Strategies for Generating Value-Driven Data to Improve Laboratory Operations

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Valley Water

Data in the Laboratory

The lab environment is data-intensive and compliance-driven

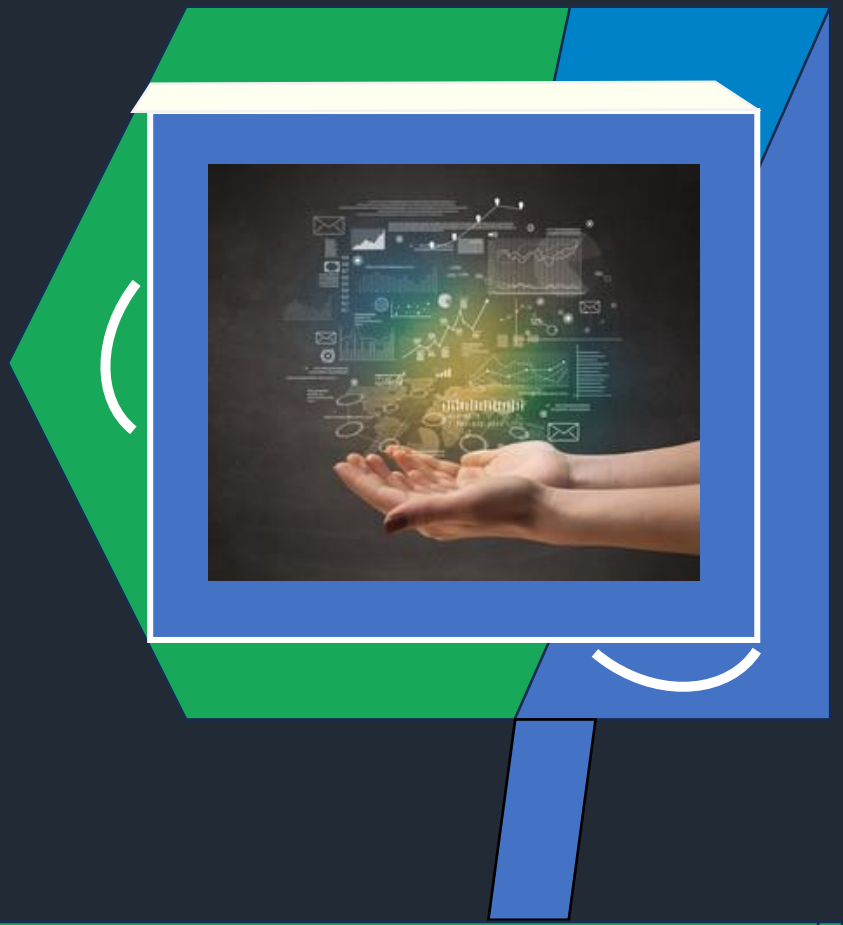
Strategic Performance Metrics
=
Better Decisions and Improvement

Today's Focus:

Linking Meaning with Data Collection

Why Collect Data in the Lab?

- Regulatory Compliance
- Quality Control
- Audits and Traceability
- Method Validation and Verification
- Instrument Calibration and Maintenance
- Trend Analysis



Let’s Ask Some Lab Folks…

Why Collect Data in the Lab?

"That's how we've always done it"

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"Everyone else is collecting this data"

"It might help during an audit, …just in case"

Meaningful Data

Data for a specific process that is:

- Relevant
- Useful
- Contextually Appropriate
- Has Clarity and Purpose

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Example: Recording temperature trends in a lab test.

→ Directly affects chemical solubility and biological activity.

Value-Driven Data

Data collected and used based on the value that it brings to:

- Decision-Making
- Outcomes
- Objectives

Emphasis on impact, not just relevance

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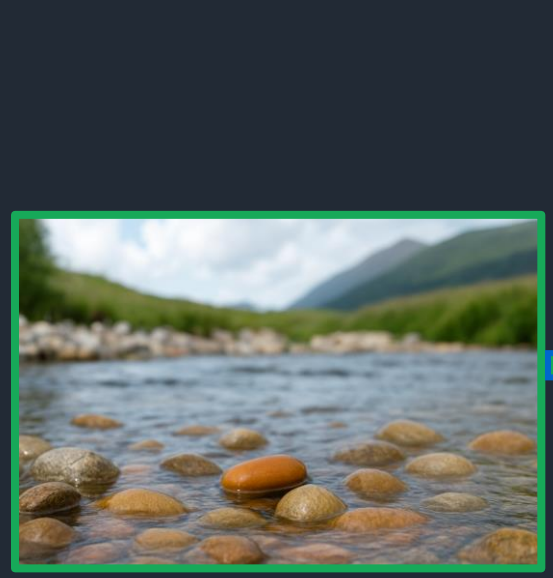
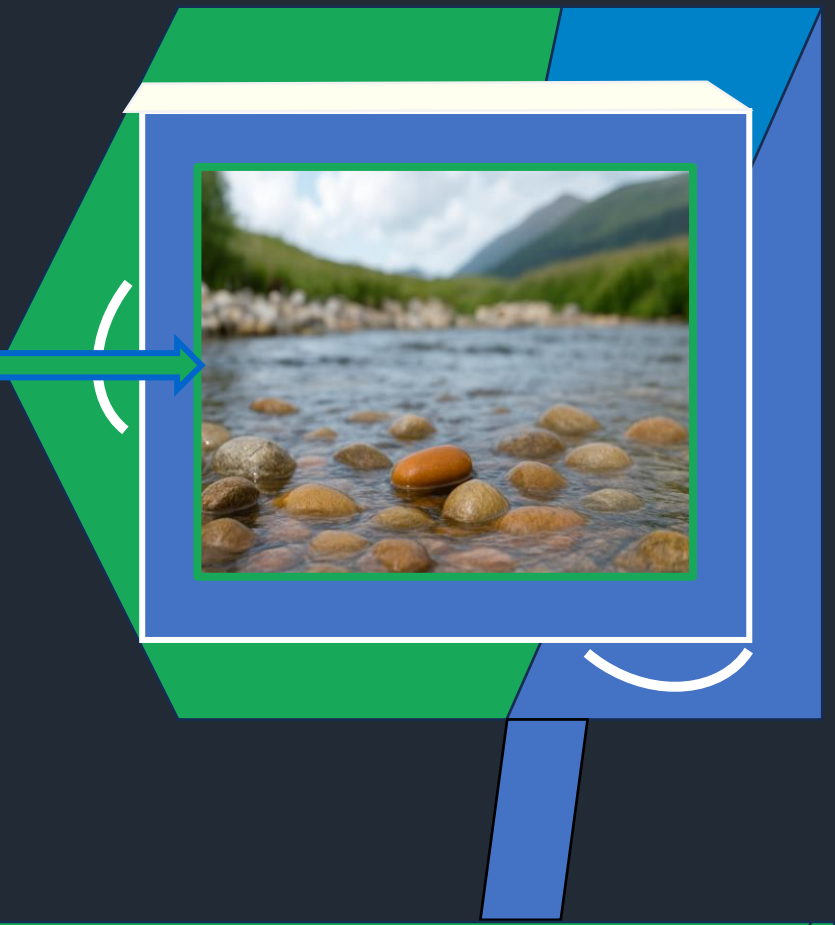
Example: Data collection to assess false positives.

