Data Ecosystems 2.0: The Data-fluid Organisation

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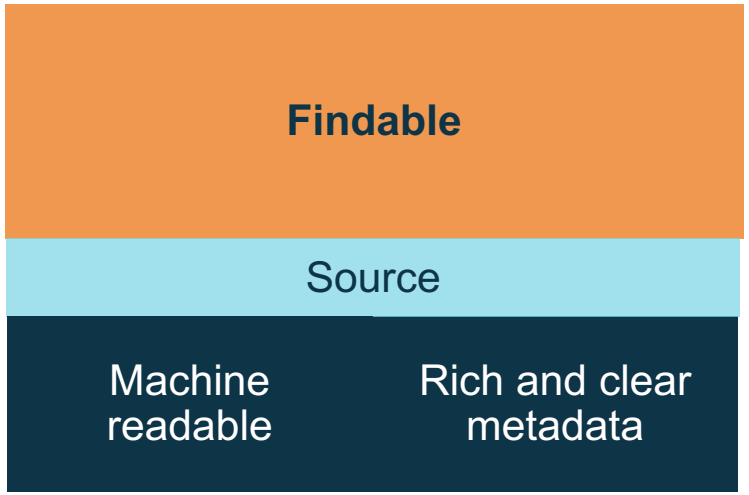
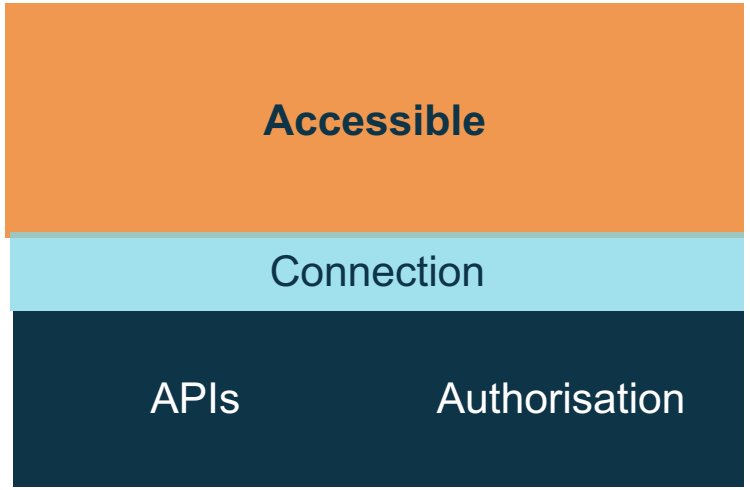
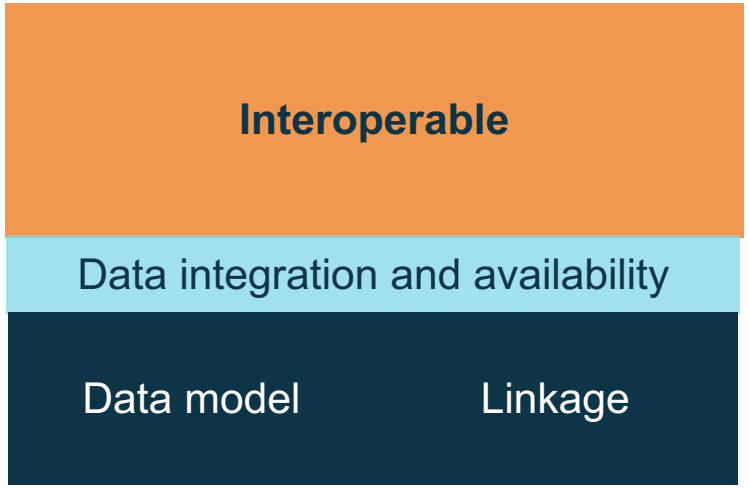
Content

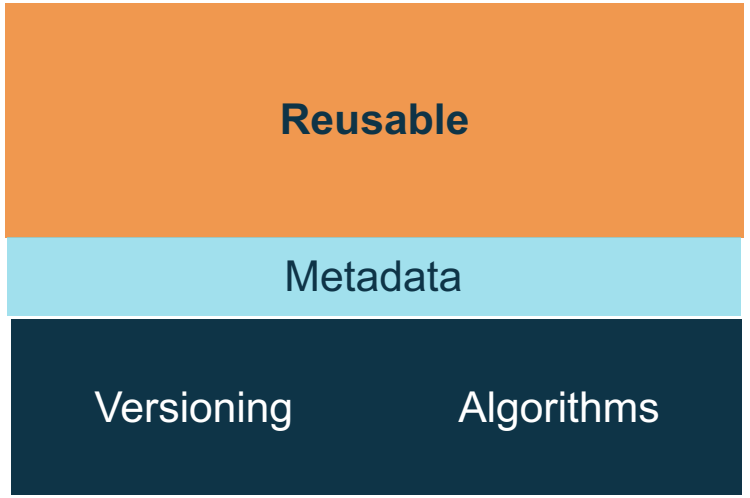
- FAIR principles overview
- FAIR issues and solutions in practice
- Examples of FAIRness in elluminate

Make it FAIR


Findable
Source
Machine readable
Rich and clear metadata


Accessible
Connection
APIs
Authorisation


Interoperable
Data integration and availability
Data model
Linkage


Reusable
Metadata
Versioning
Algorithms

Internal System Chaos

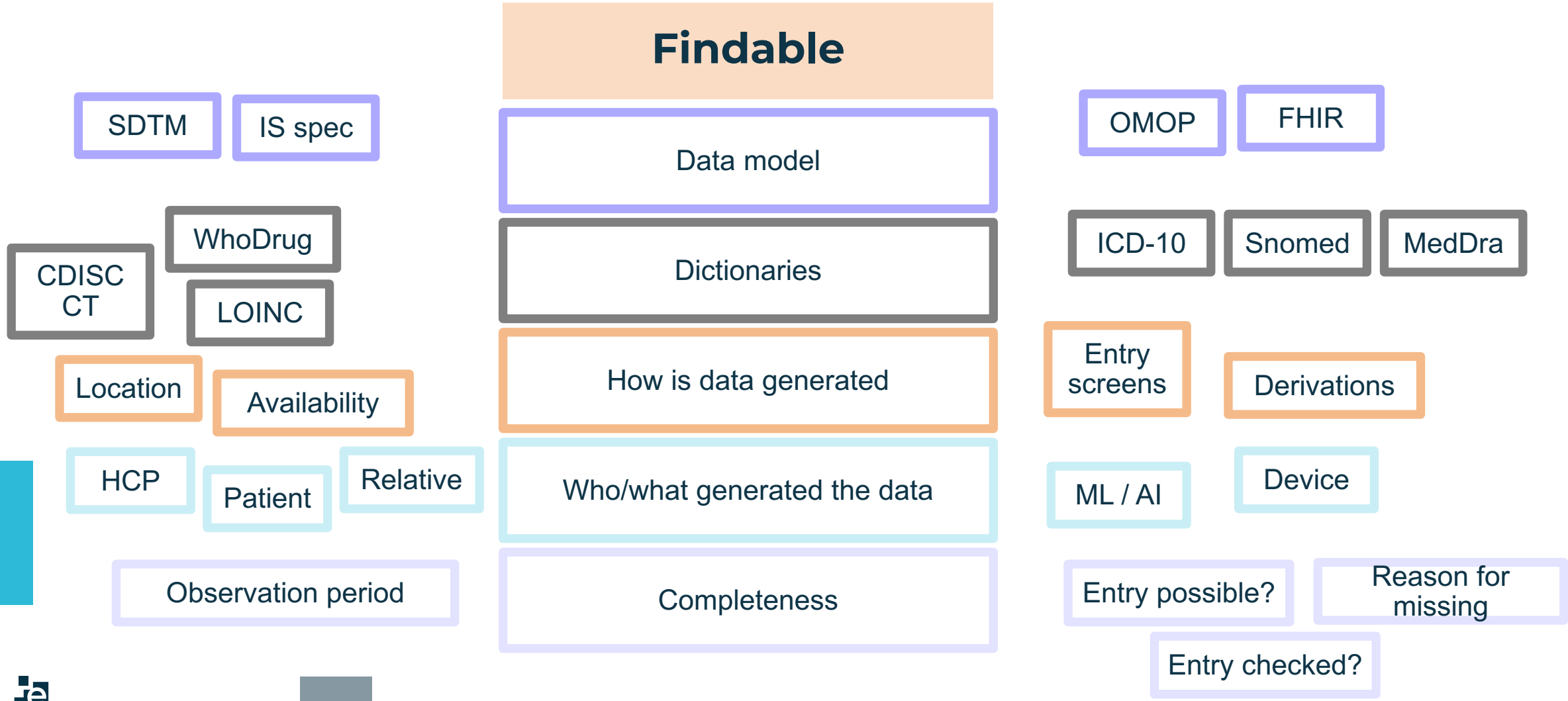
Increased
Data Complexity

Accelerated
Timelines
& Regulatory
Pressure

Digitization
Initiatives

Decentralized
Trial Models

Applying FAIR principles



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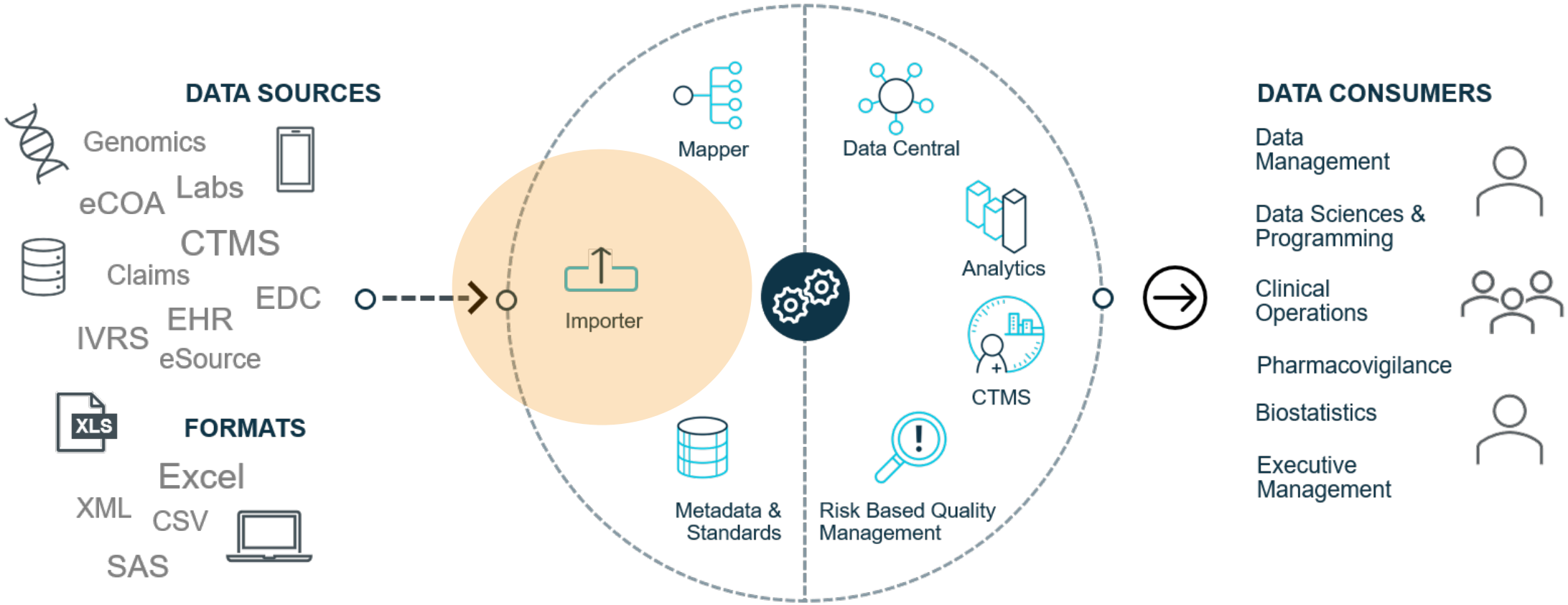
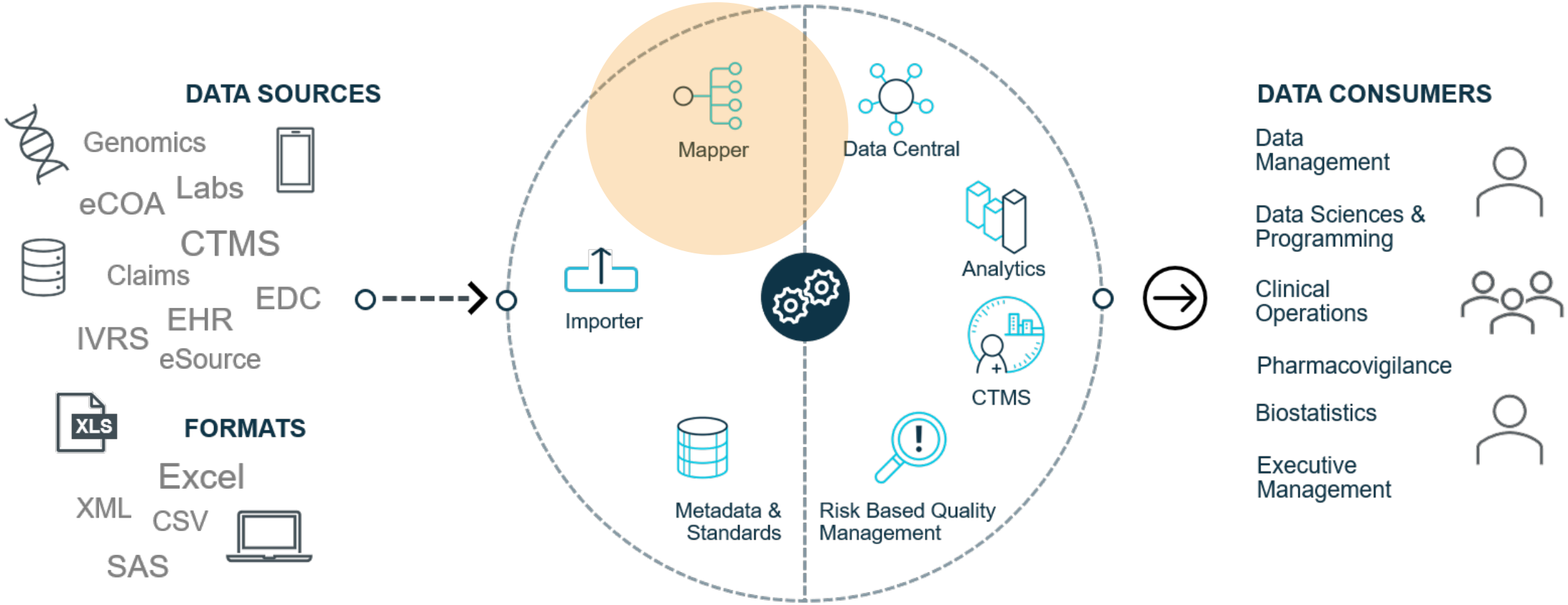


