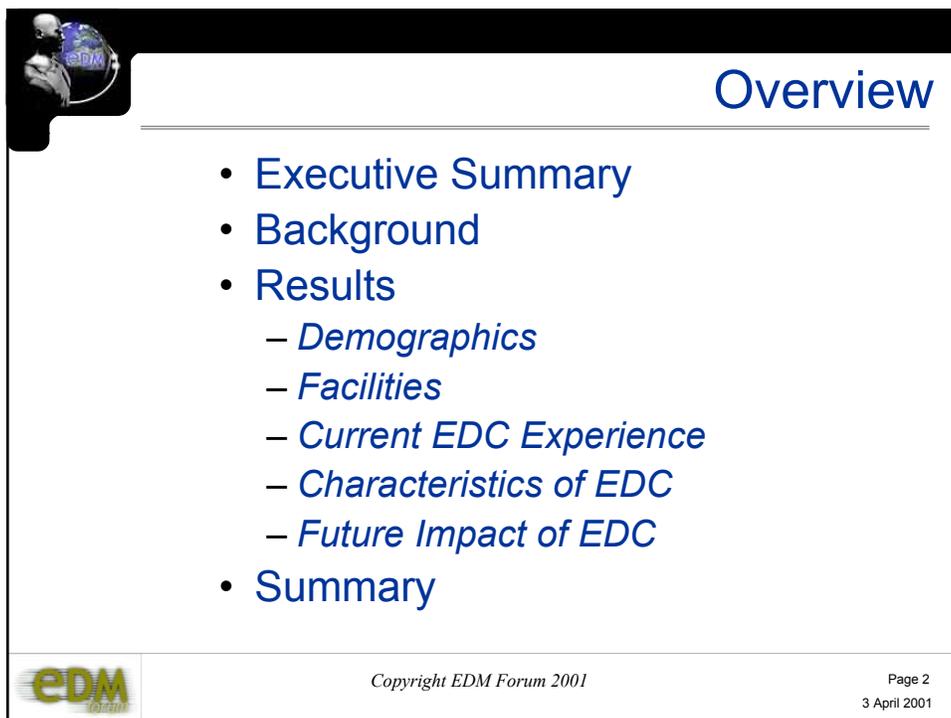


A Global Survey to  
Identify Investigational  
Site Needs Associated  
With EDC Trials

EDM Forum

July 2001



## Overview

- Executive Summary
- Background
- Results
  - *Demographics*
  - *Facilities*
  - *Current EDC Experience*
  - *Characteristics of EDC*
  - *Future Impact of EDC*
- Summary

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Executive Summary

## Executive Summary – Part 1

- The Electronic Data Management Forum was formed in 2000 by Pharmaceutical Industry representatives. It serves those members of the industry, vendors and service suppliers who are involved in electronic data capture and related initiatives.
- The group has recently conducted a global survey of investigational site experiences and expectations with EDC. The survey covered:
  - *Computer use and site facilities*
  - *Current experience with EDC*
  - *Satisfaction with features of EDC*
  - *Future expectations*
- **840 completed questionnaires were returned by both EDC experienced (52%) and EDC naïve (48%) investigators.** The results show:
  - *In the EDC experienced population **44% of current trials use EDC** compared with 28% over the previous 3 years*
  - *Although there are significant differences between continents, investigators are very computer literate with even **20-30% of EDC naïve investigators using EMail and Internet several times a day.***



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Executive Summary

## Executive Summary – Part 2

- *Investigators find **data entry a burden** that should ideally be shifted to other site staff.*
- *Despite investigators wanting to improve the speed of data entry, **only 13% of data is first entered into the eCRF.** The main opportunity to improve speed of entry lies in avoiding duplication of entry into both EDC and patient records.*
- *Gaps exist between investigator need and level of satisfaction with speed of communication, tools for **study management, direct data transfer and resources for data entry.***
- *Most EDC experienced investigators consider that EDC should be used for all trials and over **50% of investigators say that the availability of EDC will positively affect their decision to participate** in trials.*
- *If a solution could be found to print or **transfer eCRF data** for inclusion into patient records, 67% of EDC experienced investigators would enter data directly into the EDC system*
- *Only **34% of investigators felt that data could be entered directly into the EDC system in front of the patient** in most or all circumstances. Highlighting the likelihood that an interim paper record will normally exist for the foreseeable future even if the data transfer issue to patient records could be resolved*
- The results show interesting issues and trends that the EDM Forum will be exploring further.



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Background

## Background

- Aims of the survey:
  - *To explore the experience and attitudes of investigators who participate in clinical trials towards EDC.*
  - *Identify areas that the industry can improve*
  - *Indicate which areas have potential for further study.*
  - *To include EDC experienced and EDC naïve sites*
- Not intended to be a comprehensive, formal analysis of EDC practice
- EDM Forum Pharma company selection of sample
- Target was 750 investigators



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Background

## Survey Questionnaire

- 5 sections
  - Site Data – *for demographics*
  - Computer Use and Facilities – *to assess availability of hardware, use of internet and Email and comfort with computer*
  - Current EDC Experience – *for the most recent EDC trial, type of EDC used, roles, speed and percentage of eEntry, reward for timely entry*
  - Characteristics of EDC – *importance vs satisfaction with 21 characteristics*
  - Future Impact of EDC – *Expectations of EDC, impact on decision to participate in a trial, speed of entry, direct entry*



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## Background

## Caveats

- Some of the information is historical
- The survey is subjective. *Responses reflect the experience and views of individual investigators. No control of interpretation*
- No attempt was made to ensure any form of balanced coverage of investigators, companies or countries
- As the survey was anonymous, there may be multiple responses from a site



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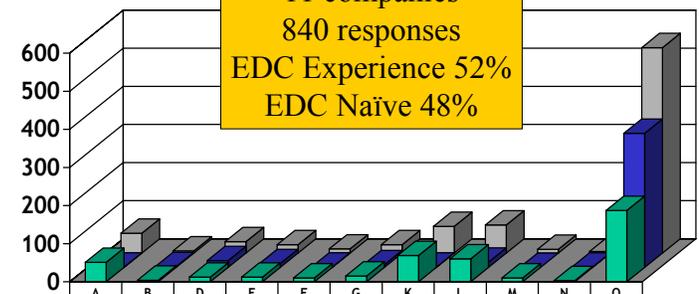
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## A. Demographics

## Questionnaire Returns

11 companies  
840 responses  
EDC Experience 52%  
EDC Naïve 48%

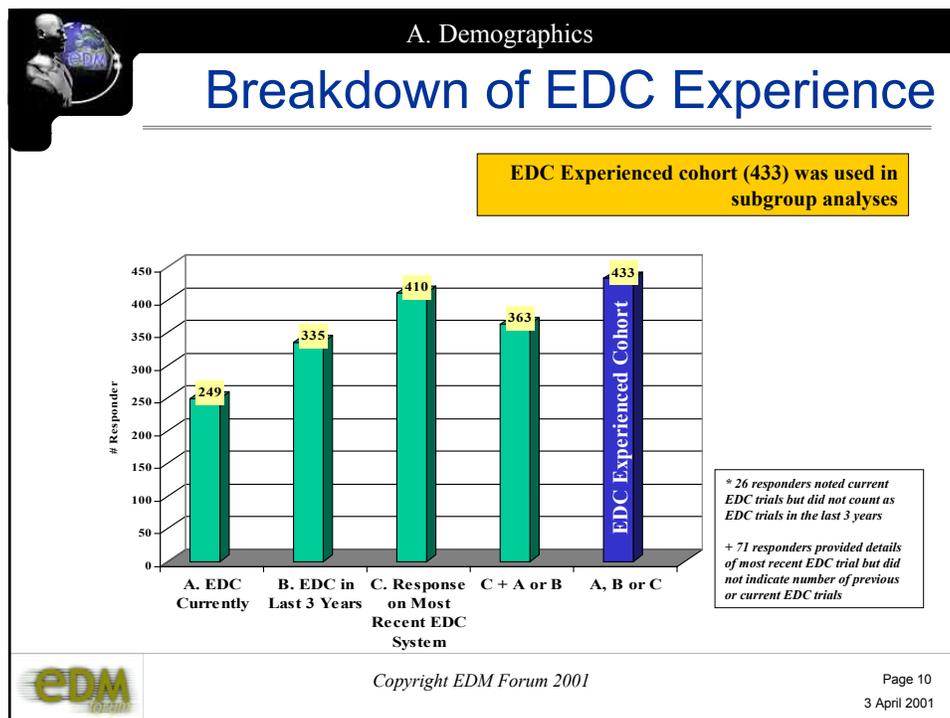
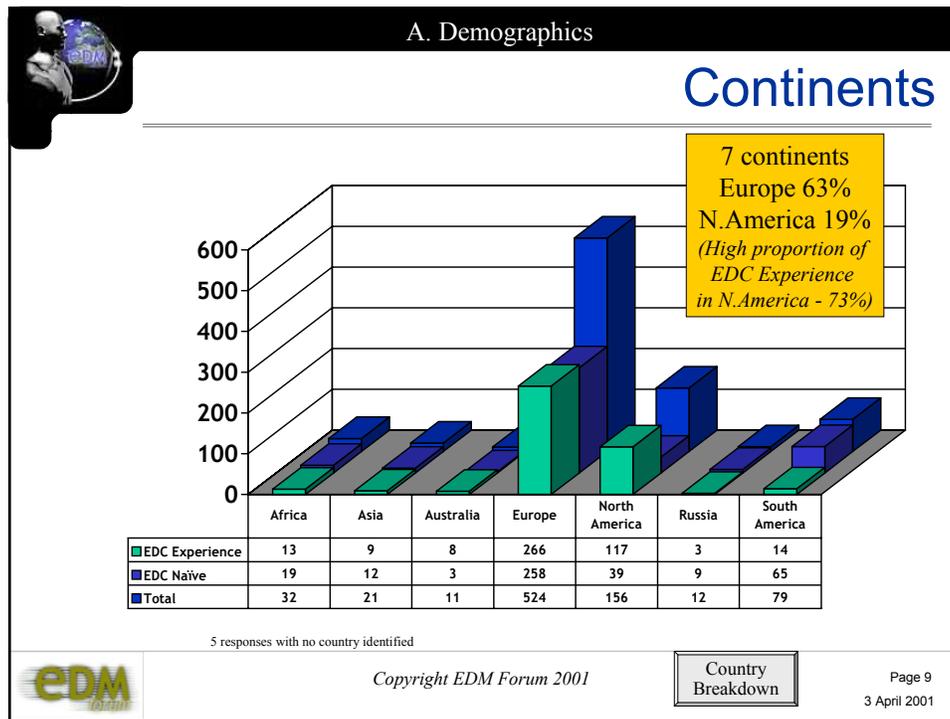


