



High performance. Delivered.

Driving value through Standardization – Industry Challenges and Best Practices

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Topics



- What is Standardization? How much or how little?
- The value of Standardization
- Challenges
- Best Practices
- Summary

What is Standardization?

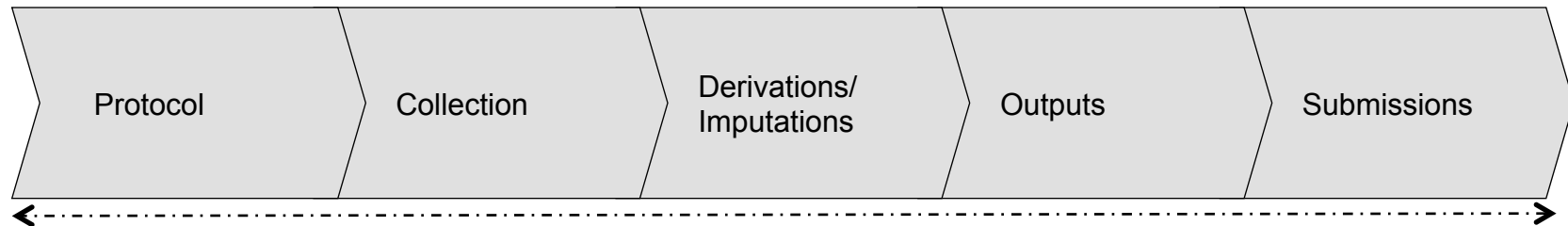


Our industry is in the business of defining, creating, managing, and reporting data. Standardization of this data has been at the forefront of our functions agenda for the last 30 years... but... what is standardization?

- Is it using the same data for all trials?
- Is it naming our data consistently?
- Is it structuring our data consistently?
- Is it having semantic unambiguity?
- Is it to meet a regulatory guidance/requirement?

The industry has defined it as one or all of these (or others) and it continues to change, and to challenge each of us

How much standardization?



