



Implementing an MDR Solution - A User Story

Wade Fairbanks – Pfizer

Barrie Nelson – Nurocor

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Agenda

- Introduction
- Project Sponsorship
- Project Planning & Execution
- Change Management
- Conclusion
- Q & A

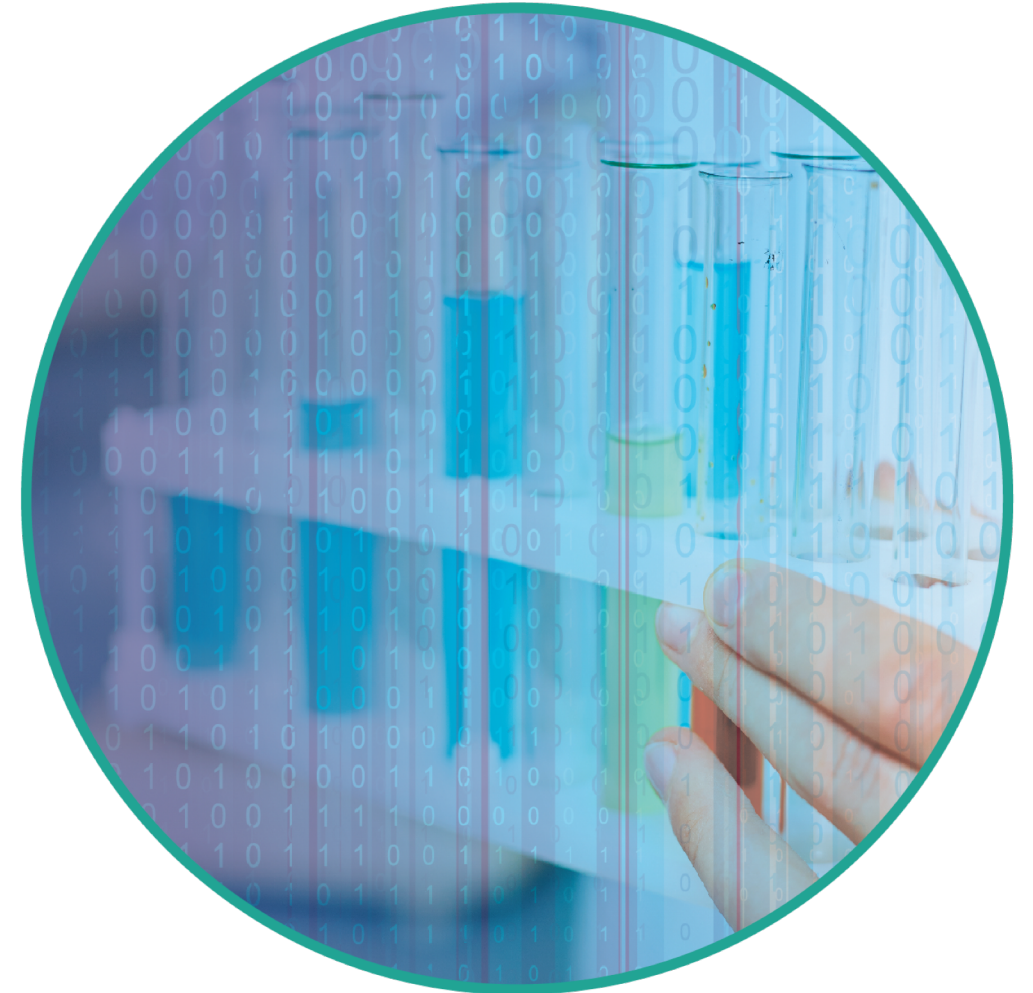
((MDR))

Metadata Repository

Introduction

Introduction

- Clinical trials are becoming increasingly more complex
- Reusability of data standards brings efficiency to the clinical process
- Robust metadata management requires a Metadata Repository (MDR)
- A successful MDR implementation needs to be carefully planned
- In this presentation a customer and a vendor share observations from an MDR implementation project



