



Centre for Healthcare Randomised Trials

Essentials of Clinical Trial Management: Effective Study and Site Specific Training

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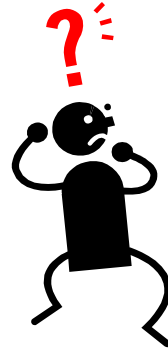
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The author accepts full responsibility for this talk.



Background

- Welcome to your new role
-now if you can just get 20 sites set up in 6 months.....
- Even better... if you could manage that within 3 months...





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- **Vault or Uterine prolapse surgery Evaluation**
 - **Randomised controlled, multi-centre pragmatic surgical trial**
 - **Funded by a 'rapid call' funding process**
 - **Timelines to set up, start, complete recruitment, and reporting substantially accelerated**
 - **Sister trial – PROSPECT**
 - **35 sites involved**
 - **High recruitment rates**
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- **Most PROSPECT sites agreed to participate in VUE**
 - **Recruit / randomise 2 participants per month**
 - **44 UK sites currently recruiting**
 - **Investigators' Day**
 - **70 attendees / 30 sites**
 - **Follow-up local site visits / Site initiation visits for those unable to attend**
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Training Research Sites

- GCP and research governance guidelines: study personnel should be 'qualified by education, training and experience'
- Training should be proportionate and tailored to the specific needs of the site/study personnel

Training Methods

- On site, centre specific Site Visit / Site Initiation Visit (SV/SIV)
- Central, multi-centre Investigator Meeting (IM)
- Regional, multi-centre Investigator Meetings
- Teleconference / Videoconference
- Online / Webinar

Investigators' Meeting

- Comprehensive overview and training for all sites
 - Standardisation of training across multiple sites
 - Collaboration between sites encouraged
 - Feedback / tips from collaborators
 - Parallel sessions
 - Allows central focus (for a whole day) on the trial
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Feedback

Investigator meetings are essential to get the whole team together to educate everyone at the same time to the protocol and to have the opportunity to learn from your colleagues and ask questions face to face.

I think it's a good idea to have the opportunity for individual questions but a good idea for the team to be together at the same time to discuss relevant points or identify potential problems.

...you get to meet other people who are going to be involved with the study and I think it gives you more of an understanding of the study.

Site Visit

- **Site specific**
- **Pragmatic organisation of trial within site**
- **Opportunity to problem solve local issues**
- **Spend time one-to-one with site staff**
- **Clearer idea of local practices/working environment / relationships**

