Optimizing Bioanalytical Outsourcing via Implementation of a Sponsor Key Performance Indicator (KPI) System for CROs

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Outline

KPIs in General

- What are KPIs
- Why KPIs
- How should they look like

Implementation of a KPI System in Roche Regulatory BA (Outsourced Activities)

- The journey (from the idea to productive tool)
- Our KPIs and acceptance criteria
- KPI evaluation and result presentation
- Experiences and learnings

Key Performance Indicators (KPIs)

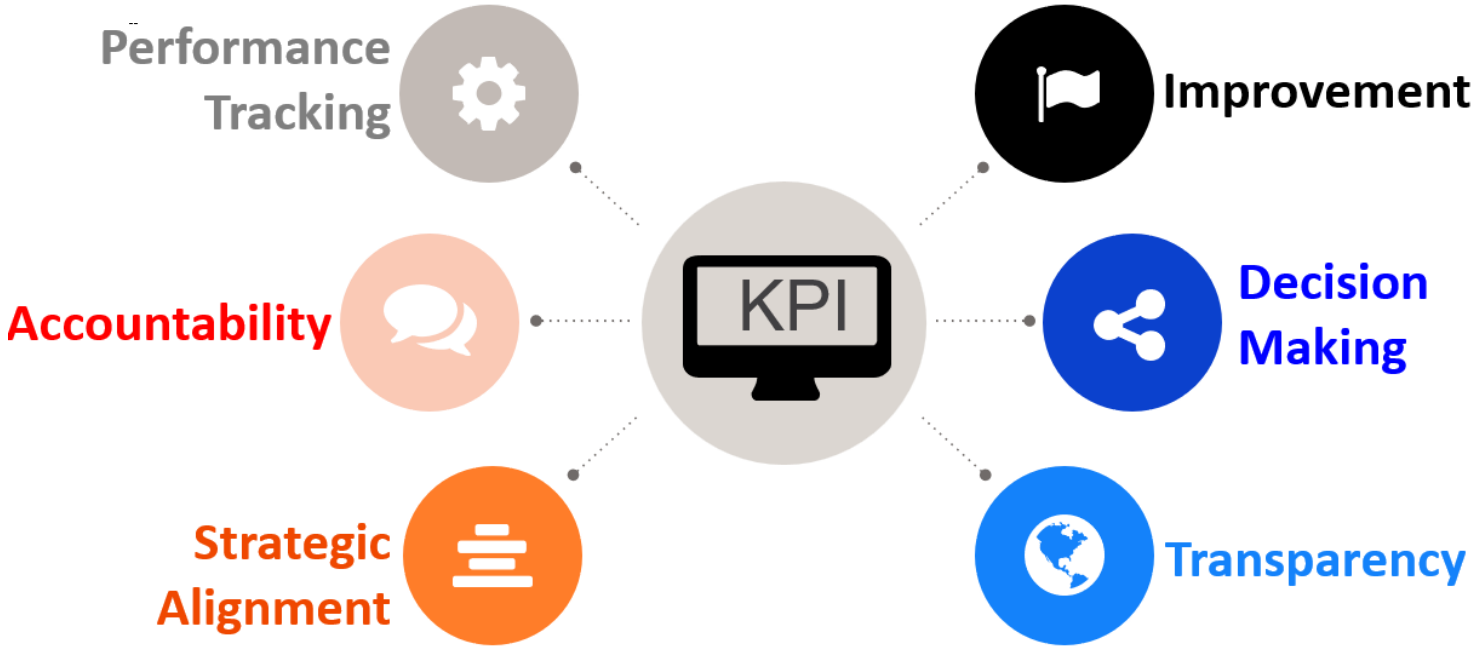
What is it, and why does it matter?



Quantifiable metrics, directly linked to an organization's strategic goals and overall success

