Gaining Effective Co-operation Between Sponsors and Health Services: using Electronic Heath Records and EDC to reduce duplication and exchange valuable data simply and quickly whilst keeping costs down.

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Remote Data Entry

Current methods used in Electronic Data Capture (EDC), primarily Remote Data Entry (RDE) have, after more than 10 years development, only managed to be implemented into an estimated 5% of clinical studies. There are many reasons for this state of affairs and to an extent the reasons are unique to each implementation attempt but many are also generic to the way in which and the environment into which the technology is being implemented.

Two major reasons for technology implementation failure are too much complexity and too high expectations. RDE is based on the concept that one PC based electronic forms system can be implemented in a large range of different study types, in different environments collecting data from diverse sources using a range of technologies. There are many interactions between these factors and this creates a dynamic complexity. To be able to manage this it needs to be reduced to detail complexity. The expectations placed on the RDE systems were; reduced study duration, reduction in errors and resource savings. The only one of these three to be consistently demonstrated is the reduction in error rates in the data returned from the Investigator. If it was the expectation to reduce trial duration there are many parts of the process outside RDE that will affect this. If it was the expectation to reduce resources, either human or financial, well there has been very little evidence in any kind of computer based information system implementation that this is the case.

Direct Data Capture

As a step in the direction of reducing the complexity from a dynamic complexity to a detail complexity it is necessary to look at the different factors affecting the EDC data capture process. One major factor is the diverse range of data sources in a trial. Demographics, medical history and other drugs being taken collected from the patient directly. Physical and lab. based examinations of the patient's current health. Electronic measurement of the patient's major functions - heart and brain activity. X-ray, MRI and other images taken and evaluated and so on. Some of these are verbal data sources, some electronic, some visual. That which is common however is that more and more are becoming electronically based allowing a new electronic data collection method; Direct Data Capture (DDC).

Direct Data Capture means connecting the EDC computer to the electronic apparatus and extracting the information. This is not a new concept, it is used in many laboratories already and many clinical trials receive electronic lab. information which can be imported directly into the clinical database. The concept of DDC means identifying the data sources, deciding on the interface and extracting the data. Some systems store the information and therefore the DDC extraction can be done én-block. Others may need a computer connected all the time. The economics of this may well be prohibitive. DDC also allows for the collection of data "directly" from the patient. Verbal responses will always be a part of data collection so DDC must also have a human interface.

Direct Data Capture will reduce the number of errors even further than RDE. It will save the Investigator time and effort. It does however require the development of a multitude of different interfaces to the different data providing sources. Complex as this may sound it is a detail complexity not a dynamic complexity. Each interface is individual and therefore the dynamic interaction is removed.

A development in the healthcare industry that may make this vision more of a reality is the push towards Electronic Health and/or Patient Records but it is important that we do not duplicate our efforts but that we co-operate to define standards we both can use.

Electronic Health and Patient Records

Driven mainly from the USA with the growing business of healthcare Management Organisations (HMO), EHRs and EPRs are an exciting development for information management. *"The collecting together of all information relative to a persons healthcare in one place and making it available to anyone providing healthcare to that person as and when it is needed"*, that should also continue … in order to identify how and where we can save money!

To understand the drive for EHR/EPRs it is useful to know a bit about how HMOs function. HMOs are large groups of healthcare providers in a local area of state that work together, they include hospitals, local clinics, labs, residential heath planning schemes etc. A person through their insurance company is registered with a HMO to provide for all their healthcare needs. The person's insurance costs are often paid by the employer. The insurance company pays the HMO for treatment provided. No job no insurance, no insurance no care! The insurance company will always try and reduce costs. By combining all the information on patient care for hundreds or thousands of patients receiving a given drug or treatment and then knowing the outcome, expensive drugs or treatments with poor outcomes can be identified as bad cost/benefit and less will be paid for them. To be able to combine information on so many patients it needs to be computerised, hence the need for EPRs.

There is a slight difference between the EPR and the EHR. The EPR assumes that the person is a patient and therefore is at the time in need of some examination or treatment. The EHR however is a bit broader, it aims to register the heath information of individuals whether or not they are current patients needing care. This then extends the information to smoking habits, dietary information, exercise routines etc.

