ISoP 2022 | 21ST ANNUAL MEETING

Verona, Italy,
20–23 September 2022

International Society of Pharmacovigilance

21st Annual Meeting
A new Era of Pharmacovigilance: Challenges and Opportunities

Conference
Programme

isoponline.org
#ISoP2022Verona

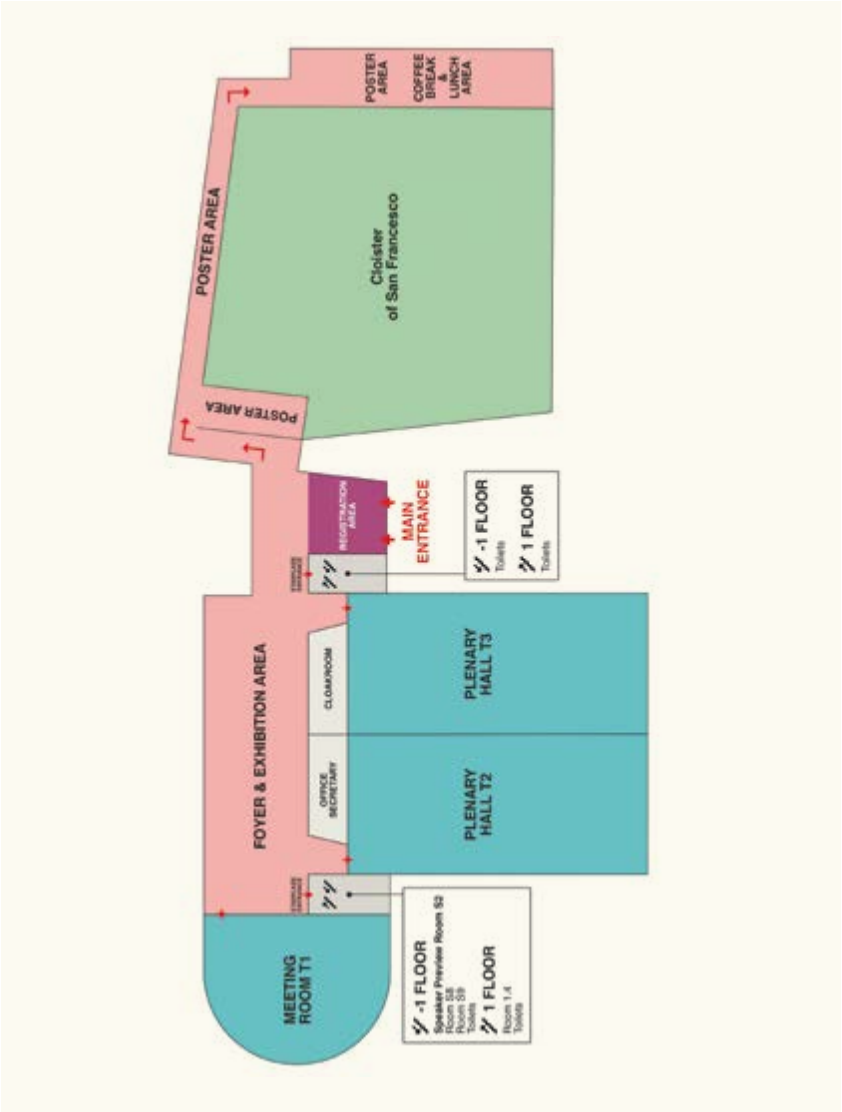
CON IL PATROCINIO DI

Comune di Verona

Contents

Venue Floor Plan	2
Verona Map	3
Welcome Message	4
About ISoP	5
Committees	6
General Information	7
Pre-Conference Programme	9
Conference Programme	12
Poster Listing	21
Flash Presentation listing	51
List of Chairpersons and Speakers	54
Networking	56
Verona	57
Companies Profiles	59
Exhibition	65
Supporters	66

Venue Floor Plan



Verona Map

Piazza dei Signori
Piazza delle Erbe - Verona
Giardino Giusti
Casa di Giulietta
Arena di Verona
ISoP 2022
21st ANNUAL MEETING
University of Verona

Welcome Message

Dear Colleagues,

On behalf of the ISoP Executive Committee and the Local Organizing Committee, we are delighted to welcome you to the 21st Annual Meeting of the International Society of Pharmacovigilance (ISoP 2022), "A New Era of Pharmacovigilance: Challenges and Opportunities" in Verona, Italy from 20th to 23rd September 2022.

Home to a legacy of great traditions, from opera to food and wine, Verona is one of the most visited cities in Italy. A UNESCO world heritage city and home of Romeo and Juliet, it is a place of history, culture, music, and architecture, waiting to be explored. Verona enjoys an easily reachable geographical location in North-East Italy; an inspiring landscape in which to discuss the importance of international pharmacovigilance to health professionals and patients, medicines regulatory agencies, scientific organizations and universities, state authorities worldwide and the pharmaceutical industry.

Several challenges have to be faced in the near future of pharmacovigilance. First of all, the COVID-19 pandemic has highlighted the direct relevance of pharmacovigilance and proper risk communication during a global healthcare emergency. Second, the development of advanced methodologies (including machine learning techniques) and the availability of large amounts of electronic healthcare data offer opportunities for optimizing drug benefit-risk profile evaluation in real-world settings. Finally, innovative therapeutics have become increasingly available in recent years, often upon accelerated pathway approval. In response to all this, pharmacovigilance must continue to evolve quickly and appropriately to protect patient safety around the world.

The ISoP 2022 Annual Meeting in Verona will be the perfect setting to discuss current challenges and future opportunities in the field of pharmacovigilance, exchanging ideas and experiences between international experts, engaging ISoP's special interest groups and many global participants with various areas of expertise.

Regardless of whether this is your first or fifteenth annual ISoP meeting, we know you will take away many positive learning experiences and also enjoy a very special time with friends and colleagues.

Welcome to Verona!

Mira Harrison-Woolrych
President of ISoP

Gianluca Trifirò
Chair of the Local Organising Committee

Angela Caro Rojas
Chair of the Scientific Committee

About ISoP

International Society of Pharmacovigilance

ISoP is a global professional, independent, not-for-profit society, open to anyone with an interest in the safe and effective use of medicinal products. ISoP aims to foster science, learning and research in pharmacovigilance in all countries. These objectives are met by providing:

- Collegial and convivial support among fellow pharmacovigilance professionals
- An open and impartial forum for sharing experience, knowledge, and solutions
- A platform for discussion and generation of new research and ideas
- Meetings, education, and affordable training
- Regional Chapters and Special Interest Groups
- Opportunities for networking in a friendly environment

ISoP Advisory Board

Executive Committee

President
Mira Harrison-Woolrych (New Zealand)

Vice President
Rebecca Chandler (Sweden)

Secretary General
Deirdre McCarthy (USA)

Treasurer
Jean-Christophe Delumeau (Czech Republic)

Board Members

Angela Caro Rojas (Colombia)
Jan Petracek (Czech Republic)
Mónica Tarapués (Ecuador)
Gianluca Trifirò (Italy)
Manal Younus (Iraq)
Li Zhang (P.R. China)

Annual Meetings (ESOP and ISoP)*

ESOP Annual Meetings

1993 Geneva, Switzerland
1994 Rouen, France
1995 Cambridge, England
1996 Lisbon, Portugal
1997 Berlin, Germany
1998 Budapest, Hungary
1999 Ankara, Turkey
2000 Verona, Italy

ISoP Annual Meetings

2001 Carthage-Tunis, Tunisia
2002 Amsterdam, The Netherlands
2003 Marrakech, Morocco
2004 Dublin, Ireland
2005 Manila, Philippines
2006 Liège, Belgium
2007 Bournemouth, UK
2008 Buenos Aires, Argentina
2009 Reims, France
2010 Accra, Ghana
2011 Istanbul, Turkey
2012 Cancun, Mexico
2013 Pisa, Italy
2014 Tianjin, China
2015 Prague, Czech Republic
2016 Agra, India
2017 Liverpool, UK
2018 Geneva, Switzerland
2019 Bogota, Colombia
2020 *Postponed*
2021 Muscat, Oman
2022 Verona, Italy
2023 Bali, Indonesia

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

Committees

Local Organising Committee

Chair

Gianluca Trifirò,
University of Verona (Italy)

Committee

Annalisa Capuano, University of Campania "L. Vanvitelli" (Italy)
Cristiano Chiamulera, University of Verona (Italy)
Salvatore Crisafulli, University of Verona (Italy)
Barbara De Bernardi, Pfizer (Italy)
Carmen Ferrajolo, Italian Drug Agency (Italy)
Ylenia Ingrasciotta, University of Verona (Italy)
Roberto Leone, University of Verona (Italy)
Giuseppe Lippi, University of Verona (Italy)
Anna Rosa Marra, Italian Drug Agency (Italy)
Pietro Minuz, University of Verona (Italy)
Ugo Moretti, University of Verona (Italy)
Giovanna Scroccaro, Pharmaceutical and Medical Device Department, Veneto Region (Italy)
Evelina Tacconelli, University of Verona (Italy)
Marco Tuccori, Academic Hospital of Pisa, Chair of ISoP Italian Chapter (Italy)

Scientific Programme Committee

Chair

Angela Caro Rojas,
Pontificia Universidad Javeriana (Colombia)

Co-Chair

Gianluca Trifirò,
University of Verona (Italy)

Committee

Andrew Bate, GlaxoSmithKline (UK)
Ghita Benabdallah, Centre Anti Poison et de Pharmacovigilance du Maroc (CAPM) (Morocco)
Gianmario Candore, Bayer (Germany)
Linda Härmark, Pharmacovigilance Centre Lareb (The Netherlands)
Deirdre McCarthy, Gates MRI (USA)
Antoine Pariente, University of Bordeaux (France)
Saad Shakir, Drug Safety Research Unit (UK)
Mónica Tarapués, Central University of Ecuador (Ecuador)

Organisers

General Information

Venue

Polo Zanotto – University of Verona
Viale dell'Università, 4
Verona, Italy

Accommodation

For help booking accommodation or if you have any queries about your hotel reservation, please visit the registration desk where one of the organisers will be able to assist you.

Cloakroom

A cloakroom is available for participants on the Ground floor next to the meeting room T3 (see floorplan).

Certificate of Attendance

A certificate of attendance will be provided for all attendees of the pre-conference training course and main conference and will be available for downloading on the registration portal once the online survey has been completed. A link to the survey will be emailed on the last day of the conference.

Emergency Procedures

In the event of an emergency of the Polo Zanotto building, please follow the instructions from the staff.

First Aid

In the event of an accident or an emergency, contact a member of the organization at the registration. Please be as accurate and as concise as possible with any information you are providing, especially the exact location of the emergency.

Internet Access

Every delegate will get a personal wi-fi login details at the registration desk.

Insurance

The conference organising committee or its agents will not be responsible for any medical expenses, loss or accidents incurred during the conference. Delegates are strongly advised to arrange their own personal insurance to cover medical and other expenses including accident or loss. Where a delegate has to cancel for medical reasons, the normal cancellation policy will apply.

Lost and Found

If you have misplaced any personal items or found an item to hand in, please visit the registration desk located on the ground floor.

Exhibition, Posters and Catering

The exhibition is taking place on the Ground Level, right in front of the main hall. Poster Area is in the Cloister of San Francesco. Refreshments will be served at the following times:

Date	Coffee break	Lunch	Coffee break
Wednesday 21 September	10:30–11:00	12:30–14:00	15:30–16:00
Thursday 22 September	10:10–10:40	12:00–13:00	14:30–15:00
Friday 23 September	10:30–11:00	13:00–14:00	

Mobile Phones

Delegates are kindly requested to keep their mobile phones on silent in all rooms where scientific and educational sessions are being held, as well as in and around the poster exhibition area.

Names Badge

A name badge will be provided on arrival to the conference upon presentation of the relevant registration documents. The name badge must always be worn and is to be visible both inside the meeting rooms and sessions, as well as at all events organised during the meeting, including the supporting social programme.

Registration Times

The registration desk will be open at the following times:

Tuesday 20 September (pre-conference courses)	8:30–17:00
Wednesday 21 September	8:00–17:30
Thursday 22 September	8:00–17:30
Friday 23 September	8:30–13:00

Smoking and Electric Cigarettes

Smoking is forbidden in all the indoor public areas, such as bars, restaurants, hotels, offices, shops, etc. except for the places with reserved smoking areas, provided with a suitable ventilation system.

