

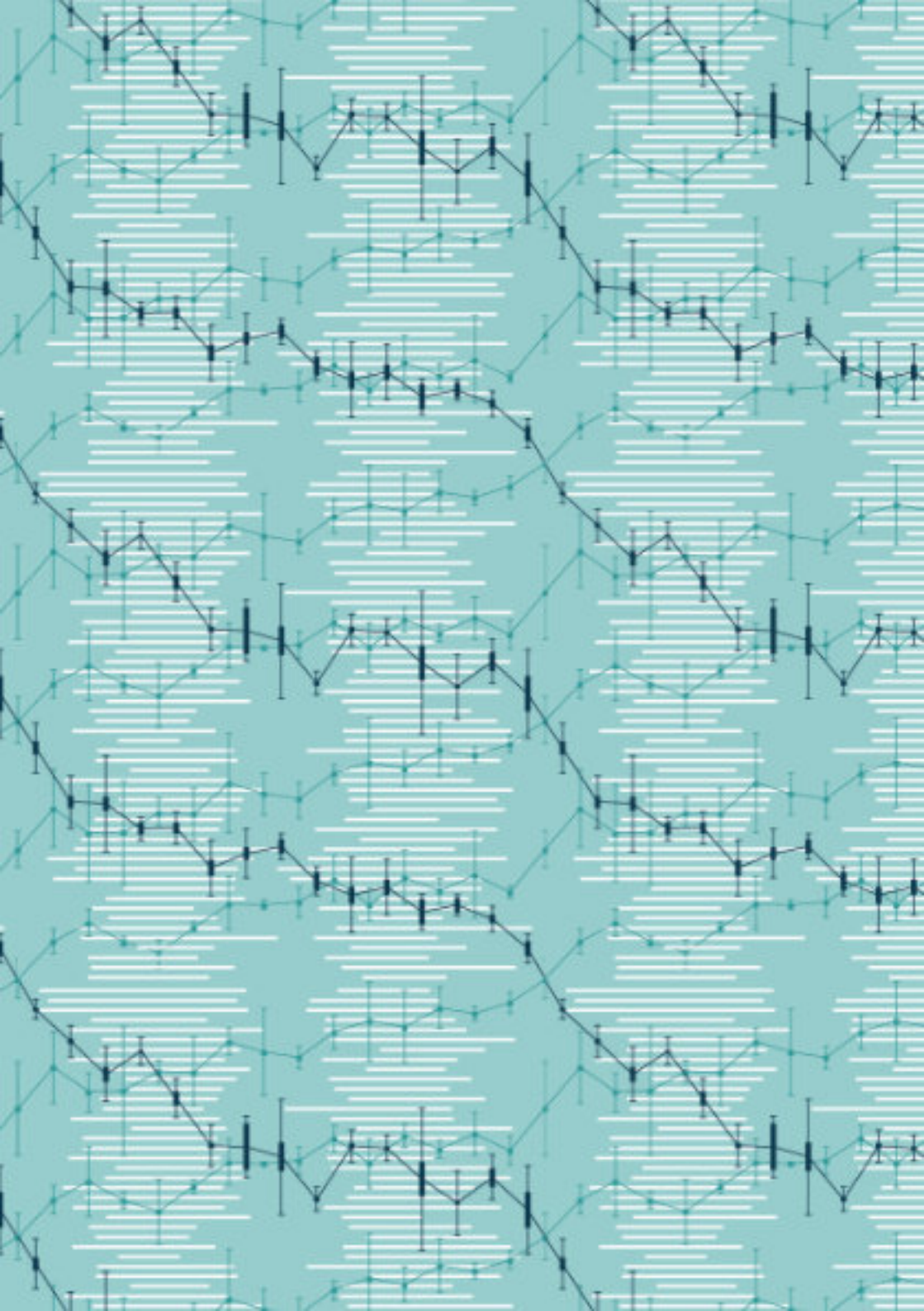


Faculty of  
Pharmaceutical  
Medicine

FPM Annual  
Symposium 2020

# ***INTO THE ROARING 20s!***

Future trends in pharmaceutical medicine





Faculty of  
Pharmaceutical  
Medicine

FPM Annual  
Symposium 2020

# *INTO THE ROARING 20s!*

## **WELCOME FROM THE FPM PRESIDENT**

**Tim Higenbottam**

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2020 has been extremely challenging for us all. As we approach the end of the year, the FPM Annual Symposium provides an opportunity to meet online, reflect on our experiences and plan for the future of our specialty. We have a fantastic programme, filled with relevant and engaging topics, and world class speakers.