Project Sponsorship

Project Sponsorship

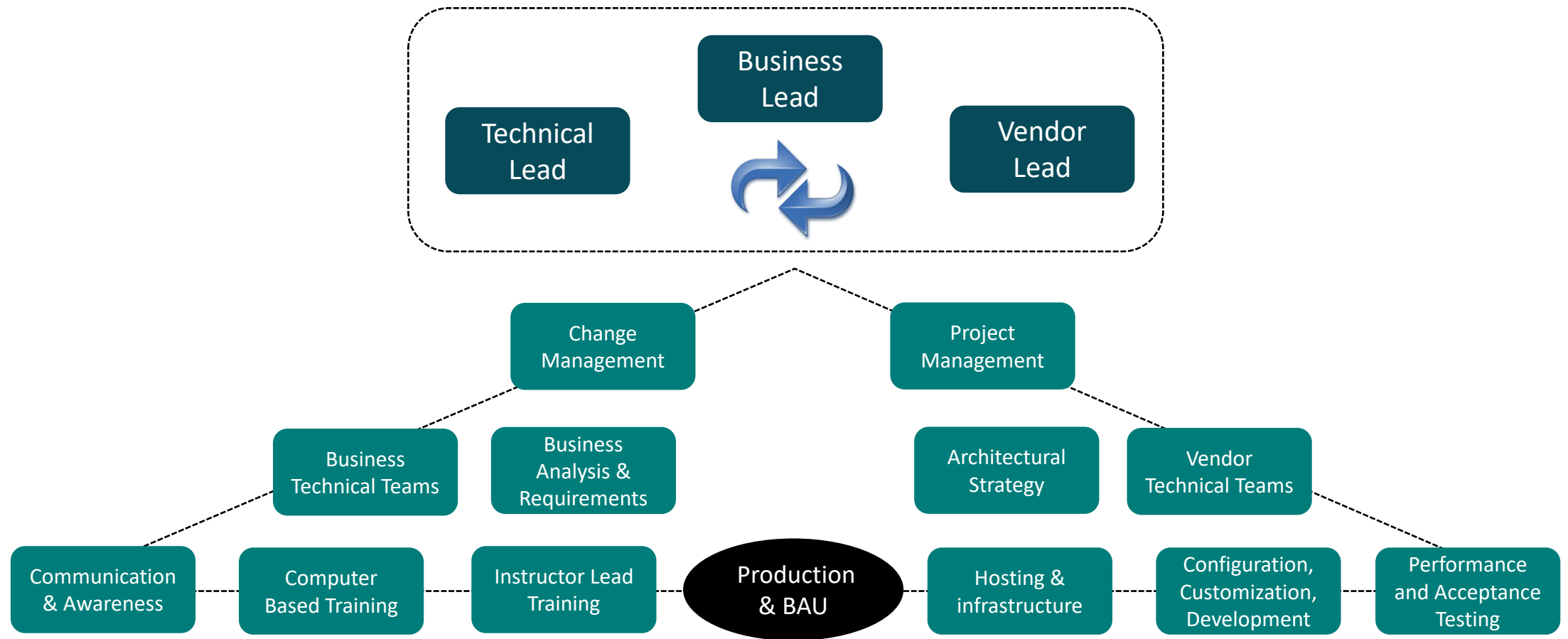
Management sponsorship is essential to implementation of an MDR

- Provides authoritative endorsement driving alignment throughout the clinical development organization
- Serves to motivate the change agent network and change management activities
- Co-sponsorship from Information Technology (IT) ensures proper provisioning and support



Lesson: Clinical Development Executive Leadership and extended team sponsorship is essential.

