


<b>Site initiation visit</b>	
	<b>SOP number</b> M02
	<b>Version number</b> 5.0
	<b>Effective date</b> 12-APR-2023 <b>Revision date</b> 12-APR-2026
<b>Standard Operating Procedure</b>	

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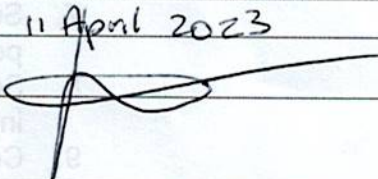
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This SOP is applicable to all TAPAS Group members and designees.

## 1 Aim

To describe the procedure for reviewing the final protocol, the Investigator's Brochure (if applicable) and regulatory requirements with the investigator and staff, and the procedure to instruct study personnel in study procedures including but not limited to subject recruitment, informed consent, (Serious) Adverse Event reporting, investigational product (if applicable) and case report form (CRF) / Electronic Data Capture (EDC) completion.

## 2 Background

Initiation visits will be performed for all clinical trials prior to subject enrolment and after obtaining ethics approval in writing. Under specified conditions and upon the documented request by the sponsor, attendance at an investigator meeting may replace an initiation visit. In case a sponsor has delegated the responsibility for site initiation to a TAPAS Group partner (consultant), the appointed consultant performs or supervises the site initiation visits for all clinical sites.

## 3 Procedure

### 3.1 Prior to Initiation Visit

#### Responsibility:

Consultant

#### Action:

1. Ensure that written and dated approval from the Ethics Committee and Competent Authority (if applicable) and all other applicable approvals have been received.
2. Verify receipt of all other required essential documents and identify outstanding documents for retrieval.
3. Ensure that procedures written in SOP M05, Laboratory visit, and SOP M06, Pharmacy visit are performed (if applicable).
4. Obtain an investigator file from the sponsor or constitute an investigator file in accordance with SOP F02.
5. Update study files.
6. Check monitoring plan for study specific site monitoring activities.
7. Schedule visit with Investigator(s) and study personnel.
8. Send a confirmation letter or email to the site including the agenda for the initiation visit.
9. Collect all study materials to carry/ship to the site.
10. Arrange for and verify investigational product shipment to site (if applicable).

### 3.2 During initiation visit.

**Responsibility:**

Consultant

**Action:**

1. Complete site monitor log (M03/F4).
2. Provide the investigator with the investigator file and instruct investigator site staff on its use.
3. Retrieve outstanding essential documents.
4. Review with the investigator site staff the following but not limited to:
  - a. Investigator's Brochure (if applicable)
  - b. Protocol
  - c. Protocol amendments (if applicable)
  - d. Investigator responsibilities according to applicable guidelines
  - e. Site signature and delegation of duties log (M02/F3)
  - f. Study planning (time lines and subject recruitment)
  - g. Ethics Committee and/or Competent Authority issues, including the assessment of the local approval/feasibility of the trial
  - h. Laboratory issues (if applicable)
  - i. Investigational Product issues (if applicable)
  - j. Case Report Forms / Electronic Data Capture
  - k. Other study supplies, if any
  - l. Adverse events/Serious Adverse Events (AEs/SAEs) procedures
  - m. Monitoring visits (tasks, schedule; attendance by site staff)
  - n. Source documents (paper /electronic) and source data verification
  - o. Retention of study documents according to applicable guidelines
  - p. Informed consent procedure

## 3.3 Following initiation visit

**Responsibility:**

Consultant

**Action:**

1. Complete site initiation visit report (M02/F1) and essential document checklist (M02/F2).
2. If the site initiation visit was delegated to another TAPAS Group partner or to an external consultant (no TAPAS Group partner), the consultant is required to sign the report as evidence of review.
3. Provide signed initiation visit report to the appropriate sponsor personnel for information, review and sign-off, if applicable. Request sponsor personnel to return a copy of the duly signed initiation visit report.
4. Make copy of the duly signed initiation visit report

and send it to the investigator with a follow-up letter or email, indicating major action points.

5. Follow-up on outstanding issues from the action list.
6. File the essential documents and other study documents in the study file.

#### 4 References

- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
- 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)
- 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/F1: Site initiation visit report

Form number M02/F2: Essential document checklist

Form number M02/F3: Site signature and delegation of duties log

Form number M02/F4: Study training log

Form number M03/F4: Site monitor log

#### 6 SOP history

Previous Version:	Effective Date:	Description of Implemented Changes:
1.0	26-FEB-2012	<ul style="list-style-type: none"> <li>• Adapted forms</li> </ul>
1.1	13-JUN-2013	<ul style="list-style-type: none"> <li>• Added on front page 'This SOP is applicable to all TAPAS Group members and designees'</li> <li>• Added electronic CRF and Electronic Data Capture (EDC) in several procedures</li> <li>• Added reference to SOP M05 and M06 at section 3.1</li> <li>• Added section 4 References</li> </ul>
2.0	21-JAN-2014	<ul style="list-style-type: none"> <li>• New template frontpage</li> <li>• 3.1.6 added "Check monitoring plan for study specific site initiation activities".</li> </ul>
3.0	30-NOV-2016	<ul style="list-style-type: none"> <li>• M02F2 Essential documents checklist: Form has been replaced by newly designed form.</li> <li>• M02F3 Site signature and delegation of</li> </ul>

- 4.0            25-MAR-2023
- duties log. Deleted text: Handwriting sample (1234567890)
  - Added new form: M02F4 Study training log.
  - Included CTR and MDR
  - Unified SOP to make SOP applicable for studies with medicinal product, medical device and for all other non-drug, non-device studies.