The International Society of Pharmacovigilance

7th ISoP Annual Meeting

21st - 24th October 2007

Bournemouth International Centre
Bournemouth, Dorset, UK

Final Programme

www.isop2007.org

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Continuing Professional Development (CPD) Accreditation:
ISoP 2007 has been awarded 16.5 CPD credits by the Faculty of Pharmaceutical Medicine

CONFERENCE SECRETARIAT

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WELCOME

Dear Colleague,

On behalf of the ISoP Executive Committee and the Local Organising Committee, we are delighted to welcome you to the 7th Annual Meeting of the International Society of Pharmacovigilance (ISoP) here in Bournemouth.

Recent complex drug safety issues have brought pharmacovigilance to the attention of a much wider audience. Expectations of patients and the public of the safety of medicines are understandably rising. More powerful and complex drugs are becoming increasingly available. Experts in pharmacovigilance recognise that, while existing methods and approaches have delivered good outcomes for public health, success has not always been timely or fully adequate. In addition, there remain considerable differences in standards between different parts of the world, therefore far more needs to be done if we are to meet all the challenges and deliver the best possible outcomes to patients worldwide.

In response to all this, pharmacovigilance continues to evolve. The evolution is happening by improving existing methods and developing new ones. Risk management, signal detection and linking the biological basis of drug safety with pharmacoepidemiology are examples of the many evolving areas. This progress needs platforms for exposition, education and debate. International meetings benefit the long established expert and the trainee; ISoP 2007 is one such forum. With pharmacovigilance and drug safety playing an important part of healthcare worldwide, we are most fortunate to be able to share these few days with an excellent mix of some of the world's leading experts in the field, along with a refreshing new supply of speakers and young researchers and of course you, the participants. We shall have a great opportunity to learn from the work of some of the best in the world and exchange our experiences with others.

Our aim for this the 7th Annual Meeting of the Society is to give everyone an opportunity to share with friends and colleagues a varied, topical and informative programme and most importantly, an enjoyable few days with us here at this annual event.

Professor Saad Shakir
Chairman, Local Organising Committee

Professor Nicholas Moore
President of ISoP

ISoP EXECUTIVE COMMITTEE

Nicholas Moore, President	France
Ken Hartigan-Go, Vice-President	Philippines
Corinne Pierfitte, Secretary General	Belgium
Brian Edwards, Treasurer	UK
Deidre McCarthy, Vice Treasurer/Secretary	Ireland
Giampaolo Velo, Past President	Italy
Alex Dodoo	Ghana
Eugene van Puijenbroek	Netherlands
Joanne Barnes	New Zealand
John McEwen	Australia
Marie Lindquist	Sweden
Thierry Trenque	France

LOCAL ORGANISING COMMITTEE

Saad Shakir	(Chairman), Director, DSRU
Lynda Wilton	Principal Research Fellow, DSRU
Vanessa Marshall	Clinical Research Fellow, DSRU
Georgina Spragg	Executive Assistant, DSRU
Ruth Walker	Manager, Education & Training, DSRU

SCIENTIFIC COMMITTEE

Giampaolo Velo	Italy, Chair
Saad Shakir	UK, Co-Chair
Nicholas Moore	France
Corinne Pierfitte	Belgium
Ken Hartigan-Go	Philippines
Richard Hill	Australia
Valerie Simmons	UK
Gerd Kassel	Germany/Japan
Lynda Wilton	UK
Paula Marquez	Spain
Marie Lindquist	Sweden
Munir Pirmohamed	UK
Luis Alesso	Argentina

SCIENTIFIC SUB-COMMITTEE

Lynda Wilton	Chair, UK
Richard Hill	Australia
Marie Lindquist	Sweden
Joanne Barnes	New Zealand
Ken Hartigan-Go	Philippines
Paula Marquez	Spain
Corinne Pierfitte	Belgium
Alex Dodoo	Ghana

POSTER PRIZE COMMITTEE

Ken Hartigan-Go	Philippines
Marie Lindquist	Sweden
Toine Egberts	Netherlands

ANNUAL MEETINGS OF ESoP AND ISoP

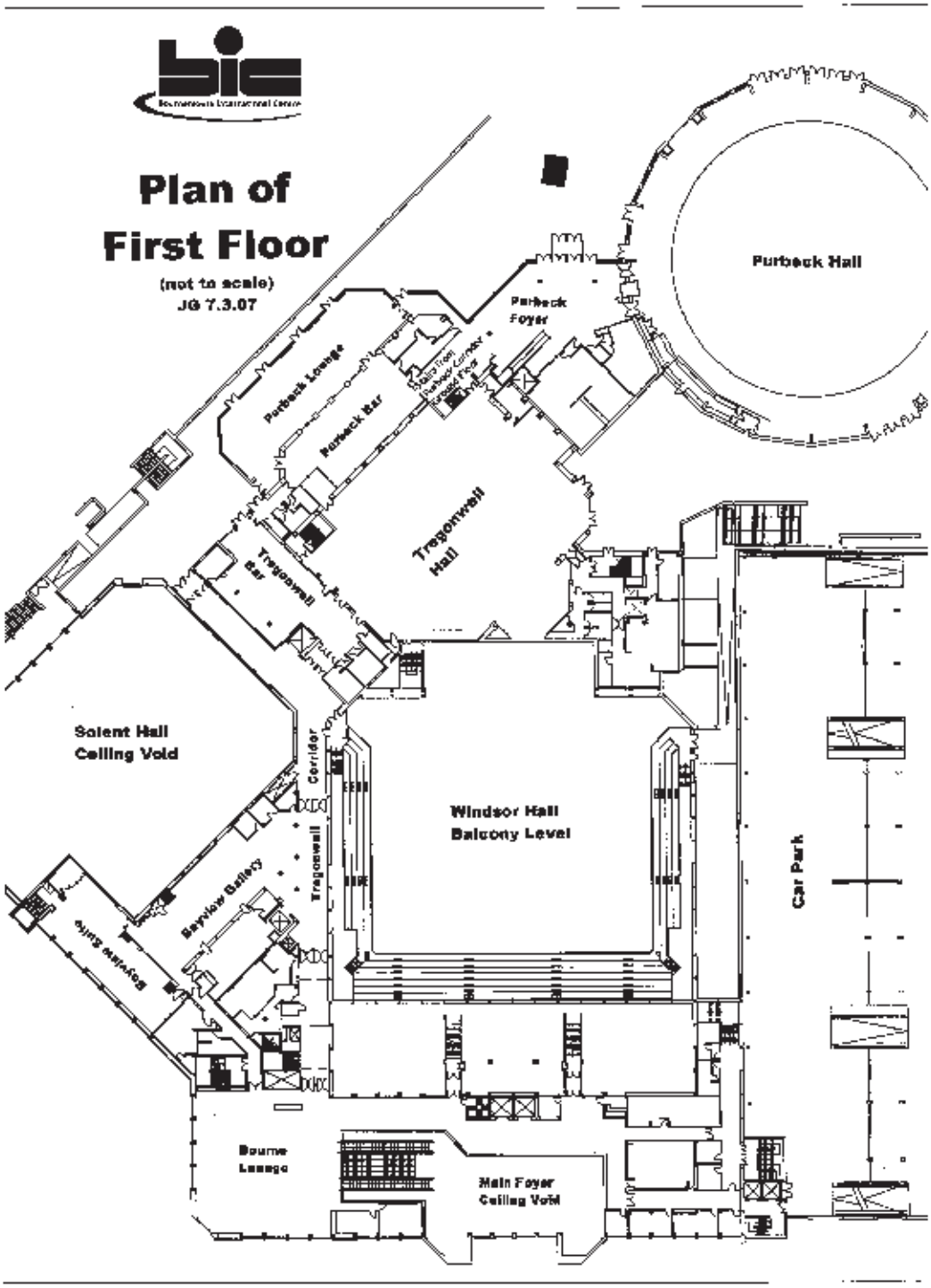
In 2000, the European Society of Pharmacovigilance (ESoP) became the International Society of Pharmacovigilance (ISoP)

1993	Geneva, Switzerland
1994	Rouen, France
1995	Cambridge, England
1996	Lisbon, Portugal
1997	Berlin, Germany
1998	Budapest, Hungary
1999	Ankara, Turkey
2000	Verona, Italy
2001	Carthage-Tunis, Tunisia
2002	Amsterdam, The Netherlands
2003	Marrakesh, Morocco
2004	Dublin, Ireland
2005	Manila, Philippines
2006	Liège, Belgium
2007	Bournemouth, UK
2008	Buenos-Aires, Argentina
2009	Reims, France

CONTENTS

VENUE FLOORPLAN

ISoP 2007 will be held at the Bournemouth International Centre (BIC), Exeter Road, Bournemouth, BH2 5BH.



The Meyrick Suite is situated on the lower ground floor below the Purbeck Foyer. The Meyrick Suite can be accessed via the stairs in the Purbeck Corridor.

