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Data Curation for Preclinical Safety reports

A US-based large pharma company, partnered with Excelra to digitize their preclinical studies in dogs in SEND format which were required to submit for regulatory filing.



CASE STUDY

Client



Industry
Big Pharma



Services used
PTRD curation, ClinPharm

Results

Data extracted from the preclinical studies in dogs were validated, digitized, and delivered in .xpt format to submit for regulatory filing.

A metadata file of the SEND file was shared with the client.

Specification

- The client had considerable toxicity data in the form of unstructured and undigitized pre-clinical assay reports associated with assets in their portfolio that needed to be digitized for any future regulatory filing.
- There were several carcinogenic and animal toxicity studies.
- Part of this pool was a 991-page report associated with toxicity studied in canine models that were required to be digitized, validated, and annotated in the prescribed SEND format that could then be used for filing for a high-value asset in the client's portfolio.

Our approach

- We gathered the scope from the client as to what files needed to be curated, the length of the report, variables to be included in the output file, and the format for the output file.
- Leveraging Excelra's Preclinical Tox Report Digitization (PTRD) curation service, we manually reviewed the client's Preclinical Safety (PCS) report.
- After examining the full report, 30 data sections were created and segregated into 3 domains. All the data in the report was mapped to relevant data sections and each section was converted to xpt using R.
- The data was finally validated using PINNACLE™(Free) and a .XML file was generated for the metadata as well.

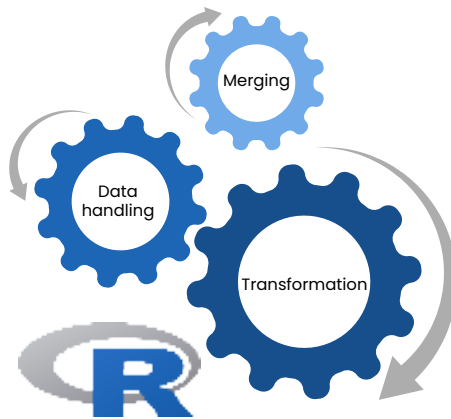
Data

Data handling and PK analysis

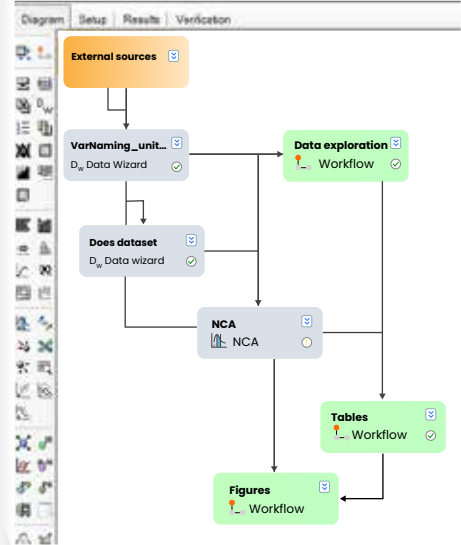
Study reports



Custom curation

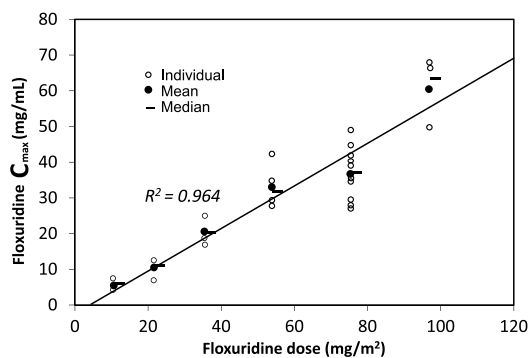


Non compartmental analysis

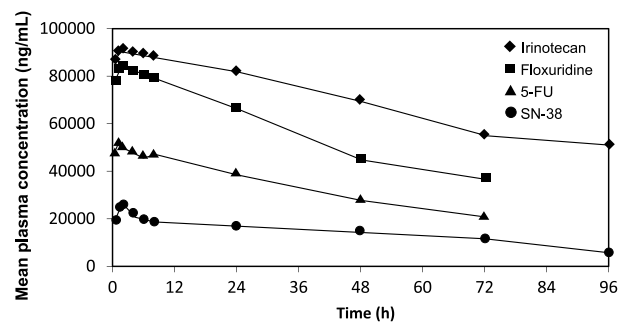


Assessment of exposure and relating exposure to safety and efficacy

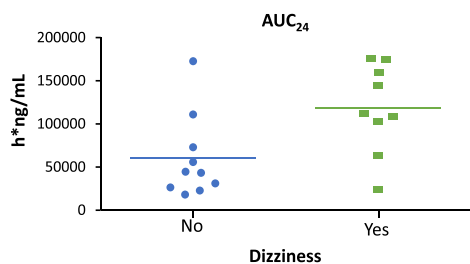
Exposure vs exposure



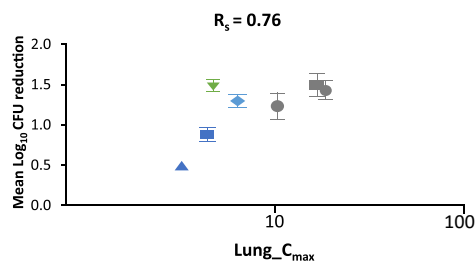
Concentration vs time



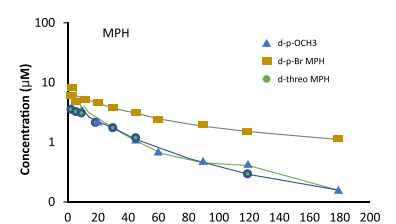
Exposure vs toxicity



Exposure vs efficacy



Compare interventions



Results

- We delivered a validated .xpt file to submit for regulatory filing for the preclinical safety studies done on dogs.
- A .XML file for the metadata of the SEND file was shared.
- Our curation services helped the client successfully receive their reports in a prescribed SEND format required to submit for regulatory filing with validated content.



Where data means more

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