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Clinical Signal Surveillance: Real-Time Dashboards for Protocol and PK Deviation Monitoring

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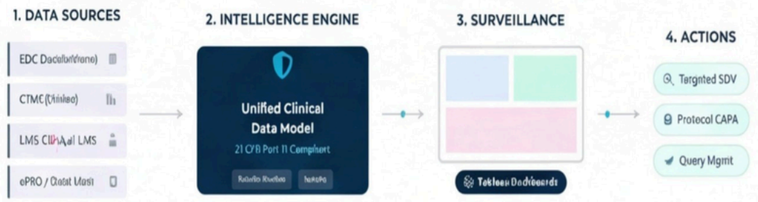
INTRODUCTION

- Clinical trials require continuous monitoring to ensure protocol compliance and accurate pharmacokinetic (PK) data
- Traditional monitoring methods relying on static reports often delay the detection of protocol deviations and PK sampling inconsistencies, creating significant risks to data quality and study timelines.
- This poster presents a real-time dashboard solution designed to innovate clinical signal surveillance, enabling proactive identification and resolution of deviations.

METHODOLOGY

System Architecture

A source-agnostic dashboard solution developed in Tableau enabling dynamic monitoring of critical signals via a Unified Clinical Data Model.

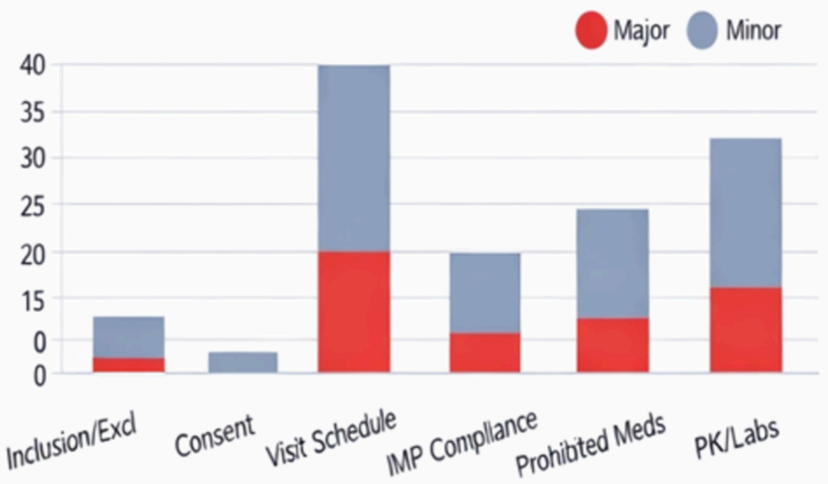


Pipeline: Data Aggregation → Intelligence Engine (Validation Rules) → Surveillance Views → Action Tracking

MONITORING WORKFLOW

Structured 4-step process: Sample Timing → Subject Checks → Visual Indicators → Drill-down.

PROTOCOL MONITORING



PK SAMPLE TIMING DEVIATIONS

Fig 1. Heatmap of sample collection deviations (min) by subject and timepoint. Red indicates >15m deviation.

Result: Identified systematic late draws at Site 104 (4h post-dose), enabling targeted retraining within 48 hours of trend emergence.

CONCLUSION

Transforming complex clinical trials into proactive oversight is achievable through real-time dashboards.

Our approach enhances early detection of protocol and PK issues, reduces operational risks, and improves data integrity.

By harnessing structured workflows and visual analytics, we enable timely intervention and ensure trial efficiency through advanced real-time monitoring.