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