

Assessing and Measuring Performance in Clinical Research

Driving Clinical Trial Performance from Downstream, a CRO's Perspective

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Clinical Trials Performance

How do you measure performance?

- Safe Patients
- Quality Data
- Complete Data
- On Time Deliverables
- Adaptation & Flexibility



Proactive or Reactive KPIs

Even though a CRO is “down stream”

- KPIs can be proactive, not reactive
- Embedded signal detection is the key
- Signals can be embedded for:
 - Data quality
 - Operational effectiveness
 - Subject safety
 - Flexibility and adaptive design



Data Quality Signal Detection

- Traditional edit checks and processes
 - Help keep data clean and complete
 - Help integrate disparate data sources
 - Are reactive by design
- Signal detection within edit checks can
 - Affirm the effectiveness of the edit check code
 - Point to training/retraining needs
 - Identify cultural differences and biases
 - Inform future CRF creation
 - Can be proactive and enhance data quality



Operational Signal Detection

- Traditional Operational Issue Identification
 - Internal and External Audits
 - CAPAs
 - Are reactive by design
- Risk Plans during Study Setup
 - Metrics embedded in risk areas
 - Predefined action plans
 - Can be proactive and enhance trial performance



Subject Safety Signal Detection

- Traditional Safety Issue Identification
 - AEs and SAEs, PhV
 - Interim Analysis
 - Subject Profiles
 - Are reactive by design
- Patient Centric Focus
 - Functional verticals transition to patient horizontals
 - Automated signal detection (Ex. Hy's Law and DILI)
 - Cross validation of all relevant data (ex. free text & concomitant medications)
 - Are proactive and can enhance subject safety



Adaptive Design Signal Detection

- Traditional Design
 - Most trials carried out as designed.
 - Trial failure instead of changes (ex dosing)
 - Painful and risky trial modifications
 - Are reactive by design
- Flexibility and Adaptive Design
 - Comprehensive feasibility
 - Embedded adaptive signals
 - Study Setup based on anticipated adaptations
 - Can be proactive and enhance trial adaptability



Questions?

