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Moving from Data Collection to Data Visualization and Analytics: Leveraging CDISC SDTM Standards to Support Data Marts

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Roadmap

- Introduction
- Data Mart Overview
- Planning to Implement a Data Mart
- Standardized, integrated data is very useful. Enjoy!

Introduction

- Clinical research is driven by data from clinical trials
- Data from clinical trials supports a wide range of clinical, safety, regulatory, and analytical groups
- All those groups share the same basic need: to efficiently access, analyze and review the data
- Standardizing and pooling data across clinical trials makes it possible to have simple, powerful access to the data from multiple clinical trials using analytic and visualization tools

Data Mart Overview
What is a Data Mart?

- A Data Mart* is a database that integrates standardized data from clinical trials across studies and therapeutic areas for a single company.

*For the purpose of this presentation

Data Mart Overview
Why create (and support) a Data Mart?

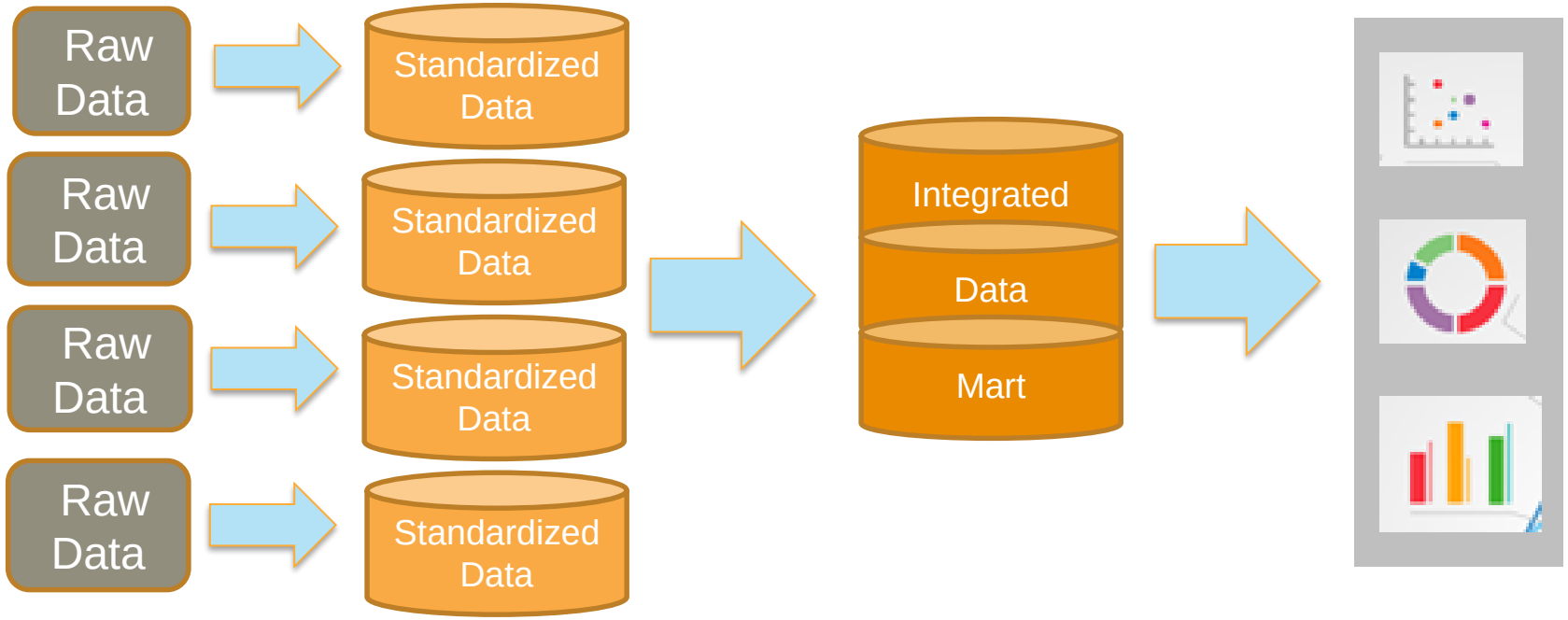
- It makes the data more useful

Data Mart Overview
Why create (and support) a Data Mart?

