Software for Planning Adaptive Enrichment Designs

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Open Source (free) Software

interAdapt (Rosenblum et al.): Multistage enrichment designs for two subpopulations; open-source; graphical user-interface.

asd (Parsons et al.): Two-stage enrichment designs for two subpopulations; early and final outcomes.

Commercial Software

ADDPLAN PE (ICON PLC): Multistage designs for multiple subpopulations; uses combination-tests; graphical user-interface.; must prespecify stage where enrichment can occur.

FACTS (Berry Consultants): Multistage designs for multiple subpopulations. Graphical user-interface; Bayesian hierarchical model for subpopulation treatment effects.

interAdapt

- For planning confirmatory trials (Phase II/III);
- Consider: marker positive subpopulation and overall population
- Compares standard randomized trial design to new adaptive enrichment designs with group sequential testing.
- Displays power curves, expected sample sizes, expected duration.
- Guarantee strong control of familywise Type I error rate for all designs
- Given to FDA partners who tested it and gave feedback we incorporated.

asd (Adaptive Seamless Design)

For planning confirmatory trials (Phase II/III)

Two-stage enrichment designs for two subpopulations; allows early and final outcomes (e.g., survival times).

Multiple choices for testing procedure, based on combination testing and closure principle (but doesn't generally use sufficient statistics).

Allows time-to-event endpoints

Only two-stages

ADDPLAN PE

For planning confirmatory trials (Phase II/III)

Can handle more than 2 subpopulations;

Graphical User-Interface;

Multiple choices for testing procedure, based on combination testing and closure principle (but doesn't generally use sufficient statistics).

Must a priori designate a particular stage at which change to enrollment can be made.

FACTS (Berry Consultants)

For planning Phase II trials

Can handle more than 2 subpopulations;

Graphical User-Interface;

Bayesian hierarchical model for subpopulation treatment effects.

Does not guarantee strong control of familywise Type I error rate (FWER), but gives simulated FWER at different distributions.