

Single Day Event

Enabling CRO Oversight and Governance
with Data Visualization

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Agenda



Trial Complexities - Need for Right Partner



Achieving Sponsor - CRO Oversight - Key Dynamics



Centralising CRO Oversight – Power of Data Visualisation



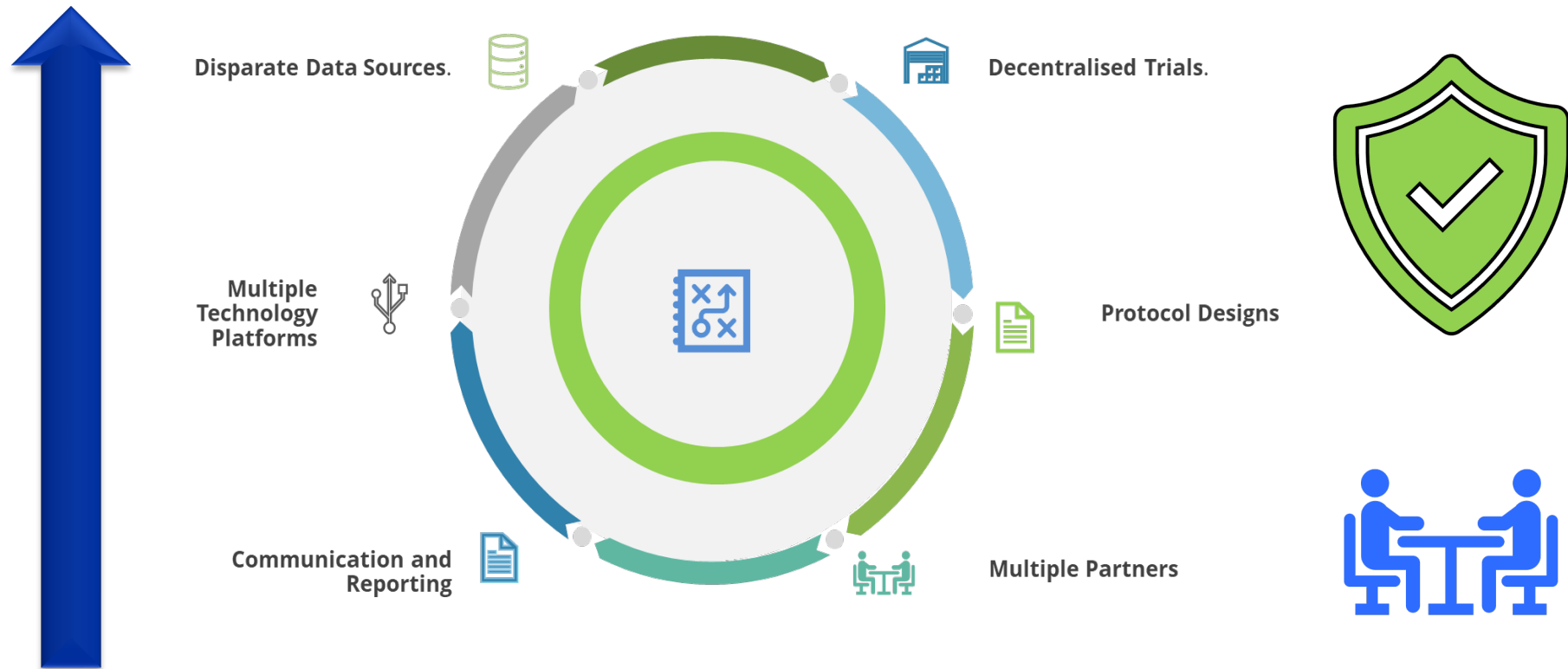
Key metrics - Enhancing Sponsor - CRO Oversight