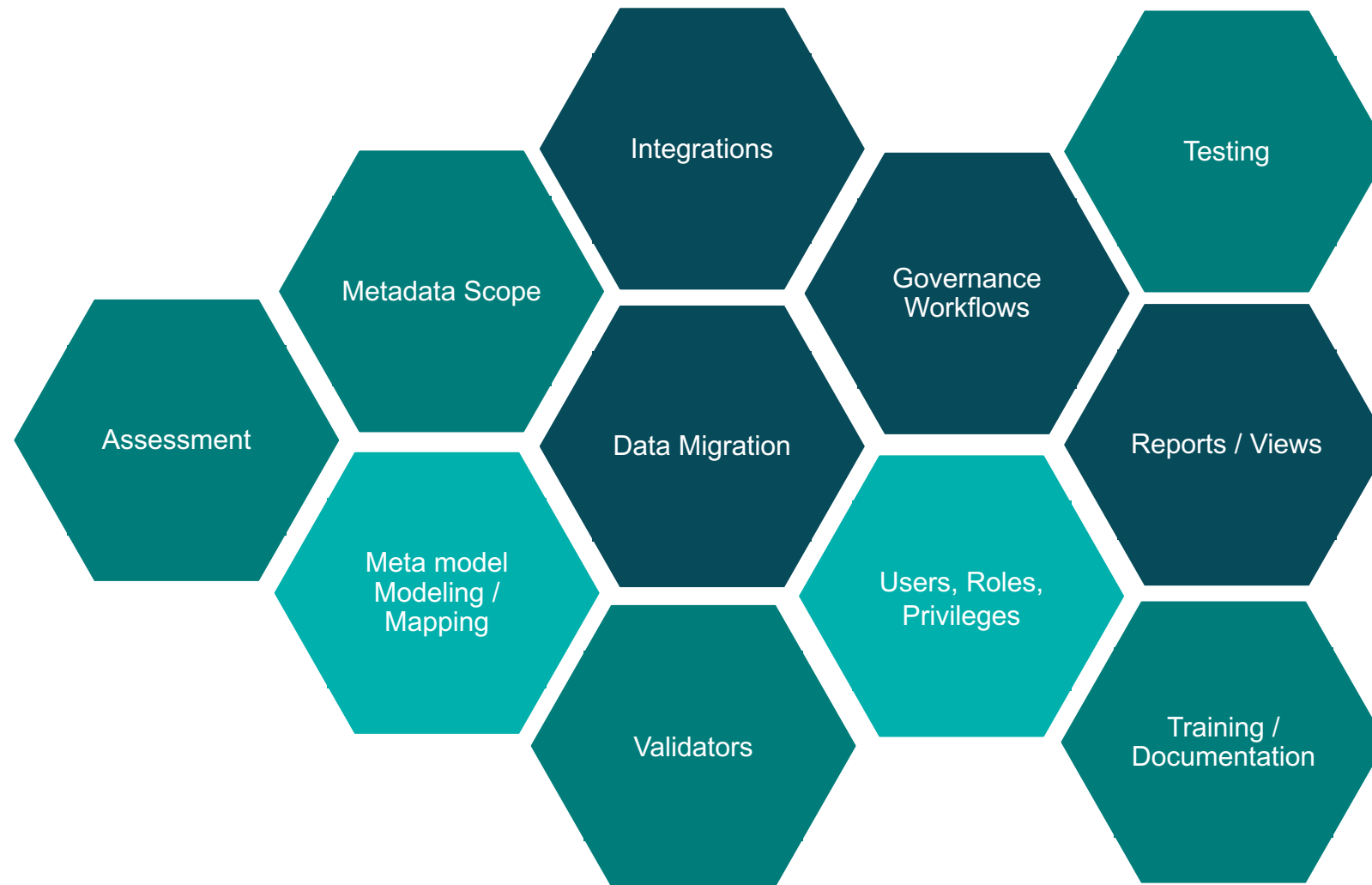
Project Leadership



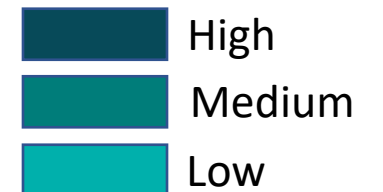
Lesson: Stakeholders and key Clinical Development personnel must be engaged early and often. Project team personnel must be given sufficient time to contribute fully and effectively to successfully implement project objectives.

