IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

THIS ISSUE

In memoriam
Professor Richard Rondel 1931 - 2021

Professor Richard Rondel MBBS, Dip. Pharm. Med., Dip. Obst. RCOG, FRCP, FFPM

29 October 1931 – 3 May 2021

Professor Richard Rondel, one of the ‘founding fathers’ of pharmaceutical medicine and of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) has passed away aged 89. Richard Rondel was a pharmaceutical physician and an active member of the British Association of Pharmaceutical Physicians and its forerunner AMAPI over many decades. With an international vision, Richard was one of the group of three physicians who laid the foundations of IFAPP in 1970, going on to serve as its President from 1978-81.

Richard Rondel graduated from the University of London in the mid-1950s. He held teaching hospital posts in general medicine and clinical pathology in the National Health Service for seven years, before entering the pharmaceutical industry. Between 1963 and 1981, he occupied senior positions in clinical research, then worked for over 15 years as an international consultant.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

He was a member of the Royal Colleges of Physicians Steering Committee that founded the Faculty of Pharmaceutical Medicine in 1989 and set up the original infrastructure, articles and standing orders. He then served as the Faculty's Registrar from 1989 to 1995.

Richard was appointed Visiting Professor in Clinical Practice at the University of Surrey in 1996. Here he was a medical director of the University's Medical Research Centre and was appointed Postgraduate Clinical Tutor to include the organisation and supervision of three MSc degree courses – in pharmaceutical medicine, clinical pharmacology and clinical quality assurance.

He was passionate about safety of medicines and wrote and edited numerous papers and books on the subject, publishing one of the first books on adverse events – 'Clinical Data Management' - in 1972. His two editions of 'Clinical Data Management' have subsequently been described as timely and important contributions to the literature in the field.

Until very recently Richard was actively involved in medical charitable work with BRIGHT Cancer Care (formerly the Liver Cancer Surgery Appeal) and in the encouragement and promotion of participant recruitment to clinical studies in the field of oncology. Throughout, Richard engaged in debate and discussion with colleagues and students and maintained a continuing interest in the growth and developments in the wider world of pharmaceutical medicine.

Most recently, in March 2021, Richard was elected an IFAPP 'HERO in Pharmaceutical Medicine', a mark of the enduring legacy of his work and passion for the specialty.
Together with his family, Richard's loss is felt by colleagues, co-workers and mentees alike from his long life and outstanding career who recognise the unfillable void he has left along the highway of pharmaceutical medicine.

Dr Peter Stonier FRCP FFPM

Clinical Trials Day 2021

Clinical research is research in which people, or data or tissue samples from people, are studied to understand health and disease. Clinical research helps find new and better ways to detect, diagnose, treat, and prevent disease (1). The International Clinical Trials Day honours all people and professionals across the globe who dedicate their time and effort to the clinical trials that yield the evidence which provides better treatments for patients.

While discoveries of a new medicine or therapies are often made in the laboratory by chance observation or at the bedside by a point-of-care physician, the function of the formal controlled clinical trial is to separate the relative handful of discoveries which prove to be true advances in therapy from a legion of false leads and unverifiable clinical impressions, and to delineate, in a scientific way, the extent of and the limitations which attend the effectiveness of drugs (Affidavit of William Thomas Beaver, 2).

Medicine development already occurred thousands of years ago in Egypt, Babylon as well as in India, China, and the Americas and in many other civilisations around the globe. Conclusions were drawn based on clinical observations.

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

MIn 1747, James Lind (1716-1794), a Scottish ship's doctor who had learned of the death of three quarters of a ship's crew during a long voyage around the world, planned a comparative trial of several popularly suggested "cures" for scurvy on the ship's next voyage. He experimented with citrus fruit to find an effective treatment for the "seafarer's disease". Twelve men with similar cases of scurvy ate a common diet and slept together. Six other pairs, however, were given different "treatments" for their malady. Two were given a quart of cider daily; two an "elixir;" two had to drink seawater (Image 1); two took a remedy suggested by the ship's surgeon (horseradish, mustard, and garlic); two vinegar; and the final two seamen were given "oranges and lemons" daily. Only the two men who had received the oranges and lemons recovered, and Lind wrote in 1753 in his historical work *A Treatise of the Scurvy* "One of those who had taken them being at the end of six days fit for duty ... The other was the best recovered of any in his condition; and being now deemed pretty well, was appointed nurse to the rest of the sick."