GENERAL INFORMATION

REGISTRATION DESK

The Registration Desk will be situated in the Purbeck Foyer of the BIC and will be open at the following times:

Sunday 21st October	08.00 – 19.30 hours
Monday 22nd October	08.00 – 17.30 hours
Tuesday 23rd October	08.00 – 17.30 hours
Wednesday 24th October	08.00 – 15.30 hours

The Registration Desk can be reached by telephone or fax on the following numbers from Monday 22nd October:

Tel: + 44 (0)1202 555309
Fax: + 44 (0)1202 559111

Members of the Local Organising Committee can be contacted through the Registration Desk.

SECURITY

Name badges **must** be worn at all times throughout the meeting. For reasons of security, delegates not wearing a name badge will be denied access to scientific sessions. Badges will be colour-coded as follows:

Delegates	no identification strip
ISoP Executive Committee	yellow identification strip
Local Organising Committee	green identification strip
Speakers	red identification strip
Exhibitors	blue identification strip
Conference Staff	orange identification strip

CLOAKROOM FACILITIES

Cloakroom facilities will be available in the Meyrick Suite for delegates to leave coats and luggage on Monday 22nd, Tuesday 23rd and Wednesday 24th October. The cloakroom will be staffed at the following times:

Monday 22nd October	08.00 - 18.00 hours
Tuesday 23rd October	08.00 - 18.00 hours
Wednesday 24th October	08.00 - 16.00 hours

For the pre-conference training courses on Sunday 21st October, coat racks will be available in Bayview Suite 2 and the Purbeck Lounge. For the Civic Wine Reception, coat racks will be available in the Purbeck Foyer.

Delegates leaving articles do so at their own risk.

MESSAGES

A message board where participants may leave messages and where messages will be placed for delegates will be situated next to the Registration Desk in the Purbeck Foyer. Delegates are asked to check the board regularly for messages.

MOBILE TELPHONES

As a courtesy to the speakers and other delegates, please ensure that mobile telephones are switched off during sessions.

SPEAKER PREVIEW
To ensure the smooth running of sessions, speakers are requested to report to the Speaker Preview Room in the Purbeck Bar **at least one hour** before the start of their session to check their presentation with the technicians. The Speaker Preview Room will open at 12.00 hours on Sunday 21st October and remain open during the conference hours.

CATERING ARRANGEMENTS
Pre-conference training courses
Morning coffee, a sandwich lunch and afternoon tea will be provided in the Tregonwell Bar on Sunday 21st October.

Conference
On Monday 22nd October, coffee and tea will be provided from 08.00 to 09.00 hours in the Purbeck Hall for those arriving early.

Mid-morning coffee, two-course buffet lunch and afternoon tea will be provided in the Purbeck Hall on Monday, Tuesday and Wednesday.

EXHIBITION
The exhibitor stands will be located in the Purbeck Hall and will be open during conference hours. Please refer to pages 46 - 48 for further information.

POSTER PRESENTATIONS
Poster presentations will be displayed in the Purbeck Hall as follows:

P.003 to P.088 on Monday 22nd October
Posters can be mounted from 08.00 to 09.00 hours on Monday 22nd October. Posters must be removed between 17.30 and 18.30 hours on Monday 22nd October.

P.089 to P.171 on Tuesday 23rd October
Posters can be mounted from 08.00 to 09.00 hours on Tuesday 23rd October. Posters must be removed between 17.30 and 18.30 hours on Tuesday 23rd October.

Please refer to pages 33 - 45 for a list of the poster presentations.

Posters that are not removed by the time stated above will be removed by the Conference Organisers and stored until the close of the conference at 15.30 hours on Wednesday 24th October. Posters that are not collected by the close of the conference will be discarded.

Prizes will be awarded for the top three posters and prizes will be presented on Wednesday 24th October during the Closing Plenary session starting at 14.10 hours.

SCIENTIFIC SESSIONS
All Plenary sessions will be held in the Tregonwell Hall.

Parallel sessions will be held in the Tregonwell Hall and Bayview Suites 1 and 2.

Full details regarding the scientific programme can be found on pages 18 - 32.

OFFICIAL LANGUAGE
The official language of the conference is English.

INSURANCE
The Secretariat does not accept responsibility for individual medical, travel or personal insurance and delegates are advised to take out their own insurance policies.

BOURNEMOUTH TOURIST BOARD
Bournemouth Tourist Board will have a stand in the Purbeck Foyer. Delegates will be able to obtain information and leaflets on local attractions. Delegates who booked their accommodation through the Bournemouth Accommodation Bureau can also direct any enquiries they may have to this stand.

ACCOMMODATION
For enquiries relating to hotel accommodation which has been booked through the Secretariat, please go to the Registration Desk. For hotel accommodation booked through the Bournemouth Accommodation Bureau, please visit the Bournemouth Tourist Board stand in the Purbeck Foyer.

CAR PARK
A multi-storey pay & display car park is located adjacent to the BIC with approximately 650 car parking spaces.

The car parking charges for 2006-2007 are as follows (correct at time of printing):

Daytime charges: 0800 – 2200 hours

	£
Up to 1 hour	1.00
Up to 2 hours	2.00
Up to 3 hours	3.60
Up to 4 hours	5.50
Up to 8 hours	8.00
Up to 24 hours	10.00

Evening charges: 2200 – 0800 hours

	£
Per visit (valid until 08.00 hours)	Free

SOCIAL PROGRAMME

Sunday 21st October – Welcome Drinks Reception
A Welcome Drinks Reception will be held at the Bournemouth International Centre on Sunday 21st October in the Purbeck Hall from 18.00-19.30 hours. The Borough of Bournemouth will be hosting the first part of this event, during which the Mayor will give the Civic Welcome to the Conference. The remainder of the reception will be hosted by ISoP/DSRU. At the reception, delegates will have the opportunity to meet the exhibitors and network with other delegates.

For admission to this event you must present your invitation card at the door.

Tuesday 23rd October – Conference Gala Dinner
The Gala Dinner and Drinks reception will take place at the Bournemouth Pavilion from 19.30 to 23.00 hours on Tuesday 23rd October. The dinner includes a drinks reception to be held from 19.30 to 20.00 hours, a three course meal, wine with dinner and entertainment. ***Admission will be strictly by ticket only.***

Restored and refurbished to its 1920's splendour and overlooking the seafront, the Bournemouth Pavilion is a three minute walk from the BIC through beautiful landscaped gardens.

Entertainment on the night will be provided by the band *Alpha Connection* whose unique style will make the evening a night to remember. There will also be Las Vegas style casino tables (tokens provided), a close-up magician and a graphologist.

Delegates wishing to purchase tickets for this event on-site should enquire at the Registration Desk as there may be a limited number of tickets still available. Tickets cost £58.00 including VAT per person. Dress code is lounge suit. Unused dinner tickets will **not** be refunded unless the ticket is subsequently re-sold.

SCIENTIFIC PROGRAMME OVERVIEW

Sunday 21st October

From 0800	Registration, Purbeck Foyer
0930 - 1700	**Pre-Conference Training Courses**, • **Back to Basics**…, Purbeck Lounge • **How to write a safety specification…**, Bayview Suite 2
1800 - 1930	Welcome Drinks Reception hosted by the Borough of Bournemouth, ISoP and DSRU, and Opening of Exhibition, Purbeck Hall
1930 - 2200	Editorial Board Meeting of 'Drug Safety' Journal, Purbeck Lounge

Monday 22nd October

From 0800	Registration, Purbeck Foyer
0900 – 0920	**Opening of the 7th Annual ISoP Meeting**, Tregonwell Hall
0920 - 0955	**Opening Plenary Lecture: Towards a new paradigm for Risk Management**, Tregonwell Hall
0955 – 1030	**Keynote Plenary Lecture: Interocular paradoxes - subverting the evidential hierarchy in pharmacovigilance**, Tregonwell Hall
1030 - 1100	Coffee, poster viewing & exhibition, Purbeck Hall
1100 - 1230	**Parallel Sessions A & B** • **A. Drug Hypersensitivity**, Tregonwell Hall • **B. How Do We Find Useful Signals?**, Bayview Suites 1 & 2
1230 - 1400	Lunch, poster viewing & exhibition, Purbeck Hall
1400 - 1530	**Parallel Sessions C & D** • **C. Vision for Pharmacovigilance**, Tregonwell Hall • **D. Symposium on EcoPharmacovigilance**, Bayview Suites 1 & 2
1530 - 1600	Tea, poster viewing & exhibition, Purbeck Hall
1600 - 1730	**Parallel Sessions E & F** • **E. Monitoring Safety of Vaccines**, Bayview Suites 1 & 2 • **F. "Bouillabaisse" (A selection of the best abstracts)**, Tregonwell Hall
1800 – 2200	ISoP Executive Committee Meeting, Blandford Suite, Marriott Highcliff Hotel

Tuesday 23rd October

From 0800	Registration, Purbeck Foyer
0900 - 1030	**Parallel Sessions G & H** • **G. Pharmacovigilance in Developing Countries**, Bayview Suite 2 • **H. Clinical Trials for Drug Safety – Challenges and Opportunities**, Tregonwell Hall

Tuesday 23rd October (continued)

