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.
**Schedule**

All times listed below ET

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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*

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2:45–3:15 PM

Break
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