Site Initiation

Site initiation is the process by which the sponsor is assured that the Principal Investigator as delegated (via agreement) is trained in the protocol and sponsor instructions and everything is in order (supported by evidence) for the site to commence the study.

The requirements for site initiation /investigator training should be considered at the protocol development/funding application stage (so costs can be considered). Sponsor/delegate will assess the requirements for site initiation during the initial/bespoke risk assessment and where this is considered a requirement (as is most likely for clinical trials) this will be documented in study-specific monitoring plan.

Records of initiation including attendance logs, correspondence, what was covered (agenda, slides, documents covered) and reports should be retained in the Study/Trial Master file (S/TMF) and at the relevant sites in the Investigator site File (ISF).

Although a Site Initiation Visit (SIV) is the most common method for initiating sites (and this is mandated for CTIMPs sponsored by a Sponsor/designee partner according to Sponsor/designee's Site Initiation and Activation SOP (Sponsor/designee) other methods of initiation and investigator training are acceptable (the method should be proportionate to the complexities and risk associated with the research) such as joint investigator/training meetings, webinars, teleconference's etc.

For CTIMPs, site initiation visits (SIVs) must take place in accordance with Sponsor/designee Site Initiation and Activation SOP (Sponsor/designee); when contracts and all relevant approvals are in place (REC, CTA and host site approval) and ideally when trial supplies have been sent to sites (study documentation /ISF/data capture tools/IMP etc). Principal Investigator attendance is required; the SIV should not go ahead without confirmation of

his/her attendance. The SIV must be reported (and reviewed) by the Sponsor/designee Sponsor Representative prior to Sponsor/designee issuing (on behalf of sponsor) a study activation notice to site - no study procedures should be undertaken by sites until they have received this is notice.

Site initiation should be conducted by someone who is familiar (trained) in the protocol and all other applicable documents, procedures and the relevant regulatory requirements where applicable.

Site Initiation will usually be the responsibility of the Chief Investigator / dedicated trial manager, however Sponsor/designee may outsource these activities to a third party (such as a CRO or freelance monitor).

The following should be considered for review during site initiation process:

- the protocol (and any amendments)-obtain the Principal Investigator's signature on the protocol signature sheet (where applicable)
- the data capture tools (pCRF/eCRF) – instructions on how to handle and complete
- randomisation procedures and code breaking (if applicable)
- IMP handling, accountability and storage (CTIMPs)
- interactions with internal support department/external departments (e.g. imaging facilities, labs etc.)
- laboratory sample handling procedures including sample storage, processing and despatch
- study supplies and documentation (ISF)
- delegation of responsibilities. The Authorised Delegation Log should be completed as part of the initiation process and signed by the Principal Investigator and a copy collected for the Trial Master File (original should be retained at site in the Investigator Site File (ISF)).
- study timelines, recruitment requirements and strategies

- source document verification procedures and access to source data (source data location logs completed)
- monitoring plan, audit and inspection
- safety and incident reporting procedures
- protocol deviations and reporting non-compliance
- review of facilities and equipment
- close-out, archive and publication

SITE INITIATION CHECKLIST

Study name:

Study code:

EudraCT number:
Sponsor / Investigator:
Name of study site:
Date of initiation visit / phone call:

Before the clinical phase of the trial commences, the quality of the site must be verified by the study monitor through:

1) Site initiation visit or
2) Site initiation phone call

The items listed in this checklist must be discussed with the Principal Investigator. If the visit is conducted through a phone call the Principal Investigator should send study documents to the study monitor for review. By signing "Site initiation checklist" the study monitor ensures that the site quality is appropriate and the clinical phase of the study can be started.

1. APPROVALS AND FAVOURABLE OPINIONS

	Date	Study monitor review
Ethics committee favourable opinion		
REGULATORY AUTHORITY NOTIFICATION		
ORGANISATIONAL APPROVAL		

Approved study documents:	Version number:
▪ Final Study Protocol	
▪ Patient Information Sheet	
▪ Informed Consent Forms	
▪ Other written information to be provided to the subjects	
▪ Advertisement for subject recruitment	
▪ Other, specify: _____	

Comments:

2. STUDY PERSONNEL

The qualification and experience of the Principal Investigator in the therapeutic area must be verified, and a current CV should be available at the site. The qualification and experience of other study personnel should be verified.

Name	Position in the study (PI, co-investigator, study nurse)

3. SITE CONTACT INFORMATION

Address:

Phone numbers:

e-mails:

4. FACILITIES AND EQUIPMENT

Are there adequate facilities and equipment available?

Comments:

5. INVESTIGATIONAL PRODUCT

Please clarify in comment section if the investigational product already has marketing approval in Finland and who supplies the investigational product for the investigator. If the product is imported to Finland for research purposes, who is responsible for the import. Has re

5.1 Name(s) of Investigational Product(s)

5.2 Who is responsible for the IP Import?

5.3 Where is the IP stored?

5.4 ARE THE DISPENSING AND ACCOUNTABILITY PROCEDURES ADEQUATE?

Comments:

6. STUDY PROCEDURES

6.1 Has the informed consent procedure been discussed?

6.2 Have the protocol required procedures been discussed?

6.3 Have the randomisation and unblinding procedures been discussed?	
6.4 ARE THERE ANY WRITTEN SOP'S AVAILABLE?	
Comments:	

7. ADVERSE EVENT REPORTING	
7.1 Have the protocol requirements for AE-reporting been discussed?	
7.2 HAVE SAE- AND SUSAR-REPORTING PROCEDURES BEEN DISCUSSED?	
Comments:	

8. **SOURCE DATA AND CRF**	
8.1 Have the source data requirements been discussed?	
8.2 HAS THE COMPLETION OF CRF'S BEEN DISCUSSED?	
Comments:	

9. INVESTIGATOR'S TRIAL FILE	
9.1 Are the GCP-required essential documents available at the site?	
9.2 HAS THE FILING AND ARCHIVING OF THE STUDY DOCUMENTS BEEN DISCUSSED?	
Comments:	

SIGNATURES

Name of Study Monitor	Date	Signature