Paper DV10

Beyond Excel: Automating Clinical Project Management with Interactive R Shiny Dashboards

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ABSTRACT

Clinical Project Managers (CPMs) play a pivotal role in the realm of clinical trials, constantly monitoring study enrollment and data quality. Traditionally, this task has involved laborious and repetitive manual data manipulation 2-3 times per week, often performed using tools like Excel or Smartsheet. The Clinical Data Analytics & Programming (CDAP) team created an R Shiny application that has reshaped the landscape of data monitoring. It automates the production of essential study metrics, providing standardized outputs at the click of a button. This innovation not only conserves countless hours of CPMs' time but also elevates the accuracy and consistency of the metrics, making them readily available across various trials. This project serves as a compelling testament to the power of automated data visualization for real-time clinical data analytics. By deploying the R Shiny application, our solution empowers CPMs to conduct data-driven decision making and focus on interpreting insights.

INTRODUCTION

ABOUT FORMATION BIO

Formation Bio is a tech-driven pharma company differentiated by more efficient drug development. Founded in 2016 as TrialSpark Inc., Formation Bio has built a technology platform that optimizes critical aspects of clinical drug development, enabling more efficient trial design, faster trial completion, and higher quality trial data. The company acquires clinical-stage drugs from pharmaceutical and biotech companies with the goal to develop them faster in order to accelerate access to new treatments for patients, and to unlock greater value per program. By developing their drug assets faster than industry norms, Formation Bio can take more shots on goal, increasing the overall likelihood of success, and ultimately increasing the number of new treatments available to healthcare professionals and their patients. Formation Bio is backed by a range of technology and biosciences investors, including Sam Altman, Michael Moritz, Sequoia Capital, Thrive Capital, Section 32, John Doerr, Spark Capital, Lachy Groom, and others.

THE CLINICAL TRIAL JOURNEY

At Formation Bio, we are committed to running trials faster and more efficiently in order to bring new treatments to patients. For each of our trials, CPMs are the commanders of the trial’s journey through preparation, enrollment, and closeout, leading a large, multidisciplinary team to safely and effectively complete the study plan and deliver the trial results. Keep in mind that the one true mission of a clinical trial is to deliver a dataset, but the people and processes around delivering those study results require decisions to be continuously made with much of that same data in order to stay on course. There are numerous activities required on this journey across clinical operations, medical, regulatory, investigational product, and clinical data capture that involve complex decision-making and frequent course correction. To do this well, CPMs continuously monitor data across all of these areas.

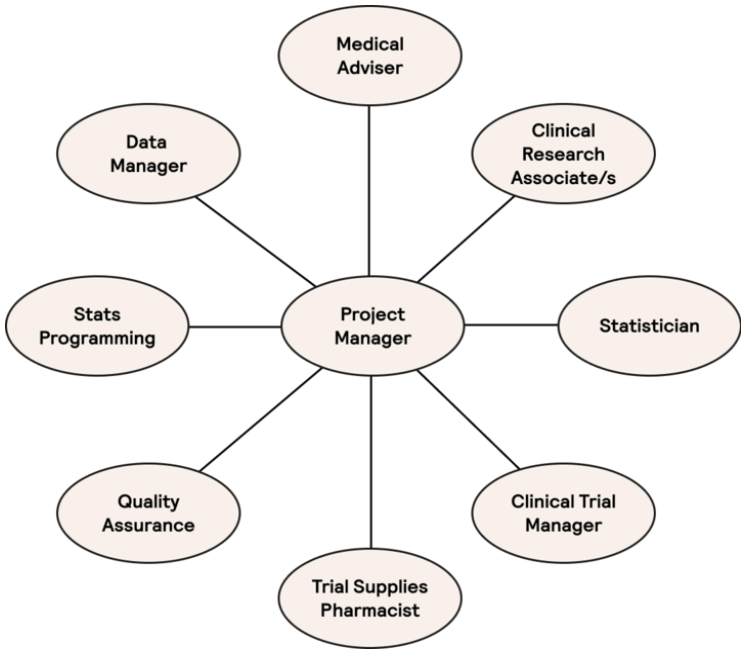

Figure 1: The study team spans many disciplines to effectively run a trial.

CLINICAL DATA ANALYTICS & PROGRAMMING AT FORMATION BIO

The Clinical Data Analytics & Programming (CDAP) team at Formation Bio is committed to improving clinical trial efficiency by decreasing the amount of manual data manipulation performed by clinical trial teams to increase the speed and accuracy of clinical insights, monitoring, and trial execution. We do so through close collaboration with clinical stakeholders to identify areas of investment in the clinical trial process that would benefit from technology and automation.

