cdisc®

2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

OpenStudyBuilder: Our Journey So Far and the Road Ahead

Mikkel Traun, Principal IT Solution Architect, Novo Nordisk A/S
Katja Glaß, OSB Community Manager, Katja Glass Consulting

Agenda

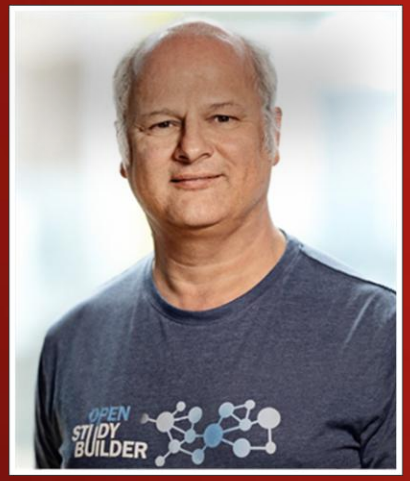
1. Introduction
2. Our Road so far
3. Our Road Ahead
4. OSB in CDISC 360i
5. Summary

Speakers

Katja Glaß

OSB Community Manager, Katja Glass Consulting

Katja is a consultant with over 20 years of experience in the pharmaceutical and life sciences industry, specializing in SAS, web technologies, ADaM, Define.xml, and TLF generation, and a strong advocate for open-source collaboration. She spent more than two decades at Bayer and now serves as community manager for the OpenStudyBuilder open-source project on behalf of Novo Nordisk. Katja also runs glacon.eu/portal, a platform promoting open-source solutions for pharma, and is a board member of the CDISC Open Source Alliance.



Mikkel Traun

Principal IT Solution Architect, Novo Nordisk A/S

Mikkel is solution architect for the next generation study builder and data standards repository solution at Novo Nordisk. Mikkel is also an active member of the TransCelerate and CDISC Digital Dataflow project, and previously the CDISC 360 project. He has worked as a principal system developer supporting the clinical data warehouse solution and the CDISC implementation at Novo Nordisk. Previously he has worked on several projects in pre-clinical, clinical and outcome research.

What is OpenStudyBuilder?

Core Components:

- The OpenStudyBuilder application
  (web-based user interface)

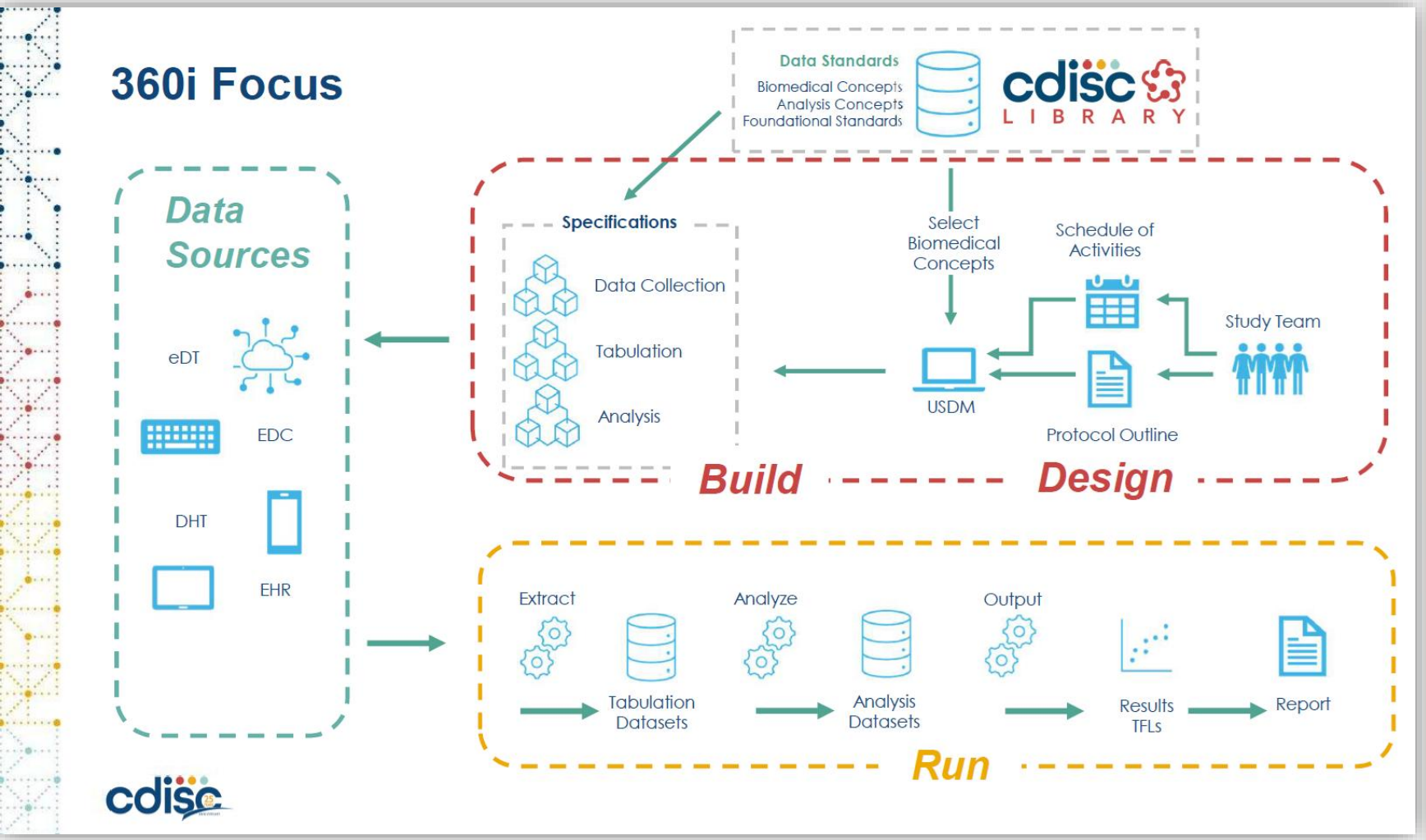
- The clinical Metadata Repository and Study Definition Repository - MDR & SDR
  (central storage, graph database)