1030 - 1100	Coffee, poster viewing & exhibition, Purbeck Hall
1100 - 1230	**Parallel Sessions I, J & K** • **I. Developments in Safety Assessment and Pharmacovigilance of Herbal Medicines**, Bayview Suite 2 • **J. From Tunbridge Wells to Bournemouth …,** Tregonwell Hall • **K. Systems of Pharmacovigilance in the Western Pacific**, Bayview Suite 1
1230 - 1400	Lunch, poster viewing & exhibition, Purbeck Hall
1315 – 1400	**ISoP General Assembly**, Tregonwell Hall
1400 - 1445	**Plenary Lecture I: The Polypill: moving from concept to reality**, Tregonwell Hall
1445 – 1530	**Plenary Lecture II: Evidence in Pharmacovigilance: Paradise Postponed?**, Tregonwell Hall
1530 - 1600	Tea, poster viewing & exhibition, Purbeck Hall
1600 - 1730	**Parallel Sessions L & M** • **L. "Fruits de Mer" (A further selection of the best abstracts)**, Bayview Suites 1 & 2 • **M. Writing a Proper Adverse Event Report for Publication**, Tregonwell Hall
1930	Gala Dinner, Pavilion Ballroom, Bournemouth Pavilion

Wednesday 24th October

From 0800	Registration, Purbeck Foyer
0900 - 1030	**Parallel Sessions N & O** • **N. Risk Management in Pharmacovigilance**, Tregonwell Hall • **O. Communications,** Bayview Suites 1 & 2
1030 - 1100	Coffee, poster viewing & exhibition, Purbeck Hall
1100 - 1230	**Parallel Sessions P & Q** • **P. Challenges of PEM and Future Directions**, Tregonwell Hall • **Q. "Zuppa di Pesce" (A further selection of the best abstracts)**, Bayview Suites 1 & 2
1230 - 1330	Lunch, exhibition & poster viewing, Purbeck Hall
1330 - 1410	**Keynote Plenary Lecture: The link between the laboratory and the clinic in asthma**, Tregonwell Hall
1410 - 1450	**Closing Plenary Lecture: The contribution of Pharmacoepidemiology to Pharmacovigilance**, Tregonwell Hall
1450 - 1505	Poster Prize Awards
1505 - 1520	Announcement for ISoP 2008, Buenos Aires
1520 - 1530	Closing Remarks
1530	**Close of ISoP 2007**

ROOM USAGE

Please refer to the floorplan shown on page 10.

The meeting will take place in the following rooms:

Tregonwell Hall	Plenary sessions, parallel sessions and ISoP General Assembly
Bayview Suite 1	Parallel Sessions
Bayview Suite 2	Pre-Conference Training Course Parallel Sessions
Purbeck Lounge	Pre-Conference Training Course Editorial Board Meeting Delegate Lounge
Purbeck Hall	Exhibition, posters and catering for morning and afternoon refreshments and lunch, including Civic Welcome Drinks Reception
Purbeck Foyer	Registration Desk
Purbeck Bar	Speaker Preview and Speaker Lounge

PROGRAMME - SUNDAY 21st OCTOBER

PRE-CONFERENCE TRAINING COURSES

A. **Back to Basics – A Basic Course in Pharmacovigilance, including Narrative Writing of Case Reports**	B. **How to Write a Safety Specification and Risk Management Plan**
Course Leaders: Lynda Wilton, PhD Principal Research Fellow, DSRU, UK Honorary Senior Lecturer University of Portsmouth, UK Vanessa Marshall, BSc MBBS Clinical Research Fellow, DSRU, UK Germano Ferreira, MPharm MPH Research Fellow, DSRU, UK University of Portsmouth, UK Venue: Purbeck Lounge	Course Leaders: Prof Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCGP Director, DSRU, UK, and Chair of the Local Organising Committee Judith Jones, MD PhD FISPE Degge Group Ltd, Arlington, Virginia, USA Monika Pietrek, PhD MD MSc Executive Vice President, Scientific & Medical Affairs Pharmaceutical Research Associates GmBH Venue: Bayview Suite 2

From 0800 Registration

0930 - 1700 Pre-Conference Training Courses

Mid-morning coffee, sandwich lunch and tea will be provided in the Tregonwell Bar. You will receive a programme on the day.

1800 - 1930 Welcome Drinks Reception hosted by the Borough of Bournemouth, ISoP and DSRU, and Opening of Exhibition, Purbeck Hall

1930 - 2200 Editorial Board Meeting of 'Drug Safety' Journal, Purbeck Lounge

From 0800 — Registration, Purbeck Foyer

0900 - 0920 — **Opening of the 7th Annual ISoP Meeting**, Tregonwell Hall

Prof Nicholas Moore MD PhD FRCP (Edin), FISPE
Université Victor Segalen, Bordeaux, France, and President of ISoP
Prof Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCGP
Director of the Drug Safety Research Unit, UK, and
Chair of the Local Organising Committee, ISoP 2007

0920 - 0955 — **Opening Plenary Lecture**

Towards a new paradigm for Risk Management
Prof Kent Woods MB BChir MA MD FRCP
Chief Executive, MHRA, UK

0955 - 1030 — **Keynote Plenary Lecture**

Interocular paradoxes - subverting the evidential hierarchy in pharmacovigilance
J K Aronson MA DPhil FRCP FBPharmacolS
Reader in Clinical Pharmacology, University of Oxford, UK

1030 - 1100 — Coffee, poster viewing & exhibition

1100 - 1230 — **Parallel Sessions A and B**

A. Drug Hypersensitivity	B. How Do We Find Useful Signals?
Venue: Tregonwell Hall	Venue: Bayview Suites 1 and 2

A. Drug Hypersensitivity
Co-Chairs:

Prof Munir Pirmohamed PhD FRCP FRCP(E)
Professor of Clinical Pharmacology and Consultant Physician, The University of Liverpool, UK

Prof Toine Egberts PhD
Professor of Clinical Pharmacy, Utretcht University, Netherlands

1100 - 1130 — **Definitions and epidemiology of cutaneous adverse drug reactions**
Prof Maja Mockenhaupt PhD
Senior Dermatologist and Head of the "Dokumentationszentrum Schwerer Hautreaktionen" (dZh), German Registry for Severe Skin Reactions
Dept. of Dermatology, University Medical Centre, Freiburg, Germany

1130 - 1200 — **Mechanisms of drug hypersensitivity**
Prof Peter Friedmann MB BChir MD FRCP FMedSci
Professor of Dermatology, School of Medicine, Southampton General Hospital, Southampton University, UK

1200 - 1230

Pharmacogenetics of drug hypersensitivity
Prof Munir Pirmohamed PhD FRCP(E)
Professor of Clinical Pharmacology and Consultant Physician, The University of Liverpool, UK

1100 - 1230

B. How do we find useful signals?
Chair:
Marie Lindquist PhD
Deputy Director, Chief Scientific Officer, Uppsala Monitoring Centre, Sweden

1100 - 1115

How do we find useful signals? – part I
Brian Edwards BSc MD MRCP
Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

1115 - 1130

How do we find useful signals? – part II
Prof I. Ralph Edwards MB ChB MRCS LRCP FRCP (London) FRACP
Director, WHO Programme for International Drug Monitoring, Uppsala Monitoring Centre, Uppsala, Sweden

1130 - 1145

How do we find useful signals? – part III
Kristina Star
Registered Nurse
Uppsala Monitoring Centre, Uppsala, Sweden

1145 - 1230

General discussion

1230 - 1400

Lunch, poster viewing & exhibition

1400 - 1530

Parallel Sessions C and D

C. Vision for Pharmacovigilance	D. Symposium on EcoPharmacovigilance
Venue: Tregonwell Hall	Venue: Bayview Suites 1 and 2

C. Vision for Pharmacovigilance
Co-Chairs:
Prof Nicholas Moore MD PhD FRCP (Edin) FISPE
Université Victor Segalen, Bordeaux, France,
and President of ISoP

Gerd Kassel MD PhD
Vice President Pharmacovigilance
Takeda Global Research and Development Centre, London, UK

1400 - 1430 **Better pharmacovigilance: European Commission initiative to strengthen and rationalise the EU system**
Peter Arlett BSc MBBS MRCP MFPM
Principal Administrator, Pharmaceuticals Unit, European Commission, Belgium

1430 - 1500 **Better pharmacovigilance: vision from a National Agency**
June Raine MA MSc FRCP FFPM
Director of Vigilance and Risk Management, Medicines and Health-Care Products Regulatory Agency, UK

1500 - 1530 **A personal vision for pharmacovigilance – time to drag ourselves out of a historical mindset or in my dreams ???**
Valerie Simmons MBBS FFPM
Lilly QPPV Executive, Global Product Safety, Eli Lilly, UK

1400 - 1530 **D. Symposium on EcoPharmacovigilance**
Co-Chairs:
Prof Giampaolo Velo MD
Professor of Pharmacology, Director Clinical Pharmacology Unit, University of Verona, Italy

Prof James Clark
Professor of Chemistry, Director Green Chemistry Centre, University of York, UK

1400 - 1415 **Why EcoPharmacovigilance?** [O.29]
Prof Giampaolo Velo MD
Professor of Pharmacology, Director Clinical Pharmacology Unit, University of Verona, Italy

1415 -1433 **Pharmaceuticals as environmental pollutants** [O.28]
Ettore Zuccato MD
Mario Negri Institute for Pharmacological Research, Milan, Italy

