Agenda

Introduction

➢ Introduction –Pascal

➢ Deployment Practices at NN -Kim

➢ Existing OSB Solutions: How to Deploy – Kim

➢ Enhancing Deployment Strategies for Companies – Marius/Kim
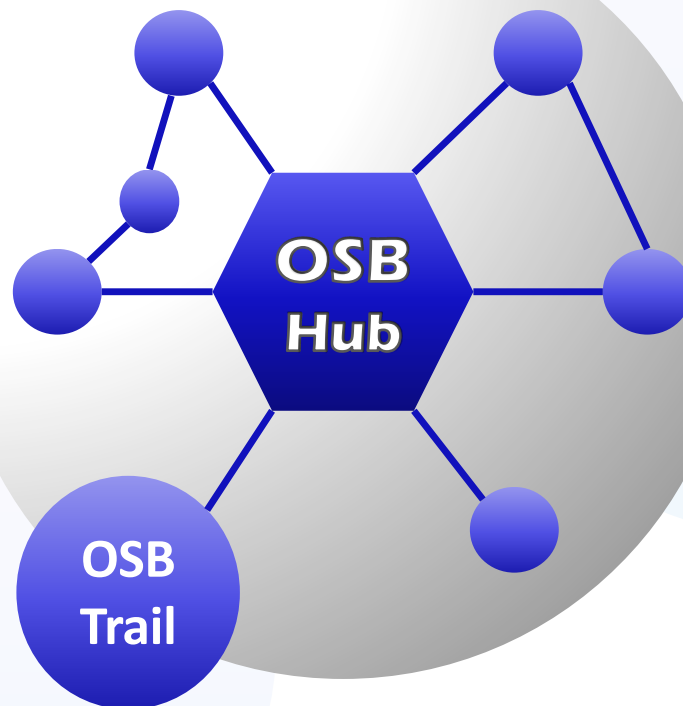
➢ Participant Feedback and Alignment on Next Steps : All

OPEN STUDY BUILDER

OSB Hub

cdisc

OPEN SOURCE ALLIANCE

OSB Trails – Focus Projects

OSB-Trail-SystemEngineering: **Objectives**

- Share knowledge on deploying and scaling OSB effectively.

- Discuss best practices, Exchange experiences.

- Build a network of experts to support and innovate within the OSB ecosystem.

- Propose guidelines, Additional Documents.
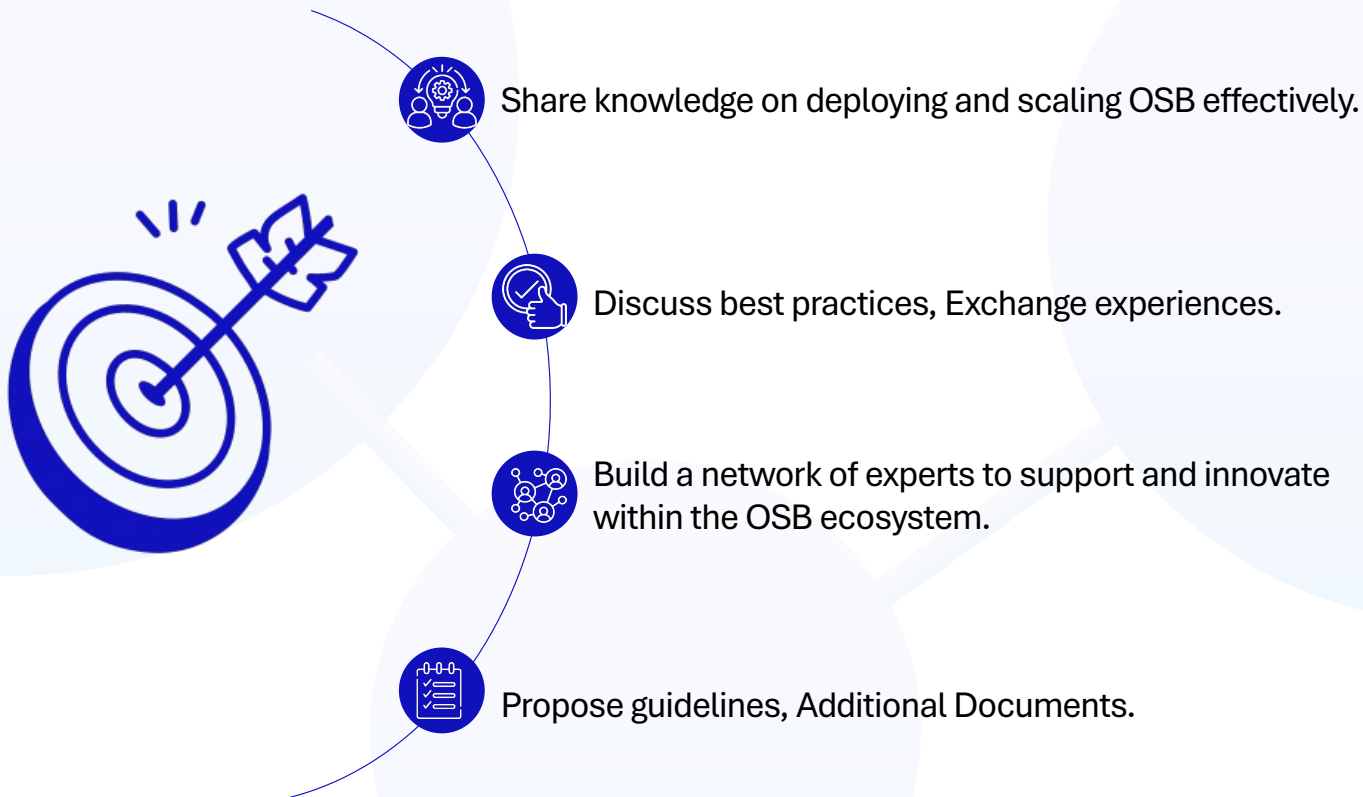
OSB-Trail-System Engineering: **SCOPE**

