

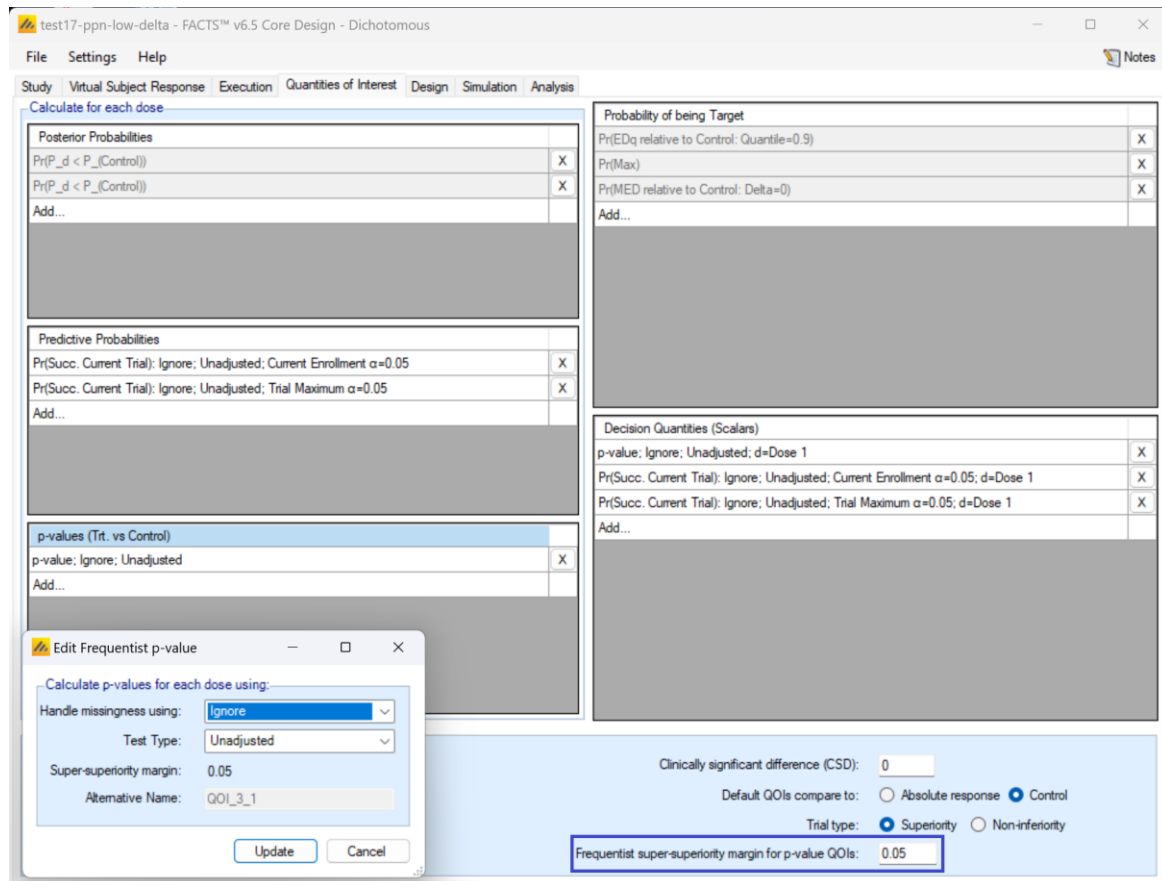
## What's New in FACTS 6.5

*To: FACTS Licensees  
From: Berry Consultants  
Nov 21<sup>st</sup> 2022*

### Introducing FACTS 6.5

Berry Consultants is delighted to announce that FACTS 6.5 has been released! FACTS users can now:

- Specify frequentist margins (“deltas”) in the calculation of p-value and predictive probability QOIs for FACTS Core and Staged designs (except Time-to-Event designs).



This is particularly useful for simulating non-inferiority trials with a frequentist final analysis and Bayesian “Goldilocks” early stopping decisions using predictive probabilities.

- Create designs with study event caps and interims triggered based on predictor events for FACTS Core and Staged Time-to-Event designs with a Time-to-Event predictor.

**Study Information**

Maximum number of subjects:

Maximum number of events refers to:  Final events  Predictor events

Maximum number of events:

Max follow-up per subject (wks):

Follow-up after full enrollment (wks):

Events indicate:  Success  Failure

Recruit subjects:  Continuously  Deterministically

**Interim Analysis Frequency**

Subject Information Defined By:

Subjects Enrolled

Complete Predictor Data

Opportunity to Complete Predictor

Events

Predictor Events

Specify Interims By:

Time - every:  weeks

First interim at:  events (predictor)

Information - at:

Interim	Predictor Events	
1	200	<input checked="" type="checkbox"/>
2	300	<input checked="" type="checkbox"/>
3	400	<input checked="" type="checkbox"/>
4	500	<input checked="" type="checkbox"/>

- Create designs where the final event endpoint analysis can be performed without any imputation based on the predictor endpoint for FACTS Core and Staged Time-to-Event designs with a predictor endpoint.
- Observe significant improvements in the mixing of MCMC chains within the Bayesian Augmented Control and Active Comparator (BAC and BAAC respectively) hierarchical models for FACTS Core and Staged and Enrichment designs.
- Generate design reports for FACTS Core Multiple Endpoint designs, FACTS Enrichment designs (Continuous, Dichotomous and Time-to-Event) and FACTS N-CRM designs.

And lastly, as always, FACTS 6.5 is backwards compatible with previous versions of FACTS!

**Design and Simulation Report**  
FACTS Dose Escalation N-CRM Design  
February 17, 2023

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