1433 - 1451 **Greener pharmaceuticals** [O.17]
Prof James Clark
Professor of Chemistry, Director Green Chemistry Centre, University of York, UK

1451 - 1509 **EcoPharmacostewardship – How to minimise any environmental impact of pharmaceuticals whilst continuing to deliver patient benefit**
David Taylor PhD FRSC FIWEM
Director Environment and Sustainability, Global Safety Health & Environment AstraZeneca, Brixham, UK

1509 - 1530 **General discussion**

1530 - 1600 Tea, poster viewing & exhibition

1600 - 1730

Parallel Sessions E and F

E. Monitoring Safety of Vaccines	F. "Bouillabaisse" (A selection of the best abstracts)
Venue: Bayview Suites 1 and 2	Venue: Tregonwell Hall

E. Monitoring Safety of Vaccines

Co-Chairs:
Prof Stephen Evans BA MSc C Stat FRCP (Edin) Hon MFPHM
Professor of Pharmacoepidemiology, London School of Hygiene & Tropical Medicine, UK

Corinne Pierfitte
Director, Medical Governance Operations and Compliance, GlaxoSmithKline Biologicals, Belgium

1600 - 1620 **An overview of safety monitoring of vaccines**
Brigitte Keller-Stanislawski
Paul-Ehrlich-Institut, Germany

1620 - 1640 **Detecting signals for vaccines in the WHO database**
Andrew Bate PhD MA
Manager, Research & Development, Uppsala Monitoring Centre, Sweden

1640 - 1700 **Optimising signal detection for vaccines**
Stephen Evans BA MSc C Stat FRCP (Edin) Hon MFPHM
Professor of Pharmacoepidemiology, London School of Hygiene & Tropical Medicine, UK

1700 - 1720 **National pharmacovigilance centres and AEFIs- practical experience from Australia** [O.20]
John McEwen PSM MBBS MSc MPS
Visiting Lecturer, Discipline of Pharmacy, University of Canberra, Australia

1720 - 1730 General discussion

1600 - 1730 F. "Bouillabaisse" (A selection of the best abstracts)

Co-Chairs:
Deirdre McCarthy
Deputy EU QPPV
Helsinn Birex Pharmaceuticals, Ireland

Luis Alesso, MD
Córdoba National University, Argentina

1600 - 1612 **A Toolkit for Signal Detection Activities Using Retrospective Real-life Data** [O.19]
Victor Kiri
PACE, PAREXEL International, Uxbridge, Middlesex, UK

1612 - 1624	**Choice of the Comparator for Signal Generation in Pharmacovigilance Databases: Impact on Detection Thresholds** [O.06] **Nicholas Moore** Université Victor Segalen, Bordeaux, France,
1624 - 1636	**When the Comparison of Spontaneous Notification Rates Helps Us to Evaluate a Signal** [O.13] **H Bagheri** Université Paul Sabatier, Centre Hospitalier Universitaire, Toulouse, France
1636 - 1648	**An automated Method to Eliminate Bias Induced by Co-Prescription in Safety Signal Generation Using Spontaneous Reporting Databases** [O.08] **Nicholas Moore** Université Victor Segalen, Bordeaux, France,
1648 - 1700	**Terminological Reasoning and Signal Detection: Past, Present and Future** [O.11] **Cedric Bousquet** INSERM, Paris, France
1700 - 1712	**Effect of Well-Established Drug-Event Associations on the Generation of New Signals in Spontaneous Reporting Databases** [O.07] **Nicholas Moore** Université Victor Segalen, Bordeaux, France,
1712 - 1724	**The Potential of Korea National Health Insurance Data as a Data Source for Pharmacovigilance** [O.23] **Yoonsook Lee** Clinical Pharmacology Team National Institute of Toxicological Research, Seoul, South Korea
1724 - 1730	Discussion
1800 - 2200	***ISoP Executive Committee Meeting, Blandford Suite, Marriott Highcliff Hotel***

From 0800 Registration, Purbeck Foyer

0900 - 1030

Parallel Sessions G and H

G. Pharmacovigilance in Developing Countries	H. Clinical Trials for Drug Safety – Challenges and Opportunities
Venue: Bayview Suite 2	Venue: Tregonwell Hall

G. Pharmacovigilance in Developing Countries

Co-Chairs:
Prof Ken Hartigan-Go MD PhD
Executive Director, The Zuellig Foundation, Manila, Philippines

Mary R Couper
Medical Officer, Quality Assurance and Safety of Medicines, Medicines Policy and Standards, WHO

0900 - 0910 **Introduction and Opening Remarks**

0910 - 0922 **Pharmacovigilance systems in developing countries: a situational analysis**
Prof I. Ralph Edwards MB ChB FRCP (Lond) FRACP
Director, WHO Programme for International Drug Monitoring, the Uppsala Monitoring Centre, Uppsala, Sweden

0922 - 0934 **Regulatory challenges in implementing pharmacovigilance in developing countries**
Churn-Shiouh Gau PhD
Deputy Executive Director Centre for Drug Evaluation, Republic of China, Taiwan

0934 - 0946 **The mass media and pharmacovigilance in developing countries**
Alex Dodoo
BPharm MSc PhD MPSGH MRPharmS Ag.
Director, Centre for Tropical Clinical Pharmacology & Therapeutics, University of Ghana Medical School, Accra, Ghana

0946 - 0958 **Therapeutic drug monitoring a tool for pharmacovigilance: The Saudi Arabian experience**
Prof Samira Ibrahim Islam PhD
Professor of Pharmacology
Head of Drug Monitoring Unit, King Fahd Medical Research Centre, King Abdulaziz University, Jeddah, Saudi Arabia

0958 - 1010 **Assessment of Pharmacovigilance Activities in the Upper East Region of Ghana** [O.26]
J. Nee-Whang
University of Ghana Medical School, Accra, Ghana

1010 - 1025 General discussion

1025 - 1030 Closing remarks

0900 - 1030 **H. Clinical Trials for Drug Safety – Challenges and Opportunities**
Co-Chairs:
Victoria Cornelius PhD
Statistician, DSRU, Southampton, UK

Glyn Belcher MA PhD MB BChir FFPM
Vice President, Drug Safety and Risk Management International, Biogen Idec, UK

0900 - 0925 **Phase I trials – safety of monoclonal antibodies challenges**
Harsukh Parmar
Executive Director, Global Experimental Medicine, and Executive Director, Discovery Medicine, Respiratory & Inflammation, AstraZeneca

0925 - 0950 **Simple clinical trials**
Nicolle M. Gatto PhD MPH
Director, Therapeutic Area Group Head, Epidemiology, Safety and Risk Management, Pfizer Inc

0950 - 1015 **No treatment is not an option**
Prof Paolo Paoloucci
Direttore Dipartimento Integrato Materno Infantile, Scuola di Specializzazione in Pediatria, U.O. di Ematologia, Oncologia e Trapianto di CSE, Italy

1015 - 1030 **Review of New Challenges for the Development of Early Phase Biologic Compounds in the Wake of the TGN1412 Clinical Trial** [O.15]
Aidan Mackey
AstraZeneca, Macclesfield, UK

1030 - 1100 Coffee, poster viewing & exhibition

1100 - 1230

Parallel Sessions I, J and K

I. Developments in Safety Assessment and Pharmacovigilance of Herbal Medicines	J. From Tunbridge Wells to Bournemouth (Bayesian Statistics and Pharmacovigilance)	K. Systems of Pharmacovigilance in the Western Pacific
Venue: Bayview Suite 2	Venue: Tregonwell Hall	Venue: Bayview Suite 1

I. Developments in Safety Assessment and Pharmacovigilance of Herbal Medicines

Co-Chairs:
Joanne Barnes BPharm PhD MRPharmS FLS
Associate Professor in Herbal Medicines, University of Auckland, New Zealand

Prof J David Phillipson
Emeritus Professor of Pharmacognosy, University of London

1100 - 1130 **Assessment of genotoxicity for herbal medicines: a European perspective**
Professor Olavi Pelkonen
Head of Dept of Pharmacology & Toxicology, University of Oulu, Finland

1130 - 1145 **Phu Chee – a Herbal Product Containing Dexamethasone** [O.22]
Solveig Vorren
University Hospital of North Norway, Tromsø, Norway

1145 - 1200 **Surveillance of Adverse Events to Natural Products: the Italian Reporting System** [O.01]
Francesca Menniti-Ippolito
National Institute of Health, Rome, Italy

1200 - 1230 **Impact of the THMPD on safety and pharmacovigilance of herbal medicines**
Dairine Dempsey
Market Surveillance Executive, Pharmacovigilance Section, Irish Medicines Board, Ireland

1100 - 1230

J. From Tunbridge Wells to Bournemouth (Bayesian Statistics and Pharmacovigilance)

Co-Chairs:
Eugene van Puijenbroek
Netherlands Pharmacovigilance Centre, Lareb, Netherlands

Prof I. Ralph Edwards
MB ChB MRCS LRCP FRCP (London) FRACP
Director, WHO Programme for International Drug Monitoring, The Uppsala Monitoring Centre, Uppsala, Sweden