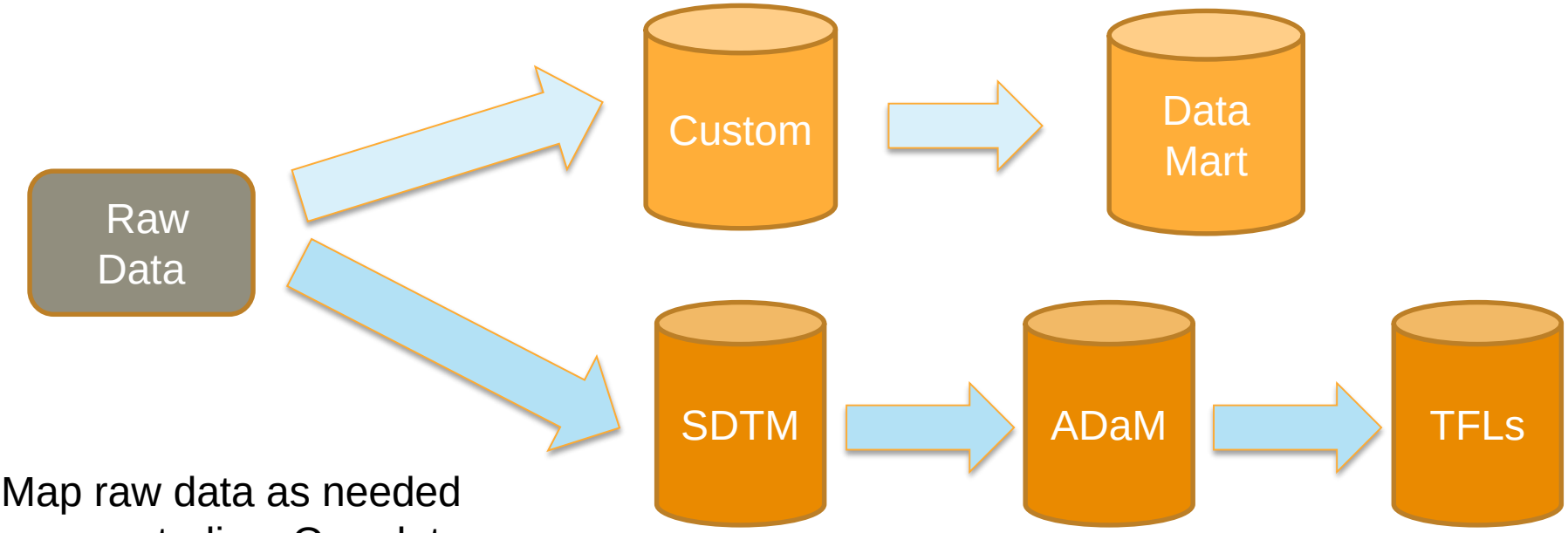
- Data can be effectively integrated from completed and ongoing studies in real time
- Data consumers can zoom in or out within and across studies, sites and subjects
- Patterns and signals that are hidden from view in a typical data environment can be detected
- That easy, versatile access can:
  - Simplify study monitoring
  - Streamline review tasks
  - Guide scientific decisions
  - Support a variety of business needs