Our title “Into the roaring 20s” may perhaps be puzzling, but the start of the new decade has undoubtedly brought a cacophony of fresh challenges! We have adapted and made full use of new technologies.

We have entered a new world, a new way of doing things, and are now looking to a future of previously unexpected opportunities.

May I welcome FPM members and non-members alike to explore all of this (and more) in our virtual home over the course of the next two days. I hope you will learn and develop your knowledge and understanding, but also engage and contribute, and I look forward to seeing you all.

## MESSAGE FROM THE FPM CHIEF EXECUTIVE

### Marcia Philbin

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I am really looking forward to our this year's FPM Annual Symposium this year. My thanks go to

all the speakers and the FPM team for putting together this fantastic event; our first two-day event and our first virtual symposium. In another first, we welcome the Stonier Lecture- a PMST trainee's opportunity to present a plenary lecture

on the theme of "my vision of the future of pharmaceutical medicine".

Our symposium is a great opportunity for us all to learn and explore the question of "How will pharmaceutical medicine develop over the next 10 years?" I hope you enjoy it.

## MESSAGE FROM THE SYMPOSIUM CHAIR

### Renata Crome

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The 2020s have started as no-one could have predicted, with a worldwide pandemic that has tested the medical profession like never before. Pharmaceutical medicine has been on the front line in this fight, and the skills, ingenuity and knowledge of FPM members, as well as our medical and scientific colleagues in all healthcare professions, have been tested to the highest degree.

The main themes of FPM Annual Symposium – rare diseases, health technologies and access to medicines – were agreed twelve months ago when

we first started planning this symposium but are even more relevant to our future now than they were then. COVID-19 brought these topics into sharp focus and highlighted how our specialty is integral in keeping the public safe.

We are excited to have developed an innovative and interactive programme with high-profile speakers from across industry, regulatory bodies, academia, patient groups and the wider health sector. I look forward to exploring our 'future trends' together over the next two days.



# *INTO THE ROARING 20s!*

## **THEMES**

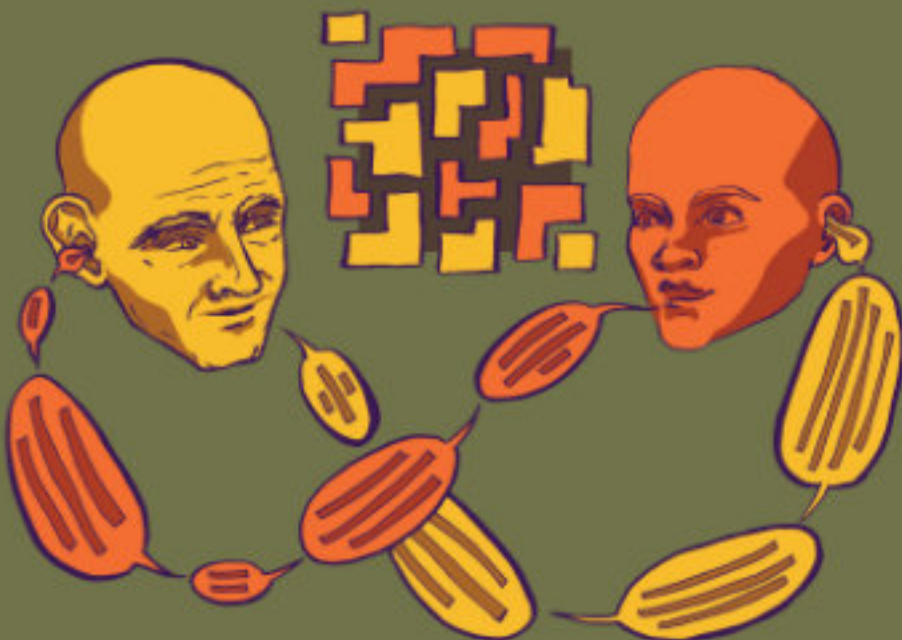
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Our world is constantly innovating and evolving, and right now more than ever. In the 2020 FPM Annual Symposium we will examine our role in the global avalanche of innovative and collaborative science and medicine, our role in delivering medicines to those who need them, and our duty to keep patients and the public safe.

The main themes running through this two-day event will be:

- Global health and access to medicines,
- Rare diseases and advanced therapies, and
- health tech, medical devices and AI.

We will also discuss how the specialty and the industry has reacted to the COVID-19 pandemic and what lessons can be learnt.





