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Using R Shiny for the Exploration, Interpretation and Presentation of Simulated Futility Analyses within a Clinical Trial for Both Acute and Chronic Treatment Effects

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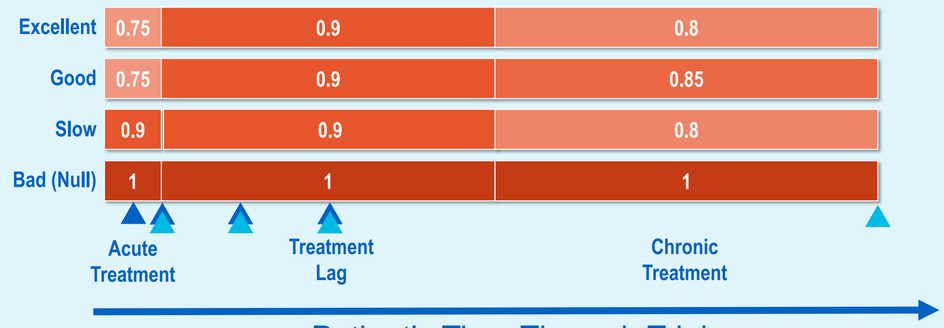
Intro - Justification

- New **TTE** trial to show both **Chronic** and **Acute** Treatment of Drug
- Multiple scenarios of treatment effect with multiple futility analyses
- Futility and Final Analyses at various times marked by ▲ & ▲ respectively
- Decided on interactive Futility App to present our findings

Scenarios for HR in Patients over Time



Simulations – Getting the Data

Patient Data

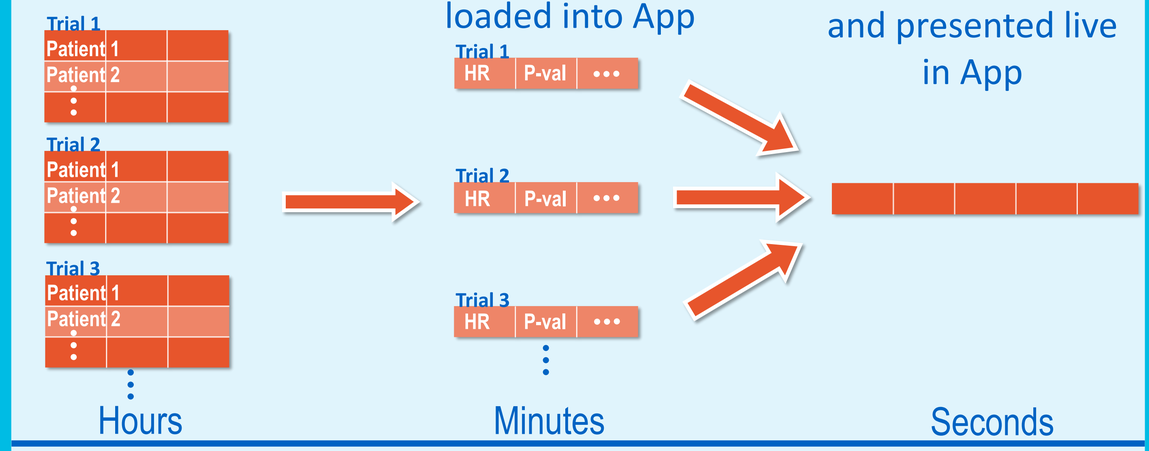
Simulations of Patient Data for each scenario

Trial Summary

Summaries at chosen time point calculated and loaded into App

Scenario Summary

Futility Scenario Summaries can then be calculated and presented live in App



Outcomes – Presenting the Data

- Each simulated trial can have one of the **4** outcomes below
- Proportions of these 4 outcomes, from simulation, are displayed in **Stacked Bar Charts** for each scenario

