



# The ISoP Star

No 35. December 2017

## Liverpool's fixture for vigilance

### Annual meeting report



*Sten Olsson, ISoP President, and Mira Harrison-Woolrych, ISoP Secretary General*

This year's annual meeting played out in the north of England, hosted by Professor Munir Pirmohamed and his team at the Mersey Yellow Card Centre for ADR Monitoring based at the University of Liverpool.

The day before the conference there were the customary full-day pre-conference training courses, this year coordinated by Marco Tuccori (ETP Europe). 95 people took advantage of the opportunity to attend either the 'Pharmacovigilance and social media' tutorials or those on 'Paediatric pharmacovigilance' - each led by a team of eminent experts.

With 57 countries represented, exhibitors primed on their stands and posters up on the boards at the ACC Exhibition Centre in Liverpool, the main conference got underway with a keynote lecture from Mark Girolami of Imperial College London 'On the importance of quantifying and propagating uncertainty in healthcare' and from there on, delegates set off on the two-and-a-half-day journey through pharmacovigilance as it stands in

2017. Professor Girolami spoke about the importance of addressing the uncertainties in assessment of 'big data' - and of avoiding seeing data as a 'black box', without any knowledge or understanding of its internal workings or meaning. More lectures on big data approaches in pharmacovigilance followed, with perspectives from the USA and UK. There was consensus that there is more work to do, and that social media has value in niche analysis, but not in broad based signal detection.

Mick Foy of the UK MHRA chaired a round-table discussion on "Medicines Regulation in the 21st Century" with individual perspectives from the EMA (Sabine Brosch), the US FDA (Judith Zander), WHO headquarters (Shanthi Pal) and, for an outsider's view, Michael Dougan, Professor of European Law at the University of Liverpool.

#### **A game of two halves**

The 2017 parallel sessions consisted of 'Training in Pharmacovigilance' versus 'Pharmacogenomics and Pharmacovigilance' on Monday 16th October, and on the next day 'Medicines for Women' pitted against the 'Implications of WEB-RADR for pharmacovigilance'. Delegates were faced with customary hard decisions on what to attend -. all four sessions had plenty to offer, with speakers from Ghana, UK, Czech Republic, Thailand, the Netherlands, Sweden and Turkey.

The speakers on training covered running a Masters level course in Africa, the ISoP Global standard for a career framework in pharmacovigilance, and pharmacology education in medical schools. In the parallel session on pharmacogenomics and pharmacovigilance, genetics and the prevention of serious cutaneous adverse drug reactions, pre-emptive genotyping for preventing ADRs, precision dosing to reduce

***Season's Greetings to ISoP members!***

ADRs in children, and whole exome sequencing in individuals with statin-induced myopathy were the topics covered.

Medicines for women presented expert lectures on medicines in pregnancy by Dr Laura Yates and the safety of HRTs and OCs, by Professor Valerie Beral. These were followed by abstract presentations on gender differences in reported adverse drug reactions of SSRIs, and patient sex distribution in a global database of suspected adverse drug reactions (VigiBase).

Although the WEB-RADR project has now finished, the outputs from its working groups should provide benefits to patients in the EU and around the world for much longer. Phil Tregunno of MHRA (who led the Work Package 5 of the project) presided over 'Implications of WEB-RADR for pharmacovigilance', which saw talks on 'Needles in hay - use of machine learning to identify references to drugs and adverse events in social media', 'Where is social media able to make a positive contribution to pharmacovigilance?', 'Regulatory implications of WEB-RADR' and 'Characteristics and quality of ADR reports submitted through new reporting tools'.

Later that evening, the Conference Gala Dinner took place at the home of Liverpool Football Club, Anfield, preceded by a tour of the changing and back-stage facilities for home and away teams, where so many of Liverpool's triumphs were hatched.

Day 2 kicked off with Lembit Rāgo, the new head of the Council for International Organizations of Medical Sciences (CIOMS) talking about the future of their work and its relevance to pharmacovigilance. Herbal and traditional medicines were not neglected, with a session on new solutions and innovations chaired by Joanne Barnes, of the University of Auckland, New Zealand, and Phil Routledge, University of Cardiff, UK.

In these days of data-mining of electronic health records and social media, the plenary talks kept the

discussion at the centre of clinical work, with valuable lectures on serious cutaneous adverse drug reactions and drug-induced liver injury.



