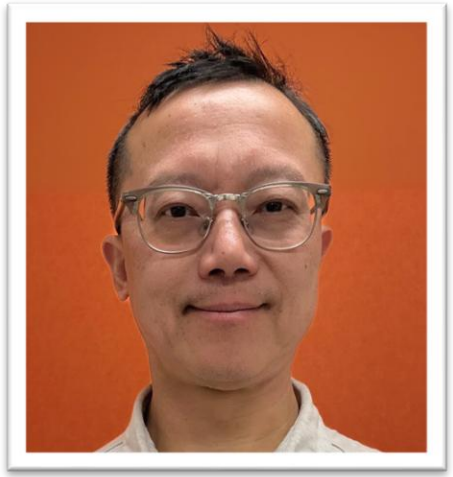
Efficiency+: Advancing Clinical Trial Operation through Statistical Innovation

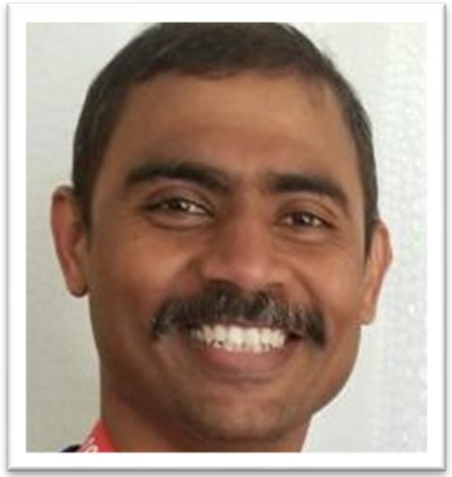
The ASA BIOP Scientific Working Group on Clinical Trial Operational Efficiency

Introducing Efficiency+

Vlad Anisimov Amgen

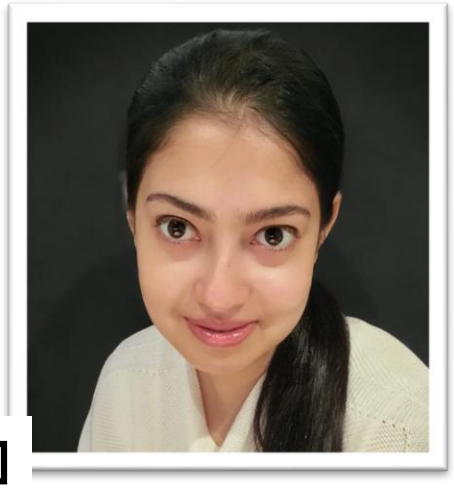


Fei Chen, JJIM



Palanikumar Ravindran, BMS

Clara Cali Mella, Bayer



Dooti Roy, BI

Christi Kleoudis, AZ

Guohui Wu, Regeneron

Leanne Goldstein, Amgen

Fei Chen, Johnson & Johnson

Efficiency+ Scientific Working Group

Bio:

- Senior Director of Biostatistics
- Statistical Modeling Methodology and Consulting at Johnson & Johnson Innovative Medicine since 2011
- Strategic and methodological support to cross-function trial design teams across portfolio of JJIM
- Trial execution optimization through collaboration with Feasibility and Supply Chain and other stakeholders
- Co-chair of Efficiency+ ASA BIOP SWG

Clinical trials face significant operational challenges

>30%
trials exceed planned enrollment timeline

50%
drug supply wasted

>50%
of dev costs are operational

“Equivalent to a free clinical trial after every 5–7 run.” — McKinsey & Co. [1]^

The question nobody asks statisticians

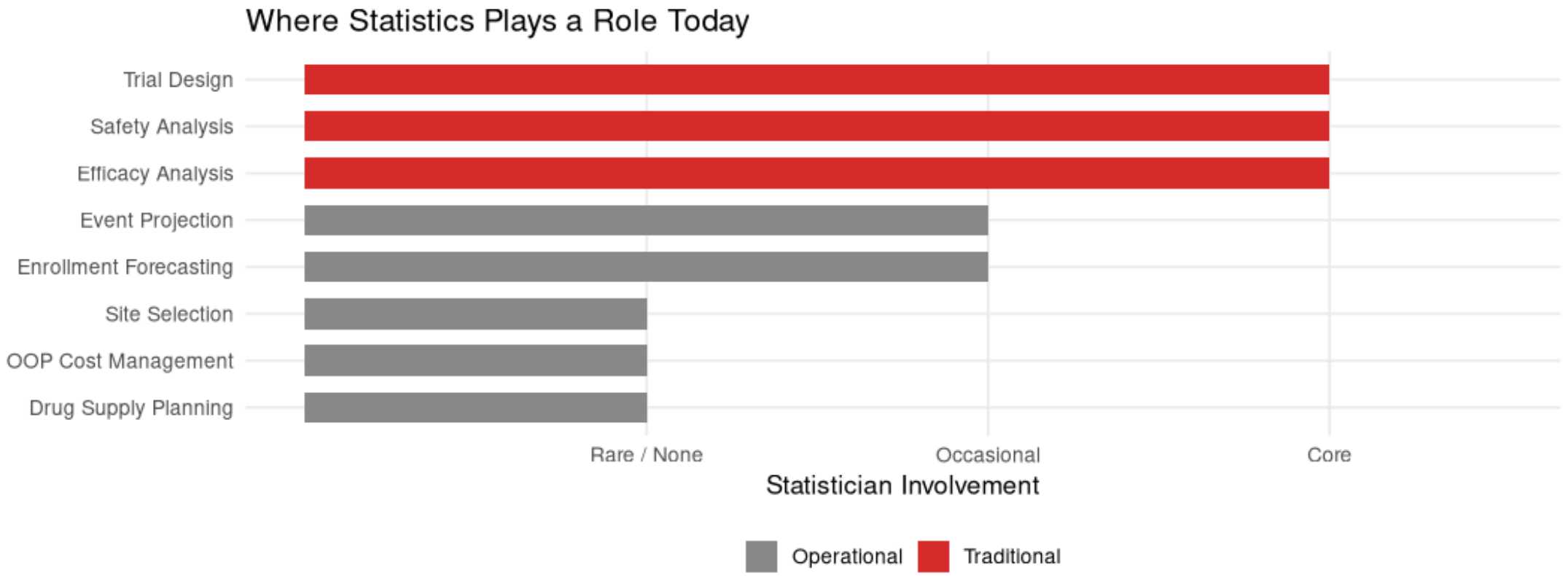
> *How many vials of drug should we ship to a site in Brazil next month?*
>
> *Should we activate five more sites in Japan to stay on track for enrollment?*

These look like operations questions.

They are fundamentally statistical problems.

Statisticians are well-equipped to contribute — but haven't been organized to do so.

The gap: statistics and operations

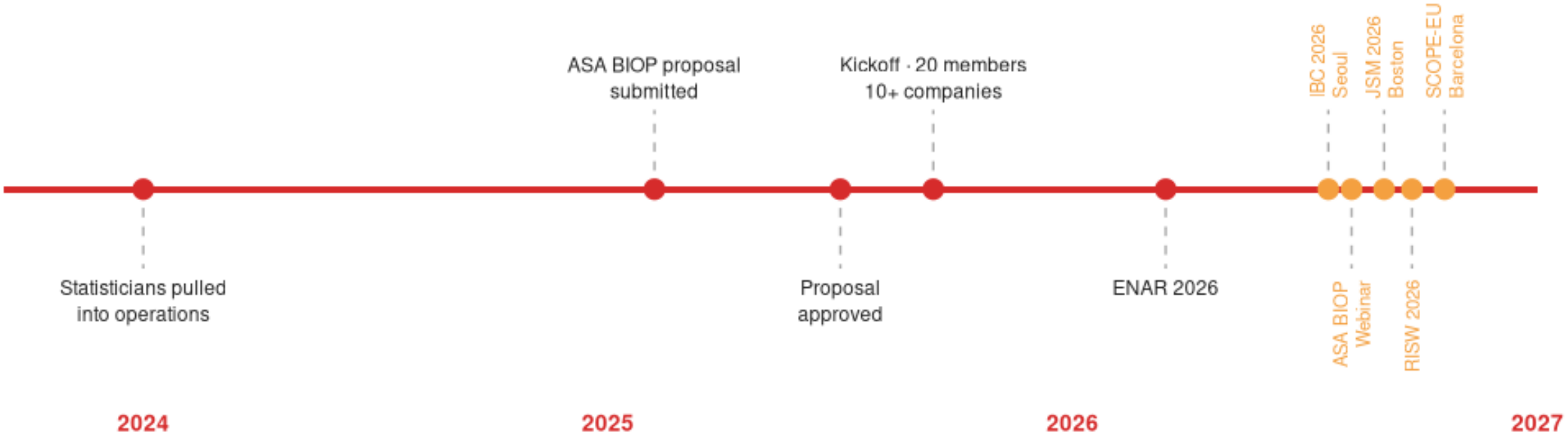


[2]^ See references slide

The Opportunity

- Clinical operations: **>50%** of drug development costs
- Even a **1–2% efficiency gain** translates to substantial savings at program scale
- Drug supply **waste**: typical phase 3 program spends $10–50M on drug supply
- **Statistical innovation** is not a “nice to have” — it is a financial imperative for the industry.
- **Cross-industry Cross-functional** — statisticians + operators working together

How Efficiency+ came to be



Efficiency+

The “+” means:

Statisticians **plus** clinical operations professionals

Statisticians **plus** data scientists

Statisticians **plus** regulatory experts

Methods **plus** real-world implementation

We are deliberately cross-functional. Moving the needle requires going beyond a typical methods-focused working group.