Priority1 Scope

1. Optimizing deployment workflows for OSB across diverse environments. First deployment and deployment of new release
   - ✓ Cloud: Azure, AWS, Google
   - ✓ Containerization of OSB: EKS, AKS, GKE, OpenShift, Vmware Tanzu, Fargate, ACI …
   - ✓ Develop a Terraform-based deployment template for easy replication across cloud environments (AWS, Azure, GCP).
2. Exploring and implementing robust authentication methods tailored to OSB.
3. Facilitating seamless integrations between OSB and other enterprise systems.
4. Inventory of OSB implementations with their technical deployment pattern
5. Monitoring of OSB/Observability
6. Archiving, Back-up, DR
7. Share Performances/Scalability Testing
8. Validation approach of OSB and Interest in developing UI testing tools to support validation.
9. Applying GraphRag on OSB
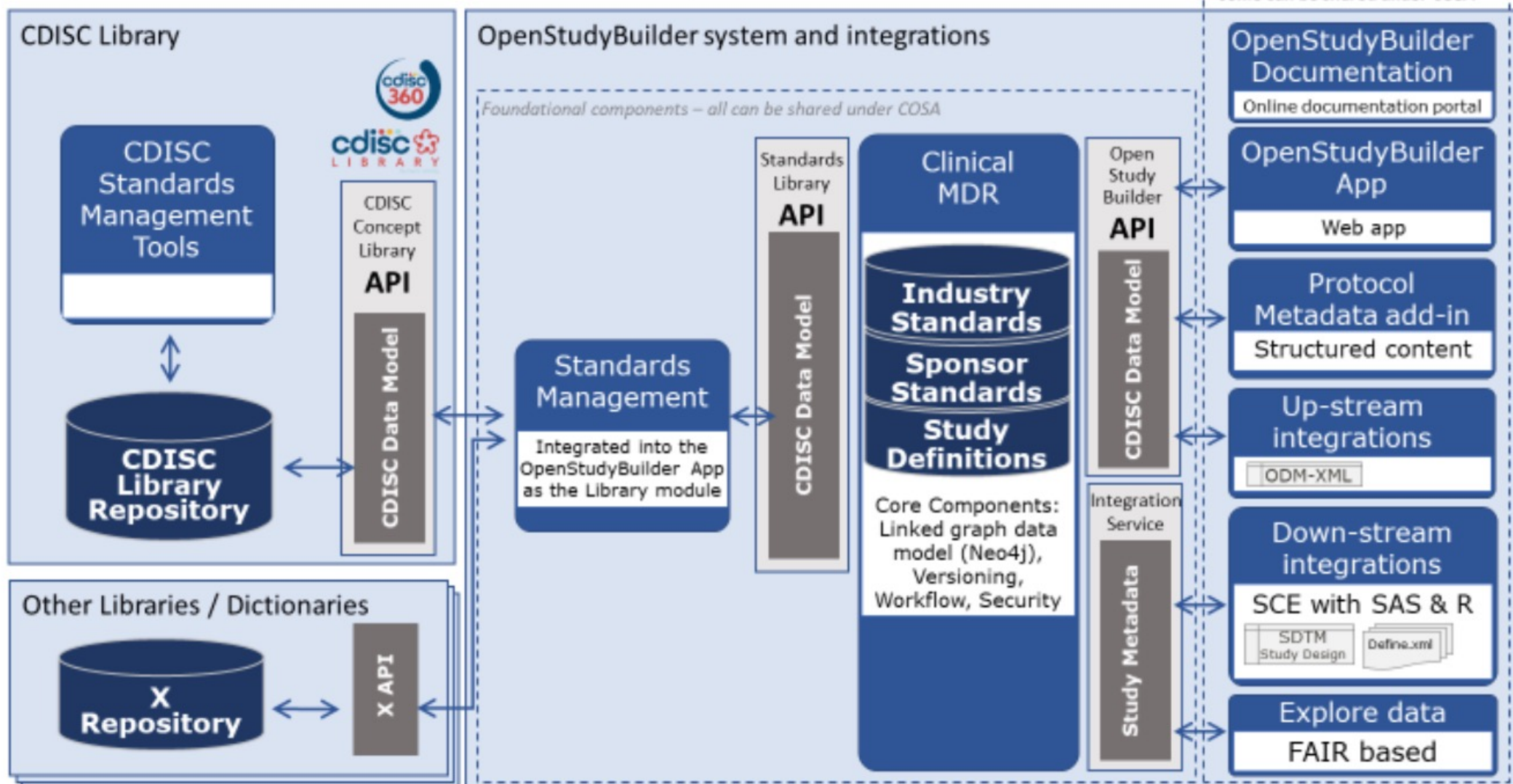10. Changing OSB CSS