→ Saves costs and improves trust with data and customers.

Strategic Planning



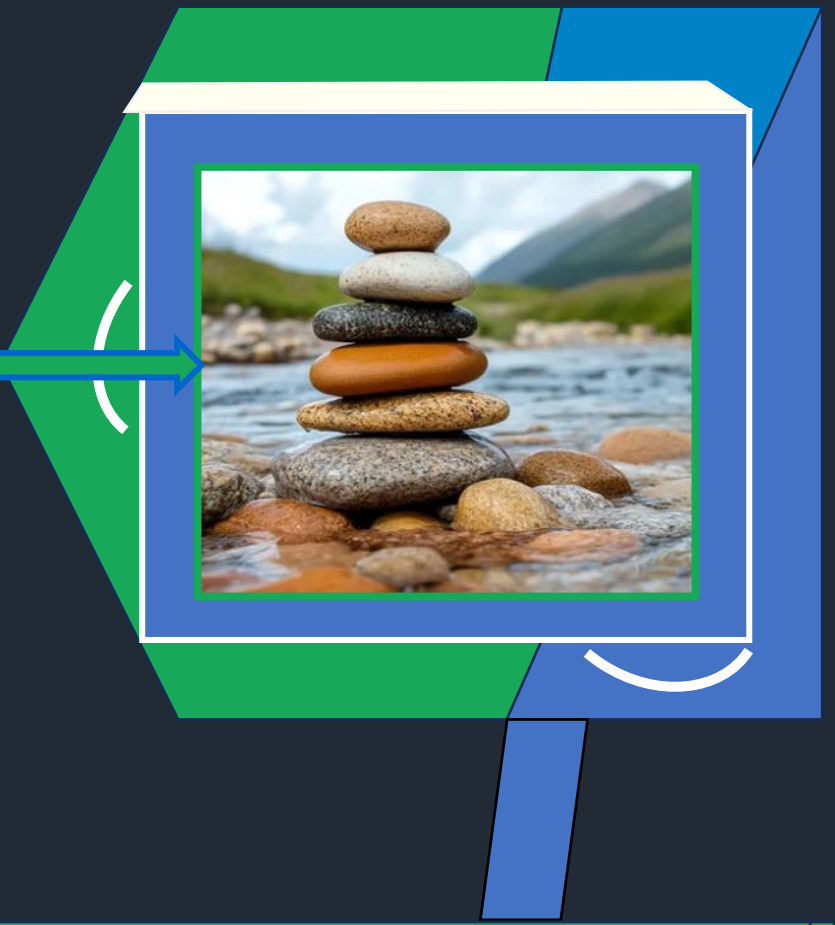
Objective: Create Natural Art



Strategic Planning

Define and Document
Begin with the End in Mind

Planning with Purpose

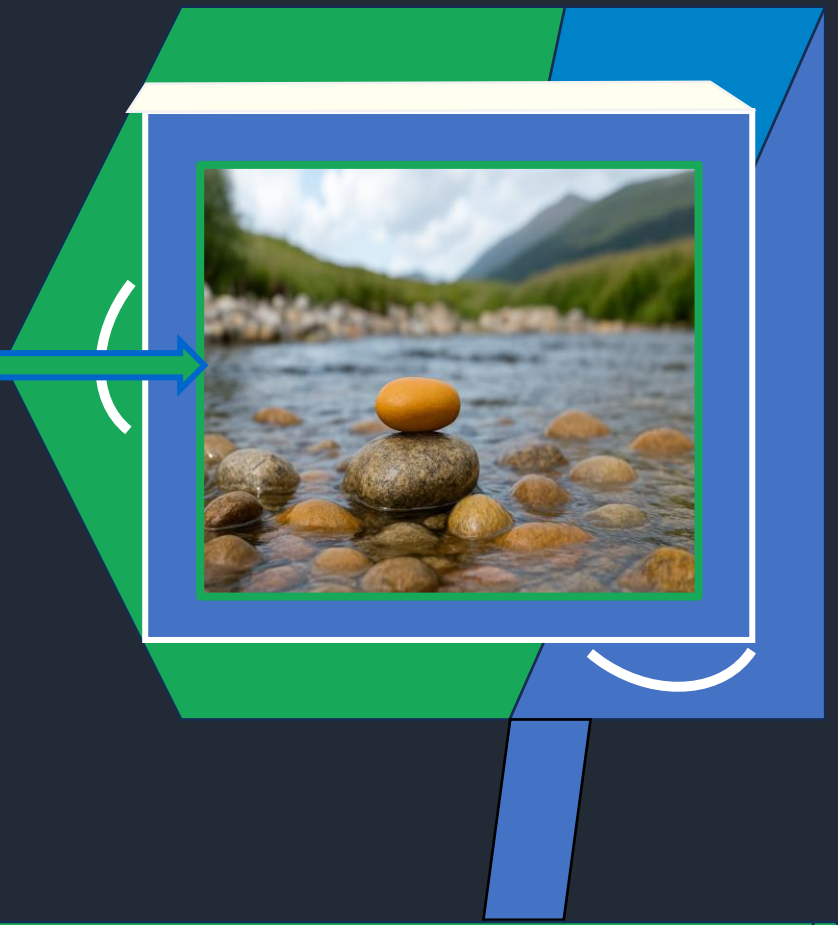


Strategic Planning

Define and Document
Begin with the End in Mind

Regulatory Standards
Compliance and Alignment

Foundational Requirements



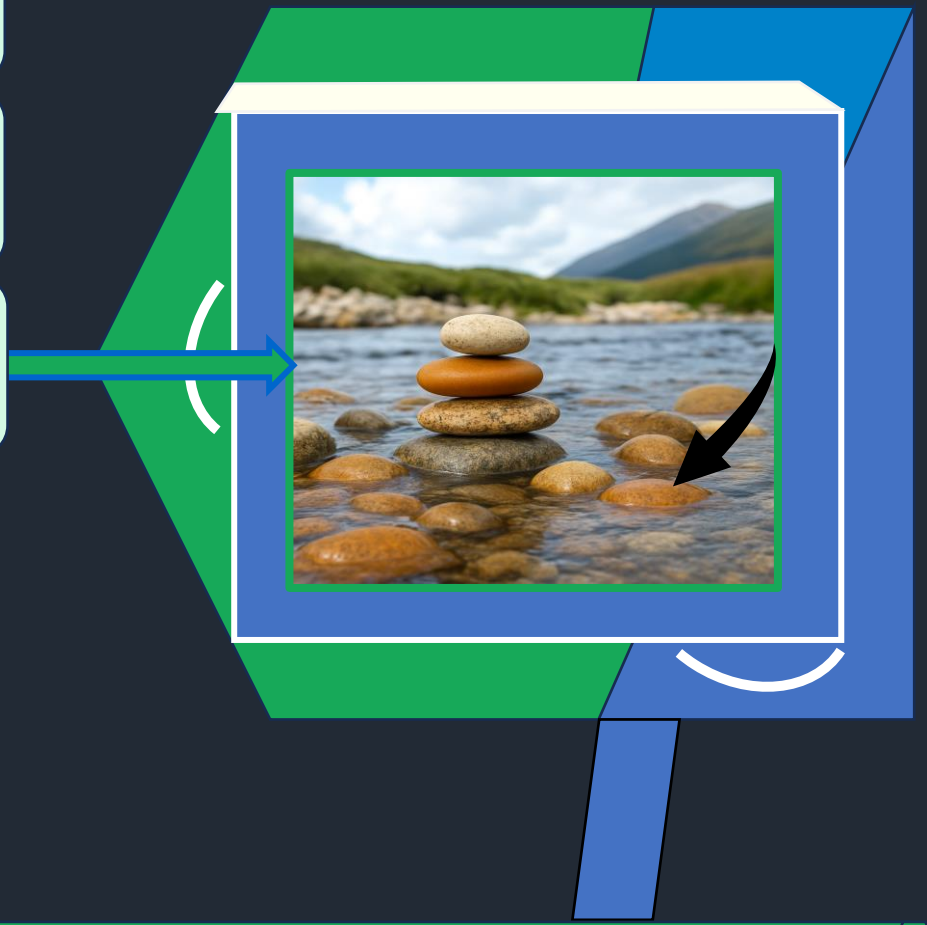
Strategic Planning

Define and Document
