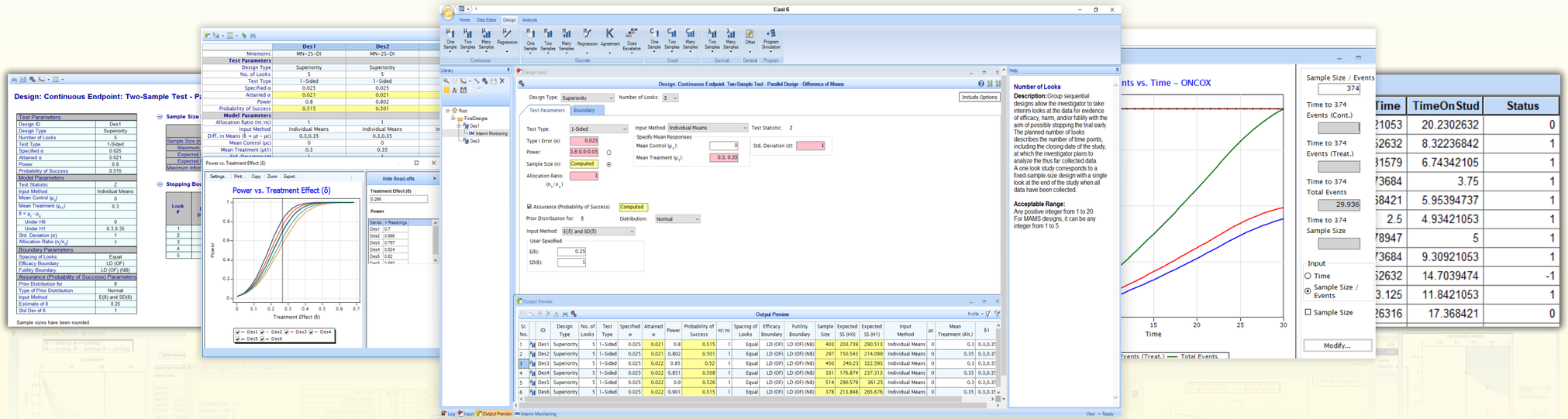
Powered By architect™

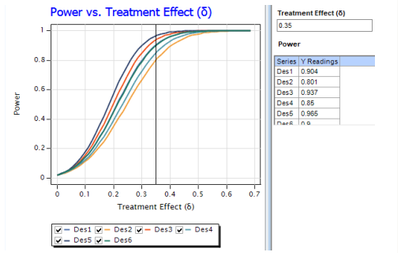
East®

Empower
Assess
Share
Trust

Cytel

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 operating characteristics
- Customize charts for effective communication with team members

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 1994, East has reliably and continu¬ously 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 verified platform, specifically built to support clinical study planning and analysis, Cytel Architect opens new possibilities for in¬novation in design software by providing:

- An intuitive user experience to make complex methods
- 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: *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

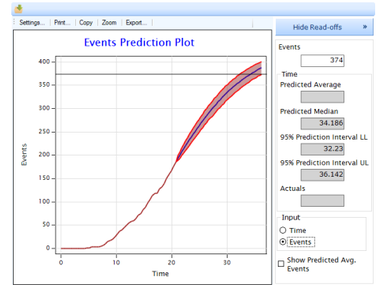
Rapidly generate multiple fixed, group sequential, and adaptive designs. Easily evaluate the robustness of your design to critical assumptions by performing sensitivity analysis. Use the tables and graphs to compare the operating characteristics of different approaches.

Share

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

Trust

Depend on East, knowing it has been fully verified and intensely tested. East-generated designs have been relied upon for 25 years in countless actual studies at all the major pharmaceutical, biotech companies, and the FDA.



- Make data driven predictions
- Predict enrollments and events at the planning as well as interim stage
- *Provide time-sensitive recommendations in an on-going study*

East®

Empower Assess Share Trust

Key Features & Benefits

- Verified and extensively tested software, currently used at the FDA
- More clinical trial designs than any other platform
- Wide choice of traditional and group sequential designs , incorporating the latest statistical methodologies to design innovative adaptive trials
- Flexible options for survival designs
- 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
- Comprehensive user manual & help tools
- Industry-leading and responsive technical support

What's New?