# PROGRAMME: DAY 1

## Thursday 26 November

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### **10.30 - 10.40 WELCOME**

*Welcome*

Tim Higenbottam, President, FPM

*Introduction to the structure and themes of the meeting*

Renata Crome, Symposium Chair, FPM

### **10.40 – 11.40 PLENARY | COVID-19 Lessons**

*Lessons learnt from COVID-19 & planning for future pandemics*

John Bell, Regius Professor of Medicine, University of Oxford

**with Q&A from 11:10**



**12.00 – 13.00 BREAKOUTS | Access in developing countries | Digital health**

Your choice of one of the following:

*How to ensure access to medicines in developing countries*

Chaired by Emma Harvey, Policy and Communications Group, FPM

*Digital Health*

Laurence Pearce, Founder and CEO, LifeLight

**14.00 – 14.50 PLENARY | Future Health Patterns**

*How can the pharmaceutical industry meet future health patterns?*

Mene Pangalos, EVP and President BioPharmaceuticals R&D, AstraZeneca, Cambridge, UK

**with Q&A from 14:30**

**14:50 - 15:30 NETWORKING | Independent Pharmaceutical Physicians**

*Independent Pharmaceutical Physicians' Coffee and Chat*

Hosted by Craig Hartford, Policy and Communications Group, FPM

**15:30 - 16:30 PLENARY | Rare Diseases**

*How can pharma support those living with a rare disease?*

Georgina Morton, Chair, ArchAngel MLD Trust

**with Q&A from 16:00**

**17:00 - 18:00 NETWORKING | 'Fail-fest'**

*Cocktail hour and Fail-fest*

Hosted by Marcia Philbin, Chief Executive, FPM



# PROGRAMME: DAY 2

## Friday 27 November

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### **09:30 - 10:00 NETWORKING**

#### *Trainees session*

Laura Campbell, Trainees Committee, FPM

### **10:00 - 10:20 PLENARY | FPM in focus**

#### *Welcome to Day 2 followed by FPM in focus*

Marcia Philbin, Chief Executive, FPM

### **10:20 - 11:10 PLENARY | Precision meds**

#### *Precision meds and genomics*

Munir Pirmohamed, MRC Centre for Drug Safety Science and Wolfson Centre for Personalised Medicine, The University of Liverpool

#### **with Q&A from 10:50**

### **11:40 - 12:40 BREAKOUTS | Devices | Gene Therapies**

Your choice of one of the following:

#### *Medical devices and you: science and regulatory challenges*

Bob Holland, Sosei Heptares, and Petar Gjorgiev, AstraZeneca

#### *Gene therapies: emerging science and ethical considerations*

Sally-Anne Tsangarides, Novartis Gene Therapies

### **13:00 - 13:30 NETWORKING | Medics in Biotechs/SMEs**

#### *Medics in Biotechs/SMEs coffee & chat*

Hosted by Emma Harvey, Policy and Communications Group, FPM

### **14:00 - 14:30 PLENARY | The Stonier Lecture**

#### *My vision of the future of pharmaceutical medicine*

Michael Holmes, Associate Professor, University of Oxford; ST6 in Pharmaceutical Medicine





**Q&A from 14:20**

**14:30 - 15:20 PLENARY | Post-Brexit regulations**

*Changes to UK regulations post-Brexit*

Jonathan Mogford, Director of Policy, MHRA

**with Q&A from 15:00**

**15:20 - 15:25 CLOSE**

*Thanks and close*

Tim Higenbottam, President, FPM



# MEET THE SPEAKERS

## Renata Crome

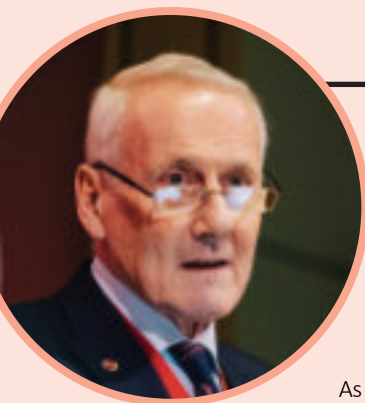


Renata is a Pharmaceutical Development Specialist with 30 years' experience in scientific development, regulatory approval and commercialisation of new medicines. She started her career in academic cardiovascular research at St Thomas's Hospital, London, then joined Roche where she led teams developing key projects including Tamiflu for influenza, and Avastin for cancer. In 2015 Renata joined Cancer Research UK heading up Project and Portfolio management.

