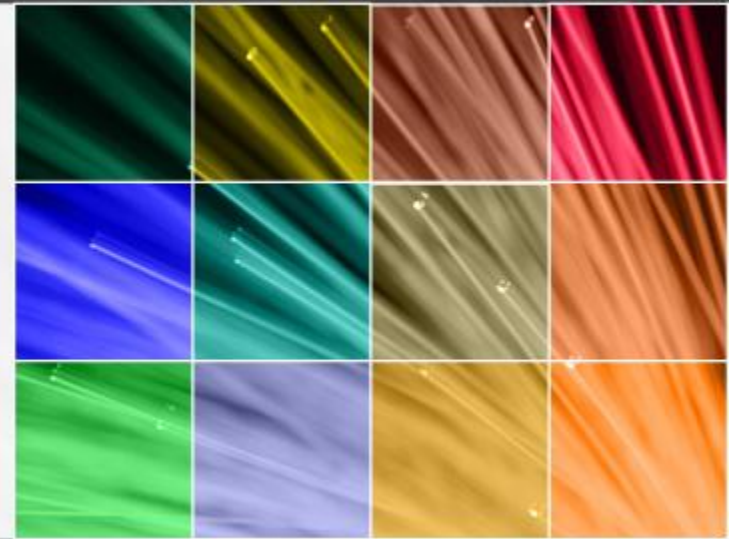
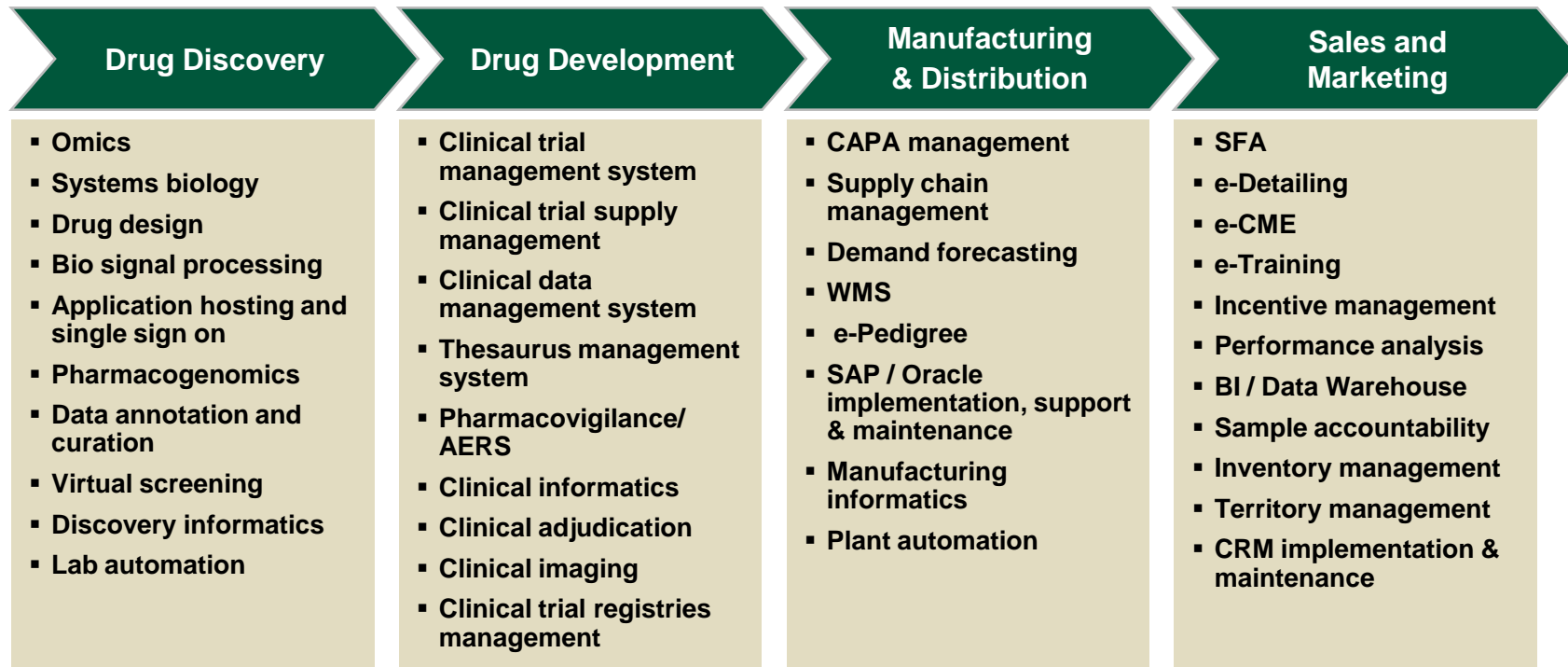


