



Adaptive. Causal. Intuitive.

FROM DESIGN TO EXECUTION

How Causal AI Is Transforming Clinical Development

CMO Summit 360°

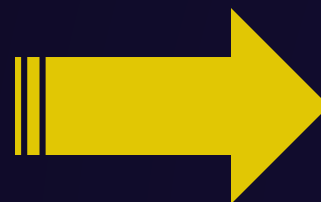
April 25, 2026



Clinical Development Is Fragmented Across the Trial Lifecycle



Design, enrollment, execution, and analysis operate in silos - limiting speed, precision, and adaptability



> **Costing Billions and Delaying Patient Access to New Therapies**

PhaseV Is the solution



The PhaseV Platform

A Continuous AI-Powered Intelligence Layer for Clinical Development

PHASEV



45+

Customers

8

Big Pharma Partners

\$65m

Capital Raised

2m+

Patient-Level Records

New Capabilities Launched in 2026

Advancing End-to-End Workflow Automation

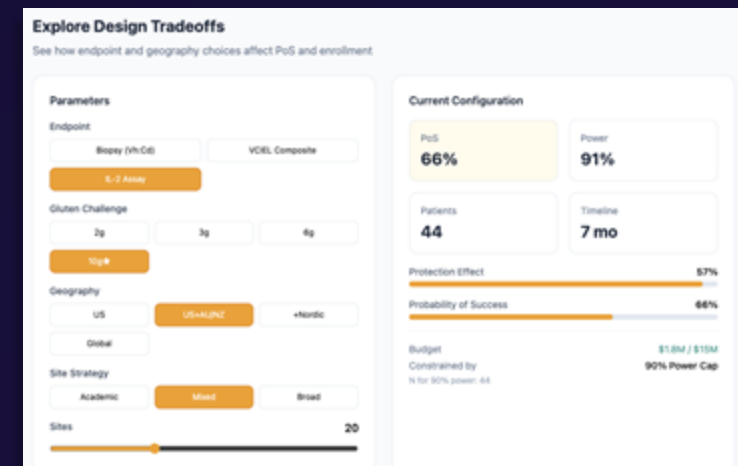
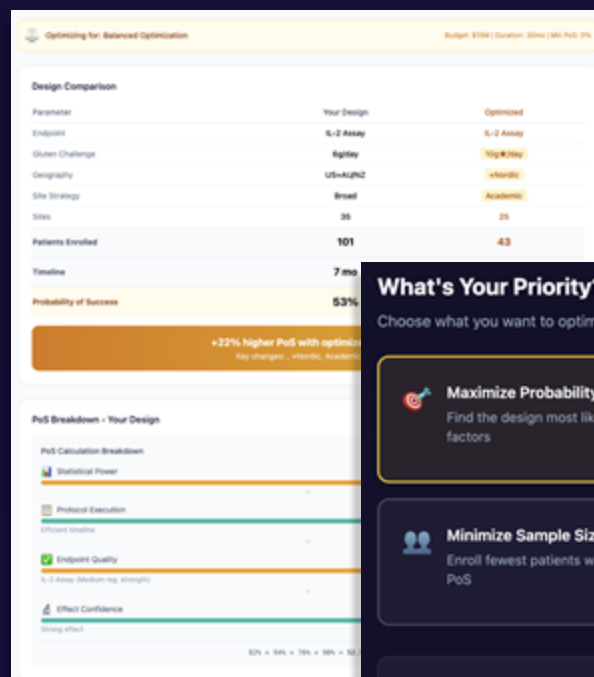
AI Conductor

Pre-Trial Documents

- + Protocol
- + CRFs
- + SAP
- + Design & Simulations

During & Post-Trial

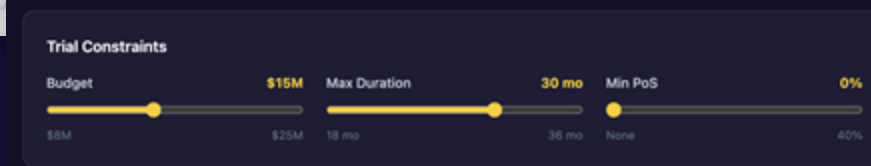
- + SDTM
- + CSR
- + TLFs
- + ADaM



What's Your Priority?

