ADDPLAN Neo 10.2.0 Release Notes

ADDPLAN Neo 10.2.0 is now available for download via App Center. In additional to several general improvements, this release marks the addition of a new feature in the Base/MC > Means > Simulation module, whereby the group sequential (GS) stopping boundaries and individual simulation paths of the Z-statistic and p-value across interims can now be visualized.

1   ADDPLAN Neo Features

As of ADDPLAN Neo 10.2.0, Base/MC > Means > Simulation module, when considering a design with a single treatment arm compared to a control arm, users can now easily visualize the GS success and futility boundaries along with 100 individual simulation paths of the Z-statistic and p-value across interims. Separate plots are shown for each simulated treatment effect.

The plot provides an intuitive view of how each simulation of the trial design behaves by showing how early/late the trial will stop for success/futility under different simulated treatment effects. In particular, under the null hypothesis (no treatment effect), the plot helps visualize type-I error instances.
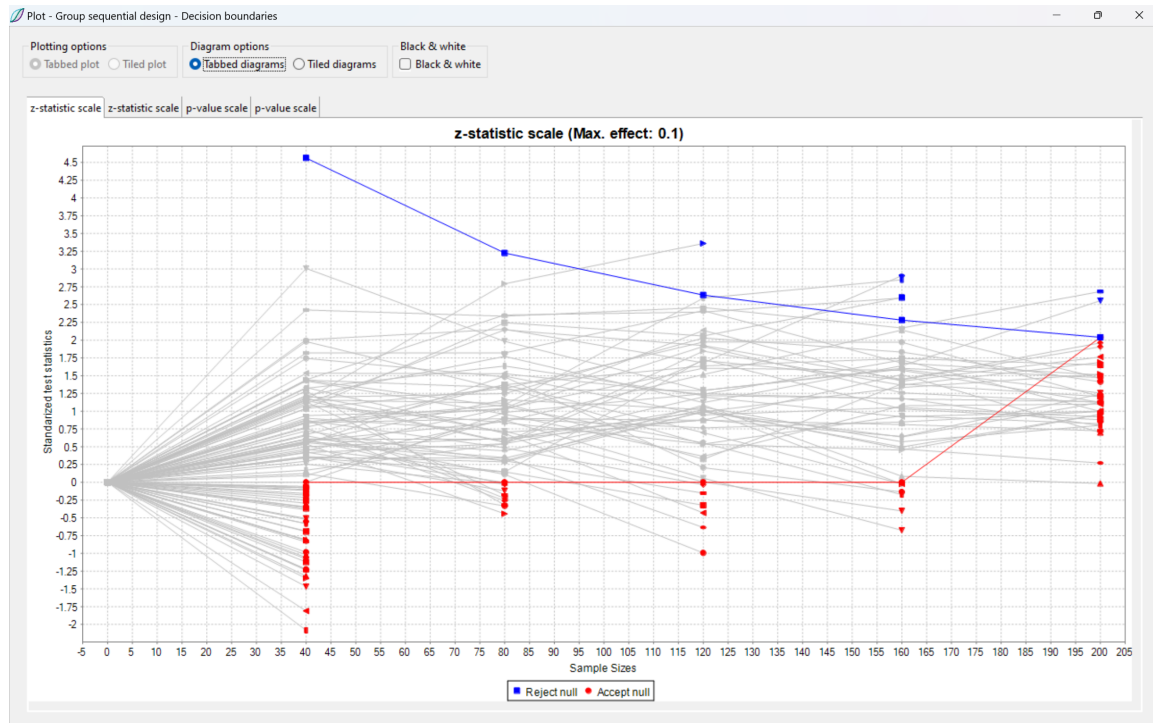
2 General Improvements

- ADDPLAN Neo will now correctly report simulation results when a single treatment effect "drift" has been specified, by displaying a single row of results pertaining to the maximum specified treatment effect.
- The "Stage 1 sample size allocation nT/nC" option on the "Sample size options" tab will now correctly be applied at the first stage.
- The Linear Interpolation ("Linear int") model used for treatment effect simulation as well as for model based contrasts in Contrast tests will now work correctly.
- The decision boundaries for the GS effect size scale plot in the Base/MC > Design module will now be calculated correctly by taking into account the calculated maximum sample size.
- Opening existing Base/MC > Design module designs and clicking on "Plot critical boundaries" will no longer cause ADDPLAN Neo to close unexpectedly.
- In all ADDPLAN Neo modules using dose response models, the underlying computation results will now always be associated with the correct underlying model.
- Existing designs created with the Base/MC > Means > Simulation module that have been opened with ADDPLAN Neo will display the selected "Selection Rules" correctly.
- The Dunnett intersection test when multiple treatment arms are present in the design will now correctly control type I-error and not over-inflate it. When variance is unknown, ADDPLAN now appropriately uses pooled estimates of variance computed using data from all stages, and uses the corresponding critical values (this however significantly increases the simulation time – use with caution, the advice is to use "known variance" for simulation, only use unknown variance for analysis).
- In ADDPLAN Neo the default Placebo/Control response is now 0 rather than 0.1
- In ADDPLAN Neo in the Base/MC > Means > Simulation module, Sample Size Options, the "Control arm sample size" options selection which previously always defaulted to "According to constant allocation ratio over stages" will now work correctly.
- In ADDPLAN Neo in the Base/MC > Means > Simulation module computation options, when "Known variance" is assumed, the "Simes" intersection test will now work correctly.

Please contact the ADDPLAN team (addplan@berryconsultants.com) regarding any questions.