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- 👉 Nycomed Imaging, Oslo
- 👉 Clinical R&D - Clinical Systems Developer
- 👉 10 years experience with computers professionally
- 👉 6 years with systems development
- 👉 Specialist interest - Human Computer Interaction

Remote Data Capture - Why?

- 1) Cut clinical trial duration times
- 2) Reduce resource use
- 3) Improve data quality

The Incentives for RDE

- ➡ Reduced time to locked database
- ➡ Resource cost 1 FTE @ £250 per day.
10 days resource saving = £2500
- ➡ 10 days opportunity cost = £10m
- ➡ Quality improvement ?

Where is it?

- 👉 10 years of experimenting
- 👉 50% of companies have at least tried RDE
- 👉 50% of those report still using RDE

- 👉 50% of Investigators have tried RDE
- 👉 75% of those would use RDE again
- 👉 85% think RDE is better than paper

- 👉 75% of all companies are still using paper!

Failure of Expectations

- × One system for all trials and all data types
- × Error free data
- × Less time used to collect data
- × More convenient
- × Investigators will fill in forms themselves
- × International data transfer

Business Case Problems

- × Requirement for parallel systems
 - Traditional and New Technology
- × Not all trials need to go faster - Critical path
- × Underestimation of cost of ownership

Legal Requirements

- + SOP**
- + GCP/GMP**
- + ICH4 - M2**
- + Electronic records with signatures - FDA**
- + SYSTEM VALIDATION**

A New Direction

- ✓ Forget one system for all idea.
- ✓ Specialist systems for each situation/data type
- ✓ Data exchange not data entry

Data Exchange

- ✓ Patient record systems - import/export
- ✓ MRI/Ultrasound machines - export data
- ✓ Repetitive measurements - spreadsheets
- ✓ Image evaluation - export data

- ✓ Less transformations of data
- ✓ Easier to validate

New Design Methodologies

- ➡ Previous IT project failures
 - Main reason - lack of user involvement
- ➡ User...User...User...User...User...
- ➡ Human-Computer Interaction
- ➡ Developer becomes a user.
- ➡ User - Developer partnership

What is Required Now?

- ✓ IT systems developers to realise users' abilities
- ✓ Medical equipment standardisation
- ✓ A systemic viewpoint
- ✓ Realistic expectations
- ✓ A better understanding of The Investigator