Planning to Implement a Data Mart
Overview

- Standardize
- Integrate
- Use



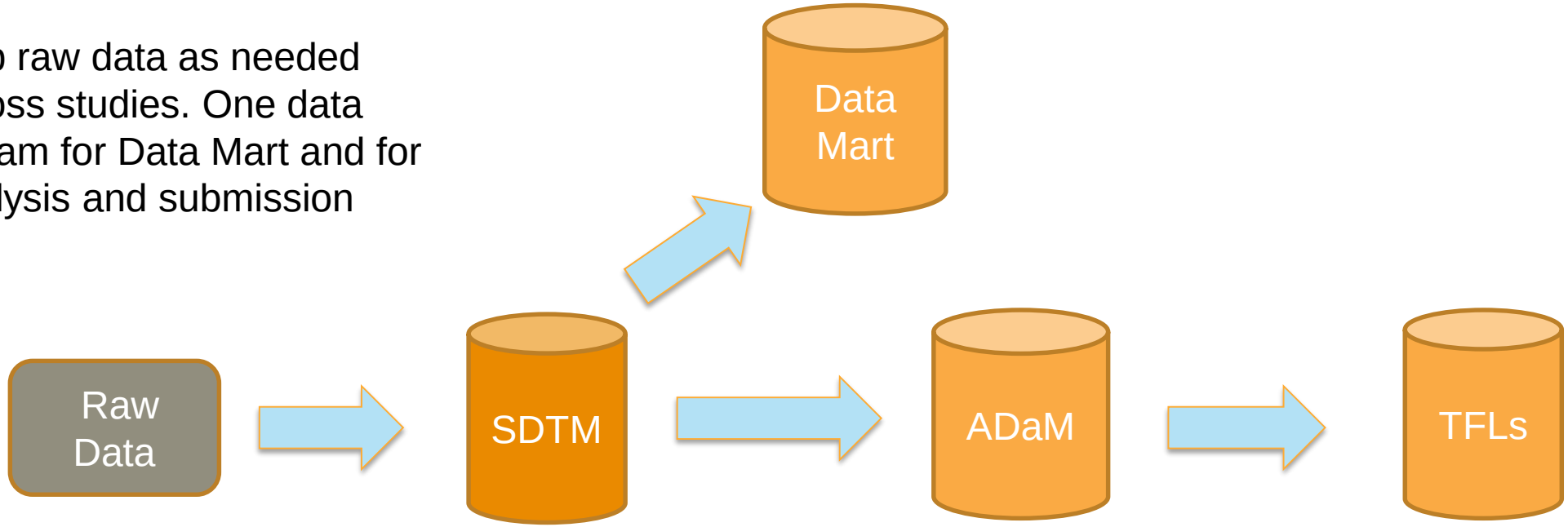
Planning to Implement a Data Mart
Custom Standardization



Map raw data as needed across studies. One data stream for Data Mart, and another for analysis and submission

Planning to Implement a Data Mart
SDTM Standardization

Map raw data as needed across studies. One data stream for Data Mart and for analysis and submission



Planning to Implement a Data Mart
Gather Information from Stakeholders

- Reach out and make sure that downstream user (data consumer) needs are met
  - Biometrics
  - CDM
  - Regulatory
  - Pharmacovigilence
  - Marketing

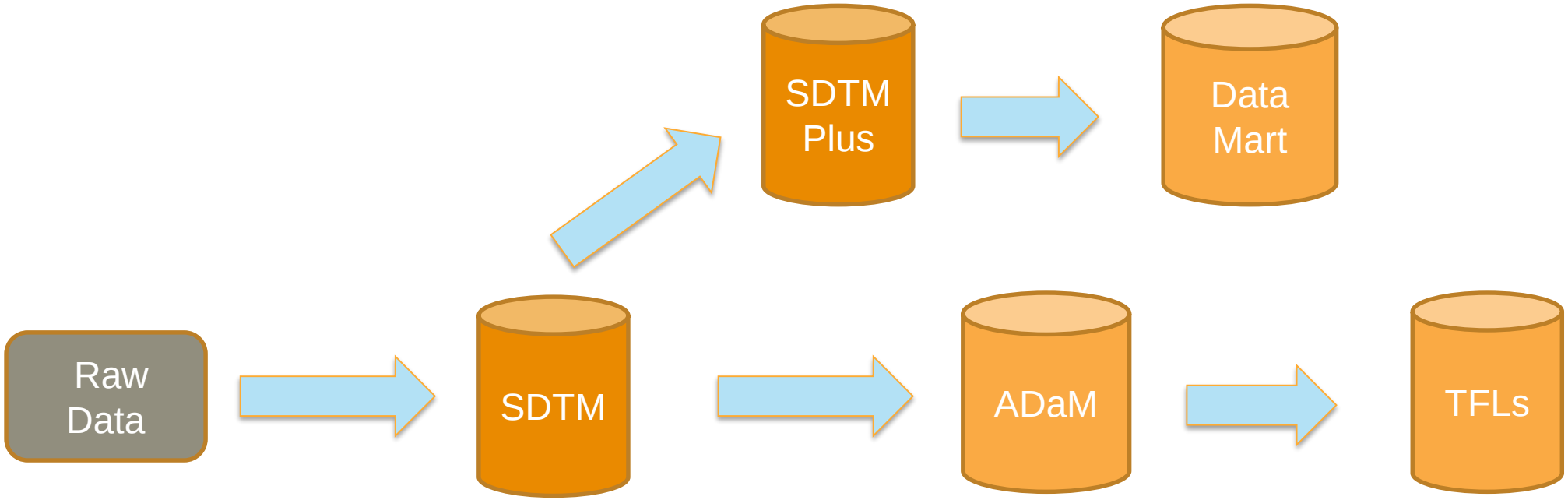
Planning to Implement a Data Mart
Scope of Inputs

