

# Close out 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

Close out 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 |

## Close out 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 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).* |
| 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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| **Status** | **Yes** | **No** | **NA** | **Comment** If No/NA always comment *Brief comment of importance* |
| Study ended and at the trial site according to protocol | Select | \_\_\_\_\_ *Note if the study was terminated early*  |
| Medical Products Agency notified of study end | Select | \_\_\_\_\_ *Only sponsor´s trial site* |
| **Final recruitment status** *number of subjects* |
| Planned: | xx | Screened:*Intended/pre-trial screening* | xxx | Included:*Signed consent* | xx | Randomized:Started study treatment:Started intervention: | xx |
| Withdrawal:*After starting study treatment* | xx | Completed: | xx |  |  |  |  |

### Summary

\_\_\_\_\_

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

*Is everything in place for close out? Are there procedures/elements that are not completed at close out?*

*In cases where monitoring and close out are performed at the same visit, both a monitoring report and a close out report is sent to sponsor.*

*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 | Are correct signed consent forms *(original document)* collected for all controlled subjects? | 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 | Have all AEs been reported and followed up in accordance with the protocol/study specific procedure? | Select | \_\_\_\_\_ |
| 2.2 | Have all SAEs been reported and followed up in accordance with the protocol/study specific procedure? | Select | \_\_\_\_\_ |
| 2.3 | Have all pregnancies been reported and followed up in accordance with the protocol/study specific procedure? | Select | \_\_\_\_\_ *If applicable, otherwise delete line* |
| 2.4 | Are all SUSAR reports available? | Select | \_\_\_\_\_ |
| 2.5 | Are all annual safety reports available? | Select | \_\_\_\_\_ *If sponsor’s trial site.* |

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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 | Are remaining queries in CRF resolved? | Select | \_\_\_\_\_ |
| 3.2 | Are CRF completed and signed by PI? | Select | \_\_\_\_\_ |
| 3.3 | Have questionnaires (for example QoL) been collected/sent to sponsor? | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 3.4 | Is a copy of e-CRF data available at the trial site? | Select | \_\_\_\_\_ *If e-CRF, otherwise delete line.*  |
| 3.5 | Are all paper CRFs and data clarification forms (DCFs) collected/sent to sponsor? | Select | \_\_\_\_\_ *If paper CRF, otherwise delete line.**Original document at sponsor and a copy at trial site.* |
| 3.6 | Have copies of all Notes to file and/or protocol deviation log been collected/sent to sponsor? | Select | \_\_\_\_\_ *Original document at trial site and a copy at sponsor.* |
| 3.7 | Are correct source data saved? | Select | \_\_\_\_\_ *For example, patient diary, questionnaires, and work sheets.* |
| 3.8 | Have copies of medical records printed for monitoring been destructed? | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 3.9 | Have clean file been confirmed and database locked? | Select | \_\_\_\_\_ *If sponsor’s trial site.* |
|  | *Add more lines if more sponsor details should be controlled* |  |  |

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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 | Is final IMP/non-IMP review done and inventory log and/or drug accountability logs up to date? | Select | \_\_\_\_\_ *Note if original document or a copy is filed at the trial site and what is filed at sponsor.*  |
| 4.2 | Has IMP/non-IMP been returned and/or destructed in accordance with study specific procedure and is it correctly documented? | Select | \_\_\_\_\_ *Note if original document or a copy is filed at the trial site and what is filed at sponsor.* |
| 4.3 | Are unused randomization envelopes and/or all code breaking envelopes handled in accordance with the agreement with the sponsor? | Select | \_\_\_\_\_ *If applicable, otherwise delete line. Specify if the original document is filed at trial site, destructed or returned to sponsor.*  |
| 4.4 | Is the trial site informed that results from code breaking should be documented in the medical record? | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* *If monitor should verify information in medical records, adjust the text in the left column.* |
| 4.5 | When close out visit at a pharmacy function, has documentation been collected 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.* |
|  | *Add more lines if more sponsor details should be controlled* |  |  |

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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 | Have all study specific laboratory samples been sent for storage/analysis according to the protocol/study specific manual and is it documented at the trial site? | Select | \_\_\_\_\_ |
| 5.2 | Have all study specific laboratory supplies been returned/destructed according to instructions? | Select | \_\_\_\_\_ |
| 5.3 | If biobank agreement according to the multicenter principle, has final report to regional e-biobank been done? | Select | \_\_\_\_\_ *If applicable, otherwise delete line.*  |
| 5.4 | When close out visit at a laboratory, has documentation been collected 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.* |
|  | *Add more lines if more sponsor details should be controlled* |  |  |

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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 delegations ended and signature and delegation log signed by PI? | Select | \_\_\_\_\_ *Control signature and delegation log.* |
| 6.2 | Are remaining questions/follow-ups from previous monitoring visit reports resolved? | Select | \_\_\_\_\_ |
| 6.3 | Have specific equipment/instruments used in the study been returned? | Select | \_\_\_\_\_ *If applicable, otherwise delete line.* |
| 6.4 | Are local agreements ended? | Select | \_\_\_\_\_ *For example, radiology.* |
| 6.5 | When visiting an external facility, has documentation been collected 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.* |
|  | *Add more lines if more sponsor details should be controlled* |  |  |

