



Vita Global Sciences

FROM RESEARCH TO REALITY

PD06

Key Metrics for Success: Measuring Project Performance and Impact in the Face of Complex Clinical Trials

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Introduction

The importance of compliance in clinical trials, the key metrics utilized by Clinical Project Managers, and how these metrics are seamlessly integrated into daily operations.

The Importance of Compliance in Clinical Trials



Patient Safety

Protecting participants from harm is a priority.
Strict adherence to protocols ensures their well-being.



Regulatory Adherence

Meeting legal and ethical standards is crucial for the approval and acceptance of trial results.



Scientific Integrity

Rigorous compliance maintains the credibility of research, ensuring accurate and reliable data for analysis.



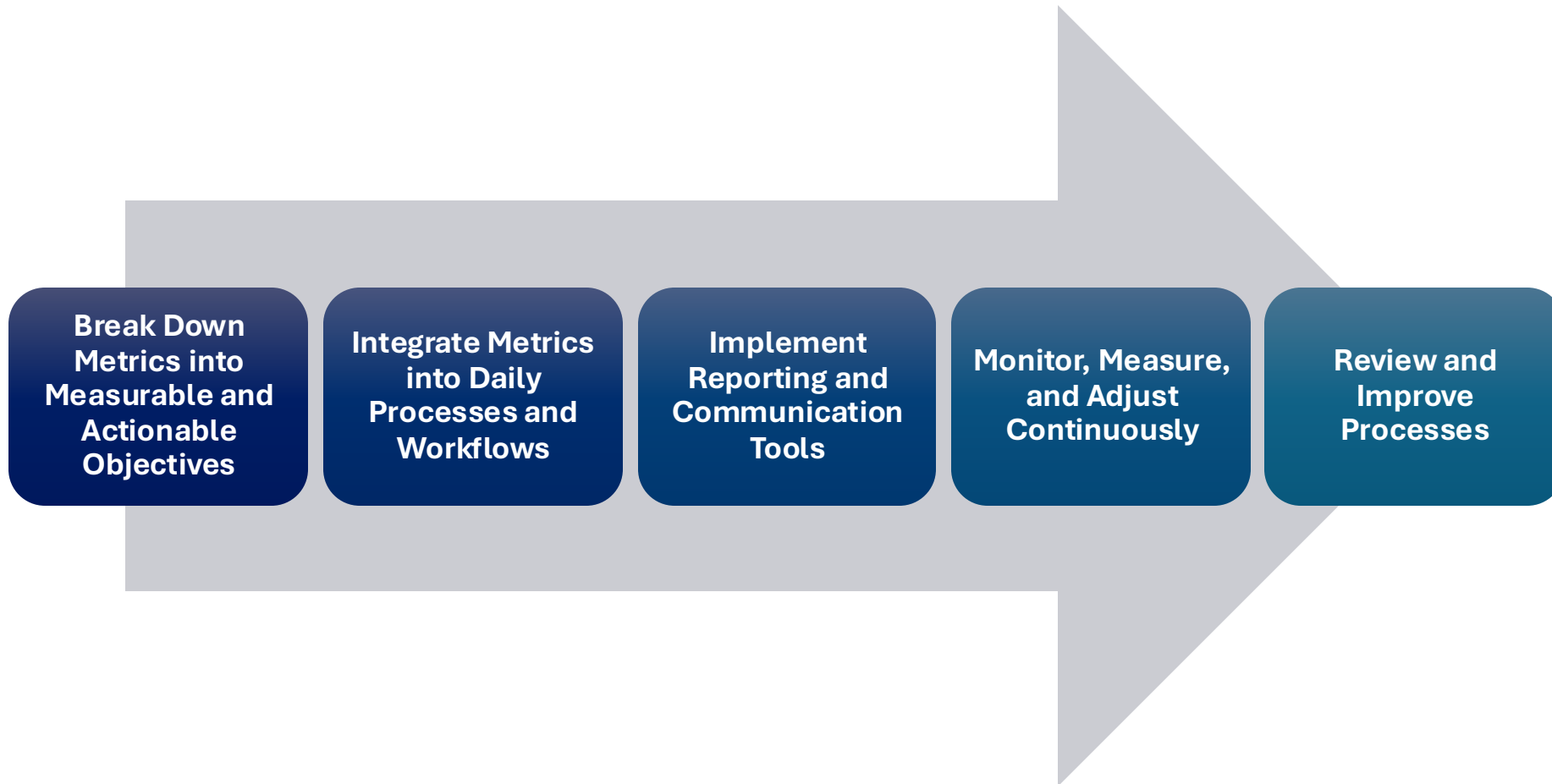
Trial Success

A well-managed trial with high compliance contributes to the overall effectiveness and success of the research.

Key Metrics for Achieving Compliance in Clinical Trials



Translating Key Metrics into Daily Processes



Governance Metrics

Governance Metrics ensure compliance, efficiency and accountability throughout the trial lifecycle.

Key Governance Metrics

1. **Regulatory compliance:** Adherence to FDA, EMA, ICH-GCP and data privacy laws (GDPR, HIPAA) and tracks protocol deviations.
2. **Audit & inspection pass rates:** Tracks audits and inspections passed without major findings.
3. **Risk management & issue resolution:** Identifies, tracks, and mitigates risks and measures success of mitigation.
4. **Stakeholder engagement:** Measures governance structure effectiveness, decision-making, and reporting transparency.
5. **Financial oversight & budget control:** Monitors budget adherence and cost variances and ensures timely payments.
6. **Data integrity and security compliance:** Ensures compliance with data protection laws and best practices.

Operational Metrics

Operational Metrics track efficiency, quality, timeliness, and overall performance of clinical trials

Key Operational Metrics