- The API layer
  (enabling interoperability with other systems)

RETHINKING CLINICAL DEVELOPMENT THROUGH DIGITAL INNOVATION

OpenStudyBuilder is the open-source solution for the industry, establishing **a single, standardized source of truth for digital study design specifications,** unlocking data- and AI-driven operational and scientific excellence across clinical development

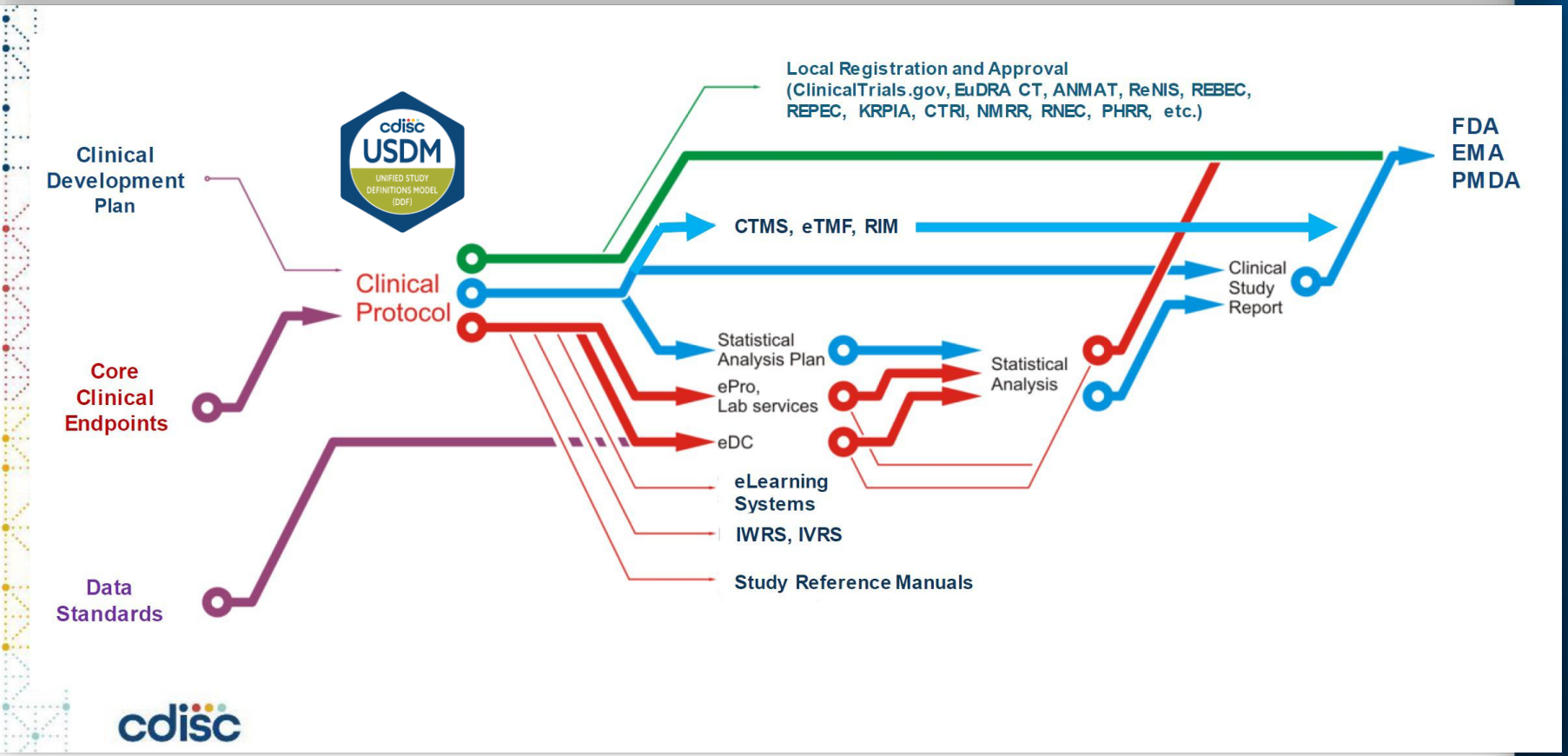
OpenStudyBuilder in Context of CDISC 360i



Drive automation through:

- Study Definitions
- Study Metadata
- Standards
- Interfaces

OpenStudyBuilder in Context of DDF



Enable DDF:

- Structured Protocol Elements
- USDM Export
- Interfaces

OpenStudyBuilder in Context of Business Processes

Input

Enable systems and users to **input clinical meta data on key study concepts** digitally

Standardize

Harmonize language

Ensure **compliance to standards**

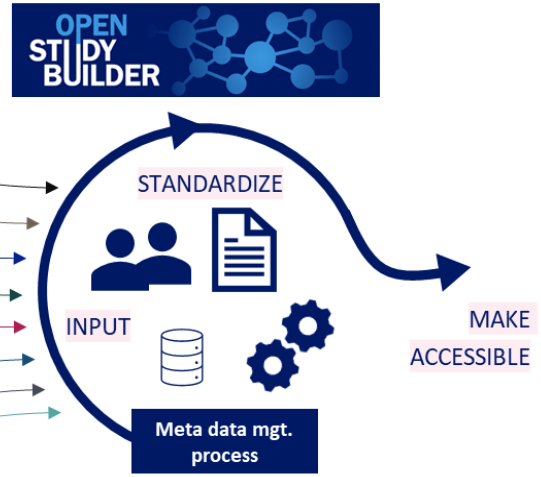
Resolve inconsistencies

Make accessible

Enabling users and digital products to **parallelize, optimize** and **automate** across downstream business processes