Project Planning & Execution

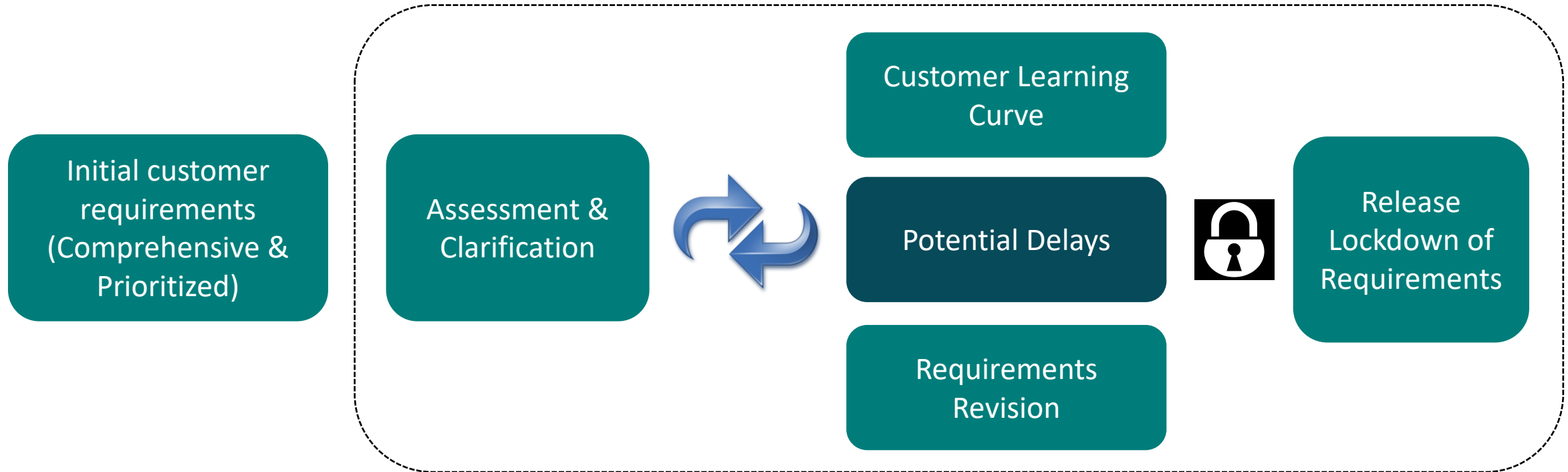
Project Planning



Level of Effort



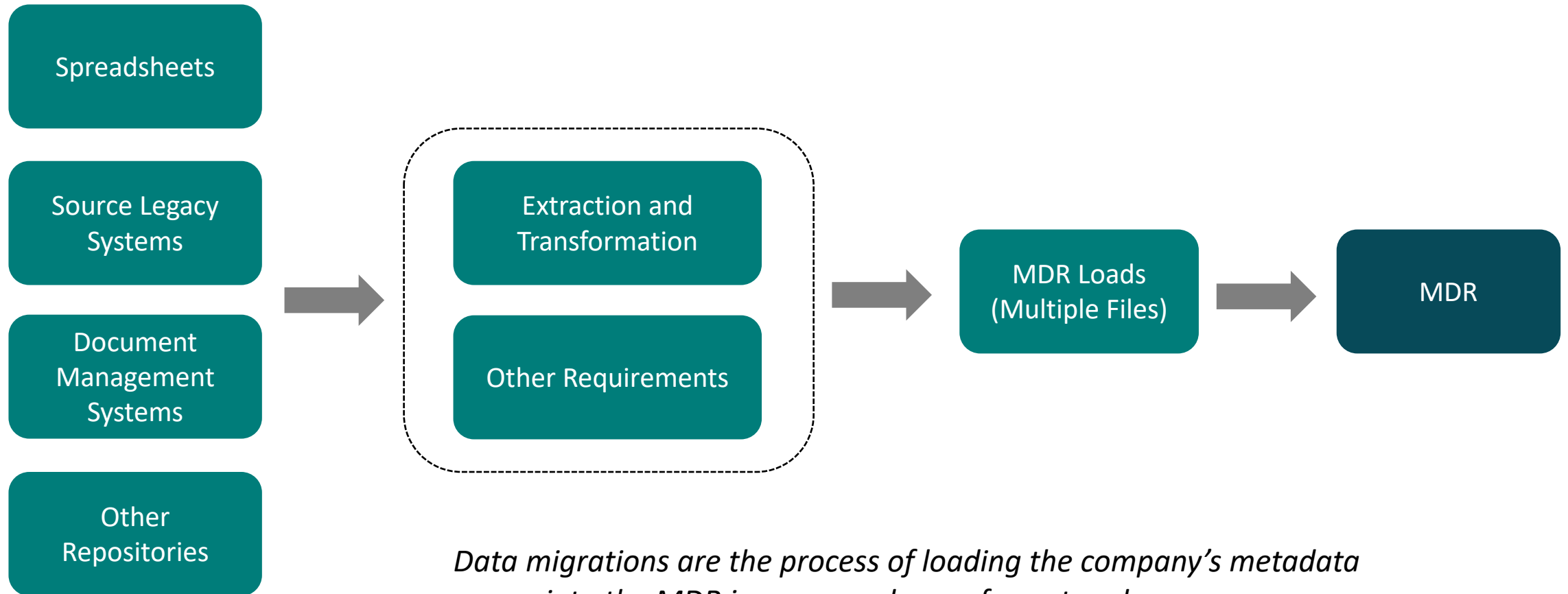
Project Requirements



Resource availability and product understanding is a challenge throughout the process