# Using Data to Accelerate Clinical Trials



**Dr. Ganesh Swaminath**  
**Head, Life Sciences Practice**

# Life Sciences Value Chain



Application Management

Process Consultancy

Enterprise Content Management

Portfolio Rationalization

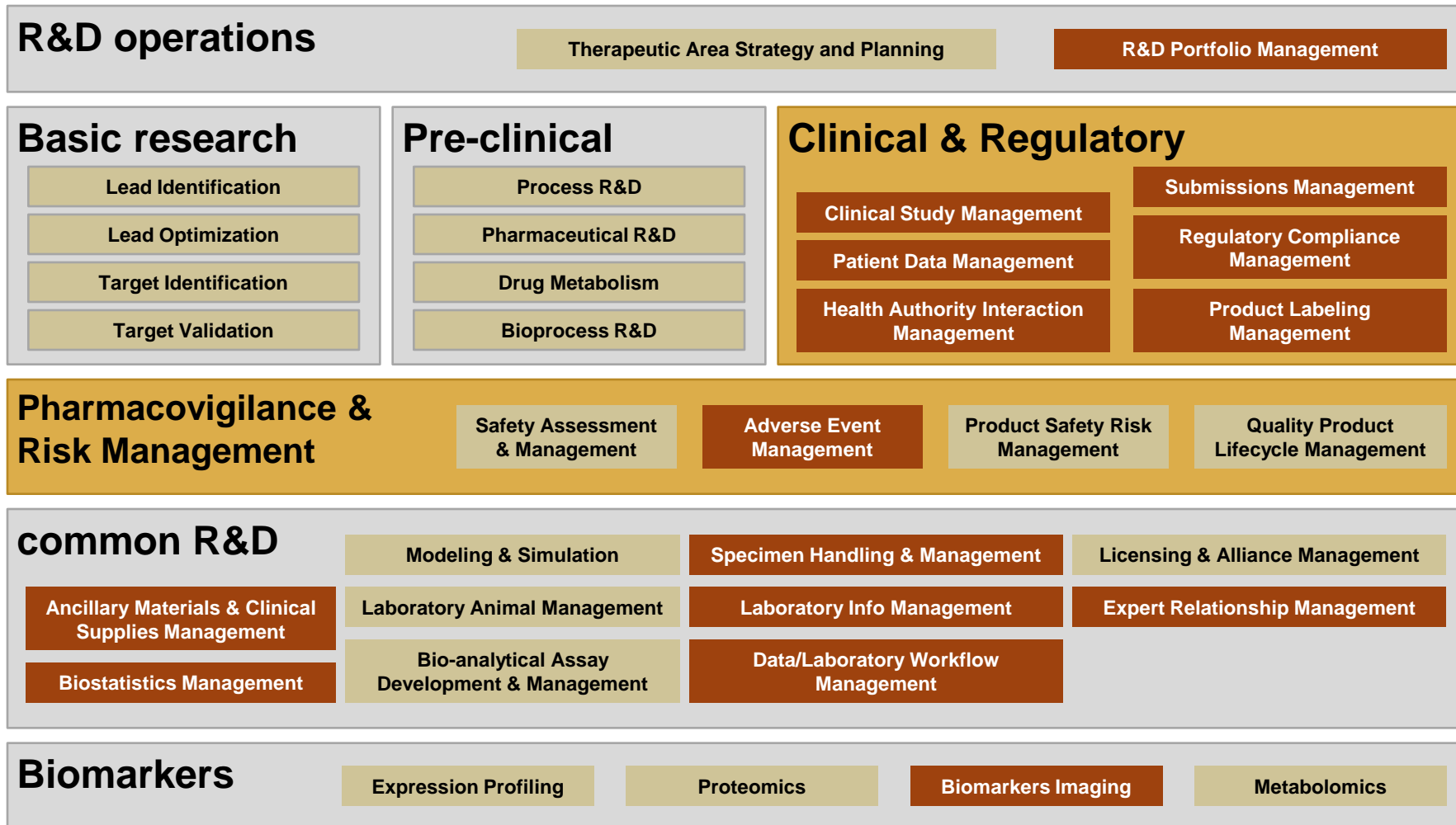
Electronic Document Management System

Lifecycle Testing

Portal Management / Knowledge Management

21 CFR Part 11, Computer System Validation

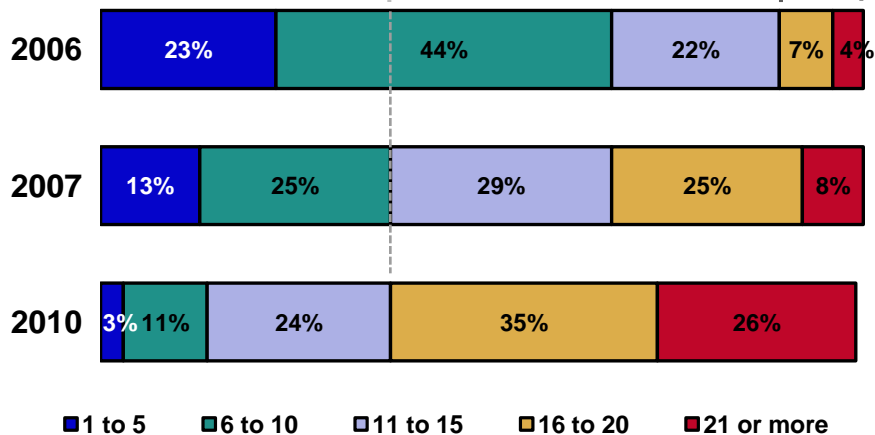
# Research and Development Landscape



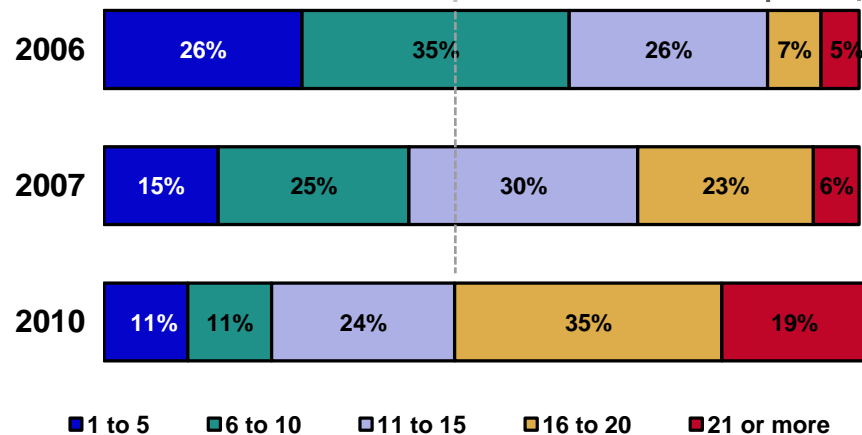
# Growth in the Number of Studies Will Add Complexity

How many phase I, II, III, IV studies did you complete in 2006? What's projected for the future? – AMR research