In the healthcare institution, a hospital for example, the development of and EHR is a major undertaking. Information Technology implementation has grown uncontrolled and uncoordinated. The admissions system (ADT system) is the one we are most familiar with if you have visited a hospital recently. All your details are registered into a computer when you arrive so that next time you don't need to do it again. Perhaps you then see a doctor for a consultation, she makes some notes, you go to x-ray and they collect the details of the pictures taken. If it turns out to be something nasty and you are admitted you may have labs. taken. Finally you are fit and well and you leave. A week later you visit you visit as an out patient for a check up and they can't find your notes! This happens in up to 30% of patient visits.

Technology choices for EHRs

The technology choices made by the healthcare industry should be a pointer for us as to what is acceptable for an investigator's routines and the hospital's function. Very high up the list at present is voice recognition. Much of the information collected on a patient visit is in the form of dictated notes, previously dictated to tape and sent to the medical records department for transcription. This can still be done with digital tape recorders and voice recognition software or the doctor can dictate directly into the PC. With training (*and an American accent*) this works very well. There are a host of medical dictionary add-ons to make this possible.

Another technology is Computer Output to Laser Disk (COLD), free text is typed into a pre defined word processor document, a template, and it is then "printed" via an interface that can interpret the structure of the form and the text in it. The text and the template are split and the data is written to a mass storage device, in this case a Laser Disk. The record can be regenerated by reading the data back into the template.

Direct Data Capture is now being used increasingly for graphical and image based data, for example the 12 lead ECG that was a long paper record is now computer based at many sites. This electronic format can easily be stored and accessed electronically together with other relevant information, the patient's history of epilepsy for example.

In many instances the patient is being asked for information. With the growth of computer literacy and ownership it is not a problem for many to fill in information at a terminal whilst they wait to see a doctor, or even together with the doctor. In the future providing information via the Internet prior to a visit will be an acceptable data collection technique. The "Patient Smart Card" will also be a future source of information. The card is an optical storage device the size of a credit card that can store all your health related information and security information such as a picture. At each visit the notes taken are stored and each time drugs are prescribed that too is stored. These cads can store up to 5Mb compressed information, enough for a lifetime for most people.

Structured data entry such as we provide for RDE comes long down the list. It requires specialist software and takes a longer time to collect the same data.

To make all the information available at the point-of-care, internet technologies are at the forefront. Intranets and Extranets, Intranets inside a healthcare institution and

Extranets between them. Data entry is very often into web enabled systems, presentation of charts, images and text based information is through web pages. Transfer of information between sites used web technology. Remote consultations use web technology. And the patient can "discuss" their healthcare on line with a doctor to avoid a visit. Information about clinical trials can be found on-line on the Internet and patients can ask their doctors to be included instead of being referred.

Duplication between EHR and RDE.

If as described the EHR collects information on demographics, medical history, background health information, drugs being taken, reactions to treatment and outcome etc. then there is a tremendous duplication if our industry requests the same information be entered into another computer in a different format, especially if RDE achieves a greater penetration than currently. The Investigators are aware of this growing problem. In the categorised responses to a survey of Investigators when asked to give a free text answer to the question "*Is there anything you would like from a data collection system based on computer technology so that you would benefit from using it?*" the second highest concern expresses was the exchange of data with other systems. This was only exceeded by Usability issues.

The solution to this problem must be co-operation between the parties demanding the Investigators time and effort, otherwise the Investigator will be forced to choose between one or the other. Patient care must win in this choice.

Electronic Health Records require the direct capture of data from source data providing equipment, the same information we require. If the data flow is from data provider to EHR database it is then possible to extract the data from the EHR database to the sponsor of a clinical trial. A suggestion from the healthcare industry to ensure confidentiality and control is to make the data request protocol driven. Our clinical protocols must drive the extraction utility so that only the data required is transferred and no more. Data will be owned by the trial site which is a requirement of ICH/GCP and the quality of the information will be their responsibility. An error discovered by the sponsor must first be corrected in the EHR system before being re-extracted to the sponsor. This ensure also for better patient care. Before this can be a reality the vendors of both EHR and EDC systems must also co-operate to ensure a standard and co-ordinated approach to the problem.

