SCDM Live

Sept. 29 – Oct. 2, 2024 | Boston, MA

SCDM 2024 Annual Conference

The Festival Of Opportunity

Using AI in Clinical Operations, Data Management & Science:

A Blueprint for Streamlined Clinical Trials

Monday, September 30
E240 Room
6:00 – 7:00 p.m.

SCDM Live

Using AI in Clinical Operations, Data Management & Science: A Blueprint for Streamlined Clinical Trials

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Pfizer

Chaired by

Sina Adibi

President & CEO

Adaptive Clinical Systems

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Today's Topics

The AI Landscape from a CRO perspective

Operational Excellence with AI in Imaging

Data Science Meets Clinical Data

Leveraging AI in Clinical Studies

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Which aspect of AI do you find most promising for improving clinical trial data quality?

ⓘ Start presenting to display the poll results on this slide.

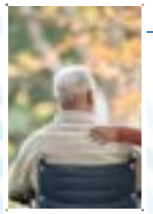
Emerging Sources of Data

Electronic Health Records (EHR)

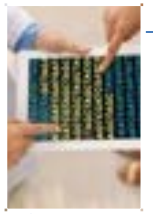
Wearable Devices

Patient-Reported Outcomes

Imaging Data



Social Determinants of Health (SDOH)



Genomic Data

AI in Data Integration, Cleaning & Visualization

Data Integration

- Automated Data Ingestion
- Smart Data Mapping
- Real-Time Integration

Data Cleaning

- Anomaly Detection
- Duplicate Removal
- Data Enrichment

Data Visualization

- Dynamic Dashboards
- Advanced Analytics
- User-Friendly Interfaces

AI Driven Innovation in Clinical Trials

Patient Recruitment and Retention:

- Predictive Analytics
- Personalized Engagement

Data Integration and Management:

- Automated Data Collection
- Real-Time Monitoring
- Natural Language Processing (NLP)
- Robotic Process Automation (RPA)

Trial Design and Optimization:

- Adaptive Trial Designs
- Simulation Models
- Machine Learning Algorithms
- Virtual Trials

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Who drives the AI strategy within your organization?

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The AI Landscape from a CRO Perspective

- Objectives
  - Explore the driving factors, business requirements, and study variables to help determine if AI is a good fit for a Sponsor's portfolio

Different Definitions of “AI”

- Sponsors, Vendors, and CROs all have different definitions
- Artificial Intelligence, Machine Learning
- Data Analytics
  - Advanced and Descriptive
- Data Aggregation and Visualization

Sponsor Requirements and Motivations for AI

- Each Sponsor has a different level of risk tolerance for AI adoption
- Program drivers
- Business drivers
- “Keeping up with the Joneses” drivers

CRO Implementation Strategies of AI for Sponsors

- One size does NOT fit all
- No standardized strategy or product package
- Each implementation is tailored to the Sponsors individual requirements

Considerations from a CRO to a Sponsor

- Does the company have a long enough runway to deploy AI?
- Does your therapeutic area provide a large enough dataset for AI to use?
- What functional areas will be using the tool and its output?

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Do you have experience with endpoints derived from blinded independent central review of imaging?

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Typical Imaging Workflow

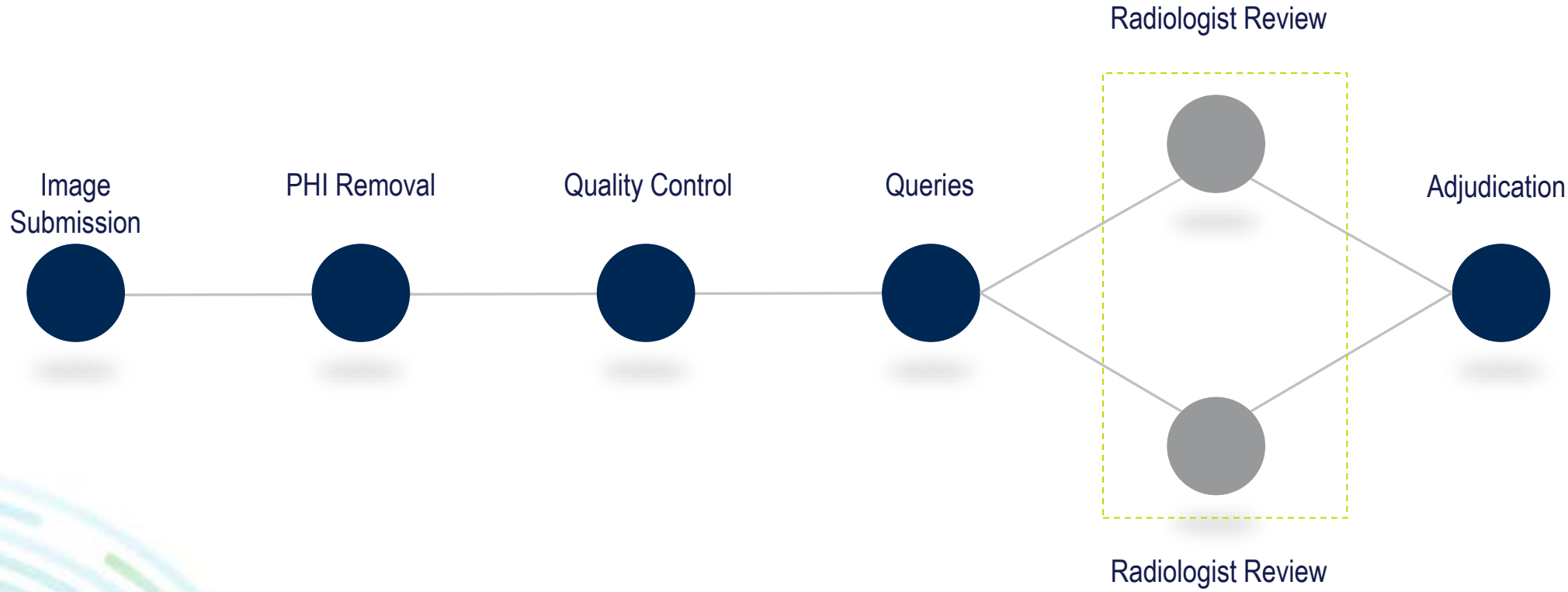


Image Upload by Site	DICOM Tags & Pixel Data	Proper Acquisition Protocol	Resolve Queries	Concurrent Blinded Reviews	Tiebreaker