Safety

Efficacy

**When safety is
efficacy**

PK/PD

Across a Program

**Across a Disease
Area/Indication**

Across a TA

Across a Company

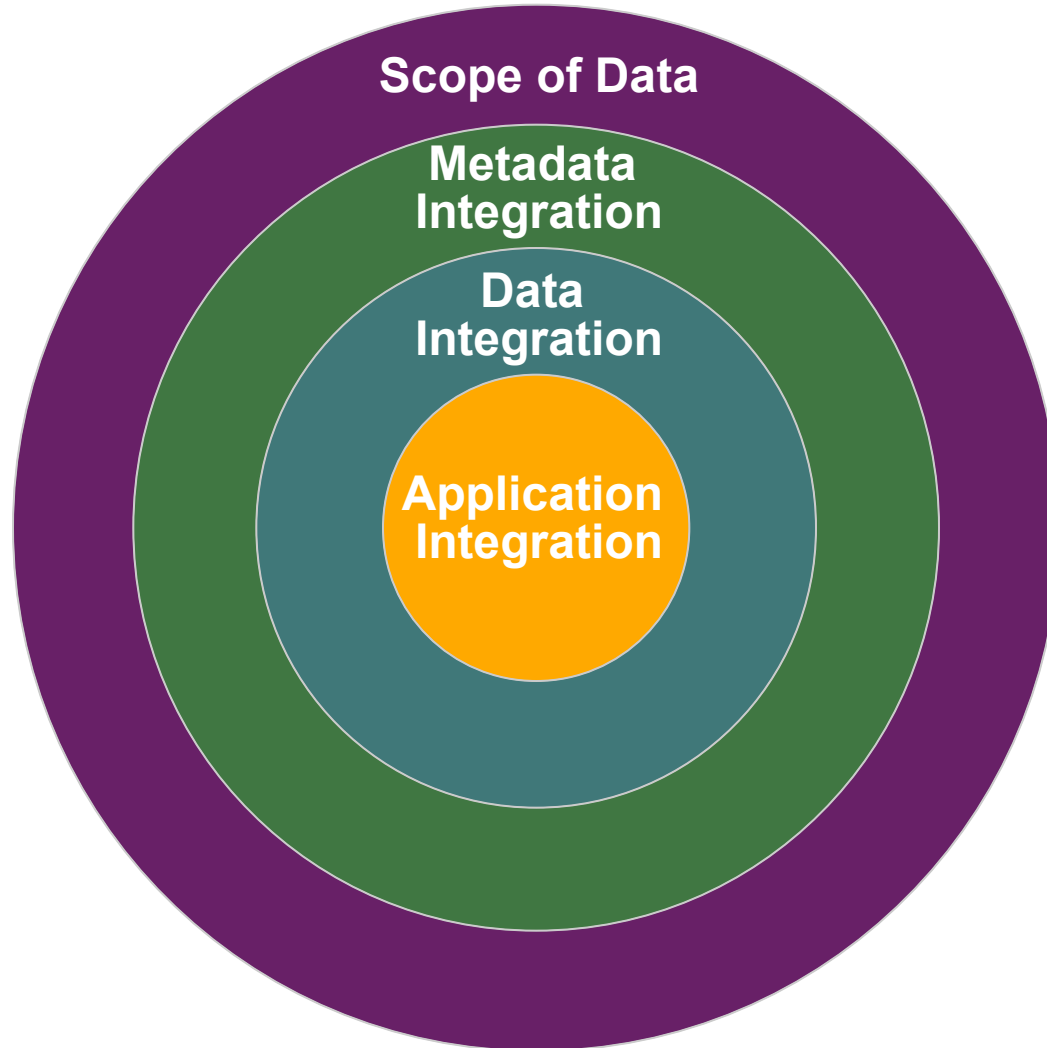
Across the Industry

The Value of Standardization

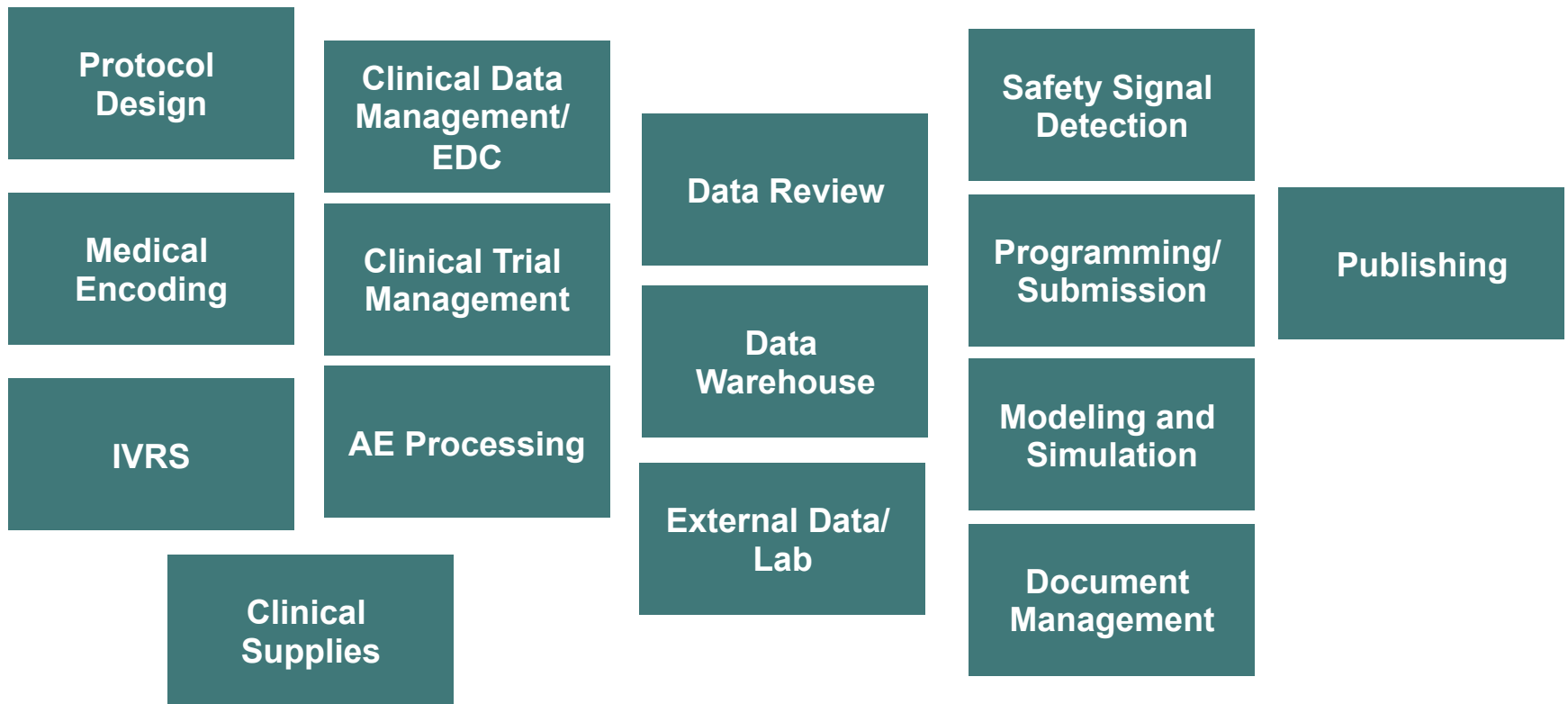
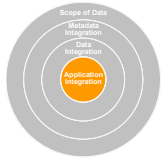


