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Improve Trial Efficiency & Quality with CTMS

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Agenda

- General trends, and challenges of clinical trial industry
- What it means from clinical trial management perspective
  - Examples
- Benefits of clinical trial management system (CTMS)

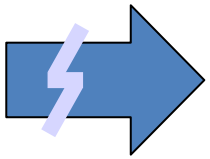
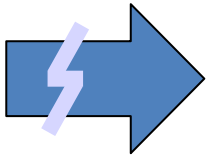
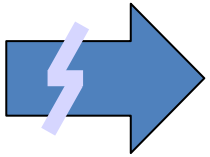
Challenges in Conducting Clinical Trials

- Globalization of R&D
- Outsource trend
- Shortage of quality investigators
- Patient recruitment bottleneck
- Complex global multi-center clinical trials
- Increasing importance of post-marketing studies
- System proliferation -- integration a must
- Data-rich *but* information-poor

Global Trial and Global Operations

Facts

- Significant shift from North America to West Europe.
  - % of trials in NA/WE fall to 38% from 55%
  - 56% sites registered are outside of US
- Global markets offer huge cost saving & growing markets
- Large research *talent pool*

CTMS Implication

- Languages, currencies, time/date format, time zones
- Support local business practices
- Comply with local reg. mandates
- Integrate with global clinical supply chain (nimble, cost-effective)
- Enable collaboration & information sharing across regions
- Maintain a unified database of all clinical trials

Find the Right Investigators

Facts	CTMS Implication
• A continuing decline in US investigators • An increase use of first-time investigators • Poor investigator retention—more than 50% investigators never conduct 2nd trial • High quality investigators in developing markets	**Identify valuable investigators and *keep them* by:** • **Know your investigators** • **Focus on high-value investigators** – **Leverage analytics tools** – **Grease the "squeaky wheels" only when necessary** • **Provide info/tools to make investigator's life easier** • **Pay investigators right & quick** • **Extend the horizon – build international network**

Target & Screen for Potential Investigators

Therapeutic area: Oncology
Past 12 months # of prescriptions: >10
Board certification: Yes
FDA blacklist: Never
Past Trail Performance Percentile: Top 50%
Responsiveness of Local IRB: High
Availability of MRI: Yes
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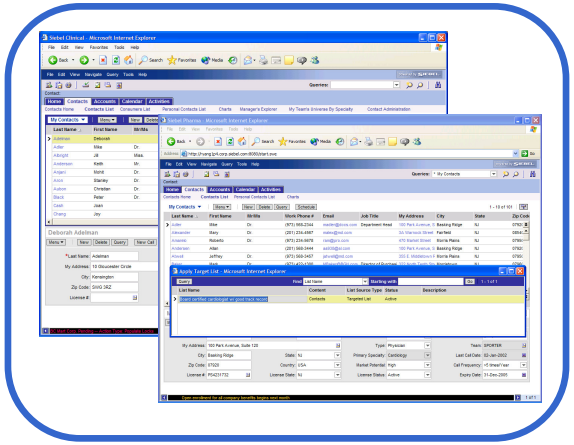
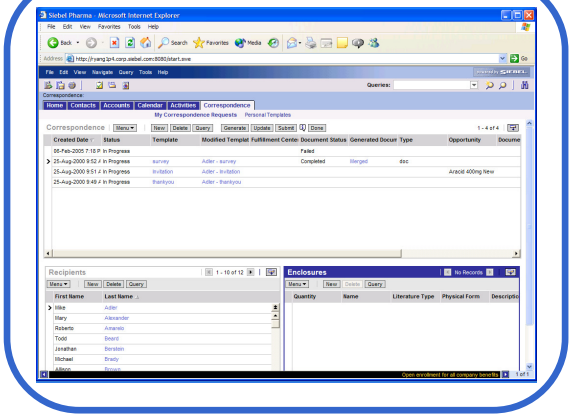
Search Inv. DB, Use BI Tools

Create target list



Apply Target List for Correspondence, Fax, Email, etc.