Correctly Continued Trial	Incorrectly Abandoned Trial Early	Incorrectly Continued Trial	Correctly Abandoned Trial Early
Everything is Good	Futility Actively Detrimental	Futility Harmless & Useless	Outcome Sad but Not Bad

Shiny App - The Star of the Show

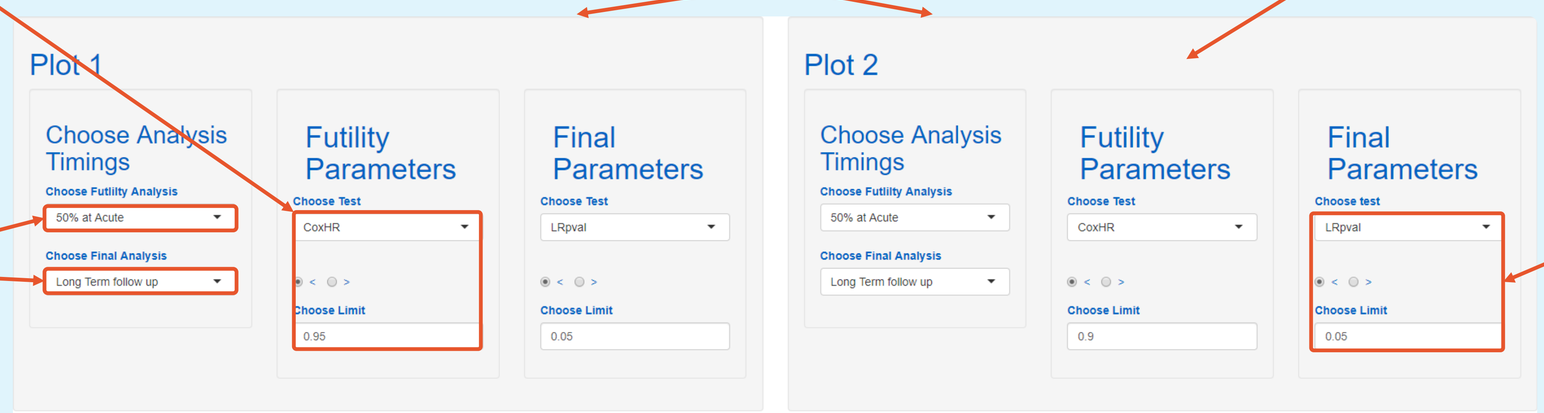
Boundary for **Continuing** at Futility Analysis

2 plots for direct comparison

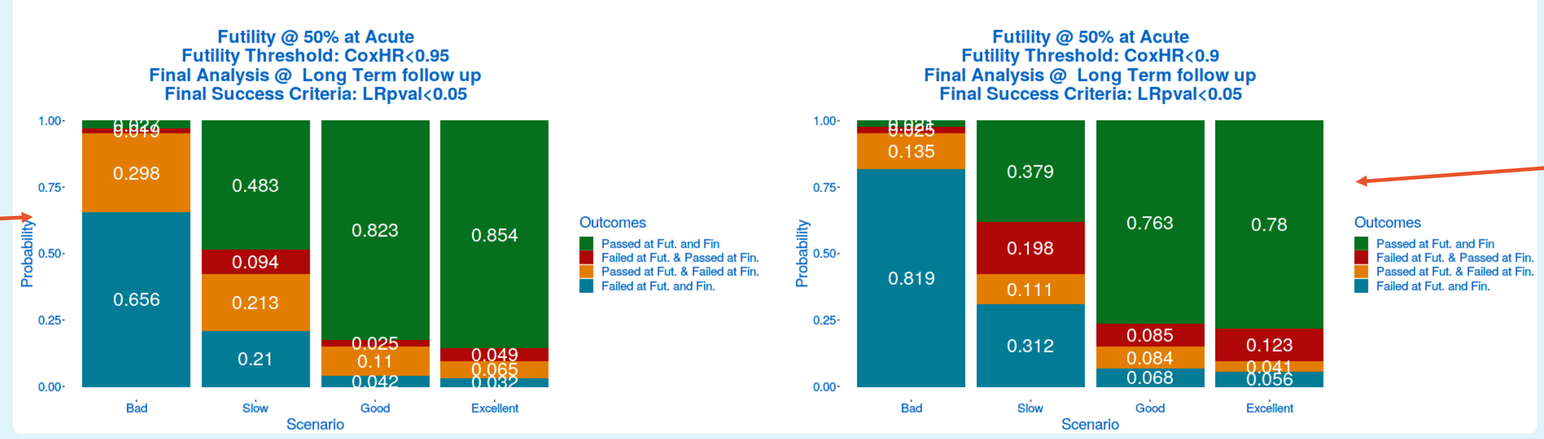
This comparison is of strictness of Futility Boundary between the 2 plots