Choose what you want to optimize for

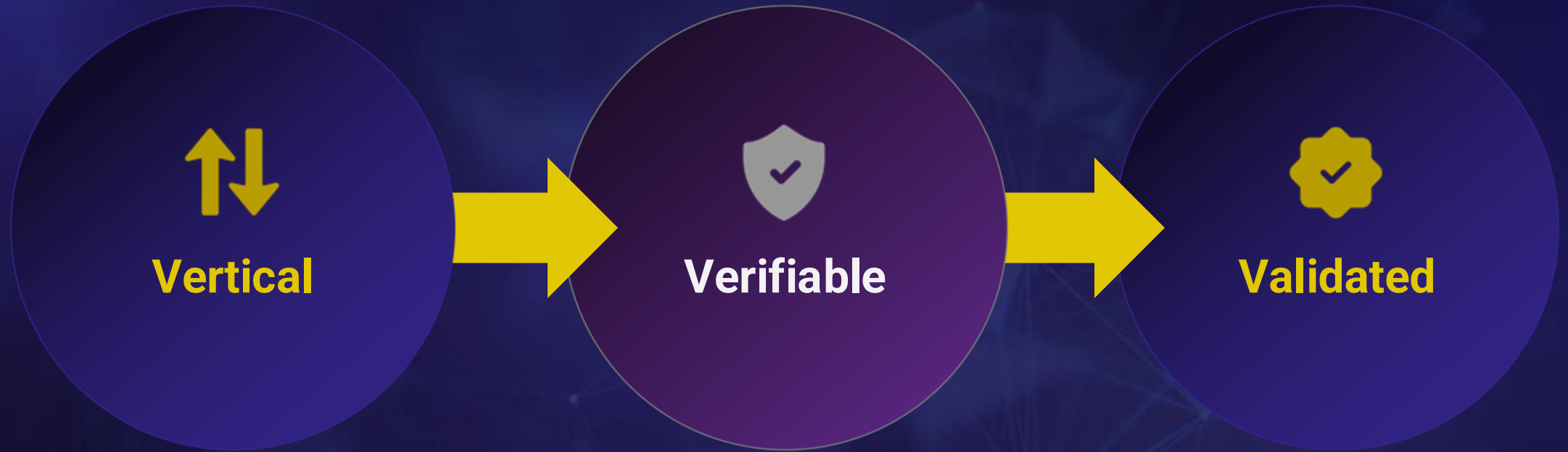
- Maximize Probability of Success**
Find the design most likely to succeed, balancing all factors
- Minimize Trial Duration**
Get results as fast as possible while maintaining adequate PoS
- Minimize Sample Size**
Enroll fewest patients while maintaining adequate PoS
- Balanced Optimization**
Balance PoS, speed, and efficiency equally



Continue →

PhaseV Is the solution

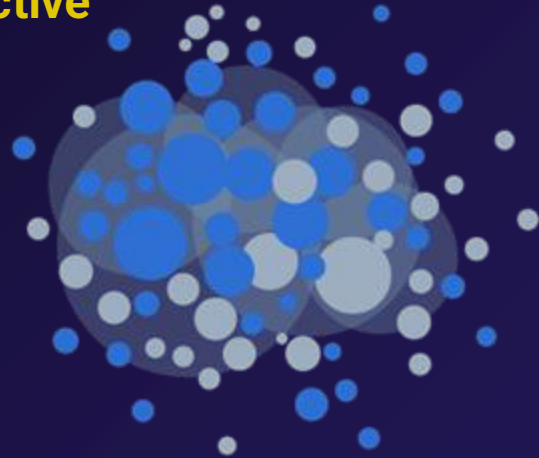
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Moving From Correlation to Causation

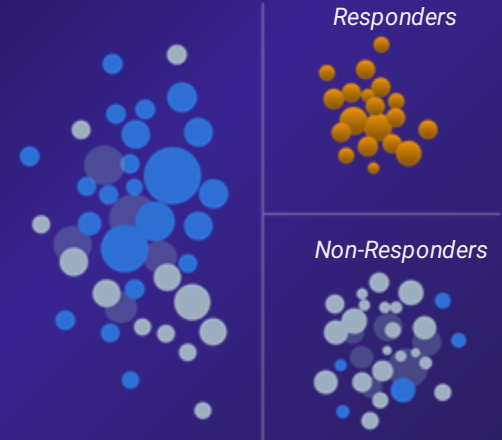
Standard Predictive Analysis (Correlation)

