



Electronic Data Lifecycle Management: Managing Information for Clinical and Legal Compliance

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Agenda

- Introduction
- Electronic Data Lifecycle Management
- Electronic Data Lifecycle Management Technologies
 - Clinical Research – EDC & CTMS
 - Drug Safety
- Future Outlook
- Essential Guidance

Information in Clinical Development Needs to Be Better Managed

- Effective progress in clinical development will be driven by more timely availability of information to support decision making
- This requires changes in the way that clinical research is done
- Near real time access to clinical data and the ability to analyze interim datasets
 - Standardized data collection
 - Electronic data collection is increasingly the norm
 - 50%+ adoption, including growth in Phase I EDC
- The need to eliminate data silos
- Expanded use of knowledge-based tools

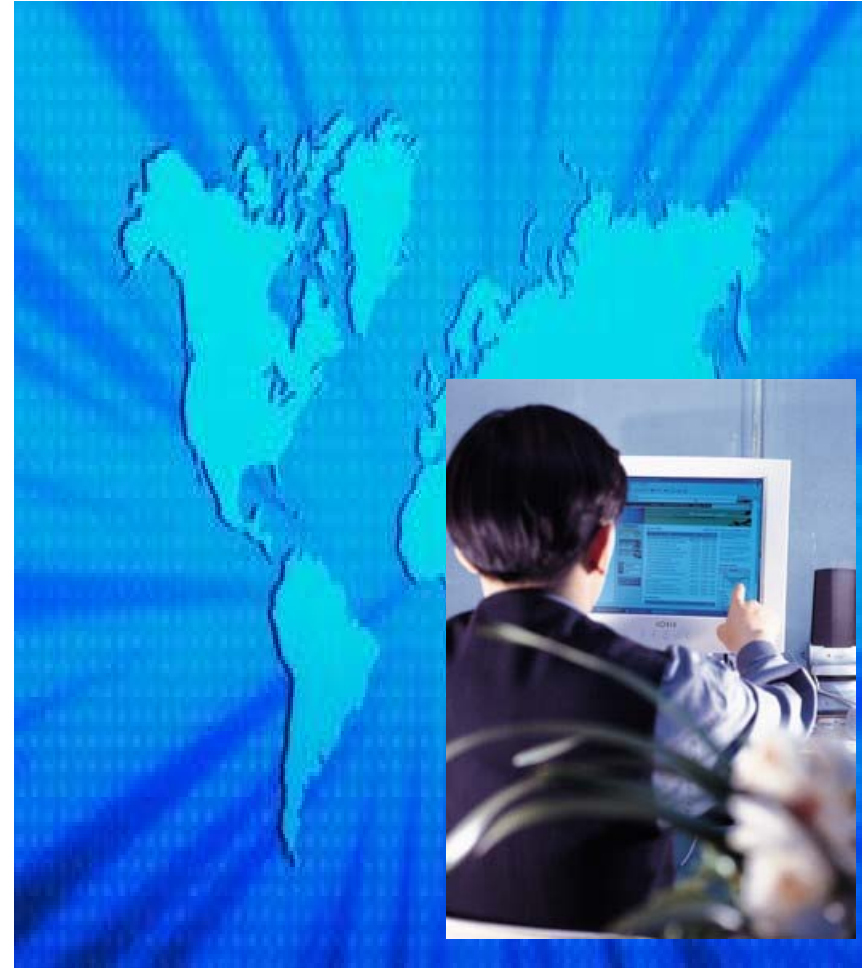


Data from Disparate Sources

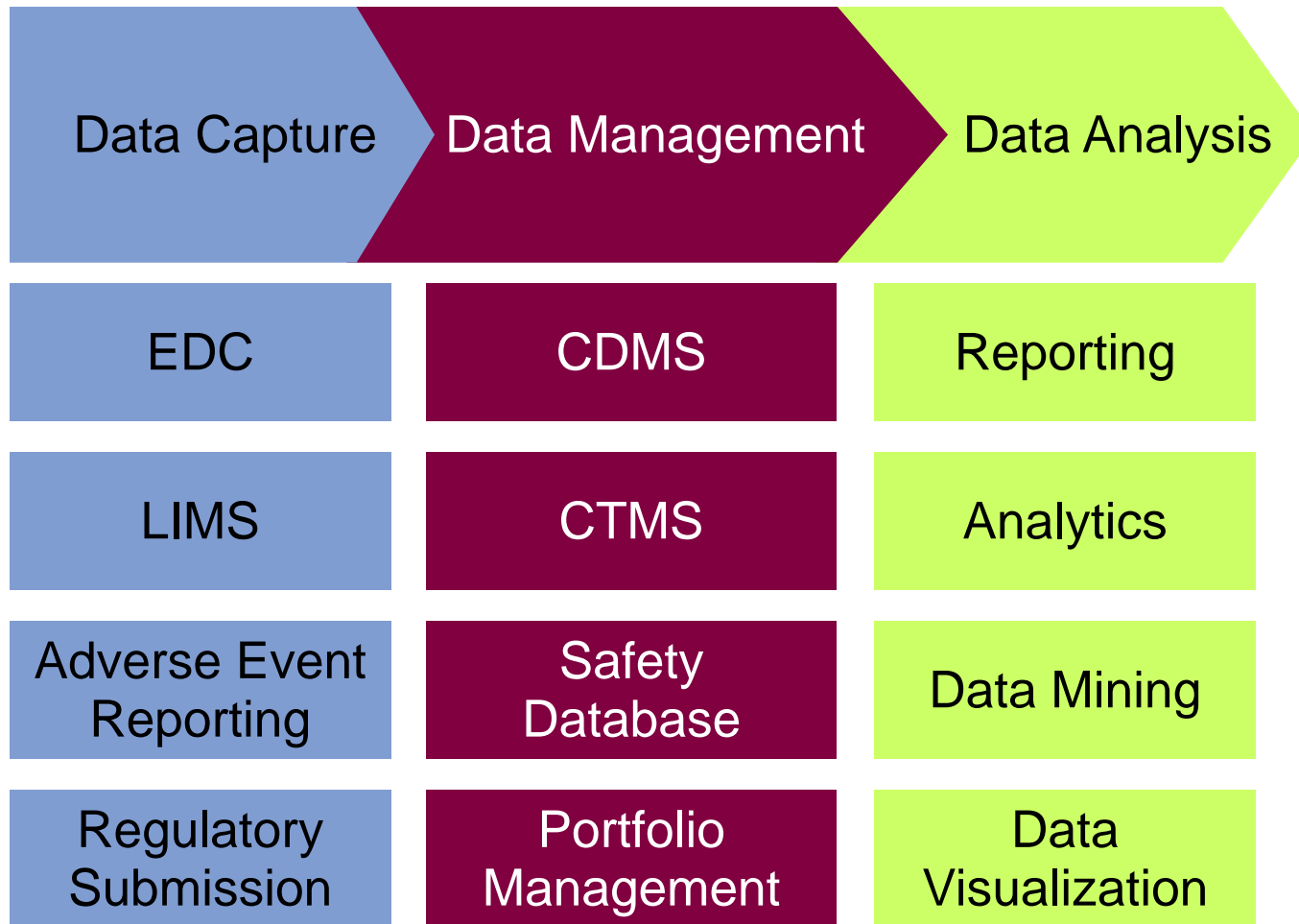
- Conflicting information
- Incomplete information
- Inconsistent information
- Change control issues
- Accuracy issues when comparing disparate data
- Difficult to manage status of information

Information Technology for Electronic Data Lifecycle Management

- Key criteria for new IT initiatives include:
 - Reduce costs
 - Increase revenue
 - Support organizational growth
 - Improve organizational effectiveness
 - Improved reporting/compliance
 - Improve decision making
 - Enable better outcomes
 - Support more accurate forecasting and budgeting