What you can expect in the next calls

Details on how to setup OpenStudyBuilder

Details on setting-up Authorization in OpenStudyBuilder

Details on how to use APIs

Demo of example of installations, and API use

OpenStudyBuilder Conceptual Architecture

CDISC Library

CDISC Standards Management Tools

cdisc 360

cdisc LIBRARY

CDISC Concept Library API

CDISC Data Model

CDISC Library Repository

Other Libraries / Dictionaries

X Repository

X API

OpenStudyBuilder system and integrations

Foundational components – all can be shared under COSA

Standards Library API

CDISC Data Model

Clinical MDR

- **Industry Standards**
- **Sponsor Standards**
- **Study Definitions**

Core Components: Linked graph data model (Neo4j), Versioning, Workflow, Security

Standards Management

Integrated into the OpenStudyBuilder App as the Library module

Open Study Builder API

CDISC Data Model

Integration Service

Study Metadata

OpenStudyBuilder Documentation

Online documentation portal

OpenStudyBuilder App

Web app

Protocol Metadata add-in

Structured content

Up-stream integrations

ODM-XML

Down-stream integrations

SCE with SAS & R

SDTM Study Design | Define.xml

Explore data

FAIR based

OSB: Existing deployment (non exhaustive)
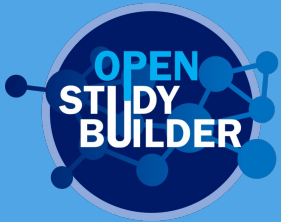
Company	Cloud	Containerization	Authentication	Use of API	Customization
Novonordisk	Azure (Bicep for IaaS)	Docker	SSO using EntraID	Yes (FastAPI used for back-end and API development)	Front-end developped with Vue.JS
Boehringer Ingelheim	AWS using AWS LoadBalancer	EKS. Target: Openshift	SSO using EntraID, however currently roles are disabled.	Testing of OSB APIs to read study data and controlled terminology.	Updated CSS for BI custom branding.
Oracle	Cloud OCI	Docker image used	OAuth using OCI Identity Service.	Yes	Authentication and authorization to work with IDCS.
Beigene	-	-	-	-	-
CapGemini	AWS	-	-	-	None
Saama	AWS	Docker image used->EKS (TBD)	-	API for integration with meta data and study design	None
eClinical	AWS	Docker image used	-	API for integration with meta data and study design	None
HealthTechPartners 42	AWS	Docker image used	None for now	Testing	None

Challenges Collected via Slack

- Impact of GPLv3 license impact

- So far we didn't care about transitioning data from version to version, but this is a "concern".

- Transitioning docker-compose into an Openshift deployment is tedious - target is helm deployment. DB initialization requires most changes doing so.

- MedRA importer would be helpful.

- Although it should be configurable for different identity providers, the authentication part had to be slightly changed to support Oracle IDCS.

- Lack of standardized deployment patterns across cloud providers.

- Integration challenges with enterprise authentication systems (OAuth, IDCS, Octa).

- Observability, monitoring, and disaster recovery best practices.

Product

StudyBuilder

- One clinical metadata repository
- An web application
- A central point for study designs (study purpose, study type, population)

Technology & Cloud

- Cloud provider & deployment
- IaC
- Programming languages for development
- Docker images & containers
- Gherkin features for validation
- Security Scanning tools
- Monitoring & Observability platform

Technology & Cloud

Microsoft Azure

Virtual machines for Neo4j (a graph database) database system

Red Hat Enterprise Linux image – an Operating System deployment

An application gateway for traffic routing

App service plans & app services as compute resources
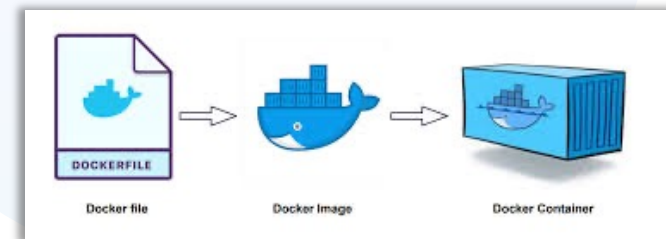
Azure Keyvaults for storing secrets & certificates

Storage accounts & recovery services vault

Technology & Cloud

- Infrastructure as Code – Bicep modules

- Python FastAPI – backend development & APIs

- Vue.js – frontend development

- Neo4j – a graph database

- Docker images in a container registry

- Deploying & running containerized web apps using Azure App services

Technology & Cloud

- Gherkin features – Pytest BDD

- Verification if certain requirements for azure resources are met

- Generation of an Allure report – showing tested resources, performed tests & their status (passed, failed, ecc)

- OAuth Single Sign-On (SSO)

Cloud Security

- Prisma Cloud to scan container images

- VeraCode – SAST tool - Static Application Security testing

Technology & Cloud

- Log analytics workspace

- Application insights – application performance monitoring

- Action groups & alert rules (CPU percentage, memory availability)

Grafana

- Performance of containers, application gateway & database cluster (total requests, failed requests, memory usage)

- CVEs in the container registries – Microsoft Defender for Cloud

- Informations about most used API endpoints, the slowest API endpoints, top users of the application
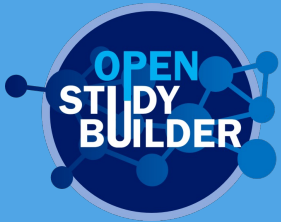
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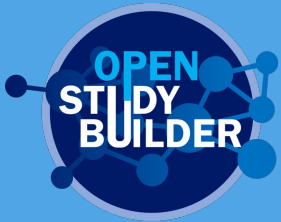
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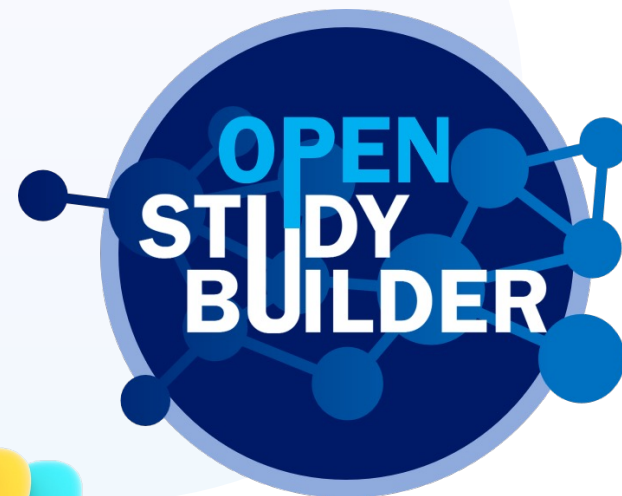➤ Participant Feedback and Alignment on Next Steps : All

