Pharmacy visit

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Standard Operating Procedure

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

1 Aim

To describe procedures concerning the monitoring of the pharmacy before and during initiation visit, regular monitoring visits and site close-out visit.

2 Background

ICH GCP (CPMP/ICH/135/95) indicates that the responsibility for investigational product accountability rests with the investigator/institution. Depending on regulatory requirements, the investigator/institution may or should assign the duties for investigational product accountability to an appropriate pharmacist or other appropriate individual who is under the supervision of the investigator/institution.
The investigational products must be used in accordance with the approved protocol and adequate records must be kept. Investigational products should be stored as specified by the sponsor. It is the task of a monitor to ensure that investigational products at the investigator site are adequately handled, stored and accounted for.

3 Procedure

The pharmacy initiation visit may only be performed by the TAPAS Group partner (consultant) or by adequately trained and experienced monitors, duly authorised by the consultant.

3.1 Initial visit to the pharmacy

3.1.1 Prior to pharmacy visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Ensure that the procedures described in SOP M01, site qualification visit, and SOP M02, site initiation visit, are followed. 2. Obtain the contact details of the pharmacist from the potential investigator. 3. Schedule an initiation visit with pharmacist. 4. Verify which documentation is needed at the pharmacy. 5. Ensure agreement on pharmacy costs, if applicable. 6. Collect/prepare required documentation.

3.1.2 During pharmacy visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Collect missing documentation 2. Discuss characteristics of investigational product(s) e.g. by reviewing relevant parts of the IB/IMPD). 3. Review relevant parts of the study protocol and discuss requirements for investigational product shipment, storage, handling and accountability. 4. Ensure the pharmacist completes the site signature and delegation of duties log. 5. Obtain CV of the pharmacist. 6. Verify receipt of investigational product at trial site as described in SOP M11 'Investigational product handling and accountability'. 7. Ensure adequate storage of investigational product.

3.1.3 Following pharmacy visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Complete the investigational product part of the initiation visit report (M02/F1) and provide it to the appropriate sponsor personnel for information, review and sign-off, if applicable. Request sponsor personnel to return a copy of the duly signed report. 2. If the pharmacy initiation visit was delegated to another TAPAS Group partner or to an external consultant (no TAPAS Group partner), and the sponsor does not sign the report, the consultant is required to sign the report as evidence of review. 3. Provide a copy of the report to the investigator and pharmacist. 4. Follow-up on outstanding issues. 5. File essential documents. 6. Complete essential document checklist (M02/F2). 7. Arrange for payment of the pharmacy, if applicable. 8. Send a follow-up letter (or email) to the responsible pharmacy staff with a copy to the investigator, indicating major action points and agreements.

3 2. Routine visits to the pharmacy

3.2.1 Prior to pharmacy visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Schedule a visit to the pharmacy preferably during each monitoring visit or as described in the study specific monitoring plan. 2. Collect study material to provide to the site, if necessary. Investigational products may not be hand carried to the pharmacy/study site. 3. Prepare visit, making use of previous (visit) reports, letters and investigational product accountability forms (SOP M11).

3.2.2 During pharmacy visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Verify/discuss at regular intervals one or more of the following investigational product related issues: a. receipt at the pharmacy b. preparation if applicable and dispensing c. returns d. accountability e. storage and temperature log. Instruct the site that if the temperature is out of range, the monitor should be contacted immediately. f. expiry dates g. randomisation codes, unblinding h. stock levels i. return to sponsor or destruction

3.2.3 Following pharmacy visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Complete the investigational product part of the site monitoring visit report. 2. Complete the investigational product accountability record and arrange sending return investigational product to the sponsor, if applicable. 3. Follow-up on outstanding issues. 4. File essential documents, if applicable. 5. Complete essential document checklist (M02/F2). 6. Arrange for payment of the pharmacy, if applicable.

7. Send a follow-up letter (or email) to the responsible pharmacy staff with a copy to the investigator, indicating major action points and agreements.

3.3 Site closure visit at the pharmacy

3.3.1 Prior to the visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Ensure that the procedures described in SOP M07, site closure visit, are followed. 2. Schedule closure visit. 3. Prepare visit, making use of previous (visit) reports, letters and investigational product accountability forms (SOP M11). 4. Review previous visit report and resolve outstanding issues if applicable. 5. Review finance, if applicable.

3.3.2 During the visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Verify investigational product: a. returns b. handling and final accountability c. documentation as described in SOP M03, Site monitoring visit, and SOP M11, Investigational product handling and accountability. 2. Ensure any investigational product still stored at the pharmacy is returned or check documentation on investigational product destruction. 3. If applicable, complete the investigational product transfer form (M11/F1) and specification form (M11/F2) and send return investigational product to the sponsor. 4. Collect code envelopes, if applicable. Ensure that documented explanations are present for any code breaks.

3.3.3 Following the visit:

Responsibility:	**Action:**
Monitor/ Consultant	1. Complete the investigational product part of the site closure visit report. 2. Follow-up on issues resulting from the site closure pharmacy visit. 3. Complete the investigational product accountability record. Arrange sending return investigational product and code envelopes to the sponsor, if applicable, or verify documentation of investigational product destruction. 4. Verify receipt of return drug shipment, if applicable. 5. Arrange for final payment to pharmacy, if applicable. 6. File essential documents, if applicable. 7. Complete essential document checklist (M02/F2). 8. Send a follow-up letter (or email) to the responsible pharmacy staff with a copy to the investigator, indicating remaining action points.

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

5 Applied forms

Form number M02/F1: Site initiation visit report
Form number M02/F2: Essential document checklist
Form number M03/F1: Site monitoring visit report
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' • Changed order in SOP procedures • Added section 4 References • Added references in several procedure sections to SOP M01, M02 and M07
2.0	21-JAN-2014	• Added at section 3.2.1 "or as described in the study specific monitoring plan." • New template frontpage
3.0	30-NOV-2016	• Corrected reference after GCP update R2. • Split the visits into prior, during and following the visit. • Added in section 3.3.2: If applicable, complete the investigational product transfer form (M11/F1) and specification form (M11/F2) and send return investigational product to the sponsor.
4.0	19-SEP-2022	• Added reference CTR (536/2014)