

An abstract digital visualization featuring a glowing blue and white network of lines and dots on a tablet, with more lines extending upwards into the air. In the background, four people are seated around a table in a dimly lit room, looking at the tablet.

Interactive R Shiny© Applications: Transforming Pivotal Clinical Trial Readouts

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Project Status:



The Critical Context: The Phase II Go/No-Go



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Program-Defining Decision: Go/No-Go determined by this pivotal Phase II data.

Timeline Pressure: A tight window between Data Lock and the Senior Leadership review.

Static Limitations: TFLs are necessary for regulatory documents but too rigid for urgent exploratory analysis.

Primary Objective: Expedite cross-functional collaboration and build data-driven confidence immediately.

The Crisis Point: Not Meeting the Primary Endpoint



The Crisis Point: Not Meeting the Primary Endpoint

Result Confirmed: Primary endpoint criteria were not met.

The Pivot: We immediately shifted focus to deep-dive secondary and subgroup analysis.

The Ask: Stakeholders required instant answers to complex 'what-if' scenarios from the data.

The Justification: The program's future hinged on our ability to quickly demonstrate the existing clinical benefit.

The Solution Architecture: TEAL/R Shiny©



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Platform: R Shiny© app built using TEAL framework.

Foundation: Utilized the TEAL efficacy template.

Efficiency Gain: Instantly accessible, validated Time-to-Event and MMRM methods.

The Shift: Programmers went with a dual output delivery approach. Topline static outputs plus dedicating resources to dynamic, program-critical visualizations.



Feature Spotlight 1: Dynamic Kaplan-Meier Plots



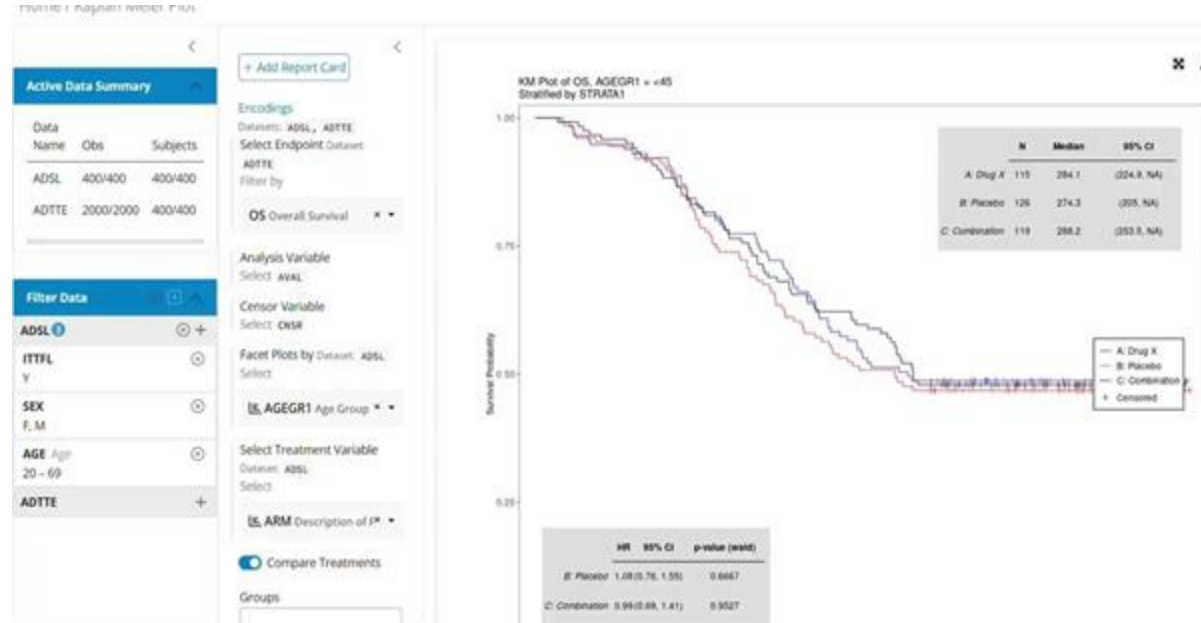
Feature Spotlight 1: Dynamic Kaplan-Meier Plots

Primary Function: The critical engine for time-to-event analysis.

