Controlling Risk Within EDC: how to manage it effectively.

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Electronic Data Capture like any new technology is an inherently risky investment. Change of any sort brings with it uncertainty and new challenges for both the organisation and the people in it but properly managed these risks can be controlled.

First however one must know what to do about risk. The first thing is to recognise that it is there and it won't just go away on its own. Recognising the risks requires one to be a little pessimistic and think what is the worst thing that can happen to me, my company, and all those involved - in clinical trials this especially means the patients. Having recognised the risks you have to accept that they really might happen. Things will go wrong and always at the worst time. Finally having accepted the risks as real you can work out a management strategy for each one such as lower the risk, transfer the risk, protect yourself against the risk. Risk management is a large area of its own.

What are the risks in a Clinical Trial? The primary risk to any trial is that for some reason it fails to meet its objectives and cannot be used for the purpose for which it was intended. From the technologists point of view, their is a risk that the technology fails to meet the expectations placed upon it.

The risks that the trial fails to meet its objectives are based on the ethical aspects of all trials set down by the authorities. The risk to patient confidentiality with new technology solutions is in some ways lower than with paper because a computer can be protected by passwords and computer disks cannot be read in the same way as the written word. But there are other risks from people in computer world for whom "hacking" is a hobby. Most are non malicious but there are some hackers who would gladly use the information hacked if the chance arose. The risk that data can be changed after it has been entered are higher on a computer than on paper. A change on paper can be detected relatively easily but on a computer an unauthorised change in an unaudited system can go easily undetected. The risk that data can be lost is greater on a computer than paper. Letters do not fall of a page but files can disappear from a disk or become corrupted. A computer is much more likely to be stolen than paper CRFs. Some systems for EDC make it difficult to change the database and entry forms after data has started to be entered. This is less true now than in earlier systems but it should be considered if you are planning an in-house system.

The way to manage these risks is to implement access logging and audit trails for all data items however they are accessed. All computer equipment that is used in the handling of clinical data is required to be validated to demonstrate that it functions according to requirements. It is best to do this on-site and with the end users. Security procedures and training should also be validated. An audit of the system should be conducted after the first study using the new technology to ensure that it has functioned according to its requirements. Clear routines for data backup must be implemented and tested. Most of all it is an idea to discuss any high risk aspects with the authority to which a submission will be made to ensure that they will not refuse the file because of the EDC system.

The risks of the technology failing to meet the expectations placed on it is a two sided coin. The technology may indeed fail to function but the other side is that expectations may be too high or not be managed correctly throughout the project. This latter risk is commonly identified as the major reason for the perceived failure of many IT projects. Some of the expectations placed on the EDC system include a reduction in trial duration, higher quality of returned data and a reduction in resource use.

The level of risk in these areas is directly proportional to the level of expectation. If you expect to save 50% of resources and complete the

trial in 50% of the time you may be disappointed, especially at the first attempt. Not all trials will benefit from the application of EDC. In project management there is a term “Critical Path” meaning the set of activities that if the duration is increased will move the final milestone. There are always activities not on the critical path and these have a flexibility called the “float”. To compare this with a sequence of trials for a file submission the pivotal Phase I, II, and III trials will probably form the critical path. Shortening any one of them or extending will move the submission date. But there are often supporting studies that are not critical, they can float in time. Applying EDC to these trials most likely will not achieve the bigger goal of submitting earlier. The resource saving potential has to my knowledge never been calculated and presented. Savings on data entry and error correction can be substantial. Setting up the study can take longer because all error checks need to be built into the system before it is implemented. Exactly how to implement the error checks in the system is as much a matter of psychology as it is data management. The risk of annoying the Investigator with too many of the wrong type of check has been shown to be quite high.

To reduce the risk of delaying the study setup and rethinking the error checks for each trial it is essential to build up a library of error checks and evaluate the effect of them at the end of each study.

Technology failure is nothing new and it can almost be listed not as a risk but a certainty. The more computers with all their software in so many environments with so many different types of user make it impossible to avoid some technological breakdown. Just to list a few things: Unrecoverable data, hardware crash, software crash, machine theft, Investigator plays games on the PC, Virus - the list goes on.

The only way to manage this risk is to create a disaster recovery plan and formalise it so that everybody involved knows what is in it and where it is. Have a backup machine ready to be sent by courier to the centre. Backup all the data and the system. Have a helpdesk available at all times when the EDC system is likely to be used, 24 hours a day if it is a multi-continental trial.

