

Beyond Excel

Automating Clinical Project Management with Interactive R Shiny Dashboards



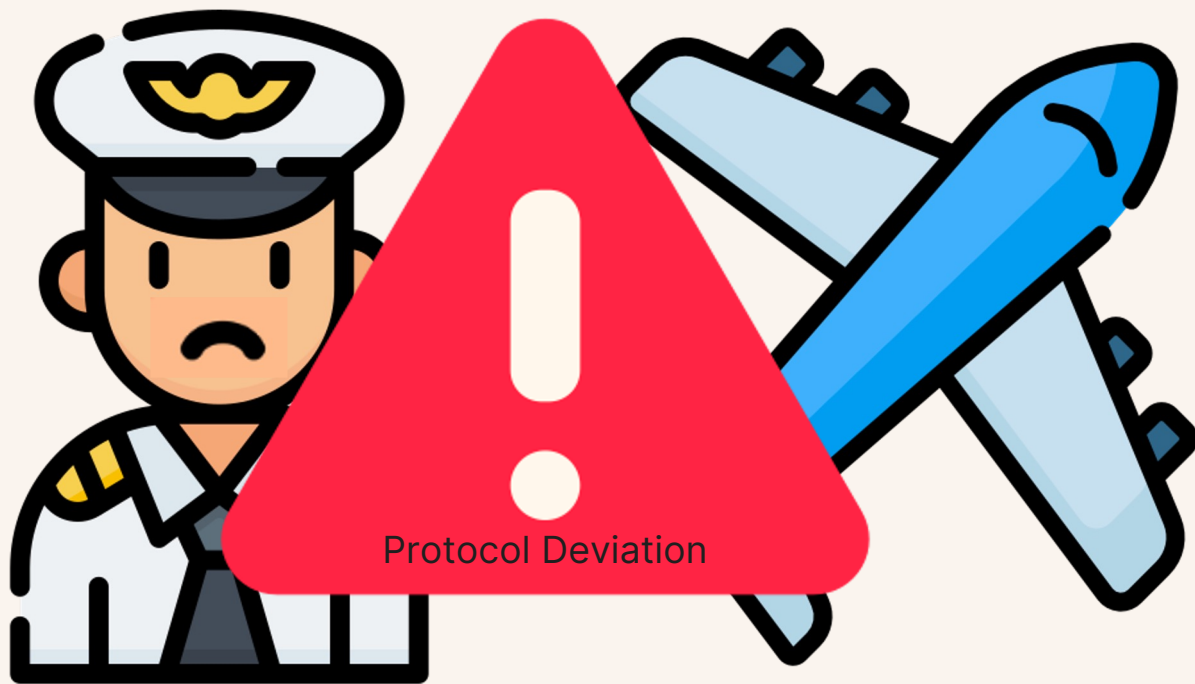
Emily Murphy, Melanie Hullings

Formation Bio

Imagine you are the captain of a clinical trial...