Key takeaways



Trial Complexities





Advantages of choosing a Right Partner





CRO Oversight – Sponsor & CRO setting the dynamics



Sponsor



CRO





Sponsor- Regulatory Oversight Requirements



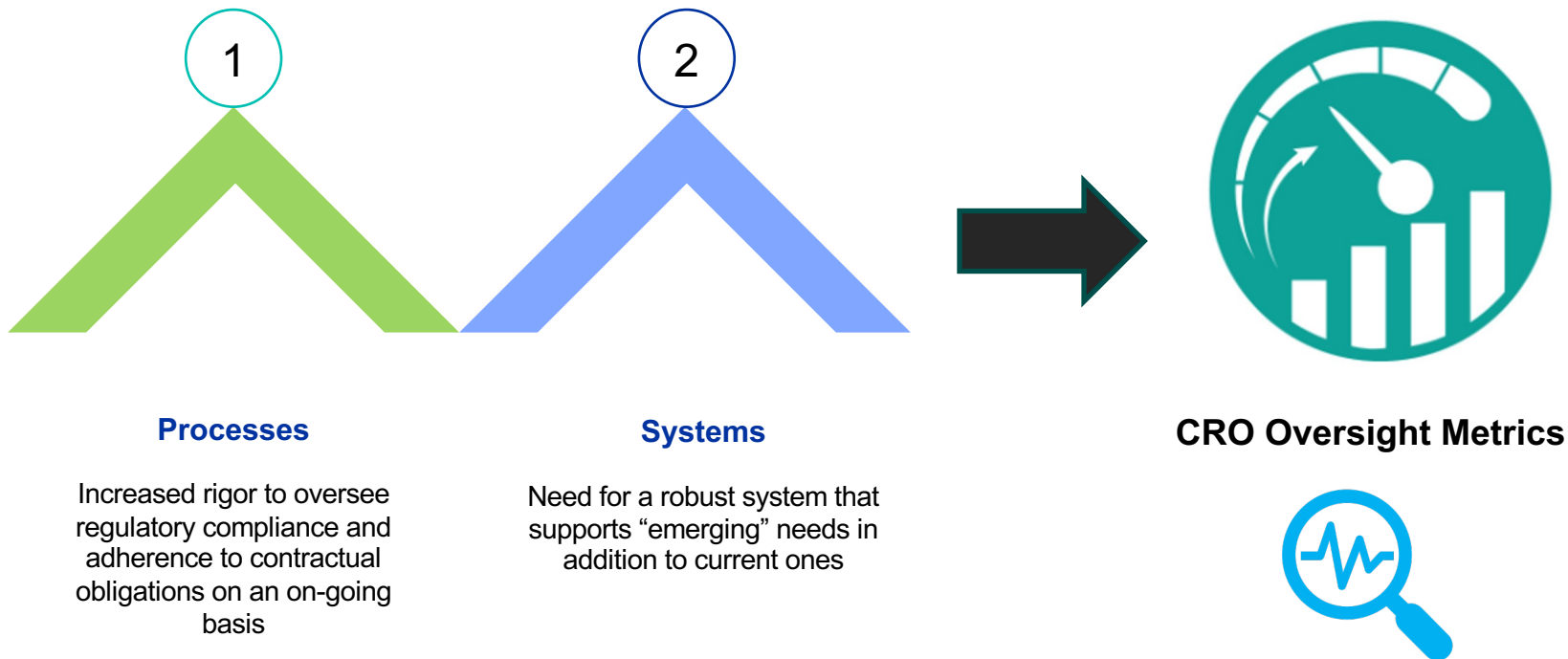
“Sponsors should implement a system to manage, throughout all stages of the clinical investigation, both risks to participants (e.g., a safety problem) and to data integrity (e.g., incomplete and/or inaccurate data).”



ICH E6(R2) (section 5.2) allows for the transfer of any or all trial-related duties to a CRO, with the reminder that the sponsor is ultimately responsible for the quality and integrity of the clinical trial

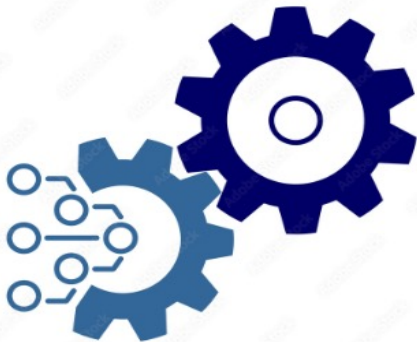


CRO Oversight Metrics Key drivers

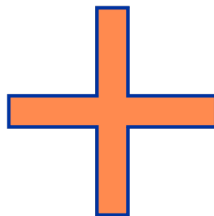




CRO Oversight Metrics with effective Data Visualization



Technology



Metrics

- A robust technology ecosystem driven by clinical data analytics can be a game-changer for CRO governance and oversight.
- Data-driven visual insights can help identify trends patterns, and recurrent issues, improve compliance, optimize vendor performance, and enhance data integrity.