BACKGROUND

FLYING BLIND

Unfortunately, industry standard practices mainly default to local Excel-based methods for reviewing tables, joining data with formulas and methods like VLOOKUP, and then passing around files between teams to facilitate review and comments. Reports are often saved and stored locally, with study team members using different datasets, or embedded in meeting minutes. Excel is a valuable tool, but not the most efficient way to perform repeated analysis and data visualization. These methods often lead to duplicative work and loss of insight into trends in metrics and issue management activities at a study level. Because it takes so long to pull together data and metrics in this way, CPMs are essentially creating and re-creating the dashboard while in-flight and flying blind the majority of the time.

TURBULENCE AHEAD

The CDAP team interviewed members of the CPM team in hopes to determine a solution. As pilots of a clinical trial, CPMs experience the following major pain points of running a trial using these manual reporting methods which have significant implications and make for a rocky flight:

- **Knitting together data from multiple sources in Excel:** Most therapeutic trials use multiple clinical data capture systems, so compiling data resembles piecing together fragmented flight plans without a comprehensive navigation system and is prone to uncertainties that could deviate the trial from its intended course.
- **Many hours spent calculating the same metrics week to week:** The repetitive nature of these manual calculations parallels a pilot continually adjusting controls, diverting attention from the broader navigation and potentially missing critical details crucial for the trial's success.
- **Metrics are not in real time:** Metrics are calculated using data from a single point in time that is available to an individual, so CPMs lack a clear view of the trial's current real-time status, inhibiting their ability to swiftly adjust course in response to emerging trends or issues. Operating without a cumulative, current dataset is akin to flying through thick fog.
- **Manual metric calculation leading to inaccuracies in reporting:** Much like relying on manual instruments in turbulent weather, the reliance on manual calculations using tools like Excel or Smartsheet introduces potential errors and inconsistencies, clouding the accuracy of reported metrics and jeopardizing the trajectory of the trial.
- **Over-reliance on meetings as a forum for sharing information:** Because it is so hard to consolidate information, many CPMs rely on constant meetings with each cross-functional team member to gain an understanding of the

current status of all trial activities. The necessity for frequent meetings mirrors pilots circling back to base repeatedly for guidance due to inadequate instrumentation, consuming valuable time and energy.

AIR DISASTER

The risk of running a trial without real-time metrics is clear. This results in the team constantly reacting to issues as they are discovered, often as the impact is felt, rather than focusing on properly investigating issues as they occur and preventing more of the same issue. The best example of this are protocol deviations, which if discovered early can often be mitigated through methods such as retraining of patients, sites, and study team members. Real-time data insights also allow for resources to be directed appropriately to keep everyone on the same path. If study startup or enrollment is behind at a certain site, more resources can be directed to support that site. If a site is enrolling faster, resources to monitor the data at that site and investigational product stored at that site can be increased. There are so many opportunities in a clinical trial where CPMs and the entire study team can make data-driven decisions to optimize cost, speed, and quality. To do this effectively, the most current, accurate, and consistent data and metrics needed to make decisions must be readily accessible to guide the journey.

METHODS

R SHINY

R Shiny is an emerging piece of technology in the clinical analytics space. The CDAP team is trained in biostatistics and bioinformatics and was already familiar with the R programming language making adoption of R Shiny a natural progression. The power of R Shiny comes from its ability to create highly customizable and interactive web applications for clinical trial data visualization. In order to share R Shiny apps in a secure, controlled manner consistent with regulatory requirements for clinical data governance, we have implemented Posit Connect, Workbench, and Package Manager.

In the evolving landscape of clinical analysis, R Shiny's emergence as a tool of choice stems from its capacity to bridge the gap between statistical expertise and user-friendly interface design. This convergence not only facilitates robust data visualization but also empowers the CDAP team to present trial metrics in a comprehensible and actionable format for CPMs. As Formation Bio continues its trajectory as a tech-enabled pharmaceutical entity, R Shiny's versatility and integration within the CDAP team's skill set solidify its position as a strategic asset, enabling agile and informed decision-making in clinical trial management.