The need for standards

Most of systems used to collect information during your stay in a healthcare institution are legacy systems with their own operating system, storage system, interface etc. and now they all need to be connected together and exchange information. The new system is the "data warehouse", the Electronic Health Record database. But it is not simply data warehousing that is the problem. When you are registered in the ADT system and are then sent to x-ray, before you get there the relevant information needs to be sent so that x-ray are prepared. These two systems being completely different, a standard is required for information exchange. This standard is called Health Level 7 (HL7), the 7 indicates that it operates at level 7 of the Open Systems Interface (OSI) 7 layer model for networking. HL7 is an ANSI approved standard and is member consensus based.

HL7 is a messaging system. Messages are structured according a to a pre-defined format and sent from one system to another. The sending system needs only to know how to convert its data into an HL7 message and the receiving system needs to know how to extract it. Message are sent by being triggered. The ADT system for example will have a trigger that is activated when a new patient is admitted. The trigger will say send the name, insurance company, address and other particulars to all other systems.

An example HL7 message

```
MSH|^~\&|ADT1|MCM|LABADT|MCM|198808181126|SECURITY|ADT^A01|MSG00001|P
|2.3|<cr>
EVN|A01|198808181123||<cr>
PID|||PATID1234^5^M11||HYDE^WILLIAM^A^Jr||19610615|M||C|1200 N ELM
STREET^^GREENSBORO^NC^27401-1020|GL|(919)379-1212|(919)271-3434||S||
PATID12345001^2^M10|123456789|987654^NC|<cr>
NK1|HYDE^KIRSTEN^G|WIFE|||||NK^NEXT OF KIN<cr>
PV1|1|I|2000^2012^01||||004777^JAMES^SIDNEY^J.|||SUR||||ADM|A0|<cr>
```

Patient William A. Hyde, Jr was admitted on July 18, 1988 at 11:23 a.m. by doctor Sidney J. James (#004777) for surgery (SUR). He has been assigned to room 2012, bed 01 on nursing unit 2000. The message was sent from system ADT1 at the MCM site to system LABADT, also at the MCM site, on the same date as the admission took place, but three minutes after the admit.

The latest version of the HL7 standard, v3.0, contains messages for clinical trials. The messages include such things as; registration and completion of a patient, trial phase information, treatment schedules, sponsor information, randomization codes, patient consent information, evaluable status.

Another two widely used standards for treatment and drug prescription information are the ICD9 and SNOWMED dictionaries. These are used by the HMOs to assign standard codes to items that will be charged to the insurance company and are the basis of the treatment/outcome analysis for cost/benefit.

A standard is emerging for image data from x-ray, MRI etc. This is DICOM. The DICOM standard specifies where and how information identifying the image is stored in the picture header. Information concerning the technical parameters of the machine taking the picture are also stored which for contrast imaging trials allows the extraction of highly repetitive information that generates many errors in trascription and entry.

The co-ordination and promotion of these standards is also being championed by the Health Information Management and Systems Society (HIMSS) and the Radiological Society of North America (RSNA) in a joint initiative called Integrating the healthcare Enterprise.

The benefits

Electronic Data Capture aimed to reduce trial duration, improve quality and reduce resource use, or as I would prefer it improve the efficiency of resource use. Quality

has improved, results of RDE supported trials presented at conferences demonstrate this. Resource use has been transferred, not reduced. The Investigator or other study site staff have inherited the burden from us. In the long run they save by not handling so many errors after the event, but Investigators act very much now, not in the future. Reducing trial duration may be taken as given if the time from last patient to database lock is reduced, but who has measured it and proved that the reduction was achieved through the use of new technology?

Another aim not often mentioned is user satisfaction. Users involved in any type of system have a feeling of satisfaction with their interaction with that system, be it paper based, machine based or computer based. It can be proved that there is a direct relationship between user satisfaction and performance in computer based systems. An increase in user satisfaction should therefore be a major aim of any IT implementation project.