One clinical data platform from ingestion to insights — across all data sources

Accessible



One clinical data platform from ingestion to insights — across all data sources

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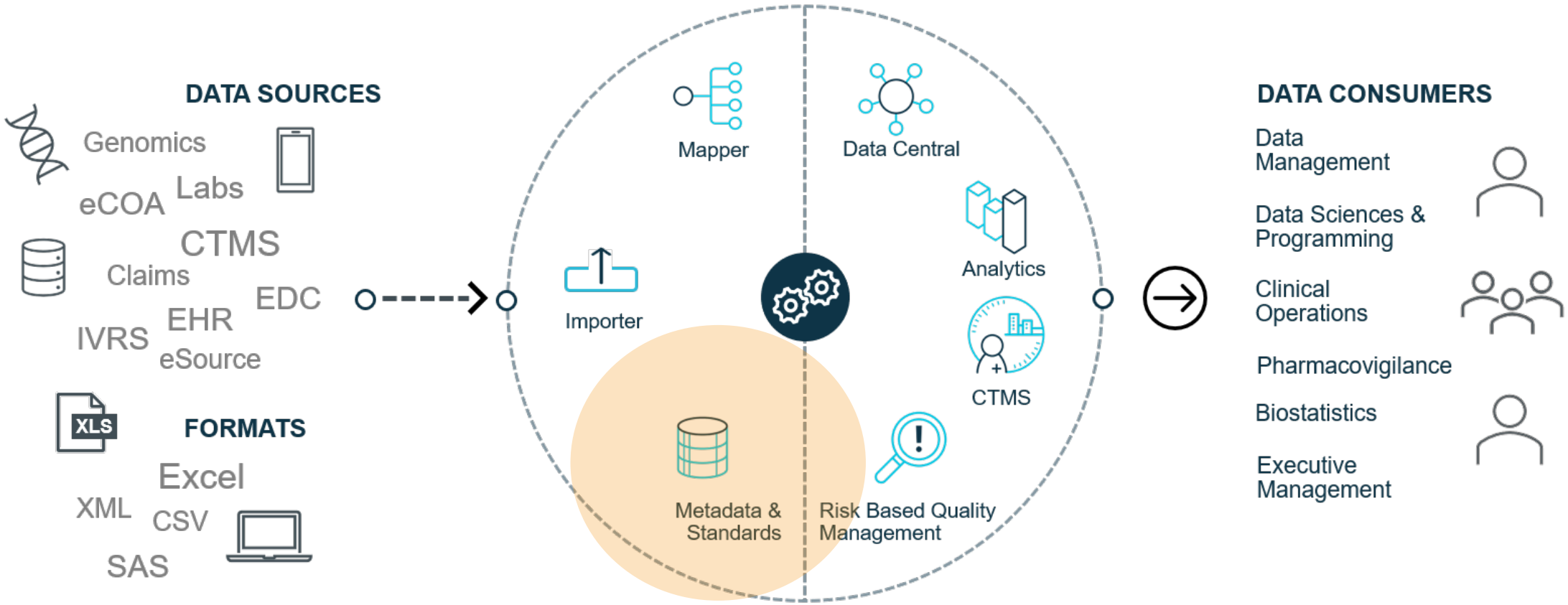
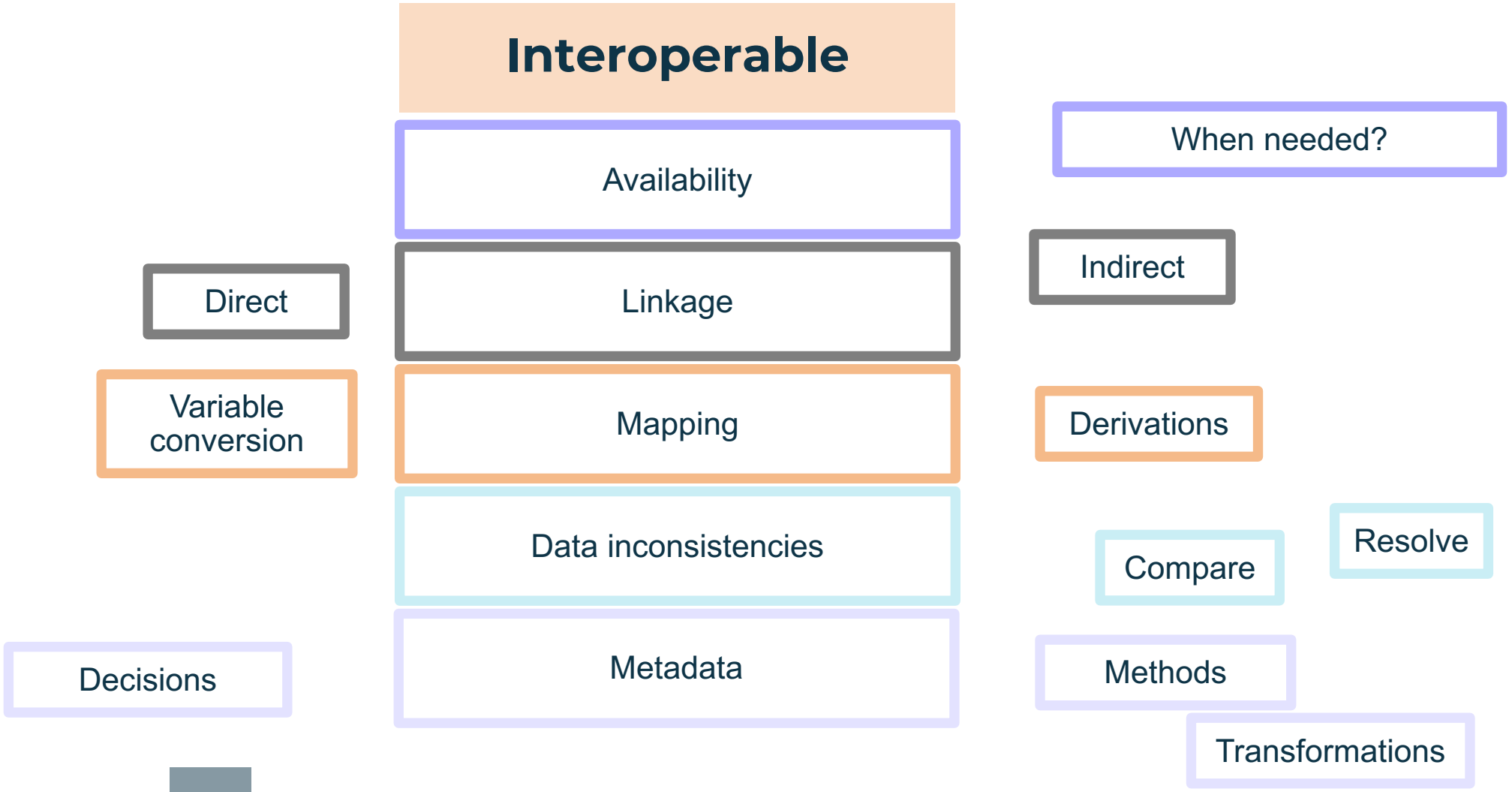


One clinical data platform from ingestion to insights — across all data sources

Applying FAIR principles



Data Standards for Drug and Biological Product Submissions Containing Real-World Data

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document or the Real-World Evidence Program, please email CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2021
Real-World Data/Real-World Evidence (RWD/RWE)

Considerations for Mapping Real-World Data to

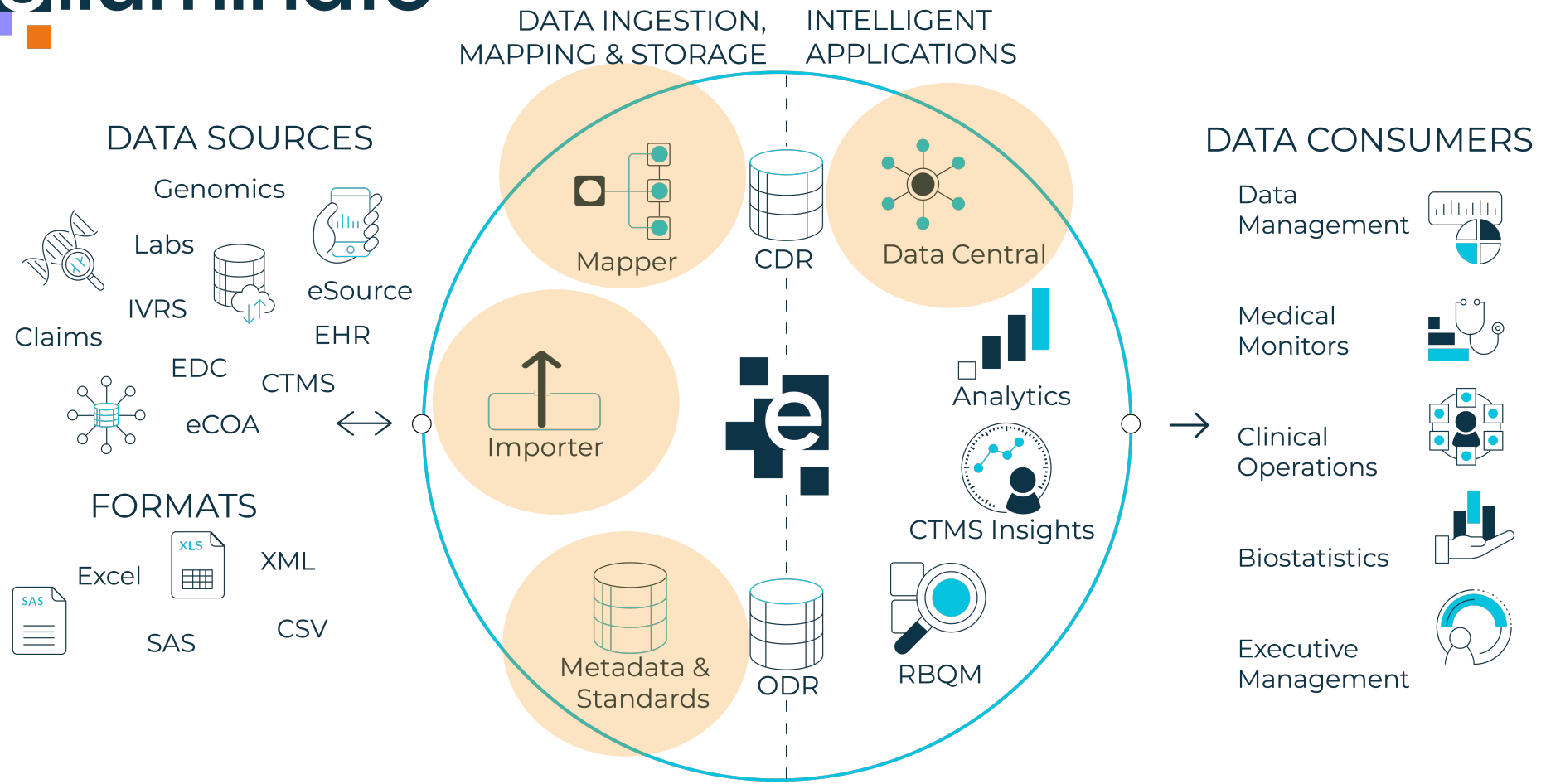
Documentation of the sponsor's rationale for choosing particular CDISC data elements for RWD and documentation of the differences between the two is critical. The sponsor should provide a description of the general approach and anticipated impact of data mapping as a part of or in an

Considerations for Data Transformations

Sponsors should document data challenges encountered during transformation to an FDA-supported data standard and a justification of their approach to enable the application of an FDA-supported data standard. Mapping of standards and terminologies can be handled using the

