Future Perspectives in Clinical Data Management

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According to figures of usage, expected usage and effective usage of new technology in clinical trials, only approximately 5% of current studies collect data electronically, despite over 10 years of in-house dry runs, pilots, scale ups and the like.

One must ask the question; is there really a problem, would we not have found a solution sooner if there was? Is the paper based system of collecting data really so bad? That depends on your definition of bad and your expectations of what would be an improvement. Designing, distributing and collecting paper CRFs is relatively simple and can, with the right incentives, function well. The part that doesn't function so well is completion and checking of the forms and later, data entry of the forms. It is at these stages that errors are generated, errors that must be removed before the data can be used. The problems seen from different people's viewpoints could be; seen from the CRA's view, too many errors made by the investigator. Seen from the data entry staff, CRAs don't remove enough errors. Seen from the data manager, data entry generates even more errors. Seen from management, data entry uses too many resources and data management don't process the data quick enough. Finally seen from the investigator's view, data management send too many DRFs! Depending on where you sit, you may see a different problem and therefore a different solution.

Relatively simple solutions can include colour coded CRFs for assisting the CRAs in spotting data that cannot be left missing. CRFs designed to be read by a computer scanner, also colour coded to reduce missing data and speed data entry. The cost of these changes in terms of both money and process change is far less than the more advanced alternatives such as Remote Data Entry (RDE) or Direct Data Capture (DDC). The benefit, depending on the size of the study and the effectiveness of your CRAs, can be high making the benefit/cost ratio high. However, the reality of many studies is that far too many errors escape detection and end up listed on the DRF back to the investigator, causing wasted time and money.

Removing the errors as close to their creation will provide maximum benefit, although the cost will also be higher when looked at in isolation. Removing errors earlier requires Electronic Data Capture (EDC) in the clinic. Remote Data Entry has been the most tried solution and the most failed. The computer applications have now achieved a level of acceptability and familiarity but it is the implementation process and the processes required for their use that still cause problems.

The data manager will need to hold a watchful eye on the external environment within the health service, which at the same time as we struggle to adapt, are themselves running full speed into the new world. Electronic Patient Records (EPR) are becoming more common in private practice and the national health services. EPRs are forcing a rethink in the data capture and storage at our data providers, which will inevitably affect our future. Computer can talk to computer and exchange data far more efficiently than their human counterparts. This is the idea of Direct Data Capture (DDC). The information once captured in one place on either paper CRF or eCRF will now be stored and arriving at the sponsor site through many different channels. Managing this data flow will be what the "Manager" in Clinical Data Manager will mean. In order to make this happen we need to drop the paradigm of the CRF containing all the information on the patient during their time as a subject in a clinical trial and think of the vCRF, the virtual CRF, with its information spread around the multitude of data providing systems. We need to concentrate on issues of standardisation, security and validation and most of all do it in harmony with our partners in the health care domain.

One of the biggest problems is that the clinical R&D organisation and understanding within pharmaceutical companies has not changed to accept technology as part of the process. Remote Data Entry was merely a electronic version of the paper CRF and therefore did not embody many of the benefits of the technology. Data Management in the future will be about identifying the best ways to use the current technologies, not even new technologies, but those that have been with us a while, for instance, Internet. The data manager will be a technology manager within the trial team. Much less time will be used removing errors manually, instead the time will be used setting up the technology to remove the errors and then overcoming the challenges of organisational reformation, standardisation, validation and security that must accompany the changes.

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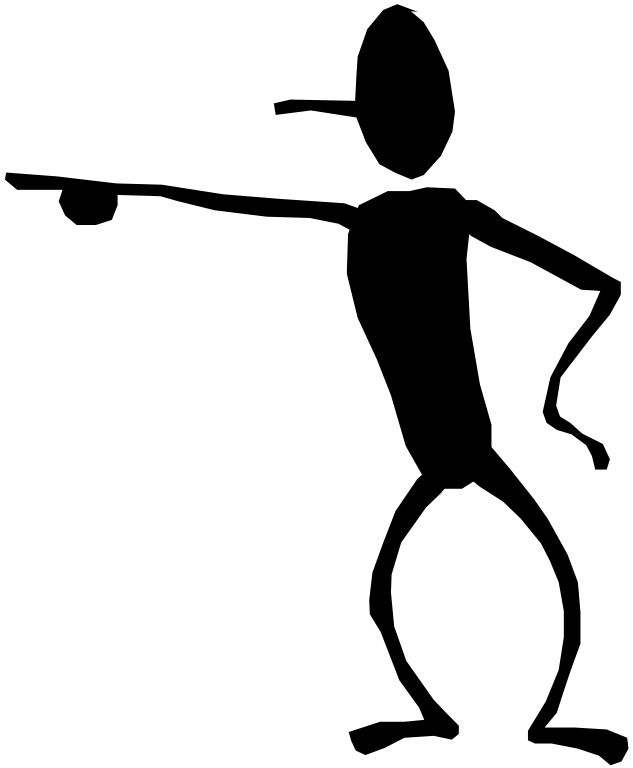
Introduction

