Experimental Medicine Training Initiative

IMMUNOPHARMACOLOGY

TUESDAY, 4TH APRIL 2017

WYNG GARDENS CONFERENCE CENTRE, CAMBRIDGE CB5 8AQ

UNIVERSITY OF CAMBRIDGE

Cambridge University Hospitals NHS
NHS Foundation Trust

Cambridge Biomedical Research Centre
NHS National Institute for Health Research

AstraZeneca

MedImmune

gsk GlaxoSmithKline

Learning Objectives

Understanding the role of immunotherapies in modern drug development

Learning novel approaches clinical development of immunotherapies phase 1-4 (pathway to approval)

Designing novel immunotherapies and identifying pitfalls in developing biologics

Dose selection and rationale

Understanding how to use experimental medicine to understand the human immune system & use novel statistical study designs to achieve reproducible results

Workshops

Practical aspects of designing a new immunotherapeutic agent

Dr Steve Martin & Dr Andrew Buchanan

Practical clinical pharmacology of immunotherapeutics

Dr Paolo Vicini & Dr Frank Waldron-Lynch

Open forum and panel lead discussion

Dr Vicini, Dr Waldron-Lynch, Dr Martin & Dr Buchanan

Resources

http://www.emi-training.org/

Royal College of Physicians CPD Activity Code: 111323 (6 credits)

SCHEDULE

FIRST SESSION		LEARNING OUTCOMES
12:00-1:00	**Registration and Lunch**	
1.00:1:05	**Introduction to the day** Dr Joseph Cheriyan (CUH)	
1:05-1:40 **1:40-1:50**	**Clinical development of immunotherapies Phase1-4 (pathway to approval)** **Key Note Speaker:** Dr Nic Wisniacki (GSK) "Journey of a biological molecule - Overview of drug development" **Q&A**	• Understand the principles of clinical development of a biological compound • Use of experimental medicine as a tool to better understand the molecule and disease of interest throughout the development continuum.
1:50-2:30	**Designing novel immunotherapies and pitfalls in developing biologics.** Dr Steve Martin (GSK) & Dr Andrew Buchanan (Medimmune) "Key technologies and challenges in pre-clinical biologics drug discovery"	• To be aware of critical attributes of candidate drug including drug affinity, species cross reactivity to support pharmacology. • The challenges biologic 'developability' • The need for collaborative teams
2:30-3:20	**Interactive workshop and Q&A** Dr Martin & Dr Buchanan	
3:20-3:50	**Break**	
SECOND SESSION		
3:50-4:30	"Dose Selection for First-in-Human Studies of Biologics" Dr Paolo Vicini (MedImmune)	• Key pharmacokinetic (PK) and pharmacodynamic (PD) concepts • Application of PK/PD through research and development • Basic PK characteristics of protein drugs • Biomarker strategies • Dose selection for First-in Human (FIH) clinical studies
4:30-5:10	**Adaptive trial designs** Dr Frank Waldron-Lynch (University of Cambridge) "Immune Cell Responses in Participants with Type 1 Diabetes after doses of Interleukin-2 in adaptive-response clinical trials"	Understanding how to: • use experimental medicine to understand the human immune system, • use novel statistical study designs – to achieve reproducible results
5:10-6:00	**Interactive workshop and Q&A** Dr Waldron-Lynch & Dr Vicini	

6:00-6:30	**Group discussion, reflection and review** lead by the panel of lecture and workshop leads	
6:30 **7.00** **7.30**	Finish and depart for Trinity Hall for dinner Drinks reception Dinner	 Latham Lawn (weather permitting) / Terrace Room Graham Storey Room

SPEAKER AND SESSION LEAD BIOGRAPHIES IN ALPHABETICAL ORDER

Dr Andrew Buchanan
Principal Scientist at MedImmune in Antibody Discovery and Protein Engineering.

Andrew is a Principal Scientist at MedImmune in Antibody Discovery and Protein Engineering working on Oncology and CVMD therapeutic projects and related technologies. He has over 15 years experience in protein engineering and project leadership in a global R&D setting. Andrew has contributed to the discovery of 10 candidate drugs that are currently in preclinical or clinical development. He is an inventor on multiple drug and technology patents and original papers. Before joining CAT, he was a postdoc at Monsanto. Andrew is a graduate of University of Oxford and has a PhD in molecular genetics from University of Bath. Outside of work Andrew is a member of his local church, and enjoys badminton and geocaching when somewhere new.

Dr Joseph Cheriyan
Consultant Physician & Clinical Pharmacologist at Addenbrooke's Hospital, Associate Lecturer, University of Cambridge, Director of the Cardiovascular Trials Office, Vice Chair of the Cambridge Research Ethics Committee

Joseph is an active clinical researcher with interests in cardiovascular medicine particularly vascular function and inflammation and is uniquely the only MHRA accredited Phase I/II clinical triallist on the Cambridge Biomedical Campus working on early phase experimental medicine studies since 2006. His post combines NHS research within a University Department, in close collaboration with GSK's only remaining in house Clinical Unit, where he is seconded as a Senior Clinical Pharmacologist.

Joseph is lead on EMI training events and has organised today's event.