Study concepts

- 0. Standards
- 1. Study design structure
- 2. Study Outcome
- 3. Study Criteria
- 4. Schedule of activities
- 5. External Data Transfer Specifications
- 6. UI Driven Data Collection Specification
- 7. Data quality elements

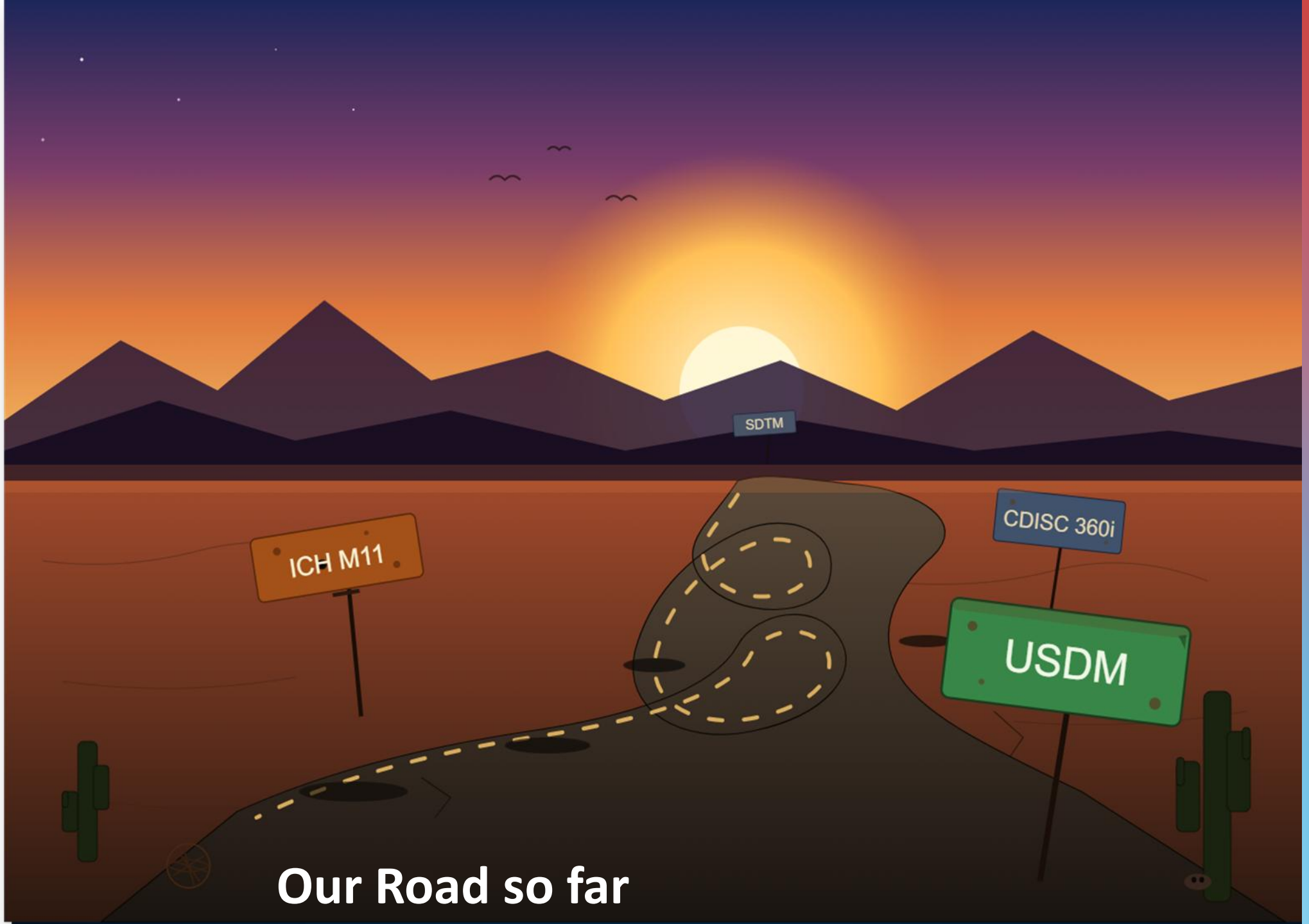


Business processes

0. Standards Utilization
1. Study Planning
2. Protocol authoring
3. Data Collection Enablement
4. Data Transformation and Sharing
5. Study monitoring and Quality
6. SDTM generation
7. Statistical Analysis, ADaM generation and TFL
8. Clinical Disclosure
9. Clinical Study Reporting
10. Submission

Supporting Business Processes:

- Maintain study data and metadata
- Harmonize
- Accessibility enabling parallelization, optimization and automation



Our Road so far

OpenStudyBuilder Status

- Manage Study Standards
- Study Design Specification
- Schedule of Activities
- CRF Standard Library

YouTube:

OpenStudyBuilder Status

OpenStudyBuilder – Open Development

Important to develop openly:

- Link to industry standards
- Enhanced quality and innovation
- Risk minimization
- Integration capabilities
- Required transparency
- Future proofing

Open-source value add

*Why **co-develop the solution via open source?***

- **Link to industry standards:** a successful implementation of industry standards builds on industry alignment.
- **Enhanced quality and innovation** through community input and testing
- **Risk minimization:** Co-developing minimizes process risk in a standardized regulated environment
- **Integration capabilities:** Broad integration capabilities with vendors
- **Required transparency:** A transparent digital foundation accelerates cross industry standardization
- **Future proofing:** Broad industry adoption ensures generalizability, extensibility & modularity for changing business requirements over time.