Change in itself is a risk. It brings with it a measure of uncertainty and managing change is essential. The risks to the trial and the technology usage can be compounded by negative social inertia. People who will try and de-rail the change if they perceive it as bad. Most people want things to be better but everybody has a different view on what better means. Investigators like the new technology, over 90% of Investigators in a survey said, for those that have used it, that it was better than paper CRFs and for those that have not used it, they think it will be better than paper CRFs for recording data. Monitors say they welcome it. CDMs are not so sure. This hits at the centre of their domain. Managers traditionally don’t know about it and need to be encouraged to become involved.

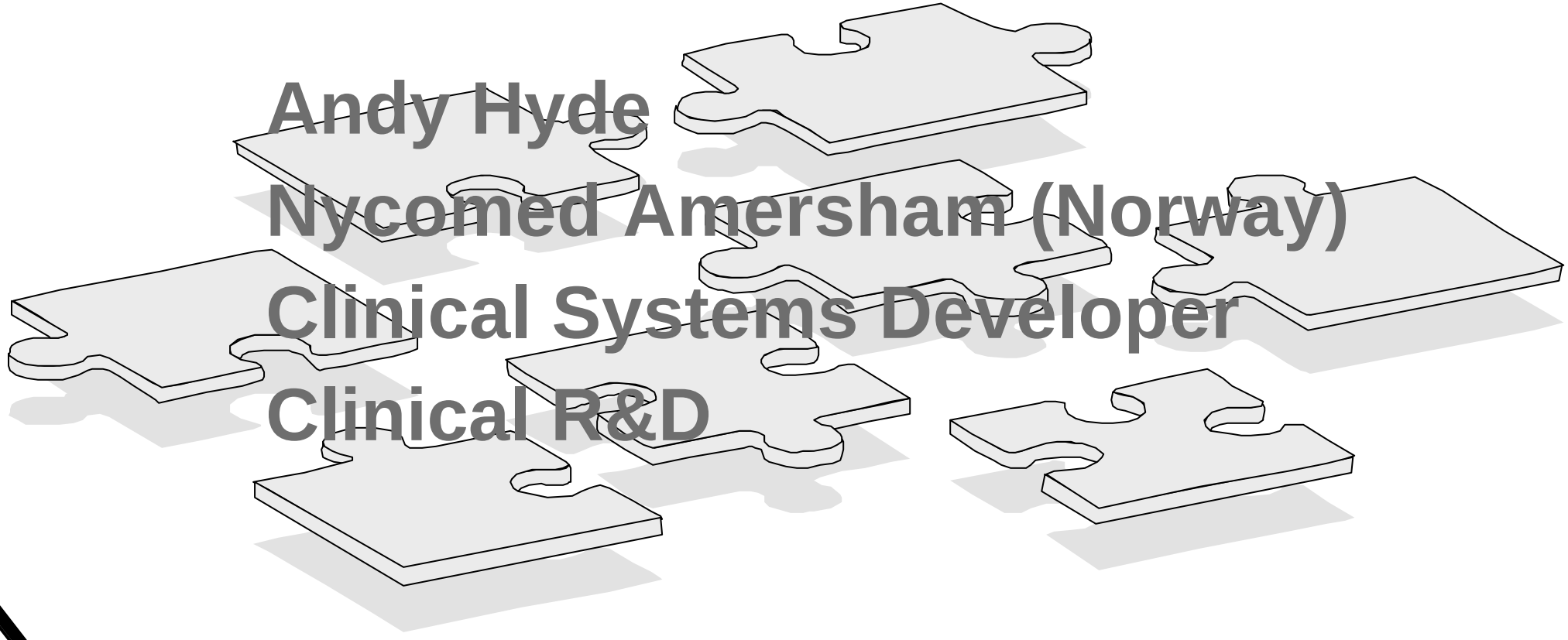
To manage this high risk is to understand change management techniques and user-centred system design methodologies. Systems Thinking provides a good platform for change management and the discipline of Human-Computer Interaction (HCI) provides a good platform for user-centred design.

Financial risk in any new venture is high. Cost/benefit of new technology projects has never really been successfully analysed. One thing is sure is that the hidden benefits and hidden costs in terms of the individual being affected should not be forgotten or underestimated. The hard costs and benefits in terms of money and time are only half of the full picture.

EDC is and can be successful. It can reduce cycle times, reduce the number of errors returned in the data and save resources but it can also do the opposite - extend trial durations, increase the errors and use more resources. By identifying, accepting and managing the risks properly and professionally projects will succeed.

