Working effectively with health services to add value to your EDC driven clinical study

Andy Hyde, MSc
Nycomed Amersham, Oslo
ahy@nycomed.com

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After 10 years or more of experimenting with Remote Data Entry (RDE) as a form of Electronic Data Capture (EDC) only an estimated 5% of trials are using or are planned to use RDE. Technology in the mean time has provided us with new opportunities which cannot be ignored.

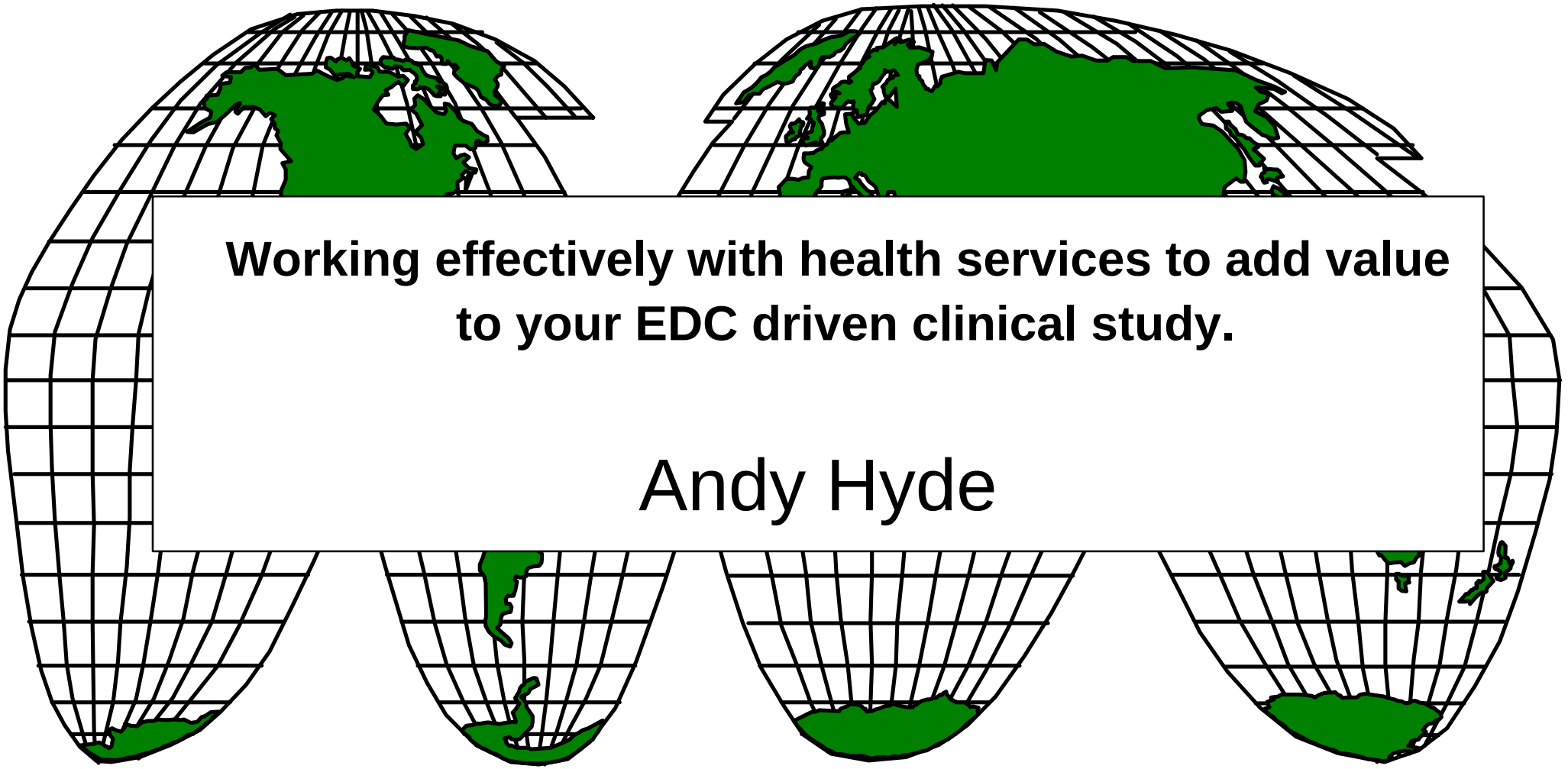
RDE has failed to meet up to expectations for several reasons, some technical, some human. The technical aspects are well known; slow computers, computers crash, theft, security. The human issues are less well known or less accepted; learning/teaching difficulties, psychological barriers, Human-Computer Interaction (HCI) design failures, resistance to change.