Challenges with Imaging Endpoints

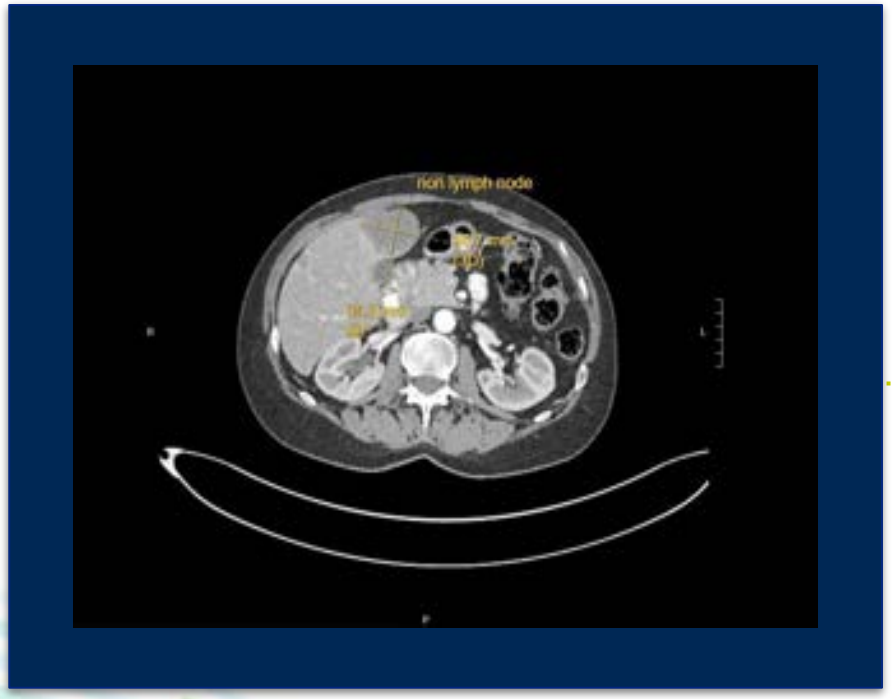
Manual, Costly & Error Prone

1. At baseline, Identify all lesions
2. Select 5 as Targets and measure
3. Remaining classified as non-targets
4. Complete & Sign eCRF
5. At next visit, remeasure targets
6. Qualitatively assess non-targets
7. Identify & assess new lesions
8. Complete & Sign eCRF

Variability

- **Central Reads: 25-40%**
  - *Overlooking new lesions*
  - Selecting inappropriate measurable lesions
  - Selecting different target lesions
- **Site vs Central: 24-29%**
  - Target lesion selection
  - Measurement errors
  - Criteria interpretation
  - Bias

How AI can help



Algorithm Phase 1: Improve efficiency & reproducibility with current gold standard assessments

- Model identifies lesions and slice with longest lesion diameter identified
- Bi-dimensional measurement placed or arrow for non-measurable
- Co-registration of baseline and follow-up identifies new lesions

Value Gained

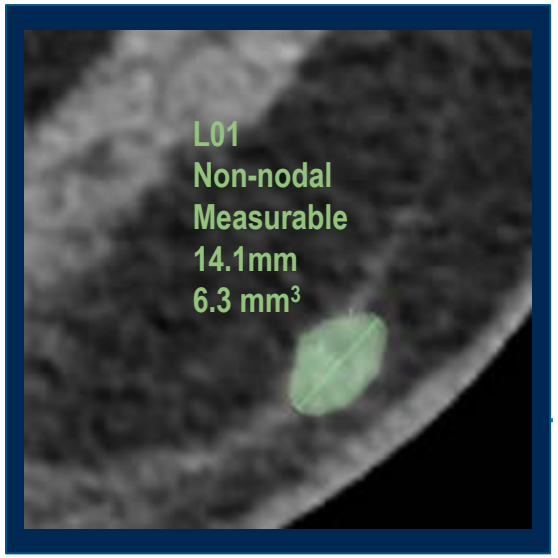
Shorten read time

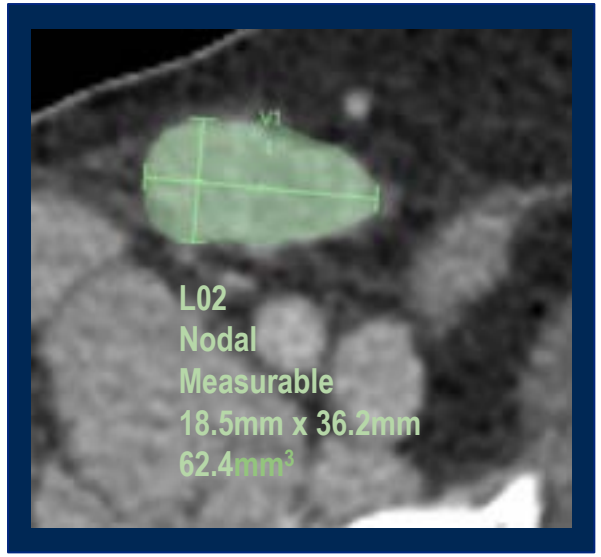
Reduce site and central read variability caused by inaccurate lesion measurements

How AI can help

Algorithm Phase 2: Establish a better standard?

- In addition to bidimensional measurements..
- Each image slice will have the lesion area delineated
- The total tumor volume will then be calculated





Value Gained

Shorten read time

Can help establish new standard upon which lesions are analyzed for clinical trials

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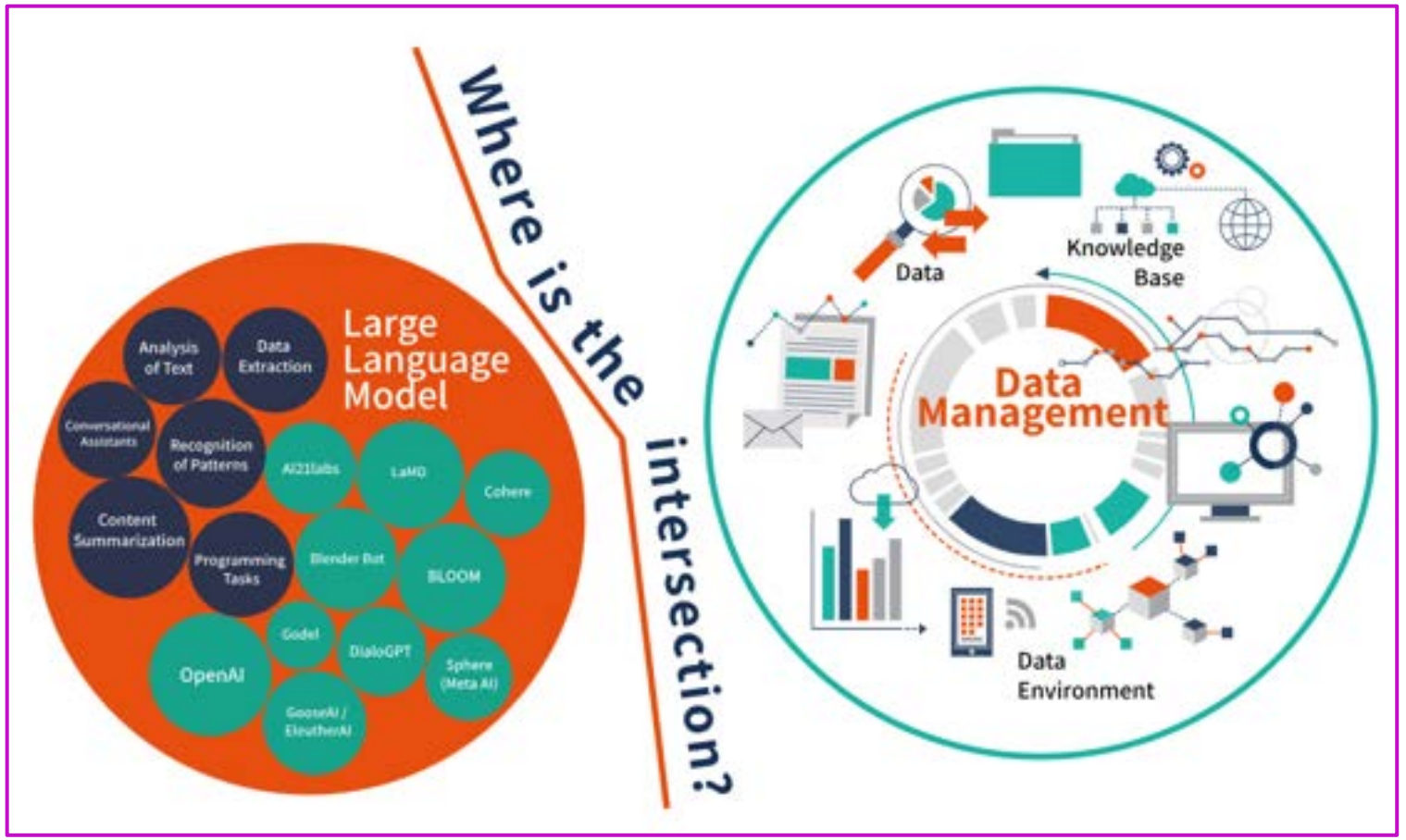
Do you think AI can enhance Clinical Data Review?

