

Next Generation Data Architecture for Clinical Data Review & Submission

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Agenda

- Introduction
- Modern Data Demands and New Architecture for Review and Submission
- As-Is Architecture Trends
- Abbvie Data Review Approach
- Abbvie Data Submission Approach
- E2E Architecture
- Concluding Thoughts

Introduction



The sponsors are trying to bring efficiency to their data review and submission process



Traditionally, the review is managed in CDM organizations, and submission is managed by Stat Programming & Biostatistics Organizations



These organizations Silos have created siloed systems for review and submission



However, modern systems are very well interconnected and have created a seamless synergy between two capabilities

Modern Data Demands New Architecture for Review and Submission



The data acquisition landscape is also changing to tools such as wearables, apps, sensors, and patches used to acquire active and passive clinical data in addition to traditional EDC, IRT & ePRO data



The competent authorities around the world are expecting Risk Based approach to clinical data review and management



The senior executives are constantly looking to optimize the timelines from DB lock to the submission

These factors necessitate a next-generation data architecture to balance data review and submission needs



Abbvie Legacy Data Review Approach

Stage 1: EDC Edit Checks

The site is responsible for data collection for each patient throughout the trial.

The methods to collect information can be:

- eCRF forms
- Lab reports

Stage 2: CDR Checks

It automates the process of clinical data standardization and generation of domain data sets for regulatory submission and FDA approval.

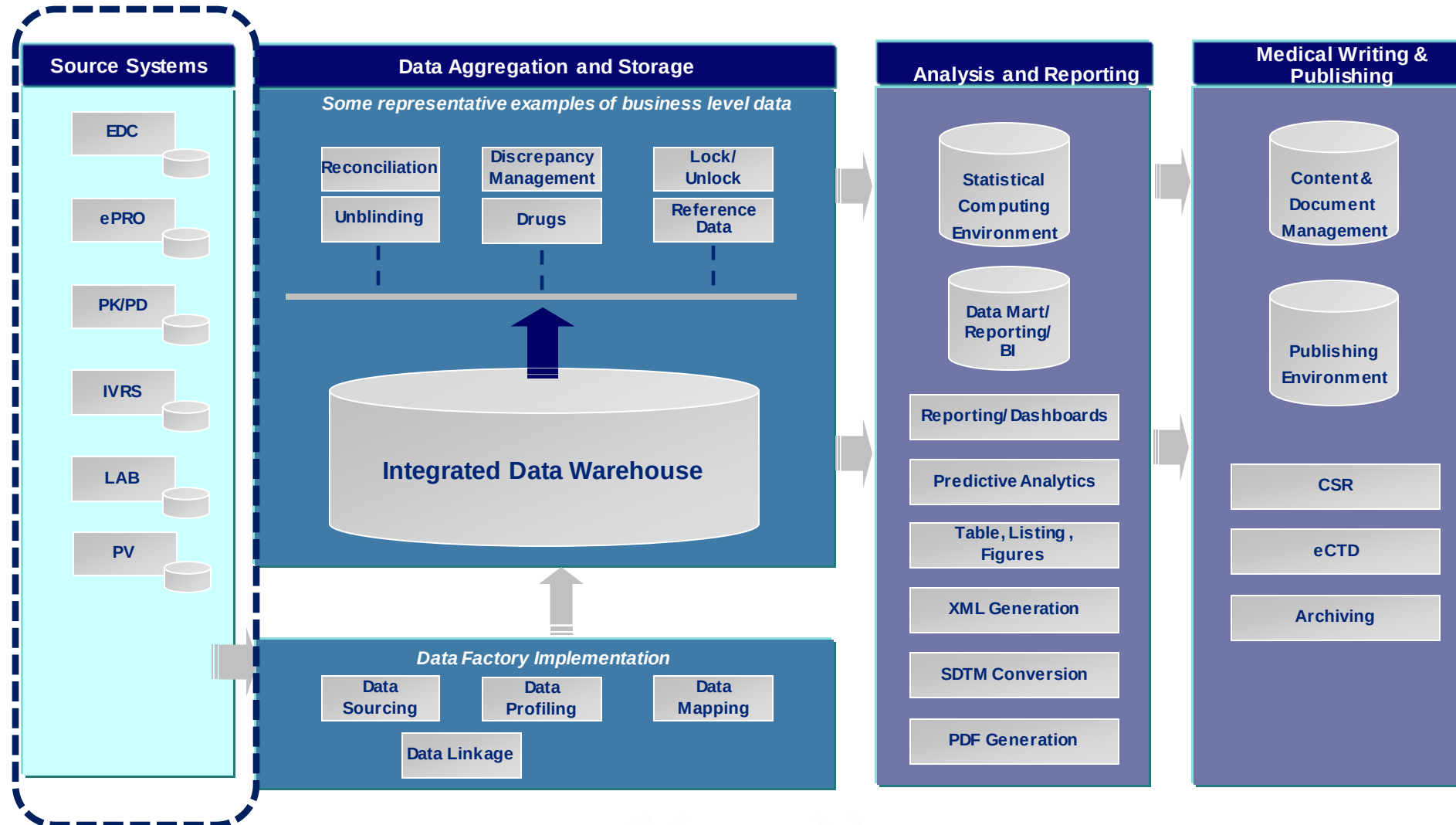
In addition, it allows for traceability of information.