« What will happen? »



PhaseV Causal Analysis (Causation)

« What could happen if...? »



Black Box Approach

- › Identifies **correlations**
- › Finds prognostic signals (who will get worse)
- › Cannot distinguish treatment effect from placebo or natural disease progression

Glass Box Approach

- › Infers **cause and effect**
- › Conditional Average Treatment Effect (CATE)
- › Determines why an outcome occurs and who truly benefits from a specific drug

Transparency at its Core

Causal Responder Detection

Tzviel Frostig^{*1}, Oshri Machluf¹, Amitay Kamber¹, Elad Berkman¹, and Raviv Pryluk¹

¹Research Department, PhaseV

June 26, 2024

Abstract

We introduce the causal responders detection (CARD) for responder analysis that identifies treated subjects respond to a treatment. Leveraging recent advances in machine learning, CARD employs machine learning techniques to identify responders while controlling the false discovery rates. Additionally, we incorporate a propensity score to mitigate bias arising from non-random treatment allocation. We demonstrate that CARD effectively detects responders in diverse scenarios.

An integer programming-based approach to construct exact two-sample binomial tests with maximum power

Stef Baas, Yaron Racah, Elad Berkman, Sofia S. Villar

Traditional hypothesis tests for differences between binomial proportions are at risk of being too liberal (Wald test) or overly conservative (Fisher's exact test). This problem is exacerbated in small samples. Regulators favour exact tests, which provide robust type I error control, even though they may have lower power than non-exact tests. To target an exact test with high power, we extend and evaluate an overlooked approach, proposed in 1969, which determines the rejection region through a binary decision for each outcome vector and uses integer programming to, in line with the Neyman-Pearson paradigm, find an optimal decision boundary that maximizes a power set, our approach exhibits higher power than other methods. The method's practical

Robust CATE Estimation Using Novel Ensemble Methods

Oshri Machluf¹, Tzviel Frostig¹, Gal Shoham¹, Tomer Milo³, Elad Berkman¹, and Raviv Pryluk¹

¹Research Department, PhaseV

July 12, 2024

Abstract

The estimation of Conditional Average Treatment Effects (CATE) is crucial for understanding the heterogeneity of treatment effects in clinical trials. We evaluate the performance of common methods, including causal forests and various meta-learners, across a diverse set of scenarios, revealing that each of the methods struggles in one or more of the tested scenarios. Given the inherent uncertainty of the data-generating process in real-life scenarios, the robustness of a CATE estimator to various scenarios is critical for its reliability. To address this limitation of existing methods, we propose two new ensemble methods that integrate multiple estimators to enhance prediction stability and performance - *Stacked X-Learner* which uses the X-Learner with model stacking for estimating the nuisance functions, and *Consensus Based Averaging (CBA)*, which averages only the models with highest internal agreement. We show that these models achieve good performance across a wide range of scenarios varying in complexity, sample size and structure of the underlying-mechanism, including a biologically driven model for PD-L1 inhibition pathway for cancer treatment. Furthermore, we demonstrate improved performance by the Stacked X-Learner also when comparing to other ensemble methods, including R-Stacking, Causal-Stacking and others.

Scientific Abstracts
Poster View Systemic lupus erythematosus

POS1014 USE OF AN INTERACTIVE ADAPTIVE-TRIAL AI SIMULATION TOOL TO INCREASE EFFICIENCY AND PROMOTE INFORMED DECISION MAKING WITHIN LUPUS CLINICAL TRIAL TEAMS, A CASE STUDY

T. Ilan Ber¹, D. Goldstaub¹, O. Machluf¹, N. Sharwetter Levit¹, R. Cohen¹, Y. Racah¹, E. Berkman¹, R. Pryluk¹, M. B. Urowitz²

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2. University of Toronto, Toronto, Canada

Statistics in Medicine

RESEARCH ARTICLE

Group Sequential Trial Design Using Stepwise Monte Carlo for Increased Flexibility and Robustness

