

issue 1  
Dec 17

President's review of the year  
Review of 'Patients first'  
Review of Digital Health conversation  
Tribute to Joseph Chiesa

Faculty

# NEWSLETTER



Faculty of  
Pharmaceutical  
Medicine

*Advancing the science and practice of pharmaceutical medicine  
for the benefit of the public*



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# Welcome!

Welcome to the new format for Faculty Newsletters! From next year the main newsletters will be send out bi-annually in this e-book format, accompanied by monthly news and events bulletins.

This short launch edition of the e-book format gives you an idea of the new look and feel. In the future editions we hope to have several articles around a theme, along with in-depth news and events analysis, interviews with key opinion leaders, careers information and book reviews.

We hope you like the new format. There is a feedback form at the end of this edition - please let us know your thoughts on this new format and also tell what you'd like to see in future editions.

*Season's Greetings  
from the  
President,  
Chief Executive,  
officers and staff of  
the FPM.*

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# PRESIDENT'S REVIEW OF THE YEAR



It has been a genuine pleasure to lead the Faculty over the past year and I wanted to say thank you to you all for helping and supporting me as President and all the activities that we have undertaken. The following details the highlights of this year, as I see them.

We have now occupied the offices in Angel Gate for almost two years and are making good use of our new facilities, with activities and meetings taking place in the building on most days. The Faculty's organisational restructuring was completed and it is now much more suited to the work that we need to do, with all the Groups and Committee's now fully functional.

We also ran the consultation and referendum about admitting non-medically qualified individuals to the Faculty as Affiliate Members. I must admit that I was disappointed with the outcome of the vote and I think it will now be difficult to grow and develop the Faculty, as I feel we could have done, by having a broader membership. Nevertheless, the membership has spoken and I accept that, but we must consider how we can now develop the Faculty of the future by other means.

We have also been successful in increasing the visibility of the Faculty externally, as organisations and individuals are coming to us increasingly for our opinions in relation to medicines. We are also being asked for Faculty representation on various committees and workgroups and to make comments on relevant news items in the media. This is a clear sign that we have expertise within the Faculty that people want to tap into.

We have also continued to develop our working relationships with other Medical Colleges, Faculties and organisations. We now have active projects underway or being discussed with the Colleges of Paediatrics, Physicians of London, Anaesthetics, Ophthalmology and Obstetrics and Gynaecology, the ABPI and the BIA.

We are also contributing to the 100,000 Genome Project being led by the Department of Health, for which we have been asked to undertake a horizon scanning project which will feed into the whole programme.

Over the year, the Faculty, together with the British Pharmacological Society (BPS), has contributed to the Life Science Industrial Strategy being led by Professor Sir John Bell with specific input into the issue of clinical pharmacology training and resources for academia, industry and the NHS. Our contributions were acknowledged in Sir John's final report published in August. As a result, the Faculty together with the ABPI, the BPS and Health Education England from the NHS have come together to form the 'Clinical Pharmacology Skills Alliance' to develop a long-term, cross-sector action plan for clinical pharmacology. These skills are of strategic importance as the UK prepares to deliver a sector deal for the life sciences.

As a Council Member of the Academy of Medical Royal Colleges (AoMRC), I take the lead on keeping my fellow Presidents informed about Brexit and the impact on medicines regulation. The Faculty also led on drafting a response on behalf of the AoMRC, to the inquiry that the House of Commons Health Select Committee are undertaking on Brexit and medicines regulation. This has resulted in me being invited to give oral evidence to the Committee, where I will be emphasising the importance of the UK, through the MHRA, having a continued relationship with the EMA post-Brexit.

In summary, it's been a very busy year and we have made significant progress as an organisation. I hope you all get some time off and relax over the Christmas period and I would like to wish you and your families a very Happy Christmas and New Year. Have a great time and I look forward to working with you all in 2018, to continue taking the Faculty forward.

Best wishes,  
Alan Boyd

# Highlights of 2017

Specialty spotlight on Pharmaceutical Medicine

April



Education Day



June

August

”

*The new convergent training program established by the British Pharmacological Society and the Faculty of Pharmaceutical Medicine could provide the mechanism for such training schemes.*

LIFE  
SCIENCES  
INDUSTRIAL  
STRATEGY

# October

The Faculty supported the MHRA-HRA 'Joint Statement on the Application of Good Clinical Practice to Training for Researchers'

Read the statement [here](#).