Stage 3: Dashboard Checks

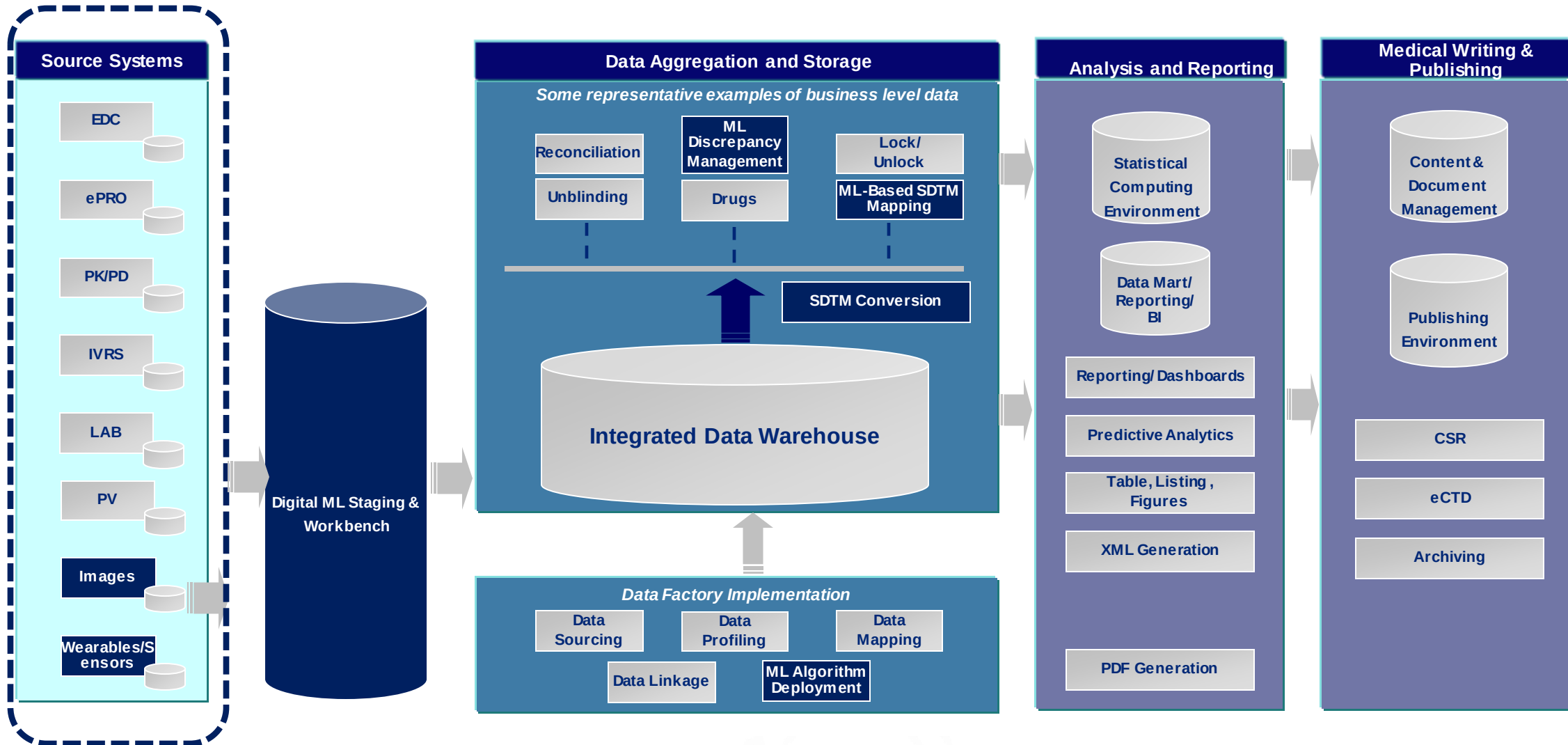
The CDR team manually reviews the SDTM data and eCRF forms.