Core goals:

Share methods & compare approaches

Develop industry best practices

Build open-source tools

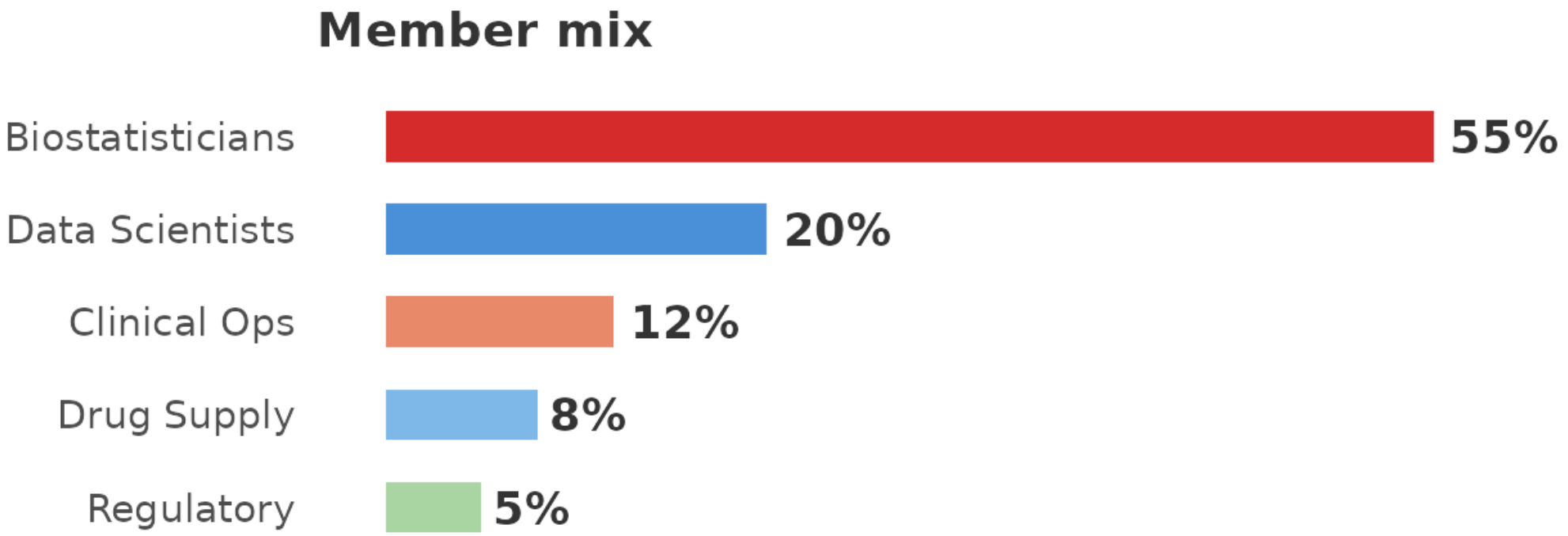
Influence regulatory acceptance

Reduce waste, accelerate timelines

E+ members


abbvie
AMGEN
AstraZeneca
BAYER
BeiGene
Boehringer Ingelheim
Bristol Myers Squibb
Cytel
Johnson&Johnson
Lilly
REGENERON
SANOFI
GILEAD
astellas
ThermoFisher SCIENTIFIC
SERVIER
THE UNIVERSITY OF TEXAS AT EL PASO
KENJI
MARS
CSDD
TUFTS UNIVERSITY

Leadership & team mix, > 25 active members



Co-Chairs

Fei Chen (J&J)
Clara Cali Mella (Bayer)

Advisors

José Pinheiro (J&J)
Inna Perevozskaya (BMS)

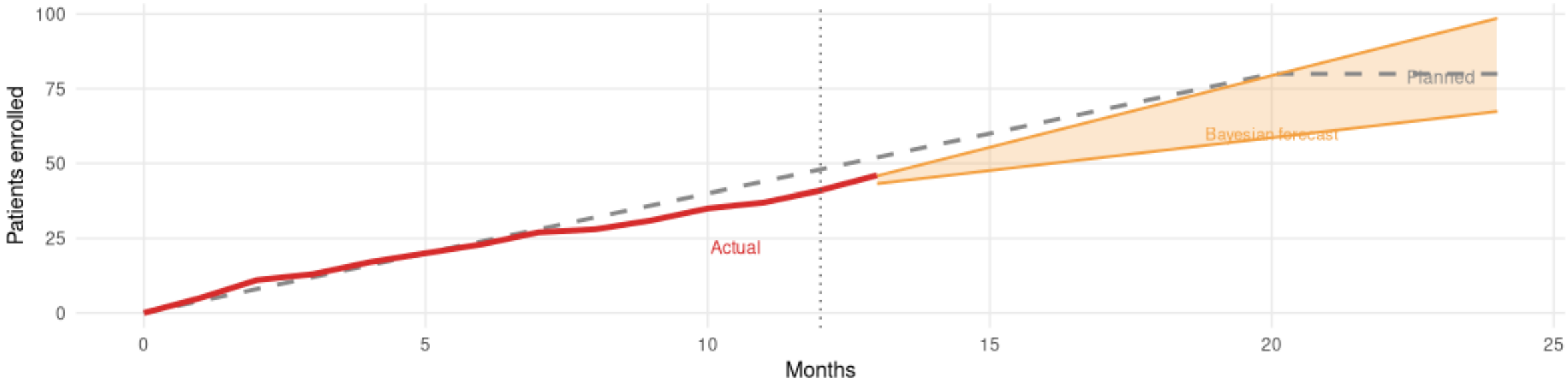
Workstream Leads

Clara Cali Mella (Bayer) &
Vlad Anisimov (Amgen)
Palani Ravindran (BMS)
Dooti Roy (BI)
Christi Kleoudis (AZ)

Communications

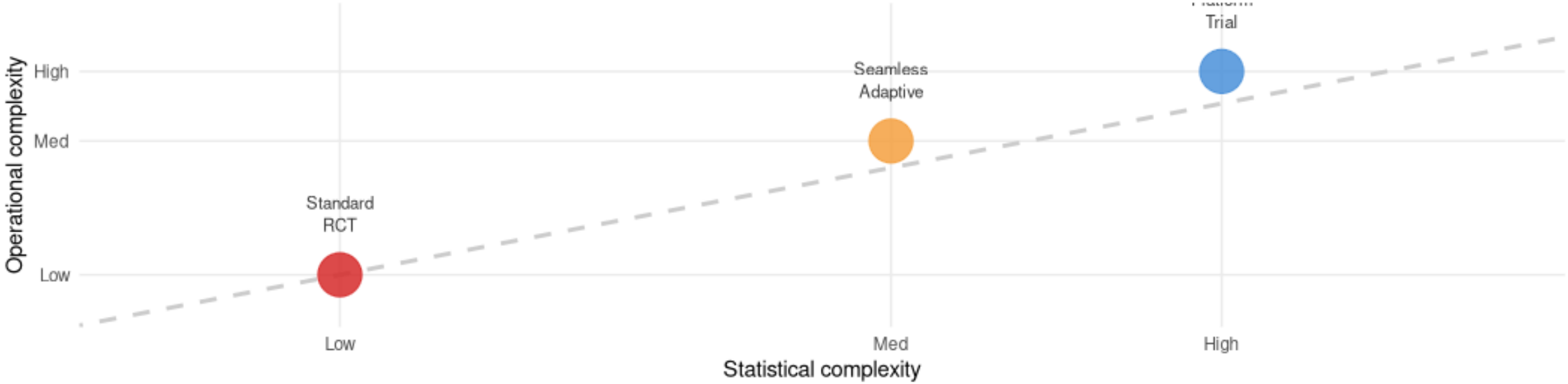
Crystal Shaw (Amgen)
Leanne Goldstein (Amgen)

Workstream 1: Patient Recruitment



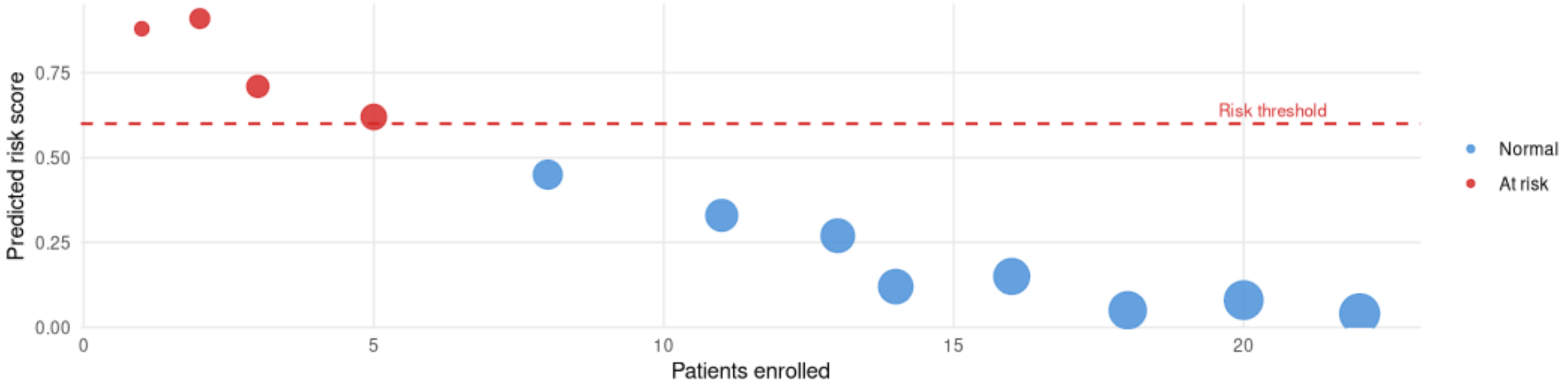
Led by Clara Cali Mella (Bayer) · Vlad Anisimov (Amgen) ·

Workstream 2: Design & Operations



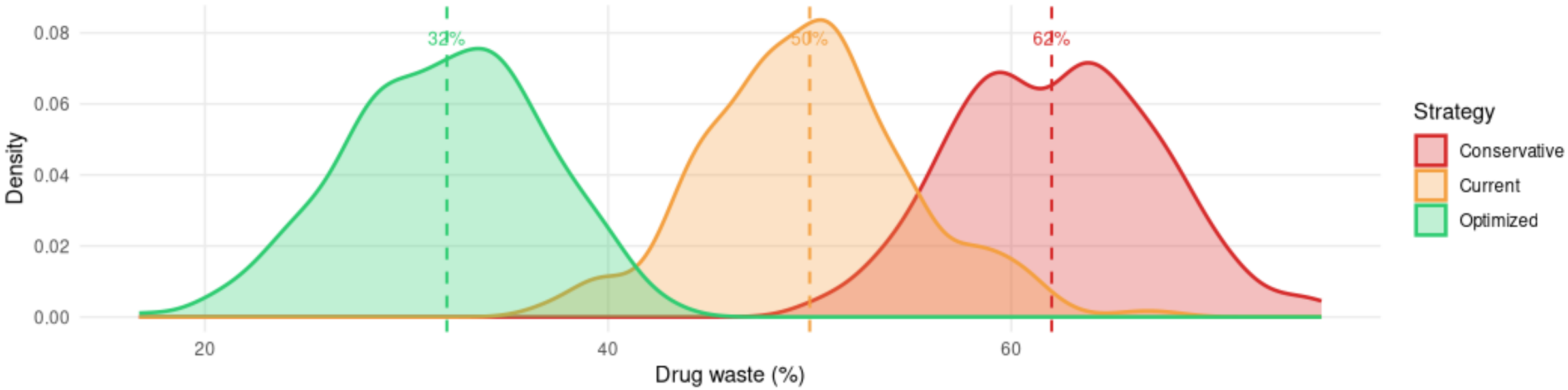
Led by Dooti Roy (Boehringer Ingelheim)

