Revisiting the eClinical Paradigm:
Investigational site perspectives on clinical trial information systems

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Slide 3

Investigational site perspectives on the future environment for clinical trial information systems

1. Backgound to the eCF Site Survey
2. Overview of results
3. Insights into
   a) Data capture
   b) Emerging eClinical technologies
   c) Secondary use of EHR data
4. Conclusions / Next Steps

Slide 4

We Need to… *understand site needs and expectation*

We Need to… *work together to create the future environment for more efficient clinical trials*

1. Background to the Survey…

- Understand investigational site experiences with today's clinical trial technologies and their perspectives on future trends

- Information to help improve today's eClinical solutions and to develop future solutions that transcend the healthcare:research divide

- A repeat of the 2001 survey
  (840 investigational sites - was widely used and reported)

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2. Overview of Results - Continents

785 responders at final cut-off 30th November 2009 *(vs 840 2001)*

- **6 continents**

- **92% experience of EDC in the previous 3 years** *(vs 52% 2001)*

Growth in Asian participation vs 2001

2001 (n=840)
2009 (n=785)

468 — Asia
141 — Europe
130 — North America
4 — Africa
21 — Australia
20 — South America

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2. Overview of Results - Roles

- **Investigators reduced to 14%** *(vs 69% 2001)*
- **Study coordinator group grown to 71%** *(vs 12% 2001)*

2001 (n=840)
2009 (n=785)

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2. Overview of Results –Technology

85% of Current EDC Trials Are Using Web-Based Online Systems *(1% in 2001)*

Compared with 2001…

Web Online ↑ *(1% 2001 to 85% 2009)*

Web Hybrid ↑ *(12% to 14%)*

eDiary ↑ *(15% to 24%)*

Pen ↑ *(8% to 12%)*

Direct Capture ↑ *(0% to 17%)*

PC Off-line ↓ *(80% to 10%)*

Fax ↓ *(34% to 9%)*

Web Online n=592

85%

n = 695

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Slide 9

3a. Experience with EDC

QUESTION 1

*What can we learn about the future environment for clinical research from site **experiences with EDC**?*

Slide 10

3a. Experience with EDC…

The Shift to EDC…

Clinical Research has moved from capturing data on paper to electronic data capture at the site

To provide faster, better quality and more reliable data to support safety and efficacy

Pharma Research

Bringing a new treatment to the market costs >800 M Euro and increases at ~10% a year

Clinical research uses 55-75% of R&D budget

Entry of Patient's Clinical Data

EDC

Physician / Investigator

3a. Experience with EDC…

Growth in Electronic Data Capture to 58% of ongoing trials (from 14% in 2001!) …

Average of 58% of trials ongoing at respondent sites use EDC

37% EDC only

13% no EDC ongoing

Source: eClinical Forum Site Survey 2009, Global data

N=719

% Responders

No EDC Trials   Percentage of EDC Trials Ongoing at Site   All EDC Trials

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3a. Experience with EDC…

In Asia, 53% of currently ongoing trials use EDC

Average of ~~58%~~ 53% of trials ongoing at respondent sites are EDC

Use varies between continents

~~13%~~ 17% no EDC ongoing

~~37%~~ 21% EDC only

% Responders

No EDC Trials   Percentage of EDC Trials Ongoing at Site   All EDC Trials

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3a. Experience with EDC…

FINDING: Not everyone is completely satisfied with EDC…

Study coordinators less satisfied

Priority improvements:
- *CRF standardisation*
- *Faster login & page turns*

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3a. Experience with EDC…

FINDING: There has been a shift in responsibilities for data entry and review to Study Coordinator…

Investigator should be more involved in data entry and review while Study Coordinator should be doing less

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3a. Experience with EDC…

FINDING: Some sites still feel that EDC creates an increase in workload…

18% of responders consider EDC creates an increase in workload *(down from 22% in 2001)*

Particularly felt by study coordinators?