- Reach out to all the data consumers and investigate
  - Understand what they plan to do with the data mart
    - Ongoing and/or completed studies
    - Data quality, demographics, safety, compliance, etc.
  - Understand what content is needed to support those plans
    - Safety (AE/SAE, Labs, Vital Signs, other?)
    - Compliance (Screen failures, Early Terminations)
  - Share/Discuss where and how it will be available in SDTM

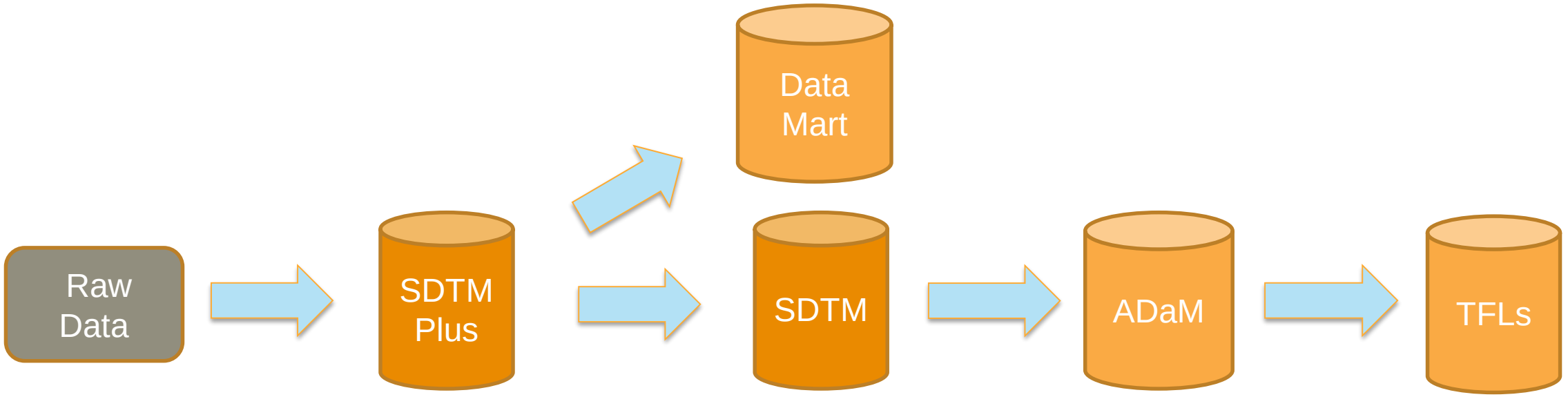
Planning to Implement a Data Mart
Data Delivery Details

- How Early
  - Really early if supporting review for ongoing studies
- How Often
  - Nightly is a different challenge than monthly
- Where will the data live
  - Need a secure environment

Planning to Implement a Data Mart
SDTM Standardization (Variation 1)



Planning to Implement a Data Mart
SDTM Standardization (Variation 2)



Planning to Implement a Data Mart
Upstream Planning (with CDASH) Helps

Leverage CDASH (Harmonize Data Collection with SDTM)

Work to collect what you submit

- Support CDASH eCRF/database standards (with edits ☺)
  - Use CDASH conventions for each variable (where appropriate) collected on an eCRF
  - Many variables directly map into SDTM
- Create SDTM mapping specifications for all domains which are used as templates (minor updates required for study specific requirements) across studies/projects
- Create standard package template for each domain that includes all documentation that can be used as a reference and training.

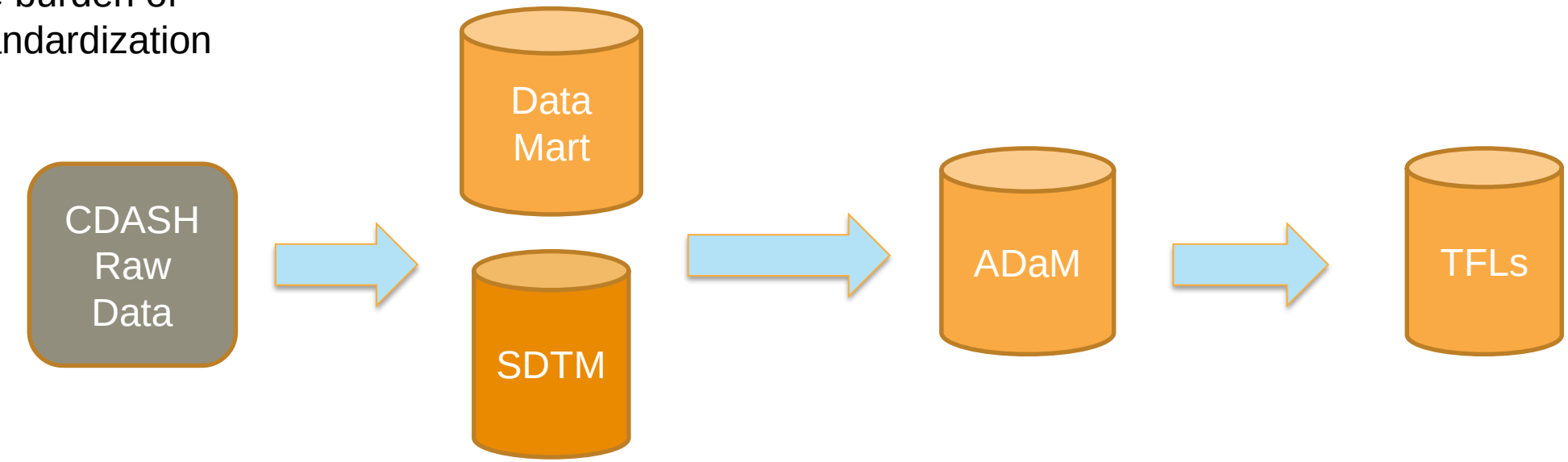
Planning to Implement a Data Mart:
Upstream Planning (with CDASH) is Better

- Safer, faster, cheaper, better

- Less manipulation
- A clearer path from collection to submission
- SDTM and Data Mart needs (however defined) in harmony
- Can leverage standard forms, mapping tools and metadata
- Easier to hire staff with experience

Planning to Implement a Data Mart
Simplify SDTM Standardization with CDASH

Collect what you submit and minimize the burden of standardization



Planning to Implement a Data Mart
SDTM Implementation

- Prepare to consistently implement SDTM with metadata*
- Create/Leverage a local SDTM Interpretation guide as a first step
  - Standardize content where practically possible
  - Local rules most critical where CDISC does not specify (nearly all) the details
    - ARM/ARMCD, QNAM/QVAL, Sponsor Terminology, rules for key derived content, etc.
  - Manage Raw Data/CRF form – SDTM domain associations.
    - Same content should always end up in the same place
  - Support standardization with metadata
  - Manage standardization needs that differ between the consumer groups
  - Is any content needed that would not be submitted?

- Standards Implementation is a process!

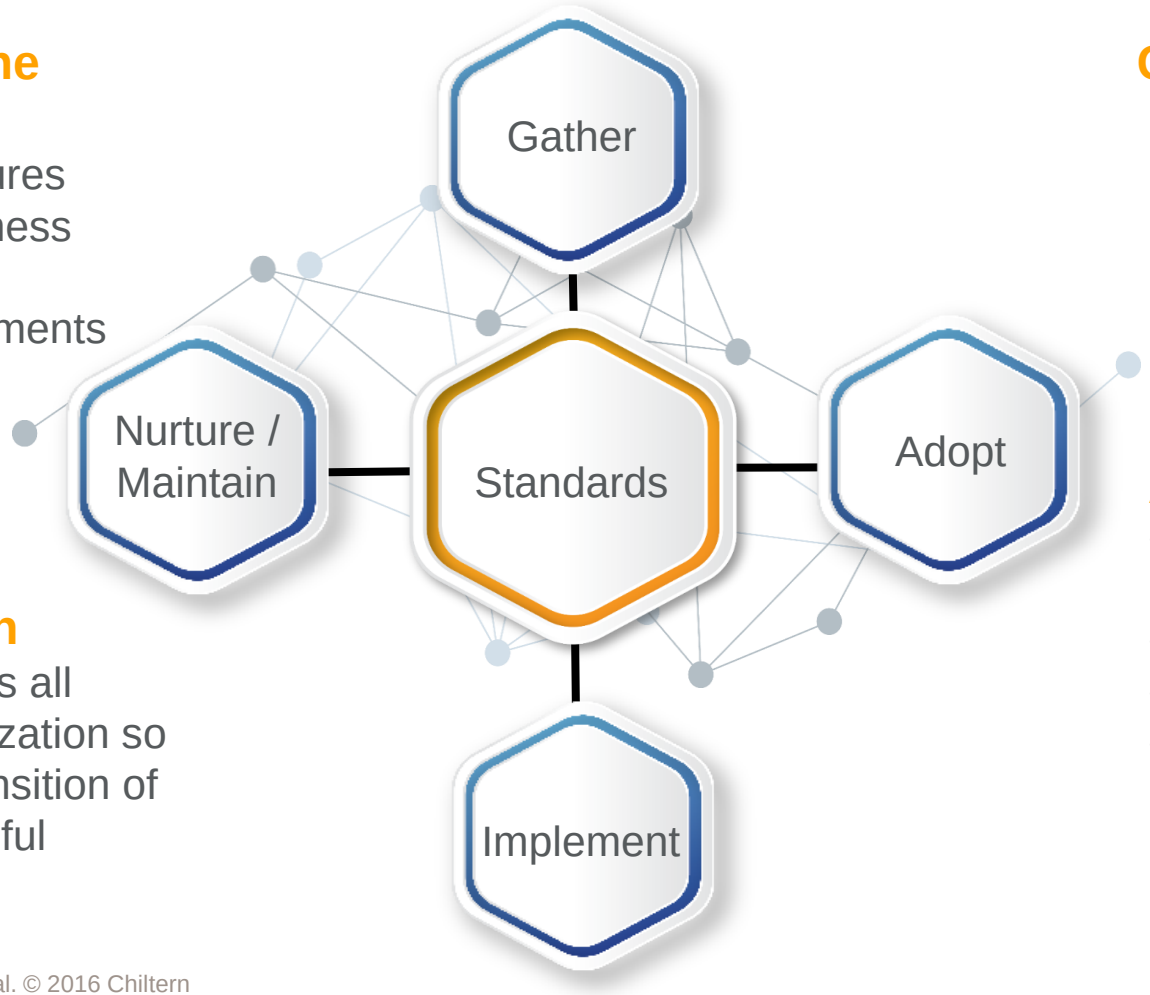
* Just to say it again, SDTM friendly protocols, CRFs and vendor data specifications can save a lot of downstream hassle

Simple Example of AE Domain
Local SDTM Interpretation Guide

DOMAIN	ORDER	KEEP_VAR	VARIABLE	LABEL	GUIDANCE
AE	1	Y	STUDYID	Study Identifier	Must match STUDYID in SDTM DM
AE	2	Y	DOMAIN	Domain Abbreviation	Set to AE
AE	3	Y	USUBJID	Unique Subject Identifier	Must match USUBJID in SDTM DM
AE	4	Y	AESEQ	Sequence Number	Base on "key" variables in the domains tab; should define unique records within a subject.
AE	7	Y	AESPID	Sponsor-Defined Identifier	Populate with the AE number from the CRF (or with the related eDC system variable).
AE	8	Y	AETERM	Reported Term for the Adverse Event	Verbatim term from CRF. Trim and make upper case. Note: Only events specifically designated in the protocol or similar as Adverse Events go in this domain.
AE	9	N	AEMODIFY	Modified Reported Term	Populate only if used for coding (for example, can be needed when verbatim AE is a combination of terms or AE terms are adjusted to get an exact match with MedDRA).
AE	10	Y	AELLT	Lowest Level Term	Dictionary coding content. (This may be integrated into a single dataset or may be available separately).

Planning to Implement a Data Mart
G.A.I.N. for SDTM

Nurture/Maintain the Standards
- Periodic Review ensures standards meet business requirements
- Create process/documents to support change requirements



Gather the Information
- Listen, understand and develop goals
- Evaluate current processes
- Develop Plan for best approach

Implement the plan
- Confirm buy in across all roles/levels of organization so enforcement and transition of standards is successful
- Provide training

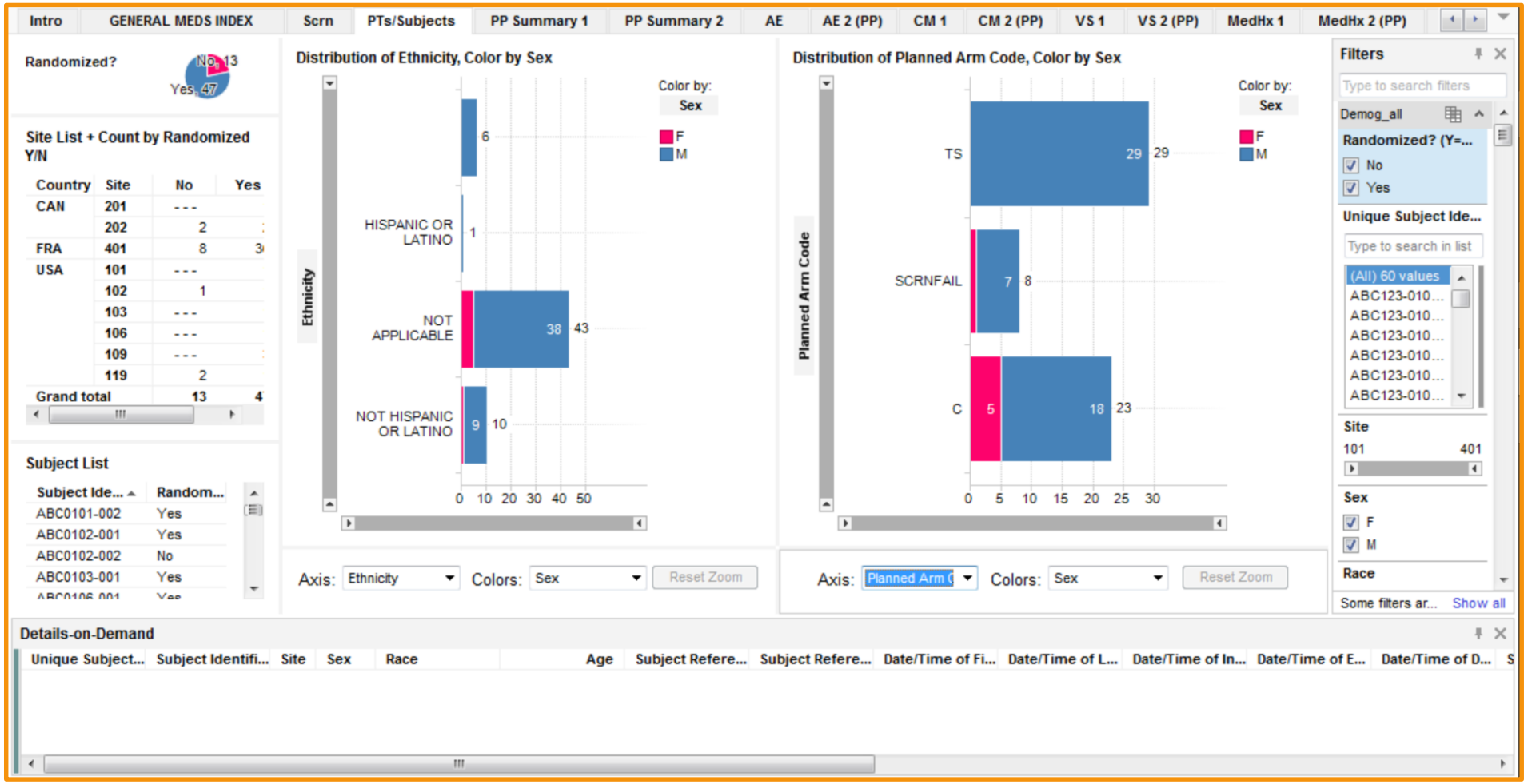
Adopt the plan
- Leverage in-house and industry knowledge to create Local SDTM IG
- Draft and review documentation
- Build and test standard
- Schedule regular review meetings

Planning to Implement a Data Mart
Support SDTM Implementation with a (non-Excel) MDR

- Migrate existing SDTM metadata into an MDR
  - Plan for an MDR as you build up SDTM metadata
    - Match the format of initial metadata with downstream MDR needs
  - Maintain (and manage/update) Metadata within the MDR
    - Support storage levels (CDISC, TA) based on practical needs
  - Do not underestimate the challenges of change management
  - Export study specific metadata by pulling relevant content from the MDR
  - Verify consistency of implementations using a standard reference
  - Work to leverage SHARE content

- With an MDR, the standards implementation process is more easily managed, verified and organized.

Standardized, Integrated Data are Useful
Enjoy the Access



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Q&A / OPEN DISCUSSION

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