*Mayor of Liverpool, Councillor Malcolm Kennedy, Hervé Le Louët and Munir Pirmohamed*

Despite all the eminent speakers, it could be argued that networking is the most important aspect of international congresses such as the ISO P annual meeting. There were plenty of opportunities for that in Liverpool, including a conference reception with the multi-lingual Mayor of Liverpool, Councillor Malcolm Kennedy who welcomed all ISO P delegates to the city.

The Bengt Erik Wiholm Lecture was given by Jeffrey Aronson, the Oxford professor well-known for both his academic work and his continuing examination of the use of language in science, manifest in his popular BMJ blog 'When I use a word...'. He gave a fascinating and witty angle on how the language of pharmacovigilance works - mainly in English of course, but with reference to other languages. He pointed out the number of

***A Happy New Year to all members!***

'lost' references in literature searches due to misspelt drug names.

After further interesting lectures: 'Adverse effects of advanced cell therapies'; 'Pharmacovigilance of biologics and biosimilars'; and 'Pharmacovigilance of anti-cancer medicines and Immune checkpoint inhibitors', there was just time for a quick sandwich on the final day before, with the ex-hurricane Ophelia abating, everyone departed for trains and planes with intellectual sustenance for their journey home.

Most of the ISoP 2017 presentations can be seen on the ISoP website in the Member section (access to members only).

**Non-members who registered at the ISoP Liverpool Annual Meeting and paid full registration fees will become ISoP members from January 1<sup>st</sup> to 31<sup>st</sup> December 2018. A very warm welcome to these newcomers!**

## Liverpool poster prizes



(L → R) Jeffrey Aronson, Deirdre McCarthy, Sarah Watson, Sten Olsson

200 abstracts were accepted as posters, representing a diverse international spread of ISoP members. At the close Jeffrey Aronson, Chair of the poster prize committee congratulated all authors who had presented their work. The winners recognized in the poster prize competition were:

**First prize:** (Abstract 68 in Drug Safety.) Tailoring signal detection methodologies in a global database to focus on safety concerns reported by patients. S. Watson, R Chandler, B Grundmark, L. Harmark, K Star, H. Taavola, F. van Hunsel.

**Second prize:** (Abstract 236.) Evaluation of the first EU-wide social media ADR awareness week: 7-11 November 2016. M. Jadeja

**Third prize:** (Abstract 122.) Opinion of Costa Rican pharmacists regarding some aspects of the Spontaneous Adverse Drug Reactions reporting 2017. V. Hall, LG. Jiménez, M. Rocha.



### Read on... in *Drug Safety*

A special edition of *Drug Safety* was published to coincide with the 2017 annual meeting (Volume 40, Issue 10, October 2017) which includes all the abstracts for the poster presentations in Liverpool. As well as the article "New Phase of ISoP" article by the ISoP Executive Committee, <https://link.springer.com/article/10.1007/s40264-017-0545-y>, this edition includes a special piece 'A New Erice Report Considering the Safety of Medicines in the 21st Century' by Ralph Edwards.

***A Happy New Year to all members!***

## Geneva awaits your ideas!



The ISoP Annual Meeting 2018 will take place in Geneva, Switzerland on 11–14 November, immediately after the 50th anniversary meeting of the WHO Programme for International Drug Monitoring. The meeting website may be found at <http://www.isop2018geneva.org> and more information will be added over coming months.

A new concept for 2018 is the call for submission of symposia proposals from ISoP members under the headings which could include:

- Pharmacovigilance and pharmacogenetics
- Patient empowerment in pharmacovigilance
- Progress in pharmacovigilance in developing countries
- Pharmacovigilance in big data era
- Risk communication in pharmacovigilance
- International approaches to pharmacovigilance.

We look forward to seeing you in Geneva !

## ISoP UMC training course

5th ISoP-UMC Training  
Shenyang, China  
11-12 January 2018

Pharmacovigilance training:  
from surveillance to inspections



Lectures, working groups and panel discussions

will be on the agenda at a 2-day ISoP seminar (11 and 12 January 2018) in Shenyang, China.

The event will address ‘How does harmonization of active surveillance and signal detection evaluated by PV inspection lead to better safety governance?’ This two day-course will be conducted with expertise from UMC, ISoP and local institutions, and will address the practical and theoretical aspects of pharmacovigilance. It will also look at the methodology of intensive safety monitoring using case studies.

