



MDR Implementation: Drivers & Challenges

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PhUSE SDE - May 14, 2015





Agenda

- Overview
- Drivers for Metadata Management Solution
- Procurement & Implementation Challenges
- Keys to Success

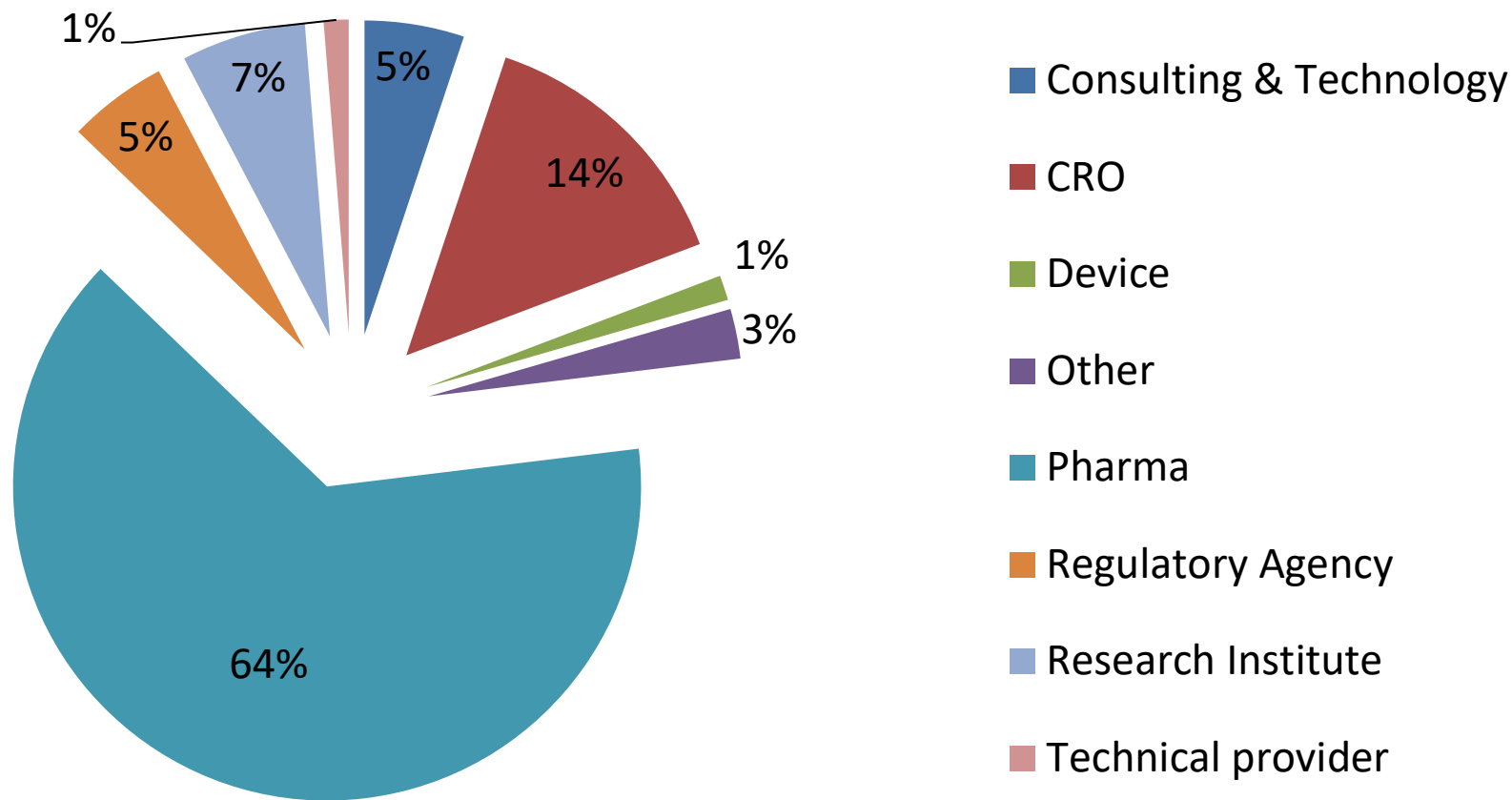
Survey Overview

“Research shows that content is growing by as much as 200% per year, and the risks of not managing it effectively are growing even faster.” (ASG)

- Survey conducted at CDISC Interchange US 2013 & EU 2014
- Goal to understand the following:
 - Where industry is in terms of standards/metadata management (MM)
 - What is driving industry in this direction
 - What challenges they face in procuring/implementing a solution
- Survey participants: 75+ globally, from 55 different organizations