1. **Project timeline & milestone tracking:** Measures milestones met vs. projected timelines and improves compliance, resource optimization, and budget management.
2. **Turnaround time:** Tracks time for key tasks (data entry, monitoring reports) and minimizes idle time.
3. **Resource utilization and forecasting:** Ensures optimal resource allocation, forecasts future needs, and identifies resource gaps.
4. **Budget management:** Compares budgeted vs. actual spending and tracks burn rates to ensure financial control.
5. **Risk management and issue resolution:** Identifies, tracks, and resolves bottlenecks and risks quickly to avoid delays.

Quality Metrics

Quality Metrics ensure high data integrity, regulatory compliance, and reliability.

Key Quality Metrics

1. **Query resolution time:** Tracks time to resolve data queries, ensuring data accuracy and preventing delays.
2. **SOP adherence:** Monitors compliance with SOPs, ensuring consistency, quality, and regulatory alignment.
3. **Audit & inspection pass rates:** Measures site compliance through audit success rates, reflecting operational excellence and adherence to industry standards.
4. **Data accuracy and integrity:** Monitors data discrepancies to maintain high standards of accuracy and integrity.
5. **Corrective and preventive actions (CAPAs):** Tracks implementation of corrective actions, ensuring continuous improvement and compliance.
6. **Protocol adherence & regulatory compliance:** Ensures study protocols are followed to maintain data validity and compliance.

Financial Metrics

Financial Metrics monitors financial health, ensures budget adherence, and optimizes resource allocation

- **Key Financial Metrics**

- **Budget variance (BV):** Compares planned vs. actual spending to identify under/overspending.
- **Earned value (EV):** Measures project performance by comparing completed work to planned work.
- **Forecast at completion (FAC):** Predicts total cost at trial completion to ensure financial control.
- **Actual cost (AC):** Tracks total expenses incurred during the trial against the planned budget.
- **Resource utilization rate:** Assesses the efficiency of resource allocation to optimize cost savings.