Amitay Kamber ✉ Elad Berkman, Tzviel Frostig, Raviv Pryluk, Bradley P. Carlin

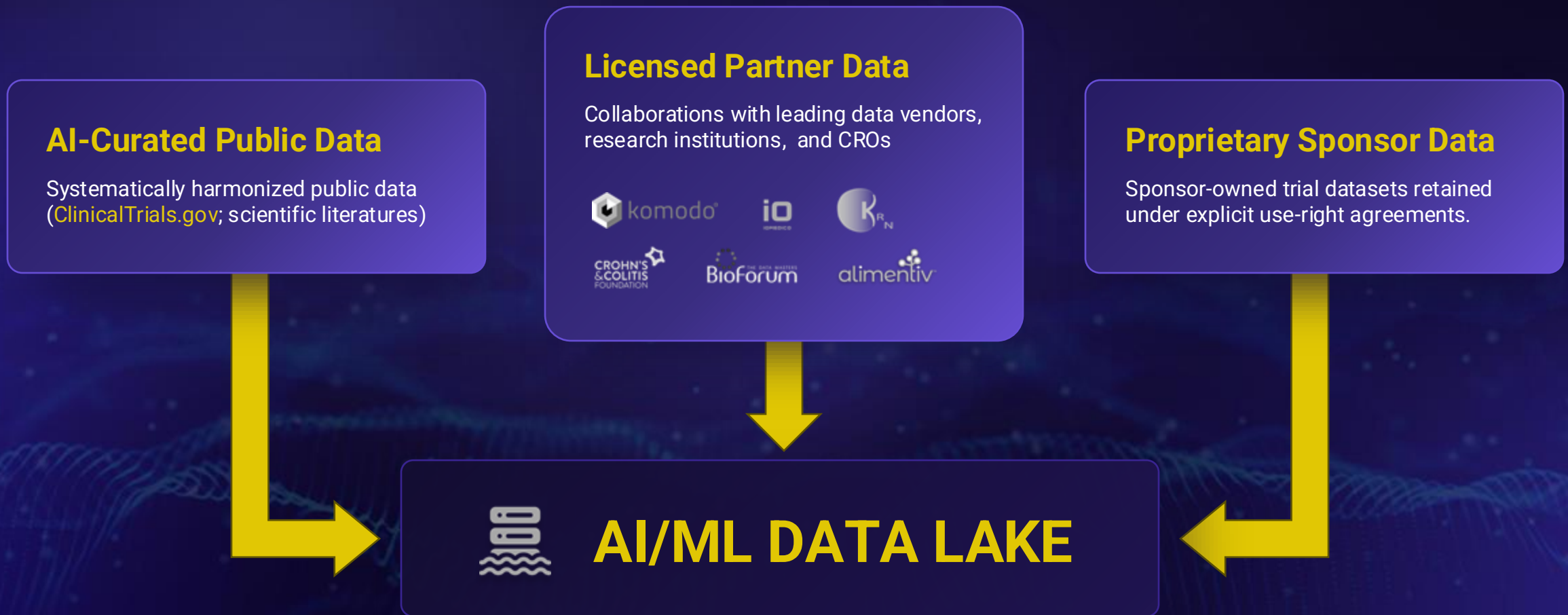
First published: 22 September 2025 | <https://doi.org/10.1002/sim.70249> |

PUB: CLINICAL THERAPEUTICS—INSULINS | JUNE 14 2024

22-PUB: Machine Learning-Based Optimization of Patient Eligibility for Oral Insulin Treatment—A Post Hoc Analysis of Phase III Trial Results **FREE**

MIRIAM KIDRON; ELAD BERKMAN; OSHRI MACHLUF; RAVIV PRYLUK; KENNETH E. HOMER; JOEL M. NEUTEL

Fueling Causal AI with Comprehensive, Multi-Source Data



PhaseV Is the solution

PHASE 



PhaseV

Measured Impact

+30%

Probability
of Success

-40%

Trial
Duration

-40%

Required
Enrollment

-50%

Development
Cost

"Values shown are based on outcomes from collaborations where PhaseV supported biopharma companies in optimizing trial design and operations; results are illustrative and outcomes depend on trial-specific context."

