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Structuring Investigator's Brochures

A US based large pharma company approached Excelra to digitize and create a structured data model for their Investigator's Brochures.

CASE STUDY

Client
Big Pharma

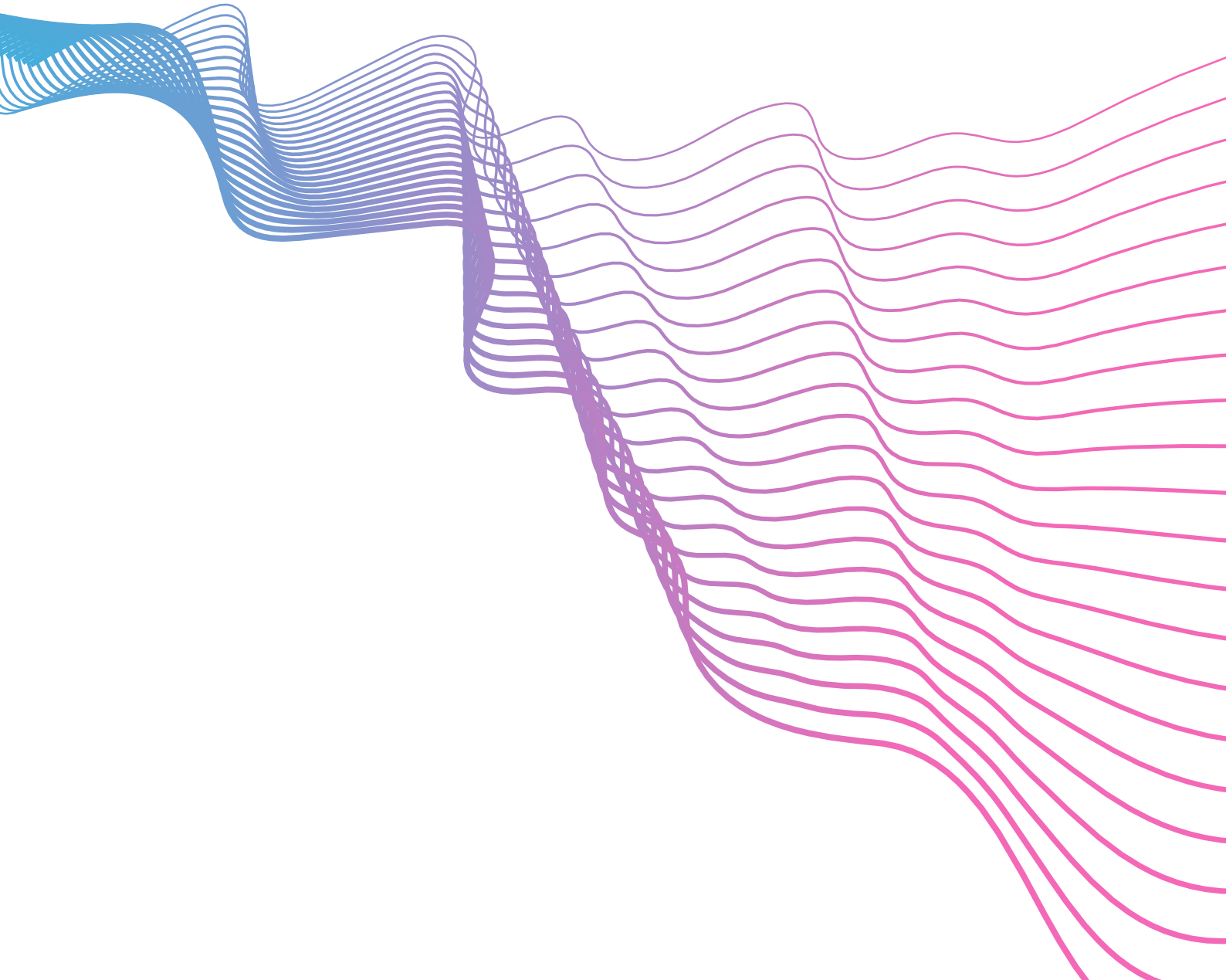
Services used
PTRD curation, ClinPharm

Results

- All the IBs were screened, and a total of 358 variables were captured.
- These variables were then structured into 9 different sections.
- A data model was created from this and delivered post client's approval.

