

Beyond Excel

Automating Clinical Project Management with
Interactive R Shiny Dashboards

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Melanie Hullings

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Programming



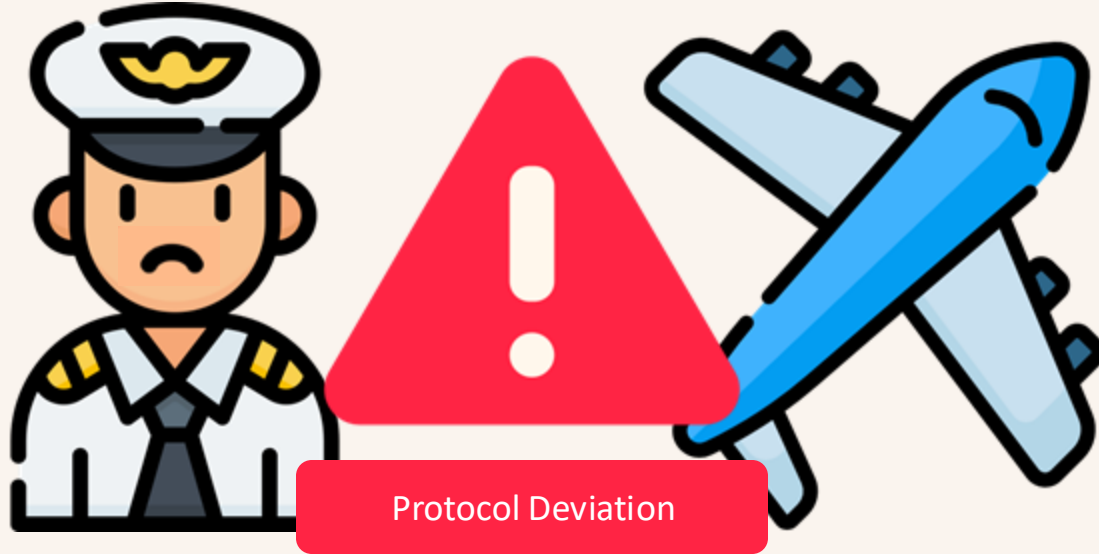
Emily Murphy

Senior Clinical Data Analyst, Statistics,
Formation Bio

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



...when the check engine light comes on



The Clinical Trial Journey

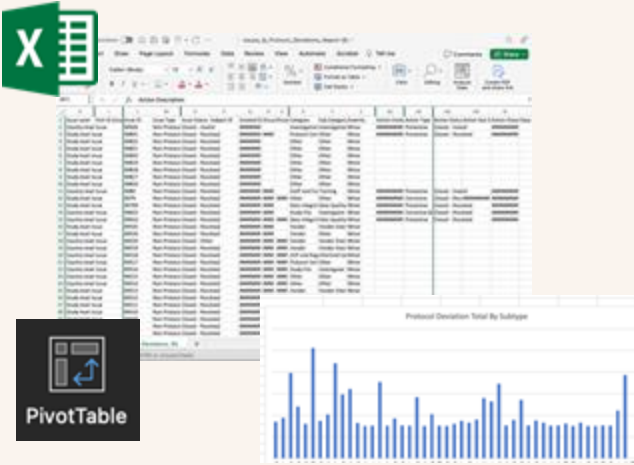
- Clinical Project Managers (CPMs) are the captain of the trial journey
- Highly cross-functional role
- Requires quick but rigorous decision-making
- Real-time data insights are needed for complex decision-making and frequent course correction