IMAGING

Controlling Risk Within EDC: how to manage it effectively



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Managing risk is :-

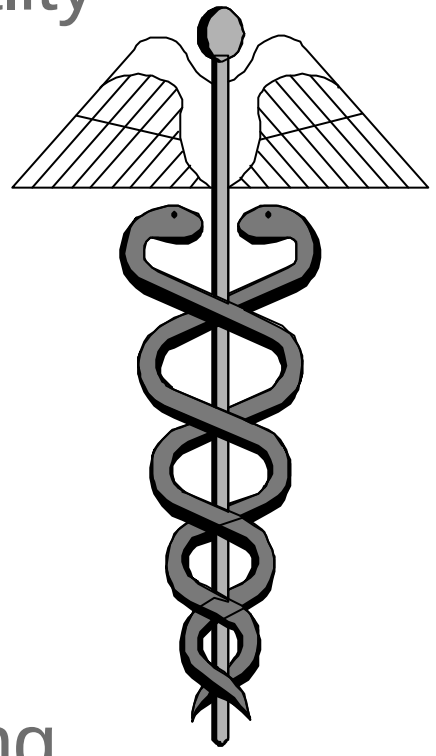
What are the risks?

- Failure of the clinical trial to meet its objectives

- Failure of the EDC system to meet expectations

Failure of the Clinical Trial to meet its objectives

- Requirements for patient confidentiality
- Requirements for data access
- Requirements for audit trails
- System Validation/Audit
- Loss of data
- Change in protocol/CRF



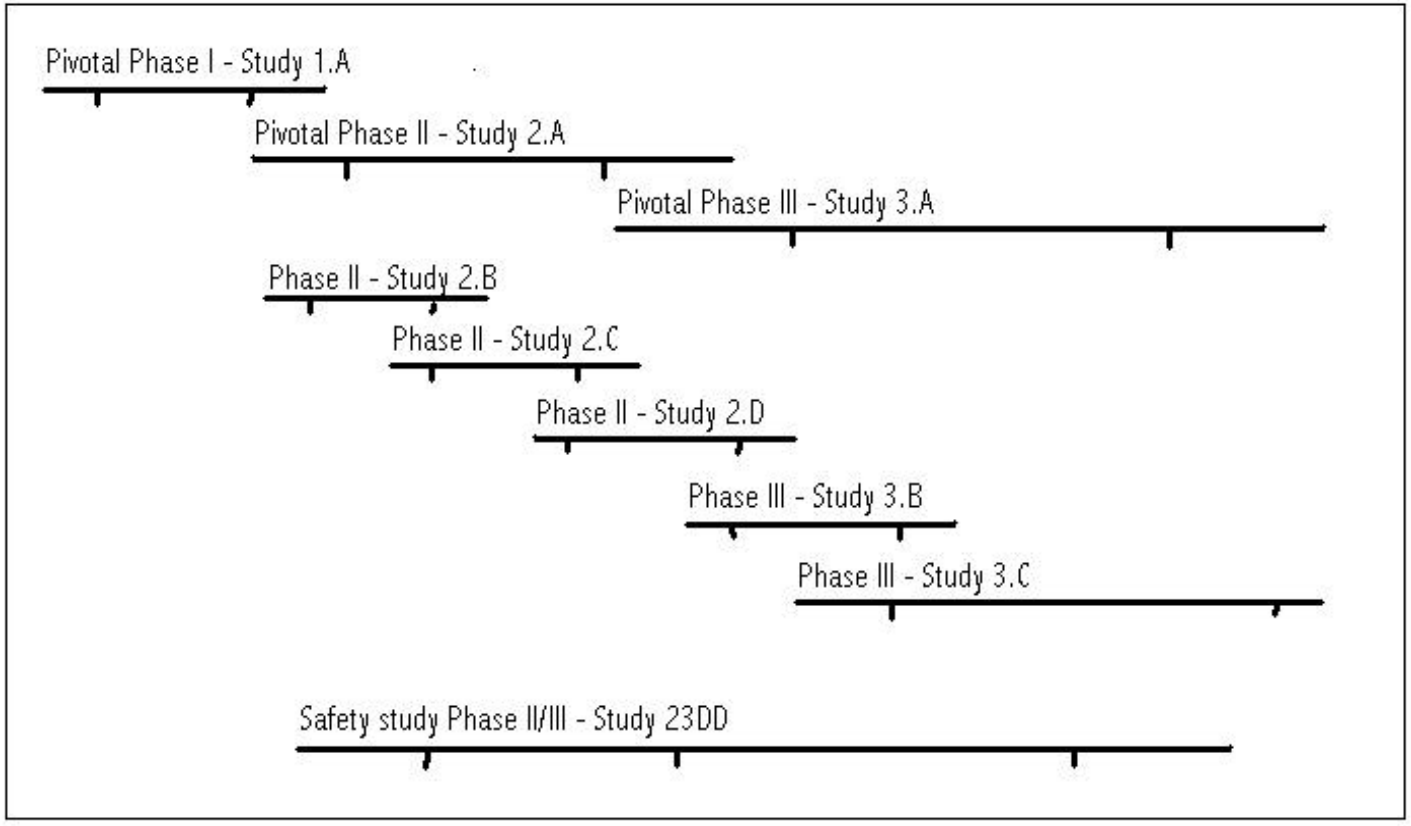
✓ Discuss with authorities before starting

