

# Monitoring visit report

Coordinated monitoring of investigator- initiated multicenter studies

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

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

## About the document

Monitoring 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 |

### Monitoring 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), monitor  Name (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 previous visit: | Click to enter date |  |  |
| Date of visit: | Click to enter date | Type of visit: | \_\_\_\_\_ *For example, visit at the trial site\*/by phone or video link (remote).*  *\*Source data verification can only take place at the trial site.* |

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| **Recruitment status** *number of subjects* | | | | | | | |
| Planned: | xx | Screened:  *Intended/pre-trial screening* | xx | Included:  *Signed consent* | xx | Randomized:  Started study treatment:  Started intervention: | xx |
| Withdrawal:  *After starting study treatment* | xx | Ongoing: | xx | Completed: | xx |  |  |

#### Summary of visit

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

*Are there critical deviations (protocol, ICH-GCP or regulations)?*

*Raise any problems to sponsor and coordinating monitor (for example, do not have time to monitor according to plan, trial site lacks any document, needs training in any process).*

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

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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 | Is a correct consent form available for all controlled subjects? | Select | | | \_\_\_\_\_ *For example, checked for: xx-xx* |
| 1.2 | Is the consent procedure correctly documented in the medical record? | Select | | | \_\_\_\_\_ *For example, checked for: xx-xx* |
| 1.3 | Are subjects included in accordance with inclusion and exclusion criteria? | Select | | | \_\_\_\_\_ *For example, checked for: xx-xx* |

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| **Section** | **Detailed description:** |
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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 | Is AE reporting done according to protocol/study-specific procedure? | Select | | | \_\_\_\_\_ *For example, checked for: xx-xx* |
| 2.2 | Is SAE reporting done according to protocol/ study-specific procedure? | Select | | | \_\_\_\_\_ *For example, checked for: xx-xx* |
| 2.3 | Is pregnancy reporting done according to protocol/study-specific procedure? | Select | | | \_\_\_\_\_ *If relevant, otherwise delete line* |
| 2.4 | Is SUSAR reporting done according to protocol/ study-specific procedure? | Select | | | \_\_\_\_\_ *If sponsors trial site* |
| 2.5 | Are SUSAR reports available at the trial site? | Select | | | \_\_\_\_\_ *If local trial site* |
| 2.6 | Is the annual safety reporting for the study completed? | Select | | | *If sponsors trial site*  Date of last report: \_\_\_\_\_ |

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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 | Is the CRF correctly completed? | Select | | | \_\_\_\_\_ *Specify whether queries were made (for example, in the eCRF or in the action list in the monitoring report)* |
| 3.2 | Are correct source data available? | Select | | | \_\_\_\_\_ *For example, patient diary, questionnaire, and worksheet* |
| 3.3 | Is source data verification done in accordance with the monitoring plan? | Select | | | \_\_\_\_\_ *Specify subjects verified* |
| 3.4 | Is the primary endpoint verified in accordance with the monitoring plan? | Select | | | \_\_\_\_\_ *Specify subjects verified* |
| 3.5 | Have CRF pages been sent to sponsor? | Select | | | \_\_\_\_\_ *If paper CRF, otherwise delete CRF pages* |
| 3.6 | Have questionnaires been sent to sponsor? | Select | | |  |
| 3.7 | Are there findings/deviations to protocol, regulations and/or GCP noted by the clinic, or identified by monitor during the visit? | Select | | | \_\_\_\_\_ *Check that the deviation log is updated by the site, attach copy of log/ Note to file* |