Computers can talk to each other and taking advantage of this can provide enormous benefit. Direct Data Capture (DDC) is becoming a new form of EDC. Many clinical studies take advantage of this through electronic collection of lab. data but much more clinical data is available electronically and as time passes even more is becoming so.

The health care industry, driven by the desire to reduce costs, is taking advantage of the technological developments to collect health and patient related data centrally into an Electronic Patient Record (EPR) in the US. and an Electronic Health Record (EHR) in Europe. There are two approaches to this task, collecting everything in one location or connecting all the legacy systems together and transferring information between them. The latter is more complex but considerably cheaper and the former is a major IT project. For the EPR/EHR to be of use as much information as possible must be stored in a analysable form electronically. This is the same problem faced by the pharmaceutical industry.

Therefore the challenge for us in the future is to maximise the benefits of the changes in our external environment by co-operating with EPR/EHR system developers and heath care institutions to ensure that they do not become unusable for us. If we can co-operate effectively then even DDC can be surpassed. The future can be the extraction of all clinical data from an EPR/EHR with only efficacy evaluation data needing special attention. With this development EDC will have finally achieved the aims that RDE set out to achieve; reduction in trial duration, less errors in data from the site, and through these a resource saving. In addition, there will be a reduction in paper usage and therefore storage.

EDC '99



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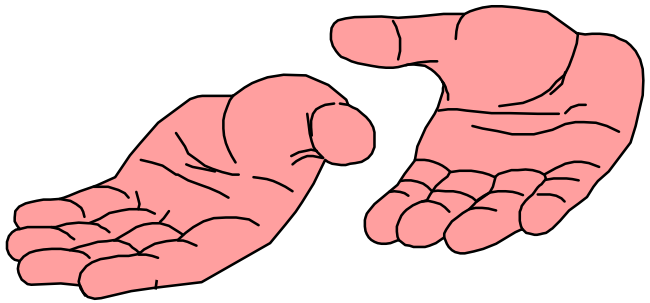
Introduction

- 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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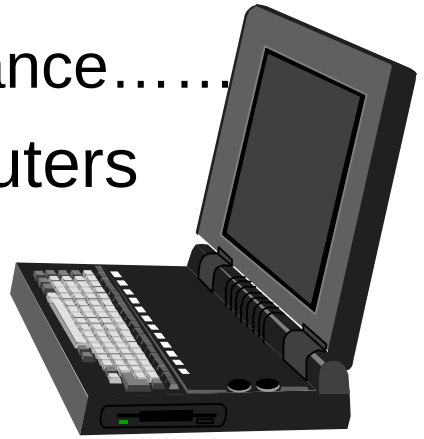
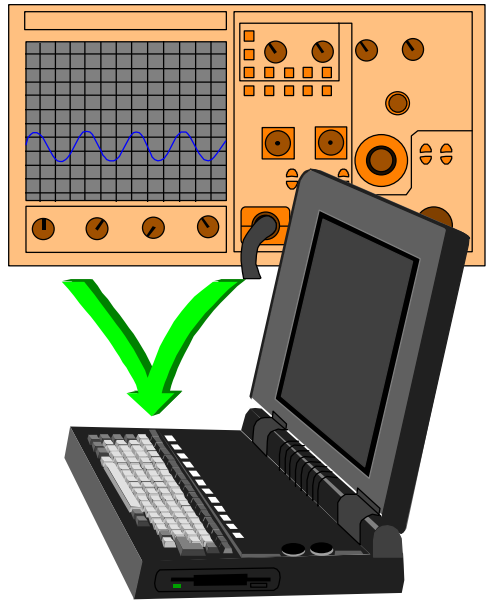
Remote Data Entry