Electronic Data Lifecycle Management: Clinical Research



Electronic Data Lifecycle Management: Clinical Research

- EDC to collect data from clinical trials, CDMS organizes cumulative data and CTMS handles the operational aspects, the business of the clinical trial
- Together, EDC, CDMS and CTMS form an end-to-end process for clinical research data
- Clinical data warehouse
 - Unites data from multiple sources for analysis
 - Interim data analysis – adaptive clinical trials
 - Cross-trial analysis

Clinical Research Benefits of Electronic Data Lifecycle Management

- Better clinical data
 - Improve decision making
 - Improved trial management
- Improve effectiveness of clinical operations
- Increase collaboration across stages of development
- Improved reporting/compliance
- Real time monitoring of clinical data
 - Interim analysis, adaptive trials
 - Better ability to predict & manage problems
 - Apply corrective actions sooner, anticipate future issues
- Reduce clinical data silos
- Manage and control access to data – all those who need it, have it, and those who don't, don't

Reasons for Investing in Electronic Data Lifecycle Management for Clinical Research

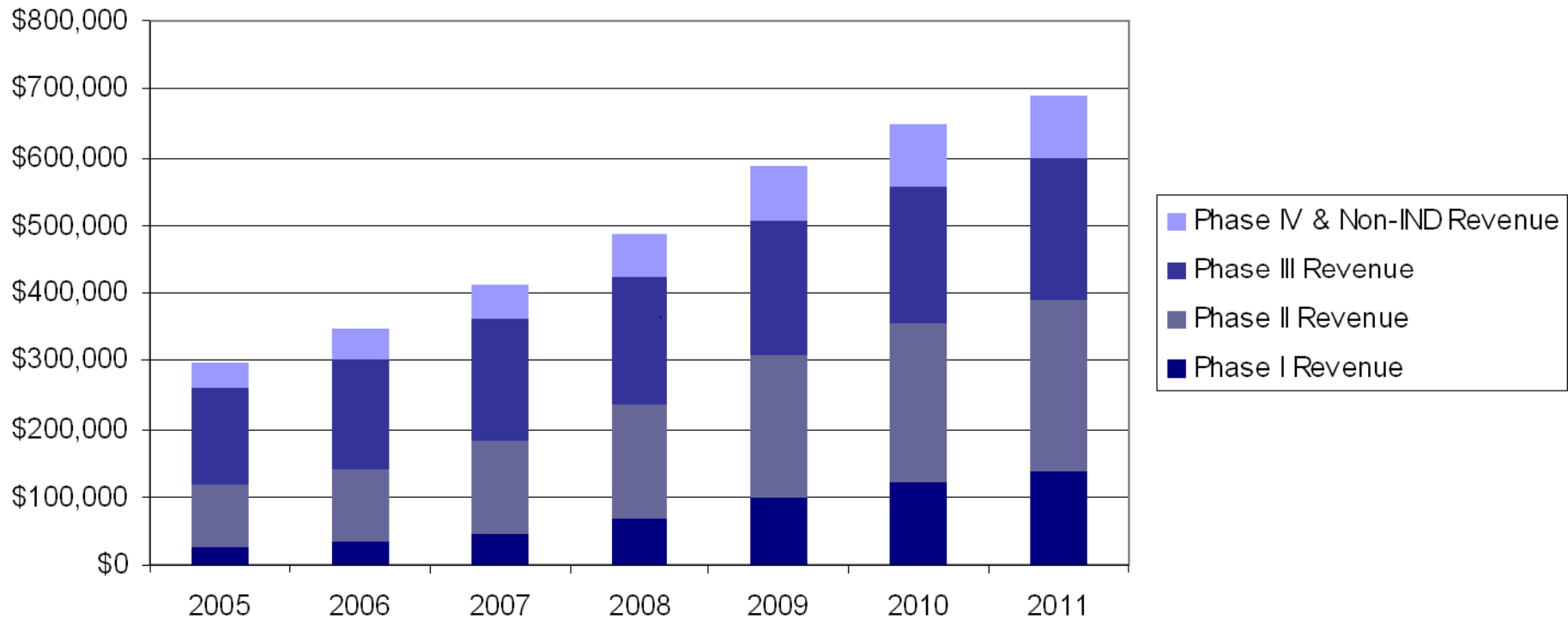
- Enable, better, more agile allocation of data management resources
- Enhance effectiveness of clinical teams by shifting resources from data collection to tasks requiring clinical expertise as a result of efficiencies
- Provide better information on clinical data during research
 - Keep on top of status and issues to prevent delays
 - Make informed decisions
- Lower costs of development as a result of efficiencies
 - Maximize resources
 - Reduce delays