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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:***Note: if the Trial master file is reviewed for sponsor’s trial site the list below must be adjusted according to ICH GCP E6* |
| 7.1 | All approved protocols *(signed by the principal investigator)* | Select | Version/ Date:\_\_\_\_\_ *List all.* |
| 7.2 | Case Report Form (CRF) *(blank version/s*) | Select | Version/ Date:\_\_\_\_\_ *List all.* *(Copy of the trial sites CRF data (paper or electronic) should be available and commented on under 3.4).* |
| 7.3 | All approved patient diary/ questionnaire/patient card *(blank version/s*) | Select | Version/ Date:\_\_\_\_\_ *List all.* |
| 7.4 | All approved subject information and consent form *(blank version/s)* | Select | Version/ Date:\_\_\_\_\_ *List all.* |
| 7.5 | All approvals from CTIS part I (Medical Products Agency), including cover letters/lists of submitted documents (*and End of trial declaration form if approved under Directive 2001/20/EG*) | Select | Approval date:\_\_\_\_\_ *List all.**If sponsor´s trial site, the complete signed application should also be filed.* |
| 7.6 | All approvals from CTIS part II (Swedish Ethical Review Authority) including cover letters/lists of submitted documents | Select | Approval date:\_\_\_\_\_ *List all.**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 | \_\_\_\_\_ *If any document is missing, it should be noted here.* |
| 7.8 | Signature and delegation log *(complete, signed)* | Select | \_\_\_\_\_ *If commented on under 6.1, no further comment is needed, refer to 6.1.* |
| 7.9 | Training log *(complete, signed)* | Select | \_\_\_\_\_ |
| 7.10 | All CV *(signed and dated by study staff)*  | Select | \_\_\_\_\_  |
| 7.11 | Documented adequate GCP training for study staff | Select |  |
| 7.12 | All Investigator’s Brochure (IB), including receipt/ Summary of Product Characteristics (SPC) | Select | Version/ Date:\_\_\_\_\_ *List all.* |
| 7.13 | Investigational medicinal product(s) (IMP) documents:***Customize the list for the study*** 1. Instructions for handling IMP
2. Right of requisition
3. Requisitions
4. IMP log (inventory log and/or drug accountability log) (*original documents*)
5. Destruction form/receipt
6. Temperature logs (room, fridge/freezer*, if applicable*)
 | Select | \_\_\_\_\_ *Indicate whether the original document or a copy is at the trial site and what is available at sponsor. If commented on under 4, no further comment is needed, refer to 4.* |
| 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 information 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 *(complete)*
5. Storage temperature log (fridge/freezer, *if applicable*) *(complete)*
6. Sample log *(complete)*
 | Select | \_\_\_\_\_*If any document is missing, it should be noted here.* |
| 7.16 | Source data location agreement *(completed and signed)* | Select | \_\_\_\_\_ |
| 7.17 | Screening log *(complete)* | Select | \_\_\_\_\_ |
| 7.18 | Subject enrolment and identification log *(complete)* | Select | \_\_\_\_\_ |
| 7.19 | Monitor visit log *(complete, signed)* | Select | \_\_\_\_\_ *Original document at trial site and possibly a copy at sponsor.* |
| 7.20 | Previous reports/follow-up letters from monitoring | Select | *\_\_\_\_\_ Including site initiation visit report* |
| 7.21 | Incident reporting documents: 1. SAE form *(blank version)*
2. Instructions for SAE reporting
 | Select | Version/Date:\_\_\_\_\_ |
| 7.22 | Deviation reporting documents: 1. Note to file form *(complete)*
2. Deviation log *(complete)*
 | Select | \_\_\_\_\_*If commented on under 3.6, no further comment is needed, refer to 3.6.* |
| 7.23 | Other:* xx
 | Select | \_\_\_\_\_ *Note if any other documents are missing according to ICH-GCP E6.* |

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| **Section**  | **Detailed description:** |
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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 | Has the trial site been informed that audits and inspections can be done after study end? | Select | \_\_\_\_\_ |
| 8.2 | Is the trial site informed about final study payments? | Select | \_\_\_\_\_  |
| 8.3 | Is the trial site informed about publication procedures and that the study report should be filed in the ISF? | Select | \_\_\_\_\_ *It is not a strict requirement that the study report is filed in the ISF. If decided not to file the study report in the ISF, the decision should be documented..* |
| 8.4 | Does the trial site have an adequate plan for archiving? | Select | \_\_\_\_\_Time for archiving: \_\_\_\_\_ Place: \_\_\_\_\_ Person to contact: \_\_\_\_\_  |
| 8.5 | Har följande bilagor inhämtats och/eller skickats till sponsor? ***Customize the list for the study*** 1. Screening log *(indicate: original/copy)*
2. Protocol signature page (c*opy*)
3. Investigator’s receipt of IB (copy)
4. Signature and delegation log (copy)
5. CV
6. Documented adequate GCP training (copy)
7. Inventory log *(indicate: original/copy)*
8. Certificate of destruction *(indicate: original/copy)*
9. xx
 | Select | \_\_\_\_\_*If relevant 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).* |
|  | *Add more lines if more sponsor details should be controlled* |  |  |

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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.* | Select |
|  |  |  |  |  | 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...*