



PRE-MEETING WORKSHOP

EARLY-STAGE
CLINICAL DEVELOPMENT:
WHAT YOU NEED TO KNOW
MAY 15, 2022



EARLY-STAGE CLINICAL DEVELOPMENT: WHAT YOU NEED TO KNOW

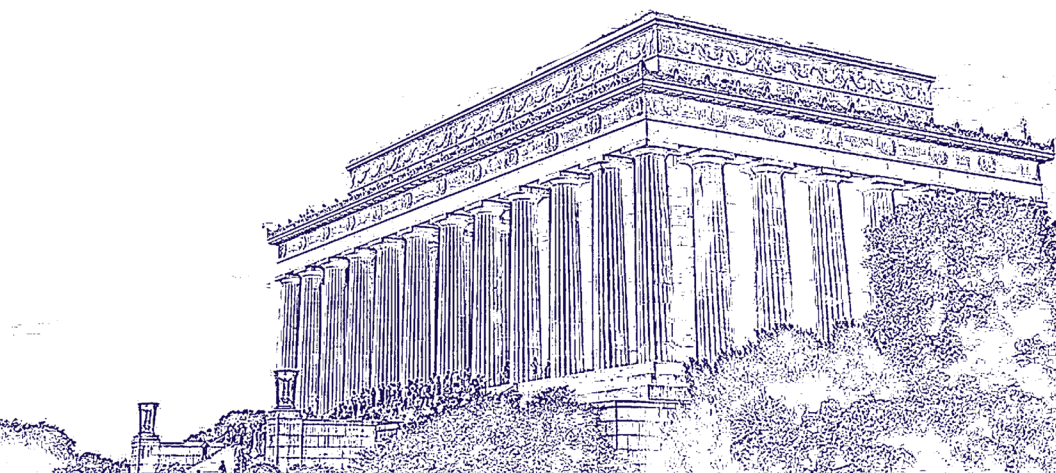
SUNDAY, MAY 15, 2022

All times listed below ET

Co-chairs: Angela Whatley, PhD, BridgeBio
Debasish Roychowdhury, MD, Partner Therapeutics

Description

In this workshop, experienced panelists will highlight how academic investigators may successfully transition from pre-clinical to clinical development. Topics will include developing a target product profile (TPP) and considering nonclinical, clinical, and CMC aspects of a development program. Additionally, the program will address breaking into the clinical trial space and partnering with biotechnology companies and CDMOs.





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Schedule

All times listed below ET

1:00–2:45 PM

Session 1 Clinical and CMC Preparations

**Defining the Issues: How Early Development Decisions
Impact Commercialization**

Katy Spink, PhD, Dark Horse Consulting

**Non-clinical Considerations in Early-stage Development: Animal Model
Selection, Assessing Animal Model Toxicity, Predictive Capability**

Larry Whiteley, DVM, PhD, Pfizer Inc.

Preparing Your CGT Clinical Protocol to Fit Your TPP

Rafael Amado, MD, Allogene Therapeutics

**CMC Considerations: Striking the Balance on Scalability, Readiness,
and Preparation in Early Development**

Mo Heidaran, PhD, GC Therapeutics

Panel Q&A

Moderated by: Angela Whatley, PhD, BridgeBio

Debasish Roychowdhury, MD, Partner Therapeutics

2:45–3:15 PM

Break

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3:15–5:00 PM

Session 2 How to Get Into Early-stage Drug Development

Overview of the Issues: How do People Learn About and Break Into the Field?

Peggy Sotiropoulou, PhD, T-Knife Therapeutics

Scope of the Problem: Developing a Skilled and Diverse Workforce

Richard McFarland, MD, PhD, Advanced Regenerative Manufacturing Institute

Partnerships, Innovative Employment Models, and Attracting and Retaining Talent

Julia Chapman, BridgeBio

CDMO Insider: Career Opportunities, Scaling Up Your Product and Understanding Lab-grade Versus Commercial-grade Products

Bruce Thompson, PhD, Resilience

Panel Q&A

Moderated by: Angela Whatley, PhD, BridgeBio

Debasish Roychowdhury, MD, Partner Therapeutics