Adopting Closed Loop Clinical Study Performance Analytics for Data-driven Decisions

Abstract

Conducting clinical studies is a time and resource intensive endeavor that incurs substantial costs for pharmaceutical companies. Clinical studies also involve a diverse group of stakeholders such as industry players, patients, government bodies and so on, each using a different set of tools to support the process. It is therefore important for the sponsors of clinical studies to have a holistic framework that monitors and measures performance on an ongoing basis, enabling well-informed decisions.

This paper explores the idea of assessing and improving clinical study performance using Key Performance Indicators (KPIs) and Key Risk Indicators (KRIs). By conceptualizing and deploying an out-of-the-box platform solution that is modular, configurable and scalable, various stakeholders involved in the study can access data and key analyses to enable timely, data driven decisions.

Assessing clinical study performance: Building a performance analytics platform

Currently, multiple systems that lack the capability to integrate data across different functionalities are used to capture and track different aspects of a clinical study. This reduces visibility into the data and makes it challenging to gather an overall picture of clinical study performance, resulting in sub-optimal decisions. Such a siloed approach also increases the cost of data transfer between stakeholders, and negatively impacts compliance and time to market.

One way to effectively address these challenges is to build a clinical study performance analytics solution that integrates data across stakeholders, and leverages a well-defined metrics library to enable strong analytics and reporting.

