

Pathway to Precision:

Strengthening Clinical Data Imaging

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The tool is a comprehensive clinical data management platform designed for the rigorous demands of oncology imaging in clinical trials. It automates the ingestion, calculation, and tracking of data, ensuring quality and consistency. By providing precise auto-generated queries and seamless integration with EDC systems, it facilitates enhanced communication and efficiency across trial sites. The platform's innovative approach to data visualization and compliance ensures accuracy and saves significant labor hours, making it a pivotal tool for advancing clinical research.



Proven Efficiency

Automated pipelines validated by experience, generating thousands of queries for 14 studies, and saving immense manual effort.

Dynamic Solutions over Static AI

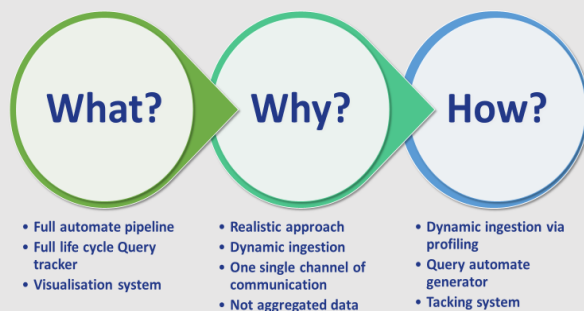
Our approach embraces versatility, avoiding rigid AI models, and ensuring meaningful validation.

Enhanced Communication & Consistency

Autogenerated queries synchronize cross-site operations, streamlining workflows.

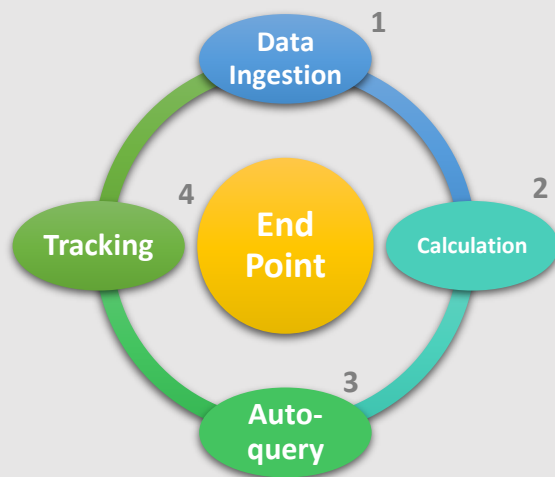
Traceability & Compliance

Our tracking system offers real-time monitoring of each record, enhancing accountability and compliance by no aggregating data.

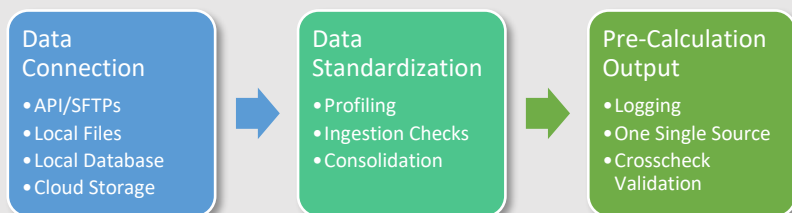


Modules:

1. **Data Ingestion:** Dynamically connect and ingest data from multiple EDC platforms, achieving standardization through sophisticated profiling.
2. **Calculation:** Implementing criteria for theoretical response calculation, matched with robust consistency checks and flagging systems.
3. **Auto-Query:** Generate queries with customizable responses, pinpointing and flagging the root of each issue for targeted resolution.
4. **Tracking:** Cross-reference current data against historical records to highlight changes, ensuring all past data remains accessible for comprehensive analysis.



