

STRATEGY DINNER

Supercharging Statistical Computing: From Chaos to Clarity

SUCCESS in clinical development can be measured by the time required to deliver important milestones such as datasets for interim analysis, narratives for data safety reviews, or tables, listings, and figures for clinical study reports.

Though each milestone stands alone, each is produced alongside other milestones in other studies, each with its own demands on data scientists, computing resources, and regulatory compliance processes.

To improve clinical trial cycle times, the clinical research enterprise must evolve from a loose confederation of individual programmers' workflows and tools into a unified Statistical Programming Operations model, or StatOps, capable of harmonizing the delivery of milestone data while offering improved capabilities that empower programmers and other data scientists. This program will discuss the ongoing business challenges and the innovative opportunities technology provides to improve cycle times for clinical trials.

AGENDA

18:00 – 18:30	REGISTRATION & NETWORKING WITH A SIGNATURE COCKTAIL ON ARRIVAL
18:30 – 18:45	WELCOME AND INTRODUCTION
18:45 – 19:15	ROUNDTABLE DISCUSSION Deconstructing the Drug Development Process: A Clarion Call for Improving R&D Efficiency (Speaker: Ken Kaitin)
19:15 – 19:45	ROUNDTABLE DISCUSSION Brace for Impact: The Looming Data Submission Implosion (Speaker: Chris Connor)
19:45 – 20:45	DINNER
20:45 – 21:45	ROUNDTABLE DISCUSSION StatOps: Tackling Inefficiency to Accelerate Cycle Time (Speaker: Chris Connor)
21:45 – 22:00	CLOSING REMARKS AND COFFEE

DATE
Thursday, 25th May 2023

VENUE
Seasons 52
FRESH GRILL | WINE BAR
3535 US-1 Suite 100B
Princeton, NJ 08540



KEY OPINION LEADERS



Chris Connor – Director of Product Management and Solution Strategy, **MaxisIT**

Chris Connor is Director of Product Management and Solution Strategy at MaxisIT where he drives strategy and the product roadmap for next-gen Statistical Computing Environment (SCE) solutions. Chris brings deep industry experience in product development and market research. Chris has driven the product roadmap for SCE solutions at SAS and d-wise, and directed eClinical product strategy at BioClinica, OpenClinica, and most recently Medidata Solutions serving as Director, Product Management for the MEDS Data Platform. Chris demonstrated his keen industry insights and technology forecasting ability at IDC where he led the Clinical Technology and Strategy service before founding eClinicalGuru in 2010.



Kenneth I. Kaitin, PhD – Professor of Medicine, **Tufts University School of Medicine** and Senior Fellow, **Tufts Center for the Study of Drug Development**

Dr. Kaitin is a Professor of Medicine at Tufts University School of Medicine and Senior Fellow at Tufts Center for the Study of Drug Development. He holds appointments as Advisory Professor at Shanghai Medical College of Fudan University in Shanghai, China; and faculty of the European Center for Pharmaceutical Medicine at the University of Basel. An internationally recognized expert on drug development science and policy, Dr. Kaitin writes and speaks regularly on factors that contribute to the slow pace and high cost of pharmaceutical R&D and efforts to improve the development process. In 2011, Dr. Kaitin received the Dr. Louis M. Sherwood Award, granted by the Academy of Pharmaceutical Physicians and Investigators. Dr. Kaitin received a B.S. from Cornell University and an M.S. and Ph.D. in pharmacology from the University of Rochester.

ABOUT MAXISIT

MaxisIT simplifies clinical development with an easy-to-use integrated technology platform that automates repetitive tasks, streamlines workflows, improves data quality, and delivers role-based data in near-real-time to all team members. Our Clinical Trial Oversight System also includes a DMW (Data Management Workbench) and SCE (Statistical Computing Environment) with 50+ data visualization dashboards, access to clinical and operational repositories, AI-enabled clinical data mapping, validated data ingestion and refresh - all connected via a standards-based clinical metadata repository. Our cloud-based platform and services allow businesses to focus on clinical R&D, stay agile, make better decisions, uncover issues faster, and ultimately improve the quality of clinical trials while improving the patient experience.