- **Efficiency**
 - **Re-usability**
- **Transparency**
 - **Ability to integrate**
 - **Ability to share**
 - **Ability to mine**
 - **Ability to submit**

Standards Value – Components of Integration



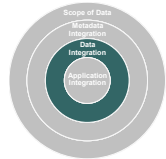
Application Integration



Data Integration



Data Standards . . .



Cross-Study Data Integration

Annual Safety/Efficacy Reports

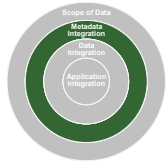
Rapid Availability of Data

Data Sharing (Internal, External)

Metadata Integration



- **Protocol Design**
- **CRF Design**
- **Data Warehouse Table Definition**
- **SAS Datasets**
- **Tables, Listings and Graphs Specifications**
- **Analysis Datasets**
- **Other data component definitions**



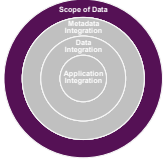
As well as the path/transformations that these data follow through the development data chain

Scope of Data

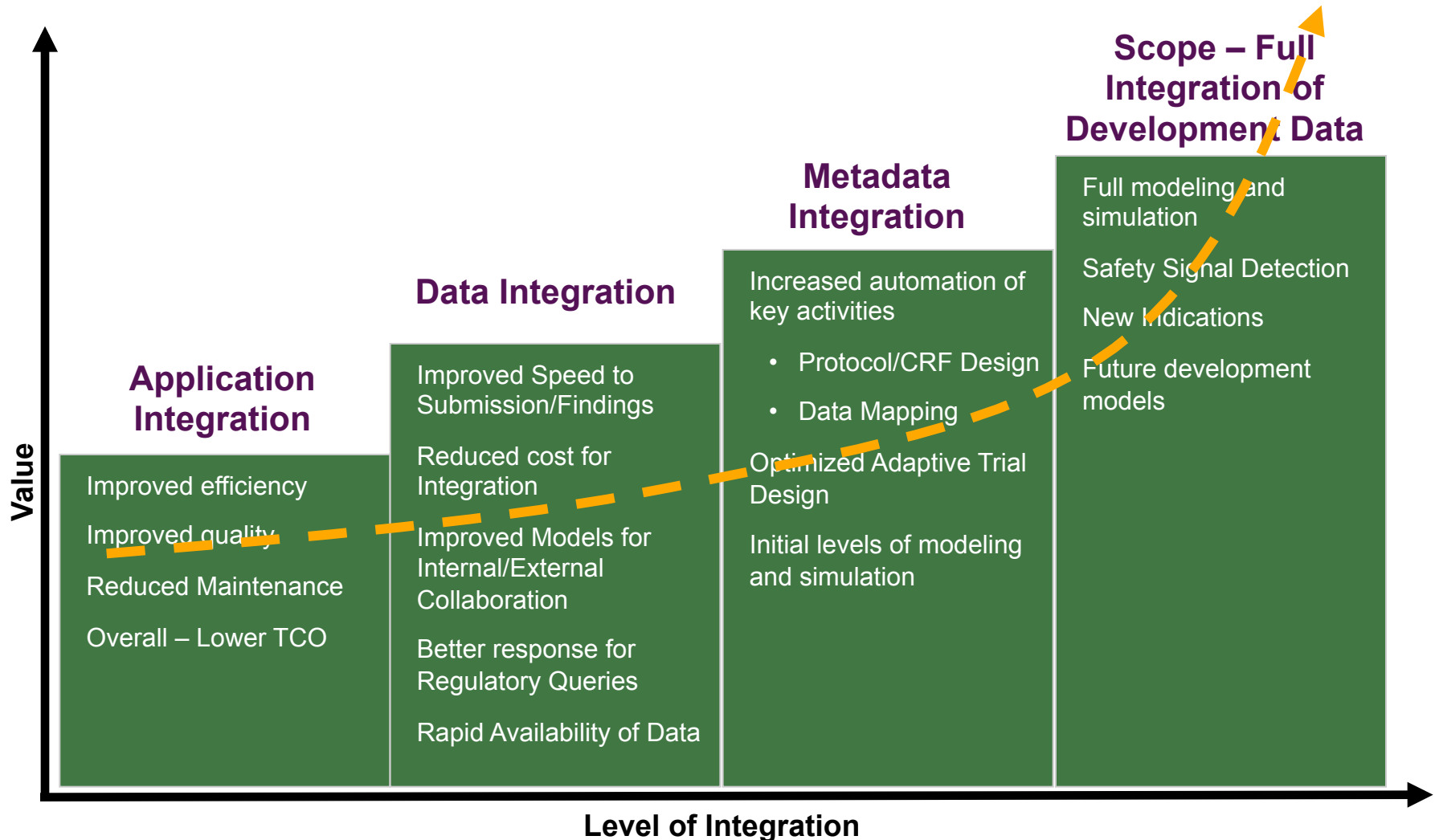


Do we integrate all data?

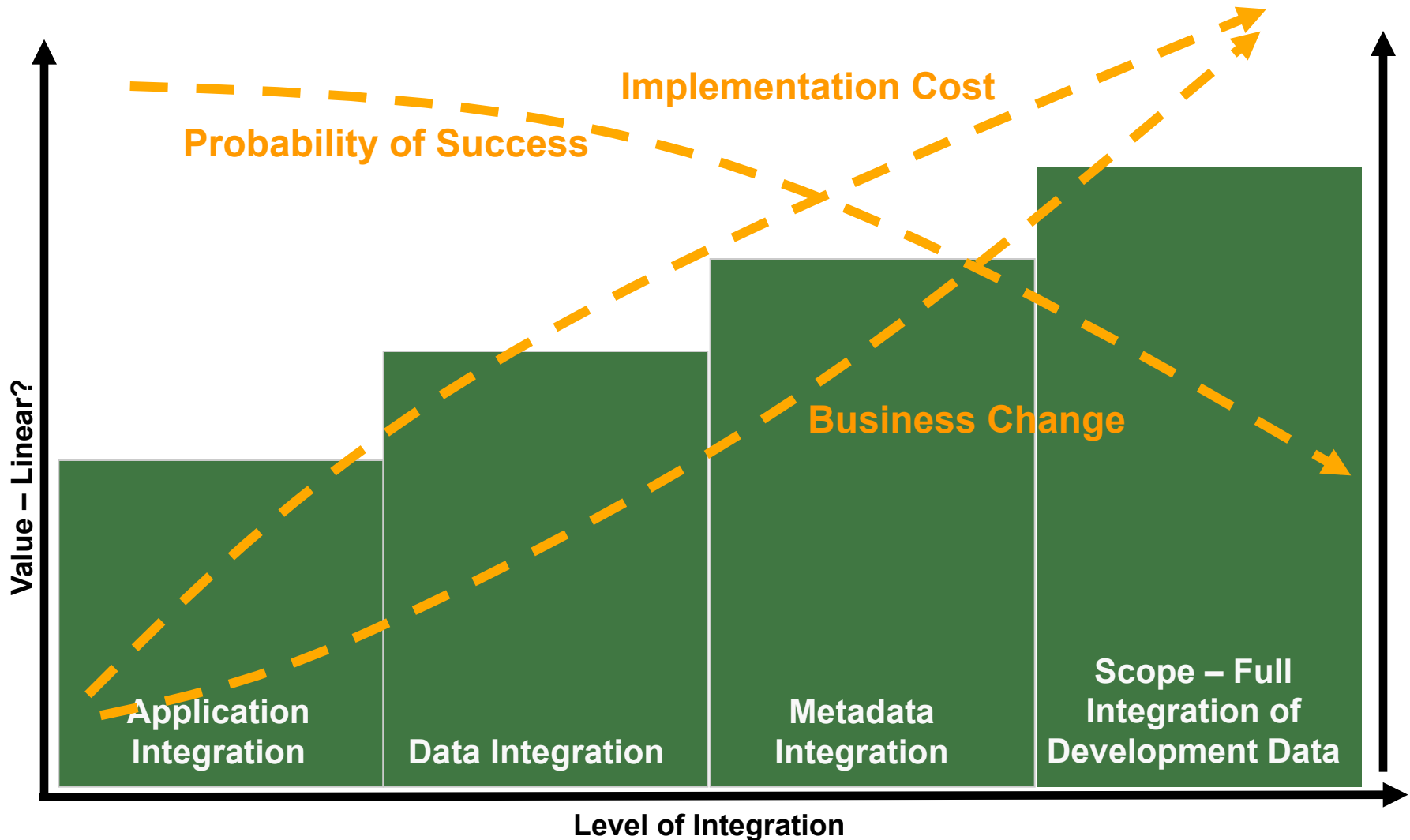
- Safety
- Efficacy
- Clinical
- Pre-Clinical
- EMR
- Others



