Allucent®
Helping bring new therapies to light

Accelerating Submissions through Data Standardization and Compliance

CDISC: The Foundation for Submission-Ready Clinical Data

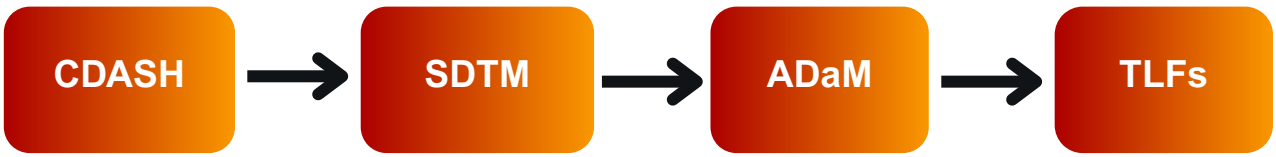
The Clinical Data Interchange Standards Consortium (CDISC) defines globally accepted standards for how clinical trial data is collected, structured, and submitted. These standards are required by the U.S. Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and are strongly encouraged by the European Medicines Agency (EMA).

Why It Matters

- Promotes **consistency and quality** across studies and systems
- Ensures traceability from source data to submission-ready formats
- Helps teams avoid rework and **minimize regulatory delays**
- **Accelerates timelines** — bringing therapies to market faster

The Core CDISC Standards

CDASH (Clinical Data Acquisition Standards Harmonization), SDTM (Study Data Tabulation Model), and ADaM (Analysis Data Model) are the core CDISC standards that support clinical data from collection through analysis — culminating in the generation of TLFs (Tables, Listings, and Figures) for regulatory review.



CDASH	SDTM	ADaM	TLFs
Standardizes data collection at the source	Formats collected data for submission	Creates analysis-ready data sets	Delivers the outputs for reporting and review

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Our CDISC Services

Ensure regulatory readiness and data integrity with our end-to-end CDISC support

CRF/CDASH Review

We begin preparing for CDISC compliant data by reviewing CRF forms during the development stage.

SDTM Dataset Generation

As soon as the EDC system has gone live, we process all collected data, including Case Report Forms (CRF)/Electronic Data Capture (EDC) entries and external data sources, to create SDTM datasets that adhere to CDISC standards.

ADaM Dataset Generation

From SDTM, our team develops ADaM datasets tailored to your Statistical Analysis Plan (SAP), ensuring they are analysis-ready and compliant with regulatory requirements.

We also perform end-to-end validation using Pinnacle 21 Enterprise to ensure that all SDTM and ADaM datasets meet regulatory standards for accuracy, structure, and compliance.

Regulatory Submission Packages

We prepare complete CDISC-compliant submission deliverables to support:

- INDs, NDAs, ANDAs, and BLAs
- Electronic Common Technical Document (eCTD) format
- Key components include:
  - define.xml files for both SDTM and ADaM
  - Clinical Study Data Reviewer's Guide: csdrg.pdf (SDTM package)
  - Analysis Data Reviewer's Guide: adrg.pdf (ADaM package)
  - Annotated CRFs (acrf.pdf)

Our packages are structured to meet FDA requirements and facilitate efficient regulatory review.

Specialized CDISC Services

We offer specialized expertise to support data needs beyond standard CDISC delivery.

Legacy Study Conversions

We integrate data across multiple studies to create pooled ADaM datasets and consolidated TLFs for ISS and ISE submissions, supported by define.xml and the Integrated Analysis Data Reviewer's Guide (iadgr.pdf).

Integrated Summaries of Safety and Efficacy (ISS/ISE)

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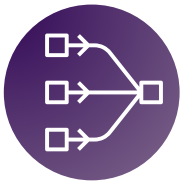


Bioresearch Monitoring (BIMO) Program Support

Develop site-level datasets and deliverables that provide insights into clinical site performance and data quality, including the BIMO Data Reviewer's Guide (bdrg.pdf), define.pdf, and by-site listings to support regulatory inspections.

Clinical Pharmacology Support for CDISC Standards

Our Clinical Pharmacology team provides specialized CDISC expertise for pharmacokinetic (PK), pharmacodynamic (PD), and immunogenicity data — ensuring alignment with regulatory expectations across early-phase and model-informed development programs.

Our services include:

- Interim PK/PD data review
- Noncompartmental Analysis (NCA)
- SDTM datasets for PK concentrations, PD parameters, and immunogenicity assessments
- ADaM datasets for pharmacokinetic and pharmacodynamic analysis
- Tables, Listings, and Figures (TLFs) with custom visualization support
- Data specifications to support Define.xml generation, and Abbreviated Reviewer's Guides (RGs)

We ensure all outputs are CDISC-compliant and validated for submission using tools like Pinnacle 21 Enterprise.

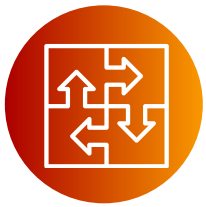
Your Trusted Partner for High-Quality, Submission-Ready Clinical Data

Partnering with Allucent provides access to a team dedicated to upholding the highest standards in clinical data services, ensuring your research meets regulatory requirements and achieves successful outcomes.

From early data collection to regulatory submission, Allucent delivers fully CDISC-compliant datasets, documentation, and analysis-ready outputs.

Our Biostatistics and Clinical Pharmacology teams bring deep expertise in SDTM, ADaM, and domain-specific data — ensuring every deliverable supports regulatory clarity, data integrity, and faster approval timelines.

End-to-end CDISC support from CRF design through eCTD submission



Integrated expertise across Biostatistics, Statistical Programming, and Clinical Pharmacology

Submission-ready outputs validated for FDA compliance using Pinnacle 21 Enterprise

Partner with Allucent to accelerate your path to approval — with structured, validated data that drives regulatory success.

Deliver quality data, faster

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