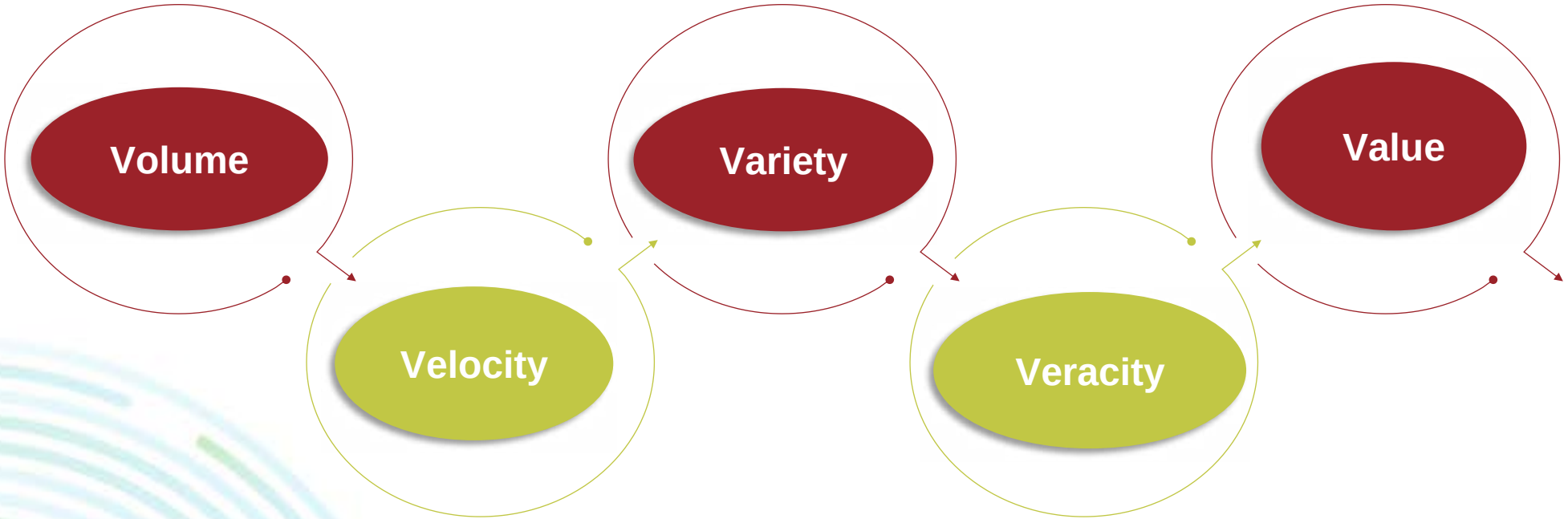


Clinical Data Review : Current State

A shift from few datapoints to more than a tens of thousands of datapoints

Integration of structured and unstructured data from a wide range of sources

Understand the value of data needed for regulatory submission from the pool of data collected



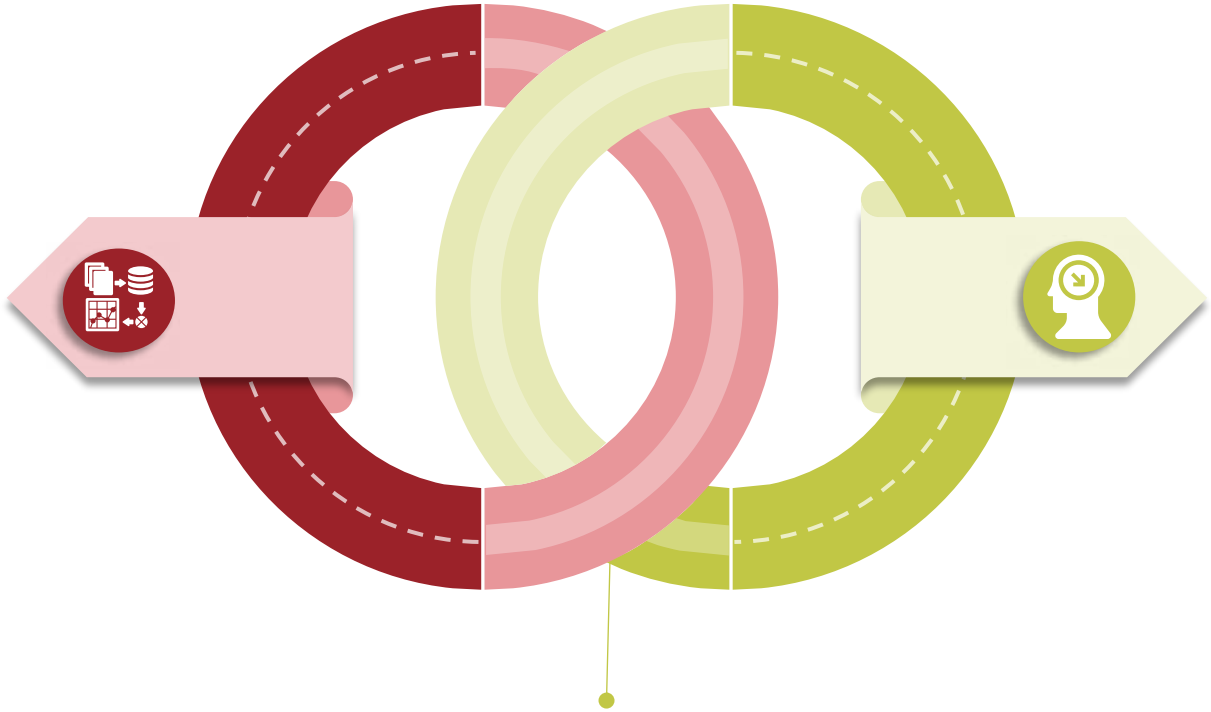
Real time data availability from multiple data sources

Ever increasing multiple sources of data

Data Review Automation Strategy

1. Select Data Review Objective

- ✓ CRF and Non-CRF data that are high on time & effort for manual data review
- ✓ Applicable across all studies & Therapeutic areas



