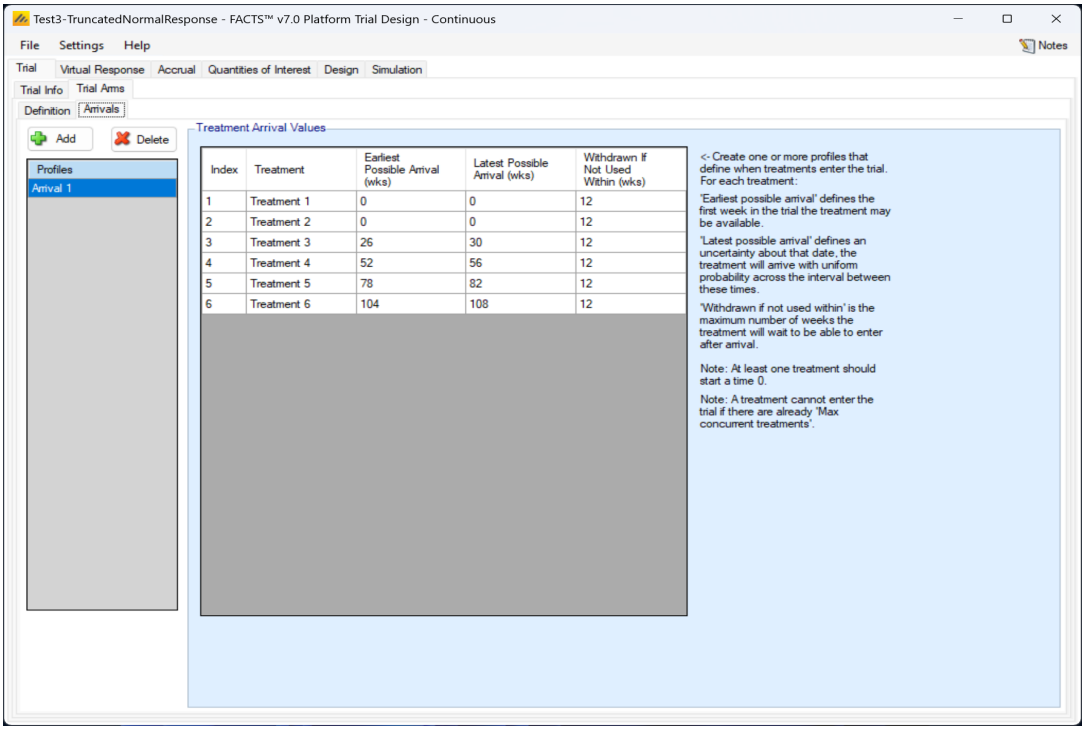
What's New in FACTS 7.0

To: FACTS Licensees
From: Berry Consultants
April 2023

Introducing FACTS 7.0

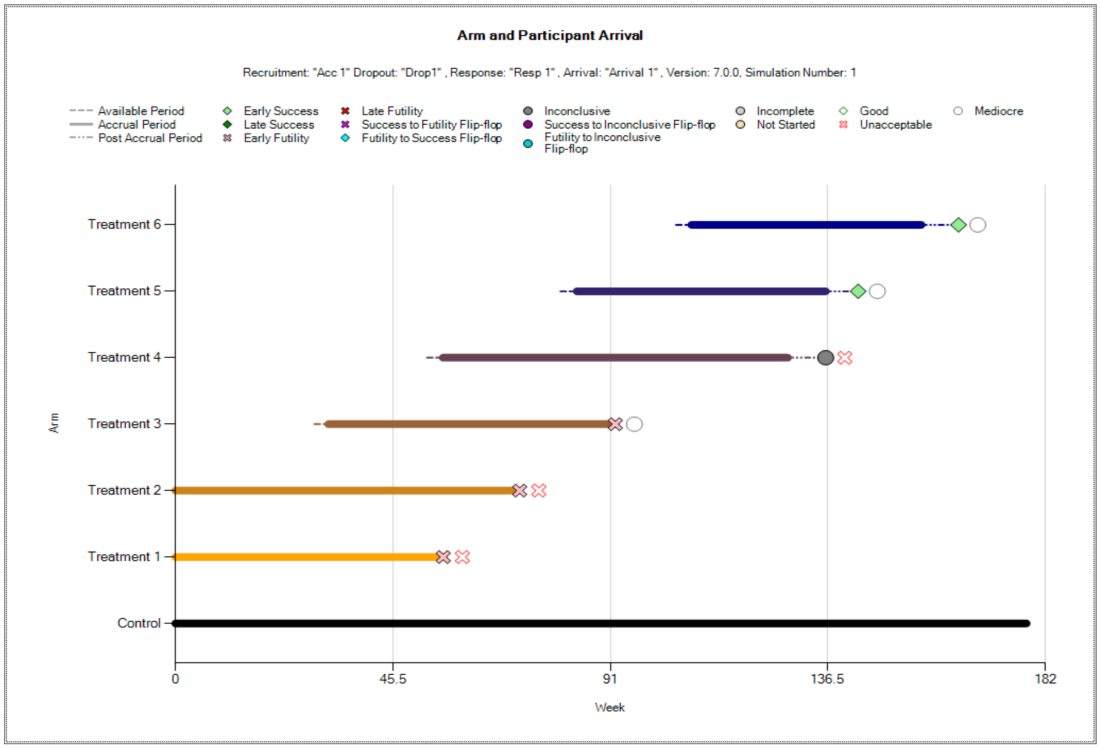
Berry Consultants is delighted to announce that FACTS 7.0 has been released! FACTS users can now:

- Simulate a platform trial, for a continuous/dichotomous endpoint, with various trial level participant and arm constraints. In particular, users can specify a maximum enrollment time, number of participants, successful treatments, participants per arm and concurrent treatments.
- Simulate a platform trial with treatments arriving at different times during the trial.