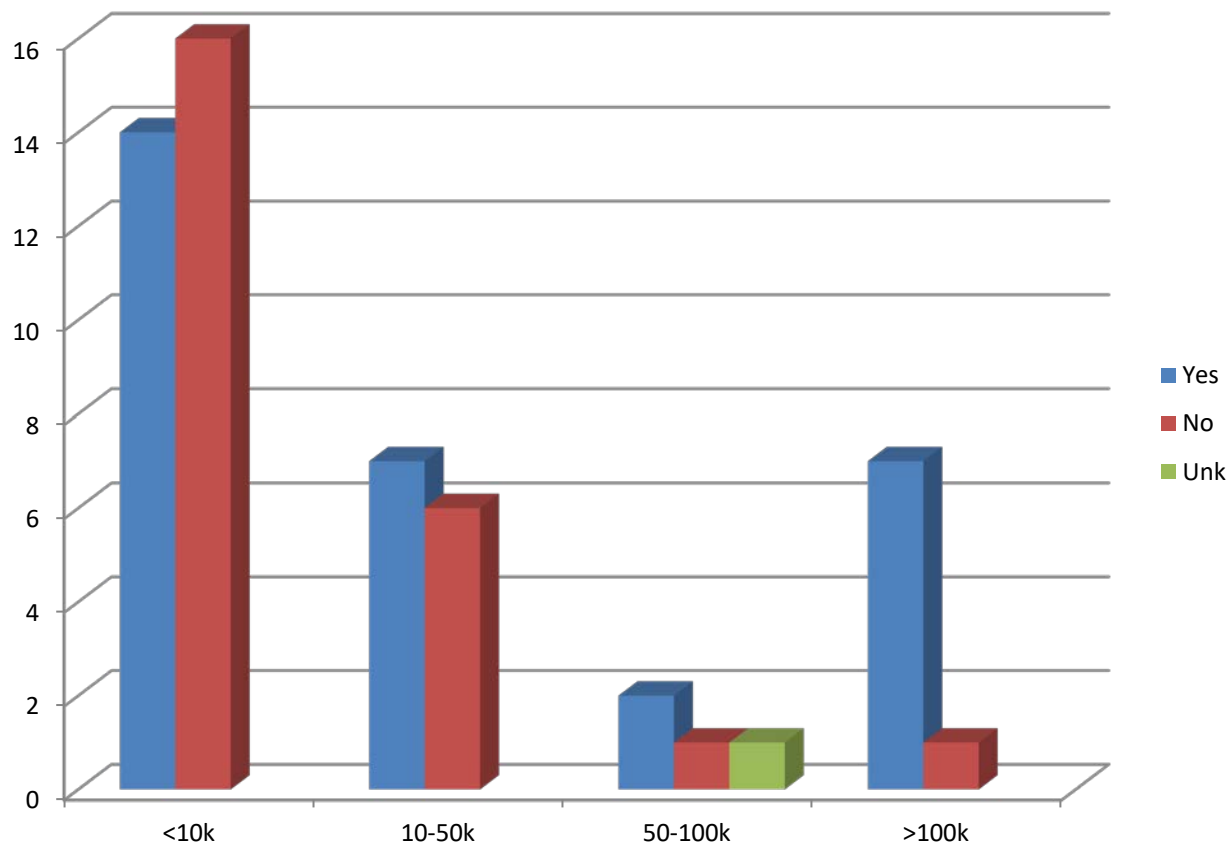


Participants by Organization Type



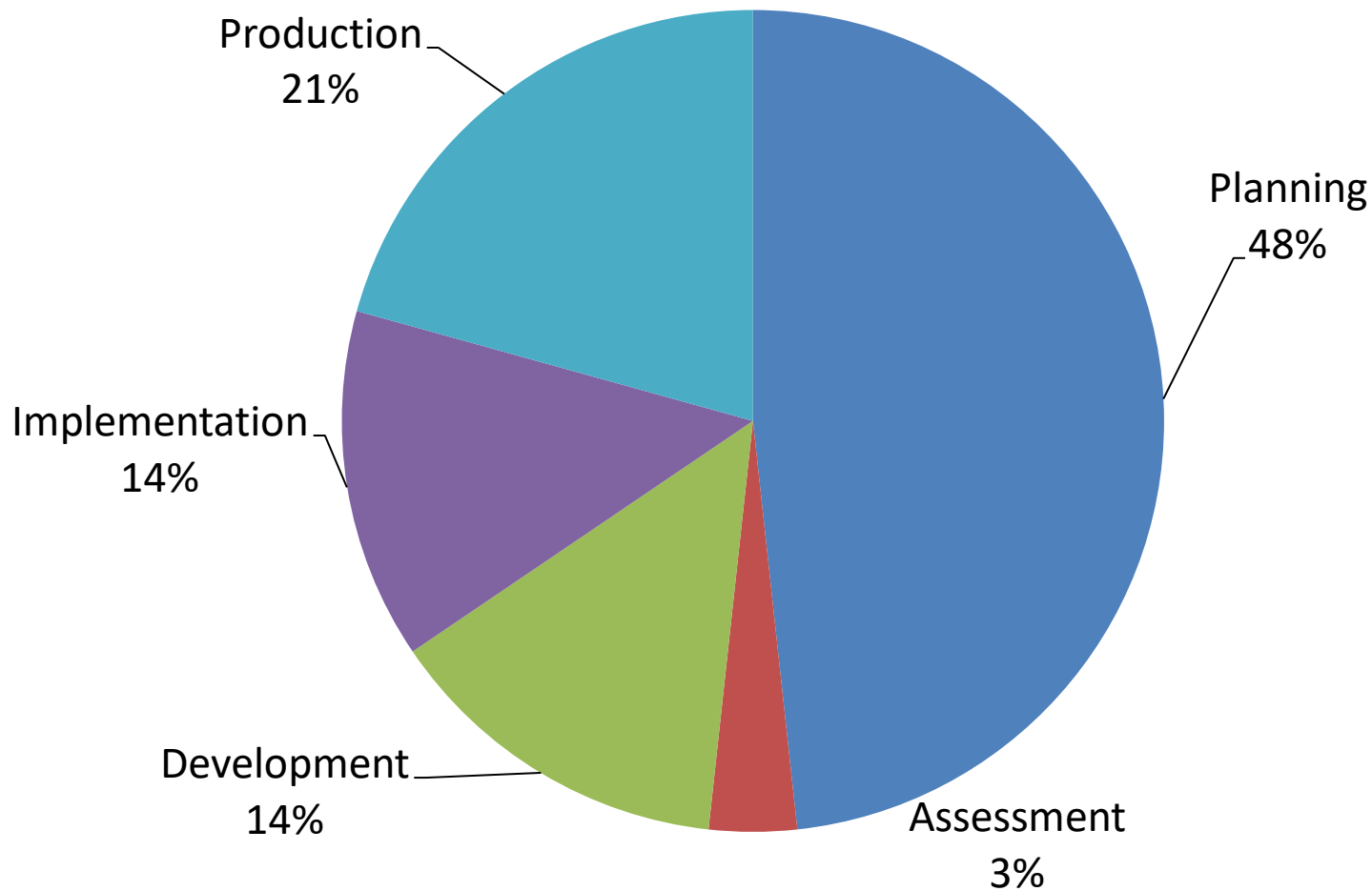


MM Projects by Company Size



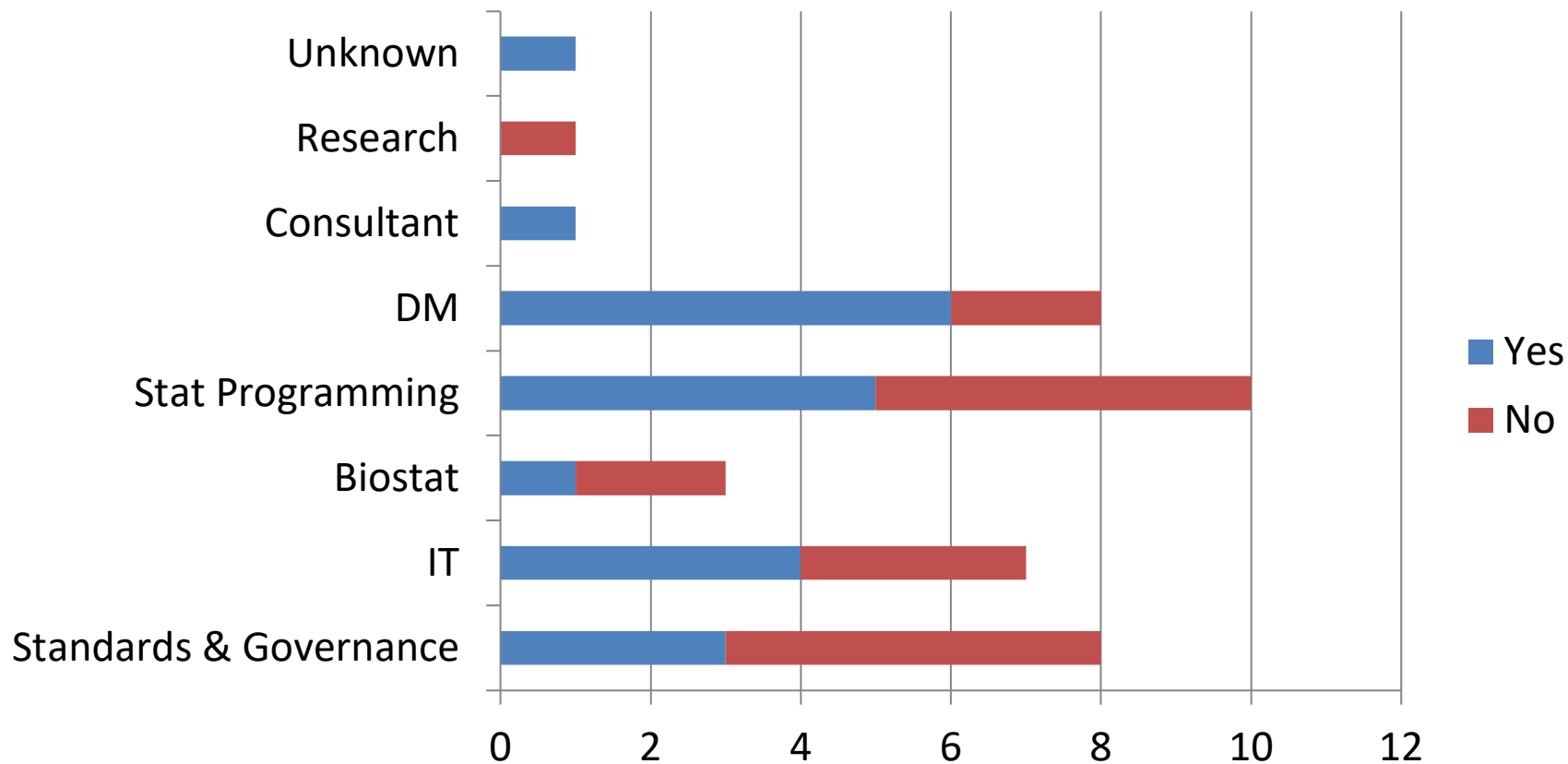


Project Stage





Satisfied with Current Solution





Reasons for Dissatisfaction

- Top 3 Answers
 - Unstable, Outdated, or Inefficient
 - CDISC Compliance
 - Version Control
- Other Answers
