Working With Investigators to Implement EDC: listening to their needs and perspectives to smooth the path to regulatory approval.

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Having keen and interested investigators in your study is essential to its success. Their first interest is to the patients, second is to the research and last probably is their interest in filling out our Case Record Forms (CRFs). Now imagine PharmaCo. asks him or her to participate in a study and asks for data to be provided electronically through the new eCRF or other data capture methods. A whole range of emotions will be generated depending on their love or hate of technology and their previous experiences or even due to good or bad rumours from colleagues and acquaintances. If PharmaCo does not recognise and take account of these emotions the success of the trial will be at best less than optimum and at worst a breach of GCP with the consequences that may follow.

Investigators do not want a straight copy of the paper CRF. This takes longer to fill in and provides no incentive to be timely. It is not simpler to complete an eCRF. There is nothing as simple as pen and paper. But “increased availability, improved legibility, long-term accessibility, (potentially) greater completeness, data encoding, and automated decision support and analysis” are some of the benefits that investigators have themselves identified as desirable. If these can be built into the system then timely completion becomes beneficial. The real benefit however is later, and because it is a kind of "benefit by absence", it is more difficult to sell. Less annoying queries long after the patient has left the study. It is difficult to see something that isn't there, so come with real examples of how much time other investigators have saved. Try and find some reference investigators who are happy to vouch for the saving.

Training in any computer system is often put into the project plan as an add on not an integral part. Training must be part of the planning and should be given its own focused team. Training should where possible be done on site in order to train not just the investigator but the other site staff who will be involved. And definitely don't put training in as the last hour of the investigators' meeting on a Friday afternoon because it won't be effective. A good user manual is essential if you want to cut down on your CRA or helpdesk calls. With correct training and a good manual the investigator should be comfortable with the system before the first patient comes through the door.

There is only one way to see the practical implications of implementing EDC at a site and that is to be there and experience it. What is the investigators office like? What is their work routine? Who else will be on the study and what do they know about computers? Is the investigator collecting data into any other systems that will mean a duplication? The CRA or another member of the study team should consider all these points in the initial site visits and asses them for suitability to an EDC based study as part of the site selection process. Finding out that you have a large number of sites where EDC is just not appropriate will slow the study down and mean a lot of extra work.

There will be several levels of problems each requiring a different support function. The investigator does not want to have to call from one person to another, be put on hold or be made to feel incompetent. Once central number that can handle all queries and get back to the

investigator within an "acceptable" length of time with an answer or at least information that the investigator is happy with is extremely beneficial. Whether you choose the CRA. an independent call centre or other solution is not important as long as the investigator gets the answer that he or she wants when they expect it. And that the problem is resolved before it causes more work. At the end of the day, if the investigator is not pleased with the system or service you may need to look at alternatives for data capture and that may be CRA based data entry.

Real time feed back is a way of engaging the investigators. Show them that the quick return of the data of high quality is giving results for the study progress. Plots of patient inclusion and other key statistics can be built into reports sent regularly as data comes in. Generating a feeling of involvement and achievement will generate higher compliance. Let them know that that through their efforts the database was locked quicker than it otherwise would have been and there is the potential to get a new drug onto the market quicker. Most of all, remember to say thank you. Two words that mean a great deal.

Because you will expend proportionately more time preparing centres and investigators with an EDC based study it makes sense to try and "re-use" the sites and investigators where possible. Generate a list of compliant centres with low error rates and quick return times. Study setup and completion times will be reduced by doing this.

Investigators ask for EDC when you contact them about a study. Investigators do like most of the EDC products they try. They do want to use them again after an initial try. The benefits are in the system, not in the product. The system being the whole process, technology and people involved. Making all these function together is no easy task but achieving it will provide happy investigators and happy investigators will prove good data quickly.

Short Biography

Andy has a Master's Degree in applied computing with his dissertation being a comparison of paper versus EDC methods of data collection in clinical trials. He has worked 10 years in applied computing, the last six in clinical R&D. During this time he has worked with diverse developments from Clinical Trial Management systems, imagine processing systems, Intranet applications and of course EDC initiatives.

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Introduction

- Understanding Investigators!
- Training
- Practical implications
- Support services
- Demonstrating results
- Re-using investigators

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Understanding Investigators!

- First they are doctors treating patients
- Second they are interested in research
- ……
- Last they are interested in filling out CRFs either paper or electronic.
- Explain the benefits clearly - with proven examples

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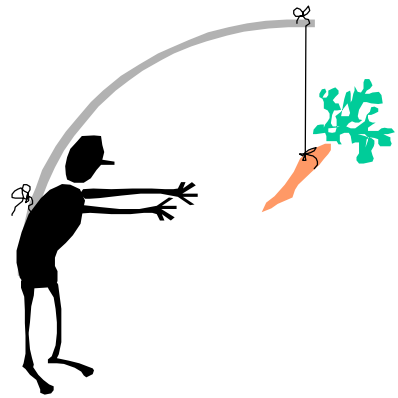
What are the benefits to the Investigator?