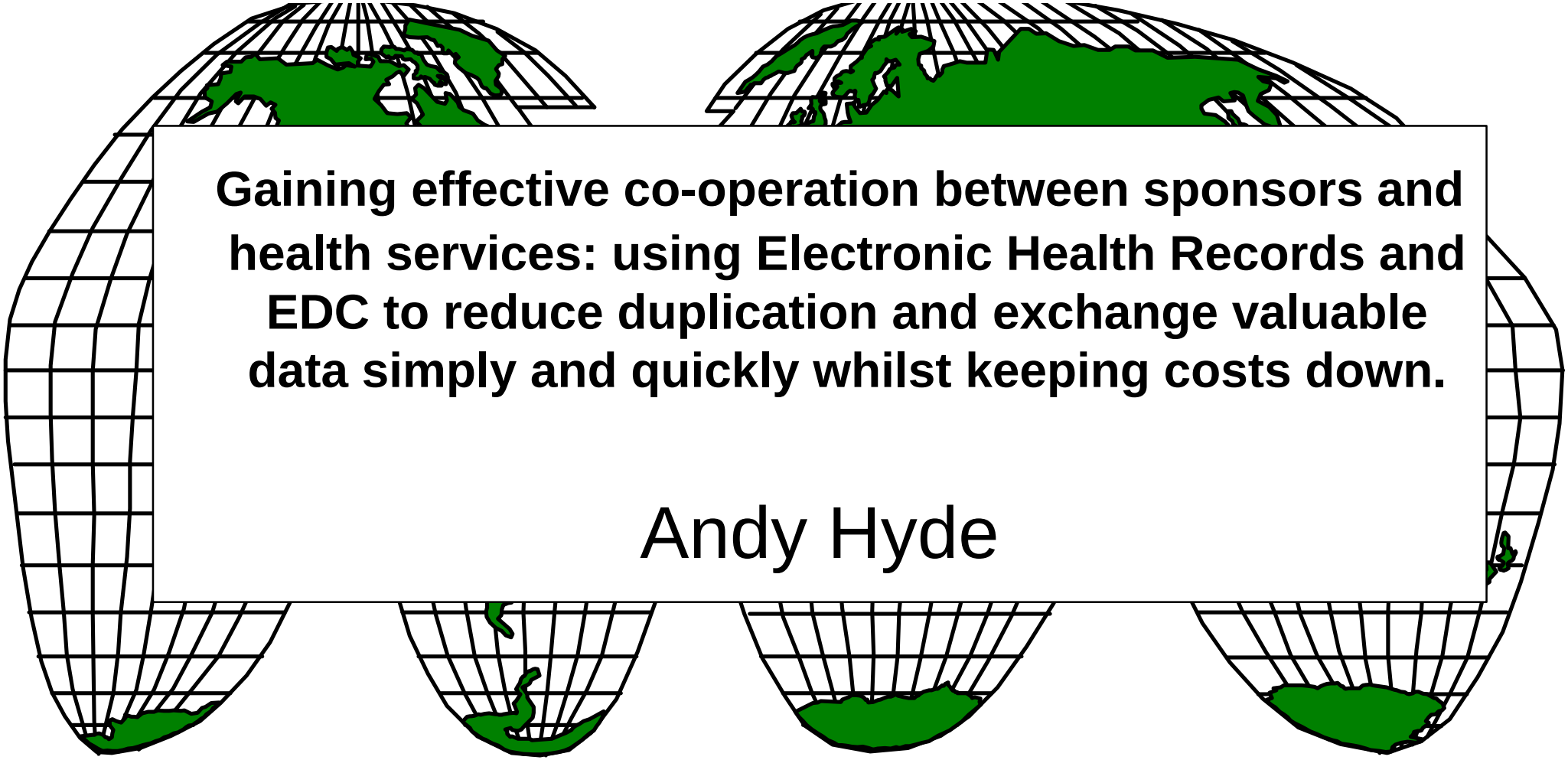
Through co-operation between vendors of EHR and EDC systems and healthcare providers and the pharmaceutical industry we can achieve a much better level of systems development. The Investigator is the common element and it is the Investigator who is most important for the patient and for our data. It is in our interests to please this group.

