New ideas in ancient cultures: advancing pharmacovigilance in Asia

19th to 22nd October, 2014
Holiday Inn Tianjin Riverside
Tianjin, China
Dear Colleagues,

On behalf of the ISoP Executive Committee and the Local Organizing Committee, it is with great pleasure that we welcome you to the 14th Annual Meeting of the International Society of Pharmacovigilance (ISoP 2014) in Tianjin, China from 19 to 22 October 2014.

This meeting entitled “New Ideas in Ancient Cultures: Advancing Pharmacovigilance in Asia” will focus on the latest developments in pharmacovigilance and on thoughts for future perspectives in China and the Asia-Pacific region. Many hot topics will be raised and discussed during the event, such as new technologies and treatment concepts, pharmacogenomics and personalised medicine, new methodologies in pharmacovigilance, risk management and outcome measurement, clinical aspects of specific ADRs, pharmacovigilance on herbal medicinal products and ethno-pharmacovigilance, and, last but not least, ADRs in specific populations and treatments.

A special focus will be given to young scientists and healthcare professionals dedicated to pharmacovigilance.

In China, along with the development of medicines and the health care system, rational drug use and drug safety has become increasingly important and is currently of high public health relevance.

In recent years, China’s ADR monitoring system has gradually developed in all aspects of pharmacovigilance. The scope of monitoring drug safety has expanded substantially, and the China Food and Drug Administration have experienced enormous growth: by March 2011, all 406 prefectures in the country had established an ADR centre. As of 2013, there were over 6.5 million ADR reports in the national Chinese database.

The 14th ISoP Annual Meeting will follow the 37th Annual Meeting of National Centers participating in the WHO Programme for International Drug Monitoring. A joint WHO/ISoP session will be organised on 19 October. This will represent a wonderful opportunity to share worldwide experience on drug safety.

The varied social programme will allow delegates to spend time catching up with friends and meeting new ones, as well as offering the opportunity to enjoy Chinese hospitality. China is one of the fastest growing countries in the world, yet it is rich in history and steeped in ancient culture. Your experience at the ISoP meeting in Tianjin is sure to be thoroughly enjoyable and stimulating.

The local organisers and the Scientific Committee look forward to welcoming you at the ISoP 2014 Annual Meeting.

Local Organizing Committee

Hervé Le Louët, President of ISoP
Dear Colleagues,

I have great pleasure in welcoming you all to the 14th ISoP Annual Meeting here in the wonderful city of Tianjin. Thank you all for taking time out of your busy schedules to attend this important and timely event.

Over the next four days we will hear about recent exciting developments in pharmacovigilance from our fellow colleagues, and leading experts from around the world. We will share the latest discoveries and innovation, and discuss areas where more research is needed in Asia. It is of particular importance that pharmacovigilance is becoming an increasingly recognised public health aspect of our host country’s evolving health care system, and this 14th meeting is timely in sharing our expertise here.

I hope you will all also take the opportunity to view the poster presentations, see the fantastic work that is being done, and encourage one another as we seek to advance pharmacovigilance in all areas of healthcare.

I hope you all enjoy the Meeting and find time to take part in the social activities and do some sightseeing in the city of Tianjin.

Chair of Scientific Committee,
Prof Ian C K Wong

---

ISoP EXECUTIVE COMMITTEE

Hervé Le Louët, France (President)
Yola Moride, Canada (Vice-president)
Ulrich Hagemann, Germany (Secretary General)
Brian Edwards, United Kingdom (Treasurer)
Ian C. K. Wong, Hong Kong (Vice Secretary, Vice Treasurer)
Andrew Bate, United Kingdom (Chair, Education and Training Programme)
Luis Alesso, Argentina
Ian Boyd, Australia
Kenneth Hartigan-Go, Philippines
Marco Tuccori, Italy
Gunilla Sjölin-Forsberg, Sweden
Alex Dodoo, Ghana (Past-President)
ORGANIZING COMMITTEES

LOCAL COMMITTEE
Ms. Lili Cao (Co-Chair)
Dr. Jean-Christophe Delumeau
Dr. Gang Cheng, MD, PhD
Ms. Xue Tang

SCIENTIFIC COMMITTEE
Prof. Ian Wong (Chair)
Ms. Lili Cao (Co-Chair)
Dr. Andrew Bate
Dr. Brian Edwards
Dr. Marie Lindquist
Dr. Kenneth Hartigan-Go
Dr. Siyan Zhan
Dr. Lynn Zhou

POSTER PRIZE COMMITTEE
Chair: Brian Edwards
Li Zhang
Lynn Zhou

ISoP ANNUAL MEETINGS
Prague, Czech Republic (2015)
Tianjin, China (2014)
Pisa, Italy (2013)
Cancun, Mexico (2012)
Istanbul, Turkey (2011)
Accra, Ghana (2010)
Reims, France (2009)
Buenos Aires, Argentina (2008)
Bournemouth, United Kingdom (2007)
Liège, Belgium (2006)
Manila, the Philippines (2005)
Marrakech, Morocco (2003)
Amsterdam, Netherlands (2002)
Carthage-Tunis, Tunisia (2001)

ESoP ANNUAL MEETINGS
Verona, Italy (2000)
Ankara, Turkey (1999)
Budapest, Hungary (1998)
Berlin, Germany (1997)
Lisbon, Portugal (1996)
Rouen, France (1994)
Geneva, Switzerland (1993)
SPEAKERS AND CHAIRS

- Luis Alesso, Universidad Nacional de Cordoba, Cordoba (Argentina)
- Priya Bahri, European Medicines Agency (EMA), London (UK)
- Andrew Bate, Pfizer UK, Surrey (UK)
- Juergen Beckmann, Member of the WHO Expert Advisory Panel on Medicine Safety, Berlin (Germany)
- Tomas Bergvall, Uppsala Monitoring Centre (UMC), Uppsala (Sweden)
- Ian Boyd, Ian Boyd Consulting, Giralang (Australia)
- Pia Caduff, Uppsala Monitoring Centre, Uppsala (Sweden)
- Lili Cao, China Center for Food & Drug International Exchange (China)
- Gang Cheng, Center for Drug Reevaluation/ National Center for ADR Monitoring, CFDA (China)
- Lung Cheung, The University of Hong Kong (Hong Kong, China)
- Chia-Yu Chu, National Taiwan University Hospital (Chinese Taipei)
- Celine Chui, The University of Hong Kong (Hong Kong, China)
- Jean Christophe Delumeau, Bayer Health Care (Singapore)
- Alex Dodoo, WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, University of Ghana Medical School, Accra (Ghana)
- Shengjie Dong (China)
- Brian Edwards, NDA Regulatory Science Ltd, Surrey (UK)
- Mick Foy, Medicines and Healthcare Products Regulatory Agency (MHRA), London (UK)
- Joshua J Gagne, Brigham and Women's Hospital, Boston (USA)
- Parthasarathi Gurumurthy, JSS University, Mysore (India)
- Ulrich Hagemann, Secretary General of ISoP, Berlin (Germany)
- Linda Harmark, Netherlands Pharmacovigilance Centre Lareb (Netherlands)
- Kenneth Hartigan Go, Asian Institute of Management, Makati City (Philippines)
- Bruce Hugman, Uppsala Monitoring Centre (UK)
- Joerg Hasford, IBE, University of Munich (Germany)
- Juhaeri Juhaeri, Sanofi, Bridgewater (USA)
- Stefan Kaehler, Celgene Europe Ltd (UK)
- Marie Lindquist, Uppsala Monitoring Centre (UMC), Uppsala (Sweden)
- Hervé Le Louët, President of ISoP, Pharmacovigilance Department, Henri Mondor Hospital, Creteil (France)
- Kenneth Man, The University of Hong Kong (Hong Kong, China)
- Yuan Meng, Pfizer, Shanghai (China)
- Yola Moride, Department of Epidemiology, University of Montreal, Montreal (Canada)
- June Raine, Pharmacovigilance Risk Assessment Committee (PRAC), London (UK)
- Jingtian Ren, Center for Drug Reevaluation/ National Center for ADR Monitoring, CFDA (China)
- Saad Shakir, Drug Safety Research Unit, University of Southampton (UK)
- Gunilla Sjölin-Forsberg, Council for International Organizations of Medical Sciences (CIOMS), Geneva (Switzerland)
- Kristina Star, Uppsala Monitoring Centre (UMC), Uppsala (Sweden)
- Haibo Song, Center for Drug Reevaluation/ National Center for ADR Monitoring, CFDA (China)
- Feng, Sun (China)
- Xue Tang, Pfizer, Beijing (China)
- Gianluca Trifire, Department of Clinical and Experimental Medicine, University of Messina - Italy; Department of Medical Informatics, Erasmus Medical Center, Rotterdam -Netherlands (Italy)
- Panayiotis Tsintis, Council for International Organizations of Medical Sciences (CIOMS), Geneva (Switzerland)
- Marco Tuccori, University Hospital of Pisa, Unit of Adverse Drug Reaction Monitoring, Pisa (Italy)
- Yuqin Wang, (China)
- Dayou Wang, Huashan Hospital, Shanghai (China)
- Ivy Wang, Pfizer Inc, Shanghai (China)
- Ian C.K. Wong, Li Ka Shing Faculty of Medicine, University of Hong Kong (Hong Kong, China)
- Yuhong Wang, Bayer (China)
- Bin Xue, China Center for Food and Drug International Exchange (China)
- Siyan Zhan, Peking University Health Science Center, Beijing (China)
- Lynn Zhou, Sanofi Beijing (China)
### PROGRAMME AT A GLANCE

