

Biomedical Concepts

The development of CDISC Biomedical Concepts (BCs) will be developed following the CDISC Standards Development process outlined in COP-001. Due to the nature of these BCs (e.g., informative content vs. normative content), there will be some modifications to COP-001 to address these differences. Listed below are the stages of development which specifically address the differences for BCs development for each stage.

Throughout all stages of development, the Data Standards BC Curation Team is considered the governance body for BC content.

Stage 0: Scoping and Planning

- Identification and prioritization of BCs will be determined by the BC Curation Team.

Stage 1: Development of Biomedical Concepts

- Concept maps will only be created to aide in the understanding of BCs during development but will not be required or published.

Stage 2: Development of Draft Standards

- BCs are developed using a templated approach that aligns with the BC and Dataset Specialization Logical Data Models and follows documented BC Principles and Curation Guidelines.
- If new terminology or standards are needed, their development will follow the appropriate existing development and governance process.

Stage 3a: Internal Review

- The BC Curation Team will be responsible for performing an Internal Review by confirming accuracy of all BC Packages.
- The CDISC Data Science Team will execute structural and semantic validation checks.
- BCs will be available in the CDISC Library as provisional content.

Stage 3b: Public Review

- Public Review will last for approximately 30 calendar days.
- The BC Curation Team review and disposition all Public Review comments.

Stage 3c: Publication

- Conformance Rules and individual education courses are out of scope for the BCs.
- BC content will be approved as final and be publicly available through CDISC Library.

Stage 4: Standard Maintenance

- Final BCs will be updated and published quarterly or semi-annually depending on content volume.
- If an issue is identified and submitted to the BC Curation Team, it will be addressed with the appropriate change control process in a future version.