East®

Empower Assess Share Trust

Powered By architect™

Key Features & Benefits

- Validated and tested software, currently used at the FDA
- More clinical trial designs than any other package
- Wide choice of traditional and group sequential designs
- Flexible options for survival designs
- Adaptive sample size re-estimation using the Promising Zone Design
- Powerful customizable simulation engines for sensitivity analysis and prediction
- Convenient trial monitoring dashboard to analyze interim data and facilitate decision-making
- Customizable charts and tables to enhance communication with stakeholders
- Excellent user manual, help tools, and technical support

What's New?

- Quickly create multiple designs at once
- Add accrual, response lag, and dropout for normal and binomial endpoints
- Disable efficacy or futility boundaries at selected interim looks
- Preview, sort, and filter a large set of designs before saving
- Import and analyze datasets; run user-created R or SAS programs
- Compute Bayesian probability of success and predictive power
- Design and simulate survival studies accounting for stratification
- Modify East simulations by integrating custom R code
- Designs for count data: Poisson and Negative Binomial rates
- Confidence-interval based sample size calculations
- Serial gatekeeping procedures for multiple endpoints

Fixed Sample Size & Group Sequential Designs

for Superiority, Non Inferiority, Equivalence, and Confidence Intervals

Continuous

One Mean
- Single Mean
- Difference of Paired Means
- Ratio of Paired Means

Two Means
- Difference of Independent Means
- Ratio of Independent Means
- Wilcoxon-Mann-Whitney for Independent Means
- Difference of Means for Crossover Data
- Ratio of Means for Crossover Data
- Multiple Endpoints Using Serial Gatekeeping

Many Means
- One Way ANOVA
- One Way Repeated Measures ANOVA
- Two Way ANOVA
- Multiple Pairwise Comparisons

Regression
- Linear Regression for Single Slope
- Linear Regression to Compare Two Slopes
- Repeated Measures Regression to Compare Two Slopes

Survival

Logrank Test
- Given Accrual Duration and Rates
- Given Accrual and Study Duration

General Design
- Sample Size-Based
- Information-Based

Discrete

One Proportion
- Single Proportion
- McNemar's Test for Matched Pairs

Two Proportions
- Difference of Independent Proportions
- Ratio of Proportions
- Odds Ratio of Proportions
- Cochran-Mantel-Haenszel Test
- Fisher's Exact Test

Many Proportions
- Trend in R Ordered Proportions
- Rx2 Chi-Square Test for Independence
- 1xC Chi-Square Test for Goodness of Fit
- 2xC Chi-Square Test for Independence
- RxC Chi-Square Test for Independence
- Wilcoxon-Mann-Whitney Test for Categorical Data
- Multiple Pairwise Comparisons

Regression
- Logistic Regression for Single Slope

Agreement
- Cohen's Kappa Test for Two and Many Proportions

Count

One Rate
- Single Poisson Rate

Two Rates
- Ratio of Poisson Rates
- Ratio of Negative Binomial Rates

Further Features & Options

Charts & Tables
- Stopping Boundaries
  - *Scales: Z, Score, P-value, Delta, Delta/Sigma*
- Error Spending
- Average Sample Number
- Power vs. Sample Size
- Power vs. Treatment Effect
- Accruals/Completers vs. Time
- Study Duration vs. Accrual

Multiple Comparison Procedures
- Dunnett's Single Step & Step Down
- Bonferroni & Weighted Bonferroni
- Sidak
- Holm's Step Down
- Hochberg's Step Up
- Fixed Sequence
- Fallback

Survival Design Options
- Piecewise Hazards, Dropout, & Accrual
- Simulate Non-Proportional Hazards
- Fixed or Variable Follow-up
- Committed Accrual Duration or Subjects
- Stratified Sampling and Stratified Logrank Test

Boundaries
- Error Spending Functions
  - *Lan-Demets [Pocock, O'Brien-Fleming], Gamma, Rho, Interpolated*
- Generalized Haybittle-Peto
- Wang-Tsiatis
- Non-Binding Futility
  - *Pampallona-Tsiatis, P-value, Conditional Power, Delta/Sigma*
- Flexible Boundaries
  - *Efficacy and/or Futility at Selected Looks, Unequal Spacing of Looks*

Interim Monitoring Dashboard
- Track Error Spent, Update Boundaries
- Conditional and Predictive Power
- Bias-corrected Inference
  - *Adjusted P-values, Point Estimates, Confidence Intervals*

Adaptive Design Options
- Promising Zone Design
- Type-1 Error Control Methods
  - *Cui, Hung, and Wang (1999); Chen, DeMets, and Lan (2004)*
- Simulations and Interim Monitoring
- Conditional Power Calculator