#### SUNDAY, OCTOBER 19th, 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registration</td>
</tr>
<tr>
<td>09:00-17:00</td>
<td>Pre – Conference Course 1 Principle of Meta-Analysis (Riverside 1)</td>
</tr>
<tr>
<td></td>
<td>Pre – Conference Course 2 Core and Emerging Issues in ADR Reporting and Pharmacovigilance (Meeting Room 2+3)</td>
</tr>
<tr>
<td></td>
<td>Pre – Conference Course 3 Communication in Pharmacovigilance (Meeting Room 1)</td>
</tr>
<tr>
<td>18:00-19:30</td>
<td>Welcome reception</td>
</tr>
</tbody>
</table>

#### MONDAY, OCTOBER 20th, 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registration</td>
</tr>
<tr>
<td>09:00-09:45</td>
<td>Opening Ceremony*(Grand Ball Room)</td>
</tr>
<tr>
<td>09:45-10:45</td>
<td>Updates from the WHO ISoP Joint Session: Latest Developments in Asian Pharmacovigilance and Thoughts on Future Directions*</td>
</tr>
<tr>
<td>10:45-11:15</td>
<td>Coffee break and poster viewing</td>
</tr>
<tr>
<td>11:15-11:45</td>
<td>Plenary sessions * Harmonization and Essential Differences in Pharmacovigilance Approach (Asian Academic Perspective)</td>
</tr>
<tr>
<td>11:45-12:00</td>
<td>Teaching Pharmacovigilance: The WHO-ISoP Core Elements of a Comprehensive Modular Curriculum*</td>
</tr>
<tr>
<td>12:00-12:15</td>
<td>ISoP Special Interest Group Risk Communication*</td>
</tr>
<tr>
<td>12:15-12:45</td>
<td>Pharmacovigilance Risk Assessment Committee (PRAC) - A New Era in Pharmacovigilance in Europe*</td>
</tr>
<tr>
<td>12:45-14:00</td>
<td>Lunch</td>
</tr>
<tr>
<td>14:00-15:30</td>
<td>Parallel session A* Pharmacogenomics and Personalized Medicine (Grand Ball Room)</td>
</tr>
<tr>
<td>15:30-16:00</td>
<td>Coffee break and poster viewing</td>
</tr>
<tr>
<td>16:00-17:30</td>
<td>Parallel session C* Dermatological ADRs (Grand Ball Room)</td>
</tr>
<tr>
<td>17:30-18:00</td>
<td>Meeting of the ISoP Chapters (Riverside 2+3)</td>
</tr>
</tbody>
</table>

#### TUESDAY, OCTOBER 21st, 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Parallel session E* Specific Populations and Treatments: Pediatrics and Women’s Health (Grand Ball Room)</td>
</tr>
<tr>
<td>09:00-10:45</td>
<td>Parallel session F Risk Management Plans (Riverside 2+3)</td>
</tr>
<tr>
<td>10:45-11:15</td>
<td>Coffee break and poster viewing</td>
</tr>
<tr>
<td>11:15-12:00</td>
<td>Plenary Lecture* (Grand Ball Room)</td>
</tr>
<tr>
<td>12:00-13:00</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:00-13:45</td>
<td>ISoP General Assembly * (Grand Ball Room)</td>
</tr>
<tr>
<td>13:45-14:30</td>
<td>Clinical Trials, Information Technologies and Benefit Assessment - Current Challenges for Pharmacovigilance</td>
</tr>
<tr>
<td>14:30-15:15</td>
<td>Open Discussion* New Developments in Pharmacovigilance and Beyond</td>
</tr>
<tr>
<td>15:15-16:45</td>
<td>Coffee break and poster viewing</td>
</tr>
<tr>
<td>15:45-16:55</td>
<td>Parallel session G* Herbal Pharmacovigilance (Grand Ball Room)</td>
</tr>
<tr>
<td>19:00</td>
<td>Conference dinner</td>
</tr>
</tbody>
</table>

#### WEDNESDAY, OCTOBER 22nd, 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-08:50</td>
<td>Parallel session I* Specific Populations and Treatments: Geriatrics (Grand Ball Room)</td>
</tr>
<tr>
<td>08:50-10:00</td>
<td>Parallel Session J Junior and Seasoned Pharmacovigilantes Presentations(Riverside 2+3)</td>
</tr>
<tr>
<td>10:00-10:15</td>
<td>Coffee break</td>
</tr>
<tr>
<td>10:15-10:45</td>
<td>Keynote Lecture* Developing a National Pharmacovigilance Strategy while Leveraging and Contributing to International Pharmacovigilance (Grand Ball Room)</td>
</tr>
<tr>
<td>10:45-11:15</td>
<td>Poster Prize Awards* Poster Prize Awards and Short Communication from the Winners</td>
</tr>
<tr>
<td>11:15-11:35</td>
<td>ISoP 2015 Presentation: Prague*</td>
</tr>
<tr>
<td>11:35-12:00</td>
<td>Closing Ceremony*</td>
</tr>
<tr>
<td>12:00-14:00</td>
<td>Lunch</td>
</tr>
</tbody>
</table>

*Simultaneous interpretation in all plenary sessions and Session A, C, E, G, I.
### SCIENTIFIC PROGRAMME

**SUNDAY, OCTOBER 19th, 2014**

**Pre-conference course 1: Network meta-analysis (Riverside 1)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.00 - 09.00</td>
<td>Registration</td>
<td></td>
</tr>
<tr>
<td>09.00 - 09.10</td>
<td>Introduction Course objectives</td>
<td>Siyan Zhan (China)</td>
</tr>
<tr>
<td>09.10 - 10.10</td>
<td>General introduction of systematic review and meta-analysis</td>
<td>Ian Wong (Hong Kong, China)</td>
</tr>
<tr>
<td>10.10 - 10.40</td>
<td>Meta-analysis in RevMan</td>
<td>Ian Wong (Hong Kong, China)</td>
</tr>
<tr>
<td>10.40 - 11.00</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>11.00 - 11.30</td>
<td>A short introduction of Bayesian meta-analysis</td>
<td>Shengjie Dong (China)</td>
</tr>
<tr>
<td>11.30 - 12.30</td>
<td>How to perform Bayesian meta-analysis using WinBUGS and R2WinBUGS</td>
<td>Shengjie Dong (China)</td>
</tr>
<tr>
<td>12.30 - 13.30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>13.30 - 15.00</td>
<td>Introduction of network meta-analysis</td>
<td>Shengjie Dong (China)</td>
</tr>
<tr>
<td>15.00 - 15.30</td>
<td>Plotting NMA figure in Stata or R, including practical</td>
<td>Feng Sun (China)</td>
</tr>
<tr>
<td>15.30 - 16.00</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>16.00 - 17.00</td>
<td>Performing NMA in Stata or R, including practical</td>
<td>Feng Sun (China)</td>
</tr>
<tr>
<td>17.00 - 17.30</td>
<td>Explaining and Presenting Results, including Limitation and pitfalls</td>
<td>Feng Sun (China)</td>
</tr>
<tr>
<td>17.30 - 18.00</td>
<td>Checklist and critical appraisal of NMA, including group work</td>
<td>Siyan Zhan (China)</td>
</tr>
<tr>
<td>18.00</td>
<td>Welcome reception (Riverside Meeting Room)</td>
<td></td>
</tr>
</tbody>
</table>

**Pre-conference course 2: Core and emerging issues in ADR reporting and pharmacovigilance (Meeting Room 2+3)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00 - 09.10</td>
<td>Introduction Course objectives</td>
<td>Ian Boyd (Australia)</td>
</tr>
<tr>
<td>09.10 - 10.30</td>
<td>The WHO-ISoP pharmacovigilance curriculum - overview and application including practical exercises</td>
<td>Juergen Beckmann (Germany)</td>
</tr>
<tr>
<td>10.30 - 11.00</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>11.00 - 12.00</td>
<td>The role and operation of consumer reporting in the Netherlands</td>
<td>Linda Harmark (The Netherlands)</td>
</tr>
<tr>
<td>12.00 - 13.00</td>
<td>Recent development of pharmacovigilance science and the possible evolution of a pharmaceutical industry model in response to the changes</td>
<td>Ivy Wang (China)</td>
</tr>
<tr>
<td>13.00 - 14.00</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>14.00 - 15.00</td>
<td>Teaching and learning pharmacovigilance</td>
<td>Parthasarathi Gurumurthy (India)</td>
</tr>
<tr>
<td>15.00 - 15.30</td>
<td>Handling vaccine crisis (an interactive session)</td>
<td>Kenneth Hartigan-Go (Philippines)</td>
</tr>
<tr>
<td>15.30 - 16.00</td>
<td>Coffee break</td>
<td></td>
</tr>
</tbody>
</table>
| 16.00 - 17.00 | Handling vaccine crisis (continued) and wrap-up | Kenneth Hartigan-Go (Philippines)  
                          Ian Boyd (Australia) |
| 18.00       | Welcome reception (Riverside Meeting Room) |                          |
Plenary sessions 09:00-12:45 (Grand Ball Room)

08:30 – 09:00  Registration
09:00 – 09:45  Top tips and basic concepts in communication in pharmacovigilance for busy people
  ♦ Moderator: Ulrich Hagemann (Germany)
  ♦ Presenter: Bruce Hugman (Thailand)

