Site Initiation Visit (SIV) Guidance
October 2017

Representatives from the ECMC Research Nurse Network Group, Cancer Research UK's Centre for Drug Development, the NCRI CTU Working Group and ECMCs have come together with the aim of improving the quality of Site Initiation Visits (SIVs) conducted by Sponsors. The intention is to produce guidance from the ECMC Research Nurse Network Group on what Research Nurses need at these visits.

The following guidance has been produced to help to ensure that Site Initiation Visits are useful for both the sponsor and site staff involved in the local conduct and management of the trial. This is document contains suggestions for how SIVs should be set-up and managed. The ECMC Programme Office is not endorsing a particular way of running SIVs.

Key Principles for SIVs

- SIVs are most successful when they are held as face to face meetings. *Note 1: This may be difficult for some national multi-centre studies where funding and Trial Manager time is limited.*
- The SIV is an opportunity for the site staff to ask questions on the protocol, in particular on how the trial should be executed
- The SIV is an opportunity for site staff, including pharmacy and pathology to obtain clarity on the procedures and interventions within the protocol to ensure effective trial delivery
- There should be no need to repeat the giving or collecting of information that has previously been done during the set-up process. *Note 2: not everyone at the SIV will have been involved with the set-up so there will be a need to give this information to some people at the SIV. E.g. usually the lead RN will attend the PSV but a more junior RN will attend the SIV and be responsible for the study*
- There should be agreed expectation of behaviour between both sides through a two-way conversation.

Example/Template Agenda

Item	**Notes**	**Time**	**Staff Required**
Background to the study/trial	Ensure the appropriate level of detail tailored to the level of experience of the staff Information on the mechanism of action Reported side effects Study design/objectives		
Patient population	Key eligibility criteria Planned recruitment timeline		

Recruitment procedure	Screening/consent procedure Patient registration/randomisation process Dose escalation process		
Schedule of events/assessments	Trial procedures, in particular those that may be additional to standard care		
How to report SAEs	Medically important events Non-reportable events		
Monitoring requirements	Clear expectations: how is monitoring performed, frequency of visits, level of monitoring etc How will remote monitoring work		
IMP/Pharmacy Management	IMP supply, ordering, storage dispensing, administration, returns, accountability Concomitant medications Prohibited medications		
PK/PD Sampling/Biological sample collection	Processing Shipments		
Data Collection/eCRF Completion	Data entry schedule Brief overview of completion guidelines Data lock process (per patient) / at end of study etc		
Site staff questions	In addition to the opportunity to ask questions throughout the discussion of each item		

Guidance

It is recommended that the sponsor sends the template agenda to their contact at the site prior to the SIV. The site would then update the agenda to show how much time should be allocated to each item and which team members will attend each session based on their knowledge of the trial and their team. The finalised agenda should be confirmed by both the site and sponsor ahead of the SIV to allow for preparation of content for the SIV. *Note 3: conflicting comments on who should complete the initial agenda with content – can the site staff complete the time and team members' information first – without the knowledge of the trial*

Areas for the sponsor to consider when arranging a SIV

- Level of experience and expertise of research staff
- The site study set up team should be consulted when deciding if a research investigator (PI or Co-I) is suitably qualified and only required to attend part of an SIV or the whole session
- Avoid repetition and duplication of information already provided/collected at pre-selection site visit [see Note 2 above]
- Be organised and prepared and arrive with the correct documentation for the SIV as required i.e. delegation logs, training logs, presentation material etc
- A full training session on GCP and definition of Serious Adverse Events is not required at SIV. The Trust are responsible for ensuring their staff are suitably trained to undertake research and adhere to the principles of GCP. Note 3: the sponsor needs to train on how to report SAEs for their trials as the process will be Sponsor specific.
- Level of background information needed, focus more on mechanisms of action
- Awareness of SOP's relating to SIV's in place at site
- Would it be useful to include details of SIV report content?
- How to manage questions not answered during the SIV