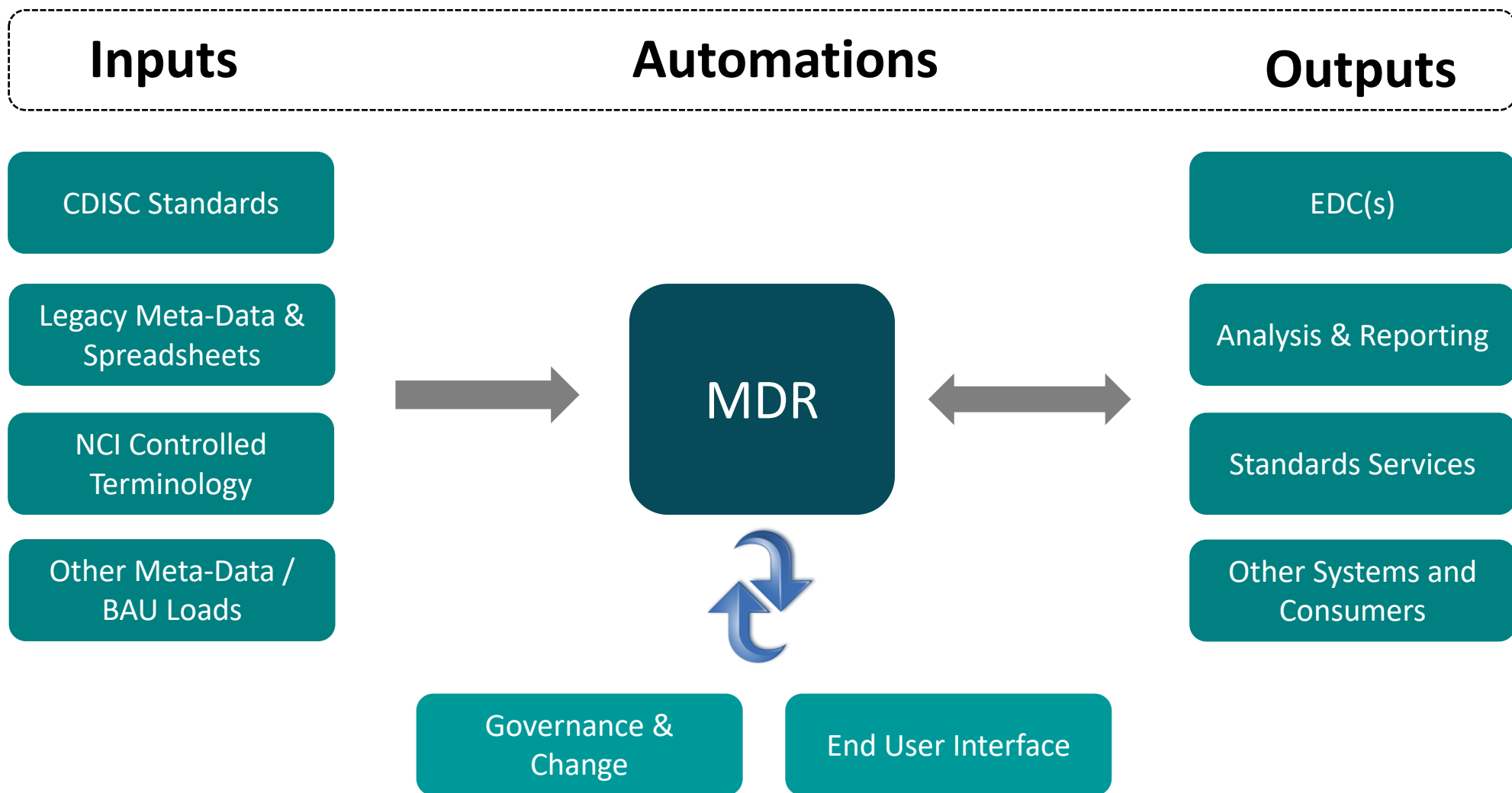
Lesson: The vendor and customer realize that finalizing robust requirements may be an iterative process. Full and detailed analysis in the assessment phase can and should reduce this using experienced personnel and SMEs .