09:45 – 10:45  Updates from the WHO ISoP joint session: latest developments in Asian pharmacovigilance and thoughts on future directions
  ♦ Marie Lindquist (WHO-Uppsala Monitoring Centre)
  ♦ Alex Dodoo (WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance)
  ♦ Gang Cheng (CFDA, China)

10:45 – 11:00  Coffee break and poster viewing
11:00 – 13.00  Harmonization and essential differences in pharmacovigilance approach (Asian academic perspective)
  ♦ Parthasarathi Gurumurthy (India)

13.00 – 14.00  Lunch break
14.00 – 14.10  Recap from the morning sessions
14.10 – 15.30  Vaccination, vaccination programmes and communication
  ♦ Presenter: Priya Bahri (UK)
  ♦ Moderators: Ulrich Hagemann (Germany), Bruce Hugman (Thailand), Kenneth Hartigan-Go (Philippines)

15.30 – 16.00  Coffee break
16.00 – 17.30  What need healthcare professionals to support patient safety?
  ♦ Discussion leaders: Priya Bahri (UK), Bruce Hugman (Thailand), Ulrich Hagemann (Germany), Marie Lindquist (Sweden)
  ♦ Panel discussions and working groups on
    ♦ Risk communication and mental health
    ♦ Risk communication and women's health
    ♦ Risk communication for sexual minorities
    ♦ Risk communication for adolescents/children

18.00  Welcome reception (Riverside Meeting Room)
Parallel session A 14:00-15:30 (Grand Ball Room)
Pharmacogenomics and personalized medicine
- Chairpersons: Marco Tuccori (Italy), Yuan Meng (China)

14:00-14:30 Drug induced liver injury
- Hervé Le Louët (France)
14:30-14:40 New biomarker for developing adverse drug reactions caused by statins
- Nikica Mirošević Skvrce (Croatia)
14:40-14:50 From the unknown to current practices of pharmacogenomics
- Sylvie Tomczyk (United States)
14:50-15:00 Relationship between structural alerts in drugs and reported idiosyncratic hepatotoxicity in the WHO
- Linda Härmark (Netherlands)
15:00-15:10 There is geographic variation of the frequency and profile of adverse drug reactions - an analysis for tyrosine kinase inhibitors
- Joerg Hasford (Germany)
15:10-15:20 Pharmacovigilance and the clinical eye – detecting new drug-induced diseases
- Ronald Meyboom (Netherlands)

Parallel session B 14:00-15:30 (Riverside 2+3)
Signal detection
- Chairpersons: Ian Boyd (Australia), Yuhong Wang (China)

14:00-14:30 Surveillance in medical records and claims - state of the art and future developments
- Andrew Bate (UK)
14:30-15:00 Web-based signal detection
- Juhaeri Juhaeri (USA)
15:00-15:30 WEB-RADR – A public-private partnership to explore the role of social media in pharmacovigilance
- Mick Foy (UK)

Parallel session C 16:00-17:30 (Grand Ball Room)
Dermatological ADRs
- Chairpersons: Luis Alessio (Argentina), Jean Christophe Delumeau (Singapore)

16:00-16:30 Dermatological ADRs
- Chia-Yu Chu (Chinese Taipei)
16:30-16:40 Dermatological adverse drug reactions with highly active antiretroviral therapy
- Emma Allan (UK)
16:40-16:50 Distribution of carriers with HLA-B allele at higher risk for SCAR in Thai population: implications for prevention of SCAR in Thailand and Southeast Asians
- Wimon Suwankesawong (Thailand)
16:50-17:00 Lacosamide (Vimpat®), a possible new inducer of Stevens Johnson Syndrome/Toxic Epidermal Necrolysis
- Sylvia H. Kardaun (Netherlands)
17:00-17:10 Liver injury in Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): A review of 72 cases
- Chia-Yu Chu (Chinese Taipei)
17:10-17:30 Research and prevention dermatological adverse drug reactions: a collaborative effort
- Lung Cheung (Hong Kong, China)

Parallel session D 16:00-18:00 (Riverside 2+3)
Need for and analyses of networks of data
- Chairpersons: Andrew Bate (UK), Siyan Zhan (China)

16:00-16:30 Recent development of Asian Pharmacoepidemiology Network (ASPEN)
- Kenneth Man (Hong Kong, China)
16:30-17:00 The U.S. FDA sentinel system
- Joshua J. Gagne (USA)
17:00-17:30 European networks of EMRs: ARITMO, SAFEGUARD and other studies
- Gianluca Trifiro (Italy)
17:30-18:00 A sum greater than its parts – joining information sources for improved pharmacovigilance
- Tomas Bergvall (Sweden)
**TUESDAY, OCTOBER 21ST, 2014**

Parallel session E 09:00-10:45 (Grand Ball Room)
Specific populations and treatments: pediatrics and women’s health
- Chairpersons: Ian Wong (Hong Kong, China), Xue Tang (China)

- **09:00-09:30**
  - A novel process to capture safety signals in spontaneous reports on children
    - Kristina Star (Sweden)

- **09:30-09:40**
  - Selective Serotonin Reuptake Inhibitor (SSRI) exposure during pregnancy and risk of autism spectrum disorders in children: a meta-analysis of observational studies
    - Henry Tong (Macao, China)

- **09:40-09:50**
  - Monitoring the safety of mass measles and Rubella immunization campaign in Morocco
    - Amina Tebaa (Morocco)

- **09:50-10:20**
  - Why can’t a woman be more like a man?
    - Pia Caduff (Sweden)

- **10:20-10:30**
  - A Pregnancy Prevention Program (PPP) for Revlimid® in China: partnership between company and HCPs
    - Xiaojing Zhan (China)

- **10:30-10:40**
  - US and EU approaches to risk management - what have we learnt?
    - Brian Edwards (UK)

Parallel session F 08:30-10:45 (Riverside 2+3)
Risk management plans
- Chairpersons: Brian Edwards (UK), Lynn Zhou (China)

- **08:30-08:50**
  - Current status for risk management in Asia: how should a pharmaceutical company respond?
    - Lynn Zhou (China)

- **08:50-09:10**
  - Risk management planning to tackle ethnicity difference
    - Henry Tong (Macao, China)

- **09:10-09:30**
  - Medication error reports: the impact of socio-cultural context in China
    - Dayou Wang (China)

- **09:30-09:50**
  - How the transparency data regulations are changing the communication regarding benefit-risk of medications
    - Sylvie Tomczyk (United States)

- **09:50-10:00**
  - Regulatory action: medical inaction?
    - Christopher Anton (UK)

- **10:00-10:20**
  - Individual risk management plans are needed for confident biosimilar prescribing
    - Banu Unal (Turkey)

- **10:20-10:30**
  - Risk management and pharmacovigilance in the Brazilian health surveillance agency: the benzydamine case
    - Fernanda do Carmo Santa Cruz (Brazil)

- **10:30-10:40**
  - Quantitative benefit-risk assessment of rosiglitazone: number needed to treat, number needed to harm and likelihood to be helped or harmed
    - Diogo Mendes (Portugal)

Plenary Session 11:15-15:45 Oct. 21st, 2014 (Grand Ball Room)

**11:15-12:00**
- **Council for International Organizations of Medical Sciences (CIOMS) Lecture**
  - **Chair**: Gunilla Sjölin-Forsberg (Sweden)
  - **Presenter**: Panayiotis Tsintis (CIOMS)
  - **Global Aspects of Risk Minimisation Practical Approaches**

**12:00-13:00**
- Lunch

**13:00-13:45**
- **ISoP General Assembly**
  - **1**
  - **2**
  - **3**

**13:45-14:30**
- The Bengt Erik Wiholm Lecture
  - Clinical trials, information technologies and benefit assessment - current challenges for pharmacovigilance
    - Joerg Hasford (Germany)

**14:30-15:15**
- Open discussion
  - New developments in pharmacovigilance and beyond
    - **Moderators**: Brian Edwards (UK) - Marie Lindquist (UMC, Sweden)

**15:15-15:45**
- Coffee break and poster viewing
**Parallel session G 15:45-16:55 (Grand Ball Room)**  
**Herbal pharmacovigilance**

- Chairpersons: Jingtian Ren (China), Alex Dodoo (Ghana)

15:45-16:15  
Adverse reaction monitoring and reevaluation for traditional Chinese medicine

- Haibo Song (China)

16:15-16:25  
Congenital malformations of Fenugreek in Morocco: an analysis of reports in the Moroccan herbal products database from 2004 to 2014

- Soud Skalli (Morocco)

16:25-16:35  
Adverse reaction monitoring and risk management of traditional Chinese medicines

- Haibo Song (China)

16:35-16:45  
Potential risks from counterfeit herbal products intended for slimming and weight loss

- Fatima Ali Albreiki (United Arab Emirates)

16:45-16:55  

- Li Zhang (China)

---

**Parallel session H 15:45-16:55 (Riverside 2+3)**  
**Topics of interest in pharmacovigilance**

- Chairpersons: Ulrich Hagemann (Germany), Stefan Kaehler (UK)

15:45-15:55  
Unifying drug safety and clinical databases

- Giovanni Furlan (Ireland)

15:55-16:05  
A signal based on spontaneous reports of convulsions in association with finasteride

- Daniele Sartori (Italy)

16:05-16:15  
Denosumab: comparative safety of two trade names

- Adel Hamdi (France)

16:15-16:25  
Duplicated case reports of stress cardiomyopathy: implications for signal detection

- Manfred Hauben (United States)

16:25-16:35  
ARV toxicity monitoring using targeted spontaneous reporting (TSR) approach: experiences from Vietnam