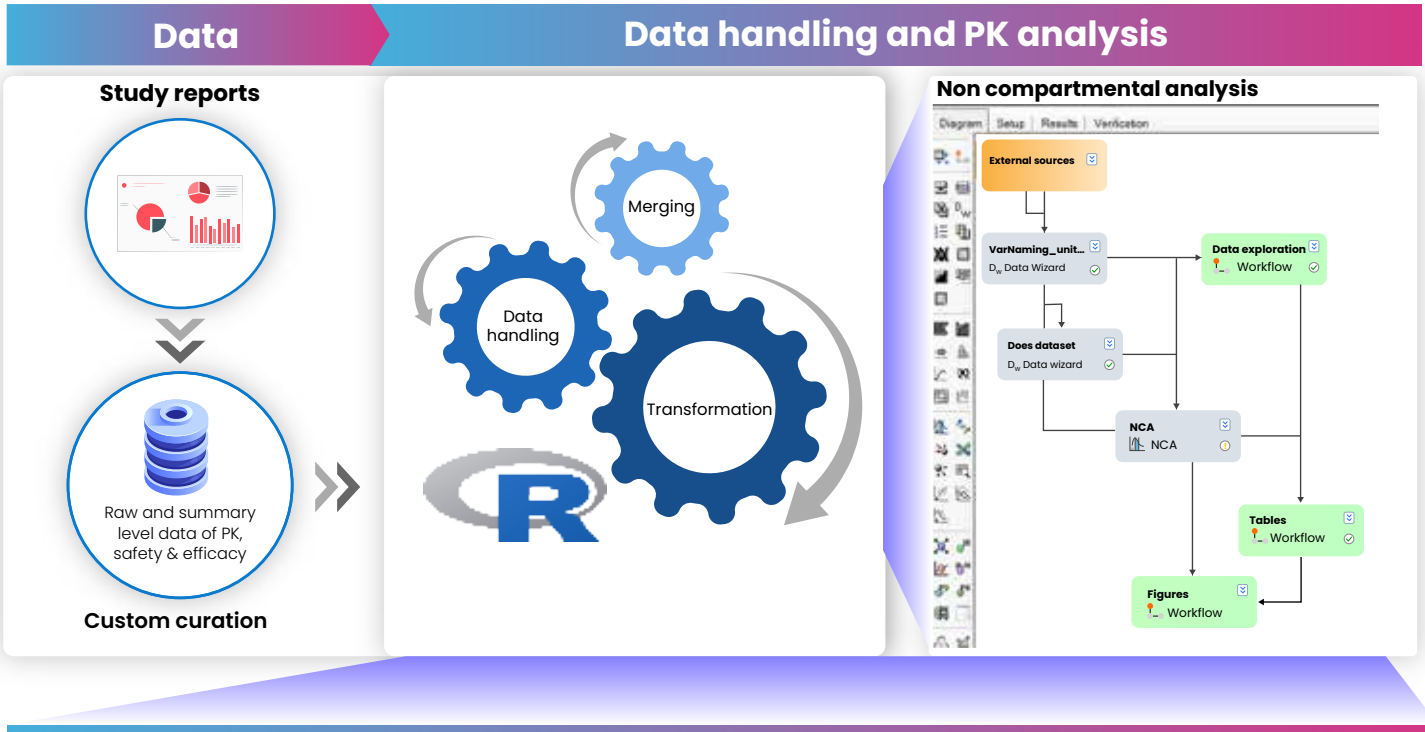
The challenge

- Our client was a large pharma based out in the US and working on multiple therapeutic areas.
- Their data was unstructured Investigator's Brochures containing Preclinical data from animal models.
- Amongst these were the 65 IBs containing Pharmacokinetic and toxicity data that needed to be structured in a prescribed format.