Typical categories

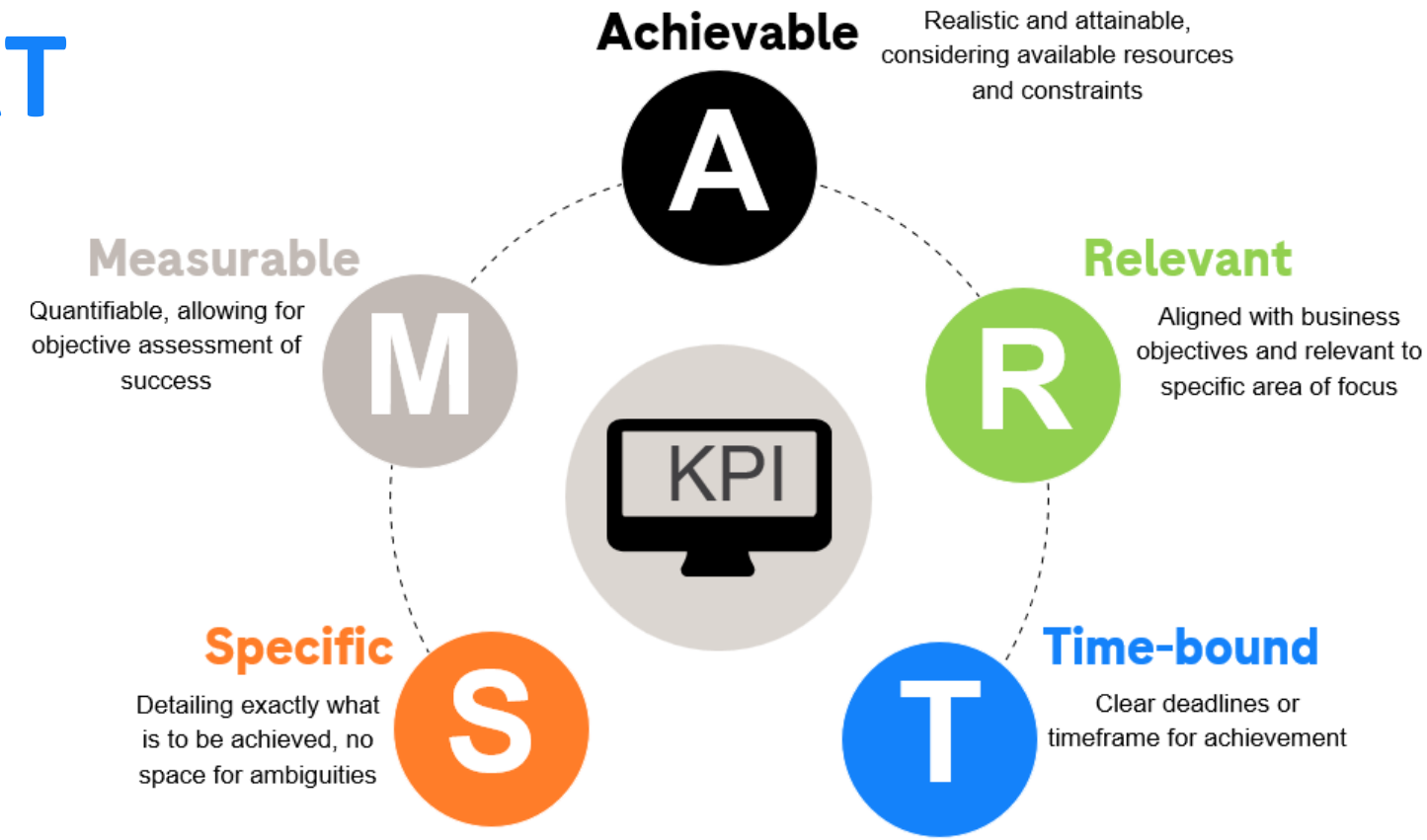
- Financials
- Operations
- Quality
- Project management
- Reg. compliance



Key Performance Indicators (KPIs)

Rules for the definition of the right KPIs

1. SMART



2. KISS

“Keep it simple, stupid” Make it as easy to understand as possible to make clear what they are about

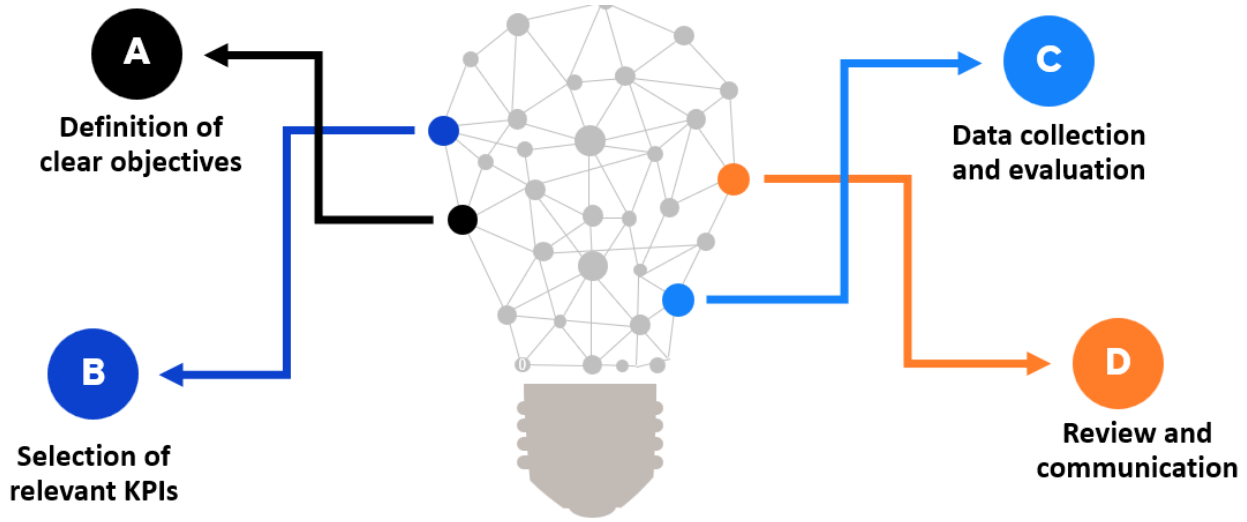
KPI-Implementation at Roche RBBO

Why

A KPI system provides a structured approach to monitor and ensure BA-CRO performance wrt