- The reality of traditional RDE
- Scanning (OMR/OCR/ICR)
- Distributed data collection, Direct Data Collection (DDC) and virtual CRFs
- The new process
- The new Data Manager role
- Site Management Organisations (SMO) and Data Management Organisations (DMO)



The Reality of Traditional RDE

- What is traditional RDE?
- Investigators will fill in the eCRF!
- Multiple studies - multiple machines.
- Non-open solutions
- Changing CRFs during inclusion
- Communications links - not so simple.
- Data entry duplication - EPR/EHR.

Scanning (OMR/OCR/ICR)

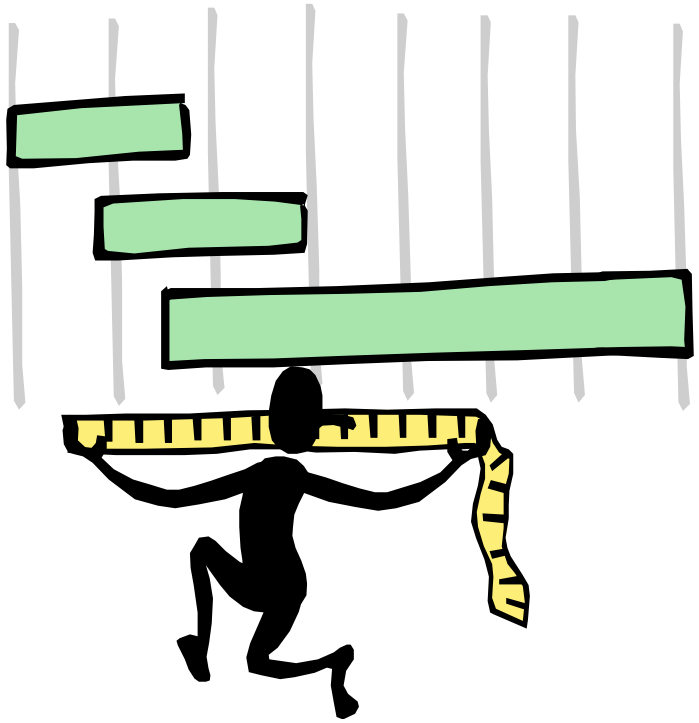
- "Simple" technology
- Low error rates
  - OMR - nearly 100%
  - OCR - 95%-99.xxx%
  - ICR - Well……
- CRF design change
- Careful training
- Can lower Investigator errors due to simplified CRF
- Still need the DRF loop
- Not a big change for Data Management

DDC and vCRFs

- Distributed data capture
- Different sources different capture technologies
  - Scanning for simple forms
  - RDE for controlled environments
  - DDC for machine based sources
  - Patient/Subject data entry
  - Smart cards
  - Body computer
  - Internet
  - Voice
- A virtual CRF - the new paradigm
- Big change for Data Management

The New Process

- Get to know the study site
  - Re-use of sites saves time
- Identify the data sources early
- Plan and test the capture
- Data Control routines must be complete before data is received
- Help desk setup
- A new type of CRA
- A new type of Data Manager

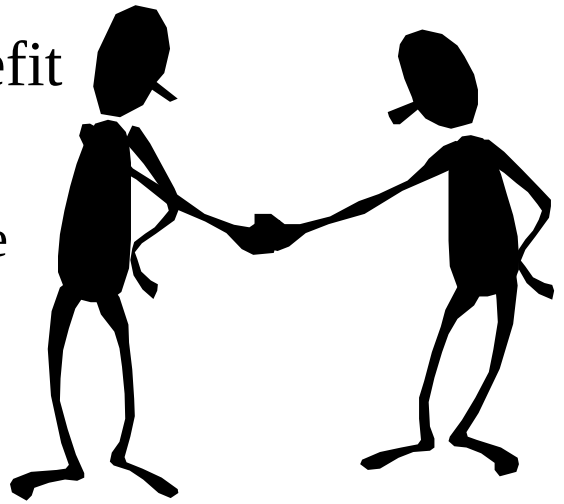


The New Data Manager

- Information and communication technology skills
- Technology integration skills
- Overall view of the study plan and sources of data
  - Participate in site initiation visit
- Technology CRA
- Technology advisor to Study Team
- Systemic and Systematic