- 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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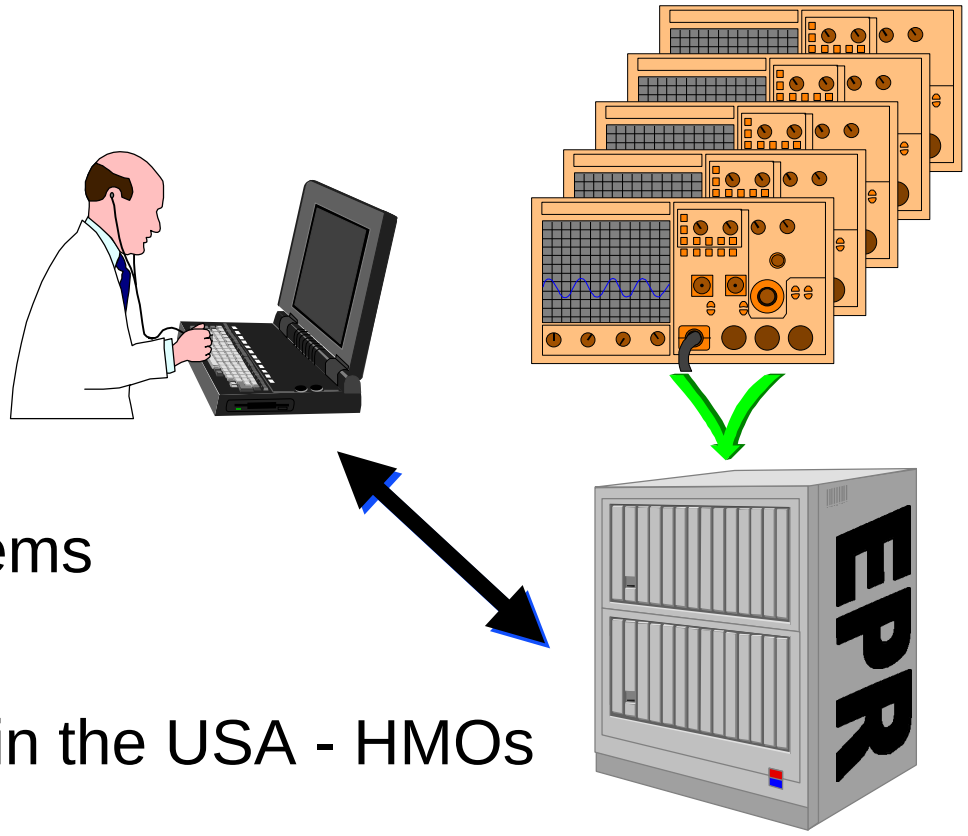
EHRs and EPRs

- 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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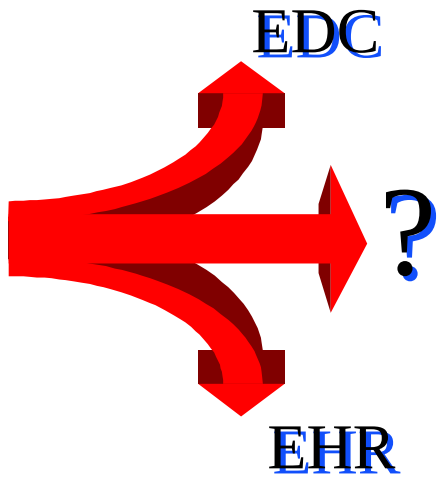
EHR Technologies

- 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?



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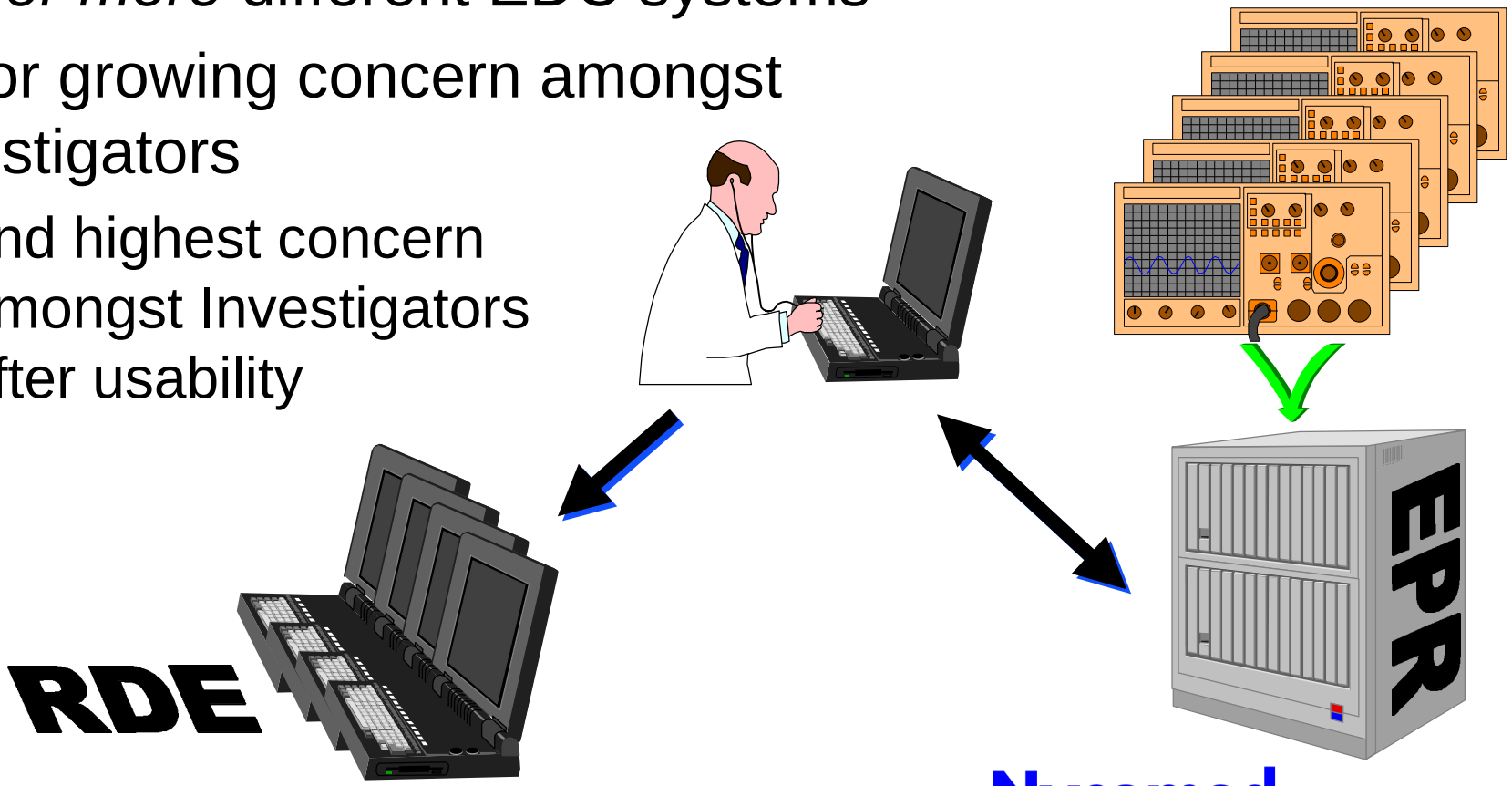
Data entry duplication