Begin with the End in Mind

Regulatory Standards
Compliance and Alignment

Efficiency
Focus on What Matters

Goals and Objectives



Strategic Planning

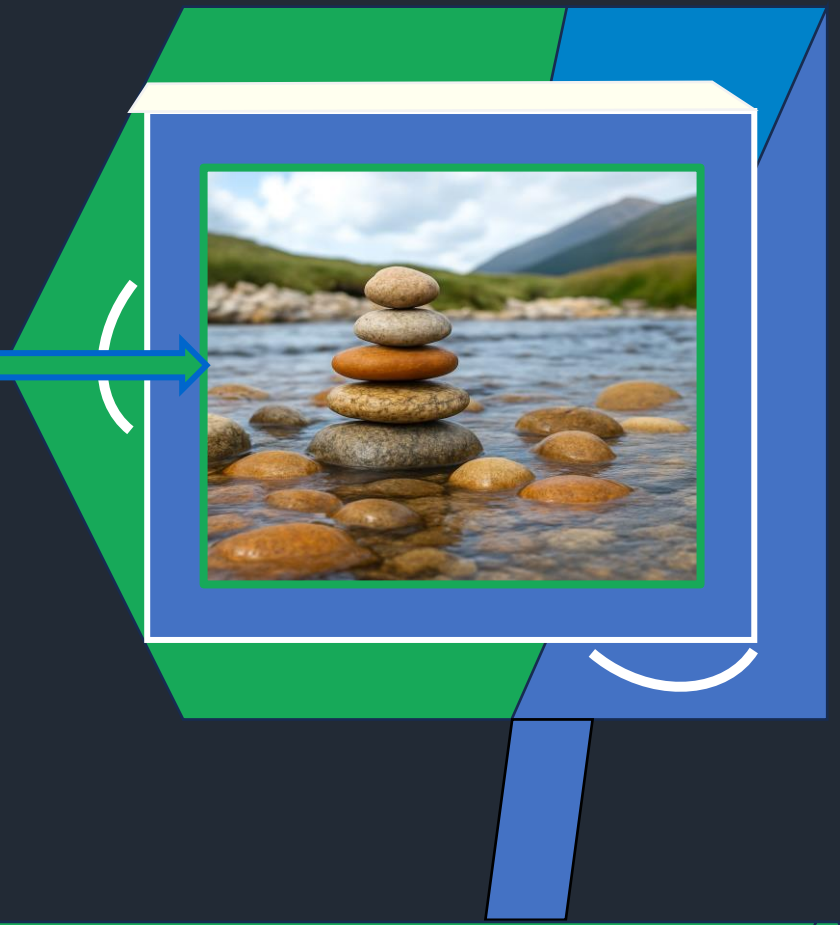
Review Alignment

Define and Document
Begin with the End in Mind

Regulatory Standards
Compliance and Alignment

Efficiency
Focus on What Matters

Accountability
Align Tasks with Measurable Goals



Strategic Planning

Continual Improvement

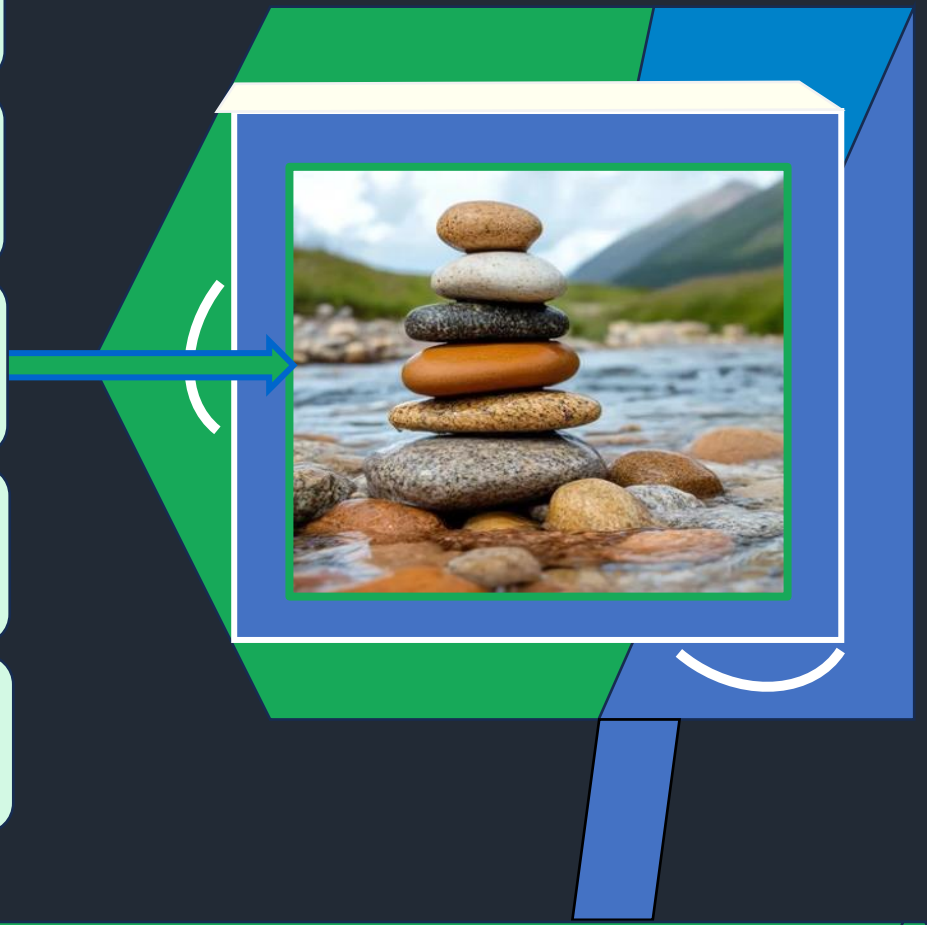
Define and Document
Begin with the End in Mind