BUILD VS BUY

Study dashboards are a common tool used in industry to monitor the progress of a clinical trial. However, companies of our size would typically purchase an off-the-shelf solution which requires extensive data integrations and lacks a degree of customization without significant investment and effort. As a tech-enabled pharmaceutical company, Formation Bio is uniquely positioned to quickly and efficiently spin up highly customizable R Shiny solutions to deliver data insights in real time.

Some benefits of an in-house developed R Shiny solution include:

- **Cross-functional collaboration:** CDAP benefits from working directly with CPM to help inform the specifications and requirements of an in-house solution. The result is an analytics team with a deep understanding of the problem space that is unique to the company.
- **Contextual understanding:** Leveraging an in-house analytics team bypasses any external learning curve and harnesses historical context and company-specific knowledge to be able to accelerate development.
- **Tailored to specific needs:** An in-house solution allows customization aligned precisely with the unique requirements and workflows of the company's clinical trials, offering tailored functionalities and metrics that address specific trial nuances. The result is a product that is tailor fit for the study needs allowing CPM to perform at the highest level.

NAVIGATING WITH DATA

The CPM team has now been using the Study Dashboard to drive team meetings, investigate data issues and findings, and put mitigations in place to address study, site, and data-related issues. They are able to quickly find all the information they need in one place without having to pull listings across multiple systems and perform one-off analyses in Excel. Instead of pivot tables, they can easily sort, group, and explore data within the R Shiny application. This then translates into the ability to quickly make real-time, data-driven decisions and act on insights. This has helped to foster a culture of data democratization and data-driven decision making on our studies.

Within one view, CPMs can navigate between different tabs to explore datasets that include key study metrics related to the following datasets:

- Site activation and enrollment
- Participant funnel from pre-screening through study completion
- Screen fail reasons with specific inclusion and exclusion criteria not met
- Protocol deviations
- Clean patient tracker

STUDY DASHBOARD MOCKUPS

Figure 2: The Study Dashboard main landing page gives a complete overview of where we are in the clinical trial journey in terms of site activation, patient screening and enrollment, and protocol deviations.

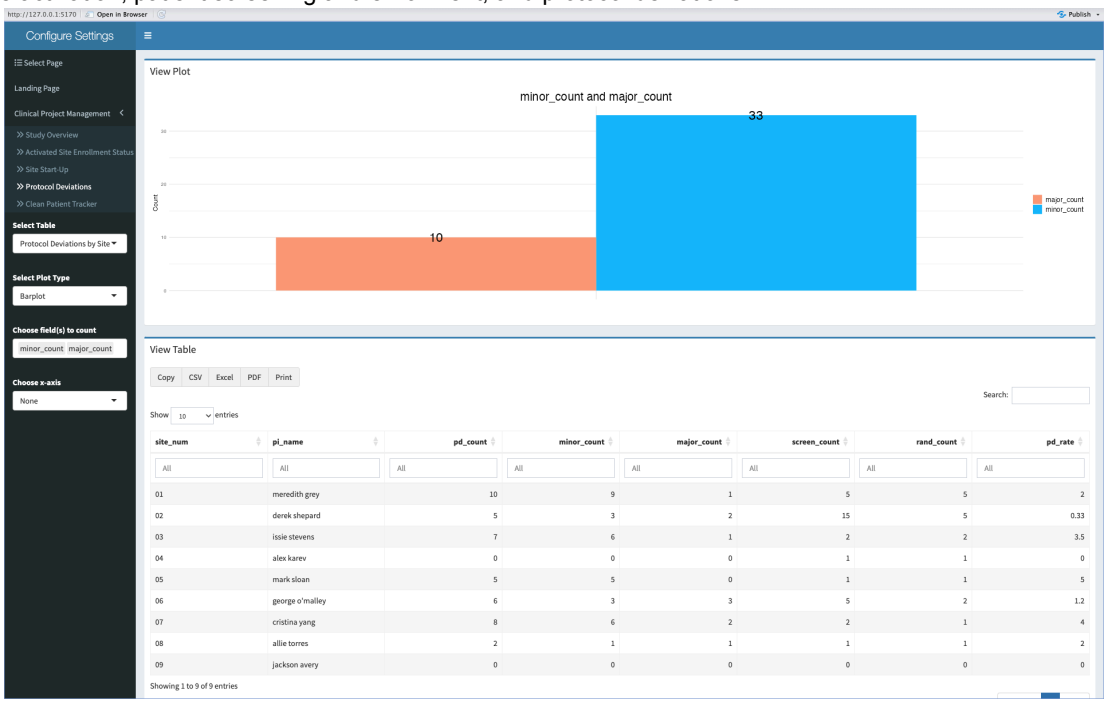

Figure 3: Datasets such as protocol deviations can then be visualized, explored, and exported in subsequent tabs.