 - Governance Support
 - Study Metadata Management
 - Not Global
 - Glossary Management
 - IT Support

DRIVERS FOR METADATA MANAGEMENT SOLUTION

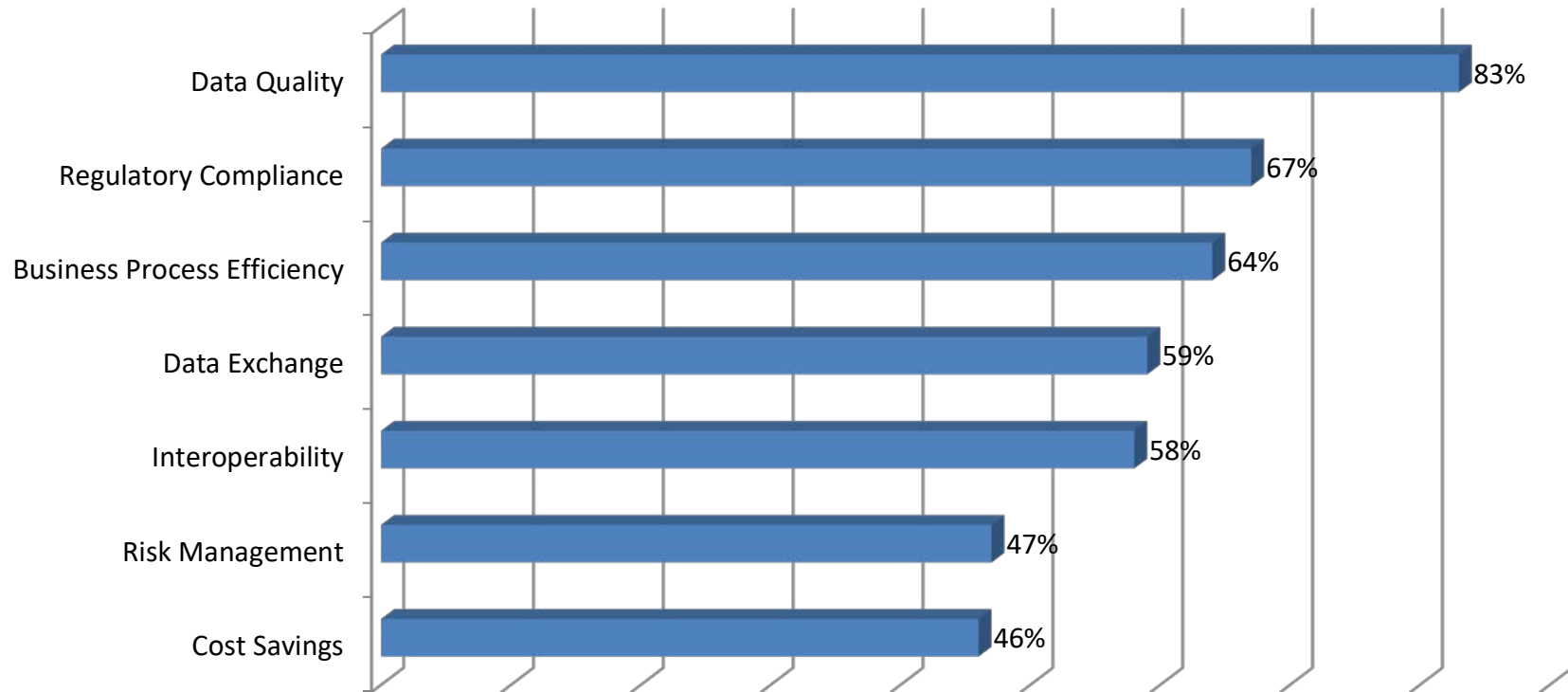


Driver selection

- Based on literature and experience
 - Regulatory Compliance
 - Data Quality
 - Business Process Efficiency
 - Data Exchange
 - Interoperability
 - Risk Management
 - Cost Savings
- ‘Other’ category added