Workstream 3: Dynamic Trial Monitoring



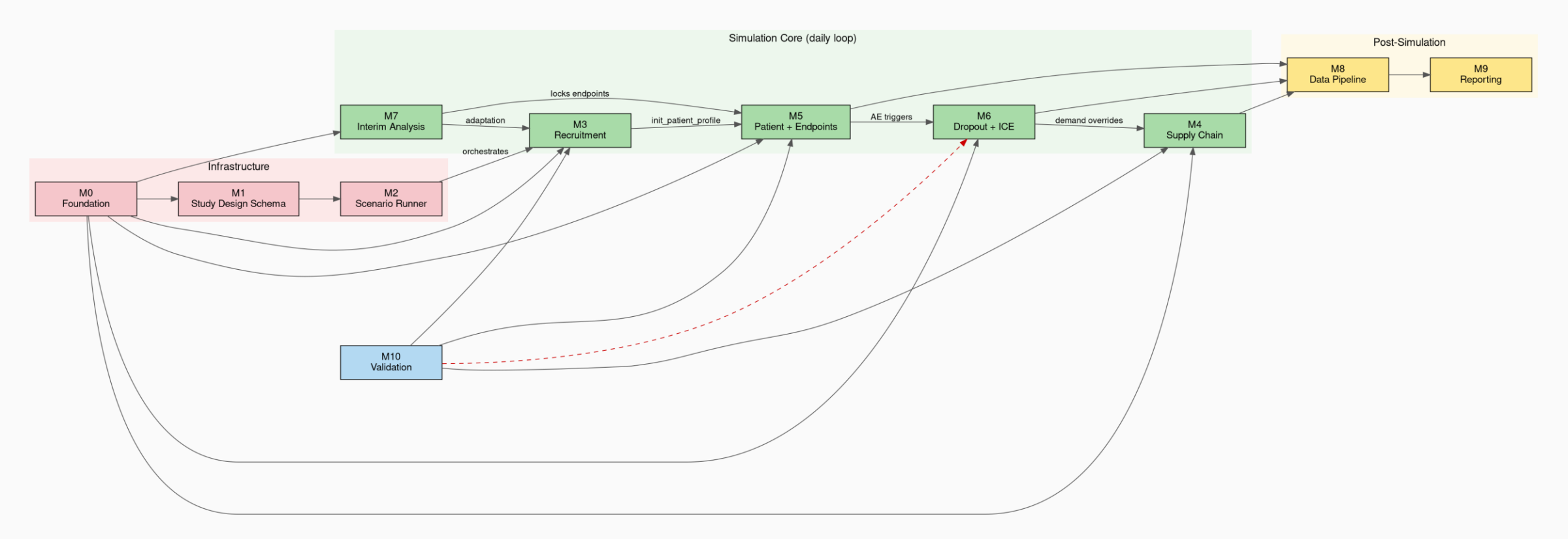
Led by Palanikumar Ravindran (BMS)

Workstream 4: Clinical Supply Chain



Led by Christi Kleoudis (AstraZeneca)

CSC simulation engine as Integration Backbone



Each workstream contributes methodology, and the shared platform ties it all together.

Enrollment Monitoring and Site Selection

Workstream 1: Patient Recruitment Monitoring & Forecasting, Site Selection

Led by Clara Cali Mella (Bayer) · Vlad Anisimov (Amgen)
· Enrollment forecasting · Poisson-Gamma Bayesian models · Adaptive site activation
Presenter: Vlad Anisimov (Amgen)

Subteam Members:

Junxiang Luo	AbbVie
Xin Wang	AbbVie
Xikun Wu	BeOne Med
Haoyu Wang	BMS
Oleksandr Savenkov	BMS
Palanikumar Ravindran	BMS
Kyle Wathen	Cytel
Bochao Jia	Lilly
Guohui Wu	Regeneron
Chenguang (CG) Wang	Regeneron
Tobias Straubinger	Bayer
Qian Meng	Servier

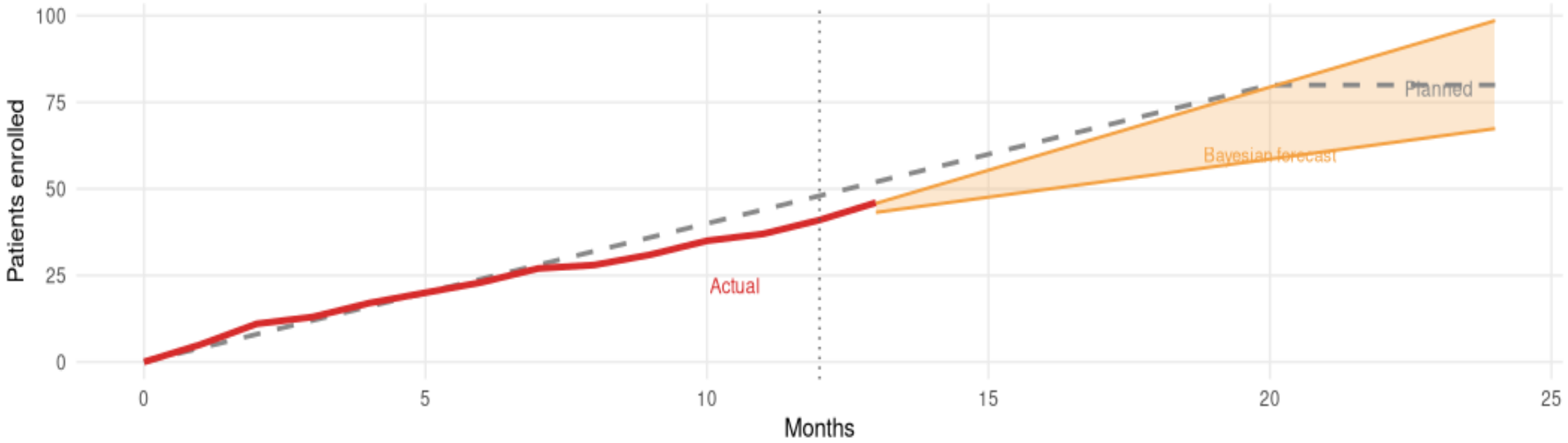
Topics of investigation

- Expanding methodology for modeling patient recruitment to time-dependent models.
- Recruitment reprojection techniques at the early start of the trial when not enough data available using Bayesian techniques
- Models and techniques for selecting best performing sites using historic data.
- Modeling screening/randomization processes and using decision rules to stop earlier to reduce oversampling.
- Optimal recruitment design at different stages over time
- Optimal recruitment reforecasting at interim stage
- Optimal clustering of sites for more accurate prediction

Why statistical methods matter for trial operations

- Clinical trials are operationally complex: hundreds or thousands of patients may need to be recruited across many sites and countries.
- Patient recruitment uncertainty is a major driver of delays, cost, and missed milestones.
- Deterministic planning may lead to inefficient trial design, delays and increased costs.
- Stochastic models can forecast with bounds and quantify the probability of completing recruitment on time.

Patient Recruitment Monitoring & Forecasting



Data-driven enrollment forecasting using Poisson-Gamma Bayesian model and adaptive site's adjustment.

Patient recruitment modelling methodology

Analytic data-driven methodology is developed*:

- Patient arrivals at each active site are modelled as Poisson processes
- Variation in between-site recruitment rates is modelled by a gamma distribution.
- Random site activation delays and closure times are explicitly incorporated.

The resulting Poisson-gamma framework gives closed-form predictive distributions and avoids heavy Monte Carlo simulation.

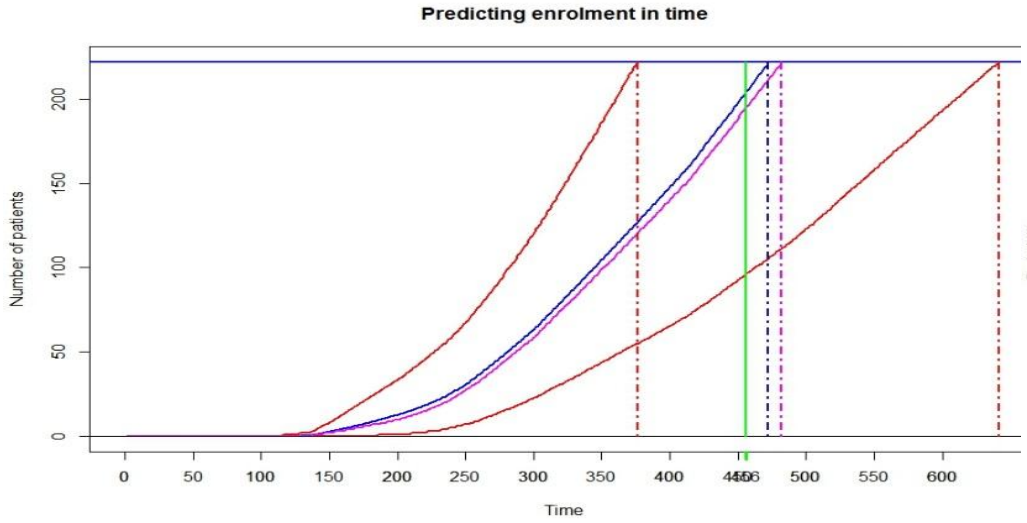
Country and global predictions are built from site-level processes using newly developed analytic approximations by PG processes where needed.

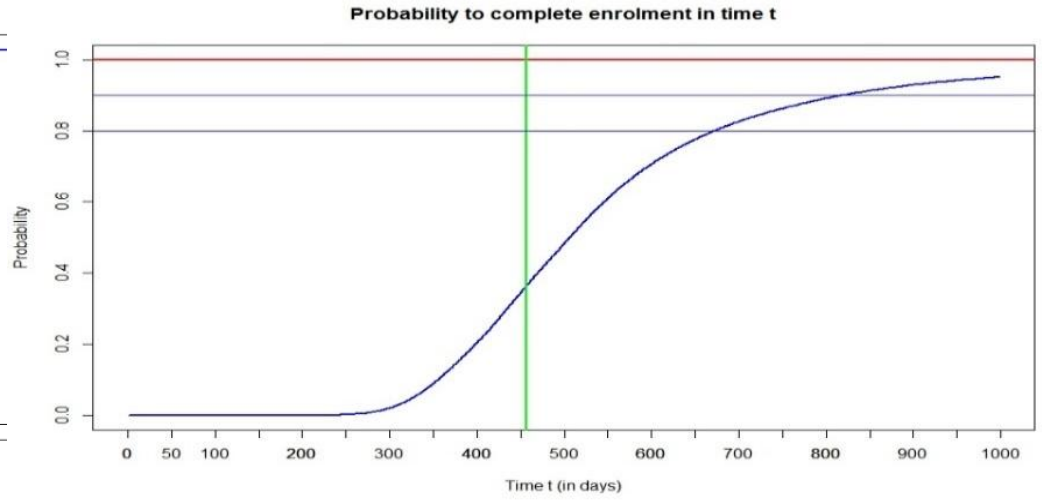
Methodology is world-wide accepted (Poisson-gamma model).

** Anisimov & Fedorov, Statistics in Medicine, 2007 (190 Google Scholar citations);*

Anisimov; Anisimov et al., 2007-2026

Forecasting outputs for design: time, bounds & PoS





- Inputs: mean and variance of recruitment rate by site/country plus site initiation schedule.
- Outputs: expected recruitment trajectory, predictive bounds, time-to-target distribution, and probability of success (PoS) – operational risk measure.
- A plan may look feasible by mean trajectory but still have a low probability of completing by the planned time.
- These outputs allow teams to plan recruitment with confidence, not just as a deterministic curve.
- Similar predictions can be created in countries and globally using a developed methodology for approximating country recruitment processes by Poisson-gamma processes.