Baseline Enrollment Challenge for the NSCLC Program

Client
Enrollment Target

**1,000 patients
in 24 months**

However, based on **PhaseV**
Baseline Enrollment Predictions

- > **Risk Detected**
- > Only **670 patients** would be enrolled by month 24
- > It would take the client **33 months** to enroll all 1000 patients

**Grounded in real client work, with details adapted and anonymized for confidentiality*

STAGE 1

Maximizing Eligible Patient Pool



> Quantifying the impact of I/E optimization on eligible patient pool and enrollment potential

Optimizing the Site Network

Original Client List Top 6 Sites

Site Name

Asan Medical Center

Samsung Medical Center

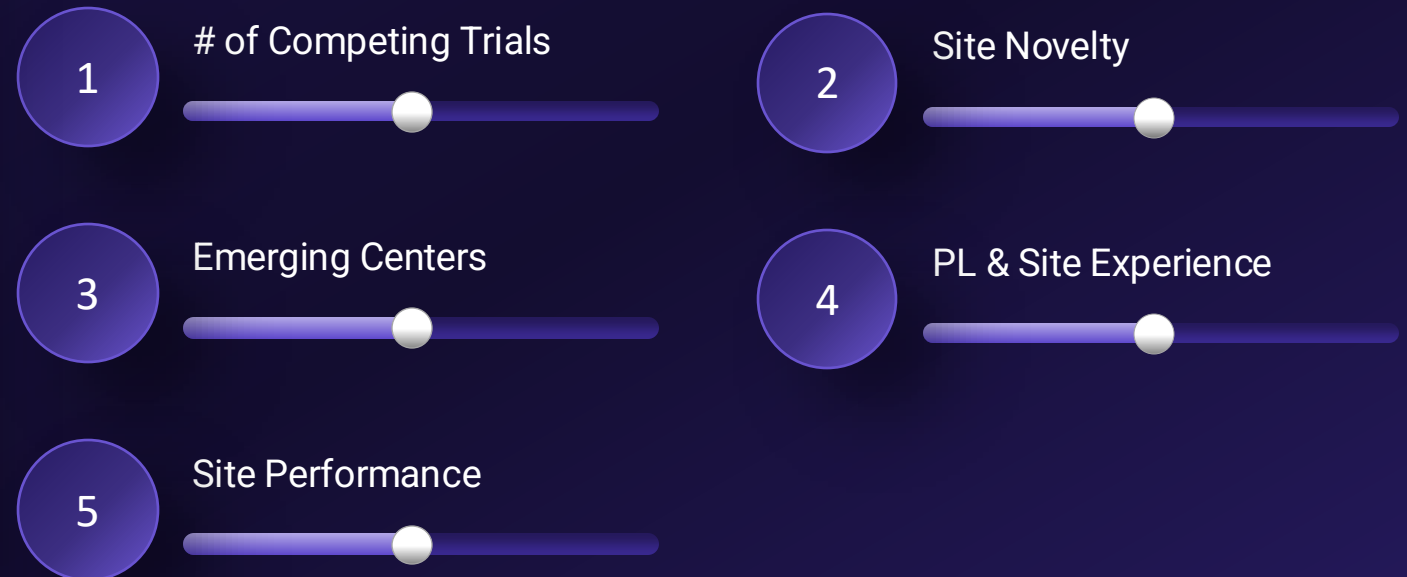
Seoul National University Hosp..

National Cancer Center

Severance Hospital

Seoul National University Bund..