Data Migrations

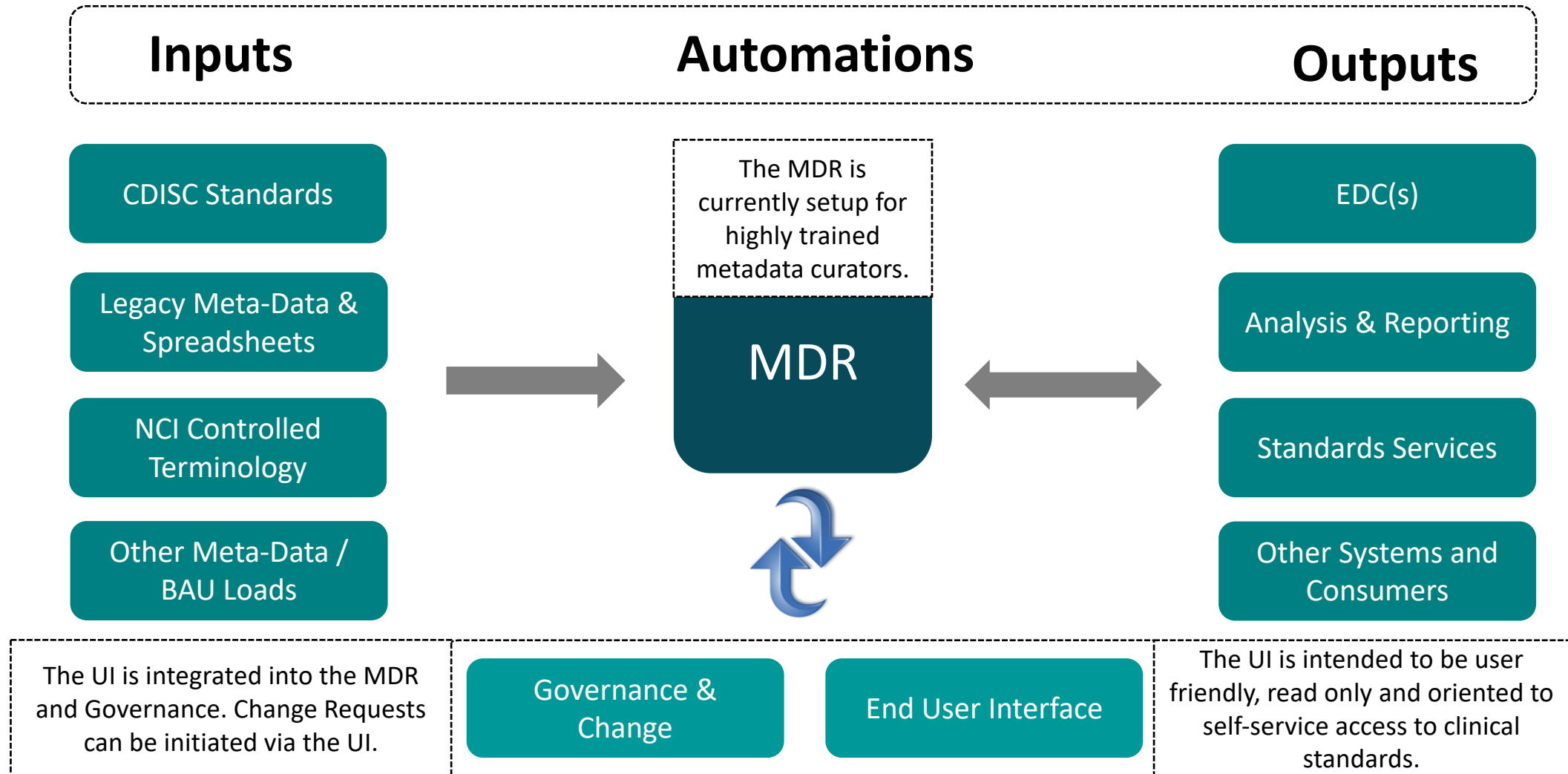


Data migrations are the process of loading the company's metadata into the MDR in an agreed upon format and sequence.

System Integrations & Automation



System Interface (User Interfaces)



Change Management

Communication

- Speak the same language
- Validate assumptions
- Weekly project status updates
- Keep the target audience engaged and informed
- Develop a communication plan and strategy
 - Roadshow presentations, Q&A sessions, email updates, newsletters, blog or wiki communications
- Over communicate, regular and repetitive communication helps to get the message over

Figure 1

Communication plan template

Communications Plan				
Project Name:		Beginning Date:		
Project Manager:		Completion Date:		
Plan Owner:				
Planning				
Project objective and key message points (high level): • • •				
Stakeholders – target audience (list) • • •				
Outline				
Timeline (date)	Team Member (responsible for communication)	Target (audience)	Tool (medium for communication delivery)	Message Points

Communications Plan Template (<http://inte5160.wikispaces.com/Communication+Plans>)
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Governance of Change

- Allow the enterprise to govern metadata evolution
- Utilize Global and Therapeutic Area expertise
- Review, authorize, deny and prioritize in a timely manner
- Integration with existing change management process can add complexity but can minimize business process change



Conclusion

Customer Conclusion

- An MDR implementation is a complex activity requiring strong sponsorship, experienced resources and a strong partnership between the Business, IT, and the Vendor
- Requirements will evolve as core and expanded teams better understand MDR capabilities and the impacts to existing and new business processes
- Migration from existing legacy systems and spreadsheets can be one of the most complex aspects of the project
- System interfaces and integrations add overhead complexity and timeline impacts. Depending upon the use case, a simple and easy to use UI may be required
- Governance should be considered as part of the business as usual (BAU) process; how is a change requested, approved and processed for use?
- Organizational readiness via awareness, training and frequent communications is a priority and requires focused resource support
- Overall, an MDR can bring real value to an organization if properly installed, populated, governed and made accessible to targeted knowledge workers supporting the clinical trial end to end process

Vendor Conclusion

- Executive level sponsorship sets the tone of the project and expectations
- Have the correct personnel engaged from the start
 - All effected business units must have subject matter experts (SMEs) engaged from project inception
 - The vendor should provide both technical know how and business knowledge
- Take time to set expectations:
 - The customer should take time to familiarize themselves with the MDR
 - The vendor should take time to fully understand customer requirements
 - Expect iterations as each side learns
- System integration discussions should start early and the customer must ensure that both sides have a point of contact available at the appropriate time
- An agile development process serves an MDR implementation well
- Communicate openly and often, challenge assumptions

Questions

End