



## Comprehensive Data Warehouse, Analytics, and SEND Management System



Savante is a seamless solution for nonclinical data query consolidation analytics and reporting.

Assemble data sets from multiple sources and format data for CDISC-SEND output and reports. And move beyond basic reporting.

Integration with TIBCO Spotfire enables flexible just-in-time data analysis and visualization.

## Comprehensive Data Warehouse, Analytics, and SEND Management System

Savante is designed to support the workflows of study directors, toxicologists, pathologists, and data scientists, enabling consistent views of study data, regardless of the source. Whether coming from internal sources or external partners, you can be sure the data will be the right format, readily accessible in a variety of formats.

### Key Benefits

Savante automates the preclinical data management workflow by allowing you to:

**Format and consolidate study data based on CDISC-SEND standards.** Take data in from a variety of formats and consolidate it, assembling it into a SEND-compliant format.

**Aggregate data from multiple sources.** Savante takes in data from a variety of formats, consolidates it, and assembles it into a SEND compliant format. The define.xml file that is required as part of the submission is created automatically.

**Automate data collection.** Synchronization from Pristima XD Core makes data collection from instruments seamless. Savante can accept XPT format from CROs or other systems, and this data can be augmented with data in CSV or Excel data files.

The screenshot shows the Savante web application interface. At the top, there's a navigation bar with 'Pristima XD' and 'Savante' logos. Below that, there are tabs for 'Studies', 'Study Setup', 'Controlled Terminology', 'Output', 'System Migration', 'Help', and 'Logout'. The main content area displays a table titled 's330390\_View/Edit'. The table has columns for 'Study Identifier', 'Domain Abbreviation', 'Unique Subject Identifier', 'Result or Finding as Collected', 'Unit of the Original Result', 'Standardized Result or Character Format', 'Standardized Result or Numerical Format', 'Unit of the Standardized Result', 'Examination Status', 'Reason Not Done', 'Baseline Flag', 'Fasting Status', 'Exclusion Flag', 'Reason for Exclusion', 'Planned Study/Day of Collection', and 'Date/Time Animal Weighed'. The table contains 12 rows of data, each with a checkbox in the first column. At the bottom of the table, there are controls for 'Show rows 10' and buttons for 'Add', 'Delete', 'Print', and 'Cancel'.

Study Identifier	Domain Abbreviation	Unique Subject Identifier	Result or Finding as Collected	Unit of the Original Result	Standardized Result or Character Format	Standardized Result or Numerical Format	Unit of the Standardized Result	Examination Status	Reason Not Done	Baseline Flag	Fasting Status	Exclusion Flag	Reason for Exclusion	Planned Study/Day of Collection	Date/Time Animal Weighed
<input type="checkbox"/>	s330390	BW	s330390-101	223.0	g	242.0	223	g	Y					-1	2007-11-19 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-101	54.0	g	544.0	54	g	Y					1	2007-11-20 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-101	170.0	g	170	g	g	Y					8	2007-11-27 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-101	188.0	g	188	g	g	Y					15	2007-12-4 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-101	300.0	g	300	g	g	Y					22	2007-12-11 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-104	138.0	g	138.0	138	g	Y					-1	2007-11-16 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-104	133.0	g	133.0	133	g	Y					1	2007-11-22 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-104	132.0	g	132.0	132	g	Y					8	2007-11-27 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-104	154.0	g	154.0	154	g	Y					15	2007-12-4 0:0:0-4
<input type="checkbox"/>	s330390	BW	s330390-104	188.0	g	188.0	188	g	Y					22	2007-12-11 0:0:0-4

Figure 1. Ensure GLP data integrity by importing multiple data sets into a study then view or edit each domain as needed.

- Perform flexible data analysis and visualization. Savante offers an integrated solution with TIBCO's Spotfire for making non clinical study data from in-house studies or partners accessible for cross study analysis.

## Xybion Your Expert Partner

- Xybion has over 20 years of experience managing laboratory workflows and helping clients streamline compliance and mitigate risk.
- Xybion has extensive global experience and works with companies of all sizes from multiple industries.
- Xybion offers deep domain knowledge of FDA regulations and has a long track record of helping clients build effective body risk mitigation strategies.

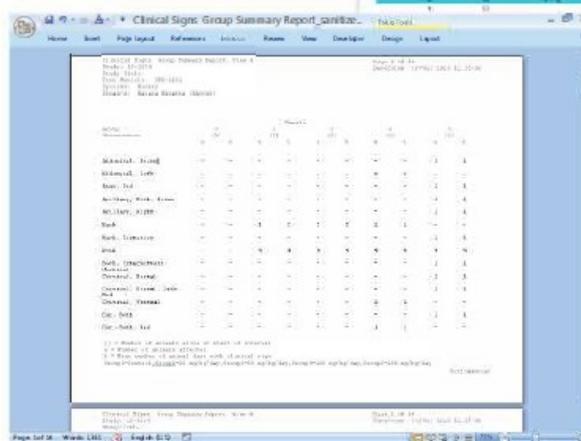
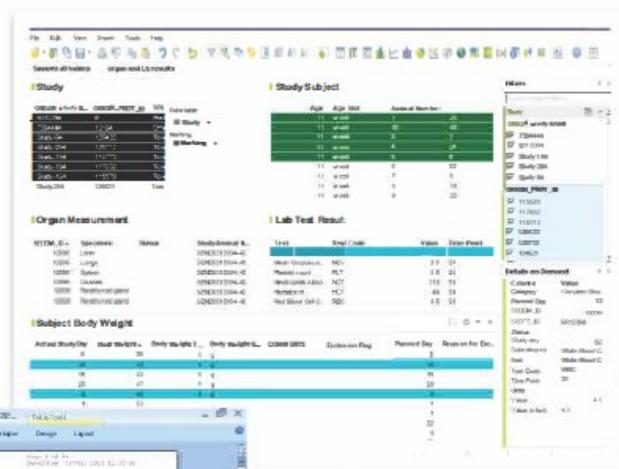


Figure 3. Dashboards can be created to summarize the data. View selections from studies through study groups, study animals and drill down into specific lab X

Figure 4. Create reports in Word and PDF formats. These reports are taken from the same data as the SEND submission and can be part of your submission package or used for internal verification.

## About Xybion

Xybion is a leading SaaS company dedicated to providing life sciences and health systems companies with innovative software solutions to accelerate the transformation of today's inventions into tomorrow's approved medicines, devices, and diagnostic tests designed to save lives and keep employees safe. Our intelligent cloud platform and software solutions help companies accelerate digital transformation of processes, speed up innovation, optimize operations, reduce compliance risks, and achieve significant cost savings.

biopharmaceutical companies. Xybion's global scale and expertise brings employees around the world to help companies in life sciences, health systems, research institutions, and governments. We help companies digitally transform their regulated business operations. Our unique solutions focus on employee health and safety, integrated preclinical lab management, early-stage drug discovery, digital lab solutions, regulatory compliance, GRC, quality management, predictive compliance, content management, and systems validation.

Xybion is serving over 160 customers in 29 countries including all the top 20 global

