

**Have you experienced the Rapid SDTM Generation advantage yet?
By missing this opportunity, your statistical programming teams
are 35% less productive and you are 40% over budget!***

**CDISC and Pharma Industry
Leaders on SDTM Automation**

**Peter Van Reusel, Sam Hume,
CDISC-360 Mission**

“Apply the 80/20 rule to ensure the Project automates 80% of the end-to-end metadata and data processing needed to generate study artifacts suitable for a regulatory submission.”

**Keith Hibbetts, Eli Lilly and
Company**

“Both MDR solutions were able to demonstrate all of the points above, and the same level of automation was achieved with each solution. Those levels were 96% of the SDTM variables, and 81% of the ADaM variables.”

- ✓ Go from EDC and Raw Data to SDTMs within Days and 24 hrs refresh SDTMs.
- ✓ Metadata Repository System with 80% SDTM Auto-Mapping saves time.
- ✓ Increase SDTM accuracy by reducing potential human errors and ensuring data consistency.
- ✓ Audit Trail Automation and Traceability with Machine-Readable SDTM Mapping Specifications.
- ✓ SDTM and ADaM Submission Ready with Built-In Compliance Dashboards, Define.xmls and SDRGs/ADRGs.

**Driving
Success For Our
Valued Customers**

We thank our customers for their trust shown in us and take pride in our accomplishments.



Global Team
US – India – Europe




5 of top 15 Pharma
Clients




10+ Years
Experience in Life
Science

**Manage Projects
with Automation
and Standards**




- ✓ One SCE integrate tool for all Submission Deliverables
- ✓ Reduce Time and Budget per Clinical Study

**Manage Submission
Process with Low-Code
Programming**




- ✓ Reduce writing SAS programs and macros
- ✓ Faster SDTMs, Define.xml and SDRG
- ✓ Auto Generate SDTM Mapping Specifications

**Monitor Safety Data
Issues with Early Alerts**



- ✓ Faster Ingestion, Curation and Harmonization
- ✓ User Interface to create SAP Cohorts

**Explore with Pre-
defined Templates**



- ✓ Reduce Time to Tables, Lists and Figures
- ✓ Drill down from summary to patient level detail

About PointCross

Platinum member of CDISC and contributor to PhUSE



Serving 60+ Biotech, CROs & large Pharma clients

Xbion is our BioPharma solutions platform for:

- ✓ Research insights from nonclinical and clinical studies, assays, biomarkers
- ✓ Validated workflows for regulatory nonclinical and clinical submission preparation
- ✓ Automated Smart Transformation for data curation from data lakes to target model
- ✓ Governance and continuous management of standards, terminology, metadata
- ✓ Trial and study data repository with role based access and controls