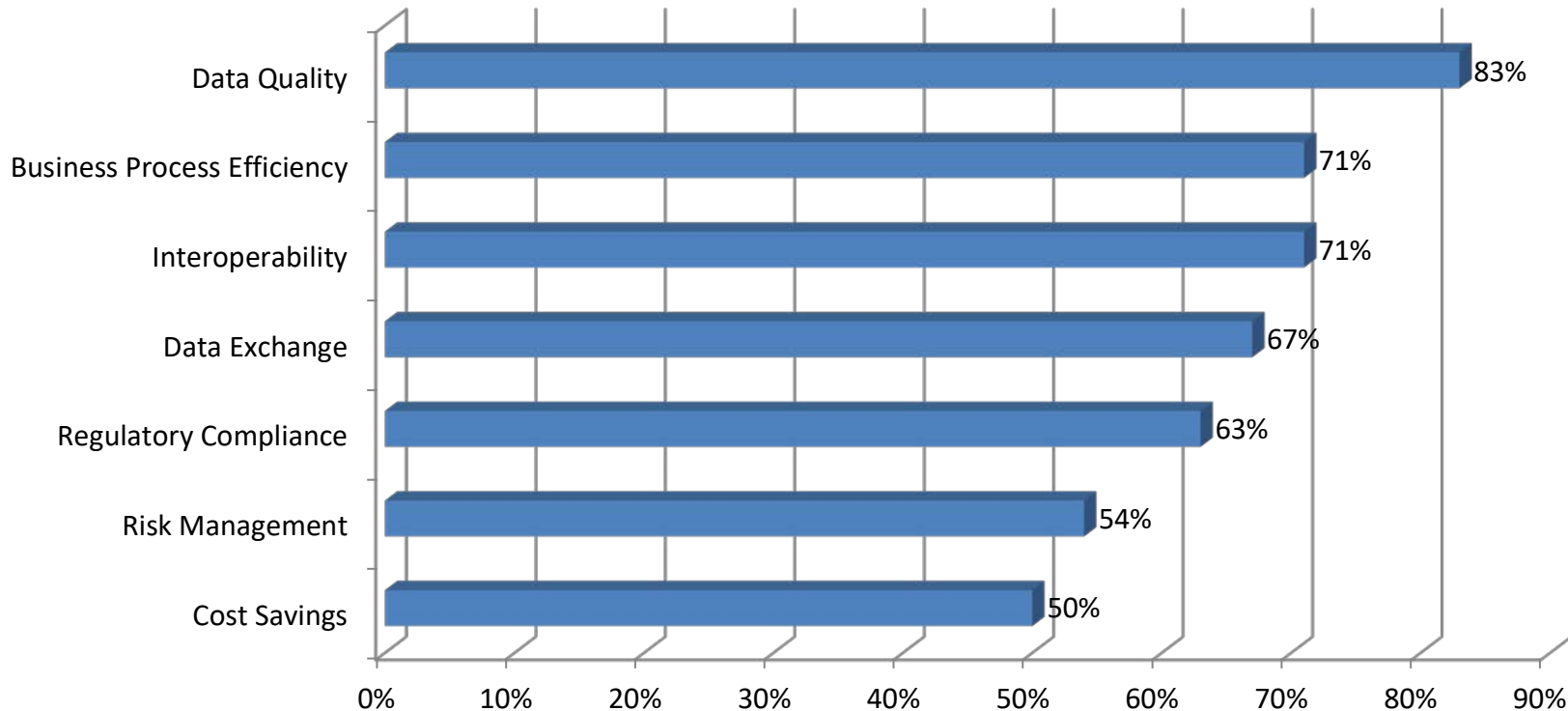


Drivers Most Chosen



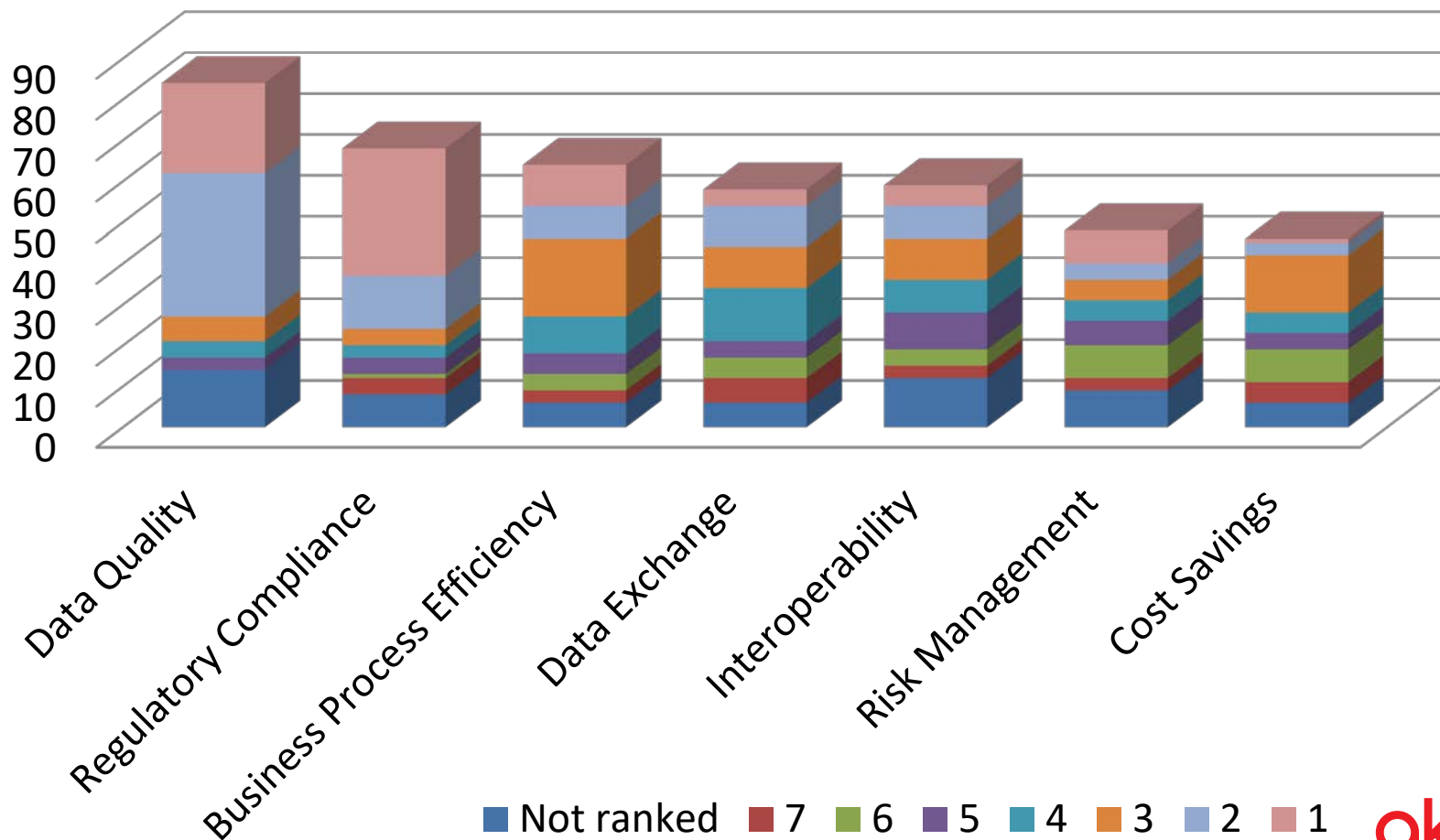


Europe/Asia Drivers Chosen



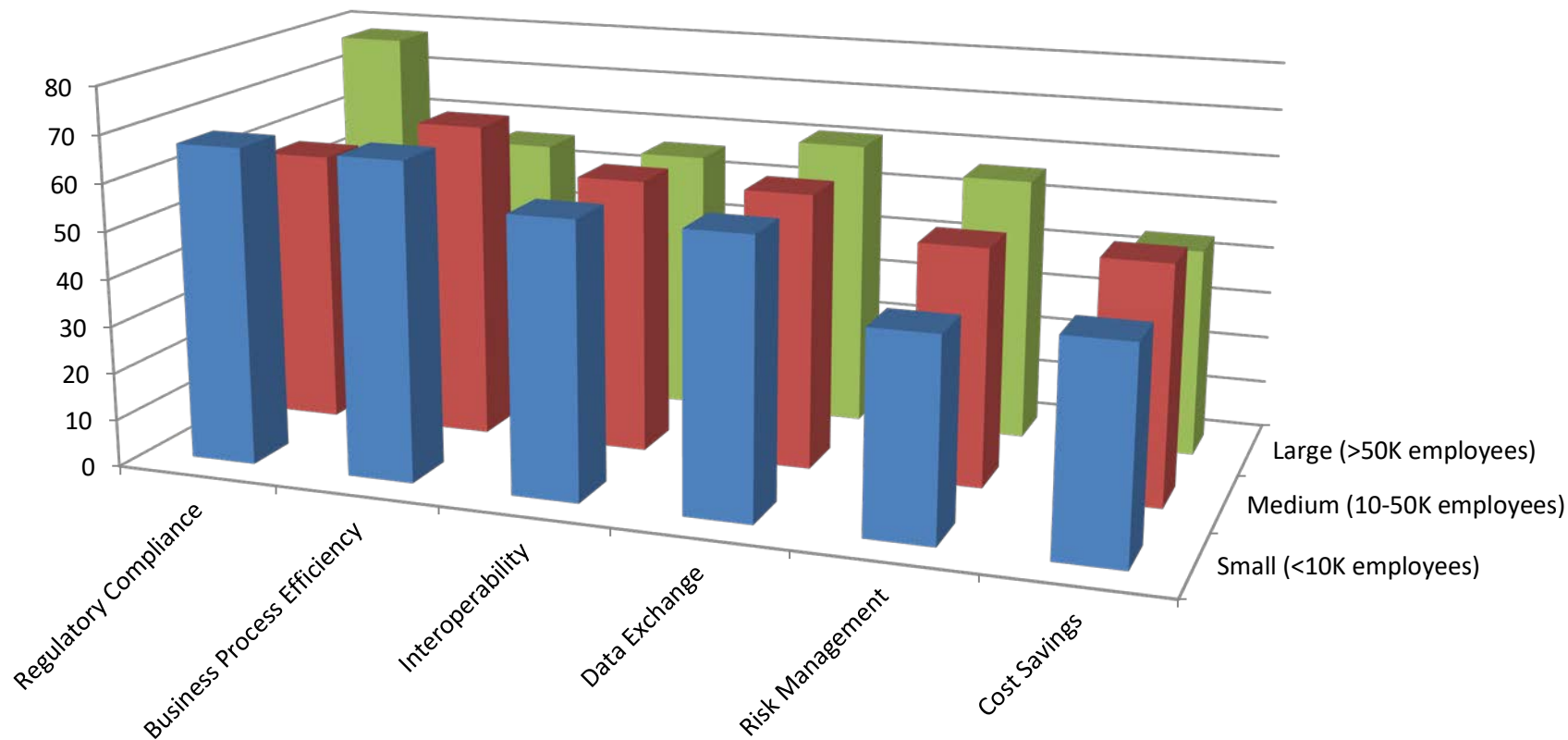


Driver Ranking by Percent of Responders



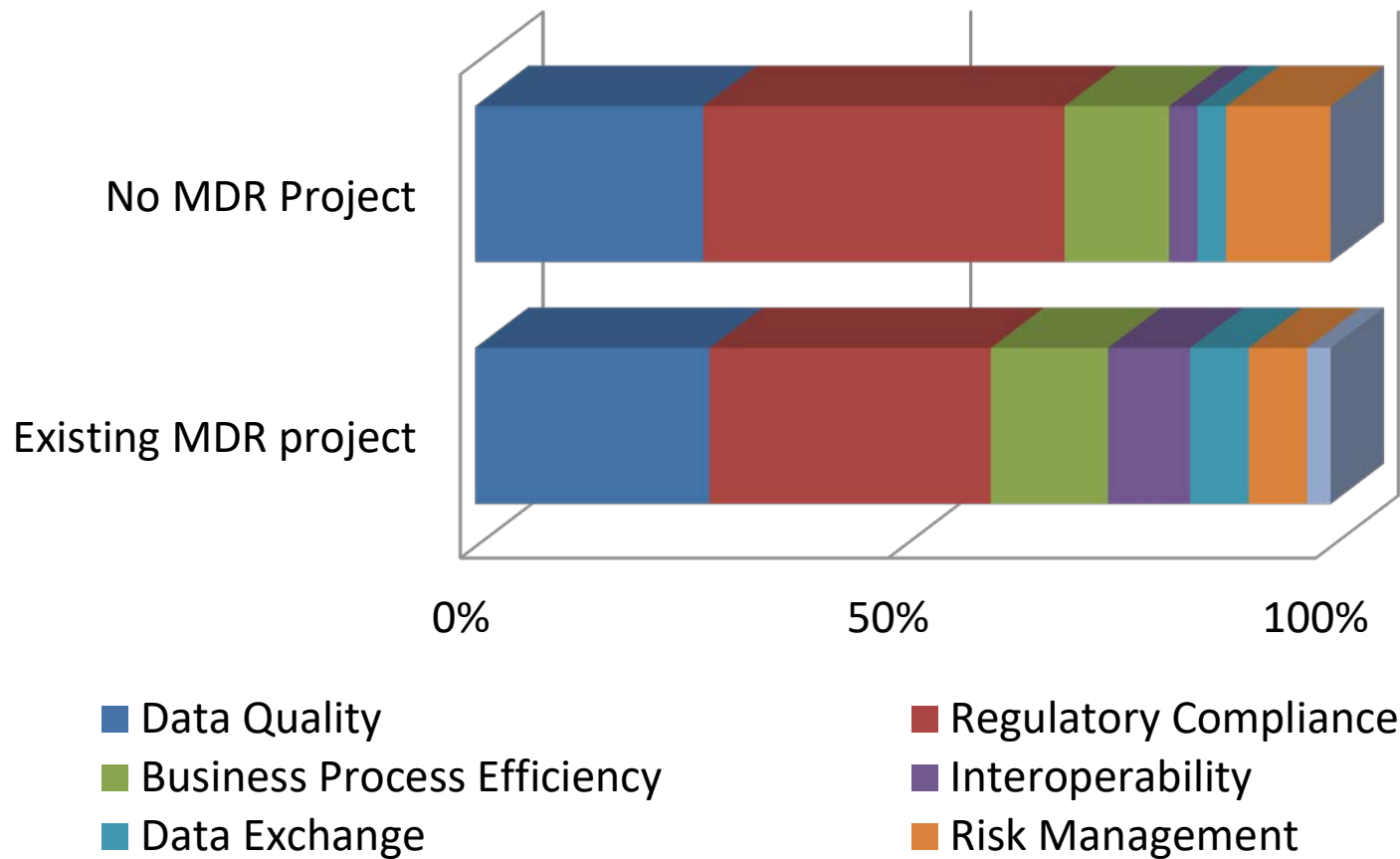


Drivers by Company Size



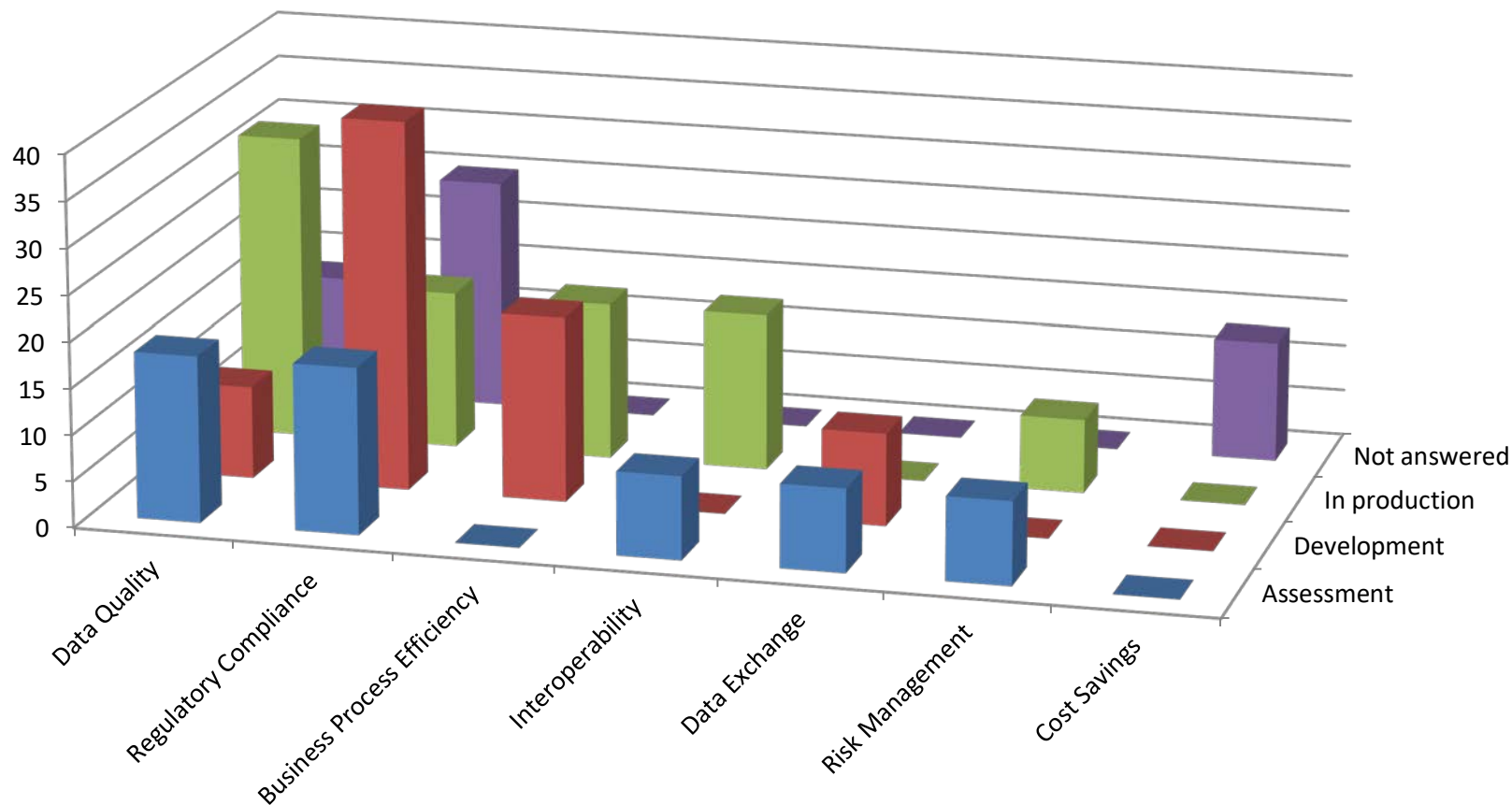


Driver Changes by MDR Project





