POINT CROSS Life Sciences

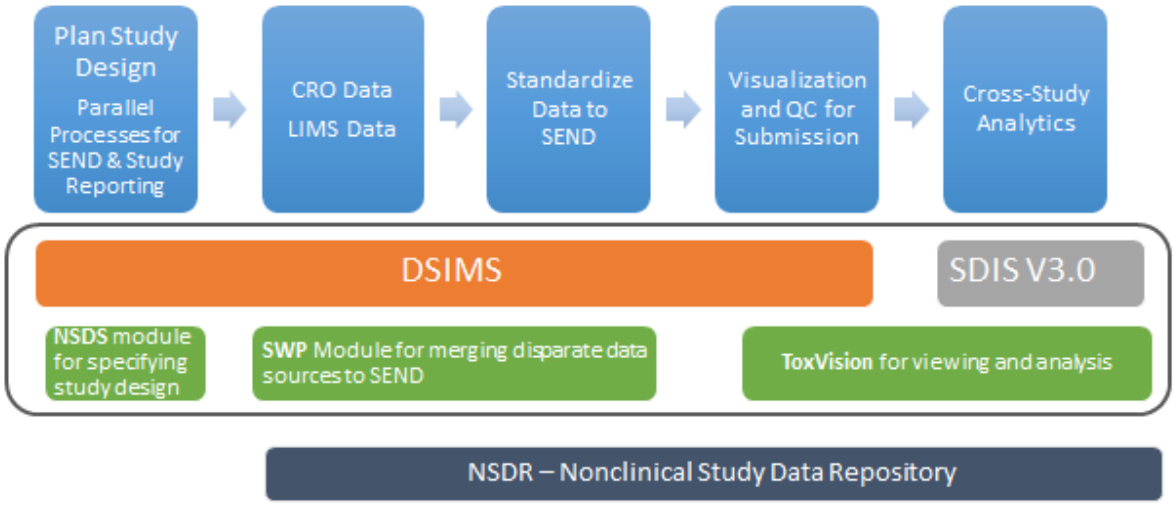
DSIMS™ Software-as-a-Service

Specify, Validate, Package and Review SEND data for FDA Submissions

DSIMS™ is the commercial version of the NIMS solution acquired by the FDA for storing, validating and reviewing nonclinical submissions in the CDISC SEND format. Use of DSIMS by CROs and sponsors reduces the costs and time required to specify and prepare SEND datasets.

Converting data from a single source, such as a specific LIMS system is not a difficult task. The challenge DSIMS addresses, and the value it provides, is the ability to merge many disparate data sources into a single SEND dataset that is compeltely consistent with the study report.

In addition to solving issues around data merging, DSIMS also includes the ToxVision module for visualization and analysis. With DSIMS, you will build a valuable long-term data repository for all of your studies to support reporting, historical reference ranges, analytics and cross-study signal detection.



DSIMS consists of three modules to manage your SEND process:

- ✓ The **Nonclinical Study Data Specification module (NSDS)** specifies the SEND or LIMS data that must be provided for merging and packaging into a single SEND study. NSDS includes the capability of specifying the SEND related Trial Design, applicable domains and the format for subject names.
- ✓ The **Study Workflow Process module (SWP)** automates the merging of SEND and non-SEND data sources into a complete SEND data package with the Study Data Reviewer's Guide and define files required by the FDA. It provides controls for versioning SEND controlled terminologies, data models, define.xml and FDA validator rules. Study data and audit trails are stored in the data repository.
- ✓ **ToxVision** reduces the costs of conducting data quality checks. It provides scientists with analysis tools, group summary and tabular/immersive graphical views designed with FDA reviewer inputs.