Slide 16

3a. Experience with EDC…

Healthcare   **Pharma Research**

Source data held in EHR may not be appropriate as source for regulated clinical studies …

Entry of Patient's Clinical Data

EHR   EDC

Physician / Investigator

Site/sponsor policies create multiple copies of data to create a 'source'

EDC system validated & compliant e.g. CSUCI, ICH GCP

3a. Experience with EDC…

FINDING: Multiple recordings of source and eSource contribute to redundant data entry and inefficiencies…

- 13% of data for the EDC trial is first entered into the eCRF *and is therefore 'source' within the EDC system*

But…

- 11% of data was entered into a pCRF *probably created to record source trial data not part of the patient's site record*

Chart values: 62%, 13%, **11%**, **13%**, 1%

Categories: Paper-based Patient File or Notes, Electronic Patient File or Notes, Paper CRF, Electronic CRF, Other

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3a. Experience with EDC…

The percentage of patient data *perceived* as entered into EDC system *and* the patient record?

70-100%!

A significant opportunity for efficiency gains!

Chart values: 6%, 2%, 11%, 14%, 67%

X-axis (% Data Duplicated): <70%, 70%, 80%, 90%, 100%

Y-axis: % Responders

Source: eClinical Forum Site Survey 2009, Global data

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3b. Emerging eClinical Technologies…

QUESTION 2

*What do sites consider as priorities for **emerging eClinical Technologies**?*

Emerging eClinical Technologies…

Emerging eClinical features would be of benefit !

Of primary importance…

- **Access to all clinical data …………………... 67%**
  available via a single portal *(e.g. central laboratory data, patient reported outcomes)*

- **Single sign-on ………………………………... 63%**
  for all study web portals

- **Online approval of documents ……………. 54%**
  via e-signature

- **Study documentation ………………………... 53%**
  posted via website

Emerging eClinical Technologies…

DIA

Emerging eClinical features would be of benefit !

Of less importance…

- **System access can be requested online**………... *49%*
- **SMS messages** ………………..……………….. *38%*
  sent to patients and site staff to aid
  scheduled visit attendance
- **Study site master file maintained online**…..…….. *38%*
- **Study management reports online**……………….. *38%*
  to aid study performance available on-line
- **Feasibility questionnaires via secure portal** …..... *37%*

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3c. Secondary Use of EHR Data…

DIA

Many healthcare professionals and researchers wonder why the different electronic sources can't be linked

This would avoid…

- Reduce redundant data entry
- Avoid data transcription errors
- Clarify the 'source issue
- Use a familiar system

Healthcare
Completing ~1400 data points per patient
A typical trial has 6000 data queries (time /cost to correct)

Pharma Research
58% of trials do not meet projected recruitment rates!

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Slide 23

In 2004 we imagined… **Patient Data Exchange Between Healthcare and Drug Development Systems**

Emerging and Future EHR-Research Connectivity and Complexity

Healthcare System

Clinical Trial System

Current Divided

Integrated Future

Interoperable Ideal

Current Divided
- EHR systems holding source for data used in clinical trials may not meet essential regulatory requirements
- Clinical care data required for clinical trials is entered into EHR and into clinical trial systems
- Research holds source data not part of normal clinical care
- Redundant data entry, transcription errors and source issues cost healthcare and industry time and money.