- Nguyen Hoang Anh (Vietnam)

16:35-16:45  
Pharmacovigilance, strategies for implementation in an emerging country

- Teresa Márquez Cabrera (Mexico)

16:45-16:55  
Completeness Score of Individual Case Safety Reports (ICSRs) in Vietnam national pharmacovigilance database

- Thuy Nguyen (Vietnam)

---

**WEDNESDAY, OCTOBER 22**

**Parallel session I 08:30-10:00 (Grand Ball Room)**  
**Specific populations and treatments: geriatrics**

- Chairpersons: Yola Moride (Canada), Lili Cao (China)

08:30-09:00  
Progress in the study of rational drug use in the elderly

- Yuqin Wang (China)

09:00-09:10  
Serious ADRs analysis in old people aged over 65

- Duo Dong (China)

09:10-09:20  
Adverse events associated with canagliflozin mechanism of action: a meta-analysis of randomized clinical trials

- Diogo Mendes (Portugal)

09:20-09:30  
Digoxin dosing and monitoring in hospitalized patients

- Ophir Lavon (Israel)

09:30-09:40  
Varenicline and abnormal sleep-related events

- Pia Caduff (Sweden)

09:40-09:50  
Drug-induced anaphylaxis monitored in a tertiary teaching hospital in South Korea

- Jin Lee (Korea)

09:50-10:00  
Update of certolizumab pegol safety profile: a systematic review and meta-analysis

- Marco Tuccori (Italy)
Plenary sessions 10:15-12:00 October 22nd, 2014 (Grand Ball Room)

10:15-10:45  Keynote lecture
Developing a national pharmacovigilance strategy while leveraging and contributing to international pharmacovigilance
♦ Kenneth Hartigan-Go (Philippines)

10:45-11:15  Poster prize awards 1st 2nd 3rd
Poster prize awards and short communication from winners

11:15-11:35  ISoP 2015 presentation: Prague

11:35-12:00  Closing remarks
♦ Hervé Le Louët, ISoP President
♦ Ian Wong, ISoP 2014 Scientific Committee Chair
♦ Lili Cao, ISoP 2014 Local Organising Committee co-chair

12:00  Lunch

ABSTRACTS OF THE INVITED SPEAKERS

Plenary Session October 20th, 2014
ISoP Special Interest Group Risk Communication
Jürgen Beckmann
Member of the WHO Expert Advisory Panel on Medicine Safety, Germany

The outstanding importance of pharmacovigilance (PV) for the safe use of medicines has increasingly been recognised during recent years. The multidisciplinary character of PV requires know-how in topics as different as molecular pharmacology, clinical medicine, pharmacoepidemiology, information technology, pharmaceutical manufacturing, legal aspects, public health policies, and medical traditions in different regions of the world. Consequently, there is a growing need for PV capacity building, in particular by professional training through high-quality PV courses with different focuses and levels of detailing. For this reason, the World Health Organization with its collaborating centres and the International Society of Pharmacovigilance have co-operated to create a curriculum for teaching PV. The purpose was to develop a systematically structured PV curriculum covering the broad scope of PV and including recent developments of relatively new topics like pharmacogenomics, consumer reporting, risk management and WHO-led international projects. Also, tasks for practical training which can be used for a wide range of audiences and in different settings were devised.

Ideas were drawn from various packages of PV topics and concepts of teaching outlined in already established PV courses, from the extensive printed material, in particular comprehensive overviews in journals and textbooks, and from guidelines developed by international organisations which are often available online.

The curriculum includes a main component consisting of 15 chapters for theoretical lecture-based training and a minor component with suggestions for hands-on exercises. The theoretical part has a hierarchical and modular structure with three evenly divided tiers. The practical part consists of twelve times three or four proposals for hands-on exercises which are related to the theoretical topics. This curriculum provides a comprehensive coverage of almost all areas of PV. The structure and content allows different kinds of focusing on specific issues and going into depth, while maintaining the overall context. It offers opportunities of tailoring courses specifically to the needs of the audience and can be applied to various forms of training, such as intensive or short overview courses or addressing specific narrow topics in perspective.

The curriculum is published in the October 2014 issue of Drug Safety and freely accessible: http://link.springer.com/search?query=teaching+pharmacovigilance

The online version also provides an extensive list of literature references as electronic supplementary material.
No patient safety without risk minimization without communication – this may be the short formula for why communication is essential to fulfilling the objectives of pharmacovigilance. It is also the quintessence of the Erice theme edition of Drug Safety in 2012. But then, with the vital need for effective communication, how do we progress to get best evidence-based communication practices into pharmacovigilance? Those who investigate risks and take decisions on safety action should also take responsibility for communication and find ways to listen to patients and healthcare providers, to understand the impact of risks fully and to see which risk minimisation measures and communication may work best in real life. It is for these reasons that in October 2013 the executive committee of ISoP decided to establish a SIG on communication with the following mandate:

- Describe, develop and promote risk communication as a sub-discipline of pharmacovigilance;
- Connect with scientists with communication-related expertise;
- Provide a forum for exchange on communication practices and experiences for lessons learnt and progress;
- Reach out to others (e.g. patient groups, healthcare providers, drug information providers, patient safety experts, scientific journals, general media) to listen and to develop communication methods facilitating informed therapeutic choice as well as trusted and safe medicines use;
- Provide for training;
- Advocate for research.

After establishment through its founding members, the SIG is now open to interested ISOP members! Its deliverables for 2014/2015 include writing up an advocacy paper, starting definitions work, reviewing the theme edition for proposals to take forward, start an inventory of publications and initiatives ISoP members know about and organising training and expert sessions at future annual meetings with outside experts.
Plenary Session October 22nd 2014
Developing a national pharmacovigilance strategy while leveraging and contributing to international pharmacovigilance
Kenneth Hartigan-Go
Asian Institute of Management, Philippines

Pharmacovigilance is like the proverbial elephant; each blind man knows only one part and interprets the world accordingly. But the science has evolved from the traditional identification and reporting of adverse drug events, ascertaining whether there was an actual adverse drug reaction, postulating pharmacological reaction, and estimating risk based on population exposure. Pharmacovigilance today is far more complex and must be an integral science developed from an interdisciplinary approach.

PV is about protecting patients and the general public exposed to the product in question. It is also about protecting the reputation and the application of public health programs. Since trade has become increasingly international, PV knowledge management can save lives globally. To be efficient and to enable us to resolve pharmaceutical problems, PV applications must not remain fragmented; therefore, horizontal integration is key.

PV principles have helped shape the 21st DRA by providing context and perspective to regulatory work. From a drug regulatory perspective, the following erroneous assumptions of PV professionals have been observed:

a. That the medical product must be of good quality and that what is observed when used in patients or large populations can only be a new adverse pharmacological response. (cGMP, bio-equivalence issues ignored).

b. That the supply chain integrity of a medical product has been adequately protected (vaccine failure and cold chain breach).

c. That industry practices ethical marketing behavior and has invested in RMP.

d. That there is collaboration among the laboratory, product registration, field inspections (PMS), regulatory and legal enforcement. So when there is a signal of possible drug harm, actions such as amended warnings or recalls are not undertaken.

e. That the use of the product is rational and correct (medication error and the involvement of PV into HTA work).

f. That those who report ADEs to centers or to authorities will be legally protected. (sovereignty ignored).

g. That clinical trial data submitted and analyzed cannot be falsified.

A DRA can put its house in order (a national PV strategy) by application of governance, ICT, bridging medical services and public health, organizing human resources for health, and answer the call for better access to medicines. Consequently, this model can help improve global pharmacovigilance and contribute to saving lives.

Parallel Session B: Signal Detection
Web-based signal detection methods
Juhaeri Juhaeri
Sanofi, Bridgewater, USA

Background: While Pharmacovigilance has been primarily based on reports from patients, health care professionals, and pharmacists, several studies have been done to evaluate the use information provided by internet users for analyses of adverse events. Less is known about the reliability (and accuracy) of the methods that can be used for web-based pharmacovigilance. The objectives of the study were to evaluate and develop the methods for web-based signal detection and to evaluate the reliability of those methods.

Methods: Query log database from Microsoft Bing search engine was used in the study and the FDA Adverse Events Reporting System (FAERS) was used as a comparison. Query Log reaction Score or QLRS (Yom-Tov, 2013) as well as Proportional Query Log or PQR were used to measure the associations in the query log database. The performance of these methods (sensitivity, specificity, positive predictive value/PPV and negative predictive value/NPV) was evaluated using FAERS as a standard. Different cutoff points were used to define signal and different time periods (separate and overlapping) were analyzed to evaluate the impact of the performance. Receiver operating characteristic (ROC) curve was also used to evaluate the overall performance of the methods.

Results: for PQR, the sensitivity ranged from 40% to 80% and specificity from 40% to 60%, depending on the cutoff points and time periods. Low PVP (1% - 10%) and high NPV (90-99%) were observed. Based on ROC analysis, PQR had a higher predictability than QLRS, with a maximum area under curve (AUC) of 65% for overlapping periods.

Conclusion: using FARS as a standard, PQR and QLRS has a low to moderate sensitivity/specificity, low PVP and high NPV. The use of different standards other than FAERS may produce different results.
Drug complications are the most common type of adverse events during hospitalization and the skin is among
the organ most often affected. Cutaneous adverse reactions to drugs occurred in 2–3% for hospitalized patients.
Fortunately, most of them presented as benign maculopapular exanthema or urticaria. However, severe cutaneous
adverse reactions (SCARs) do occur and may affect about 1 of every 1000 inpatients.