# November

## Clinical Pharmacology Skills Alliance



BRITISH  
PHARMACOLOGICAL  
SOCIETY



**NHS**  
*Health Education England*

The FPM, British Pharmacological Society, ABPI and Health Education England have formed the Clinical Pharmacology Skills Alliance. The Alliance will develop creative solutions for growing the clinical pharmacology skills pipeline and the delivery of key competencies in line with priorities across the healthcare and life sciences sectors. The Alliance aims:

1. To understand the demand for clinical pharmacology skills and associated career pathways
2. To drive high awareness of clinical pharmacology in the potential talent pool
3. To deliver a high quality and streamlined training experience
4. To be the stewards of clinical pharmacology, now and into the future



# December

Professor Alan Boyd gives oral evidence to the House of Commons Health Select Committee inquiry into Brexit: the regulation of medicines, medical devices and substances of human origin.

Watch it live [here](#)  
19<sup>th</sup> Dec, 2.30 pm

# LOOK BACK AT

## DIGITAL HEALTH CONVERSATION



### REVIEW BY DR LETTY HANNING-LEE

On October 11th, a Faculty of Pharmaceutical Medicine conversation meeting was held, where teams from both Sanofi and GSK presented on their experience of using digital technologies in clinical trials.

Sanofi presented on their clinical trial VERKKO, which was run to test a glucose monitoring device. What was unique about this trial was that it was the first European completely remote clinical trial. This meant that during the course of the trial, no site visits were conducted, and instead participant interaction depended entirely on digital technology. This digital interaction included:

- Participant recruitment through social media sites
- Electronic informed consent
- Active guidance through a virtual website
- Automatic upload of glucose results from the device onto the website

The study was deemed a success with the principal investigator stating that it was the “most convenient clinical trial” they had ever participated in and 90.8% of participants rating their satisfaction with how the trial was run as high or very high (with 100% exit feedback response).

Sanofi compared the VERKKO trial to an earlier comparator study that was not completely remote, noting that compared to this trial there was a:

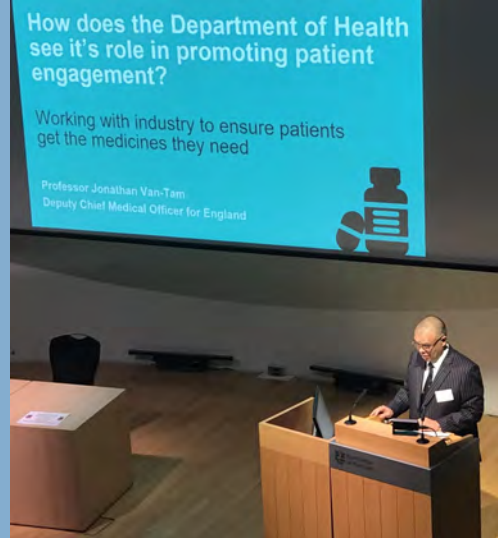
- 18% increase in compliance
- 22% faster profile completion
- 56% increased recruitment rate
- 66% decrease in study time spent on study coordination activities (owing to the majority of the study being managed between a single investigator and a study nurse)

GSK also gave some current examples of how they had used digital technology in their clinical trials. With one of the presenters wearing a ‘wearable sensor’ that confirmed that despite his increased heart rate he had managed to stay upright to give his presentation. To demonstrate how this wearable technology can be used in clinical trials, GSK gave the example of the on-going non interventional one year study, 201283. This study will assess if digital wearable technology can track disease progression (e.g. percentage of time walking/standing etc.) and if it is then possible to quantify these data metrics and validate new clinical endpoints.

Another option for utilising digital technologies is mobile phone apps. GSK discussed the Patient Rheumatoid Arthritis Data From Real WORLD Study (PARADE) as an example of how a mobile phone app can be used in clinical trials. This study again used social media to enrol patients, allowing them to recruit 399 patients within 30 days. After giving “e-consent”, patients are tracked for three months as they use their mobiles to submit data such as joint pain, fatigue and mood. In addition, sensors on the phone can evaluate more objective measures, such as wrist extension and flexion (using gravity and acceleration over time). Results from this study are still pending.