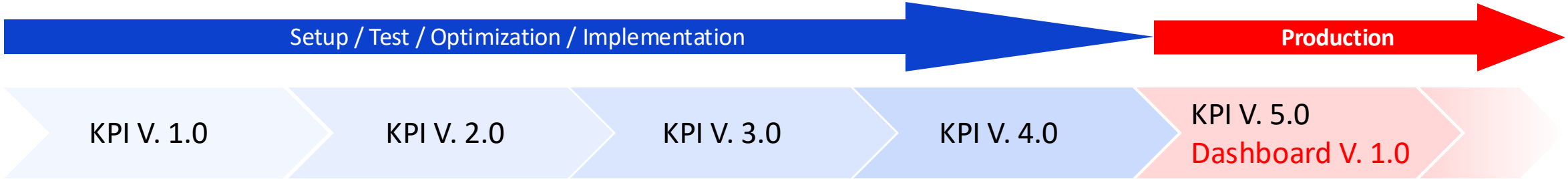
- **Quality**
  - Ensurance of high quality standards in BA work
  - Reliability of generated data
  - Regulatory compliance
- **Timelines and Efficiency**
  - Tracking timelines of deliverables (BA work, data deliveries, reporting)
- **Continuous improvement**
  - Identification of areas for improvement
  - Implementation of corrective actions

How



KPI History at Roche RBBO

A long way to go …



KPI V. 1.0

Scope:

PK (SM/LM)/ADA assay validation, sample analysis

Definition of

3 quality KPIs
4 time KPIs
Acceptance criteria

Setup of

KPI collection process
Exel sheet for KPI collection

KPI V. 2.0

Changes

More detailed acceptance criteria for two time KPIs

„Business days" -> „consecutive business days "

Additions

Time KPI (TAT for revised report versions)

Monthly KPI collection

Deletion

KPI (number of validation runs)

KPI V. 3.0

Additions

PD now also in scope

Assay transfers and qualifications added

KPI spot-checks

- Completeness
- Correctness

Documentation of FU actions described

KPI V. 4.0

Simplification:

Combination of two time KPIs

Changes

CRO QA review included in TATs

Additions

One time KPI added

QA review included in TATs

Deletions

One quality KPI skipped (number of draft report revisions)

KPI V. 5.0 Dashboard V. 1.0

Simplification:

Combination of KPIs

Lower number of acceptance criteria

Quarterly KPI collection

Roche's Key Performance Indicators for BA CROs

Actual KPI set V. 5.0 (production phase running since Q1 2023)

Metric	Description	Target
T1	**Duration of assay transfer (LBA, CC)** exp. start date to data delivery (qualified or validated assays) **Duration of assay development (CC)** exp. start date to data delivery	**≤ 10 days*** (PK, PD, BM, ADA) (PK, metabolites)
T2	**Duration of assay validation** exp. start date (run 1) to to final report **Only core validations incl. 1 month LTS**	**≤ 70 days*** (PK/PD/ADA assays) **≤ 80 days*** (**clinical** ADA assays)
T3	**Study sample data delivery and reporting (BAR)** **Timely data delivery** expected vs actual date **Availability of final BAR** time after QA'd data delivery	 **100%** **≤ 40 days***
Q1	**Analytical run pass rate** **Assay validation** process errors (e.g. spiking) **Sample analysis** failed runs	 **≥90% per analyte** **≥90% per analyte**

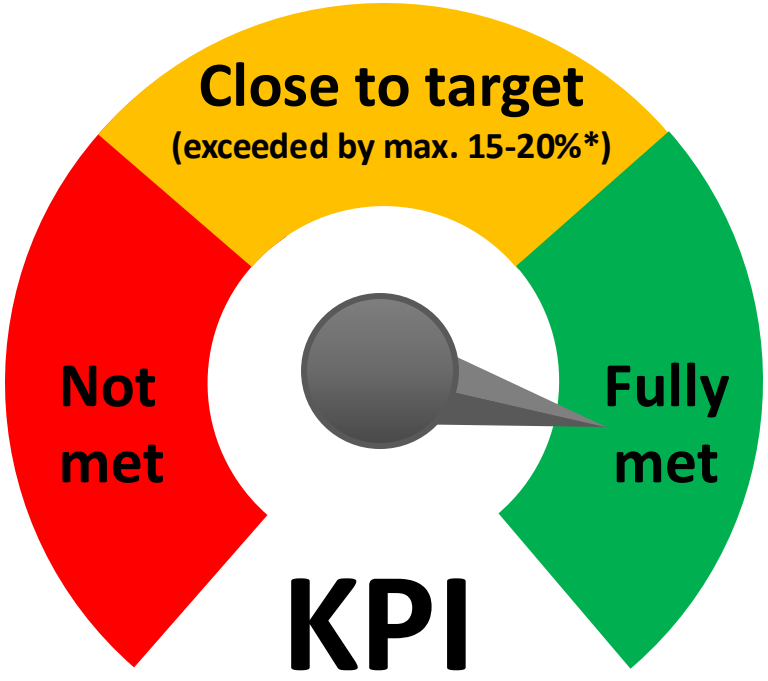
* Consecutive business days

- **Maximum simplification with the minimum number of KPIs,** required to reflect the overall output
- **KPI collection** via Excel sheet **for preferred providers only**
- **CROs provide input**, BA Managers perform checks of provided data
- After correction, KPI files are uploaded to a dashboard for evaluation
- **Bi-yearly KPI review** meetings with CROs
  - Presentation of KPI readout
  - Definition of action items
  - Performance ranking
  - Follow up meetings to monitor progress