Dynamic Control: Instant filtering (faceting) across endpoints and baseline risk factors.

Robustness Check: Single-click switching between stratified and unstratified models.

Real-Time Metrics: HRs and p-values computed and displayed in real time.



Feature Spotlight 2: The Subgroup Forest Plot



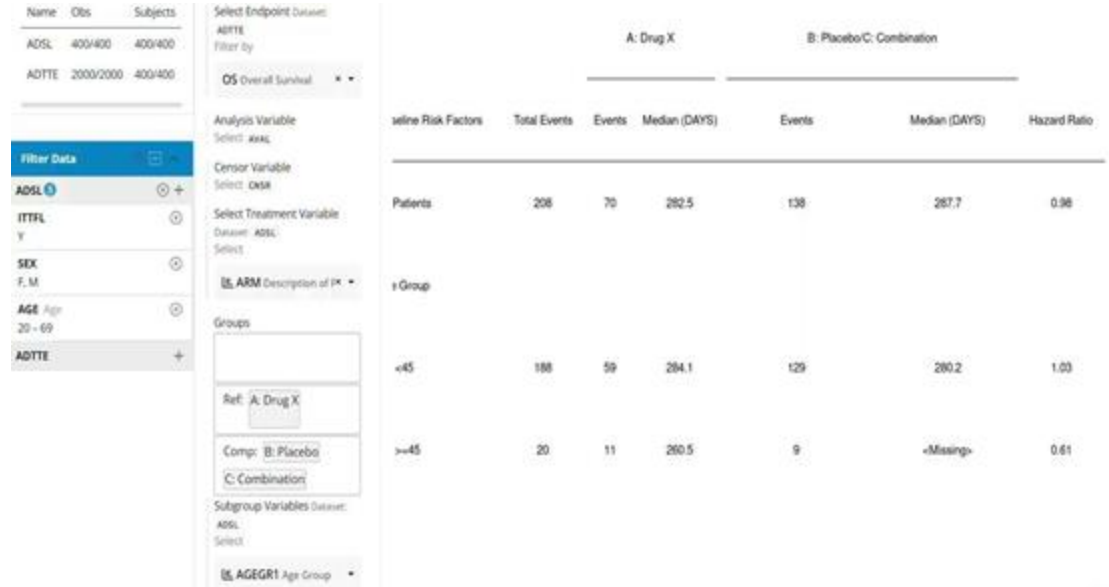
Feature Spotlight 2: The Subgroup Forest Plot

Primary Function: The critical engine and overview for time-to-event analysis.

Dynamic Control: Instant filtering (faceting) across baseline risk factors and demographic subgroups.

Robustness Check: Single-click switching between risk factors and subgroups.

Real-Time Metrics: Overview of treatment effects with HRs and Median Time-To-Event in real time.



The Results Story: Collaboration and Confidence



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Collaboration: collaborative feedback from Biostatistics and Clinical Science.

Confidence: Programmers kept control of app to ensure correct data handling and responsible interpretation.

Convenience: Quick export of outputs for further use, eg slides for senior leadership.

The Conclusion: Program Went on to Phase III



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Acceleration: successful real-time evidence generation in an intense read-out week.

Data Integrity: Verified views and responsible data handling.

Confidence: Endpoint not met but evidence-based recommendation to senior leadership.

Future Directions



Future Directions

Leverage Technology: Use state of the art technology to facilitate decision making

Time Aspect and Confidence: Dynamic and real time evidence generation with confidence.

Stakeholder Guidance: Provide verified views and results to guide well-founded decision making

Thank You & Contact/Q&A



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Doing now what patients need next

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