Three new modules:
MCPMOD, ENRICH, PROGRAM

- *Design and analyze dose-finding studies using MCPMod methodology*
- *Simulate clinical trials with flexible adaptation options for population enrichment and strong control of type-1 error*
- *Simulate a sequence of oncology trials with flexible Go/ No-Go rules*

Disable efficacy or futility boundaries at selected interim looks

Compute Bayesian probability of success and predictive power

Design and simulate survival studies accounting for stratification

Test multiple hypotheses using graphical methods

Major Enhancements to Existing Modules:

BASE
design trials with Super Superiority margin

SEQUENTIAL
design group sequential trials for equivalence studies

SURVIVAL
Generate Go/No-Go based survival simulations with survival and binary intermediary endpoints

ADAPT/SURVADAPT
Conduct SSR(sample-size re-estimation) for Non-Inferiority design and flexible monitoring with Muller and Schafer

MAMS
Generate MAMS (multi-arm multi-stage) designs with Discrete endpoint and p-value combination approach, Survival endpoints as well as continuous endpoints

PREDICT
predict events using Weibull distribution

ESCALATE
alternative method mTPI-2

ENDPOINTS
simulate trials with mixed endpoints

Fixed Sample Size & Group Sequential Designs
for Superiority, Non Inferiority and Equivalence

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
Sample Size/Events 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

Display boundaries on multiple scales
(Z, score, delta, conditional power)
Selectively apply efficacy and/or futility boundaries at each look

Families
Error Spending Functions
(Lan-Demets[Pocock, O'Brien-Fleming], Gamma, Rho, Interpolated)
Generalized Haybittle-Peto
Wang-Tsiatis
Pampallona-Tsiatis
p-value
Conditional Power
Delta/Sigma

Options
Unequal Spacing of Looks
Boundaries at Selected Looks
Non-Binding Futility Boundaries

Interim Monitoring Dashboard

Error Spending Function
Conditional Power
Adjusted p-value
Adjusted Point Estimate
Post-Hoc Power
Repeated Confidence Intervals

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Request an Evaluation Today
sales@cytel.com

www.cytel.com

East 6.5

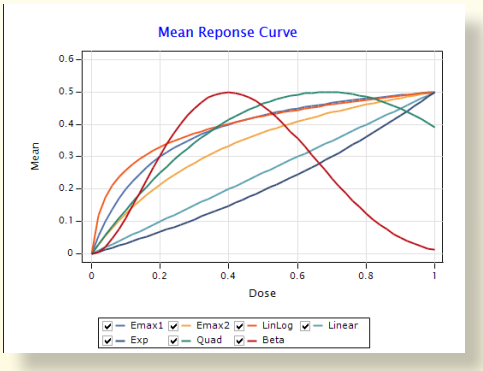
Cytel

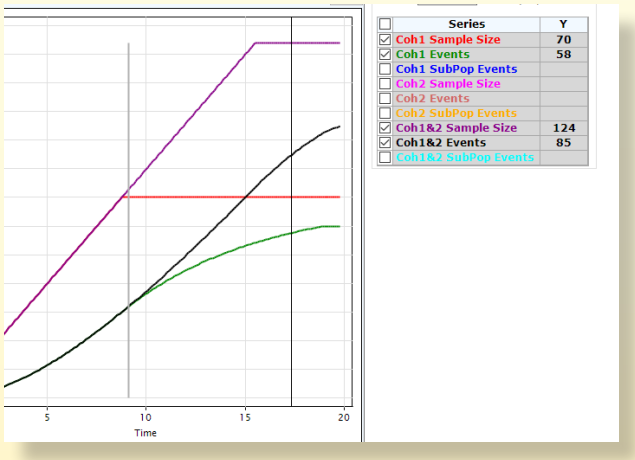
East® version 6.5 continues Cytel's 20+ years tradition of reliable innovation in the design, monitoring and simulation of clinical trials.

Game-changing new features in Multiple Comparison Procedure - Modelling, Population Enrichment, and Program Design, address emerging and persistent challenges in modern drug development.

East MCPMOD

The European Medicines Agency (EMA) has qualified the Multiple Comparison Procedure – Modelling (MCP-Mod) approach as an efficient statistical methodology for design and analysis of phase II dose finding studies under model uncertainty. East MCPMOD allows for the design and analysis of such studies for normal, binomial and count endpoints, with a variety of candidate models, dose selection criteria, and optimal allocations.