Training will be delivered through lectures (in English with simultaneous translation), working groups and panel discussions.

The programme will cover:

- Individual case safety reports and Spontaneous Reporting Systems
- Signal detection and management
- Logical application of causality
- Pharmacovigilance inspection
- Risk communication
- Intensive safety monitoring programs

## Register now!

This course will take place in the city of Shenyang, China, in collaboration with the ISoP China chapter and the International Food and Drug Policy and Law Research Center (IFDPL) at Shenyang Pharmaceutical University. The registration form is available from the ISoP Administration at [administration@isoponline.org](mailto:administration@isoponline.org) or at the ISoP website.

## Canberra training



In March 2018, the mid-year training will take place in Australia for the first time in ISoP history.

***A Happy New Year to all members!***

This course will address the specific needs and interests of people working in pharmacovigilance in regulatory agencies, pharmaceutical companies, academia, hospitals or community settings in the Western Pacific region. The programme will cover pharmacovigilance and risk-management issues in the context of the Australian and New Zealand health systems and particularly the specific situation of rapidly growing countries and health economies.

## Register now!

The first day will take the form of lectures, with opportunity for discussion through questions and answers and panel discussion, while the second day will focus on hands-on interactive tasks in smaller workshop groups. The second part of the course will focus on risk management and minimization approaches. Participants will gain hands-on experience of the development of Risk Management Plans (RMPs) and the conduct of benefit-risk assessments. This two-day course will have a strong focus on practical examples and real-life solutions.

“Pharmacovigilance in the Western Pacific: Global approaches to risk-management of medicines” will take place on 15-16 March 2018.

More information on the website <http://isoponline.org/training/midyear-training-canberra-15-16-march-2018/>

## Reflections from Boston

*Deirdre McCarthy*

We are delighted to report on our first ever training course in North America. Entitled 'Intelligent Automation in Pharmacovigilance', the seminar was held on 4 and 5 December 2017 in Boston/Cambridge, Massachusetts. It was co-hosted with PrimeVigilance and kindly supported by Biogen. Over 67 participants gathered for a combination of presentations, panel discussions and plenty of lively interaction. Speakers ranged from industry, service and technology providers to regulators, including FDA and MHRA representatives. Day 1 topics included advances to date with the automation of key pharmacovigilance

processes, such as case intake and signal detection. On Day 2 the conversation turned to career implications and opportunities in the new 'Pharmacovigilance 4.0', covering new skillsets and service mixes, and implications for outsourcing models. The seminar received very positive feedback and ISO<sub>P</sub> is hopeful that a follow-up can be held next year.



*Jan Petracek, coordinator of the Boston seminar*

## Links

ISO<sub>P</sub>'s representative on the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, ENCePP, is now Hervé Le Louët. Coordinated by the European Medicines Agency (EMA), ENCePP is a voluntary group which brings together expertise and resources in pharmacoepidemiology and pharmacovigilance to strengthen the monitoring of the benefit-risk balance of medicines, primarily by facilitating the conduct of high quality, multi-centre, independent post-authorisation studies (PAS) with a focus on observational research.

Sten Olsson, the President of ISO<sub>P</sub> represented the Society at the WHO Coalition of Interested Partners (CIP) Task Force for regulatory systems strengthening meeting in Kampala, Uganda on 9-10 November 2017.

Since the last ISO<sub>P</sub> Star, new Chapters have been formed. Welcome to:

- Indonesia (President: Dr Jarir At Thobari), and
- South Asia (President: Prof Gurumurthy Parthasarathi).

***A Happy New Year to all members!***

## ...and three new SIGs

Special Interest Groups (SIGs) with ISoP now include:

Herbal and traditional medicines (Co-ordinator: Joanne Barnes)

Medication Errors (Co-ordinators: Brian Edwards/Ian C.K. Wong)

PV Professional Qualification Framework (Co-ordinator: Jan Petracek)

They join the Women's Medicine, Risk Communication, and Risk Minimisation Methods for Asian countries Groups. For details on how to get involved in a SIG, contact ISoP administration.

## 2017 General Assembly

At the ISoP General Assembly some administrative changes to the ISoP Statutes, - mainly concerned with aligning the Society's rules with the Swiss civil code (ISoP is registered in Switzerland) - were adopted. ISoP will be registered in the Trade Register of Geneva.