Regulatory Standards
Compliance and Alignment

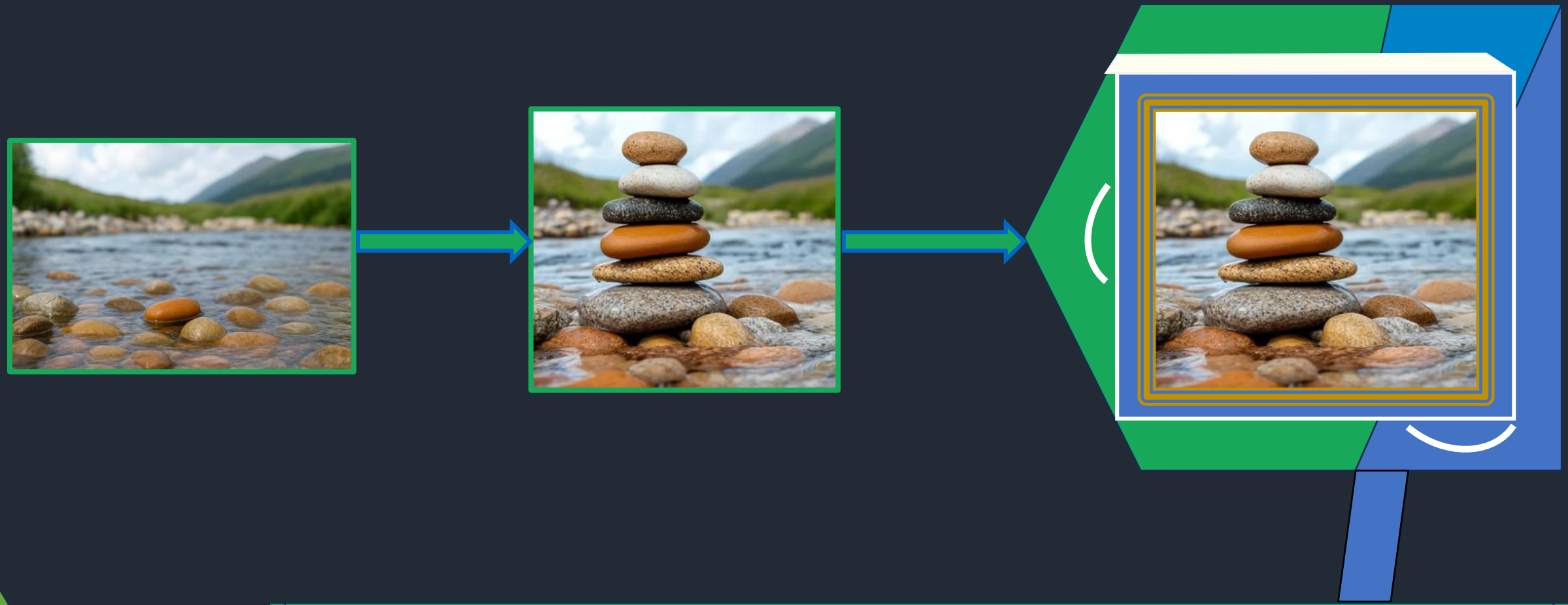
Efficiency
Focus on What Matters

Accountability
Align Tasks with Measurable Goals

Momentum
Actions and Improvements



Strategic Planning = Desired Results



Strategic Planning = Desired Results

Define and Document
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Focus on what matters

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Align Tasks with Measurable Goals

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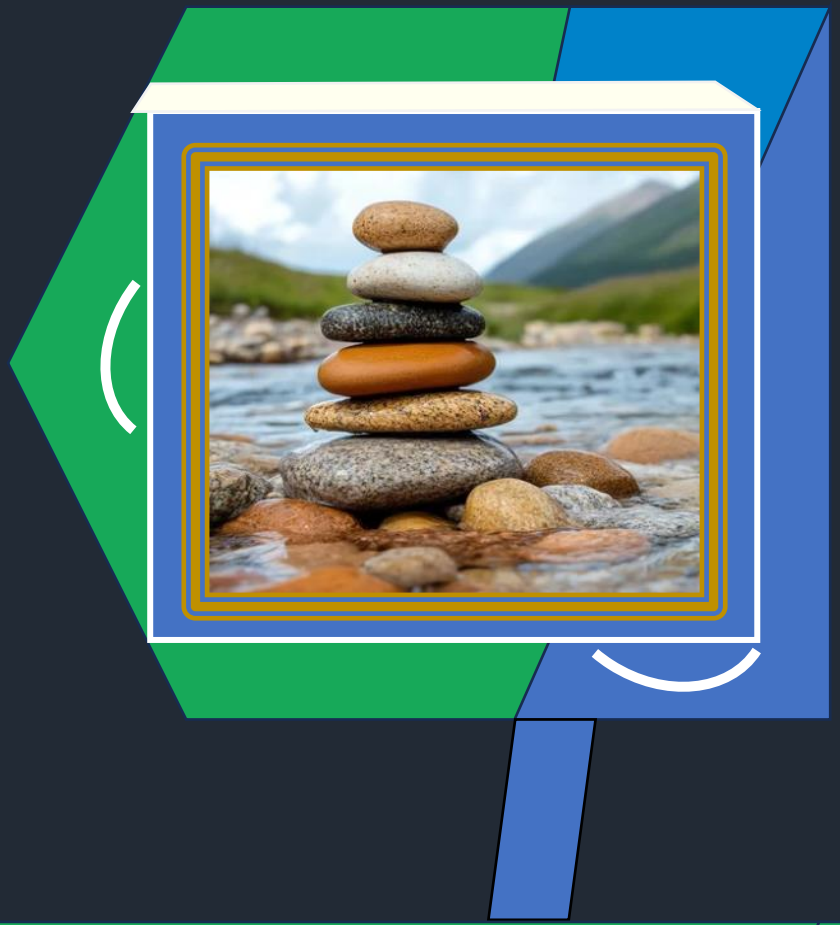


Performance Metrics

Performance Metrics

- **OKRs** - Objectives and Key Results
- **KPIs** - Key Performance Indicators
- **KQIs** - Key Quality Indicators
- **KRIs** - Key Risk Indicators

OKRs – Objectives and Key Results

- Goal-setting framework
- Strategic goals linked to measurable outcomes
- Identify processes to review and monitor

OKRs - Examples

1. Build Quality Culture as the Foundation for Reliable Data
2. Improve the corrective action closure rate
3. Shorten sample turnaround time
4. Strengthen SOP version control
5. Improve internal audit program assignments
6. Develop a skilled workforce through trainings
7. Build a Business Continuity Plan

