cCOG Guidance on performing successful Site Initiation Visits

05 December 2017

Commercial Clinical Operations Group

Who is this guidance for…

- This guidance has been produced based on feedback from:
  - the review of SIVs at the NHS Tayside Board to optimise the current practice
  - a separate review by cCOG of industry practice

- It acts as a supportive guidance for:
  - CRAs & Local Project Managers
  - CRA Line Managers
  - Investigator Sites

cCOG
Commercial Clinical Operations Group

What are the potential benefits…

- **Better, more effective, more engaging SIVs**
- **Less protocol deviations**
- **Cleaner data**
- **Better recruitment**
- **Greater efficiencies across the whole trial** – less time spent on issue resolution

cCOG
Commercial Clinical Operations Group

What are we proposing as guidance…

- **SIV after Regulatory Green Light** (or as close as possible to RGL) – this has several major benefits around more effective training & learning, enthusiasm around the study, and a potential for improved study recruitment
- **Use common sense** – document decisions which are not the norm
- **Review feasibility prior to SIV**:
  - What questions did the site(s) have
  - What were the areas of concern
  - Did the PI help write the protocol…
- **Keep the SIV on-track** – start on time and finish on time.
- **Well produced slides** – don't replicate the Investigator Meeting

Commercial Clinical Operations Group

What are we proposing as guidance…

- **Documented review of the SIV slide-deck** – not just a tick box exercise, justification as to why slides are included
- **Allow more time for discussion** – gauge understanding and raise points / areas not previously ventured before
- **Ensure sufficient time is confirmed with attendees prior to the SIV** – adequate time with each individual, not squashed / abbreviated to fit timings
- **Review your training materials ahead of time** – know your subject matter and brainstorm potential questions with other CRAs / PM etc
- **More online / web training prior to SIV** (especially vendor info/training) – the actual SIV should be more of a discussion / run through of operations / potential issues prior to study start

CCOG
Commercial Clinical Operations Group

What are we proposing as guidance…

- **Feedback** – ask the Chief Investigator to review the training slide-set
- Take **ownership** of the SIV
- Ensure you **include in the SIV**:
  - **The entire site staff**
  - **The local network** (NIHR, NRS, HCRW, NICRN) including Industry Operations Manager (where applicable)
  - **R&D**
  - **Supporting functions** - Pharmacy, Local Labs, Radiology, Records etc
- **Keep the SIV on-track** - start on time and finish on time

cCOG
Commercial Clinical Operations Group

What are we proposing as guidance…

- **Use as much hands-on training as possible** - most effective training
- **Analyse and review the session as you go** - be on the lookout for what works best. When you discover a new method that engages the group better, note it on your training materials so it can be incorporated into the training outline to be used in future sessions
- **Solicit feedback on the SIV** - critiques work best when they are written and anonymous

cCOG
Commercial Clinical Operations Group

Feedback

Please provide us with any feedback you have on this guidance to commercialcog@outlook.com

Any additions or changes you provide will be reviewed and guidance re-issued, where applicable

Many thanks

cCOG
Commercial Clinical Operations Group