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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, Health and Care Research Wales, 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