...when the check engine light come on



Race against the clock to make high impact clinical decisions quickly

Export data

5+ Steps

Issue Level	Issue ID	Issue Type	Issue Status	Subject ID	Created Date	Deviation Category	Sub Category	Severity	Action Create Action Type	Action Status	Action Due Date	Action Close Date
Country level issue	JAM026	Non-Protocol Closed - Invalid	Resolved	#####	#####	Investigation	Investigation	Minor	#####	Preventive	Closed - Invalid	#####
Study level issue	JAM041	Non-Protocol Closed - Resolved	Resolved	#####	#####	Protocol Con Other	Other	Minor	#####	Closed - Resolved	#####	#####
Study level issue	JAM022	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Study level issue	JAM021	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Study level issue	JAM020	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Study level issue	JAM019	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Study level issue	JAM018	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Study level issue	JAM017	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Study level issue	JAM016	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	#####	#####
Country level issue	JAM002	Non-Protocol Closed - Resolved	Resolved	#####	#####	Staff and Training	Other	Minor	#####	Preventive	Closed - Invalid	#####
Study level issue	JAM079	Non-Protocol Closed - Resolved	Resolved	#####	#####	Other	Other	Minor	#####	Preventive	Closed - Resolved	#####
Study level issue	JAM069	Non-Protocol Closed - Resolved	Resolved	#####	#####	Data Integrity Data Quality	Minor	Minor	#####	Preventive	Closed - Resolved	#####
Country level issue	JAM022	Non-Protocol Closed - Resolved	Resolved	#####	#####	Study File	Investigation	Minor	#####	Preventive	Closed - Resolved	#####
Country level issue	JAM016	Non-Protocol Closed - Resolved	Resolved	#####	#####	Data Integrity Data Quality	Minor	Minor	#####	Preventive	Closed - Resolved	#####
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Country level issue	JAM018	Non-Protocol Closed - Resolved	Resolved	#####	#####	Vendor	Vendor Own	Minor	#####	Preventive	Closed - Resolved	#####
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Country level issue	JAM016	Non-Protocol Closed - Resolved	Resolved	#####	#####	Vendor	Vendor Own	Minor	#####	Preventive	Closed - Resolved	#####
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Study level issue	JAM010	Non-Protocol Closed - Resolved	Resolved	#####	#####	Vendor	Vendor Own	Minor	#####	Preventive	Closed - Resolved	#####
Study level issue	JAM009	Non-Protocol Closed - Resolved	Resolved	#####	#####	Vendor	Vendor Own	Minor	#####	Preventive	Closed - Resolved	#####
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Study level issue	JAM005	Non-Protocol Closed - Resolved	Resolved	#####	#####	Vendor	Vendor Own	Minor	#####	Preventive	Closed - Resolved	#####
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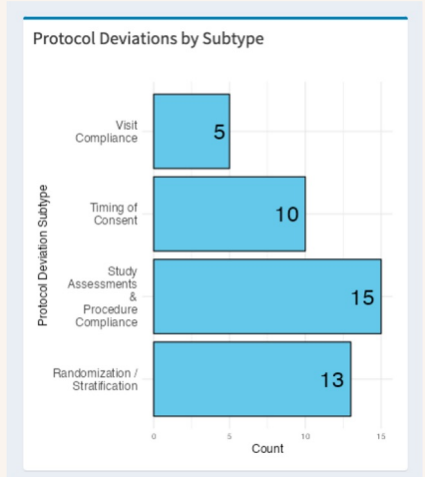
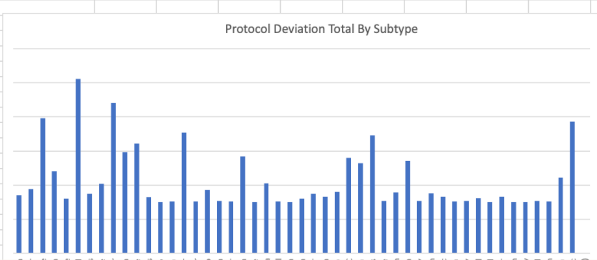
VS



1 Click



PivotTable



Agenda

Introduction

The Problem

The Solution

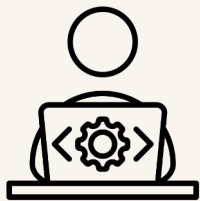
Demo

Results and Impact



Introduction

Clinical Data Analytics & Programming (CDAP)



Team of data scientists, clinical data analysts, and systems developers



Improve speed and accuracy of clinical insights



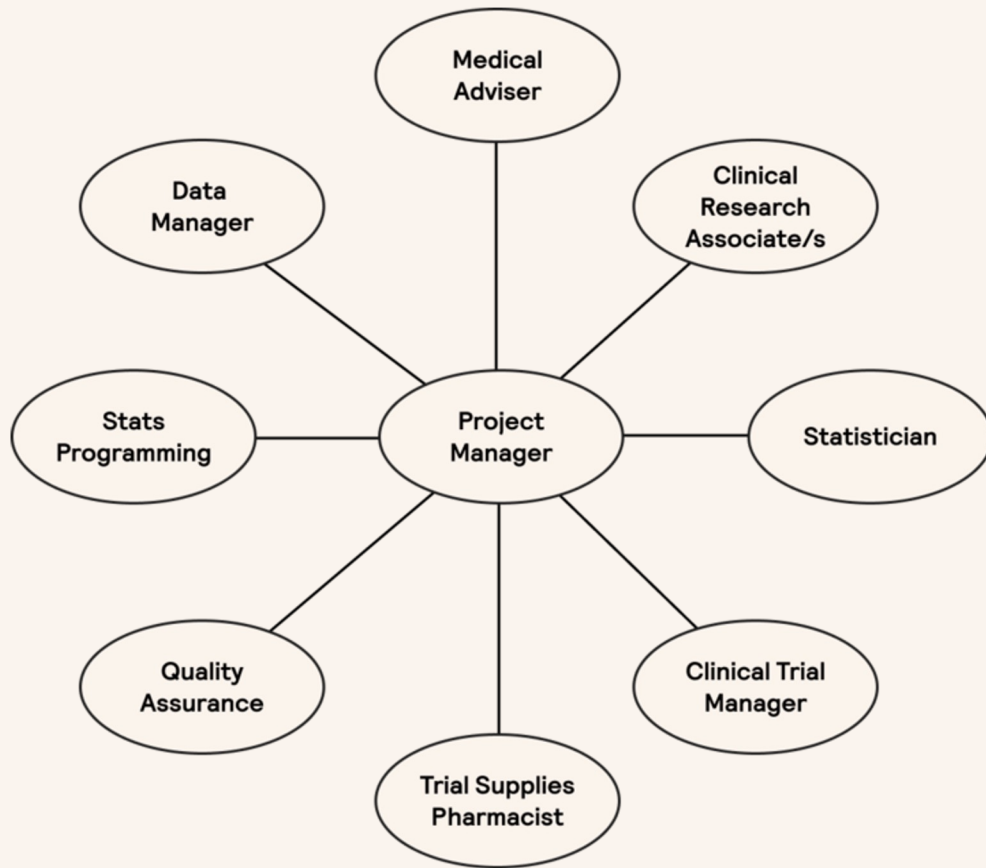
Collaborate closely with clinical study team members to provide reporting