Severe cutaneous adverse reactions (SCARs) to drugs are groups of hypersensitivity reactions with a
heterogeneous clinical presentation. Two of the most notorious SCARs are Stevens-Johnson syndrome (SJS)
and toxic epidermal necrolysis (TEN) because of their high morbidity and mortality rates. SJS and TEN are
characterized by erythema evolving into sometimes extensive blistering that resembles a second degree burn.
This is accompanied by mucosal erosions, especially affecting the mouth, the lips, the conjunctiva, and the
genitalia. There may be typical target-like lesions, which are made up of two concentric rings surrounding an
erythematous center and are sharply demarcated. These are distinguished from atypical target lesions that are
less well demarcated and have a less well-defined zonal structure. SJS is characterized by a preference for the
trunk or generalized dissemination of rather atypical target lesions and maculae. Recently, another SCAR starts
to be noticed for its unique clinical presentation and unrevealed pathogenesis—drug reaction with eosinophilia and
systemic symptoms (DRESS), also called drug-induced hypersensitivity syndrome (DIHS).

Acute generalized exanthematous pustulosis (AGEP) is characterized by very acute widespread erythema with
dozens of small non-follicular pustules, especially along the skin folds and on the flexor surfaces. Patients have
acute fever and neutrophilia on blood tests. Fixed drug eruption (FDE) is a distinct cutaneous drug eruption
characterized by well-demarcated dusky-red or heavily pigmented patches involving the skin and mucosae.
Sometimes, blisters or erosions formed within pigmented patches. Generalized bullous fixed drug eruption (GBFDE)
is thought to be a particular form of FDE characterized by widespread blisters and erosions involving the whole
body as well as the typical FDE lesions. Because of extensive cutaneous or mucosal involvement in GBFDE,
clinically, it is sometimes difficult to differentiate GBFDE from SJS and TEN.

A growing number of ongoing international research networks (e.g. Sentinel, OMOP, EU-ADR, PROTECT,
ARITMO, SAFEGUARD, VAESCO etc.) are based on the combination of multiple electronic medical record (EMR)
databases for the conduct of active surveillance studies in the area of drug and vaccine safety. The rationale for
combining multiple EMR databases is the earlier detection, strengthening and confirmation, and hence earlier
management, of potential drug safety signals by augmenting statistical sample size and heterogeneity of exposure.
Several technical challenges however are encountered when combining multiple healthcare databases, especially
at European level, due to differences in the underlying healthcare systems, type of information collected, drug/
vaccine and medical event coding systems, and language. In recent international projects several approaches have
been developed for the harmonization of medical data extraction through homogeneous coding algorithms. Another
challenge is the choice of the best performing work models for data management and analyses while respecting
country-specific regulations concerning data privacy and anonymization.

The aim of this presentation is to provide an overview about benefits, pitfalls, and methodological challenges
concerning the conduct of post-marketing multi-database drug safety studies, as documented in several European
international initiatives.
Parallel Session E: Specific populations and treatments: pediatrics and women health

A novel process to capture safety signals in spontaneous reports on children

Kristina Star

Uppsala Monitoring Centre, Sweden

Children constitute only a small portion of the total population, and other age groups are far more significant consumers of medicines. Why should time and effort be spent to prevent problems resulting from children's use of medicines? One obvious reason is that, as the thalidomide tragedy has taught us, adverse drug reactions that affect children can involve years and even decades of suffering, not to mention staggering cost to society and industry. Every child who can be protected from harm means not only the restored possibility of a long and satisfying life for that individual but also significant savings in health-care services and litigation costs.

This presentation will describe a recent initiative that incorporates novel methods for signal detection of paediatric data in VigiBase by the Uppsala Monitoring Centre. The presentation will cover a range of important aspects and considerations that informed the evolution of this new project, for example, the continuous nature of childhood development, the challenges of prescribing and administering medicines to children [1], and the characteristics of paediatric data in VigiBase [2].

In September 2014, screening of VigiBase reports was initiated by using four paediatric age groups [3] to account for the developmental differences in childhood. New drugs (drugs reported for the first time in the age group during the past five years), serious reactions and medication errors were selected as focus areas. The drug and adverse reaction combinations by each age group and focus area were screened and prioritised according to a recently developed strength-of-evidence measure, vigiRank [4]. Previously unrecognised or incompletely documented medicine-related problems for the paediatric age group were selected to merit further evaluation. The aim with the project is to detect and communicate new and important information on paediatric medicine-related problems from VigiBase that can enable regulators and clinicians to provide safer medication to children.


Parallel Session F: Risk management plans

US and EU approaches to risk management: what have we learnt?

Brian Edwards

NDA Regulatory Science Ltd., UK

The principle of risk management planning arose from ICH E2E which described ‘pharmacovigilance planning’. The new EU legislation enforces the legal basis of risk management plans (RMPs) as described in greater detail the risk management system for all new marketing authorisation applications. A RMP may be imposed in the post-marketing phase if there are concerns. The focus of a RMP should be on prospective, dynamic and risk proportionate planning. The new EU pharmacovigilance risk assessment committee has set up new procedures for requesting and assessing RMPs being established. A Summary of the RMP is now being made public. RMP templates were released in November 2012. RMPs must be continually updated.

In the US, FDA has set up Risk Evaluation and Mitigation Strategies (REMS) and as of September 2014 there have been about 85 REMS. They are not required for every medicine. Their main aim is on goals and methods of minimising risks. So unlike the EU RMP does not contain background/detail of risks. REMS can also be terminated once objective achieved.

There is an urgent need to share experience and to develop training courses in ‘Risk’ for the pharmaceutical sector. There is confusion between day-to-day managing the product risk and regulatory RMPs. There are unintended consequences as older medicines are outside the RMP with the focus on the new medicine. We need to develop a common understanding of what an important risk so we can focus on what is truly clinically important in term. It is difficult to measure the effectiveness of RMP and REMS in terms of public health benefit. We need to develop consensus about what the primary endpoint should be, what the criteria for “success” and how we develop multiple-methods for evaluating REMS/RMP impact.
Medication Error Report - The Impact of Culture and Habitude in China
Dayou Wang
Huashan Hospital, Fudan University, China

The institute of medicine report “To err is human” identified that everyone will make mistakes and that efforts to improve safety must focus on systems rather than providers. Pressure needs to shift from individual healthcare professionals to the organizational level—to induce changes in institutional performance. Obviously, more responsibilities for error are involved with managerial and organizational decisions (or lack of decisions) of the superior leaders. Though reporting systems provide a key strategy for learning from errors and preventing their recurrence, there is little ME report collected until now in China. Main challenges of reporting are the sociocultural context. Not only exists the positive traditional error culture, such as the famous remarks: “no one is perfect, just like no gold can be hundred percent pure”, “person’s mistake just like the eclipse of the sun or moon and has been seen by everyone. If correct, would be respected by everyone”, but also the negative social conventions: “king is the king (supreme ruler), official is the official (under the ruler), father is the father, son is the son”, “conceal a disgrace for a senior generation, conceal the error for a wise man”, “prefer to speak positively, rather than speak ill of something”. ME reporting sometimes still require someone to take responsibility for causing the ADE, which is especially problematic in a society in which blame is often placed on those whose actions result in the undesired outcome. Report or not? The stakeholders including health authorities, hospital administrators and healthcare professionals make judgment based on ethics, rules and requirements, and their own interests. Conclusions: ME reporting should be considered as a system which is “social and cultural in origin, structure, function and significance”. It is viewed differently by different countries and stakeholders (e.g. social groups and individuals) and then the outcome different.

ORAL PRESENTATIONS

Parallel Session A
P098-New Biomarker for Developing Adverse Drug Reactions caused by Statins
N. Mirošević Skvrce
P108-From the Unknown to Current Practices of Pharmacogenomics
S.T. Tomczyk, B.C. Carleton
P074-Relationship Between Structural Alerts in Drugs and Reported Idiosyncratic Hepatotoxicity in the WHO-Database
N.T. Jessurun, E.P. Van Puijenbroek, L. Hämark
P048-There is Geographic Variation of the Frequency and Profile of Adverse Drug Reactions - An Analysis for Tyrosine Kinase Inhibitors
K. Pawar, T. Tran, J. Hasford
P041-Pharmacovigilance and the Clinical Eye – Detecting New Drug-Induced Diseases
R.H.B. Meyboom

Parallel Session C
P030-Dermatological Adverse Drug Reactions with Highly Active Anti-Retroviral Therapy
E.G. Allan, P.S. Allan
P114-Distribution of Carriers with HLA-B Allele at Higher Risk for SCAR in Thai Population: Implications for Prevention of SCAR in Thailand and Southeast Asians
S. Mahasirimongkol, W. Rungapiromonman, S. Kumperasart, N. Satproedprai, S. Wattanapokayakit, W. Inunchot, N. Wichukchinda, W. Suwankesawong
P116-Lacosamide (Vimpatt®), A Possible New Inducer of Stevens Johnson Syndrome/Toxic Epidermal Necrolysis
S.H. Kardaun, R.H.B. Meyboom, S. Watson, P. Caduff
P022-Liver Injury in Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): A Review of 72 Cases
C.Y. Chu, I.C. Lin, H.C. Yang, C. Strong

Parallel Session E
P049-Monitoring the Safety of Mass Measles and Rubella Immunization Campaign in Morocco
A. Tebaa, S. Beimalem, D.S. Tanani, R. Benkirane, R. Soulamani
P036-A Pregnancy Prevention Program for Revlimidi® in China: Partnership between Company and HCPs
X.Z. Zhan, M.L. Li, J.Z. Zou, C.L. London, R.W. Bwire