Multi-channel Campaign, investigator Recruitment

Web & Email

Call Center

UNITED STATES POSTAL SERVICE
mail

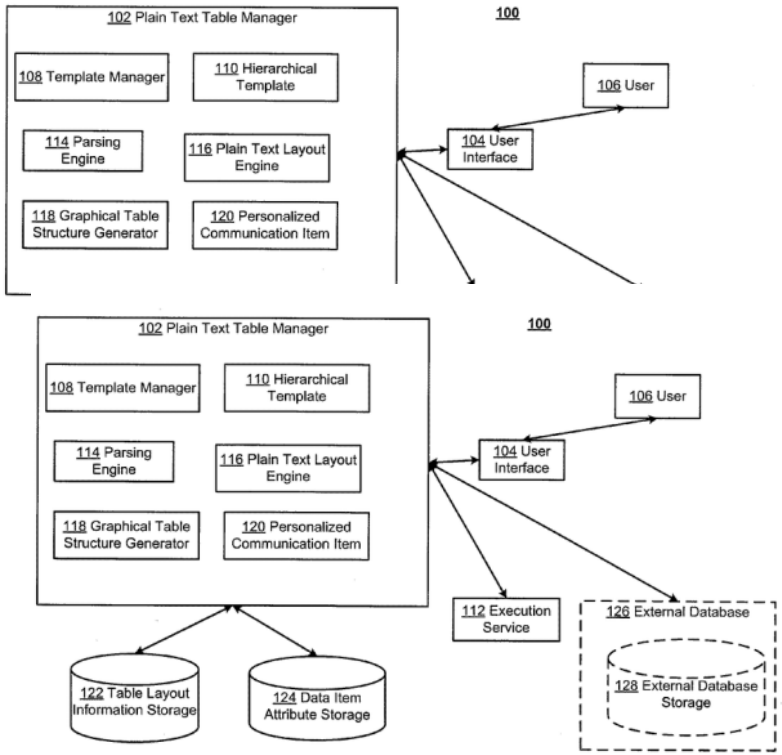
Field

Define Search Criteria

Buried with Data, but Starved for Information

KEY CHALLENGES	EXAMPLES
Lack of visibility into study performance & processes	• Limited understanding of CRF data flow • Poor recruitment forecast accuracy • Lack of CRA coverage visibility
Lack of site insight to recruit most effectively	• No comprehensive (360°) view of site relationship • Lack insight into site effectiveness • Unable to identify high value from low value sites
Unable to drive CRA process consistency and best practices	• Low/inconsistent adoption of CTMS system by CRAs • Poor or inconsistent data quality • Unable to drive consistent study process and compliance
Time wasted gathering data to manage and report	• Continued reliance on management-by-spreadsheet • Disparate reporting and poor internal distribution • Data in multiple systems – EDC, CTMS, IVRS, Financial • No single source of the truth

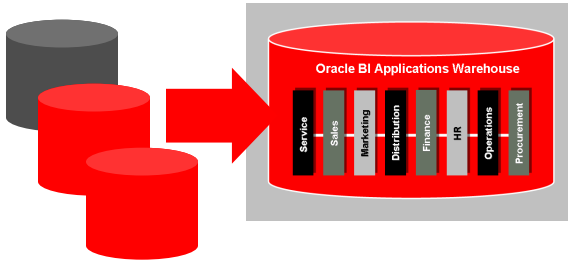
Turning Data into Insight



Business Intelligence For Everyone

1. Integrates Data for Analysis and Reporting
   - Pre-built integration of data from Oracle Clinical/RDC, Siebel Clinical, Oracle AERS and other sources into an integrated data warehouse optimized for analysis
2. Provides User-Friendly Analytic Model of Enterprise Information and Metrics
   - Embedded best practice calculations, metrics, and KPIs
   - Easy for business people to access, analyze, and use the information
3. Delivers Personalized Performance Dashboards for Everyone
   - Pre-built dashboards, reports, and alerts by business function and role

1



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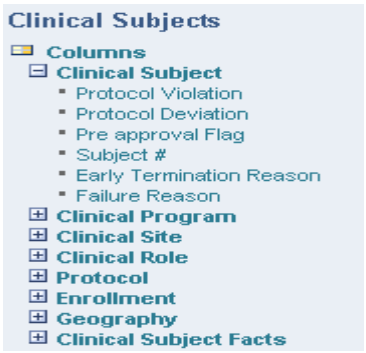