Sites evaluated using a multi-factor framework,
including but not limited to



Optimizing the Site Network

PhaseV Optimized List

Top 6 Sites

Site Name

Kangbuk Samsung Hospital

Inha University Hospital

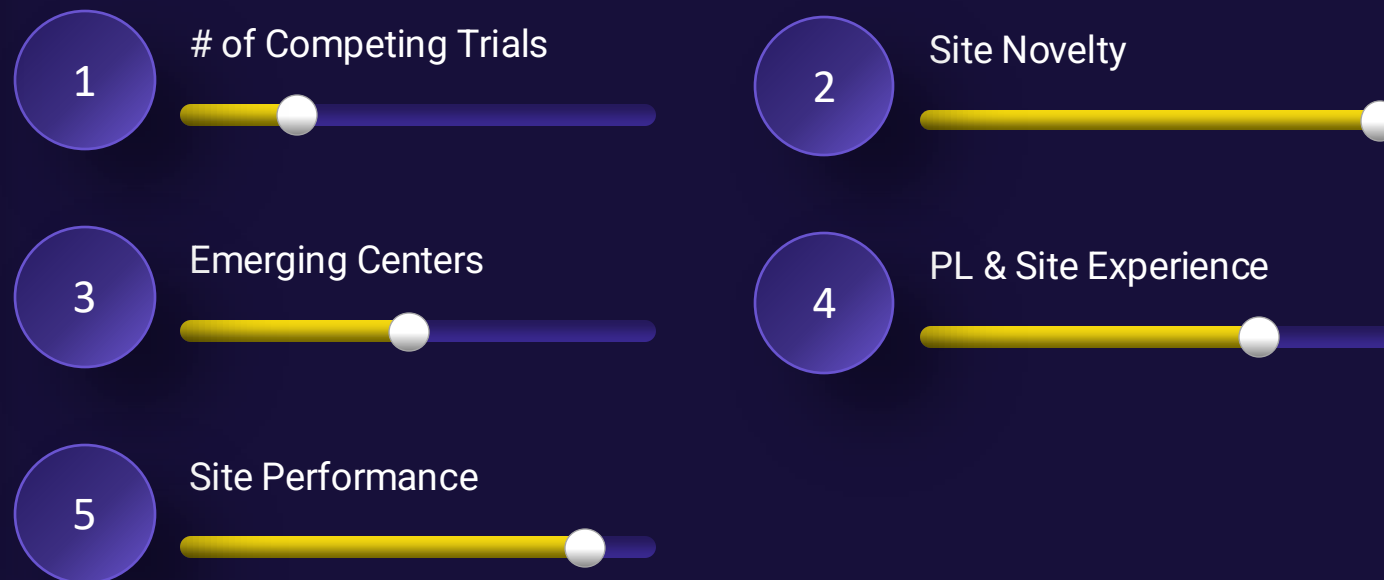
Kosin University Gospel Hospital

Keimyung University Dongsan Hosp...

Chonman And Chosun University ...

Gyeongsang National University ...