- Must provide a perceived benefit
  - not just electronic copy of paper entry
- Not saving time now
- Not simplicity
- BUT - "increased availability, improved legibility, long-term accessibility, (potentially) greater completeness, data encoding, and automated decision support and analysis"
- Saving time later

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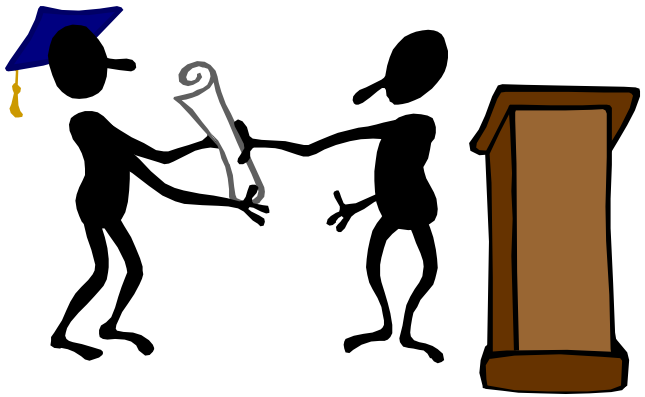
Training



- Right from the start - not just an add on
- Repeat if necessary
  - "Train train and train us…" *Heather Smith*
- Training time will be repaid many-fold later in the study
- Produce a good user manual specific for the study.

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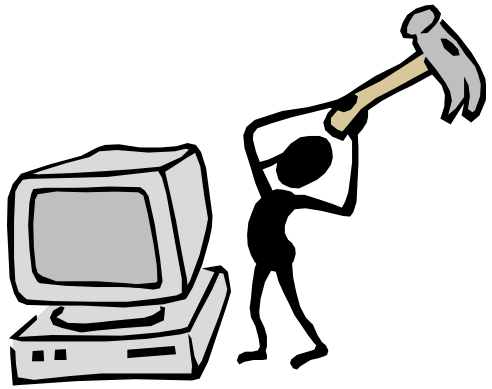
Practical Implications



- Consider the investigator's & other staff's routines
- Consider other data collection requirements at the site
- Consider investigators computer literacy and competence
- Consider the Investigator!

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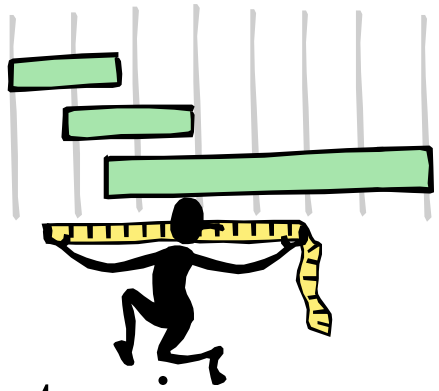
Support Services

- Protocol support - built in?
- Technical support
  - first line - CRA
  - second line - Helpdesk
- No question is too stupid
- CRA data entry if all goes wrong or the investigator decides not to do it?!

Demonstrating Results



- Feedback on how the investigator is doing
  - Quality
  - Response time
  - Study progress
- Show that there are less errors (DCFs)
- Show that the database was locked quicker
- Say thanks!

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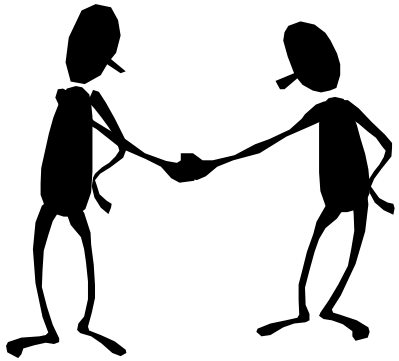
Re-using Investigators



- Saving on training
- Quick compliance with systems
- Many investigators want to use it again

- Especially if ***they*** saw the benefits first time.

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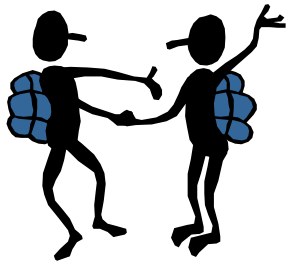
Conclusions



- Investigators like EDC
- EDC is not just a replacement of paper
- The benefit is “systemic”
- The benefit is there for both sponsor and investigator
- You need to consider the investigator at every stage of the process

QUESTIONS?