1100 - 1122 **Bayesian statistics: what is it and what can it offer pharmacovigilance?**
Deborah Ashby BSc MSc PhD CStat Hon MRCR
Professor of Medical Statistics, Queen Mary, University of London

1122 - 1144 **How to Shrink: the Bayesian approach to shrinkage and some of its properties**
David Madigan PhD
Columbia University, USA

1144 - 1207 **Do we need to shrink?**
Manfred Hauben MD MPH DTM&H
Medical Director, Safety Evaluation and Epidemiology, Pfizer Inc

1207 - 1230 **What is on the horizon/ in the future in quantitative signal detection?**
Andrew Bate PhD MA
Manager, Research & Development, Uppsala Monitoring Centre, Sweden

1100 - 1230 **K. Systems of Pharmacovigilance in the Western Pacific**
Co-Chairs:
Prof Nicholas Moore, MD PhD FRCP (Edin) FISPE
Université Victor Segalen, Bordeaux, France,
and President of ISoP

Mira Harrison-Woolrych, BM DM DFFP MRCOG
(Chapter Co-ordinator)
Director, Intensive Medicines Monitoring Programme, New Zealand Pharmacovigilance Centre, University of Otago, New Zealand

1100 - 1110 **Introduction**
Mira Harrison-Woolrych BM DM DFFP MRCOG
(Chapter Co-ordinator)
Director, Intensive Medicines Monitoring Programme, New Zealand Pharmacovigilance Centre

1110 - 1125 **Australia**
John McEwen PSM MBBS MSc MPS
Visiting Lecturer, Discipline of Pharmacy, University of Canberra

1125 - 1140 **New Zealand**
Mira Harrison-Woolrych BM DM MRCOG DFFP
Director, Intensive Medicines Monitoring Programme, New Zealand Pharmacovigilance Centre

1140 - 1155 **Philippines**
Suzette Lazo MD
Professorial Lecturer of the Department of Pharmacology and Toxicology of the University of the Philippines College of Medicine

1155 - 1210 **Taiwan**
Churn-Shiouh Gau PhD
Deputy Executive Director Centre for Drug Evaluation, Republic of China, Taiwan

1210 - 1230 **Discussion: Aims of the Western Pacific Chapter**
Panel and delegates

1230 – 1400 Lunch, poster viewing & exhibition

1315 - 1400 ***IsoP General Assembly, Tregonwell Hall***

1400 - 1530 **Plenary Lectures I and II**, Tregonwell Hall

Chair: **Prof Toine Egberts** PhD
Professor of Clinical Pharmacy, Utrecht University, Netherlands

1400 - 1445 **Plenary Lecture I**
The Polypill: moving from concept to reality
Prof Nick Wald FRS
Director of the Wolfson Institute of Preventive Medicine at Barts and The London Queen Mary's School of Medicine and Dentistry

1445 - 1530 **Plenary Lecture II**
Evidence in Pharmacovigilance: Paradise Postponed?
Prof Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCGP
Director of the Drug Safety Research Unit, UK, and
Chair of the Local Organising Committee, ISoP 2007

1530 - 1600 Tea, poster viewing & exhibition

1600 - 1730 **Parallel Sessions L and M**

L. "Fruits de Mer" (A further selection of the best abstracts) Venue: Bayview Suites 1 and 2	**M. Writing a Proper Adverse Event Report for Publication** Venue: Tregonwell Hall

L. **"Fruits de Mer"** (A further selection of the best abstracts)
Co-Chairs:
Deborah Layton BSc MRPharmS MPhil ClinDipPharm
Senior Research Pharmacist, DSRU, UK

Alex Dodoo BPharm MSc PhD MPSGH MRPharmS Ag.
Director, Centre for Tropical Clinical Pharmacology & Therapeutics, University of Ghana Medical School, Accra, Ghana

1600 - 1615 **Adrenal Insufficiency with Inhaled Corticosteroids: an Under-Recognised Event** [O.24]
Nicholas Moore
Université Victor Segalen, Bordeaux, France, and President of ISoP

1615 - 1630 **Hypersensitivity Reactions Due to Antiepileptic Drugs: a Chemical Structure Based Association?** [O.10]
Toine Egberts
Utrecht Institute for Pharmaceutical Sciences, Netherlands

1630 - 1645

How to Distinguish 'Ischaemic Hepatitis' from Drug Induced Liver Injury (DILI) [O.21]
Christopher Buckley
AstraZeneca, Macclesfield, Cheshire, UK

1645 - 1700

Renal and Auricular Adverse Drug Reactions are Linked through a Predictive Mechanistic Commonality [O.04]
Marianne Verdel
Utrecht Institute for Pharmaceutical Sciences, Netherlands

1700 - 1715

Hyponatraemia During Psychotropic Medication: Results from the International AMSP Project [O.02]
Anastasios Konstantinidis
University of Vienna, Austria

1715 -1730

Gastrointestinal and Thromboembolic Events with Etoricoxib: Case Series from a Prescription-Event Monitoring (PEM) Study in England [O.03]
Deborah Layton
Drug Safety Research Unit, England, UK

1600 - 1730

M. Writing a Proper Adverse Event Report for Publication
Co-Chairs:
Professor Nicholas Moore MD PhD FRCP (Edin) FISPE
Université Victor Segalen, Bordeaux, France, and
President of ISoP

Judith Jones MD PhD FISPE
Degge Group Ltd, Arlington, Virginia, USA

1600 - 1620

The Problems associated with writing and submitting adverse event reports for publication
Judith Jones MD PhD FISPE
Degge Group Ltd, Arlington, Virginia, USA

1620 - 1640

Writing and submitting the adverse event report for herbal products
Joanne Barnes BPharm PhD MRPharmS FLS
University of Auckland, New Zealand

1640 - 1700

The new ISPE/ISoP jointly developed guidelines on submitting adverse event reports for publication
William N. Kelly PharmD FISPE
William N. Kelly Consulting, Inc., Oldsmar, FL, USA

1700 - 1710

Getting the guidelines universally adopted
Prof Nicholas Moore MD PhD FRCP (Edin) FISPE
Université Victor Segalen, Bordeaux, France, and President of ISoP

1710 - 1730

Panel and audience discussion

1930

Gala Dinner, Pavilion Ballroom, Bournemouth

From 0800 Registration, Purbeck Foyer

0900 – 1030

Parallel Sessions – N and O

N. Risk Management in Pharmacovigilance	O. Communications
Venue: Tregonwell Hall	Venue: Bayview Suites 1 and 2

N. Risk Management in Pharmacovigilance

Co-Chairs:
Susana Perez-Gutthann MD MPH PhD FISPE FRCP
Head Epidemiology Europe, RTI Health Solutions,
Barcelona, Spain

Patrick Waller MD FRCPEd
Consultant in Pharmacoepidemiology, Southampton, UK

0900 - 0930 **Regulator's experience from RMPs: highlights from the review and learning project**
Ingemar Persson
Professor and Senior Expert
Medical Products Agency and Karolinska Institutet, Sweden

0930 - 1000 **Case studies of RMPs from an assessor: The good, the bad and the ugly**
Lesley Wise
Manager Pharmacoepidemiology Research Unit, MHRA, UK

1000 - 1030 **Risk management in special circumstances: new developments for emerging situations**
Xavier Kurz
Scientific Administrator
European Medicines Agency (EMEA), Sector Pharmacovigilance and Post-Authorisation Safety and Efficacy of Medicines, London, UK

O. Communications

0900 - 1030

Co-Chairs:
Brian Edwards BSc MD MRCP
Director, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Andrzej Czarnecki MD PhD DSc MFPM Dip Epi
Director, Deputy EU QPPV, Global Patient Safety, Lilly

0900 - 0930 **Communicating drug safety - the role of the specialist journal**
Rosie Stather MA (Cantab)
Editor, Drug Safety

0930 - 1000 **Communicating drug safety - the role of medical journals**
Giselle Jones
Editorials Editor
British Medical Journal (BMJ)

1000 - 1030 **Communicating drug safety – the role of the editor of a medical journal**
Kamran Abbasi MB ChB MRCP
Editor of the Journal of the Royal Society of Medicine, CEO and editor-in-chief of Onmedica

1030 - 1100 Coffee, poster viewing & exhibition

1100 - 1230 **Parallel Sessions – P and Q**

P. Challenges of PEM and Future Directions	Q. "Zuppa di Pesce" (A further selection of the best abstracts)
Venue: Tregonwell Hall	Venue: Bayview Suites 1 and 2

P. Challenges of PEM and Future Directions
Co-Chairs:
Mira Harrison-Woolrych BM DM MRCOG DFFP
Director, Intensive Medicines Monitoring Programme, New Zealand Pharmacovigilance Centre

Lynda Wilton PhD
Principal Research Fellow, DSRU, Honorary Senior Lecturer, University of Portsmouth

1100 - 1115 **PEM in England** – its beginnings, the present and the future
Lynda Wilton PhD
Principal Research Fellow, DSRU, Honorary Senior Lecturer, University of Portsmouth

1115 - 1130 **Safety Profile of Tacrolimus used in General Practice in England: a Prescription-Event Monitoring Study** [O.05]
Yvonne Buggy
Research Fellow
Drug Safety Research Unit, England, UK