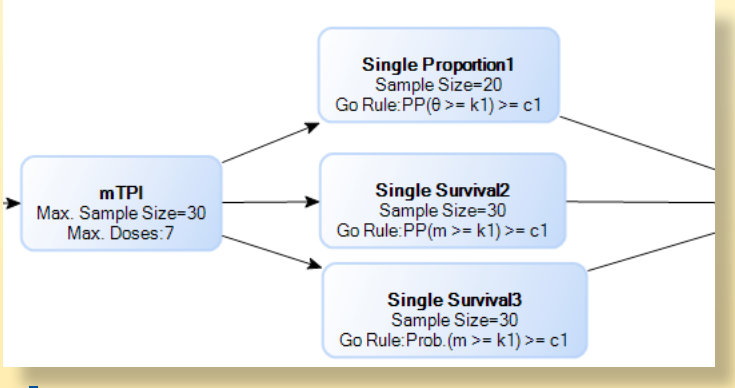


East ENRICH

East ENRICH supports the simulation of clinical trial designs with adaptation options for population enrichment, while strongly controlling type-1 error rate. It provides flexibility in defining the promising zone for sample size increase, and enrichment zone for subgroup selection.

East PROGRAM

East PROGRAM simulates a sequence of clinical trials within an oncology program. One can simulate a dose escalation trial (3+3, mTPI, CRM, BLRM, from East ESCALATE) followed by a cohort expansion phase. Alternatively, one can simulate a single-arm Phase 2 trial followed by a two-arm Phase 3 two trial. Both alternatives allow for the incorporation of flexible Go/No-Go rules.



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Other Enhancements:

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Super Superiority

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Binomial multi-stage
Survival p-value combination

SEQUENTIAL
Equivalence Group Sequential

ADAPT/SURVADAPT
SSR for Non-Inferiority designs

PREDICT
Weibull distribution

ESCALATE
mTPI-2

MEP
Mixed endpoint type
gMCP

Contact us for a free trial
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Learn more at
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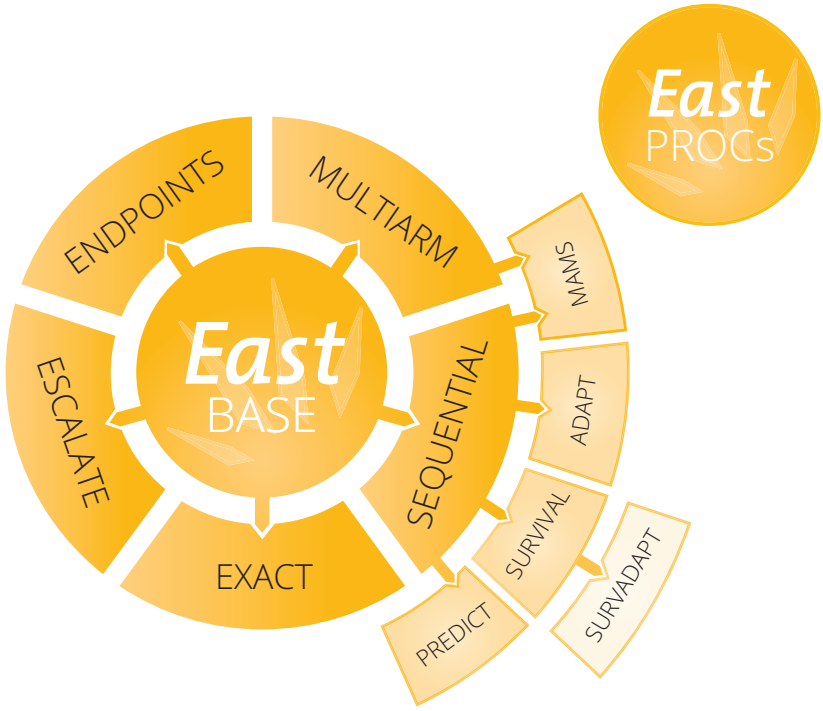
East Modules

East® supports flexible configurations of Fourteen modules, allowing users to choose a variety of packages based on their unique design needs.



New Modules

May Require Additional Modules

MCPMOD | ***ENRICH*** | ***PROGRAM***

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