Any suspicious data entries are queried back to the site.

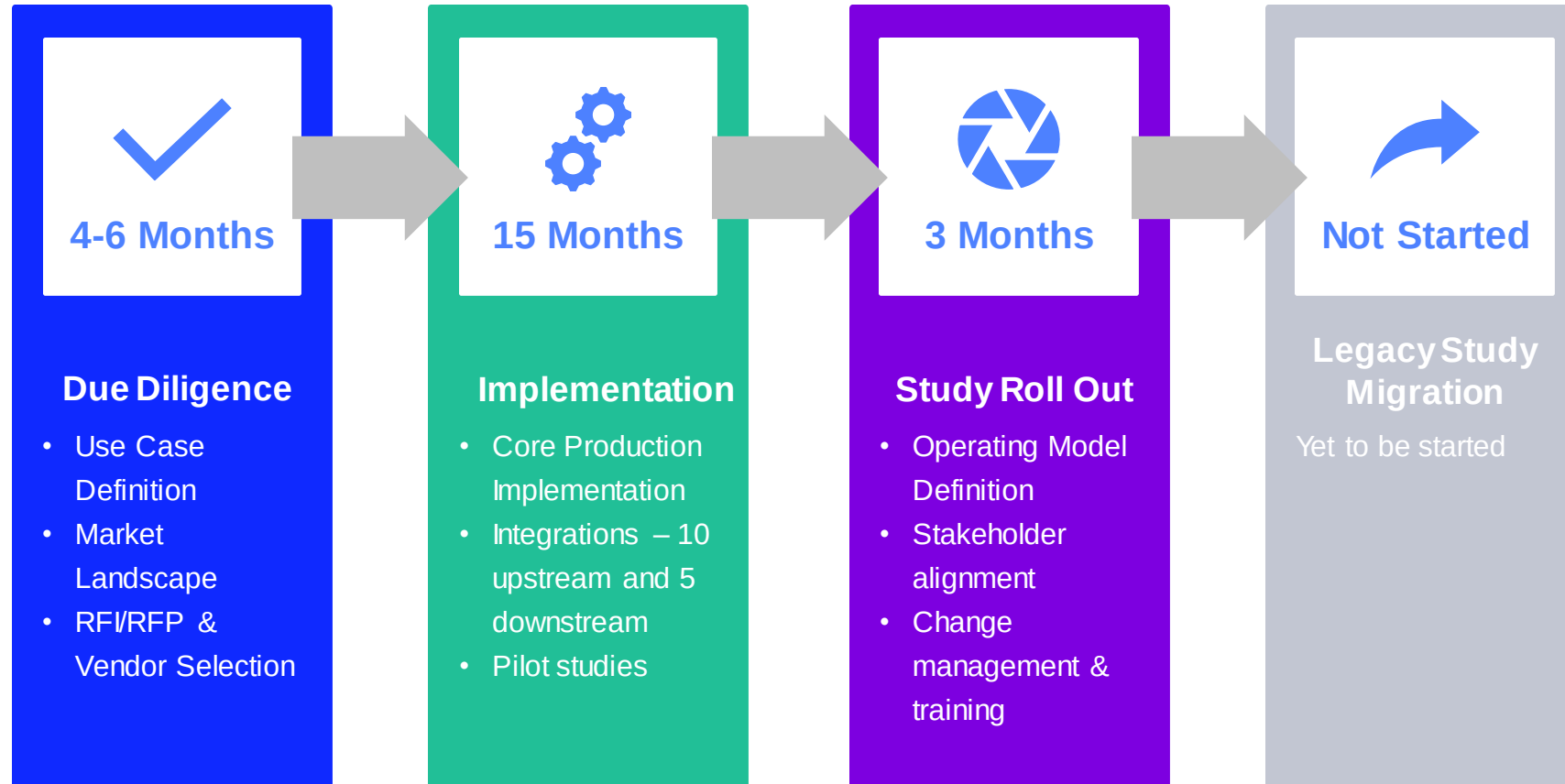
Abbvie Legacy Architecture



Abbvie Modern Architecture



Abbvie's Transformation Journey



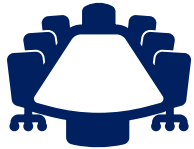
Concluding Thoughts



Review & Submission modernization is a long and tireless journey. It may take around three years to complete your full vision



Agile approach should be deployed MVPs should be quickly deployed to realize quick business value



Stakeholder alignment and change management should be of the utmost priority because of complex ecosystems



Role of modern technology and a vendor partner is very important because that will inform the success of this journey