1130 - 1145 **Signal Detection in Prescription-Event Monitoring: Finding needles, pins and haystacks**
Germano Ferreira MPharm MPH
Research Fellow
Drug Safety Research Unit, England, UK
University of Portsmouth, UK

1145 - 1200 **Apples and Oranges – Undertaking Comparisons in PEM**
Debbie Layton BSc MRPharmS MPhil ClinDipPharm
Senior Research Pharmacist, Honorary Senior Lecturer, University of Portsmouth, UK
Drug Safety Research Unit, England, UK

1200 - 1215 **PEM in New Zealand**
Mira Harrison-Woolrych BM DM MRCOG DFFP
Director, Intensive Medicines Monitoring Programme, New Zealand Pharmacovigilance Centre

1215 - 1230 General discussion

1100 - 1230 **Q. "Zuppa di Pesce"** (A further selection of the best abstracts)

Co-Chairs:
Prof Samira Ibrahim Islam PhD
Professor of Pharmacology
Head of Drug Monitoring Unit, King Fahd Medical Research Centre, King Abdulaziz University, Jeddah, Saudi Arabia

Jamie Coleman
Specialist Registrar in Clinical Pharmacology, University Hospital Birmingham NHS Foundation Trust, UK

1100 - 1112 **The influence of Notoriety Bias on ADR Spontaneous Reporting Rate** [O.09]
Giampaolo Velo
University of Verona, Italy

1112 - 1124 **The Culture of Safety: Why a Product is Only as Safe as the Healthcare System Allows** [O.16]
Axel Olsen
Pharmaceutical Safety Institute, New Hope, Pa, USA

1124 - 1136 **Medication Safety Reports in Intensive Care Units: a Prospective Multicentric Study** [O.12]
Raja Benkirane
Moroccan Pharmacovigilance Centre, Rabat, Morocco

1136 - 1148 **Individualising the Risks and Benefits of Postmenopausal Hormone Therapy** [O.18]
Tim Williams
GPRD, London, UK

1148 - 1200 **Intensive Monitoring of Adverse Events (AE) to Antiretroviral Drugs (ARV) in Ghana** [O.25]
Alex Dodoo
University of Ghana Medical School, Accra, Ghana

1200 - 1212 **Community Pharmacists' Adherence to the Isotretinoin Pregnancy Prevention Program in the Netherlands** [O.14]
Aukje Mantel-Teeuwisse
Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht, Netherlands

1212 - 1224	**Benefits of Spontaneous Reporting ADR Systems to Public Health Programmes in Sub-Saharan Africa** [O.27] **Alex Dodoo** University of Ghana Medical School, Accra, Ghana
1224 - 1230	Discussion
1230 - 1330	Lunch, poster viewing and exhibition
1330 - 1410	**Keynote Plenary Lecture**, Tregonwell Hall **The link between the laboratory and the clinic in asthma** **Prof Stephen Holgate** BSc MBBS MD DSc FRCP FRCPath FIBiol FMedSci FRSA Medical Research Council Clinical Professor of Immunopharmacology at the University of Southampton
1410 - 1450	**Closing Plenary Lecture**, Tregonwell Hall **The contribution of pharmacoepidemiology to pharmacovigilance** **Joan-Ramon Laporte** Fundació Institut Català de Farmacologia, Spain
1450 - 1505	Poster Prize Awards
1505 - 1520	Announcement for ISoP 2008, Buenos Aires
1520 - 1530	Closing Remarks
1530	Close of ISoP 2007

POSTER PRESENTATIONS

Posters will be on display in the Purbeck Hall as follows:

P.003 – P.088 – Monday 22nd October **P.089 – P.171 – Tuesday 23rd October**

Please note that the numbers are not consecutive, however the numbers listed correspond to the numbers of the poster boards in the Purbeck Hall at the time of going to print.

P.003 Evaluation of Patients' Experiences with Antidepressants Reported to a Medicine Reporting System
ECG van Geffen, SW van der Wal, R van Hulten, MCH de Groot, ACG Egberts, ER Heerdink
Science shop for Medicines, Utrecht, Netherlands

P.004 The Application of a Risk Based Approach to Your Pharmacovigilance Operations
M Giffin, C Holmes, R Petherick, O Steck
WCI Consulting Limited, Denmead, Hampshire, UK

P.005 A System-Based Approach for Product Risk Management
TC Aquilina, AB Mendelsohn, L Benaise, J Roncal, S Yonren
MedImmune, Inc., Gaithersburg, MD, USA

P.006 The European Paediatric Regulation: The Pharmacovigilance implications for the Healthcare System and for Industry
A Konstanidis, JW van der Velden, P Smit-Marshall
PharmaNet, Zumikon, Switzerland

P.007 DRESS: Is Oxcarbazepine Safer Than Carbamazepine?
T Trenque, L Thomas, H Le Louet
Department of Pharmacovigilance, Creteil, France

P.008 The Frequency of Heparin-induced Thrombocytopenia with Low Molecular Weight Heparin in an Academic Teaching-Hospital
ACG Egberts, MJ ten Berg, PMLA van den Bemt, A Huisman, AFAM Schobben, WW van Solinge
Utrecht Institute for Pharmaceutical Sciences, Utrecht, Netherlands

P.009 Independent Safety Evaluation for Newly Licensed Medicines: An In-Depth Study of Expert Opinion within Industry and Society
CR Knight, J Wilkinson
University of Hertfordshire, Hatfield, UK

P.010 The ARIADNE Concept – One Thread to Follow in the Risk Information Labyrinth
S Joelson, L Estborn, B Sjöström
AstraZeneca R&D, Mölndal, Sweden

P.012 Use of Antihypertensive Drugs in Internal Medicine Departments in Italy (1998-2003)
AB Bottoni, GC Cipola, CM Meneghin, EM Moro, FC Crema
(Drug Safety, Roche S.p.A., Monza (MI), Italy)

P.013 Pharmacovigilance in European Clinical Trials: Duties of Sponsor
D Bertram, V Plattner
Délégation à la Recherche Clinique, Hospices Civils de Lyon, Lyon, France

P.014 Hospitalisation as a Determinant for Discontinuity of Drug Use
R Stuffken, ER Heerdink, PC Souverein, ACG Egberts
Tergooi Hospitals, Department of Clinical Pharmacy, Hilversum, Netherlands

P.015 ADRs Prevention in Patient Undergoing Myelogram: A Multidisciplinary Approach
J Yothapitak, T Leeyutthanon, W Punyawathanee
Surat-thani Hospital, Surat-thani, Thailand

P.016 Views and Behaviours Towards Effectiveness and Safety of Chinese Herbal Medicine (CHM): Qualitative Interviews with CHM Shop/Clinic Employees in London
L Teng, D Shaw, J Barnes
Centre for Pharmacognosy and Phytotherapy, School of Pharmacy, University of London, London, UK

P.017 Characteristics of Chinese Herbal Medicine Retail Outlets in London: a Cross-Sectional Study
L Teng, D Shaw, J Barnes
Centre for Pharmacognosy and Phytotherapy, School of Pharmacy, University of London, London, UK

P.018 Monitoring of Adverse Drug Reactions Associated with Antihypertensive Medicines at a University Teaching Hospital in New Delhi
M Aqil, A Hussain, F Imam, F Khurshid, MS Alam, P Kapur, KK Pillai
Faculty of Pharmacy, Hamdard University, Hamdard Nagar, New Delhi, India

P.019 Prospective Surveillance for Adverse Drug Reactions Among Hospitalized Patients in Department of General Medicine in an Indian Tertiary Care Hospital
J Jose, PGM Rao, B Jimmy
Manipal College of Pharmaceutical Sciences, Manipal University, Manipal, India

P.020 A 12-Month Modified Prescription-Event Monitoring Report for Travaprost
MN Davies, N Paiba, L Wilton, SAW Shakir
Drug Safety Research Unit, Southampton, UK

P.021 EFEMERIS : A French Database Allowing Evaluation of Risks Related to Drugs in Pregnancy
H Bagheri, C Damase-Michel, I Lacroix, C Hurault, JL Montastruc
Université Paul Sabatier, Centre Hospitalier Universitaire, Toulouse, France

P.022 Risk Factors for Developing Serious Adverse Drug Reactions (ADRs)
NM Mirosevic, IJ Jankovic, ML Lovrek, DK Krnic, VMS Macolic, ST Tomic, CD Duggan, IB Bates
Agency for Medicinal Products and Medical Devices, Zagreb, Croatia

P.023 Drug Perception by Children: a Survey of 138 Children at School in South-West France
H Bagheri, C Damase-Michel, AS Desaubliaux, G Durrieu, JL Montastruc
Université Paul Sabatier, Centre Hospitalier Universitaire, Toulouse, France

P.024 Biosimilars: How to Manage Risks
S Mayall, O Lefebvre, K Seamon, L Mclean, A Banerjee
Regulatory, Drug Safety & Risk Management Practice, Pope Woodhead & Associates, Cambridge, UK

P.025 Addressing Safety Issues and Providing Safety Assessment to Regulatory Authorities in the Post-Marketing Period
A Czarnecki
Lilly Research Laboratories, Erl Wood Manor, Windlesham, UK