Renata is a trustee of PTEN Research Foundation, holds a number of Non-Executive Directorships and Scientific advisor roles, and is a member of the Policy and Communications Committee of the Faculty of Pharmaceutical Medicine.

This year, Renata was called upon by the government to form the UKRI sponsored team of pharmaceutical experts to develop treatments for COVID-19.

## Tim Higenbottam



Tim is our president and a giant of our specialty. Whilst working as an NHS Consultant at Papworth Hospital, Cambridge he developed intravenous prostacyclin (the first therapy to improve survival in idiopathic Pulmonary Arterial Hypertension), as well as inhaled nitric oxide as a future treatment for neonatal pulmonary hypertension.

As Professor of Medicine, Sheffield University, he established the national network of accredited centres for the treatment of pulmonary hypertension, and led an international programme to construct the first "virtual lung" for the study of pharmacology of inhaled therapies. Later, as Corporate Clinical Director of Chiesi Farmaceutici, Tim began the development of the first triple inhaler for COPD, Trimbrow. Alongside his FPM commitments, he is currently a scientific advisor to several companies, that are using his expertise to work on COVID-19 related therapies.

## John Bell

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Sir John is Regius Professor of Medicine at Oxford University. His research interests are in autoimmune diseases and immunology, where he has contributed to our understanding of immune activation in autoimmune diseases. He served as President of the Academy of Medical Sciences from 2006 to 2011 and chaired the Office for the Strategic Coordination of Health Research until 2017.



In 1993 he founded the Wellcome Trust Centre for Human Genetics. In 2001 he was appointed non-executive director of Roche Holding AG and in 2008 he joined the Gates Foundation Global Health Advisory Board, which he has chaired since 2012.

In 2011 Sir John was appointed a UK Life Sciences Champion by the PM. He sits on the board of Genomics England Limited and chairs its Science Advisory Committee. He was knighted (GBE) in the 2015 New Year Honours for services to medicine, medical research and the life science industry.



## Laurence Pearce

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Laurence is founder and CEO of xim, developers of 'Lifelight' software which enables standard smartphones to perform contactless measurement of blood pressure and other vital signs with clinical grade accuracy. Lifelight has been developed over five years and is currently undergoing regulatory approval. Laurence has a long background in healthcare informatics strategy and implementation across Europe, USA and the Middle East.

He is passionate about the human application of technology in terms of user experience, computer vision, machine learning and connected digital health. With a background in computer science and an MBA, he is an experienced entrepreneur and active mentor.

## Mene Pangalos



Sir Mene is the Executive Vice-President, R&D BioPharmaceuticals at AstraZeneca (AZ). Prior to this, he served as Executive Vice-President of AZ's IMED Biotech Unit and Global Business Development, and held senior R&D roles at Wyeth and GSK. He led the transformation of R&D productivity at AZ through the development of the "5R" framework, resulting in a greater than four-fold increase in success rates compared to industry averages. He champions an open approach to working with academic and other external partners, transforming academic-industry collaboration.

Mene is a Fellow of, amongst others, the Academy of Medical Sciences and the Royal Society of Biology. He also sits on the Council of the MRC, co-chairs the UK Life Sciences Council Expert Group on Innovation, Clinical Research and Data and is on the Boards of The Francis Crick Institute, Cambridge University and Dival Pharma. In 2020 Mene was awarded a Knighthood for his services to UK science.

## Craig Hartford



Craig is an independent Pharmaceutical Physician with special interest in Medicines/Medical-Devices Benefit-Risk Management & Pharmacovigilance. He graduated MB BCh, MSc Med, PhD and held full-time academic/research posts until 1998. He then joined Pfizer R&D and in 2010-2019 was Vice President in Drug Safety at Pfizer, overseeing Safety Signal Detection/Evaluation and Benefit-Risk Management for 700+ products across the product drug lifecycle.

He is an FPM Appraiser and a committee member for our Policy and Communications Group and member of our Government and Healthcare Policy Expert Group. He holds a GMC License to Practise Pharmaceutical Medicine.





## Georgina Morton

Georgina is the founder and Chairperson of ArchAngel MLD Trust. Having spent almost 20 years as a television producer, her life and career changed dramatically in 2013 when her daughter Ava was diagnosed with a rare lysosomal storage disorder, Metachromatic Leukodystrophy. When Ava was accepted onto a clinical trial of Gene Therapy for MLD in 2014, the experience led Georgina to form a charity, in order to support medical teams around the world working on treatments for MLD and to offer grants to affected families.

