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CDISC Biomedical Concepts for Breast Cancer: A CDISC 360i Perspective

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ABSTRACT

Biomedical concepts serve as the essential semantic framework that connects and aligns various standards across clinical research. These concepts provide a common language for representing critical study data, ensuring consistency, accuracy, and interoperability across systems. By linking key standards such as USDM, SDTM, and ADaM, biomedical concepts enable seamless data flow and support regulatory compliance across diverse platforms. This paper explores the vital role of biomedical concepts in advancing data harmonization in the context of the CDISC 360i, an initiative designed to close gaps in data standards by adding the required semantic layer to enable end-to-end automation. Using a breast cancer use case readers will gain insights into how biomedical concepts are being applied to enhance data exchange and foster cross-disciplinary collaboration, paving the way for more efficient and transparent clinical research.

INTRODUCTION

Clinical research relies on standardized data structures to support regulatory submissions, cross-study analysis, and data interoperability. CDISC has developed widely adopted standards including SEND, USDM, CDASH, SDTM, ADaM, and Analysis Results Standard. While they define how clinical data should be structured, they do not always explicitly capture the clinical meaning of the observations being represented. Differences in interpretation across implementations can lead to inconsistencies and limit opportunities for automation. Biomedical concepts address this challenge by first defining the meaning of clinical observations independently from the data standards used to represent them. These concepts serve as a semantic layer that connects across standards and enables consistent interpretation of clinical data across systems. The CDISC 360i initiative leverages this approach by illustrating how biomedical concepts can be integrated across the clinical research lifecycle. This paper highlights the role of biomedical concepts within this framework and demonstrates their application using a breast cancer example.

CDISC BIOMEDICAL CONCEPTS

Biomedical concepts provide standardized definitions for clinical observations, measurements, and events. Each concept describes the clinical meaning of an observation and consists of two primary components, the conceptual layer and the implementation layer. The conceptual layer describes the clinical concept in the real world, independent of any study or data standard. The implementation layer describes how the concept is represented within a specific standard such as SDTM or CDASH. Separating these layers allows biomedical concepts to maintain consistent clinical meaning while supporting multiple implementations across systems and studies.

BIOMEDICL CONCEPTS FOR BREAST CANCER

CDISC Therapeutic Area User Guides (TAUGs) extend CDISC Foundational Standards to represent disease-specific clinical data. A series of TAUGs have been developed for several cancer types including breast cancer, colorectal cancer, lung cancer, pancreatic cancer, and prostate cancer. However, many concepts are shared across the oncology space. An analysis of the current CDISC Oncology TAUGs using ChatGPT, estimated that approximately 70–85% of oncology concepts represented were the same across all existing oncology TAUGs, while 15–30% were specific to individual indications.

This level of reuse highlights the value of biomedical concepts in supporting scalable metadata frameworks across oncology studies. In the breast cancer example, biomedical concepts help define key clinical observations such as tumor measurements, biomarker status, and disease progression. The SDS Oncology Team has been working on a version 2.0 of the Breast Cancer TAUG. As part of this work, the team has been creating biomedical concepts for both the conceptual and implementation layer (CRF and SDTM) to support future reuse in other areas of oncology as

well as machine readability.

BIOMEDICAL CONCEPTS IN CDISC 360I

The CDISC 360i is an initiative aimed at enabling end-to-end automation across the clinical research lifecycle. The initiative leverages biomedical concepts to help create a connected framework supporting study design, data collection, data standardization, and analysis. Within this framework, biomedical concepts serve as a central anchor connecting each stage of the workflow. Clinical meaning is defined once and reused throughout the lifecycle of a study. As part of the Phase 2 of the 360i initiative, a breast cancer use case focusing on progression-free survival will illustrate how both the conceptual layer and the implementation layer can support the development of a schedule of activities, study build, and analysis concepts.

CONCLUSION

Biomedical concepts provide a semantic layer that connects standards across the clinical research lifecycle. By defining the clinical meaning of observations independently from data standards, these concepts enable consistent interpretation of clinical data across study design, data collection, tabulation, and analysis.

The breast cancer example illustrates how biomedical concepts can support reusable metadata frameworks and improve traceability across oncology studies. Within the CDISC 360i initiative, biomedical concepts contribute to greater interoperability and support the broader goal of enabling end-to-end automation in clinical research.

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