

The Release of FACTS 6.1

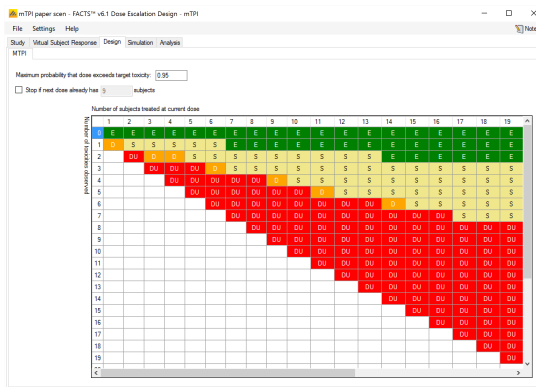
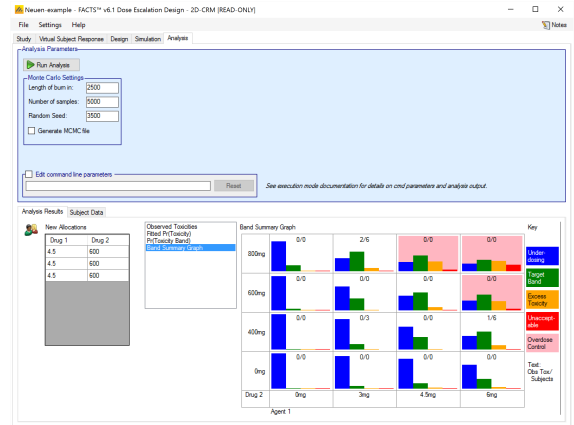
To: *FACTS Licensees*
From: *Berry Consultants*
November 2nd 2017

Introducing FACTS 6.1

Berry Consultants is delighted to announce that FACTS 6.1 is ready for release!

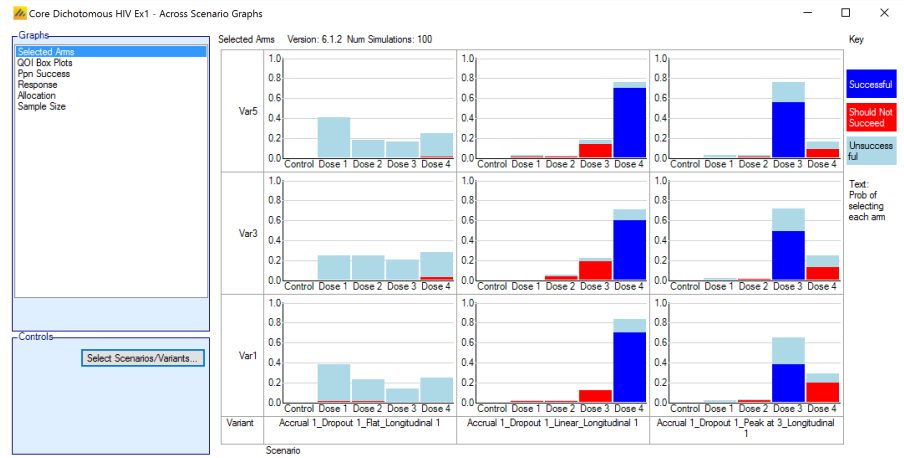
Building on FACTS 6, FACTS 6.1 adds two new Dose Escalation simulation types: “FACTS 2D-CRM” and “FACTS mTPI”:

- FACTS “2D-CRM” is a simulator that runs simulations of dose escalation trials testing combinations of doses from 2 drugs. The implementation follows that of the 2D-CRM prototype that was available earlier this year.



- FACTS mTPI is an implementation of Yuan Ji’s “Modified toxicity probability interval method for dose-finding trials”.

FACTS 6.1 also adds a major piece of simulation functionality across (almost) all FACTS engines: ‘Design Variants’, these allow you to have within one “.facts” file, multiple designs with different maximum sample sizes. This makes it much easier to estimate the required sample size for a design. The feature includes the ability to mark specific treatment arms or groups as ‘correct choices’, and FACTS now summarizes not only the proportions of successful and unsuccessful trials, but also proportions of successful trials that also made correct choices.



FACTS 6.1 is fully backwards compatible with FACTS 6 and 5 – it can load and run all your FACTS 6 and FACTS 5 designs – and then use new FACTS 6.1 features with those designs.

You can have FACTS 6.1 and FACTS 6 installed on the same machine, so it’s easy to have a transition period as you move to the new version.

Key New Features

FACTS Dose Escalation:

- Design Variants in N-CRM.
- 2D-CRM
- mTPI

FACTS Enrichment Designs:

- Design Variants
- The ability to extend hierarchical modeling with clustered model.

FACTS Core:

- Design Variants
- Better control over which frequentist calculations are performed.
- The ability to use p-value QOIs for early success/futility decision making.

FACTS Staged Design:

- Design Variants
- There is now an ‘Analysis’ tab in Staged Design.