KPIs – Key Performance Indicators

- KPIs define Success
  - Measure to track the performance of process elements
- Baseline to determine risk
- Foundation for OKRs and quality initiatives
- Measure progress towards OKRs
- Alignment with lab objectives and regulatory requirements
- Management defines and reviews KPIs that matter

KPIs - Examples

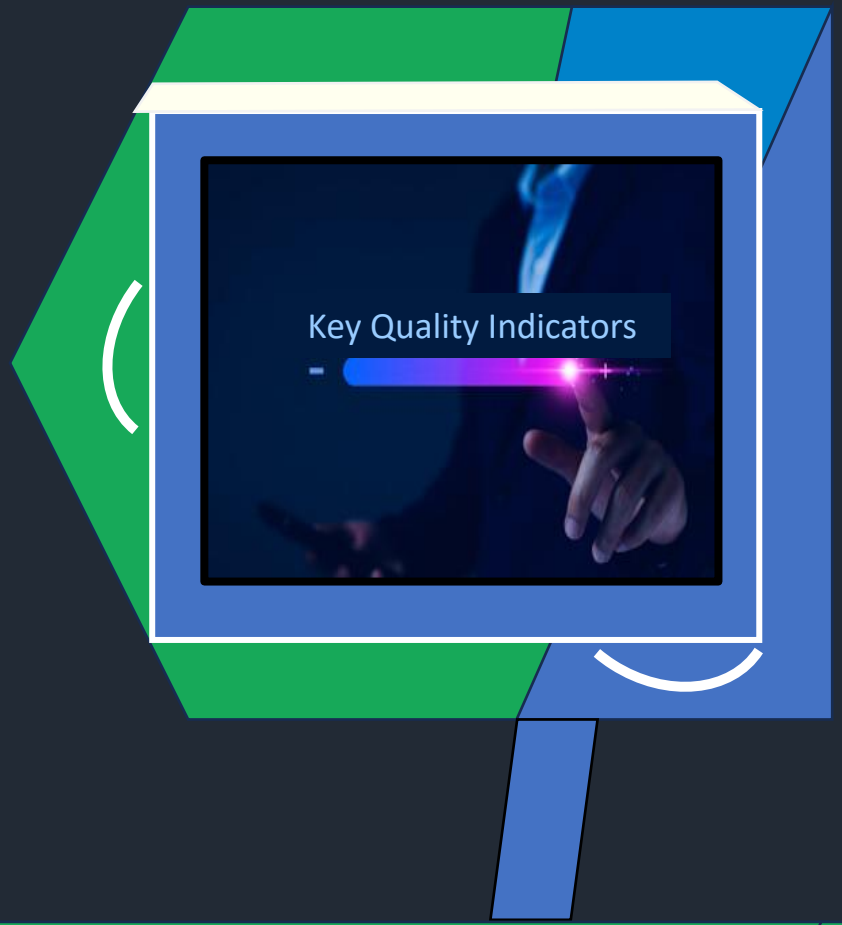
1. Turnaround Time Conformance Rate
2. Sample Acceptance Rate
3. Corrective Action Closure Rate
4. Proficiency Testing Pass Rate
5. Analyst Training Compliance

KPIs - Examples

1. Turnaround Time Conformance Rate
2. Sample Acceptance Rate
3. Corrective Action Closure Rate
4. Proficiency Testing Pass Rate
5. Analyst Training Compliance
6. Equipment Check Completion Rate
7. Client Satisfaction Score
8. Internal Audit Completion Rate
9. Document Review Completion Rate
10. Sample Holding Time Compliance Rate

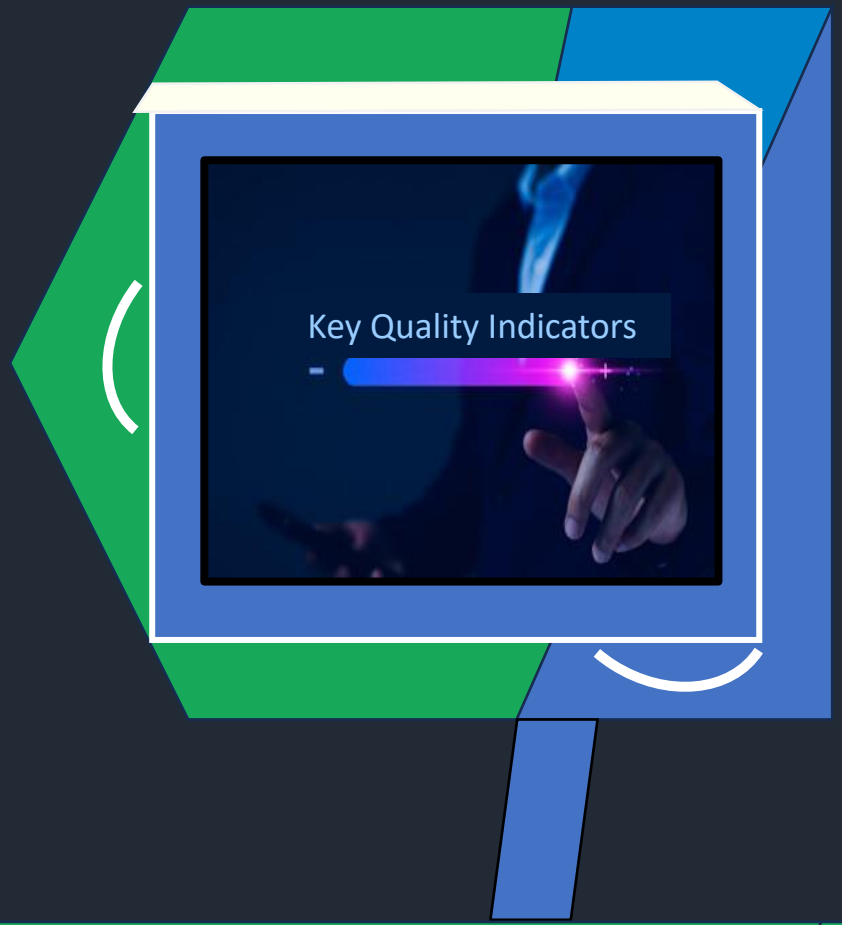
KQIs – Key Quality Indicators

- KQIs reflect overall lab health and client value
- Validate KPI effectiveness
- Useful for management insights
- Valuable to define opportunities for improvement