OpenStudyBuilder Collaboration

Open Source is not enough - we need a close collaboration backing the product:

- Increase contributions
- Roadmap synergies
- Solution quality
- Lowering cost
- Accelerated adoption
- Ecosystem influence
- A neutral, capable enabler
- Risk reduction

Collaboration value-add

*Why do we **need an collaboration backing the open-source product?***

- **Risk reduction:** Reduce solution reliance on one or few PharmaCos.
- **Increase contributions:** Accelerate roadmap contributions to lower development costs.
- **Roadmap synergies:** Accelerate co-development by unlocking roadmap synergies and increasing contributions
- **Solution quality:** Improve solution quality by avoiding over-customization.
- **Lowering cost:** Lower operational and integration costs through a strong joint voice.
- **Accelerated adoption:** Accelerate adoption through shared learnings and knowledge exchange.
- **Ecosystem influence:** Footprint to shape the industry.
- **A neutral, capable enabler:** An efficient organization to fuel the above benefits.

Our Road Ahead

OpenStudyBuilder Collaboration

- Strong strategic collaboration
- Collaborative development of a future-ready OpenStudyBuilder
- Alignment with evolving standards through initiatives such as CDISC 360i

The OpenStudyBuilder collaboration aims to accelerate co-development and value from future-proof solutions for digital study design specifications and standards management based on existing and emerging clinical data standards through an industry partnership.

OpenStudyBuilder Collaboration

cdisc®

OpenStudyBuilder Collaboration - Ambition

Establish OSB as a true industry solution, through industry engagement and shared responsibilities

Mature and consolidate the OSB product as market leading through accelerated feature development

Accelerate the digital implementation of clinical data standards for optimized value and adoption across the industry

OpenStudyBuilder Collaboration - Ambition

Now

ESTABLISH & OPERATIONALISE

- **Collaboration model** finalized
- **Agreement signed** with three pharma partners
- **Shared environment for co-development** under preparation
- **Ongoing operationalization** and roadmap alignment of the collaboration

