * Approved, signed CIP incl. attachments * Approved, signed amendment(s) * Signature pages from all sites * Superseded versions[[1]](#footnote-1)1 | *The signature page should include signatures from the sponsor and coordinating investigator (for multicenter trials) and/or principal investigator(s).* |
|  | **Case Report Form (CRF/eCRF)** | * CRF/printed version of eCRF (template) * CRF access log * CRF completion guidelines/Data handling instructions, if applicable * Superseded versions1 * Annotated CRF * Complete CRF data; paper (original) or electronic, signed and dated by the principal investigator or his/her authorized designee(s) * Data Clarification Form (DCF)/Data Query Form (DQF); paper (original) or electronic | *If subject diaries and/or questionnaires etc. are not included in the main CRF these should be included here (template and completed forms).* |
|  | **Data Management** | * Data Management Plan * Clean File Form * Database lock * Critical Error Form (if relevant)\* | \*Critical Error Form. *To be used if the database is locked but a critical error that can affect analyses is discovered, and the database thus needs to be unlocked. Document the reason why the database was unlocked and actions required before the database was re-locked.* |
|  | **Subject Information and Informed Consent Form** | * Current Subject Information and Informed Consent Form. Original and translated version(s) if relevant * Other written information provided to participants (e.g., advertisements, diaries, Patient ID card/emergency card, questionnaires), including translations if relevant. * Superseded versions if changes have been made1 | *Signed consent shall only be stored at the site.* |
|  | **Swedish Medical Products Agency (Läkemedelsverket, LV)**  **and**  **Swedish Ethical Review Authority (Etikprövnings-myndigheten, EPM)** | * Complete Notification/Application, signed. Incl. attachments[[2]](#footnote-2)2 * Amendment, signed. Incl. attachments2 * Approvals, dated (initial and for any amendments). * Notification of clinical investigation close-out * Related correspondence | *Note that types of notification/application and acknowledgement of receipt/approval/ confirmation of valid application depends on the type of investigation.*  *Ethical approval must include participants at meeting for approval.* |
|  | **Other applications, notifications and registrations** | * Biobank agreement incl. application, application(s) for amendment, approval(s). MTAs[[3]](#footnote-3)3 and correspondence * Notification/registration in accordance with GDPR. Incl. application, application(s) for amendment and correspondence * Registration to public database |  |
|  | **Contracts/agreements and financial aspects** | Financial contracts/agreements, such as   * Sponsor and CRO * Sponsor and site/Investigator * CRO and site/Investigator * Investigator/institution and authority (if applicable) * Laboratory agreements * Monitoring agreement * Other agreements * Data Processing Agreement * Budget and financial accounting/documentation | *Financial agreements can be kept separate from the sponsor file. If so, note the location.* |
|  | **Site personnel; delegations and CVs** | * Updated signature and delegation list, signed. Copies from all sites * Training log/records. Copies from all sites * CV for responsible Investigators, sub-Investigators as well as other personnel who are delegated tasks in the investigation with documentation regarding GCP training\* (signed, dated) * CV for monitor * CV for other relevant personal if applicable, such as laboratory staff and radiology personnel * Declaration of conflict of interest from principal investigators and investigators, including updates (if applicable) | \**ISO14155:2020 certificate or ICH-GCP certificate and documented ISO14155:2020-training.* |
|  | **Investigational Device, device description** | * Current Investigator’s Brochure (IB)[[4]](#footnote-4)4 or instructions for use\*, for all included investigational devices * IB superseded versions1 * IB shipping receipt for all sites * Safety updates | *Separate rows can be used if there are several investigational devices.*  *\* if investigational device is CE marked and used as intended by manufacturer* |