Race against the clock to make high impact clinical decisions quickly

Export data

5+ Steps



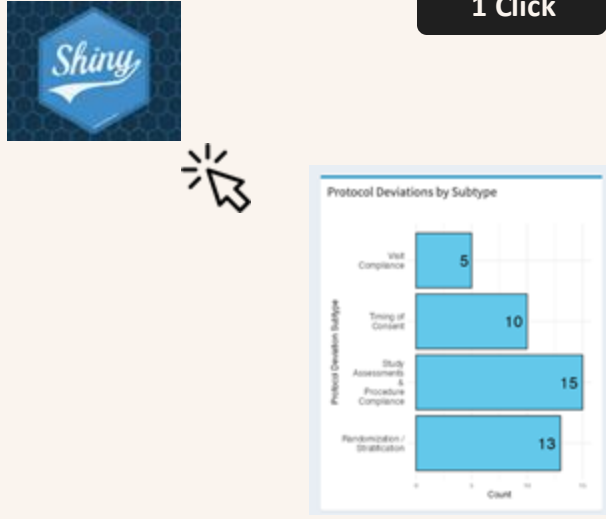
PivotTable

The screenshot shows a Microsoft Excel spreadsheet with a large table of data. A PivotTable is visible in the bottom right corner, and a bar chart titled 'Protocol Deviation Total By Subtype' is displayed below the table. The data table has columns for 'Study Name', 'Protocol Deviation Subtype', 'Count', and 'Total Count'.

VS

Shiny

1 Click



Protocol Deviations by Subtype

Protocol Deviation Subtype	Count
Unit Compliance	5
Timing of Consent	10
Study Assessments & Procedure Compliance	15
Randomization / Stratification	13

The screenshot shows a Shiny web application interface. It features a bar chart titled 'Protocol Deviations by Subtype' with four categories: 'Unit Compliance' (5), 'Timing of Consent' (10), 'Study Assessments & Procedure Compliance' (15), and 'Randomization / Stratification' (13). The x-axis is labeled 'Count'.

Clinical Data Analytics & Programming (CDAP)



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



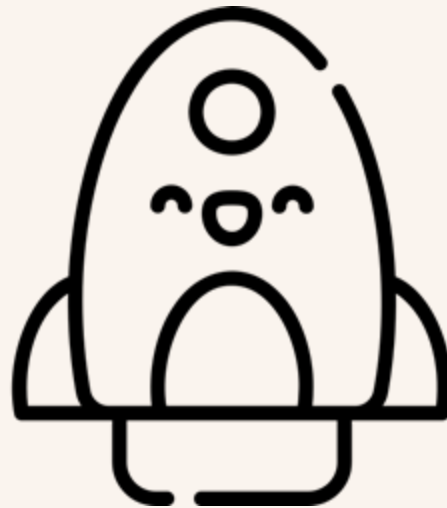
Improve speed and accuracy of clinical insights



Collaborate closely with clinical study team members to provide reporting

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



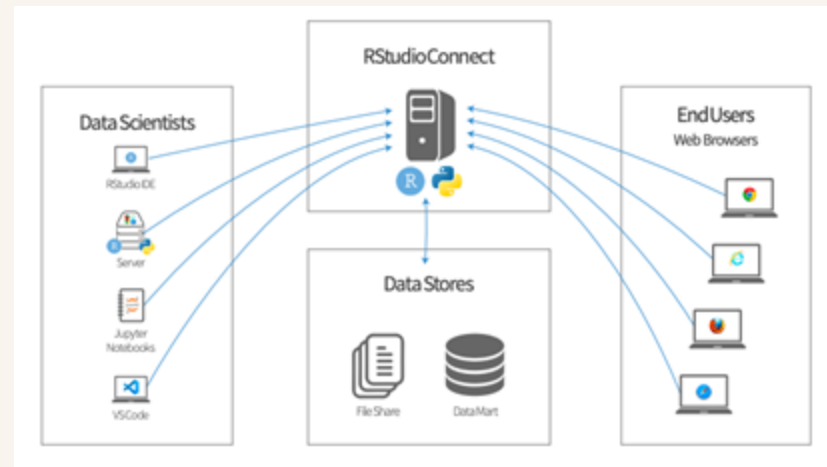
Air Disaster: Real time metrics can increase trial oversight

- 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)