Cost-efficient design: select countries and sites

- Decision problem: choose countries and site numbers that achieve the recruitment target within planned time with a required probability.
- Objective: minimize operational cost while maintaining

  Pr(recruitment time <= planned time) >= P

  - above the agreed confidence level.
- Constraints can include lower/upper site numbers, country caps, costs in countries.
- The approach supports the planning paradigm: “design a trial with, say, 80-90% chance to complete recruitment on time.”
- Analytic tools are developed using different criteria of optimality (non-linear constraint optimization*, genetic evolution algorithms and metaheuristic optimization**).

*Anisimov & Austin, 2022; **Schepps, Wong, Austin, Anisimov, 2021, 2024

Beyond recruitment:
forecasting downstream operational processes

- Many trial operations are triggered by patient arrivals:
  follow-up visits, randomization, events, costs, and supply needs.
- Recruitment plus patient follow-up can be represented as a hierarchical evolving stochastic process.*
- Closed-form methods support predicting event counts in event-driven trials (oncology) accounting for ongoing recruitment, cure, dropout and different distributions for time to event.**
- Using hierarchical evolving processes also supports forecasting screening/randomization pipelines and identifying when screening should stop earlier to reduce over-recruitment. ***

* Anisimov, Communications in Statistics - Simulation & Computation, 2016

** Anisimov, Pharma. Statistics, 2011, chapter, 2020; Anisimov et al., 2021, 2022

*** Anisimov, 2025; Anisimov & Gortzak, 2026;

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2. Anisimov V., Downing D., Fedorov V., Recruitment in multicentre trials: prediction and adjustment, in book: mODa 8 – *Advances in Model-Oriented Design and Analysis*, Physica-Verlag, 2007, 1–8.

3. Anisimov V., Predictive modelling of recruitment and drug supply in multicentre clinical trials, *Proc. of JSM*, USA, 2009, 1248-1259.

4. Anisimov V., Statistical modelling of clinical trials (recruitment and randomization), *Communications in Statistics – Theory and Methods*, 40: iss. 19-20, 2011, 3684-3699.

5. Anisimov V., Predictive hierarchic modelling of operational characteristics in clinical trials, *Communications in Statistics - Simulation and Computation*, 45, iss. 05, 2016, 1477 – 1488.

6. Anisimov V., Modern analytic techniques for predictive modeling of clinical trial operations, in book *"Quantitative Methods in Pharmaceutical Research and Development"*, O. Marchenko, N. Katenka (Eds), Springer, 2020, 361-408.

7. Anisimov V., Austin M., Centralized statistical monitoring of clinical trial enrollment performance, *Communications in Statistics – Case Studies and Data Analysis*, v.6, iss. 4, 2020, 392-410.

References

8. Anisimov V., Modern analytic techniques for predictive modeling of clinical trial operations, in book *"Quantitative Methods in Pharmaceutical Research and Development"*, O. Marchenko, N. Katenka (Eds), Springer, 2020, 361-408.

9. Anisimov V., Austin M., Centralized statistical monitoring of clinical trial enrollment performance, *Communications in Statistics – Case Studies and Data Analysis*, v.6, iss. 4, 2020, 392-410.

10. Schepps M., Wong WK., Austin M., Anisimov V., Optimizing patient enrollment in clinical trials with metaheuristics, *Biostatistics*, 2021.

11. Anisimov V., Austin M., Forecasting and optimizing patient enrolment in clinical trials under various restrictions, chapter 23, in book: "*Stochastic Processes, Statistical Methods, and Engineering Mathematics*", Springer, Proc. in Mathematics & Statistics 408, 2022, 511-540.

12. Schepps M., Wong WK., Austin M., Anisimov V., Optimizing Patient Recruitment in Global Clinical Trials using Nature-Inspired Metaheuristics, *Statistics in Biopharmaceutical Research,* Mar 2024, 1-15.

13. Anisimov V., Oliver L., Modeling/forecasting patient recruitment in multicentre clinical trials using time-dependent models, in book: Data Analysis and Related Applications 5, Models, Methods and Techniques, Y. Dimotikalis, C. H. Skiadas Edt., vol. 13, Wiley, 22 Aug 2025, pp.1-22.

14. Anisimov V., Gortzak L, Joint forecasting of screening/randomization processes in multicentre clinical trials and predic optimal enrolment stopping time, chapter in: "Data Analysis and Related Applications 5", Wiley, 2026, 14pp.

Design and Operations

Boehringer Ingelheim

Rubber, meet the Road: At the interface of Statistical Design and Clinical Operation

Dooti Roy, Head of Innovation, Clinical Data Science and Methodology

On Behalf of

Efficiency+ Sub-team of Design and Operation

ASA BIOP Webinar July 2026

Life for E+

Disclaimer

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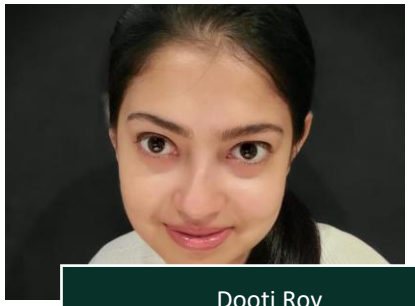
Dooti Roy – Short Bio

Dr. Dooti Roy is Executive Director of Global Biostatistics and Data Sciences at Boehringer Ingelheim, where she serves as Head of Innovation for Clinical Data Science and Methodology (CDSM) and U.S. Head of CDSM. She leads innovation across statistics, statistical programming, and data science, driving the adoption of scientific and technological advances to accelerate high-quality drug development. A passionate leader, mentor, and statistician, she is committed to building future scientific talent and advancing data-driven, equitable solutions in healthcare. Dr. Roy also holds an adjunct faculty appointment at the University of Connecticut and actively contributes to various cross-industry initiatives and professional associations.

Sub-Team Members



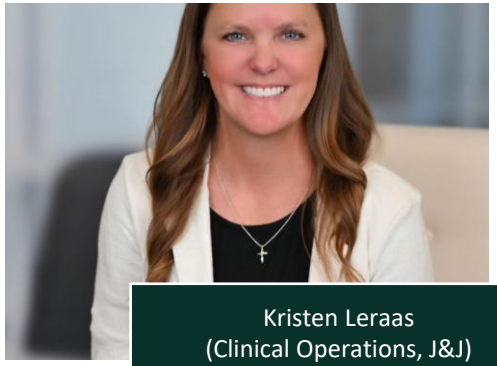
Dooti Roy
(Statistician, Boehringer Ingelheim)

Angela Zhu
(Statistician, Boehringer Ingelheim)

Kristen Daniels
(Early Asset Lead, Boehringer Ingelheim)

Haoyu Wang
(Statistician, BMS)

Jessica Cannon-Hill
(Statistician, Devices, J&J)



Kristen Leraas
(Clinical Operations, J&J)

Vlad Anisomov
(Statistician, Amgen)

Kristel Rens
(Drug Supply, J&J)

Boehringer Ingelheim

A brilliant design no site can run delivers zero value

Objective

Inspire differently informed clinical trial designs where optimization extends beyond power and sample size

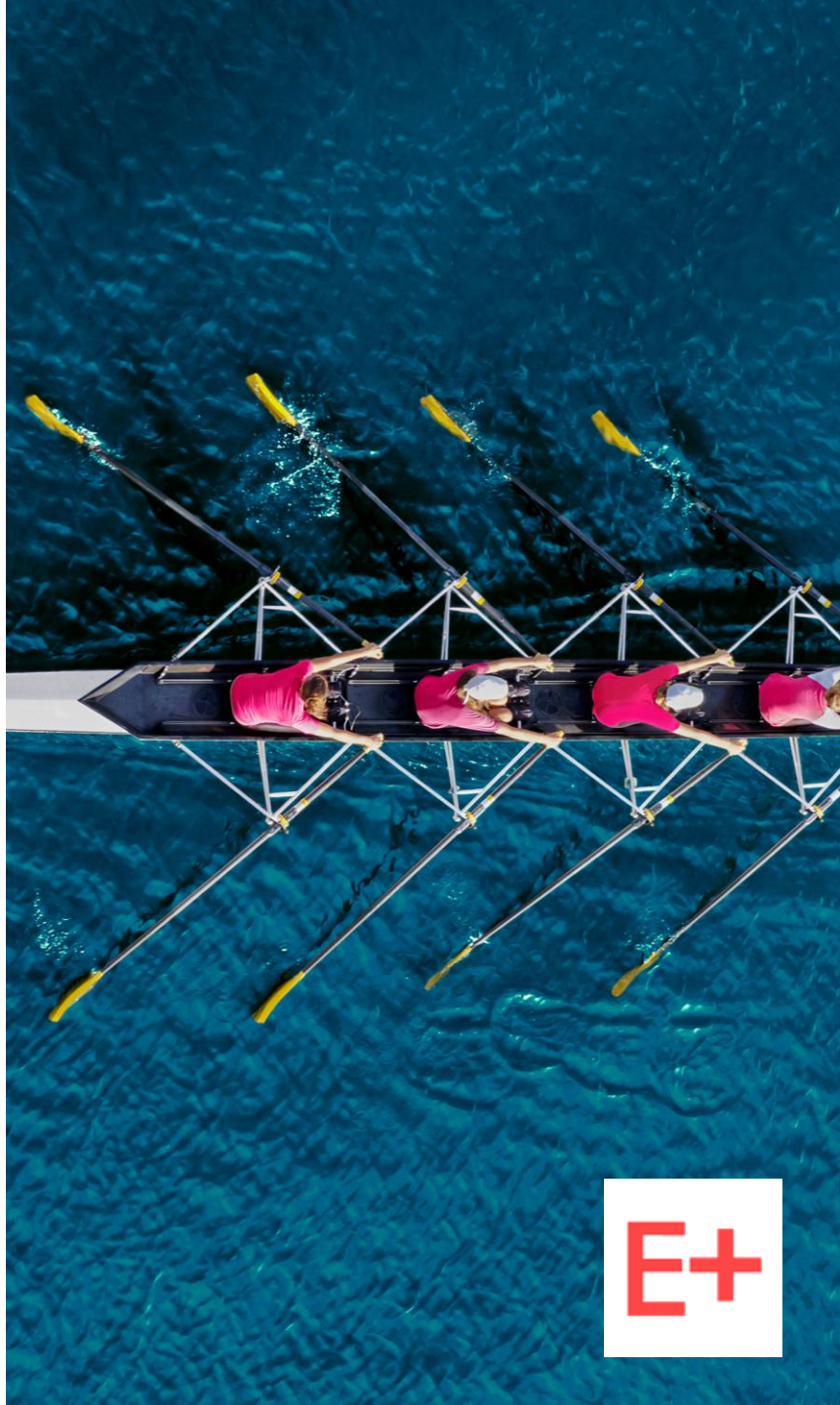
Approach

Forging a deeper, mutual understanding of role and impact of statistical trial design on partnering functions

Partners in Focus

Clinical Operations, Drug Supply and IRT (Interactive Response Technology)