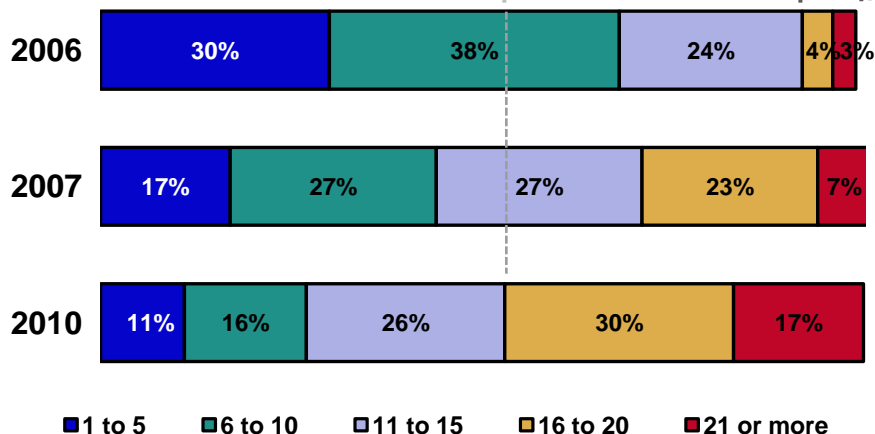
## phase I



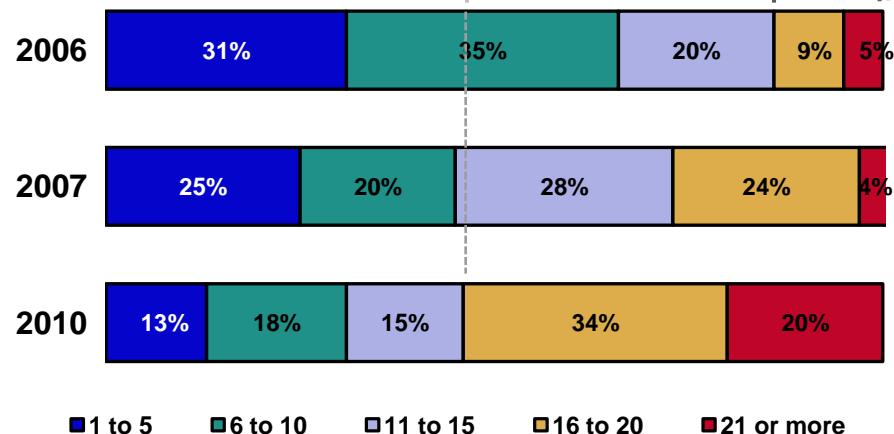
## phase II



## phase III



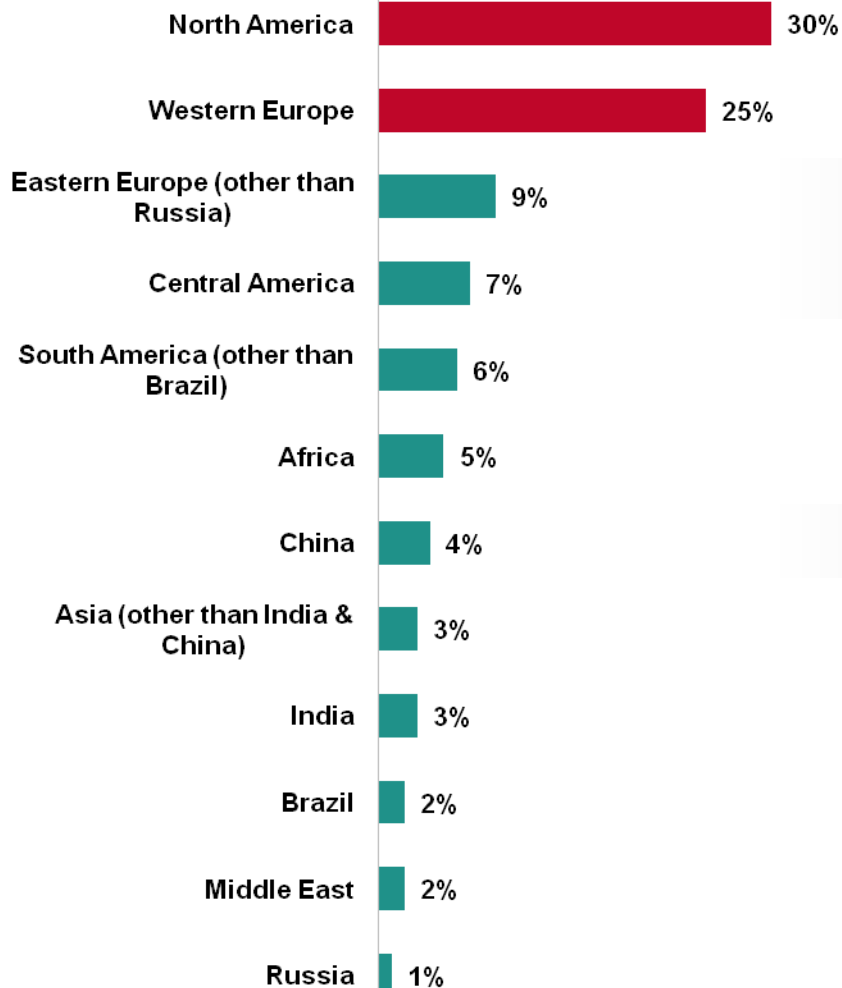
## phase IV



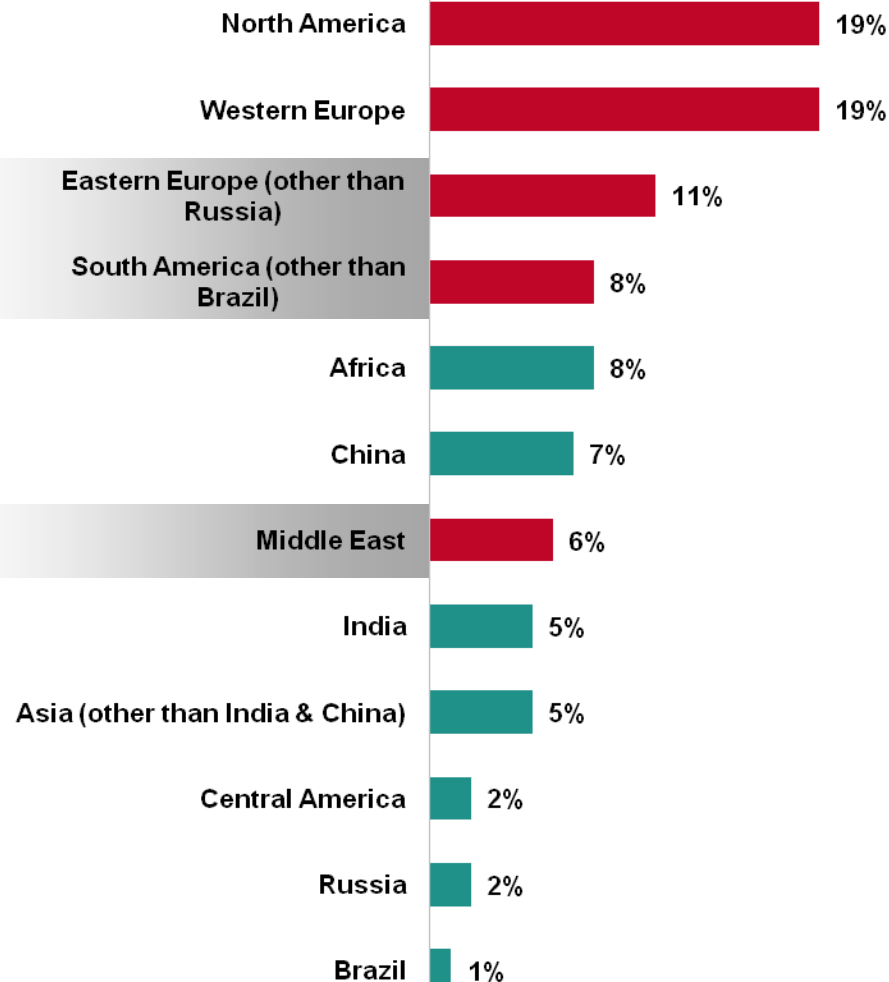
# Geographic Spread of Clinical Trials – Going Global

In which countries did you administer clinical trials (directly or through partners) in 2006? What's projected? – AMR research