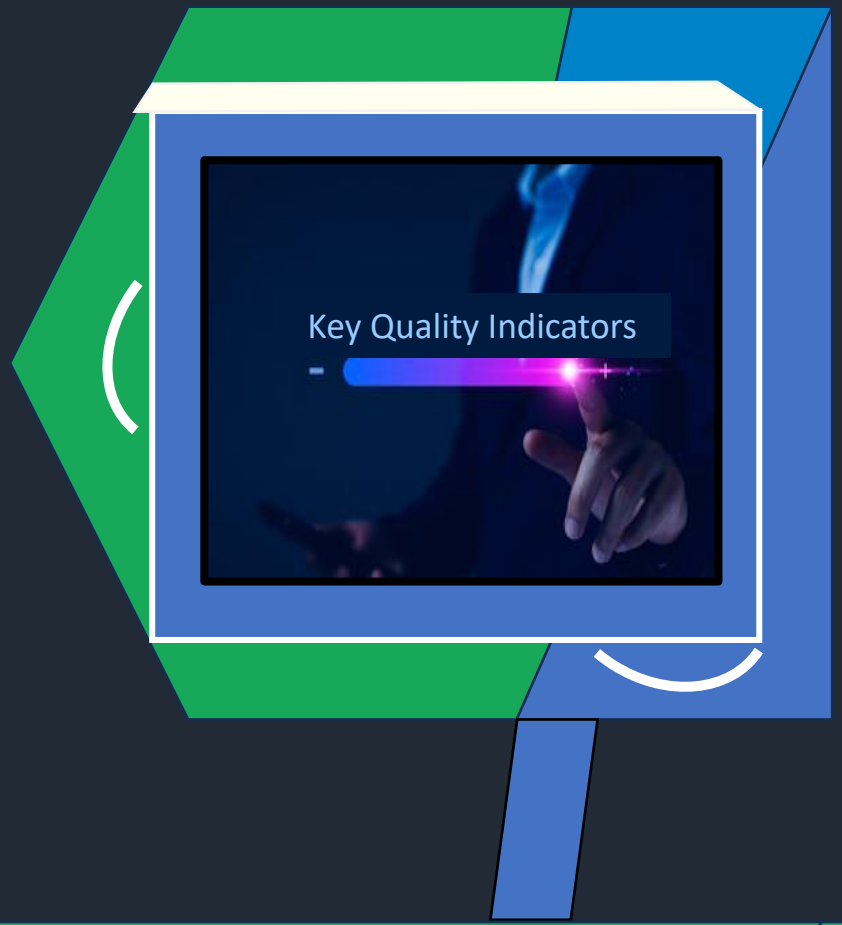
KQIs - Examples

1. Client Satisfaction Rate
2. Internal Audit Pass Rate
3. Proficiency Testing Consistency
4. Report Amendment Frequency
5. Staff Training Completion Rate



KQIs - Examples

1. Client Satisfaction Rate
2. Internal Audit Pass Rate
3. Proficiency Testing Consistency
4. Report Amendment Frequency
5. Staff Training Completion Rate
6. Regulatory Audit Findings Count
7. Data Entry Error Rate
8. Corrective Action Effectiveness
9. Client Retention Rate
10. Instrument Performance and Reliability



KRIs – Key Risk Indicators

- KRIs help to identify issues before they escalate
- Flags Risks to Performance or Compliance
- Identify threats to KPI/KQI Success

KRIs - Examples

1. Number of Corrective and Preventive Actions (CAPAs)
2. Missed Instrument Calibration Events
3. Expired Reagents or Standards in Use
4. Staff Competency Gaps
5. Repeat Proficiency Test Failures

KRIs - Examples

1. Number of Corrective and Preventive Actions (CAPAs)
2. Missed Instrument Calibration Events
3. Expired Reagents or Standards in Use
4. Staff Competency Gaps
5. Repeat Proficiency Test Failures
6. Incomplete or Missing Documentation
7. High Sample Rejection Rate
8. Noncompliance with Holding Times
9. Audit Findings Severity
10. Turnaround Time Deviations

Mapping Framework

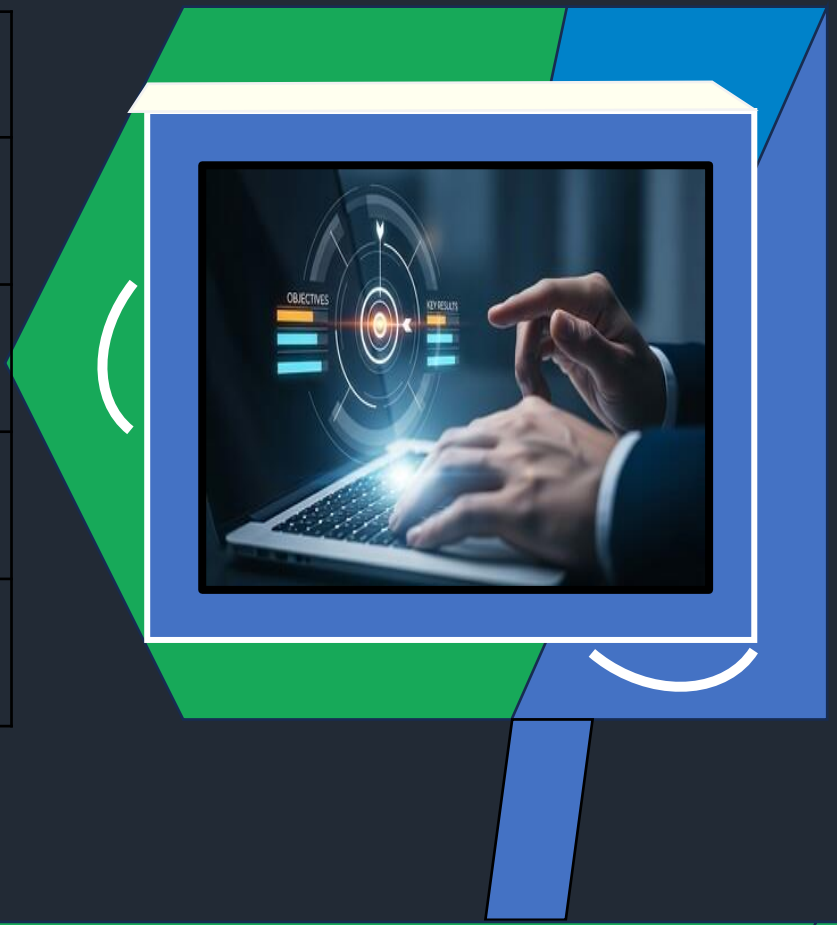
	Relationship
OKR	Drives KPI
KPI	Measures OKR
KQI	Validates KPI
KRI	Threatens KPI

Mapping Framework - Examples

	Relationship	Example-I
OKR	Drives KPI	Ensure 100% traceability of samples from collection to reporting
KPI	Measures OKR	% of samples with complete and signed COC documentation
KQI	Validates KPI	Audit findings data for COC documentation reviews
KRI	Threatens KPI	# of samples flagged for missing or incomplete COC records