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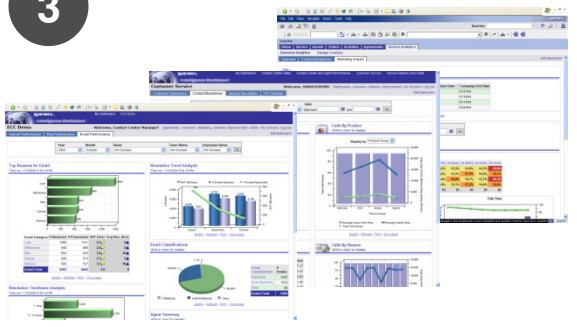


Actionable Analytic Workflows

Business Objectives/ Issues

Gain Insights

Take Action

Accelerate Enrollment

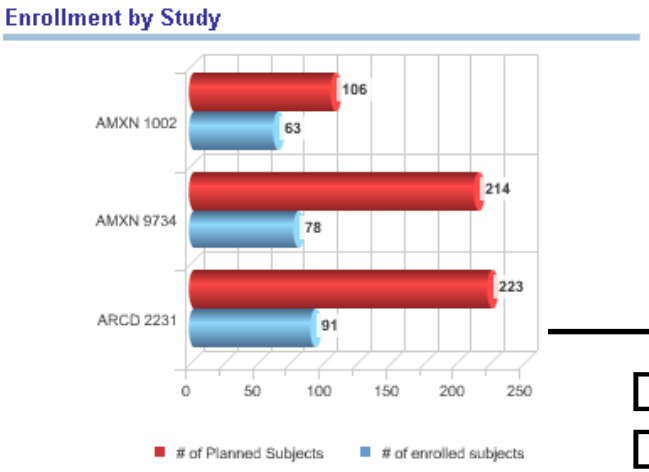
Is Program on target?

Which studies are behind?

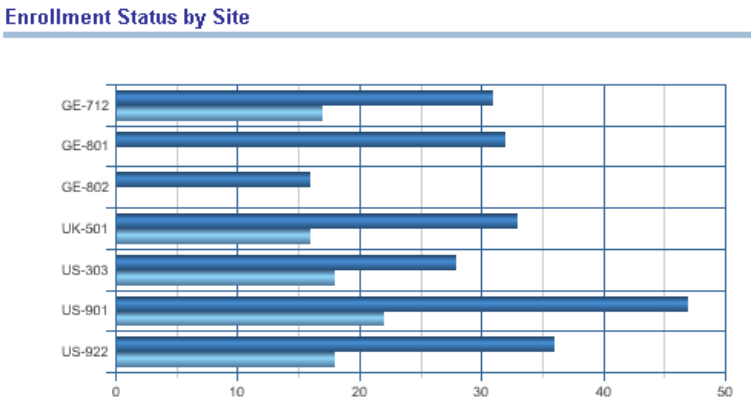
Which sites are slowest recruiters?