The Problem

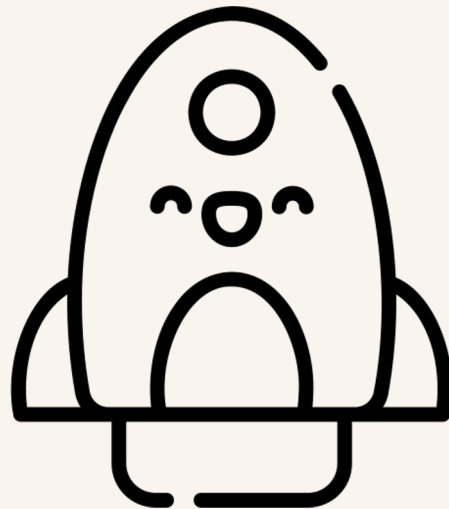
The Clinical Trial Journey

- Clinical Project Managers(CPMs) are the commanders of the trial journey
- Highly cross-functional role
- Requires quick but rigorous decision-making
- Real-time data insights are needed for complex decision-making and frequent course correction



Flying Blind: Manual processes make monitoring data difficult

- Industry standard data analysis procedures are manual and time intensive
- Results in loss of insight into trends in metrics and issue management activities at a study level
- Overall can have a major impact on data quality and trial success



Air Disaster: Real time metrics can increase trial oversight

- Without real-time metrics, the study team often discovers issues too late and has to be reactive as impact is felt
- Real-time metrics allows the study team to proactively prevent issues and optimize cost, speed, and quality in areas such as:
 - Resourcing
 - Timelines
 - Protocol deviations (PDs)

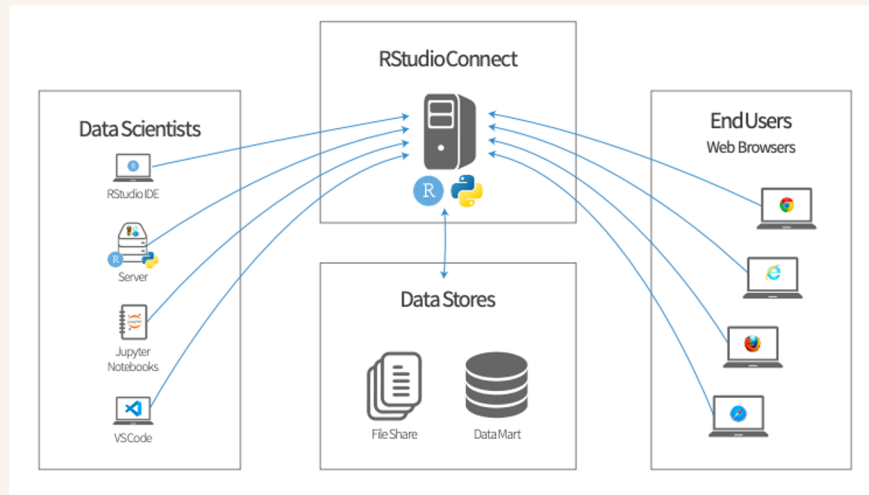




The Solution

R Shiny Dashboard Solution

- Highly customizable and interactive web applications for robust data visualization
- Bridge the gap between statistical expertise and user-friendly interface design
- Enables agile and informed decision-making in clinical trial management





