

MTR/REG 622: New Trends in Medicine and Vaccine Discovery

Fall 2024

Wednesdays, 3:30-6:30pm

Location: classroom 8030 on the 8th floor of Maloney, HUP

Course Director:

Name: Claudine Bruck, Ph.D.

Title: Co-Founder Prolifagen LLC, Former Vice-President, Ophthalmology Discovery Unit, GlaxoSmithKline

*syllabus is subject to change at professor's discretion

Description and desired results:

The purpose of this course is to provide an overview and points to consider of drug and vaccine discovery, with emphasis on:

- Technologies that empower drug and vaccine discovery.
- Newer treatment modalities beyond small molecule drugs
- Recent areas of progress: new vaccine technologies, rare diseases, immuno-oncology, precision medicine, biomarkers and diagnostics, artificial intelligence
- The regulations governing medicine discovery and development
- Business aspects, building start-up biotechs from academic research, the importance of intellectual property
- Pandemics by new pathogens in the context of drug and vaccine discovery
- Societal aspects, from affordability to healthcare company considerations to medicine pricing
- How leadership skills impact success in biotechnology

Students will be guided through these topics by a group of experts who will discuss their experience in the field. While learning this content, students will be taught to interrogate and interpret scientific literature as well as present a scientific topic to an audience. At the end of this course, students will have a broad view of the creative, regulatory and business-related aspects of modern medicine discovery and development and be primed to participate in this process.

Students will be evaluated by their performance in class discussions, case studies, virtual discussion threads, 2 presentations and an original paper requiring a literature search. Some basic knowledge in molecular biology is desirable at the start.

Most courses will be in person, with some speakers presenting remotely. **The 11/20 class will be entirely online.**

Please note that the 12/11 student presentation date is on a Penn reading day. Some students will have their presentation on that day.

Schedule of lectures, activities and speakers

DATE	THEME	SPEAKER(S)	ASSIGNMENTS	DESCRIPTION
SEPT 4	Introduction to Drug Development and Scientific Roles	<ul style="list-style-type: none"> •Rick Keenan PhD Pharmaceutical Consultant Former Vice President Chemistry, GlaxoSmithKline (GSK) •Claudine Bruck, PhD Chairman, Prolifagen LLC Former Vice President Ophthalmology TA, GSK 	Assignment: Vaccine technologies pre-read	Students will be led through the development of a class of diabetes medicines, learning about the different steps ultimately on the path to registration of a new medicine, from target discovery to preclinical and clinical development. The course uses a literature-based approach, teaching students to follow the development of new medicines based on scientific literature. The lecture will be followed by a discussion of the different scientific roles in this process.
SEP 11	HPV Vaccine Development	<ul style="list-style-type: none"> •Claudine Bruck, PhD •Gary Dubin, MD, PhD Senior Vice President and Head, Medical Affairs & Policy, Takeda Vaccines 	<p>Due: Vaccine technologies pre-read</p> <p>Assignment: Discussion Thread on CRISPR/Cas</p>	Students will learn the process of development of a novel vaccine, from preclinical to clinical development, by lecturers who were active players in this field
	In class Case Study			
SEP 18	Artificial Intelligence in Drug Development & AI search engines as a resource	<ul style="list-style-type: none"> •Claudine Bruck, PhD •Pankaj Agarwal, PhD Chief Computational Biologist, BioInfi 	Due: Discussion Thread on CRISPR/Cas	<p>Value of AI and big data in drug discovery:</p> <ol style="list-style-type: none"> 1. Discuss the terms and technologies behind AI and big data 2. Present and discuss recently published examples of AI's impact in drug discovery. 3. Discuss how to evaluate scientific papers and claims based on AI. <p>Goals: be conversant with AI terminology, learn to effectively use AI search tools while developing a critical appreciation of the strengths and weaknesses of the claims based on AI methods.</p>

