# CONCEPTUAL AND OPERATIONAL STANDARDS (COSMOS), Version 1.

*This Charter was reviewed and approved by xxxx on xxxx. 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 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

**Note:** Standards development for BCs will not require compliance with CDISC Standards Development Operating Procedure (COP-001)

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
* Process for managing CT subsets
* Initial batch of BCs which pass testable conditions for MVP
* Loading of initial batch of BCs into CDISC Library (includes data model, data pipeline, API design and other tooling ecosystem)
* 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

## Working Structure and Governance

tbd

## Dependencies

tbd

## Timelines (tbd)

* 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
  + Assuming resourcing plans achieved

## Appendix 1

Content Development Roles

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

## History of Changes

|  |  |
| --- | --- |
| **Version, Date** | **Description** |
| Version 1, xxxxxxxxxx | Initial Version |