Oversight Metrics Ecosystem



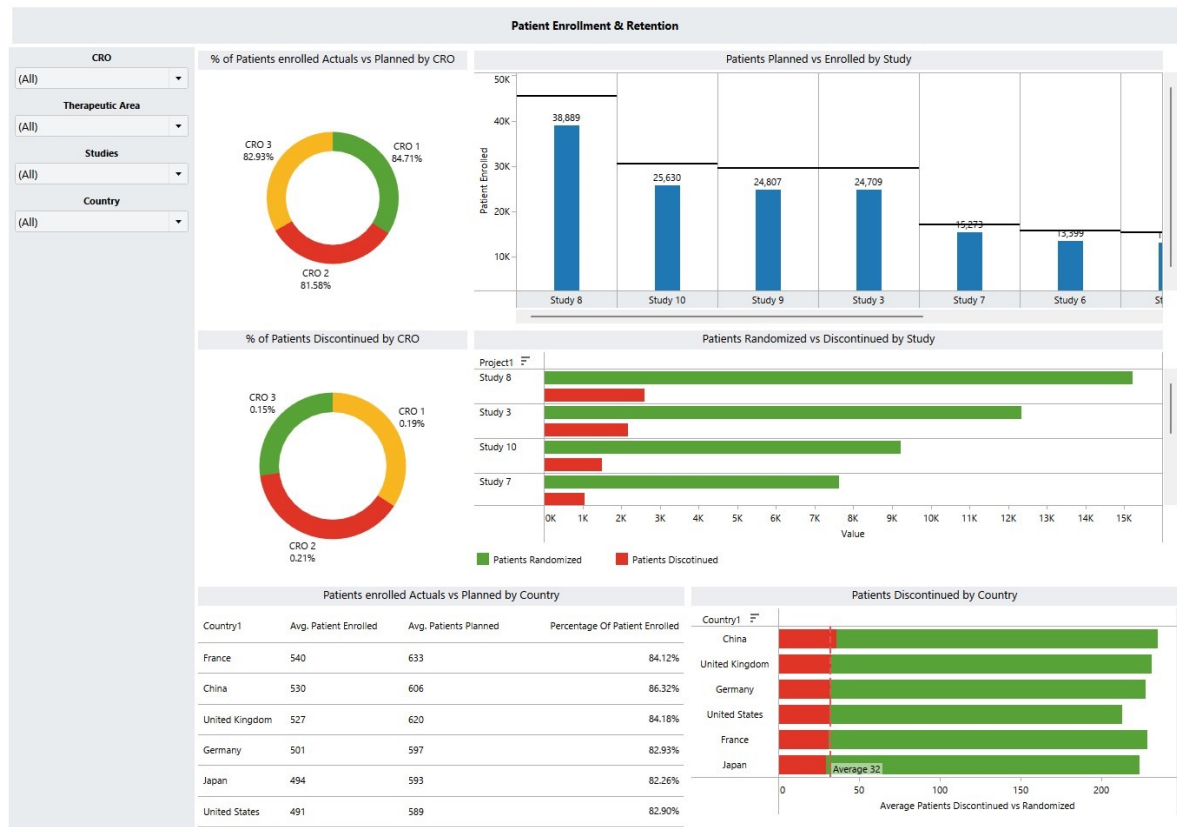
With every new CRO partner, it is critical to establish clear goals and objectives for the partnership

- Set clearly defined vendor policies
- Metrics to monitor progress, outcomes, gaps, and success
- Multi-level communication frameworks to ensure transparency
- Incorporate multiple feedback mechanisms (e.g., surveys)
- Review to jointly remediate during governance meetings

Data sources: CTMS, EDC, TMF, timeline trackers and metrics, finance systems, etc.