ArchAngel is also currently spearheading a campaign to have all UK babies screened for MLD (and other rare diseases) at birth.



## Marcia Philbin

Marcia (PhD CChem FRSC MAPM) is the Chief Executive of FPM. She was previously the Assistant Director for Research and Policy at the Royal College of Paediatrics and Child Health.

She has a wealth of experience in research and policy development as well as project management, which she gained in both the public and private sectors.

Marcia sits on the Management Group Committee as well as the Inclusion and Diversity Committee of the Royal Society of Chemistry, is on the editorial board of the National Health Executive, a Trustee of a Multi-Academy Trust and is a passionate supporter for equal opportunities for all.



## Laura Campbell

Laura is the Neurometabolic Global Medical Director at Orchard Therapeutics, specialising in gene therapies for rare diseases. Since joining industry in 2015 from a surgical career, she has experienced roles in large pharma and biotech at the global, EU, and local affiliate levels.

Her portfolios have ranged from primary care to ultra-orphan indications, and she has worked in both the UK and US. She is in her final year of PMST training and sits on the FPM trainees' committee.



## Munir Pirmohamed

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Sir Munir is David Weatherall Chair in Medicine at the University of Liverpool, and a Consultant Physician at the Royal Liverpool University Hospital. He is Director of the MRC Centre for Drug Safety Sciences, and Director of the Wolfson Centre for Personalised Medicine. He is an inaugural NIHR Senior Investigator, Fellow of the Academy of Medical Sciences in the UK, Commissioner on Human Medicines and is a non-executive director of NHS England and has been appointed as President of British Pharmacological Society.



He was awarded a Knights Bachelor in the Queen's Birthday Honours in 2015. His research focuses on personalised medicine, clinical pharmacology and drug safety.

## Bob Holland

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Bob is highly experienced across all phases of Drug Discovery and Development, especially in the CNS and Oncology Therapy Areas.

A career long interest in the utility of biomarkers and a desire to ensure that patients receive drugs with the mechanisms most likely to provide benefit led Bob to establish and lead AstraZeneca's first Department of Personalised Healthcare & Biomarkers in 2010. Subsequently, interested in the tremendous potential of next-generation sequencing and the practicalities of converting biomarkers into medically useful products, Bob became CMO of the molecular diagnostics company Oxford Gene Technology (now part of Sysmex). Currently, Bob works as Senior Clinical Fellow at Sosei Heptares and is a member of the FPM Medical Devices and Diagnostics Expert Group.



## Petar Gjorgiev

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Petar worked as a general practitioner in Bulgaria before moving to the UK where he has pursued a career in pharmaceutical medicine. Petar has worked as a licenced physician in the pharmaceutical industry since 2013 and has experience in all phases of clinical trials as a research physician and principal investigator.

In 2016 he joined Amgen in his first role as a safety physician. Currently Petar works as a Global Safety Physician at AstraZeneca in the oncology therapeutic area.

## Sally-Anne Tsangarides

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Sally-Anne has spent almost 35 years in the pharmaceutical industry, beginning in manufacturing and supply chain in 'big pharma'. She soon transitioned to commercial roles and leadership, moving into areas of increasingly specialised medicine and, latterly, has led launches of five innovative products to address high unmet needs in paediatric rare conditions at three different companies.

She believes it is an immense privilege to be responsible to launch the first potentially transformative AAV9 gene therapy from Novartis Gene Therapies into the UK and works with stakeholders in the clinic, patient organisations, the NHS and policymakers to deliver for affected families.





## Emma Harvey



Emma is Global Head of Medical Affairs at F2G Ltd, a UK and Austria based biotech where she is responsible for the global medical and commercial strategies for a novel antifungal drug for serious systemic infections, in clinical development.

She has 20 years' experience in the pharmaceutical industry and 10 years' experience in antifungals. Her background is in internal medicine, undertaking her medical training at University College and the Middlesex School of Medicine, London.

## Jonathan Mogford



Jonathan is the Director of Policy at the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The MHRA Policy Division, which Jonathan heads, helps the Agency carry out its public health mandate in alignment with wider UK Government priorities and requirements. The Division leads for the Agency, and the UK Government, in the management of EU and International business relating to pharmaceuticals and medical devices regulation.

Prior to joining the Agency, Jonathan held a wide variety of policy posts since joining the UK Department of Health in 1990, including secondments to the Foreign Office and to the European Commission in Brussels; he has also headed policy teams in the UK Department of Health responsible for pharmaceutical industry policy and for private sector provision of healthcare services for NHS patients; he was also the Department's Head of European Affairs for 4 years to 2009.