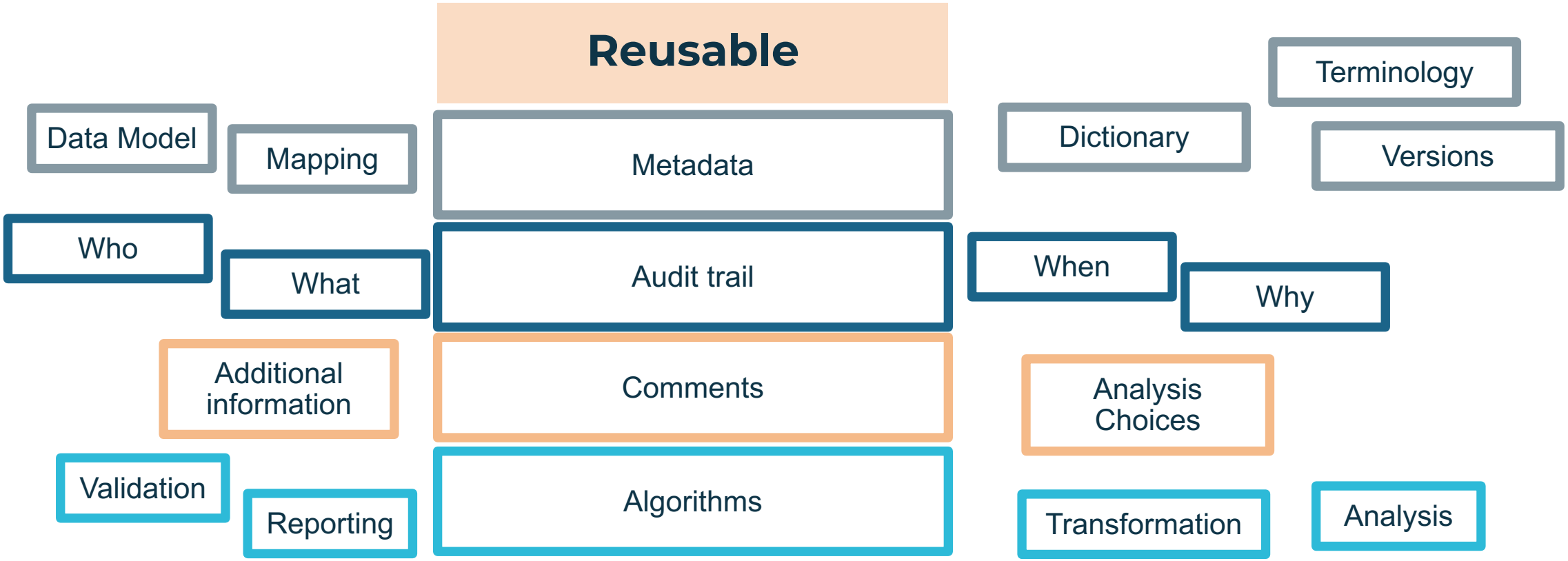
Applying FAIR principles

Interoperable | **Findable**



One platform for clinical and operational data from ingestion to insights
-across all data sources

Applying FAIR principles



Data Chaos

CTMS

Safety

EHR

EDC

EHR

Genomics

eSource

Labs

Images

Wearables

Biomarkers

Labs

eCOA

Biomarkers

ePRO

EDC

Safety

SAS

eCOA

XLS

CTMS

Images

DCTs

Practical examples in elluminate

The Clinical Data Platform of Choice

Helping the industry move to digital

- Increased control via one source of truth across all data sources with automated ingestion via flexible APIs & Connectors
- End to end platform, fit for purpose capabilities optimized for common use cases
- Out of the Box Analytics: Clinical Cross Trial & Operational/CRO Oversight
- Comprehensive Data Review for reduced cycle times and data intelligence
- Enabling self-service and simplified user experience
- AI/ML Capabilities coming for RBQM and Data Review

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