Social Media

Follow @ISoPonline on twitter, LinkedIn, Instagram, and Facebook and get all the latest updates. We encourage you to tweet and post your highlights during the conference using the hashtag #ISoP2022Verona.

Share with ISoP your experience!

Take photos during the conference, when networking, or even enjoying time with friends and colleagues, and tag us at @ISoPonline on Facebook, Instagram, Twitter, and LinkedIn – we will repost all photos and make a collage with the best highlights of the Verona event!

Speaker Preview Room Times

The Speaker Preview room is located on the -1 floor, in Room S2, and is open at the following times:

Tuesday 20 September	8:30–17:00
Wednesday 21 September	8:00–17:30
Thursday 22 September	8:00–17:30
Friday 23 September	8:30–13:00

Useful Telephone Numbers

Italy country code is 0039. For international calls, dial 00 + national code + area code + personal number.

118: for sanitary emergencies or dangerous situations
112: Carabinieri (Italian military police)
113: Police
115: Fire department

Verona Tourism

Maps and tours information are available at the registration desk.

Networking

Please see page 56 for details of the official networking events.

Pre-Conference Programme

Tuesday 20 September 2022

Pre-Conference Course 1

Advanced signal detection

09:00–17:00, Room T3

The approach to signal generation, refinement, and confirmation has evolved over years, opening new frontiers of debate about the roles of different stakeholders in the process and the need for an implementation of regulatory frameworks, publication rules, and risk communication strategies. In 2021, the circumstances of the approval of COVID-19 vaccines were exceptional and provided an unprecedented challenge for signal detection that deserves to be studied in-depth. This one-day pre-conference course will illustrate the process of signal detection using a step-by-step approach, starting from basic elements and concluding with discussion on the most current challenges being faced.

Chairs: Marco Tuccori (University of Pisa, Italy) and Ugo Moretti (University of Verona, Italy)

Pre-Conference Course 2

Introduction to pharmacoepidemiology studies and their role in Pharmacovigilance

09:00–12:45, Room T2

The aim of this half-day course is to provide a basic understanding of the concepts and practice of pharmacoepidemiology. You will learn about the fundamentals of pharmacoepidemiology, its practical uses, and its limitations, as well as how pharmacoepidemiology and pharmacovigilance can be used together to inform medicines safety.

Chair: Rebecca Chandler (ISoP Vice-President, Coalition for Epidemic Preparedness Innovations, Sweden)

Co-Chairs: Gianmario Candore (Bayer, Germany) and Houda Sefiani (Moroccan Pharmacovigilance Centre, Rabat WHO Collaborating Centre, Morocco)

Pre-Conference Course 3

Regulatory Updates across the Continuum of Spontaneous Reporting to Risk Minimization

13:30–17:00, Room T2

This half-day course will address regulatory challenges and 'state-of-the-art' methodological approaches to current issues across the continuum of spontaneous reporting to risk minimization. With a multi-region focus, learn about how the QPPV role has evolved to deal with increasingly complex pharmacovigilance regulations; hear from EMA speakers about the EU's novel analytical methodologies in signal detection and risk assessment and methods for effectiveness evaluation of risk minimisation measures (RMMs); and learn about how Morocco is prioritizing multi-stakeholder involvement in risk management planning and implementation on a local level.

Chairs: Deirdre McCarthy (Gates MRI, USA) and Giampiero Mazzaglia (Milano Bicocca university, Italy)

Pre-Conference Course 1

Morning
Room T3

Advanced signal detection

Chairs: Marco Tuccori (University of Pisa, Italy) and Ugo Moretti (University of Verona, Italy)

08:30–09:00	**Registration** *Polo Zanotto Main Entrance*
09:00–10:00	**Fundamentals of signal detection for drugs and vaccines** *Eugene Van Puijenbroek (The Netherlands Pharmacovigilance Centre Lareb, Netherlands)*
10:00–10:30	**Open source PV databases as sources for signal detection: strengths and limitations** *Ugo Moretti (University of Verona, Italy)*
10:30–11:00	**Publishing signal detection analysis: quality criteria** *Francesco Salvo (University of Bordeaux, France)*
11:00–11:15	Coffee break
11:15–12:00	**State of the art in signal detection – a regulatory perspective** *Phil Tregunno (Medicines and Healthcare products Regulatory Agency – MHRA, UK)*
12:00–12:45	**Patients reporting and signal detection: strengths and limitations** *Linda Härmark (The Netherlands Pharmacovigilance Centre Lareb, Netherlands)*
12:45–14:00	Lunch break

Pre-Conference Course 2

Morning
Room T2

Introduction to pharmacoepidemiology studies and their role in Pharmacovigilance

Chair: Rebecca Chandler (ISoP Vice-President, Coalition for Epidemic Preparedness Innovations, Sweden)

Co-Chairs: Gianmario Candore (Bayer, Germany) and Houda Sefiani (Moroccan Pharmacovigilance Centre, Rabat WHO Collaborating Centre, Morocco)

09:00–09:10	**Welcome and Introduction**
09:10–09:40	**Overview of study designs in pharmacoepidemiology** *Ylenia Ingrasciotta (University of Verona, Italy)*
09:40–10:10	**Essential statistics for pharmacoepidemiology** *Edward Burn (University of Oxford, UK)*
10:10–10:30	**Q&A**
10:30–10:45	Coffee break
10:45–11:15	**Sources of error in pharmacoepidemiology** *Ersilia Lucenteforte (University of Pisa, Italy)*
11:15–11:45	**Overview of large health care databases** *Edward Burn (University of Oxford, UK)*
11:45–12:15	**Pharmacoepidemiology and its role within pharmacovigilance** *Samantha Lane, Drug Safety Research Unit (DSRU), UK*
13:00–14:00	Lunch / End of Course 2

Pre-Conference Course 1 **Advanced signal detection** *Chairs: Marco Tuccori (University of Pisa, Italy) and Ugo Moretti (University of Verona, Italy)*	Afternoon Room T3	Pre-Conference Course 3 **Regulatory Updates across the Continuum of Spontaneous Reporting to Risk Minimization** *Chairs: Deirdre McCarthy (ISoP Executive member, Gates MRI, USA) and Giampiero Mazzaglia (Milano Bicocca university, Italy)*	Afternoon Room T2
14:00–14:45	**Causality and chance in recent pharmacovigilance signals of COVID-19 vaccines: what evidence for public health decisions?** *Bernard Bégaud (University of Bordeaux, France and chair of the EPIPHARE scientific committee)*	13:30–14:10	**QPPV Role: Insight and trends** *Barbara De Bernardi (Pfizer, Italy)*
14:45–15:30	**Signal detection using Pharma industry databases** *Maria Maddalena Lino (Pfizer, Italy)*	14:10–14:50	**Novel analytical methodologies in signal management and risk assessment** *Cosimo Zaccaria (European Medicines Agency – EMA, Netherlands) (Virtual presentation)*
15:30–15:45	Coffee break	14:50–15:10	Coffee break
15:45–16:15	**Signal detection for oncologic drugs** *Emanuel Raschi (University of Bologna, Italy)*	15:10–15:50	**Methods for effectiveness evaluation of risk minimisation measures (RMMs)** *Tomas Goedecke (European Medicines Agency – EMA, Netherlands) (Virtual presentation)*
16:15–17:00	**Managing signal detection during crisis in Regulatory Agencies and Pharmacovigilance Regional Centers** *Pasquale Marchione (Agenzia Italiana del Farmaco (AIFA), Italy)*	15:50–16:30	**Importance of multi-stakeholder involvement in risk management planning and implementation** *Ghita Benabdallah (Centre Anti Poison et de Pharmacovigilance du Maroc (CAPM), Morocco)*
		16:30–17:00	**Panel discussion and wrap-up**

19:30–21:00	Welcome Reception – University of Verona, Cloister of San Francesco

Conference Programme

Wednesday 21 September 2022

08:00	08:30	**Registration**	Polo Zanotto Main Entrance
08:30	09:00	**1A0** **Opening session** *Mira Harrison-Woolrych (President of ISoP, New Zealand)* *Angela Caro Rojas (Scientific Chair ISoP 2022, Pontificia Universidad Javeriana, Colombia)* *Gianluca Trifirò (Local Chair ISoP 2022, University of Verona, Italy)* *Giorgio Racagni (President of the Italian Society of Pharmacology, Italy)* *Pierfrancesco Nocini (University of Verona, Italy)*	Room T2/T3
Plenary Session 1A **Lessons learned from COVID-19 pandemic** *Chairs: Gianluca Trifirò (ISoP Board member, University of Verona, Italy) and Achille P. Caputi (Emeritus Professor of the University of Messina, Italy)*			09:00–10:30 Room T2/T3
09:00	09:30	**1A1:** **How post marketing drug/vaccine surveillance has been dealt with in Europe** *Bernard Bégaud (the University of Bordeaux, France, and chair of the EPIPHARE scientific committee)*	
09:30	10:00	**1A2:** **COVID-19 pandemic: the experience of the Italian Drug Agency** *Patrizia Popoli (President of Scientific Technical Committee of the Italian Drug Agency, Italy)*	
10:00	10:30	**Q&A / Panel discussion**	
10:30	11:00	Coffee Break & Poster viewing	
Plenary Session 1B **Traditional and innovative approaches for post marketing surveillance of COVID-19 vaccines** *Chairs: Rebecca Chandler (ISoP Vice-President, Coalition for Epidemic Preparedness Innovations, Sweden), Evelina Tacconelli (University of Verona, Italy)*			11:00–12:30 Room T2/T3
11:00	11:30	**1B1:** **A large distributed European database network for rapid COVID-19 vaccine surveillance** *Miriam Sturkenboom (University of Utrecht, Netherlands)*	
11:30	12:00	**1B2:** **Advancing the Science of Vaccine Safety: Introducing the International Network of Special Immunisation Services** *Karina Top (Canadian Center for Vaccinology Dalhousie University, IWK Health Centre, Canada)*	
12:00	12:30	**Q&A / Panel discussion**	
12:30	14:00	Lunch Break & Flash Poster Presentations	

Parallel session 1C		14:00–15:30 Room T2	Parallel session 1D		14:00–15:30 Room T3
PV of Biotechnology drugs: from Advanced Therapy medicine products to biosimilars *Chairs: Qun-Ying Yue (Chair of the Pharmacogenomics SIG, Uppsala Monitoring Centre, Sweden) and Annalisa Capuano (PRAC Member – University of Campania Luigi Vanvitelli, Italy)*			**Strategies to prevent Medication errors: new approaches** *Chairs: Brian Edwards (Chair of the Medication Error SIG, Husoteria Ltd, UK) and Angela Caro Rojas (Universidad Javeriana, Colombia)*		
14:00	14:30	**1C1:** **Interchangeability between originators and biosimilars: Clinical and methodological considerations** *Thijs Giezen (EMA Biosimilar working party, Netherlands)*	14:00	14:30	**1D1:** **ECAMET Alliance: Patient Safety Project experience** *Alix Bullman (ECAMET Alliance, Belgium)*
14:30	15:00	**1C2:** **Large scale research network for biologic post marketing surveillance in Italy** *Ylenia Ingrasciotta (University of Verona, Italy)*	14:30	15:00	**1D2:** **Interaction between the Institute for Safe Medication Practices (ISMP) and ISoP** *Rita Jew (Institute for Safe Medication Practices (ISMP), USA)*
15:00	15:10	**1C3** (Abstract Presentation) **O-001** **Effectiveness and Tolerance of Biotherapy in the Treatment of Chronic Inflammatory Diseases and Rheumatism in children** *Rania Mourchid (Mohammed V University, Morocco)*	15:00	15:10	**1D3** (Abstract Presentation) **O-003** **Potentially Inappropriate Medication in Older Adult's Adverse Drug Reactions Spontaneous Reports** *Fátima Roque (Research Unit for Inland Development, Polytechnic of Guarda (UDI-IPG), Portugal)*
15:10	15:20	**1C4** (Abstract Presentation) **O-002** **European Pharmacovigilance Analysis of Cardiac Arrhythmias Events with Immune Checkpoint Inhibitors** *Annamaria Mascolo (University of Campania Luigi Vanvitelli, Italy)*	15:10	15:20	**1D4** (Abstract Presentation) **O-004** **Analysis of Medication Errors in Children and Adolescents Reported to HALMED** *Morana Pavičić (HALMED, Croatia)*
15:20	15:30	**Q&A**	15:20	15:30	**Q&A**
15:30	16:00	Coffee Break & Poster viewing			

Parallel session 1E

16:00–17:30
Room T2

How to communicate risk in crisis?