Image 1: James Lind (1747) treating a man with citrus against scurvy

Lind's test is considered to be the first clinical trial in history. At first Lind questioned his own experimental results, however, by the time he published them (1753 and 1757), they were recognised as important. Nonetheless, the British Navy did not supply citrus fruit to their ships until 1795 (Suzanne White Junod, 3).
However, there is doubt nowadays that Lind's trial actually took place. What is important is his description of a very early "fair test" and that Lind described that he controlled the variables, that all subjects were in similar conditions, he was able "to compare like with like". In fact, others before Lind had already advanced such proposals, starting with the Persian physician Al-Razi in the tenth century and others such as the Flemish Jan Baptist van Helmont, the Englishman George Starkey. The story of Lind is "a useful marketing tool to promote the vital importance of fair tests in medicine". So whatever Lind did or did not do is irrelevant, he set other researchers on the path to a practical cure for scurvy (4).

To honour the achievements of such clinical research, the International Clinical Trials Day is now held every year on May 20.

The randomised clinical trial is still the gold standard to understand whether one treatment is better than another. Study participants make an important contribution to medical research and development. When a drug candidate has completed all preclinical tests positively and is considered safe in animal models, it can be used in humans for the first time. This marks the beginning of the phase known as the clinical trial phase - the step before a drug can be approved. Clinical trials mean progress for each individual patient, society, the economy, the research location, healthcare, and medicine on a global level.

The honour this year of the International Clinical Trials Day goes to all stakeholders involved in clinical trials but, in particular, to all volunteers and clinical trial professionals of SARS-CoV-2 vaccine trials enabling the generation of evidence in large randomised controlled trials to initiate the largest vaccine programmes across the globe to control the COVID-19 pandemic. THANK YOU!

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

References:

1. NIH Dictionary https://www.cancer.gov/publications/dictionaries/cancer-terms/def/clinical-research

2. Affidavit of William Thomas Beaver, M.D. in the case of Pharmaceutical Manufacturers Association v. Robert H. Finch and Herbert Ley, Civil Action No. 3797, United States District Court for the District of Delaware. Dr Beaver was the clinical pharmacologist at Georgetown University who is credited with drafting the initial regulations defining "adequate and controlled" clinical studies. (Personal correspondence, Peter Barton Hutt Esq. and Dr. Robert Temple, FDA, December 2007, FDA History Office Files)

3. FDA and Clinical Drug Trials: A Short History by Suzanne White Junod, Ph.D. (FDA and Clinical Drug Trials: A Short History, download 23 May 2021)

4. James Lind and Scurvy: The First Clinical Trial in History? https://www.bbvaopenmind.com/en/science/leading-figures/james-lind-and-scurvy-the-first-clinical-trial-in-history/ (download 24 May 2021)

PD Dr Ghazaleh Gouya Lechner (CEO Gouya Insights, Board Member GPMed and member of IFAPP Communication Working Group)

Czech Association of Pharmaceutical Medicine

The Czech Association of Pharmaceutical Medicine was founded in 1997 under its original name, the Clinical Trial Association (CTA). The association focused mainly on Research and Development (R&D) topics and primarily attracted Clinical Operations staff from both pharmaceutical companies and CROs. However, shortly after its inception, the CTA began to also attract members from other institutions (regulatory authorities, ethics committees, hospitals, etc.) and other professionals (from Regulatory Affairs, Pharmacovigilance, and Medical Affairs). For years it served as the main platform for sharing knowledge and discussions between the industry and government institutions. From the very beginning, the CTA also organised lectures and courses focused on, amongst other things, GCP, pharmacovigilance and regulatory affairs.

2006 was a milestone year for our association when it was renamed the Association of Pharmaceutical Medicine (AFM). This allowed us to better reflect the variety of our members' professions.

The same year we also began the first Course in Pharmaceutical Medicine in cooperation with the Charles University in Prague which has since been held almost every year.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

The lecturers at these courses are each highly skilled specialists in all areas of Pharmaceutical Medicine, while the attendees are quite diverse, and include industry professionals, regulatory authority staff, hospital research staff and Ethics Committees members. Since 2006 we have successfully organised 11 such courses, and almost 400 professionals have graduated from this training programme to date.

Despite this very successful training programme, since 2015 we have faced decreased interest in membership of the Association. An increased number of in-house company training courses, the generally high workload of people in the industry, and limited financial resources for AFM activities have been identified as the main obstacles for further development. This is a trend we have been battling against since 2017. Another milestone came in 2018, when we decided to become a member of the IFAPP, thereby giving us an opportunity to increase our international contacts. We also strengthened our cooperation with academia – Ondřej Slanař, Head of the Institute of Pharmacology at Charles University, was appointed to the Association Board and, shortly after, was elected President.