SEP 25	Gene Therapy; Rare Diseases; Cell Therapies and Regenerative Medicine	<ul style="list-style-type: none"> •Claudine Bruck, PhD • Karen Kozarsky, PhD Founder and CSO SwanBio •Carlo Russo, MD Chief Medical Officer Genenta Science 	Assignment: Discussion Thread on Rare Diseases	Active players in the field of gene therapy and rare diseases will illustrate the recent development of gene and cell therapy medicines and the role they can play in modern medicine, including in the treatment of rare diseases.
OCT 2	Historical Perspective on AIDS Drug and Vaccine Development	<ul style="list-style-type: none"> •Claudine Bruck, PhD 	<p>Due: Rare Diseases Discussion Thread</p> <p>Assignment: Discussion Thread on HIV epidemic</p>	<p>The lecturer will share her experience in drug and vaccine discovery to HIV, having been an active player in the field from 1985-1995.</p> <p>The lecture will cover all steps from the early observations of unusual infections to the discovery of HIV and the development of HAART treatment regimens. The societal aspects of the HIV epidemic will also be addressed.</p>
OCT 9	Development of Biological Medicines: Proteins / monoclonal antibodies	<ul style="list-style-type: none"> •Claudine Bruck, PhD •Aaron Hinken, PhD, Vice President, Immunology; Johnson & Johnson Innovative Medicine •Bruno Marques, PhD Vice President Process & Product Development, Century Therapeutics 	<p>Due: Discussion Thread on HIV epidemic</p>	<p>Biologicals, such as monoclonal antibodies (mAb), are an important and growing class of medicines for a variety of indications.</p> <p>Aaron Hinken will share his experience with development of a classical biological medicine Tremfya (a monoclonal antibody to IL-23) from the biological and medical perspective.</p> <p>Biomanufacturing processes play a major role in the pharmaceutical industry's ability to deliver these products to patients effectively and economically. Bruno Marques' lecture will provide an overview of the key elements of monoclonal antibody production. He will also describe the controls to be performed in order to satisfy regulatory requirements.</p>

OCT 16	Patient characterization/ Biomarkers/Diagnostics and Precision Medicine	<ul style="list-style-type: none"> •Claudine Bruck, PhD •Ruth Tal-Singer, PhD -President & Principal Consultant TalSi Translational Medicine Consulting, LLC -Global Allergy and Airways Patient Platform CSO -Former President and CEO, COPD Foundation 	Assignment for 10/23 Student Presentations	Yolanda Sanchez will summarize the state of the regenerative medicine field and highlight examples of new technologies applied to the development of curative medicines and advanced therapies.
	mRNA Technologies for Drug and Vaccine Development	Yolanda Sanchez, PhD		. Yolanda Sanchez will discuss novel mRNA technologies as a platform for new therapeutics and vaccines, highlighting the current challenges and opportunities in the field and the historic accelerated development of COVID-19 vaccines
	Introduction to Drug Repurposing	•Claudine Bruck, PhD		
OCT 23	Student Presentations (drug repurposing)	•Claudine Bruck, PhD	Due: Student Presentations	
	Overview of cell and Gene Therapy CMC aspects	•Bruno Marques, PhD		Bruno Marques will discuss the CMC aspects of cell and gene therapy
OCT 30	Regenerative Medicine	<ul style="list-style-type: none"> •Claudine Bruck, PhD •Yolanda Sanchez, PhD 	Assignment for 11/20 Precision medicine paper	Yolanda Sanchez will summarize the state of the regenerative medicine field and highlight examples of new technologies applied to the development of curative medicines and advanced therapies.
	5 pm: Hot Topic Immuno-Oncology – “From therapeutic vaccines to immune checkpoint blockade to CAR-T therapies”	•Jeremy Waight, PhD Scientific Director, Immuno-Oncology, GlaxoSmithKline	Assignment for Nov 6: Topic selection for final presentation	Jeremy Waight will share recent progress in immuno-oncology, where the harnessing of successful attack of invasive cancers by patients’ immune functions has led to spectacular anti-tumor efficacy.
NOV 6	Overview of General Regulatory Processes	•Amy Ebel, PharmD Global Strategic Labeling Head at GlaxoSmithKline		Amy Ebel will describe the role of regulatory agencies in drug and vaccine development, the path to regulatory approval of a

medicine and general regulatory processes.

In the second half of this module, she will focus on creation of the Drug Label, the process by which a drug label is built by Pharma and controlled by the FDA.