P.026 Medic-Al: a French Network in Pharmacovigilance about Drugs During Breastfeeding; Focus on Herbal Medicine and Over the Counter Drugs
RS Serreau, VR Rigourd, AA Amirouche, SA Aubry, ML Leveque
Clinical Research Unit Necker Hospital, Paris, France

P.027 Statin-associated Psychiatric Adverse Events: a Case/Non Case Evaluation of an Italian Database of Spontaneous Reporting of Adverse Drug Reactions
M Tuccori, U Moretti, F Lapi, D Coli, A Testi, M Moschini, A Vannacci, C Blandizzi, A Mugelli, M Del Tacca
Interdepartmental Center for Research in Clinical Pharmacology and University of Pisa, Pisa, Italy

P.028 Integrating Pharmacology with Pharmacovigilance: Developing Tools to Examine Pattern of Risks Within Drug Classes in Prescription-Event Monitoring (PEM)
D Layton, G Ferreira, SAW Shakir
Drug Safety Research Unit, Southampton, UK

P.029 Non-Steroidal Anti-Inflammatory Drug (NSAID) Utilization Factors in the Netherlands
D Layton, PC Souverein, ER Heerdink, ACG Egberts, SAW Shakir
Drug Safety Research Unit, Southampton, UK

P.030 Gastrointestinal and Thromboembolic Events with Valdecoxib: Case Series from a Prescription-Event Monitoring (PEM) Study in England
D Layton, V Marshall, SAW Shakir
Drug Safety Research Unit, Southampton, UK

P.031 Treatment and Care of Children and Adolescents Diagnosed with Attention Deficit/Hyperactivity Disorder in the Eastern Cape, South Africa
I Truter, S Snyman
Nelson Mandela Metropolitan University, Port Elizabeth, South Africa

P.032 Prescribing Patterns of Combination Analgesics to a Medical Aid Patient Population in South Africa
I Truter
Nelson Mandela Metropolitan University, Port Elizabeth, South Africa

P.033 Therapeutic Drug Monitoring of Tipranavir: About 2 Cases of Adverse Side Effects
M Andréjak, AS Lemaire-Hurtel, L Masson, L Hary, H Masson,
Regional Center of Pharmacovigilance, Amiens, France

P.034 Hepatitis Caused by a Natural Product?
J Røed, J Schjøtt
Regional Drug Information Centre (RELIS Vest), Haukeland University Hospital, Bergen, Norway

P.035 The Drug Compliance: a "Random" Variable whose Taking into Account is Essential: Example of the Oral Anticoagulants Treatment (OAT)
M Andréjak, V Gras-Champel, V Brenet-Dufour, H Masson, J Moragny, C Chourbagi
Pharmacovigilance Center, University Hospital, Amiens, France

P.036 Hemolytic Uremic Syndrome Following Combined Chemotherapy with Rituximab, Oxaliplatin and Gemcitabine: Case Report
N Bernard, L Mege, D Bertram
CRPV, Lyon, France

P.037 Episodes of Psoriasis in a Patient Treated by Different TNFa-inhibitors
M Andréjak, V Gras-Champel, E Carmi, F Grados, C Chourbagi, R Cevallos
Pharmacovigilance Center, University Hospital, Amiens, France

P.038 Probable Ischemic Hepatitis Following a R-CHOP Chemotherapy: a Case Report
N Bernard, L Mege, D Bertram
CRPV, Lyon, France

P.039 Unwanted Selective Serotonin Reuptake Inhibitors Interactions Can Decrease Drug Safety During Depression Pharmacotherapy
J Woron, T Kaczmarzyk, R Korbut, A Arab
University Centre for Adverse Drug Reactions Monitoring and Investigation, Krakow, Poland

P.040 Safety of Polypharmacy During Pain Treatment
J Woron, T Kaczmarzyk, J Dobrogowski, M Trojan
University Centre for Adverse Drug Reactions Monitoring and Investigation, Krakow, Poland

P.041 Perception of Pharmacovigilance by Health Professionals: a Survey Conducted in Rabat
A Tebaa, A Daouda, RB Benkirane, RS Soulaymani
University of Medicine, Rabat, Morocco

P.042 Nilutamide and Chromatopsia: Suggestion for a Possible Mechanism
EP van Puijenbroek, MCH de Groot, AC van Grootheest
Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, Netherlands

P.043 Knowledge and Attitude of General Practitioners Towards Reporting Adverse Drug Reactions
EP van Puijenbroek, M ten Napel, JLM Passier, AC van Grootheest
Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, Netherlands

P.044 Polypharmacy in a Psychiatric Inpatient Population: Results from the AMSP (Arzneimittelsicherheit in der Psychiatrie) Study Group
A Konstantinidis, U Moser, R Grohmann, A Horvath, R Engel, S Kasper
Medical University of Vienna, Vienna, Austria

P.045 Development of a Unit of Pharmacovigilance in a Private Hospital: First Experience in Uruguay
I Olmos, G Giachetto, V Olmos
Asociacion Española Primera de Socorros Mutuos, Montevideo, Uruguay

P.046 Development of a New Causality Assessment Method for Thai Adverse Drug Reaction Monitoring and Reporting
P Tragulpiankit, W Suwankesawong, J Yothapitak, R Songsiriphun
Faculty of Pharmacy, Mahidol University, Bangkok, Thailand

P.047 Retailers and Herbal Product-Related Adverse Drug Reactions: Whose Responsibility Is It?
R Walji, H Boon, J Barnes, GR Baker, Z Austin
University of Toronto, Toronto, Canada

P.048 Drug Therapy Problems Management by Pharmacist in Paediatric Intensive Care Unit at a Large Teaching Hospital, Thailand
P Piebpien, P Tragulpiankit, A Preutthipan, P Montakantikul
Faculty of Pharmacy, Mahidol University, Bangkok, Thailand

P.049 Spontaneous ADRs Reports of Drug-induced Renal and Urinary Disorders in Taiwan
CH Su, YW Hsieh, CS Gau
National ADR Reporting Center in Taiwan, Taipei, Taiwan

P.050 Risk Assessment of Medicines Containing Extracts from Compositae in a German Pharmacovigilance Network of Anthroposophical Physicians in Primary Care
C Lueke, E Jeschke, T Ostermann, D Buchwald, J Huebner, M Tabali, H Matthes
Research Institute and Community Hospital Havelhoehe, Berlin, Germany

P.051 Adverse Drug Event of Rheumatoid Arthritis and Osteoarthritis Ambulatory Patients in a Large Teaching Hospital in Thailand
P Tragulpiankit, S Chulavatnatol, T Limsuwan, U Sirikhedgon, S Somjarit
Department of Pharmacy, Faculty of Pharmacy, Mahidol University, Bangkok, Thailand

P.052 Ocular Adverse Drug Reactions: Analysis of an Italian Spontaneous Reporting Database
R Leone, P Cutroneo, A Cocci, O Leoni, M Moschini, A Vargiu, ML Iorio
Clinical Pharmacology Unit, University of Verona, Verona, Italy

P.053 New Signals and New Information. Outcomes from a Review of Thiazolidinediones Using Voluntary Adverse Reaction Reports, Literature and Regulatory Sources
RL Savage
New Zealand Pharmacovigilance Centre, University of Otago, Dunedin, New Zealand

P.054 Fluoroquinolones-Induced Anaphylaxis: Analysis of an Italian Spontaneous Reporting Database
ML Iorio, D Coli, D Motola, M Passiu, AL Rivolta, A Russo, A Conforti
Clinical Pharmacology Unit, University of Verona, Verona, Italy

P.055 More or Less Risk of Hypoglycaemia in Users of Angiotensin Receptor Antagonists? A Study of Spontaneous Reporting
N Moore, F Gregoire, A Pariente, F Haramburu
CHU de Bordeaux, Bordeaux, France

P.056 Quality Control of Coding in a Spontaneous Reporting Database: Is It Necessary?
U Moretti, P Porcelli, LMagro, O Tartaglia, I Meneghelli, F Renda, R Leone, M Venegoni
Veneto Pharmacovigilance Centre, Verona, Italy

P.057 Toxicity Profile of Ticlopidine: Unavoidable Reactions?
I Meneghelli, C Biagi, ML Iorio, F Salvo, S Scotto, A Testi, GP Velo
Clinical Pharmacology Unit, University of Verona, Verona, Italy

P.058 Use of Natural Products Among Pregnant Women in Tuscany: a Pilot Survey
F Lapi, A Vannacci, M Moschini, G Banchelli, M Di Pirro, E Gallo, E Cecchi, F Cipollini, F Firenzuoli, A Mugelli
Department of Preclinical and Clinical Pharmacology, Florence, Italy

P.060 Documentation Grading of ICSRs and Improved Data Quality Management in Vigibase
M Lindquist
The Uppsala Monitoring Centre, Uppsala, Sweden

P.063 Identifiying Clinically Significant Preventable Serious Adverse Drug Reactions Caused by Specific High Alert Medications in Taiwan
WW Chen, YW Hsieh, CS Gau
Taiwan National ADR Reporting Center, Taipei, Taiwan

P.066 Drug Use in Pregnancy – Are There Differences Between Common Sources of Information?
SK Frost, J Schjøtt
Regional Drug Information Centre (RELIS Vest), Haukeland University Hospital, Bergen, Norway