Currently we are focusing on enlarging our educational activities, and thereby increasing our attractivity for members, by organising the 'Meet the Expert Symposium', together with our regulators, the State Institute for Drug Control. It will take place this autumn and will focus on current topics such as clinical trials during the COVID-19 pandemic, e-tools in clinical trials, and efficient patient recruitment. The next class of the Course in Pharmaceutical Medicine will take place in early 2022, and we are also focusing on both our webpage and improved e-communication with our members. And our secret wish? To organise an international event with other IFAPP members....

Prof. Ondřej Slanař, M.D., Ph.D., President of the AFM
Jiri Paseka, M.D., Member of the AFM Board and IFAPP Delegate

AMPIF – Envisioning a Portuguese Pharmaceutical Medicine Association "in Tune" with New Times

AMPIF was created in 1989 by its founding associates, professionals from the Pharmaceutical Industry, as a non-profit association able to represent all medical doctors working in the Pharmaceutical Industry with the aim to share experiences and knowledge.

30 years went by and not only the profile of Pharmaceutical Medicine professionals changed, but also a changing world raised the need to develop new skills and highly flexible capabilities in a healthcare environment in a "steady state" of continuous revolution.

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

In 2018, AMPIF changed its charter to allow members, other than medical doctors, dedicated to Pharmaceutical Medicine but with a background in health and or/life sciences, whose roles or functions support Medical Departments of the Pharmaceutical Industry. The number of associates grew by 35% and new associates joined, setting the tone to amplify the activities of AMPIF with focus on 3 core areas: 1- Skills & Competencies; 2- Patients & Society and 3- Academic education of future healthcare professionals. While concentrating activities in the three core areas, the objective of AMPIF is to support scientific and technical development as well as to build and promote a network of professionals in Pharmaceutical Medicine. During the last years, AMPIF developed a series of conferences, learning courses, network events and debates in areas, such as medical affairs, clinical research and development, market access, and defense of ethical and deontological principles, in respect of patients' health and welfare. In the several initiatives that were promoted, AMPIF has counted upon the partnership of relevant stakeholders and institutions including patient, as well as professional associationslike the Medical Science Liaison (MSL) Society.

AMPIF has been able to establish strong partnerships with key stakeholders like APIFARMA - the local Pharma Industry association, the Physicians' Council, and the Pharmacists' Council. These partnerships are critical to leverage AMPIF's voice and presence. AMPIF is recognised by APIFARMA as a key stakeholder, taking part in the "Medical Forum" – the consultancy group for the Physicians' Council and was involved by the Pharmacists' Council on the preparation of the Pharmaceutical accreditation norm.
Today, AMPIF represents 105 associates, Pharmaceutical Medicine professionals in Portugal and is a proud member of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP).

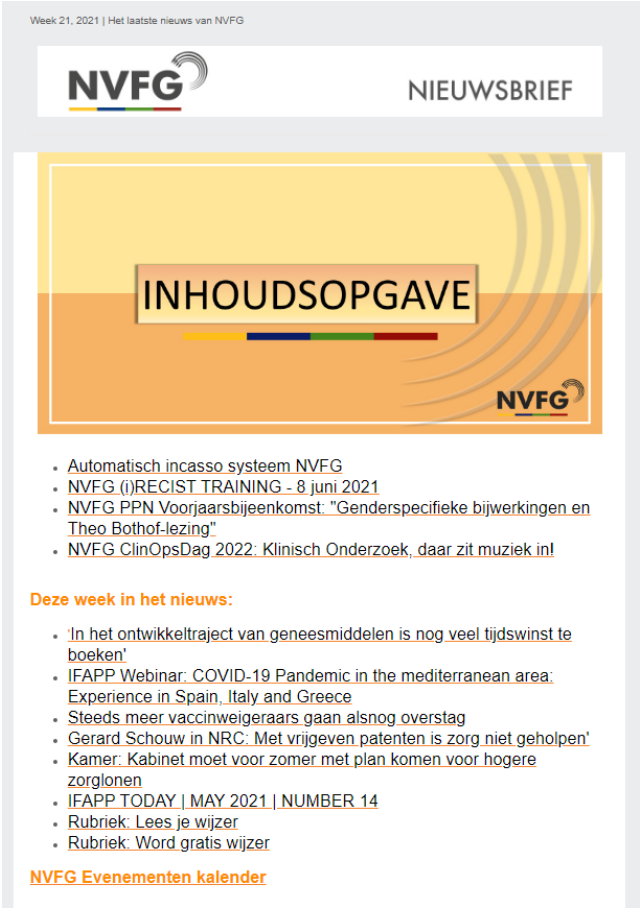
Ines Pargana Cardoso, PharmD
Chairman of the fiscal council of AMPIF; Global Director xDROID Optimize, Novartis

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

Newsletters from National Member Associations:
The Dutch Association for Pharmaceutical Medicine (NVFG)

The Dutch Association for Pharmaceutical Medicine (NVFG) has its own weekly newsletter. The deadline for submitting copy is every week on the Wednesday at 5:00 PM. All conferences, congresses and courses which are organized by the NVFG (approximately 15 on an annual basis) are mentioned and promoted in the newsletter, just like other interesting conferences and activities from adjacent organisations. Whenever feasible, the proceedings are also published in the newsletter.