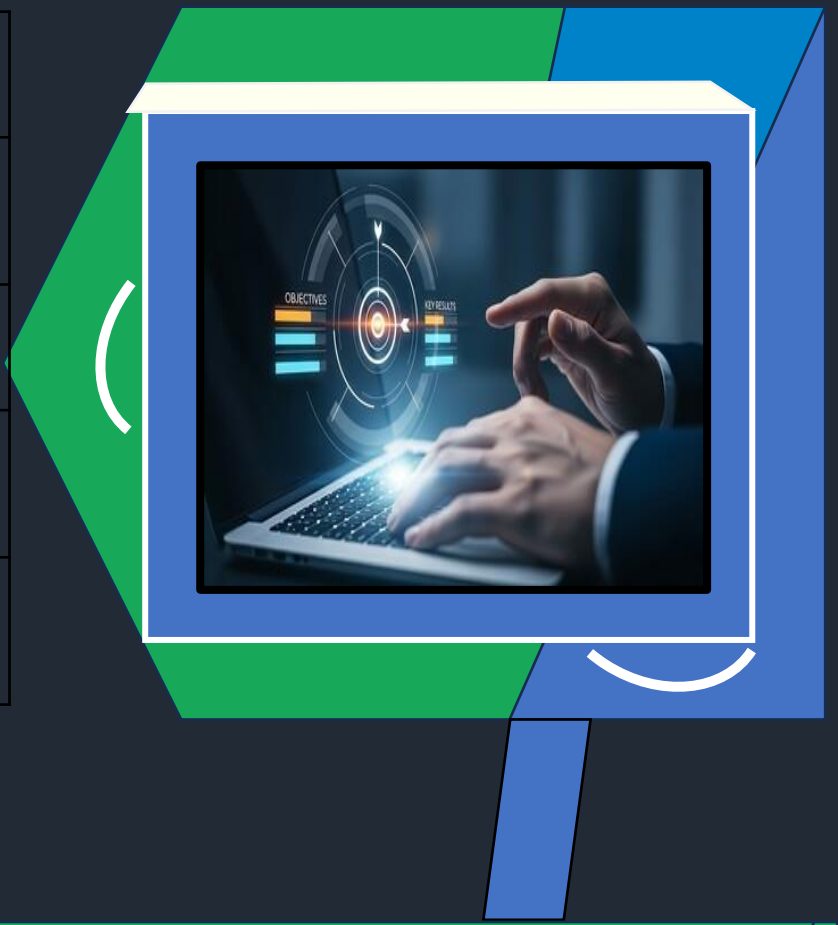
Mapping Framework - Examples

	Relationship	Example-II
OKR	Drives KPI	Complete 100% of planned internal audits within the fiscal year
KPI	Measures OKR	% of internal audits completed on schedule
KQI	Validates KPI	% of internal audits with no major findings resulting in corrective actions
KRI	Threatens KPI	# of overdue audits or audits skipped due to resource constraints



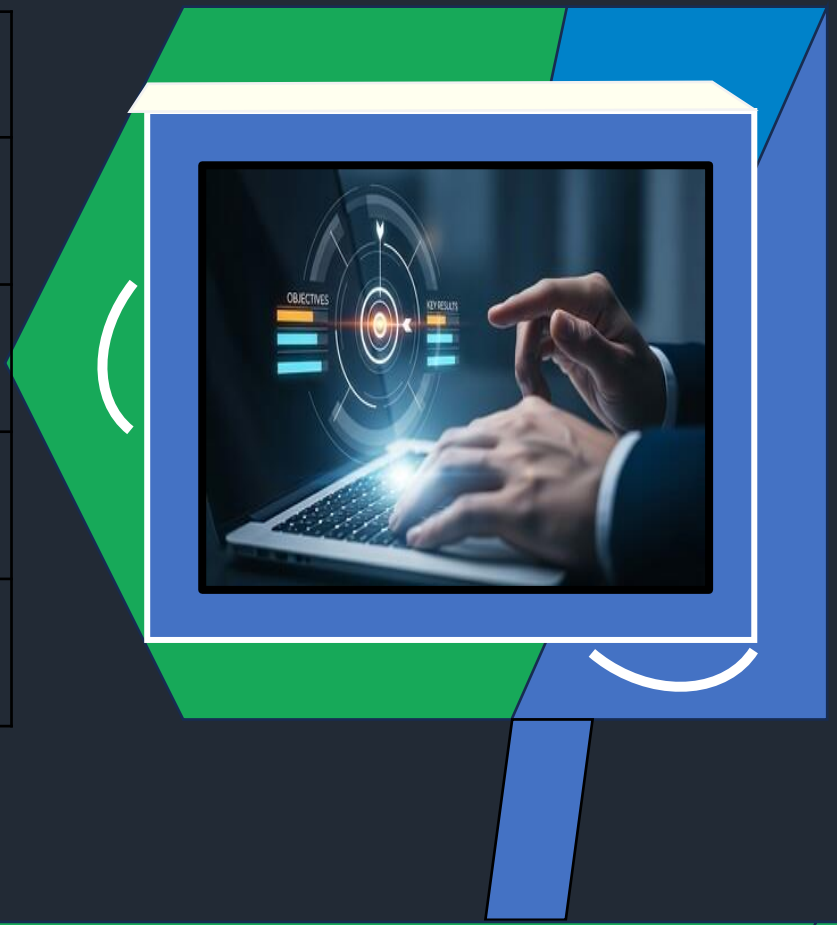
Mapping Framework - Examples

	Relationship	Example-III
OKR	Drives KPI	Improve Client Satisfaction and reduce customer complaints
KPI	Measures OKR	Average lab response time, in days
KQI	Validates KPI	Customer Satisfaction Score, Post-resolution survey rating
KRI	Threatens KPI	# of unresolved or recurring complaints per quarter