Patient Enrolment and Retention



Patients enrolled-planned vs actuals (by CRO and study)

Patient discontinuation (by study, country and CRO)



Quality Metrics



CRO/Study level
quality status

Country-wise metrics
for findings,
resolutions and
compliance issues



Compliance Metrics- SAE Reporting



Tracking delays in SAE reporting delays and teething compliance issues



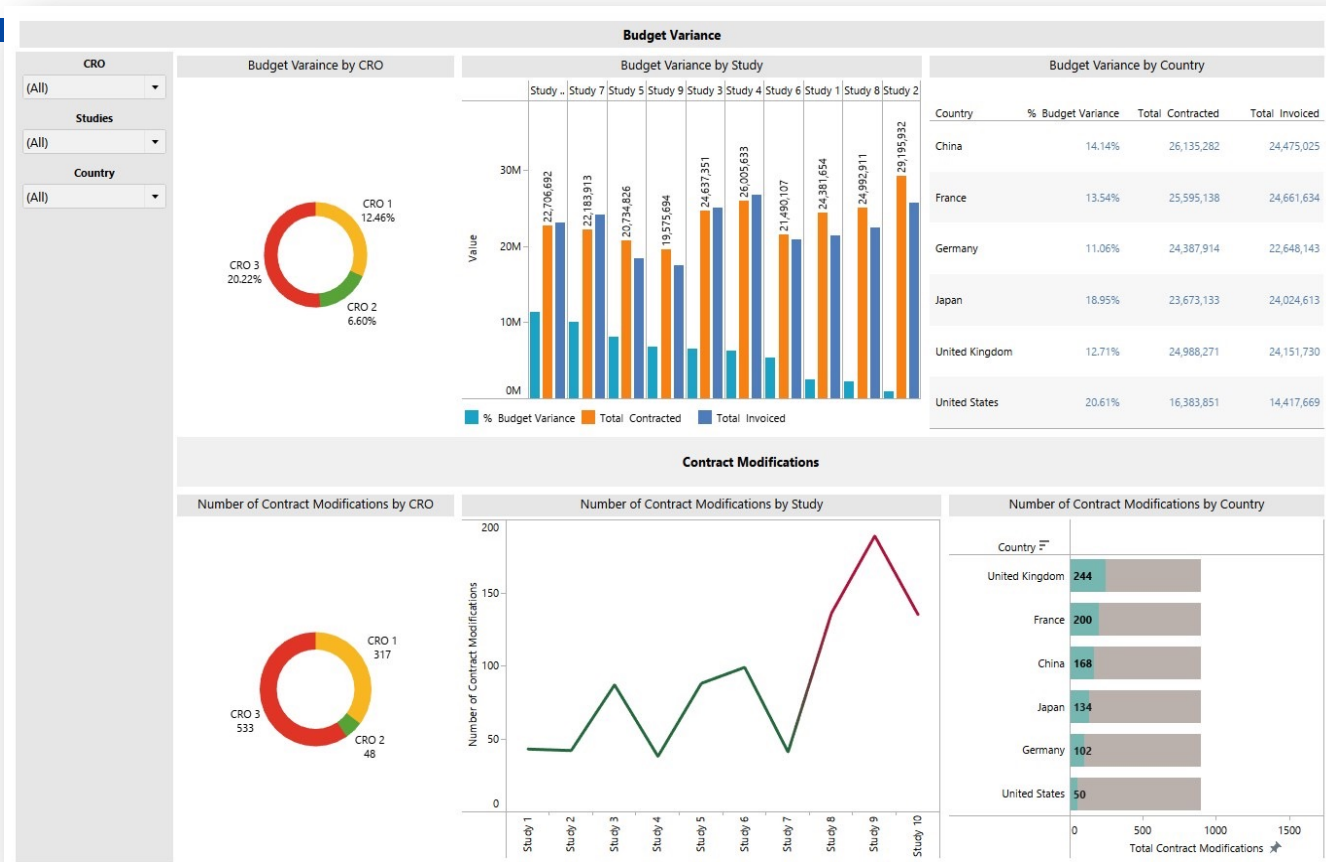
Compliance Metrics - Protocol Deviation



Protocol deviations by
study-country-site and
criticality



Finance Metrics- Contracts and budgets



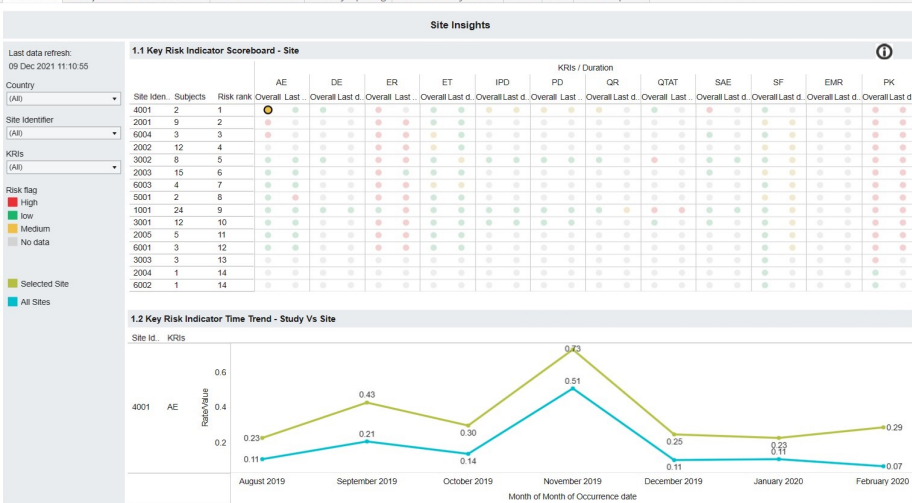
Budgetary variance/
change orders by CROs,
by study and country



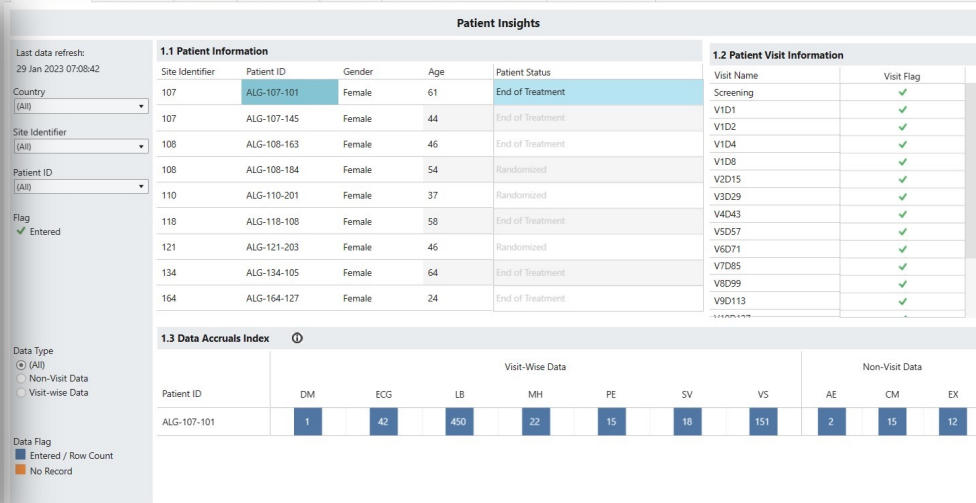
Next Generation Data Visualization

- Study- level insights for monitoring patient recruitment, retention, investigator payments and documentation

1 Site Index | 2 Subject Recruitment and Ret... | 3 Protocol deviation | 4 Safety reporting | 5 Data currency metrics | 6 EMR | 7 PK | 8 Data Explorer



1 Patient Index | 2 Standard Analysis - Overall | 3 Standard Analysis - Events | 4 Critical Data - Tumor Evaluati... | 5 SAE Reconciliation



- Overcoming site health issues with early detection

- Patient profiles and safety summaries to derive critical safety insights in early development



Key Takeaways

- Choosing the right Partner by Sponsor is paramount important
- CRO oversight metrics is key element for the right partner
- Data analytics along with visualization helps to enhance CRO oversight through various Key Performance Indicators (KPIs) and Metrics visually.
- Proactively addressing trends and ensuring transparent data for informed decisions, while maintaining a constant state of audit readiness.

Thank you



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