During the discussion it was clear that key questions on the impact of these and future digital technologies on clinical trials remain. For example, what is the regulatory stance on new novel endpoints? What potential liabilities will pharmaceutical companies face if wearable sensors detect a medical emergency? Despite these concerns, all agreed that like winter, digital technologies are coming.

# PATIENTS FIRST SYMPOSIUM



## REVIEW BY DR NEIL SNOWISE

The Seligman Theatre at the Royal College of Physicians was almost full on the 22nd November for the FPM's annual symposium. After a welcome from the FPM President, Professor Alan Boyd, the first presentation was made by the recently appointed Deputy CMO for England, Professor Jonathan Van-Tam, who addressed the role of the Department of Health in promoting patient engagement and several other topics.

He updated us on the government's Life Sciences Industrial Strategy, which had been the subject of a recent report in August 2017. The aim is to demonstrate the UK's existing strengths and new opportunities in life sciences, involving a range of companies across the sector.

In particular, Professor Van-Tam discussed how the Accelerated Access Pathway, to be introduced in 2018, is intended to get new transformative and innovative technologies to patients more quickly. The aim of the scheme is to enable up to five new medicines or technologies annually to be fast tracked. An area that we were all keen to hear about was the UK regulatory position post Brexit. The government aims to deliver a regulatory system post Brexit which will protect the best interests of UK patients, although there is no clarity yet on how this will occur.

This was followed by an interesting presentation from Simon Denegri, Chair of INVOLVE and health campaigner, discussing why patients should participate in clinical trials. There are many reasons why patients want to take part in research, including the desire to access better care themselves and to help others, to feel empowered and to contribute to science. He discussed how patient involvement could be improved and how subject recruitment to trials might change in the future. Unsurprisingly social media is likely to play an increasingly important role.

The final two presentations looked at patient engagement (or the preferred term – 'involvement') in R&D. We had committed and enthusiastic speakers from two patient charities, Bipolar UK and the Brittle Bone Society. Both presentations highlighted the benefit of patient involvement and using their expertise as part of decision making. For example, patients can offer insight into their experience of a medical condition, the use of medical services and the relevance of the study to clinical practice. The clear message from both presentations was look to charities if you want to involve patients and embrace the many benefits of patient involvement.

The remainder of the day was spent in seminars which allowed for very active participation from all the delegates. There was a choice of attendance at two out of three seminars, ranging from real world data, the challenges of how companies can engage better with patients and the media's role in shaping public opinion about clinical trials and medicines.

The seminars were all led by experienced people in their field. For example, Andrew Jack from The Financial Times was provocative about the media's role and this encouraged a very lively debate.

The varied format, with some plenary presentations and a choice of seminars, worked extremely well, allowing active participation from all the delegates and much discussion during the day. Overall this was a very stimulating meeting, focused on the needs of patients, in keeping with the FPM's Mission Statement 'Advancing the science and practice of pharmaceutical medicine for the benefit of the public'.



# TRIBUTE TO DR JOSEPH CHIESA

BY DR FLIC GABBAY

Joseph Chiesa died suddenly on 12 September 2017. Known to many in the Faculty and in pharmaceutical medicine, it is quite a shock that such a talented, vibrant, dynamic person should be taken from us so unexpectedly.

Joseph graduated from the School of Medicine at the University of Buenos Aires in 1969. He qualified in Clinical Pharmacology in 1976 and joined Wellcome the same year, working in Buenos Aires and Beckenham, as a medical adviser. He was then recruited to become Medical Director UK for Le Petit (Dow) and, following on from that, he spent many years in ICI (Zeneca, now AZ) steadily being promoted from medical adviser to more senior scientific and therapeutic roles. In the late '90s, he moved to some phase I CROs, as they emerged as highly sophisticated early development units, but will probably be best known to pharmaceutical physicians for his high-profile role as Medical Director at Covance in Leeds until 2015.

