Site Qualification Visit Checklist

The purpose of a SQV is to assess whether it is feasible for a site to run a study from the sponsor perspective. You will still need an internal feasibility assessment to discuss the study in much more detail in particular recruitment strategies and targets.

Logistics:

- [ ] Book a room and establish if F2F or virtual.
- [ ] Be prepared to give a tour of your facility including support departments e.g. pharmacy.
- [ ] Ensure you have display screen equipment for SQV slides. If your organisation does not allow encrypted or external devices, request that the slides are sent in advance.
- [ ] Invite appropriate people from relevant departments e.g. pharmacy or radiology, or consider if they will have a separate meeting with the sponsor.
- [ ] Make sure you can accommodate the number of attendees, internally and from the sponsor and/or the CRO and allow for additional guests.

Preparation Needed:

- [ ] Ensure your department is clean and tidy and be aware of confidentiality with departmental documents.
- [ ] Review material provided e.g. protocol synopsis, training slides and compile questions.
- [ ] Check you have equipment required e.g. fridge, freezer, centrifuge and space resource. If not, make a list of what is required.
- [ ] Collate any information about previous sponsor audits or site inspection outcomes.

During the Meeting:

- [ ] Ask the following questions:
  - [ ] What is the status of the study?
  - [ ] What are the study timelines?
  - [ ] What is the expected target?
  - [ ] What is the recruitment period?
  - [ ] Number of UK sites?
  - [ ] Is the protocol finalised? Can amendments be suggested by PI and site staff?
  - [ ] If the study is already open what have the challenges been?
  - [ ] What is the screen failure rate?
- [ ] Identify any equipment that the sponsor will need to provide or fund and who will order them. Ensure this is discussed and clear at an early stage. Do not wait until SIV when the contract will likely have been finalised.
- [ ] Review recruitment strategy.

- [ ] Will they allow PIC sites?
- [ ] What support do you need from the sponsor e.g. what advertising materials are provided? Is there the opportunity to suggest alterations?

- [ ] Ask when the sponsor will inform the site if they have been selected or not.

After the Meeting:

- [ ] Follow up with any actions.
- [ ] Be prepared to provide documentation such as GCP certificates, CV's, calibration certificates, FDF and a contact list of staff.
- [ ] If you are not selected as a site, remember to ask for feedback.

Site Initiation Visit Checklist

The sponsor run the SIV, however the lead site staff can utilise this opportunity to ask any remaining queries regarding the protocol and identify any outstanding requirements.

Logistics:

- ☐ Book a room and establish if F2F or virtual.
- ☐ Ensure you have display screen equipment for SIV slides. If your organisation does not allow encrypted or external devices, request that the slides are sent in advance.
- ☐ Invite all staff who will be working on the study. If they are not available they can review the slides after the event. Best practice would be to book SIV when all key site staff are available. The PI may only be needed for part of the meeting.
- ☐ Invite appropriate people from support departments e.g. pharmacy or radiology and consider if they will have a separate meeting with the sponsor.
- ☐ Make sure you can accommodate the number of attendees internally and from the sponsor/CRO. Be prepared for additional external staff to attend.
- ☐ Some SIVs can last the full working day. Ensure you are clear on how long the meeting is meant to be and ensure you are aware of lunch arrangements i.e. is the sponsor providing or funding.

During the Meeting:

- ☐ Complete the SIV attendance log or send a list of attendees to the CRA.
- ☐ Circulate the delegation log if not already completed.
- ☐ Raise any queries about missing equipment, documents etc.
- ☐ Review inclusion and exclusion criteria.
- ☐ Source document review - Agree what documents are source and what electronic systems the monitors will need access to.
- ☐ Decide who will be reviewing the safety reports.

After the meeting:

- ☐ Record the SIV training on the finance tracker so it can be invoiced.
- ☐ Put a plan in place for screening the first participant.
- ☐ Review the participant recruitment pathway.
- ☐ Consider a dummy run especially if numerous support departments are involved.
- ☐ Request any amendments to the contract that are identified.
- ☐ Make worksheets if not already prepared at this point.

Thank you to Patient Recruitment Centre: Leicester for providing this content

Version 1 - March 2023