Boehringer Ingelheim



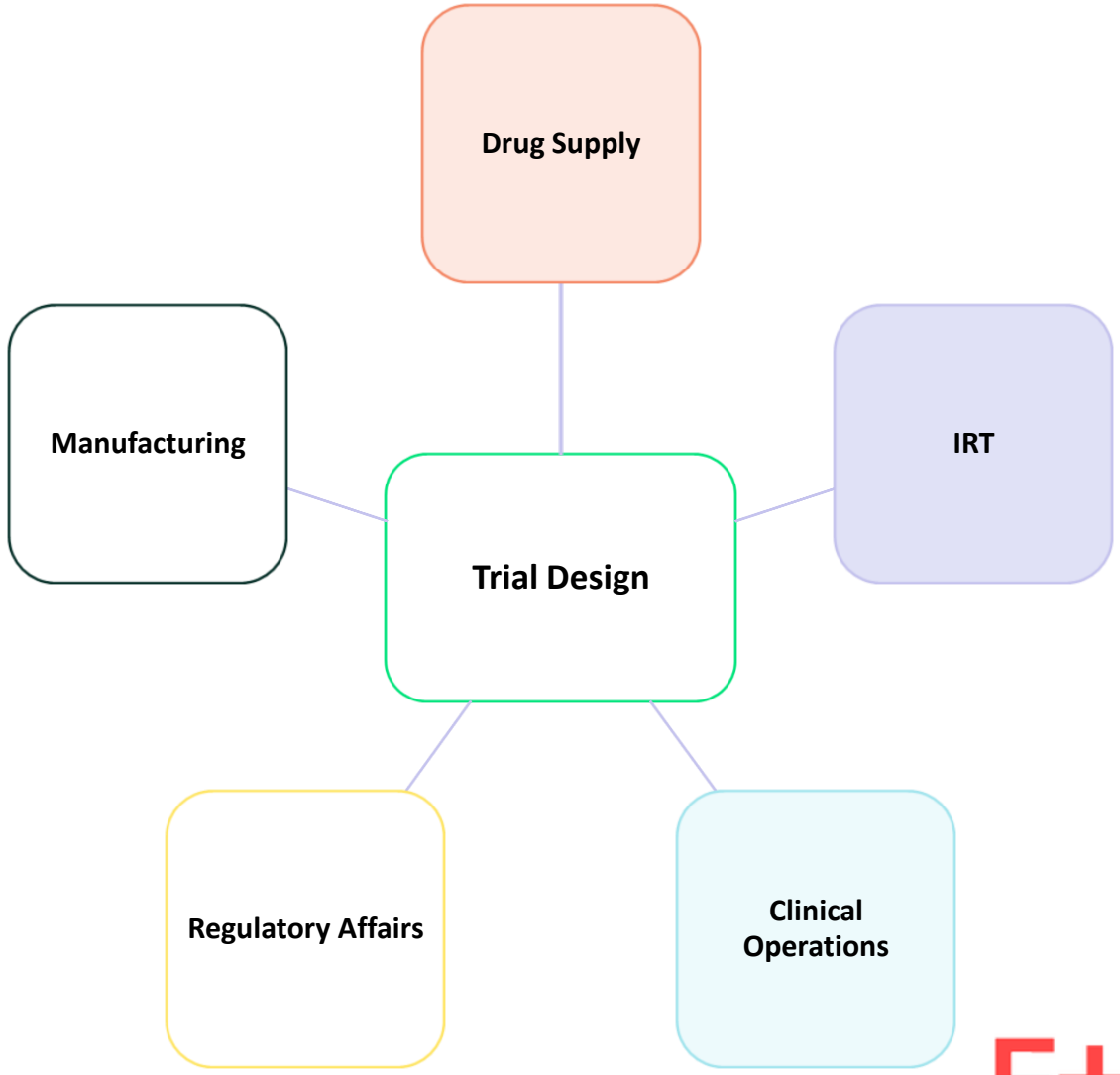
Statistical trial design as part of a BIGGER picture

Status quo

In a recent systematic literature review[1] of all published studies between 2010 and 2020, out of 1,263 screened trials, only 317 were adaptive in nature. Of those, it was found that only 8.5% of trials (27/317) reported using a seamless 2-3 design.

Statisticians often design innovative (adaptive) trials without fully understanding the impact of such designs on other functions such as clinical operations, manufacturing, regulatory affairs, drug supply or IRT (Interactive Response Technology).

Deepening mutual understanding can help improve internal acceptance, adoption and ease implementation of such designs.



1: Adaptive designs in clinical trials: a systematic review-part I | BMC Medical Research Methodology | Springer Nature Link

Considerations of a seamless 2-3 design on Clinical Operations (*teaser*)

Clearly defined Phase 2 to Phase 3 transition criteria

Operational feasibility of amendments without enrollment halts, or minimized pauses in enrollment

Alignment between statistical assumptions and real-world site, patient, and system behavior

Forward planning for cumulative amendment burden (training, contracts, systems, TMF)

Early clarity on what must be learned now vs what can safely wait to reduce asset risk

Designing operational flexibility upfront to preserve strategic optionality as evidence evolves

Workstream Outputs

- **Manuscript:** End of 2026: Manuscript under preparation summarizing connectivity, and impact of implementation of seamless 2-3 design on operations, drug supply and IRT

- **Organizational Cross-functional upskilling resource:** The manuscript (and the associated research) will be used to generate contain focused content summaries which will improve biostatisticians' cross-functional understanding within their organizations.

- **Public Education and Awareness:** Ongoing including conference presentations and webinars

Monitoring and Data Quality

EFFICIENCY+

Dynamic Trial Monitoring & Data Quality

Workstream update for ASA BIOP webinar

High-level awareness for cross-pharma audience

Palanikumar Ravindran, BMS
Workstream lead | 8-minute update

Suggested framing: move from reactive issue-finding to proactive, risk-based trial oversight.

Core question

Which operational metrics and AI/ML techniques can reliably detect emerging risk during trial conduct — and how should organizations respond?

Why now?

Global trials are more complex, dispersed, and data-rich.
Regulatory direction increasingly emphasizes risk-based quality management.
The practical gap is less “how to detect” and more “what to do next.”

Audience takeaway: a practical operating model, not just methods.

Main subtopics to cover

Study-level QTLs

Systemic quality oversight using pre-specified parameters / acceptable ranges.

Site-level KRIs

Operational risk signals such as AE reporting, queries, screen failures, enrollment, retention.

Patient/site anomaly detection

Data-driven statistical monitoring for unexpected patterns, misconduct, sloppiness, or systematic error.

AI/ML decision support

Predict dropout, monitor event accrual and enrollment, summarize issue narratives, support triage.

Signal-to-action pathways

Triage, investigation, CAPA/escalation, and documentation with named functional ownership.

Cross-functional governance

Statistics, clinical ops, data management, medical, monitoring and quality aligned in a regular forum.

2 | Proposed “detect → investigate → act → learn” framework

Three monitoring tiers, one governed response model

Study level	**QTLs / acceptable ranges**	Systemic quality issues; governance and CSR documentation
Site level	**KRIs and risk scores**	Operational risk patterns; CRA / central monitoring triage
Site + patient level	**Anomaly detection / CSM**	Unexpected clinical-data patterns; specialized review and cross-functional investigation

Key message: risk signals are hypotheses — action should be timely, documented, and proportionate.

Suggested 8-minute narrative

Past → Current → Next

Activities completed / underway

Cross-company subgroup formed and meeting cadence established
Literature / invited talk review
White paper draft structured around methods + operating model
Industry benchmarking and examples gathered

Ongoing research themes

QTL/KRI calibration and probability-funnel methods
Anomaly detection and Data Inconsistency Score approaches
Predictive dropout, event monitoring, enrollment forecasting
Human-in-the-loop AI/ML and agentic AI for signal triage

Planned deliverables

ASA BIOP webinar awareness deck
White paper / journal article contribution
Shared simulation engine inputs for stress testing thresholds
Practical framework for signal review, escalation, and documentation

Takeaway for industry audience: standardize the bridge between statistical detection and operational response — with AI/ML as governed decision support.

Clinical Supply

Christi Kleoudis, AstraZeneca

Efficiency+ Scientific Working Group

- Senior Director of Biostatistics
- Supporting regulatory submissions in GI, HIV, and autoimmune diseases for 40 years
- Driving process change to accelerate submissions while maintaining study integrity and quality
- Providing key support to RTSM functionality
- Leading the Clinical Trials Supplies workstream

Clinical Trials Supplies Modeling

Presenter: Christi Kleoudis, AstraZeneca

Subteam Members:

- Fei Chen, J&J
- Cunyi Wang, J&J
- Guohui Wu, Regeneron
- CG Wang, Regeneron
- Vlad Anisimov, Amgen
- Kaifeng Lu, Beonemed
- Allison Gray, J&J

Beyond Drug Minimization

- Not just about drug minimization
- Model drug waste, drug & shipping costs, and stockout probability based on weighted importance
- Modules to model
  - Manufacturing & labeling
  - Flow to drug depots
  - Flow to sites

- Design aspects to consider
  - Stratified, adaptive, multiple doses, titration, enrollment caps