Study Dashboard Walkthrough

Configure Settings



Select Page

Landing Page

Clinical Project Management

>> Study Overview

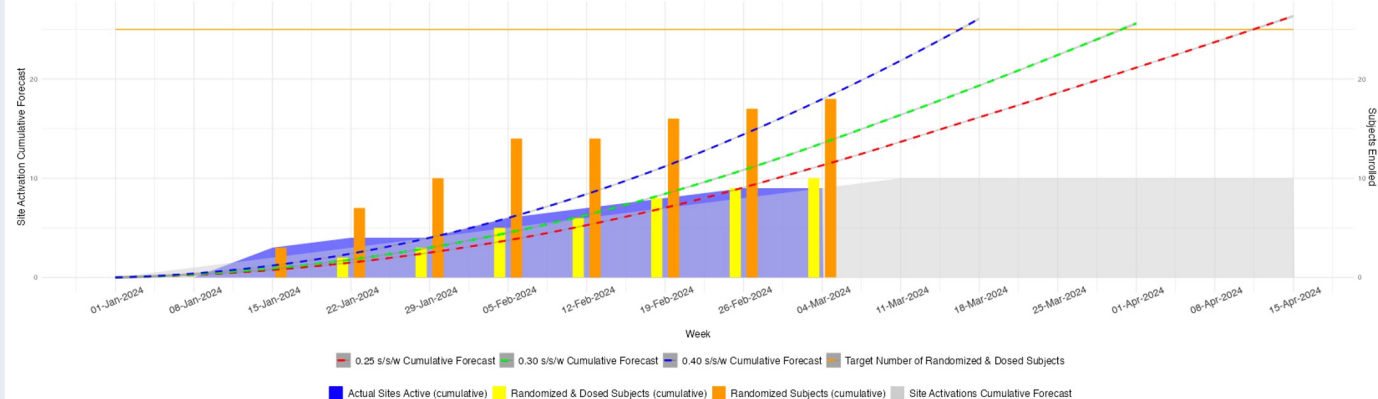
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>> Site Start-Up

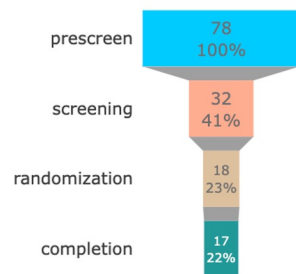
>> Protocol Deviations

>> Clean Patient Tracker

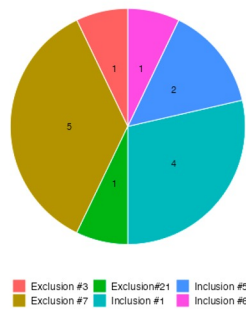
Site Activation and Enrollment Curve



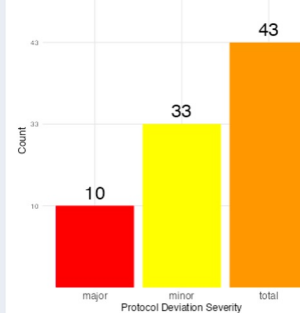
Subject Enrollment Funnel



Screen Fails by I/E Criteria



Protocol Deviations by Severity



Protocol Deviations by Subtype



Configure Settings



Select Page

Landing Page

Clinical Project Management

» Study Overview

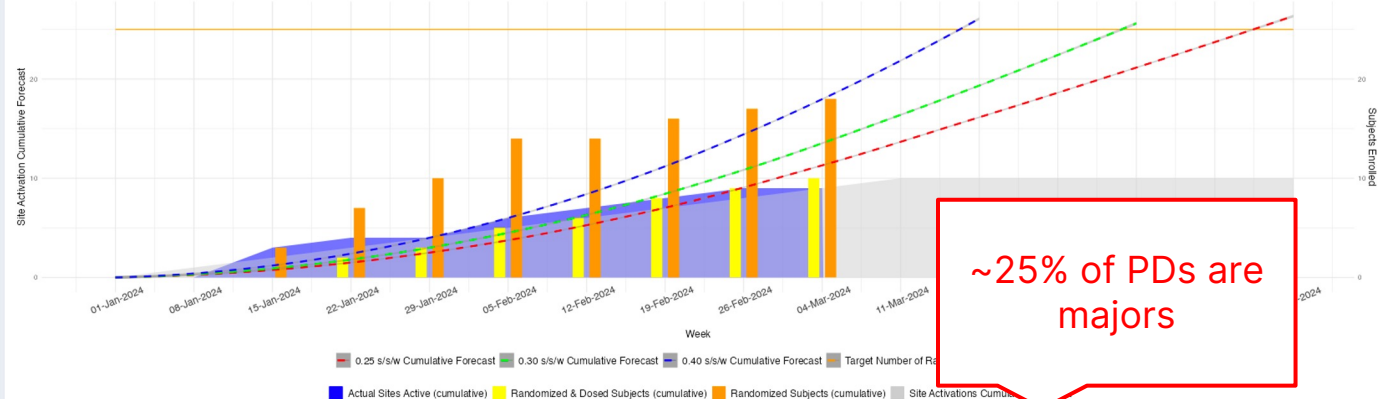
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» Site Start-Up