Chairs: Priya Bahri (Chair of the Risk Communication SIG, Netherlands) and Ulrich Hagemann (ISoP, Germany)

16:00	16:10	**Introduction with examples of various crisis scenarios in pharmacovigilance** *Priya Bahri (Chair of the Risk Communication SIG, Netherlands)*
16:10	16:30	**1E1:** **How do regulatory decisions relate to public health decisions? Communicating about Dengvaxia in the Philippines between science and emotions** *Kenneth Hartigan-Go (Asian Institute of Management, Philippines)*
16:30	17:00	**1E2:** **How do local contexts relate to public health communication? – Communicating about COVID-19 vaccines in Italy and the Netherlands** *Marco Tuccori (University Hospital of Pisa, Italy) and Agnes Kant (The Netherlands Pharmacovigilance Centre Lareb)*
17:00	17:10	**1E3** (Abstract Presentation) **O-005** **Animated Explainer Videos as an Effective Way to Communicate Statistical Methods in Pharmacovigilance** *Eva-Lisa Meldau (Uppsala Monitoring Centre, Sweden)*

Parallel session 1F

16:00–17:30
Room T3

Medicines for Women: Global Challenges and Initiatives

Chairs: Mira Harrison-Woolrych (President of ISoP, Chair of the Women's Medicines SIG, New Zealand) and Brian Edwards (Chair of the Medication Error SIG, Husoteria Ltd, UK)

16:00	16:10	**Welcome and Introduction to the session and to the ISoP Women's Medicines SIG** *Mira Harrison-Woolrych (President of ISoP, Chair of the Women's Medicines SIG, New Zealand)*
16:10	16:40	**1F1:** **Pregnant women in clinical trials: ethical, scientific and safety aspects** *Katarina Ilic (Takeda, USA)*
16:40	16:50	**1F2** (Abstract Presentation) **O-007** **Impact of the 2018 Pregnancy Prevention Program on the Use of Oral Retinoids in Childbearing Age Females in Europe** *Carlos Durán (University Medical Center Utrecht, Netherlands)*
16:50	17:20	**1F3:** **COVID-19 vaccines and menstrual disorders** *Birgitta Grundmark (Norwegian Medicines Agency, Norway)*

17:10	17:20	**1E4** (Abstract Presentation) **O-006** **Visual Communication of Safety Data in Ongoing Studies: The Adaptive Benefit-Risk Assessment tool for Clinical Trials (ABRA-CTV)** *Christopher T. Bond (Bristol Myers Squibb, USA)*	17:20	17:30	**Discussion**
17:20	17:30	**Discussion moderated by Co-Chair Ulrich Hagemann and Wrap-up** *Chair: Priya Bahri (Chair of the Risk Communication SIG, Netherlands)*			
18:00	19:30	**Student Meet and Greet**			Cloister of San Francesco
18:00	19:00	**ISoP Special Interest Groups (SIGs) Meetings**			
		Medication errors			Room 1.4
		Risk Communication			Room S8
		Vaccines			Room S9
		EcoPV			Room T1

Thursday 22 September 2022

Plenary Session 2A

08:30–10:10
Room T2/T3

Big Data for PV – are we delivering on the promises?

Chairs: Gianmario Candore (Bayer, Germany) and Deirdre McCarthy (Gates MRI, USA)

08:30	09:00	**2A1:** **Big data vs. smart data for post-marketing surveillance of drugs/vaccines** *Gianluca Trifirò (University of Verona, Italy)*
09:00	09:30	**2A2:** **How big data support post marketing surveillance in USA: the Sentinel initiative** *Darren Toh (Harvard Medical School and Harvard Pilgrim Health Care Institute, USA)*
09:30	10:00	**2A3:** **Data Analysis and Real World Interrogation Network (DARWIN EU®)** *Andrej Segec (European Medicines Agency – EMA, Netherlands)*
10:00	10:10	**Q&A**
10:10	10:40	Coffee Break & Poster viewing

Parallel session 2B

10:40–12:00
Room T2/T3

AI/Machine learning for drug safety signal detection in PV: where do we stand?

Chairs: Antoine Pariente (University of Bordeaux, France) and Rosa Gini (Agenzia regionale di sanità della Toscana, Italy)

10:40	11:05	**2B1:** **Current status of machine learning across the pharmacovigilance lifecycle: A systematic review** *Andrew Bate (GSK, UK)*
11:05	11:30	**2B2:** **AI/Machine learning for drug safety signal detection in PV: where do we stand? The perspective of a public pharmacovigilance center** *Antoine Pariente (University of Bordeaux, France)*

Parallel session 2C

10:40–12:00
Room T1

Interaction between Pharmacovigilance and Clinical Practice

Chairs: Mónica Tarapués (Central University of Ecuador) and Birgitta Grundmark (Norwegian Medicines Agency, Norway)

10:40	11:05	**2C1:** **The potential contributions of pharmacovigilance to healthy medical prescribing** *Joan Ramon Laporte (Autonomous University of Barcelona, Spain)*
11:05	11:30	**2C2:** **Do we really understand what happened? – Reflections on case assessment** *Eugene Van Puijenbroek (The Netherlands Pharmacovigilance Centre Lareb)*

11:30	11:40	**2B3** (Abstract Presentation) **O-008** **Performance of an Artificial Intelligence System Tool for the Detection of ADRs from Patients' Reports During the Covid-19 Vaccination Campaign** *Guillaume Louis Martin (Synapse Medicine, France)*	11:30	11:40	**2C3** (Abstract Presentation) **O-010** **Search for Additional Cases in Electronic Health Records (EHRs) to Strengthen Potential Signals from Spontaneous Reporting** *Agnes Kant (The Netherlands Pharmacovigilance Centre Lareb)*
11:40	11:50	**2B4** (Abstract Presentation) **O-009** **Investigating Hidden Networks in Spontaneous Reporting Systems** *Michele Fusaroli (University of Bologna, Italy)*	11:40	11:50	**2C4** (Abstract Presentation) **O-011** **Do Monitored Dosage Systems Increase Risk for Patients' Safe Discharge from Hospital? A Retrospective Analysis of Pharmacists' Interventions** *Leeanne Stewart (University of Birmingham, UK)*
11:50	12:00	**Q&A**			**Q&A**
12:00	13:00	Lunch Break & Flash Poster Presentations			

2D: ISoP General Assembly

13:00–14:30
Room T2/T3

Committed to safer use of medicines worldwide

Chairs: *Mira Harrison-Woolrych (President of ISoP, New Zealand) and Deirdre McCarthy (Secretary General, Gates MRI, USA)*

Agenda

1. Welcome, introductions, housekeeping
2. Tribute to Sten Olsson
3. Approval of Agenda
4. Approval of Minutes GA 2021
5. President's overview of ISoP activities
6. Report from the new ISoP Scientific Board
7. By-law updates
8. Membership Report
9. Financial Report
10. Report from Chapters
11. Report on SIGs
12. Fellowship and Honorary Member Awards 2022
13. Advisory Board election results
14. Looking forward
15. AoB and Q&A

14:30	15:00	Coffee Break & Poster viewing

2E: Global Pharmacovigilance: Hot topics

15:00–17:30
Room T2/T3

Chairs: *Mónica Tarapués (Central University of Ecuador) and Angela Caro Rojas (Pontificia Universidad Javeriana, Colombia)*

15:00	15:45	**2E1:** **SIGs & Chapters highlights**
15:45	17:30	**2E2:** **Abstract presentations**

	2E2.1 – O-012: **Signal of Hypertension Associated with COVID-19 Vaccination: VigiBase® Data and Evidence from Real World** *Marco Bonaso (University of Pisa, Italy)*
	2E2.2 - O-013: **Risk of Glaucoma Diagnosis in Patients Who Received Intravitreal Injections of VEGF Inhibitors: a Cohort Study** *Andrea Spini (Azienda Ospedaliera Universitaria Senese, Italy)*
	2E2.3 - O-014: **A Revised Time-to-onset Signal Detection algorithm in the Context of Mass Vaccination** *Lionel Van Holle (OpenSourcePV, Belgium)*
	2E2.4 - O-015: **Adverse Events to COVID-19 Vaccines and Policy Considerations that Inform the Funding of Safety Surveillance in Low- and Middle-Income Countries** *Comfort Ogar (WHO, Nigeria)* *(Virtual presentation)*
	2E2.5 - O-016: **Factors Associated with Hospital Death in Patients with Adverse Drug Events in Brazil, from 2011 to 2020** *Paulo Sérgio Dourado Arrais (Universidade Federal do Ceará, Brazil)*
	2E2.6 - O-017: **Effectiveness and Safety of Maintenance Immunosuppressive Drug Therapies in Kidney Transplant: A Real-World Retrospective Cohort Study in Italy** *Marco Finocchietti (ASL Roma 1, Italy)*
	2E2.7 - O-018: **Are COVID-19 Vaccines Safe in Children? Comparative Analysis of European Web-Based Prospective Monitoring vs. Pivotal Trials** *Nicoletta Luxi (University of Verona, Italy)*
	2E2.8 - O-019: **The Risk of Oligospermia with Tyrosine Kinase Inhibitors: A Disproportionality Analysis from Vigibase and AERS Databases** *Luis Velez-Nandayapa (University of Basel / Novartis, Switzerland)*
	2E2.9 - O-020: **Perception and Utilization of Skin Lightening Agents Among Females of Asmara City: A Lesson for Strengthening Cosmetovigilance** *Mulugeta Russom (Ministry of Health, Eritrea)*
	2E2.10 - O-021: **Drug-related Hospital Admissions in Paediatrics – Is There Potential for Prevention?** *Irmgard Toni (Universitätsklinikum Erlangen, Germany)*
19:30 22:00	**Conference Dinner – Giardino e Palazzo dei Conti Giusti**

Friday 23 September 2022

Parallel session 3A	09:00–10:30 Room T1		Parallel session 3B	09:00–10:30 Room T2/T3	
Training and Professional framework of PV *Chairs: Linda Härmark (The Netherlands Pharmacovigilance Centre Lareb) and Jan Petracek (Institute of Pharmacovigilance, Czech Republic)*			**Herbal and Traditional Medicines PV Advances** *Chairs: Souad Skalli (Chair of ISoP Herbal and Traditional Medicines SIG, Mohammed V University, Morocco) and Francesca Menniti Ippolito (Italian National Health Institute and Chair of herbal remedies monitoring in Italy)*		
09:00	09:20	**3A1:** **PV specialist professional development** *Jan Petracek (Institute of Pharmacovigilance, Czech Republic)*	09:00	09:30	**3B1:** **Restructuring of the University Curriculum by Introducing the Teaching of Phytovigilance: Importance or even Urgency** *Souad Skalli (Chair of ISoP Herbal and Traditional Medicines SIG, Mohammed V University, Morocco)*
09:20	09:40	**3A2:** **The Eu2P experience** *Francesco Salvo (University of Bordeaux, France)*	09:30	10:00	**3B2:** **Introductory remarks/ Food supplements vigilance systems in a public health perspective: the European context** *Francesca Menniti Ippolito (Italian National Health Institute and chair of Herbal Remedies Monitoring, Italy)*
09:40	10:00	**3A3:** **Pharmacovigilance training for health care professionals** *Linda Härmark (The Netherlands Pharmacovigilance Centre Lareb)*			
10:00	10:10	**3A4** (Abstract Presentation) **O-022** **Development and Evaluation of a Blended Pharmacovigilance e-Learning Course in Africa** *Lara Magro (University of Verona, Italy)*	10:00	10:10	**3B3** (Abstract Presentation) **O-024** **Recommended Best Practices of Pharmacovigilance of Herbal Medicinal Products** *Florence Van Hunsel (The Netherlands Pharmacovigilance Centre Lareb, Netherlands)*
10:10	10:20	**3A5** (Abstract Presentation) **O-023** **Teaching Pharmacovigilance to French Medical Students during the Covid-19 Pandemic: Interest of Distance Learning Clinical Reasoning Sessions** *François Montastruc (Toulouse University Hospital, France)*	10:10	10:20	**3B4** (Abstract Presentation) **O-025** **Safety of Medical Cannabis: A Descriptive Study using the Quebec Cannabis Registry** *Yola Moride (YolaRX Consultants, Canada)*
10:20	10:30	**Q&A**	10:20	10:30	**Q&A**
10:30	11:00	Coffee Break			