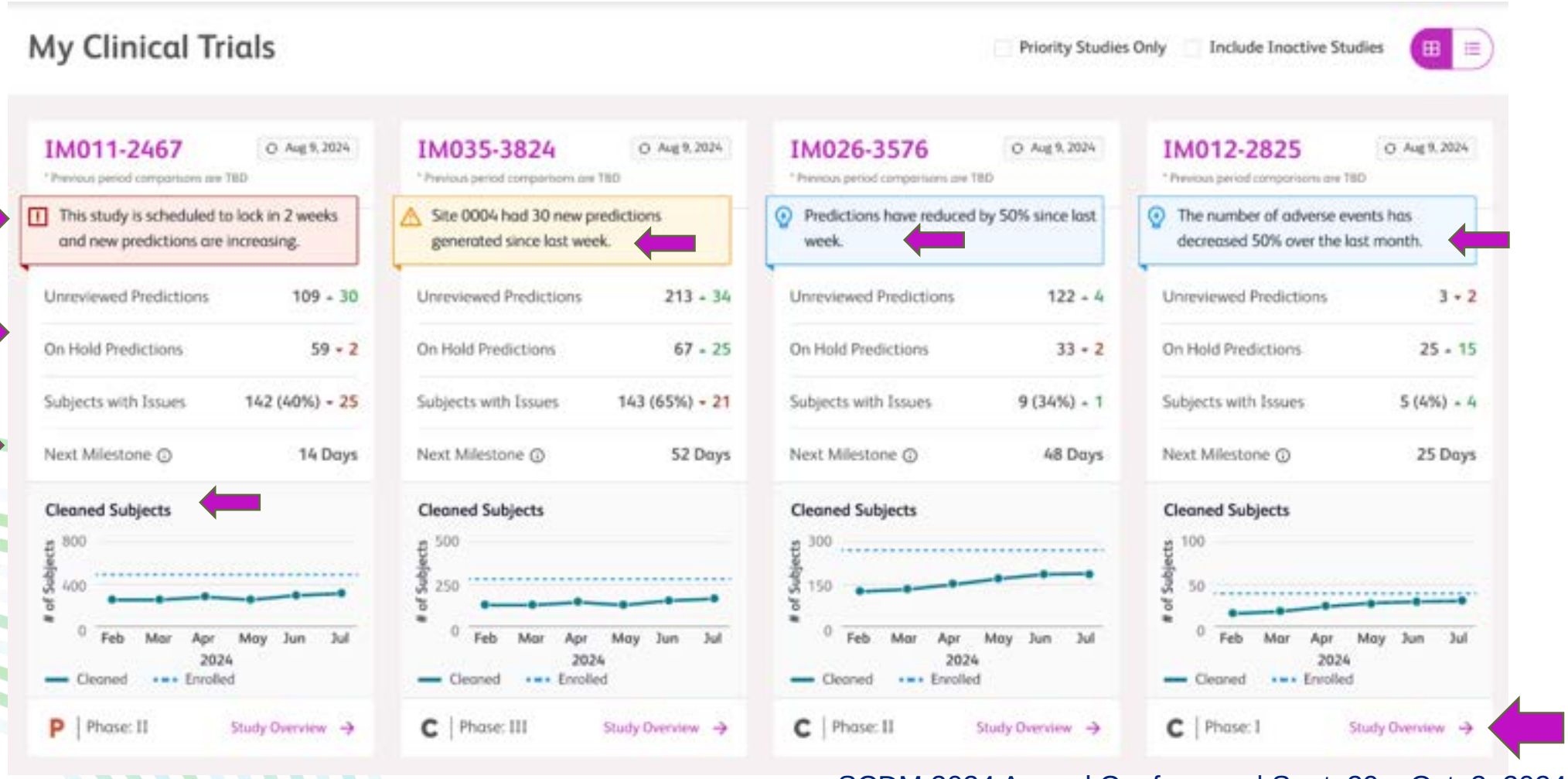
2. Explore the Solution

- ✓ Edit Checks and Exception Listings
- ✓ Combination of NLP & Predictive analytics
- ✓ Develop an innovate & scalable product

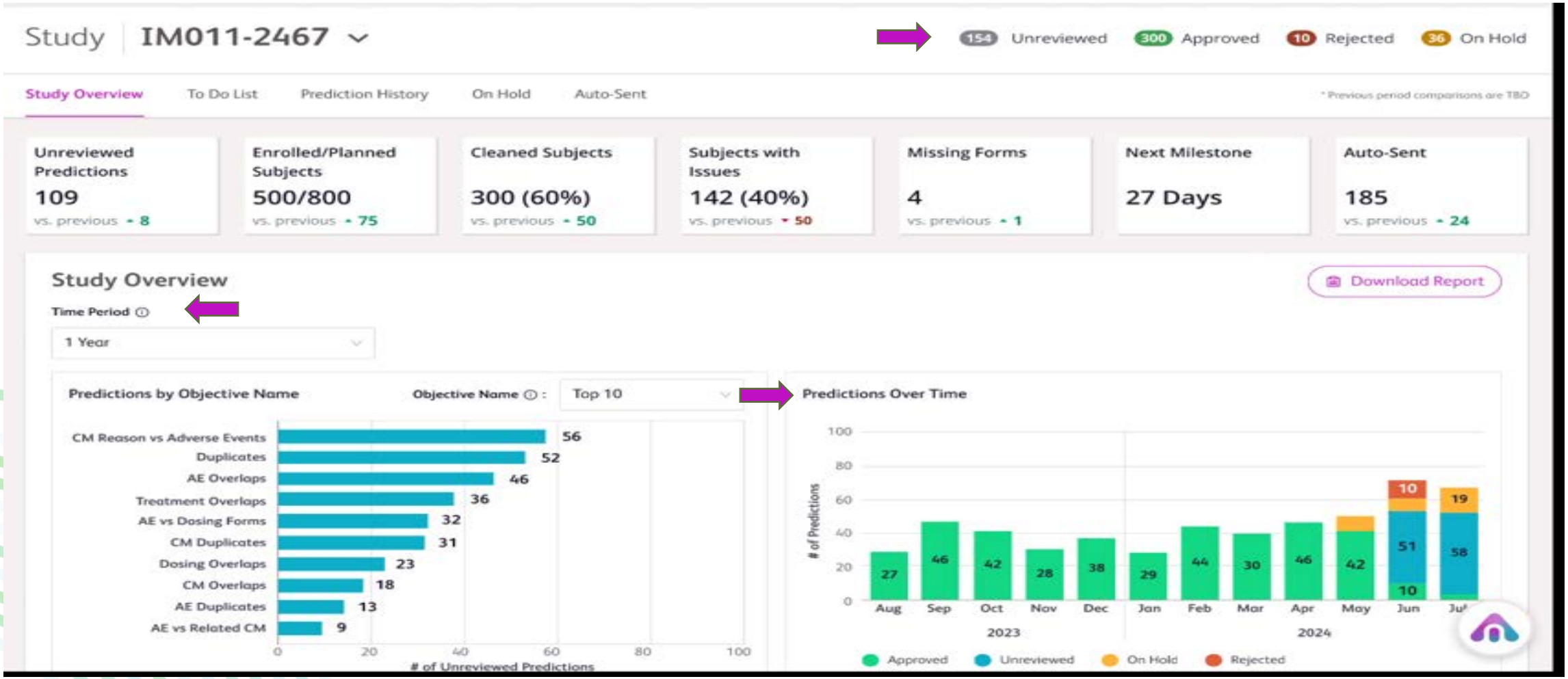
3. Value

- ✓ Measure the Turn around time
- ✓ Manual vs Automation solution
- ✓ Have you achieved the time efficiency?
- ✓ Check the data quality
- ✓ Check the count of rejected queries generated by LLM Model

