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Single Day Event

Emerging Therapeutic Technologies, Future Developments, and Their Impact on Clinical Data Analysis

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POLL RESULTS

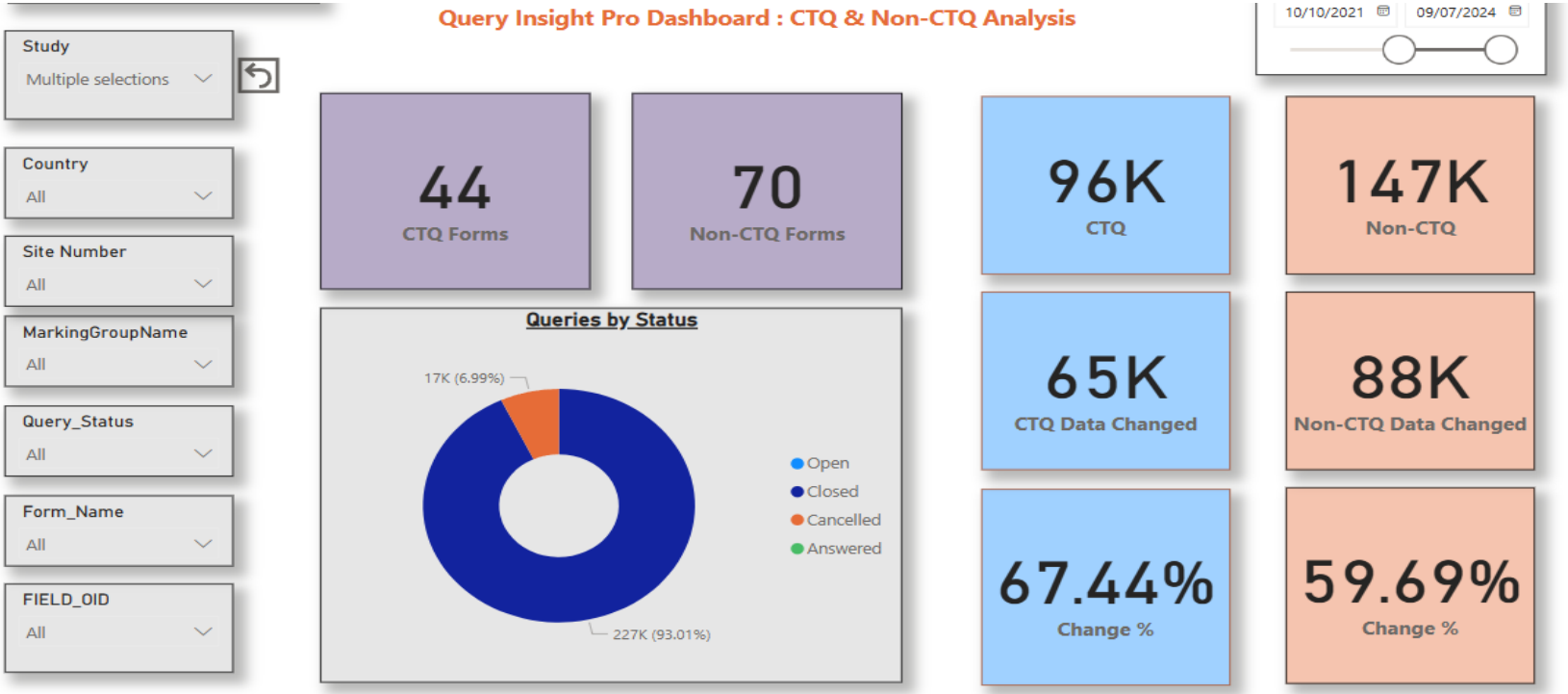
*In a recent AstraZeneca device study of 100 patients over 6 months, we collected **XXXX** the data points that we routinely collect in 1 year across the **entire AZ portfolio (~200 studies)***

5X *10X* *20X* *50X*

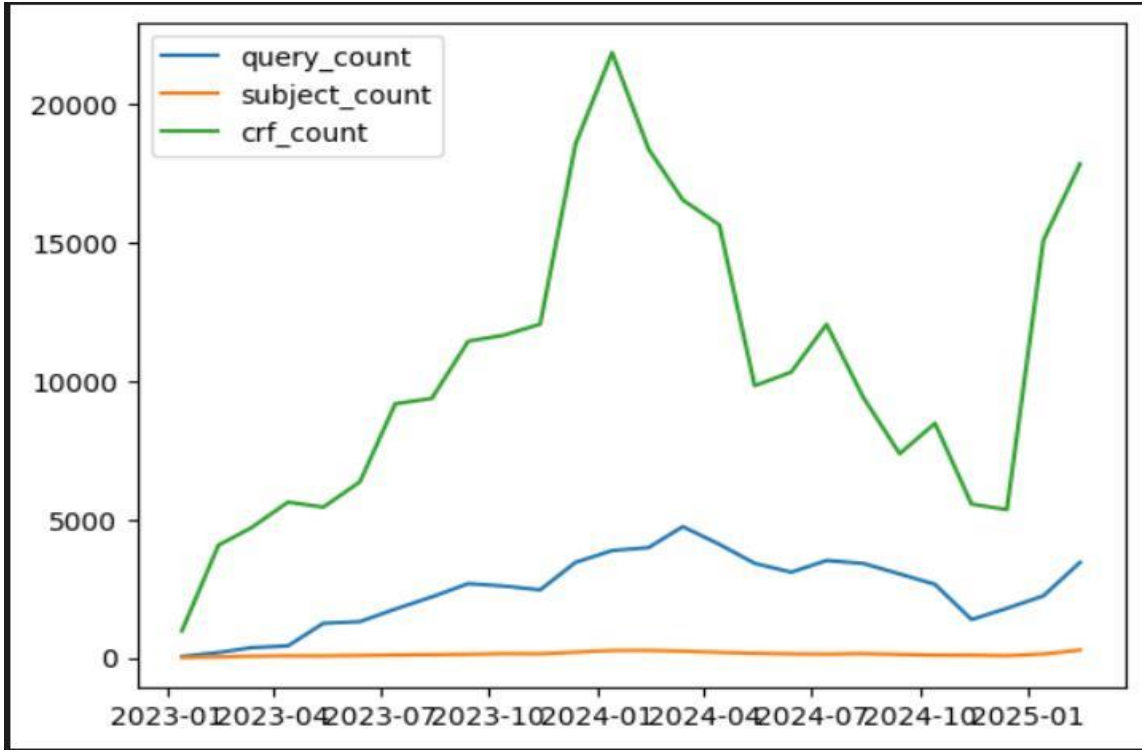
Emerging Therapeutic Areas

ADCs and Radioconjugates	Next-gen IO bispecifics	Cell therapy and T-cell engagers	Gene therapy and gene editing
Replace systemic chemotherapy and radiotherapy	Replace existing PD-1/ PD-L1 inhibitors	Develop scalable cell therapies and T-cell engagers across therapy areas	Make cure possible for a range of rare diseases

Critical to Quality (CtQ) data insights



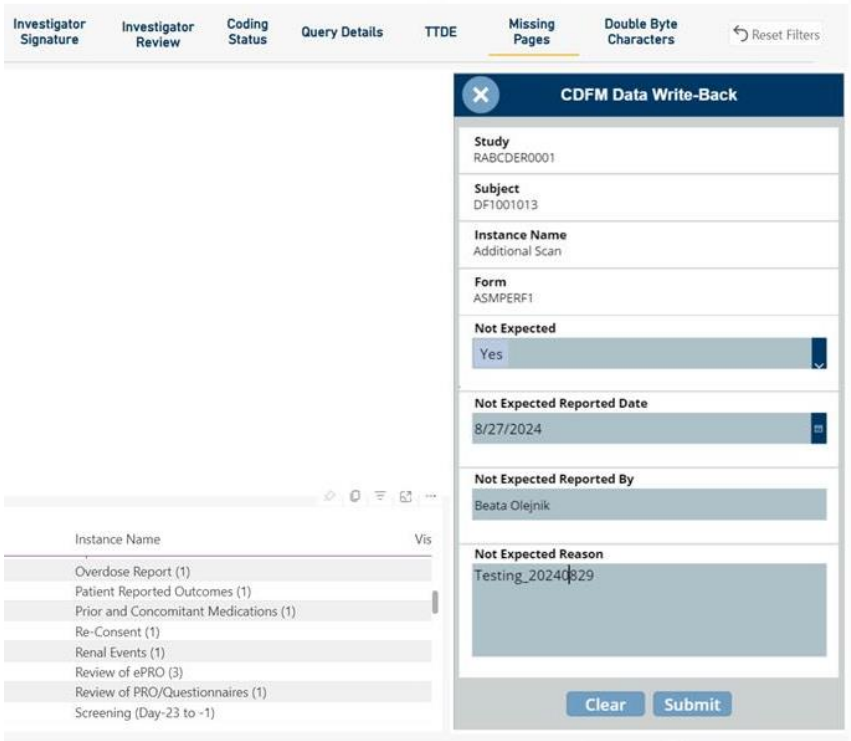
Time Series Forecasting Model



Implement "Time Series Forecasting Model' to view metrics evolution over time and to have a prediction tool which enable better IA/DBL planning

This feature will enable the Study Teams to proactively follow up with Sites based on the forecasting improving the site performance.

Write Back Solution



Implement 'Write Back Solution' for allowing Users to comment/flag on the outstanding pages as missing or acceptable

Study Teams can mark the eCRF forms in the Missing Pages Report and SDV report based on the milestone/ visit cycle. This feature is expected to reduce the number of follow ups from Data Management and Site Monitoring Teams with Site Users on the outstanding forms

What is EHR2EDC?

Clinical Site

Electronic Health Records

(*Patient Medical Records)*

Replacing manual entry

With submitting data in one go

Electronic Data Capture

(*Patient data in Clinical Trials*)

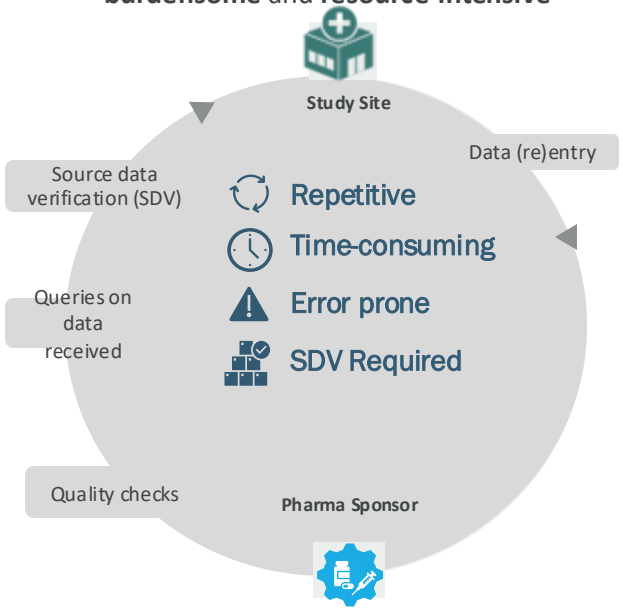
Electronic Health Record (EHR)	Electronic Data Capture (EDC)
• Digital version of subject medical records • For the clinical research industry, EHR data contains a wealth of information regarding population health, disease prevalence, and the usage, side effects and benefits of medical treatments	• EDC is software that stores subject data collected in clinical trial • Automation of source data acquisition from patient medical record systems to clinical trials research databases

EHR to EDC Summary

*AZ's **cross-functional team** has partnered with EHR to EDC technology providers and major hospital **networks to assess technology, data availability,** and **data quality** for automated data transmission, which **holds the potential to significantly improve clinical trial delivery***

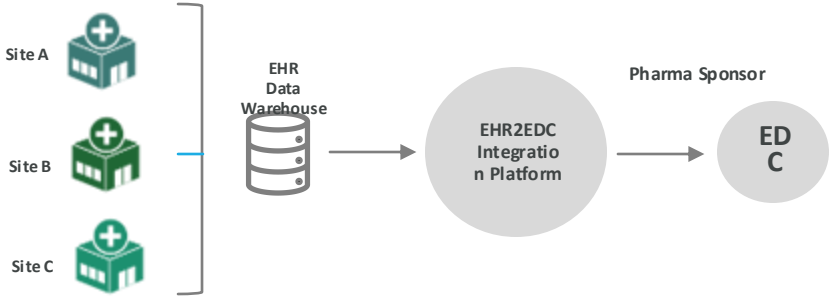
CURRENT STATE

Today's **manual** process of EHR to EDC data transmission is **burdensome** and **resource-intensive**



FUTURE STATE

Automation of time-consuming data entry (e.g., local labs) **reduces site burden** and **increases productivity**



- Automated
- Accurate
- Scalable
- Sustainable

→ Improved **data quality** and **reduced data queries and SDV**

→ Site Personnel & Site Monitors can **focus on the priority tasks** needed

→ Increased opportunities to become the **sponsor of choice**

PROGRESS

Time to data entry reduced

- Influencing patient safety with relatively real time access to clinical data
- Quicker access to data means more time to review/clean for milestones

Improvement to Local Lab Reference Range (LLRR) Issues

- Up-front mapping of lab values / units means no requirement to chase sites for ranges / units
- Top 5 data related risks to milestones across the organization

Direct and Indirect reduction of queries

- Data mapped and transferred as per source, no misinterpretations or transcription errors
- Indirect query reduction – coordinators able to focus entry of more complex/critical forms (AEs/SAEs/etc)

Reduction in Site burden

- Leverage technology to prevent unnecessary "manual data transfer"

Influencing source (EHR) data structure

- Some EHR2EDCs allow for customization of EHR data build (due to site contracts/agreements) by configuring clinical trial 'modules'
- Allows AZ to influencing builds (implement AZ standards) within EMR/EHR systems (source data)

The Global Healthcare Data Science Community

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