## 2006

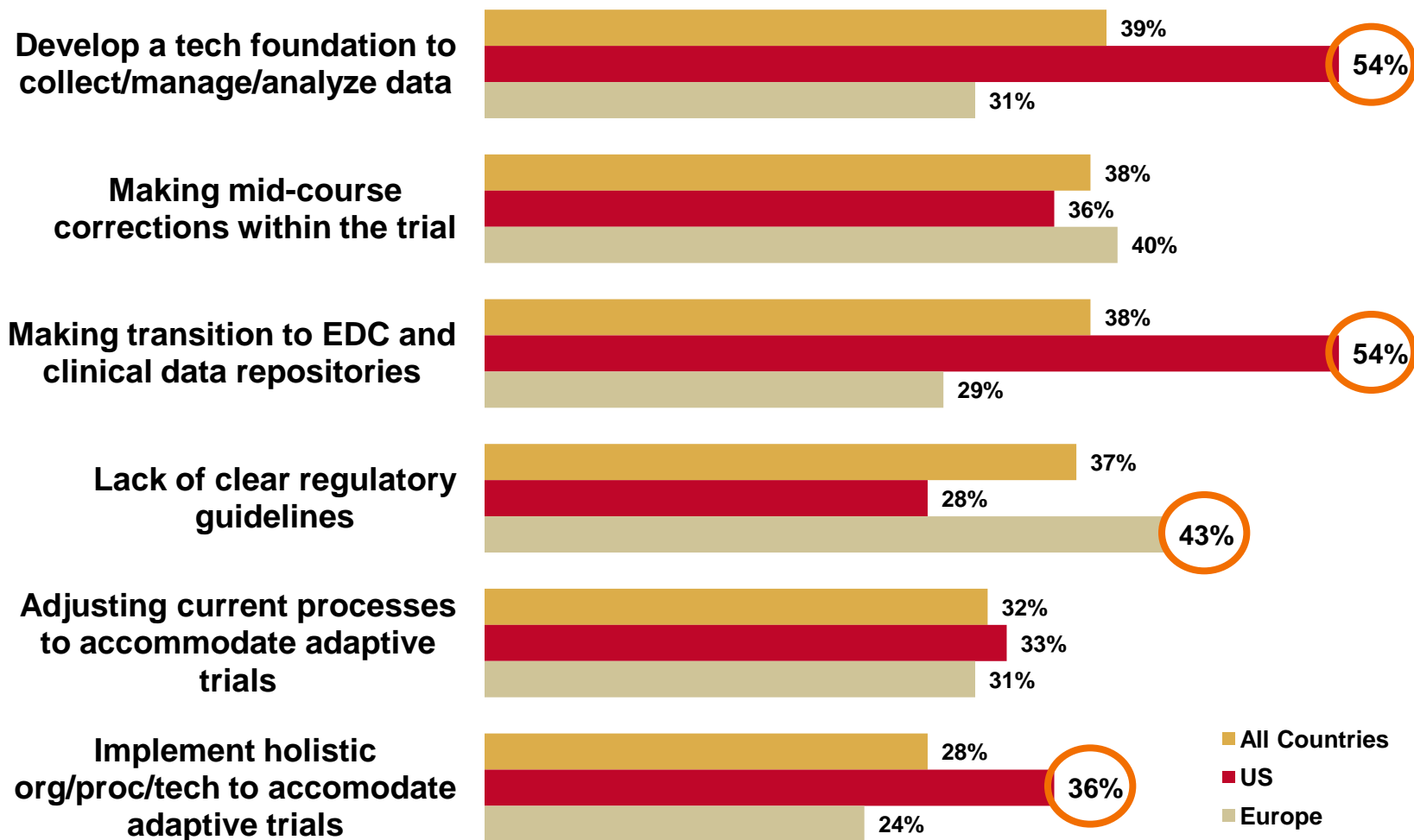


## 2010



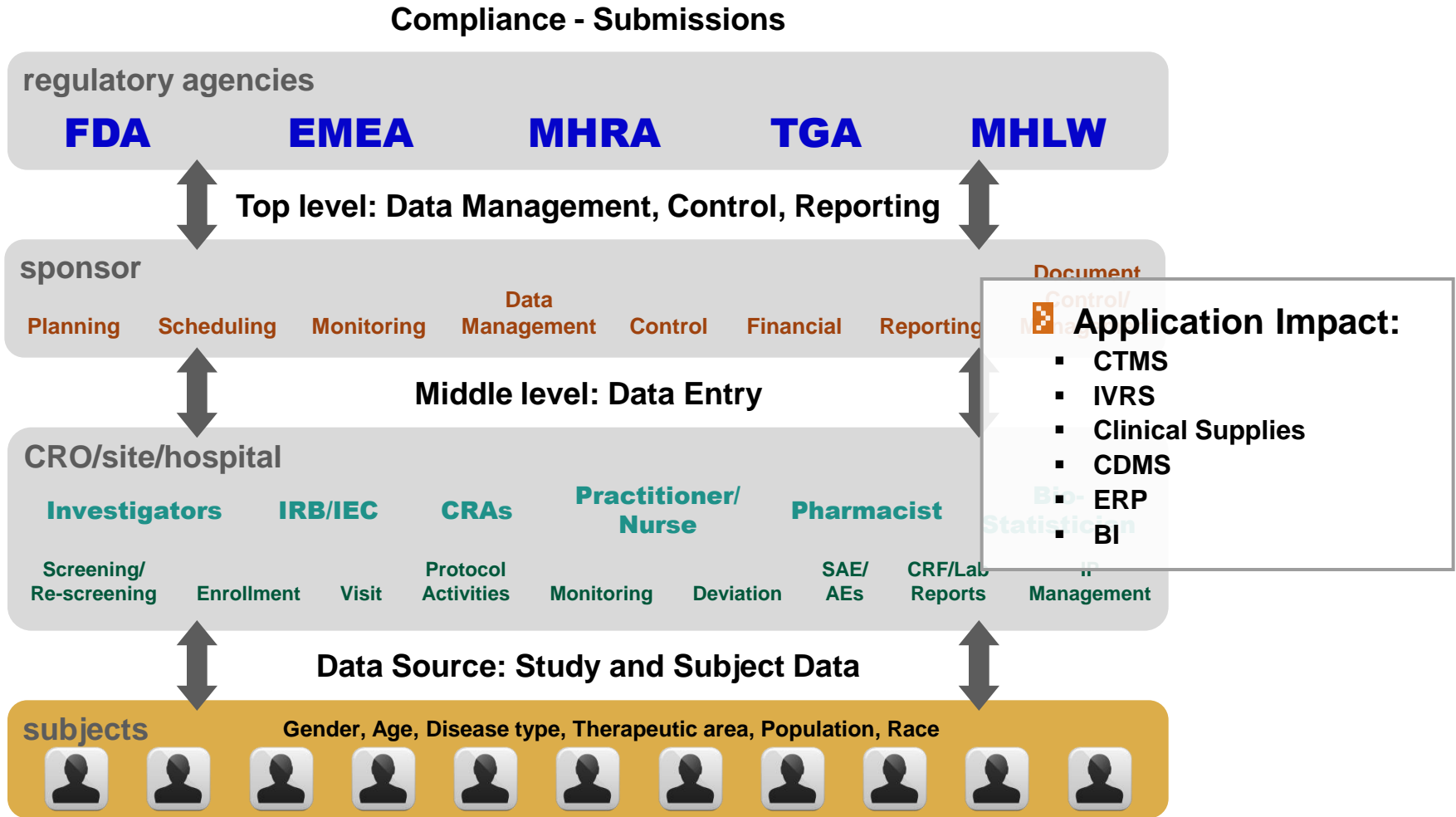
# Major Challenges to Conducting Adaptive Trials

What are the major challenges/barriers in conducting adaptive trials? – AMR research