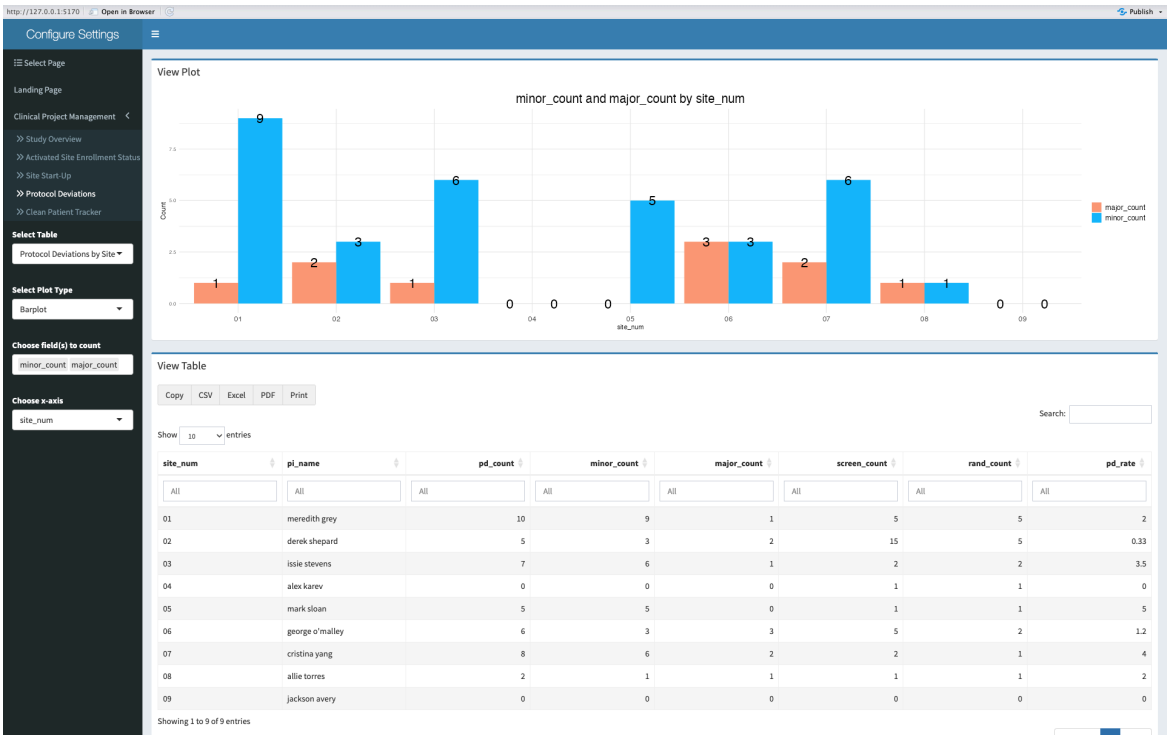

Figure 4: Datasets can be subset by site.