SMOs and DMOs

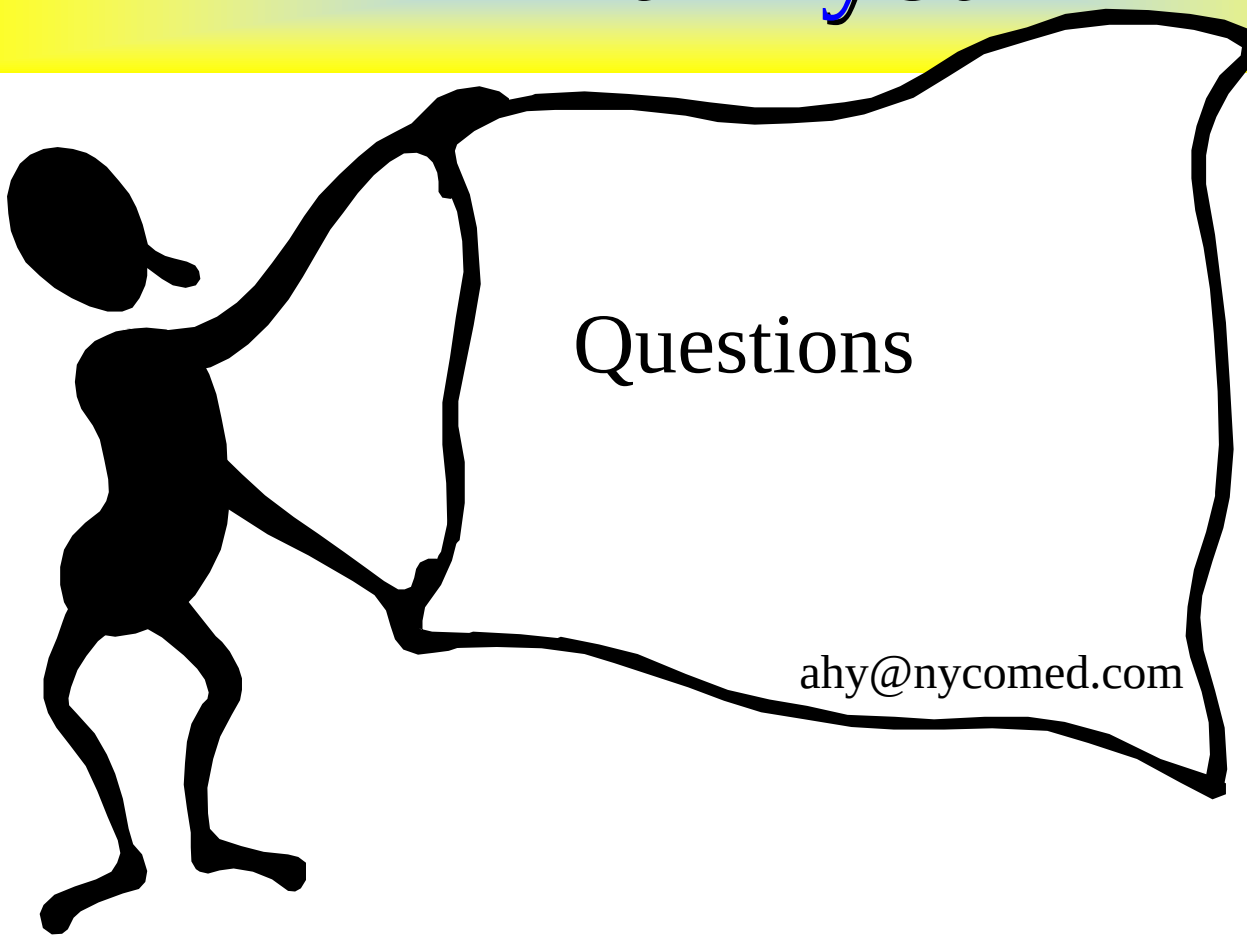
- Growing need for close co-operation with sites
- Re-use of study sites now of greater benefit
- Investigators don’t need to enter data
  - BUT queries resolved by SMO staff at source before data are sent
- DMOs are half way between CROs and SMOs
  - Pharmaceutical and Heath Care Technology specialists for data capture where technology and data capture is the core business



Conclusions

- Traditional RDE has not and will not deliver on expectations
- RDE will be part of a distributed solution involving :
  - DDC, RDE, Internet, Scanning, Patient data collection, Voice, etc…...
  - Future technologies integrated to the vCRF
- Data Management and the whole R&D process will change
- Technology is not “Core Business” and will therefore be outsourced

Thank you



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