Failure of the EDC system to meet expectations - what expectations?

- Reduction in trial duration
- Higher quality of returned data
- Reduction in data management resources
- Technology failure
- Acceptance of change
- Cost/benefit

Reduction in trial duration

- Less benefit on non "Pivotal" trials.

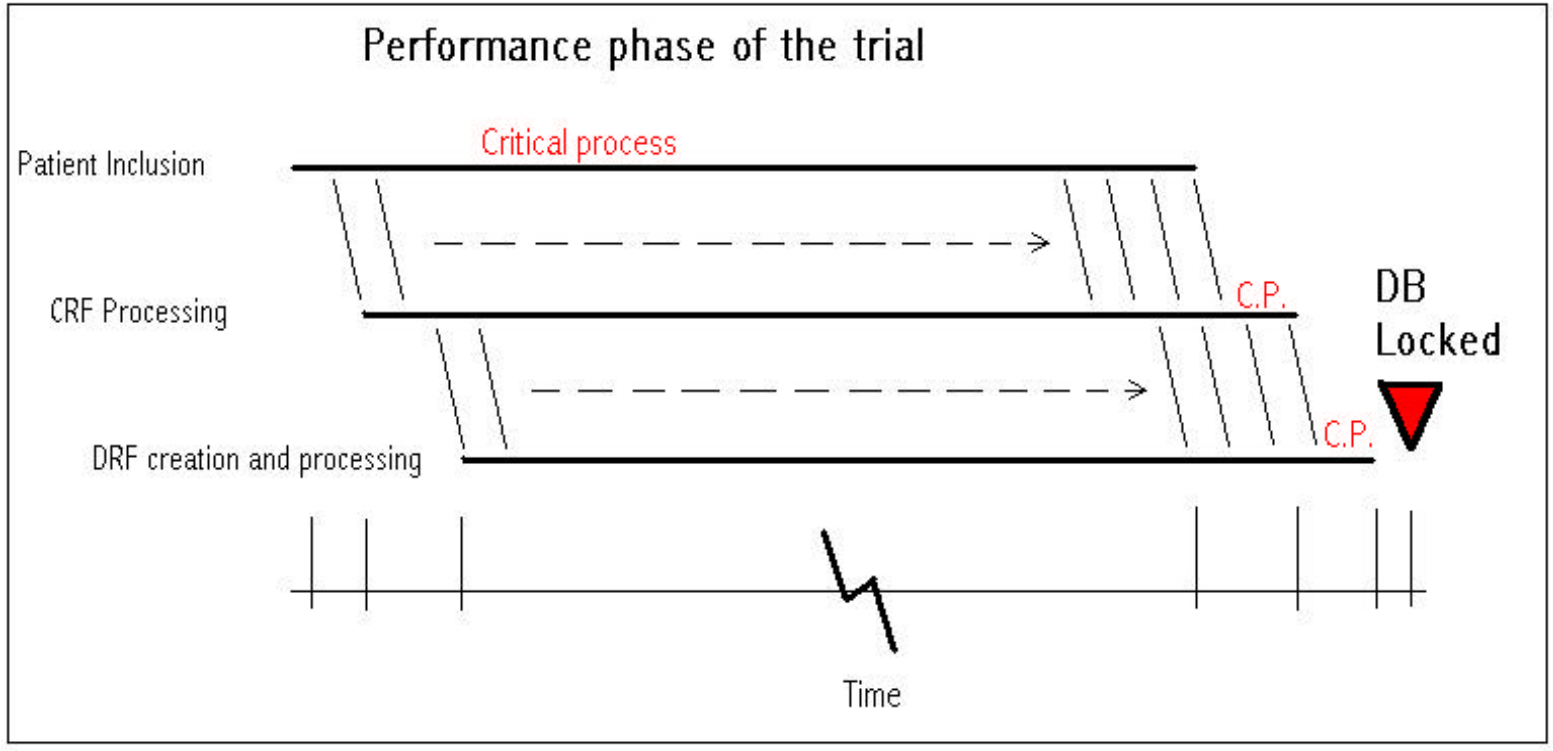


Streamlining Clinical Data Management through Electronic Data Capture. 7th April 1998.

