

# Site Initiation Visit report

Coordinated monitoring of investigator-initiated multicenter studies

**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

Site Initiation Visit report was first published 2023-03-14. This is version 1.0.

The first instruction pages should not be included in the report and must be removed when using the template.

* *Text in red and italics is an instruction that provides information about what can or should be described under each section. The text must be deleted in the final document.*
* Text in green is mandatory text that must be replaced with study-specific information and marked black in the final document.
* Text in black is a suggested text that can be used or adapted as needed.
* Instructions like; ***must be customized according to the current study*** are seen in sections 7 and 8 and here it is important for the coordinating monitor to adjust the template after the study, so that final report templates are identical for all monitors in the study.
* Rows/sections can be removed by the coordinating monitor to further adjust the template to a specific protocol/study.
* Yes/No/NA answers: A No should always be followed by a brief comment and/or a detailed description.

When answering NA, an assessment if a short comment can be of help for the receiver of the report to understand the report is needed.

* NA can be checked if an activity is not applicable on the current visit or if there was no time to do the activity.
* A follow-up report (enter new information to an existing report and re-sign) can occur at initiation and close-out as follow-up of actions to document that the site is ready for start and close-out respectively.

According to ICH GCP E6: 5.18.6, the monitoring visit report must be a written report to the sponsor. This includes a summary of what the monitor reviewed, key findings, deviations and deficiencies noted, as well as conclusions and actions taken or to be taken to ensure compliance with study protocol, ICH GCP, laws and regulations. Conclusions from the monitoring visit should be documented in sufficient detail to verify compliance with the established monitoring plan. If central monitoring is carried out by any party, this must also be reported to the sponsor. Central monitoring can be independent of on-site visits and other templates for reporting can be used.

This template is adapted for coordinated monitoring of intervention studies with drugs and has its origins in the principles of ICH GCP. If the template is to be used for other types of studies, parts can be removed/added or adapted. Note that the template does not directly cover reporting requirements for medical device clinical trials according to ISO14155.

Review and follow-up of reports is the sponsor's responsibility and must be documented to ensure sponsor oversight (see Checklist sponsor), and if necessary, updates to the study's risk analysis and monitoring plan are made. For coordinated monitoring projects, the coordinating monitor must have the opportunity to take part of reports and updates.

According to ICH GCP E6 (R2) paragraph 8.0, the following reports must be filed:

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| **Document**  | **Purpose** | **Investigator site file** | **Sponsor file** **Trial master file** |
| Site Initiation Visit report | To document that study procedures have been reviewed with the trial site and to document that they are ready to start the study.  | X | X |
| Monitoring visit report | For documentation of visits and findings during the study. |  | X |
| Close-out visit report | To document that all activities required to close the study are completed and copies of essential documents are in the appropriate file (Investigator Site File and/or Sponsor File).  |  | X |

## Site Initiation Visit report

*Red italic text is supportive and should be deleted before signing.*

Green text should be replaced and changed to black before signing.

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| --- | --- |
| Study title:  |  |
| EudraCT/ EU CT no: |  |
| Principal investigator: |  | Sponsor/ Sponsor’s representative: *Person signing the report* |  |
| Local monitor: |  | Coordinating monitor: |  |
| Present and role: | Name (first and last name),monitorName (first and last name),investigator Name (first and last name),research nurse/ study coordinator*Add more if needed* |
| Visit at other units:  | \_\_\_\_\_ *For example, pharmacy, laboratory, radiology* |
| Date of visit: | Click to enter date | Type of visit: | \_\_\_\_\_ *For example, visit at the trial site/by phone or video link (remote).* |
| If follow-up report, date for follow-up:  | Click to enter date | Type of visit: | \_\_\_\_\_ *For example, visit at the trial site/by phone or video link (remote).* |

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| **Recruitment** |
| Number of planned subjects: | xx | Inclusion period: | From- To | Study duration: | xx years/months |

### Summary

*General summary that provides information on the status of the trial site.*

*Is everything in place or is anything missing for study start?*

*Note any discrepancies in approvals from Medical Products Agency/Swedish Ethical Review Authority/ /biobank/radiology etc.*

*Is the trial site ready for study start?*

*For specific actions see list at the end of the document.*

## The following sections (1-8) have been informed about and discussed:

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| --- | --- | --- | --- | --- |
| 1. **Subject information and consent**
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 1.1  | Recruitment procedure | Select | \_\_\_\_\_ |
| 1.2  | Screening procedure | Select | \_\_\_\_\_ *Review instructions for screening log and subject identification list.* |
| 1.3  | Informed consent procedure | Select | \_\_\_\_\_ |
| 1.4  | Inclusion and exclusion criteria | Select | \_\_\_\_\_ |

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| **Section**  | **Detailed description:** |
| x.x | \_\_\_\_\_ *Add more lines if needed* |

