



# ACCELERATING SDTM SUCCESS

## EXPERTISE THAT ADAPTS

At the core of our clinical data services lies deep expertise in SDTM implementation. From global pivotal studies to specialized therapeutic research, we deliver regulatory-compliant datasets with adaptive timelines, high-volume processing capabilities, and rapid turnaround that pharmaceutical sponsors require for critical data deliverables.

### OUR SDTM CAPABILITIES: BUILT FOR COMPLIANCE. POWERED BY INSIGHT



#### EXPERTISE ACROSS SDTM STANDARDS

Since 2012, we've supported over 1,000 SDTM packages across IG versions 3.1.1 through 3.4.

Our services include:

- Package development (XPT files, Annotation CRF, Define-XML, and Clinical Data Reviewers' Guide)
- Regulatory gap assessment
- Revisions
- Version upgrades for FDA/PMDA/EMA submissions
- Enterprise data warehouse integration
- Legacy data conversion



#### COMPREHENSIVE STUDY TYPE SPECIALIZATION

Proven experience supporting SDTM implementation for:

- Clinical trials across diverse therapeutic areas
- Tobacco and nicotine product studies for CTP submission
- Medical device studies
- Non-clinical/animal studies with SEND requirements



#### OPTIMIZED WORKFLOW AND FRAMEWORK

Adaptive team architecture optimized for high-throughput processing demands with comprehensive end-to-end SDTM lifecycle support, featuring:

- Dataset creation and validation with proprietary tools
- Controlled terminology and dictionary management with version governance
- Multi-tiered QC review cycles with automated validation engines
- Metadata-driven SDTM libraries with enterprise data warehouse integration

# WHY CHOOSE US?



**Trusted for regulatory readiness**



**Accelerated timelines without compromising quality**



**Seamless collaboration with biostats, programming & data management**



**FROM COMPLEXITY TO CLARITY.  
FROM DATA TO SUBMISSION.**

## **ABOUT ClinChoice**

ClinChoice is a leading global full & functional service CRO, renowned for its exceptional product development and lifecycle management capabilities across the pharmaceutical, biotechnology, medical device, and consumer health sectors. With three decades of proven expertise and outstanding results, we excel in delivering top-tier services.

Our deep regulatory expertise, clinical trial execution, and robust pharmacovigilance and biometrics capabilities position us as a trusted partner in global markets. ClinChoice proudly maintains a strong presence across the Americas, Europe, and Asia-Pacific, ensuring comprehensive support for our clients worldwide.

### **HEADQUARTERS**

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