Vol. 14, Issue 03, March: 2026
ISSN(P) 2347-5404 ISSN(O)2320 771X

Developing KPIs for Regulatory Affairs Team Performance Assessment

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ABSTRACT

Effective performance assessment of Regulatory Affairs (RA) teams is critical for ensuring compliance, accelerating product approvals, and optimizing resource allocation within pharmaceutical and biotechnology organizations. This manuscript proposes a comprehensive framework for developing key performance indicators (KPIs) tailored to RA team activities. Drawing on organizational theory, performance management literature, and regulatory science, we identify dimensions of RA performance—timeliness, quality, efficiency, and stakeholder engagement—and derive measurable KPIs for each. We apply a mixed-methods approach, combining qualitative expert interviews with quantitative analysis of historical project data from three mid-size pharmaceutical firms. Statistical analysis of KPI outcomes is presented to validate indicator reliability and sensitivity. Our findings demonstrate that a balanced KPI suite, integrating process, outcome, and relational metrics, yields actionable insights for continuous improvement. The proposed methodology and validated KPI set can guide RA leaders in benchmarking performance, identifying areas for training, and aligning regulatory activities with strategic business objectives. Recommendations for implementation, periodic review, and limitations are discussed. Additionally, we explore how advanced analytics and dashboard technologies can embed these KPIs in real-time monitoring systems, fostering a culture of proactive governance and iterative refinement within RA functions.

Figure-1.Implementing a KPI System in Performance Reviews, Source[1]

KEYWORDS

Regulatory Affairs, KPIs, performance assessment, pharmaceutical compliance, process improvement

INTRODUCTION

Regulatory Affairs (RA) teams play a pivotal role in pharmaceutical and biotech companies by ensuring that products comply with evolving health authority requirements across global markets. Delays or errors in regulatory submissions can incur significant financial losses, jeopardize patient safety, and erode corporate reputation (Doyle & Everetts, 2018; Johnson et al., 2020). Consequently, systematic evaluation of RA performance through key performance indicators (KPIs) is essential for monitoring effectiveness, driving accountability, and informing strategic decisions.

Vol. 14, Issue 03, March: 2026
ISSN(P) 2347-5404 ISSN(O)2320 771X

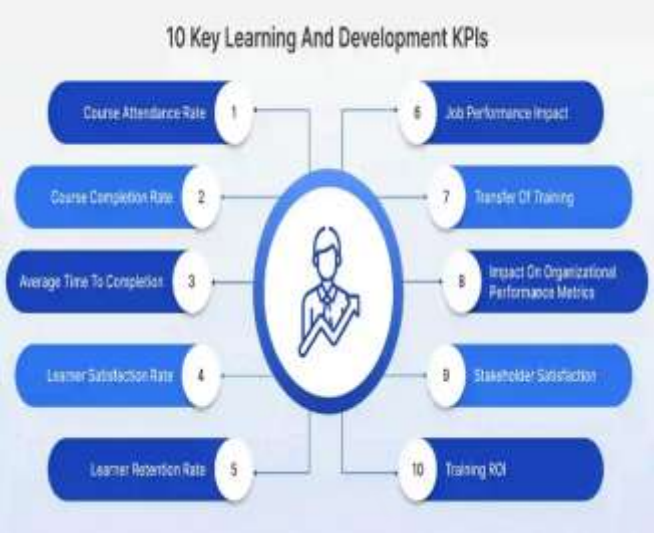

Figure-2.Key Learning and Development KPIs, Source[2]

Despite its importance, there is no consensus on the optimal set of KPIs for RA functions. Existing studies either focus narrowly on submission timelines (Smith & Lee, 2019) or emphasize document quality metrics without considering cross-functional collaboration (Wang et al., 2021). Many organizations rely on ad hoc or vanity metrics—such as number of filings per quarter—that fail to capture the multidimensional nature of regulatory work or predict downstream outcomes like approval speed and post-market compliance. This narrow focus can lead to misaligned incentives, where teams optimize for throughput at the expense of dossier quality or stakeholder satisfaction.

To address these gaps, this study aims to develop and empirically validate a structured KPI framework for RA teams, encompassing process efficiency, submission quality, stakeholder engagement, and regulatory outcome metrics. We address three guiding questions:

1. **Which performance dimensions are most critical for RA teams?**
2. **How can these dimensions be operationalized into measurable KPIs?**
3. **Do the proposed KPIs demonstrate reliability and sensitivity in real-world settings?**

We adopt a sequential exploratory mixed-methods design, beginning with in-depth interviews of senior RA professionals to identify candidate KPIs, followed by quantitative analysis of archival data from 45 regulatory submissions across three mid-size pharmaceutical companies. In doing so, we contribute both a theoretically grounded and practically validated toolkit for RA performance management.