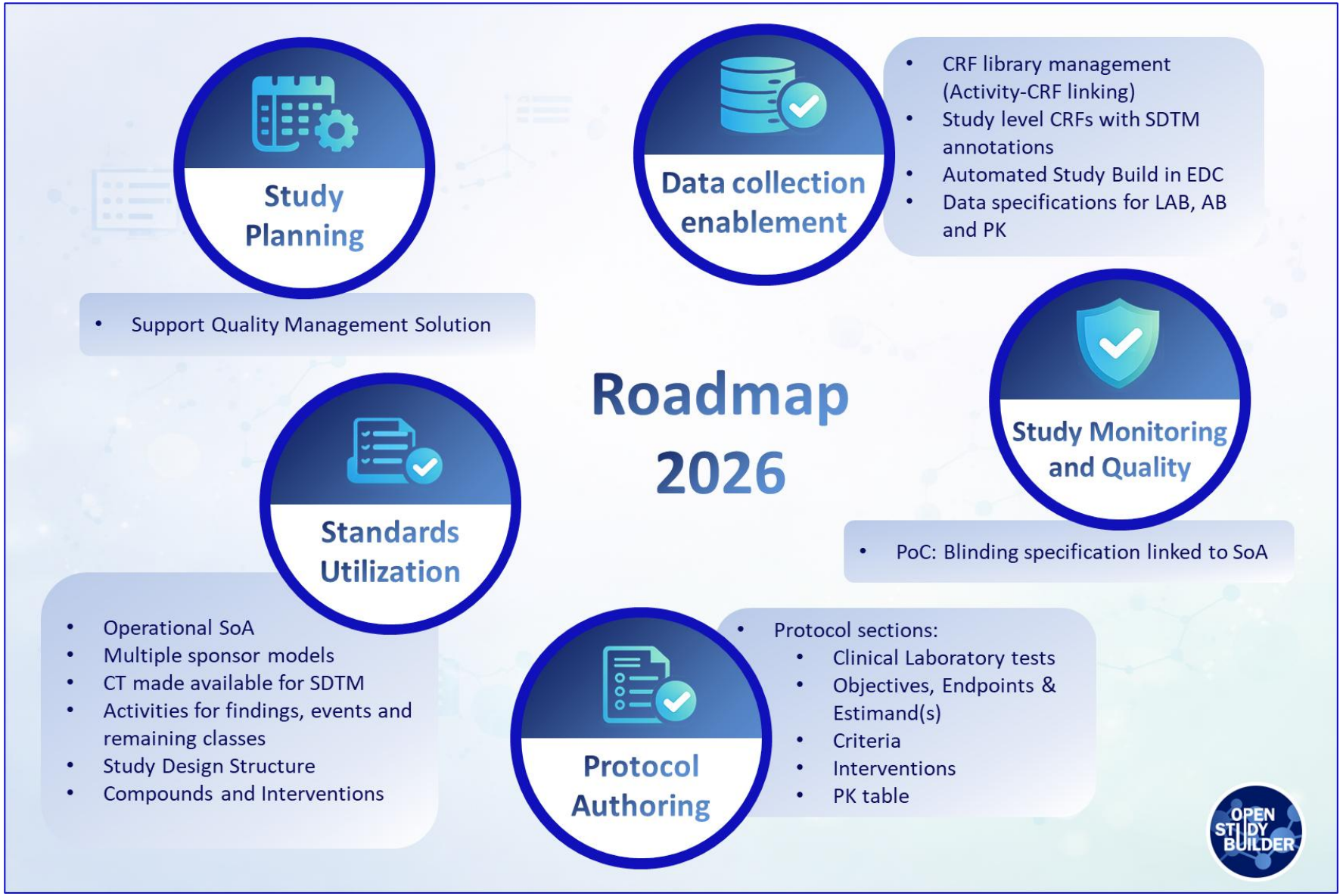
Mid-Term

MATURE AND EXPAND

Long-Term

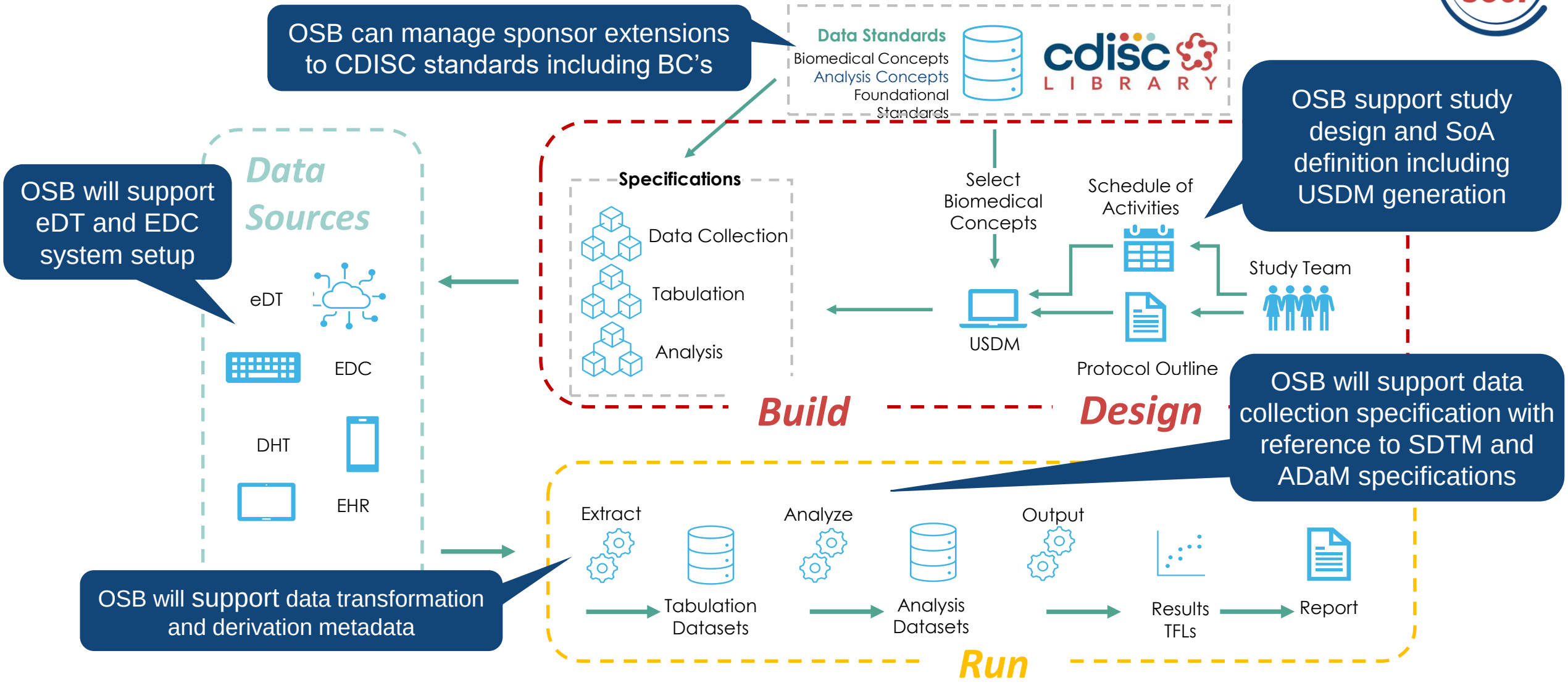
SCALE AND EVOLVE

Roadmap as of now:



OSB in CDISC 360i

OpenStudyBuilder and CDISC 360i



OpenStudyBuilder and CDISC 360i

OSB can manage sponsor extensions to CDISC standards including BC's

Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY

OSB support study design and SoA definition including USDM generation

OSB will support eDT and EDC system setup

Data Sources

eDT

EDC

DHT

EHR

Study Team

OSB will support data collection specification with reference to SDTM and ADaM specifications

Results TFLs → Report

OSB will support data transformat and derivation metadata

Now:

- Improve Activity Concept model and link to BC
- Support for Non-Standard Variables

Next:

- Support simple Derived Activity Concepts
- Improve import and use of sponsor SDTMIGs
- Improve CRF support in ODM incl NSVs
- Improve USDM support

Later:

- ADaM
- Analysis Concepts

OpenStudyBuilder and CDISC 360i

OSB can manage sponsor extensions to CDISC standards including BC's

OSB will support eDT and EDC system setup

OSB will supp
and der

Now:

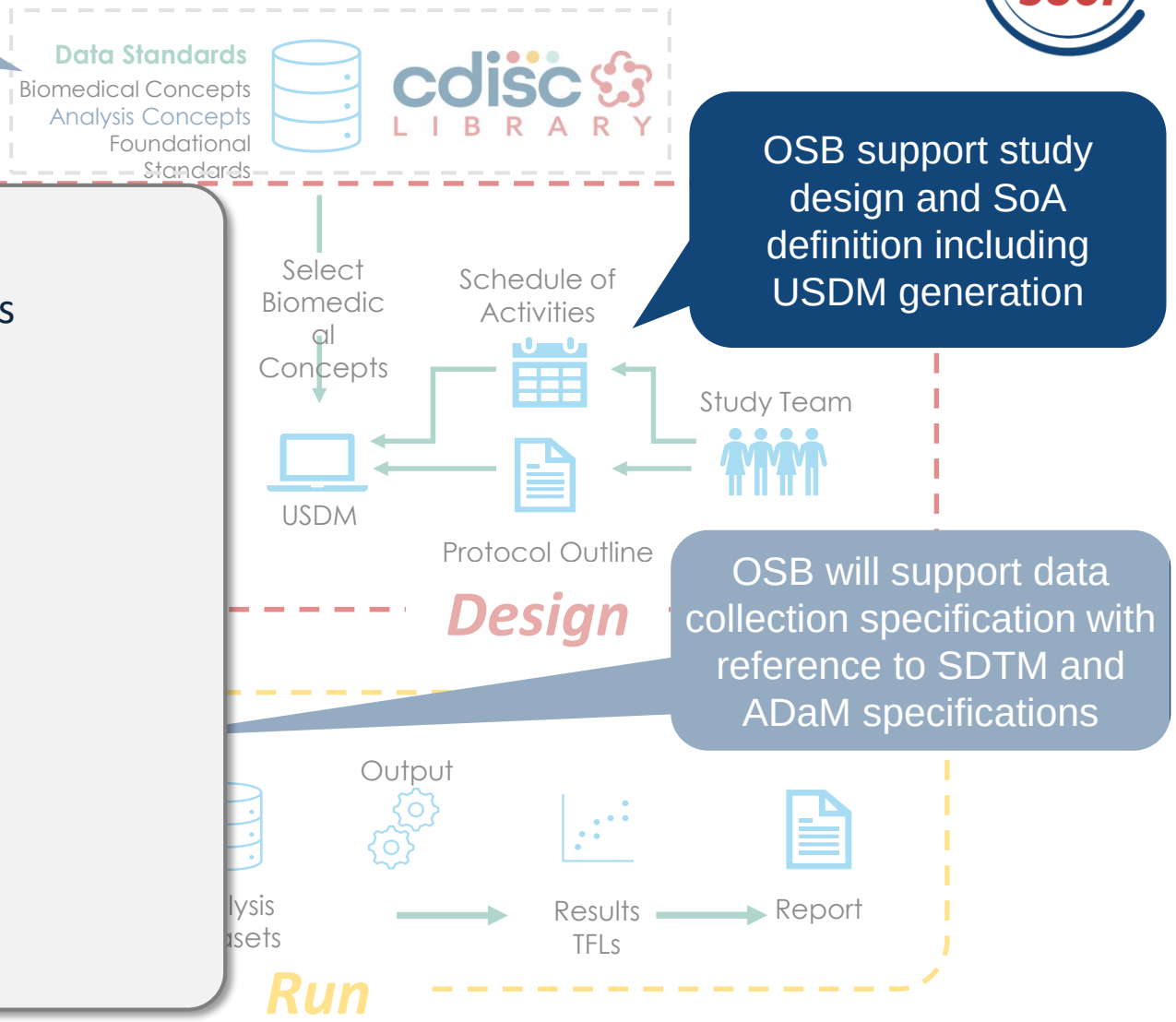
- Support more Trial Summary Parameters
- Support review comments in SoA
- Increase USDM coverage

Next:

- Improve study visit setup
- Improve study intervention setup

Later:

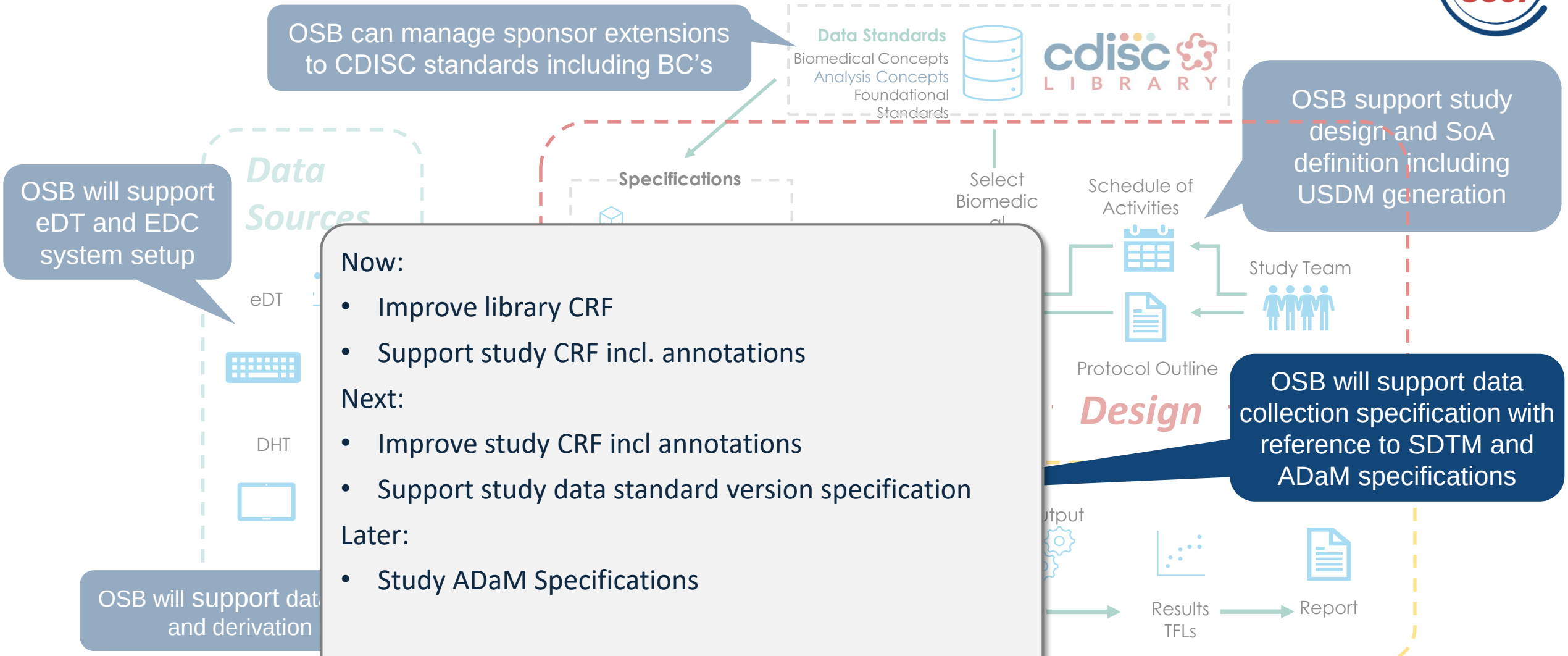
- Study Analysis Specifications



OSB support study design and SoA definition including USDM generation

OSB will support data collection specification with reference to SDTM and ADaM specifications

