Site Qualification visit and Pre-study visit

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Standard Operating Procedure

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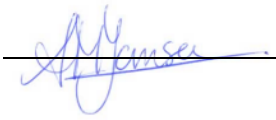
Signature	
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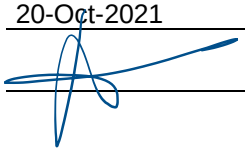
Signature	
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This SOP is applicable to all TAPAS Group members and designees

1 Aim

To describe the evaluation of the ability of a study site to successfully conduct the proposed clinical trial and the evaluation of the credentials of study personnel and the adequacy of clinic facilities.

2 Background

The investigator should be qualified by education, training and experience and should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely. This is to ensure that the rights, safety and well-being of trial subjects will be protected, and that trial data will be reliable. In case a sponsor has delegated the responsibility for site selection and recruitment to a TAPAS Group partner (consultant), the appointed consultant performs or supervises the site qualification visits for all clinical sites prior to study initiation.

'Green light' procedure to document that a site is qualified and allowed to enrol subjects is out of the scope of this SOP.

3 Procedure

3.1 Site qualification visit

3.1.1 Prior to site qualification visit

Responsibility:	**Action:**
Consultant	1. Assess, if possible, qualifications, credentials and experience in intended therapeutic area of Principal Investigator, and verify that medical licenses for Principal Investigator and all medical sub investigators are current. Consult, where applicable 'investigator blacklists' (e.g. FDA). 2. Provide potential investigator with a confidentiality agreement. 3. After receipt of the signed confidentiality agreement, provide protocol/ synopsis and up-to-date additional relevant product information (If applicable).

3.1.2 During site qualification visit.

Responsibility:	**Action:**
Consultant	1. Review/discuss the following: a. Responsibilities and qualifications of study personnel: • Check if the investigator

- is qualified by education, training and experience to assume responsibility for the proper conduct of the trial.
- meets all the qualifications specified by the applicable regulatory requirements.
- provides evidence of such qualifications through up-to-date CV.

- Discuss monitoring and auditing (allow direct access to all requested trial related records for monitors, auditors and regulatory authorities) and retention of the trial related essential documents as long as necessary.
- Review individual responsibilities of study personnel for proposed trial.
- Check if the investigator can demonstrate a potential for recruiting the required number of suitable subjects within the recruitment period and that he/she has sufficient time to properly conduct the trial. Assess the impact of other trials running at the site at the same time.
- Discuss informed consent procedure.
- Check if adequate number of qualified staff and adequate facilities for the foreseen duration of the trial are available.

b. Investigator's Brochure, if applicable
c. Protocol.
d. Competent Authority and Ethics Committee issues, including the assessment of the local feasibility of the trial.
e. All other activities and facilities necessary to evaluate the ability of a study site to successfully conduct the clinical trial.
Read SOP M05, Laboratory Visit, for necessary information to evaluate the laboratory, if required.
Read SOP M06, Pharmacy Visit, for necessary information to evaluate the Pharmacy, if required.

2. Discuss site specific procedures for conducting a medical device study at this site, if applicable.
3. Discuss the financial aspects of the trial.

3.1.3 Following site qualification visit

Responsibility:	**Action:**
Consultant	1. Complete a site qualification visit and pre-study visit report (M01/F1)

2. If the site qualification 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 the 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 site qualification visit report.
4. If required or considered necessary, discuss findings with appropriate sponsor personnel to determine acceptability of site for proposed study.
5. Write a letter or email to investigator outlining findings, agreements and outstanding actions.
6. Prepare Letter of Intent if applicable.

3.2 Pre-study visit

In some cases it is necessary to visit a selected site on one or more occasions before the initiation visit can take place. In these cases the site is already selected and agreed by the sponsor.

3.2.1 Prior to pre-study visit

Responsibility:	**Action:**
Consultant	1. Schedule a visit with the relevant study personnel. 2. Send confirmation letter or email outlining the purpose of the visit and items for discussion.

3.2.2 During pre-study visit

Responsibility:	**Action:**
Consultant	1. Discuss all relevant issues.

3.2.3 Following pre-study visit

Responsibility:	Action:
Consultant	1. Complete a site qualification visit report and pre-study visit report(M01/F1). 2. Provide the 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 report. 3. Write a follow-up letter or email to investigator/study personnel confirming agreements, providing requested information and requesting any additional information necessary. 4. Update the essential documents checklist (M02/F2), 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)
- per 31 January 2022 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 M01/F1: Site qualification visit report and pre-study visit report

6 SOP history

Previous Version:	Effective Date:	Description of Implemented Changes:
1.0	26-FEB-2012	• Adapted forms
1.1	29-APR-2012	• Added Pre-study visit to SOP title • Added on front page 'This SOP is applicable to all TAPAS Group members and designees' • Added section 4 References • Added reference at section 3.1.2 to SOP M05 and M06 • Added pre-study visit report to title of form M01/F1
2.0	21-JAN-2014	• New template frontpage

		• 3.1.1 added “and additional relevant product information (If applicable)” • 3.1.2 added “Discuss site specific procedures for conducting a medical device study at this site, if applicable”.
3.0	30-NOV-2016	• 3.1.1 action point 3. Old text: After receipt of the signed confidentiality agreement, provide protocol and up-to-date Investigator’s Brochure and additional relevant product information (If applicable). New text: After receipt of the signed confidentiality agreement, provide protocol/ synopsis and up-to-date additional relevant product information (If applicable) • 3.1.2 action 1a (bullet 2). Old text: Obtain investigator’s agreement. to conduct the trial in compliance with GCP and the applicable regulatory requirements and with the agreed protocol, to comply with procedures for data recording/reporting, to permit monitoring and auditing (allow direct access to all requested trial related records for monitors, auditors and regulatory authorities) and to retain the trial related essential documents as long as necessary. • New text (bullet 2 and 3): Obtain investigator’s agreement. • Discuss monitoring and auditing (allow direct access to all requested trial related records for monitors, auditors and regulatory authorities) and retention of the trial related essential documents as long as necessary. • Minor textual changes
4.0	25-MAR-2020	• Implement minor audit observation in section background • Corrected reference after GCP update R2. • Added reference CTR (536/2014) • Deleted applied forms M02/F2 • Minor updates: - deleted 3.1.1.action 4: prepare indemnity agreement, if applicable

- deleted 3.1.2 action 1: obtain investigator's agreement
- deleted 3.1.3. action 1: the use of essential document checklist
- added 3.1.3 action 6
- deleted 3.2.2 the completion of site monitor log