# STONIER PRIZE

PMST Trainees and new entrants to pharmaceutical medicine are integral in shaping and driving the future of our specialty. Therefore, as part of the symposium schedule we held a competition to give someone in the early stages of their career in pharmaceutical medicine the opportunity to give a presentation, as part of a plenary session, on their vision of what the next 10 years will hold for the specialty of pharmaceutical medicine and the wider industry.

We named the presentation the 'Stonier Lecture' in recognition of Prof Peter Stonier's longstanding and ongoing commitment to the specialty training programme and support for trainees and new entrants.

Michael Holmes is the inaugural winner of the Stonier Prize and will deliver his lecture "Using human genetics to guide the development of medicines".



*I am excited to hear Michaels' lecture, with its promise of an evidence-based insight into the genomic contribution to the study and delivery of targeted therapies for unmet medical needs. Extrapolation of genetic understanding and application to all areas of medicines development offers to break the cycle of expensive failure and attrition in the search for new medicines. You are never far from a gene these days, whether it's a single research project or publication of the human genome, and their penetration to the heart of pharmaceutical medicine offers an abundance of opportunity too important to miss.*



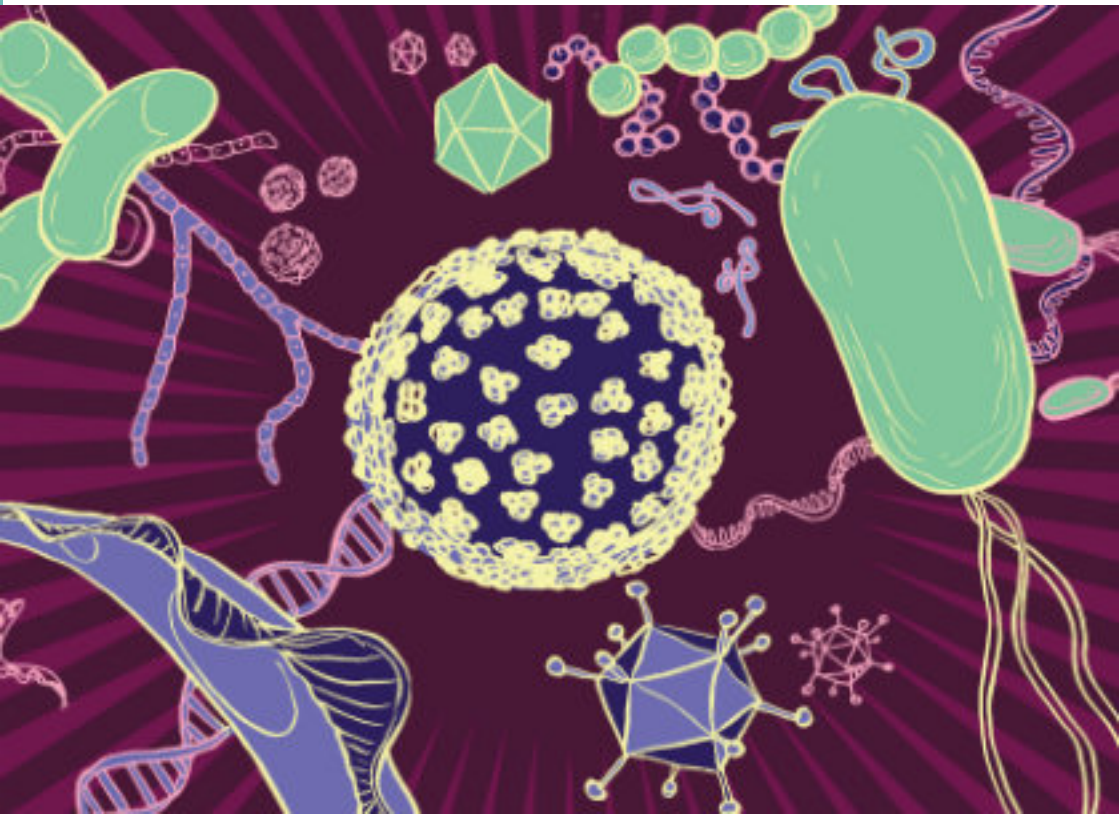
Prof Peter Stonier



## Michael Holmes

Michael Holmes is a Pharmaceutical Medicine Specialty Trainee and Associate Professor at University of Oxford. He studied Preclinical Medicine at University of St. Andrews and graduated with distinction in Clinical Medicine from The Royal Free & University College Medical School. Following working in the NHS as an academic Foundation/Core Medical Trainee, he graduated with distinction in Epidemiology from LSHTM and undertook a PhD in Genetic Epidemiology at UCL.