AI Data Review Assistant



AI Data Review Assistant



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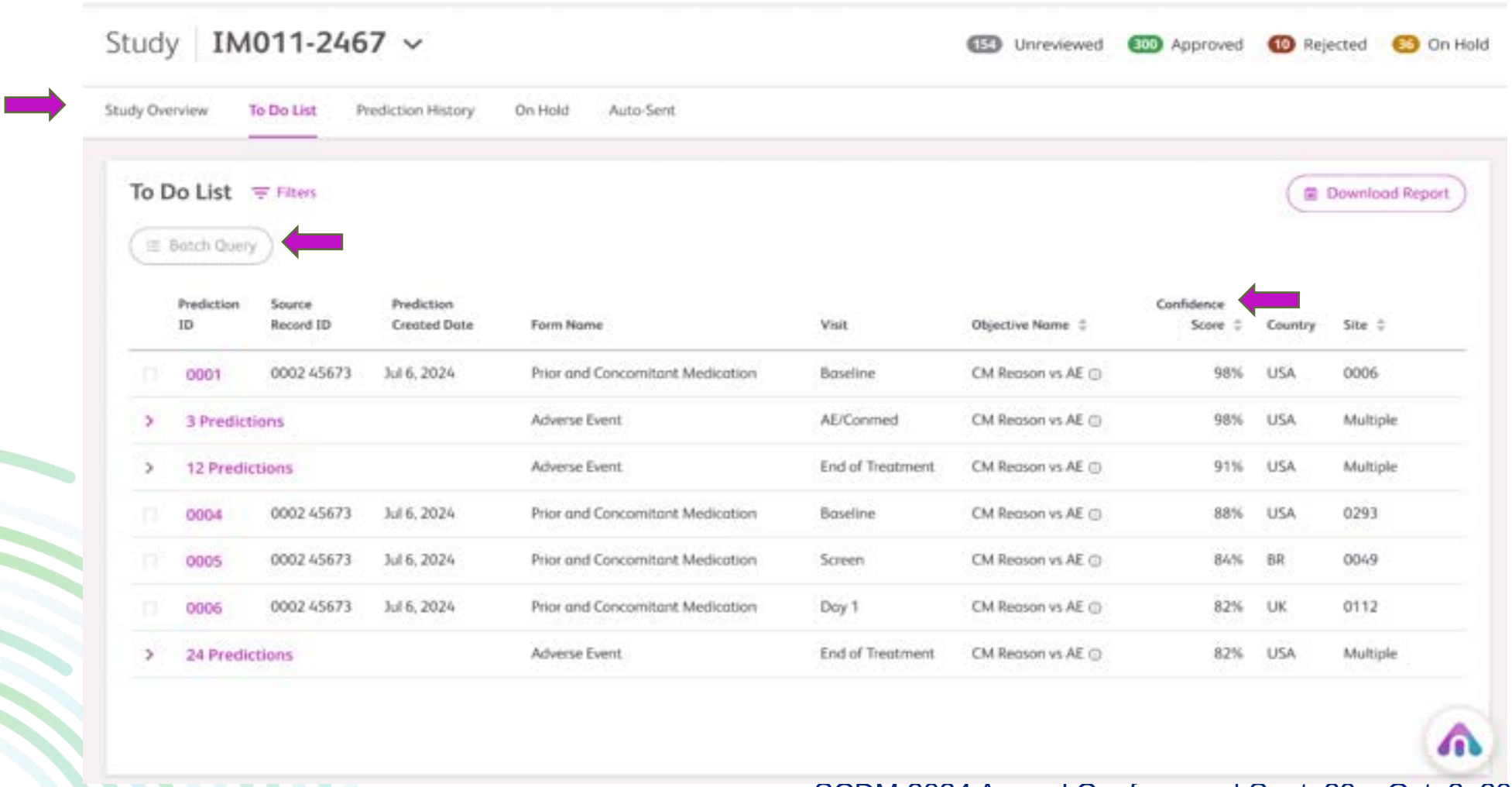

