

Kraken –

A Shiny Application for Visualizing SDTM Data in Early Phase Clinical Trials

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Agenda

1. Introduction
2. Overview of Early Phase Clinical Trial
3. Limitations of Traditional Reporting Methods
4. Kraken – At a Glance
5. Kraken in Action
6. Technical Framework
7. Challenges & Solution
8. Future Enhancements
9. Conclusion
10. Q&A

Overview of Early Phase Clinical Trials & Data Challenges

Importance of Early Phase Trials	Data Management Complexity	Regulatory Compliance Necessity
Establishes drug safety and efficacy, providing essential data for clinical development and regulatory submissions.	Requires advanced strategies to manage large volumes of data for accurate analysis and timely decision-making.	Adherence to strict standards ensures data integrity, reporting accuracy, and successful drug approval.

Limitations of Traditional Reporting Methods

01

Static Reports

02

Time-Consuming Processes

03

Limited Customization

04

Data Handling Challenges

05

Regulatory Compliance Complexity

Kraken – At a Glance

Primary Stakeholder: Clinicians, Statisticians

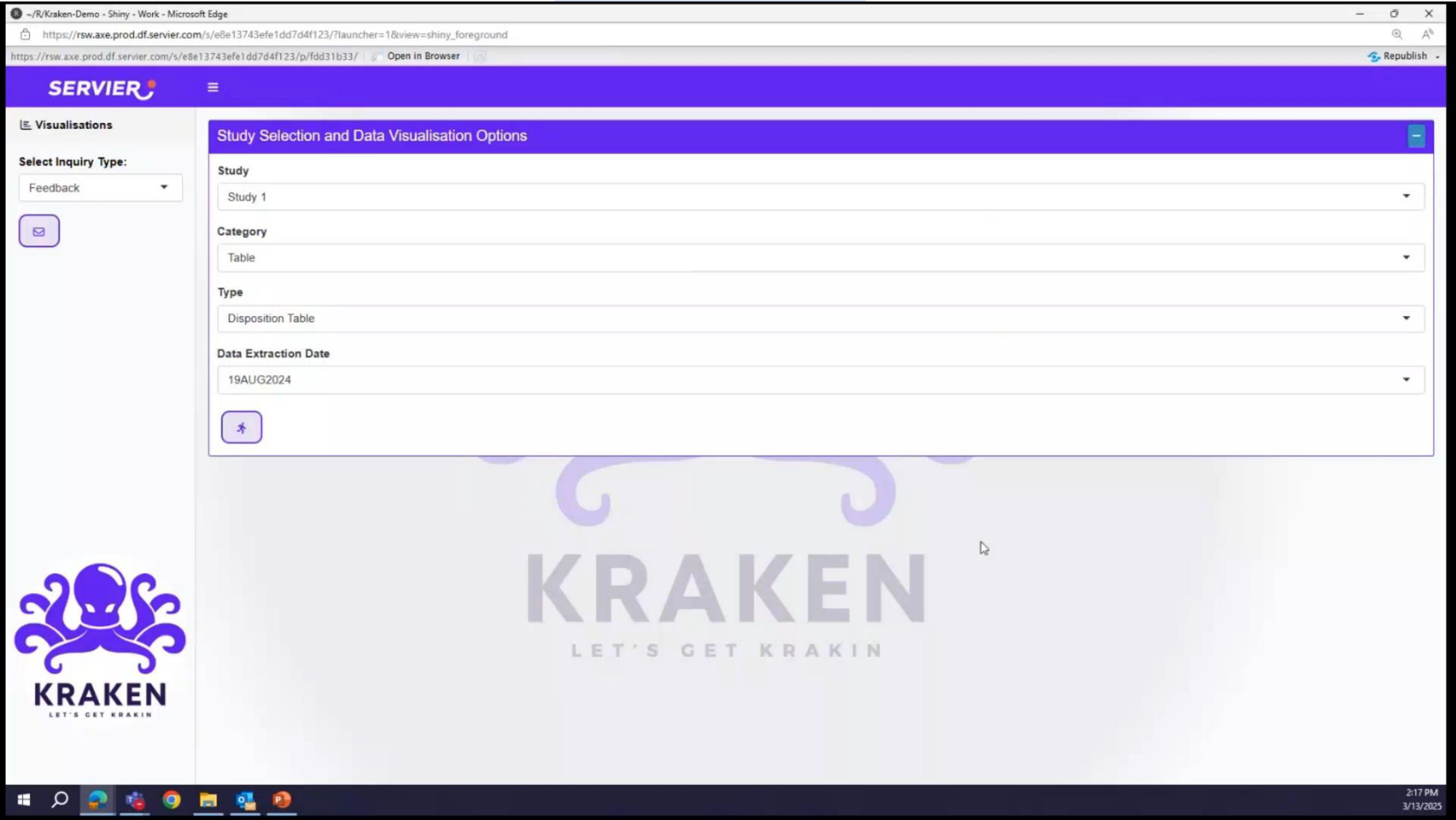
Why: To efficiently address ad-hoc data requests by enabling seamless data exploration and on-demand customizable data visualization.