Dr Steve Martin
VP and Head of BioPharm Discovery, GlaxoSmithKline

Steve is VP and Head of Biopharm Molecular Discovery at GSK, responsible for the creation of new biopharmaceutical medicines in therapy areas including oncology, immune-inflammation and respiratory disease. His team develop and apply cutting edge technology to improve the lives of patients, with inhaled biologics and bispecific antibodies for example. Steve collaborates with technology and therapy area area experts inside and outside GSK, and has successful partnerships with academic institutions and biotech companies across the globe. He has over 20 years pharma R&D experience in small molecule and biopharmaceutical drug discovery. Steve has a Chemistry degree and a Ph.D in molecular biology from the University of Oxford.

Dr Kiran Nistala
Physician and Director, Cytokine Chemokine Complement Discovery Performance Unit, Immunoinflammation, R&D, GlaxoSmithKline

Kiran is currently an experimental medicine physician at GSK specialising in Drug Discovery Project Leadership, Early Phase Clinical Trial Design, Medical Monitor, Physician Community Global Lead. Currently based at Great Ormond Street Hospital since 2005 as an Honorary Consultant in Paediatric Rheumatology where he carries out research into the causes of childhood arthritis and juvenile dermatomyositis, a rare cause of muscle inflammation in children. Through a series of publications, Kiran was the first to show that IL-17 secreting T cells played a pathogenic role in childhood arthritis (Juvenile Idiopathic Arthritis (JIA). In 2011 he was selected to attend a Nature Medicine/Industry sponsored translational medicine course at the Eureka Institute and learnt a range of skills important in the drug discovery pathway. In 2012 he began a Wellcome Intermediate Clinical Fellowship to investigate the molecular control of B cell differentiation using a mouse model of autoimmunity and to translate these findings to the study of human idiopathic inflammatory muscle (IIM) disease.

Dr Paolo Vicini
Senior Director of Clinical Pharmacology and DMPK (Drug Metabolism and Pharmacokinetics), MedImmune

Paolo is Senior Director of Clinical Pharmacology and DMPK (Drug Metabolism and Pharmacokinetics) at MedImmune. Previously, Paolo was a Research Fellow with Pfizer in San Diego. His research was on quantitative pharmacology approaches, with emphasis on translational PK-PD (oncology molecularly targeted agents). Before Pfizer, Paolo was a Bioengineering faculty member at the University of Washington, Seattle, where he remains an Affiliate Faculty in Bioengineering and Pharmaceutics.
Paolo served on the NIH Biomedical Computing and Health Informatics Study Section (2005-2009). He is a Fellow of the American Association of Pharmaceutical Scientists (2011). He published to date 120 peer-reviewed articles, and is an Associate Editor of *Pharmacometrics and Systems Pharmacology* and is on the Advisory Editorial Board of the *Journal of Pharmacokinetics and Pharmacodynamics* and of *Clinical Pharmacology and Therapeutics*. He is a member of the American Society of Clinical Pharmacology and Therapeutics, the American Association of Pharmaceutical Scientists, the Biomedical Engineering Society, the IEEE Engineering in Medicine and Biology Society, the International Society of Pharmacometrics, the International Society for the Study of Xenobiotics, the American Diabetes Association and of Beta Gamma Sigma.

Dr Frank Waldron Lynch
Physician-Scientist, Experimental Medicine and Immunotherapeutics, University of Cambridge

Frank is a globally trained Physician-Scientist at the University of Cambridge, where he leads a multifunctional Experimental Medicine Team that develops novel immunotherapeutic strategies to treat and ultimately prevent autoimmune diseases in patients. The aim of this programme is to accelerate the development of immunotherapies targeted to genetically validated human disease pathways in type 1 diabetes and other autoimmune diseases.

The experimental medicine programme is focused on adaptive mechanistic clinical trials of immunotherapies. By understanding the response of the human immune system to therapy we aim to establish the correct dose and frequency prior to testing clinical efficacy in disease.

Professor Ian Wilkinson
Professor of Therapeutics, Director of Cambridge Clinical Trials' Unit, Director of the Office of Translational Research, University of Cambridge

Ian has a long track record in clinical pharmacology and arterial haemodynamics. His research interest is in clinical/experimental studies designed to understand the mechanisms underlying arteriosclerosis and cardiovascular disease, and to understand the importance of novel biomarkers of arterial function in risk prediction. He directs the Cambridge Clinical Trials' Unit and is also a director of the Office of Translational Research in Cambridge. He has considerable experience of translational research, and in forming academic collaborations with Industry.

Dr Nic Wisniacki MDPhD
Head of Translational Medicine – Experimental Medicine Unit, GSK

Nic completed his clinical training in Cardiology and Internal Medicine and subsequently gained his PhD at the University of Liverpool in 2005. He completed Higher Medical Training in Pharmaceutical Medicine in 2010 and has been working in Drug Development for over 10 years starting his career at Centocor, sanofi-aventis and more recently at Biogen-Idec as Director in Immunology.

Nic joined GSK in June 2014 as Head of Translational Medicine – Experimental Medicine Unit leading a group of physicians and clinical scientists working in early development programmes. He is also working as the Early Development Lead for a molecule in early clinical development.

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