# CONCEPTUAL AND OPERATIONAL STANDARDS (COSMOS), Version 2.

*This Charter was reviewed and approved by the CDISC Leadership Team during 4Q2022. This charter is reviewed when changes occur that impact the roles, remit and/or governance accountability of the project.*

## Background

Translation of the study protocol to data collection and the subsequent mapping of collected data to SDTM is difficult, inefficient, and resource intensive:

* Study protocols are neither specific enough to facilitate data collection nor specify data in a machine-readable format
* Translation of the study protocol needs to be further detailed in eDC/CRF for collection
* Collected data needs to be mapped to CDISC SDTM and standard controlled terminology
* Transparency issues can arise during analysis and reporting

## Purpose

The purpose of the Conceptual and Operational Standards Project (COSMoS) is to start filling the gap in current standards by delivering Minimal Viable Product (MVP) scoping and use cases for the development, curatation and governance of Biomedical Concepts (BCs).

## Approach

The project will start small, grow fast and deliver value:

* Deliver solution-oriented value to implementers in small increments on a regular basis
* Use agile Scrum approach to develop capabilities throughout MVP
* Focus on use cases and demonstrating value
* Fill gaps in existing standards
* Deliver value before growth

## Scope

The scope of BC MVP development and implementation includes:

* MVP 1.0 focuses on 3 high-value use cases with testable conditions
  + Retrieve Define-XML content including Value Level Metadata
  + Retrieve a list of assessments for a study design
  + Retrieve standards, specifications and templates for use in authoring standards
* MVP 1.0 curation process and infrastructure
* Light-weight governance process

Out of scope for the project:

* Creating medical dictionary
* Creating CDISC ontology
* Re-inventing the foundational standards

## Deliverables

The key outputs for COSMoS project include:

* High level road map, budget and staffing plan
* MVP 1.0 use cases
* MVP 1.0 objectives and key results (OKRs)
* Infrastructure and tooling
* BC curation and governance processes including principles and guidelines
* Validation Process
* Package releases of BCs which pass testable conditions for MVP
* Loading of BCs into CDISC Library (includes data model, data pipeline, API design and other tooling ecosystem)
* Process for managing volunteer curators
* Backlog for MVP

## Key Inputs to MVP BC Development

The key inputs to the BCs are:

* GSK MDR export
* Define-XML mining
* CDISC CT Codeable mapping files
* LB to LOINC mapping
* QRS
* Oncology TAUG standards

## Working Structure and Governance

Light Weight Governance Process aligned with COP-001 (no GGG rev

## Dependencies

tbd

## Timelines for Initial Rollout

* Confirm MVP 1.0 use cases: 2 weeks
  + Identify data source for each use case
* Initial load: 3 months
  + Data model, Data pipeline, API design, Data migration, other tooling ecosystem
* Initial curation: 1 month
* Initial governance: 1 month concurrent with curation
* Provisional release: Summer 2022

## Appendix 1

Content Development Roles

|  |  |  |
| --- | --- | --- |
| **Role** | **Description** | **Name** |
| Content Owner | Approve use cases & their testable conditions | Bess LeRoy/Peter Van Reussel |
| Lead Curator | Lead curation & governance process | Bess LeRoy/Jon Neville |
| Metadata Reviewer | Primary content contributor & reviewer | Linda Lander/  CDISC Curation Team |
| Terminologist | Good definition process | Erin Muhlbradt |
| Clinical SME | Provide ad-hoc support with clinical knowledge | Rebecca Baker |
| Foundational Standards SME | Provide ad-hoc support with foundational standards knowledg | Diane Wold |
| CDISC Library Curator | Ensure successful data load & retrievals | Julie Chason |
| Software Engineer | Backend & frontend software development. Automate tests | New |
| Software Engineer | Data conversion, data migration, and API development | New |
| Data Architect | Data modeling | Lex Jansen |
| CDISC Library Architect | Ensure successful integration with CDISC Library | New |

## History of Changes

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| --- | --- |
| **Version, Date** | **Description** |
| Version 1, 10-01-2022 | Initial Version |
| Version 2, 05-22-2025 | Minor updates |