EDC: an Electronic Data Lifecycle Management Example

- Before EDC, the average delay from data entry to data availability (in the database) was ~ 6 weeks
- After EDC, the average delay from data entry to data availability (in the database) is now ~2 days
- Before EDC, the average delay from the patient encounter to data entry was ~2 weeks
- After EDC, the average delay from the patient encounter to data entry is now ~1 week
- So now that we have this information available sooner, what are we doing with it?

EDC Spending Forecast

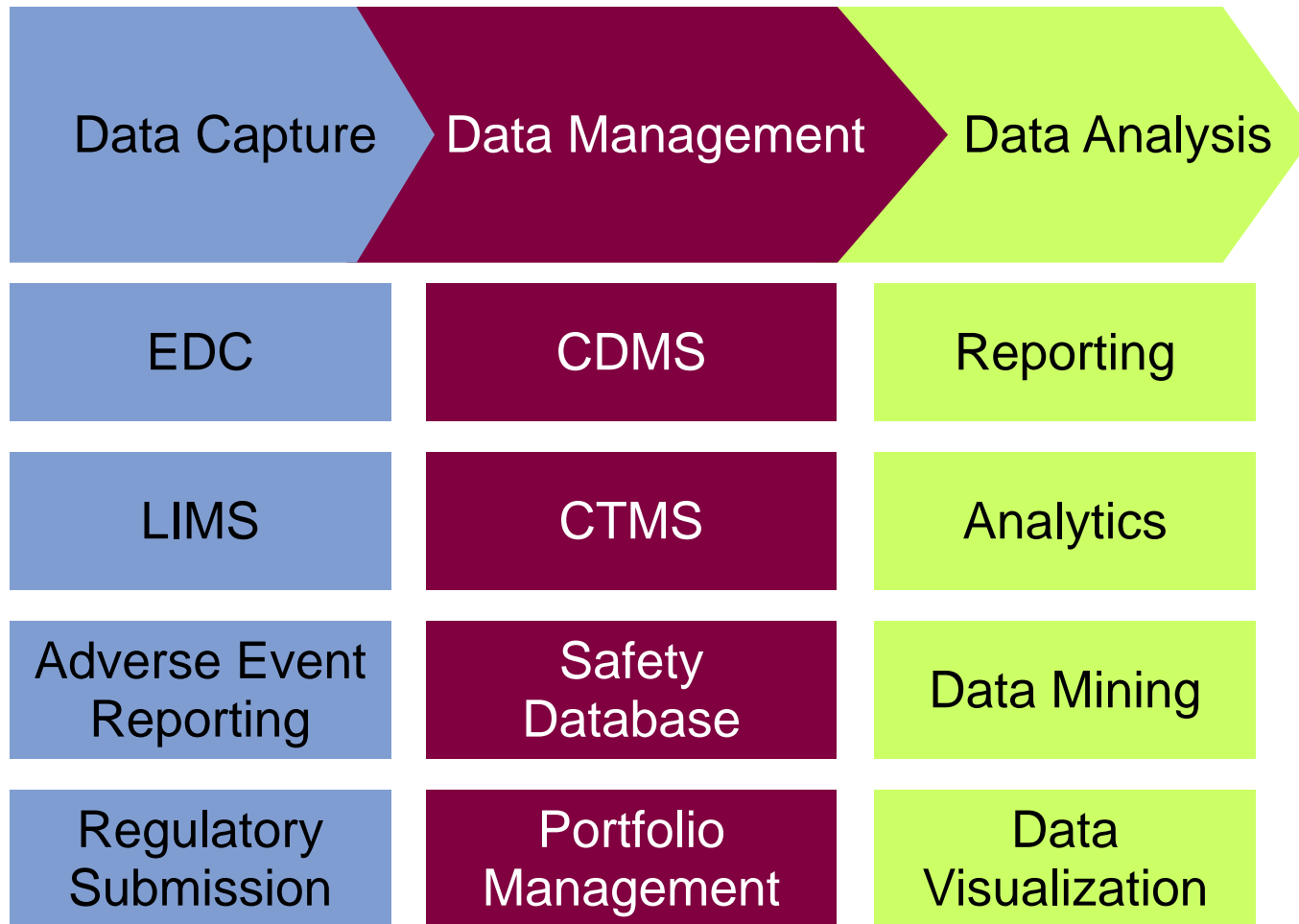
EDC Software Revenue Forecast 2005-2011



Clinical Research: Future Plans for Electronic Data Lifecycle Management

- Accelerate review cycles for clinical data
- More accessible analytics
- Increase cross-team/cross-enterprise data availability and consistency
- Increase web-based reporting tools and technologies
- Enhance ability to anticipate and respond to problems
- Explore the potential of adaptive clinical trials

Electronic Data Lifecycle Management: Drug Safety



Electronic Data Lifecycle Management: Drug Safety

- Electronic collection and submission of safety data via adverse event reporting applications
 - Regulatory reporting
- Safety database
 - Interoperable with company data warehousing applications
 - Available to all stages of research
 - Preclinical – PK/PD and toxicology data, animal studies
 - Clinical safety – all stages
 - Post approval – adverse events for marketed drugs
- Analytics
 - Reporting
 - Data mining – proactive signal detection

Safety Data Lifecycle Management: Benefits

- Better data to improve decision making
- Reduce safety data silos
- Increase collaboration across stages of development
- Improve effectiveness of safety efforts
 - More effectively compare safety data on a common value scale
 - Better safety surveillance
- Better ability to predict & manage problems
 - Apply corrective actions sooner, anticipate future issues
- Improved reporting/compliance
- Address clinical safety concerns
- Real time monitoring of adverse events
- Improved risk management