The Value of Integration to an Organization Increases in Direct Proportion to the Degree of Integration



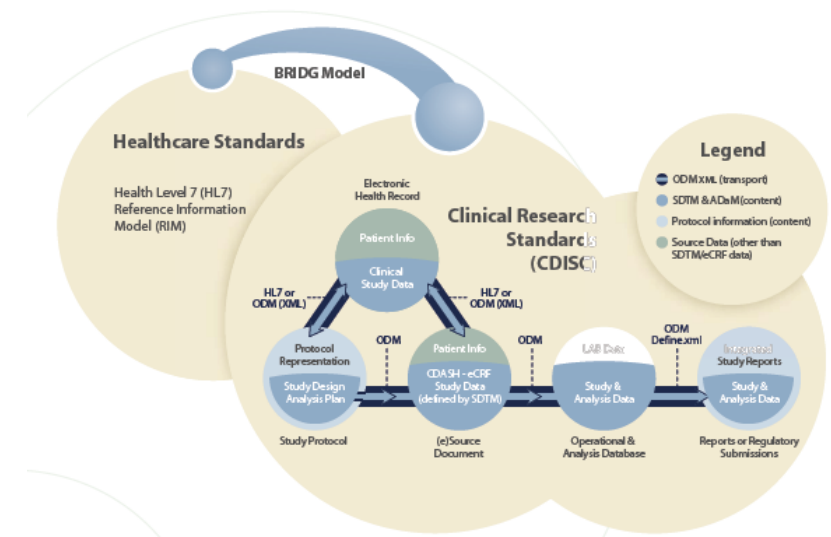
To Achieve the Desired Outcomes a Successful Implementation Must Balance both The Costs and Risks of Integration



The Industry is Faced with Numerous Implementation Challenges and Considerations



- Standards – which standard? CDISC? Others?
- Standards – Where do I implement them?
 - Collection, Data Warehouse, SAS
- Standards – When do I implement them?
- Data Mapping
- Data Warehouse vs. SAS



Best Practices



- Business ownership and executive sponsorship
- Effective, small, empowered Governance
- Metadata Management – Technically Enabled
- Investment – Dedicated People
- Allowing CDISC to evolve with you
- Determination and commitment to Long Term Success
 - Ability to survive the valleys of despair

Summary



- Standards have been a challenge in our industry over the last 30 years
- The value of standards is unquestionable, across driving efficiency and transparency
- Achieving that value is fraught with challenges that continue to evolve with industry challenges
- Most, if not all of us, will continue to drive standardization and therefore ongoing collaboration and learnings are critical to our success