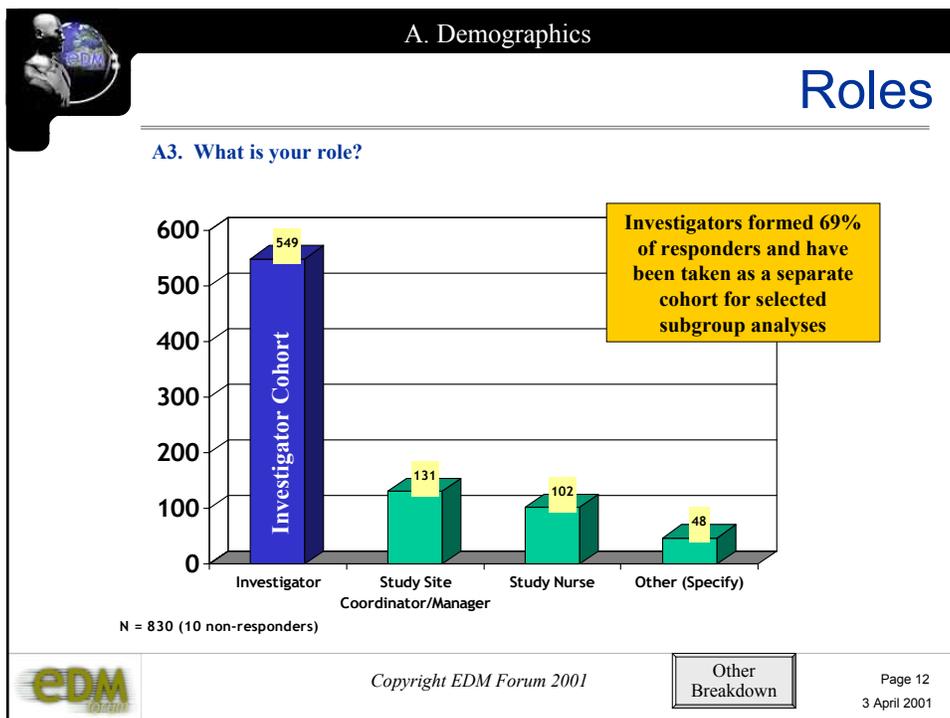
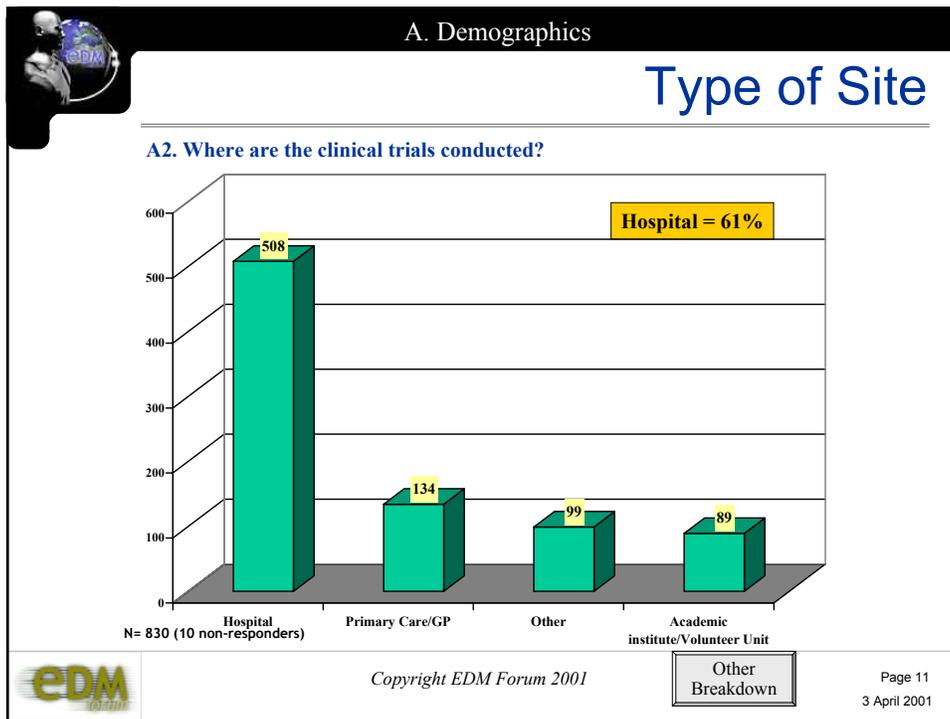
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| EDC Experience | 51 | 4 | 12 | 12 | 10 | 15 | 69 | 60 | 10 | 3 | 187 | 433 |
| EDC Naïve      | 1  | 2 | 18 | 10 | 1  | 7  | 1  | 14 | 0  | 1 | 352 | 407 |
| Total          | 52 | 6 | 30 | 22 | 11 | 22 | 70 | 74 | 10 | 4 | 539 | 840 |

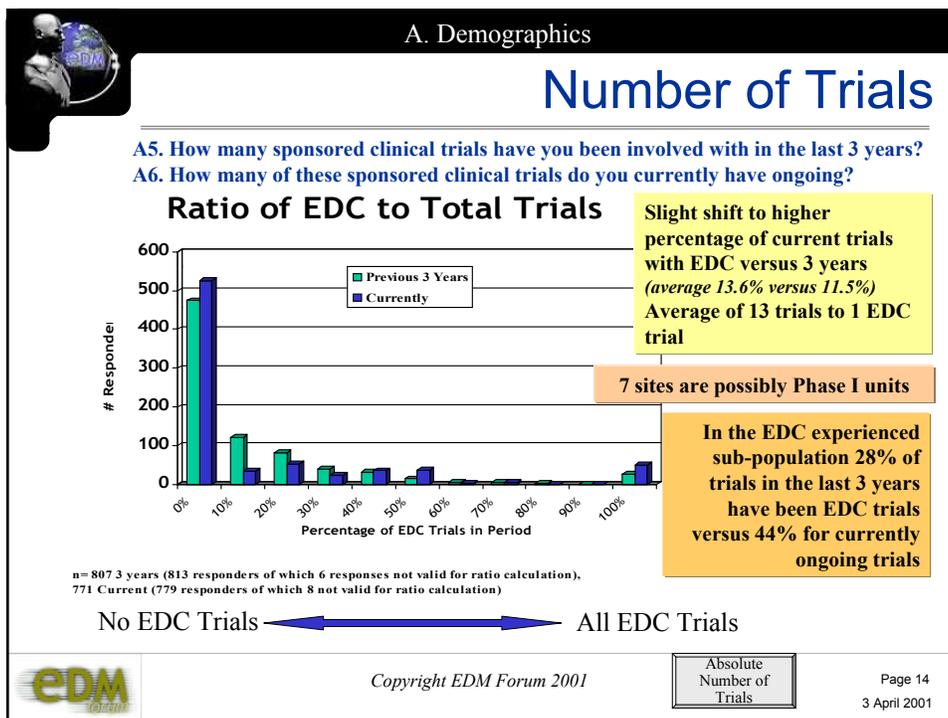
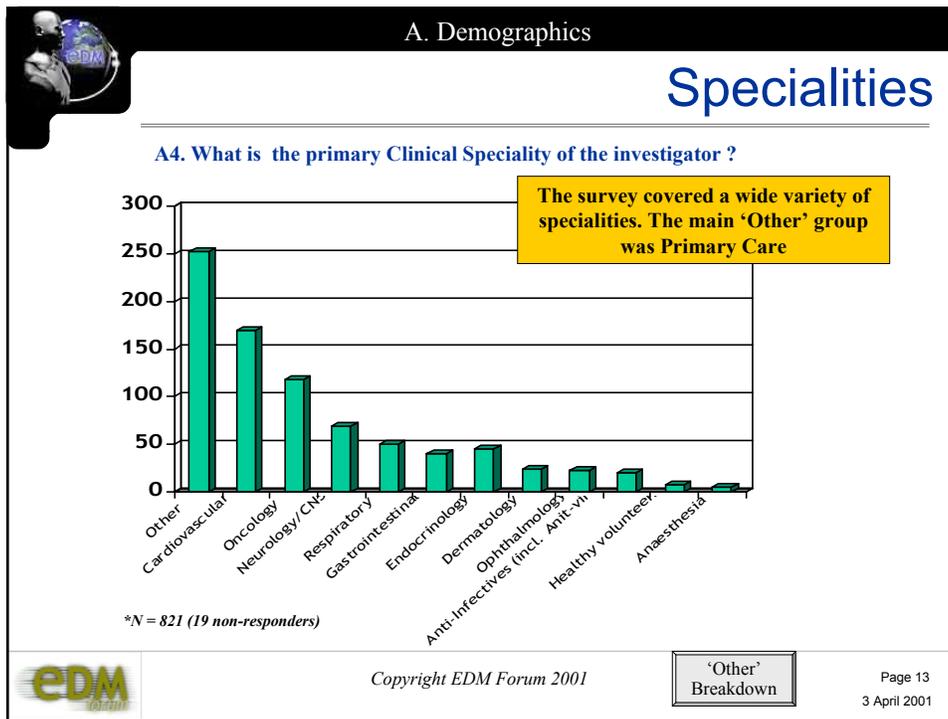


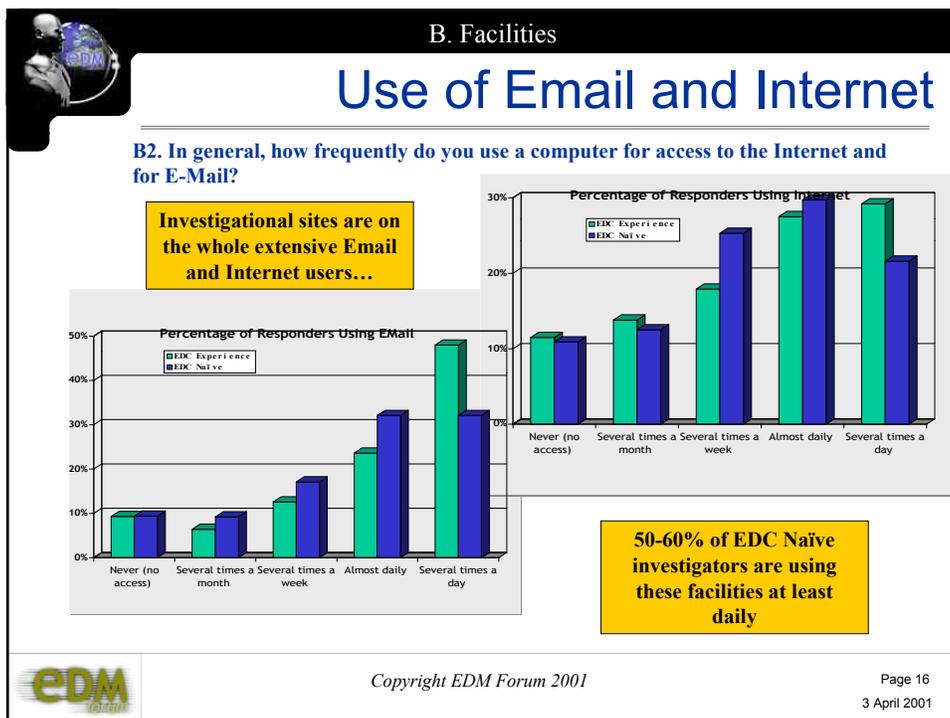
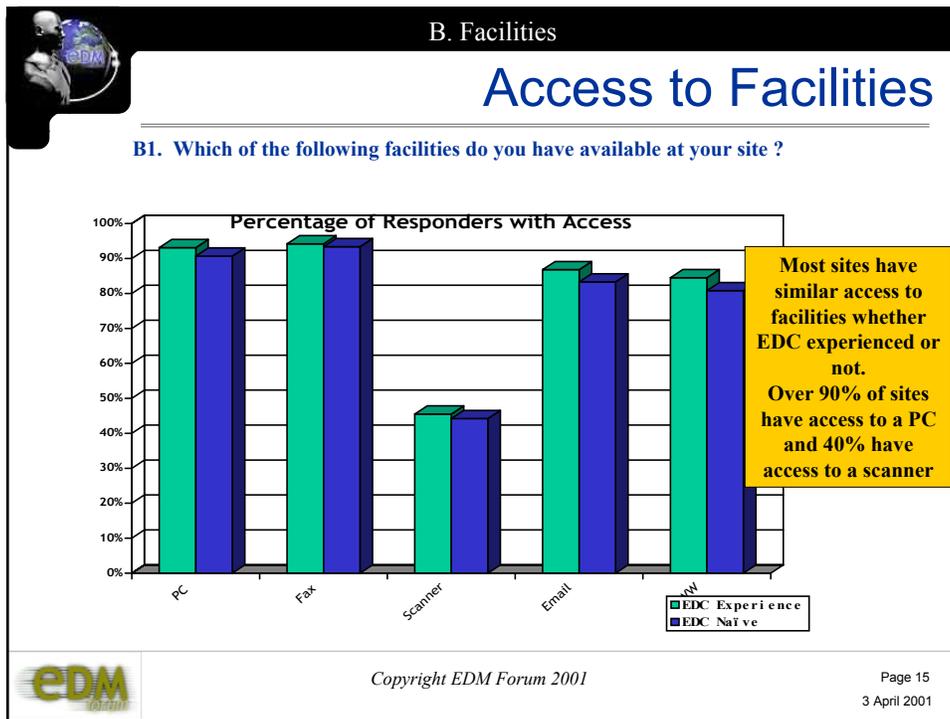
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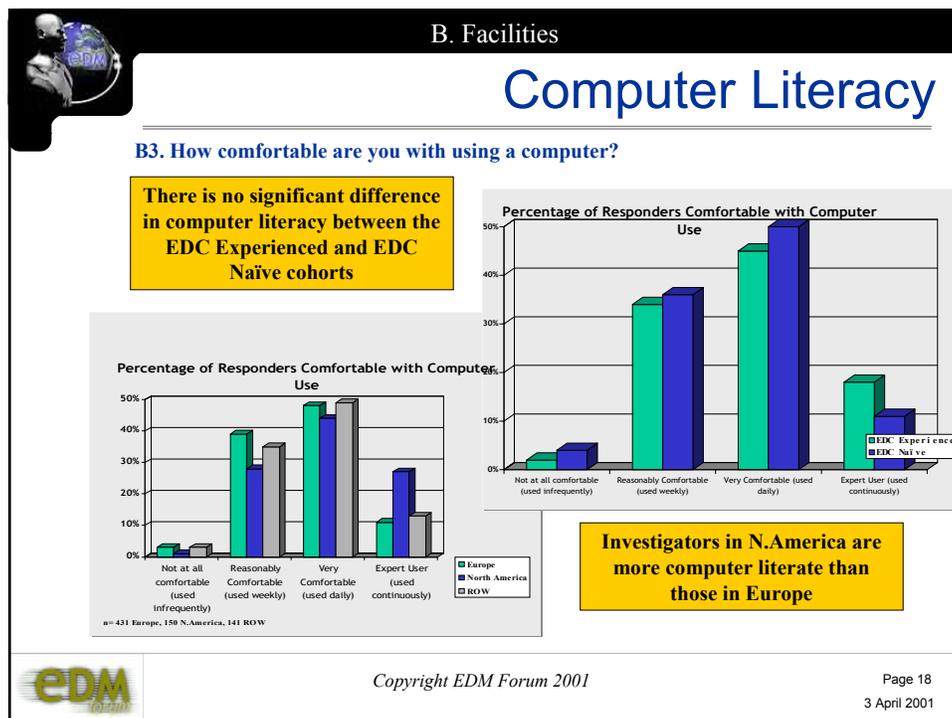
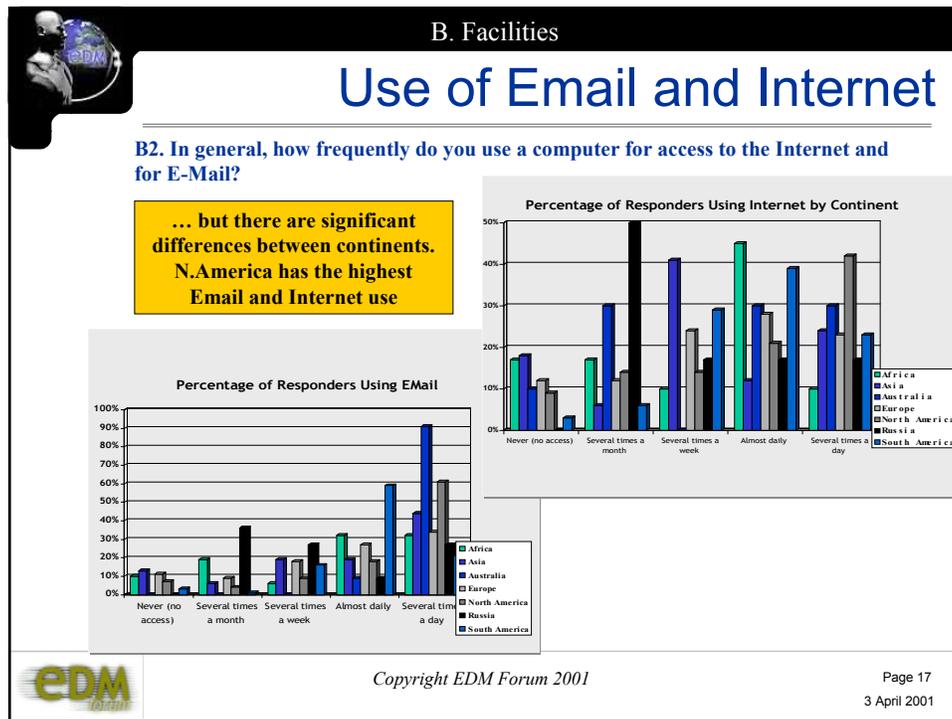
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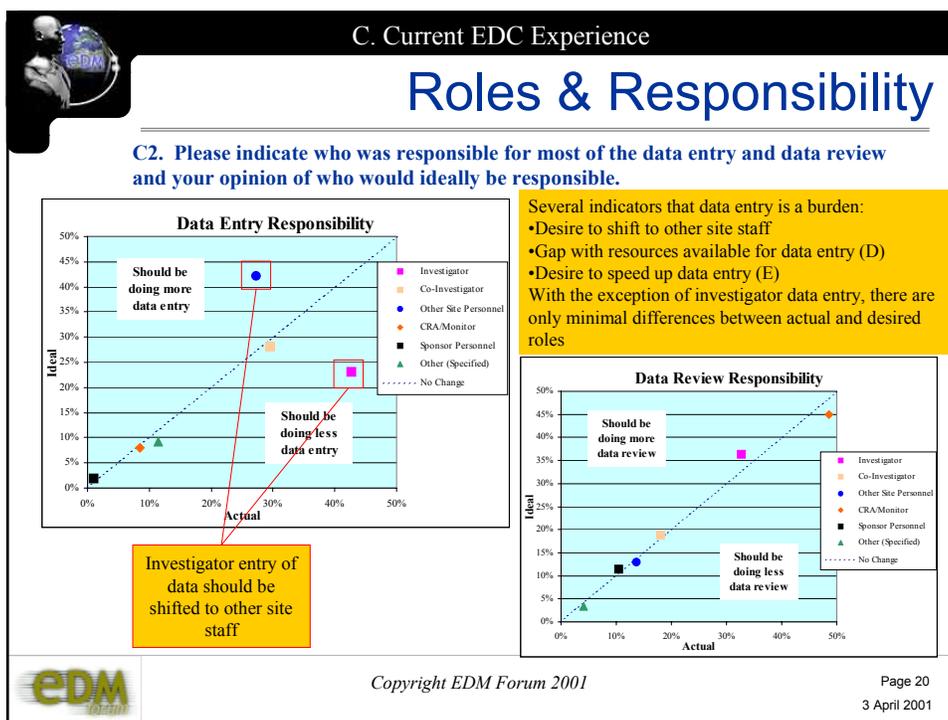
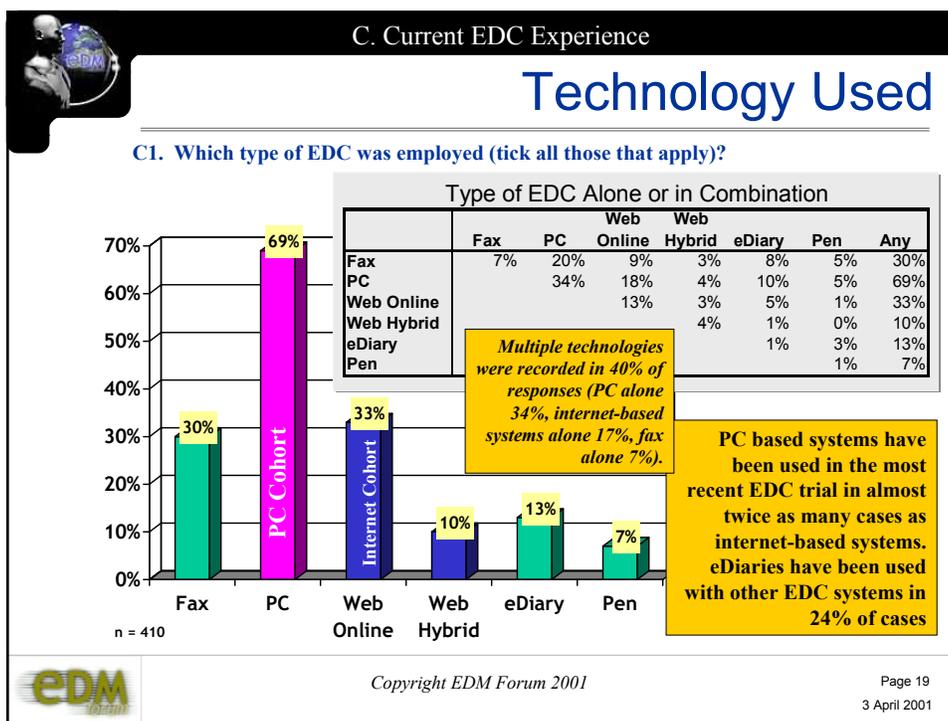


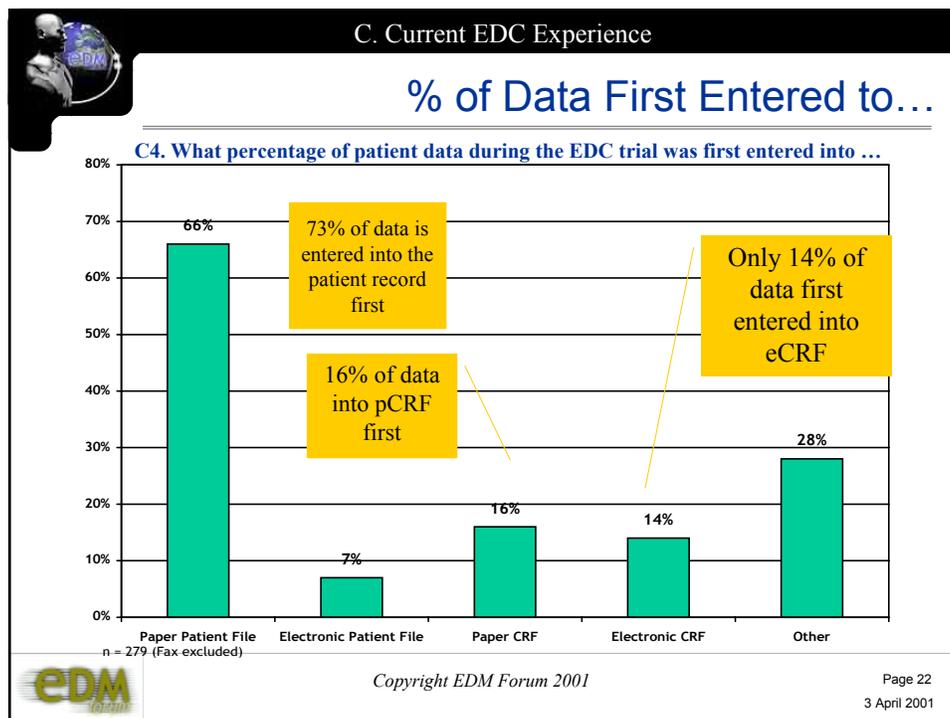
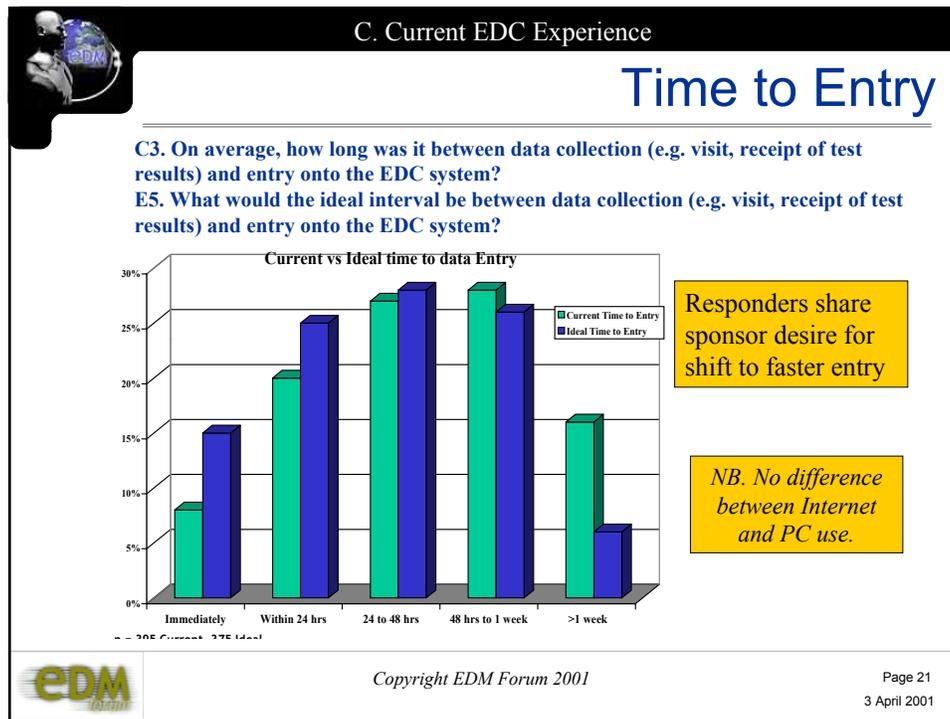


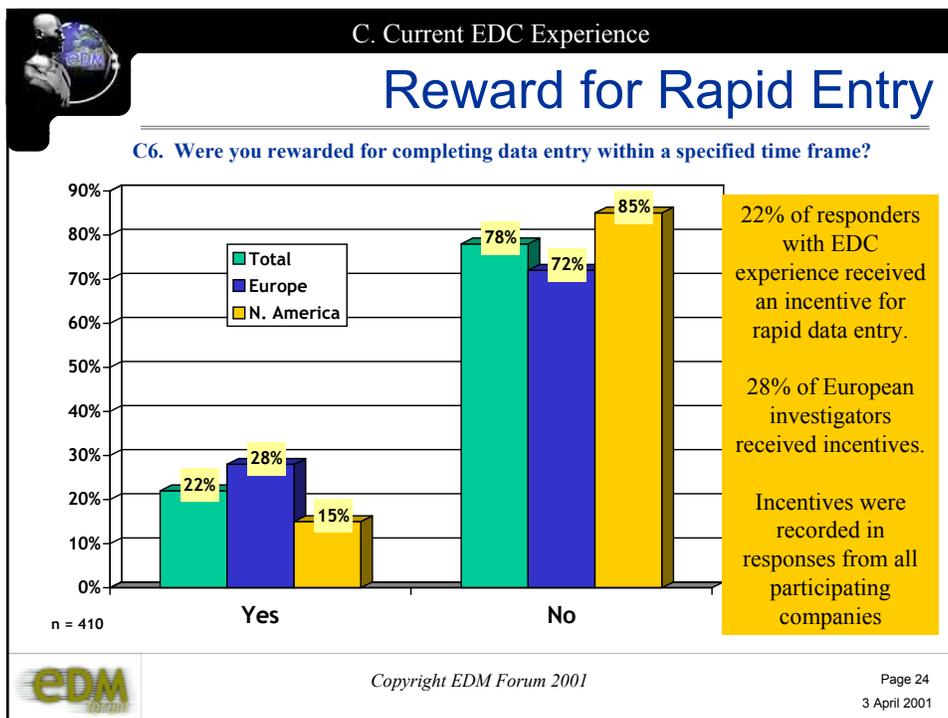
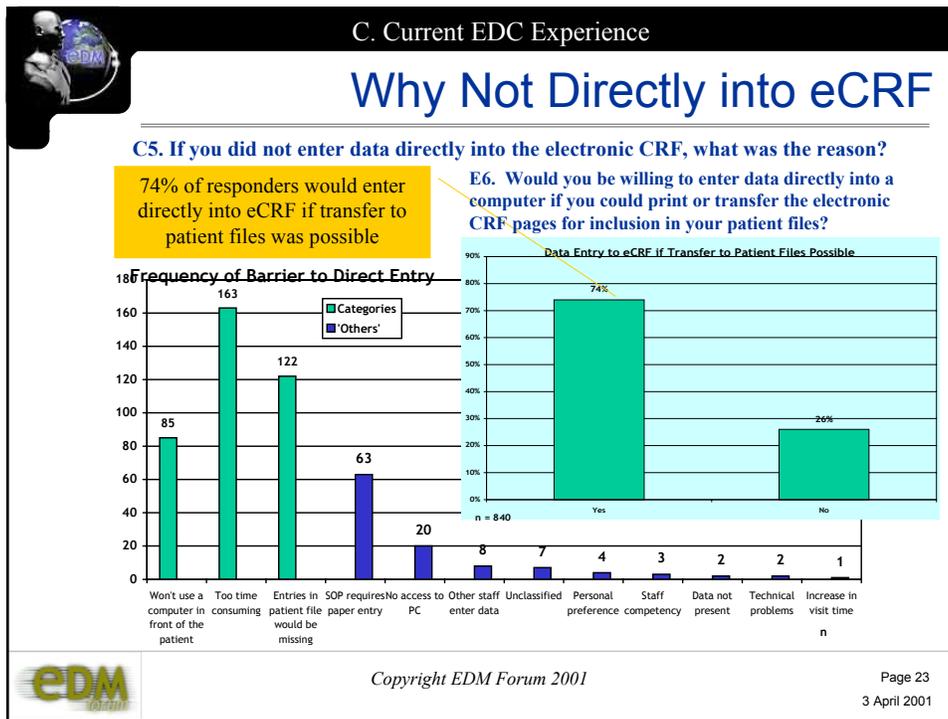


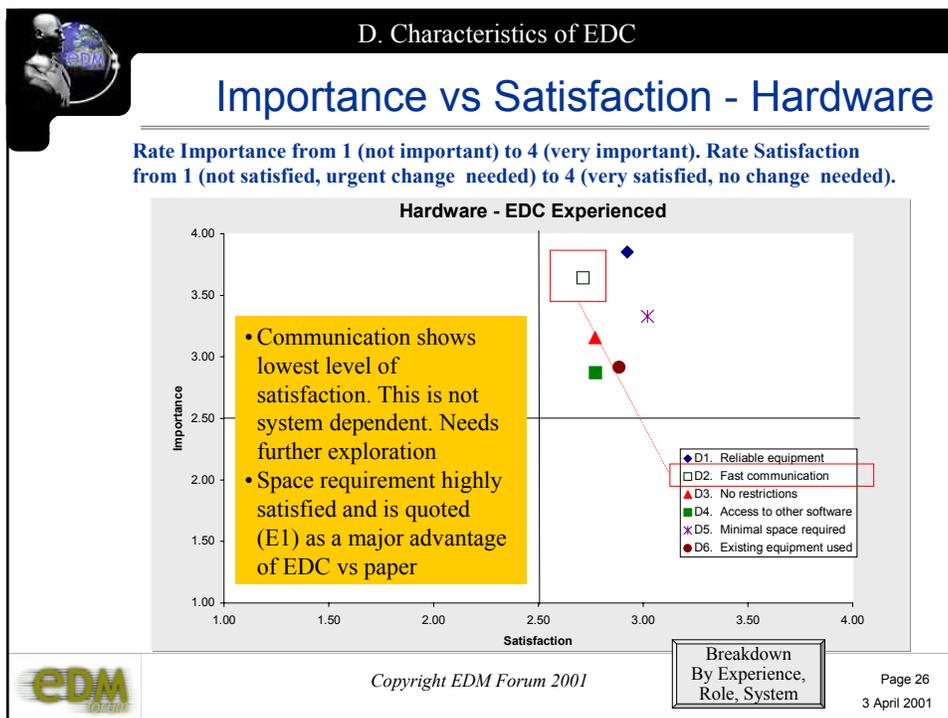
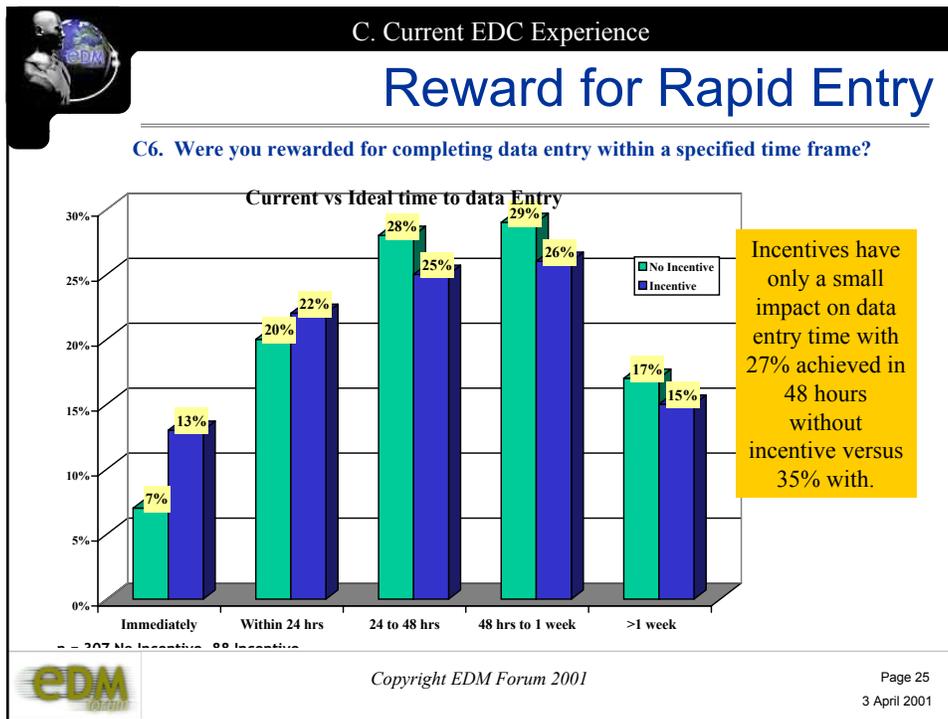


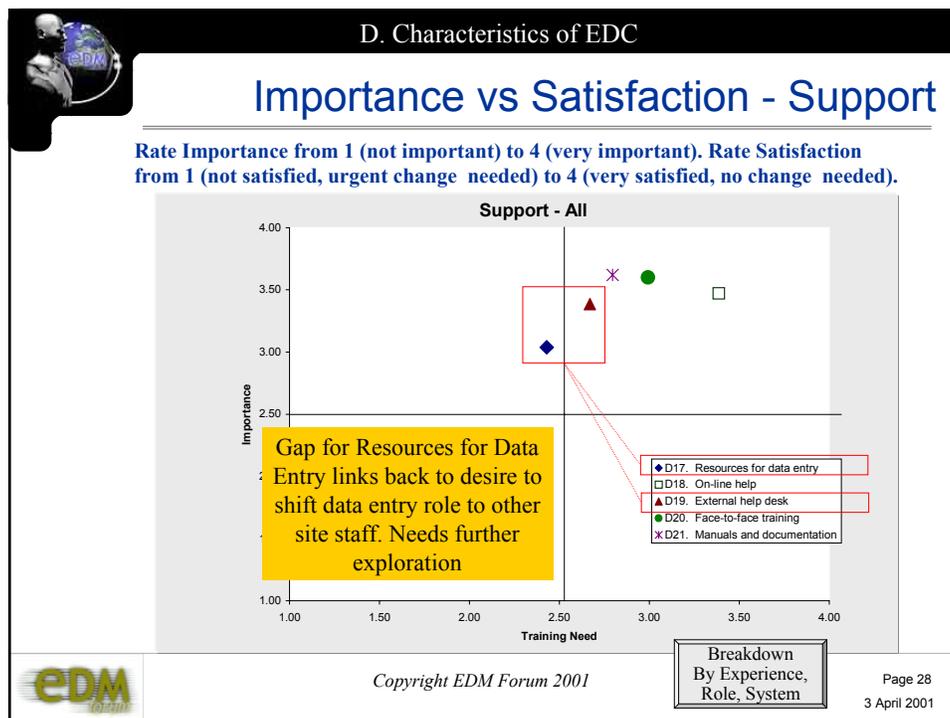
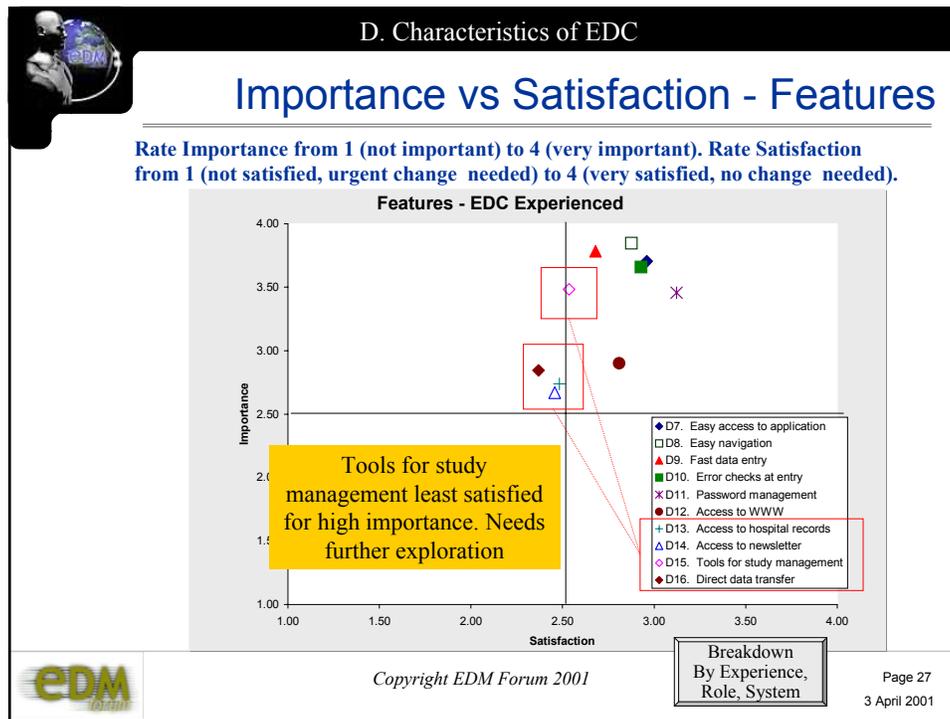


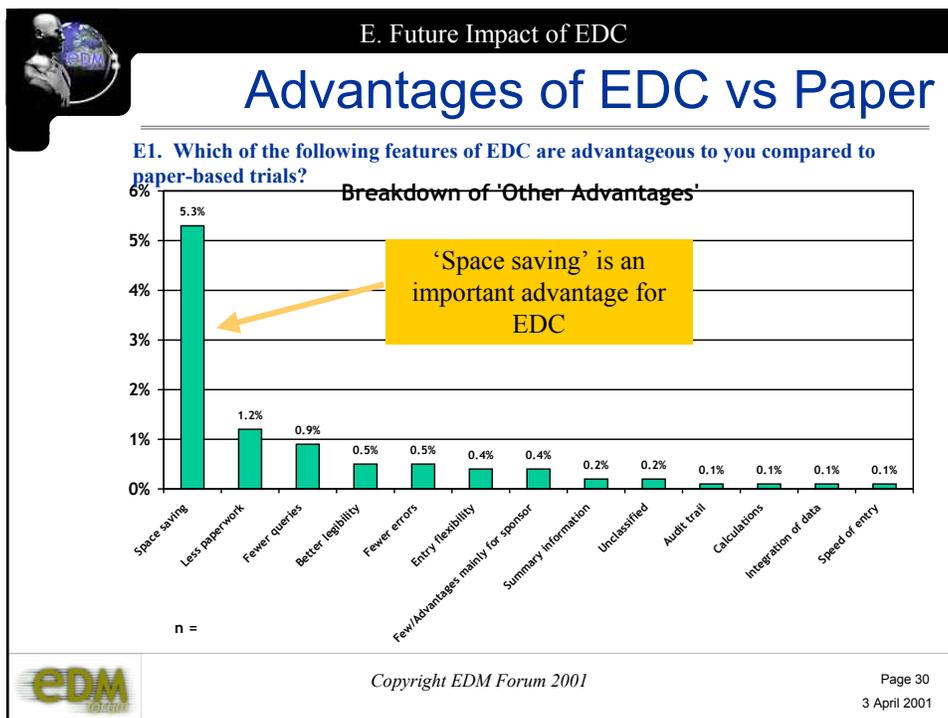
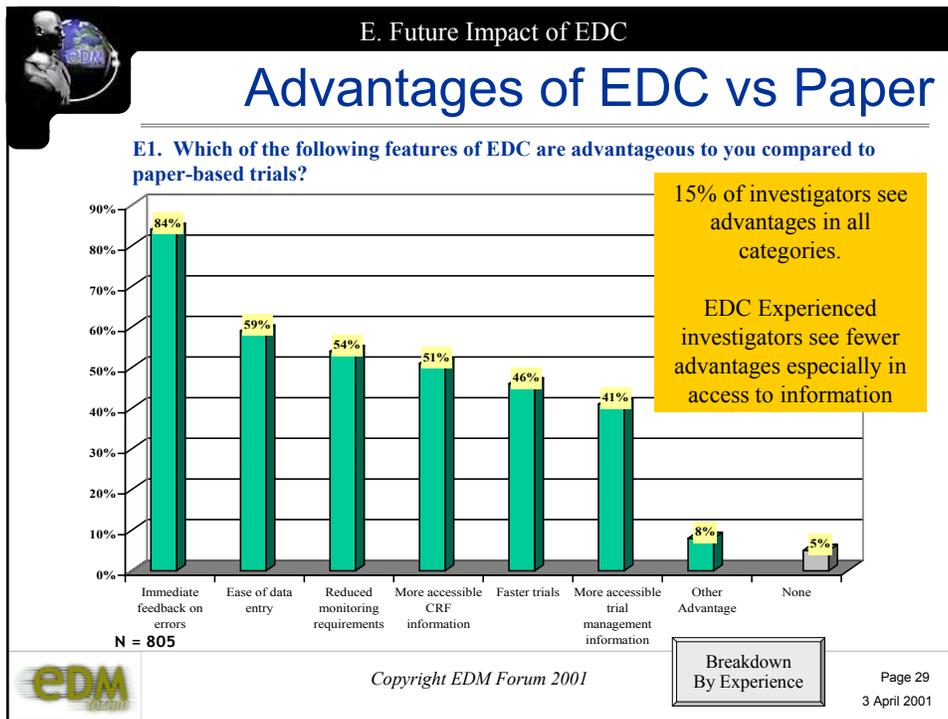


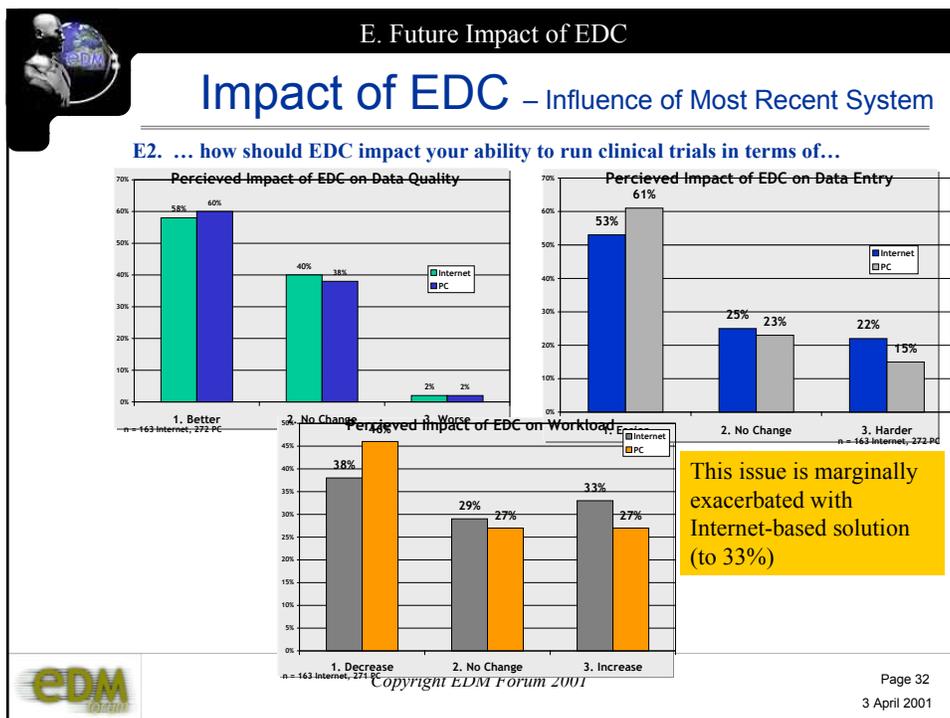
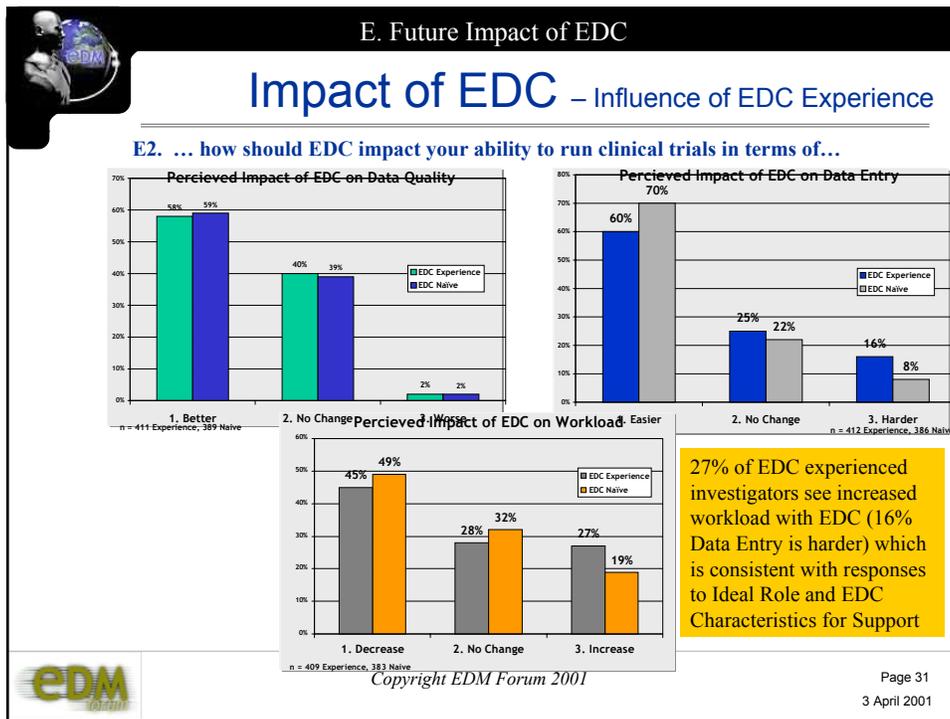


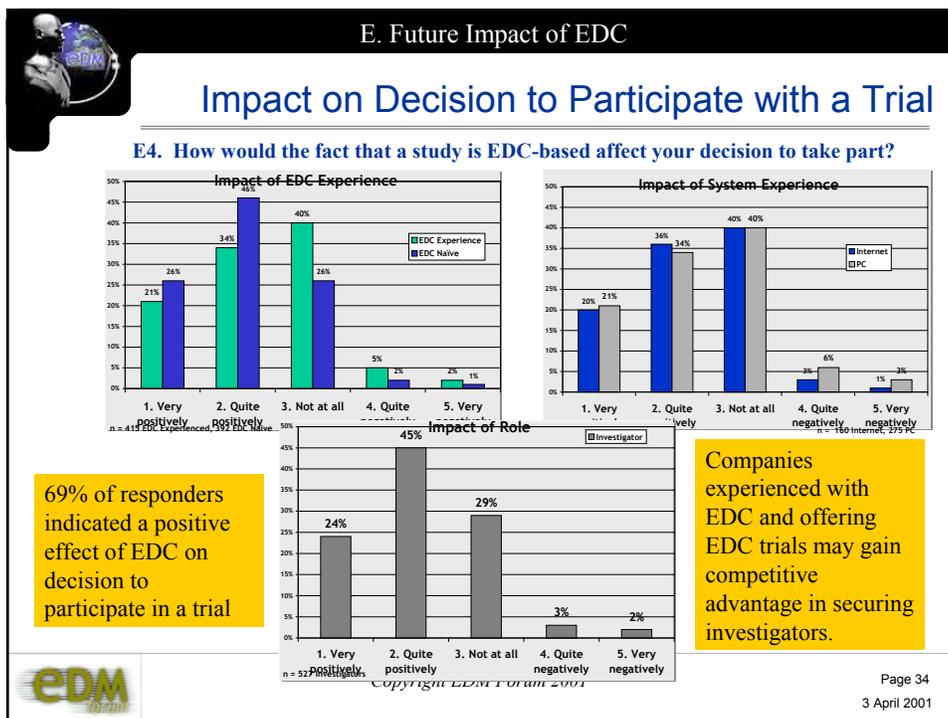
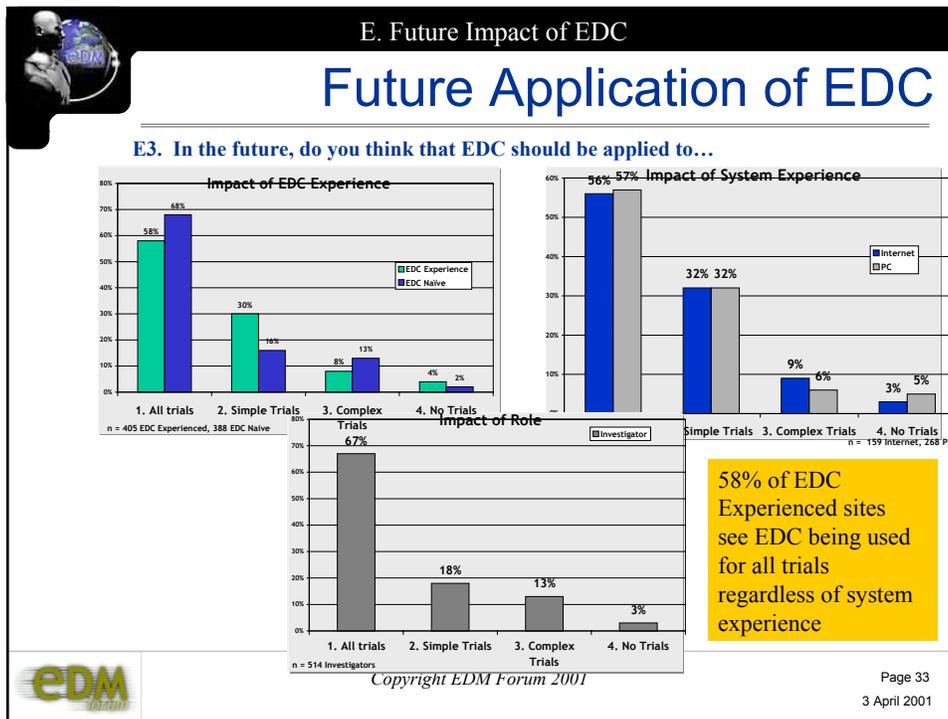


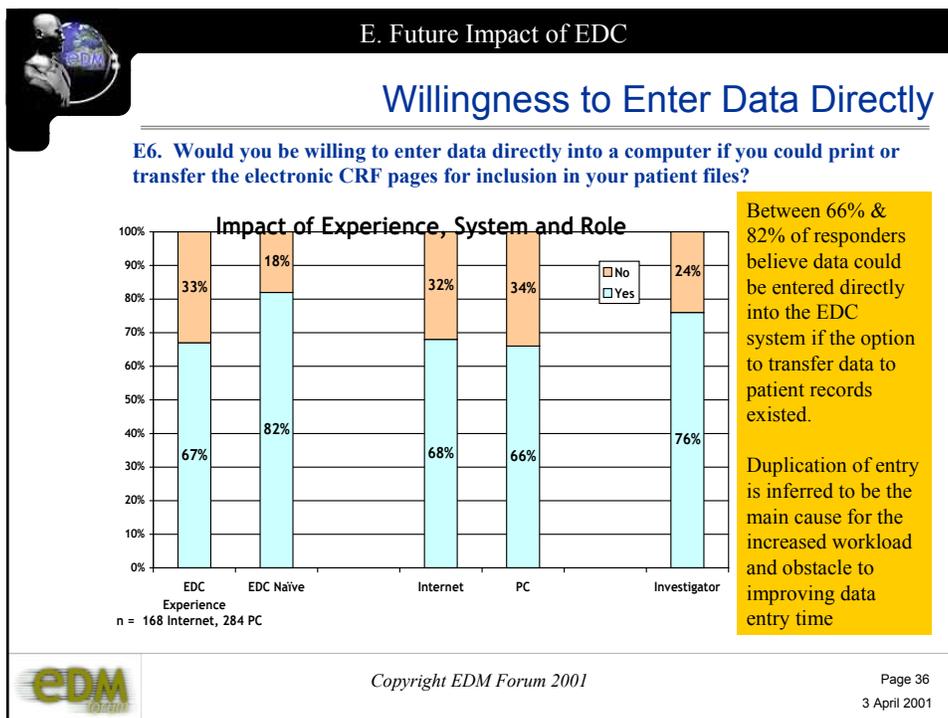
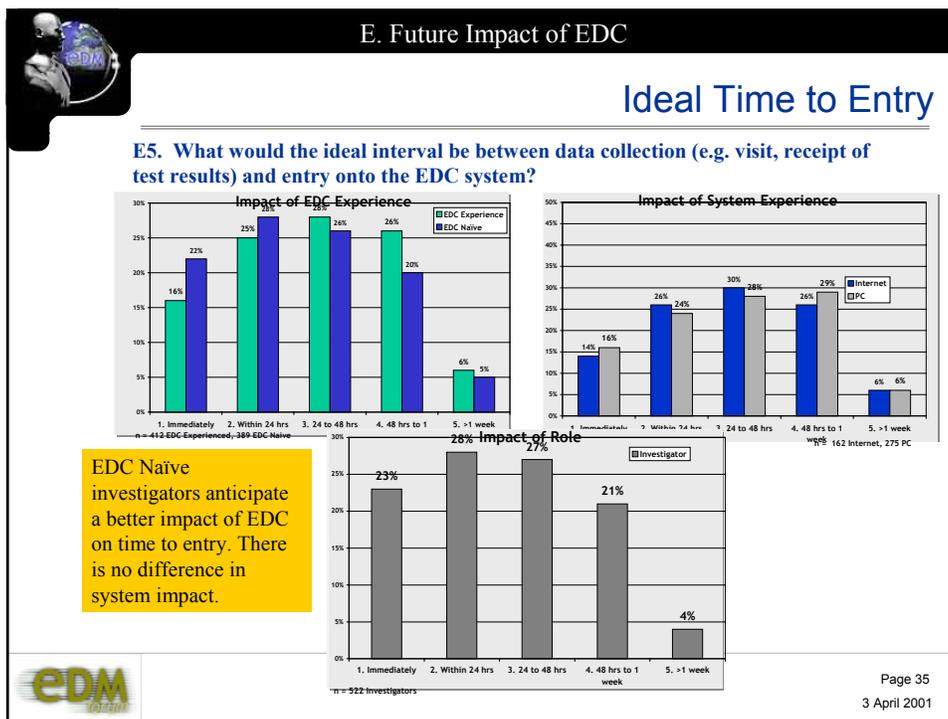


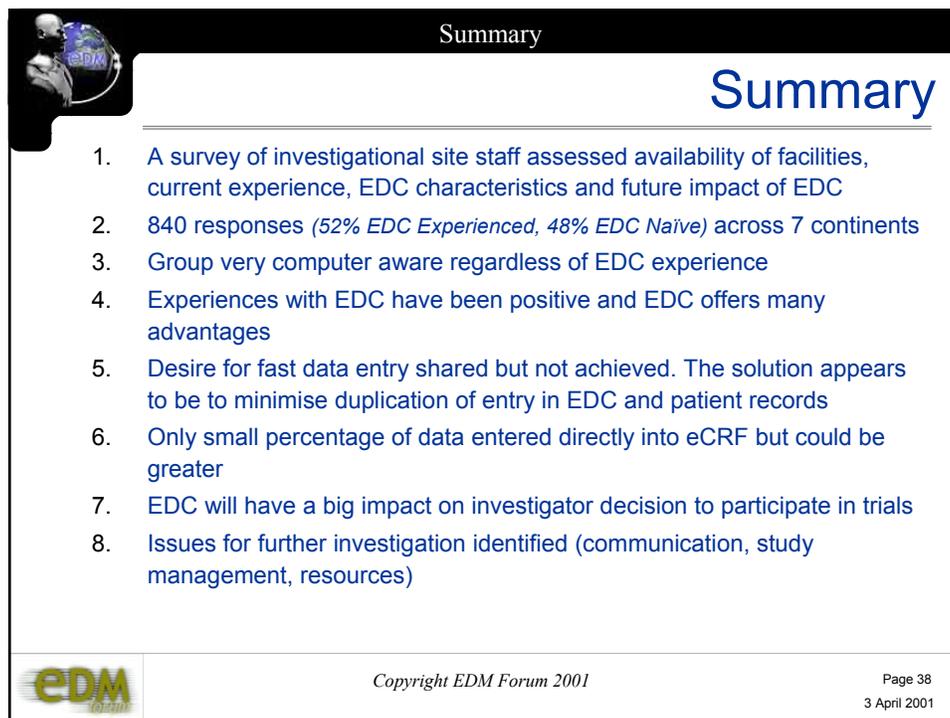
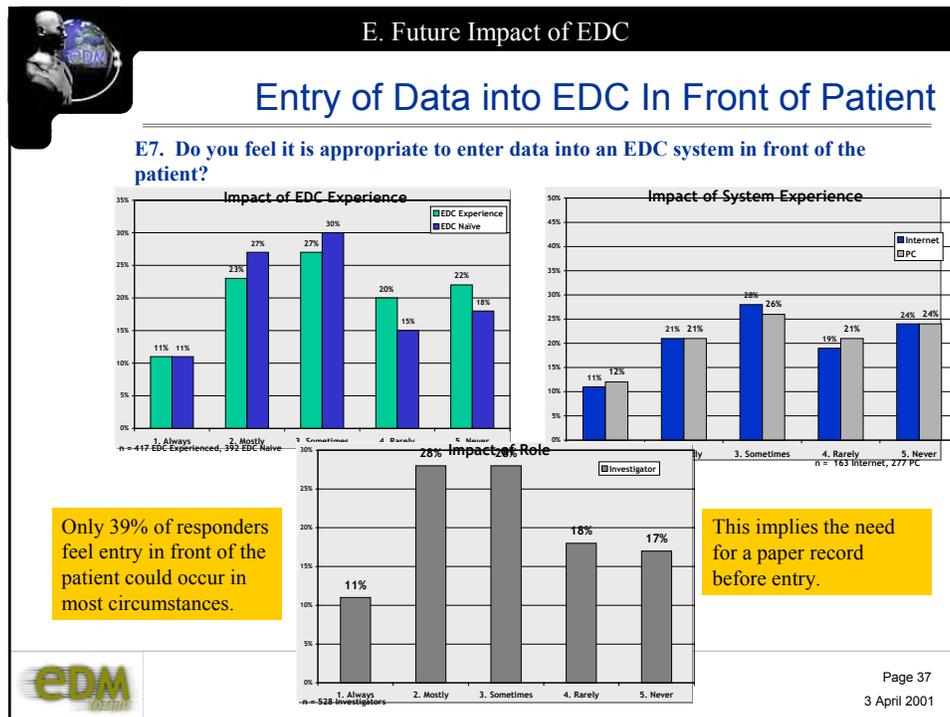


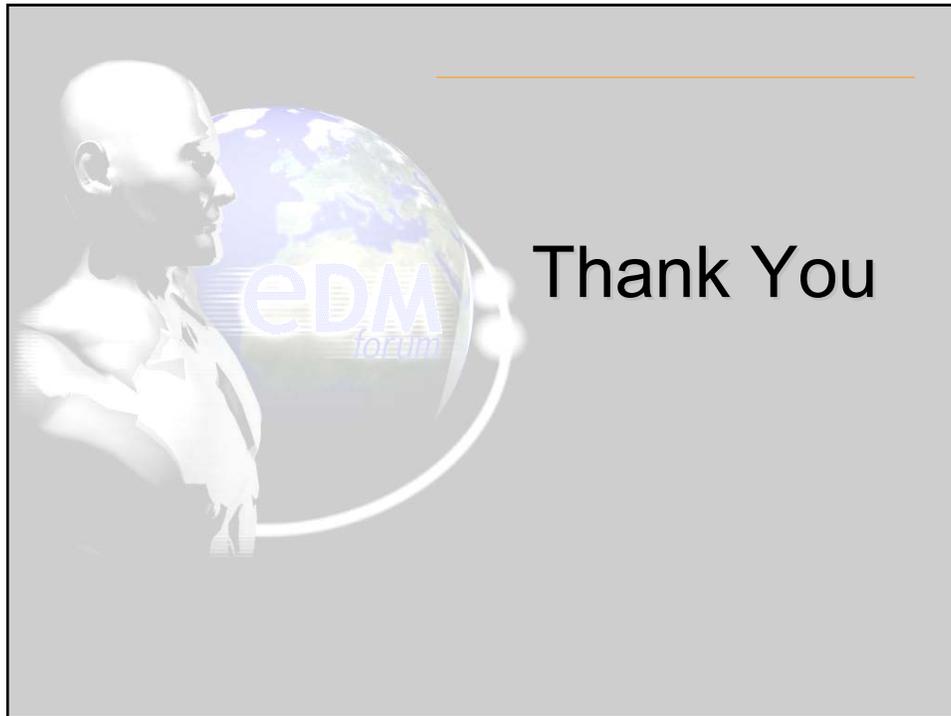












Appendix 1

## Survey Materials

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[Survey Questionnaire](#)  
[Investigator Instructions](#)