NOV 13		<ul style="list-style-type: none"> •Claudine Bruck, PhD 		
	Working in a company environment: teamwork and leadership skills –	Letizia Amadini-Lane PharmD; Founder & CEO of the LAL Group		Climbing the ladder in the industry environment involves skills above scientific prowess and IQ. Through an interactive course, Letizia will create awareness if this by sharing some of her knowledge as an executive coach.
NOV 20	Medicines, Vaccines, Diagnostics, Science and Business	<ul style="list-style-type: none"> •Claudine Bruck, PhD •Medha Kapil 	Due: Discuss topic of student presentation in class	Dr. Kapil will describe the process by which scientific discoveries in an academic environment can lead to the successful formation of new biotechnology companies.
		<ul style="list-style-type: none"> •Brian McDonald, MD, ChD, PhD, Senior Advisor and Director, Disc Medicine 		Dr. McDonald will discuss his own experience as a founder of Merganser and Dodeca through an interactive session.
NOV 27	No course (Thanksgiving break)		Due: Precision Medicine Paper	
DEC 4	Final Student Presentations	<ul style="list-style-type: none"> •Claudine Bruck, PhD 	Due: Student Presentations	Students will be asked to present on a topic pre-agreed with the Course Director.
				Interactive session, discussion on impact of changing landscape of medicines and vaccine development
DEC 11	Final Student Presentations	<ul style="list-style-type: none"> •Claudine Bruck, PhD 	Due: Student Presentations (if not all covered on Dec. 4)	Lawson MacArtney will walk the students through the different parameters affecting drug pricing, issues related to the high price of medicines and discuss possible future developments in this domain.
	Societal Aspects: Payers, Drug Pricing and Affordability Discussion	<ul style="list-style-type: none"> •Lawson MacArtney, DVM, PhD, FRCPath Former Chief Executive Officer and President of Ambrx, Inc. 		Interactive session, discussion on impact of changing landscape of

Evaluation and Due Dates:

The following table is a quick reference guide for assignments, due dates, and percent of course grade for each. More detailed information about each assignment is listed below. Please note that assignment criteria are subject to change.

Activity or Assignment	Due Date (2021)	Evaluation %
Participation (in person discussion and case studies and online discussion threads)	Ongoing participation; Discussion threads due: 9/18, 10/2, 10/9	25%
Presentations	10/23 and 12/4	50% - Drug repurposing presentation, 10% - Final presentation, 40%
Short Paper	11/27	25%

Participation and discussion threads (25%)

In Person

Students are expected to attend *and participate* in all classes. Each class will involve discussion in which you are expected to participate. While participation will not be tracked in each class, you will be given an overall score at the end of the course. Your engagement and participation are important not only for your own learning but also the learning of others. If for any reason you will not be in class, you should contact the course coordinator prior to class to alert them of the absence and make arrangements to make up course content. One excused absence is allowed during the course which will not affect the attendance grade. All absences require students to make up content which may include watching a recording or an assignment as assigned by the instructor.

In some cases or under extenuating circumstances, students may be permitted to attend class via Zoom (although it should be noted that the course is designed for in-person interaction). Please contact the Course Coordinator in advance for access to the Zoom link if you find yourself in a situation that precludes in-person attendance.

Online

To extend the collaborative learning community online, you will be required to post your own and respond to others' comments, thoughts, insights, or reflections with respect to the course videos, materials, and your own related experiences through online discussion threads on Canvas. Use this virtual space to connect with other classmates to help you think through the concepts we are learning in the course.

As everyone's participation is essential in creating this virtual community, a minimum of 2 posts per designated discussion is required. One post must be created on your own, and the second must respond to a classmate. Beyond the 2-post minimum, you can create or comment as many times as you would like.

For the 2-post minimum, each post must be substantive, meaningful, and 200-400 words which may include:

- Interpretation of information or data from the video or materials provided in class or online;

- Experiences you have or points you would like to contribute based on your own understanding or your peers' comments.

Due dates for online posts:

Tue, Sep 17 – CRISPR/Cas

Tue, Oct 1 – Rare Diseases

Tue, Oct 8 – HIV

Online posts are due by 11:59PM on the day they are scheduled, the day before class.

Discussion Thread Wrap-up

After the closure of a discussion thread, we will spend the first 10-15 minutes of the next class with a discussion about the thread which will help to bring the thread full circle so that your thoughts are put in context of the group's thoughts and any questions or issues can be addressed in a face-to-face manner.

Presentations (50%)

A significant part of graduate education is learning how to research a topic, critically analyze your findings, and then disseminate your discoveries to an audience. There will be 2 presentations over the course of the semester, one on drug repurposing and another on a topic of your selection (details below).

Presentation 1: Drug Repurposing Presentation

Length: Short (TBD)

Topic: Drug repurposing

Due date: Wed, 10/23

Weight: 10% of grade

Description: “Drug repurposing” stands for situations where a medicine developed for treating a given disease is applied and effective to treat an apparently unrelated disease. Several medicines have followed that path, and students will be given some literature on that topic. Students’ presentations will focus on specifics of **one example** of the development of a repurposed molecule, either past or present, **or** a description of national or international coordinated efforts towards drug repurposing.