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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* |
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| 4.1 | Is randomization performed according to protocol? | | Select | | | \_\_\_\_\_ *If applicable, otherwise delete line.*  *When using randomization envelopes, check that the correct number has been used.* |
| 4.2 | Are code breaking envelopes intact? | | Select | | | \_\_\_\_\_ *If applicable, otherwise delete line.*  *When using code breaking envelopes, check that they are intact.*  *If codebreaking has been performed, verify that it has been documented according to the procedure set up for the study.* |
| 4.3 | Is the blinding intact? | | Select | | | \_\_\_\_\_ *If applicable, otherwise delete line* |
| 4.4 | Are subjects compliant with IMP/non-IMP use and dosage? | | Select | | | \_\_\_\_\_ *If deviations, list these in the detailed description below.* |
| 4.5 | Is IMP/non-IMP handling (requisition, delivery control, storage, temperature, logs, and destruction) done according to protocol/ study-specific procedure and is it documented? | | Select | | | \_\_\_\_\_ *Check temperature logs (transport/storage), note any deviations in the detailed description below.* |
| 4.6 | Is inventory log accurate and up to date? | | Select | | | \_\_\_\_\_ *For example, the following investigational medicinal products were checked at this visit ex 1-10.* |
| 4.7 | Is the drug accountability log accurate and up to date? | | Select | | | \_\_\_\_\_ *For example, the following investigational medicinal products were checked at this visit ex 1-10.* |
| 4.8 | If IMP/non-IMP is available at the clinic, is it appropriate for use? | | Select | | | \_\_\_\_\_ *Check availability and expiration date, note any deviations in the detailed description below.* |
| 4.9 | Is returned/destructed IMP/non-IMP correctly documented? | | Select | | | \_\_\_\_\_ |
| 4.10 | When visiting a pharmacy function, has documentation been collected/checked in accordance with the agreement with the sponsor? | | Select | | | \_\_\_\_\_ *If applicable, otherwise delete line.*  *If deviations have been identified during visit, please provide a detailed description below.* |

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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 | Is handling, labelling, storage and transport of samples done according to the protocol/sample-specific manual? | | Select | | | \_\_\_\_\_ *Check temperature logs and documentation for sending samples, note any deviations in the detailed description below.* |
| 5.2 | Are method descriptions and/or laboratory reference values valid? | | Select | | | \_\_\_\_\_ |
| 5.3 | When visiting a laboratory, has documentation been collected/checked in accordance with the agreement with the sponsor? | | Select | | | \_\_\_\_\_ *If applicable, otherwise delete line. If deviations have been identified during visit, please provide a detailed description below.* |

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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 | Are conditions regarding study staff, equipment/materials, premises, or other agreed service unchanged? | Select | | | \_\_\_\_\_ |
| 6.1.1 | If no to 6.1.  Can the study continue to be conducted safe and correct? | Select | | | \_\_\_\_\_ |
| 6.2 | Is new study staff trained and correctly delegated in the study? | Select | | | \_\_\_\_\_ *Check the training log and delegation list, note any deviations in the detailed description below.* |
| 6.3 | Is CV for new staff available? | Select | | | \_\_\_\_\_ |
| 6.4 | Is documented adequate GCP training for new staff available? | Select | | | \_\_\_\_\_ |
| 6.5 | Are specific equipment/instruments used in the study validated/calibrated? | Select | | | *If applicable, otherwise delete line.*  \_\_\_\_\_ *Specify equipment/instrument such as scale blood pressure cuff, thermometer, and date of last validation/calibration if relevant.* |
| 6.6 | When visiting an external facility, has documentation been collected/checked in accordance with the agreement with the sponsor? | Select | | | *If applicable, otherwise delete line.*  \_\_\_\_\_*If deviations have been identified during visit, please provide a detailed description below.* |

