**Monitoring Visit Report Template**

**Disclaimer**

This document reflects the views of the Monitoring Platform of the Swiss Clinical Trial Organisation (SCTO).
The SCTO cannot be held liable for any use that may be made of the information contained herein.

**Instructions for use**

This [Monitoring Visit Report Template](https://www.scto.ch/de/network/scto-platforms/monitoring.html)is licensed under CC BY-NC 4.0. The content can be shared and adapted as long as you follow the license terms. To view a copy of this license, visit <http://creativecommons.org/licenses/by-nc/4.0/>.



This cover page is for information purposes and can be removed when using the template.

The text written in grey is intended to help you fill out the specific field. Once you have completed the field, delete the text in grey.

**Questions or suggestions?**

To obtain competent answers to general monitoring questions or to offer feedback on this document,
contact us at monitoring@scto.ch.



|  |  |
| --- | --- |
| **Monitoring Visit Report** <insert study ID> | **Report no.** |
| **[ ]** On-site | **[ ]** Remote |
| Study AND visit details |

|  |  |
| --- | --- |
| Study title: |       |
| Sponsor: |       |
| Type of study and categorisation(Switzerland only): | Type:Category:  | Choose an item.Choose an item. |
| Site (location): |       |
| Principal investigator (PI): |       |
| Visit date(s): | Click to choose a date. |
| Date(s) of previous visit: | Click to choose a date. | **[ ]**  N/A |
| Planned date(s) of next visit: | Click to choose a date. | **[ ]**  tbd |
| **List of study staff present:**  |
| Name: | Function: |
|       | Monitor |
|       |       |
|       |       |
| Main purpose of this visit: |
|       <Describe monitoring activities performed (e.g. SDV, review of informed consent process, ISF, resolution of queries, safety, drug accountability). For example, if the monitoring visit was carried out over more than one day, the date for each activity should be mentioned. Possible deviations from the monitoring plan can also be described.> |

|  |
| --- |
| Participant status AND study progress |

|  |  |
| --- | --- |
| No. of participants planned:  |       |
| No. of participants screened: |       |
| No. of participants enrolled: |       |
| No. of participants active: |       |
| No. of drop-outs: |       |
| No. of participants that completed study: |       |
| 2.1 Participant enrolment rate in accordance with trial timelines? | Choose an item. |
| 2.2 Study progress discussed with site staff? | Choose an item. |
| **Comments:**       <For example, mention measures discussed to enhance recruitment or measures to limit number of participants lost to follow-up.> |

|  |
| --- |
| Ethics committee (EC) / regulatory authority (RA) |
| 3.1 Since last visit, amended / new documents submitted to**EC:** Choose an item.**RA:** Choose an item. Amended / new documents approved by **EC:** Choose an item.**RA:** Choose an item. |  |
| 3.2 Have new document versions been appropriately filed?  | Choose an item. |
| 3.3 Are clinical trial registries up to date? | Choose an item. |
| **Comments:**       <Adapt or delete list below as required>

| Type of document: | Document version: | Date EC approval: | Date RA approval: |
| --- | --- | --- | --- |
| Protocol / CIP |       |       |       |
| PIC |       |       |       |
| IB / SmPC / IFU |       |       |       |
| CRF |       |       |       |
|       |       |       |       |

 |
|  |

|  |
| --- |
| Participant informed consent / participant eligibility / randomisation |

|  |  |
| --- | --- |
| 4.1 Has informed consent been appropriately obtained? | Choose an item. |
| 4.2 Have participants received a copy of the signed PIC? | Choose an item.  |
| 4.3 Is the consent process and trial participation appropriately documented in the medical records? | Choose an item. |
| 4.4 Has consent been obtained prior to any study procedures being conducted? | Choose an item. |
| 4.5 Are the screening log and the enrolment and ID log up to date, legible, and complete? | Choose an item. |
| 4.6 Have eligibility criteria been met for all the participants reviewed? | Choose an item. |
| 4.7 Has intervention been assigned to participants according to the randomisation list? | Choose an item. |
| **Comments:**       <State which ICFs were checked and if any issues were observed. Details about dates of signature and version numbers are not mandatory but can be mentioned in the table below if needed. This table can be moved to appendix if too long, or deleted if not used.>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant no.: | Date of Participant information: | Date of Participants signature: | Date of site’s signature: | ICF version no. and date: |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

 |
|  |

|  |
| --- |
| Source data verification (SDV) / case report form (CRF) review / data queries |

|  |  |
| --- | --- |
| 5.1 Are the available source data attributable, legible, contemporaneous, original, accurate, and complete? | Choose an item. |
| 5.2 Are print-outs from electronic medical records signed and dated? (certified copies) | Choose an item. |
| 5.3 Are CRF entries up to date? | Choose an item. |
| 5.4 Are CRF entries consistent with source data for all CRF reviewed? | Choose an item. |
| 5.5 Have all discrepancies been discussed and resolved?  | Choose an item. |
| 5.6 Are there any open queries?  | Choose an item. |
| 5.7 Is the source data location list up to date? | Choose an item. |
| **Comments:**       <Add information on SDV performed: List details of SDV **either** here **or** in the appendix (delete table if not required).>

|  |  |  |
| --- | --- | --- |
| Participant no.: | Level of SDV: | Visits / items reviewed: |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