The presentations on examples of repurposing will cover

- the description of the medicine,
- the molecular target of the medicine,
- initial clues that led the researchers to the repurposing idea,
- the path followed to lead to registration of the medicine for the new application, and
- the impact on patients.

Grading will be based on the pertinence of the example, as well as clarity and accuracy. Students focusing their presentation on national/international efforts for repurposing will discuss the challenges and opportunities of these efforts and the potential societal impact. We will communicate point to consider for a good presentation ahead of the presentation.

Presentation 2: Chosen Topic

Length: 15 min presentation, 5 min Q&A

Topic: Chosen by student

Due date: Wed, 12/4 and 12/11

Weight: 40% of grade

Description: Students are asked to share specifics on one area of the course that they feel inspired by. They could for instance describe how a new medicine against a specific rare disease was or is being developed, discuss the promise and shortcomings of Cancer Vaccine or cell therapy approaches, analyze what public health efforts could help development of a future pandemic virus vaccine or medicine, explore new areas of treatment enabled by CRISPR-Cas technology, discuss business application of a specific discovery, share thoughts/examples about drug pricing and societal aspects, etc.

Grading will be based on pertinence of the topic, depth and accuracy, as well as clarity.

Short Paper (25%)

Due: Wed, 11/27

Length: 2 pages, single-spaced, with 1-inch margins

This 2-page paper will describe an effort in the area of precision medicine that students choose. Precision medicine is applied to many areas, from oncology to neurosciences, and students will integrate information they learnt from course presentations, e.g. gene/cell therapy and patient characterization-focused courses, to choose a new example or opportunity for precision medicine. They will discuss the following aspects:

- Describe the chosen therapeutic application of precision medicine and what it means to the patient
- Technological progress that has enabled this application of precision medicine
- Differences in the development path, regulatory aspects, need for diagnostic
- How this differs from the traditional treatment approach and what advantage it brings to the patient over traditional one-size-fits-all medicine
- What different approaches the treating physician needs to take
- The cost impact and impact on society

The restriction to 2 pages, single spaced with 1-inch margins, will require students to be concise and summarize their thoughts.

Course Policies and Procedures

Attendance:

Students are expected to attend and participate in all classes. If for any reason a student will not be in class, they should contact the Course Coordinator prior to class to alert them of the absence and make arrangements to make up course content. One excused absence is allowed during the course which will not affect the attendance grade. All absences require students to make up content.

Academic Policies:

As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst

others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

Canvas:

All course materials (ppts, announcements, lecture recordings) and assignments will be posted on Canvas. Contact the course coordinator with questions. Log in with Pennkey.

Course Evaluations:

Course evaluations are completed in the BLUE system. These are a required part of course participation. An email from the BLUE team will be sent to students with a link and directions on how to complete the course evaluation(s).

Student Disabilities Services:

The University of Pennsylvania, provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with me as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215.573.9235. The office is located in the Weingarten Learning Resources Center at Stouffer Commons 3702 Spruce Street, Suite 300. All services are confidential.

Course Lecturer Bios

Pankaj Agarwal, PhD, Chief Computational Biologist, BioInfi

Dr. Pankaj Agarwal has 23+ years of strategic and tactical experience utilizing bioinformatics to enable drug discovery and create pipeline value. He has collaborated extensively with numerous pharmaceutical project teams, academic/biotech partners, and top informatics talent. Dr. Agarwal has 50+ publications in top journals, including Nature Rev Drug Discovery, Nature Biotechnology, and Clinical Pharmacology & Therapeutics, as well as multiple patents. In 2016, he was among a group of select scientists appointed as senior fellows at GSK. Dr. Agarwal has also served on NSF, NIH, FDA and PhRMA panels. He possesses a B.Tech. in Computer Science & Engineering from IIT, Delhi and a Ph.D. in Computer Science from the Courant Institute of Mathematical Sciences at NYU. He is a founder and senior member of the International Society for Computational Biology (ISCB). Most importantly, Dr. Agarwal is passionate about drug discovery and helping patients.

Letizia Amadini-Lane, PharmD CEO & Founder of LAL Group

LAL Group is a results-focused consulting firm providing development, coaching, and training to boost performance in leaders, boards, and organizations. Letizia is also creator of Visiva Leadership®, an innovative and transformational experience that builds deeper self-awareness and strengthens personal connections across leadership teams and boards.

Letizia has extensive experience in corporate development, business transformation, strategic alliance creation, and government relations, primarily in the life sciences. She was VP, Strategic Alliances for Sanford Burnham Prebys Medical Discovery Institute. Previously, she held multiple executive roles at GlaxoSmithKline, including VP & Global Head of Employee Value Proposition, VP & Head of R&D Leadership Culture, and VP, Strategy, Operation and Alliance Management for Worldwide Business Development. Prior to joining GSK, she was an independent consultant in the cardiovascular therapeutic area for SmithKline Beecham, where she created a strategic alliances function. She was the principal of AXTEN-Health Corporation, an international case management, consulting and referral service. Prior to AXTEN, she was pharmaceutical specialist for The World Bank.

Letizia holds a Doctor of Pharmacy from University of La Sapienza and Master of Herbal Medicine from University of Urbino. Her interest in the underlying drivers of business success led her to shift from profit center leadership to organizational and leadership development, with further personal development and training in psychology.

Claudine Bruck, PhD Course Director, ITMAT, University of Pennsylvania and Chairman, Prolifagen

Before her current roles, Dr. Bruck was Vice-President and Head, Ophthalmology Discovery Unit at GlaxoSmithKline from 2008 to 2015. Before that, Dr Bruck was a founding member and Vice-President of the Center of Excellence for External Drug Discovery (CEEDD) and part of the leadership team responsible for managing a diverse drug discovery portfolio of external research alliances. In the CEEDD, she helped design GSK's initial externalization strategy and gained valuable business development experience. Before that she held various positions in the Biopharmaceutical and Vaccine R&D groups at GSK. Dr. Bruck has a PhD from University of Brussels. She was a post-doctoral student at Harvard University Medical School and an Assistant Professor at Tufts Medical School.

Gary Dubin, MD**President, Global Vaccines Business Unit at Takeda**

Dr. Dubin has more than 28 years in vaccine research and development and has spent the last 25 years at Takeda GlaxoSmithKline (GSK) Bio (now GSK Vaccines) where, since 2010 he held the role of Vice President and Head, Global Late Clinical Development. During his career at GSK, he led global teams responsible for the clinical development and licensure of a broad range of vaccines addressing important unmet medical needs, including seasonal influenza (Fluarix Quadravalent and FluLaval Quadravalent), pandemic influenza (Pandemrix and Aprepandrix), meningococcal meningitis (Menhibrix and Nimenrix); human papilloma virus (Cervarix), rotavirus (Rotarix), strep pneumonia (Synflorix and protein-based vaccine in phase II development), malaria (RTS,S vaccine; submitted for licensure), herpes zoster (phase III); measles/mumps/rubella (US development program, phase III); tuberculosis (phase II), and others. He also supported Medical Affairs activities for these development programs and served as a core member of all major medical governance committees at GSK, including their Vaccines Medical Governance Board and the Vaccines Safety Board. Gary holds a Medical degree from the University of Pennsylvania and completed his Adult Internal Medicine residency training at the University of Colorado. He also completed a fellowship in Clinical Infectious Diseases and a postdoctoral research fellowship in Molecular Virology at the University of Pennsylvania. Prior to joining GSK, Gary served as Assistant Professor of Medicine in the Infectious Diseases Division at the University of Pennsylvania School of Medicine and currently serves as Adjunct Associate Professor of Medicine at the same institution. He holds numerous patents in the vaccine field and has co-authored more than 75 scientific publications.

Amy Ebel, BS, PharmD**Senior Director, Global Strategic Labeling Head at GlaxoSmithKline**

Amy is a clinical pharmacist who has led the development and revision of prescriber and patient labeling for US and global markets for close to 15 years. She has led labeling teams across the medication lifecycle from early drug development to the postmarketing setting for over 50 GSK products and across numerous therapeutic areas including anti-infectives, cardiovascular, diabetes, hematology/oncology, respiratory, and vaccines. Prior to working in Regulatory Affairs, she held previous positions within Medical Information at GSK and has published papers on both Regulatory and Medical Information topics, including most recently, a review of compliance with the Physicians Labeling Rule (new prescribing information format and content regulations). She has been a member of the FDA/Brookings Institute Patient Medication Information initiative for over 2 years – a working group established to improve patient medication information communications. Amy obtained her B.S. in Pharmacy at Oregon State University, her PharmD at the University of Utah, and completed a Specialized Residency in Drug Information at Oregon Health Sciences University. Before joining GSK, she trained or worked in retail, ambulatory care, and inpatient pharmacy settings, and continues to utilize these varied pharmacy experiences to advance improvements in clear and effective labeling communications for healthcare prescribers and patients.

Aaron Hinken, PhD**Vice President, Compound Development Team Leader (CDTL) at Johnson & Johnson Innovative Medicine**

Currently, Aaron leads the Early Development portfolio strategy for the Immunology Therapeutic Area as well as is CDTL responsible for all research & development activities for JNJ-4804, the first immunology combination product (IL23i/TNFi) in late development, across multiple disease areas. This role is accountable for overall asset vision and delivery of development strategy through leadership of a high performing cross

functional team. Aaron joined J&J/Janssen in 2020 as a CDTL covering the Early Development GI portfolio and Business Development for opportunities spanning Therapeutic Areas.

Aaron has over 15 years of pharmaceutical development experience across multiple therapeutic areas in both pharma and biotech companies. Prior to joining J&J, he was at GSK where he was the Head of the Muscle Metabolism Discovery Performance Unit, building and leading a portfolio of small and large molecule programs from discovery through early development in inflammatory, metabolic, and rare diseases. Before joining GSK, Aaron worked across multiple therapeutic areas for biotech companies, Five Prime Therapeutics, Inc and Cytokinetics, Inc., in the San Francisco Bay Area.

Aaron received a Ph.D. in Medical Pharmacology and Physiology at the University of Missouri and completed a post-doctoral fellowship at the University of Illinois.

Karen Kozarsky, PhD

Founder & Chief Scientific Officer at SwanBio Therapeutics

Karen is the founder and CSO of SwanBio Therapeutics, a gene therapy company active in rare diseases. Dr. Kozarsky previously served as Vice President of Research and Development at REGENX Biosciences, LLC (now REGENXBIO Inc.) where she was responsible for R&D strategy and execution. Dr. Kozarsky has over 15 years of experience in research and development in the pharmaceutical industry. She headed and helped found the Gene Therapy group in the Biopharmaceuticals R&D Unit at GlaxoSmithKline and was a Research Assistant Professor at the University of Pennsylvania in the Institute for Human Gene Therapy. Dr. Kozarsky received a PhD in Biology from the Massachusetts Institute of Technology and a B.A. in Biology from Amherst College.

Rick Keenan, PhD

Pharmaceutical Consultant; Former Vice President Chemistry, GlaxoSmithKline (GSK)

Rick Keenan has over 30 years of experience in drug discovery including 10 years as a drug discovery consultant working with biotech, venture capital, philanthropic groups and large pharmaceutical company clients in the US and India/China. Rick brings a critical approach to scientific problem solving derived from an integrated understanding of the entire drug discovery and development process. He not only contributes strategically to overall drug discovery strategy, but also plays an active role in directing hit and lead optimization chemistry and the identification of candidates for clinical development. In addition, Rick has developed an extensive virtual network of CROs and external consultants to support drug discovery efforts. At GlaxoSmithKline (GSK), Rick was a founding member and Vice-President of the Center of Excellence for External Drug Discovery (CEEDD) and part of the leadership team responsible for managing a diverse drug discovery portfolio of external research alliances. In the CEEDD, he helped design GSK's initial externalization strategy and gained valuable business development experience. Rick also spearheaded open and collaborative approaches to industry-wide research on neglected tropical diseases and led the efforts to publish whole cell malaria screening data online. Over the course of his research career in medicinal chemistry, he has contributed directly to the discovery of numerous clinical development compounds from a variety of therapeutic areas, including two marketed drugs: the Angiotensin Receptor blocker *Teveten* and the TPO receptor agonist *Promacta*. He is listed as an inventor on over thirty patents and has co-authored more than fifty research publications. Rick obtained a PhD in organic chemistry at Stanford University with Professor Paul Wender and earned a BS in Chemistry from the University of Pennsylvania.

Lawson MacArtney, DVM, PhD, FRCPath

CEO, Scout Bio Inc

Dr. MacArtney served as the Chief Executive Officer and President of Ambrx, Inc. from January 2013 to June 2015. He was Senior Vice President of Emerging Business Unit at Shire plc (Shire AG) since February 2011 and

was accountable for discovery initiatives through Phase III development of Shire's Specialty Pharmaceutical portfolio. He was successful in expanding and diversifying the pipeline of the Specialty Division through in-house discovery and extensive partnering activities. He spent nearly 20 years working with GlaxoSmithKline (GSK) from 1999 to 2011, where he served as Senior Vice President of Global Product Strategy and Project/Portfolio Management from 2007 to 2011, Senior Vice President, Cardiovascular and Metabolic Medicine Development Center from 2004 to 2007, and as Vice President, Global Head of Cardiovascular, Metabolic and Urology Therapeutic Areas from 1999 to 2004. Throughout his time at GSK, Dr. MacArtney held leadership roles in the Cardiopulmonary Therapeutic Area, from Project Leader to Global Head for Cardiovascular, Metabolic and Urology. His role is currently CEO, Scout Bio Inc. He has been the Chairman of Viking Therapeutics, Inc. since June 4, 2015 and serves as a Director of Viking Therapeutics, Inc since May 2014. He served as a Director of Ambrx, Inc. since January 7, 2013 until June 2015. He served as Executive Director, Commercial Operations at AstraMerck, Inc. He worked at AstraMerck and Astra Pharmaceuticals in leadership roles in operations, marketing, sales, and customer service. He has global drug development and commercialization experience. Dr. MacArtney is trained as a veterinarian and in diagnostic pathology. He is a Fellow of the Royal College of Pathologists. He holds B.V.M.S. (equivalent to a D.V.M.) from Glasgow University Veterinary School. Dr. MacArtney received his PhD from Glasgow University Veterinary School in Scotland where he was a Royal Society Research Fellow.

Brian MacDonald, MB, ChB, PhD

Senior Advisor and Director, Disc Medicine

Dr. McDonald is a physician scientist with over 20 years of experience in biopharmaceutical drug development. Before his current role, he was the Founding CEO of Dodeca Therapeutics. Before that, he was CEO of Merganser, guiding the company through its seed financing stage and Series A financing. He is an experienced biotech executive with extensive R&D experience. Before founding Merganser in 2011 Brian was CEO of Zelos Therapeutics and previously worked in senior management roles at Tetralogic Pharmaceuticals and 3-Dimensional Pharmaceuticals and as Group Director of Clinical R&D at SmithKline Beecham (subsequently GlaxoSmithKline). He received his medical degree and a PhD in musculoskeletal cell biology from the University of Sheffield, UK and trained as a rheumatologist at the Royal National Hospital for Rheumatic Diseases in Bath, UK.

Bruno Marques, PhD

Vice-President, Process & Product Development, Century Therapeutics

Bruno Marques leads the Process & Product Development team at Century Therapeutics, with a focus on genetically engineered, universal iPSC-derived immune effector cell products (NK, T cells) to target hematologic and solid tumor cancers. Prior to Century, Bruno spent 14 years developing and commercializing biopharmaceutical products at Merck and GlaxoSmithKline, while directing biotechnology industry-related courses at Rutgers University. At GSK, Bruno held leadership roles in process development and portfolio management, contributing to the launch of drugs such as Nucala (mepolizumab). He eventually joined GSK's Cell & Gene Therapy platform as Director of Manufacturing Strategy in support of autologous immunotherapies. Bruno is a Chemical Engineer by training, with a PhD from Carnegie Mellon University and a BS from the Illinois Institute of Technology.

Medha Kapil, JD

former Head of Legal and Corporate Development at BioMotiv

Medha Kapil is a business executive and lawyer with experience in business/corporate development, early-stage investment in the life sciences sector and all aspects of related legal transactions in that space. She has

experience with forming and growing early-stage biotech companies and a passion for all things start-up, innovative and entrepreneurial. She served as the Head of Legal and Corporate Development at BioMotiv, a life sciences accelerator/fund that operates in the translation space - they license-in early-stage technologies from research institutions and then spin-out and operate the companies virtually. Medha joined BioMotiv in its early stages, helped them scale-up the platform and operations to a team of 60+. She has since transitioned out and is searching for her next adventure in the start-up/innovation ecosystem. Medha holds a Bachelor's Degree in Accounting and Finance from Elmhurst College and a JD from Case Western Reserve University School of Law.

Carlo Russo, MD

Chief Medical Officer, Genenta Science

Dr. Russo serves as Chief Medical Officer for Genenta, an Italian gene therapy company. Before that, he was Chief Medical Officer and Executive Vice President of Avalanche Biotechnologies, Inc. and before that, he was Chief Medical Officer and Head of Development at Annapurna Therapeutics SAS. Prior to joining Annapurna, he served as a Senior Vice President in various R&D capacities at GSK, including as head of Development of the Biopharm Unit and as head of R&D of the Rare Diseases Unit. Under his leadership, GSK filed Market Authorization Application (MAA) in Europe for gene therapy treatment of severe combined immunodeficiency syndrome (ADA-SCID) patients. He served as the President and Chief Executive Officer of VaxInnate Corporation. He has been a leading expert in immunology and vaccine development for over 20 years. Prior to VaxInnate Corporation, he served as Executive Director and head of the Global Strategic Regulatory Development of Merck Research Laboratories. Dr. Russo oversaw the development of innovative vaccines including vaccines against Human Immunodeficiency Virus (HIV), Human Papilloma Virus (HPV), Rotavirus and combination pediatric vaccines of Merck Research Laboratories. He has held academic appointments at Cornell and is an author on 72 research papers.

Yolanda Sanchez, PhD

Scientific Consultant and Expert in Residence, Pharma and Biotech

Yolanda has 25+ years of combined academic and industry experience in translational research and drug discovery, including 14 years at GSK where she was Vice-President and Discovery Performance Unit Head (Respiratory Therapy Area), responsible for a portfolio of mechanisms to address disease progression in chronic respiratory diseases. Her group at GSK focused on cellular stress responses and mechanisms of repair and remodeling in lung disease, using genetics, functional genomics and other 'omics approaches to identify, validate and progress to the clinic several novel drug targets. Yolanda's expertise spans target/pathway identification and validation, lead optimization, clinical candidate selection, translational studies, biomarkers, and early clinical studies, with an established track record of delivering innovative approaches to enable the discovery and progression of novel clinical candidate molecules. She has managed numerous academia-industry collaborations and published in high quality journals (Science, Journal of Clinical Investigation, Journal of Cell Biology, American Journal of Respiratory and Critical Care Medicine, Journal of Immunology). Yolanda obtained her PhD at the University of Oviedo (Spain) and did her postdoc at the National Institutes of Health (Bethesda, MD).

Ruth Tal-Singer, PhD

President & Principal Consultant, TalSi Translational Medicine Consulting

Former President and CEO, COPD Foundation

Ruth is a PhD Scientist and Pharmaceutical Executive with Bio-Medical experience including 19 years of Research and Development in a large pharmaceutical company, and 5 years clinical experience in respiratory

critical care. Before her role at the COPD Foundation, she was Vice President and Medicine Development Leader in GSK's Respiratory R&D, leading a multidisciplinary international team accountable for transforming clinical development through strategic partnerships that drive quality in Respiratory clinical trials through improved disease understanding and application of the digital ecosystem. Ruth was trained as a Critical Care nurse, obtained a PhD in Molecular Virology from the University of Pennsylvania and postdoctoral training at the Wistar Institute. She led several preclinical and clinical drug discovery departments and was accountable for the development and optimization of novel technologies used to progress anti-inflammatory agents and bronchodilators into clinical development resulting in subsequent registration of therapies for patients with chronic obstructive pulmonary disease (COPD). Ruth developed and applied molecular markers and novel clinical endpoints in Phase I-III trials and spearheaded GSK's transition to digital clinical trials in respiratory diseases. In addition to successfully leading early drug development efforts, Ruth led GSK's Galaxy Project: a cross-functional team focused on furthering the understanding of COPD and Asthma and the qualification of drug development tools through private public partnerships. As evident from over 100 scientific publications, Ruth is recognized as a leader in pre-competitive partnerships focused on COPD disease understanding consortia (e.g. ECLIPSE, COPDMap, ERICA, COPDgene and SPIROMICS), and the qualification of drug development tools (Industry chair of the COPD Foundation-led Biomarker Qualification Consortium which achieved the first FDA qualification for a COPD biomarker in 2015). Throughout her career, Ruth has trained and mentored students, Postdocs and research fellows who progressed into scientific leadership positions.

Jeremy Waight, PhD

Scientific Director ImmunoOncology Research Unit, GSK

PhD-trained immunologist with >10 years of industry-related experience in the field of cancer immunotherapy. A background in innate and adaptive immunity, associated immune checkpoints, and FcγR biology. Jeremy has been with GSK since 2019, where he leads the biology for several development programs (including the CD226 axis programs – CD96, PVRIG, and TIGIT), as well as modality-agonistic target discovery/validation for the IOC RU. Prior to GSK, spent time at Merck KGaA and Agenus, leading multiple cancer immunotherapy programs from discovery and validation to early clinical studies.