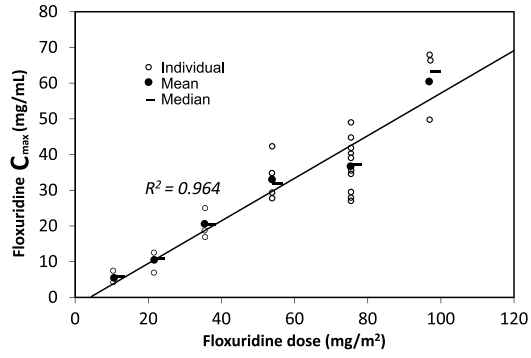
Our approach

- We discussed the details of the project with the client and gathered the necessary information about the reports to be curated.
- The IBs were then manually curated and multiple variables were captured from the reports as discussed in the scope.
- These variables were then siloed into 9 different sections. A total of 358 variables were captured and put up into respective sections.
- A structured model was created from these sections and delivered to the client once approved by them.

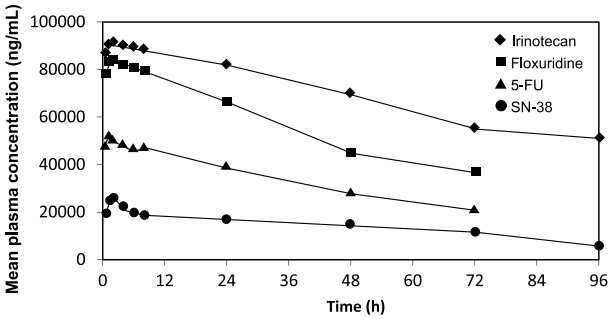


Assessment of exposure and relating exposure to safety and eficacy

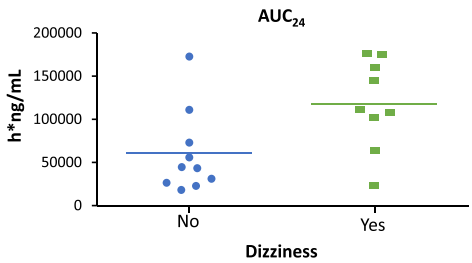
Exposure vs exposure



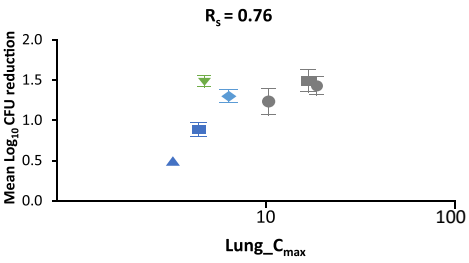
Concentration vs time



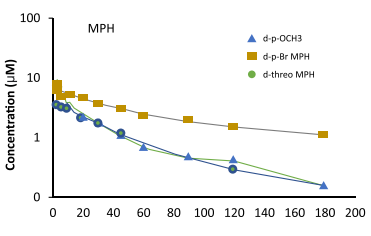
Exposure vs toxicity



Exposure vs efficacy



Compare interventions



The results

- A well-structured model with all the data consolidated into it was delivered to the client for further analysis.

Conclusion

- The Investigator's Brochure is an extensive document of the clinical and non-clinical data of the assets in the portfolio and is of critical importance.
- This information is usually captured by different people who are part of the trials and is unstructured making it difficult for any analysis.
- Excelra contributed by structuring all the available data in a unified fashion which clients can use for further analysis using our Preclinical Tox Report Digitization (PTRD) curation services.
- The details from the IBs were refined and structured by creating multiple data sections and the variables were annotated and mapped to the accurate section.
- A final data model was created using this and delivered to the client for their further analysis.