Modules

Manufacturing & labeling

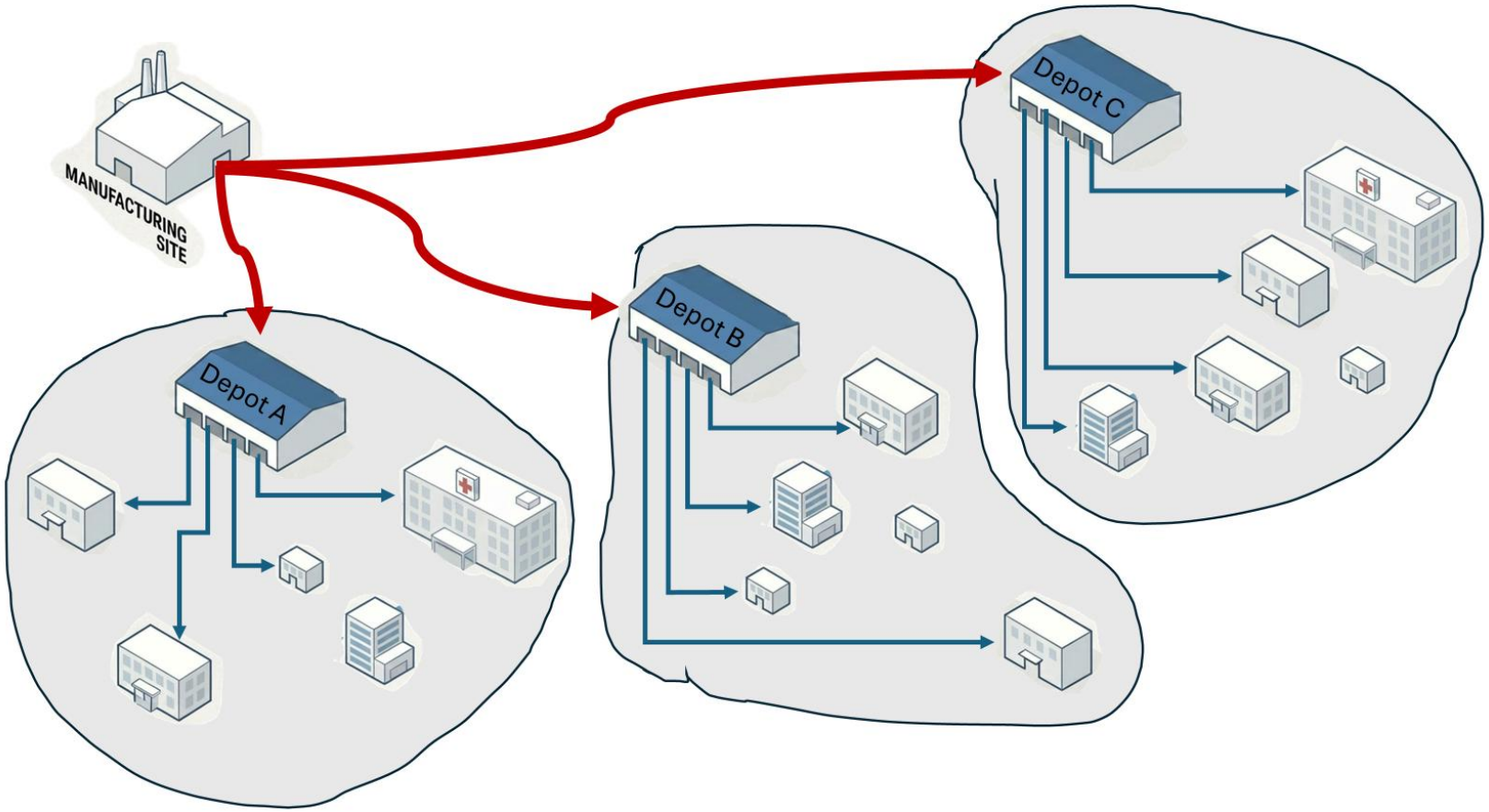
- Batch quantity manufactured
- # Depots
- Languages
- Shelf Life

Drug depots

- Customs lead time
- Countries/languages covered
- Shelf-life requirements
- Regional recruitment projections

Sites

- Shipment lead time
- Site recruitment projections
- Proportion randomized to each treatment
- Withdrawal rate

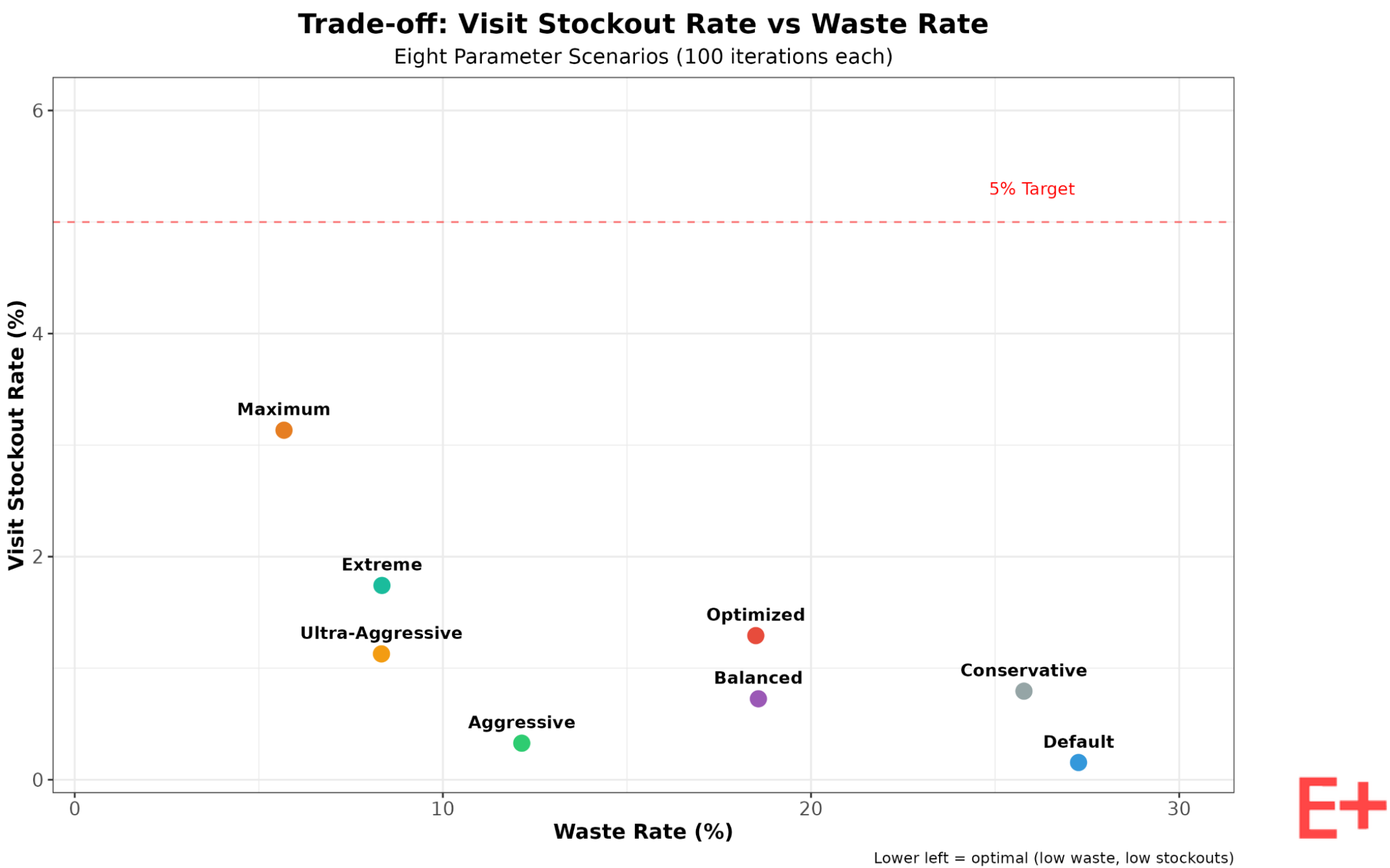


Process

- Capture specifications for logistics and assumptions
- Determine how to weight importance of optimizing drug wastage, costs, and stock out
- Use AI to create a simulation plan
- Conduct interactive simulations until all modules are complete
- Perform sensitivity analyses to check simulation logic
- Model against the outcomes: drug wastage, stock out
- Verify code generated by AI

AI-generated Simulation Code Generated from Trial Specifications

```r
############################################################
PARAM <- list(
  # ---------- Global simulation controls ----------
  seed                    = 20260206,
  seed_mode               = "fixed",      # "fixed" or "random"
  sim_horizon_days        = 2 * 365 + 120,
  day0                    = 0,
  verbose                 = FALSE,

  # ---------- Network structure ----------
  n_sites_eu              = 13,
  n_sites_cn              = 10,

  # ---------- Patient targets ----------
  n_patients_total        = 250,
  n_patients_eu           = 100,
  n_patients_cn           = 150,

  # ---------- BW strata distribution ----------
  p_bw_lt90_eu            = 0.70,
  p_bw_lt90_cn            = 0.80,

  # ---------- Recruitment model (Gamma-Poisson per site) ----------
  enroll_gamma_shape      = 2.0,
  enroll_gamma_rate   = 40.0,

  # ---------- Pre-position for FUTURE enrollments (dynamic pairwise A/B) ----------
  preposition_enabled                 = TRUE,   # Only active before global enrollment completes
  preposition_pair_kit_type           = "5ml",  # Kit type to pre-position pairwise (default weekly kit)
  preposition_cover_months            = 1.0,    # Target pairs = monthly enrollment forecast * cover_months
  preposition_pairs_rounding          = "ceil", # Rounding for target pairs: ceil/round/floor
  preposition_starter_horizon_days    = 14,     # Starter horizon (days) to derive units per arm per pair
  preposition_min_pairs               = 0L,     # Lower bound on pairs
  preposition_max_pairs               = Inf,    # Upper bound on pairs (use Inf if not needed)
```


Trade-off: Visit Stockout Rate vs Waste Rate
Eight Parameter Scenarios (100 iterations each)
Visit Stockout Rate (%)
Waste Rate (%)
0
2
4
6
0
10
20
30
5% Target
Maximum
Extreme
Ultra-Aggressive
Aggressive
Optimized
Balanced
Conservative
Default
Lower left = optimal (low waste, low stockouts)

Next Steps

Short term

- Add Costs to model
- Verify manufacturing, depot, and site modules from simulation plan
- Test against multiple designs
- Generate simulation code automatically from specification

Long term

- Dynamic modeling using real enrollment data to update drug flow throughout the study

Reading Group

Guohui Wu, Regeneron

Bio:

Guohui is currently Director of Biostatistics at Regeneron, with over 12 years of industry experience in statistical methodology, software development, and clinical trial design and analysis. His work focuses on applying rigorous statistical thinking and data-driven approaches to improve the execution of clinical trials.

Patient Recruitment Monitoring & Forecasting, Site Selection

Vlad Anisimov

Amgen

Modern technologies for forecasting and optimizing clinical trials operations

Fei Chen

Johnson & Johnson

Practical topics in enrollment monitoring

Clara Cali Mella & Tobias Straubinger

Bayer

An operations lens: how we work at clinical trials feasibility

Guohui Wu

Regeneron

Poisson-Gamma model for clinical trial enrollment

Qian Meng

Servier

Dynamic prediction tool for patient enrollment using hierarchical semi-parametric Bayesian modeling

Dynamic Trial Monitoring / Data Quality

Bochao Jia

Eli Lilly

Analytics transforming clinical trial oversight

Inna Perevozskaya

Bristol Myers Squibb

Methods in trial monitoring and operational excellence: an overview

Dan Beaudry

CluePoints

Modern approaches to centralized monitoring using CluePoints

Clinical Supply Chain

Christi Kleoudis

AstraZeneca

Clinical supply chain modeling and optimization

Kaifeng Lu

BeOne Medicines

Drug demand forecasting through statistical modeling and simulation

Guohui Wu

Regeneron

Clinical drug supply modeling: a review of tools

Study Design and Operations Impact

Su Chen

AbbVie

Treatment-control comparisons in platform trials: leveraging nonconcurrent controls

AI & Other Topics

Jimeng Sun

Keiji AI

Reimagining clinical trials with AI agents

Xikun Wu

BeOne Medicines

Statistics in preclinical research and CMC

Yanxun Xu

Johns Hopkins University

Statistics in the age of generative AI: reconstructing, resolving, and synthesizing clinical evidence