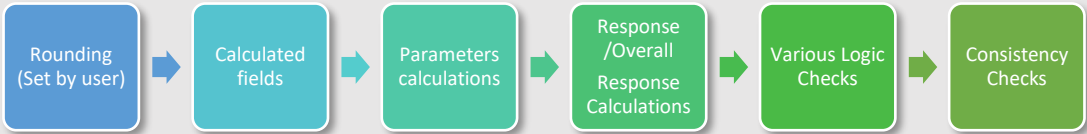
1 Data Ingestion Module



Facilitates seamless data integration from diverse sources such as APIs, SFTP, local or cloud storage, and databases. It standardizes data through profiling and checks, consolidating it for consistent processing. Finally, it ensures data integrity before further calculations with comprehensive logging, unification, and crosscheck validation.

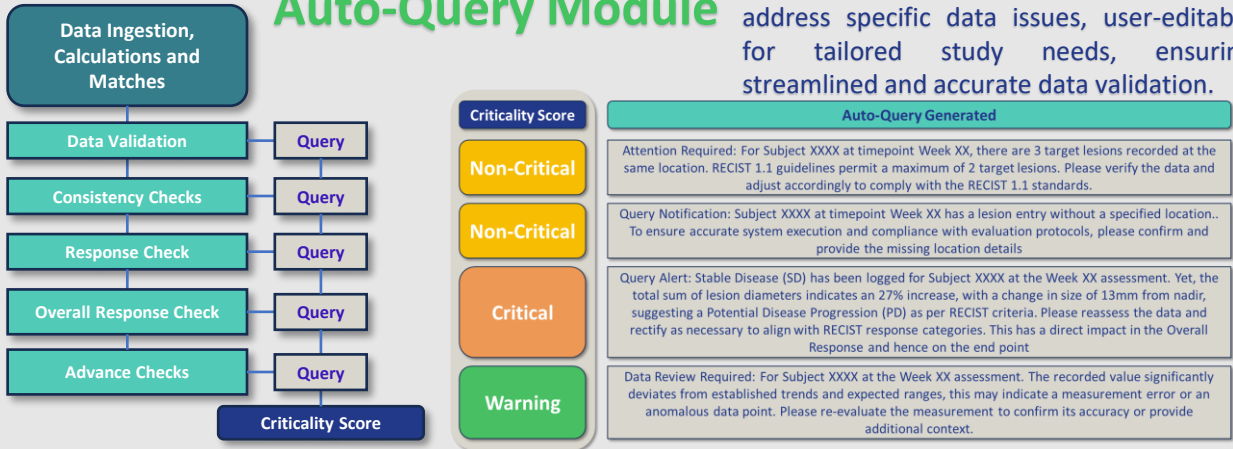
2 Calculation Module

The Calculation Module efficiently progresses from user-defined data rounding to field calculations, parameter computations, and response analysis, culminating in stringent consistency and logic checks to ensure accuracy and reliability.



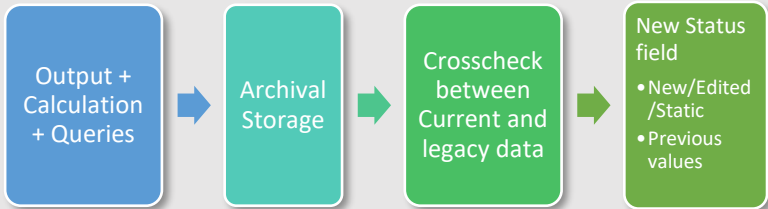
3 Auto-Query Module

The tool's generates dynamic queries and address specific data issues, user-editable for tailored study needs, ensuring streamlined and accurate data validation.



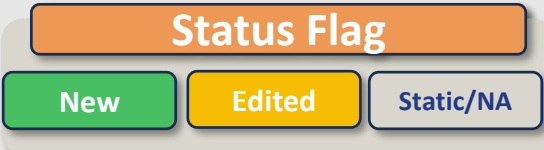
4 Tracking Module

This module evidently tracks the data from output and calculation, including query generation, moves it into archival storage, performs crosschecks between current and historical (legacy) data, and updates the status field to reflect new, edited, or unchanged data, keeping a record of previous values for reference. It's a comprehensive solution for overseeing data integrity and history.