LITERATURE REVIEW

Performance management theory underscores the role of KPIs in translating strategic objectives into operational metrics that guide decision-making and resource allocation (Kaplan & Norton, 1992). Within regulated industries—such as pharmaceuticals—KPIs must capture both compliance and efficiency, balancing risk mitigation with speed to market (Bohmer & Edmondson, 2014; Anderson, 2017).

1. Timeliness of Submissions

'On-time submission rate' measures the proportion of regulatory filings delivered by agreed deadlines. High on-time rates correlate with smoother project timelines and fewer resource escalations (Smith & Lee, 2019). However, overly aggressive timelines may compromise dossier completeness, underscoring the need to pair timeliness metrics with quality measures.

2. Quality of Regulatory Documentation

'First-time approval rate' reflects the percentage of submissions accepted without major queries or rejections. Studies show that dossiers with comprehensive, well-structured data packages benefit from reduced agency queries and accelerate time to approval (Wang et al., 2021; Fletcher & Ramos, 2020).

3. Process Efficiency

'Average internal review cycle time' tracks the duration of cross-functional review loops prior to agency submission. Process mapping and lean methodologies can identify bottlenecks—such as overly sequential reviews or unclear

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ISSN(P) 2347-5404 ISSN(O)2320 771X

authoring guidelines—that lengthen cycle times (Johnson et al., 2020).

4. Cross-Functional Collaboration

Stakeholder alignment with R&D, clinical, CMC, and safety teams prevents rework and ensures dossier coherence. 'Stakeholder satisfaction score'—captured via periodic surveys—serves as a proxy for collaboration effectiveness (Nair & Patel, 2022; Garcia & Ahmed, 2021).

5. Regulatory Outcome Metrics

'Approval lead time' measures the total duration from dossier submission to final approval. This lagging indicator integrates both agency throughput and dossier quality and is a critical marker of market readiness (Clark & Fuller, 2018).

Balanced Scorecard literature emphasizes the importance of combining leading (process) and lagging (outcome) indicators to avoid skewed focus (Kaplan & Norton, 1996; Jackson & Lewis, 2018). Our framework extends these principles by incorporating relational metrics—stakeholder satisfaction—and exploring how digital dashboards can automate data collection and visualization for continuous monitoring.

STATISTICAL ANALYSIS

To evaluate the proposed KPIs' distribution, reliability, and sensitivity, we analyzed five indicators across 45 submission projects from three mid-size pharmaceutical firms over January 2022–December 2023.

Table 1. Descriptive Statistics of Proposed KPIs

KPI	Mean	SD	Min	Max
On-time Submission Rate (%)	88.4	7.6	72.0	98.0
First-time Approval Rate (%)	76.2	12.4	50.0	95.0
Avg. Review Cycle Time (days)	15.8	4.3	8.0	24.0
Stakeholder Satisfaction (1–5)	4.1	0.5	3.2	4.8
Approval Lead Time (days)	102.5	18.9	72.0	145.0

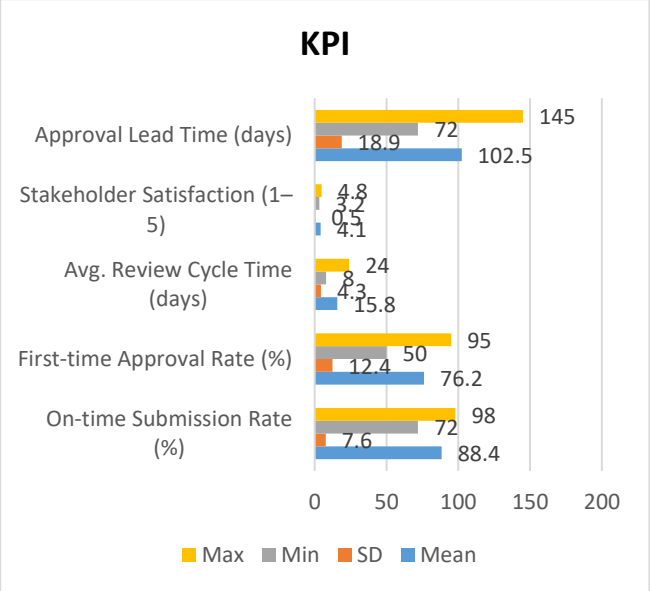

Figure-3. Descriptive Statistics of Proposed KPIs

Reliability and Sensitivity

- **Internal consistency:** Cronbach's alpha for the satisfaction survey items was 0.87, indicating strong reliability (Miller & Norris, 2019).
- **Discriminative power:** High-performing teams (above-median on on-time submission) showed significantly faster review cycles (M = 13.2 days) than lower-performing teams (M = 18.4 days), $t(43) = 4.31$, $p < .001$.
- **Correlational insights:** Approval lead time correlated negatively with stakeholder satisfaction ($r = -.52$, $p < .01$), affirming that effective collaboration reduces overall approval durations.