OpenStudyBuilder and CDISC 360i



Now:

- Improve library CRF
- Support study CRF incl. annotations

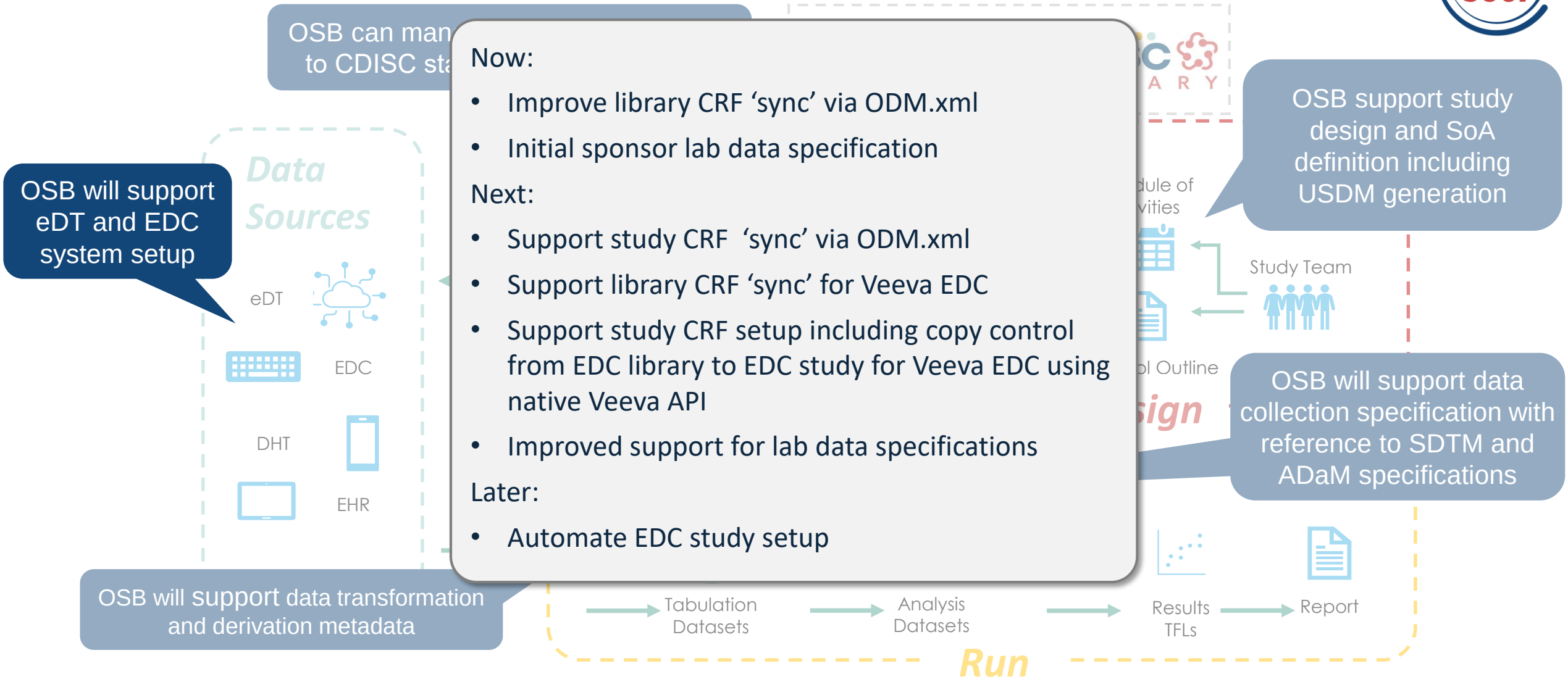
Next:

- Improve study CRF incl annotations
- Support study data standard version specification