Drill to Site Detail

Call Site to Understand Low Enrollment

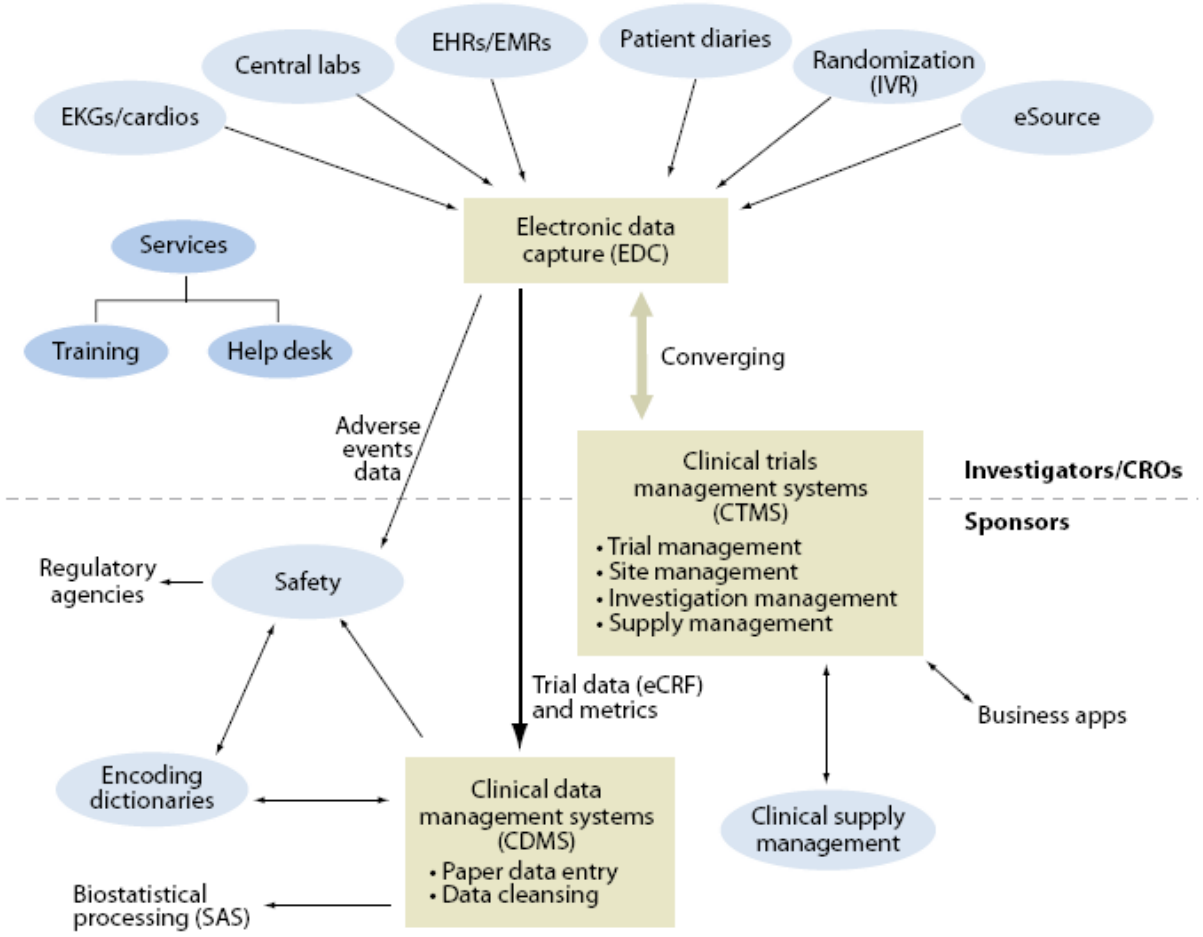


Drill to Detail



Principal Investigator	# Planned Subjs	# Enrolled	Attainment %	Paid to Date	Contract Value	Contract Balance	% Spent
Mary Alexander	124	68	55%	$759,996.00	$1,240,000.00	$480,004.00	61%

Wider Adoption of eClinical Technology



Source: Forrester Research, Inc.