Parallel session F
P103-How the Transparency Data Regulations Are Changing the Communication regarding Benefit-Risk of Medications
S.T. Tomczyk
P020-Regulatory Action; Medical Inaction?
C. Anton, A.R. Cox, R.E. Ferner
P094-Individual Risk Management Plans are Needed for Confident Biosimilar Prescribing
B. Unal, N.D. Aydinkarahaliloglu, S. Sardas
P110-Risk Management and Pharmacovigilance in the Brazilian Health Surveillance Agency: The Benzydamine Case
F.C.S.C. Santa Cruz, M.G.O. Oliveira, F.S.G. Gasparotto
P055-Quantitative Benefit-Risk Assessment of Rosiglitazone: Number Needed to Treat, Number Needed to Harm and Likelihood to be Helped or Harmed
D. Mendes, C. Alves, F. Batel-Marques

Parallel session G
P008-Congenital Malformations of Fenugreek in Morocco: An analysis of Reports in the Moroccan Herbal Products Database from 2004 to 2014
S. Skalli, A. Chebat, N. Smirriss, R. Benkirane, M. Taloubi, K. Forci, R. Soulaymani Benchekh
P023-Adverse Reaction Monitoring and Risk Management of Traditional Chinese Medicines
H.B. Song, X.X. Du
P067-Potential Risks from Counterfeit Herbal Products Intended for Slimming and Weight Loss
F.A. Al-Braik, M.A. AlGhamrawi, A.S. Elgharbawy, M.Y. Hasan

Parallel session H
P007-Unifying Drug Safety and Clinical Databases
G. Furlan, M. Bertazzoli, B. Burnstead
P038-A Signal Based on Spontaneous Reports of Convulsions in Association with Finasteride
D. Sartori, S. Hult, L. Sandberg, S. Watson
P070-Denosumab: Comparative Safety of Two Trade Names
A. Hamdi, M.P. Roux, F. Krabansky, M. Abou Taam, S. Dukic, T. Trenque

Parallel session I
P112-Serious ADRs Analysis in Old People Aged Over 65
Duo Dong, Xiao-xi Du
P059-Adverse Events Associated with Canagliflozin Mechanism of Action: A Meta-Analysis of Randomized Clinical Trials
C. Alves, A. Penedones, D. Mendes, F. Batel-Marques
P057-Digoxin Dosing and Monitoring in Hospitalized Patients
O. Lavon
P095-Varenicline and Abnormal Sleep-Related Events
R.L. Savage, A. Zekarias, P. Caduff-Janosa
P052-Drug-Induced Anaphylaxis Monitored in A Tertiary Teaching Hospital in South Korea
P024-Update of Certolizumab Pegol Safety Profile: A Systematic Review and Meta-Analysis

Parallel session J
P001-Effects of Methylphenidate Treatment for Attention-Deficit/Hyperactivity Disorder on Trauma Related Accident and Emergency Admissions: Self-Controlled Case Series Study
P031-Validation of Prescribing Errors Definition in Saudi Arabia
H. Aljadhey, M.A. Mahmoud, A. Hassali
P044-Effectiveness of Gastroprotective agents on Prevention of Dabigatran Related Gastrointestinal Bleeding: A Population-Based Retrospective Cohort Study
POSTER PRESENTATIONS

The posters will be displayed between October 20th-22nd, 2014 in the Ballroom Foyer of the Holiday Inn Tianjin Riverside (5th Floor).

P002-Retrospective Evaluation of Polymorphisms of Angiogenesis in Patients Treated with Sorafenib
E. Tenti, A. Casadei Gardini, G. Marisi, M. Scarpin

P003- Risk and Benefit Evaluation of Oral Ketoconazole: A Review from Taiwan Adverse Drug Reaction Reporting System and Health Insurance Database
Y.-H. Chen, W.-I. Huang, W.-W. Chen

P004-Self Medication and Self Prescription. Relevance in Daily Medicine
M. Ponte, L. Wachs, A. Serra, L. Othatz, S.M. Scuto, A. Wachs

P005- Economic Burden of ADRs in a Tertiary Care Hospital
M. Ponte, L. Wachs, A. Serra. Buenos Aires, and A. Wachs

P009- New Signal Management: Lower Limb Edema Induced by ERIP-K4
D. Soussi Tanani, N. Baddrane, A. Tebaa, R. Benkirane, A. Soulouamyani, R. Souloumanyani Bencheikh

P010- Palonosetron: Similarities and Differences in the Safety Profile as Compared to Other Drugs of the Same Class
G. Furlan, G. Clerici, M. Bertazzoli

P011- Palonosetron: 10 Years of Post-Marketing Use
M. Bertazzoli, G. Clerici, G. Furlan

P013- Risk Management of Anti-TB Drugs Induced Liver Injury in Morocco
D. Soussi Tanani, A. Tebaa, R. Benkirane, A. Soulouamyani, R. Souloumanyani Bencheikh

P014- Current Reporting Status & Challenges of Asian Countries-National Centres for Pharmacovigilance under WHO-UMC
V. Kalaiselvan, P. Thota, R. Mehra, S. Gakhar, G.N. Singh

P017- A Survey On Pharmacovigilance Awareness Amongst Physicians In Major Cities Of Pakistan
M.E. Rizvi, M. Abbas

P018- Evaluation of Adverse Drug Reactions Among In-Patients Admitted into the Adult Medical Wards of University of Ilorin Teaching Hospital, Nigeria
S.O. Ayetoro, A.O. Olaogunju, K.A. Laiyemo

P019- Pharmacovigilance of Generic Medicines versus Originator Medicines
R. Ouled Errhissi, L. Ait Moussa, A. Tebaa, R. Benkirane, R. Souloumanyani Bencheikh

P021- Safety of Palonosetron and Ondansetron in Preventing Chemotherapy-induced Nausea and Vomiting in Pediatric Patients Receiving Moderately- or Highly-Emetogenic Chemotherapy
G. Kovacs, A.E. Wachtel, E.V. Basharova, T. Spinelli, P. Nicolas, S. Cipriani, E. Kabickova

P025- Characterization of the Risk of Bleeding with Novel Oral Anticoagulants and Warfarin: A Pilot Case-
Control Study

P026- Sampling Frame Stratification is Crucial in Evaluating the Effectiveness of Additional Risk Minimisation Activities (ARMAs)

P027- Distinguishing Different Study Types, Biomedical Research, Market Research, Non-Interventional Studies and Clinical Trials: A Newly Developed Decision Tree
S.T. Kaehler, N. Walsh, N. Minton, D. Gillen, J. Freeman, R. Bwire

P028- Breast Discomfort in HIV Positive Patients Treated with Highly Active Anti-Retroviral Therapy
E.G. Allan, P.S. Allan

P032- Pharmacovigilance at a University Hospital: Strategies Developed for Increasing Adverse Drug Reactions and Medication Errors Reporting
L. Garza-Ocañas, E. Perez-Rodríguez, C. González-Nieto, S. Guzmán-López

P033- A Review of Allopurinol Hypersensitivity in Vietnam National Pharmacovigilance Database
A.H. Nguyen, T.T. Le, H.M. Nguyen1, D.V. Bui, D.V. Nguyen

P035- Intensive Pharmacovigilance in Outpatient of Internal Medicine in the Hospital Universitario De Puebla, Mexico
J.A. Morán Domínguez, T. Márquez Cabrera, L.M. Méndez López, O. Guzmán González

P037- Sources of Disagreement between Investigator and Sponsor in Causality Assessment of Serious Adverse Events during Academic French Clinical Trials
J. Bezin, G. Miremont-Salamé, M. Razafimanantsoa, F. Salvo, N. Moore, F. Haramburu, A. Gimbert

P039- The Association between Oral Fluoroquinolone use and the Development of Retinal Detachment: a Systematic Review and Meta-analysis of Observational Studies
C.S.L. Chui, I.C.K. Wong, L.Y.L. Wong, E.W. Chan

P042-Towards Comprehensive Monitoring of Biopharmaceuticals
R.H.B. Meyboom

P043- Adverse Drug Reactions of Antiepileptic Therapy: A Retrospective Study in the Moroccan Pharmacovigilance Database
L. Moussa, R. Ouiedenkhs, R. Benkirane, R.S. Bencheikh

P046- Risk Minimisation Actions within Pharmacovigilance Centres: Building a Public Health New Risk Minimisation Plan
G. Benabdallah, L. Ali, R. Benkirane, R.S. Bencheikh

P047- Implementing the Moroccan Database by an Automated Signal Detection Method
S. Belamael, R. Benkirane, A. Soulaymani, I. Talibi, R. Ouled Enrhiss, A. Tebba, A. Khadmaoui, A. Mokhtari, R.S. Bencheikh

P050- High-dose Methotrexate: Drug-Drug Interaction and Toxicity
J. Mahe, G. Veyrac, C. Tourillon, P. Jolliet

P051- Acute Pancreatitis after Morphine Sulfate Ingestion: Report of Two Cases

P053- Chemotherapy-Induced Thrombocytopenia: Frequency and Relative Risk in Cancer Patients in Tertiary-Care Hospitals in Malaysia
M.S. Iqbal, M.Z.Iqbal, M.B. Bahari, M.W. Iqbal

P054- Pioglitazone and Risk of Bladder Cancer Among Type 2 Diabetic Patients: A Malaysian Perspective
M.S. Iqbal, M.B. Bahari, M.W. Iqbal, M.Z.Iqbal

