# Xybion Announces SEND Intelligence Service

**Xybion is providing a holistic, artificial intelligence driven, automated and integrated solution to the life science organizations to help meet SENDIG v3.1 submission requirements effective from March 15th, 2019 for NDA / BLA submissions to FDA**


**Lawrence, Sep 21, 2018 (**Issuewire.com**)** - Considering the sense of urgency to meet SENDIG 3.1 deadline and the need to improve data capture, data processing and report efficiently, Xybion, a US-based global technology-enabled business solutions provider for companies operating in the highly regulated industries, announced today that it has launched “SEND Intelligence Service” for SEND IG v3.0 and v3.1. This is a fully integrated technology and service bundle offers that will help CRO and sponsor companies to simplify processes, capture data right and identify data issues automatically for SEND ready dataset right the first time.

Beginning March 15, 2019, all the Life Sciences Organizations must align their nonclinical datasets with SENDIG 3.1 (Standard for Exchange of Nonclinical Data). However, as per the PhUSE 2018 report, over 41% of Life Sciences Organizations are either not ready for SENDIG v3.1 or intend to have ad-hoc strategies for SENDIG v3.1 submissions. Nearly half the time, the sponsor organizations are facing issues while exchanging and consolidating SEND data with the CROs. Companies that are SENDIG ready are facing significant data challenges resulting in submission delays and a large consulting spend to make data reportable.

With the introduction of Labwise™ and the upgraded version of Savante™ that works seamlessly with Pristima® and other pre-clinical data management solutions, Xybion established a right solution for Life Sciences Organizations to streamline their nonclinical datasets in compliance with the latest standards of CDISC-SEND submissions. In the recent years, Xybion’s has produced over 1000 SEND v3.0 submissions. Now, it’s fully integrated, automated and intelligent products and services will produce both v3.0 for on-going studies and v3.1-compliant datasets for studies that run in any pre-clinical systems.

Kamal Biswas, President, and COO of Xybion said “The SEND-as-a-service business has been an exciting growth opportunity for Xybion. From my consulting experience, I could understand that the

industry needed to solve this problem by combining technology and services together. The early automated detection and correction of data issues can make the process much more efficient, error-free, cost-effective and significantly reduce data integrity issues. We thank our client community which provided detailed guidance and assistance throughout the six-month beta testing period that led up to the release; this beta program was invaluable and assures the functionality and quality datasets to be submitted to the FDA."

Xybion offers SEND-related services to the companies looking to improve their current operations and companies with limited expertise or SEND utilities in-house. Carlos Frade, VP of Pre-clinical R&D Solutions, stated "For those clients who conduct preclinical studies without the use of Pristima, or who utilize CROs that do not provide SEND-compliant submission datasets, Xybion can provide this expertise immediately and cost-effectively. Our arsenal of tools has been greatly expanded with this release."

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