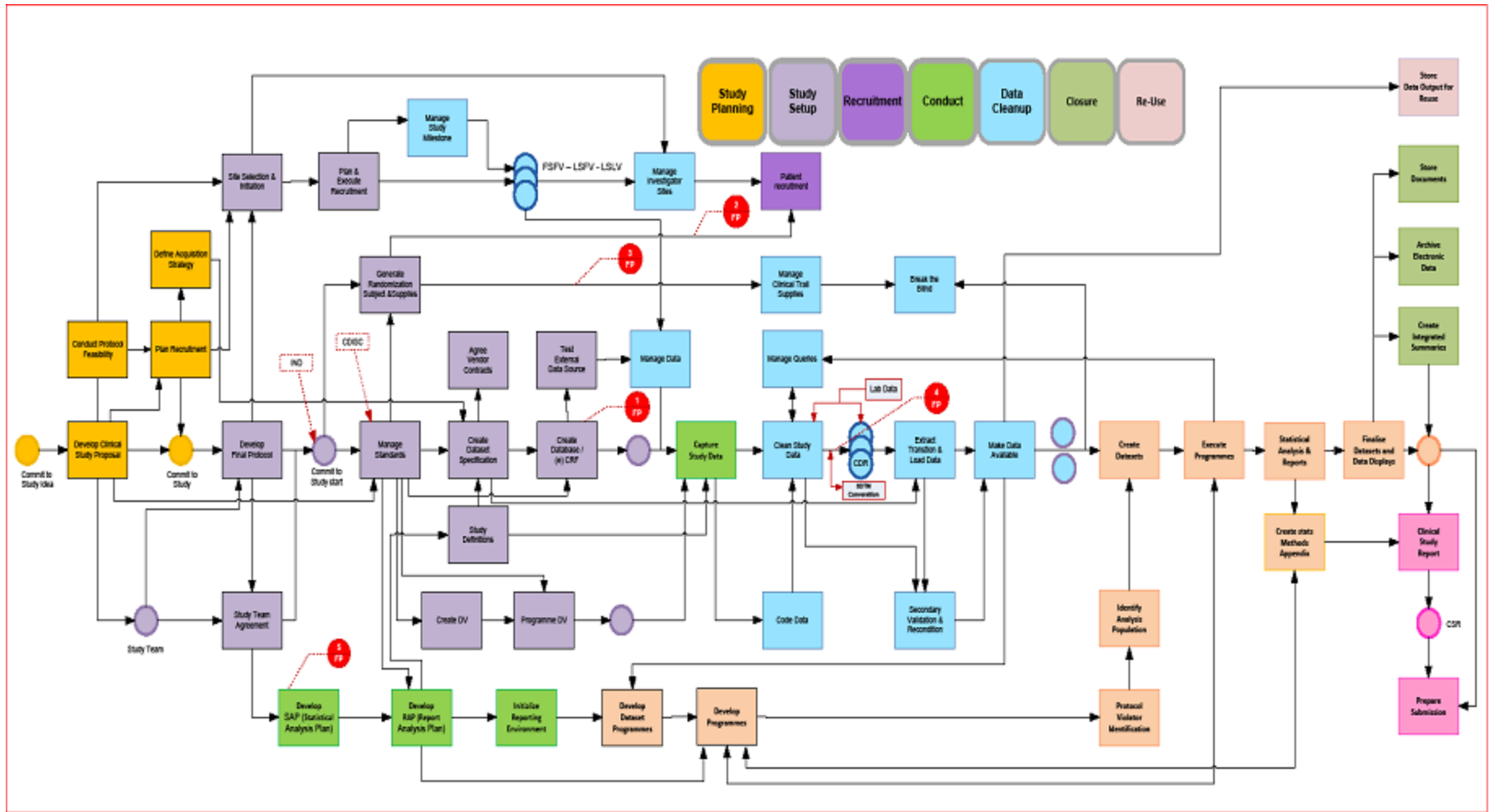


# Clinical Trial Management Systems

BUSINESS ARCHITECTURE

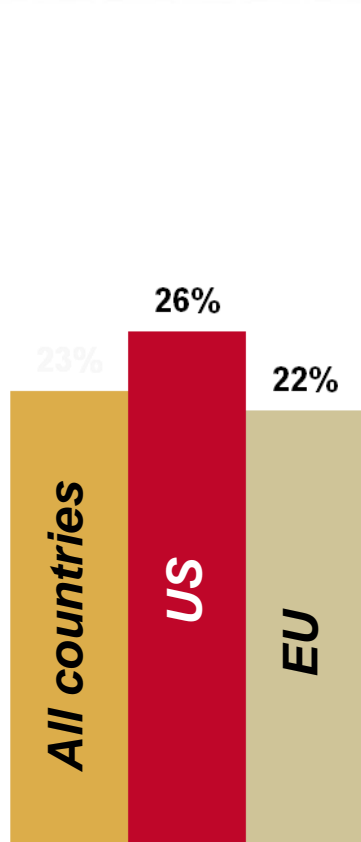


# Clinical Data Management Business Process

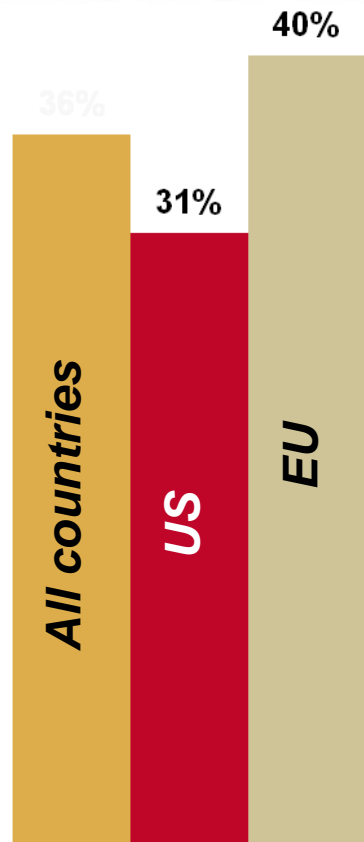


# Current Clinical Trial Supply Chain Process

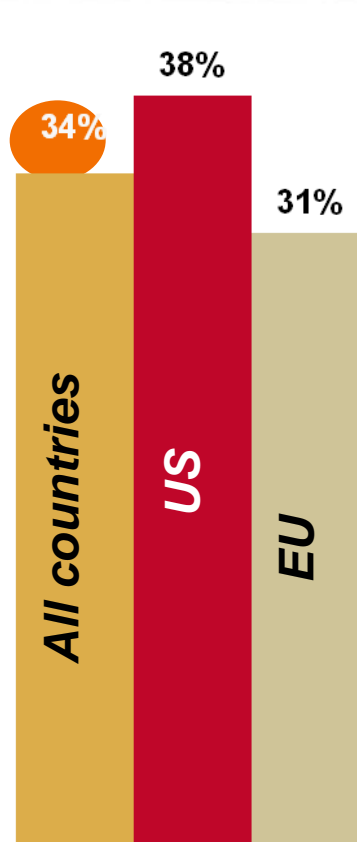
How would you describe your current clinical trial supply chain process? – AMR



**Extremely effective.** Meetings are well-attended and schedules are closely monitored with high schedule adherence

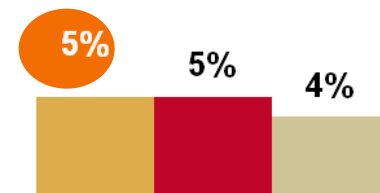


**Continuously improving.** The team has a clear roadmap to improve the CTSC process with clear attainment of goals.



**In transition.** Due to major shifts in the business, the process has undergone major changes. The team is working to redefine the process.

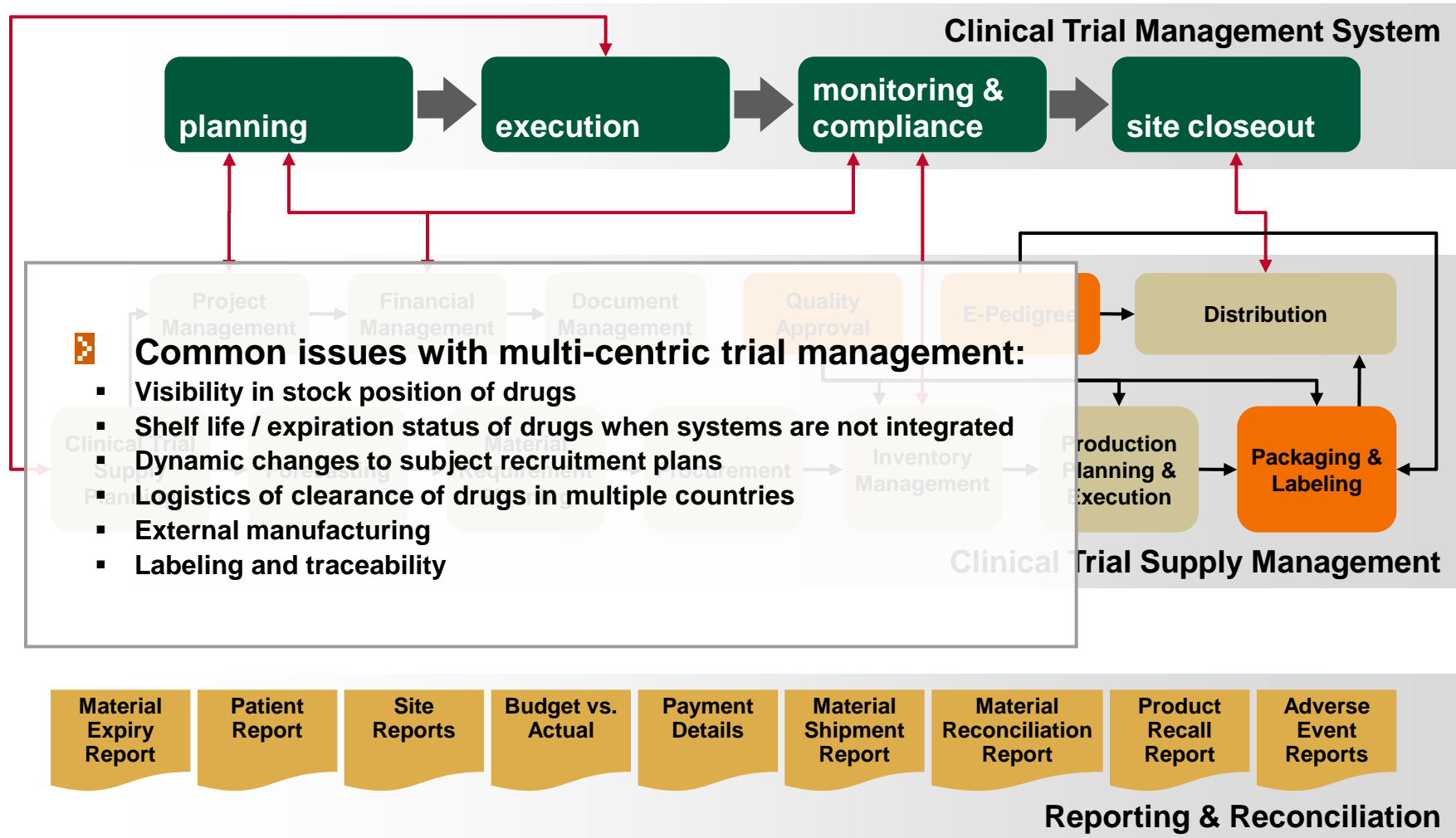
*Many companies are in the nascent stages of improvement*