P056- Urinary Diamonds with Perioperative Prophylactic Amoxicillin: A Regional Investigation to Define Causes and Prevent Further Cases
C. Alves, A.F. Macedo, D. Mendes, F. Batel-Marques

P057- Drug Safety Alerts Issued by Regulatory Authorities: Usefulness of Meta-Analysis in Predicting Earlier Risks
C. Alves, A.F. Macedo, D. Mendes, F. Batel-Marques

P061- Drug Safety Signals Generation Using Disproportionality Analysis of Spontaneous Reporting Databases – A Systematic Review
P. Dias, A. Penedones, D. Mendes, C. Fontes-Ribeiro, F. Batel-Marques

P062- Safety Monitoring of Ophthalmic Biologics: A Systematic Review of Pre- And Post-Marketing Safety Data
A. Penedones, D. Mendes, C. Alves, F. Batel-Marques

P063- Quantitative Methods for Detecting Signals of Drug-Drug Interactions – A Comparison of Two Approaches
M. Banovac, C.H. Fry

P065- Deliberate Self-Poisoning with Drugs in Mali: An 11-Year Retrospective Study
H. Hami, T. Diallo, A. Maiga, A. Mokhtari, R. Soulaymani-Bencheikh, A. Soulaymani

P068- Knowledge, Attitude and Practice (KAP) Analysis of Pharmacovigilance (PV) Among Jordanian Healthcare Professionals (HCPs)
M.B. Belbisi

P069- Drug-Induced Eosinophilic Pneumonia and NSAIDs
F. Krabansky, A. Hamdi, M. Abou Taam, N.-P. Roux, E. Herlem, T. Trenque

P072- Warfain Pharmacogenetics – Ethnicity Considerations
F.J. Ryan, B.J. Mulchrone, G.B. OBrien, N. Baker
P073- Safety Profile of Propofol, Midazolam, Diazepam and Lorazepam Using the Korean Adverse Event Reporting System (KAERS) Database
H.J. Park, J.Y. Shin, M.H. Kim, B.J. Park

P075- Comparative Study on the Pattern of Erectile Dysfunction Treatment Drug Usage Among Hospital Patients and General Population
H.J. Jung, S.Y. Jung, B.G. Kim, B.J. Park

P076- Development and Evaluation of an Algorithm for Named Entity Recognition of Drugs in Global Pharmacovigilance
J. Ellenius, C. Elleen, G.N. Norén

P077- Monitoring Batch Related Safety of Vaccines
W.J.A. Hilgersom, H.C. Rümke, A.C. Kant, E.P. Van Puijenbroek

P078- Traditional Chinese Medicine and Other Phytotherapeutic Preparations Associated With Drug Induced Liver Injury

P080- Two Cases of Interaction between Tacrolimus and Nicardipin in Tunisian Patients
S. El Ferjani, E. Gaies, M. Ben Sassi, S. Trabelsi, R. Charfi, I. Salouage, M. Lakhal, A. Klouz

P081- Adverse Drug Effects Induced by Anti-Infective Drugs in Elderly Patients
R. Charfi, R. Daghtfous, M. Lakhal

P082- Delayed Elimination of Methotrexate and Possible Origin

P083- Sulfamethoxazole-Thrimethoprin and Cyclosporine Interaction in Bone Marrow Allograft Patients

P084- Therapeutic Drug Monitoring in Acetaminophen Intoxications

P085- Phone Communication of Medical Results: Consequences of a Misheard Result

P086- The Value of Patient Reporting in Signal Generation
D. Darko, G. Sabbah, K. Ampomsa-Achiano, K.O. Antwi-Agyei

P087- Herbal Medicines: Are they Really Safe?
D. Darko, G. Sabbah, A. Amoakohene, A. Gwira

P088- Drug-Induced Stuttering: A Review of the French Pharmacovigilance Database
J. Bénè, M. Auffret, S. Fedrizzi, M.B. Valnet-Rabier, J. Caron, S. Gautier

J. Bénè, S. Gautier, F. Richard, D. Leys, C. Cordonnier, R. Bordet, J. Caron

P090- Aortic Dissection during Rivaroxaban Therapy: A Challenging Care
J. Bénè, J.L. Auffrey, M. Auffret, J. Caron, S. Gautier

P091- PRES Syndrome Induced by Cyclosporine with Normal Blood Concentration

P092- Cyclosporin Therapeutic Monitoring in Non-Infective Serious Uveitis

P093- Feasibility of Pharmacist-Participated Anticoagulation Management Service (PAMS) in A Regional Hospital in Shanghai: A Pilot Study

P096- Reporting of Adverse Drug Reactions by the End Users - Patients in Pakistan
S. Qamar, A. Noureen, M. Naveed

P097- Experience of Implementation of Risk Management Plans in Argentina
C. Santucci, I. Bignone, R. Heredia, C. Prokope, R. Papale

P099- Adverse Drug Reactions Caused by Hepatotoxicity of Drugs Reported to Agency for Medicinal Products and medical Devices
N. Miroševič Škvrč

P101- Anticancer Drugs' Side Effects
I.A. Aouint, G. Lakhoua, A.Z. Zaïem, R. Sahnoun, R.D. Daghfous, S.E. Aïdli

P104- Therapeutic Drug Monitoring in the Treatment of Tuberculosis: Minimizing the Risks of ADRs
M.S. Iqbal, M.Z. Iqbal, M.B. Bahari, M.W. Iqbal

P105- Drug-Induced Gynecomastia
A. Zaïem, I. Aouinti, G. Lakhoua, R. Sahnoun, S. Kastalli, R. Daghfous, M. Lakhal, S. Elaiidi

P106- Drug-Induced Acute Pancreatitis
A. Zaïem, I. Aouinti, G. Lakhoua, R. Sahnoun, S. Kastalli, R. Daghfous, M. Lakhal, S. Elaiidi

P107- Sexual Disorders Associated with Drugs
I. A. Zaïem, G. Lakhoua, R. Sahnoun, S. Kastalli, R. Daghfous, M. Lakhal, S. Elaiidi

P113- Pharmacovigilance with Special Focus on the Geriatric Patients at a Public Teaching Hospital
P. Tiwari, A. Malik, S. D'Cruz, A. Sachdev

P115- Cutaneous Adverse Drug Reactions in Morocco: A Prospective Study

P117- Dipeptidyl Peptidase-IV Inhibitors and Bullous Pemphigoid in France: Analysis of Spontaneous Reports from French Regional Pharmacovigilance Centers and Manufacturers
SOCIAL ACTIVITIES

Welcome Reception
Date: October 19th, 2014
Time: 18:00-19:30
Venue: Riverside Meeting Room on 5th Floor
Description: A buffet reception is provided for participants to spend time catching up with friends and meeting new ones at round tables. A selection of salads, drinks and traditional Tianjin snacks will be available.

Conference Dinner
Date: October 21st, 2014
Time: 19:00-20:30
Venue: Grand Ball Room on 5th Floor
Description: Chinese cuisine with traditional Tianjin snacks as an appetizer will be offered at the conference dinner. During the dinner there will be performances including Chinese traditional music, dance and more.

CONGRESS VENUE
Holiday Inn Tianjin Riverside
Address: Phoenix Shopping Mall A, East Haihe Road, Hebei District, Tianjin, 300141
P. R. China
Tel: +86-400-880-2832

Holiday Inn Tianjin Riverside is located at Phoenix Shopping Mall A on East Haihe Road, in the rapidly developing Hebei District. The hotel is surrounded by several sightseeing spots, such as Ancient Culture Street, Da Bei Temple and the 140-meter-high Eye of Tianjin Big Wheel. The hotel is within 3 kilometers of the Tianjin Train Station only 30 minute drive to the Tianjin international Airport and 120 kilometers to Beijing.

Most activities include conference, sessions and conference dinner will be carried out on 5th floor of the hotel. The Plenary Meeting will be held in the Grand Ballroom on 5th floor of the hotel.
GENERAL INFORMATION

OFFICIAL WEBSITE
www.isop2014.org

REGISTRATION
Registration for pre-conference courses starts on October 18th at 10:00.
Registration for the conference starts on October 19th at 08:00.

METHOD OF PAYMENT
Cash payments shall be made in US Dollar (USD), no other currency will be accepted. 50 USD will be charged as the administration fee.
In addition, payments can also be made by credit card (MasterCard or VISA). Please note that cheques will not be accepted.

REGISTRATION AND INFORMATION DESK
Registration desk opening hours:

<table>
<thead>
<tr>
<th>Date</th>
<th>Opening Time</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 18th</td>
<td>14:00–18:00</td>
<td>Lobby (1st Floor)</td>
</tr>
<tr>
<td>October 19th</td>
<td>08:00–10:00</td>
<td>Foyer (5th Floor)</td>
</tr>
<tr>
<td>October 19th</td>
<td>10:00–18:00</td>
<td>Lobby (1st Floor)</td>
</tr>
<tr>
<td>October 20th</td>
<td>08:00–18:00</td>
<td>Foyer (5th Floor)</td>
</tr>
<tr>
<td>October 21st</td>
<td>08:00–18:00</td>
<td>Foyer (5th Floor)</td>
</tr>
<tr>
<td>October 22nd</td>
<td>08:00–13:00</td>
<td>Foyer (5th Floor)</td>
</tr>
</tbody>
</table>

SECURITY AND BADGES
You will receive a personalised badge when collecting your registration documents. During the Meeting, this badge must be clearly visible at all times to grant access to the scientific sessions and to the exhibition area.
Badges will be labeled one of the following:
ISOP EXECUTIVE COMMITTEE- RED
SPEAKER / CHAIR- PINK
DELEGATE- DARK BLUE
EXHIBITOR- SKY BLUE
STAFF- GREEN
ACCOMPANYING PERSON- BROWN

SPEAKER’S ROOM
It is essential for the smooth running of the sessions that all speakers hand in their PowerPoint presentations well in advance and at least one hour before the start of their session to check their presentation with the technicians. Speakers are requested to check their presentations to ensure integrity of their file. We also suggest letting us know if you require special assistance regarding video or the use of Macintosh computers.