Step 2: Integrate Metrics into Daily Processes and Workflows

Governance

- Automate audits and track SOP compliance.
- Use risk registers to monitor and mitigate risks.
- Practice transparent reporting to stakeholders.
- Real-time tracking of audit success and deviations.

Operational

- Use project management tools for timeline tracking.
- Integrate resource timesheets with project trackers for real-time allocation.
- Automate milestone tracking to prevent delays.

Quality

- Embed query resolution into EDC systems.
- Monitor SOP adherence through Electronic Quality Management Systems.
- Use CTMS to track protocol deviations and CAPAs.

Financial

- Use financial planning tools to track budget variance and actual cost.
- Monitor earned value to assess cost and schedule performance.
- Forecast total costs using the Forecast at Completion (FAC) metric.



Step 3: Implement Reporting and Communication Tools

Governance

Tools: Compliance dashboards, Regulatory Management Software (Veeva Vault QMS).

Implementation:

- Use automated reports to track compliance, audit results, and regulatory updates.
- Regularly share governance updates in team meetings, ensuring accountability.
- Use collaboration tools (Microsoft Teams, Outlook) for ongoing communication with team members and stakeholders.

Operational

Tools: Project Management Software (MS Project), Resource Management Tools (Smartsheet).

Implementation:

- Set up dashboards to monitor timelines, resource allocation, and task completion rates.
- Use real-time updates for milestone tracking and resource utilization.
- Share weekly or bi-weekly progress reports and adjust resource allocation based on insights.

Quality

Tools: Electronic Quality Management Systems (eQMS) (ZenQMS), Clinical Trial Management Systems (CTMS).

Implementation:

- Utilize real-time monitoring to track data quality, errors, and protocol deviations.
- Set up dashboards to visualize key quality metrics, such as error rates or data integrity issues.
- Regularly review quality reports to identify patterns and areas for improvement.
- Regularly review compliance reports to identify non-compliance among team members.

Financial

Tools: Financial Management Software and Budget Tracking Tools

Implementation:

- Set up automated reporting to compare planned vs. actual spending, monitor burn rates, and track earned value.
- Use forecasting tools to predict future costs and adjust budgets as needed.
- Share financial updates during regular project meetings and adjust strategies based on financial health.



Step 4: Monitor, Measure, and Adjust Continuously

Governance

- **Monitor** compliance with regulations via trial management systems and automated alerts.
- **Measure** audit pass rates and stakeholder engagement.
- **Adjust** based on audit feedback and regulatory updates.

Operational

- **Monitor** project timelines and resource utilization with real-time dashboards.
- **Measure** milestone completion and efficiency of resource use.
- **Adjust** by reallocating resources and adjusting timelines as needed.

Quality

- **Monitor** data accuracy and protocol adherence through monitoring systems.
- **Measure** error rates and data quality.
- **Adjust** processes and training based on quality control findings.

Financial

- **Monitor** budget vs. actual spending with financial tracking tools.
- **Measure** budget variance, earned value, and resource utilization.
- **Adjust** financial forecasts and spending based on trial performance.



Step 5: Review and Improve Processes



Governance

- Regular audits and assessments of compliance data.
- Align with regulatory updates (FDA, EMA).
- Integrate automation to improve reporting accuracy.
- Train staff on new compliance regulations.

Operational

- Analyze timeline adherence and recurring delays.
- Assess resource allocation for efficiency.
- Use agile practices to improve flexibility.