Integration Headache

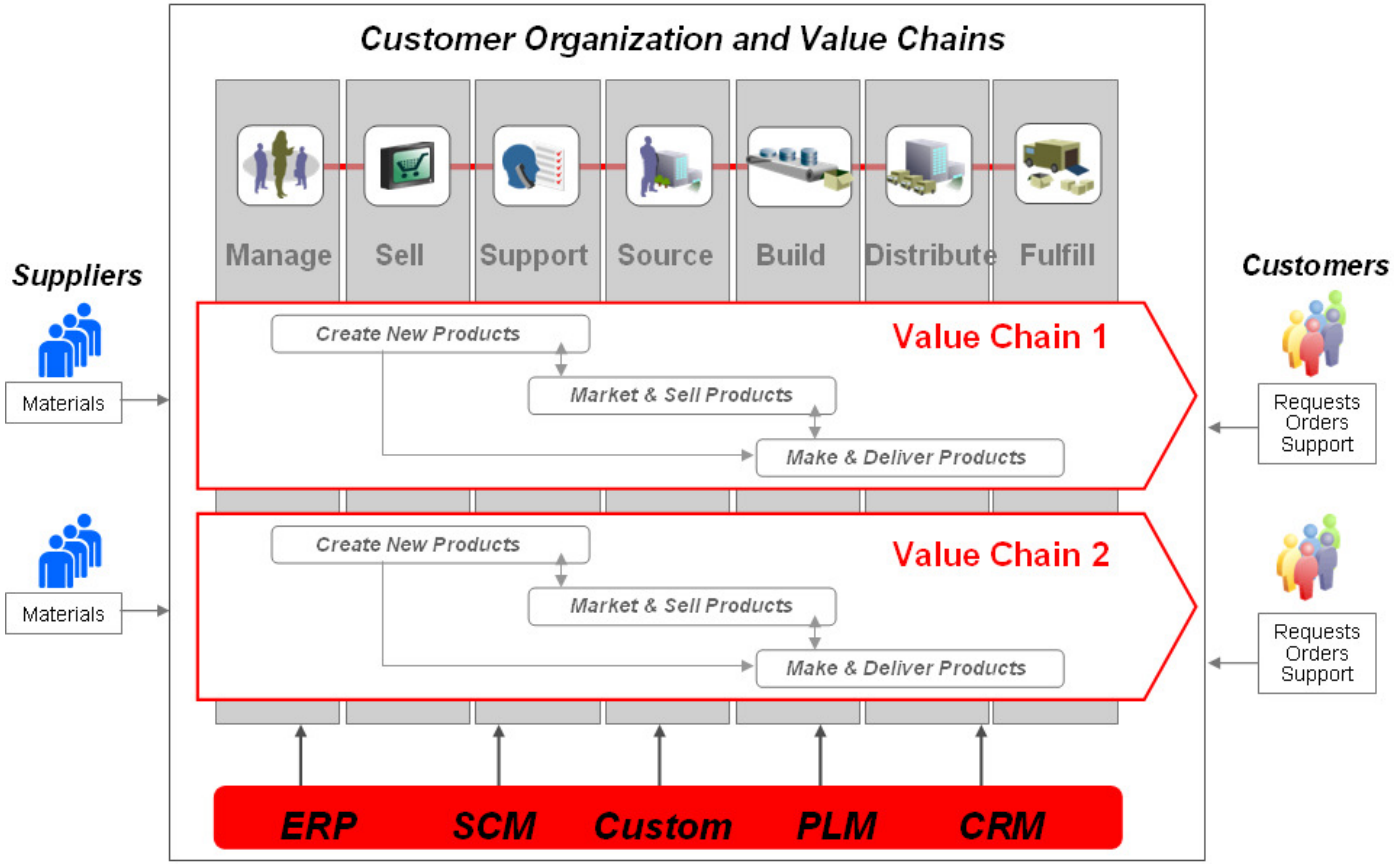
- Point-to-point integration is insufficient and costly to build and maintain
- Standard based, integration “hub” provides a more desirable solution with lower TCO
- SOA based solution breaks down the traditional application barriers, and enables cross-application business flows

Business without Boundaries SOA Approach to Process Integrations

"SOA can frequently be part of the answer by providing a sound architectural framework to help CIOs address their challenges."