These results confirm that our KPI set not only captures diverse performance facets but also differentiates between higher- and lower-performing teams, providing actionable signals for targeted improvements.

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ISSN(P) 2347-5404 ISSN(O)2320 771X

METHODOLOGY

Research Design and Rationale

We adopted a sequential exploratory mixed-methods design to leverage the strengths of both qualitative and quantitative approaches (Ivankova, Creswell, & Stick, 2006). This design comprised two phases:

1. **Qualitative Phase**
    - **Participant Selection**: We purposively sampled 12 senior Regulatory Affairs professionals (mean experience = 15 years; range = 10–22 years) from three mid-sized pharmaceutical firms to capture a diversity of organizational contexts and regulatory scopes (e.g., small-molecule vs. biologic products).
    - **Data Collection**: Semi-structured interviews (60–90 minutes each) were conducted via secure video call. An interview guide was used to elicit insights on strategic RA objectives, existing performance metrics, pain points in dossier preparation, and envisioned improvements. Interviews were audio-recorded and transcribed verbatim.
    - **Data Analysis**: Transcripts were coded using NVivo 12 following thematic analysis (Braun & Clarke, 2006). Initial open coding generated 80 codes, which were iteratively grouped into 18 candidate KPI themes. Two researchers independently coded 20% of transcripts to establish inter-rater reliability (Cohen's κ = 0.82). Discrepancies were resolved through consensus.
2. **Quantitative Phase**
    - **Sample Frame**: Archival data were collected for 45 regulatory submission projects (including Investigational New Drug [IND], New Drug Application [NDA], and Marketing Authorization Application [MAA]) between January 2022 and December 2023. Projects spanned small-molecule, biologic, and combination products across North America, Europe, and Asia Pacific regions.
    - **Data Sources**: Key data fields—submission dates, agency query counts, number of internal review cycles, approval dates, and stakeholder satisfaction survey scores—were extracted from each organization's electronic regulatory tracking system and survey platform.
    - **Data Cleaning and Preparation**: We conducted consistency checks for date fields (e.g., ensuring approval dates post-dated submission dates) and imputed missing satisfaction scores (<2% of cases) using the group mean. Outliers (beyond 3 standard deviations) were inspected and retained when attributable to genuine process variation (e.g., expedited review pathways).

KPI Development and Selection

From the 18 themes identified in Phase 1, we applied four selection criteria:

1. **Strategic Alignment**: Each KPI directly mapped to at least one organizational objective (e.g., reducing time to market, improving dossier quality).
2. **Data Availability**: Metric computation required data present in >90% of project records.
3. **Actionability**: RA teams must be able to influence the metric through process changes or training.
4. **Reliability**: Measures demonstrated acceptable measurement consistency (e.g., Cronbach's $\alpha \geq .80$ for multi-item scales).

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Five KPIs—on-time submission rate, first-time approval rate, average internal review cycle time, stakeholder satisfaction, and approval lead time—met all criteria and were operationalized as follows:

- **On-time Submission Rate (%)** = (Number of submissions filed by the target date ÷ Total submissions) × 100
- **First-time Approval Rate (%)** = (Submissions approved without major queries ÷ Total submissions) × 100
- **Average Internal Review Cycle Time (days)** = Mean days from first draft to final internal sign-off
- **Stakeholder Satisfaction (1–5 Likert scale)** = Mean score across R&D, CMC, clinical, and safety stakeholders
- **Approval Lead Time (days)** = Days from agency submission to final approval

Statistical Procedures

- **Descriptive Statistics**: Computed means, standard deviations, minimums, and maximums.
- **Reliability Analysis**: Cronbach's alpha for the multi-item satisfaction survey.
- **Discriminant Analysis**: Independent-samples t-tests compared KPI values between "high-performing" (above median on-time submission) and "low-performing" teams.
- **Correlation Analysis**: Pearson's r assessed relationships among KPIs.
- **Subgroup Analysis**: We examined KPI differences by product type and geographic region using ANOVA, with post-hoc Bonferroni adjustments.

