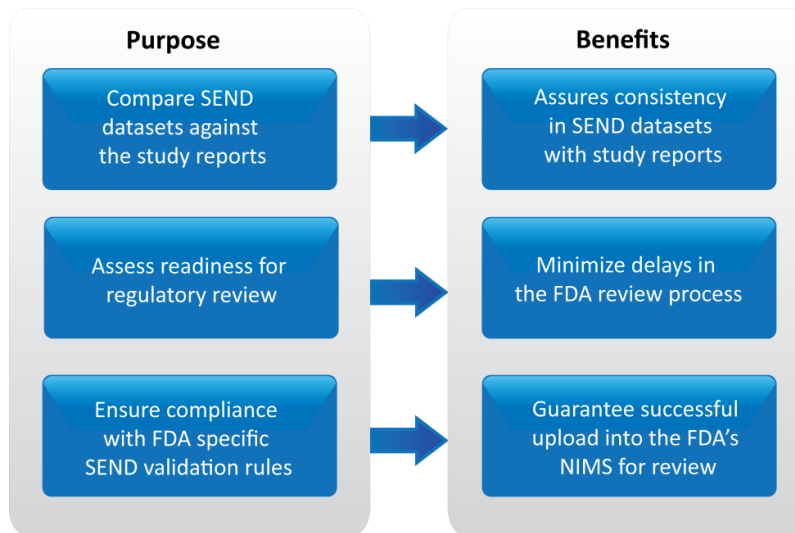POINT CROSS Life Sciences

SEND-ASSURE™

Assuring your SEND Datasets are Consistent with your Study Report

The major challenge to both industry and FDA continues to be ensuring consistency between the SEND dataset and study report. This is because SEND datasets typically require multi-site coordination of CROs, LIMS systems and in-house labs. The task of accurately merging the source files is more challenging than the industry expected. Due to the discrepancies we've seen in datasets we created the SEND-ASSURE service to ensure your final SEND submission is fit-for-review.

SEND-ASSURE

Purpose

- Compare SEND datasets against the study reports
- Assess readiness for regulatory review
- Ensure compliance with FDA specific SEND validation rules

Benefits

- Assures consistency in SEND datasets with study reports
- Minimize delays in the FDA review process
- Guarantee successful upload into the FDA's NIMS for review

What you receive from SEND-ASSURE

- ➢ SEND-Assure report detailing:
  - A summary of the discrepancies found between the SEND datasets and study report
  - A summary of the discrepancies identified in the SEND datasets against the version of the SEND IG and SEND CT used to standardize the data
  - A summary of the errors and warnings identified during validation of the SEND datasets with the Pinnacle 21 and NIMS validators.
  - Suggestions to mediate any validation and SEND conformance issues identified by the PCLS data services team
- ➢ NIMS Validator Report: the results of validation of the dataset against the NIMS validator
- ➢ Pinnacle 21 Validator Report: An Excel file that contains the results of validation of the dataset against the Pinnacle 21 validator
- ➢ Pinnacle 21 Validation, set to DEFINE standard, of the Define.xml file
- ➢ Modifications/suggestions for the SDRG

Silver Spring, MD   Foster City, CA   Paris, France   Bangalore, India