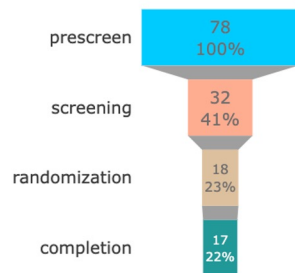
» Protocol Deviations

» Clean Patient Tracker

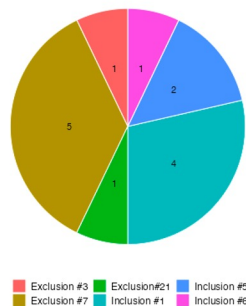
Site Activation and Enrollment Curve



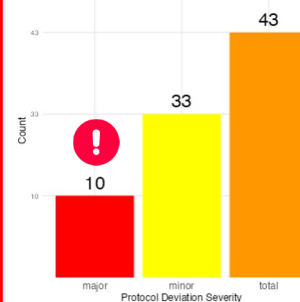
Subject Enrollment Funnel



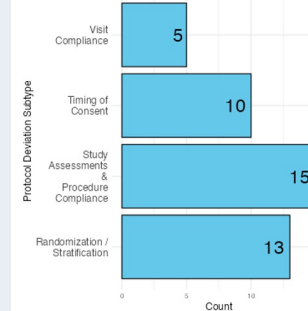
Screen Fails by I/E Criteria



Protocol Deviations by Severity



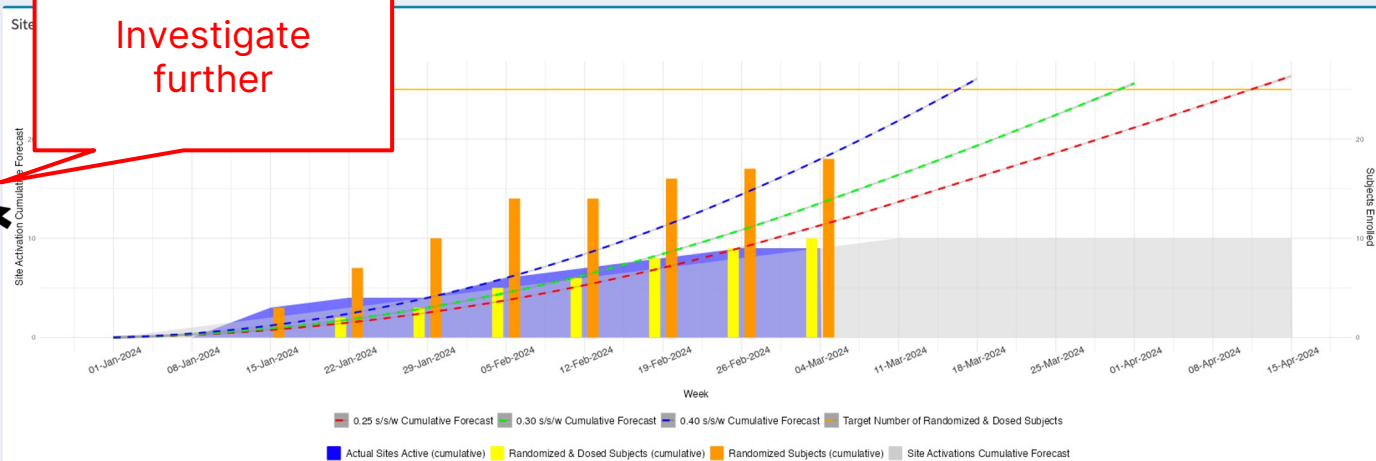
Protocol Deviations by Subtype



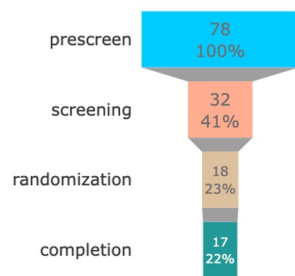
Configure Settings

- Select Page
- Landing Page
- Clinical Project Management
 - Study Overview
 - Activated Site Enrollment Status
 - Site Start-Up
 - Protocol Deviations**
 - Clean Patient Tracker