Week 21, 2021 | Het laatste nieuws van NVFG

NVFG NIEUWSBRIEF

INHOUDSOPGAVE

NVFG

- Automatisch incasso systeem NVFG
- NVFG (i)RECIST TRAINING - 8 juni 2021
- NVFG PPN Voorjaarsbijeenkomst: "Genderspecifieke bijwerkingen en Theo Bothof-lezing"
- NVFG ClinOpsDag 2022: Klinisch Onderzoek, daar zit muziek in!

Deze week in het nieuws:

- 'In het ontwikkeltraject van geneesmiddelen is nog veel tijdswinst te boeken'
- IFAPP Webinar: COVID-19 Pandemic in the mediterranean area: Experience in Spain, Italy and Greece
- Steeds meer vaccinweigeraars gaan alsnog overstag
- Gerard Schouw in NRC: Met vrijgeven patenten is zorg niet geholpen'
- Kamer: Kabinet moet voor zomer met plan komen voor hogere zorglonen
- IFAPP TODAY | MAY 2021 | NUMBER 14
- Rubriek: Lees je wijzer
- Rubriek: Word gratis wijzer

NVFG Evenementen kalender

The newsletter has a few regular columns such as "Read yourself wiser" in which interesting and inspiring books are introduced and recommended. Another regular column is “Become wiser for free”. In this column interesting webinars and courses which have free access are shared. We also post the ‘IFAPP TODAY’ as well as the invitations to IFAPP webinars.

Every week the secretariat compiles the newsletter and prepares the layout based on the incoming copy and other interesting articles. To ensure consistency a member of the Communication Committee edits the weekly newsletter (each committee members take turns performing the check for the period of one month). He/she receives the draft newsletter Wednesday evening and will send the revised draft back to the secretariat Friday morning at 12:00 noon at the latest.

Every Friday afternoon the newsletter is sent to all the members and stakeholders with a total reach of more than 1,000 people. It is also published on the website of the Dutch Association as well as on the Group and Company page of LinkedIn.

Rita Lobatto, MD, MPH
Board Member and Chair Communication Committee

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

IFAPP Activities in June

17 June: Free Webinar COVID-19 Pandemic in the Mediterranean Area:
Experience in Spain, Italy and Greece. Click here for more information and registration

28 June: House of Delegates Meeting
We would like to remind all members of the House of Delegates meeting on **28th June 2021, 1.00 - 2.30 pm CET**. There will be elections (1) of the Board of Officers and we hope that you will all attend. Please note that Delegates or their Deputies (Deputy name to be communicated to the Board Secretary, Kotone Matsuyama: kotoneco1@gmail.com, at the latest 4 weeks prior to the meeting) can only vote if the respective National Member Association (NMA) has paid the annual membership fee for 2021 (2). If a Delegate or his/her Deputy cannot attend, you can vote in writing before the meeting by sending an email to Kotone Matsuyama. Please also note that, as per the Constitution, Individual Affiliates cannot vote. All Delegates and Affiliates will receive the agenda with supporting documentation soon. Due to the complicated voting system the meeting will be recorded.

(1) IFAPP Voting System as per the Constitution (online on https://ifapp.org/about/constitution)
Number of votes per National Member Association:
1 vote: 1-50 members
2 votes: 51-100 members
3 votes: 101-1000 members
4 votes: 1000 or more members

(2) NMAs that have not yet paid their annual membership fee can still do so and thus activate their voting rights

THE FLAG

IFAPP secretariat - Leidsestraatweg 41d - 3443 BP Woerden - The Netherlands
Chamber of Commerce 30224375 – VAT number NL817747321B02
Phone: (+31) 6 2291 1039 – e-mail: secretariat@ifapp.org – website: www.ifapp.org

IFAPP Communication Working Group
Raeefuddin Ahmed, Varvara Baroutsou, Simone Breitkopf, Frank Bringstrup, Brigitte Franke-Bray, Epaïnète Gawa, Ilker Gelisen, Ghazaleh Gouya Lechner, Kyoko Imamura, Qaddafi Jahangir, Ji-Hyun Kim, Rob van Maanen, Hasan Mahmood, Kotone Matsuyama, Anna Rodet, Johanna Schenk, Peter Stilting, Chinnie Tan, Ajay Tiku.

IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

Follow us on: