Site closure visit

SOP number	**M07**
Version number	**5.0**
Effective date	**22-NOV-2022**
Revision date	**22-NOV-2022**

Standard Operating Procedure

Author

Name	Tijtje van Dam
Function	Clinical Research Consultant
Date	20-11-2022
Signature	DocuSigned by: Tijtje van Dam 11D2509C2CAD4EC...
For 'revision' without changes	
Date	
Signature	

Reviewer

Name	Anneke van de Wetering
Function	Clinical Research Consultant
Date	18-11-2022
Signature	DocuSigned by: Anneke van de Wetering E2BED76992AB4E5...
For 'revision' without changes	
Date	
Signature	

Approver

Name	Sandra Jansen
Function	Clinical Research Consultant
Date	18-11-2022
Signature	DocuSigned by: Sandra Jansen BE53C80A705146A...
For 'revision' without changes	
Date	
Signature	

This SOP is applicable to all TAPAS Group members and designees.

1 Aim

To describe the procedures to be conducted during the final monitoring visit to an investigational site at the end of a clinical trial. Upon completion of the site closure visit no queries should be outstanding and all required essential documents should be present in the investigator file.

2 Background

All clinical trials will have a final close-out visit after the last study subject has completed the study and the database has been locked or at early termination of the study.

3 Procedure

3.1 Prior to site closure visit

Responsibility:	**Action:**
Monitor/ Consultant	1. Schedule close-out visit. 2. Check monitoring plan for study specific site closure activities. 3. Prepare visit, making use of previous visit reports, letters, documents and the essential document checklist (M02/F2). 4. Review and resolve outstanding issues, if applicable. 5. Check outstanding queries and close them if possible. 6. Review TAPAS Group site specific study master file. 7. Ensure that any documents missing from the investigator file, sponsor file and/or TAPAS Group site specific study master file are retrieved prior to the visit. If necessary, remind the investigator site staff to obtain missing information (e.g. from pharmacy, local laboratory, hospital board, etc). 8. Review finance for site.

3.2 During site closure visit

Responsibility:	**Action:**
Monitor/ Consultant	1. Complete site monitor log (M03/F4) and obtain a copy for the sponsor file and/or TAPAS Group site specific study master file. 2. Retrieve all missing essential documents (copies or originals, as applicable) and finalise essential document checklist (M02/F2). 3. Investigational product, if applicable:

- Complete inventory of investigational product and ensure that any investigational product provided to the study site is accounted for.
- Document any discrepancies.
- Retrieve signed copies of investigational product handling for sponsor and/or TAPAS Group site specific study master file.
- Arrange, if applicable, for return to the sponsor of any remaining investigational product at the site (used/unused) or check documentation on investigational product destruction.
- Collect randomisation code envelopes, if applicable, ensuring that any code breaks are fully documented.

4. Ensure other study materials such as labkits if applicable are returned to the sponsor or destroyed on site.
5. Ensure Investigator file is up to date.
6. Ensure any remaining queries are resolved and adequately closed.
7. Meet with the investigator for close-out and discuss the following:
   - Communication on any required follow up of SAEs that occurred during the study.
   - If applicable, communication with the Ethics Committee on safety issues and the end of trial declaration (SOP M10).
   - Communication with the hospital board on completion/premature discontinuation of the study.
   - Any outstanding issue.
   - Requirements for study record retention and confirm location of archiving.
   - Access to (e)CRF data.
   - Request that the Principal Investigator will review and sign the final clinical study report, if applicable.
   - If applicable, remind site staff to inform the sponsor of any change that occurred in the information mentioned in the Financial Disclosure form until 1 year after completion (Last Subject Last Visit (LSLV))
   - Outstanding financial issues.
   - Agreement on publication policy.
   - Possibility of audit/inspection after close-out

3.3 Following close-out visit

Responsibility:	Action:
Monitor/ Consultant	1. Complete the site closure visit report (M07/F1). 2. Provide the signed site closure visit report to the appropriate sponsor personnel for information, review and sign-off, if applicable. In case the sponsor signs the report, request sponsor personnel to return a copy of the duly signed report. 3. In case the sponsor does not sign the report, the consultant is required to sign the report as evidence of internal review. 4. Complete essential document checklist (M02/F2). 5. Follow up on issues resulting from the site closure visit. 6. Write a follow-up letter to investigator(s)/study personnel. 7. If applicable, complete the investigational product transfer form (M11/F1) and specification form (M11/F2) and send returned investigational product to the sponsor. 8. Verify receipt by the sponsor of returned investigational product, if applicable. 9. File remaining study documents according to sponsor policy and procedure. 10. Arrange for final payment to investigator, if applicable.

4 References

- Guideline for Good Clinical Practice E6 (R2) (EMA/CHMP/ICH/135/1995)
- EU Directive on GCP for the Conduct of Clinical Trials (2001/20/EC)
- EU Regulation on clinical trials on medicinal products for human use (536/2014)
- EU Directive on GCP regarding IMP (2005/28/EC)
- GMP Annex 13 of the Guide to Good Manufacturing Practice: Manufacture of investigational medicinal products
- 21 CFR, Part 11 Electronic Records and signatures

5 Applied forms

Form number M02/F2: Essential document checklist
Form number M03/F1: Site monitoring visit report
Form number M03/F4: Site monitor log
Form number M03/F7: Monitoring Plan
Form number M07/F1: Site closure visit report
Form number M11/F1: Investigational product transfer form

Form number M11/F2: Investigational product specification form

6 SOP history

Previous Version:	Effective Date:	Description of Implemented Changes:
1.0.	26-FEB-2012	• Added on front page 'This SOP is applicable to all TAPAS Group members and designees' • Added section 4 References
2.0.	21-JAN-2014	• New template frontpage • 3.1.2 Added "Check monitoring plan for study specific site closure activities".

3.0	30-NOV-2016	• Added to 3.2:
		  ○ Ensure other study materials are returned to the sponsor or destroyed on site.
		  ○ Access to (e)CRF data.
		  ○ If applicable, remind site staff to inform the sponsor of any change that occurred in the information mentioned in the Financial Disclosure form until 1 year after completion (Last Subject Last Visit (LSLV).
		• Corrected reference after GCP update R2.
		• Added applied form: Form number M03/F7: Monitoring Plan
		• Changed names of files based on updated SOP F01.
		• Minor textual changes

4.0	19-SEP-2022	• Added reference CTR (536/2014)