- Manage and control access to data

Safety Data Lifecycle Management: Reasons for Investing

- Better, more agile allocation of drug safety resources
- Enhance effectiveness of safety teams by shifting resources from data collection to analysis and action
- Provide better information on safety profiles during research and post marketing
 - Proactive
 - Manage problems to reduce fallout
- Develop project synergy and a common vision of safety goals across the organization
- Solutions allow manufacturers to incorporate new regulatory requirements more easily

Safety Data Lifecycle Management: Future Plans

- Better signaling capabilities in clinical and post-marketing
- More accessible analytics
- Increase cross-team/cross-enterprise data availability and consistency
- Increase web-based reporting tools and technologies
- Enhance ability to anticipate and respond to problems

Future Outlook: Electronic Data Lifecycle Management

- Connected ecosystem
 - Discovery, clinical, safety, post-marketing
 - Changes to dividing lines between solutions
- Transparent access to the right information for the right person at the right time
 - Researchers working on the next product or indication
 - Marketers working on the last product or indication
- Increased efficiency of clinical processes facilitated by available data and information
 - Resource management
 - Staffing and sourcing
- Real-time decision making
 - Trial progress and subsequent trial planning
 - Portfolio management
 - Planning and adjustment – adaptive trials

Essential Guidance: Electronic Data Lifecycle Management

- Start or continue to invest in solutions that enhance connectivity and interoperability of data
 - Consolidated data warehouses
 - Federated data marts
 - Embed intelligence into architecture
- Tools for analysis
 - Flexible approach to tools
 - Needs now, open ended solutions extend for future needs
 - Leverage embedded intelligence to better exploit data
- Corporate governance
 - Facilitate sharing of data
 - Empower teams to act

Questions

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