General Meeting Agendas and Notes

Efficiency+ SWG

Outline

- Initial Kick-off <July 16, 2025>
- General Meeting <August 14, 2025>
- Workstream Topics

Efficiency+

Initial Kick-off <July 16, 2025>

Introduction

People

- Co-Chairs

Who	Where	Email	Interests
Fei Chen	JJIM	fchen6@its.jnj.com	Regulatory
Bohdana Ratitch	Bayer	bohdana.ratitch@bayer.com	Outreach

- Members

	Who	Where	Interests
1	Xin Wang	Abbvie	Site selection
2	Vlad Anisimov	Amgen	Methodology
3	Christi Kleoudis	AZ	
4	Gabriel Abreu	AZ	
5	Andrew Chen	Bayer	Site selection and assessment
6	Clara Cali Mella	Bayer	Recruitment monitoring
7	Tobias Straubinger	Bayer	Forecasting
8	Kaifeng Lu	Beonemed	Drug demand forecasting
9	Haoyu Wang	BMS	
10	Inna Perevozskaya	BMS	Methodology
11	Oleksandr Savenkov	BMS	
12	Palanikumar Ravindran	BMS	AI/ML/Viz
13	Zhuoxin Yu	BMS	AI/ML/Viz
14	Kyle Wathen	Cytel	Software
15	Robert Abugov	FDA	
16	Bhargava Reddy	JJIM	Operations
17	Forrest Williamson	Lilly	Pediatric
18	Jun Xing	Sanofi	

Efficiency+

Workstreams

- Literature review, gap analysis and case studies Outreach
- Organize invited sessions and short courses
- Methodology Forecast modeling Drug supply
- Regulatory Aspects
- Explore potential collaborations with other related SWGs
- Role of GenAI???

Conferences in Planning

BASS 2025 workshop

ENAR 2026 invited

IBC 2026 invited

Question Raised

How to facilitate communication between workstreams on different focus areas and promote collaboration

General Meeting <August 14, 2025>

Efficiency+

Attendance

	@	Who	Where	Interests
1		Xin Wang	Abbvie	Site selection
2		Vlad Anisimov	Amgen	Methodology
3		Christi Kleoudis	AZ	
4		Gabriel Abreu	AZ	
5		Andrew Chen	Bayer	Site selection and assessment
6	Y	Bohdana Ratitch	Bayer	Outreach
7		Clara Cali Mella	Bayer	Recruitment monitoring
8		Tobias Straubinger	Bayer	Forecasting
9		Kaifeng Lu	Beonemed	Drug demand forecasting
10		Haoyu Wang	BMS	
11		Inna Perevozskaya	BMS	Methodology
12		Oleksandr Savenkov	BMS	
13		Palanikumar Ravindran	BMS	AI/ML/Viz
14		Zhuoxin Yu	BMS	AI/ML/Viz
15		Kyle Wathen	Cytel	Software
16		Robert Abugov	FDA	
17		Bhargava Reddy	JJIM	Operations
18	Y	Fei Chen	JJIM	Regulatory
19		Forrest Williamson	Lilly	Pediatric
20		Jun Xing	Sanofi	
21		Benjamin Hofner	PEI	Group Advisor
22		Cristiana Mayer	JJ Vision	
23		Bochao Jia	Lilly	Site selection and assessment
24		Jessica Cannon-Hill	JJ Vision	

Member Changes

- - Bob Abugov, FDA
- + Benjamin Hofner, PEI
- + Cristiana Mayer, Jessica Cannon-Hill, JJ Vision
- + Bochao Jia, Lilly

Efficiency+

Potential EMA Leads from Bretz

- Kit Roes <kit.roes@radboudumc.nl>
- Frank Pétavy <frank.petavy@ema.europa.eu>

Group Advisor Role

Group Advisor Responsibilities (Minimal Time Commitment)