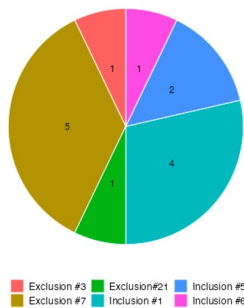
Investigate further



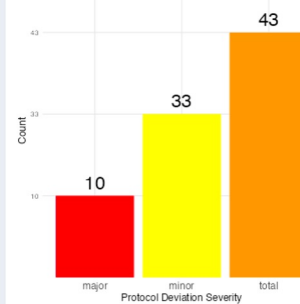
Subject Enrollment Funnel



Screen Fails by I/E Criteria



Protocol Deviations by Severity



Protocol Deviations by Subtype



Configure Settings

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>> Study Overview

>> Activated Site Enrollment Status

>> Site Start-Up

>> Protocol Deviations

>> Clean Patient Tracker

Select Table

Protocol Deviations by Site ▾

Select Plot Type

Barplot ▾

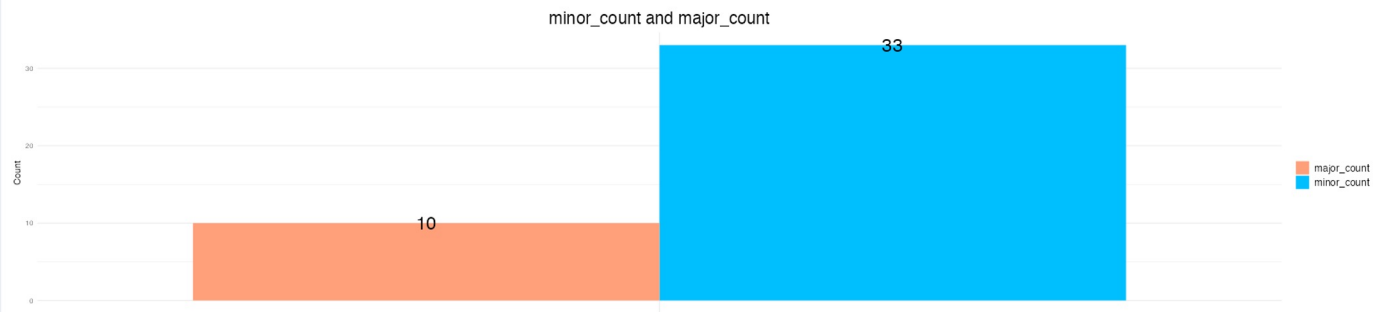
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minor_count major_count

Choose x-axis

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View Plot



View Table

Copy CSV Excel PDF Print

Search:

Show 10 ▾ entries

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02	derek shepard	5	3	2	15	5	0.33
03	issie stevens	7	6	1	2	2	3.5
04	alex karev	0	0	0	1	1	0
05	mark sloan	5	5	0	1	1	5
06	george o'malley	6	3	3	5	2	1.2
07	cristina yang	8	6	2	2	1	4
08	allie torres	2	1	1	1	1	2
09	jackson avery	0	0	0	0	0	0

Showing 1 to 9 of 9 entries

Configure Settings

Select Page

Landing Page

Clinical Project Management <

>> Study Overview

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>> Site Start-Up

>> Protocol Deviations

>> Clean Patient Tracker

Select Table

Protocol Deviations by Site ▾

Select Plot Type

Barplot ▾

Choose field(s) to count

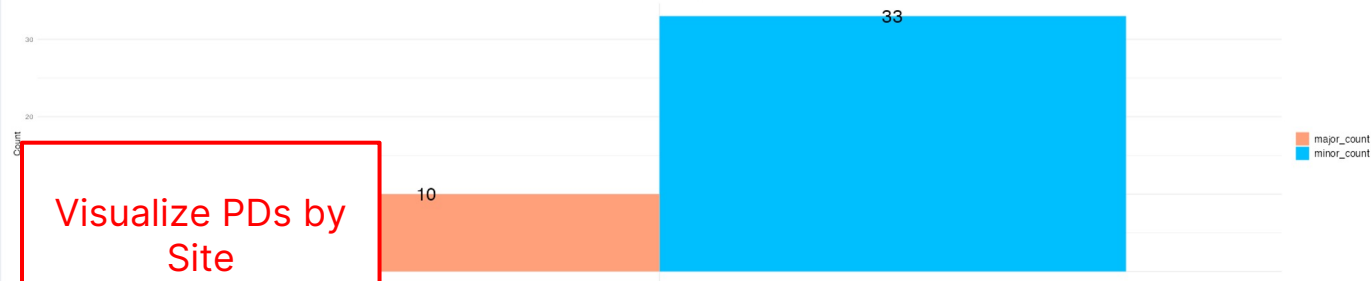
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Choose x-axis

