

# EMI TRAINING EVENT

FRIDAY, 02 SEPTEMBER 2016

MOLLER CENTRE, STOREY'S WAY, CAMBRIDGE, CB3 0DE

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Cambridge University Hospitals   
NHS Foundation Trust

Cambridge Biomedical Research Centre

  
National Institute for  
Health Research

AstraZeneca 

 MedImmune

 GlaxoSmithKline

# LEARNING OBJECTIVES

**UNDERSTANDING THE MEANING OF EXPERIMENTAL MEDICINE  
IN ITS MODERN CONCEPT**

**LEARNING NOVEL APPROACHES TO DRUG DEVELOPMENT**

**UNDERSTANDING THE USE OF STATISTICS AND  
PHARMACOVIGILANCE IN EXPERIMENTAL MEDICINE**

**LEARNING PROOF OF CONCEPT STUDY DESIGN IN  
OSTEO-ARTHRITIS OR DIABETES MELLITUS**

## RESOURCES

**[WWW.STUDENT-SYSTEMS.ADMIN.CAM.AC.UK/MOODLE](http://WWW.STUDENT-SYSTEMS.ADMIN.CAM.AC.UK/MOODLE)**

**ROYAL COLLEGE OF PHYSICIANS CPD  
ACTIVITY CODE: 107338**

## SCHEDULE

### FIRST SESSION

12:00-1:00	<b>Registration and Lunch</b>	Study Centre, Milling Area
1:00-1:05	<b>Introduction to the day</b> Dr Joseph Cheriyan (CUH)	
1:05-1:40	<b>Introduction to Experimental Medicine</b> Dr Danielle Gerlag (GSK)	<hr/> <b>Suite 1</b>
1:40-2:00	<b>Q&amp;A</b>	
2:00-2:40	<b>Quantitative considerations for EM studies</b> Jacquie Christie, Kirsty Hicks (GSK) Followed by:	
2:40-3:20	<b>Interactive session with examples and Q&amp;A</b>	
3:20-4:20	<b>Break out session</b> Small group discussion on either Osteoarthritis or Diabetes Mellitus. Group Leads: Dr Danielle Gerlag, Dr Kiran Nistala, Dr Caroline Savage (GSK) Dr David Howe, Alex Godwood (MedImmune)	<hr/> <b>Suite 1 &amp; Rooms 5, 12, 13, 14</b>
4:20-4:40	<b>Break with refreshments</b>	Study Centre, Milling Area

### SECOND SESSION

4:40-5:00	<b>Group discussion on OA and DM</b> Return to the main room for whole group discussion	
5:00-5:40	<b>Analysing PK/PD relationships and considerations for dose escalation</b> Dr Paolo Vicini (MedImmune)	
5:40-6:00	<b>Q&amp;A</b>	<b>Suite 1</b>
6:00-6:40	<b>Pharmacovigilance</b> Dr Steffen Ernst (Astra Zeneca)	
6:40-7:00	<b>Q&amp;A</b>	
7:00-7:05	<b>Closing speech</b> Professor Ian Wilkinson (EMIT)	
7:05-7:30	<b>Pre-dinner drinks and networking</b>	<b>Wegner Lounge</b>
7:30- end	<b>Dinner</b>	<b>Main Restaurant</b>

## SPEAKER AND SESSION LEAD BIOGRAPHIES IN ALPHABETICAL ORDER

### **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 trialist 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.

### **Jacque Christie**

**Clinical Biostatistics Therapeutic Area Head for Immunology and Neuroscience, GlaxoSmithKline**



Jacque Christie has worked in the pharmaceutical industry for over 20 years in various roles. She has a particular interest in experimental medicine study design and analysis.

### **Dr Steffen Ernst**

**Senior Safety Medical Director, AstraZeneca, Gothenburg, Sweden**



Currently Senior Safety Medical Director Steffen Ernst is responsible for cardiovascular and metabolic disease products/projects up to and including Phase IIb. Additional product responsibilities for Lokelma (sodium zirconium silicate) and Diprivan (propofol). Medical background in Anesthesiology. MD in 1995 from Ludwig Maximilian University Munich, Germany. PhD training in Toxicology at the University of Kansas Medical Centre, USA (1996). US Board certified in Toxicology since 2002. MBA at the Edinburgh Business School (Heriot Watt University, 2015). Previously various senior preclinical and clinical positions at the (former) Hoechst AG, Boehringer Ingelheim, AstraZeneca and Pfizer. 18 years industry experience. Co-founder of start-up pharma company supported by the Cambridge University Judge Business School 'Accelerate Cambridge' program.

### **Dr Danielle Gerlag**

**Head, Clinical Trial Unit Cambridge (CUC), GlaxoSmithKline**



Daniëlle Gerlag, MD PhD, is the head of the CUC since September 2013. She came from an academic background being an associate professor at the Division of Clinical Immunology and Rheumatology EULAR & FOCIS Centre of Excellence Academic Medical Centre, University of Amsterdam in The Netherlands, where she headed up the clinical trial team performing early phase experimental medicine studies in inflammatory joint diseases for about 10 years. As head of the CUC she and her team focus on performing experimental medicine studies in early drug development to help bring down attrition rates by learn about the pathogenesis of disease and the effects of the compounds studied.

**Alex Godwood**  
**Science Associate Director at MedImmune, Cambridge**



Alex Godwood has worked as a biostatistician at MedImmune for 6 years. At MedImmune, he has worked on the design and analysis of phase I & II studies in respiratory and autoimmunity. He has also worked at AZ, GSK and Pfizer on a variety of indications and phases and studied mathematics at Warwick University.