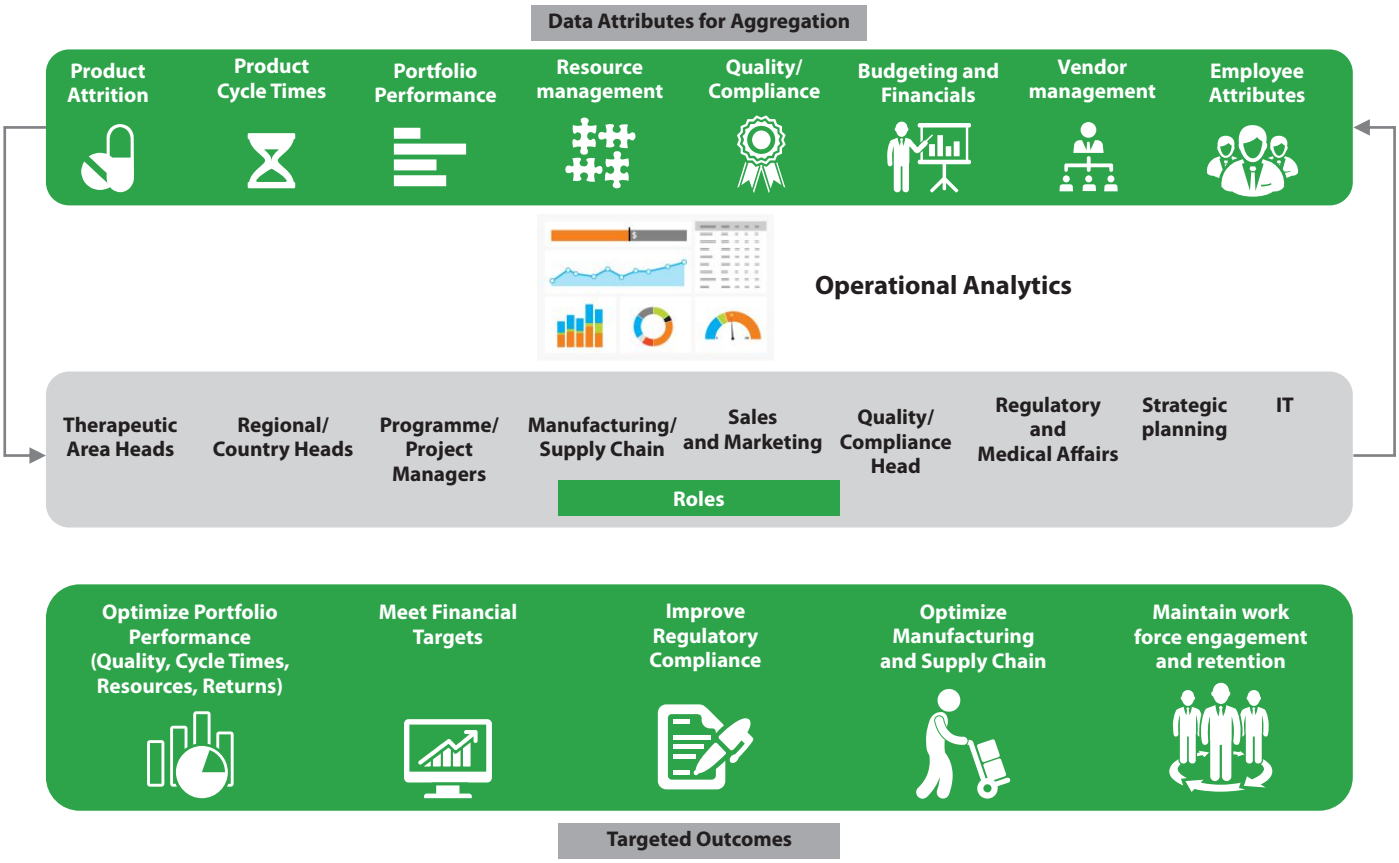

Figure 1: Framework for CLSPA

Figure1 highlights the proposed framework for a Closed Loop Study Performance Analytics solution (CLSPA), comprising three major components:

1. **Relevant data attributes required for reporting:** Data attributes across different functionalities that are captured on multiple source systems need to be pulled into the platform solution for analysis.
2. **Potential users of data:** Stakeholders who need robust data to take well-informed decisions need to be identified, enabling organizations to incorporate role-based analytics. For example, a Study Data Manager may want to view data that highlights data issues across different sites, whereas a Project Manager may be interested in the overall performance of clinical studies across different sites.
3. **The targeted outcomes:** The outcomes of the data-driven decisions that users take will also need to be defined. These include improved compliance, optimized manufacturing and so on.

Once the scope of the clinical study along with its data attributes, source systems and users are established, the metrics for the study must be defined. These include metrics based on which the clinical study will be monitored, such as adverse event rate, patient recruitment rate, patient screening failure rate and so on.

Enabling data-driven decisions using key risk indicator approach

Typically, various stakeholders and departments involved in a clinical study have a siloed view of data and metrics, with little or no ability to view integrated data. For instance, the Head of Quality and the Head of Safety have very different views of study data in terms of the metrics and analytics. Figure 2 represents a typical decision making hierarchy for stakeholders involved in a portfolio of clinical studies.