Integrated Future
- EHRs used to…
  - Evaluate Patient Populations
  - Accelerate Patient Recruitment
  - Capture CT Data
  - Exchange CT Data
- The EHR becomes the patient data repository

Interoperable Ideal
and research systems work
lessly together so that groups
t from data access and mining
bilities across healthcare and
rch data sets
arch systems and healthcare
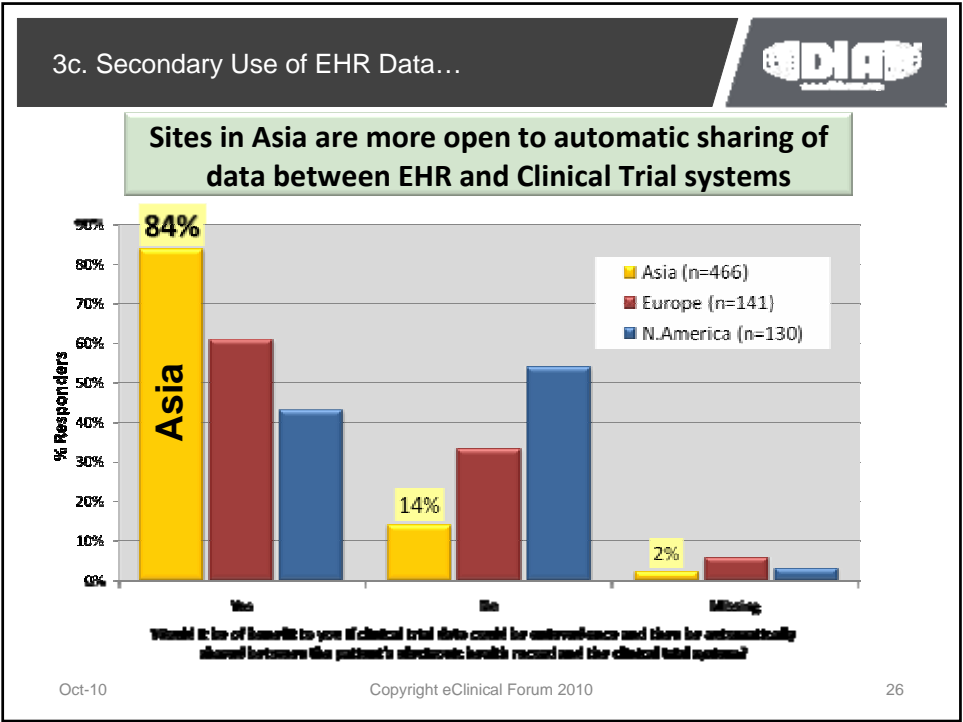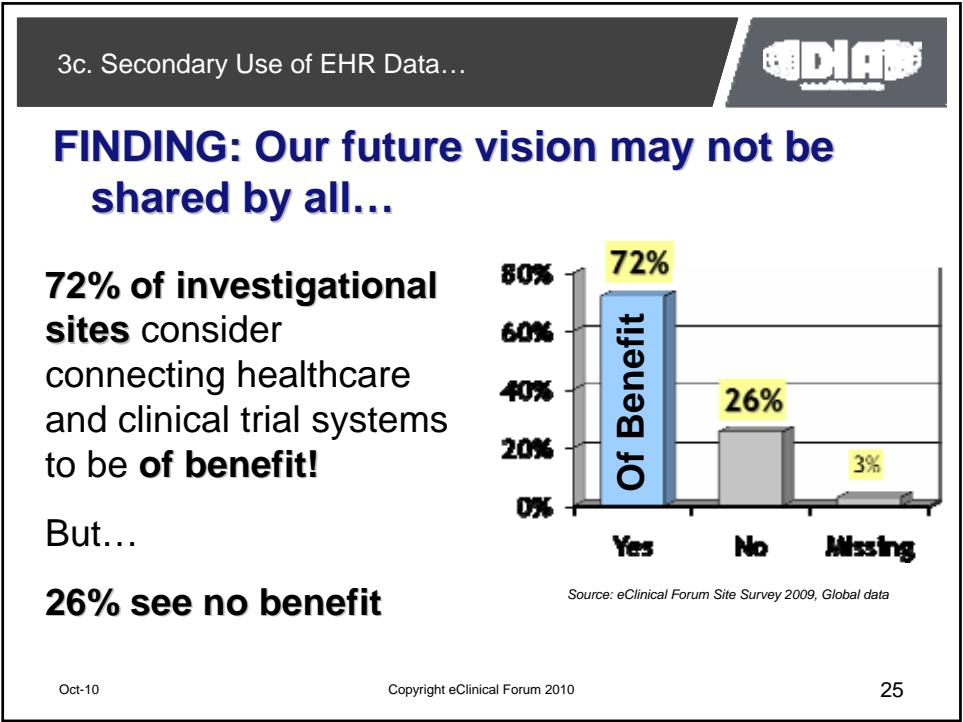ms sit on the same spine
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Slide 24