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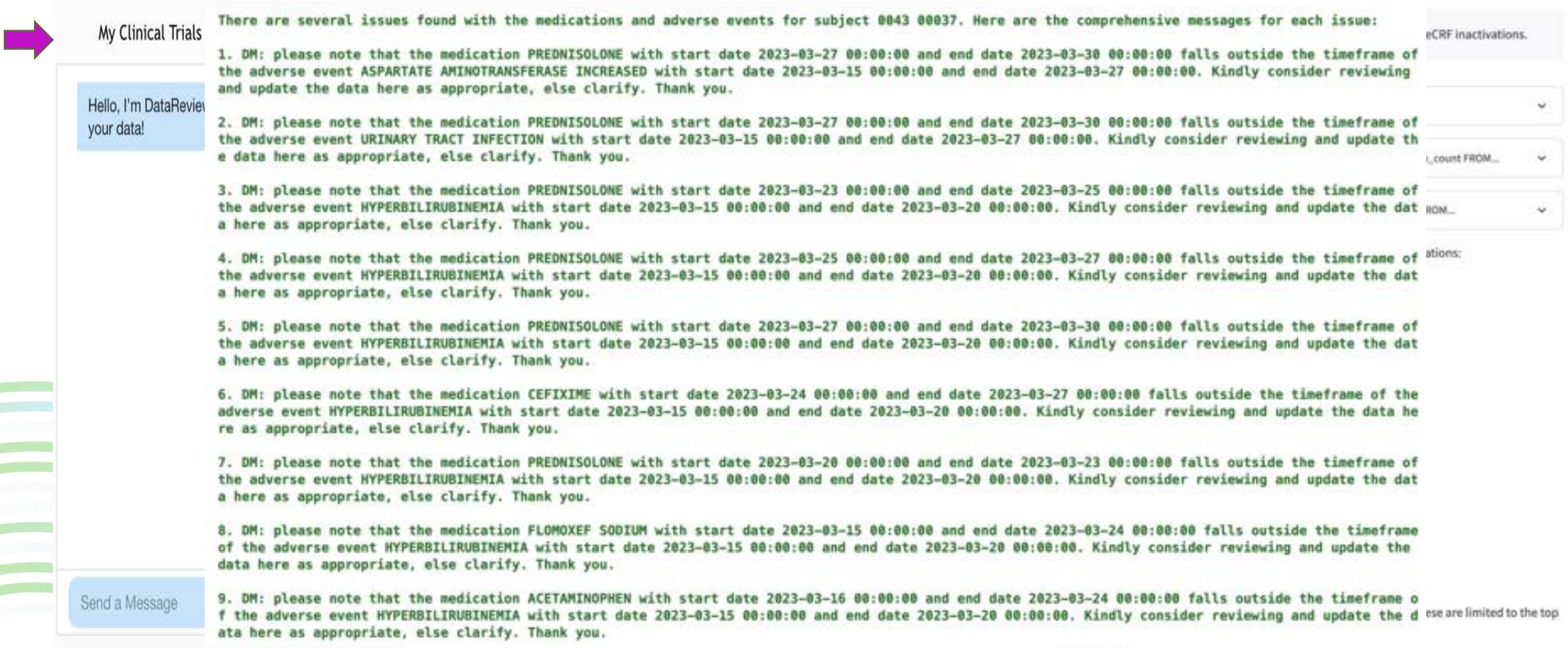
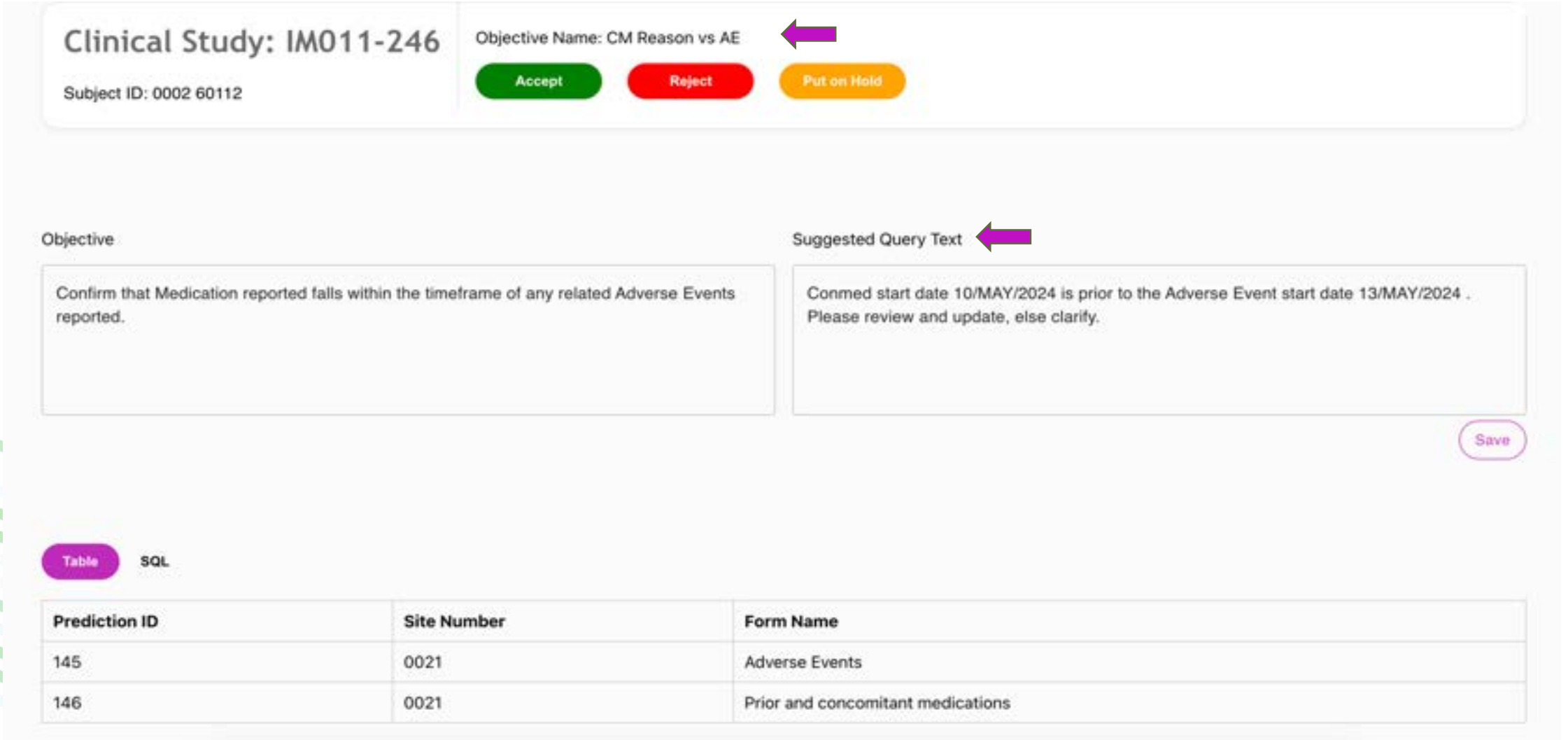
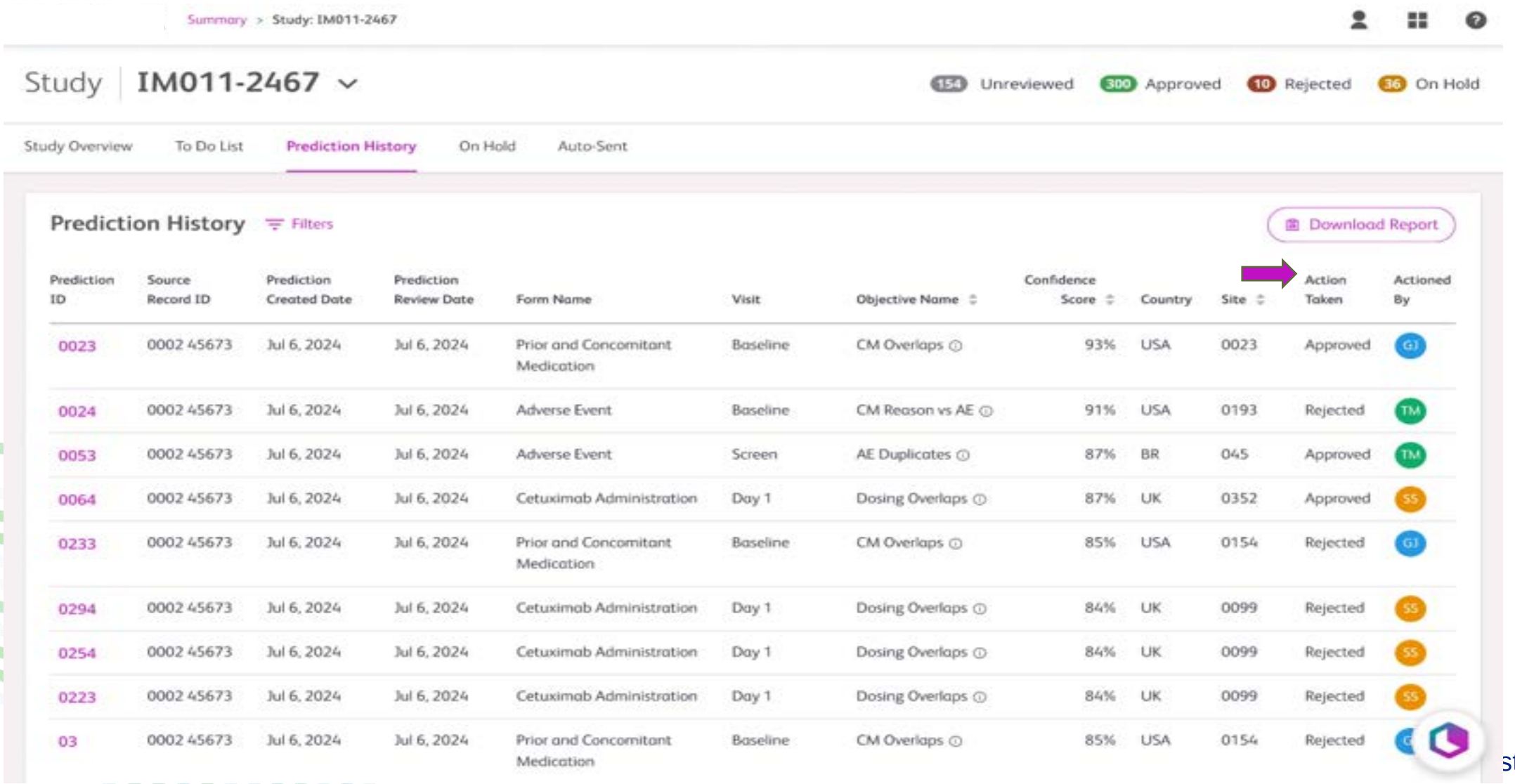
AI Data Review Assistant