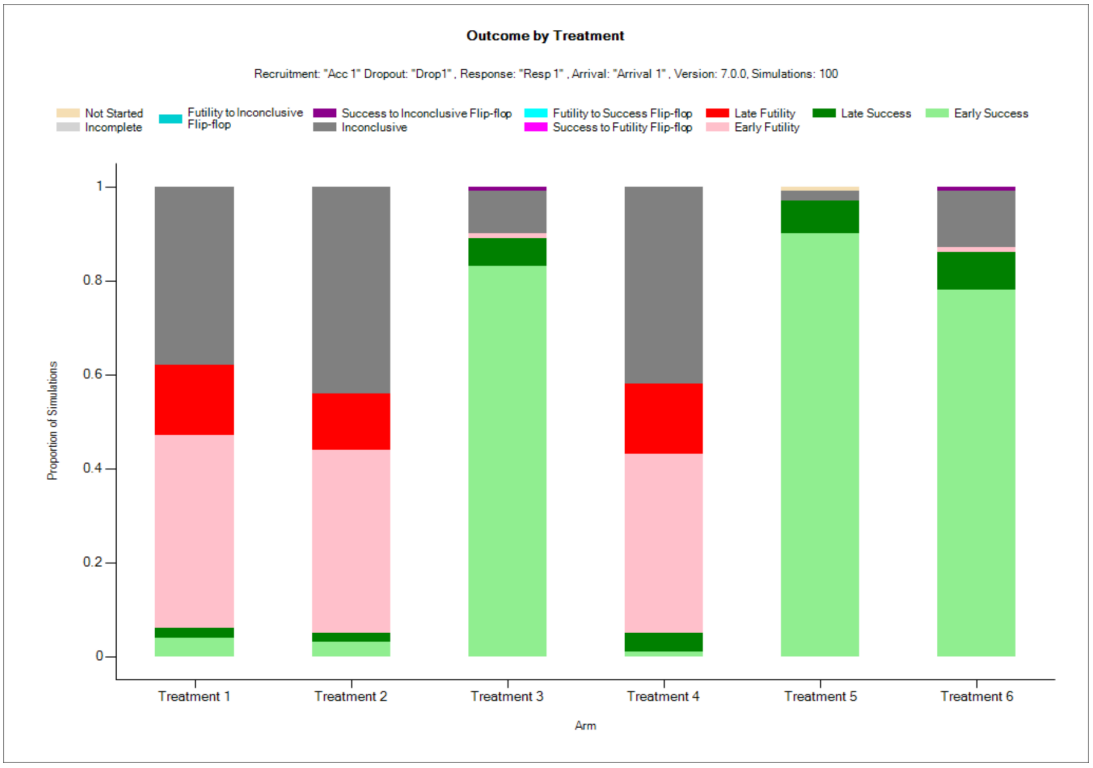


- Specify simulated arm responses/effects to be a fixed value or sampled from a distribution.
- Simulate participant accrual, responses, and dropout rates as per FACTS Core.

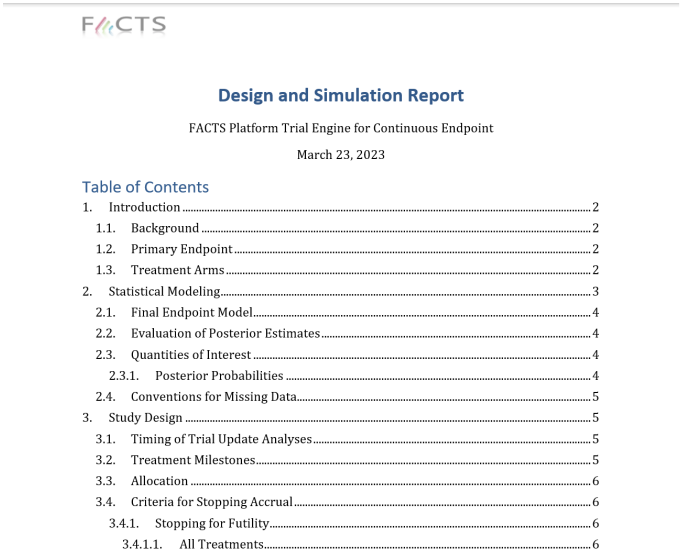
- Specify a constant proportion of participants allocated to the control arm, or an allocation dependent on the number of treatments currently in the trial.
- Specify fixed allocation between the treatments or response adaptive randomization.
- Analyze participant data and estimate mean treatment responses using a Bayesian independent arm model, or frequentist p-values, comparing treatment arms to a common control arm.
- Specify "Trial Update" information and frequency, at which analyses are performed and allocation ratios may get updated.
- Specify when to evaluate "Treatment Milestones", at which decisions can be made about treatment outcomes.
- Specify final success/futility criteria that apply to all treatments, or to a specific treatment. Optionally specify early success/futility criteria, also that apply either to all treatments or to a specific treatment.



- View granular simulation and summary results of various Platform Trial operating characteristics.



- Generate a Platform Trial design report outlining the characteristics of the simulated design in a Word document.



FACTS

Design and Simulation Report

FACTS Platform Trial Engine for Continuous Endpoint

March 23, 2023

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And lastly, as always, FACTS 7.0 is backwards compatible with previous versions of FACTS!