

### **East Horizon Data Sheet**



Multi-Arm Multi-Stage

# Powerful Trial Design Platform

Analytical and simulation-driven design tools that allow comparison of promising design types.

## **Built to Drive Design Innovation**

Easy access to adaptive designs, group sequential designs, Bayesian methods, and other leading, innovative clinical trial approaches.

#### **Confidence**

Opportunities to refine superior clinical trial designs using industry-trusted software.

#### **East Horizon Base Features**

Size Calculations	(MAMS) Designs
Sample Size Re-Estimation Designs	MCPMod Designs and Analysis
Fixed Designs	Population Enrichment Designs
Exact Designs	Multiple Endpoints Designs
Group Sequential Designs	Crossover Designs
Bayesian Designs	Program Simulations
Dose Escalation	Custom R Code Integration
System Requirements	
Optimally displayed on Google Chrome browser	R versions 4.3.0, and R 4.3.2 are supported for R integration
Internet Connectivity	Mac OS

**Key Capabilities** 

Power and Sample

Feature	Details		
Cloud-based Simulation Resources	Integrated scalable Azure cloud computing to support design simulation and exploration		
Visualization	<ul> <li>Analyze &amp; identify designs of choice by comparing different analytical designs and simulations side by side</li> </ul>	Evaluate individual designs with the help of detailed output tables in addition to plots	
Open-source R Integration	<ul> <li>Gain the flexibility and freedom to create custom designs using R alongside the built-in capabilities in East Horizon</li> <li>Al chatbot for R-code generation</li> </ul>	<ul> <li>Leverage the Cytel R template library to speed code development</li> <li>File management capabilities to make it easier to manage your R code and data files</li> </ul>	

Windows 10

User & Access Management

Administrative control over access to systems and projects



### **East Horizon Design Modules**

Module	Functions	
Fixed Sample	<ul> <li>A wide variety of fixed sample options (continuous, binary, time-to-event)</li> <li>Analysis of multiple scenarios at once</li> <li>Complex patterns of accruals, dropouts, and follow-up time</li> <li>Simon's two stage design</li> </ul>	<ul> <li>Exact single-stage designs for small-sample trials (binary)</li> <li>Phase II single-arm screening trials</li> <li>Bayesian probability of success (continuous, binary, time-to-event)</li> </ul>
Group Sequential	<ul> <li>Continuous, binary, and time-to-event endpoints for two-arm designs</li> <li>Extensive selection of families of stopping rules for efficacy and futility</li> <li>Display boundaries on multiple scales</li> <li>Go-No-Go based on surrogate endpoints</li> </ul>	<ul> <li>Conditional and predictive power calculations for interim decisions</li> <li>Optimize trial design for savings in sample size, study duration, and cost</li> <li>Stratification and subpopulation analysis</li> </ul>
Multiplicity	<ul> <li>Multi-Arm Multi-Stage (MAMS) designs</li> <li>Extension of Group Sequential Designs (GSDs) to more than 2 arms</li> <li>Charts for events, sample size, accrual and study duration prediction</li> <li>Two-stage Treatment Selection design using p-value combination approach by Poschet. al. (Statistics in Medicine, 2005)</li> <li>Strong control of the family-wise error rate</li> <li>Mixed endpoints, gMCP</li> <li>Power: global, disjunctive, conjunctive, marginal</li> </ul>	<ul> <li>Tests include: Dunnett, Bonferroni, Sidak, Holm, Hochberg, Hommel, Fixed Sequence, and Fallback</li> <li>Piecewise hazard rates, accruals, and dropouts</li> <li>Simulate non-proportional hazards</li> <li>Multi-Arm Multi-Stage (MAMS) designs</li> <li>Serial and parallel gatekeeping</li> <li>Variable and fixed subject follow-up</li> <li>Fast design by batch simulation</li> <li>Continuous, binary, and time-to-event endpoints</li> </ul>
Adaptive	<ul> <li>Adaptive rules for increasing sample size in full or sub-populations</li> <li>Specific adaptive tools for survival (e.g. adapt sample size and events)</li> <li>Promising Zone design based on unblinded interim data</li> </ul>	<ul> <li>Adjusted unbiased point estimates, confidence intervals, and p-values</li> <li>Population enrichment for a time-to-event endpoint</li> <li>Adaptive rules for increasing sample size</li> <li>Methods include CHW, CDL, Müller-Schäfer</li> </ul>
Dose Escalation	<ul> <li>Dose recommendations for next cohort of patients</li> <li>Simulate dose-toxicity profiles and designs</li> <li>Additional Bayesian approaches for dose escalation</li> </ul>	<ul> <li>Methods include: 3+3, Continual Reassessment Method, Bayesian Logistic Regression Model, and modified Toxicity Probability Interval</li> <li>Dual-agent dose combination designs (BLRM, PIPE, mTPI-2)</li> </ul>
Dose Finding	MCPMod methodology for design of dose-finding clinical trials	MCPMod methodology analysis of continuous, binary or count data

\*Ask about East Horizon Add-On Products



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