



THE WORLDWIDE LEADER IN PHARMACEUTICAL SERVICES



> [quintiles.com](http://quintiles.com)

# **Re-Use of Clinical Care and of Clinical Trial Data**

## **A Contract Research Organisation (CRO) point of view**

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**EuroRec Conference 2009  
Sarajevo**

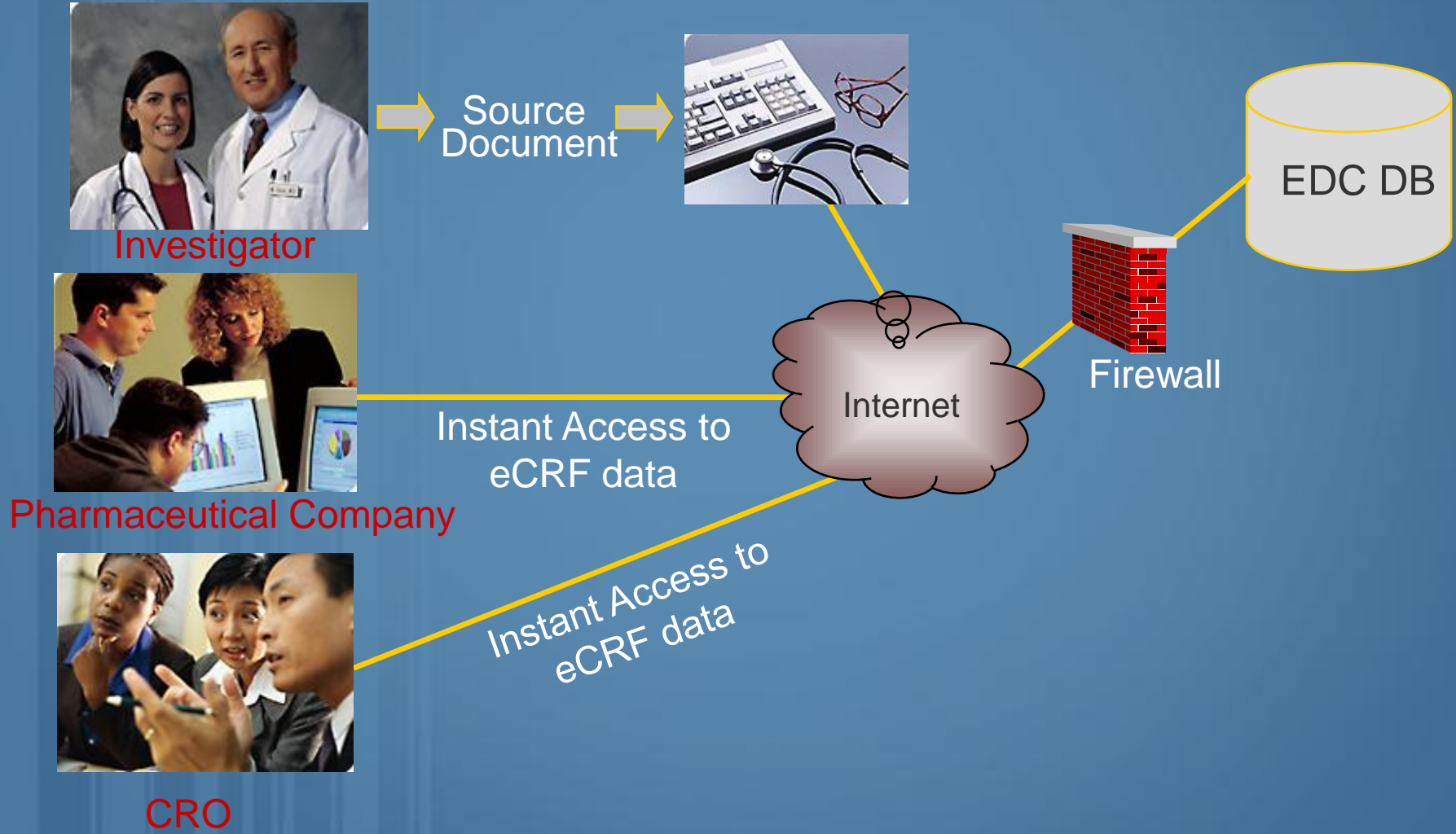
**Selina Sibbald  
Director  
Global Electronic Data Capture (EDC)  
Quintiles**