For those in the Faculty, "Joe" was best known to us as an immense supporter of professional pharmaceutical medicine, first through BrAPP and IFAPP, where he helped organise courses and meetings in Buenos Aires as well as the UK.

He was a Fellow of the Faculty, an Educational Supervisor, a Member of the Education Committee and a long-standing Member of the Board of Examiners. He was also a Specialty Adviser. His plan had been to continue to support pharmaceutical medicine in his retirement in Argentina, where he was a visiting professor at the Universidad del Salvador (USAL) in Buenos Aires.

As part of Joseph's distinguished and innovative career, he supported many mature products and helped design early development programmes for a whole range of our modern medicines. At the time of his death, he had been a Senior Partner in TranScrip for only a relatively short period but he was a key member of teams for European, US and Australian clients and was in the office most days when he wasn't travelling.

In addition to having an awesome curriculum vitae and lots of drive, Joe was a wonderful person, always cheerful and a real pleasure to work with. I am sure the many pharmaceutical physicians he worked with and taught will recognise these qualities and, for those of us who cannot remember the number of years we have known him, he will always be remembered as a key contributor to our profession.

There will be a memorial evening in London for Joseph on the 20th February 2018 - details below.

Tue 20 Feb 2018 from 18:00 – 19:30

*Memorial Event to Celebrate the Life and Work of Joseph Chiesa*

Royal Society of Medicine's Chandos House, 2 Queen Anne Street,  
London W1G 9LQ

Drinks and Canapes will be served, while tributes are made by Alan Boyd, President of the Faculty of Pharmaceutical Medicine and Martin Chiesa, son of Joseph Chiesa.

RSVP: Sandy Donoghue [sandy.donoghue@transcrip-partners.com](mailto:sandy.donoghue@transcrip-partners.com)





## FPM Conversation: The ethics of clinical trials - exploring the needs of vulnerable populations and the impact of innovative treatments

30th January 2018  
6.00 to 9.30 pm

**Baroness Ilora Finlay** FMedSci  
*Independent Crossbench member of the House of Lords  
Professor of Palliative Medicine at Cardiff University*

**Professor John Harris** FMedSci Member Academia Europaea. FRSA  
*Professor Emeritus, University of Manchester  
Visiting Professor in Bioethics, Department of Global Health & Social Medicine, School of Global Affairs, King's College London*

For this special 'conversation' on the ethics of clinical trials we are joined by two of the preminent thinkers in the ethics of healthcare and medical research. Baroness Finlay and Professor John Harris will lead the conversation on involving vulnerable populations, people with mental impairment, such as the seriously ill, and those with mental health problems or dementia, in clinical trials of new or existing medicines, and how to generally foster their engagement with clinical research. We hope to also touch upon the ethics of conducting studies in orphan diseases, and with newer types of treatments, such as gene and cell therapies.

Find out more and register [here](#).

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## Chief Medical Officer Summit 2018

5th March 2018, 8:45 am - 7:00 pm  
Wellcome Collection, London



Chief Medical Officer Summit  
Connecting CMOs to advance  
drug development

This inaugural event, will define and address the unique challenges associated with managing Medical Affairs functions with limited resources. The summit aims to enable CMO and R+D executives to understand possible routes for raising capital, partner with big Pharma, address and support the skills required to be a CMO in a SME and create a network to share ideas, solutions and support. Regulatory considerations around innovation support, clinical trials and Brexit will also be debated.

Early bird rates are available to FPM members throughout December 2017. Click [here](#) to find out more and register.

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## Education Day Ethics

Tuesday 12 June 2018  
National Council for Voluntary Organisations (NCVO), King's Cross, London.

## AGM, Awards Ceremony and Annual Dinner

Thursday 1 November 2018  
Royal College of Physicians, London

## Annual Symposium

Friday 2 November 2018  
Wellcome Collection, London

# Feedback

We would really value your feedback and comments on this new format for the FPM Newsletter. Please let us know if you have any ideas for articles or features.

## Staying in touch



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Members of the Faculty can now update their contact details and other information by logging on the Faculty website. If you have not registered previously please click on the Log In button on the homepage to begin your registration. Once logged in click on the My FPM button and then the My Details option.

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