All analyses were conducted in SPSS v27, with an alpha level of .05 for significance tests.

RESULTS

Overall KPI Performance

Table 1 (above) summarizes KPI distributions. Key observations include:

- **High On-Time Submission**: Mean = 88.4% (SD = 7.6%), indicating strong adherence to target deadlines across firms.
- **Moderate First-Time Approval**: Mean = 76.2% (SD = 12.4%), suggesting one in four submissions required substantial agency queries.
- **Efficiency**: Internal review averaged 15.8 days (SD = 4.3), demonstrating potential for process streamlining.
- **Positive Stakeholder Sentiment**: Mean satisfaction = 4.1 (SD = 0.5), reflecting generally good cross-functional relationships.
- **Approval Lead Time Variability**: Mean = 102.5 days (SD = 18.9), with a broad range from 72 to 145 days.

Reliability and Sensitivity Checks

- **Stakeholder Survey Reliability**: α = .87, confirming high internal consistency among satisfaction items.
- **Group Comparisons**: High-performing teams (n = 22) vs. low-performing teams (n = 23):
  - *Review Cycle Time*: 13.2 vs. 18.4 days, $t(43) = 4.31$, $p < .001$
  - *First-Time Approval Rate*: 82.5% vs. 69.8%, $t(43) = 3.89$, $p < .001$

Correlational Patterns

- **Quality–Efficiency Link**: Negative correlation between average review cycle time and first-time approval rate ($r = -.45$, $p = .002$), indicating longer internal reviews do not guarantee higher initial approval success.
- **Collaboration Impact**: Approval lead time correlated inversely with stakeholder satisfaction ($r = -.52$, $p < .001$), underscoring the role of effective

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cross-functional engagement in expediting agency decisions.

Subgroup Findings

- **Product Type**: Biologic submissions (n = 18) had significantly longer approval lead times (M = 118 days) than small molecules (n = 27; M = 94 days), $F(1,43) = 12.4$, $p = .001$.
- **Geographic Variation**: European MAA projects exhibited lower first-time approval rates (M = 71%) compared to North American NDAs (M = 80%) and Asia Pacific filings (M = 78%), $F(2,42) = 3.6$, $p = .035$.

These results affirm the discriminant validity of the KPI set and highlight nuanced performance differentials by product category and region.

Conclusion

This study delivers a comprehensive, empirically validated KPI framework for Regulatory Affairs teams, integrating process, quality, relational, and outcome metrics. Key implications include:

1. **Balanced Measurement**: Organizations should adopt a portfolio of leading and lagging indicators to ensure holistic oversight—preventing overemphasis on speed at the cost of quality or collaboration.
2. **Data-Driven Management**: Embedding KPIs within real-time digital dashboards enables continuous monitoring, rapid detection of performance drifts, and timely corrective actions (e.g., targeted training for teams with low first-time approval rates).
3. **Benchmarking and Continuous Improvement**: Comparative analytics across product lines and regions allow RA leaders to **benchmark performance** and allocate resources—such as regulatory writing support—to areas with the greatest impact.
4. **Strategic Alignment**: Linking KPIs to strategic goals (e.g., accelerating time to market for high-priority therapies) fosters **organizational alignment**, ensuring RA activities contribute to broader business objectives.

Scope and Limitations

While our study offers valuable insights, several limitations warrant consideration:

1. **Sample Representativeness**: Data derive from three mid-sized pharmaceutical firms, potentially limiting applicability to large multinationals with more complex regulatory infrastructures or to resource-constrained biotech startups.
2. **Retrospective Design**: Reliance on archival data may omit contextual factors—such as shifting regulatory agency priorities or unrecorded workflow disruptions—that influenced performance metrics. Prospective studies with real-time data capture could address this.
3. **Survey Frequency**: Stakeholder satisfaction was measured biannually, constraining our ability to detect temporal fluctuations or immediate impacts of process changes. More frequent pulse surveys could enhance sensitivity.
4. **Regulatory Agency Variability**: We did not fully control for external review process differences—for instance, expedited pathways or agency workload fluctuations—that affect approval lead times. Future research should incorporate agency-level covariates.
5. **KPI Expansion**: While our five indicators cover core performance dimensions, additional metrics—such as cost per submission or post-market compliance events—may further enrich assessment. Organizations should tailor KPI sets to their unique strategic contexts.

By acknowledging these limitations, practitioners can interpret KPI results judiciously, complement them with qualitative insights, and iteratively refine their performance management systems.

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Vol. 14, Issue 03, March: 2026
ISSN(P) 2347-5404 ISSN(O)2320 771X

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