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.

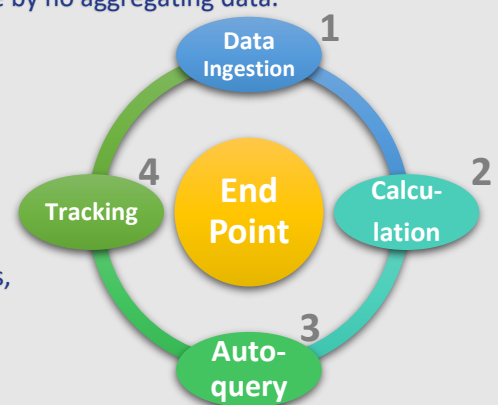**Traceability & Compliance :** Our tracking system offers real-time monitoring of each record, enhancing accountability and compliance by no aggregating data.
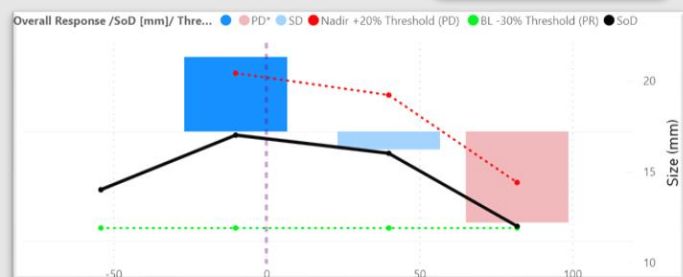
Modules:

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.

Criticality Score	Auto-Query Generated
Non-Critical	Attention Required: For Subject XXXX at timepoint Week XX, there are 3 target lesions recorded at the same location. RECIST 1.1 guidelines permit a maximum of 2 target lesions. Please verify the data and adjust accordingly to comply with the RECIST 1.1 standards.
Non-Critical	Query Notification: Subject XXXX at timepoint Week XX has a lesion entry without a specified location.. To ensure accurate system execution and compliance with evaluation protocols, please confirm and provide the missing location details
Critical	Query Alert: Stable Disease (SD) has been logged for Subject XXXX at the Week XX assessment. Yet, the total sum of lesion diameters indicates an 27% increase, with a change in size of 13mm from nadir, suggesting a Potential Disease Progression (PD) as per RECIST criteria. Please reassess the data and rectify as necessary to align with RECIST response categories. This has a direct impact in the Overall Response and hence on the end point
Warning	Data Review Required: For Subject XXXX at the Week XX assessment. The recorded value significantly deviates from established trends and expected ranges, this may indicate a measurement error or an anomalous data point. Please re-evaluate the measurement to confirm its accuracy or provide additional context.

4. Tracking: Cross-reference current data against historical records to highlight changes, ensuring all past data remains accessible for comprehensive analysis.

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.
- Automates query dispatch to study sites for prompt issue resolution.

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