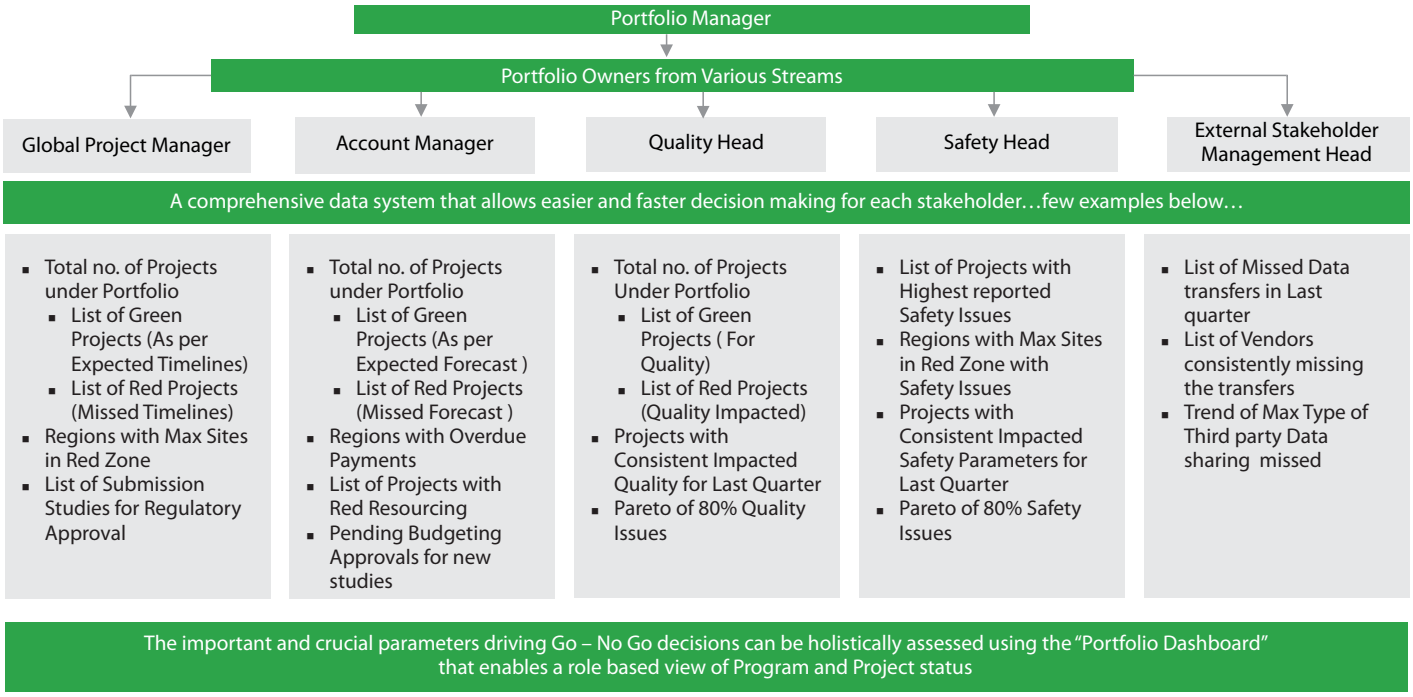

Figure 2. A representation of portfolio review

The proposed CLSPA solution takes into consideration the needs of all stakeholders, and helps define risk and performance indicators across the following categories for each study:

- Project milestones
- Patient recruitment and retention
- Study design and data management
- Safety
- Drug supply and randomization
- Budgets and payments
- Regulatory activities such as compliance and protocols

Each of the risk indicators is then assigned a threshold. Using rule-based algorithms, the solution triggers an appropriate action when any of the indicators hit the threshold value. A RAG (Red-Amber-Green) status is displayed on the dashboard to alert stakeholders (see Table 1). The RAG status can be tailored to user requirements and set up based on a single metric or a combination of metrics.

For example, by plotting the protocol deviation rates for each clinical study site along with the threshold values, it is also

possible to identify the outliers i.e. the sites that fall outside the threshold values. This information can then be used to isolate a particular protocol deviation within the sites such as a missing visit, missing sample, age criteria not met, and so on . The data from different sites can be interconnected with each other in such a way that it makes it easy to holistically analyze the protocol deviation metrics.

S. No	RAG Status	Monitoring Action
1	Red	Perform additional on-site monitoring
2	Amber	Perform additional remote monitoring
3	Green	No Action

Table 1: Sample RAG status and action triggered

Deploying a holistic clinical study performance data dashboard

As important as it is to integrate data across multiple stakeholders and sites, it is just as critical to get a top down view of performance of a particular group. For instance, the Portfolio Manager might want to understand the performance of the entire portfolio rather than individual studies. The CLSPA solution can be quipped to provide a holistic view of all dashboards at the enterprise level - across therapeutic areas and studies (see Figure 3). This, in turn, will help users drill down to understand the status of the clinical study at various levels. By enabling one-click access to various dashboards, the solution can highlight critical factors that have significant positive or negative impact on operations, empowering users to take timely decisions. For example, if the dashboard shows that there could be potential safety concerns at a certain study site, the sponsor can confidently take important decisions such as terminating the study or moving the subjects of the study from one site to another.