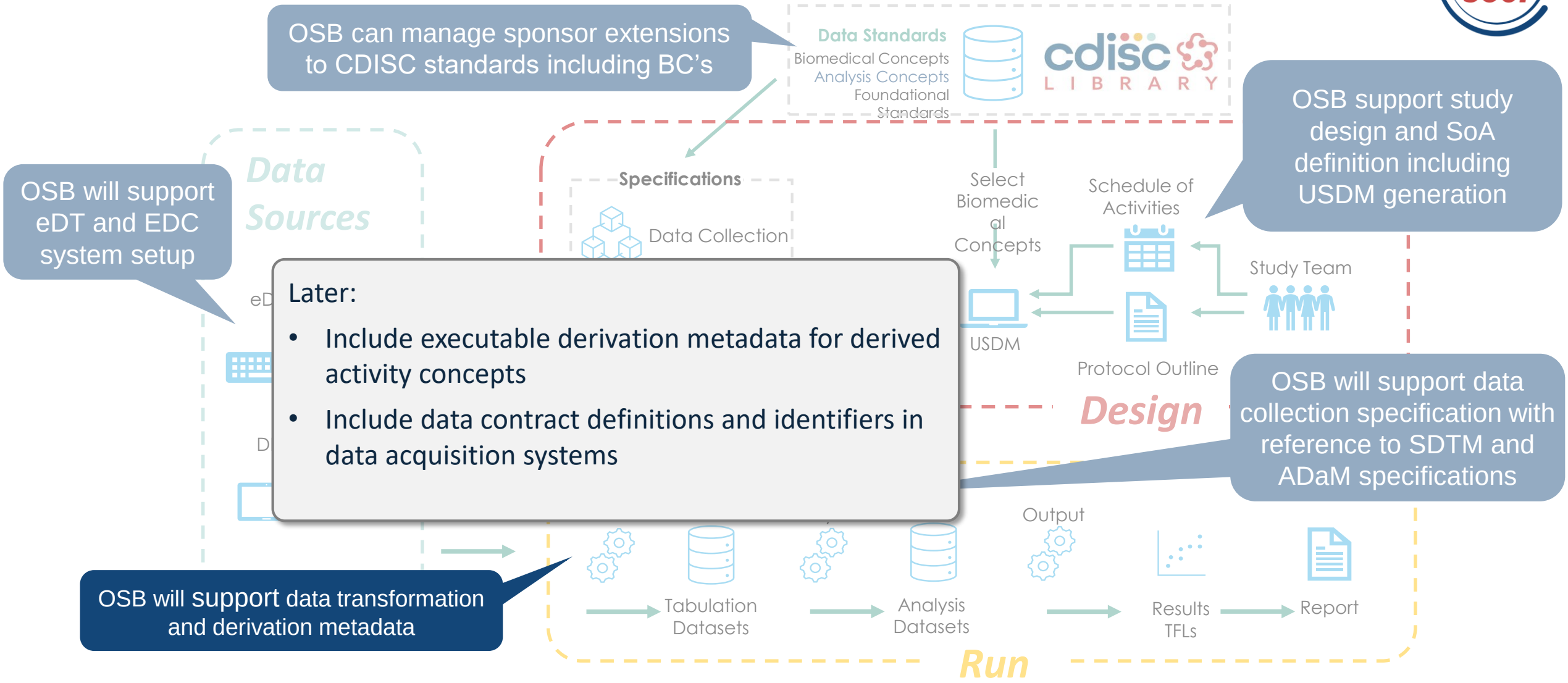
Later:

- Study ADaM Specifications

OpenStudyBuilder and CDISC 360i



OpenStudyBuilder and CDISC 360i



Summary

Summary

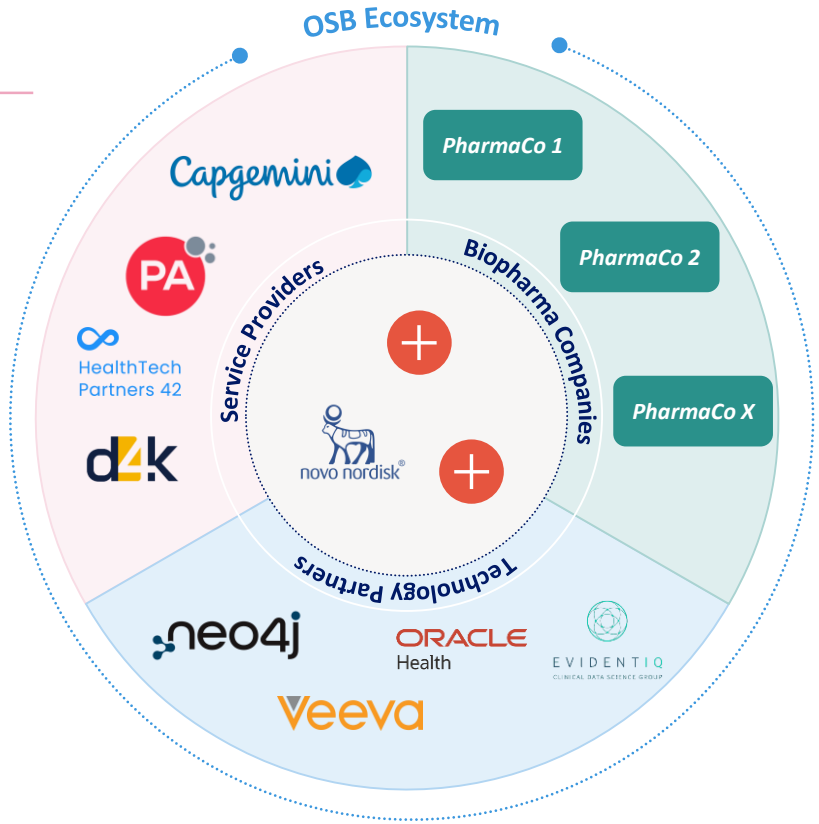
- Solving complex challenges together
  - Community-driven solutions for complex industry challenges
  - Join the CDISC 360i initiative
  - Join the OpenStudyBuilder ecosystem
  - Build strong cross-industry collaborations

- Enabling digital data flow across the industry
  - Collaboration and shared understanding
  - Solutions designed for the entire industry - not just individual organizations
  - Flexibility through a variety of approaches and solutions

OpenStudyBuilder Ecosystem

Service Providers

Implementation partners & consultancies offering services, expertise, and resources for StudyBuilder development & maintenance, as well as CDISC standardization



Biopharma Companies

Other pharma companies that leverage OpenStudyBuilder as their MDR / SDR solution and operate dedicated instances as part of their individual clinical data flows.

Technology Partners

Either key technology providers of the OSB solution (e.g., neo4j) or other partners offering integrations to additional clinical solutions / platforms (e.g., EDC systems)

cdisc®

Thank You!
Questions?

- Questions or need more information

- Mikkel Traun, mt@novonordisk.com
- Katja Glass, katja.glass@glacon.eu
- OpenStudyBuilder contact: OpenStudyBuilder@gmail.com