Driver Changes Throughout MM Project





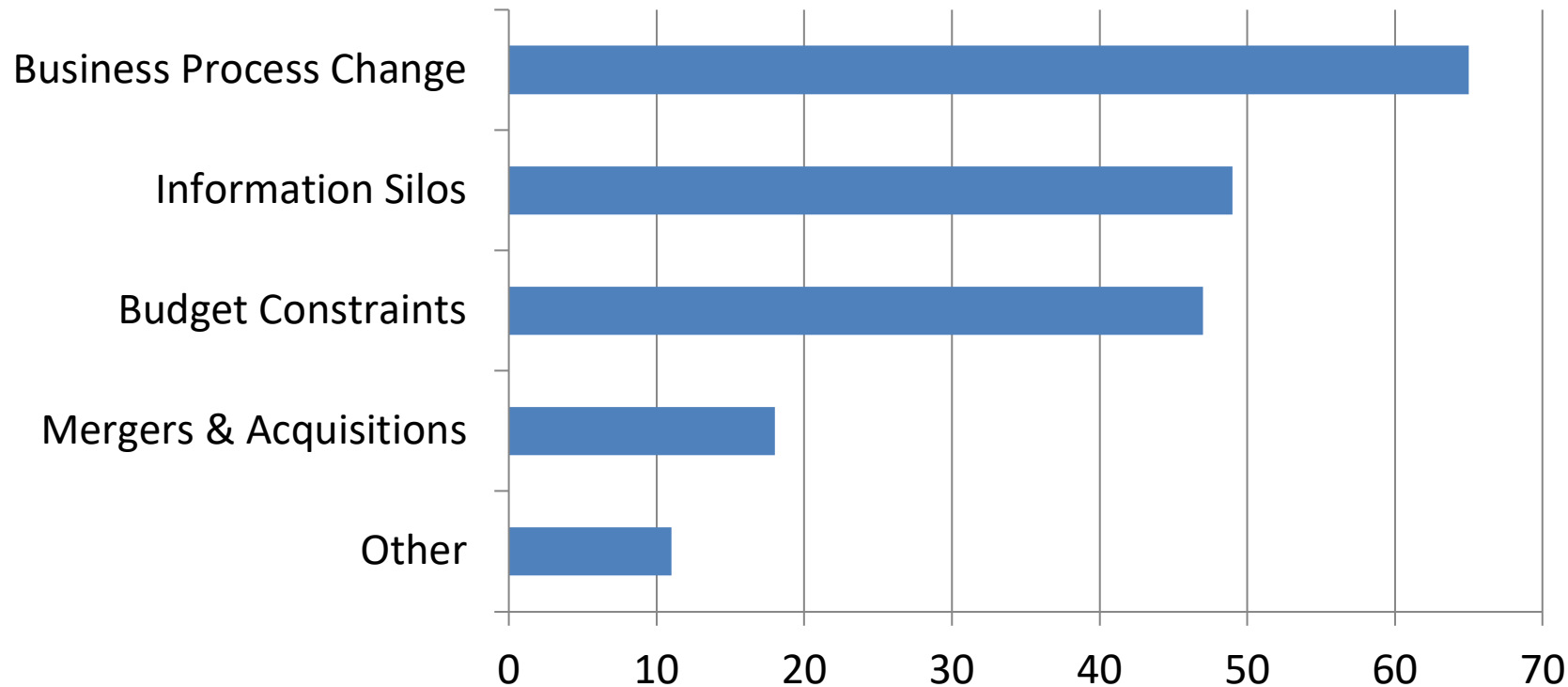
How MDR Can Facilitate Drivers

- Regulatory compliance with clear traceability from source to submission and standards compliance
- Data quality via controlled metamodel, validations, and decreased need for human review and interpretation
- Study artifact production from standards
- Business process automation to augment/replace manual processing
- Interoperability by tying data to standards and semantics
- Data exchange through integrations, semantics interoperability, and standardized exchange formats
- Risk management via industry semantics and terminology use, data quality, compliance, and business process efficiency
- Cost savings through process automation