Speakers room – Business Center
Opening hours:
- October 19th: 08:00–18:00
- October 20th: 08:00–18:00
- October 21st: 08:00–18:00
- October 22nd: 08:00–12:00

POSTERS
The posters will be displayed between October 20th, 21st and 22nd at the Ballroom Foyer of the Holiday Inn Tianjin Riverside (5th Floor) according to the following schedule:
- Poster set up: October 19th at 17:00 and October 20th at 8:00
- Poster dismantling: October 22nd at 12:30

Poster discussions will take place in front of the posters. Presenters should be next to their posters during the viewing dates and times, usually during coffee break (morning), and should have handouts of their poster available.
All posters must be removed at 12.30 on Wednesday, October 22nd.
The Conference secretariat is not responsible for the posters that have not been removed after the session.

POSTER PRIZES
The three best posters will be announced on October 22nd during the congress. The winners will be awarded by the Poster Prize Committee during the closing ceremony on October 22nd.

OFFICIAL LANGUAGE
Official language of the meeting is English.
CERTIFICATE OF ATTENDANCE
Certificates of attendance will be provided to all registered delegates at the end of the meeting.

COFFEE BREAKS AND LUNCHES
During breaks, coffee, tea, and fruit will be served at the Foyer (5th Floor) and we encourage you to visit the exhibition area. Badges must be worn to access the buffet. We have ensured dietary options such as vegetarian food is available.

INTERNET ACCESS
Free internet Wi-Fi access will be available in the conference venue. Each delegate will receive a password.

TIME
The time zone of P. R. China is GMT +8.

ELECTRICS
In China, electricity is set at 220 volts. Additionally, wall sockets and plugs may differ from those in your home country. A plug adaptor may be needed.

CURRENCY
In China, the currency is the RMB. ATMs are widely available in the centre of Tianjin. There is an ATM machine in the lobby of the Holiday Inn Tianjin Riverside.

WEATHER
Tianjin enjoys a monsoon-influenced humid continental climate.

<table>
<thead>
<tr>
<th>Month</th>
<th>Average High Temp.</th>
<th>Average Low Temp.</th>
<th>Average Rain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct.</td>
<td>66°F/20°C</td>
<td>48°F/9°C</td>
<td>0.6mm</td>
</tr>
</tbody>
</table>

HOSPITALS NEAR THE VENUE
The Second Hospital of Tianjin
Address: No.296, Zhongshan Road, Hebei District, Tianjin
Tel: +86-22-26352821

The PLA 254 Hospital
Address: No.60, Huangwei Road, Hebei District, Tianjin

INSURANCE
The congress organiser does not accept responsibility for individual medical, travel or personal insurance, and delegates (or accompanying persons) are advised to take out their own insurance policy (personal, health, accident and travel insurance). Delegates leaving articles at the conference venue or at the social events locations do so at their own risk.

EMERGENCY TELEPHONE NUMBERS
Police: 110
Fire: 119
Telephone Numbers: 114
Municipal First-Aid Center: 120
Foreign Affairs Office of Police: 7216795

ORGANISING SECRETARIAT
Division of External Cooperation, China Center for Food and Drug International Exchange
Addr.: Rm 1106, Office Building B, Maples International Center No.32, Xizhimen Beidajie, Haidian District, Beijing, 100082, P.R.China
Phone: +86-10-8221-2866
FAX: +86-10-8221-2857
nanxi@ccpie.org
Phone: +86-10-82212866(ext) 6009
TOURIST INFORMATION OF TIANJIN

Situated on the sea so close to the capital, Tianjin has long been a transport hub for international commerce, and so a great deal of history has accrued to the municipality. It has played its role as a hub for Chinese transport as well, its spokes radiating out to a dozen northern provinces. This is an area which has seen considerable activity through the centuries as a consequence with the varied comings and goings of foreigners and Chinese from many different regions and of many different ethnicities.

Today, Tianjin boasts the largest artificial harbor in northern China with 30 different sea routes leading to over 300 of the world's ports, a magnet for international trade now more than ever. Nor is its activity confined to commerce, as an increasing number of Chinese seek adventure overseas, and cruise liners proliferate.

Tianjin's Rare Architectural Treasure

The history of Tianjin has seen a great deal of foreign political influence as well as commerce. From 1860 to 1903, the United Kingdom, the USA, France, Germany, Japan, Russia, Italy, Belgium and other western nations compelled the Qing regime to cede eastern Tianjin to them, dividing it up between themselves. This led to a proliferation of national architectures of the period, a jumble of fascinating buildings from various localities brought together uniquely into one small area.

What remains of them may be seen on five remaining streets in downtown Tianjin, now a national treasure. What has survived is far from insignificant. In total, the buildings occupy a total of 1.3 million square metres, including over 100 imposing residencies with their traditional architectures, and a further 300 of more modest proportions. On the two banks of the Hai River, Ming and Qing architectural styles are preserved along with these giving the area a unique flavor unparalleled elsewhere in China, or the world.

The Five Great Avenues

These are now to be found on the southern side of modern downtown Tianjin, running east-to-west. There are in excess of 230 buildings of interest preserved from the days of colonial Tianjin. Many are modest, but 50 or so were made for rich and famous Europeans in markedly opulent style. In keeping with the fashion in Europe at the time, the bewildering array of architecture is made still more startling by the incorporation of styles revived from the Renaissance, ancient Greece, Gothic, and the Romantic period. To complete the mix, the array of European and ancient styles are complemented by the architecture of Qing-dynasty China itself. There is nowhere else that such a collision and mixing of civilizations has led to such an explosion of architectural styles so beautifully preserved, and the Five Ancient Avenues are a sight not to be missed.

The Hai River

Originating at the King Bridge in Beijing, running for more than 70 km before emptying out into the sea at Da Gukou, the Hai is the arterial river running through Tianjin. It is also one of the better places from which to view the fascinating architecture of the old town arrayed along its banks.

The Tianjin Eye

The Tianjin Eye, (or, to give it its full title, the Yongle Bridge Tientsin Eye), is a huge ferris wheel spanning the Hai River. It serves both as a bridge and as a spectacular fun ride from which to see Tianjin from an elevated height. How high? Well, raised above the bridge, and with a diameter of 110 metres, it's the equivalent of a building 35 storeys in height and dwarfs its surroundings.

With 64 transparent, 360-degree viewing gondalas hanging from it, each able to seat eight people, it's a fascinating ride in the 30 minutes it takes to rotate with views of up to 40 km. Even if you don't take a ride on it, the eye itself is an incredible sight, particularly at night when it is lit up in changing colors.

Opening hours: Every day from 9.30am to 9.30pm except Mondays, when it is closed in the morning.

Pleasant Memories Celebrity Teahouse

The teahouse takes its 'celebrity' name from its being used for performances, three times each day, in the morning, at noon and in the evening. Performances may be anything, by anyone of any age, and is thus similar to a western-style cabaret, (only with Chinese characteristics, of course). There are two branches of this particular teahouse - one is located on the Ancient Culture Street, the other on Xinhua Road. The one on Ancient Culture Street is livelier, perhaps even too crowded at times, while that on Xinhua Road is more relaxed with a more authentic feel to the decor. These are also good venues for seeking out both traditional snacks and traditional crafts, both of which are on sale.
Yan Yue Teahouse
For those wanting to get off the tourist track and to experience for themselves Tianjin as the locals know it, the Yan Yue Teahouse is strongly recommended. Located in Heping district, this is a quiet, modest teahouse favoured by Tianjin's residents. Here too there is a stage for performances, but whereas those in the Pleasant Memories teahouse are met with polite and quiet admiration, here the audiences are more inclined to join in with the fun on offer, passing comment as they eat melon seeds and gossip between themselves. This teahouse is of particular note for having played host to some of the earlier performances of the famous crosstalk artiste Ma Sanli.

The Porcelain House
The Porcelain House is a traditional French building furnished with antiques. It is located on the Tianjin Chifeng Road. The owner, Zhang Lianzhi, has taken considerable care over its furnishing and decoration, with a particular eye to ceramics through items he has collected over some considerable period, the main showcase of the Porcelain House to which it thus owes its name. Here you may find exquisite pieces of porcelain ware, as well as stone items of white marble, crystal, agate and other decorative materials. As well as the traditional porcelain ware people have in their homes, Mr. Zhang has collected tens of thousands of tiles. There are also cultural relics on display, including 300 lions of all kinds and sizes which lurk in every corner of the building, adding to the singular atmosphere.

Tianjin International Cruise Port
Before you leave, it's worth paying a visit to the port to see how far Tianjin has come from its early roots as gateway to the world for imperial China. Perhaps the most stunning example of its new modernity is to be found in the magnificent ships in the International Cruise Port. Several ships from several international lines are already making Tianjin their home ports, a fitting tribute to a city that has come far in the modern era while retaining so much of its vibrant past.