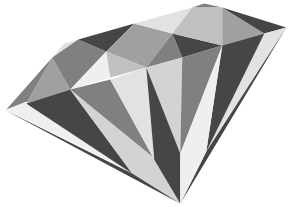
Nycomed Amersham

Reduction in trial duration

- Process efficiencies



Higher quality of returned data.

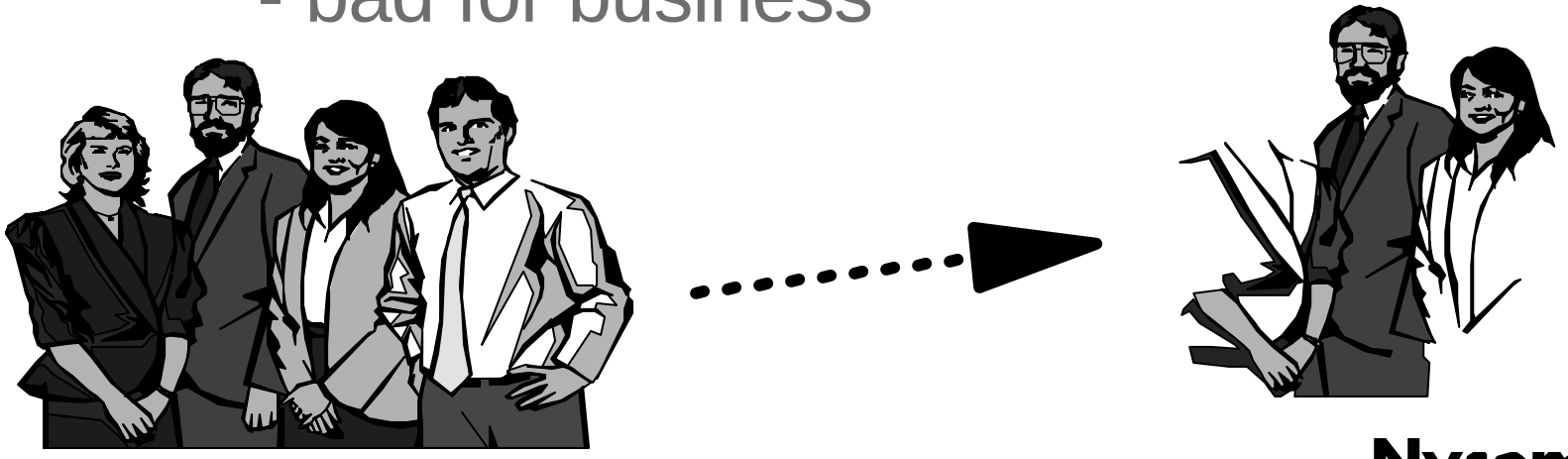


- Dependent upon error checks
- Up front planning - process change
- Hard or soft
- Parallel or sequential monitoring

- ✓ Standardised error checking
- ✓ Job responsibilities - clarity and acceptance

Reduction in Data Management resources.

- ▲ If you get EDC to work this should follow!?
- ✖ Don't use this as you main aim
  - bad for business



Technology Failure

- Unrecoverable data
- Backup CRFs
- Machine failure
- Equipment ageing
- Theft
- .....

✓ Formalise a disaster recovery plan

Acceptance of change

- Many Investigators like it
- Many monitors like it
- Many CDMs fear it
- Many managers don't know anything about it
- Everybody expects something different from it

- ✓ Openness and understanding
- ✓ User centred systems development (HCI)

Sustaining Cost/Benefit

COSTS

- Equipment costs & Depreciation
- Maintenance costs - Travel
- 24 hour helpdesk - global trials
- Investigator good will

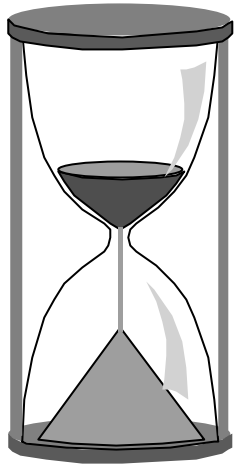
BENEFITS

- More efficient resource use
- potential to reduce trial duration

CONCLUSIONS

- EDC is high risk
- EDC involves a lot of different risks
- The risks are manageable
- The competitive advantage is still there
- The benefits are potentially enormous

THANK YOU



QUESTIONS?

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