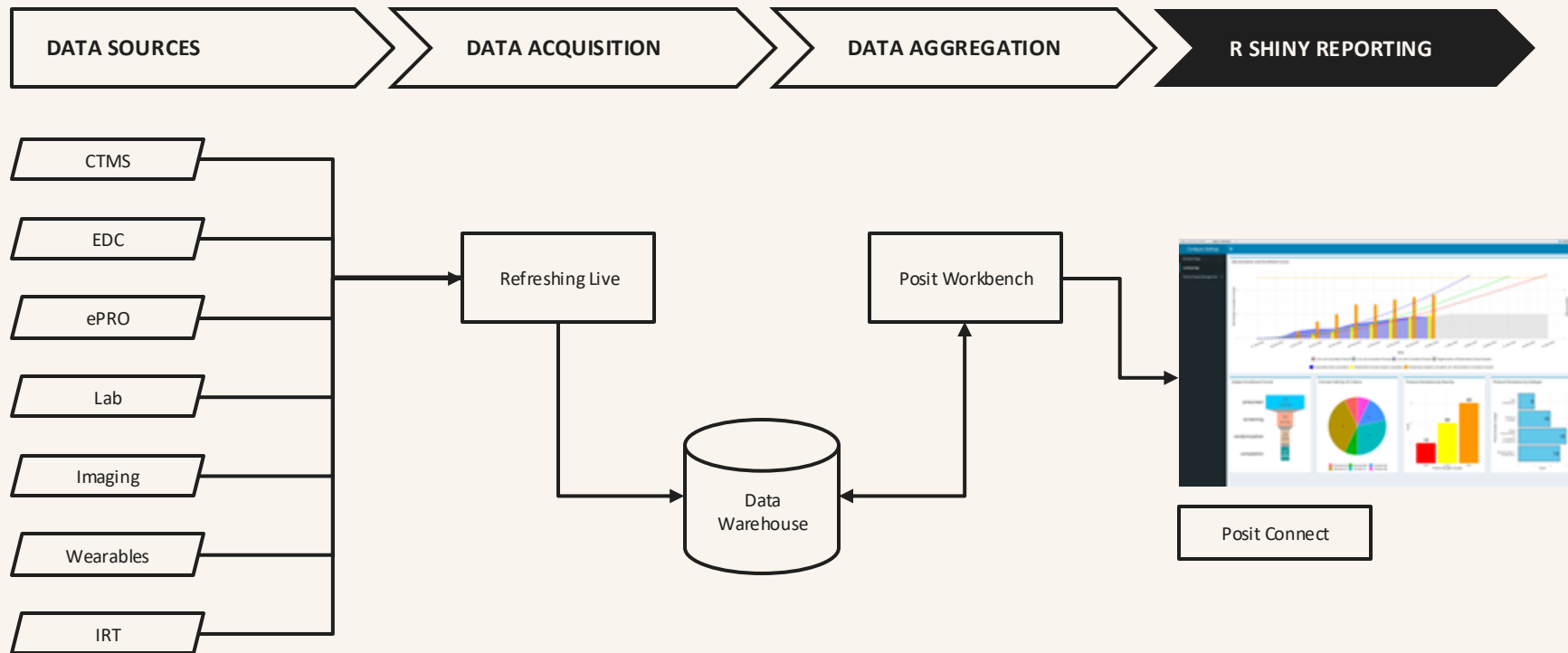


R Shiny Dashboard Solution

- 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



Clinical trial data journey



Configure Settings

Select Page

Landing Page

Clinical Project Management

Study Overview

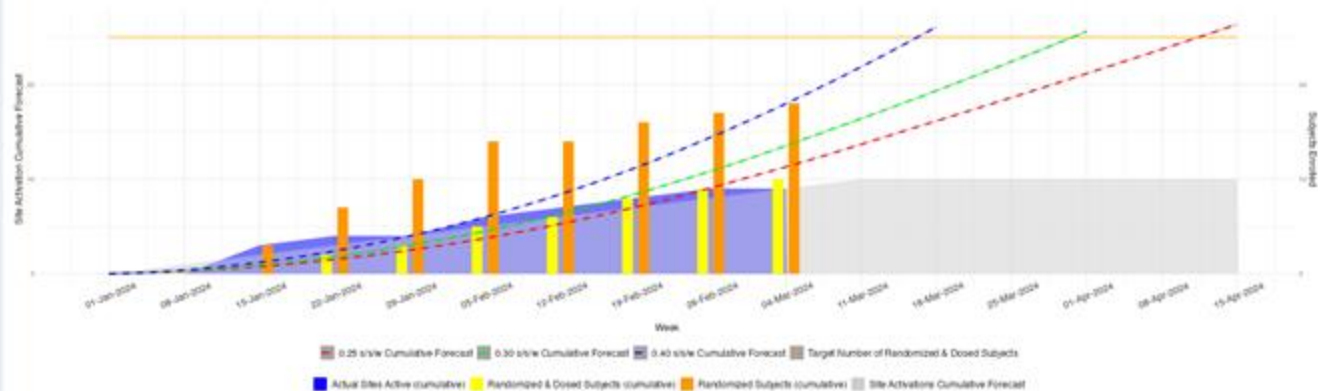
Activated Site Enrollment Status

Site Start-Up

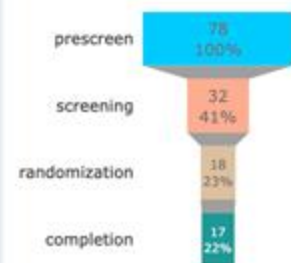
Protocol Deviations

Clean Patient Tracker

Site Activation and Enrollment Curve



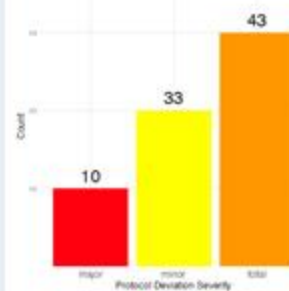
Subject Enrollment Funnel



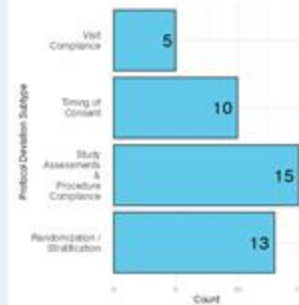
Screen Fails by I/E Criteria



Protocol Deviations by Severity



Protocol Deviations by Subtype



Configure Settings

Select Page

Landing Page

Clinical Project Management

Study Overview

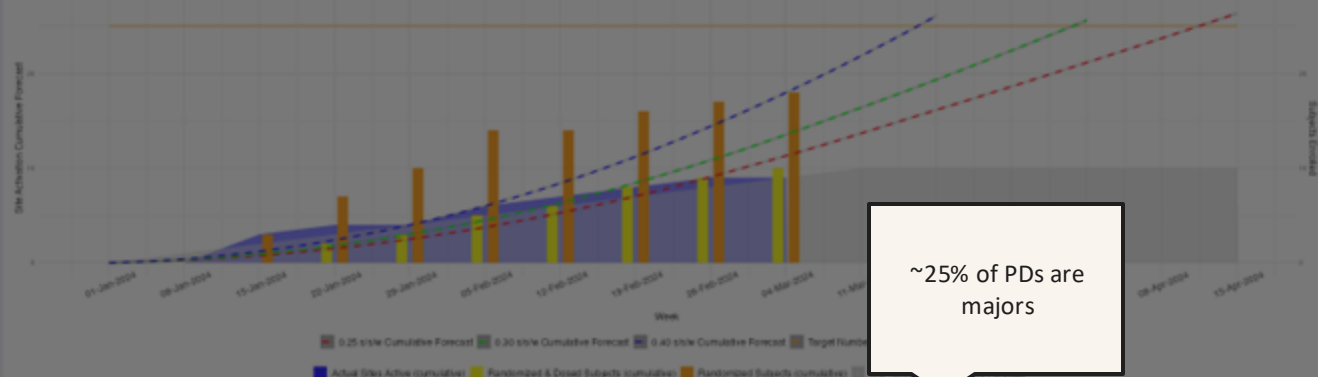
Activated Site Enrollment Status

Site Start-Up

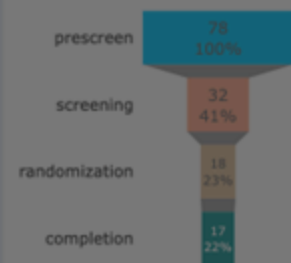
