

Study on the Adoption and Attitudes of Electronic Clinical Research Technology Solutions and Standards

August 2007

Summary of Results

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Results Overview Agenda

- Background
- Methodology
- Respondent profiles
- Results review
 - Current usage
 - Perceptions, attitudes and experiences
 - Actual, perceived and expected usage impact
 - Reasons for adoption delays
- Conclusions

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Background and Methodology

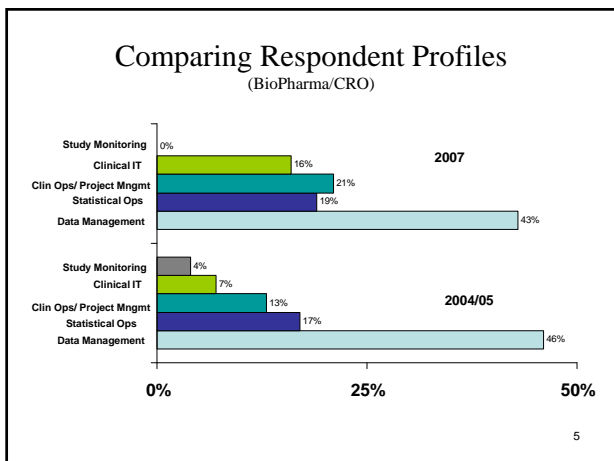
- Objectives
 - To update adoption and attitudinal data measured from 2000-2005
 - To refine and improve upon assessments of adoption to better reflect market behaviors and experiences (i.e. more extensive survey)
- Methods
 - Survey development with external assistance (CDISC and experts)
 - Implementation assistance; notification
 - Online survey (March – August 2007)
 - Interview-guided survey (June – August 2007)

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Survey Response Overview

- 81 total respondents
 - 44% pharma
 - 24% biotech
 - 1% device
 - 31% CROs
 - Note: sites not well-represented
- 68 total usable individual sponsor and CRO company respondents
 - 65% US
 - 31% Western Europe
 - 4% Rest of World

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Respondent Profile

- Average number of trials
 - 80 in 2003 (29% in Phase III)
 - 74 in 2006 (32% in Phase III)
- Geographic Reach
 - 85 % global (15 % domestic)
- CDISC Members
 - (71% in 2007 vs. 43% in 2002 and 32% in 2004/05)

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eClinical Technology and Standards Usage

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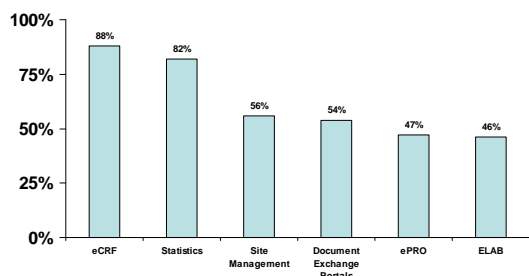
Technology Usage Practices

“Which of the following technologies is your company currently using?”

- Site Oriented Project Management
- Project Management
- Clinical Data Informatics
- Statistical Analyses

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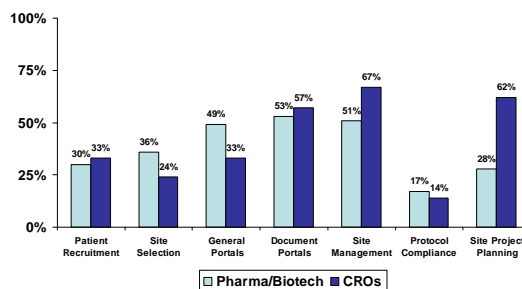
Highest Adoption Technologies



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Site Oriented Project Management Technology Usage

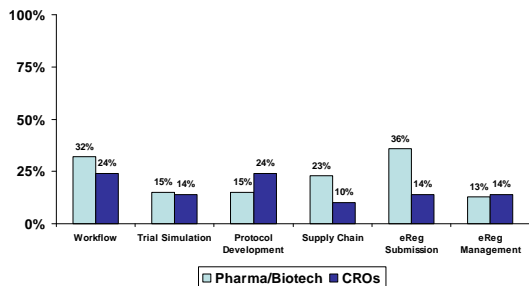
By Company Type



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Sponsor/CRO Project Management Technology Usage

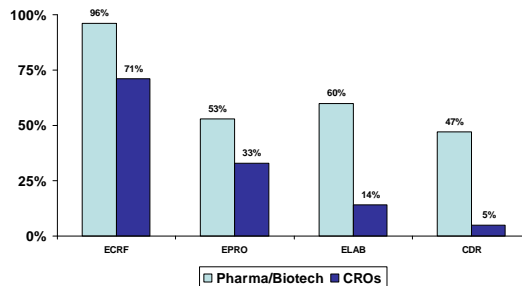
By Company Type



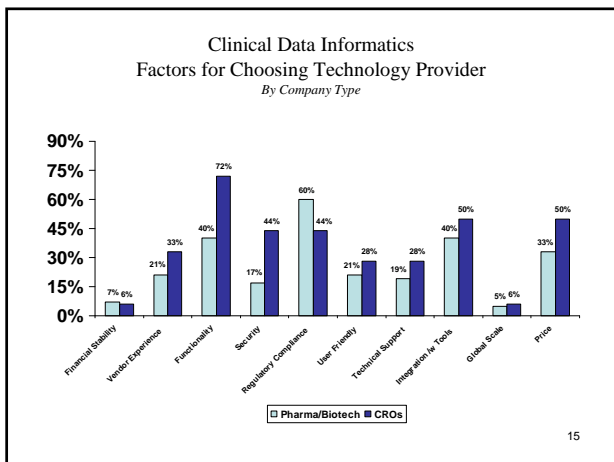
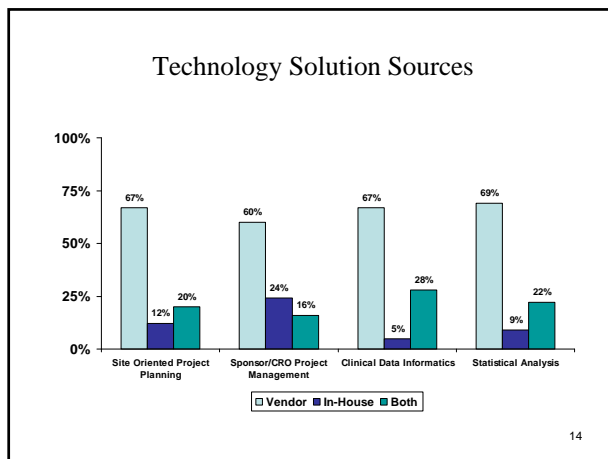
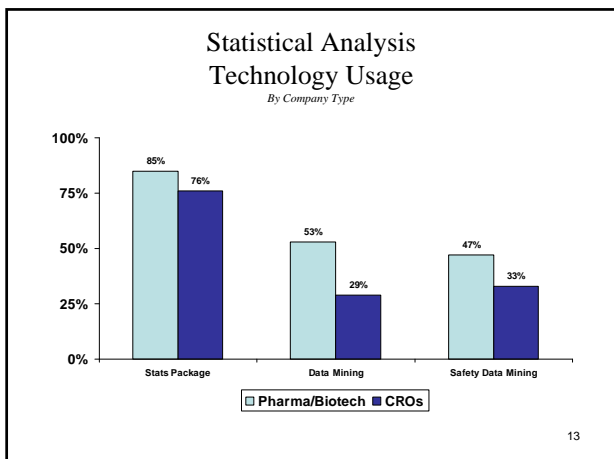
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Clinical Data Informatics Technology Usage

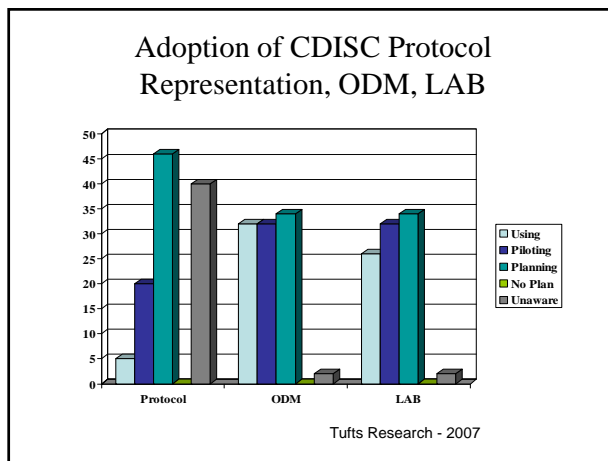
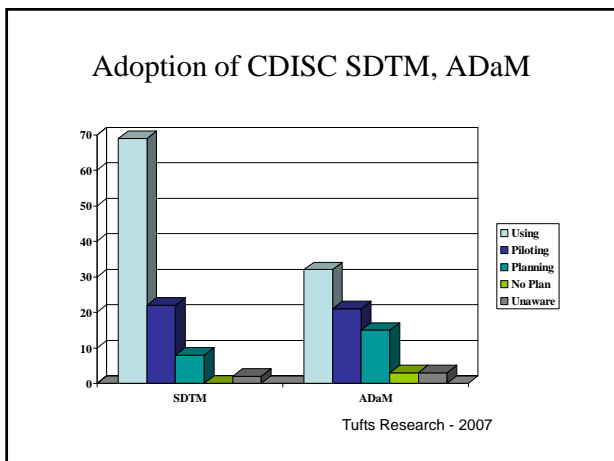
By Company Type

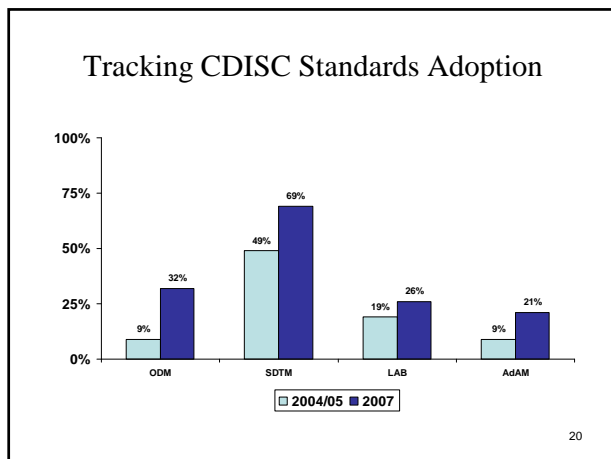
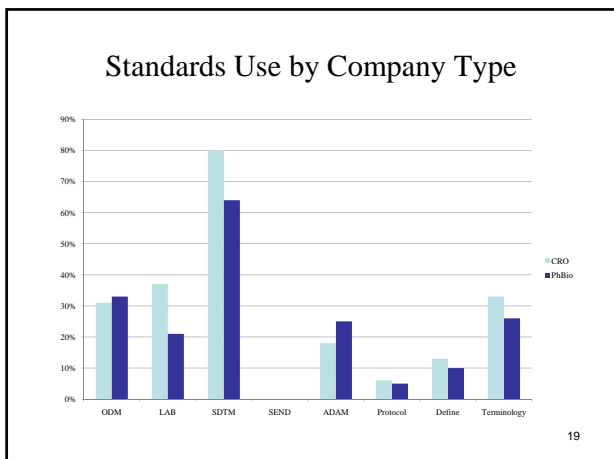


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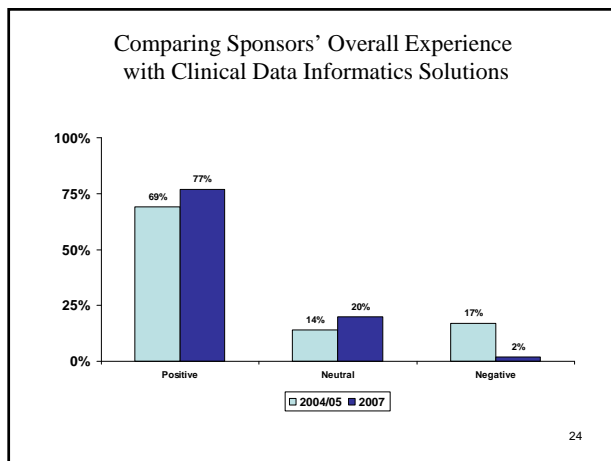
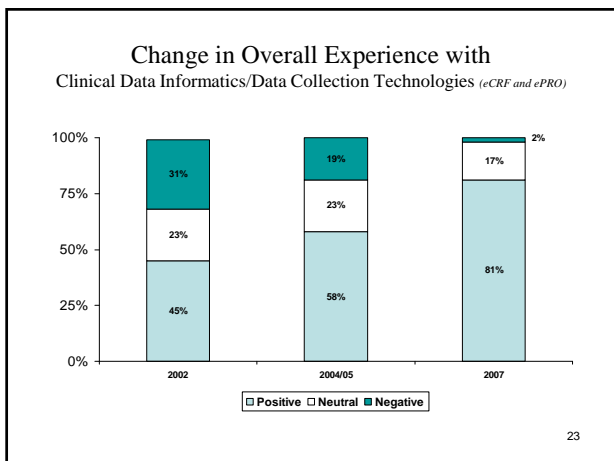
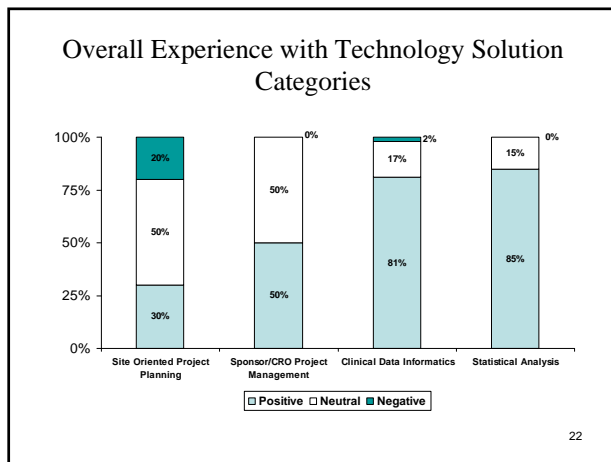
- ### Shift in Top Vendor Selection Factors
- Most Important
 - Integration with other tools/solutions
 - Functionality
 - Price
 - Regulatory Compliance
 - Less important
 - Financial stability of vendor
 - Global scale of vendor
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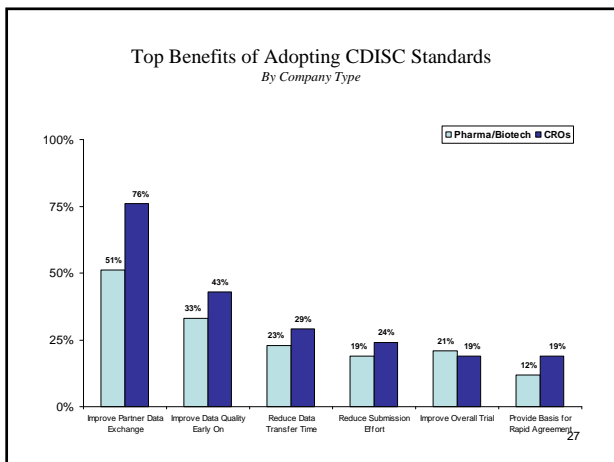
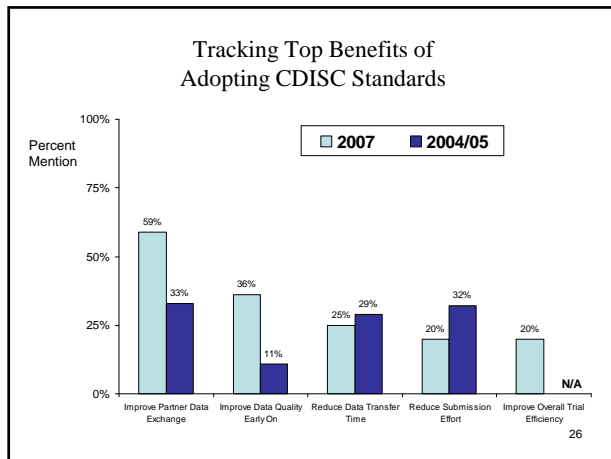
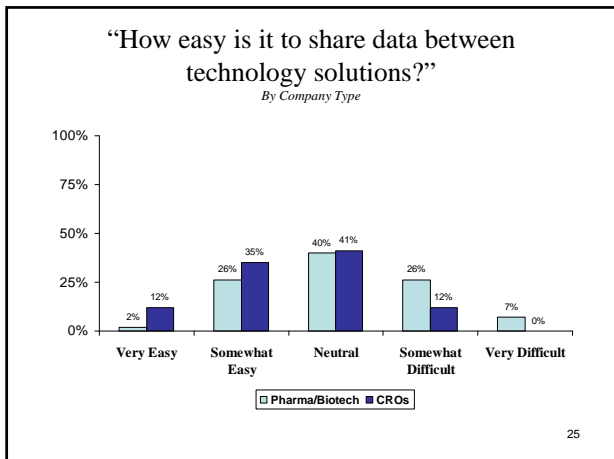




Technology and Standards Usage Attitudes and Experiences

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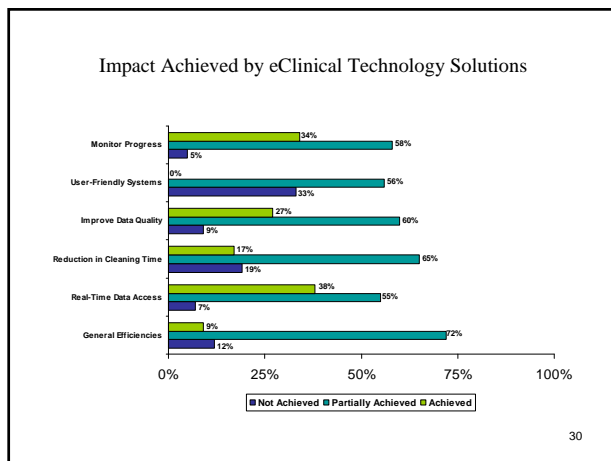
Standardization & CDASH

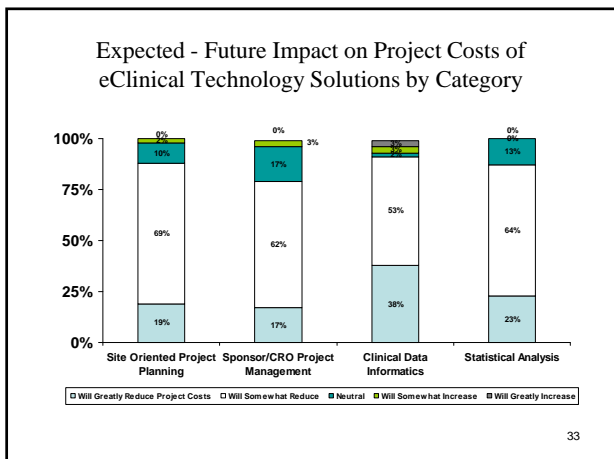
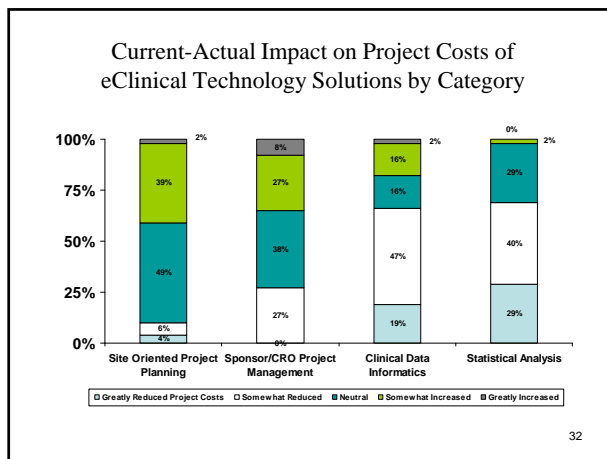
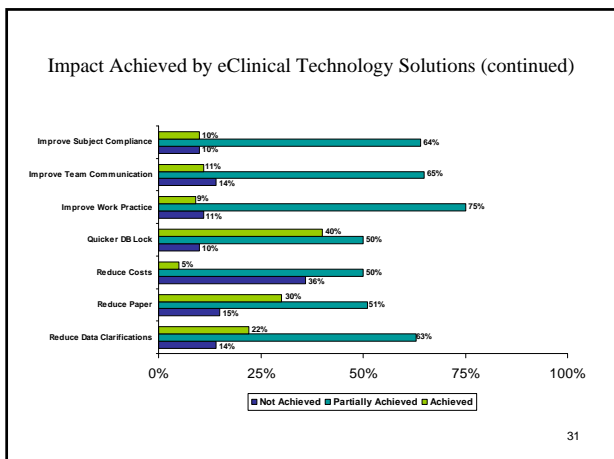
- 97% of participants would find it valuable if the content and format of data collection instruments were standardized
- 100% of pharma/biotech participants would find it valuable if the content and format of data collection instruments were standardized, in comparison to 90% of CROs
- 62% of pharma/biotech and 67% of CRO participants have heard of CDISC’s CDASH initiative

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*Impact:
Perceived and Experienced*

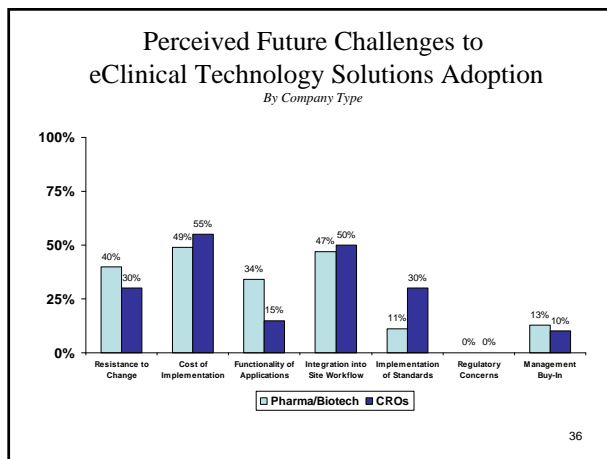
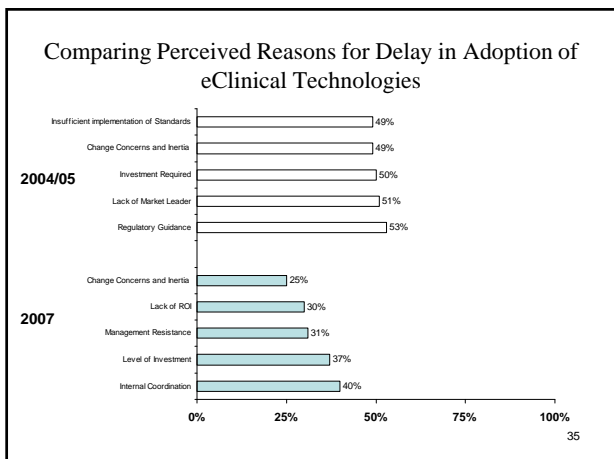
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Perceived Adoption Delays

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Preliminary Conclusions

- High levels of adoption – particularly for most mature/established technology solutions and standards categories
- Growing levels of usage across broad categories of solutions
- Higher levels of positive experience reported, especially for more mature and established technology solutions and standards; certain benefits achieved
- Shift in areas of concern to implementation-oriented issues vs. nascent/emerging adoption issues

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