3C: Lecture in memory of Prof. Giampaolo Velo

11:00–11:50
Room T2/T3

Chair: Roberto Leone (University of Verona, Italy)

11:00	11:05	**3C1: Introduction** *Roberto Leone (University of Verona, Italy)*
11:05	11:20	**3C2: Remembering Giampaolo Velo** *Ralph Edwards (former Director of the Uppsala Monitoring Centre, Sweden)*
11:20	11:50	**3C3: EcoPharmacovigilance: challenges and opportunities** *John Wilkinson (University of York, UK)*

3D: Bengt Erik Wiholm Lecture

11:50–12:25
Room T2/T3

Chair: Mira Harrison-Woolrych (President of ISoP, New Zealand)

11:50	11:55	**3D1: Introduction** *Mira Harrison-Woolrych (President of ISoP, New Zealand)*
11:55	12:25	**3D2: Pharmacovigilance: where we are, where we came from and where we are going** *Saad Shakir (Drug Safety Research Unit, UK)*

3E: Closing Ceremony

12:25–13:00
Room T2/T3

Chairs: Mira Harrison-Woolrych (President of ISoP, New Zealand)
Angela Caro Rojas (Scientific Chair ISoP 2022, Pontificia Universidad Javeriana, Colombia)
Gianluca Trifirò (Local Chair ISoP 2022, University of Verona, Italy)

12:25	12:35	**3E1: Poster Prize Awards** **Poster Prize Committee:** *Ghita Benabdallah (Chair) (Centre Anti Poison et de Pharmacovigilance du Maroc (CAPM), Morocco), Helaine Carneiro Capucho (Brazilian Health Regulatory Agency – ANVISA, Brazil), Ylenia Ingrasciotta (University of Verona, Italy)*
12:35	12:45	**3E2: Host presentation for ISoP 2023**
12:45	13:00	**3E3: Final remarks and closure**
13:00	14:00	Light Lunch

Poster Listing

341 posters have been successfully accepted for this year's 21st ISoP Annual Meeting. Posters will be displayed in the Cloister of San Francesco area with half of the posters being displayed on Wednesday and half on Thursday.

Poster judging will take place during the conference and the four best posters will be awarded during the poster prize ceremony on Friday, 23 September, at 12:20.

Presenting authors are kindly requested to be present throughout the official poster viewing times, but due to the large number of posters, the Poster Committee will not only view the posters during the official sessions but during the conference on Wednesday and Thursday.

Official poster session times

Date	Time	
Wednesday, 21 September	10:30–11:00	15:30–16:00
Thursday, 22 September	10:10–10:40	14:30–15:00

Official poster flash session times

Date	Time	
Wednesday, 21 September	12:50–14:00	
Thursday, 22 September	12:20–13:00	

Assistance for poster mounting / dismantling will be available at the Poster desk located in the poster area.

Poster No. / Paper Title / **Presenter**

SESSION 1 POSTER PRESENTATION WEDNESDAY 21 SEPTEMBER

Artificial Intelligence, Machine learning, and big data

P001 Pharmacovigilance and Drug Safety Simulation Game: Innovative Approach for Training and Capacity building
Sefiani Houda, Moroccan Pharmacovigilance Centre, Rabat WHO Collaborating Centre, Morocco

P002 Embedding Digital Health, AI/ML and RWD in Managing Safety Risks and Enhancing Pharmacovigilance
Ghosh Rajesh, Genentech/Roche, USA

P003 Integration and Modeling of Translational Safety Data for Post-marketing Surveillance
Mestres Jordi, Chemotargets SL, Spain

P004 Online Interest in Cannabis and Psychedelics in Peri-pandemic Europe for Robust Pharmacovigilance
Al-Imam Ahmed, Poznan University of Medical Sciences, Poland

P005 Challenges of Local Medical Literature Monitoring and Possible Automation
Horilyk Artem, Pharmaceutical Education and Research Center (NPO PHARMA-ER), Ukraine

P006 Hyperacute Multisystem Toxicities with Immune Checkpoint Inhibitors in the FDA Adverse Event Reporting System: The Immune-Adversome
Raschi Emanuel, Alma Mater Studiorum – University of Bologna, Italy

P007 Temporal Evolution of Disproportionality Parameters: Study of the Case of Opioids in Relation to QTc Interval Prolongation
Keller Guillermo Alberto, Administración Nacional de Laboratorios e Institutos de Salud (ANLIS Malbran), Argentina

P008 Identifying Medications Underlying Communication Atypicalities: A Pharmacosurveillance Study Within the FDA Adverse Event Reporting System
Fusaroli Michele, University of Bologna, Italy

P009 Competitive Intelligence in Pharmacovigilance – A Case Study on Two Covid-19 Vaccines
Van Holle Lionel, OpenSourcePV, Belgium

P010 A Method for Identification of Renal Disease in Unstructured Clinical Narratives
Davies Heather, University of Liverpool, United Kingdom

P011 Automated PV: What Are We Waiting for?
Markey Jen, Insife, United Kingdom

P012 Automated De-identification of Case Narratives Using Deep Neural Networks for the UK Yellow Card System
Meldau Eva-Lisa, Uppsala Monitoring Centre, Sweden

Medication errors prevention

P013 Prescription Error: A Case of Metronidazole-induced Pancreatitis
El Aidli Sihem, University of Tunis El Manar Faculty of Medecine of Tunis -UR17ES12, Tunisia

P014 IoT and the Future of Signal Reporting, Medication Management, Clinical Research and Drug Safety with New Tools and Process
Nurse Lloyd, Patient Advocate, Guyana

P015 Litigation Following Adverse Drug Reactions: Impact of Regulator Oversight – A Case Scenario of a Ceftriaxone Medication Error
Byomire – Ndagije Helen Byomire, National Drug Authority, Uganda

P017 Clinical Impact of Pharmacotherapeutic Follow-up and Pharmaceutical Interventions in a Reference Hospital in Mexico City
Maza Jose Antonio, Instituto Nacional de Cardiología Ignacio Chávez, Mexico

P018 Management of the Anticholinergic Burden in a Nursing Home in Sardinia
Sanogo Seydou, ARES – Sardegna, Italy

P019 Measuring the Effectiveness of Electronic Prescription Systems in Reducing Medication Errors in Hospital Setting in Egypt
Rostom Hadir, ISoP Egypt Chapter- MSA University, Egypt

P020 Paracetamol, a New Awareness on an Old Drug: A Survey Report on its Clinical Use in a Cancer Institute
Calabro Concetta, Cancer Institute of Bari, Italy

P021 Assessment of the Quality of MedDRA Coding in a Sample of COVID-19 Vaccine Medication Error Data
D'souza Joan, Institute of Pharmacovigilance, Switzerland

P022 Intoxications in a Pediatric Population: A Regional Retrospective Analysis
Baiardi Giammarco, University of Genoa, Italy

P023	**Identifying Adverse Drug Reactions from Free-text Dutch EHR in Hospitalized Patients with the Development of an Algorithm (IADRESS)** Van De Burgt Britt, Catharina Hospital Eindhoven, Netherlands
P024	**Are Monitored Dosage Systems Causing Drug Related Problems? A Retrospective Analysis of Hospital Admissions** Stewart Leeanne, University of Birmingham, United Kingdom
P027	**Clinical Pharmacist Interventions in Critically Ill Patients with COVID-19** Hida Amina, Faculty of Medicine and Pharmacy of Rabat, Mohamed V Souissi University, Morocco
P028	**A Survey of Medication Errors Reported Due to Look-Alike Antiretroviral Therapy amongst Adult Clients at Mbagathi Hospital in Nairobi, Kenya** Wambura Catherine, Mbagathi Hospital, Kenya
P029	**Acute Liver Failure Following Therapeutic Doses of Paracetamol in Patients with Neuromuscular Diseases: A Preventable Medication Error** James Henry, Christian Medical College & Hospital, India
P030	**Children Voluntary Intoxications: Cases of Attempted Suicide** Mousannif Soumaya, Faculty of Medicine and Pharmacy of Rabat, Morocco
P031	**Is Preventability a Good Criterion for Medication Errors? A Proposal to Assess Continuous versus Binary Faultiness, Seriousness, Contribution to ADRs** Beckmann Juergen, Former head of the PV division of the German drug regulatory authority BfArM, Germany
P032	**COVID-19 Vaccination Errors During Tunisian Vaccination Campaign Collected from March 13, 2021 To September 29, 2021** El Aidli Sihem, University of Tunis El Manar Faculty of Medecine of Tunis -UR17ES12, Tunisia
P034	**Pre-Registration Evaluation of Proposed Invented Names for Human Medicinal Products: Saudi Food and Drug Authority Experience** Al Draihm Abdulaziz, Saudi Food and Drug Authority, Saudi Arabia
P035	**Overview of Paediatric Opioid Overdose Cases in France** Habib Hanawy Dina, Agence Nationale de Sécurité du Médicament et des Produits de Santé, France
P036	**Types and Frequency of Errors in the Preparation and Administration of Drugs in Pediatric Inpatient** Mousannif Soumaya, Faculty of Medicine and Pharmacy of Rabat, Morocco
P038	**Need of Drugs and Supplements Recognition in Oncological Patients: Role of the Clinical Pharmacologist** Stefanelli Berenice, University of Salerno, Italy

Pharmacovigilance of biologics originator and biosimilar

P040 The Risk of Acute Kidney Injury in Bladder Cancer Patients Who Have Undergone Radical Cystectomy
Pan Xianying, Bristol Myers Squibb, USA

P041 Safety Assessment of Biologics for Immune-Mediated Inflammatory Diseases Using Italian VALORE Healthcare Database Network and National Spontaneous Reporting System
Benoni Roberto, University of Verona, Italy

P042 An Overview of the Pharmacovigilance System in Ghana
Onasanya Seun, University of KwaZulu-Natal, Westville Campus, South Africa

P043 An Overview of the Pharmacovigilance System in Nigeria
Onasanya Seun, University of KwaZulu-Natal, Westville Campus, South Africa

P044 Adverse Drug Effects Related to Biotherapy Used in the Treatment of Chronic Inflammatory Rheumatism at El Ayachi-Sale Hospital, Morocco
Lakhmiri Rim, Faculty of Medicine and Pharmacy,Mohammed V University Rabat, Morocco

P046 Safety Profile of PCSK9 Inhibitors in Clinical Practice: An Italian Prospective Pharmacovigilance Study
De Sarro Giovambattista, Seoul National University Hospital, Republic of Korea

P047 Regorafenib-Related Myocardial Injury in Patient with HepatoCellular Carcinoma (HCC) Post Orthotopic Liver Transplant (OLT): Prevention and Management
Pascale Giulia, University Magna Græcia of Catanzaro, Italy

P048 Meeting the Need: A Training Course for Data Safety Monitoring Board (DSMB) Members in LMIC
Sturkenboom Miriam, ASST GOM Niguarda, Italy

P049 Biologic Drugs: Pharmacovigilance Study Detecting Safety Profile and Therapy Effectiveness in Psoriasis and Psoriatic Arthritis
Pezzuto Benedetta, ASL Brindisi

P050 Biological Medicines in Accidents with Poisonous Animals: Integrating Data from Various Sources
Keller Guillermo Alberto, UMC Utrecht, Netherlands

P051 Use of Biological Drugs for Psoriasis: A Drug-utilization Study Using Tuscan Administrative Databanks
Giometto Sabrina, Administración Nacional de Laboratorios e Institutos de Salud (ANLIS Malbran), Argentina