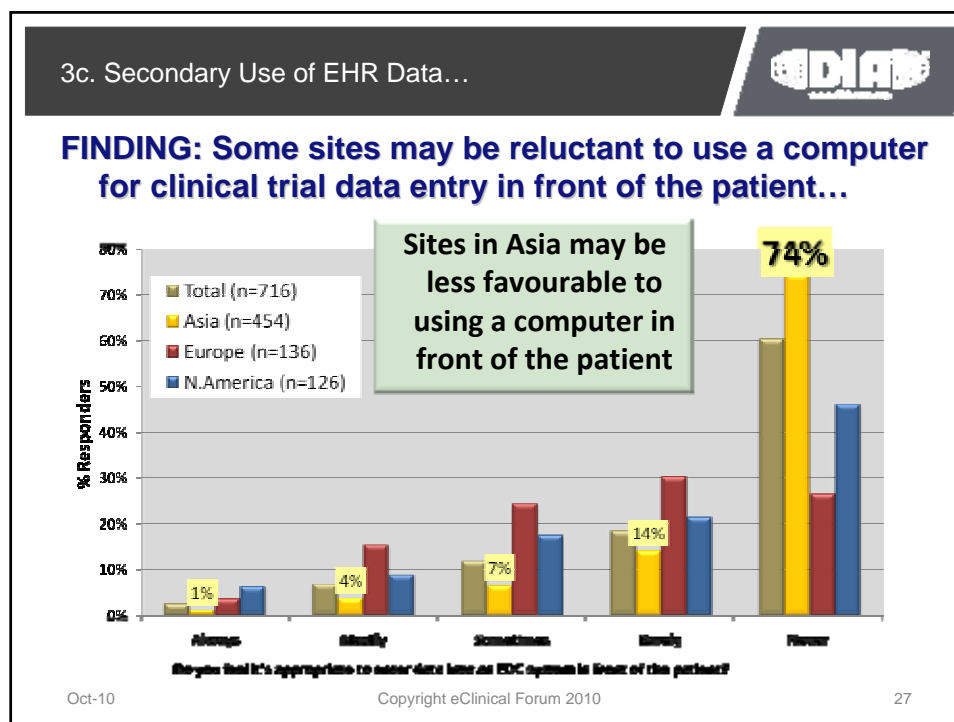# QUESTION 3

How do sites view the potential of **secondary use of EHR data**?

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3c. Secondary Use of EHR Data…

FINDING: Some sites may be reluctant to use a computer for clinical trial data entry in front of the patient…

Sites in Asia may be less favourable to using a computer in front of the patient

- Total (n=716)
- Asia (n=454)
- Europe (n=136)
- N.America (n=126)

74%

1%   4%   7%   14%

% Responders

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4. Conclusion and Next Steps…

1. The eCF Site Survey gives an important insight into the needs and expectations of sites for the emerging environment for Clinical Trials
   - Data capture
   - Emerging eClinical technologies
   - Secondary use of EHR data

2. The following areas need to be considered…
   - Not everyone is completely satisfied with EDC
     - Source
     - Increase in workload and data entry effort
     - Change of responsibilties
   - Some emerging eClinical technologies are of more importance to sites
   - Not everyone sees benefit in connecting healthcare and research

A review of only a small proportion of the survey data

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Download presentation from eclinicalforum.org

Full report available in November

Any Questions…