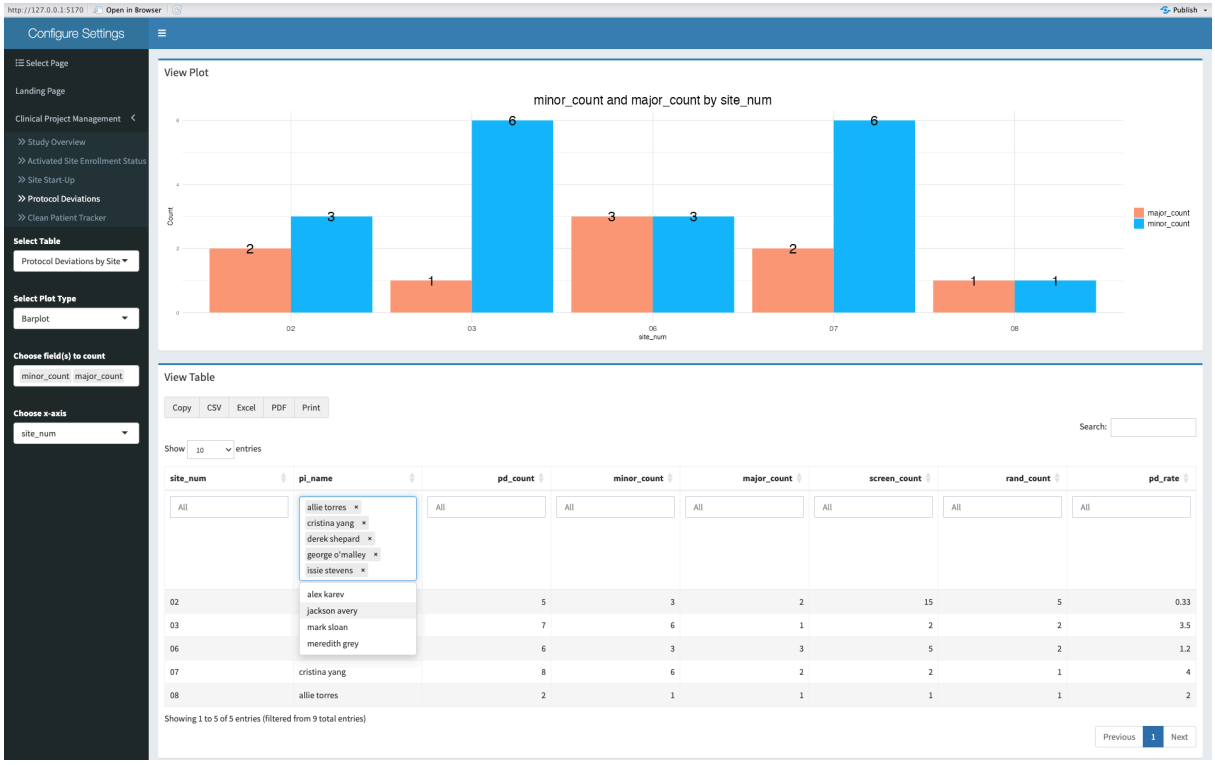

Figure 5: Datasets can be further filtered and subset to specific sites.

RESULTS

SKY HIGH EFFICIENCY

A customized and interactive Study Dashboard can have a large impact on efficiency and accuracy of repeated reporting tasks for a CPM team. Implementation saves multiple CPMs time per study per week by eliminating the need to manually

manipulate data to prepare for meetings. This significant time gain empowers a CPM team to shift their focus towards more strategic decision-making, in-depth interpretation of trial insights, and proactive resourcing.

Additionally, the self-service aspect of the R Shiny application democratizes access to critical study metrics. Data previously only available in meetings or to those willing to dive into the raw data becomes readily available to all study members. This reduces the burden on CPMs to be solely responsible for sharing trial metrics out to the rest of the clinical study team. This essentially eliminates the reliance on meetings to share information. R Shiny's built-in interactivity plays a pivotal role in reducing a CPM's time-to-decision. By empowering a CPM to explore the data independently, we reduce their reliance on an analytics support team for every one off request or investigation. This gives them the tools they need to come to a data-driven decision faster and more efficiently.

CONCLUSIONS

SUCCESSFUL JOURNEY

Overall, an R Shiny Study Dashboard proved to not only save countless hours for the study team, but to be an effective long-term solution for running trials more efficiently. In the context of clinical trials where strict data governance requirements and protocol-specific data models lead to very specific needs for each study, R Shiny is a fit-for-purpose tool for creating secure, customizable, and interactive solutions. It is optimal over out-of-the-box solutions where these types of customizations would rely on a third party to implement and would incur additional cost and time if feasible.

In addition to our technical infrastructure, the CDAP team's structure also allows for effective development of the Study Dashboard. Centralizing this function so that analysts can align agile development workflows while also embedding analysts on the study team during study start-up allows us to apply engineering principles in ways that directly impact clinical trial operations. We rely heavily on CPMs and the cross collaboration with all study teams to develop user stories and validate our R applications. These close feedback loops allow us to create detailed, interactive reports that support specific workflows, meetings, and decisions.

The Study Dashboard reduces time to decision for the study team so that they can focus on investigating issues quickly and preventing further issues of the same type. This not only translates to higher quality data for analysis, but also to a faster trial.

THE GREAT BEYOND

We have demonstrated that the Study Dashboard is critical for efficient trial operations, so for all trials at Formation Bio the dashboard development is incorporated into study startup timelines. Having a robust flight plan allows us to efficiently start up and execute studies and continue to build them out with more functionality, information, and features for other study team members and functions. We are also working to track data quality as our north star as part of an "air traffic control" dashboard that looks across studies at data quality metrics to evaluate the impact of our work.

CONTACT INFORMATION

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