- Regulatory Guidance: Provide regulatory perspectives relevant to operations and promote applications of statistics and “design of operations” when appropriate.
- Ad Hoc Consultations: Participate in brief (e.g., quarterly) meeting(s) to share insights on regulatory trends or answer targeted questions from the group.
- Review Major Outputs: Review and comment on major deliverables (e.g., position statements, white papers) from a regulatory standpointlimited to essential feedback.
- Networking Connector: Recommend, if possible, other experts or resources for deep dives beyond the advisor’s scope or time constraints.
- Advisor role ideally requires no more than 1 hour/month on

Meeting Frequency

- Every two weeks to build a strong foundation of contents
- Slow down to once a month in 6-12 months
- Slow further once sub workstreams gain momentum

Conferences

RISW 2025

- Reserve a room for us on Wednesday (9/24) of the meeting: Santoro, Kathleen <kathleen@amstat.org>
- RISW co-chairs for 2025: Yingwen.dong@sanofi.com and Wanjie.sun@fda.hhs.gov

BASS 2025 workshop (November 2025 Savannah)

Anyone interested in presenting?

ENAR 2026 Indianapolis

- Kyle Wathen: Chair
- Inna Perevozskaya: Methods in Trial Monitoring and Operational Excellence: An Overview
- Vlad Anisimov: Advanced Data-Driven Statistical Technologies for Designing and Forecasting Clinical Trial Operations
- Forrest Williamson: Challenges of Pediatric Studies: Unlocking Opportunities for Operational Innovation
- Ziqian Geng: Complexities of Randomization Setup in Platform Trials: A Statistician’s Perspective

IBC 2026 Seoul

- Fei Chen: Efficiency+ Scientific Working Group
- Xun Chen: Data-Driven Decision Making: The Role of Statistical Modeling in Improving Clinical Trial Success
- Eun Young Suh : Operational Challenges and Lessons Learned in a Very Large Phase 3 Program
- Vlad Anisimov : Advanced Data-Driven Statistical Technologies for Designing and Forecasting Clinical Trial Operations
- Palanikumar Ravindran : Integrating GenAI-Enabled Machine Learning Models for Optimization of Clinical Trial Operations and Success Metrics
- Kyle Wathen : Emerging Software Tools for Planning and

Other Conferences To Do

- MBSW 2026
- JSM 2026 SWG working session?
  - Contact chair Steve Novick (steven.novick@takeda.com) in March 2026
- RISW 2026
- PSI 2026
  - Central Monitoring SWG

Operations Focused Conferences?

Society for Clinical Trials (SCT) Annual Meeting	Clinical trial design, implementation	Oct 2026
Clinical Trials Methodology Conference	Advanced clinical trial design, methodology	Feb 2026
Conference on Statistical Practice (CSP)	Practical statistical approaches in pharma trials	Sept 2025

Teams and Github

Teams chat works?

Media

Web

https://efficiencyplustrials.github.io

Linkedin

https://www.linkedin.com/groups/13353006/

X

@efficiencyplus

Collaboration with Other SWGs

- Centralized Statistical Monitoring and Quality Tolerance Limits
  - Cannot find any information

Notes

Workstream Topics

- Please enter ONE key question that would be most important for you to address under the focus area that you would like to contribute to.

Site selection and performance modeling using data-driven approaches

- Bohdana Ratitch: Which predictive analytics and ML approaches are the most suitable and effective for data-driven site performance modeling?
- Palani Ravindran:
  - How do data privacy or access limitations impact the effectiveness of above?
  - How to use RWD or external data sources to identify additional sites
- Zhuoxin Yu: What public available data or commercially available database could be leveraged to select sites, investigators, and study committee members? How to utilize these data?