Communications

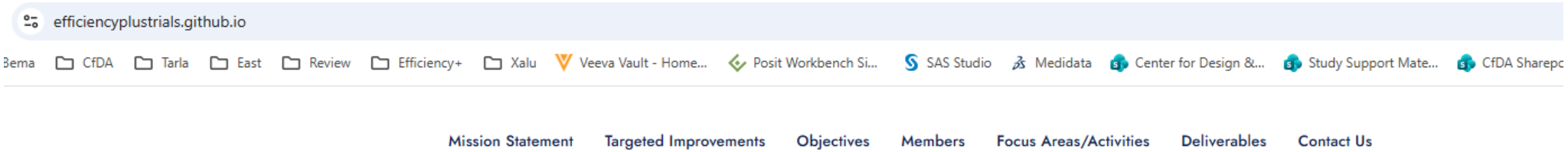
Communications Team

Leanne Goldstein, Amgen

- Biostatistics Manager
- Study Lead Statistician for Oncology Phase 1/2 trials
- UCLA School of Public Health, Biostatistics DrPH

Crystal Shaw, Amgen

- Biostatistics Manager
- Study Lead Statistician for Oncology Phase 1-3 trials
- UCLA School of Public Health, Biostatistics PhD

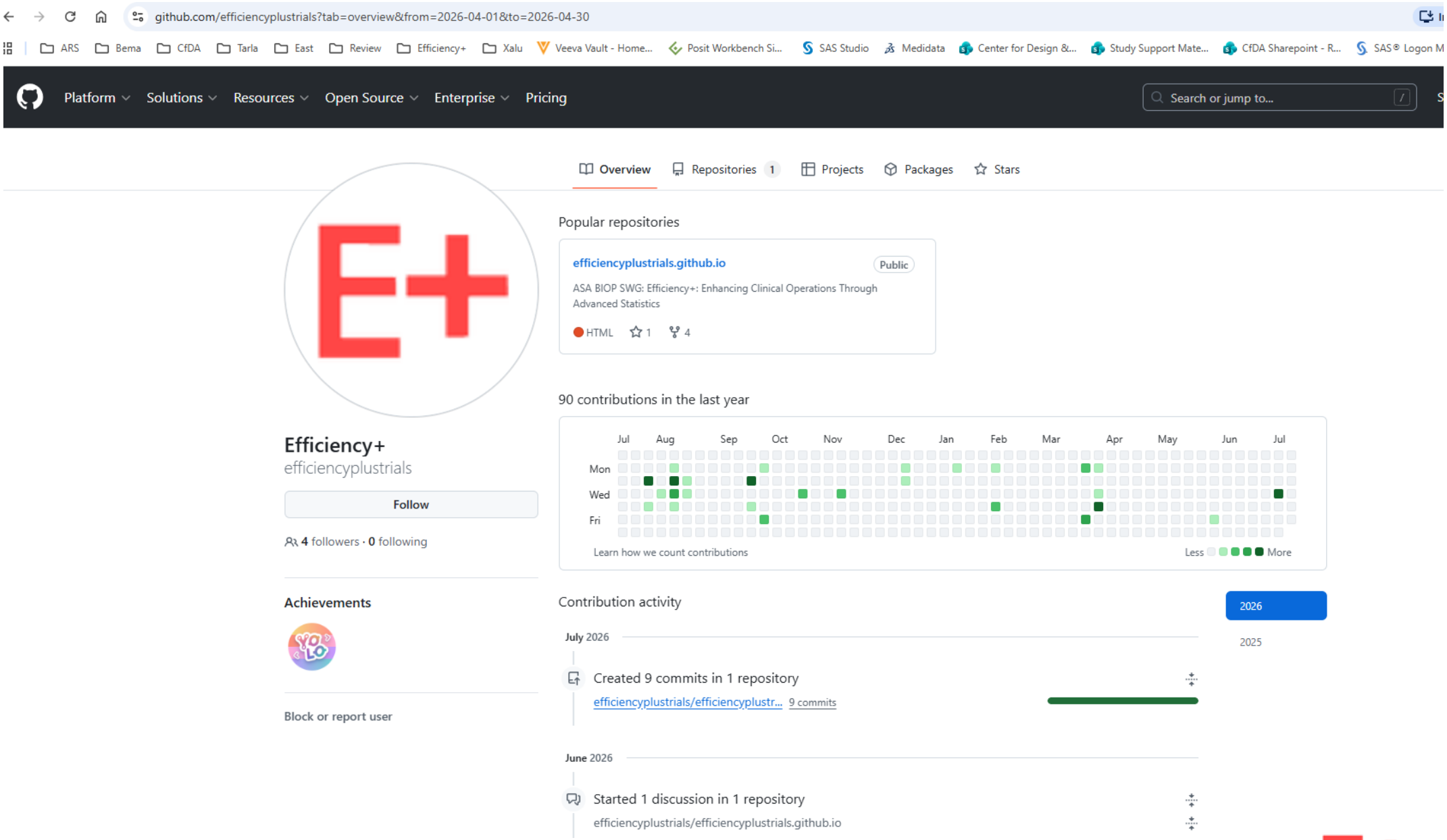


EFFICIENCY+:
Enhancing Clinical Trial Operations through **Advanced Statistics**

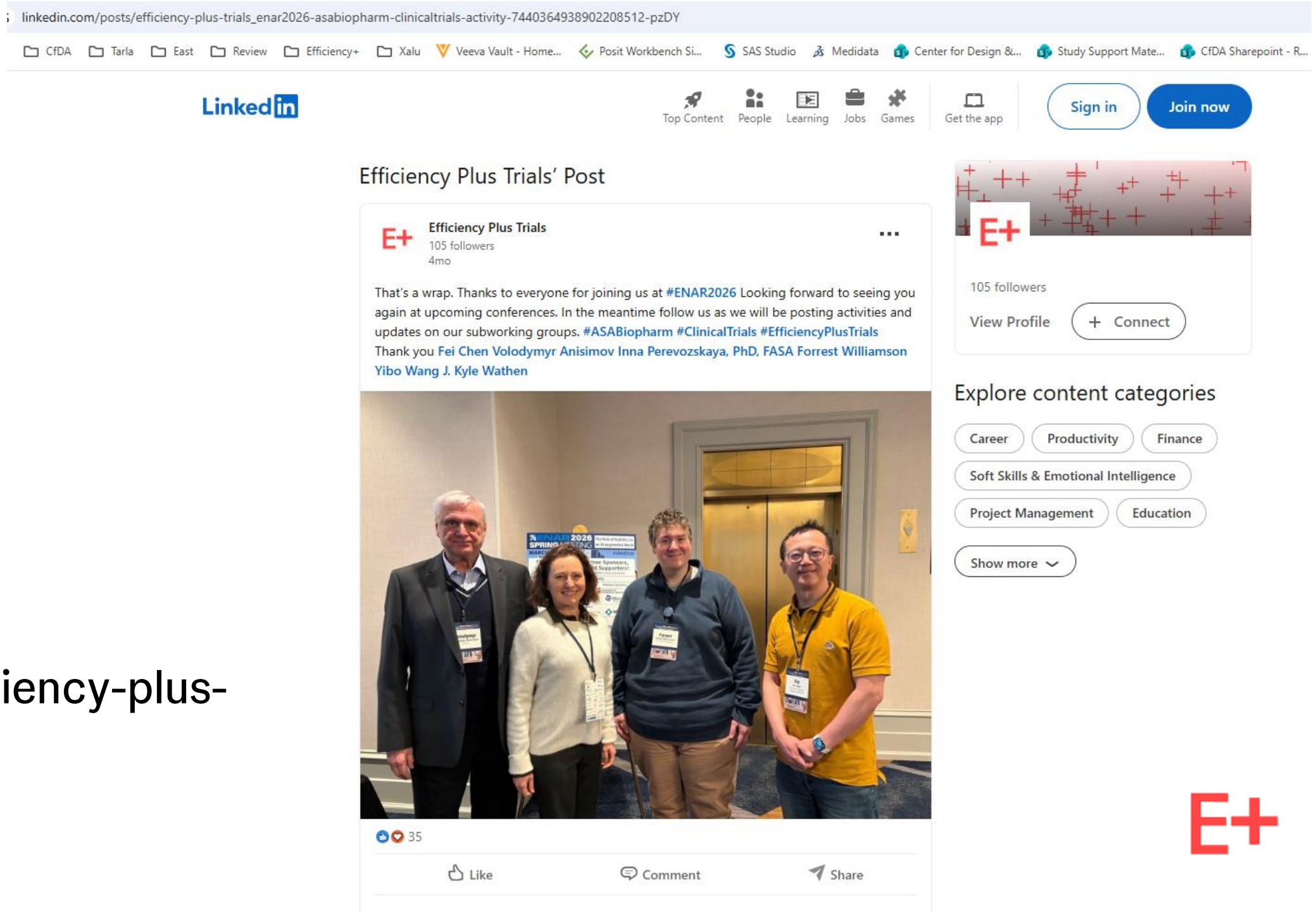
https://efficiencyplustrials.github.io

Mission Statement

Our mission is to advance clinical trial operations by championing cross-pharma and cross-functional collaborative research and driving statistical innovations. We are dedicated to fostering interdisciplinary progress in trial design and execution, ensuring the highest standards of study conduct. We will actively share insights, experiences, and identify gaps observed across the pharma industry to learn from one another, adopt best practices, and collectively improve clinical trial execution. Through these efforts, we aim to best represent label claims, optimize efficiency, and reduce waste, ultimately impact the clinical development process.



https://github.com/efficiencyplustrials



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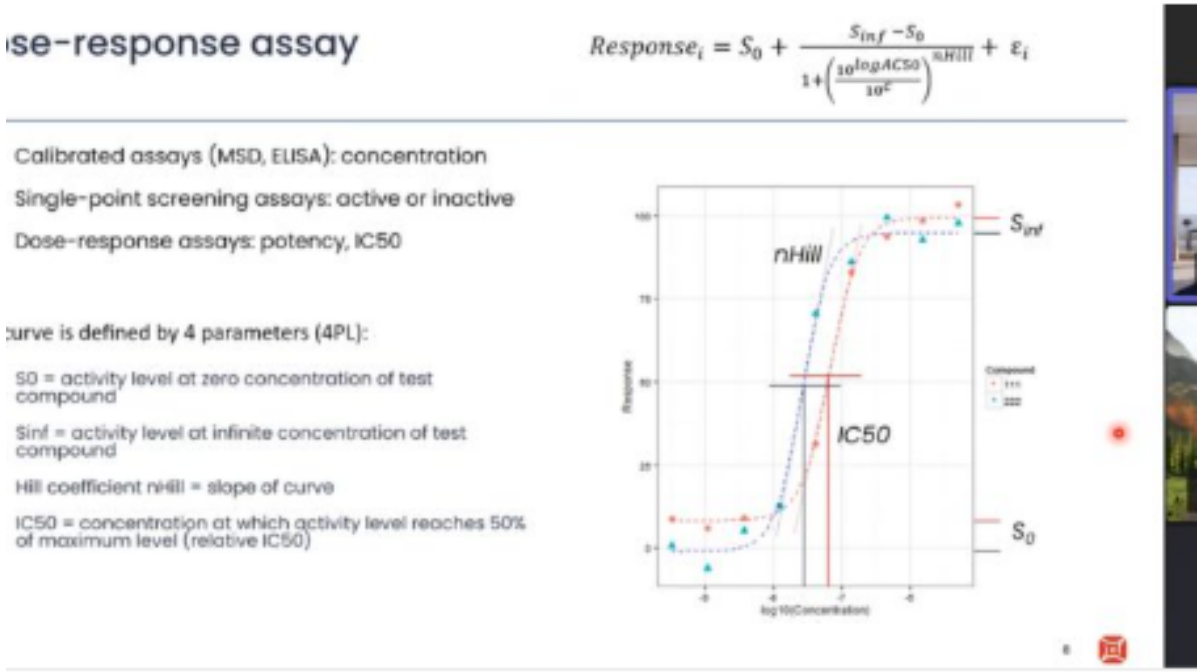
)id we miss you Monday? We had a great discussion with Xikun Wu , hoste
Guohui Wu on statistical analysis in #preclinical studies. We can't wait to h
ack to hear more about #CMC. Stay tuned for our next reading group on
Efiiciency in #ClinicalTrials. #EfficiencyPlusTrials #ASABiopharm