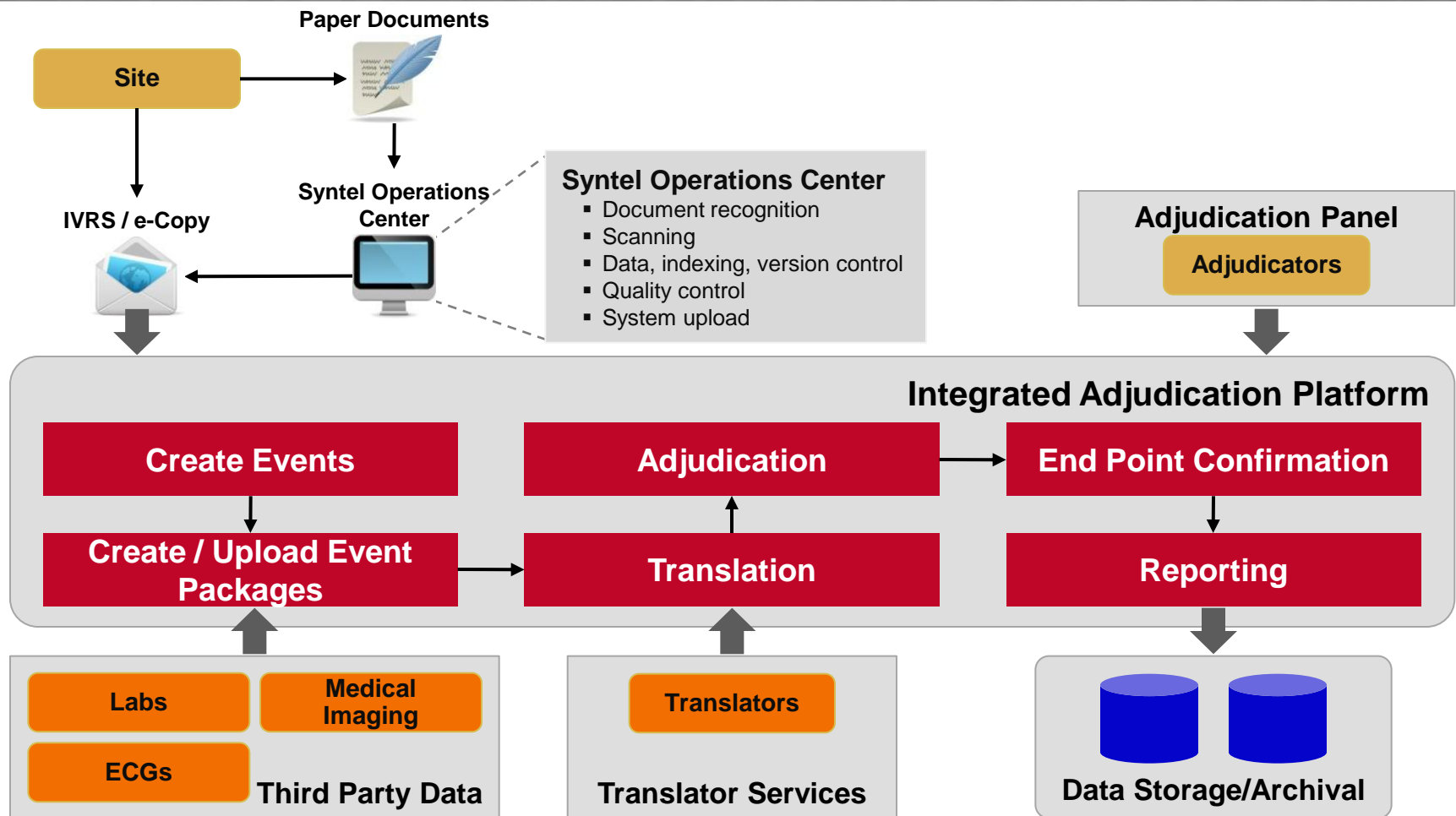
**Getting better.** The team is slowly getting better, but meeting attendance is not consistent, and there is the lack of a clear goal and sponsor

# Clinical Supply Management: Integrated Business Process

BUSINESS PROCESS



# Clinical End-Point Adjudication Solution



## Features:

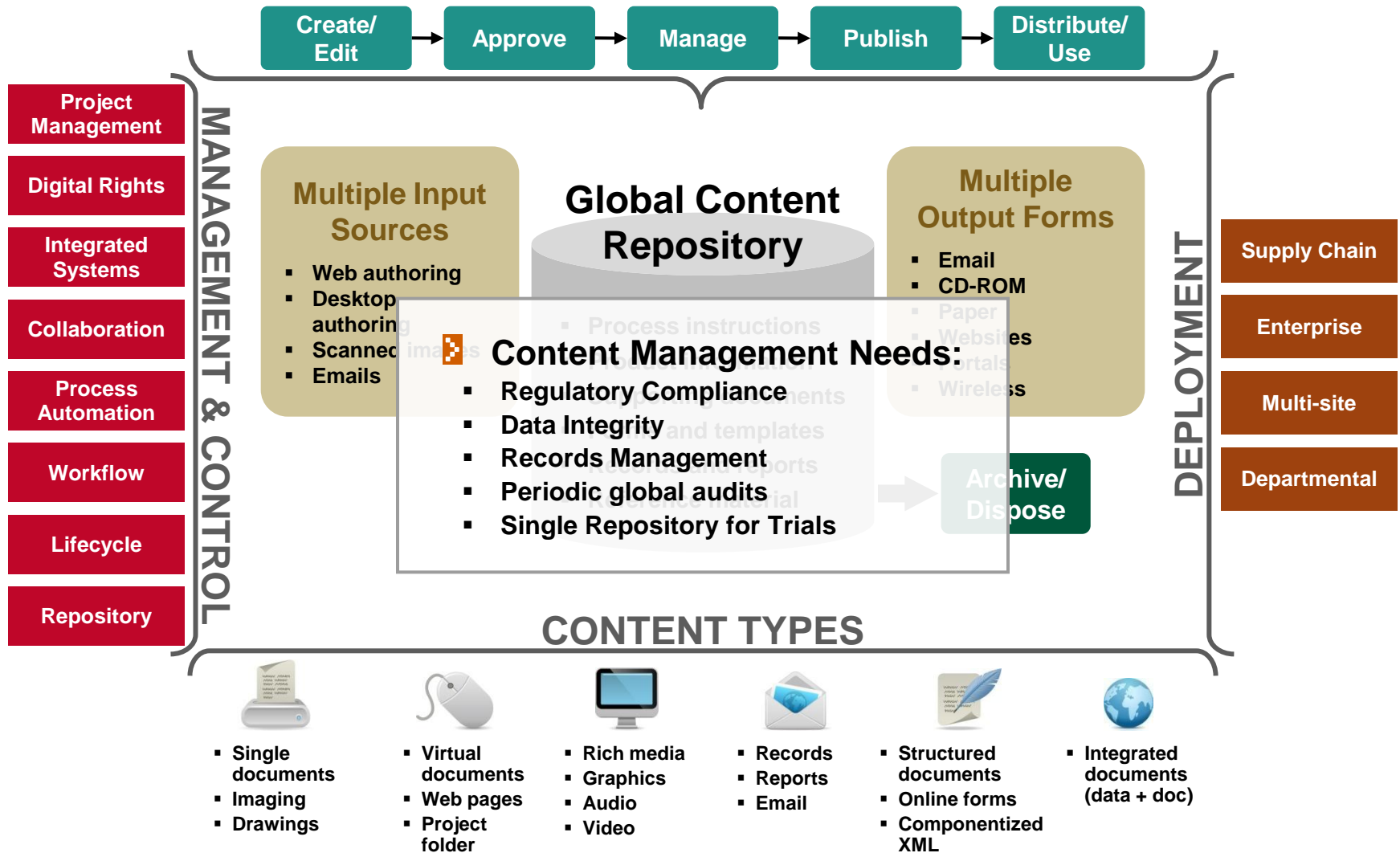
21 CFR Compliant

Web-based

Secure

Integrates with existing systems

# Clinical Submissions



# Drug Safety & Pharmacovigilance Landscape

Strategy Areas

Process Areas

IT Areas

AE Collection & Follow-up

Case Processing

Report Writing

Report Development

Proactive PV & E

- Process Re-engineering & Optimization
- Offshore Process Transition

- Recommend & Implement Innovation in Process, People & Technology
- Process Automation Support