Time of the Primary and Futility **Analyses**

Boundary for **Success** at Primary Analysis (default p-val<0.05)



Graph represents **Split** of **Outcomes** in simulations

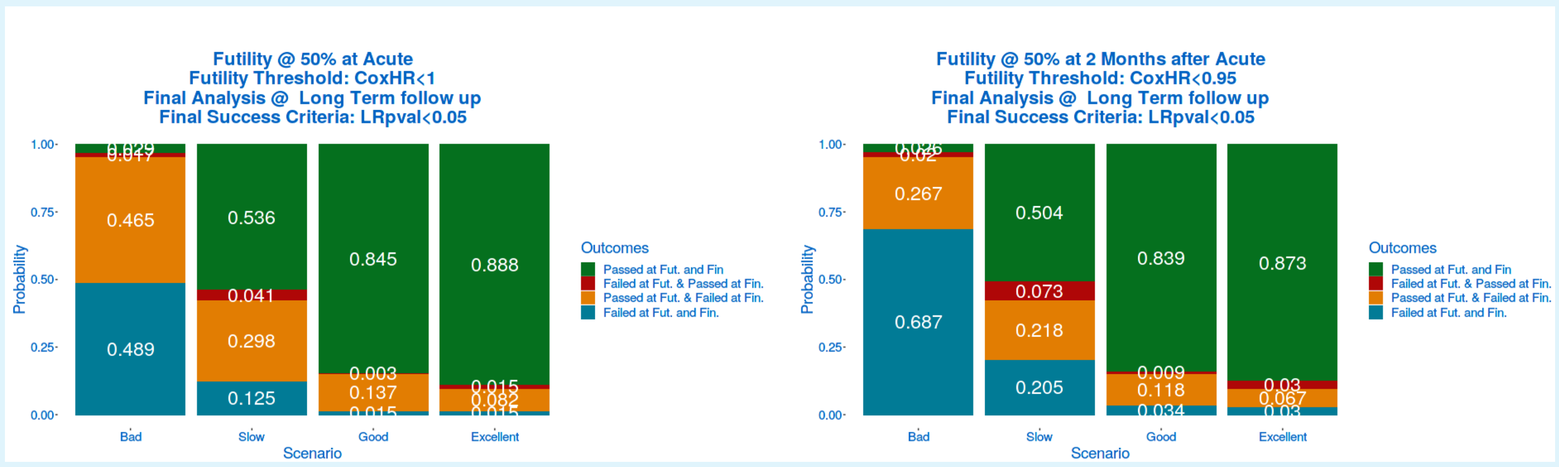


- Shows cost of **Harsher** Fut. Boundary
- Green bar decreases as red increases

More Scenarios – What they tell us

Softer Futility Boundary

- Benefit of less **False Abandonment**
- Cost of much more **Unnecessary Continuation** (Especially in Bad and Slow case)
- Means Futility doesn't do it's job



Later Futility Analysis

- Futility more **Accurate**
- More correct continuation & abandonment
- Doing Futility later means **Higher Cost** and could defeat the point of a Futility