- 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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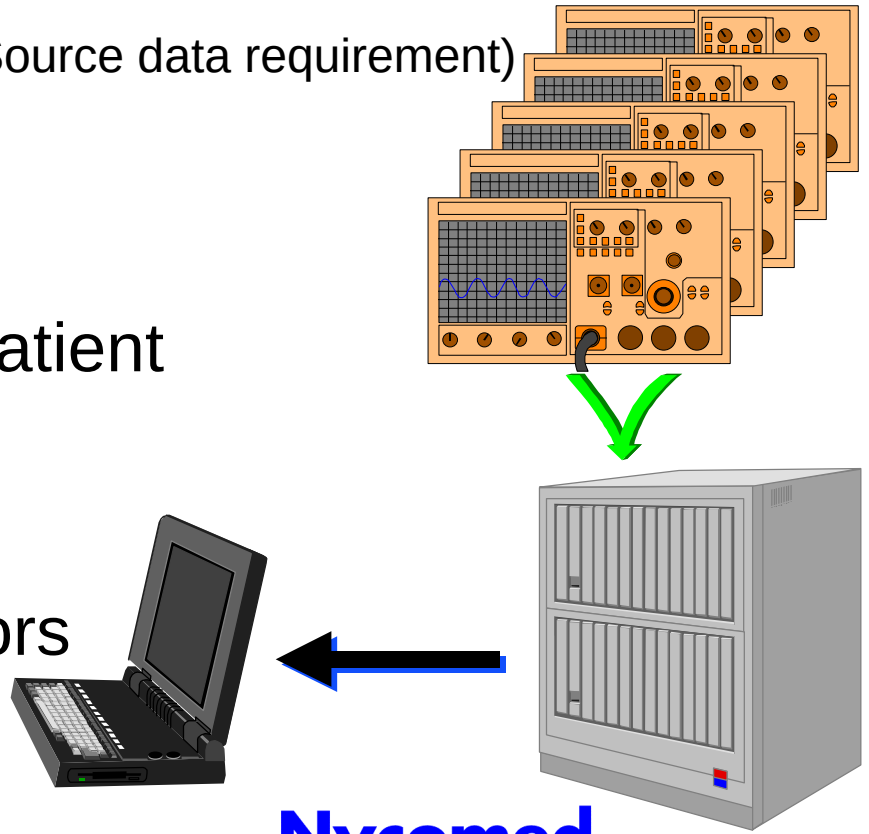
A co-operative solution

- 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 Challenges

- Limiting the standards
- Access to information/privacy
- Managing the changes
  - Technology
  - People
- ???

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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

ahy@nycomed.com

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