Roche RBBO's BA-KPI Evaluation

KPI rating and follow up actions

The traffic light system



Actions to be taken

Fully met:	**None**, activities are running smoothly
Close to target:	**Usually no direct impact** No immediate reaction required Identification of root cause Implemenation of required changes
Not met:	**Risk of direct impact** on quality or timelines Immediate reaction required **Single event:** Issue resolution plan to be setup within 4 weeks **Recurring event:** Roche/CRO meeting, CAPA
Not met**	Roche didn't deliver, KPIs are cleaned for such events and are not counted/evaluated

* Buffer zone variable, depending on KPI

** Roche is checking reasons and implements corrections in case of persistent failures

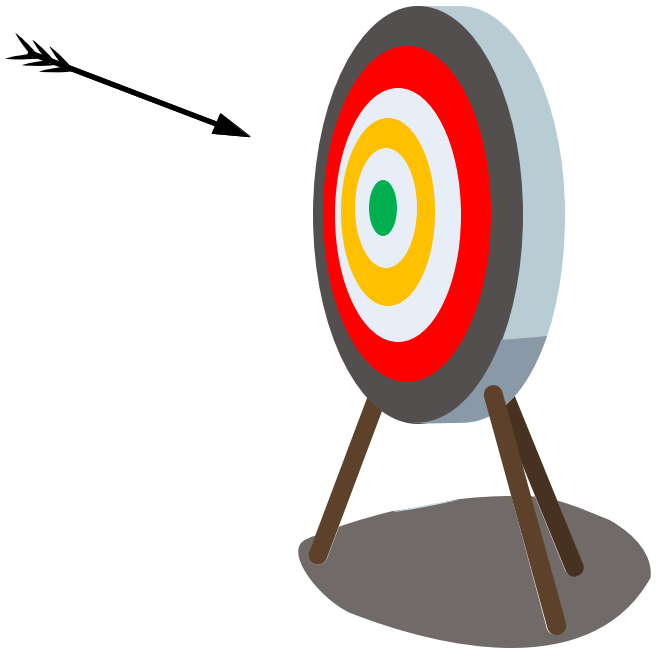
KPI Performance Assessment

What are meaningful KPI pass rates?

- A meaningful KPI pass rate should accurately reflect the performance and success of a specific process, activity, or organization in achieving predefined goals

- The definition of "meaningful" depends on the context and specific objectives, Roche's expectations* are

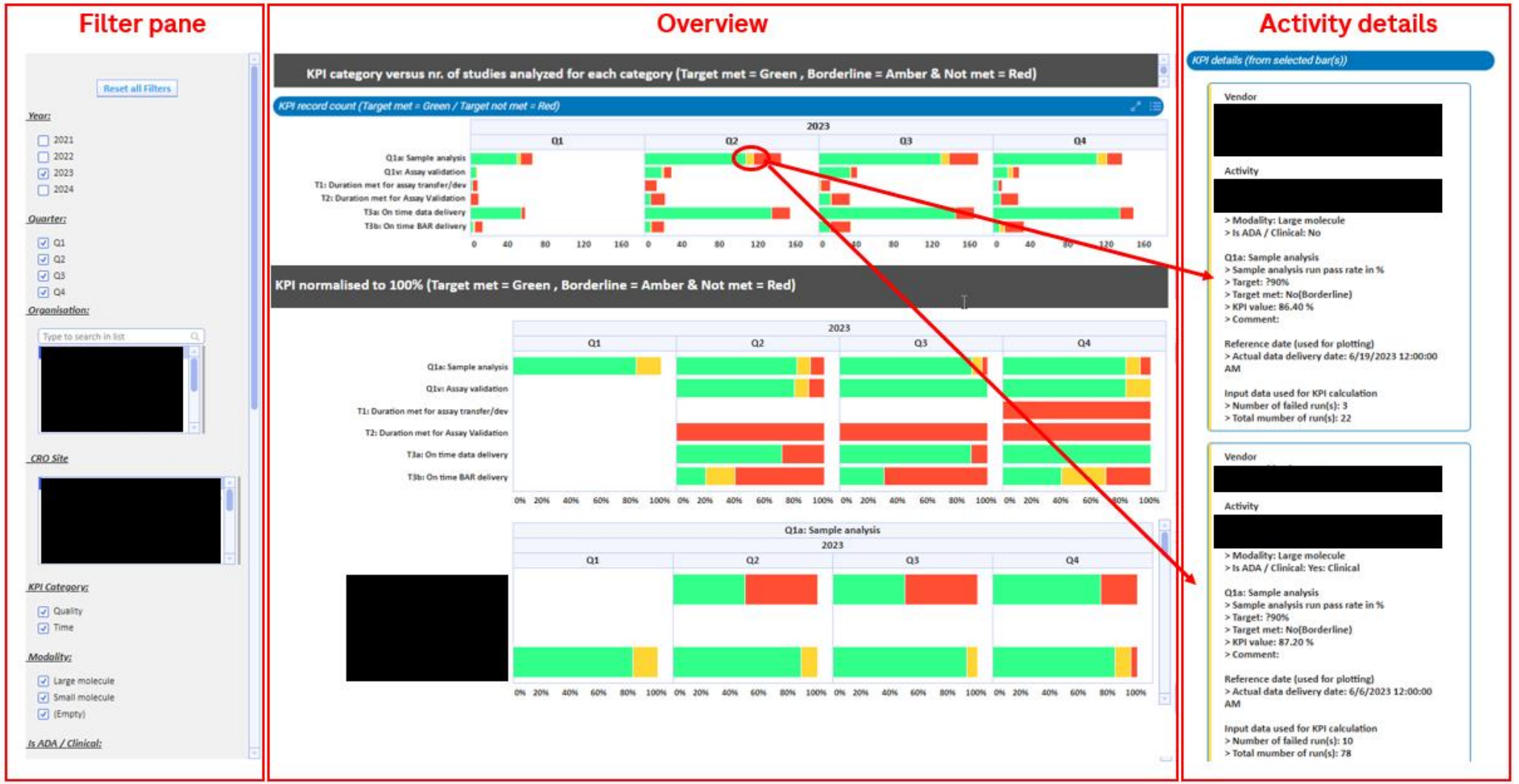
	KPI	Pass rate
1	Assay success rates ≥85%:	90%
2	Assay transfer/validation timelines:	95%
3	On-time BAR deliveries	95%
4	On-time sample data deliveries:	98%