The effects of the changes to the Statutes are that an ISoP special general assembly must be convened by the President if at least one fifth of the members wish it (previously one third), and that the Statutes can be changed only on the proposition of the Executive Committee, or as a result of a petition of at least one fifth of the members having paid their fees (previously one quarter).

## Webinars

What could become a regular series of ISoP webinars was launched on 27 September 2017, with the assistance of Springer Nature, with a session on 'Good publication practice'. 45 participants heard Nitin Joshi, Editor-in-Chief of *Drug Safety*. The webinar covered what an editor looks for in a manuscript and how to write a good original research article. Mr Joshi showed how to produce a strong manuscript and hopefully we see some more publications from ISoP members in the coming months.

ISoP intends to offer these webinars at times better suited for members in other time zones and thanks to the success of the first webinar, another free webinar will be offered to members on **6 February**

**2018 at 7pm GMT, or 7 February 2018 at 8am NZ time.** For those who cannot attend the webinar, ISoP is exploring ways to post the videos on the website (member section). In this presentation, Nitin Joshi, will talk about choosing the right journal for your research. As every rejection can set you back by about three months, it is vital that your research is published as soon as possible and in a journal with the right target audience. We will start with some strategies on how to produce a strong manuscript and then discuss in detail the steps for choosing the right journal.

Save the date! ISoP members will receive a link to register.

## Events for the diary

- ISoP-UMC training course in Shenyang, China 11 - 12 January 2018
- Course for Indian PvPI programme, New Delhi, India dates to be confirmed, 2018
- ISoP webinar 6 February 2018, 7pm GMT
- ISoP Mid-year training course, Canberra, Australia 15 - 16 March 2018
- ISoP-UMC training course, Ecuador 24 - 26 September 2018



Yet to be confirmed, a possible Eurasian training course in Belarus.

## ISoP in touch

We are on Twitter [@ISoPonline], LinkedIn and our website [isoponline.org](http://isoponline.org)

## 2018 Membership renewal

Renewal forms have been sent out by email. Please remember to renew your membership by 30 January 2018. Only members who are paid-up will have access to incentives, Chapters/SIGs.

***A Happy New Year to all members!***

**IMPORTANT:** If there is a mistake in our database, or you have changed your e-mail address, do let us know as soon as possible!

## Benefits for members

20% discount on Wiley-Blackwell Pharmacology and Pharmaceutical Medicine books for all ISoP members!

Fast, simple and secure ordering! You can order books online at [www.wiley.com](http://www.wiley.com) (this offer is not available through bookstores). The promotion code to allow access to the 20% discount has been sent with your renewal membership notice.

More discounts for books at

<http://www.isoponline.org/index.php?page=membership>

## Drug Safety journal

As part of their membership, all ISoP members will receive electronic access to the journal *Drug Safety*, and therefore the printed version of the *Drug Safety* journal is no longer available to members.

The link to the journal *Drug Safety* must be clicked from within **the ISoP Members' Area on the ISoP website** in order to obtain online access (and not from the Springer/Drug Safety website). Only members who are paid-up will have access to membership benefits.

## ISoP Privacy Policy

Your contact details are kept on a computer at the Administration Office, but will not be released to any other organisation or individual outside ISoP except to Springer publishers (*Drug Safety*). For the purpose of electronic distribution of the *Drug Safety* journal as part of membership and based on a contract between ISoP and Springer publishers, ISoP Administration will forward your registered e-mail address to Springer publishers. The processing of the data itself and rendering of the e-mail services can be performed by a non-Springer company or its related companies. Information/alerts about relevant *Drug Safety* journal activities will be sent to ISoP members by e-mail, unless you ask for them not to be sent.

More about the ISoP privacy policy can be seen on [www.isoponline.org](http://www.isoponline.org).

## www.isoponline.org

Please visit our website regularly to stay informed about ISoP and its many activities!

Please send your letters, comments, ideas and contributions for ISoP Star to:

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## Contact details

If you have changed your address, and most importantly your e-mail address, do let us know as

soon as possible. We would like to keep members informed of ISoP news and with an easy access to the journal *Drug Safety*, electronic mail is the best way of sending certain types of information. Please e-mail your correct details to us, we will be able to update our address lists.

Thank you!

**Have  
you  
moved?**

***A Happy New Year to all members!***