P052 **Local Experience on Adalimumab and Etanercept Biosimilar Drugs: Safety and Efficacy Confirmation Encourages Rheumatologist Biosimilar Prescription**
Babaglioni Giorgia, University of Pisa, Italy

P053 **Clinicians' and Patients' Involvement in Reporting Adverse Drug Reactions and Adherence to Treatment of Biological Drugs in Rheumatology, Dermatology, Gastroenterology**
Ricciardelli Rita, ASST Spedali Civili Brescia, Italy

P054 **A Rare Case of Polydactyly in a Newborn from Mother Affected by Multiple Sclerosis**
Galuppi Chiara, Regional Pharmacovigilance Centre of Emilia-Romagna, Italy

P056 **Safety of Biologic Therapy for Crohn's Disease: An Active Pharmacovigilance Study**
Ruffolo Livia, ASST Spedali Civili of Brescia, Italy

P057 **Safety of Biological Drugs in Naïve Patients in Dermatological Field: Real Life Data from an Active Pharmacovigilance Project in Calabria Region**
Verduci Chiara, University of Catanzaro, Operative Unit of ClinicalPharmacology, Mater Domini University Hospital, Italy

P058 **Venetoclax and Tumor Lysis Syndrome (TLS): Data Mining of the FDA Adverse Event Reporting System (FAERS) Database**
Pascale Giulia, University of Catanzaro, Operative Unit of Clinical Pharmacology, Mater Domini U, Italy

P060 **Secondary Depression Associated to TNF-α Inhibitors**
Jabri Fatma Ezahra, ASST GOM Niguarda, Italy

P061 **Safety Profile of Dupilumab Approved for Chronic Rhinosinusitis with Nasal Polyposis: Analysis from the European Spontaneous Adverse Event Reporting System**
Barbieri Maria Antonietta, University of Tunis el Manar – Faculty of Medicine of Tunis: research unit UR17ES12, Tunisia

P062 **Safety Profile of Tyrosine Kinase Inhibitors Approved for Gastrointestinal Stromal Tumors: Analysis from the European Spontaneous Adverse Event Reporting System**
Barbieri Maria Antonietta, University of Messina, Italy

P063 **Safety Profile of Tyrosine Kinase Inhibitors Used in Non-Small-Cell Lung Cancer: An Analysis from The Italian Pharmacovigilance Database**
Sorbara Emanuela Elisa, University of Messina, Italy

P064 **Focus on the Management of Reporting for Drug Ineffectiveness**
Giannandrea Almagrazia, University of Messina, Italy

P065 Real-World Pharmacovigilance Analysis of Lenvatinib Use in Qatar
Omar Nabil Elhadi, ASL BA, Italy

P066 Psoriasis Associated with Interferon Bêta-1b in a Multiple Sclerosis Patient with Positive Rechallenge
El Aidli Sihem, National Centre for Cancer Care and Research, Hamad Medical Corporation, Qatar

P067 Optic Neuritis: A Serious Adverse Effect of Etanercept
Daghfous Riadh, University of Tunis El Manar Faculty of Medecine of Tunis -UR17ES12, Tunisia

P068 Safety of Biologic Therapies for Severe Asthma: An Analysis of Adverse Reactions Reported in the WHO Pharmacovigilance Database
Cutroneo Paola Maria, Université Tunis el Manar Faculté de médecine de Tunis, Tunisia

P069 Tofacitinib-Induced Acute Pancreatitis
Charfi Ons, Sicily Pharmacovigilance Regional Centre, University Hospital of Messina, Italy

Pharmacogenomics – Patient-oriented pharmacovigilance

P070 Collection of Data for Detecting Adverse Drug Events in Smart Hospitals via Electronic Health Records, the GTT, Sensors and IoMT
De Pretis Francesco, VTT Technical Research Center of Finland Ltd, Finland

P071 Voriconazole-Induced Junctional Tachycardia: A Case Report
Zghal Khaled, University of Sfax – Faculty of medecine of Sfax, Tunisia

P072 Safety of Linagliptin in Patients with Type 2 Diabetes Mellitus: A Systematic Review and Meta-Analysis
Al-Fadel Nouf, Saudi Food and Drug Authority, Saudi Arabia

P075 Drug Related-Problems in Hospitalised Patients with Chronic Kidney Disease
Alruqayb Wadia S, University of Birmingham – School of Pharmacy, United Kingdom

P076 Factors Associated with Patient-Experienced Burden of Adverse Drug Reactions of Non-Vitamin K Oral Anticoagulants
Von Kreijfelt Gabriëlla, The Netherlands Pharmacovigilance Centre Lareb, Netherlands

P077 Factors Affecting Clopidogrel Cafety in the Montenegrin Population
Vukicevic Veselinka, Institute for Medicines and Medical Devices, Montenegro

P078	Urinary MicroRNAs as Possible Biomarkers of Cisplatin-Induced Nephrotoxicity in Patients with Head and Neck Cancer	Moriel Patricia, State University of Campinas, Brazil
P079	ABCC2 Gene Polymorphism and Adverse Reactions to Carboplatin and Paclitaxel Treatment in Non-small Cell Carcinoma Patients	Moriel Patricia, State University of Campinas, Brazil
P080	Development of a Clinical Focus Pharmacovigilance System	Maza Jose Antonio, Instituto Nacional de Cardiología Ignacio Chávez, Mexico
P081	Falling for Amiodarone – A Safety Analysis in Patients 60 Years and Older	Rudolph Annette, Uppsala Monitoring Center, Sweden
P082	Pharmacogenomics (PGx) as a New Special Interest Group (SIG) at ISOP	Yue Qun-Ying, Uppsala Monitoring Centre, Sweden
P085	Influence of the CYP450 Genetic Variation in Lipid Abnormalities with Clozapine Treatment: A Pilot Study in Patients with Psychiatric Disorder	Kleber Novais Pereira João, UNICAMP, Brazil
P086	Clinical Pharmacokinetics and Pharmacodynamics of Moxifloxacin in Human Tuberculosis	Onasanya Seun, University of KwaZulu-Natal, Westville Campus, South Africa
P087	Evaluation of Circulating MicroRNAs as Biomarkers of Hematological Adverse Reactions in Lung Cancer Patients Treated with Carboplatin and Paclitaxel	Moriel Patricia, State University of Campinas, Brazil
P088	ABCB1 Transporter Allelic Variants and Dermatologic Adverse Reactions Related to Gefitinib Therapy in Lung Cancer Patients: A Pilot Study	Moriel Patricia, State University of Campinas, Brazil
P089	Prescribing Patterns in Hospitalised Chronic Kidney Disease Patients: An Observational Study	Alruqayb Wadia S, University of Birmingham – School of Pharmacy, United Kingdom
P090	Associations of Genetic Polymorphisms of the Transporters with Cisplatin-Induced Renal Adverse Reactions in Patients with Head and Neck Cancer	Moriel Patricia, State University of Campinas, Brazil

Pharmacovigilance in healthcare emergency: lessons learned from COVID-19: vaccines – medicines

P099 COVID-19 Vaccine Safety Surveillance and Causality Assessment of Adverse Events Following Immunisation: Lessons from South Africa

Meyer Johanna C, Sefako Makgatho Health Sciences University, South Africa

P100 mRNA COVID-19 Vaccines Induced-Sudden Sensorineural Hearing Loss (SSNHL): Descriptive Analysis of French Pharmacovigilance Database (FPDB)

Bagheri Haleh, Faculty of Medicine, France

P102 Upgrade of Croatian ADR e-Reporting System for COVID-19 Prospective Cohort Event Monitoring (ACCESS Project)

Dujmović Blažok Sandra, HALMED, Croatia

P103 Psoriasis Induced by COVID 19 Vaccine

El Aidli Sihem, University of Tunis El Manar Faculty of Medecine of Tunis -UR17ES12, Tunisia

P104 Incidence of ischaemic Stroke Following Comirnaty™ Administration: Comparison of Data from ASST GOM Niguarda and FAERS

Pascale Giulia, ASST GOM Niguarda, Italy

P105 COVID Vaccines AEFI Monitoring in Tunisia: March 2021 to May 2022

Aouitni Imen, Centre national de pharmacovigilance, Tunisia

P106 Maternal, Fetal, and Neonatal Outcomes among Pregnant Women Receiving COVID-19 Vaccination: the Preg-Co-Vax Study

Fraenza Federica, Campania Regional Centre for Pharmacovigilance and Pharmacoepidemiology, Italy

P107 COVID-19 Vaccines and Reproductive Disorders: An Analysis of the European Database EudraVigilance

Riccardi Consiglia, Center of Pharmacovigilance and Pharmacoepidemiology, Campania Region, Naples, Italy

P108 Pharmacovigilance Regulatory Actions by National Pharmacovigilance Centres in Fourteen Middle Eastern Countries Following COVID-19 Pandemic

Al-Zubiedi Sameh, School of Pharmacy/ The Univesity of Jordan, Jordan

P109 Title of My Abstract: The Impact of SARS-CoV-2 on Mental Health. Focus on depression, Antidepressants Consumption and ADRs Signal Detection

Zerial Giovanna, Public Health Center of Pharmacovigilance, Friuli-Venezia Giulia Regional Office, Italy

P110 **Ivermectin-Induced Liver Injury when Used as Self-Medication in SARS-CoV-2 Infection**
Oscanoa Teodoro Julio, Universidad Nacional Mayor de San Marcos, Peru

P111 **COVID-19 Vaccine Pharmacovigilance Spontaneous Reporting in a Pandemic – Notes from a Small Country**
Kenyon Susan, Ministry of Health, New Zealand

P112 **Factors Influencing Patient Reporting of Adverse Reactions to Covid-19 Vaccines**
Anton Christopher, West Midlands Centre for Adverse Drug Reactions, United Kingdom

P113 **Digital Media and Pharmacovigilance: The SIMeF Pharmacovigilance Working Group Perspective**
Stagi Lisa, Roche spa, Italy

P114 **Previous Use of Proton Pump Inhibitors (PPI) in Hospitalized Patients and COVID-19 Mortality in Peru**
Oscanoa Teodoro Julio, Universidad Nacional Mayor de San Marcos, Peru

P115 **Utilization WHO Vaccine Hesitancy Tool to Assess the Refusal Rate of Routine Immunization Among Parents in Egypt**
Rostom Hadir, ISoP Egypt Chapter – MSA University, Egypt

P116 **Active Monitoring of Adverse Events in a Closed Population: Contributions from Colombia to COVID-19 Vaccines Safety**
Vaca Claudia, National University of Colombia, Colombia
Juanita Vahos Zambrano, National University of Colombia, Colombia

P118 **COVID-19 Pandemic: A Surge in Counterfeit Medicines**
Ussai Silvia, University of Cagliari, Italy

P119 **Pharmacovigilance in Healthcare Emergency: Lessons Learned from COVID-19: Uganda**
Byomire - Ndagije Helen Byomire, National Drug Authority, Uganda

P120 **Impact of the Inclusion of Covid-19 Vaccines in the National Pharmacovigilance Database on the Measurement of Disproportionality**
Talibi Ismail, Centre Antipoison et de Pharmacovigilance du Maroc, Morocco

P121 **Evaluation of Suspected Adverse Reactions to COVID-19 Vaccines in Patients with Autism Spectrum Disorder: Analysis of VAERS Database**
Di Carluccio Chiara, Italian National Institute of Health, Italy

P122 **Safety and Pharmacokinetic Profile of an Immunobiological Drug (anti SARS-Cov-2) in the Treatment of CoViD-19**
Keller Guillermo Alberto, Administración Nacional de Laboratorios e Institutos de Salud (ANLIS Malbran), Argentina

P123 **Self-Medication Among Romanian Patients in General and in the Context of the COVID-19 Pandemic**
Farcas Andreea, Iuliu Hatieganu University of Medicine and Pharmacy, Romania

P124 **Systemic COVID-19 vaccines Adverse Events Following Immunizations and Their Associated Factors: A Comparative Study Using Iraqi Consumers' Self-Reported Data**
Al-Shimran Ban, Ministry of Health, Iraq

P125 **How Covid-19 Pandemic Affected the National Pharmacovigilance System in the Czech Republic**
Kopecká Jana, State Institute for Drug Contol, Czech Republic