**Dr David Howe**  
**Senior Director, MedImmune, (Respiratory, inflammation, autoimmunity)**

Experienced in translational medicine/early drug development  
Immunoinflammation, Obstetrics & Gynaecology, Biomarkers Target validation.  
Therapeutic areas: COPD, asthma, rheumatology, gastroenterology, type 1 diabetes, immunology, reproductive endocrinology and maternal-fetal medicine.

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



Kiran Nistala 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 Caroline Savage**  
**Head of the Experimental Medicine Unit within the Immunoinflammation Therapy Area, GlaxoSmithKline**



Caroline Savage is Head of the Experimental Medicine Unit within the Immunoinflammation Therapy Area. She joined GSK in July 2010 following a one year secondment from The University of Birmingham where she was Professor of Nephrology and Director of the Wellcome Trust Clinical Research Facility. She is a fellow of the Academy of Medical Sciences and has served on its Council. Presently she serves on the Population and Systems Medicine Board, Medical Research Council.

Dr Savage has a long-standing interest in pathogenic mechanisms of autoimmune and inflammatory diseases, particularly vasculitides. The strategic aim of the Experimental Medicine Unit is to expedite innovative approaches to early medicines development for immunoinflammatory diseases through implementation of small, biomarker-rich studies that demonstrate whether a compound is safe, active on its target and can lead to meaningful efficacy in patients.

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

Paolo Vicini 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.

**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.

## BREAK OUT DISCUSSION GROUPS

### OSTEOARTHRITIS 1

#### ROOM 12

#### **Caroline Savage**

Paolo Vicini  
Vik Selvarajah  
Ed Banham-Hall  
Elena Fischeleva  
Craig Tipple  
Jane Hughes  
Lisa Butler  
Omar Mukhtar  
James Mackay  
Gemma Bocking  
Julie Forman  
Graeme Young

### OSTEOARTHRITIS 2

#### ROOM 13

#### **Kiran Nistala**

Amit Shah  
Catherine Tchinou  
James Goodman  
Adam McGeoch  
Rona Smith  
Fred Reid  
Konstantia-Maria Chavele  
Katherine Vousden  
Gemma Banham  
James Hurlock  
Sile Griffin  
Ellie Edlmann

### OSTEOARTHRITIS 3

#### ROOM 14

#### **Danielle Gerlag**

Simon Taylor  
Douglas Maslin  
Subramanya Kumar  
Takahiro Yamamoto  
Ryan Wang  
Gillian Tannahill  
Matthew Lindon  
Tian Zhao  
Arlette Vassallo  
Alicia Gore

### DIABETES MELLITUS 1

#### SUITE 1

#### **David Howe**

Frank Waldron-Lynch  
Judith Molnar  
Shaun Flint  
Lucinda Kennard  
Spoorthy Burli  
Gerben Bouma  
Jessica Neisen  
Victoria Parker  
Petra Sulentic  
Elizabeth Wlodek  
Sabine Klager  
Paula Kareclas

### DIABETES MELLITUS 2

#### ROOM 5

#### **Alex Godwood**

Steffen Ernst  
Disala Fernando  
Meena Jain  
Ben Challis  
Michalis Kostapanos  
Karen Miller  
Hoang Thong  
Kaisa Maki-Petaja  
Kathleen Connolly  
Claire Connell  
Emma Day

Ian Wilkinson, Joseph Cheriyan, Lutz Jermutus, Jacquie Christie, Kirsty Hicks floating between groups

## ATTENDEES

### EMIT

Professor Ian  
Wilkinson  
Dr Joseph Cheriyan  
Dr Kaisa Maki-Petaja  
Dr Vik Selvarajah  
Dr James Goodman  
Dr Douglas Maslin  
Dr Adam McGeoch  
Lucinda Kennard  
Dr Rona Smith  
Dr Petra Sulentic  
Dr Kathleen Connolly

### ASTRA ZENECA-MEDIMMUNE

Dr David Howe  
Dr Steffen Ernst  
Dr Phil Ambery  
Dr Paolo Vicini  
Dr Hoang Thong  
Dr Lisa Butler  
Dr Fred Reid  
Dr Lutz Jermutus  
Dr Katherine Vousden  
Dr Victoria Parker  
Dr Meena Jain  
Alex Godwood  
Dr Ben Challis  
Dr Catherine Tchinou

### GLAXOSMITHKLINE

Dr Caroline Savage  
Dr Danielle Gerlag  
Dr Kiran Nistala  
Jacquie Christie  
Dr Ed Banham-Hall  
Dr Michalis Kostapanos  
Dr Amit Shah  
Dr Konstantia Chavele  
Elena Fischeleva  
Jane Hughes  
Mathew Lindon  
Dr Karen Miller  
Dr Gerben Bouma  
Dr Disala Fernando  
Dr Shaun Flint  
Dr Ryan Wang  
Craig Tipple  
Dr Gillian Tannahill  
Dr Jessica Neisen  
Dr Judit Molnar  
Dr Simon Taylor  
Dr Subramanya Kumar  
Graeme Young  
Kirsty Hicks

### UNIVERSITY/NHS

Dr Arlette Vassallo  
Dr Claire Connell  
Dr Elizabeth Wlodek  
Dr James Mackay  
Dr Takahiro Yamamoto  
Dr Omar Mukhtar  
Dr Tian Zhao  
Dr Gemma Banham  
Dr Sabine Klager  
Gemma Bocking  
Dr Emma Day  
Dr James Hurlock  
Alicia Gore  
Dr Spoorthy Burli  
Dr Frank Waldron-Lynch  
Julia Forman  
Sile Griffin  
Ellie Edlmann  
Paula Kareclas

## NOTES