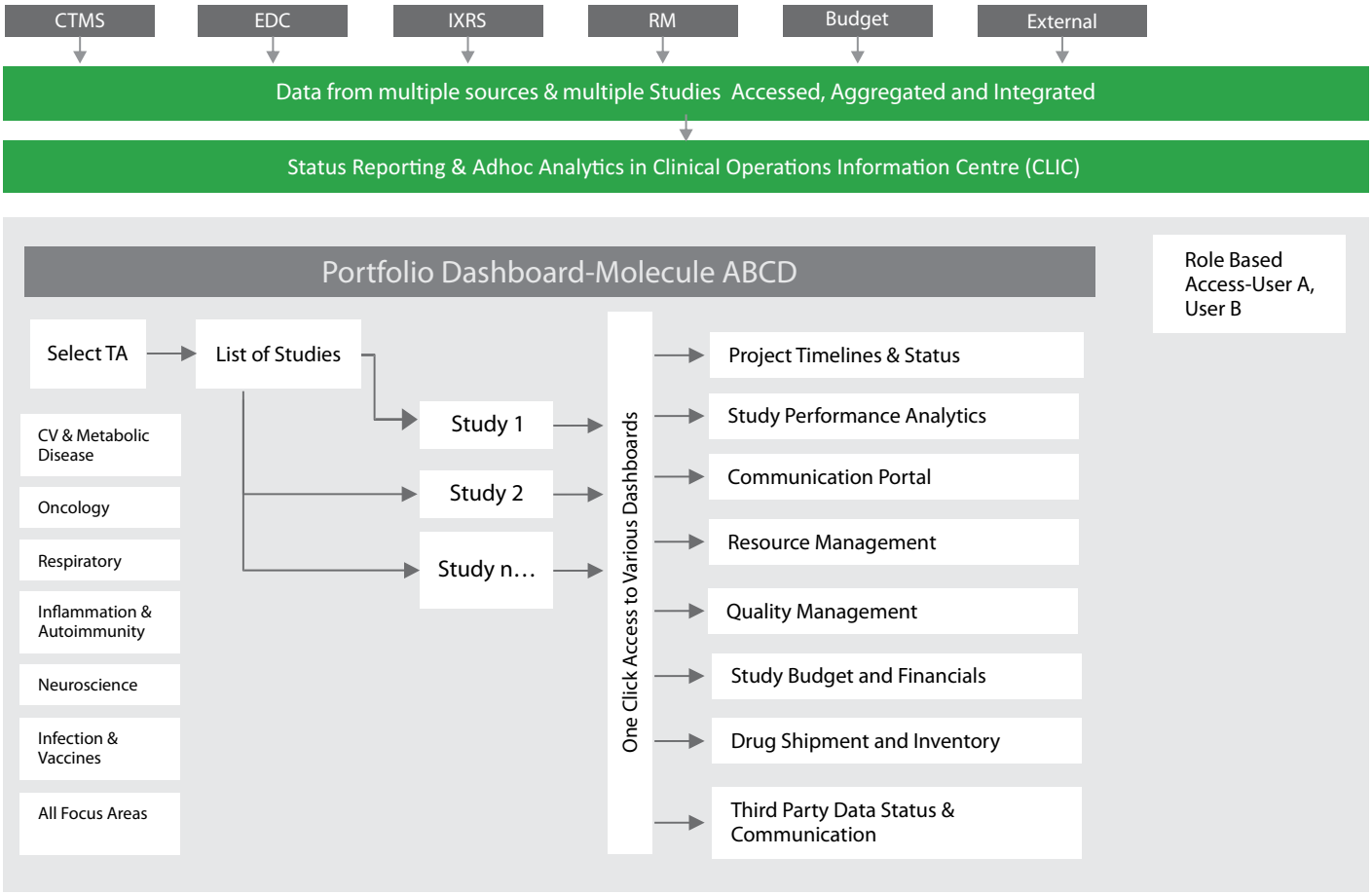

Figure 3: Portfolio Review

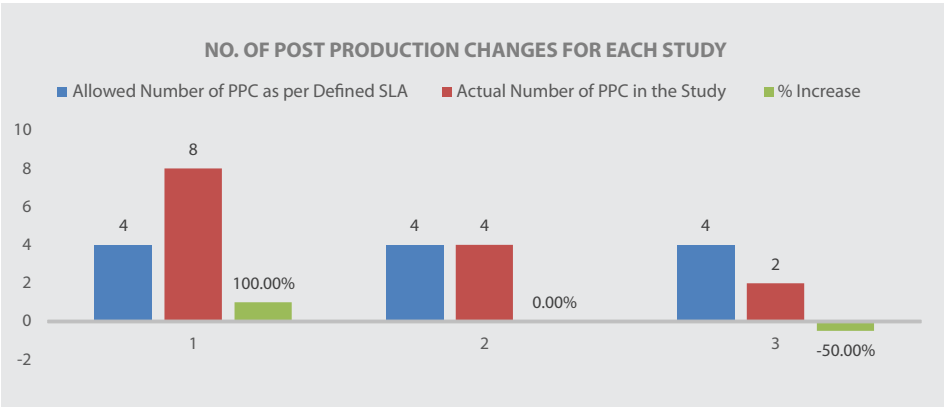

Figure 4: Protocol Deviation KRI

Information Integration: The key to successfully deploying CLSPA

In order to facilitate the successful deployment of a CLSPA solution, the following key elements need to be in place:

Create a responsive data model

Varied sources of data result in data being received in multiple file formats. It is therefore imperative that the data be

available in a format which is not only easily ingestible by the solution, but also convenient for vendors, sponsors and other data sources to use. For instance, an ODM compliant XML is one such easy to use format.

Ensure record level traceability

The warehouse or data mart receives data as and when the source systems have new or updated data. Since the focus of the CLSPA approach is integrating data across different source systems and taking decisions based on KPIs, it is imperative to track the outliers or risk elements to the source data. This can be done in the following ways:

1. Trace data flow from source system to the target (data lineage), enabling a customizable view that is relevant to the user
2. Use record identifiers and versioning at the record level, eliminating record duplication and ensuring traceability from source to the record

Deploy an alert mechanism

Assessing trial risks involves identifying the risks that could degrade patient safety or data quality, establishing processes to minimize those risks, and identifying risk indicators and thresholds that trigger an investigation and corrective action. Such corrective action fall into one of the following categories, and must be tracked and monitored until they are closed:

System-driven – These actions are generated automatically by the system once the KRIs are evaluated against the threshold values. Based on the RAG status and the pre-defined actions, the system can be programmed to generate actions and initiate workflows so that every outlier is tracked at every point in time.

Manually induced – The central monitor of the clinical study is tasked with constantly reviewing the data and monitoring the trial. It is possible that the central monitor may want to manually initiate an action at some point in time. Such an action needs to be tracked in the system. This is especially true for KPIs where the metrics are not evaluated against the threshold. For instance, tracking an efficacy parameter that lacks historical data.

Looking at clinical trials through the lens of the future

Complexity is cited as one of the top challenges faced by globally dispersed stakeholders responsible for running clinical studies.[1] Amidst all the complexity, sponsors of clinical studies are increasingly required to ensure transparency to both regulatory bodies and patients. This is a tough ask given that the data resides across multiple systems. A CLSPA solution with customizable and intuitive visualization capabilities lays the foundation for enabling such transparency, bringing effective decision making and operational efficiencies into the drug development process. Over a period of time, the solution can be further developed into an Artificial Intelligence (AI) based cognitive process capable of predicting clinical actions, with minimal human intervention.

References

[1] https://knect365.com/clinical-trials-innovation/article/e414c9b9-8de9-4525-8fe6-fe6264d36df0/report-biggest-challenges-clinical-trials-pt-1

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