Recruitment monitoring and forecasting: best practices and tools

- Haoyu Wang: How best to predict enrollment given too slow/too fast scenarios are not uncommon at all?
- Tobias Straubinger: What are the best-suited models for recruitment, which parameters improve the model and how can historic trial performance be used for future trial performance forecasting?
- Fei Chen: How to mix different sources of information in to the forecast, with what weight? Sources of information include: actuals, historical projections on sites, expecations of local teams, baseline plan
- Bochao Jia: We may need to differentiate the screening projection, enrollment (randomization projection) and the projection of time for enrollment completion may be more

Forecasting and cost-efficient designing restricted recruitment in clinical trials

- Vlad Anisimov: Including using restrictions on recruitment in countries/regions as country caps or subject minimum and optimal enrollment design

Study design and its impact on operations

- Haoyu Wang: How to further facilitate/simplify/remove hurdles when implementing innovative designs (e.g., inferential seamless) given current operational challenges/complexities?
- Forrest Williamson:

Efficiency+

Operational efficiencies in non-traditional trial settings (e.g., DCTs, PCTs)

- Jun Xing: How can we design and implement decentralized, pragmatic, and observational trials in a way that optimally balances operational feasibility, gap between trail design assumptions between efficacy and effectiveness, and struggle to maintain high data quality, while aligning with real-world clinical practice?

Ensuring representativeness of trial populations and generalizability

- Bohdana Ratitch: How to dynamically monitor characteristics of participants enrolled in a clinical trial with respect to the key characteristics of the target population and provide site enrollment targets for an ongoing trial to meet population representativeness objectives?

Clinical drug supply optimization

- Kaifeng Lu: Improving drug supply assumptions and forecasts by providing more accurate discontinuation/loss-to-follow up/skipping-visit modeling
- Fei Chen: Overview of 4C and other drug demand forecast software and workflows and provide practical guidelines on how to engage stakeholders to improve their workflow
- Fei Chen: simulation based platform for 4C + OMP
- Fei Chen: how to demonstrate value of statistics: retroactively using existing supply software like 4c counter-factual outcomes through simulation

Efficiency+

Dynamic Trial Monitoring & Adaptive Operations

- Palani Ravindran: Which operational metrics and AI/ML techniques are most predictive and reliable for emerging risks in ongoing clinical trials (e.g., site/patient anomalies, protocol deviations)?
- Zhuoxin Yu: How to better predict and monitor events and dropouts, both at study level and at region/site level?

Regulatory perspectives

- Fei Chen: push regulatory to promote rigorous operational planning into study design
  - ICH E20 Adaptive Design
    - 5.6:855 Operational Considerations
      - Use of an adaptive design can add challenges to the operational execution of a clinical trial and these should be addressed at the trial planning stage.
    - Propose to add the following paragraph to section

Adaptations in clinical trials inherently introduce unpredictable demands on drug supply, potentially causing

Efficiency+

delays that adversely impact trial timelines. This challenge presents a significant opportunity to underscore the crucial role of operational planning in adaptive design strategies. An enhanced focus should be placed on thoroughly assessing the operational characteristics—specifically examining the impacts of adaptations on drug supply, randomization processes, data quality, and considerations for Multi-Regional Clinical Trials (MRCT), Decentralized Clinical Trials (DCT) and Pragmatic Clinical Trials (PCT). When evaluating the benefits and drawbacks of adaptive designs in contrast to traditional approaches, these operational aspects are pivotal. Moreover, the introduction of a 'design for adaptive operations' should be championed, ensuring that operational planning is as rigorously conceived as the statistical methods detailed in this

guidance document. Doing so will help align operational strategies with statistical rigor to optimize trial efficiency and mitigate risks associated with supply fluctuations and other operational challenges.

Stakeholder engagement

- Fei Chen: How to effectively engage and collaborate across different operational teams and functions (e.g. clinical supply chain vs trial delivery & execution), convince stake holders to embrace change and overcome territorial issues
- Fei Chen: how to demonstrate value through retrospective counter-factual analysis based on existing workflow?

Efficiency+

Strategic data collection and analysis planning for alignment with Target Product Profile

- Zhuoxin Yu: What is the best blood sample collection strategy for PK, ADA, biomarkers, to reduce the total amount of blood needed from patients while maintain the quality of data analyses.

Efficiency+

Please enter a new focus area if the above list does not represent your key interests

Patient engagement: and best practices for evaluating participant satisfaction

Analysis implementation efficiency

=====

Please enter a new focus area if the above list does not represent your key interests

- Patient engagement: and best practices for evaluating participant satisfaction
- Analysis implementation efficiency