

Reproduction & Teratology

Pristima[®] XD Core is a fully integrated, end-to-end enterprise solution for tracking and managing veterinary facilities and research subjects throughout the preclinical research process.

For over 40 years, global pharma companies and CROs have relied on Xybion to drive data collection workflows while ensuring quality, efficiency, and compliance.

Need flexible deployment?
Xybion offers on-premise or hosted solutions.

Are You SEND Ready?
Pristima[®] XD Core's Savante[™] module provides the most automated solution to produce SEND datasets.

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Comprehensive Laboratory Data Management

*Pristima[®] XD Core's preclinical data management suite employs a phase-based study protocol and data management philosophy. The system is designed to address the requirements of **General Toxicology and Reproduction/ Teratology** study designs.*

All measurements available for adult animals in the Animal Room, Necropsy Room, and Clinical Pathology modules are leveraged for Reproduction/ Teratology studies. Additionally, capabilities may be licensed to manage dam, fetal and pup measurements, including estrus cycle data, mating data, interim and final cesarean section data and fetal observations. The capability to collect and maintain litter data and pup developmental and behavioral observations is also included. Observational data is entered from user-defined master tables and may be defined in two languages.

Data Management and Reporting Features

- Estrus cycle evaluation
- Mating/fertility data
- Interim and final c-section data
- Fetal pathology
- User-defined template formulation instructions
- Wide variety of formulation types
- Litter data (signs, weights, mortality)
- Culling/weaning activities
- Developmental milestones
- Behavioral evaluations
- Fully integrated component of the Pristima[®] XD Core
- 21 CFR Part 11 electronic signatures and audit trail compliant

Software Validation

Preclinical research clients using Pristima[®] XD Core must comply with GLP guidelines which require validation of all laboratory information management systems. Our experts deliver timely services in compliance with current guidelines and best practices to ensure a successful, timely, and cost-effective validation project.

- Project management
- Requirements documentation
- IQ/OQ/PQ test protocols
- Custom user guides
- Validation trace matrices
- Validation report