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| 1. **Incident reporting**
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 2.1  | Procedure for reporting AE including assessment | Select | \_\_\_\_\_ |
| 2.2  | Procedure for reporting SAE | Select | \_\_\_\_\_ |
| 2.3  | Procedure for reporting pregnancy | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 2.4 | Procedure for reporting SUSAR | Select | \_\_\_\_\_ *If sponsor´s trial site, procedure for reporting to authorities and other trial sites. If local trial site, procedure for communication of SUSAR from sponsor and receipt and notification to study staff.* |
| 2.5 | Pregnancy restrictions and/or other safety aspects | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 2.6 | Annual safety report | Select | \_\_\_\_\_ *If sponsor´s trial site.* |

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| **Section**  | **Detailed description:** |
| x.x | \_\_\_\_\_ *Add more lines if needed* |

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| 1. **Data collection (CRF/e-CRF) and source data verification**
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 3.1  | Overview of protocol and endpoints according to the monitoring plan | Select |  |
| 3.2  | Instructions for CRF, such as access, completion and signing | Select | \_\_\_\_\_ |
| 3.3  | Patient diaries, questionnaires, and work sheets | Select | \_\_\_\_\_ |
| 3.4  | Requirements for documentation in medical record and other source data | Select | \_\_\_\_\_ |

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| **Section**  | **Detailed description:** |
| x.x | \_\_\_\_\_ *Add more lines if needed* |

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| 1. **Investigational** **and non-investigational medicinal products (IMP/non-IMP)** *(defined in accordance with the protocol)*
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 4.1  | Routine for randomization/treatment allocation | Select | \_\_\_\_\_ |
| 4.2 | Routine for blinding | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 4.3 | Routine for breaking the code | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 4.4 | IMP/non-IMP handling (requisition, delivery control, labelling, storage, temperature, logs, and destruction) | Select | \_\_\_\_\_ |
| 4.5 | Is the IMP/non-IMP available at the trial site | Select | \_\_\_\_\_ |
| 4.6 | Routine for information to subjects about use, storage and return of IMP/non-IMP | Select | \_\_\_\_\_ |
| 4.7 | If initiation/qualification visit has been done at a pharmacy function, has documentation been collected in accordance with the agreement with the sponsor? | Select | \_\_\_\_\_ *If deviations have been identified during visit, please provide a detailed description below.* |

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| **Section**  | **Detailed description:** |
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| 1. **Laboratory samples**
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 5.1 | Handling, labelling, storage, and transportation of samples according to the protocol/sample-specific manual. | Select | \_\_\_\_\_ *If sample-specific manual, note version.**Specify if local and/or central laboratory* |
| 5.2 | Are study specific supplies available at the laboratory and clinic? | Select | \_\_\_\_\_ |
| 5.3 | If specific laboratory equipment is needed (freezer, centrifuge etc.), is this available at the trial site? | Select | \_\_\_\_\_ |
| 5.4 | If initiation/qualification visit has been done at a laboratory, has documentation been collected in accordance with the agreement with the sponsor? | Select | \_\_\_\_\_ *If deviations have been identified during visit, please provide a detailed description below.* |

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| **Section**  | **Detailed description:** |
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| 1. **Resources including study staff, equipment, and premises**
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 6.1 | Conditions (study staff, equipment/materials, premises, or other agreed service) required to conduct the study. | Select | \_\_\_\_\_ |
| 6.2 | Procedure for training and delegation and updated signature and delegation log. | Select | \_\_\_\_\_ |
| 6.3 | CV  | Select | \_\_\_\_\_ *Control that CVs are signed and dated by study staff.* |
| 6.4 | Documented adequate GCP training | Select |  |
| 6.5 | Specific equipment/instruments for the study | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* *Specify equipment/instrument, e.g., scale, thermometer, blood pressure cuff, and date of latest validation/calibration if relevant.* |
| 6.6 | If initiation/qualification visit has been done at external function, has documentation been collected in accordance with the agreement with the sponsor? | Select | \_\_\_\_\_ *Specify where, e.g., radiology.* *If deviations have been identified during visit, please provide a detailed description below.* |

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| **Section**  | **Detailed description:** |
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| 1. **Study documentation** *Section 7 must be customized according to the current study*
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| **The following documents can be found in the Investigator Site File:** |
| 7.1 | Approved/current protocol *(signed by the principal investigator)* | Select | Version/Date:\_\_\_\_\_ |
| 7.2 | Case Report Form (CRF) *(blank version)* | Select | Version/Date:\_\_\_\_\_ |
| 7.3 | Approved/current patient diary/ questionnaire/patient card *(blank version)* | Select | Version/Date:\_\_\_\_\_ |
| 7.4 | Approved/current subject information and consent form *(blank version)*  | Select | Version/Date:\_\_\_\_\_ |
| 7.5 | Approval from CTIS (Medical Products Agency), including cover letter/list of submitted documents | Select | Approval date:\_\_\_\_\_*If sponsor´s trial site, the complete signed application should also be filed.* |
| 7.6. | Approval from CTIS part II (Swedish Ethical Review Authority) including cover letter/list of submitted documents | Select | Approval date:\_\_\_\_\_*If sponsor´s trial site, the complete signed application should also be filed.* |
| 7.7 | Other agreements/registrations: ***Customize the list for the study***1. Study agreements (investigator’s contracts)
2. Local approval from radiation protection committee
3. Pharmacy agreement
4. Biobank agreement
5. Radiology/other functional units, Local/central laboratory
6. Notification of handling of personal data
7. Registration in public database *(if* *sponsors trial site)*
8. xx
 | Select | \_\_\_\_\_*If any document is missing, it should be noted here.* |
| 7.8 | Signature and delegation log *(updated and current)* | Select | \_\_\_\_\_ *If commented on under 6.2, no further comment is needed, refer to 6.2.* |
| 7.9 | Training log | Select | \_\_\_\_\_ *If commented on under 6.2, no further comment is needed, refer to 6.2.* |
| 7.10 | CV *(signed and dated by study staff)*  | Select | \_\_\_\_\_ *If commented on under 6.3, no further comment is needed, refer to 6.3.* |
| 7.11 | Documented adequate GCP training | Select | *If commented on under 6.4, no further comment is needed, refer to 6.4.* |
| 7.12 | Investigators Brochure (IB) including receipt/Summary of Product Characteristics (SPC) | Select | Version/ Date:\_\_\_\_\_ |
| 7.13 | Investigational medicinal product(s) (IMP) documents: ***Customize the list for the study*** 1. Instructions for handling
2. Right of requisition
3. IMP log (inventory log and/or drug accountability log)
4. Destruction form/receipt
5. Temperature logs (room, fridge/freezer, if applicable)
 | Select | \_\_\_\_\_*If any document is missing, it should be noted here.*  |
| 7.14 | Randomization documents: ***Customize the list for the study*** 1. Randomization routine
2. Emergency code break routine
3. Results from code break (after study end)
 | Select | \_\_\_\_\_ *If applicable for the study, otherwise delete line.**If any document is missing, it should be noted here.* |
| 7.15 | Laboratory documents: ***Customize the list for the study*** 1. Reference value list, including update if any change (if applicable)
2. Accreditation including annexes or CV for relevant staff
3. Laboratory manual and referral form
4. Sample shipping documentation
5. Storage temperature log (fridge/freezer, if applicable)
6. Sample log
 | Select | \_\_\_\_\_*If applicable for the study, otherwise delete line.**If any document is missing, it should be noted here.* |
| 7.16 | Source data location agreement *(completed and signed)* | Select | \_\_\_\_\_ |
| 7.17 | Screening log | Select | \_\_\_\_\_ |
| 7.18 | Subject enrolment and identification log | Select | \_\_\_\_\_ |
| 7.19 | Monitor visiting log *(updated and signed)* | Select | \_\_\_\_\_ |
| 7.20 | Secrecy Agreement for monitor *(completed and signed)* | Select | \_\_\_\_\_ |
| 7.21 | Incident reporting documents: 1. SAE form *(blank version)*
2. Instructions for SAE reporting
 | Select | Version/Datum:\_\_\_\_\_ |
| 7.22 | Deviation reporting documents: 1. Note to file form *(blank version)*
2. Deviation log *(blank version)*
 | Select | \_\_\_\_\_ |
| 7.23 | Other:1. xx
 | Select | \_\_\_\_\_ |

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| **Section**  | **Detailed description:** |
| x.x | \_\_\_\_\_ *Add more lines if needed.* |

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| 1. **Other** *Section 8 must be customized according to the current study*
 | **Yes** | **No** | **NA** | **Comment** If No, always comment *Brief comment of importance or refer to detailed description below* |
| 8.1 | Have the following attachments been collected and/or sent to sponsor?***Customize the list for the study*** 1. Agenda site initiation visit
2. List of participants at site initiation visit (*copy*)
3. Protocol signature page (*copy*)
4. Investigator´s receipt of IB (*copy*)
5. Signature and delegation log (*copy*)
6. CV and documented adequate GCP training (*copy*)
7. xx
 | Select | \_\_\_\_\_*If applicable for the study, otherwise delete line.**Indicate whether the original document or a copy is at the trial site and what is available at sponsor (generally, original documents should be where they were created).* |

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| **Section**  | **Detailed description:** |
| x.x | \_\_\_\_\_ *Add more lines if needed.* |

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| **Questions and issues to follow up** *Refer to sections above* |
| #*(refer to above)* | **Date***(when issue was noted)* | **Question/Issue** | **Responsible** | **Date resolved** *(when verified)* |
|  | yyyymmdd | \_\_\_\_\_*Copy from comments above or write question/issue with reference to section above if relevant.* |  |       *When an issue is resolved and controlled note the date here. Leave the issue as resolved in the report, and then delete in the next report.* |
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**Monitor**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

**Sponsor/Sponsor’s representative**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name and role: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

*Please add a short supportive text for local monitor on how to communicate the report. For example: Signed report is sent by post/ scanned and emailed to xxx...*