AI Data Review Assistant



AI Data Review Assistant



Summary > Study: IM011-2467

Study | IM011-2467

154 Unreviewed 300 Approved 10 Rejected 36 On Hold

Study Overview | To Do List | Prediction History | On Hold | Auto-Sent

Prediction History Filters Download Report

Prediction ID	Source Record ID	Prediction Created Date	Prediction Review Date	Form Name	Visit	Objective Name	Confidence Score	Country	Site	Action Taken	Actioned By
0023	0002 45673	Jul 6, 2024	Jul 6, 2024	Prior and Concomitant Medication	Baseline	CM Overlaps	93%	USA	0023	Approved	GJ
0024	0002 45673	Jul 6, 2024	Jul 6, 2024	Adverse Event	Baseline	CM Reason vs AE	91%	USA	0193	Rejected	TM
0053	0002 45673	Jul 6, 2024	Jul 6, 2024	Adverse Event	Screen	AE Duplicates	87%	BR	045	Approved	TM
0064	0002 45673	Jul 6, 2024	Jul 6, 2024	Cetuximab Administration	Day 1	Dosing Overlaps	87%	UK	0352	Approved	SS
0233	0002 45673	Jul 6, 2024	Jul 6, 2024	Prior and Concomitant Medication	Baseline	CM Overlaps	85%	USA	0154	Rejected	GJ
0294	0002 45673	Jul 6, 2024	Jul 6, 2024	Cetuximab Administration	Day 1	Dosing Overlaps	84%	UK	0099	Rejected	SS
0254	0002 45673	Jul 6, 2024	Jul 6, 2024	Cetuximab Administration	Day 1	Dosing Overlaps	84%	UK	0099	Rejected	SS
0223	0002 45673	Jul 6, 2024	Jul 6, 2024	Cetuximab Administration	Day 1	Dosing Overlaps	84%	UK	0099	Rejected	SS
03	0002 45673	Jul 6, 2024	Jul 6, 2024	Prior and Concomitant Medication	Baseline	CM Overlaps	85%	USA	0154	Rejected	G

AI Solution: Principles and Benefits

Solution Principles

- ✓ Building **Trust** – Consistent solution, reliable and how the outcome is generated is explainable
- ✓ **Flag** true exceptions / anomalies – Most of the data entries are accurate and does not need human eye.
- ✓ **Shortlisting** anomalies for human data review
- ✓ **Data surveillance system** - Understanding the data review objective like a human and flag issues as quickly as data enters our ecosystem
- ✓ **Traceable** and **transparent**
- ✓ Provide **holistic/comprehensive** review of data from multiple data sources and data formats (EDC, eCOA, sensors etc and listing files)

Benefits

- ✓ Increase in the identification of data discrepancies
- ✓ Reduction in time to identify data discrepancies
- ✓ Reduce burden on data reviewers (data reviewer satisfaction)
- ✓ Improve accuracy - reduce human error and ensure uniform quality of data review process across team
- ✓ Overall reduction of query count by query consolidation

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Do you think AI can enhance Clinical Data Review?

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How many in the audience are using Copilot in their daily work?

ⓘ Start presenting to display the poll results on this slide.

Challenges in Identifying and Verifying Protocol Deviation

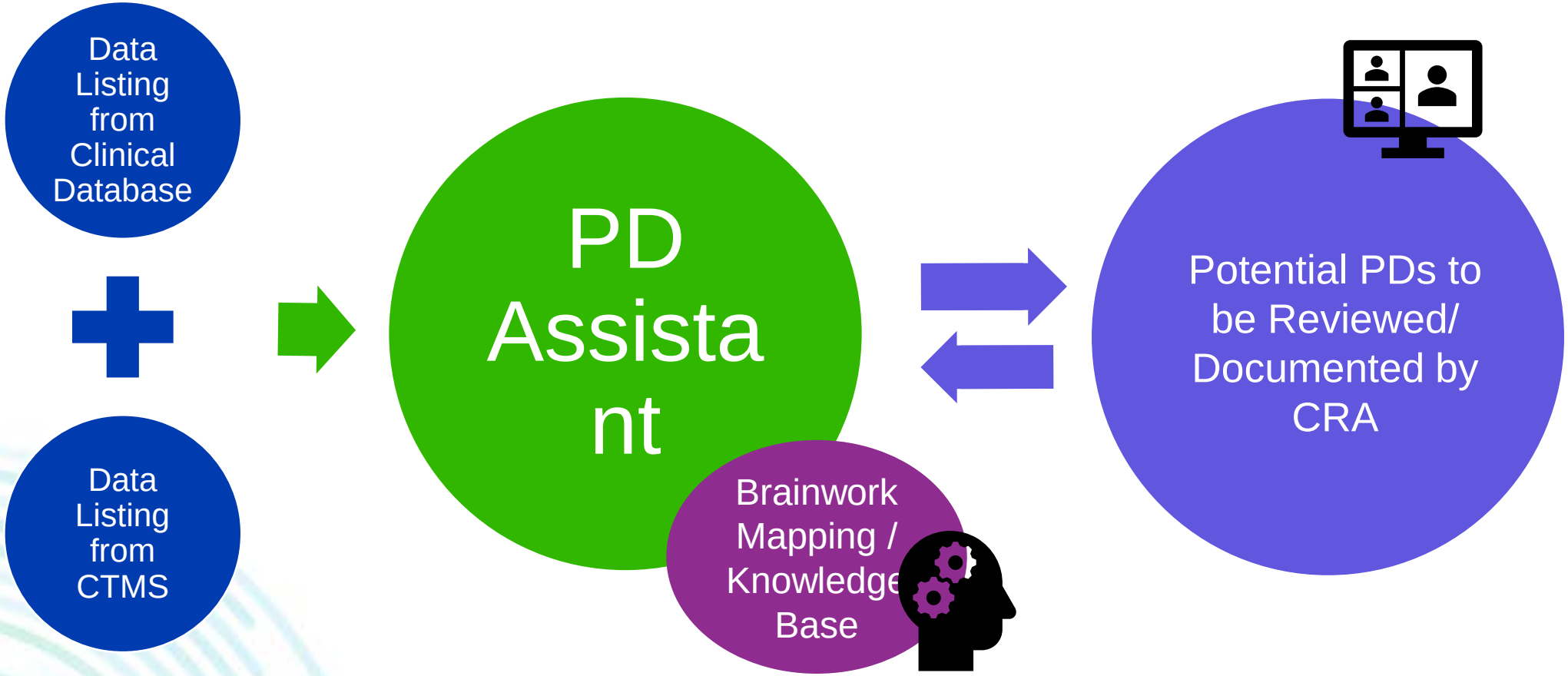
- Protocol Deviation:
  - manual process
  - Hard to verify whether all potential PDs were reviewed, verified and documented
  - Error prone
  - Time consuming