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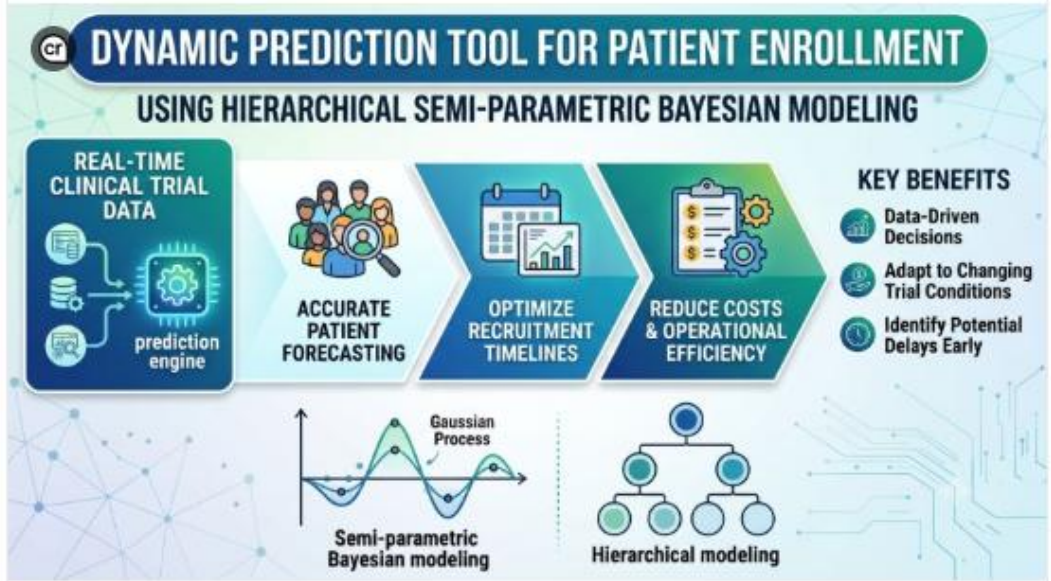
Join us next Monday July 20 at 10AM EDT for an exciting presentation and discussion on Dynamic Prediction Tool for Patient Enrollment Using Hierarchical Semi-parametric Bayesian Modeling by Qian Meng, facilitated by Guohui Wu. Send a message or leave a comment to get the link. Join us!



2

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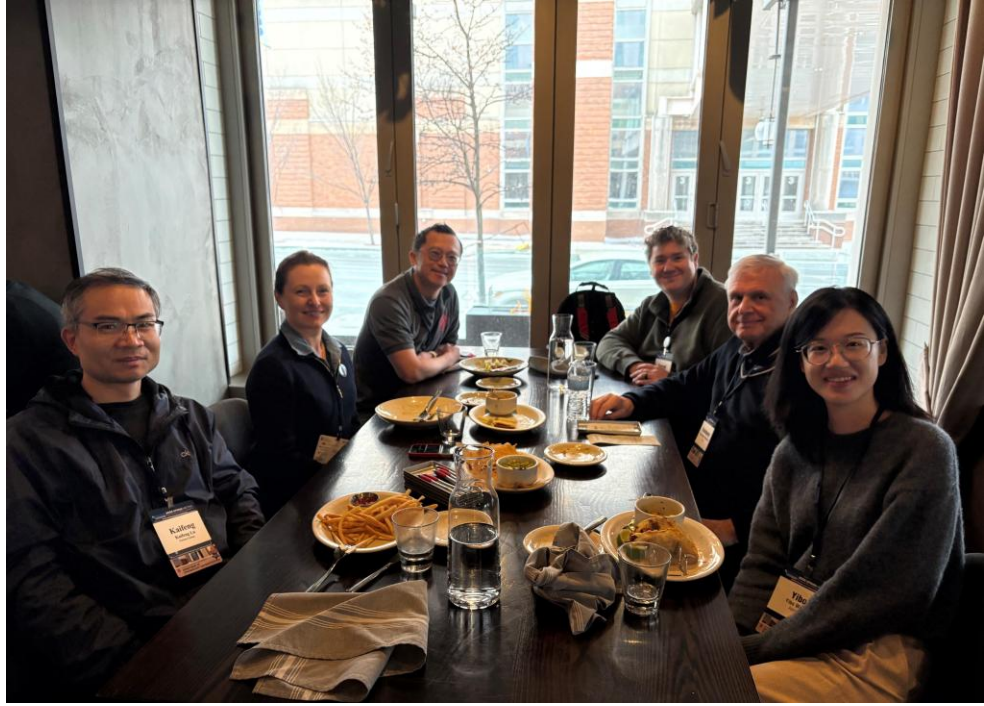

Kailong


Enhancing Clinical Trial Efficiency through Statistics, AI, and Collaborative Innovation
Organizer: Fei Chen, JJIM
Chair: Kyle Wathen, Cytel
Speakers:
Inna Perevozskaya, BMS
Vlad Anisimov, Amgen
Forrest Williamson, Eli Lilly
Yibo Wang, Abbvie
Johnson&Johnson
Innovative Medicine

Efficiency Plus Trials ASA Working Group Presents

Session 110. Enhancing Clinical Trial Efficiency through Statistics, AI, and Collaborative Innovation

Speaker: Inna Perevozskaya
Bristol Myers Squibb

Speaker: Vlad Anisimov
Amgen

Speaker: Yibo Wang
Abbvie

Speaker: Forrest Williamson
Eli Lilly

Chair: Kyle Wathen
Cytel

Organizer: Fei Chen
Johnson & Johnson Innovative Medicine

Wednesday, March 18th
8:30 AM – 10:15 AM
Indiana Ballroom C-D

Efficiency Plus Trials ASA Working Group Presents
Session OP.02. Clinical Trial Operations and Safety Signal Detection

Speaker: Vlad Anisimov
Amgen

Organizer: Fei Chen
Johnson & Johnson Innovative Medicine

Speaker: Nicolas Sauvageot
Johnson & Johnson Innovative Medicine

Speaker: Kyle Wathen
Cytel

Speaker: Cunyi Wang
Johnson & Johnson

Monday, July 14th
10:45 AM – 12:15 AM
Room 401D

THE ASA BIOPHARMACEUTICAL SECTION

REGULATORY-INDUSTRY STATISTICS WORKSHOP

September 16–18, 2026 • Rockville, MD

Impactful Transdisciplinary Decision-Making in the Evolving Digital Era

COMMUNITIES IN ACTION: ADVANCING SOCIETY

JSM2026

BOSTON, MA • AUGUST 1–6

CAMBRIDGE HEALTHTECH INSTITUTE'S 9TH ANNUAL

SCOPE EUROPE

POWERING THE FUTURE OF CLINICAL RESEARCH

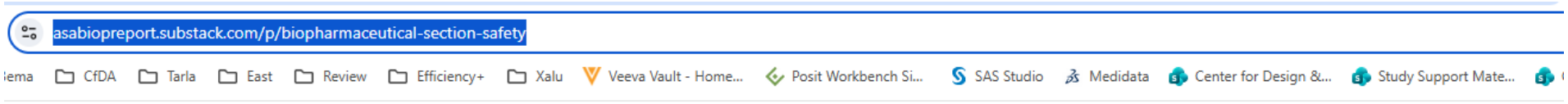
13-14 OCTOBER 2026 | InterContinental Barcelona (Fira Center) Barcelona, Spain

Pre-Conference Workshops and ***Capital & Innovation*** at SCOPE Europe on 12 October

E+

2026-2027 roadmap

- **Special journal issue** — white papers from each workstream
- **Expanded simulation tools** — dashboards, scenario optimization
- **Cross-SWG collaboration** — Safety, Bayesian, Software Engineering
- **Regulatory engagement** — FDA, EMA alignment with ICH E6(R3)



Biopharmaceutical Section Safety Working Group: Accomplishments and Recent Developments

Lothar Tremmel (CSL Behring), Jürgen Kübler (QSciCon), Tarek Hammad (Takeda)

ASA BIOPHARMACEUTICAL REPORT
MAY 09, 2025

A brief History: The ASA Biopharmaceutical Safety Working Group was formed in 2014, which began as a working group supporting "Safety Strategies and Analysis". This led to the creation of the Safety Monitoring Working Group in the Fall of 2015 by founding co-chairs Olga Manchenko and Qi Jiang, followed by Judy Li and William Wang with a mission "to help empower the biostatistics community to better enable qualitative and quantitative safety monitoring". Their motivation was aptly summarized in an article by Judy Li et al (https://magazine.amstat.org/wp-content/uploads/2019/06/AMSTATJULY.pdf). In 2017, the group expanded into an interdisciplinary working group, with Jim Buchanan and Mengchun Li serving as non-statistical co-chairs and kept a strong focus on this aspect ever since.

Governance structure: This working group is governed by a system of rotating co-chairs, with one incoming, one resident, and one outgoing chair, each serving a three-year term. Current co-chairs are Tarek Hammad (incoming), Lothar Tremmel (resident), and Jürgen Kübler (outgoing). However, the real action happens within the

https://asabiopreport.substack.com/p/biopharmaceutical-section-safety

Summary

- Clinical trial operations are inefficient, costly, and largely **untouched by statistical methods** despite statistics being central to trial design and analysis.
- **Efficiency+** is an ASA BIOP Scientific Working Group formed to close this gap — cross-industry, cross-functional, and focused on actionable methods.
- **The opportunity is enormous.** Even small efficiency gains across the industry translate to faster, cheaper drug development — and ultimately, faster access to treatments for patients.

Join us

People we especially want:

Regulatory agency participants (FDA, EMA) — ensure methods align with evolving guidelines

Clinical trial operations professionals — ground our statistical work in operational reality

Statisticians and data scientists with experience in:

- Bayesian modeling
- AI/ML for clinical data
- Drug supply chain analytics
- Clinical trial simulation

How to get involved:

📧 efficiencyplustrials@gmail.com

🌐 efficiencyplustrials.github.io

💼 @efficiency-plus-trials on LinkedIn