|  | **Investigational Device (and comparator, if applicable), handling** | * Labeling of Investigational Device * Shipping documents (to all sites) * Ordering instructions, if applicable * Device accountability log for sponsor * Temperature log, template, if applicable * Related correspondence   **At clinical investigation end**   * Investigational device log from site(s) (inventory log and / or device accountability log per site or per subject).\* * Disposal form, template as well as completed forms from participating centers * Documentation (including shipping records) of investigational device return or disposal\*\*, where applicable. | *\* Template/-s and completed documents from participating sites at the end of the clinical investigation*  *\*\* Should include documentation of proper disposal of biohazardous materials or other materials that require special disposal (if applicable)* |
|  | **Randomization and decoding** | * Randomization procedure * Randomization list (if relevant) * Instructions for emergency decoding (if relevant) * List of code-break envelopes (if relevant) | *Documentation of code-breaking is done at the end of the investigation, including which envelopes were used and which were not used (if applicable).* |
|  | **Laboratory information** | * List of laboratories * List of reference ranges from local labs at all sites and external labs (if relevant)\* * Method descriptions for non-accredited analyses * Instructions for sampling, handling, and storage * Temperature log from all sites (copy) * Certification, accreditation or established quality control or external quality assessment * Other validation of the laboratory, if relevant to the clinical investigation * Identification and qualification (CV) of the laboratory director, if relevant to the clinical investigation\*\* | *\*Local, e.g., for sites routine samples.*  *External for other contracted labs*.  *\*\*Identification and qualification of the laboratory director are only needed for non-accredited analyses performed by specialists/research laboratories.*  *Including updates* |
|  | **Equipment relevant to the clinical investigation** | * Instructions * Referrals/forms * Validation of equipment * Certificates * Equipment maintenance and calibration documentation, including updates (if applicable) | *Including updates* |
|  | **Screening log** | * Screening log template * Copy of screening log from all sites\* | *\* Note screening log must not contain full name or personal identity number* |
|  | **Monitoring** | * Current monitoring plan, as well as superseded versions * Correspondence |  |
|  | **Monitoring reports** | * Investigation site selection report(s) * Documentation from planning meeting, Investigator meeting(s) * Site initiation visit report for all sites * Follow up letter from site initiation (all sites), and correspondence with all sites * Monitoring reports from all sites * Follow up letter to all sites from monitoring visits (if applicable) * Report from close-out meeting from all sites, as well as national close-out report * Related correspondence |  |
|  | **Reporting of adverse events, adverse device effects and device deficiencies (AE, SAE, ADE, SADE, USADE and DD)** | * Instructions for reporting, incl. reporting forms * Reported AE/ADE/SAE/SADE/DD for all sites * Reported USADEs in the clinical investigation * Opinion from DSMB (if applicable) * Reports of SAEs/DDs by sponsor to regulatory authorities * Reports by sponsor to investigators of SAEs occurring at other sites | *Reporting forms can also be included in the CRF (section 3).*  *Reports of AE from principal investigator or sponsor to EC may be required in some countries.* |
|  | **Deviations** | * Note to files for all sites * GCP deviations and clarifications from all sites * CIP deviations and clarifications from all sites |  |
|  | **Correspondence** | * Relevant communication for the clinical investigation (emails, letters, phone contact reports, etc.) * Reports from Investigator meetings * Newsletter |  |
|  | **Reports** | * Clinical investigation report(s)\* * Statistical analyses | \**one or more to comply with MDR and ISO14155:2020* |
|  | **Archiving** | * Archive list including location |  |
|  | **Other** | * Insurance(s) * Shipping records for clinical investigation-related documents and materials * Audit certificate/inspection report (if applicable) |  |

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1. 1 Superseded versions to be stored here or in another folder. If another folder is used, there might be a reference in the index to where superseded documents are stored. Mark superseded documents “Inactive” to avoid accidental use. [↑](#footnote-ref-1)
2. 2Should be version controlled [↑](#footnote-ref-2)
3. 3 Material Transfer Agreement [↑](#footnote-ref-3)
4. 4Investigator’s Brochure can be stored separately from the Sponsor File, e.g., electronically, in which case the location should be documented [↑](#footnote-ref-4)