Michael's work focuses on translational applications of human genetics, identifying modifiable risk factors and potential therapeutic targets. He was awarded the prestigious John French Lecture by the British Atherosclerosis Society in 2020.



# ABOUT FPM

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We are the Faculty of Pharmaceutical Medicine (FPM), a charity and professional membership body on a mission to advance the science and practice of pharmaceutical medicine. We set the highest scientific and ethical standards to help unlock the full potential of new medicines and make sure they are as safe as possible for patients. We provide a collective voice for our 1,500 members who are striving to advance the research and development of new medicines to help prevent and overcome diseases that impact on the lives of patients worldwide. They are all medically-qualified and employed within the pharmaceutical

industry, research organisations, drug regulatory authorities – or working as independent consultants. Our mission is to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public. If you aren't already an FPM member you can find out about eligibility and the benefits of membership on our website: [www.fpm.org.uk](http://www.fpm.org.uk)





# ABSTRACTS: DAY 1

## *How to ensure access to medicines in developing countries*

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It is vital that no matter where they are, prescribers and patients around the world can access effective treatments at the right price. This seminar will explore the mechanisms and logistical issues and also the ethical and practical points to consider

when implementing access programmes. It will also consider, given the radical effect of the COVID-19 pandemic, how countries, organisations and communities can come together to expedite these technologies for the benefit of all in the future.

### *Digital Health*

Laurence Pearce, LifeLight

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The world of medical diagnostics and digital health is evolving rapidly and looks set to support clinicians to make even better clinical decisions and revolutionise patient interactions and engagement over

the coming decades. This seminar will look at specific examples of new and emerging technologies and also examine their role in drug development programmes.

### *Independent Pharmaceutical Physicians coffee and chat*

Craig Hartford

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An open house networking session for independent pharmaceutical physicians hosted by Craig Hartford.



## *Turning science into medicine*

**Mene Pangalos, EVP and President BioPharmaceuticals R&D,  
AstraZeneca, Cambridge, UK**

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The future treatment for many of today's complex diseases lies in discovering new biology, understanding and challenging scientific hypotheses and evolving the way we design and conduct our clinical trials. Improving R&D productivity is critical to the success of future drug discovery and development, with failure rates from pre-clinical development to launch often in excess of 90 percent.

The advent of data science, artificial intelligence and digital technologies,

coupled with ever more sophisticated platform technologies has the potential to increase the probability of success, and to discover new medicines more efficiently and deliver them more effectively.

Our ambition is to transform the lives of patients with improved outcomes and a better quality of life, through more effective treatment and prevention, ultimately working toward a cure for some of the world's most complex diseases.

## *How can pharma support those living with rare disease?*

**Georgina Morton, Chairperson of ArchAngel MLD Trust**

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The diagnosis of a rare disease can be a thunderbolt and the subsequent realisation that the condition has no effective treatment a direct lightning strike. However, thanks to increasing investment in orphan drug development projects, the world of rare diseases is beginning to become a less devastating place to find yourself. This lecture will

outline one family's hopeful journey through Gene Therapy for Metachromatic Leukodystrophy; from diagnosis and the challenges of accessing a clinical trial, to the inspiration which has led to the formation of a charity and a campaign calling for review and expansion of the entire UK New-born Screening system.

## *Cocktail Hour and Fail fest*

Marcia Philbin, Chief Executive, FPM

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Failure is a reality for us all but how we respond to it will determine whether we remain stuck in limbo or are able to move forward.

Fail Fest is a fast-paced, interactive exploration of the important role failure plays in driving innovation. In this relaxed open mic session, you will be invited to

share your tales of failure and what you learned from it, in a safe, non-judgmental environment. Please note that this will be conducted under Chatham House Rules.

At the end of the session, attendees will vote for the failure that had the most impact and a prize will be awarded to the Failure Champion!



# ABSTRACTS: DAY 2

## *Trainees networking session*

Laura Campbell, Trainees Committee, FPM

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An informal session for trainees, hosted by Laura Campbell and joined by Cecilia Chisholm (MHRA), Marc Watson (safety, AZ) and Mahesh Kudari (clinical development, Oxford). We will be looking

at the different career paths that are open to people after PMST, and you will have the opportunity to ask questions of each of us in the final 10 minutes.