MDR PROCUREMENT & IMPLEMENTATION CHALLENGES

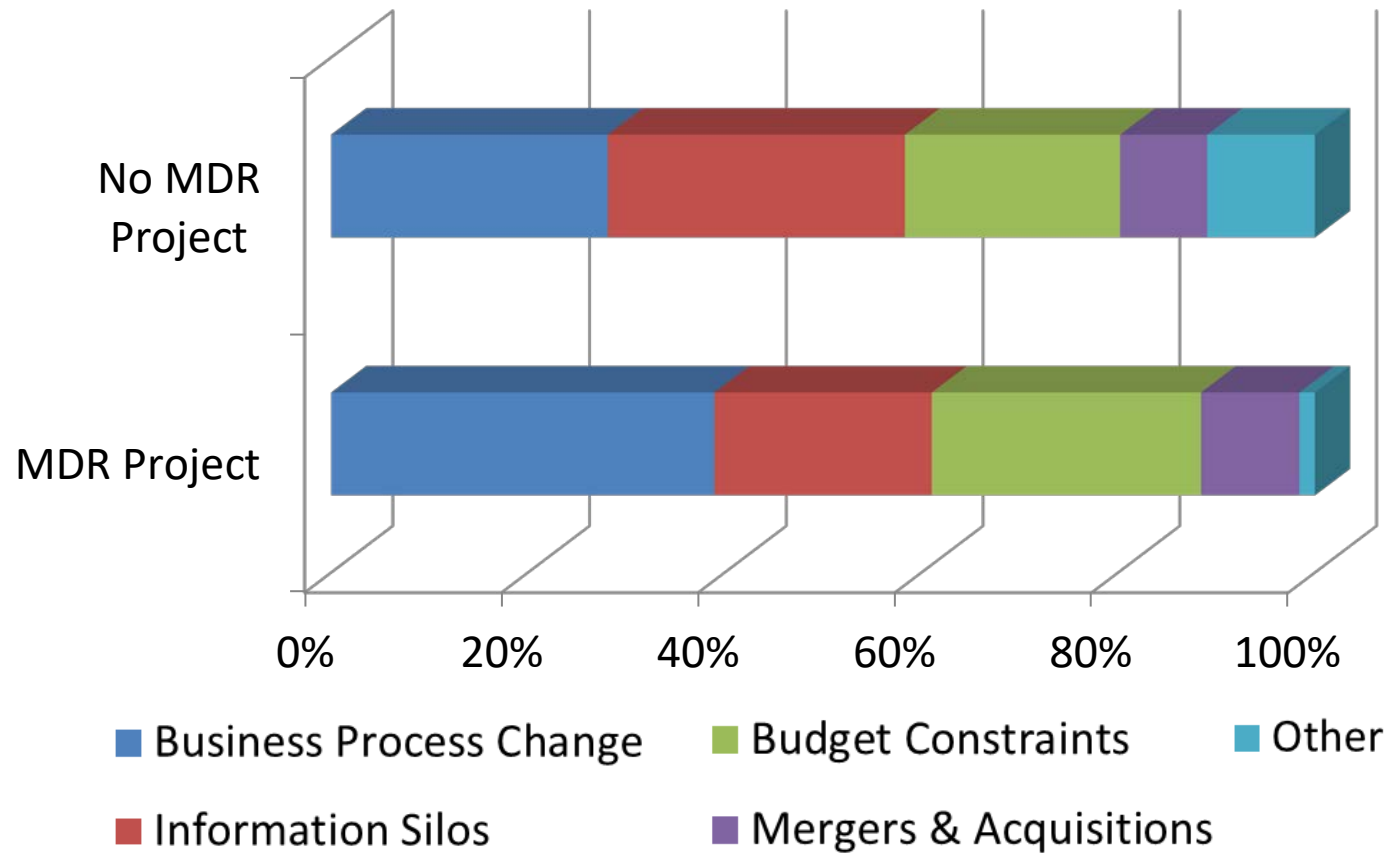


Overall Challenges



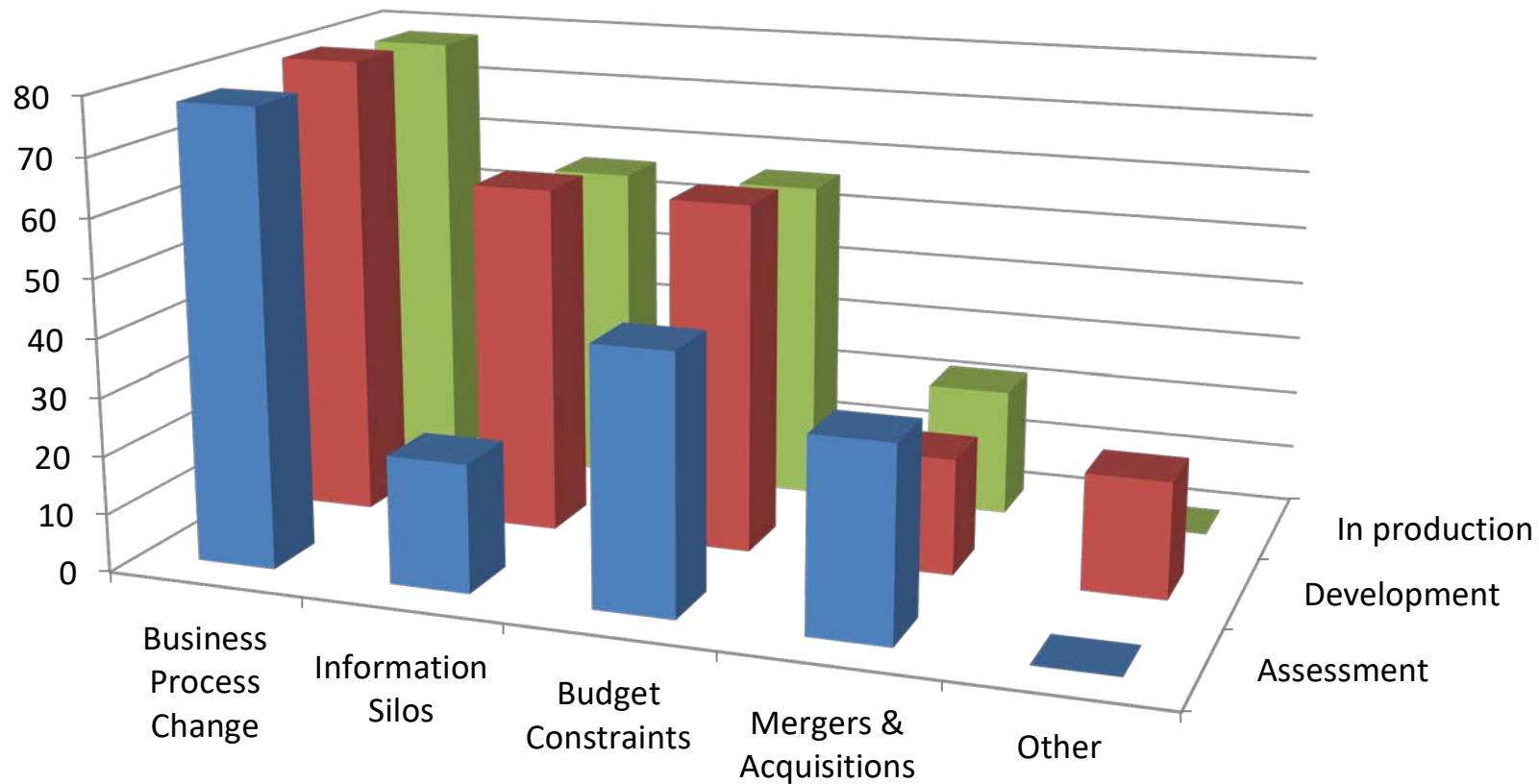


Perceived vs. Actual Challenges





Implementation Challenges



Challenges - Beyond the Metrics

- Organizational change management
- Trying to take on too much at once
- Training and skillsets
- Managing external factors/changes (regulations, acquisitions/mergers, standards, etc.)
- Roles & responsibility changes

Key recommendations for procuring a solution and key requirements

KEYS TO SUCCESS



Pre-Implementation Recommendations

- Develop a long-term vision for your organization
- Clearly understand existing business processes
 - What is the process
 - Who are the stakeholders
 - What are the handoffs
 - What works well in current processes
 - Where is there room for improvement
 - What are the input artifacts to each process
 - What artifacts result from each process
- Have a core project team to drive the project forward
 - Project Manager
 - Architect and/or business analyst
 - Management support (e.g., steering committee)

Pre-Implementation Recommendations (2)

- Ensure Sr. Leadership support and ownership of project
- Document requirements, even if only at high level (e.g., current business case and future business case)
- Use a process for vendor evaluation/selection
- Document high level implementation goals
 - Scope
 - Timelines
- Clearly scope implementation phases/releases:
 - Small enough to roll out releases quickly to the business
 - Large enough to see real benefit
 - Examples:
 - R1 – get standards in system and governance processes established
 - R2 – study level metadata implementation across priority functions
 - R3 – increase constraints, processing, automation, and add more business functions
- If not already existing, establish governance organization

Implementation Recommendations

- Secure budget up front, but expect ongoing re-justification
- Strong business sponsorship
- Dedicated IT & business project manager(s)
 - Manage timelines, budget, and project resources
 - Ensures ongoing buy-in from the business
 - Primary contact with vendor(s)
 - Organizes meetings
 - Documents meeting minutes
 - Ensures action items are carried through
 - Works through any contract details
 - Keeps project on track
 - Oversees the business change management

Implementation Recommendations (2)

- Small, agile core team
 - Clearly allocated time to project
 - Knows the business and project well
 - Can bring in appropriate resources as needed
 - Has the ability/authority to make decisions
 - Works through assessment with vendor
 - Writes test scripts & organizes system testing
 - Works on new process documentation, SOPs, policies, training materials, etc.
- Do not underestimate the size of the project
- Do not rely too heavily on consultants/vendors



Key Solution Requirements

- Flexible model for consistent management of metadata
- Configurable governance processes
- CDISC standards compliance (current and future)
- Support for multiple standards levels and study level metadata
- Reporting/metrics capabilities
- Version management
- Validation of metadata
- Business process automation
- Traceability of data throughout its lifecycle
- Integration capabilities
- Role-based user access
- Ability to notify users of work assignments
- Import/export capabilities
- Web-based UI

 Q&A

- Questions?