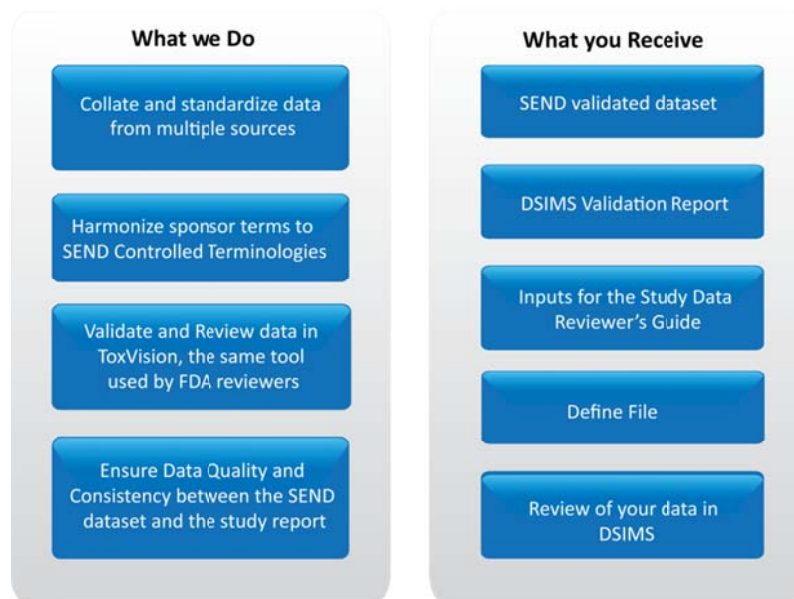


## Data Standardization Services

Receive a SEND package guaranteed to load into the FDA's Nonclinical Portal

PointCross delivers high quality SEND datasets consistent with FDA requirements and your study report. Our data services team includes industry leading toxicologists and data specialists who work directly with FDA reviewers and serve on CDISC/PhUSE teams. We have hands-on knowledge of FDA expectations, SEND standards and ToxVision™; the same visualization tool acquired by FDA for their reviewers. To date, we have standardized over 6,000 studies, and this collective expertise gives us a unique advantage to ensure that your datasets are properly standardized and fit for agency review.

### Data Standardization



### What you receive

- The guarantee that your SEND datasets will load into the FDA's Nonclinical Portal
- A define file consistent with the contents of your SEND submission
- FDA specific SEND rules validation report
- Excel report containing results of validation of the dataset against the Pinnacle 21 Validator
- Pinnacle 21 validation report, set to DEFINE standard, of the Define.xml
- Study Data Reviewer's Guide inputs

### Benefits

- Your SEND package is created by SEND experts who work directly with FDA reviewers
- Our data services specialists ensure consistency between SEND datasets and study reports
- Established tools and processes for standardizing and merging data from many sources