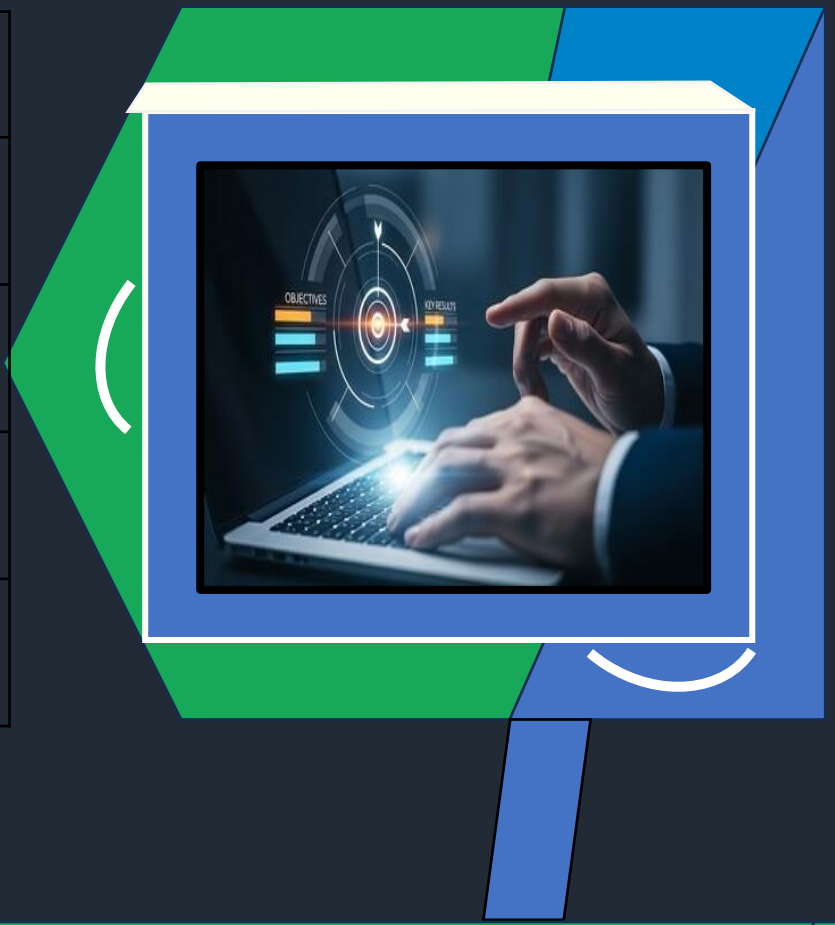
Mapping Framework - Examples

	Action	Example-IV
OKR	Drives KPI	Ensure reliable reagent supply with zero disruptions to testing workflow
KPI	Measures OKR	Target: ≥98% On-time delivery of reagent orders
KQI	Validates KPI	Target: ≤1% Reagents failed QC checks.
KRI	Threatens KPI	2 testing delays due to incorrect shipments, delays, and expired stock



Mapping Framework - Examples

	Action	Example-V
OKR	Drives KPI	Ensure 100% use of current, approved SOPs across all lab sections
KPI	Measures OKR	% of SOPs reviewed and updated within the scheduled review cycle
KQI	Validates KPI	Major findings during internal audits for document control section
KRI	Threatens KPI	# of outdated or uncontrolled documents found in active use



Planning With Metrics

- Understand OKRs
- Define KPIs
- Choose KQIs
- Identify KRIs

Planning With Metrics

- Build Strategy: Begin with the end in mind.
- Match strategy with current reality
- Communicate with the team and get buy-in
- Link objectives to measurable actions
- Perform timely reviews
- Share results
- Seek and evaluate feedback
- Make adjustments and improvements

Improving Metrics

- Measurable
- Meaningful
- Accurate
- Timely
- Comprehensive
- Actionable
- Relevant
- Consistent
- Verified
- Balanced

Build a Dashboard

- Use platforms like LIMS or Power BI
- Visualize KPIs, KQIs, and KRIs

Leverage Data Analytics

- Trend analysis reveals improvement opportunities
- Predictive analytics can be used for resource planning
- Integration options for disparate systems

  Example: Predict inventory from historical usage

Automation

- Use systems that auto-alert on anomalies
- Email Notifications upon trigger exceedances
- Reports auto-generated weekly/monthly
- Examples: 1) Flag TAT deviations > 5%

  2) Results exceeding regulatory Levels

Quality Management

- Identify Quality elements that are linked
- Establish closed-loop review and escalation mechanisms
- Align metrics with SOPs and QMS documents
- Map metrics to QMS requirements to review in Audits
- Incorporate metrics into Management Reviews

Quality Management

	Action	Example-V (Previous)
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KRI	Threatens KPI	# of outdated or uncontrolled documents found in active use

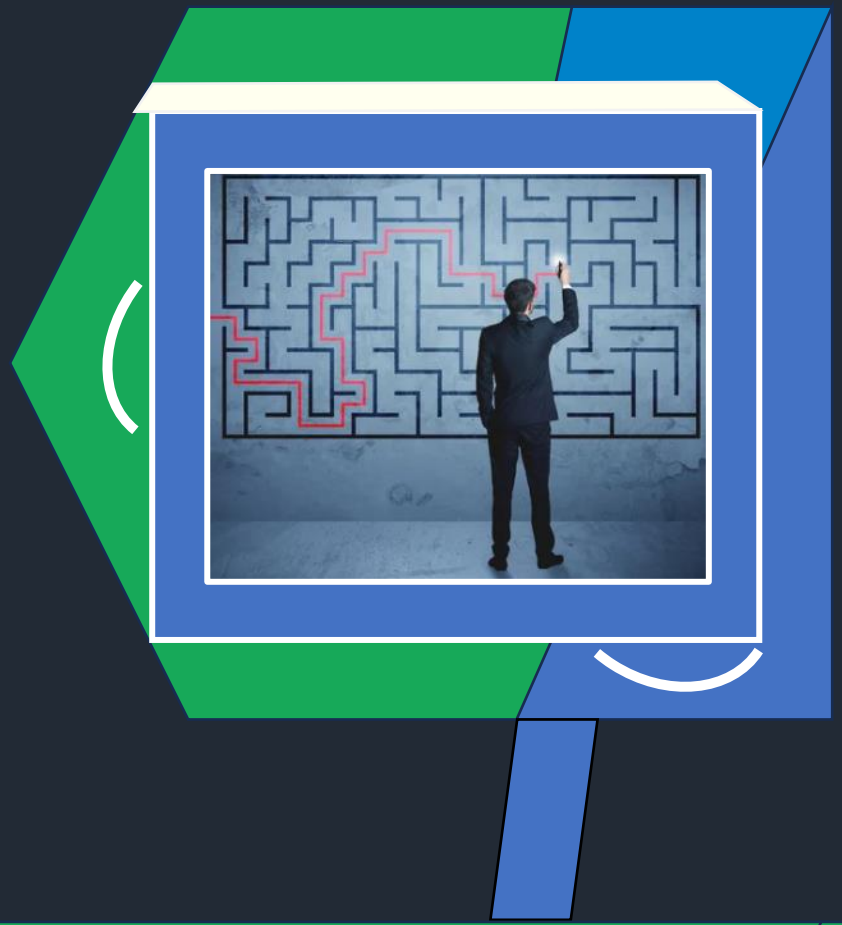
Example: TNI Requirements: (KQI) 4.3.1 & 4.3.2 (Document Review & Retention)
(KRI) 4.3.1.4 (Control of Documents)

Challenges

- Metric overload or misalignment
- Resource limitations
- Fragmented data across LIMS, logs, Worksheets, etc.
- Reactive response vs. Proactive optimization
- Manual tracking vs. automation

Solutions

- Develop internal champions for metric ownership
- Prioritize people as much as systems
- Focus on fewer, high-impact metrics
- Options for gradual scaling
- Prioritizing sustainability and learning over quick wins



Management Review

- Review and Optimize OKRs/KPIs/KQIs/KRIs
- Balance review elements across operational functions
- Follow-up on action items

Review Meetings with Staff

- Share OKRs/KPIs/KQIs/KRIs across teams
- Use data to guide action plans
- Celebrate wins and adapt strategies

Continual Improvement

- Feedback informs next cycle of OKRs
- Builds culture of data-driven excellence

In Summary…

- Value-driven data collection isn’t just about numbers, it is about unlocking the full potential of your lab.
- Harness the power of relevant, and timely data to optimize allocation of resources.
- Linking process elements, regulatory requirements, and quality assurance/quality control objectives result in actionable data that drives continual improvement.

QUESTIONS