 |

|  |
| --- |
| Safety aspects |

|  |  |
| --- | --- |
| 6.1 Have any new SAEs / AEs or other events as specified in the protocol occurred? | Choose an item. |
| 6.2 Have all SAEs / AEs or other events as specified in the protocol, including follow-up information, been correctly reported to the sponsor? | Choose an item. |
| 6.3 Have safety events been reported to EC / RA as required? | Choose an item. |
| 6.4 Is the SAE log up to date, legible and complete? | Choose an item. |
| 6.5 Have all SAE / AE or other events as specified in the protocol been correctly documented in the source data and reported in the eCRF? | Choose an item. |
| 6.6 Has the annual safety report been sent to both EC and RA (if applicable) | Choose an item. |
| 6.7 For visits at the sponsor’s site in investigator-initiated trials: Have all SAEs been assessed for causality / expectedness by the sponsor? | Choose an item. |
| 6.8 For visits at the sponsor’s site in investigator-initiated trials: Are AE / SAE listings reviewed by the sponsor on a regular basis? | Choose an item. |
| **Comments:**       |

|  |
| --- |
| Laboratory aspects |

|  |  |
| --- | --- |
| 7.1 Are laboratory results evaluated, signed and dated? | Choose an item. |
| 7.2 Are the laboratory reference ranges / laboratory certifications up to date? | Choose an item. |
| 7.3 Is management of the collected biological samples compliant with the protocol / lab manual and adequately documented (analysis, storage, destruction)? | Choose an item. |
| **Comments:**       |

|  |
| --- |
| Intervention [ ]  N/A |

|  |  |
| --- | --- |
| 8.1 Has IP been dispensed according to the protocol or other instructions as required? | Choose an item. |
| 8.2 Are IP accountability records correct and up to date (accountability log, dispensation log)? | Choose an item. |
| 8.3 Has IP been stored according to the protocol or other instructions as required?  | Choose an item. |
| 8.4 Are there sufficient IP supplies on site (considering study timelines and expiry date)? | Choose an item. |
| 8.5 Are IP returns and / or destruction done properly and is documentation available? | Choose an item. |
| 8.6 Has the blinding been maintained? | Choose an item. |
| **Comments:**       <Delete table if not needed>

|  |  |
| --- | --- |
| Participant no.: | IP review (visits) |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |

 |

|  |
| --- |
| Site staff and facilities |

|  |  |
| --- | --- |
| 9.1 Have there been any changes in the study team since the last visit? | Choose an item. |
| 9.2 Are CVs and GCP-certificates adequate and filed as required? | Choose an item. |
| 9.3 Is the study site personnel authorisation form up to date, legible, and complete? | Choose an item. |
| 9.4 Have all study staff members been trained on the current version of the protocol / CRF / PIC / IB / other aspects of the trial as applicable (training log updated)? | Choose an item. |
| 9.5 Have all tasks related to the study been performed by authorised personnel? | Choose an item. |
| 9.6 Have any issues been observed regarding the facilities (including laboratories, equipment and respective documentation) and their suitability for the proper and safe conduct of this study? | Choose an item. |
| **Comments:**       |

|  |
| --- |
| Site study records |

|  |  |
| --- | --- |
| 10.1 Are all sections of the ISF / TMF complete and up to date? | Choose an item. |
| 10.2 Is the monitoring site visit log complete and up to date? | Choose an item. |
| 10.3 Have any documents been collected for the sponsor? | Choose an item. |
| **Comments:**       <List any documents collected for the sponsor.> |

|  |
| --- |
| Protocol / GCP Deviations |

|  |  |
| --- | --- |
| 11.1 Have any deviations been identified and properly documented? | Choose an item. |
| 11.2 Have deviations been reported to the sponsor? | Choose an item. |
| 11.3 Were actions taken to prevent re-occurrence? | Choose an item. |
| **Comments:**       <Delete table if not required.>

| Participant no.: | Deviation: | Deviation reported in the eCRF / SD? | Action taken: |
| --- | --- | --- | --- |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

 |

|  |
| --- |
| Additional comments |

|  |
| --- |
|       |

|  |
| --- |
| Action list |

| Description: <In the description of the action, the section number should be indicated (e.g. Ad. 11.3). In case actions from previous visit report remain open, please write here an update / follow-up; Actions that have been closed in the previous monitoring report can be removed from the list.> | Responsible for follow-up: | Deadline for resolution(date): | Dateopened: | Dateclosed: |
| --- | --- | --- | --- | --- |
|        |       |       | Click to choose a date. | Click to choose a date. |
|       |       |       | Click to choose a date. | Click to choose a date. |
|       |       |       | Click to choose a date. | Click to choose a date. |
|       |       |       | Click to choose a date. | Click to choose a date. |
|       |       |       | Click to choose a date. | Click to choose a date. |
|       |       |       | Click to choose a date. | Click to choose a date. |
|       |       |       | Click to choose a date. | Click to choose a date. |

|  |
| --- |
| Summary of the visit |

|  |
| --- |
|       <The conclusions of the monitoring visit and general comments can be added here.>  |

|  |
| --- |
| Signatures |

|  |  |  |
| --- | --- | --- |
| CTU Monitor:      | Date: | Signature: |
| CTU Reviewer (if applicable):      | Date: | Signature: |
| Sponsor:      | Date: | Signature: |

|  |
| --- |
| **Sponsor’s comments / Actions taken:**  |
| <The sponsor or designated person on behalf of the sponsor can add comments to the monitoring report. The sponsor can inform the monitor, if other actions are planned for the raised issues than described in the monitoring report.> |

**Appendix**

<adapt / replace / delete list as needed>

| **Participant no.:** | **Level of SDV:** | **Visits / items reviewed** | **Remarks:** |
| --- | --- | --- | --- |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |