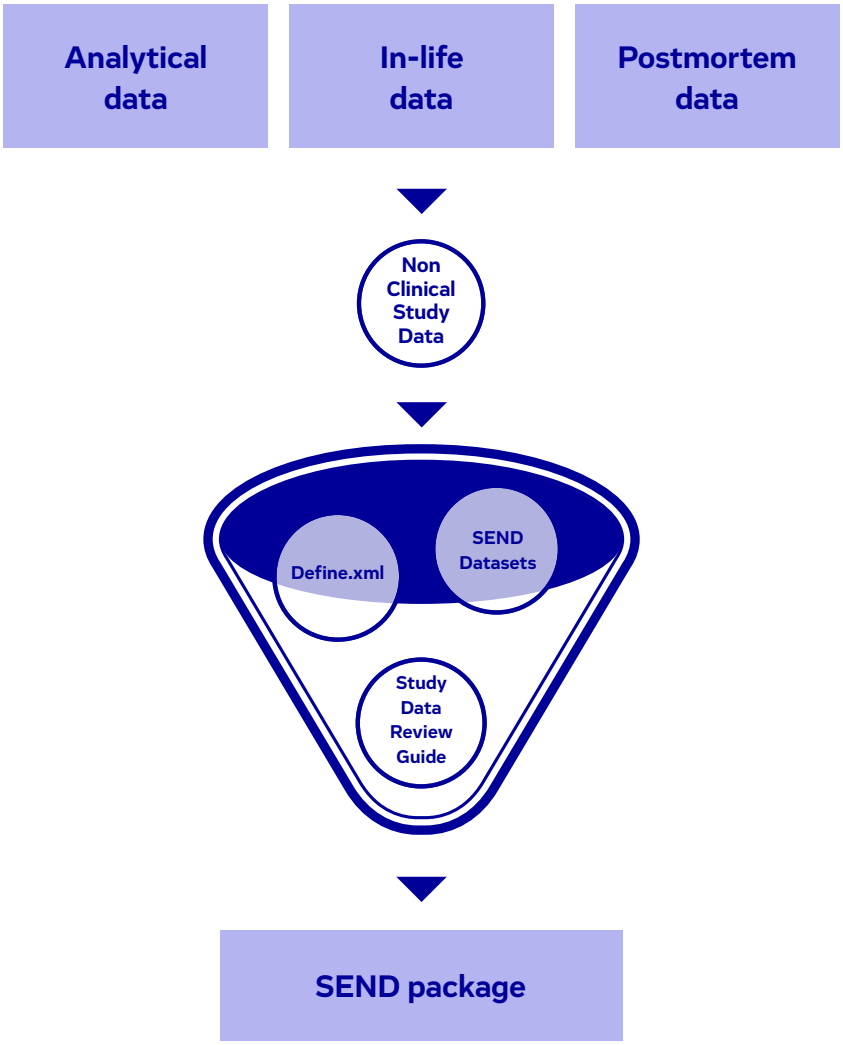
evotec

#RESEARCHNEVERSTOPS

SEND (Standard for the Exchange of Non-clinical Data)

- High quality service for internally and externally executed preclinical studies
- More than 10 years of experience in data management
- Cutting-edge technology for data collection, management and presentation
- SEND data sets provided within 10 days of the report date
- More than 100 SEND packages standardised with 100% successful submission



The Standard for Exchange of Non-clinical Data (SEND), an implementation of the CDISC Standard Data Tabulation Model (SDTM), identifies an approach for representing non-clinical data in a structured format which has been widely adopted by the pharmaceutical industry as it is required for data submission to FDA. SEND has become analysis data model for toxicology data and represents a significant opportunity to apply analytics and modelling across multiple studies.

Evotec Standardization Framework

- Complete knowledge of CDISC-SEND domain and related compliance requirements
- Complete control of the standardisation process (no black box perception)
- Flexible solutions to:
  - Promptly and independently adopt any new controlled terminology version
  - Promptly and independently adopt any new SEND standard version released
  - Develop adapter (data-model focused) to
    - integrate with any additional external legacy system
    - read raw data externally generated (format independent)
  - Manage and adapt framework configuration in case of complex study design

Data Standardization Service Deliverables

- For internally and externally executed studies
- SEND Standardised datasets in XPT format
- Define.XML files compliant with CDISC specifications
- Study Data Reviewer's Guide (nSDRG)
- SEND dataset and define.xml validation reports generated by Pinnacle21 validator

3rd Party SEND Verification Service Deliverables

- Discrepancies between SEND datasets and Study Report
- Discrepancies between datasets and FDA standards requirements
- SEND dataset and define.xml validation reports generated by Pinnacle21 validator
- Suggestion how to solve SEND conformance issues identified by Verification Service

Studies Supported

- General toxicology
- Carcinogenicity
- Safety pharmacology: Cardiovascular & respiratory
- Non-GLP studies included in a regulatory submission
- Abbreviated Trial Summary file for legacy studies in submission

Additional Benefits of SEND for:

- Evotec Study Directors
  - Study monitoring and study analysis can also be enhanced by the ability of SEND datasets to be used with a visualisation tool
  - Faster study data controls comparing data from different sources/LIMS increase the controls on the data
- 3Rs application
  - Clinical Score sheet
  - Severity Limits Score Sheets