## *Precision Meds and Genomics*

Munir Pirmohamed, MRC Centre for Drug Safety Science and Wolfson Centre for Personalised Medicine, The University of Liverpool

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A key issue for the genomic revolution is how it will help in improving treatment for diseases. As the number of people globally who have their genomes sequenced increases, the depth and breadth of information available will allow us to progress personalised or precision medicine, to ensure that patients get the right treatment at the right dose and at the right time. This will be crucial in ensuring that we optimise the benefit-risk ratio of all therapies (new and old) maximizing efficacy and minimizing safety. In some cases, genomic information will be directly relevant to the development of new therapies – this is an appropriate strategy given that drugs which are developed on the basis of genetic information seem to have a higher success

rate to go to market. Furthermore, we also need to consider how we can use genomics to help in stratifying early phase trials so that not only the correct drug, but also the correct dose can be identified. Genomic information can also provide insights that may lead to re-purposing of medicines for diseases for which there is unmet medical need. Genomic information may also be important in improving the use of drugs which have been available over many years to (a) change the intensity of therapy; and (b) improve the benefit-risk profile. In summary, the genomic revolution offers many opportunities for therapeutics – the key issue will be to develop the evidence base which allows the genomic findings to be translated into patient care.



## *Medical devices and you: science and regulatory challenges*

Bob Holland, Sosei Heptares, and Petar Gjorgiev, AstraZeneca

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Advances in Medical Devices and In Vitro Diagnostics have the potential to generate improvements in healthcare of a magnitude at least comparable to those generated by new medicines. However, delivering these improvements requires that the devices and diagnostics actually work as intended and provide the results claimed without adding risks of injury by the device or incorrect treatment through a wrong diagnostic result.

In this session we will briefly review the evolving regulatory landscapes (with a focus on diagnostics), and proposals and requirements for safety vigilance (especially for devices). Important lessons must be drawn from the UK's response to the Covid 19 pandemic and some of the difficulties we have experienced in the implementation of very advanced science will be used to stimulate discussion.

## *Gene therapies: emerging science and ethical considerations*

Sally-Anne Tsangarides, Novartis Gene Therapies

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The concept of gene therapy was introduced in the 1970s and the first gene therapy trial began

in 1990 in a four-year-old girl with adenosine deaminase (ADA) deficiency. However, it took until 2012 for the European Medicines Agency to award the first ever licence for gene therapy in Europe, for the treatment of an ultra-rare blood disorder. There are now over 2,600 gene therapy clinical trials completed, ongoing or approved worldwide and horizon scanning indicates that NICE is due to assess between 27 to 33 advanced therapeutic medicinal products by 2023. The NHS provided its first gene

therapy, to treat blindness, under routine commissioning early in 2020.

This seminar will present perspectives on the current state of UK readiness to develop and adopt gene therapies and the potential for these new health technologies to transform outcomes for patients with genetic conditions.

Guest speakers: Eric Alton, Professor of Gene Therapy and Respiratory Medicine at Imperial College, London and Chair of the NIHR ATMP Coordinating Group. Arseniy Lavrov, Clinical Development Head EMEA, Novartis Gene Therapies. Jayne Spink, Chief Executive, Genetic Alliance UK

## ***Medics in Biotechs/SMEs coffee & chat***

Emma Harvey, Policy and Communications Group, FPM

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An informal session for medics working in biotechs and SMEs to chat and network, hosted by Emma Harvey.

## ***The Stonier Lecture: Using human genetics to guide the development of medicines***

Michael Holmes, Associate Professor, University of Oxford;  
ST6 in Pharmaceutical Medicine

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It costs ~\$1bn to bring an investigational medicinal product (IMP) to market.

Fewer than 1 in 10 IMPs succeed from phase 1 to marketing authorisation.

Novel approaches to characterising the effects of therapeutic targets outside of conventional trial settings may help forestall the high failure rate.

In this presentation, I will outline how applications of human genetics can

inform each stage of drug development, providing early support of causation and characterising target-mediated intended and adverse effects.

Human genetics represents a burgeoning field of opportunity for informing the development of therapies and one that the Pharmaceutical Medicine community should embrace.

## ***Changes to UK regulations post-Brexit***

Jonathan Mogford, Director of Policy, MHRA

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This plenary session will give the delegates a vital and timely update on how the UK regulations for medicines development and approval are being adapted modified to be fit-for-purpose post-Brexit.

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