P126 **Active Surveillance for Safety Monitoring of COVID-19 Vaccines in Saudi Arabia**
Alhabardi Saja, Saudi Food and Drug Authority, Saudi Arabia

P127 **RESPIR'Nantes Study: What About the Safety?**
Ruellan Anne-Lise, University Hospital Center, France

P128 **Covid-19 Vaccines: Is the Seriousness Criterion "Medically Important" Applied Correctly in Reports and Are There Differences between HCPs and Non-HCPs?**
Scholz Irene, Swissmedic, Switzerland

P129 **Hepatic Disorders in Adults Associated with the Use of Ivermectin for SARS-CoV-2 Infection: A Pharmacovigilance Study in VigiBase**
Oscanoa Teodoro Julio, Universidad Nacional Mayor de San Marcos, Peru

P130 **Strengthened Pharmacovigilance in France for Monitoring COVID-19 Vaccines and Therapeutics Toward a New Surveillance Era?**
Pierron Evelyne, French National Agency for the Safety of Medicines and Health Products, France

P131 **Background Incidence in Spontaneous Reporting: Observed/Expected analysis of Myocarditis and Pericarditis with COVID-19 Vaccines in The Netherlands**
Van Eekeren Rike, Netherlands Pharmacovigilance Centre Lareb, Netherlands

P133 **Role of the Hospital Pharmacist in the Evaluation of the Anti-COVID-19 Vaccine Safety Profile in the Post-Marketing Phase**
Costantino Laura, Università degli Studi Magna Graecia di Catanzaro, Italy

P134 **Sotrovimab – Flashes of Safety in COVID-19 Patients**
Al Braik Fatima, UAE University, United Arab Emirates

P136 **Characteristics of Spontaneous Reports of Thrombosis with Thrombocytopenia Syndrome after COVID-19 Vaccines in the Netherlands**
Van Eekeren Rike, Netherlands Pharmacovigilance Centre Lareb, Netherlands

P137 **How a Community Approach Can Drive Pharmacovigilance Activities in Low-Resource Settings during a Public Health Emergency: Lessons from COVID-19**
Walker Ryan, University of Oxford, United Kingdom

P140 **Pharmacists' Engagement in the Adverse Drug Reactions Reporting Process During the COVID-19 Pandemic**
Gavazova Evelina, Medical university of Plovdiv, Bulgaria

P141 **How to Handle a Sudden Tenfold Increase in ICSRs – Lessons Learned During the SARS-Cov-2 Pandemic**
Samdal Hilde, Norwegian Medicines Agency, Norway

P143 **PharmaCovigilance: Role of the Pharmacist During COVID-19 Vaccination Campaign**
Martignoni Isabella, Ospedale P. Pederzoli, Italy

P144 **Covid-19 Vaccines and Menstrual Disorders: Reports from Sardinian Regional Centre of Pharmacovigilance**
Puddu Enrica Maria, University of Cagliari, Italy

P145 **Lessons Learned from COVID19: Enhancing the Discipline of Communications in Pharmacovigilance**
Abatemarco Danielle, BeiGene, USA

P146 **Cross-Reactivity between Pfizer/BioNTech and Johnsson Vaccines: A Case Report**
Zghal Khaled, University of Sfax – Faculty of medecine of Sfax, Tunisia

P147 **COVID-19 Vaccines Surveillance: Asl Brindisi Pharmacovigilance Data**
Pezzuto Benedetta, ASL Brindisi

P148 **Cerebro-Vascular Accident after Covid-19 Vaccination**
El Aidli Sihem, Université Tunis El Manar/Faculté de Médecine de Tunis/ UR17ES12, Tunisia

P149 **Myocarditis Related to SARS-CoV-2 Vaccines: Comparing Spontaneous Adverse Drug Reaction Reports with Intensive Monitoring of Nationwide Health-Registers in Sweden**
Sundström Anders, Swedish Medical Products Agency, Sweden

P150 **Bell's Palsy and Covid-19 Vaccination**

Charfi Ons, Université Tunis el Manar Faculté de médecine de Tunis / Unité de recherche UR17ES12., Tunisia

P151 **Rates of ADR Reports by Number of Administered SARS-CoV-2 Vaccination Doses in Sweden: Large Temporal Variations Especially in Consumer Reporting**

Sundström Anders, Swedish Medical Products Agency, Sweden

P152 **Fixed Drug Eruption after ChAdOx1 nCoV-19 Vaccine**

Jabri Fatma Ezahra, University of Tunis el Manar – Faculty of Medicine of Tunis: research unit UR17ES12, Tunisia

P153 **Adverse Reactions Associated with Comirnaty® Among Healthcare Professionals: A Cohort Event Monitoring Study in a Portuguese Hospital**

Abrantes Joana Rita, Association for Innovation and Biomedical Research on Light and Image, Portugal

P154 **The Impact of the COVID-19 Pandemic on Spontaneous Reporting of Adverse Drug Reactions in the Central Region of Portugal**

Abrantes Joana Rita, Association for Innovation and Biomedical Research on Light and Image, Portugal

P155 **Acute Angle Closure Glaucoma Following COVID-19 Vaccination**

Daghfous Riadh, Department for the collection and analysis of adverse reactions, Tunisia

P156 **Do patients with SARS-CoV-2 Vaccine-Induced Chronic Urticaria Can Have Their Second Dose?**

El Aidli Sihem, Université Tunis El Manar/Faculté de Médecine de Tunis/ UR17ES12, Tunisia

P157 **Establishing Patient Safety Monitoring in the Benefit-Risk Paradigm for Off-Label and Emergency Use of Medications for COVID-19: A Pharmacovigilance Perspective**

Malikova Marina, Boston Medical Center, Boston University School of Medicine, USA

P158 **Active Pharmacovigilance in COVID-19 Patients: The Role of a Clinical Pharmacist in the Reporting of Adverse Drug Events**

Hida Amina, Faculty of Medicine and Pharmacy of Rabat, Mohamed V Souissi University, Morocco

P159 **Urticaria Reactions after COVID-19 Vaccination: A Case Series**

El Aidli Sihem, Université Tunis El Manar/Faculté de Médecine de Tunis/ UR17ES12, Tunisia

P160 **Dermatomyositis Following Pfizer BioNTeh Covid-19 Vaccination**
El Aidli Sihem, Centre national de pharmacovigilance, Tunisia

P161 **Investigating a Signal of Acquired Haemophilia Associated with COVID-19 Vaccination: A Systematic Case Review**
Cappello Emiliano, University Of Pisa, Italy

P162 **COVID-19 Vaccines and Thromboembolic Events with Thrombocytopenia: Data from Italian Pharmacovigilance Public Database**
Bonaso Marco, University of Pisa, Italy

P163 **Leveraging Free-Text Information to Detect Duplicates in COVID-19 Vaccine Adverse Event Reports**
Barrett Jim, Uppsala Monitoring Centre, Sweden

P164 **Enhanced Surveillance of Italian Vaccinovigilance Group During COVID-19 Pandemic**
Petronzelli Fiorella, Italian Medicines Agency, Italy

P165 **Pharmacovigilance Contribution During National Mass Immunization Days**
Lakhoua Ghozlane, Université Tunis El Manar/ Faculté de Médecine de Tunis/ Unité de recherche UR17ES12, Tunisia

P166 **The Italian Approach to Improve Standard Quality of ICSRs for COVID 19 Vaccines: From Patient Data to Causality Assessment**
Petronzelli Fiorella, Italian Medicines Agency, Italy

P167 **COVID-19 Vaccination and Herpes Zoster/ Herpes Simplex Reactivation in the Elderly Population: A Pharmacovigilance Analysis**
Battini Vera, Università degli Studi di Milano, Italy

P168 **Menstrual Changes Following COVID-19 Vaccination: A Pharmacovigilance Study Based on Spontaneous Reports of Adverse Events Following Immunization (AEFI)**
Mosini Giulia, Università degli Studi di Milano, Italy

P169 **Risk Management Strategy to Promote the Uptake of COVID-19 Vaccination at a Tertiary Care Facility in Kenya**
Aywak Dorothy, Kenyatta National Hospital, Kenya

P170 **Cases of Guillan Barré Syndrome Following COVID-19 Vaccination**
Charfi Ons, Université Tunis el Manar Faculté de médecine de Tunis / Unité de recherche UR17ES12., Tunisia

P172 **Notoriety Bias in the Reporting of Adverse Events Following Immunization with COVID-19 Vaccines in the United States and Canada**
Castillon Genaro, YolaRX Consultants, Canada

P173 **Thromboembolic Events and COVID-19 Vaccine**
Charfi Ons, Université Tunis el Manar Faculté de médecine de Tunis / Unité de recherche UR17ES12., Tunisia

P174 **Adverse Effects of Hydroxychloroquine in COVID-19 Patients – a Review of Eudravigilance Database**
Matos Cristiano, Instituto Politécnico De Coimbra, ESTESC-Coimbra Health School, Portugal

P175 **Guillan-Barré Syndrome Following COVID-19 Vaccines: Analysis of the Vaccine Adverse Event Reporting System (VAERS) Database**
Gaio Mario, University of Campania "L. Vanvitelli", Italy

P176 **Capillary Leak Syndrome and COVID-19 Vaccines: An Analysis of the European Spontaneous Reporting System EudraVigilance**
Di Napoli Raffaella, University of Campania "Luigi Vanvitelli", Italy

P177 **European Safety Analysis of mRNA and Viral Vector COVID-19 Vaccines on Glucose Metabolism Events**
Di Mauro Gabriella, Campania Regional Centre for Pharmacovigilance and Pharmacoepidemiology, Italy

P178 **Safety of mRNA-Platform based Covid-19 Vaccines in Pediatric Population: An Analysis of the European Pharmacovigilance Database Eudravigilance**
Ruggiero Rosanna, University of Campania Luigi Vanvitelli, Department of Experimental Medicine, Italy

P179 **Pharmacovigilance Among Patients from the Perspective of Pharmacists: A Survey Study in Morocco**
Oullada Oumaima, National Higher School of Electricity and Mechanics, ENSEM, Hassan II University, Morocco

P180 **Vogt-Koyanagi-Harada Uveitis Following Covid-19 Vaccine**
El Aidli Sihem, University of Tunis El Manar Faculty of Medecine of Tunis -UR17ES12, Tunisia

P182 **Pattern of Adverse Effets of COVID-19 Vaccine Among the People of Bangladesh**
Sharmin Elora, Bangabandhu Sheikh Mujib Medical University, Bangladesh

P187 **Ecchymotic Plaques Induced by Spikevax: About 2 Cases**
Zghal Khaled, University of Sfax – Faculty of medecine of Sfax, Tunisia

P188 **Pharmacovigilance Before and After COVID-19 Pandemic: A 3-Years Analysis of Adverse Drug Reactions Reporting at the University Hospital of Catania**
Drago Filippo, University of Catania, Italy

P189 Adverse Drug Reactions Associated with Anti-Infective Agents Reported to the National Pharmacovigilance Centre in Saudi Arabia: A Descriptive Study

Alshehri Ghadah, Princess Noura Bint Abdularahman University, Saudi Arabia

Risk communication

P190 Post-marketing Safety of Onasemnogene Abeparvovec and Nusinersen in Pediatric Population: Analysis of FAERS Database

Zinzi Alessia, University of Campania "Luigi Vanvitelli", Italy

P191 Risk Communication: Ethionamide Mediated Gynecomastia

Mwesigwa Douglas, National Drug authority of Uganda, Uganda

P192 Signal of Congestive Cardiomyopathy in Association with Olanzapine – Evidence Review from Pharmacovigilance Data

Alakeel Abdulaziz, Saudi Food and Drug Authority, Saudi Arabia

P193 Isotretinoin Associated Risk of Blood Growth Hormone Decrease-Signal Review

S Almutairi Abdulrahman, SFDA, Saudi Arabia

Miscellaneous

P393 Phase-Wise Implementation of a Quality Management System to Improve the National Program for Adverse Events Following Immunization Surveillance in India

Joshi Jyoti, International Centre for Antimicrobial Resistance Solutions, Denmark

SESSION 2 POSTER PRESENTATION
THURSDAY 22 SEPTEMBER

Pharmacovigilance of biologics originator and biosimilar

P045 Does Omalizumab Increase the Risk of Malignancy? A Retrospective Case-Control Study in a Single Tertiary Hospital
Kim Hyun Jee, Seoul National University Hospital, Republic of Korea

