



**Li Chen**  
Amgen

Moderator



**Fanni Natanegara**  
Eli Lilly

Panelist



**Janet Wittes**  
Wittes LLC

Panelist



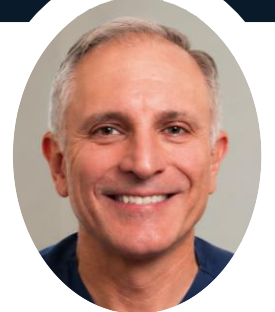
**Kun He**  
Independent  
Consultant

Panelist



**Lei Nie**  
FDA

Panelist



**Roger Lewis**  
UCLA and Berry  
Consultants

Panelist

SCT 47<sup>th</sup> Annual Meeting

***Data Monitoring Committees –***

***Advancing Best Practices and Developing Next Generation Experts***

*May 19, 2026, 10:00 – 11:30 am*

# Agenda

- Opening Remarks
- Panelist Introductions
- Moderated Panel Discussion
- Open Floor / Questions from the Audience
- Closing Remarks

# Panelist Introduction

- Fanni Natanegara, PhD (Eli Lilly)
- Janet Wittes, PhD (Wittes LLC)
- Kun He, PhD (Independent Consultant, formerly FDA)
- Lei Nie, PhD (FDA)
- Roger Lewis, MD, PhD (UCLA; Berry Consultants)

# BSLC DMC Workstream Introduction

To meet the increasing demand of DMCs in clinical trials

- Synthesize current best practices and evolving regulatory guidance
- Establish industry consensus positions that promote consistency and clarity across sponsors while preserving DMC independence
- Create sustainable infrastructure for cultivating the next generation DMC experts

Collaboration across academic, industry, government sectors, professional societies, and DMC members

# Key Questions

- **What** gaps remain in current DMC practices and guidance?
- **How** can we better prepare the next generation of DMC members and reporting statisticians?
- **Where** can industry, regulators, and academia collaborate more effectively?

# Panel Discussion Topics – Best Practices

- Communication from DMC to sponsor around efficacy interim boundary
- Transparency around clinical trial efficacy data provision to DMC during safety monitoring
- Guiding principles to minimize DMC's conflict of interest
- Evolving nature of DMC reports and involvement of key stakeholders in the process to plan and execute
- Key areas where industry DMC practices could be strengthened from regulatory perspective

# Panel Discussion Topics – Next Generation Experts

- More curated DMC training curricula, including development of core competency frameworks, through close collaboration with cross-sector stakeholders and professional societies
- Strategies to strengthen and diversify the DMC talent pipeline, including earlier identification, mentorship, and development of promising future DMC members and reporting statisticians

# Audience Q&A

# Closing Remarks

The future of effective and trusted DMC oversight depends on our **collective** ability to **bridge** current gaps, **strengthen** collaboration, and **invest** in developing the next generation of experts