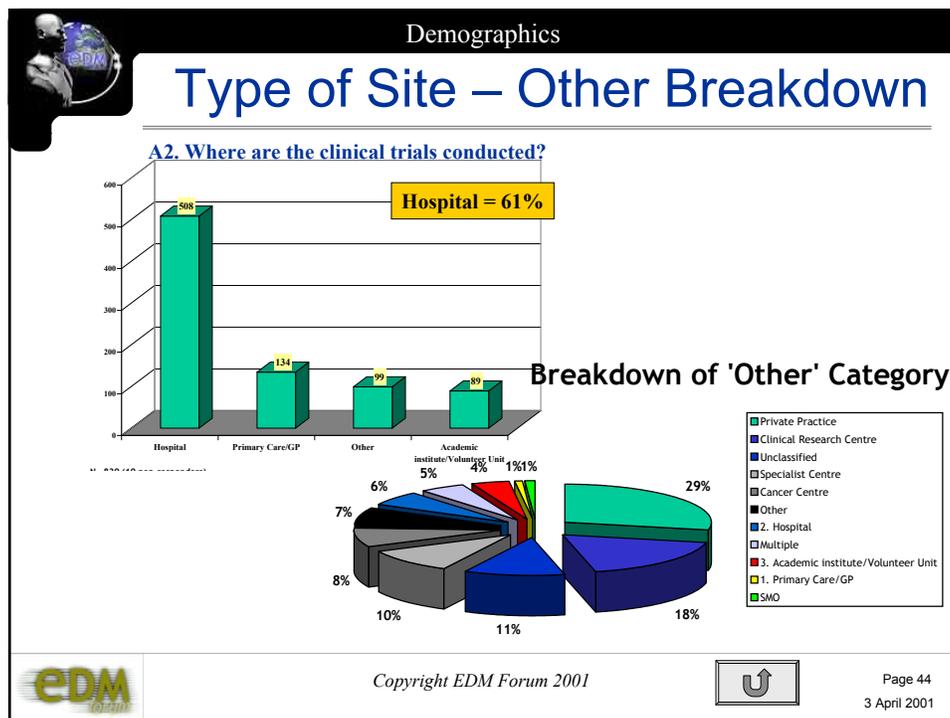
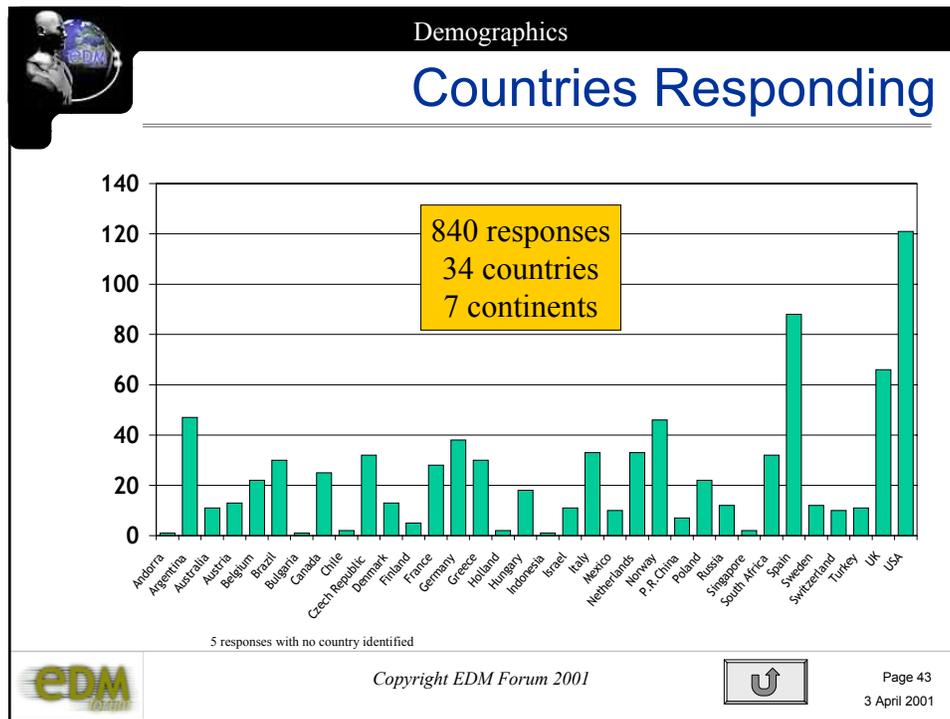
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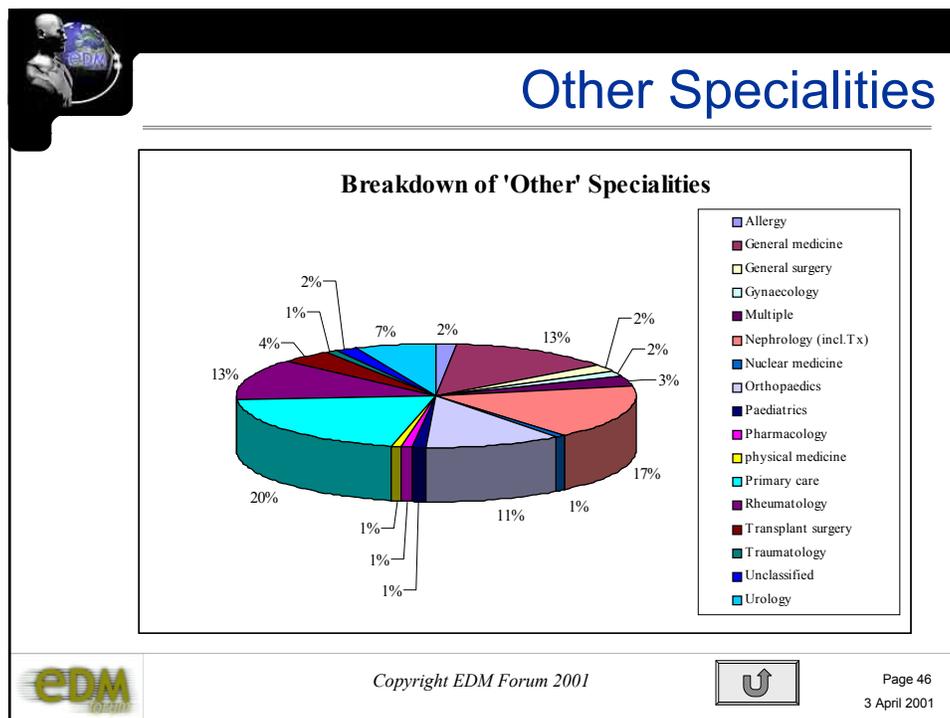
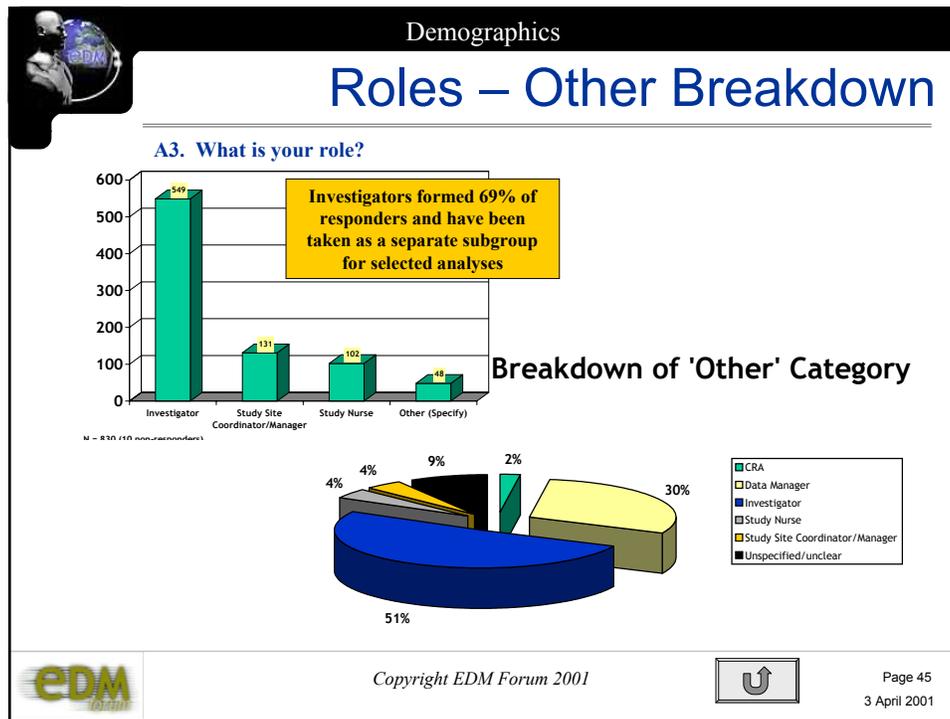
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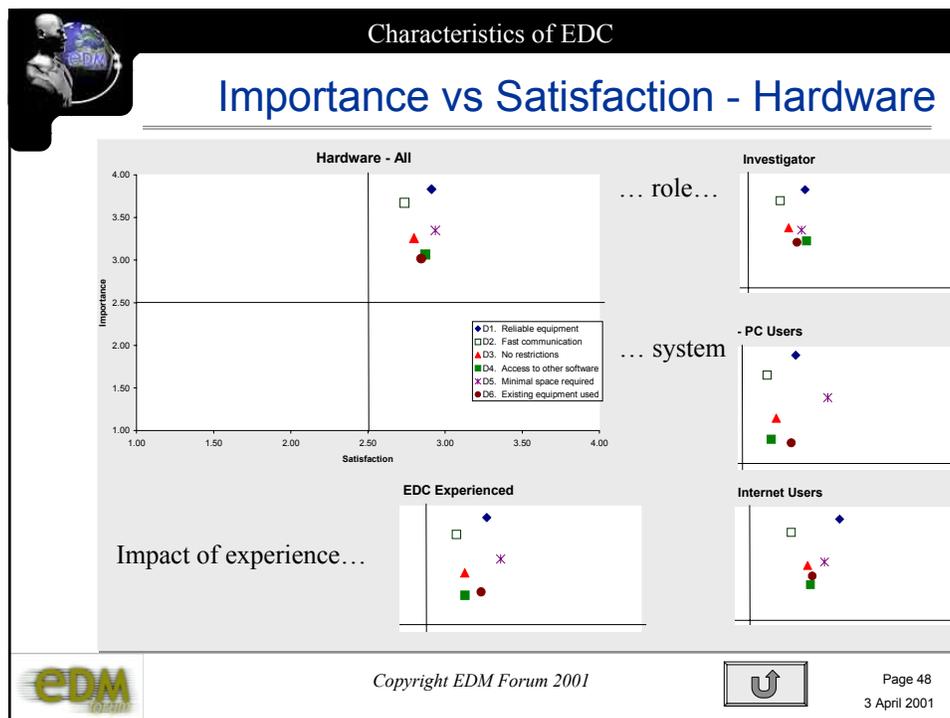
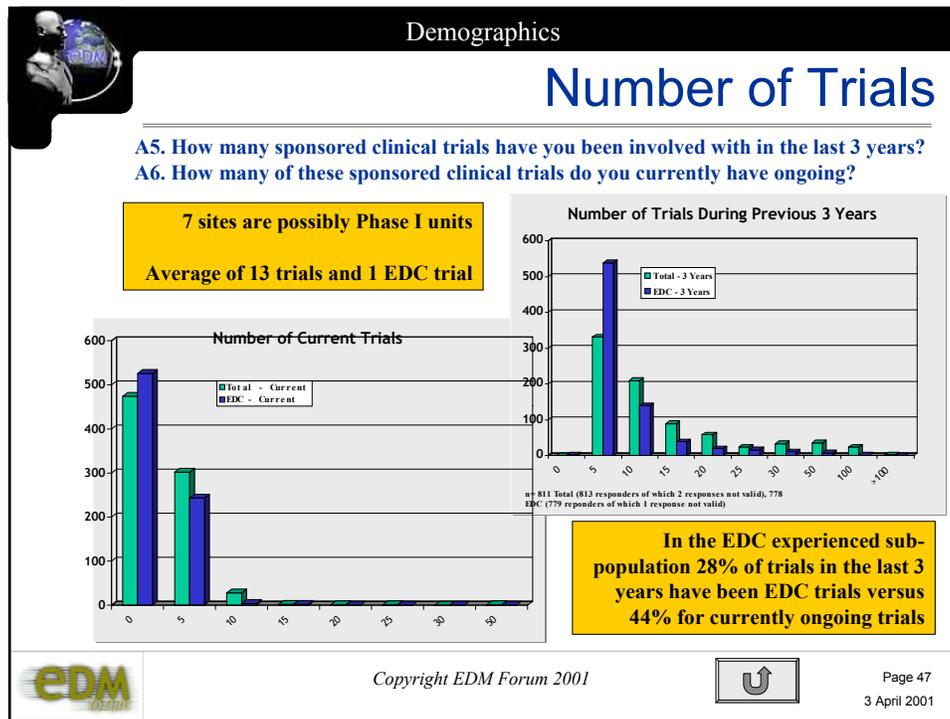
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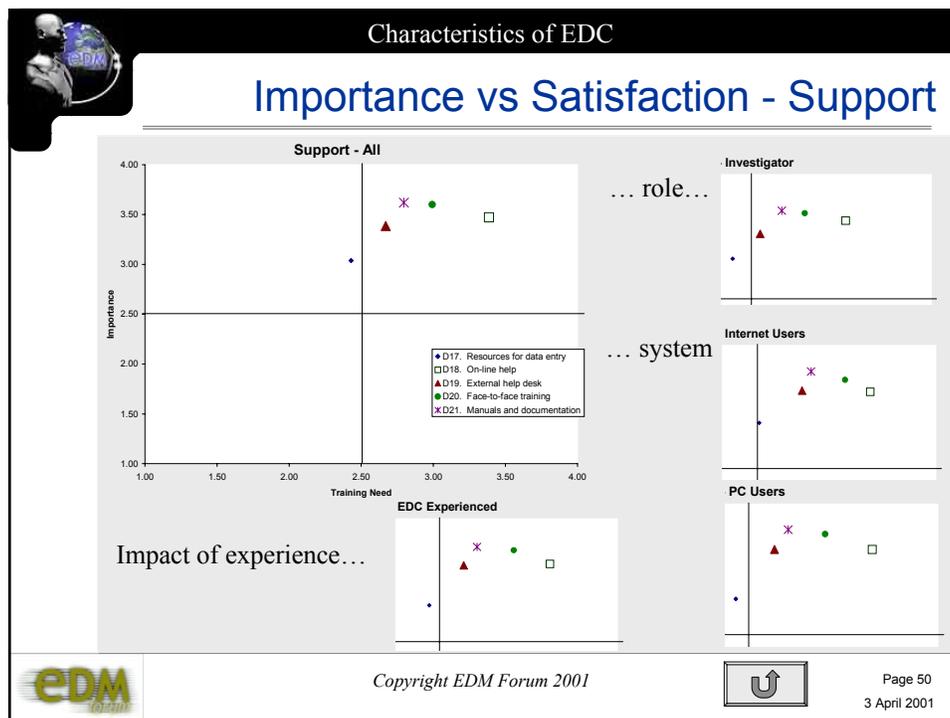
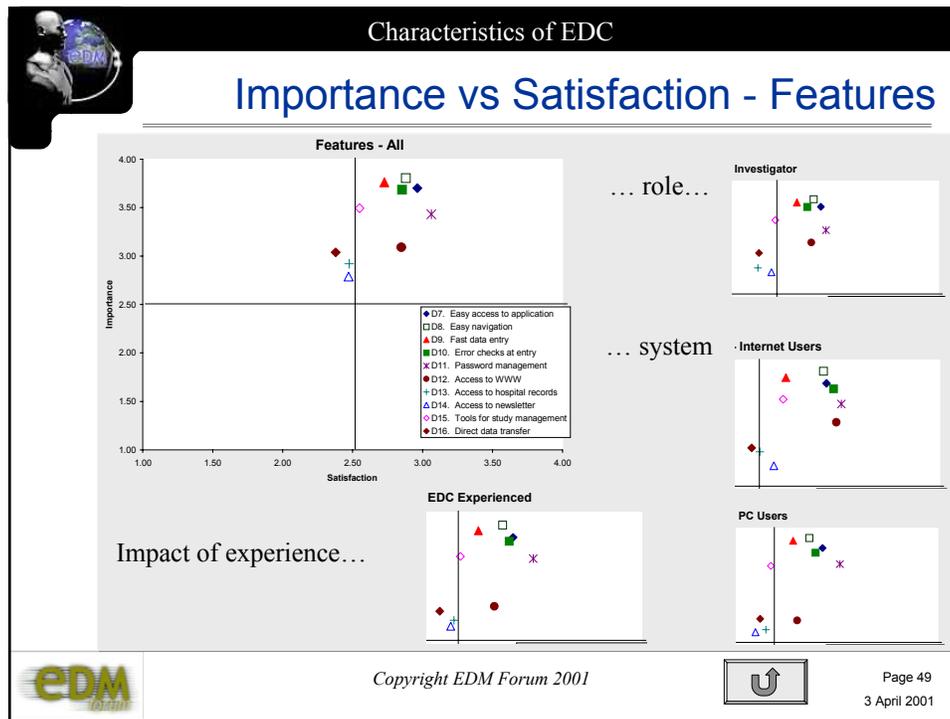
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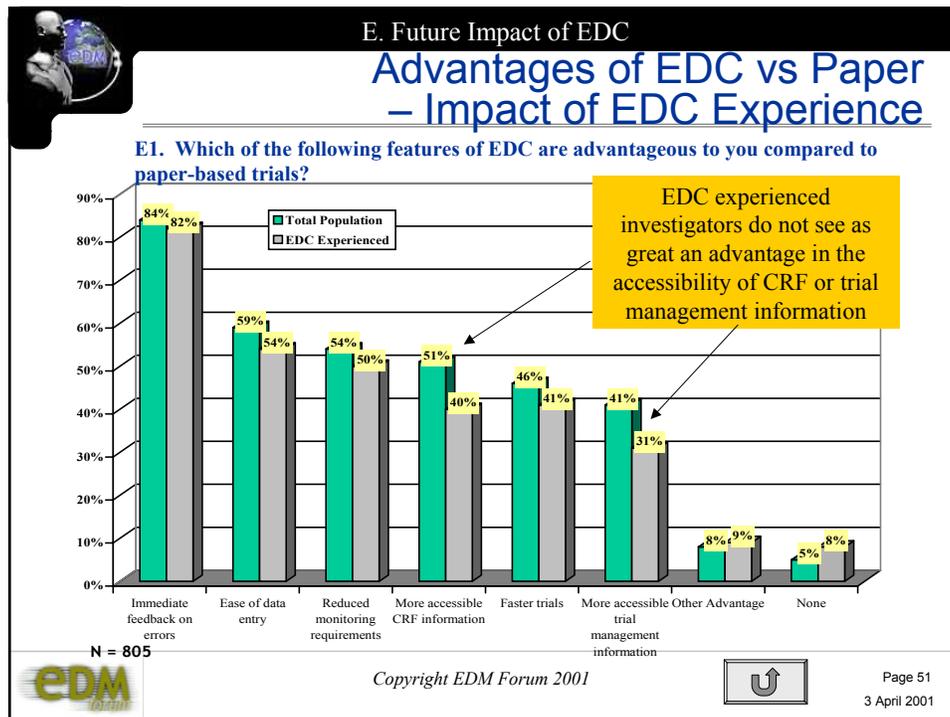
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### Appendix 3

## Source Data

Anonymised source data is available to members of the EDM Forum.

Contact Richard Perkins at  
[Richard.Perkins@Con7.com](mailto:Richard.Perkins@Con7.com)  
 or  
[EDMForum@EDMForum.Com](mailto:EDMForum@EDMForum.Com)  
 for information

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