The use of Direct Data Capture with one element of this capture being the extraction of data from the EHR system should produce cost savings. The extraction only need be done once at the beginning of the study to check the data is as expected and once at the end of the study. In the future, as with DICOM images, much of the transfer will be linked to the Internet and data can be exported directly to the sponsor site without further intervention.

The Future of the Clinical Data Manager

So what will the CDM do in the future? There will be no CRFs, the data will be clean, there will be no need for error checks, no data entry screens! Of course that is not entirely true, but the job will change. The data manager is often required to have an IT based education but the work of many CDMs does not fully utilise this knowledge. The new roll will. The CDM will manage not just the data but the whole data collection process. They will be the technology expert in the clinical team. They will travel to centres and discuss DDC and EHR related issues and manage the data transfer and extraction.

EDC ‘99



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Andy Hyde

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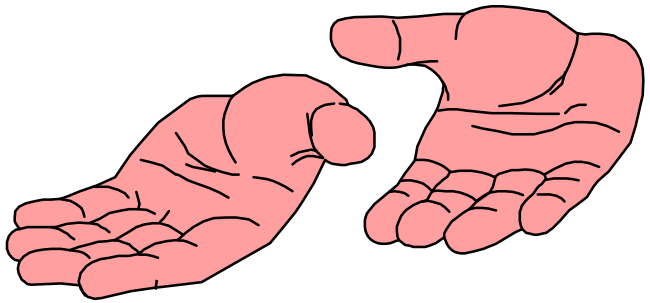
Introduction

- If current EDC methods are failing what else can we do?
  - Direct Data Capture?
- Developments in the Healthcare industry
  - Electronic Health Records (Europe) and Electronic Patient Records (USA)
- Increasing Duplication for Investigators
- Co-operative development
  - standards (HL7, DICOM, ICD9 etc)
  - technologies
- Benefits of co-operation
- The future Data Management role



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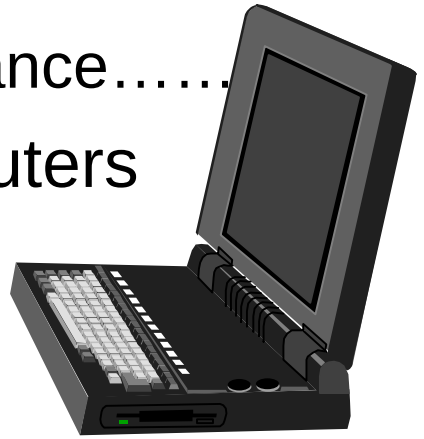
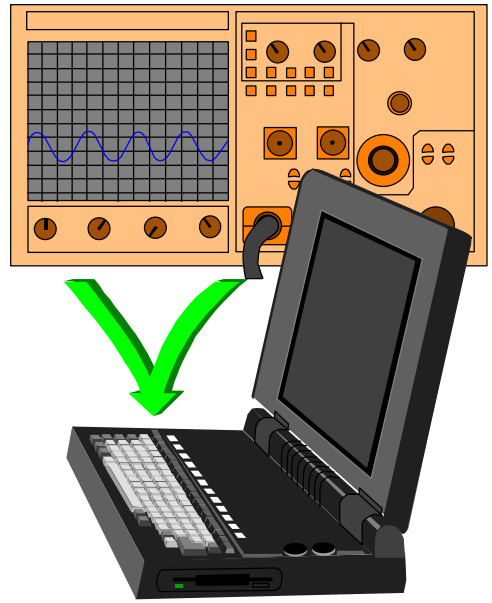
Remote Data Entry

- The use of a computer for collecting data instead of paper and pen
- Requires Investigator to have a computer with electronic form application installed
  - Purchase, setup, storage, distribution, maintenance……
- Several trials/several sponsors - several computers
- “complex” technology (Dynamic complexity)
- Expectation failure
- 5% (est.) of clinical trials use EDC after 10 years.