What does it do:

1. Enables real-time exploration of SDTM data through interactive dashboards and dynamic filtering.
2. Generates customizable visualizations and summary tables on demand, tailored to specific clinical study needs.
3. Facilitates efficient data analysis and reporting with exportable outputs in multiple formats (RTF, Excel, PNG, PDF).



Kraken in Action



Kraken in Action

https://rsw.axe.prod.df.servier.com/s/e8e13048705bfb7bf586/p/8dacc6ec/ | Open in Browser

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Visualisations

Select Inquiry Type:
Feedback

Study Selection and Data Visualisation Options

Study
Study 1

Category
Table

Type
Disposition Table

Data Extraction Date
19AUG2024



KRAKEN
LET'S GET KRAKIN

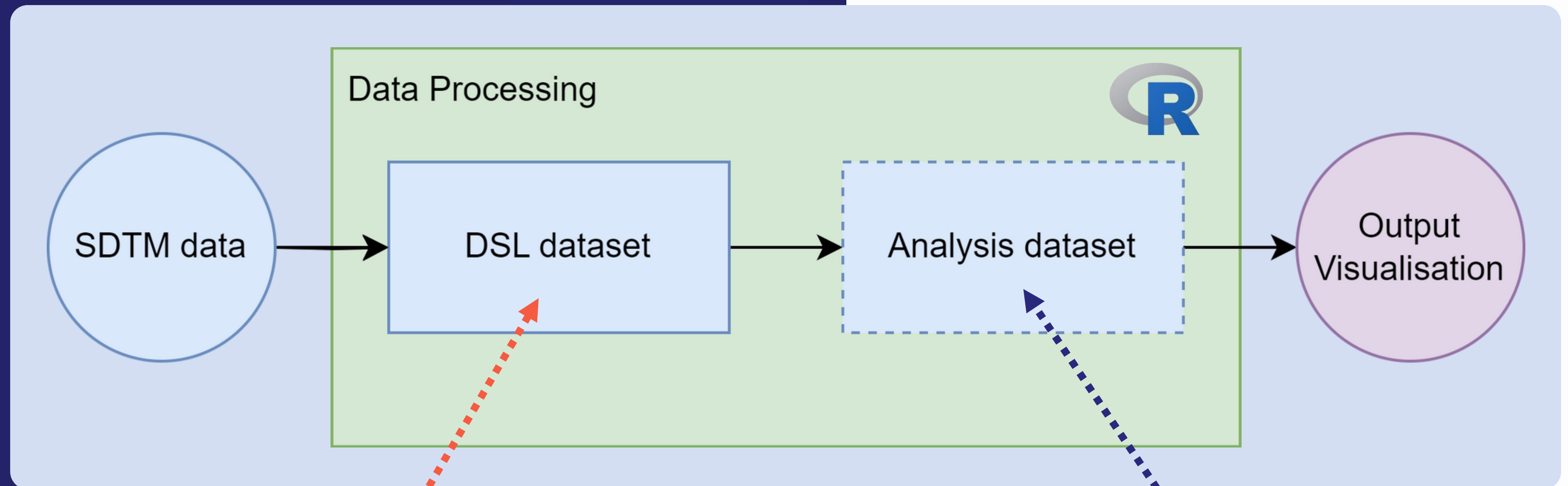


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LET'S GET KRAKIN

Kraken in Action



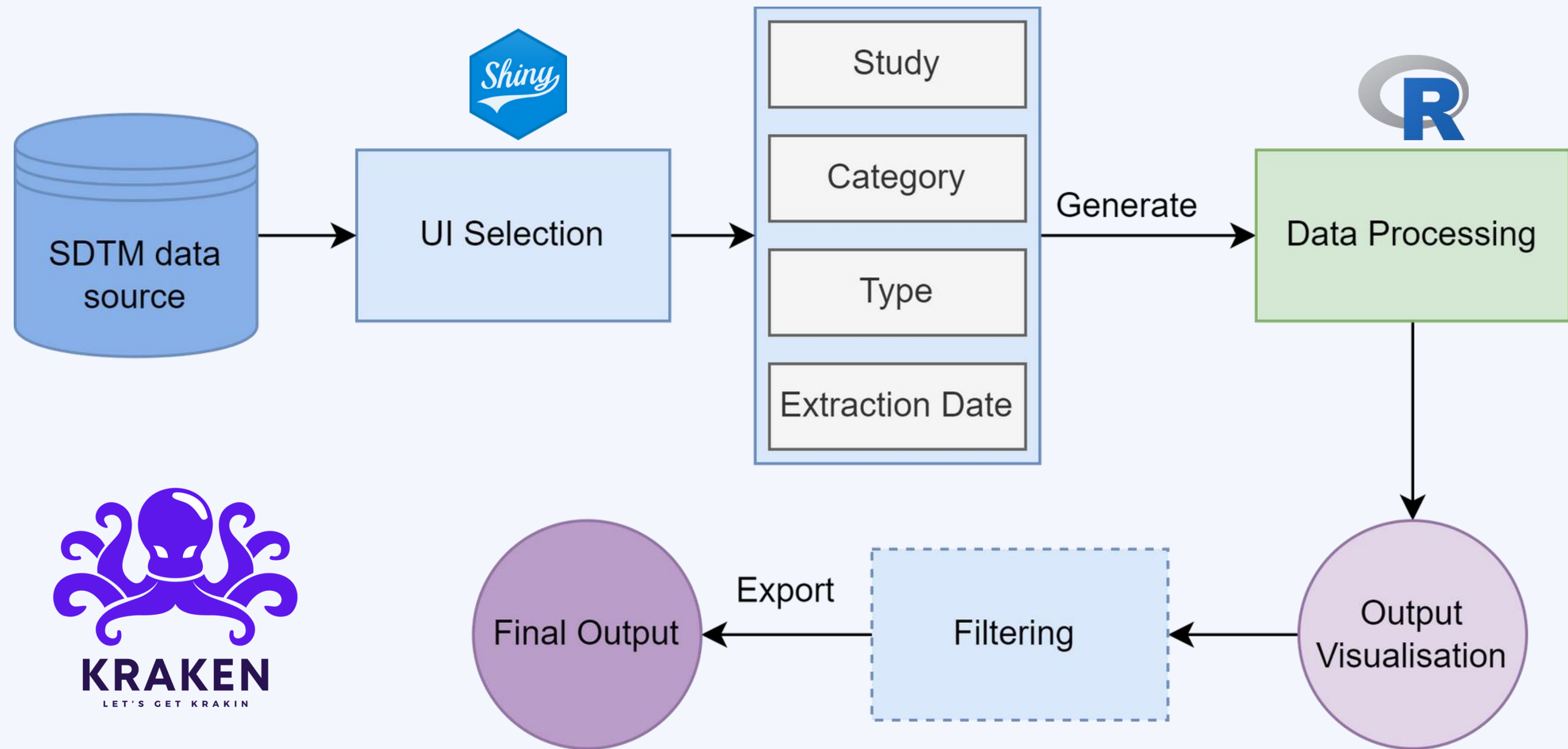
Technical Framework: Data Workflow



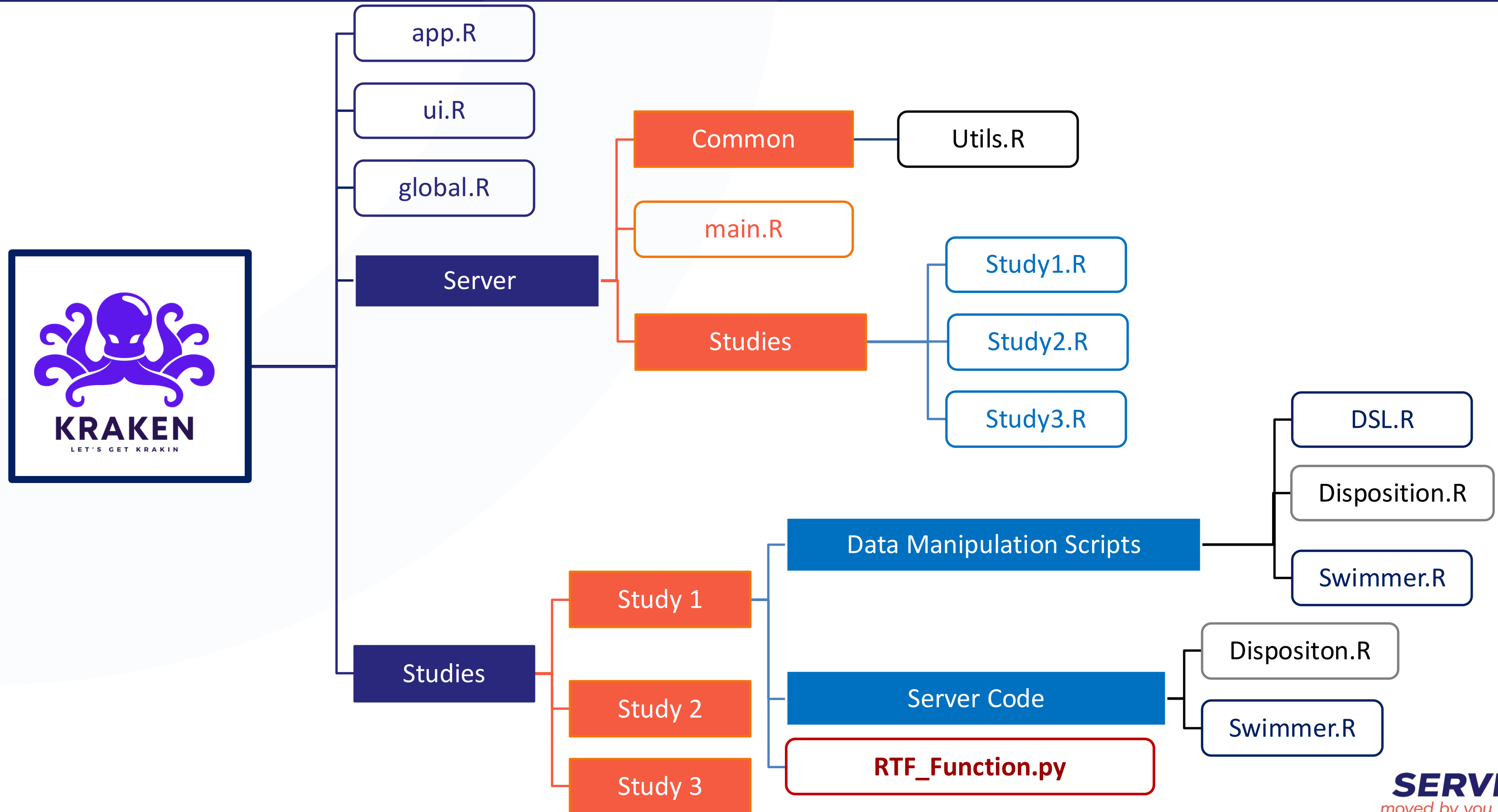
Consolidates SDTM data into a derived-subject-level dataset, traceable format for analysis.

Combines DSL with additional SDTM domains (e.g., RS, DS, TR) to generate tailored datasets for deeper insights.

Technical Framework: Overall Workflow



Technical Framework: Modular Architecture



Challenges Encountered & Solutions Implement

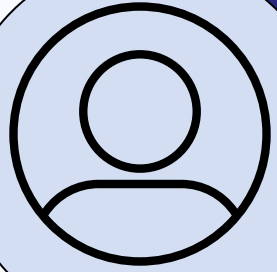
RTF Output Formatting

Custom RTF generation using **Python's docx** library integrated via **Reticulate**.

Interactive Visualization Complexity

Switched from Plotly to **ggiraph** for interactive, compliant visualizations.

Future Enhancements



Patient Profile Features: More Visualization options for individual patient analysis.

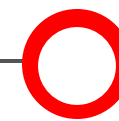


AI Integration: Automating data mapping and reducing manual processing.



Performance & Scalability Improvements

Conclusion - Impact of Kraken



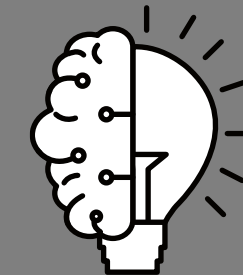
**Transforming
Data Analysis**



**Enhancing
Insights**



**Boosting
Efficiency**



**Future Grown
& Innovation**



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Thank You!