Protocol Deviations

Clean Patient Tracker

Site Activation and Enrollment Curve



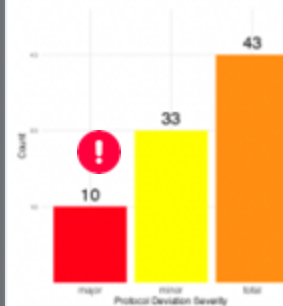
Subject Enrollment Funnel



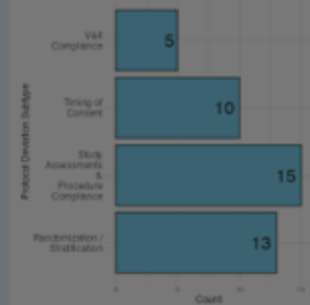
Screen Fails by I/E Criteria



Protocol Deviations by Severity

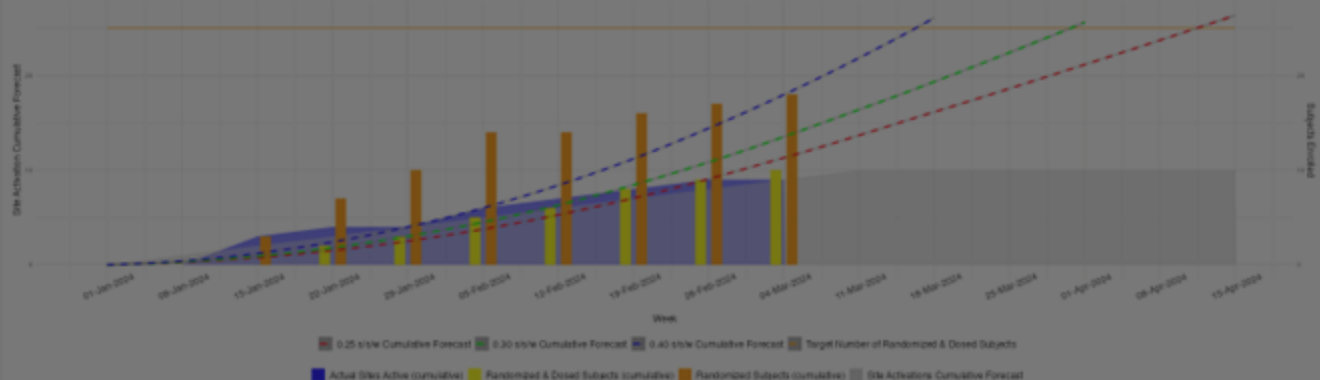


Protocol Deviations by Subtype

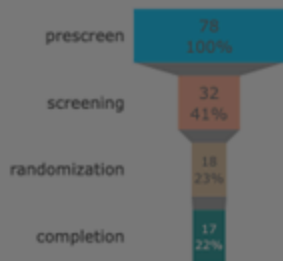


Investigate
further

Site Activation and Enrollment Curve



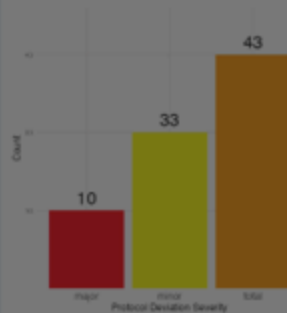
Subject Enrollment Funnel



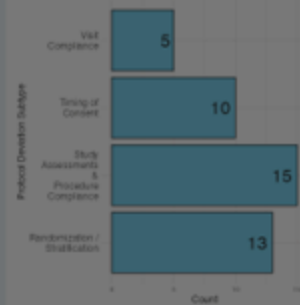
Screen Fails by I/E Criteria



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

Select Table

Protocol Deviations by Site

Select Plot Type

Barplot

Choose field(s) to count

minor_count major_count

Choose x-axis

None

View Plot

minor_count and major_count



View Table

Copy CSV Excel PDF Print

Search:

Show 10 entries

site_num	pi_name	pd_count	minor_count	major_count	screen_count	rand_count	pd_rate
All	All	All	All	All	All	All	All
01	meredith grey	10	9	1	5	5	2
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 tones	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

Activated Site Enrollment Status

Site Start-Up

Protocol Deviations

Close Patient Tracker

Select Table

Viewing upcoming PDs

Visualize PDs
by Site

Choose x-axis

None

View Plot

minor_count and major_count



View Table

Copy CSV Excel PDF Print

Search

Show 10 entries

site_num	pi_name	pd_count	minor_count	major_count	screen_count	rand_count	pd_rate
All	All	All	All	All	All	All	All
01	meredith grey	10	9	1	5	5	2
02	derek shepard	5	3	2	15	5	0.33
03	isole stevens	7	6	1	2	2	3.5
04	alex karav	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 tones	2	1	1	1	1	2
09	jackson every	0	0	0	0	0	0