Direct Data Collection

- Collection of data from source by computer to computer links
  - Laboratory equipment, Imaging technology (MRI, x-ray, Ultrasound), EEG, ECG, etc etc etc
- Removes duplication of data entry
- Requires standardisation of interfaces
- Duplication of data collection and storage at the hospital
- Parallel development of interfaces



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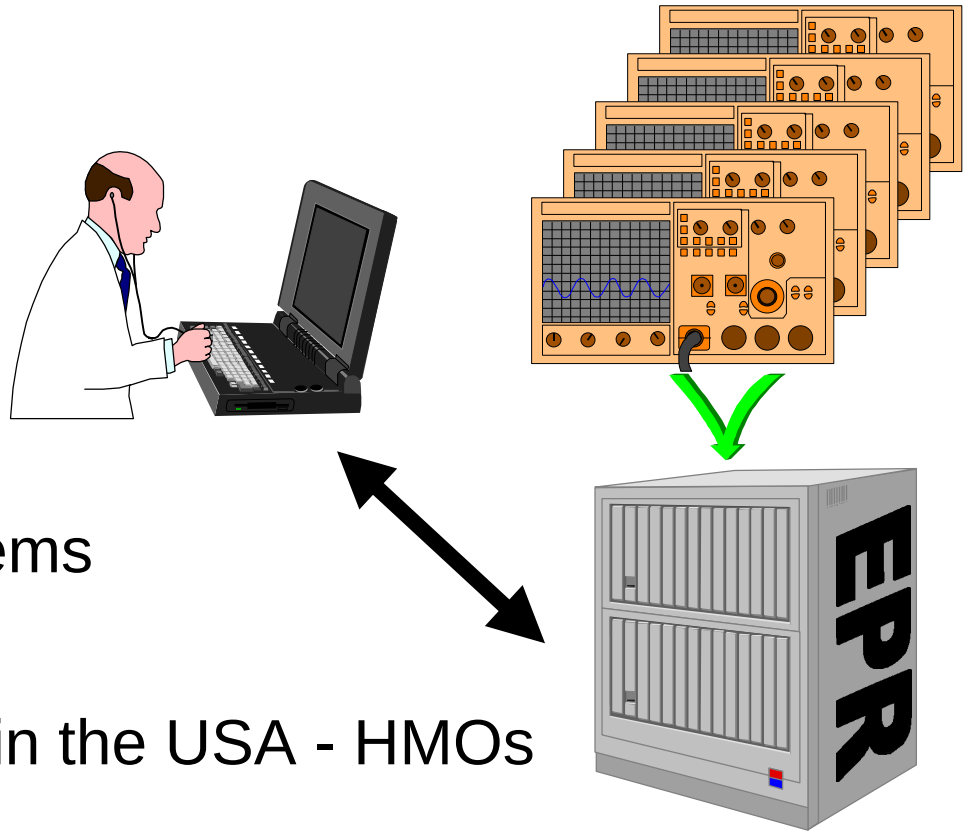
EHRs and EPRs

- Collecting all relevant health or patient information into one electronic “file”
- Why?
  - Better patient care
  - Mobile patients
  - Manage costs
- How
  - Integration of legacy systems
- Massive investment
  - Cost driven development in the USA - HMOs
- 10 years of development