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Cytel

Request an Evaluation Today

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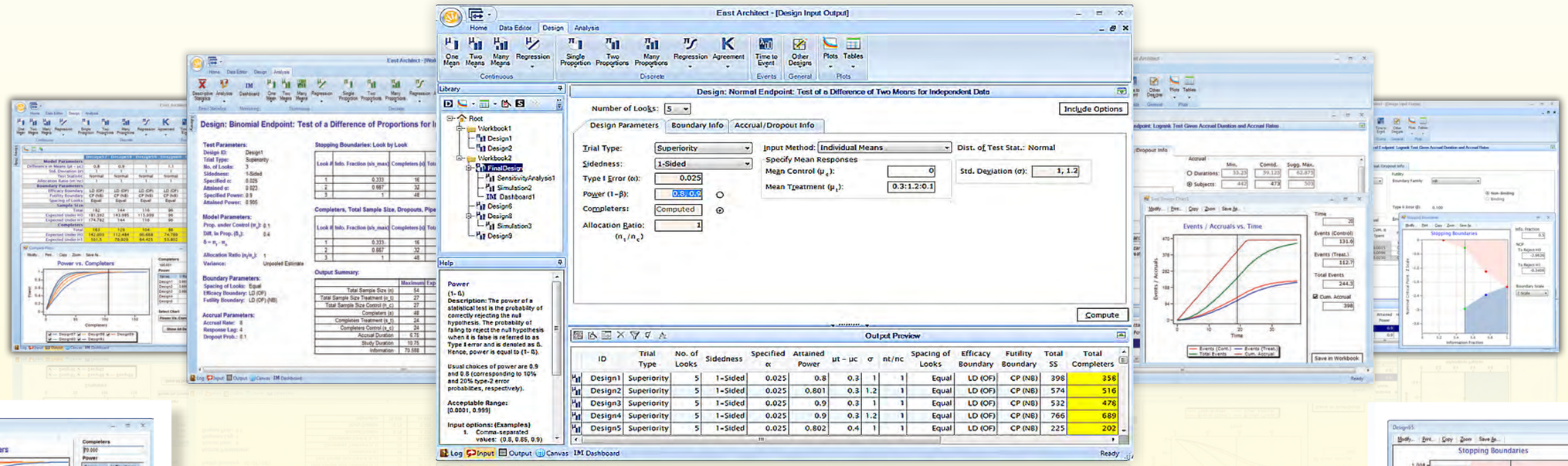
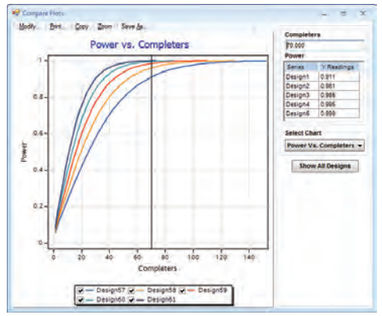
Streamline the Design, Simulation, and Monitoring of Fixed and Adaptive Clinical Trials





- Simultaneously compare and contrast power curves for several designs
- View plot data to create tabular displays of the trial's expected operating characteristics
- Customize your charts for effective communication with study planning team colleagues

Succeed with East®

Successful studies begin with the right design. East is the industry standard for designing adequate and well-controlled clinical trials as per FDA and EMA guidance. Since its introduction in 1994, East has reliably and continuously enabled drug and medical device trial sponsors of all sizes to optimize their trial planning and monitoring efforts.

About Cytel Architect™

A modern and fully validated platform, specifically built to support clinical study planning and analysis, Cytel Architect opens new possibilities for innovation in design software by providing:

- Intuitive user experience makes complex methods easily accessible
- Powerful simulation capabilities and data exploration tools
- R and SAS integration for users to extend core capabilities
- Customizable reporting tools to create documents with all the salient design operating characteristics
- A common integrated environment for all of Cytel's design packages: *SiZ®*, *Compass™*, and *East®*

Empower

Play a more strategic role in your organization. East simplifies and automates study design and simulation, freeing more of your time to contribute in greater ways to the success of your trial or program.

Assess

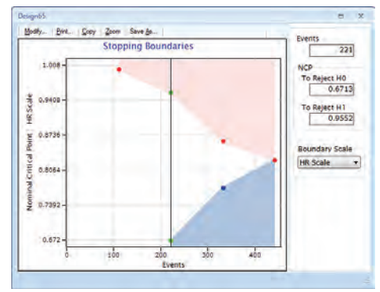
Rapidly generate multiple fixed, group sequential, and adaptive designs. Quickly evaluate your design's robustness to critical assumptions by performing sensitivity analysis. Use tables and graphs to compare the operating characteristics of different approaches.

Share

Communicate the merits of various trial design options to the project team with the help of readily understood graphs, tables, and flexible reporting capabilities. Share design properties in real time with East Architect's powerful simulation capabilities.

Trust

Depend on East, knowing it has been fully validated and intensely tested. East-generated designs have been relied upon for close to 20 years in countless actual studies at all the major pharmaceutical, biotech companies, and the FDA.



- Selectively apply efficacy and/or futility boundaries at each look
- Input futility boundaries on conditional power or delta/sigma scales
- Display boundaries on multiple scales *(Z, score, delta, conditional power)*
- Wide range of boundary options *(Power, Lan DeMets, Gamma, and Rho Spending functions, Haybittle Peto)*