Risk communication

P194 Pfizer-BioNTech COVID-19 Vaccine Associated Risk of Olfactory Hallucinations-Signal Review
I Fouda Mohammed , SFDA, Saudi Arabia

P195 Effect of Direct Healthcare Professional Communication on Citalopram and Escitalopram
Köberle Ursula, Drug Commission of the German Medical Association, Germany

P196 Regulatory Action Following Dextromethorphan Misuse in Adolescents in the Czech Republic
Deščíková Veronika, State Institute for Drug Control, Czech Republic

P198 Survey on Pharmacovigilance Knowledge and Activities in Sardinia
Sanogo Seydou, ARES – Sardegna, Italy

P201 Patch Tests and Cross-Reactivity Among Antiepileptic Drugs
Salvo Francesco, Universite de Bordeaux, France

P202 Stevens-Johnson Syndrome Induced by Lidocaine at the University Hospital of Libreville in Gabon: A Case Report
Ntoutoume Nzoghe Pierre Constant, Faculty of Medicine and Pharmacy Rabat, Morocco

P203 Experience in Communicating Vaccine Side Effects in a Covid-19 Population Vaccination Centre in North-East Italy
Montesarchio Livio, University of Verona, Italy

P205 Impact of Risk Communication on the Number of Pharmacovigilance ICSRs in Brazil
Capucho Helaine, Brazilian, Brazil

P206 Digital Risk Minimization Measures: Qualitative Feedback from Healthcare Professionals in Egypt
Rostom Hadir, ISoP Egypt Chapter – MSA University, Egypt

P207 Risk Communication about Medicines: Initiatives for improving in Saudi Arabia
Alowedi Nada, Saudi Food and Drug Authority, Saudi Arabia

P208 Risk Communication: Ensuring an Appropriate Benefit Risk Ratio in the Safety Profile of a Medicinal Products in Ghana
Owusu Ronald Aboraah, Pokupharma Limited, Ghana

P209 Decision Tree to Distinguish Important Urgent Safety Concern Types and Other Safety Concerns to Fulfill Reporting Requirements
Kaehler Stefan, Bristol Myers Squibb, Austria

P210 Evolving Global Requirements for Signal Notification to Health Authorities: How to Standardize and Harmonize Signal Communication
Pruvot Fanny, BMS, France

Database networks for post-marketing surveillance for vaccines and medicines

P215 Riluzole Prescribing Beyond Therapeutic Indications in Clinical Practice
Crescioli Giada, University of Florence, Italy

P216 A Safety Profile Analysis of Adverse Events After Measles-Mumps-Rubella and Varicella Immunization Based on Italian Pharmacovigilance Network in Veneto Region
Soriolo Nicola, University of Verona, Italy

P217 The Case Review Vignette
Nagpal Sumit, USA

P220 Expansion of VigiFlow® Network to a Third Level for Post-Marketing Surveillance of COVID-19 Vaccines in Iraq
Younus Manal, MOH, Iraq

P222 Genital Itching and Other Genital Discomforts Associated with the Parenteral and Oral Clindamycin in Vigibase
Beltrán Cecilia, Pharmacovigilance and Technovigilance National Center of Peru, Peru

P223 Monoclonal Antibodies Diseases Modifying Agents: A Drug Safety Surveillance Study in Patients with Multiple Sclerosis
Alghamdi Eman, Saudi Food and Drug Authority, Saudi Arabia

P224 Adverse Events Related to Lutetium (177Lu) Oxodotreotide (Lutathera): "Real-Life" Data from the Eudra-Vigilance Database
Dal Mas Liana, Università degli Studi di Padova Dipartimento di Scienze del Farmaco, Italy

P225 **A Retrospective Analysis of Adverse Drug Events Leading to Hospitalization or Prolonged Hospitalization in Saudi Arabia**
Alqadheeb Eman, SFDA, Saudi Arabia

P226 **The Effect of the COVID-19 Vaccine on Menstruation and Hair loss Amongst the Saudi Population Using the National Reporting System**
Alblowi Fotoun, Saudi food and drug authority, Saudi Arabia

P227 **Assessing the Post-Marketing Experience of Drug Ineffectiveness Reports Received by the Saudi Vigilance System**
Alolayet Rayan, Saudi Food and Drug Authority (SFDA), Saudi Arabia

P228 **The Impact of Mobile Apps for Spontaneous Reporting: Experience from COVID-19 Vaccines Safety Surveillance**
Magro Lara, University of Verona, Italy

P229 **Adverse Drug Reactions in Older People Reported to the Portuguese Pharmacovigilance System during 2019**
Herdeiro Maria Teresa, iBiMED – Instituto de Biomedicina Dpt. Ciências Médicas, Univ. Aveiro, Portugal

P230 **Immune Checkpoint Inhibitors and Pregnancy: A Pharmacovigilance Analysis in VigiBase®**
Noseda Roberta, Institute of Pharmacological Sciences of Southern Switzerland, Switzerland

P231 **Follow-up of Covid-19 Vaccinated Pregnant and/or Breastfeeding Women in Tunisia**
El Aidli Sihem, University of Tunis El Manar Faculty of Medecine of Tunis -UR17ES12, Tunisia

P232 **Cutaneous Adverse Reactions Reported with Antiepileptic Drugs in Tunisian Pediatric Population**
El Aidli Sihem, Centre national de pharmacovigilance, Tunisia

P233 **A Survey on the Adverse Drug Reactions of Covid-19 Vaccines Administered within the Local Health Authority of Verona**
Schmid Francesca, University of Padova, Italy

P234 **Spontaneous Reports of Delayed Urticaria Following Booster Vaccination with Spikevax® in Switzerland**
Müller Laura, Institute of Pharmacological Sciences of Southern Switzerland, Switzerland

P235 **Signal Detection by Disproportionality Analysis in the Monitoring of COVID-19 Vaccine Safety in Switzerland**
Noseda Roberta, Institute of Pharmacological Sciences of Southern Switzerland, Switzerland

P236 Vitamin D-Induced Cardiovascular Toxicity: Preliminary Evidence from the FDA Adverse Event Reporting System (FAERS)
Gringeri Michele, Università degli Studi di Milano, Italy

P237 Symptoms Potentially Related to Small Fiber Neuropathy (SFN) and Anticovid Vaccines
Giannandrea Almagrazia, ASL BA, Italy

P238 Safety Profile of Antiviral Therapies for the Early Treatment/Prevention of COVID-19: Analysis of the International Pharmacovigilance Database VigiBase
Bellitto Chiara, University of Verona, Italy

P239 Real-World Patterns and Trends of Idarucizumab Use in an Italian Region: A Probabilistic Record-Linkage Approach in the Period 2015–2020
Lombardi Niccolò, University of Florence, Italy

P240 Antipsychotic Drugs Use in the Territory of the Central Tuscany Healthcare Authority – Preliminary Results of the ANTIGONE Project
Crescioli Giada, University of Florence, Italy

P241 Herpes-Zoster Reactivation Following SARS-CoV-2 Vaccines
Daghfous Riadh, Université Tunis el Manar Faculté de médecine de Tunis, Tunisia

P242 Cytolytic Hepatitis Following mRNA Vaccination
Zaiem Ahmed, Université Tunis el Manar Faculté de médecine de Tunis, Tunisia

P243 Myocarditis Following SARS-CoV-2 Vaccines: A Series of Six Cases
Daghfous Riadh, Université Tunis el Manar Faculté de médecine de Tunis, Tunisia

P244 Demonstration of TreeScan Techniques on a Federated Real-World Data Network
Kundrot Steven, TriNetX, LLC, USA

P245 VAC4EU: A Pan-European Research Network For Collaborative Post-authorization Vaccine Safety And Benefit Monitoring
Sturkenboom Miriam, UMC Utrecht, Netherlands

P246 Adverse Events Following HPV Vaccination in the Veneto Region: Data from Spontaneous Reporting
Dalla Valle Diana, University of Verona, Italy

P247 Medicinal Cannabis and Related Products – Analyses of Quality Defects and Adverse Drug Reactions Reported by German Community Pharmacists
Neumann Paul Robert, ABDA, Germany

Clinical decisions in pharmacovigilance

P249 Gemcitabine-Induced Leukocytoclastic Vasculitis
Zaiem Ahmed, National Center Chalbi Belkahia of Pharmacovigilance, Tunisia

P250 A Dashboard to Visualize Adverse Events Data from the United States National Library of Medicine ClinicalTrials.gov Database
Bond T. Christopher, Bristol Myers Squibb, USA

P251 Comparison of the Pathologic Complete Response of Pseudopolumorphic Forms of Docetaxel 80 mg in an Oncology Outpatient Clinic in Brazil
Marques Cavalcante-Santos Lincoln, University of São Paulo, Brazil

P252 Strong Signs of Increased Number of Intoxications Following Rise in Prescription of Promethazine
Thunander Sundbom Lena, Swedish Medical Products Agency, Sweden

P253 What Is the Safety Profile of Cannabis-Based Medications? Analysis of the Post-Marketing Signals from the FDA Adverse Event Reporting System
Lunghi Carlotta, University of Bologna, Italy

P254 Risk of Psychotic Disorders Among Patients with Medical Cannabis Authorization: A Longitudinal Cohort Study
Lunghi Carlotta, University of Bologna, Italy

P255 Assessing the Brighton Collaboration Case Definition of Sensorineural Hearing Loss in Ghana
Sturkenboom Miriam, UMC Utrecht, Netherlands

P258 Safety and Tolerability of Dimethylfumarate, an Analysis of Pharmacovigilance Data Within the Region of Sardinia
Anania Lorenzo, University of Cagliari, Italy

P259 Post-Marketing Safety of Anti-Calcitonin Gene Related Peptide Antibodies: A Disproportionality Analysis of the FDA Adverse Event Reporting System
Giunchi Valentina, University of Bologna, Italy

P260 A Case Report of Possible Pembrolizumab-Induced Myasthenia Gravis from an Italian University Hospital: A Fatal Case Report
Pivato Lisa, University Hospital of Padova, Italy

P261 The Approaches to Assess Robustness of Disproportionality Findings in Pharmacovigilance. A Meta-Epidemiological Research
Fusaroli Michele, University of Bologna, Italy

P262 Paliperidone and Potential Risk of Hyponatremia
Al-Fadel Nouf, Saudi Food and Drug Authority, Saudi Arabia

P263 **Drug-Induced Acute Pancreatitis Cases Notified to the CNPV**
Jabri Fatma Ezahra, University of Tunis el Manar – Faculty of Medicine of Tunis: research unit UR17ES12, Tunisia

P264 **Personalized Approach to the Diagnosis and Treatment of Acute Psychoactive Substance Poisoning in Adolescents**
Zhdanova Olga, Voronezh State Medical University named after N. N. Burdenko, Russian Federation

P265 **Adverse Drug Events In an Intensive Care Unit: A Pilot Study Using the Global Trigger Tool**
Moriel Patricia, State University of Campinas, Brazil

P266 **A Cross-Sectional Investigation for Verification of Falsified Medicinal Product in Egypt, Indicated by vials of Ampicillin/Sulbactam**
Ayman Yomna, MUP – Medical Union Pharmaceuticals, Egypt

P267 **Erythema Multiforme Reactions Following Pfizer/BioNTech (BNT162b2) and Oxford/AstraZeneca (chAdOx1-S) COVID-19 Vaccination: A Case Series**
Charfi Ons, Université Tunis el Manar Faculté de médecine de Tunis / Unité de recherche UR17ES12., Tunisia

P268 **The Risk of Posterior Reversible Encephalopathy Syndrome with Tyrosine Kinase Inhibitors: A Disproportionality Analysis from Vigibase and AERS Databases**
Velez-Nandayapa Luis, University of Basel / Novartis, Switzerland

P269 **Evaluation Of Deprescribing Services In Frail Patients: A Systematic Review**
Alshatti Dalal, University of Birmingham, United Kingdom

P270 **Using Real-World Data for Rapid Safety Investigations: Value of Near-Real-Time Clinical Data Querying**
Dimbil Mohamed, TriNetX, LLC, USA