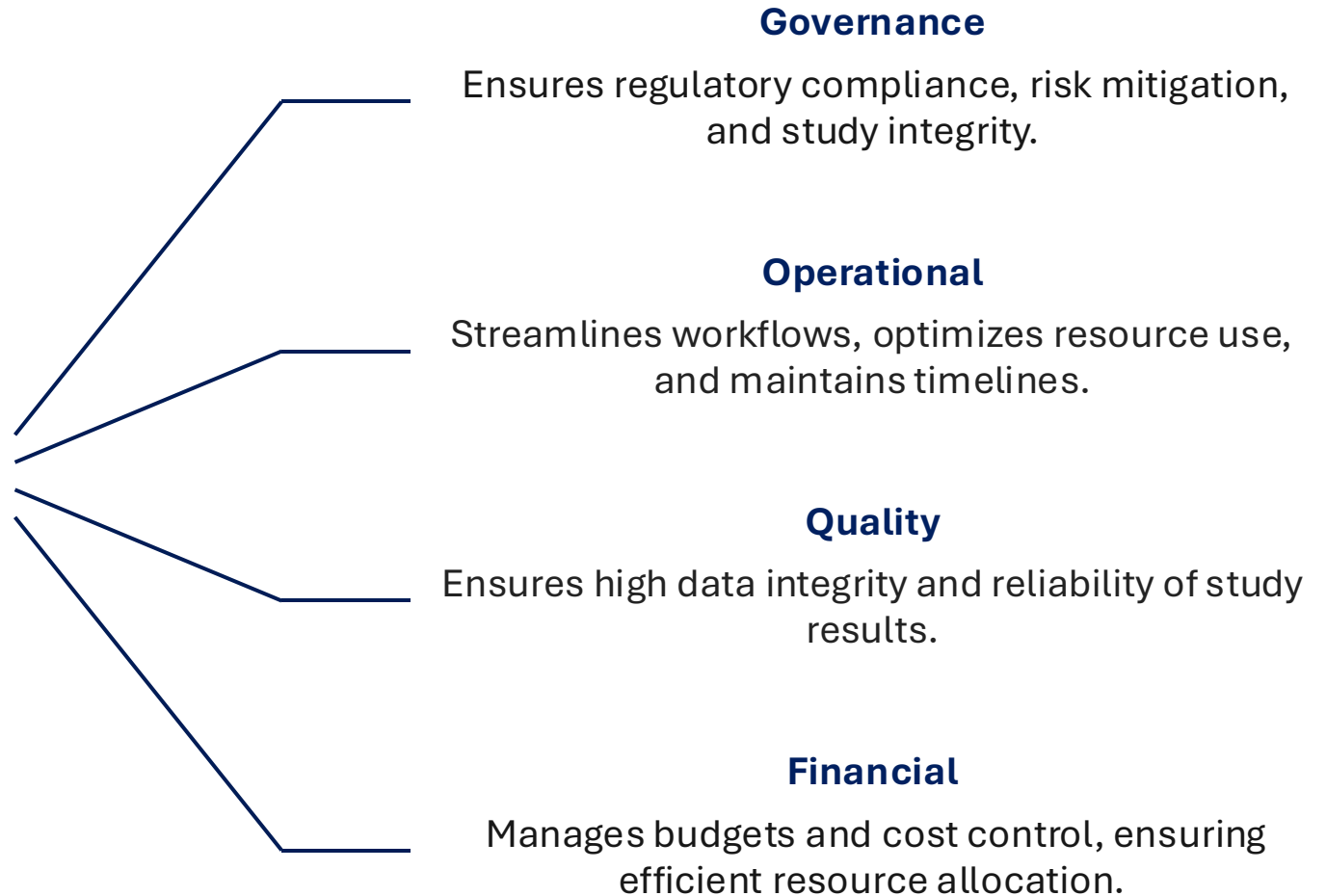
Quality

- Track data accuracy and error trends.
- Review quality issue frequencies and root causes.
- Implement additional quality checks and validation steps.

Financial

- Regularly compare budgeted vs. actual costs.
- Conduct variance analysis to identify financial discrepancies.
- Tighten budget controls and approval workflows.
- Update financial forecasts based on project performance.

Conclusion



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Benefits of a Metric-Driven Approach:

1. Enables data-driven decisions
2. Adapts quickly to challenges and improves processes.
3. Improves patient outcomes
4. Drives efficient trials and supports healthcare research.

Questions?

Thank You



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