PG26. Jump Start: A beginner’s guide to drug and company development in an academic setting

**Morning session**

An introduction to drug development in lung diseases - Academic perspective

- Challenges and excitement of commercializing ideas and drug candidates that result from basic research in an academic lab
- Pros and cons of engaging large corporate partners or forming a new start-up
- Pros and cons of enlisting venture capitalists in start-up formation

*Dean Sheppard, MD, Division Chief of Pulmonary, Critical Care, Allergy and Sleep and Director of the Lung Biology Center, UCSF and Scientific Founder of Pliant Therapeutics*

What’s mine is mine: promoting and protecting your IP during publication

- Understanding the initial steps to protect your IP during the public disclosure process
- Discussion of all IP steps as well as training programs (ICorps@NIH program)

*Nicholas Kenyon, MD/MA, Division Chief of Pulmonary, Critical Care, and Sleep Medicine, UC David Health and ICORPS leader*

The importance of target engagement studies in preclinical research

- Design of target engagement studies in academia vs pharma
- Importance and implementation of target engagement studies in preclinical research

*Lynne Murray, PhD, Respiratory, Inflammation, Autoimmunity IMED unit, AstraZeneca*

**Expert fireside chats: The future of pulmonary medicine**

- Discussion of innovative approaches for drug development in pulmonary medicine
- Examples of development of the most successful and innovative drugs for lung diseases
- An academic and industry perspective on challenges in drug development

*Silke Hobbie, PhD, Global Head of Business Development & Licensing, Respiratory, Boehringer Ingelheim*
Case based panel discussion – Taking the next steps after discovery

Building on earlier topics and discussions, this case-based panel discussion will be:

- Centered on the process of taking novel scientific discoveries from the bench to the bedside
- How academic basic scientists and clinical researchers can work with their own University resources
- How to work with outside investors and interested parties
- How to successfully advance novel discoveries into clinical development programs – at both established pharma/biotech and newly formed research companies

Robert Tarran, PhD, Professor, Department of Cell Biology & Physiology, University of North Carolina and CSO of Eldec Pharmaceuticals that develops anti-inflammatory peptides for the treatment of chronic lung disease

Alan H Cohen, MD Global Clinical Leader, Bayer U.S. LLC. board-certified Pediatric Pulmonologist (x38+ years) responsible for a number of early/translational, mid and late stage clinical development programs. As entrepreneur, he worked with numerous pre-IPO start-ups as well as with public companies worldwide (Aridis Pharma, Therabron Therapeutics, Boehringer Ingelheim, Intermune)

Moderator: Milica Vukmirovic, PhD, Michael DeGroote Innovation, Commercialization, and Entrepreneurship Fellow, McMaster University. She specialized in entrepreneurship in academia with focus on development of new therapies or devices in lung field. She is currently developing a new anti-fibrotic drug, thyroid hormone mimic to treat Idiopathic pulmonary fibrosis in collaboration with Dr Naftali Kaminski from Yale.

Introduction to pre-IND enabling studies and clinical trials

- Design and execution of pre-IND enabling studies in an academic setting
- Challenges of animal models and developing a pre-clinical package
- Developing trial protocols and working with Contract Research Organizations and regulatory agencies

Toby Maher, MD/PhD, Professor of Interstitial Lung Disease, NHL Institute, Imperial College, London
Power Lunch - Navigating and growing an academic startup

- A how-to discussion on spinning out and continuing to lead an academic-based startup company (foundation, funding, operations and conflict of interest management)
- A unique perspective on commercialization of University-based technologies that are translated to the clinic

Rama Mallampalli, MD, Professor and Chair, Department of Internal Medicine, Ohio State University College of Medicine. Dr Mallampalli serves as consultant and cofounder of Koutif, a startup company that has successfully acquired IND approval for a first-in-class oral E3 ligase compound for inflammatory lung disease.

Jason J Rose, MD/MBA, Assistant Professor of Medicine and Bioengineering, University of Pittsburgh School of Medicine, President, CEO, and co-Founder of Globin Solutions, Inc that develops a rapidly acting antidote for carbon monoxide poisoning, the most common human poisoning.

Afternoon session

Expert chats: Funding made easy

- Different paths to obtain funding by early stage companies before they are ready for VC
- Non-dilutive funding opportunities such as SBIR/STTR grants & University resources

Jacob S Brenner, MD/PhD, Assistant Professor, University of Pennsylvania’s Pulmonary, Allergy, & Critical Care Division and Founder of RightAir. He has started 3 funded medical device companies based on nanotechnologies for drug delivery and macro-scale medical devices.

Chelsea Magin, PhD, Assistant Professor, Division of Pulmonary Sciences and Critical Care Medicine, Departments of Medicine and Bioengineering, University of Colorado, Anschutz Medical Campus. Her laboratory engineers innovative biomaterials that model chronic pulmonary diseases and lung-tissue regeneration. Before returning to academia, Dr. Magin served as the Director of Product Development for Sharklet Technologies, Inc., a medical device start-up, where she contributed to the acquisition of over $15M in non-dilutive funding, including multi-phase SBIR awards. She continues to collaborate with Sharklet as both a research partner and consultant.

Moderator: S. Vamsee Raju, PhD, Assistant Professor at University of Alabama at Birmingham. Dr Raju is actively involved in translating patented small molecule discoveries emerging from his academic laboratory and serves on ATS- Drug/Device Discovery & Development Committee.
Lessons from venture capitalists – Do’s and don’ts when developing a new drug

- Demystify the world of venture capital
- Paths to secure venture capital funding
- What to expect when working with VC companies

David Morris MD, Operating Partner, Novartis Venture Fund and Chief Medical Officer of Enterprise Therapeutics. Previously he held multiple leadership positions in company development and clinical operation at Novartis and Roche.

6 min Presentations from 4 early stage drug development companies

1. Pneumax (Presenter: Kambez Benam, PhD, Assistant Professor, University of Colorado)

Dr. Benam is the Founder of Pneumax and will briefly present his journey on setting up this startup to develop and commercialize an advanced lung organomimetic which reproduces human airway pathophysiology, to accelerate preclinical translational studies in pulmonary space.

2. Fibronox (Presenter: Louise Hecker, PhD, Associate Professor, University of Arizona).

Dr. Hecker is the Founder and Chief Scientific Officer (CSO) of Fibronox. Dr. Hecker was the first to identify a novel target, Nox4, and its critical role in mediating fibrosis (scar tissue). She will provide an overview on her journey from target identification and validation and the pre-clinical development of small molecule inhibitors that selectively target Nox4. Fibronox is actively working to bring these inhibitors through the preclinical pipeline in order to reach patients, and ultimately to revolutionize treatments for fibrotic disease.

3. Pliant Therapeutics (Presenter: Scott Turner PhD, Vice President of Translational Science)

Pliant Therapeutics is a clinical stage biotechnology company in South San Francisco. Dr Turner will present an overview of the company and their approach to targeting integrins for the treatment of IPF.

4. Mediar Therapeutics (Presenter: David Lagares, PhD, Assistant Professor of Medicine at Harvard Medical School)

Dr Lagares is the Founder of Mediar Therapeutics. Seminal work from Dr Lagares’s laboratory includes the identification of the ADAM10-sEphrin-B2 pathway in lung fibrosis. During his talk, Dr Lagares will discuss his entrepreneurial journey that has led him to co-found Mediar Therapeutics, a biotech company developing innovative anti-fibrotic therapies targeting pathological mechanisms identified in Dr. Lagares’s research laboratory.
1H WORKSHOP – WORK IN GROUPS

Prepare 5min pitch slide deck to promote your key discoveries
Work with Mentors from postgraduate course
Present your pitch to postgraduate course participants and obtain feedback from experts