



CDISC SDTM Research Outsourcing Services

Our CDISC SDTM research outsourcing services ensure your clinical trial data is standardized, validated, and submission-ready, aligning with global regulatory authorities like FDA, EMA, and PMDA.

Our CDISC SDTM Research Capabilities

Our data managers, clinical programmers, and statisticians deliver fully compliant SDTM datasets, metadata, and define.xml files, supported by robust QA/QC and audit trails.

Types of CDISC SDTM Research We Handle

- SDTM Mapping from Raw Clinical Data
- CRF Annotation and Traceability
- Define.xml File Creation
- Controlled Terminology Implementation
- Validation and Compliance Checks
- SDTM IG v3.x to v4.x Conversion
- Legacy Data Conversion to SDTM
- ADaM Dataset Creation and Linkage
- ISS and ISE Data Preparation
- Integrated Study Data Mapping
- Standardized Medical Coding Integration
- Lab Data Normalization and SDTM LBs
- Vital Signs SDTM Domain Development
- Adverse Events SDTM Domain Preparation
- Exposure and Dosing Domain Design
- Pharmacokinetics Data in SDTM
- Device and Procedure SDTM Datasets
- SDTM Metadata QC and Harmonization
- Multi-Center Study SDTM Harmonization
- Therapeutic Area-Specific SDTM Design
- Custom Domain Development
- Automated SDTM Conversion Tools
- CDISC SDTM Compliance Validation
- Study Data Reviewer's Guide Drafting

- Define.xml and Reviewer's Guide Sync
- Dataset Transfer and Archiving
- Project-Specific SDTM Training
- Submission Package Compilation
- Regulatory Submission Consulting
- Custom SDTM Project Execution

Key Research Outsourcing Services Offered

- Raw Data Mapping to SDTM Domains
- CRF Annotation with Traceability
- SDTM IG Compliance Checks
- Define.xml Development and QC
- ADaM Dataset Creation and Linking
- Controlled Terminology Integration
- MedDRA and WHO-DD Coding Support
- Standard and Custom Domain Design
- Validation Report Generation
- Reviewer's Guide Preparation
- Legacy Data Conversion Solutions
- Multi-Study Data Pooling
- Automated Mapping Scripts
- Data Cleaning and QC Checks
- Cross-Domain Consistency Reviews
- Regulatory Audit Trail Documentation
- Clinical Study Submission Package
- Compliance with FDA, EMA, PMDA
- Data Transfer and Archival
- Progress Reports and Updates
- Publication-Ready Dataset Summaries
- Secure Cloud Data Storage
- Confidentiality and NDA Coverage
- Detailed SOPs and Technical Reports
- Post-Project Compliance Support
- Training Workshops for CDISC SDTM
- Long-Term Data Management Partnerships
- Custom Regulatory Consulting
- QA/QC Audit Support
- Submission Troubleshooting Assistance

Why Choose Us for CDISC SDTM Research Outsourcing?

Our experts ensure your datasets are fully CDISC SDTM compliant, saving time and costs during regulatory submission and enhancing reviewer acceptance rates.

Industries & Sectors We Serve

- Pharmaceutical and Biotech Companies
- Clinical Research Organizations (CROs)
- Medical Device Manufacturers
- Academic Medical Research Units
- Regulatory Submission Consultancies
- Global Clinical Trial Sponsors

Customized CDISC SDTM Solutions

We design flexible mapping plans, metadata templates, and validation workflows tailored to your therapeutic area and study design for seamless submissions.

Quality Assurance & Regulatory Compliance

Our processes adhere to CDISC standards, FDA and EMA guidelines, ensuring complete traceability, audit trails, and submission-ready packages.

Case Studies & Client Success Stories

Explore how our CDISC SDTM services have streamlined study submissions, improved compliance scores, and reduced review cycles. References available on request.

How It Works: Our Research Outsourcing Process

1. **Requirement Gathering:** Understand raw data, CRFs, and study endpoints.
2. **Proposal & Quotation:** Provide mapping plan, timelines, and cost structure.
3. **Execution and Mapping:** Perform mapping, validation, and compliance checks.
4. **Data Reporting:** Deliver validated SDTM datasets, define.xml, and guides.
5. **Post-Project Support:** Assist with submission troubleshooting and regulatory responses.

Frequently Asked Questions (FAQs)

Q: Do you handle legacy studies needing SDTM conversion?

A: Yes — we specialize in converting older study data to current SDTM standards.

Q: Can you prepare complete submission packages?

A: Absolutely — we deliver ready-to-submit SDTM packages with guides and metadata.

Q: How secure is clinical trial data?

A: NDAs, encrypted servers, and controlled access ensure complete data protection.

Get Started / Request a Quote

Contact us today to discuss your CDISC SDTM project and receive a detailed plan and cost estimate aligned with your submission timeline.

Contact Us

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