Showing 1 to 9 of 9 entries

Configure Settings

Select Page

Landing Page

Clinical Project Management

Study Overview

Activated Site Enrollment Status

Site Start-Up

Protocol Deviations

Clean Patient Tracker

Select Table

Protocol Deviations by Site

Select Plot Type

Barplot

Choose field(s) to count

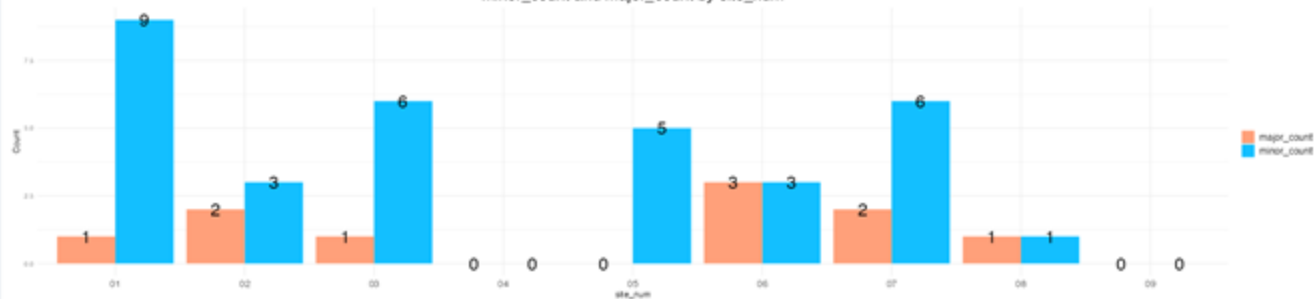
minor_count major_count

Choose x-axis

site_num

View Plot

minor_count and major_count by site_num



View Table

Copy CSV Excel PDF Print

Search:

Show 10 entries

site_num	pi_name	pd_count	minor_count	major_count	screen_count	rand_count	pd_rate
All	All	All	All	All	All	All	All
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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 tones	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

