
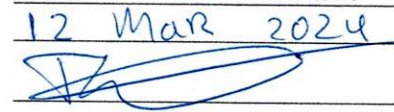


Laboratory visit	
	SOP number M05
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Standard Operating Procedure	

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1 Aim

To describe the activities to be undertaken at laboratory facilities involved in clinical trials at the initial visit, during regular monitoring visits, and during close-out of a trial. The purpose of the visits is to ensure that facilities are adequate and that study related procedures are performed in accordance with the study protocol, applicable SOPs and regulatory requirements.

2 Background

Before study initiation all laboratory procedures from the study protocol should be discussed thoroughly with the appropriate laboratory personnel. Laboratory facilities should be checked for their adequacy. Before the start of the study, a written signed agreement with the laboratory/hospital should be in place regarding the handling, storage and analysis of samples and the reporting of results. During the trial, laboratory procedures may change (i.e. equipment, reference ranges, reporting procedures, QA/QC procedures). It is necessary to check whether these changes affect the study related procedures. Relevant changes should be documented in the various study files and relevant staff should be informed of the changes.

In some trials, samples are collected and temporarily stored before their shipment to another (central) laboratory for analysis. Storage and shipment of these samples need to be checked regularly.

3 Procedure

3.1 Initial visit to the laboratory

The initial visit to the laboratory should be completed before subjects are enrolled in the study. This visit may only be performed by the TAPAS Group partner (consultant) or by an external consultant (no TAPAS Group partner) duly authorised by the consultant.

Responsibility:

Consultant

Action:

1. Ensure that the procedures described in SOP M01, site qualification visit, and SOP M02, site initiation visit, are followed.
2. Verify if the laboratory is able to fulfill all assessments/analyses according to the specifications in the protocol.
3. Obtain signed and dated normal laboratory values/ laboratory reference ranges for all parameters.
4. Verify that transport of samples from investigator to laboratory is done timely and that storage conditions are adequate.
5. Verify laboratory certificates and/or participation in internal/external quality control programs.
6. Verify if the laboratory has the relevant standard

- operating procedures and whether these are up-to-date.
7. Verify that there are maintenance contracts for vital analytical equipment during the study period.
 8. Findings from the laboratory visit should be integrated in the initiation visit report (M02/F1) and provided to the appropriate sponsor personnel for information, review and approval, by sign-off, if applicable. Request sponsor personnel to return a copy of the duly signed report.
 9. In case the consultant has delegated the initial laboratory visit to another TAPAS Group partner or to an external consultant (no TAPAS Group partner) and the sponsor does not sign the report, the project leader is required to sign the report as evidence of internal review.
 10. Send a follow-up letter (or email) to the responsible laboratory staff, indicating major action points. In case a laboratory does not meet some/all requirements to start, inform responsible site staff and sponsor accordingly.
 11. Non-selected laboratories will be informed of this decision.

3.2 Routine visits to the laboratory

Responsibility:	Action:
Consultant	1. Decide on frequency of routine visits to the laboratory.
Monitor	2. Check whether the required samples are collected, labelled, stored (temperature log) and/or shipped following the agreed procedures.
	3. Review changes in normal laboratory values/ laboratory reference ranges and inform data management and investigator, if applicable.
	4. Check for changes in key analytical equipment.
	5. Some protocols include parameters, for which the analysis requires special (bio) chemicals. If these parameters are considered to be primary parameters, it may be necessary to document changes in the batch of the (bio) chemicals used. Sponsor requirements for this should be verified.
	6. The findings from the routine laboratory visits should be integrated in the site monitoring visit report (M03/F1).

3.3 Final visit to the laboratory

Responsibility: Action:

Monitor

1. Ensure that the procedures described in SOP M07, site closure visit, are followed.
2. Check whether the required samples are collected, labelled, stored and/or shipped following the agreed procedures.
3. Review changes in normal laboratory values/ laboratory reference ranges.
4. Arrange for transport or destruction of samples, if applicable.
5. Review outstanding financial issues.
6. The findings from the final laboratory visit should be integrated in site closure visit report (M07/F1).

4 References

- Guideline for Good Clinical Practice E6 (R2) (EMA/CHMP/ICH/135/1995)
- ISO 14155, third edition 2020-07
- EU Directive on GCP for the Conduct of Clinical Trials (2001/20/EC)
- EU Regulation on clinical trials on medicinal products for human use (CTR 536/2014)
- EU Directive on GCP regarding IMP (2005/28/EC)
- Medical Device Regulation (MDR 2017/745)

5 Applied Forms

Form number M02/F1: Site initiation visit report

Form number M03/F1: Site monitoring visit report

Form number M07/F1: Site closure visit report

6 SOP history

Previous Version:	Effective Date:	Description of Implemented Changes:
1.0.	26-FEB-2012	<ul style="list-style-type: none"> • Added on front page 'This SOP is applicable to all TAPAS Group members and designees' • Added section 4 References • Added references in several procedure sections to SOP M01, M02 and M07
2.0.	21-JAN-2014	<ul style="list-style-type: none"> • Minor lay out and text changes • New template frontpage
3.0	30-NOV-2016	<ul style="list-style-type: none"> • Corrected reference after GCP update R2. • Minor textual changes

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| 4.0 | 26-NOV-2019 | <ul style="list-style-type: none">• Added actions to be taken in case of a non-suitable laboratory in section 3.1, bullet points 10 and 11. Addition of sponsor approval in section 3.1, bullet point 8. |
| 5.0 | 14-JUN-2021 | <ul style="list-style-type: none">• Included CTR, ISO14155 and MDR |