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Guidance on performing successful Site Initiation Visits

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Who is the 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 (Pharma & CRO)

It acts as a supportive guidance for:

- CRAs & Project Managers
- CRA Line Managers
- Investigator Sites

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

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 against the norm
- Review site feasibility prior to SIV:
    - What questions did the site(s) have
    - What were the areas of concern
    - Did the PI help write the protocol – adapt as appropriate
- Well produced slides – don't replicate the Investigator Meeting
- Documented review of the SIV slide-deck – not just a tick box exercise, justification as to why slides are included

What are we proposing as guidance? cont...

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

- 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
- 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
- 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

What are the desired outcomes of this guidance?

- Smarter, more effective, more engaging SIVs
- Reduction in protocol deviations
- Improvement in data quality
- Increased / more efficient recruitment
- Greater efficiencies across the whole trial – less time spent on issue resolution