Activated Site Enrollment Status

Site Start-Up

Protocol Deviations

Close Patient Tracker

Select Table

Protocol Deviations by Site

Select Plot Type

Barplot

Choose field(s) to count

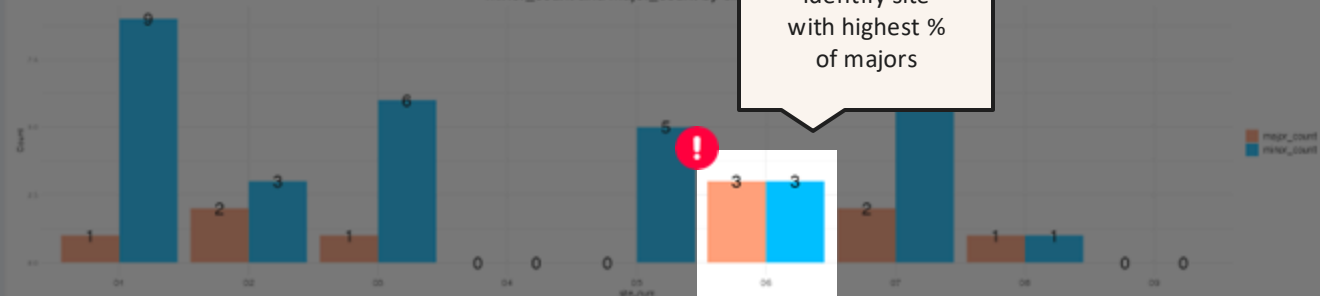
minor_count, major_count

Choose x-axis

site_num

View Plot

minor_count and major_count by site



View Table

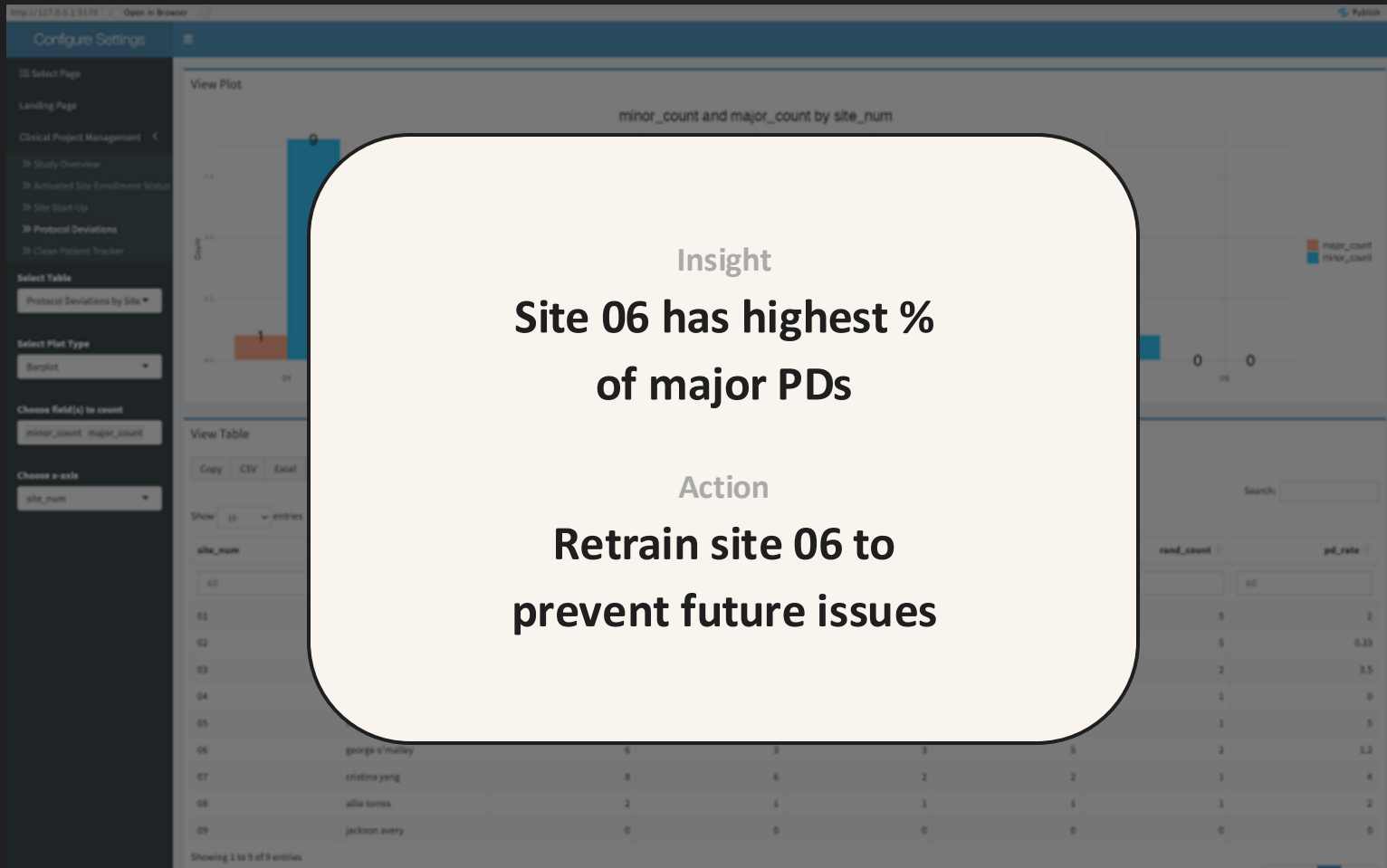
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08	allie tones	2	1	1	1	1	2
09	jackson every	0	0	0	0	0	0

Showing 1 to 9 of 9 entries



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
- Empowered CPM teams to shift their focus towards strategy
- Democratized data access
- Reduced burden on CPMs

"I am now able to explore the data I need without any help from the CDAP team to quickly make a decision in real-time during a meeting instead of spending at least an hour finding and digging into data"



The Great Beyond: What's Next?

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



Created by Amethyst Studio
from Noun Project

Questions?



Thank You

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