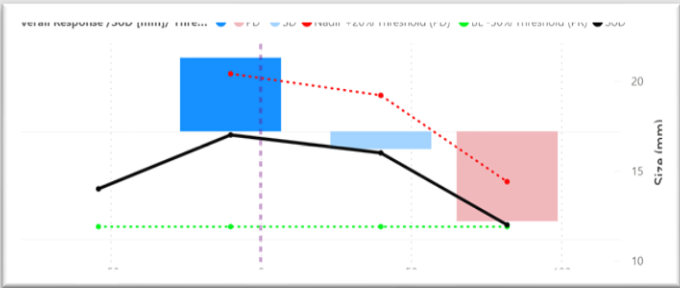


Calc_Response	Site_Response	Calc_Overall_Resp	Site Overall_Response
PD	Stable Disease (SD)	PD	Progressive Disease
PD	Stable Disease (SD)	PD	Progressive Disease
PD	Stable Disease (SD)	PD	Progressive Disease
PD	Stable Disease (SD)	PD	Progressive Disease

Previous value (Date): Stable Disease



Outputs/Reports



- Data Visualization Tool:
 - Integrates Standardized Criteria with exploratory analysis for enhanced data interpretation.
 - Provides a detailed, subject-centric view to support targeted decision-making.
 - Facilitates comprehensive Safety Reviews with data-driven insights.

- Automates query dispatch to study sites for prompt issue resolution.
- Employs a robust monitoring system to track the volume and status of queries.
- Offers complete Life Cycle Study monitoring, from initiation to closeout



- [illegible]

Customize Report: The tool can generate a Customize Report only showing the error/flags that have been detected or automatically send the query.

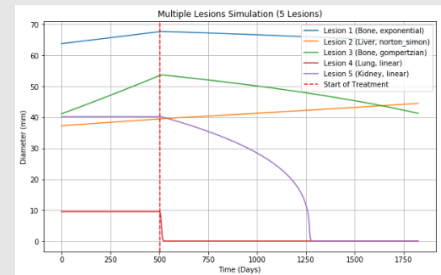
Disclaimer: The data presented is generated through a synthetic process and should be used for simulation and system testing purposes only.

Revolutionizing Clinical Data Analysis with AI-Driven Precision

- Integrates exploratory and standardized analysis for deeper clinical insights.
- AI-driven query generation improves data accuracy with features like outlier detection and unit conversion.
- Versatile criteria suite adaptable to various studies, including all RECIST standards and Lugano Classification.
- Cross-domain application standardizes eCRF analysis, enhancing data checks and safety tracking.
- Saves hours of manual labor with smart query automation.
- Advanced pipelines for efficient DICOM feature extraction streamline workflows.

Innovative Synthetic Data Generator: Pioneering Implementation and Analysis

- Pipeline Acceleration:** Elevates pipeline development and implementation speed, enabling faster go-to-market and iteration cycles.
- Pre-Data Deployment:** Operates effectively in pre-data ingestion phases, allowing for comprehensive system testing and validation without the need for real patient data.
- Comprehensive Coverage:** Designed to simulate all conceivable scenarios and implementations, ensuring robust system preparedness.
- TGK-Based Modelling:** Utilizes Tumor Growth Kinetic models to generate realistic and varied synthetic datasets, enriching testing environments.
- Reverse Engineering Capability:** Sophisticated algorithms can reconstruct synthetic raw data from desired end-points, facilitating deeper insights and predictive model tuning.
- Test Case Generation:** Produces a suite of negative and positive test cases, crucial for system verification and ensuring a broad spectrum of scenario testing.



Time	Lesion 1	Lesion 2	Lesion 3	Lesion 4	Lesion 5
0	65	40	40	30	30
250	68	42	40	30	30
500	70	45	40	30	30
750	70	45	40	30	30
1000	70	45	40	30	30
1250	70	45	40	30	30
1500	70	45	40	30	30
1750	70	45	40	30	30

Thank You!

Let's Connect!

For a deeper dive into our system's capabilities or to discuss how we can tailor it to your clinical trial needs, please don't hesitate to reach out. We are here to assist you in harnessing the full potential of the data management platform.

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Looking forwards to exploring the possibilities together