GLOSSARY

Core Concepts

Activity: A specific task or function performed as part of a clinical trial process, contributing to the delivery of trial objectives.
Actor: An individual, team, organization, or system outside the primary system being described that interacts with it to achieve a goal.
Analysis Concept: A machine readable definition of an analysis. It describes the statistical method and specifies its formula and constraints, as well as its dependency to variables and how missing data is going to be managed.
Biomedical Concept: A structured, standards-based definition of a clinical or biological concept (e.g., vital sign, lab test, adverse event) that ensures consistent representation across digital protocols and data systems.
Category: A grouping mechanism that organizes related use cases, concepts, or design elements into higher-level clusters for easier navigation and alignment.
Class: A standards-based grouping of related biomedical or analysis concepts that share common properties and can be reused across studies.
Scenario: A textual description of the sequence of executed functions from input to output, including the triggering event and result.
System of Interest: Any application, platform, or infrastructure used to support clinical trial processes.
Use Case: A description of a set of interactions between an actor and a system that produces an observable and valuable result for the actor, without detailing the system's internal workings.

Roles

Ancillaries Supplier: An entity responsible for providing non-drug materials (e.g., devices, kits) needed for a clinical trial.
Central Provider: An organization or service that provides centralized trial-related activities (e.g., imaging, central lab).
Clinical Operations SME: A subject matter expert specializing in clinical trial operations, ensuring feasibility, compliance, and operational excellence.
Clinical Research Lead: An individual responsible for the scientific and operational leadership of a clinical study.
CT (Clinical Trial) Study Drug Manufacturing: A team or facility responsible for manufacturing the therapeutic product (e.g. study-drug, device) to be evaluated in the study.
IWRS Analyst: A specialist who configures and manages the Interactive Web Response System, enabling randomization and supply management in trials.
Investigator: A clinician responsible for conducting a clinical trial at a site, ensuring participant safety, protocol compliance, and data integrity.
Materials Inventory SME: An expert responsible for tracking and managing inventory of study materials and supplies.
Materials Packaging & Shipping: A team responsible for packaging therapeutic products and trial supplies, and managing logistics to sites.
Medical Writer: A professional who prepares scientific documents (e.g., protocols, clinical study reports) in compliance with regulatory and scientific standards.
Observational Model Library: A repository or collection of pre-defined data collection models for observational research studies.
Patient Data SME: A subject matter expert who ensures the appropriate capture, integration, and interpretation of patient-level data.
Patient-facing Site Staff: Personnel at the trial site who directly interact with patients, conducting visits, procedures, and data collection.
Patient Screening Facility: a healthcare organization that participates in the screening of potential study-subjects following relevant national/regional patient data privacy laws.
Regulatory Agency: A governmental body responsible for overseeing and authorizing clinical trials to ensure patient safety and compliance with regulations.
Regulatory Authority Representative: An official from a regulatory body responsible for reviewing and approving clinical trial documentation.
Regulatory Reviewer: An individual within a regulatory agency who assesses submitted trial documentation for compliance and approval.
Sponsor: The organization (often a pharmaceutical company) responsible for initiating, managing, and financing the clinical trial.
Sponsor Regulatory Representative: A representative of the sponsor who manages communications and submissions to regulatory authorities.
Standards SME: A subject matter expert who ensures clinical trial design, data, and processes comply with industry and regulatory standards.
Statistician: A professional who designs the statistical aspects of the study and analyzes trial data.
Study Designer: An individual responsible for defining the study design, structure, and elements in alignment with scientific and regulatory requirements.
Study Team: A cross-functional group responsible for planning, executing, and closing the study.
System: A software application, platform, or technological component that enables or supports specific clinical trial processes.
Trial Financial Analyst: A specialist managing financial aspects of the clinical trial, including budgeting, cost tracking, and payments.

Systems

Clinical Trial Management System (CTMS): A software system used to manage planning, tracking, and reporting of clinical trial activities.
Design Elements: The building blocks of a study design, such as arms, visits, endpoints, procedures, or data collection points, defined in structured form for reuse and downstream automation.
Digital Study Design: A study design represented in structured, machine-readable format, enabling automation, reuse, and integration across clinical trial systems.
Digital Study Design Elements: Structured representations of the components of a study design (e.g., eligibility criteria, endpoints, visits, procedures) that can be digitally authored, stored, and exchanged.
Patient Screening Facility Data System: a repository of patient health information owned and maintained by a healthcare organization.
Protocol Store: A centralized repository where final, approved study protocols are stored and accessed.
Regulatory Information Management System: A system that manages regulatory submissions, correspondence, and commitments across a study lifecycle.
Regulatory Trial Registry: A public or regulatory database where key trial information is registered (e.g., ClinicalTrials.gov).
Sponsor-Study Site Selection Database: A system containing information on potential and active study sites for feasibility and selection.
USDM-compliant Information Stream: A source and destination of digital study element information that is comformant to the USDM standard -- e.g. a study definition repository.
Trial Data Repository (eDC, eCOA, Sensors, etc.): A centralized storage location for trial data from various collection sources, such as electronic data capture, clinical outcome assessments, and devices.
Trial Site CTMS: A clinical trial management system used at the site level to track study activities.
Trial Site EHR: An electronic health record system used at the site to manage patient health information relevant to the trial.