P.067 Central Adverse Drug Reactions (ADRs) Induced by Non Neuropsychotropic Drugs: A Survey on French PharmacoVigilance Database
H Bagheri, M Biboulet, JL Montastruc
Centre Régional de Pharmacovigilance, Toulouse, France

P.069 Psoriasis Drug Induced
R Daghfous, A Chaabane, S Sraïri, S El Aïdli, S Kastalli, MH Loueslati, M Lakhal, CH Belkahia, R Amrani
National Centre of Pharmacovigilance, Tunis, Tunisia

P.070 Electronic Reporting of ADRs: A Recording Quality Study
S Gonçalves, A Araújo, C Martins, F Bragança, I Clérigo, S Queiroz, R Pombal, R Carmona
INFARMED, Lisbon, Portugal

P.072 Drug-induced Hepatitis Due to Doxycycline : A Case Report
MC Perault-Pochat, F Chavant, C Lafay-Chebassier, F Al Khidir, M Beauchant,
Pharmacology Department, Poitiers University Hospital, Poitiers, France

P.073 Birth Outcomes in Women Exposed to Acenocoumarol
R Daghfous, K Ksouda, S Kastalli, S Sraïri, S El Aïdli, R Charfi, A Chaabane, MH Loueslati,
M Lakhal, CH Belkahia
National centre of Pharmacovigilance, Tunis, Tunisia

P.075 Preventability Scale of Adverse Reaction in a Geriatric Population Within a Centre of Long Stay
MB Valnet Rabier, JP Kantelip, A Wollner, V Daucourt, C Verdot
Pharmacovigilance Department, University Hospital of Besançon, Besançon, France

P.076 Adverse Events in a Cohort of Alzheimer's Disease Patients Treated with Memantine
S Spila-Alegiani, F Clerici, A Elia, N Vanacore, S Pomati, R Da Cas, R Raschetti, C Mariani
National Centre for Epidemiology, National Institute for Health, Rome, Italy

P.077 Putative Role of Drugs in Emergency Hospitalization During Heat Wave in a University Hospital in France
MB Valnet Rabier, JP Kantelip, JC Besançon, T Desmettre
Pharmacovigilance Department, University Hospital of Besançon, Besançon, France

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Uppsala, Sweden

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RL Savage, M Tatley
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Medical Unit, Pfizer Spain S.A., Madrid, Spain

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Netherlands Pharmacovigilance Centre Lareb, 's Hertogenbosch, Netherlands

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HEGP Assistance Publique-Hopitaux de Paris, Paris, France

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Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, Netherlands

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AJ Mackey, CJ Wadsworth
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MO Bittencourt, LFS França, LAM Silva, MF Dias
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A Oteri, P Cutroneo, G Polimeni, L Borsellino, S Campo, AP Caputi
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PAREXEL International, Uxbridge, UK

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Department of Pharmacology, School of Medicine, UBA, Buenos Aires, Argentina

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CESPU- Instituto Politécnico de Saúde do Norte, Gandra-Porto, Portugal

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Regulatory and Risk Management Practice, Pope Woodhead & Associates, Cambridge, UK

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Department of Pharmacoepidemiology and Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht, Netherlands

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RFW University, Bonn, Germany

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Department of Pharmacology and Therapeutics, Universidad de la República, Montevideo, Uruguay

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Nelson Mandela Metropolitan University (NMMU), Port Elizabeth, South Africa

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West Midlands Centre for Adverse Drug Reactions, Birmingham, UK

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Asociacion Española Primera de Socorros Mutos, Montevideo, Uruguay

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University of Benin/Teaching Hospital, Benin City, Edo State, Nigeria

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Unidade de Farmacovigilância do Norte da Faculdade de Medicina da Universidade do Porto, Porto, Portugal

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Public Health School Pharmacovigilance Center, School of Medicine, Córdoba National University, Córdoba, Argentina

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RHB Meyboom, J Pokladnikova
The Uppsala Monitoring Centre, Uppsala, Sweden

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Centre Anti Poison et de Pharmacovigilance du Maroc, Rabat, Morocco

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INSERM, Bordeaux, France

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Université Victor Segalen, Bordeaux, France

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University of Ghana Medical School, Accra, Ghana

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University of Ghana Medical School, Accra, Ghana

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University of Ghana Medical School, Accra, Ghana

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Health Canada, Ottawa, Canada

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P Sriphiromya
Food and Drug Administration, Nonthaburi, Togo

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GM Moses, TM McGuire
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G Saarony, U Gerke
PAREXEL International, Lowell, MA, USA

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GLC Ferreira, L Wilton, SAW Shakir
Drug Safety Research Unit, Southampton, UK

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R Kasliwal, V Cornelius, L Wilton, SAW Shakir
Drug Safety Research Unit, Southampton, UK

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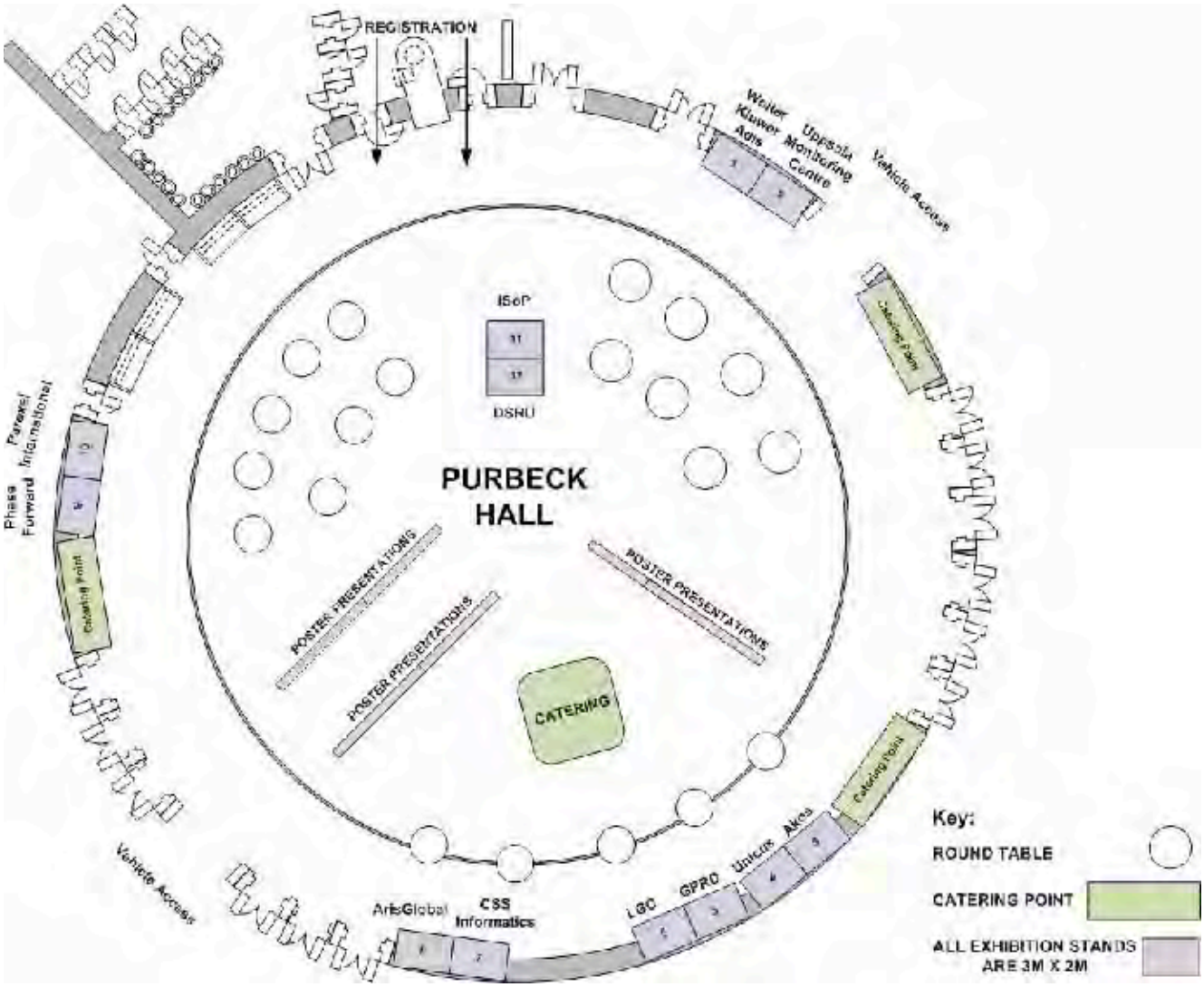

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The General Practice Research Database (GPRD) is the most used observational database for drug safety studies. A new Risk Management Tool, ExEtrac, will also be presented as will details of access to data from Europe and the USA.

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The Uppsala Monitoring Centre **Stand 2**

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The Uppsala Monitoring Centre (the UMC) is the WHO Collaborating Centre for International Drug Monitoring. An independent centre of scientific excellence with a global perspective, the UMC offers products and services derived from the WHO Adverse Drug Reaction database reported from WHO Programme member countries. The UMC provides resources for the WHO Programme, regulatory agencies, health professionals, researchers and the pharmaceutical industry.

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