- Can generate List of potential PDs based on protocol specification from EDC clinical database
  - Comparing documented free text formatted PDs with above list is challenging
  - Acronym
  - Alternative
  - Protocol specified
  - PK Visit/Day/timepoints
  - Freetext is hard to parse;

History of Development

- Developer is intern without any previous Excel macro development experience, no exposure to Copilot. Copilot is used in various steps of the development, including:
- To identify Excel formulas and generate scripts
- To learn and create freetext mappings on visit, analytes, test abbreviations…
- To complete the development/testing of the tool within 10 weeks

PD Assistant



Match can be found at different levels

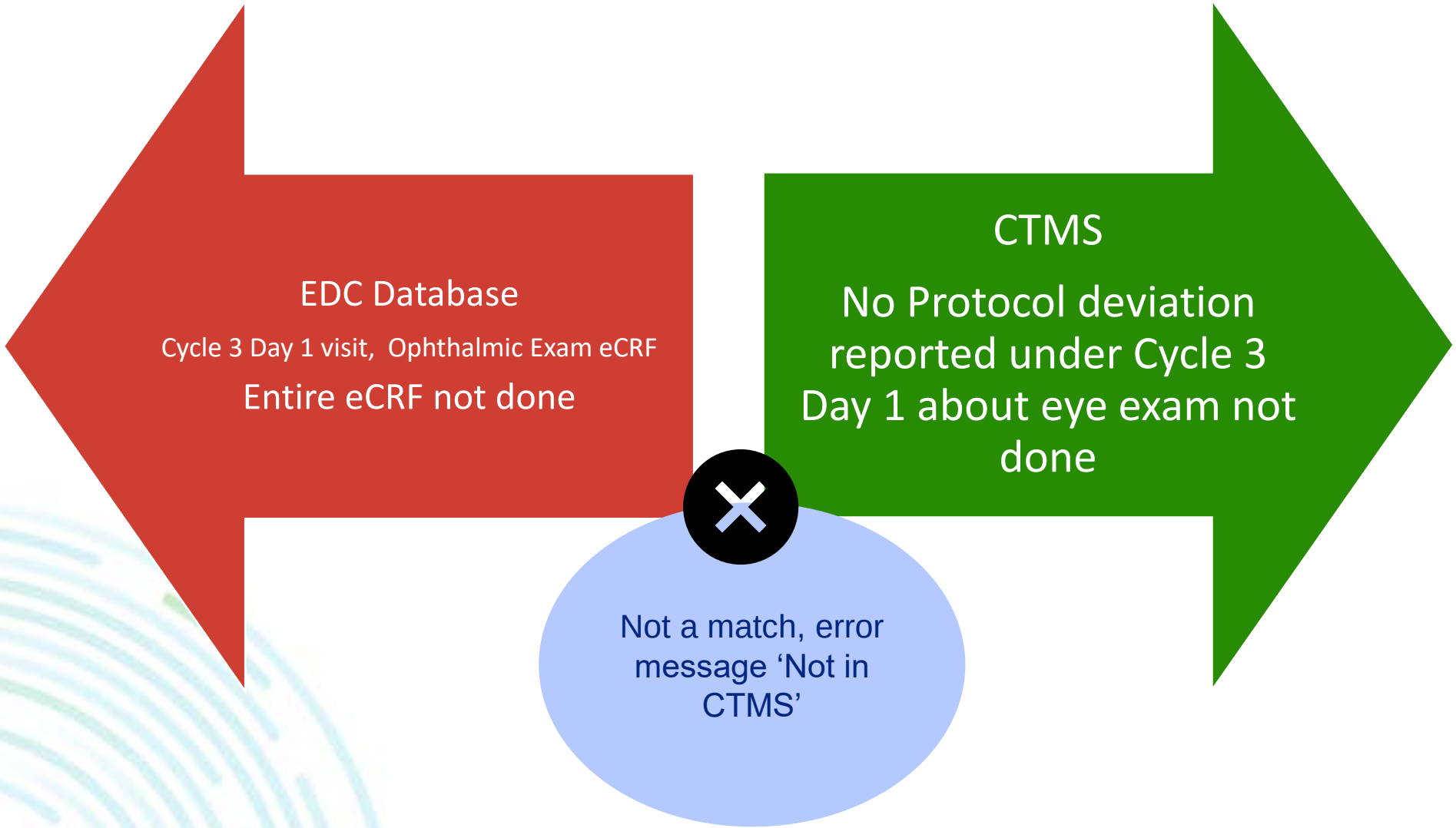
Visit
- EDC Database ‘Cycle 5 Day 1’ not done
- CTMS ‘C5D1 not done’

Form
- EDC Database ‘Cycle 3 Day1’ visit, ECG form not done
- CTMS ‘EKG not performed’ reported under Cycle 3 Day 1

Test
- EDC Database ‘Lactate Dehydrogenase’ not done
- CTMS ‘LDH not collected’

Sample
- EDC Database 2 PK samples in Cycle 4 Day 1 not done
- CTMS ‘PK not collected because lab kit was not provided to site’

Cases


EDC Database
Cycle 3 Day 1 visit, Ophthalmic Exam eCRF
Entire eCRF not done
CTMS
No Protocol deviation reported under Cycle 3 Day 1 about eye exam not done
Not a match, error message 'Not in CTMS'

Outcome

- The tool can identify potential PDs with a 98% accuracy on the tested studies.
- The tool can reduce manual work for CRAs to review potential PDs significantly
- The tool can better track PD review process so no potential PD is unreviewed or not documented.
- More efficiency
- Time saving

A note about (Excel) AI . . .

- Extremely helpful for those without encyclopedic Excel formula knowledge
- Cannot rely on AI 100%, be mindful of possible mistakes especially where complex concepts are involved, and scientific or technical terms are used
- tool needs validation and human proof checking.

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Thank you

Question & Answers

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Where do you think AI can help you?

ⓘ Start presenting to display the poll results on this slide.

References

- ✓SCDM, June 2022, The automation of Clinical Data Management Driven Activities. Available at https://scdm.org/wp-content/uploads/2022/06/SCDM-Automation-of-CDM-Driven-Activities-FINAL.pdf
- ✓SCDM, April 2022, The evolution of Clinical Data Review. April 2022. https://scdm.org/the-evolution-of-clinical-data-review/
- ✓SCDM, March 2022, The 5Vs of Clinical Data. Available at https://scdm.org/the-5vs-of-clinical-data/
- ✓King R et al (2022), Data Review for Today and the Next Generation. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ppd.com/wp-content/uploads/2020/06/Pharmaceutical_Outsourcing_0620.pdf
- ✓Large Language Models 101: History, Evolution and Future (scribbledata.io)