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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:\_\_\_\_\_  Previous Version/Date:\_\_\_\_\_ *List all.* |
| 7.2 | Case Report Form (CRF) (*blank version/s*) | Select | | | Version/Date:\_\_\_\_\_  Previous Version/Date:\_\_\_\_\_ *List all.* |
| 7.3 | Approved/current patient diary/questionnaire/patient card *(blank version/s)* | Select | | | Version/Date:\_\_\_\_\_  Previous Version/Date:\_\_\_\_\_ *List all.* |
| 7.4 | Approved/current subject information and consent form (*blank* *version/s*) | Select | | | Version/Date:\_\_\_\_\_  Previous Version/Date:\_\_\_\_\_ *List all..* |
| 7.5 | Approval from CTIS part I (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 sponsor`s trial site)* 8. Xx | Select | | | \_\_\_\_\_*Specify whether changes to agreements and registrations are relevant.* |
| 7.8 | Signature- and delegation log *(updated and current)* | Select | | | \_\_\_\_\_ *If commented under 6.2, no further comment is needed, refer to 6.2*. |
| 7.9 | Training log (*documented for new staff or when updating documents)* | Select | | | \_\_\_\_\_ *If commented under 6.2, no further comment is needed, refer to 6.2*. |
| 7.10 | CV *(signed and dated by study staff)* | Select | | | \_\_\_\_\_ *If commented under 6.3, no further comment is needed, refer to 6.3*. |
| 7.11 | Documented adequate GCP training for  study staff | Select | | | \_\_\_\_\_ *If commented under 6.4, no further comment is needed, refer to 6.4*. |
| 7.11 | Investigators Brochure (IB) including receipt/Summary of Products Characteristics (SPC) | Select | | | Version/Date:\_\_\_\_\_  Previous Version/Date:\_\_\_\_\_ |
| 7.12 | Investigational medicinal product(s) (IMP) documents:  ***Customize the list for the study***   1. Instruction för handling 2. Right of requisition 3. Requisitions 4. IMP log (inventory log or drug accountability log) 5. Destruction form/receipt 6. Temperature logs (room, fridge/freezer *if applicable*) | Select | | | \_\_\_\_\_  *If any document is missing, it should be noted here.*  *The frequency of checks for documents is determined by the Monitoring Plan.* |
| 7.13 | Randomization documents: ***Customize the list for the study***   1. Randomization routine 2. Emergency code break routine | Select | | | \_\_\_\_\_ *If applicable for the study, otherwise delete line.*  *If any document is missing, it should be noted here.* |
| 7.14 | Laboratory information documents: ***Customize the list for the study***   1. Reference value list, including update if any change *(if applicable)* 2. Accreditation including annexes or CVs for relevant staff 3. Laboratory manual and referral forms 4. Sample shipping documentation 5. Storage temperature log (fridge/ freezer, *if applicable*) 6. Sample log | Select | | | \_\_\_\_\_  *If any document is missing, it should be noted here.* |
| 7.15 | Source data location agreement *(completed and signed)* | Select | | | \_\_\_\_\_ *Is the agreement still up to date?* |
| 7.16 | Screening log *(updated och current)* | Select | | | \_\_\_\_\_ |
| 7.17 | Subject enrolment and identification log *(updated and current)* | Select | | | \_\_\_\_\_ |
| 7.18 | Monitor visit log *(updated and signed)* | Select | | | \_\_\_\_\_ |
| 7.19 | Previous reports/follow-up letters from monitoring | Select | | | \_\_\_\_\_ *Including site initiation visit report.* |
| 7.20 | Incident reporting documents:   1. SAE-form *(blank version)* 2. Instructions for SAE reporting | Select | | | Version/Date:\_\_\_\_\_ |
| 7.21 | Deviation reporting documents:   1. Note to file form 2. Deviation log | Select | | | \_\_\_\_\_*If commented under 3.7, no further comment is needed, refer to 3.7.* |
| 7.22 | Other   1. xx | Select | | | \_\_\_\_\_ *Specify if applicable, otherwise delete line.* |

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

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| 1. **Other** *Section 8 should 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 | Is the inclusion rate as planned? If not comment. | Select | | | \_\_\_\_\_ |
| 8.2 | Have the following attachments been collected and/or sent to sponsor?  ***Customize the list for the study***   1. Protocol signature page (*copy*) 2. Investigator´s receipt of IB (*copy*) 3. Signature- and delegation log (*copy*) 4. CV 5. Documented adequate GCP training (copy) 6. 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** (from this and previous monitoring visits) | | | | | |
| #  *(refer to above)* | **Date**  *(when issue was noted)* | **Question/Issue** | **Responsible** | **Date resolved** *(when verified)* | **Deviation**  **Protocol/ GCP** |
|  | ddmmmyyyy | \_\_\_\_\_  *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.* | Select |
|  |  |  |  |  | Select |
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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...*