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View Plot

minor_count and major_count



View

Copy CSV Excel PDF Print

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Select Page

Landing Page

Clinical Project Management

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>> Site Start-Up

>> Protocol Deviations

>> Clean Patient Tracker

Select Table

Protocol Deviations by Site

Select Plot Type

Barplot

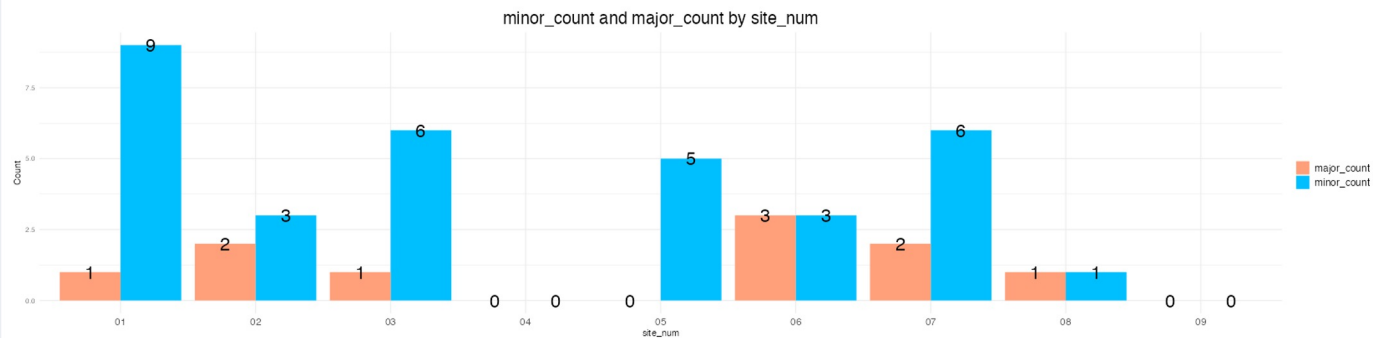
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Choose x-axis