# Quintiles

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- ▶ Fully integrated biopharmaceutical services company offering clinical, commercial, consulting and capital solutions worldwide
- ▶ 23,000 staff
- ▶ More than 50 countries around the world
- ▶ **PURPOSE:**
  - ▶ Quintiles helps to improve healthcare worldwide by providing a broad range of professional services, information and partnering solutions to the pharmaceutical, biotechnology and healthcare industries

# Electronic Data Capture



# Old World versus New World

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Patient  
Data

- Paper Health Records

Data  
Entry

- Clinical Research Co-ordinator enters data into EDC system via Internet

Research  
Data

- Research database updated
- Study team can view via Internet

# Old World versus New World

Patient  
Data

- **Electronic** Health Records

Data  
Entry

- **Redundant step??**

Research  
Data

- Research database updated
- Study team can view via Internet

# Clinical and Research Data Overlap

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- ▶ 50-60% data needed for Clinical Trials is also in the Electronic Health Record (EHR)
- ▶ Good news!
- ▶ Why don't we just integrate the two systems and transfer the data?
  - ▶ Saves a lot of work for the investigative sites
  - ▶ Reduces checking as no room for human error
- ▶ **Not quite as easy as it seems.....!!**

# Clinical Research Regulations

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- ▶ Clinical Research very highly regulated
- ▶ Summary of FDA Good Clinical Practice:
  - ▶ Attributable
  - ▶ Legible
  - ▶ Contemporaneous
  - ▶ Original
  - ▶ Accurate
- ▶ Multiple regulations/requirements
  - ▶ Variation across different countries
- ▶ Consider that data used for Healthcare decisions should be equally high quality as it is also potentially life affecting

## Small Study - Possible

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- ▶ Sponsor = Pharmaceutical Company
- ▶ Trial Management = CRO
- ▶ 1 investigator site using a commercial EHR system
  
- ▶ Several proof of concept studies
- ▶ 1 to 1 transfers between EDC system and EHR system
  
- ▶ **Unfortunately....**

# Majority of Clinical Studies

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- ▶ Sponsor = Pharmaceutical Company
- ▶ Trial Management = CRO
- ▶ More than 100 investigator sites using a large variety of commercial and locally developed EHR systems
  
- ▶ Direct integration is not physically possible
  - ▶ Costs are prohibitive
  - ▶ Time needed also prohibitive
  
  - ▶ Data from many current EHR systems is not acceptable to Regulatory Authorities for research purposes

# Obstacles to Data Integration

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- ▶ Data ownership/good computer practice
  - ▶ Secure log in process
  - ▶ Individual accountability for data
  - ▶ Audit trail
- ▶ Lack of standardisation
  - ▶ openEHR
  - ▶ Archetypes
- ▶ Anonymising data
- ▶ Multiple languages
- ▶ Free text

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**However, there is huge potential in improving the options available to healthcare providers if we can join Clinical Care and Clinical Research**

# Potential Improvements

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- ▶ Reduced administrative work for the investigative sites
  - ▶ Easier to perform clinical research
  - ▶ More investigative sites may be available
- ▶ Ability to mine for potential subjects
  - ▶ More predictable recruitment curves
- ▶ Reduced time and costs
  - ▶ Reduced time to bring new drugs to market
  - ▶ Less expensive/more options

# Perfect Future

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- ▶ EHR systems use standard collection tools
- ▶ Good computer practice is built in to all EHR systems
- ▶ Design of the tools and coding dictionaries facilitates the use of multiple languages
- ▶ A secure 'layer' allows two way data traffic
  - ▶ Anonymous on the way out of the EHR
  - ▶ Tied back to the correct patient on the way back into the EHR

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**Thank you for your  
attention!**

**Any Questions?**