Next Meeting

March 24th 2025 - 3 pm CET

https://github.com/cdisc-org/osb-hub/wiki

OSB Hub

OPEN STUDY BUILDER

We need YOUR Feedback!

OSB-Trail-System Engineering: References

1. [OpenStudyBuilder Gitlab](#)

2. OpenStudyBuilder Installation

   ✓ Comprehensive information on various aspects of the application, including installation procedures: [OpenStudyBuilder Documentation Portal](#)

   ✓ [Developer Setup Guide](#)

3. We can integrate with OSB through its REST APIs. Here are some useful links:

   ✓ OpenStudyBuilder APIs: [API - OpenStudyBuilder](#)

   ✓ OpenStudyBuilder Authorization setup: [clinical-mdr-api/doc/Auth.md · main · Novo Nordisk / NN-Public / OpenStudyBuilder / OpenStudyBuilder-Solution · GitLab](#) It explains the code flow and shows that integration are implemented in the API. You basically need to request a token from your authority (e.g. OKTA), and then pass it along with your API calls for authorization.

COSA Collaboration Team

OSB Hub

Mission and Vision:

Support the utilization and enhancement of the OpenStudyBuilder open-source tool.
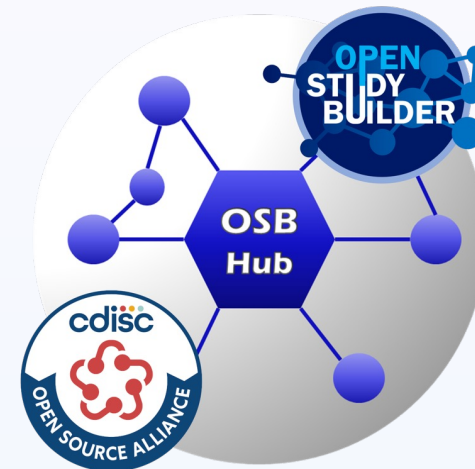
Core Objectives:

Collect feedback, run focused projects, drive innovation through community engagement.

Participants:

Everybody is invited!
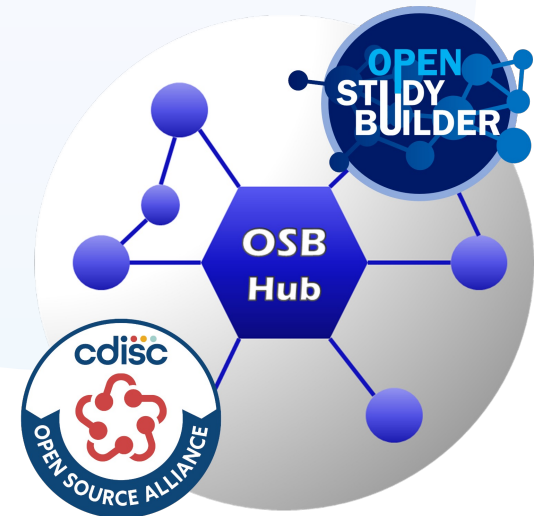
Purpose of OSB Hub

COSA Community

- List, add and discuss use-cases

- Feedback & community interest

- Prioritise use-cases of interest

- Manage and run focus projects

- Utilization and enhancement of the OpenStudyBuilder

😊 Join us on Slack: Invite

💡 Feedback on Use-Cases: Discussions

📚 Checkout Information: Wiki

OSB Trails – Focus Projects

Work as a community on:

- Enhanced documentation
- Best practices
- Additional requirements
- Supporting tools
- Concepts for integrations
- …

Community powered Use Cases:

- Objective is to create a focused group for addressing technical challenges in deploying and operating OSB.
- Together, we'll chart the course for our upcoming trails.