* Target values include fully and close to target KPIs

BA-KPI Dashboard

Quick and simple KPI visualization



KPI Evaluation

From colors to numbers

Per CRO

1. KPI counting and cleaning

- Counting of met and failed KPIs
- Cleaning of KPIs for which the external vendor is not responsible

2. KPI pass rate calculation (% success rate)

- Per KPI: Number of successful instances / total number of instances

3. Weighting of KPIs

- Weighting for the most important deliverables
  - Sample data delivery timelines
  - BAR delivery timelines

4. Calculation of overall KPI pass rates

- Averaging of pass rates across KPIs

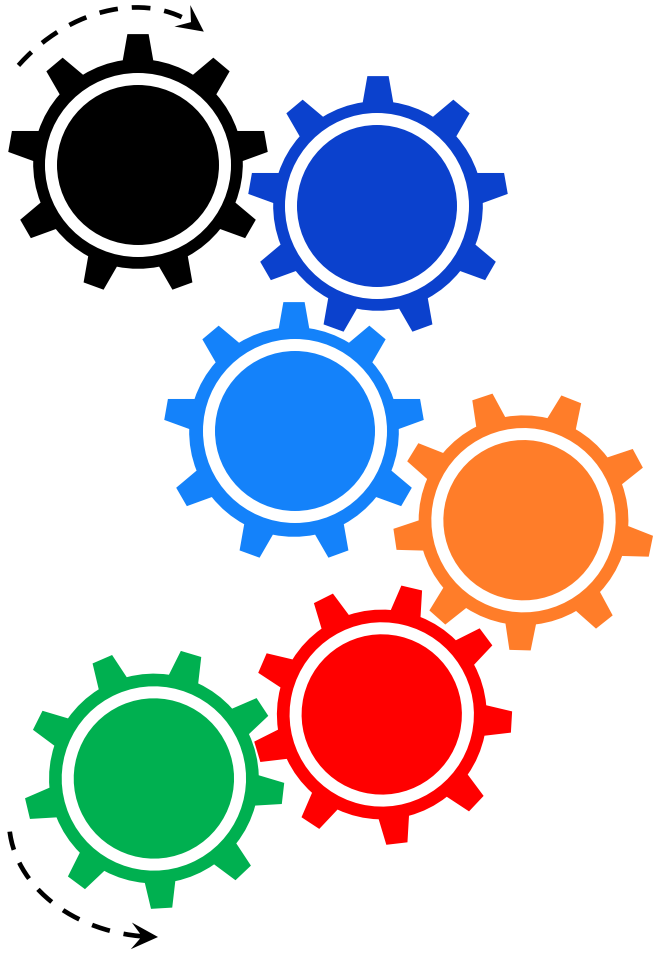
Across CROs

5. Averaging overall KPI pass rates

- Calculation of CRO-specific KPI pass rates against average

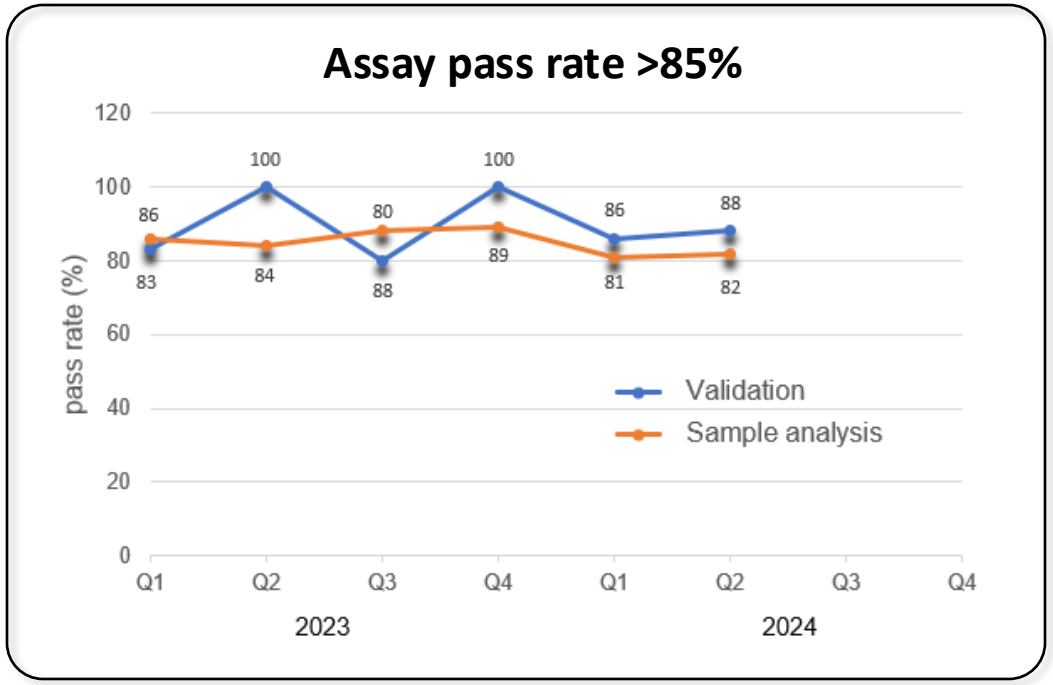
6. Ranking and trending

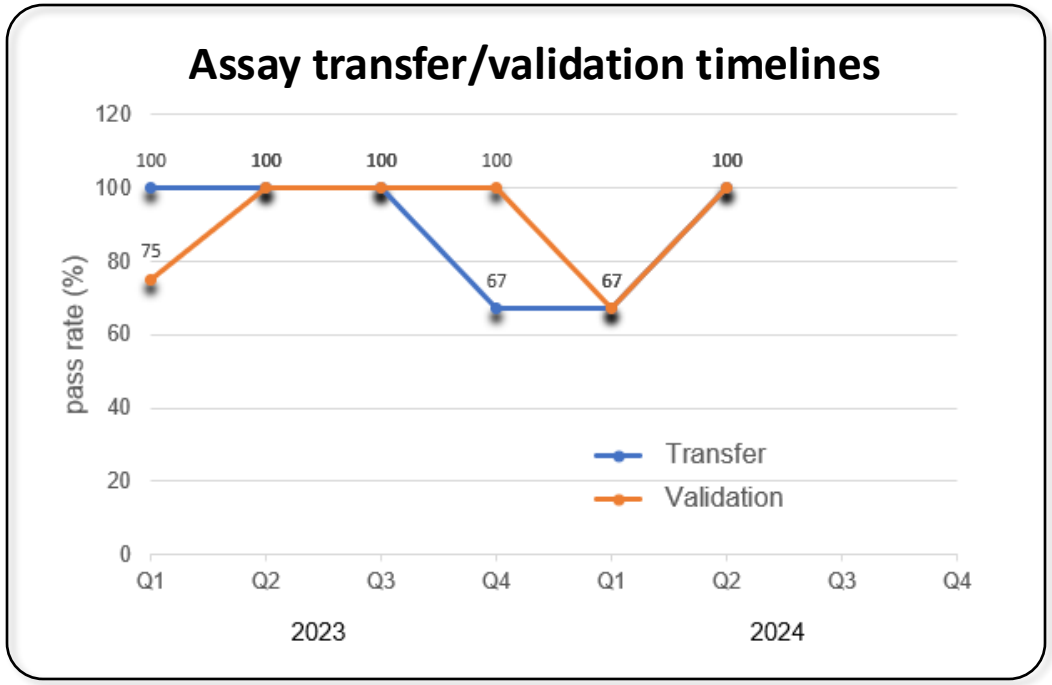
- Data visualization (plotting)



KPI Outputs

CRO-specific metrics and trending



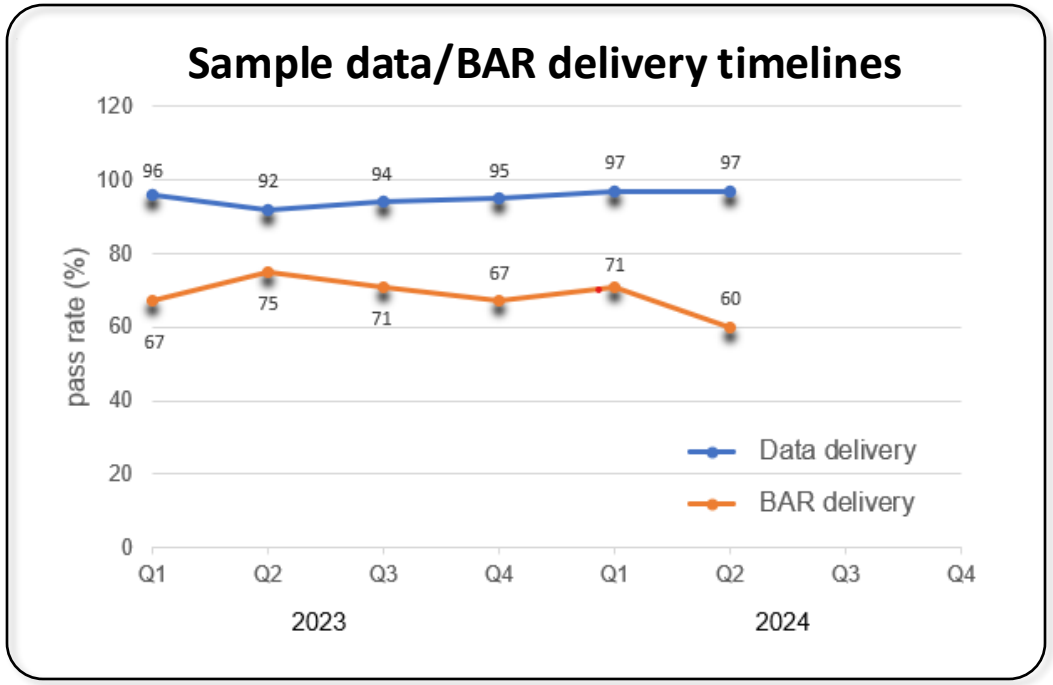


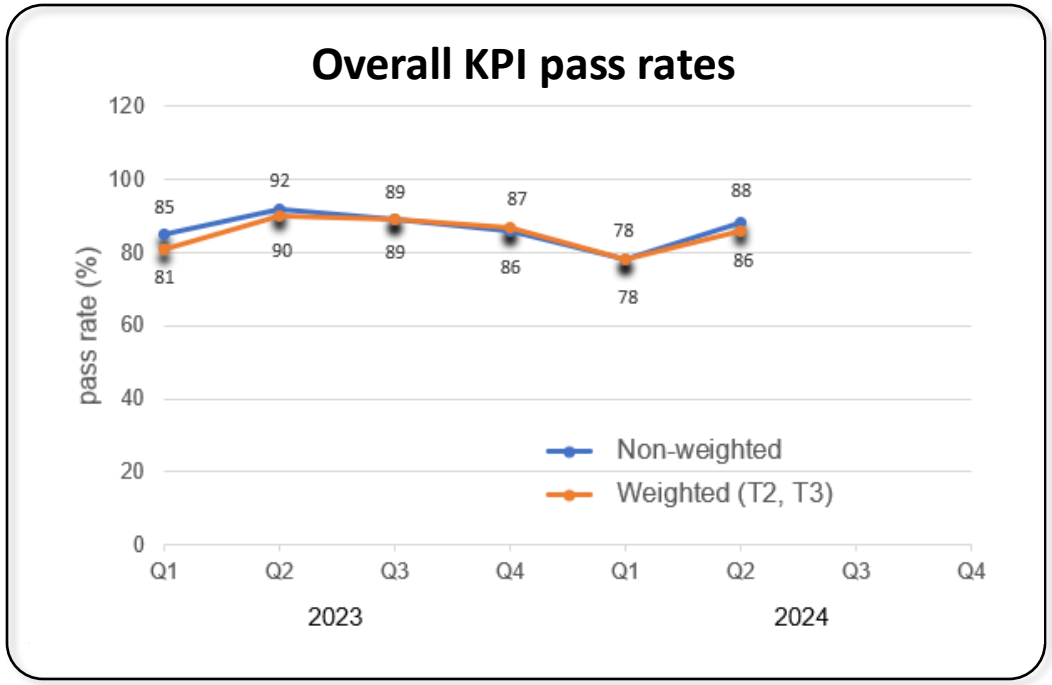
- Different success rates between validation and sample analysis (different analysts)
- Certain loss of efficiency (repeat analyses, potential impact on timelines), success rates to be improved

- Highly variable success rates with potential impact on timelines for upcoming sample analyses
- Reasons to be assessed and corrective actions to be taken

KPI Outputs

CRO-specific metrics and trending





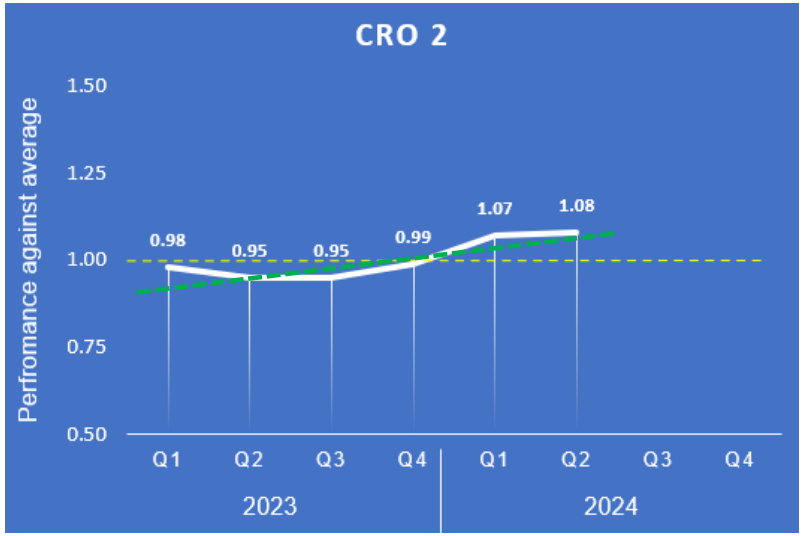
- Good and stable adherence to sample data delivery timelines
- Unsatisfactory BAR delivery timelines clearly below expectations with potential impact on timelines (CSRs, submissions)

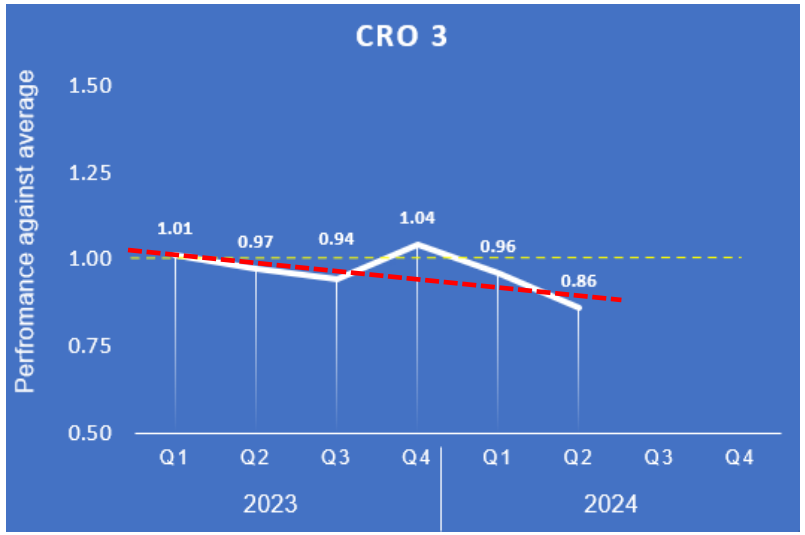
- Overall stable situation with action items for improvement in individual areas
- Minimal impact of delayed BAR delivery timelines on overall KPI passs rate

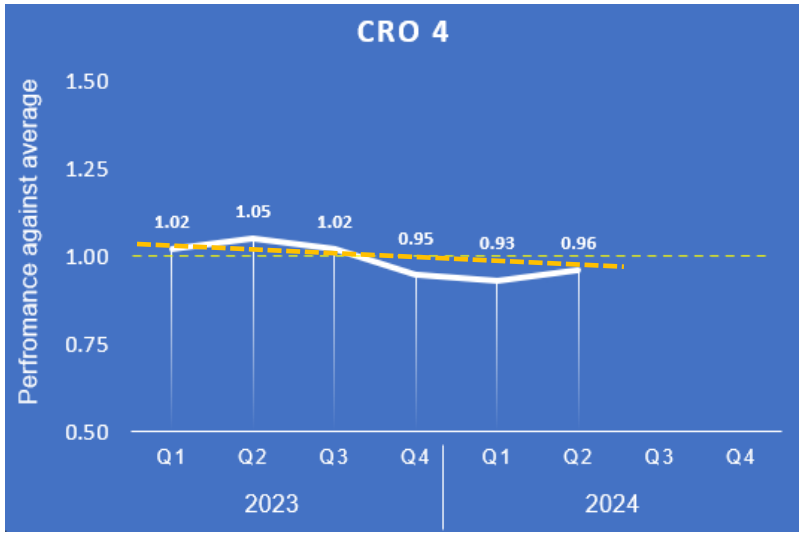
KPI Outputs

Longitudinal comparison of overall CRO performance against competitors









- Simple visualization and trending of overall CRO performance against competitors
- Interdependent analysis, since individual CRO pass rates are calculated against average
- Quarterly assessments ensure timely identification of issues
- Plots are shared with preferred CROs and are used for performance discussions

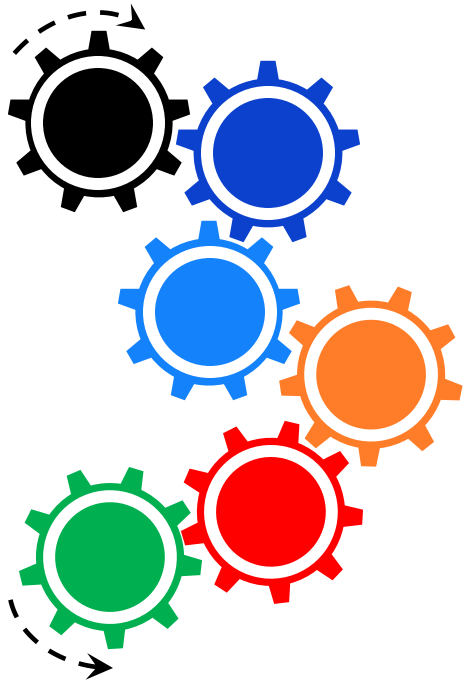
Considerations for Effective KPI Use

Learnings and potential challenges

- **Identified areas requiring improvements across our preferred CROs**
  - Assay transfer/validation timelines, reporting timelines, in some cases assay pass rates
- **Time Requirement**
  - A meaningful period (≥1 year) is needed to get a certain overview and to identify clear trends
- **Close Monitoring**
  - Regular monitoring is time-consuming, but essential
  - Concrete follow up actions must be identified in the event of any findings
- **Complementary Data**
  - **KPIs are not the sole source of truth**; qualitative data (communication/cooperation, scientific excellence) should also be considered for strategic decisions
- **Inflexibility**
  - Not simply adjustable for special cases
  - Deprioritized KPIs can lead to unjustified failures

Summary

Roche has successfully implemented a KPI system to monitor the performance of our preferred BA CROs for key deliverables



Key Benefits

- KPIs provide objective, **measurable data over subjective information**
- KPI can identify areas for enhancement to **foster ongoing improvement**
- KPIs enable **direct benchmarking** against targets, historical performance, and competitors and support **informed decision-making**
- KPIs allow **real-time adjustments and improvements** through continuous monitoring
- KPIs can **identify trends** and potential issues supporting a **proactive risk management**

Conclusion

Roche's KPI system already demonstrated significant short-term benefits for monitoring BA-CRO performance, proactive risk assessment and informed decision making

Further development may be needed to optimize the output (refinement of metrics, potential use of AI)

Acknowledgement

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Matthew Barfield

Our preferred vendors



Doing now what patients need next