SEND Intelligence Services

SEND Services for Life Sciences

Xybion

SEND Intelligence Services

Your Trusted SEND Expert

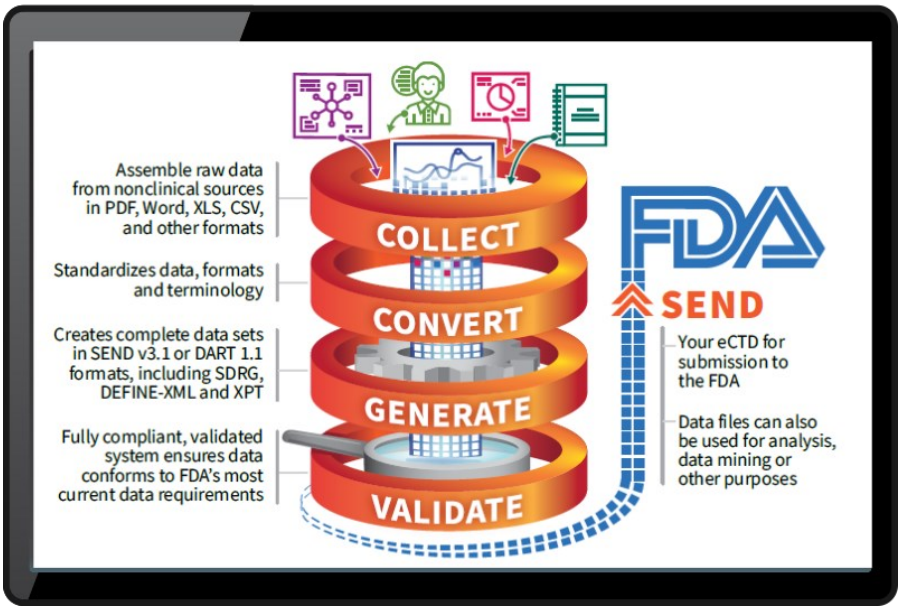
SEND is a standard for the collection and formatting of nonclinical data so that it may be included in preclinical data submission to the FDA and other regulatory bodies that adopt the standard. By standardizing the format in which the data is submitted, SEND naturally impacts data collection and aggregation by harmonizing study designs and normalizing the terminologies used by scientists today. This homogenization of the preclinical data facilitates and leads to efficiencies on the part of the reviewers, accelerating the regulatory review process for NDA, IND and certain BLA submissions.

Importantly, with the standardization of data formats and the normalization of the terminologies used in the data set, the SEND standard also provides a long-sought transport mechanism by which CROs may transmit data to their Pharmaceutical clients for purposes other than submissions, such as data analyses and data mining. Business partners can also use this standard to transfer study data when the rights to compounds are transformed

With the SEND mandate in effect since Dec 17, 2017, Life Sciences organizations – specifically CROs and Sponsors – have been busy evaluating the most efficient and ideal ways to manage SEND internally and with their external partner ecosystems. CROs who create SEND files and Sponsors who are responsible for complying with SEND are assessing vendors and developing strategies to lessen the impact SEND has on their everyday business. Organizations with very little room for error require the right business partner to provide expert SEND guidance in the areas where they truly need it and not a “one size fits all” approach.

Additionally, with the passing of the March 15, 2019, v3.1 deadline requiring Safety Pharmacology domains for NDA and some BLA submissions, SEND has become even more complex to manage.

Xybion has developed a clear set and structured line of services and solutions that meet organizational needs across the SEND spectrum. Xybion proudly and confidently introduces our SEND-as-a-service platform, cou-



SEND Conversion Services

Xybion has invested in dedicated expert resources for the sole purpose of assisting our customers and their study partners with the creation of SEND files for submission. SEND Intelligence Services enable us to automate the transformation of your raw data files of preclinical research and the production of SEND data sets without the need to acquire a new system or increase staff. As part of our service, we utilize our own Savante® software. Savante is one of the first on the market to achieve full compliance with SEND IG v3.1 with a validated solution.

>> Study data collected manually or from any third-party system

>> Study data/report in PDF, Word, .xls, .csv or other formats – Data in.xls or .csv can be loaded directly

>> Can output to SEND IG v3.0 or v3.1 as well as DART 1.1 for reproduction studies

>> Controlled terminology mapping using the latest (or a selected) CT version

>> Automatically creates and validates SEND outputs (SEND data sets, Define-XML & drafts the nSDRG)

>> QC compliance checked against the Study Data Report and its tables

>> Final SEND output ready for delivery

>> SEND data sets in .xpt for regulatory submission. Data can also be output as .xml or .csv files

Our comprehensive set of deliverables ensures that you receive a complete SEND package ready for submission. Organizations are adopting SEND as the format of choice for data analytics and visualizations across their nonclinical data repositories. Xybion can utilize our SEND Intelligence Service to quickly convert legacy study data into SEND files for a homogeneous nonclinical data format across your portfolio. Organizations also utilize our SEND study services as a release valve for study conversion backlogs during peak customer demand or shifting internal priorities.

SENDVerify Service

Xybion's SENDVerify Service delivers an independent expert review of customer's completed SEND package to ensure quality and compliance throughout the file. SENDVerify is system- and source-agnostic, and serves as a final quality checkpoint to ensure that the SEND file accurately represents the study data prior to submission. A full summary, including review outline and detailed findings is provided upon completion of the verification process.

>> We receive the Study data already in SEND format (which is created either by CROs or internally by the Sponsors) and the Final Study Report and Protocol

>> Nonclinical Study Data Reviewer's Guide (nSDRG)

>> Xybion's SEND experts perform data validation & SEND data set compliance check

>> Xybion's SEND experts compare SEND data sets, Define-XML, and nSDRG against the Study Report and Protocol to find and document any discrepancies

– We can then return to you the suggested changes to be made by either the CRO or Sponsor who originally created them, OR we can correct the SEND data sets, Define-XML, or nSDRG materials according to the findings

SEND Education Courses

Xybion meets the educational needs of organizations based on their maturity level with SEND. Whether you are a beginner or a SEND expert, we provide structured learning modules for practical application across the business. As an active member of both CDISC and PhUSE SEND work groups, we have the expertise to provide a fully-structured learning agenda based on your organizational and human capital needs.

Subject matter includes:

>> In-scope studies and overview of required domains

>>Interchange of SEND data and process of preparing a SEND data set

>> SEND study design concepts

>> SEND best practices

>> Contents of a completed SEND data package (FDA validation ruleset, SDRG, Define-XML, CT, current IG and data files)

>> Custom developed agendas to address mixed audiences

Call Today to speak with a SEND Expert

Click Here to Learn More about SEND Intelligence Services

Or

Call 844.291.4430 or email sales@xybion.com

SENDConsult

Many organizations struggle to fully understand the steps required, and in some cases, the investment in the systems to confidently manage SEND. Regardless of organizational size, Xybion can provide client-specific SEND advisory services tailored to any area of SEND management and compliance should customers require additional guidance. Xybion has provided SEND advisory services to the most prestigious Pharma, BioPharma, Biotech, and CROs, as well as small startups in Cambridge and the Silicon Valley. Xybion will work with internal and external resources to identify challenge areas and identify the most ideal and efficient way for your organization to manage SEND.

>> Fully outsourced SEND management
>> SEND consultancy services
>> SEND implementation support
>> SEND expert support
>> Prepare organizations, nonclinical departments, cross-functional teams and individual resources to comply with current regulatory standards
>> Nonclinical data management support throughout the SEND lifecycle
>> SEND submission test-pilots
>> Manage expectations with your external study partner ecosystem

SEND Intelligence Automation

Xybion's SEND Intelligence technology allows us to convert and verify data sets quicker and more accurately than other manual process vendors. Utilizing Savante, our industry-leading SEND solution, we've been able to automate much of the workflow for creating, quality-assuring and verifying SEND files for customers. SEND Intelligence technology has transformed what was once a manual, time-consuming, and end user heavy process into a seamless automated workflow. As a result, we are able to provide customers with a more cost-effective service completed ahead of expected deadlines. Whether you require a solution to create SEND data sets, or services to convert data into SEND format, our SEND Intelligence technology provides an edge in time and cost unseen in the SEND marketplace.

With the standardization of data formats and the normalization of the terminologies used in the data set, the SEND standard also provides a long-sought mechanism by which CROs may transmit data to Pharmaceutical clients for purposes other than submissions, such as data analysis, data visualization, and advancing research and development across the drug portfolios.

About Xybion

Xybion is a leading software, services, and consulting company dedicated to helping corporations solve business problems. Through intelligently designed systems and business processes, we help companies become more efficient, reduce costs, manage compliance, regulatory adherence, and risk. Serving clients in 16 countries, we have the global scale and expertise to bring employees around the world together to manage complex business processes and improve program administration. Xybion business segments include life sciences, workplace health, manufacturing, government, and enterprise solutions. We put our expertise into action every day to help companies transform the digital workplace.

Xybion has grown through acquisitions and organically since its inception in 1977. Xybion today is the result of a successful execution of a strategic vision of creating a global solutions company with specialized software and services.

Ever since its inception, Xybion has supported over 150 clients including all of the top 20 global Pharmaceutical companies. Now, with its digital acceleration platform, Xybion offers Platform-as-a-Service (PaaS) or individual modules for three major domains including Digital Lab for Life Sciences & Healthcare, Risk, Quality & Compliance, and Workplace Health & Safety.

Our Offices

Global strength…Local footprint

Xybion supports clients across the globe. We provide compliance, quality management and preclinical software, and a host of validation and compliance consulting services to the leading Life Sciences companies and other global companies working in highly regulated industries. Our offices are strategically positioned to best serve our customers at a local level.

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