Sites evaluated using a multi-factor framework, including but not limited to



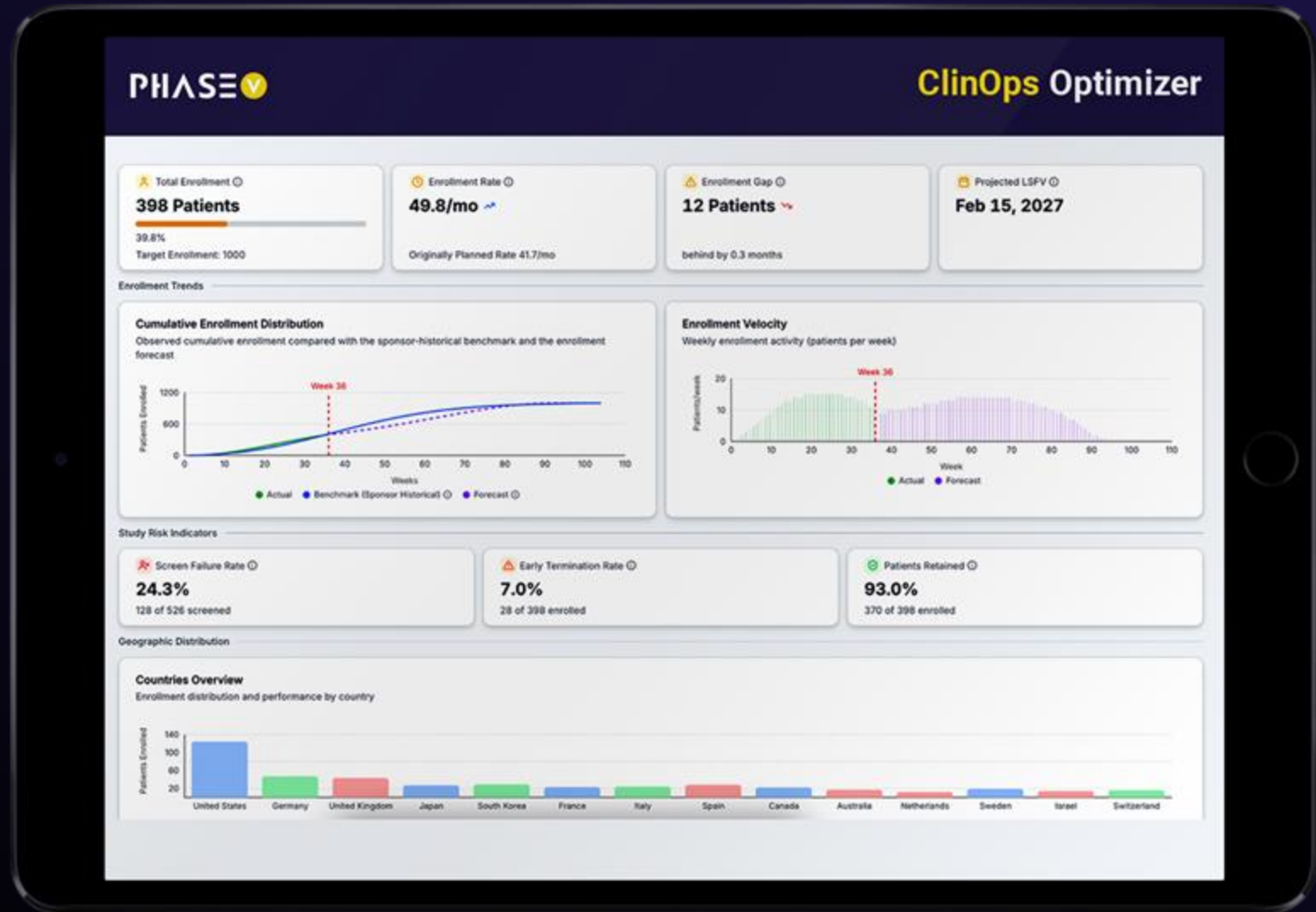
Additional Outputs

> **15 Sites Added**
(New to Client - "Novelty")

> **12 Sites Excluded**
("Competition")

> **3 Sites on Reserve**
("PI on Vacation")

Tracking Real Time Performance



PhaseV Operational Impact Delivered

33

Underperforming
Site Avoided

9

Months
Time Saved


\$30M

Estimated
Cost Saved

3

Additional
Countries Added

3 Years. 80+ Programs and Counting

Therapeutic Area	Trial Rescue & Subgroup ID	Trial Design & Site Optimization	Portfolio & Lifecycle Management
Oncology 	<ul style="list-style-type: none"> • Several Solid tumors: Breast; Ovarian; Pancreatic; Prostate; other 	<ul style="list-style-type: none"> • Global NSCLC Phase 3 • HNSCC Phase 3 	<ul style="list-style-type: none"> • PD-L1, Causal Modeling
Metabolic 	<ul style="list-style-type: none"> • Oral Insulin for Diabetes 	<ul style="list-style-type: none"> • MASH, Adaptive Design 	<ul style="list-style-type: none"> • Top-5 Pharma, M&A • Obesity, RWE Estimation • MASH, ISS
Immunology 	<ul style="list-style-type: none"> • Crohn's Disease; UC • Osteoarthritis; IgAN; PMN • COPD 	<ul style="list-style-type: none"> • SLE, ML Surrogate Endpoint • Osteoarthritis; IgAN; PMN • COPD 	<ul style="list-style-type: none"> • Top Pharma, Asthma; COPD; Allergic Rhinitis
Neurology 	<ul style="list-style-type: none"> • Seizure Disorder; ALS; MS; DPNP; MDD 	<ul style="list-style-type: none"> • PD, ML Surrogate Endpoint • Alzheimer's, Adaptive Design • MDD 	<ul style="list-style-type: none"> • Parkinson's, Causal Modeling
Others 	<ul style="list-style-type: none"> • Ischemic stroke 	<ul style="list-style-type: none"> • Anti-obesity asset for COPD • Infectious Disease • Ischemic stroke 	<ul style="list-style-type: none"> • Anti-obesity asset for CHD • MPS II (rare disease) • Coronary Heart Disease



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Contact information

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