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View Plot



View Table

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Select Table

Protocol Deviations by Site

Select Plot Type

Barplot

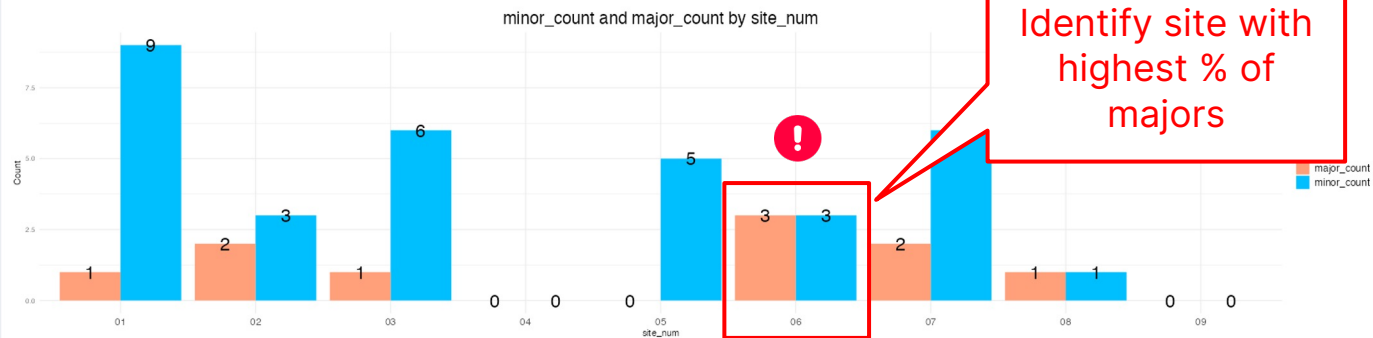
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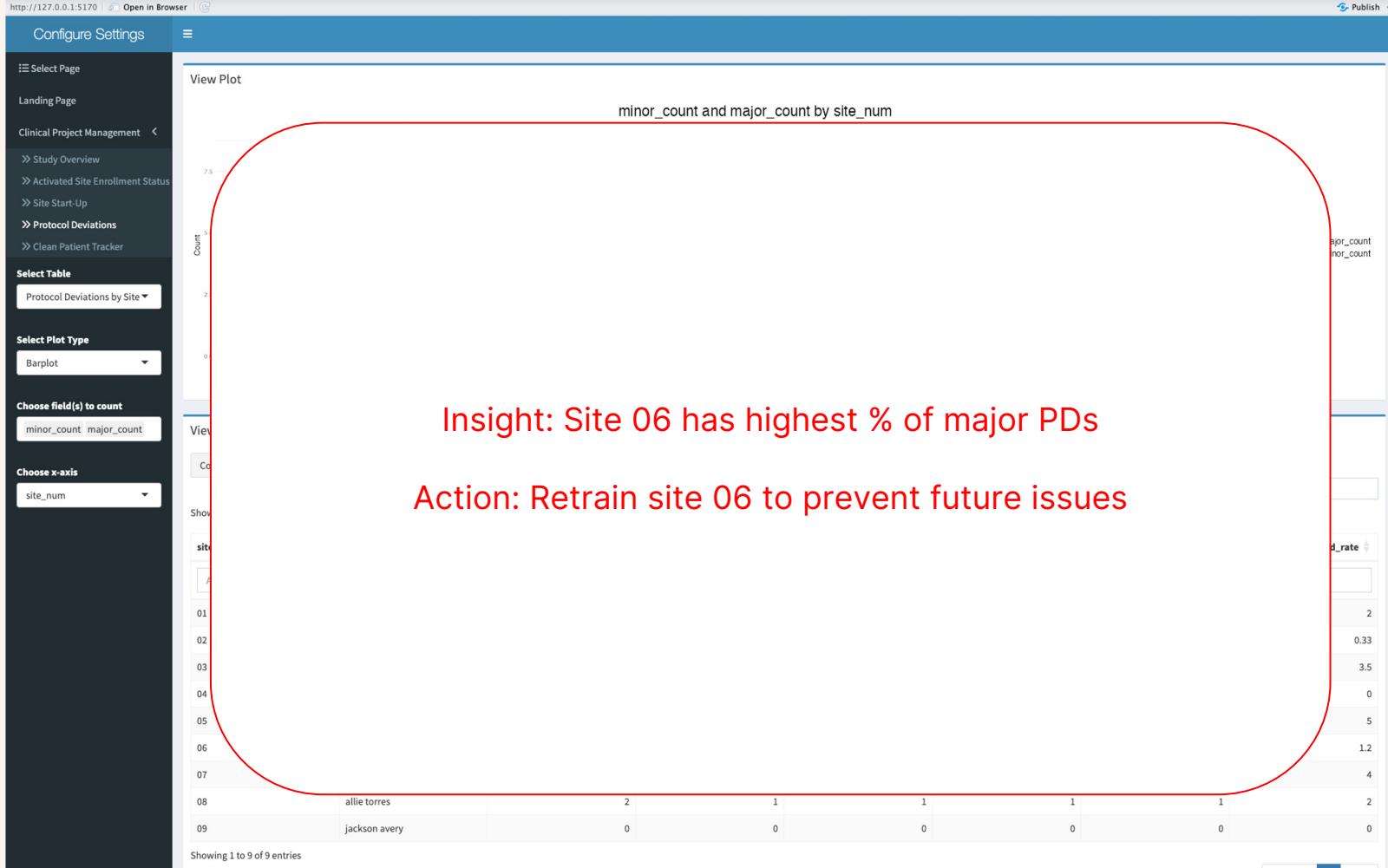
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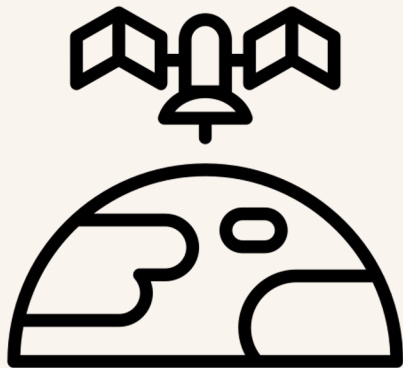
Impact and Results

Navigating with Data: Real-time metrics unlock data-driven decision making

R Shiny's built-in interactivity reduces a CPM's time-to-decision and drives:

- Improved efficiency and accuracy of repeated reporting tasks
- Empowered CPM teams to shift their focus towards more strategic decision-making, in-depth interpretation of trial insights, and proactive resourcing
- Democratized data access through self-service aspect of the R Shiny application
- Reduced the burden on CPMs to be solely responsible for sharing trial metrics

By empowering a CPM to explore the data independently, this gives them the tools they need to come to a data-driven decision faster and more efficiently leading to higher quality data for analysis, but also to a faster trial



The Great Beyond: Next Steps

- Since demonstrating Study Dashboard's criticality for efficient trial operations we will:
 - Continue to work closely with CPM and other teams to add more features
 - Build Study Dashboards tailored to specific study needs during study start up for each trial
 - Track data quality impact as our north star in an “air traffic control” dashboard





Questions?



Thank You

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