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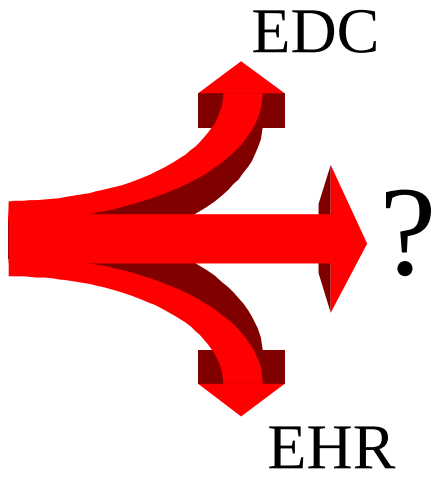
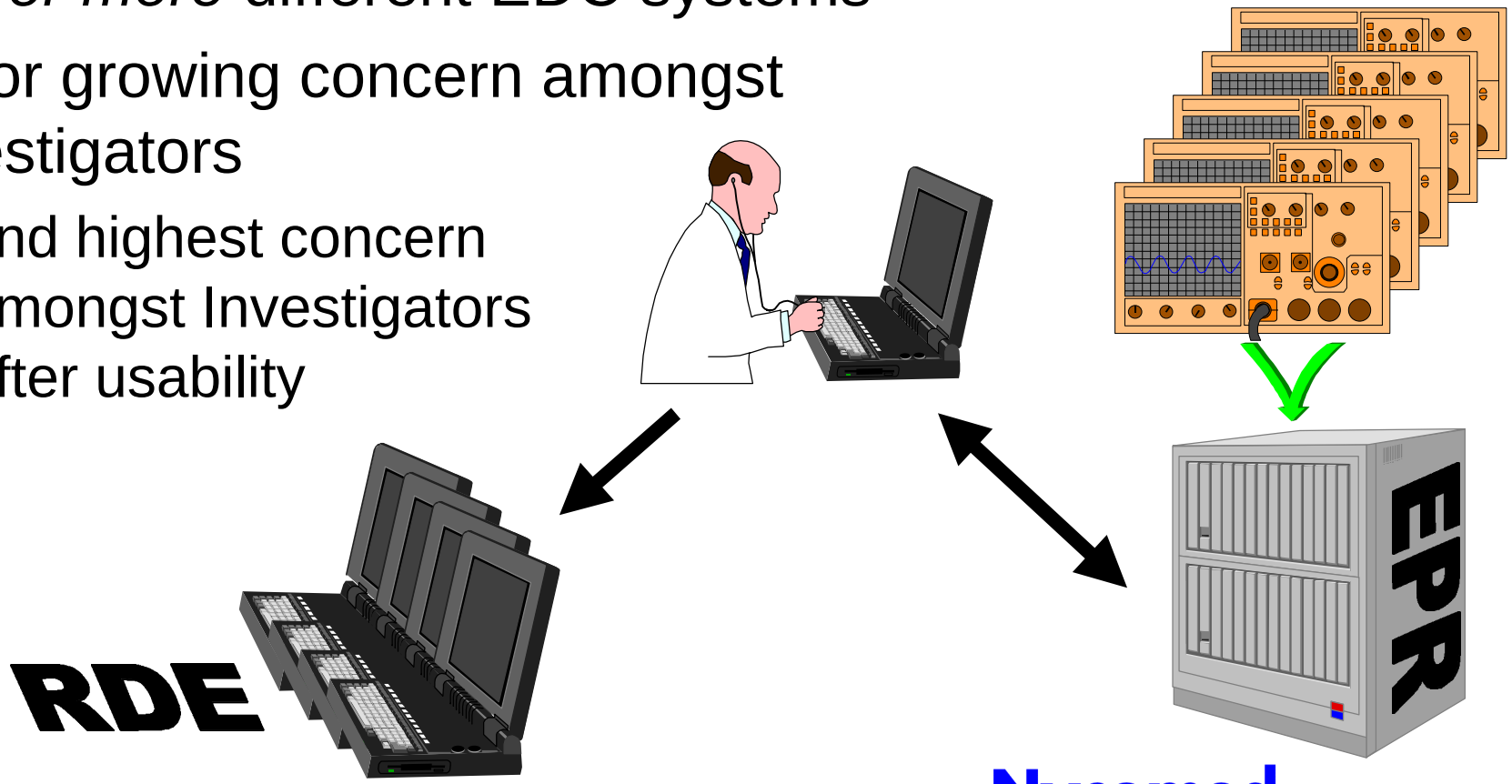
EHR Technologies

- Technology choices in EHR are different than EDC
- Pragmatic situation based data collection
  - Voice dictation
  - Free Text based note taking with COLD
  - Direct Data Capture (EKG, images etc.)
  - Structured data entry (slow)
  - Patient entry
  - Patient smart card - ***patient owns information***!
- Can we learn why EDC has failed to gain acceptance from these choices?