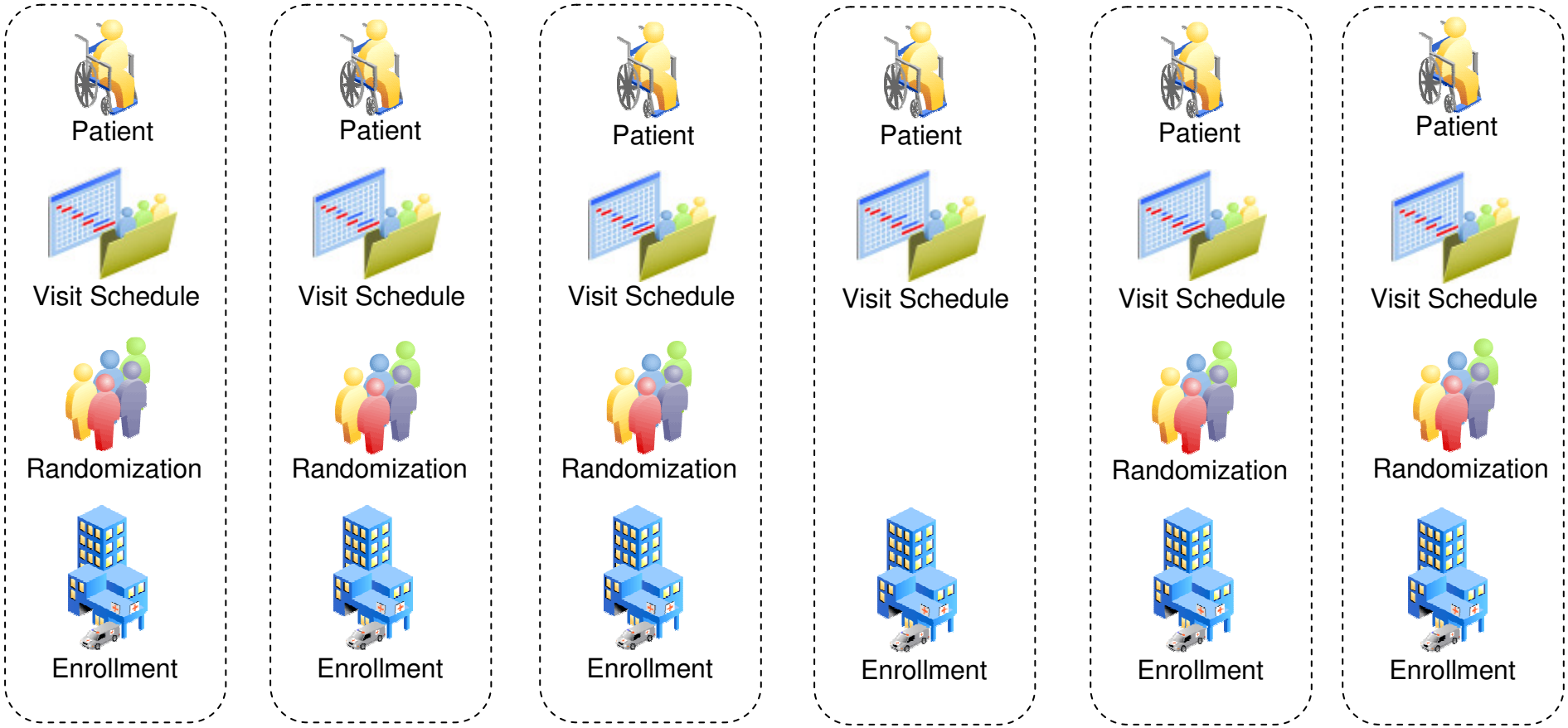
L. Frank Kenney,
Research Director

Gartner



Quote source: Gartner Symposium/ITxpo: Emerging Trends, April, 2007

Process Integration in Clinical Trials



Customer Reported CTMS Benefits

Reduced Site Initiation time to 10 weeks from 12 weeks
Reduced CRA monitoring effort by 30%
Reduced Subject Enrollment time to 16 weeks from 25-30 weeks
Reduced system support costs by 50% vs previous custom system
Reduced man-hours required for investigator payment processing: $500,000/yr
Eliminated payments for missed visits: From 3% of payments to 0%
Reduced travel expenses by 15%
Reduced monitoring visits by 10%-20%
Consolidated real-time view of trial status: Reduced to days from weeks
Globally standardized processes, enhanced compliance
Better and more timely decisions: Qualitative estimates
Supports better customer experience for investigators and sites
Allows for early recognition of progress/ quality issues at sites

Leveraging Clinical Trial Technology for Efficiency and Quality Improvement

- More and more companies in North America and Europe have deployed enterprise CTMS, and start to reap the benefits brought about by an efficient trial management process.

- Opportunities abound for organizations in developing markets to leverage the experience in developed markets, and establish new ways to increasingly efficiency, effectiveness and quality of trials using clinical trial technologies.

Thank You