- IT Strategy Development
- Strategic Decision Support
- COTS Evaluation

Voice-Based Call Center

- AE reports
- Medical enquiries
- Product complaints
- AE case follow-up

Non-Voice Business Processing

- Handling safety communication

Knowledge Process Outsourcing

- Literature review for published AEs

Non-Voice Business Processing

- Case entry
- Case entry QC

Knowledge Process Outsourcing

- Medical coding
- Medical review
- Case validation & lock

- Dictionary Management System
- OCR System

Knowledge Process Outsourcing

- Regulatory medical writing
- Scientific medical writing
- Patent exposure estimation

Non-Voice Business Processing

- PSUR Template Pre-filling

- PSUR Workflow Tool
- Report Submission Management Tool

Global Safety Warehouse

- Custom development
- Maintenance & support
- Enhancement & integration of additional data sources

- Data Migration
- E2B Gateway Implementation
- Local Regulatory Compliance Support

Knowledge Process Outsourcing

- Statistical analysis & reporting
- Population studies & pharmaco-epidemiologic assessment

Signal Detection System

- Custom development
- COTS implementation
- Enhancements & customization

- Adverse Event Reporting System

- Custom Development

- COTS Implementation

- Enhancements & Customization

- COTS Upgrade

- System Maintenance & Support

- Data Migration

- System Upgrade

- Application Helpdesk

# Drug Safety & Pharmacovigilance Landscape

Strategy Areas

Process Areas

IT Areas



## PARTNER FOR BUSINESS TRANSFORMATION

- Recommend & Implement Innovation in Process, People & Technology
- Process Automation Support

- IT Strategy Development
- Strategic Decision Support
- COTS Evaluation

## DELIVER BUSINESS PERFORMANCE

### Voice-Based Call Center

- AE reports
- Medical enquiries
- Product complaints
- AE case follow-up

### Non-Voice Business Processing

- Literature review for published AEs

### Non-Voice Business Processing

- Case entry
- Case entry QC

### Knowledge Process Outsourcing

- Medical coding
- Medical review
- Case validation & lock

### Knowledge Process Outsourcing

- Regulatory medical writing
- Scientific medical writing
- Patent exposure estimation

### Non-Voice Business Processing

- PSUR Template Pre-filling

- Dictionary Management System
- OCR System

- PSUR Workflow Tool
- Report Submission Management Tool



### Concerns:

- Dependency on Information thru IVRS integration
- Support for multiple languages
- Adherence to external submission schedules
- Diverse Regulatory guidelines in different geographies
- Need to integrate and track AE across different geographies and manage timely submissions

- Adverse Event Reporting System

- Custom Development

- COTS Implementation

- Enhancements & Customization

## REDUCE OPERATING COSTS

- Data Migration

- System Upgrade

- Application Helpdesk



# Potential Clinical Development Integration Needs

## focus areas

- ❑ Architecture
  - ❑ Regulatory Issues
  - ❑ Geographical
  - ❑ Data Issues
  - ❑ Decision support
  - ❑ Application Issues
  - ❑ BI / Reporting Capabilities
  - ❑ Portal Capabilities
- 
- ❑ P2P Integrations
  - ❑ Web Services
  - ❑ Clinical Trial Exchange Platform

## existing technical approaches

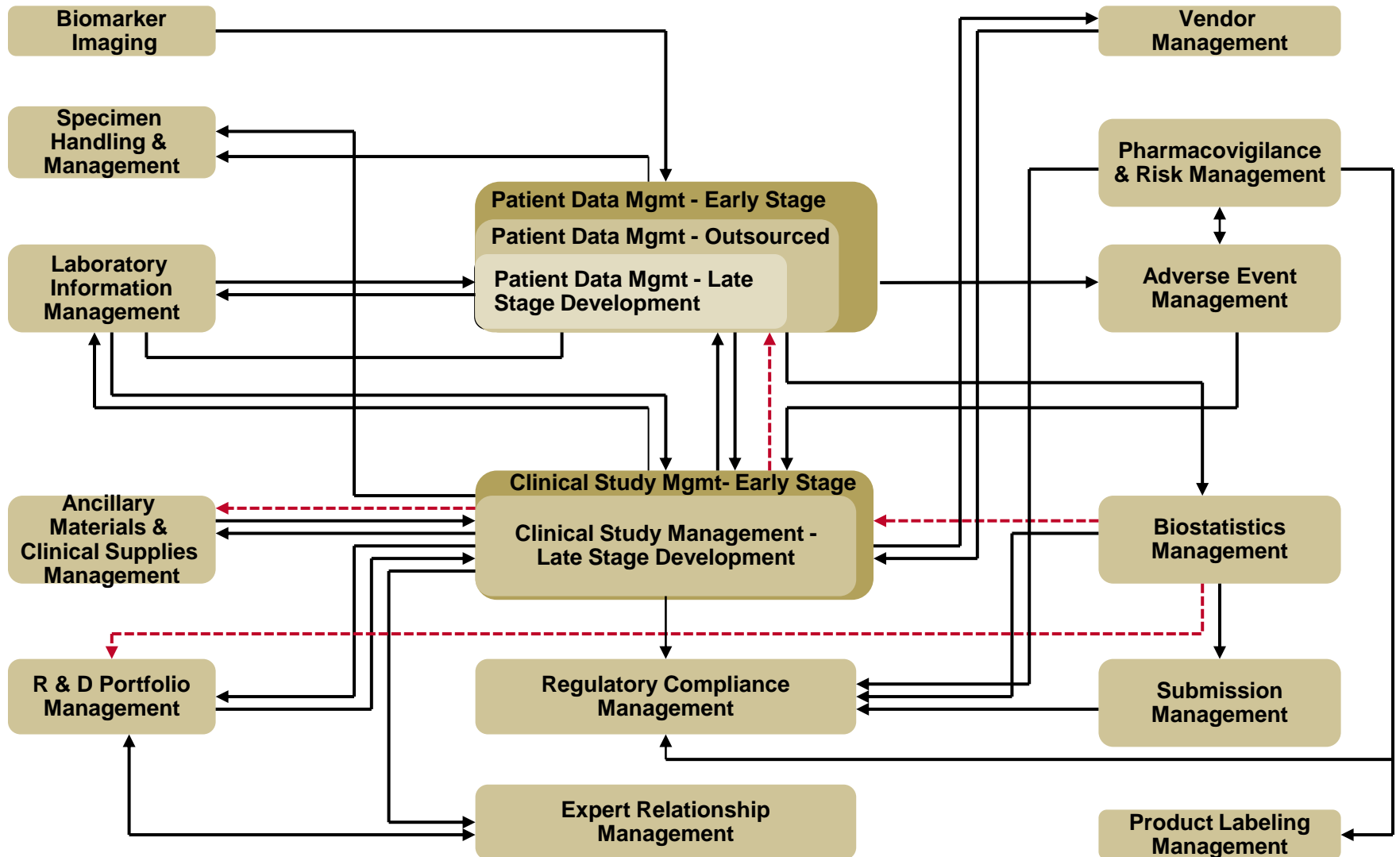
# The Cost of 1 Day

- Total cost of project staff and operations, internal and external
  - \$70,000 per day (average)
- Advance 1 day towards expiry date (risk further delay)
- Advance 1 day further through seasonality of indication (risk full year delay)
- Delayed revenue in patent life
  - \$500 million drug: 1 lost day costs \$1.3 million+
  - \$1 billion drug: 1 lost day costs \$2.7 million+