Data entry duplication

- Investigators enter data into an EHR and also into one *or more* different EDC systems
- Major growing concern amongst Investigators
  - 2nd highest concern amongst Investigators after usability



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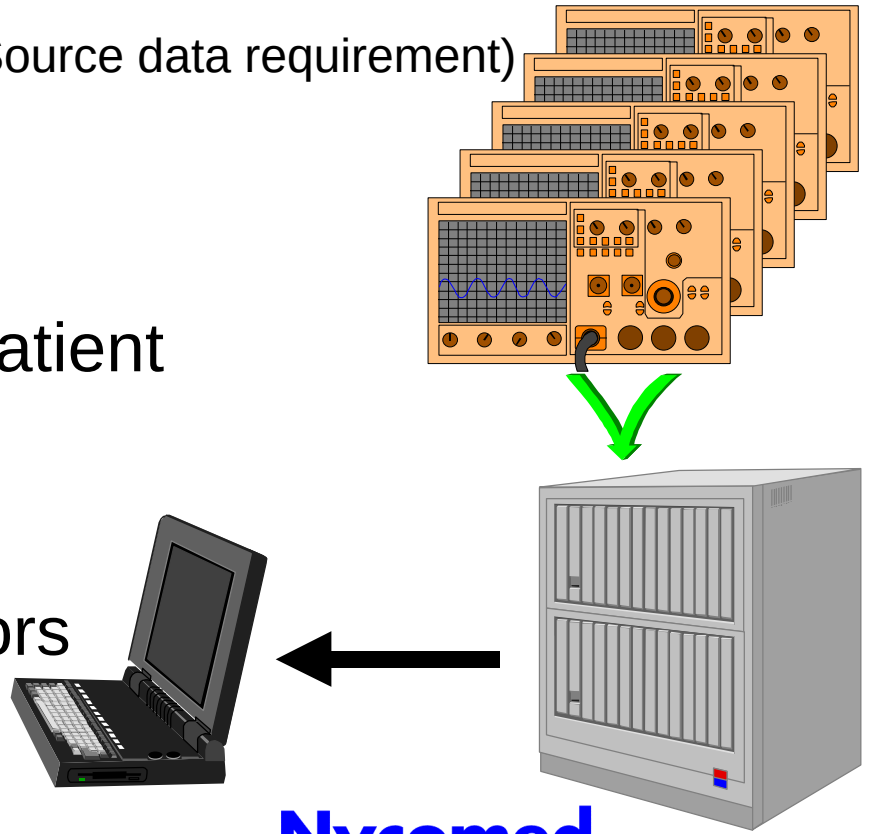
A co-operative solution

- Collection and storage of data in one place for multiple re-use
- All data under hospital control (Source data requirement)
- Data flow greatly improved
- Data quality guaranteed
- Data export utility required on Patient Record systems (Protocol driven)
- Co-operation with sites
- Co-operation with system vendors
  - EDC and EPR



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Available standards

- HL7 (Health Level 7)
  - Legacy system messaging standard for data interchange
- DICOM for Images
- ICD9 & SNOWMED - treatments and diagnoses dictionaries
- Supported by HIMSS & RSNA (Joint working party)
- ACDM Lab data format
- etc etc… Rationalisation needed?

The Benefits

- More effective systems development
- Less diverse standards
- Reduced work load for the Investigator
- Greatly reduced error rates
- Potential cost savings (no CRF, no EDC PC)
- Faster data return
- Faster Time to Market - well, did EDC do this?
- Less paper

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The Future Data Manager

- Expert in current and future technology in Clinical research and Healthcare
- Technological advisor to clinical trials
- Technology interface with trial centres
- Data co-ordination

- Much less data checking!

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Information Sources

- HL7 - http://www.hl7.org/
- HIMSS and RSNA - http://www.rsna.org/IHE/ and www.himss.org/IHE
- The Medical Records Institute - http://www.medrecinst.com/
  - Annual conferences TEPR (Towards an Electronic Patient Record) and TEHRE (Towards and Electronic Health Record in Europe)

Thank you

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