Feedback

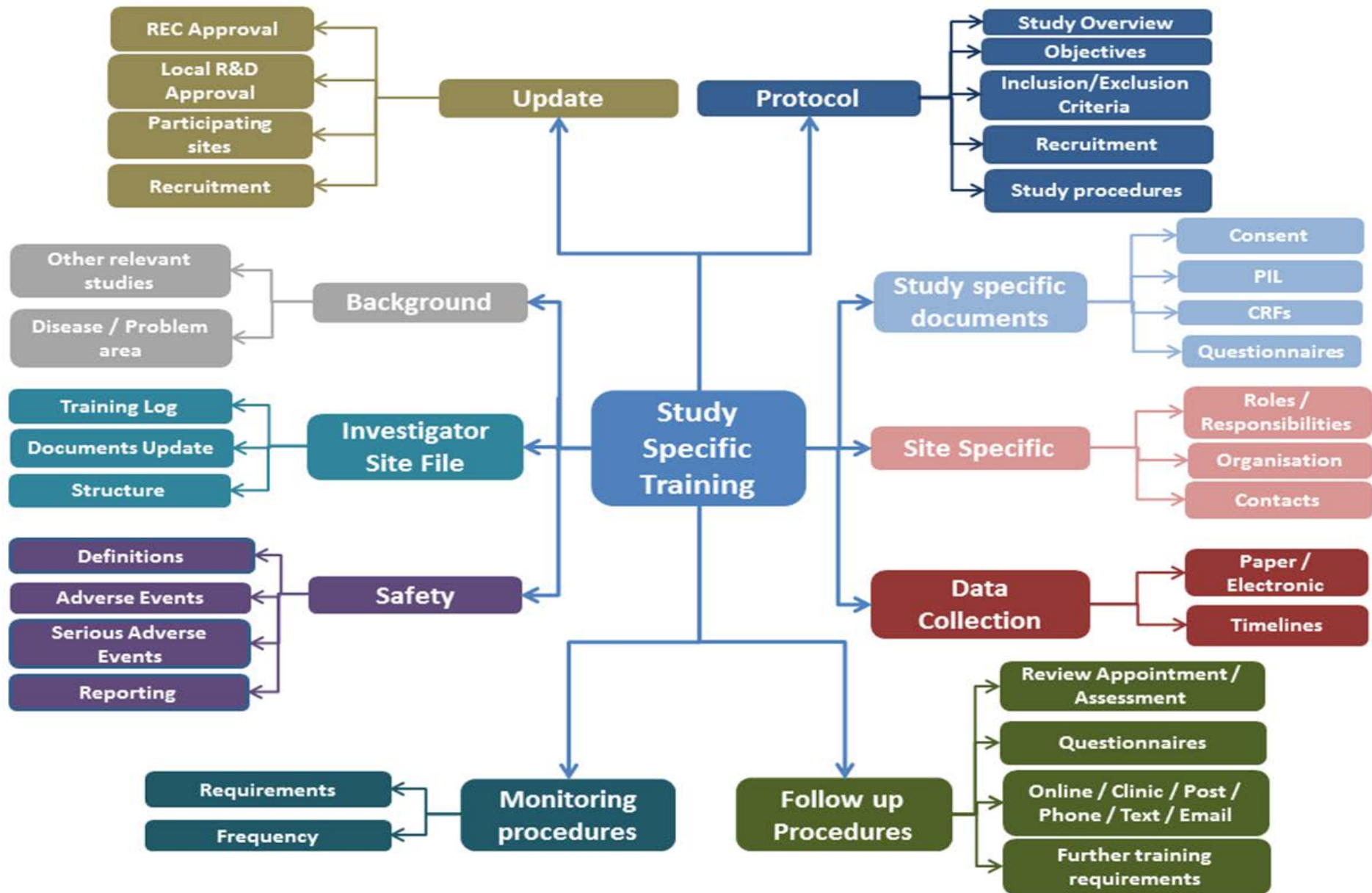
I felt the one to one training was more useful as I was able to relate specifically to my locality and ask relevant questions when they arose. I think in a bigger forum this opportunity may have been lost.

I do feel more comfortable asking questions in smaller groups.

very beneficial... you get more specific training suited just for you.

...allows you to get to know the trial co-ordinator and also to ask any 'silly' questions.

Training



Training Packs

- Training presentation
- Flow diagram
- Clinical guides
- Consent form guidelines
- Paperwork / PIL / CRFs
- Randomisation labels
- Delegation log
- Clinic poster

Training Packs

Very comprehensive, particularly the laminated flow diagram / study definitions.

...helpful and enabled me to gain better understanding of surgical procedures and process of trial.

Found them very useful and great training aid for new staff.

I like these a lot very useful and informative.

Excellent reference

Schematic Training Aids

- Don't underestimate the power of a laminate!
- Can be used in clinics / offices as reference tools
- More likely to be retained by site
- Useful in times of staff change over

Ongoing Training

- Regular meetings/ teleconferences/ emails/ newsletters to update sites on recent events
- Updates on 'Study News' web pages
 - » FAQs
 - » Discussion forum
 - » Training aids available to download
- Collaboration is key
- Update training slides / aids as trial progresses

Training Certificate

...useful for records (part of study documents and personal).

Yes, especially in view of emphasis on GCP etc. in research recently.

It is nice to get a certificate of training as it helps with evidence of PREP, as a nurse.

PREP – post-registration education and practice

Training Feedback

The regular teleconferences are excellent and allow us to keep up to date and address any queries we may have with the trial.

Liked the separate nurse /doctor sessions.

I enjoyed meeting the trial manager and felt able to ask any questions, whether they seemed silly. I enjoyed learning about how the study would run/work and hearing of tips with recruitment strategies.

Training was informal, which always facilitates communication and productivity.

Very informal, felt confident to ask questions. Felt confident to start recruitment following this.

Conclusions

- Training is a collaborative effort
- In person training visits followed by regular teleconferences / updates / emails / newsletters to ensure training is up to date
- Informal in nature, but comprehensive in terms of material covered
- Laminated flow diagrams / training aids
- Training packs and certificates particularly well received

Questions

Thank you!

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