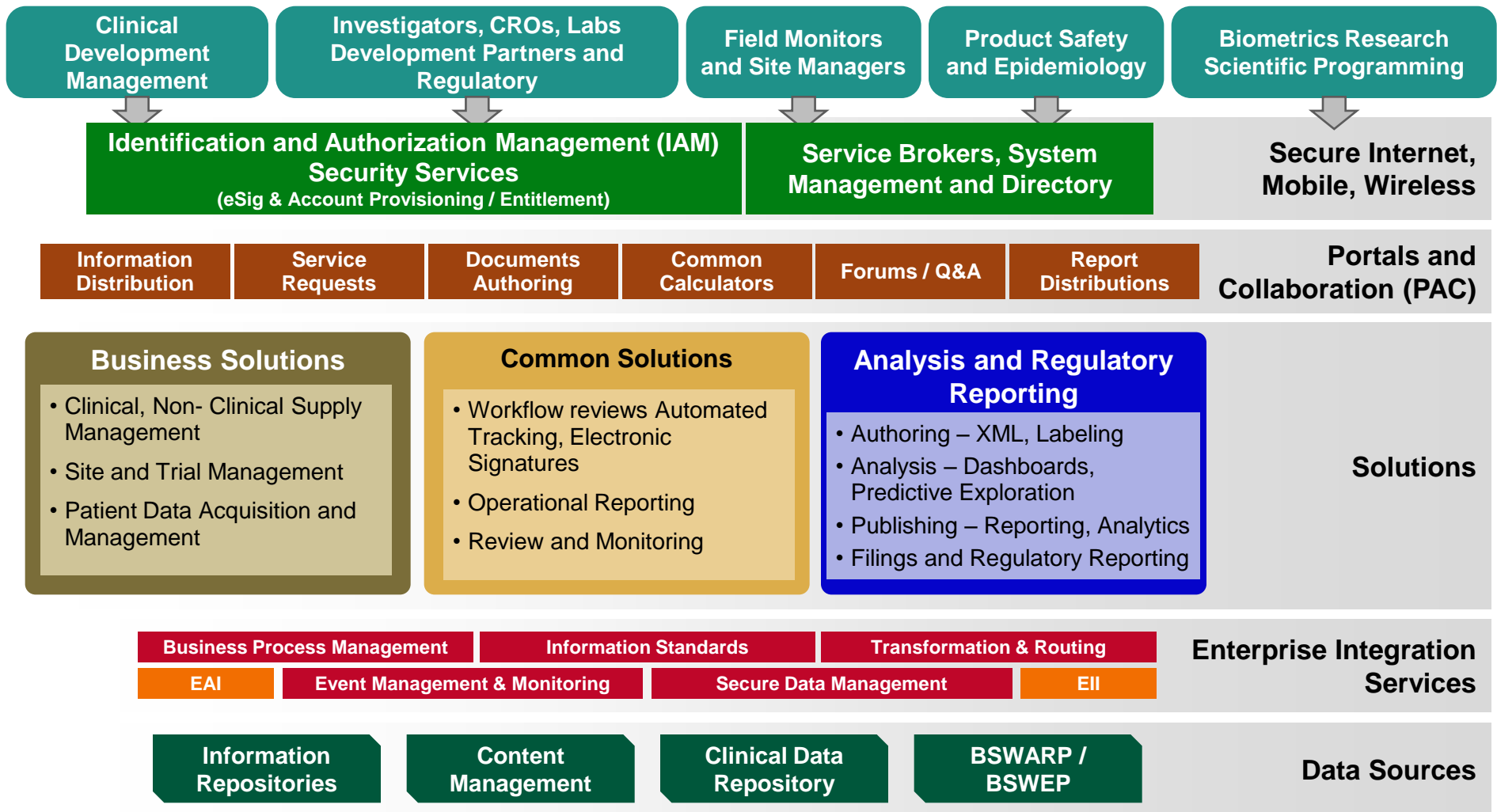
**The cost of delayed revenue is  
*unrecoverable* at end of patent life**

Source: Rockwell Automation, Inc.

# Integrated Clinical Development Landscape



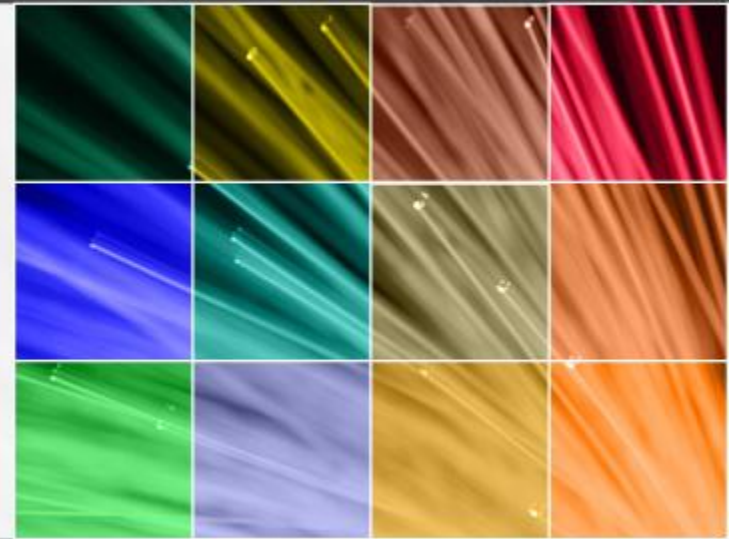
# Integrated Clinical Development Framework: A Best Practice Approach



# Potential Benefits

- **An integrated approach to manage clinical development needs**
- **Data security, visibility and integrity**
- **Strict adherence to regulatory compliance and patient safety**
- **Reduced timeframes for CT and Increased ROI**

# About Syntel

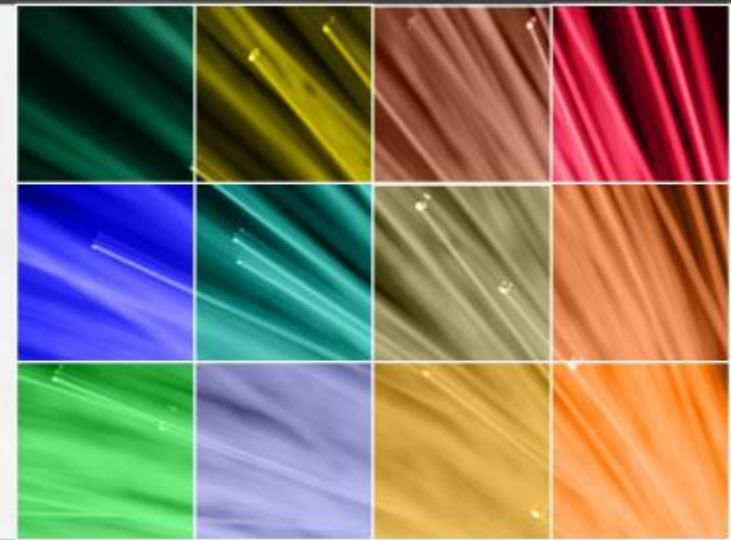


# Syntel Fast Facts



<b>Company Headquarters:</b>	Troy, Michigan, USA
<b>Founded:</b>	1980
<b>Exchange/Symbol:</b>	SYNT: NASDAQ since 1997 - Adherence to SEC norms and NASDAQ listing requirements
<b>Revenue:</b>	2009 revenues: \$419 Million Zero debt, Profitable since inception in 1980 Financials audited & certified in US
<b>Employees:</b>	12,500+
<b>Global Presence:</b>	Global Development Centers: India (8) and US (3), 15 sales offices
<b>Corporate Governance:</b>	ISO 9001 [Quality Assurance], CMMi Level 5 [Process Excellence], ISO 27001 [Information Security], SOX compliant, SAS Type II Audit

# Q&A



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