
Using R Shiny to Increase the Efficiency of a Study Team

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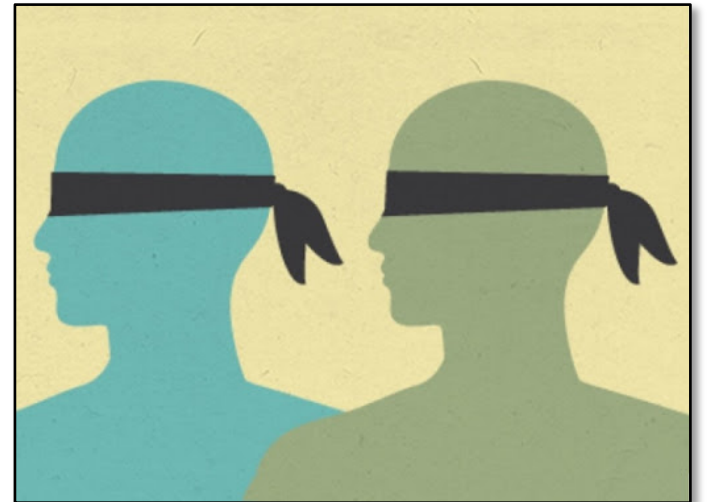


Agenda

- Study background
 - Why was the R Shiny App needed?
- Approach taken to building app
- Demo
- Benefits
 - How much time/resource did we actually save?
 - Stakeholder understanding
 - Reputation of SPA & IDDs

Study background

- Phase 3 pivotal trial with 2 parts
 - Part 2 was double blind & results were key to EU filing
- Met primary endpoint, but only 2 out of 3 secondary endpoints
- Data not only useful for regulatory purposes but also for conferences and papers



Why was the R Shiny App needed?

- Endpoints used different to what was considered 'normal' for the disease area
 - Anticipated many questions around these
 - Visuals of the outputs for individual subgroups were needed
 - Having access to the data and being able to subset visuals without the need for SPA input was going to be hugely beneficial
- Back to back reporting events for study programming team
 - Finalizing 3 month safety update for FDA Filing
 - Answering Health Authority questions
 - Additional study readouts across the project
 - Preparation of datasets for eSub purposes

Approach taken to build app

- Kick-off meeting & ongoing talks with stakeholders (Biostatistics, Clinical Science, Patient Centred Outcomes Research (PCOR)) about requirements
 - When showcasing the app on an ongoing basis, you understand what stakeholders are most interested in looking at and can tailor the app accordingly
- Based on an app created for another project
 - Would HIGHLY encourage code sharing between projects as this saves time & duplication of efforts
 - Adapted code and endpoints and created additional tabs to suit the needs of the study



APP DEMO

Benefits:

How much time/resource did we actually save?

- App used in Data Interpretation Meeting
 - Able to answer questions and produce outputs within the meeting to help guide conversations
 - By showing visuals there and then, it prevented unnecessary ad-hoc requests for the study programming team
 - Estimated about **40 static outputs** were prevented from being created erroneously from just 1 meeting
- Visuals used for investigator meetings
 - Around **160 visuals** were taken from the app for a slide deck (and no, that's not an exaggeration), with no need for additional programming

Benefits:

Stakeholder Understanding

- All key stakeholders were given access to the app
 - A session was set up to go through the features of the app as well as the key variables and parameters that would be needed to recreate the analysis shown in the static outputs
 - Spreadsheets and other guidance were also provided
- Stakeholders could guide their own analysis and look into the data themselves, improving their understanding of what was in the data and the analysis that was conducted

Benefits:

Reputation of SPA & IDD's

- Stakeholders LOVED using the app
- Less cautious about using IDD's
- SPA no longer seen as capable of producing only static outputs
 - Able to input more into the analysis and conclusions

Overall

Has the app increased the efficiency of the team?

Would I recommend that others take a similar approach?

Would I create a similar app for each study I work on in the future?

What disadvantages did I see with using this app?



Please feel free to leave questions in the Q&A box!

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