P271 **Localized Edema Occurring During Treatment with Risperidone**
Daghfous Riadh, Department for the collection and analysis of adverse reactions, Tunisia

P272 **The Risk of Myasthenia Gravis with Tyrosine Kinase Inhibitors: A Disproportionality Analysis from Vigibase and AERS Databases**
Velez-Nandayapa Luis, University of Basel / Novartis, Switzerland

P273 **Osteomalacia Following Rifampicin-Induced Hypovitaminosis D**
El Aidli Sihem, Centre national de pharmacovigilance, Tunisia

P274 **Obinutuzumab and Non-Overt Disseminated Intravascular Coagulation: A Case Study of Signal Detection and Management in Italy**
Valdiserra Giulia, University of Pisa, Italy

P276 **Pharmacovigilance of Cytotoxic Drugs in Childhood Cancer: A Retrospective Study**
Mousannif Soumaya, Faculty of Medicine and Pharmacy of Rabat, Morocco

P277 **Photoallergic Eczema Induced by Fenofibrate**
Zaiem Ahmed, National Center Chalbi Belkahia of Pharmacovigilance, Tunisia

P278 **Recurrent Erythema Multiforme with Paracetamol**
Zaiem Ahmed, National Center Chalbi Belkahia of Pharmacovigilance, Tunisia

P279 **Assessment of Adverse Drug Reactions to Off-Label Drug Use in an Oncological Population Treated in a Northern Italian Hospital**
Berti Elena, ISTITUTO ONCOLOGICO VENETO IRCCS, Italy

P281 **Interferon -β Induced Psoriasis in a Multiple Sclerosis Patient with Positive Rechallenge**
Zaiem Ahmed, Tunis el Manar University Faculty of Medicine of Tunis / Research Unit UR17ES12. Chalbi Belkahia National Centre for Pharmacovigilance, Tunisia

P282 **Oxybutynin Induced Blidness in a Child**
Zaiem Ahmed, Tunis el Manar University Faculty of Medicine of Tunis / Research Unit UR17ES12. Chalbi Belkahia National Centre for Pharmacovigilance, Tunisia

P283 **GRESIF: A Project for the Management of Severe Adverse Drug Reactions (SCARs). The Experience of Lombardy and Piedmont**
Pascale Giulia, ASST GOM Niguarda, Italy

P284 **Adverse Events of Imatinib**
Aouitni Imen, Centre national de pharmacovigilance, Tunisia

P285 **Carbamazepine-Acetazolamide Interaction Leading to an Hepatocellular Liver Injury: A Relevant Case Report**
Mansour Khadija, Department of Clinical Pharmacology, Tunisia

Ecopharmacovigilance

P286 **Chronic Effects of Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Hormones on the Animal Model Danio Rerio**
Grisotto Jacopo, University of Verona, Italy

P287 **The Value of International Pharmacovigilance Databases to Help Contain Antibiotic Resistance from a 'One Health' Perspective**
Mitchell Joseph, Uppsala Monitoring Centre, Sweden

Women's medicines

P290 **Medications use while breastfeeding – prevalence and attitude of women**
Liiv Ekaterina, Almazov National medical research centre, Russian Federation

P291 **Comparative Safety of Metformin and Insulin in Gestational Diabetes – a Retrospective, Case-Control Study**
Staynova Radiana, Medical University of Plovdiv, Faculty of Pharmacy, Bulgaria

P293 **Breastfeeding Women's Knowledge Toward Spontaneous Reporting of Adverse Drug Reactions – a Pilot Study from Bulgaria**
Staynova Radiana, Medical University of Plovdiv, Faculty of Pharmacy, Bulgaria

P295 **Drug-Induced Liver Injury (DILI) and Ulipristal: A Cautionary Tale**
Avó-Baião Rita, Faculdade de Medicina da Universidade de Lisboa, Portugal

P296 **Pharmacovigilance of Selective Serotonin Reuptake Inhibitors and Gender Differences in Stroke Incidence**
Sellitto Carmine, University of Salerno, Italy

P297 **Safety of Painkillers during Pregnancy a Retrospective Analysis of Reports from the Italian Veneto Region and VigiBase**
Rudolph Annette, University of Verona, Italy

P298 **Pharmacovigilance of Medicines for Controlled Ovarian Hyperstimulation – a Study of Patients` Perspective**
Stoev Svetoslav, Medical University Pleven, Bulgaria

Herbal and Traditional Medicines and dietary supplements

P300 **DNA Barcoding as a Tool to Overcome the Challenges of Phytovigilance of Natural Health Products Quality: The Example of Saffron**
Skalli Souad, Faculty of Sciences Mohammed V University in Rabat, Morocco

P301 **"Title Case" = A case of Death Following the Application of "Nicotiana Glauca"**
Rhaymi Chaimae, Faculty of Medicine and Pharmacy, Mohammed V University in Rabat, Morocco

P303 **Surveillance of Suspected Adverse Reactions to Beehive Products**
Ippoliti Ilaria, Istituto Superiore di Sanità, Italy

P305 **Improving the Knowledge Attitude and Practice of Pharmacovigilance Amongst Herbal Medicine Practitioners in Lagos**
Oreagba Ibrahim, ACEDHARS University of Lagos, Nigeria

P306 **Safety of Therapies and Use of Supplements. The Pharmacy Clinical Desk Experience in the National Cancer Centre CRO Aviano**
Baldo Paolo, Centro di Riferimento Oncologico CRO Aviano-IRCCS, Italy

Medical Device Safety

P307 The AOUI Verona Task Force for Improvement of Post-Market Clinical Surveillance for Medical Device
Marini Paola, AOUI Verona, Italy

P308 Risk-Based Quality and Safety Management in Clinical Trials with Combination Devices in Changing Global Regulatory Environment
Malikova Marina, Boston Medical Center, Boston University School of Medicine, USA

P310 Reported Health Problems Associated with the Use of Copper Intrauterine Devices
Leonardo Alves Teresa, Dutch Reporting and Expertise Centre for Adverse Effects of Medical Implants (MEBI), Netherlands

P311 Insights into the Dutch Reporting and Expertise Centre for Adverse Effects of Medical Implants: A 5-Year Perspective
Leonardo Alves Teresa, Dutch Reporting and Expertise Centre for Adverse Effects of Medical Implants (MEBI), Netherlands

Patient Engagement

P314 Consumer's Self-Assessment Form as a Source of COVID-19 Vaccine Surveillance Data in Iraq
Al-Shimran Ban, Ministry of Health, Iraq

P316 First Patient Reports in Montenegro
Vukicevic Veselinka, Institute for Medicines and Medical Devices, Montenegro

P317 Pharmacovigilance Evolution: Patient-Oriented Opportunities in Pharmaceutical Industry
Facchinello Daniela, Roche S.p.A., Italy

P319 Patients' Attitudes Towards Deprescribing – A Cross-sectional Study in Older Patients in Romania
Bucsa Camelia, Iuliu Hatieganu University of Medicine and Pharmacy, Romania

P320 Quasi-experiment Study on Use of Toll-free Phone Systems for Adverse Event Reporting by Patients and Clinicians
Byomire – Ndagije Helen Byomire, National Drug Authority, Uganda

P321 Reporting ADR as a Citizen: Analysis of Data from Sardinian Region
Ferrari Alessandra, Sardinia Regional Center of Pharmacovigilance, Italy

P322 Assessment of Safety of Use of Antismoking Drug Cytisine in a Hospital Setting
Chiamulera Cristiano, University of Verona, Italy

P323 Evaluating the Impact of Pharmaceutical Interventions on the Clinical Outcomes of Palliative Care Patients: A Single-Arm Clinical Trial
Marques Cavalcante-Santos Lincoln, University of São Paulo, Brazil

P324 How Do You Find Monitored Dosage Systems?
Stewart Leeanne, University of Birmingham, United Kingdom

P325 Are Pharmaceutical Companies Engaged with Patients for Pharmacovigilance? – A Search on Industry Accomplishement Regarding Patient Reporting of ADRs
Matos Cristiano, Instituto Politécnico De Coimbra, ESTESC-Coimbra Health School, Portugal

Miscellaneous

P328 Spontaneous Reporting of Adverse Events Following Immunization in Veneto: Direct Transfer of Reports from the Local Vaccination Registry
Schievano Francesco, University of Verona, Italy

P329 Am2P : A New Accredited Academic Training Program in Pharmacovigilance and Pharmacoepidemiology Designed for US, Canadian and Caribbean Healthcare Professionals
Palin Karine, Université de Bordeaux, France

P330 Knowledge, Attitudes and Practices on Pharmacovigilance and Phytovigilance among students of MSc in Nursing Sciences
Di Nolfi Annachiara, Italian National Institute of Health, Italy

P331 Children's Pill School Evaluation: Healthcare Professionals' Views and Recommendations
Rashed Asia N, King's College London, United Kingdom

P332 When the Drug Becomes Toxic! : Lyell Syndrome in a Moroccan Context
Imane Zhim, Pharmacy Unit, Morocco

P333 ADHD Medication Use and Psychiatric Comorbidity, Trauma and Mortality in Children and Young Adults: A Cohort Study from Quebec, Canada
Lunghi Carlotta, University of Bologna, Italy

P334 Medication-Induced Delirium in Older People Hospitalized in General Wards Care: A Systematic Review
Marques Cavalcante-Santos Lincoln, University of São Paulo, Brazil

P335 Applying a Launch Excellence Framework in Patient Safety
Strother Rachel, BMS, USA

P336	Development of a Framework for the Integration of Two Major Biopharmaceutical Organizations and Guidance for Pharmacovigilance Di Menno Di Bucchianico Roberta, Bristol Myers Squibb, Italy
P337	Let's Make a PV Agreement: Three Solutions You Can Use to Enhance Your PVA Process Kilgour-Christie Jean, Novartis Pharma GmBH, Germany
P338	Facial Paralysis Associated with Pembrolizumab Use: Adverse Events- Signal Review Alamri Roaa, Saudi Food and Drug Authority, Saudi Arabia
P339	Perception and Behavior towards Risk Information in the Patient Information Leaflet in Saudi Arabia Alamri Roaa, Saudi Food and Drug Authority, Saudi Arabia
P340	Sexual Disorders with Selective Serotonin Reuptake Inhibitors: A Comparative Study Trenque Thierry, CHU Reims, France
P342	Future of Healthcare and Opportunities/Challenges for Pharmacovigilance in the Digital Age Ghosh Rajesh, Genentech/Roche, USA
P343	The Global Pharmacovigilance Professional Certification (GPPC) Petráček Jan, Institute of Pharmacovigilance, Czech Republic
P345	PVReg: A Comprehensive Global Pharmacovigilance Requirement Profiling and Analysis System Delumeau Jean-Christophe, Institute of Pharmacovigilance, Czech Republic
P346	A Comprehensive Global Repository of Pharmacovigilance-Relevant Regulations Delumeau Jean-Christophe, Institute of Pharmacovigilance, Czech Republic
P347	Pilot Implementation of the Global Pharmacovigilance Professional Certification (GPPC) Delumeau Jean-Christophe, Institute of Pharmacovigilance, Czech Republic
P348	Proactive Drug Safety Monitoring of Adverse Drug Events in Saudi Arabia: 2021 Experience Al-Fadel Nouf, Saudi Food and Drug Authority, Saudi Arabia
P349	Sertraline and the Potential Risk of Pulmonary Eosinophilia Drug-Induced Al-Fadel Nouf, Saudi Food and Drug Authority, Saudi Arabia

P350 The Antidepressant Effects of Hypoglycaemic Agents: New Insights from an Analysis of the FDA Adverse Event Reporting System (FAERS) Database

Carnovale Carla, Università degli Studi di Milano, Italy

P351 Drug-Induced Canaliculitis: An Observational Postmarketing Study

Trenque Thierry, CHU Reims, France

P352 Spontaneous Reports vs Cohort Event Monitoring: Differences in Collecting Information on Adverse Drug Reactions of Non-Vitamin K Oral Anticoagulants

Von Kreijfelt Gabriëlla, The Netherlands Pharmacovigilance Centre Lareb, Netherlands

P353 Eritrea's Experience in Safety Monitoring of Mass Administration of Praziquantel

Bahta Merhawi, Ministry of Health, Eritrea

P354 Pharmacovigilance in no Profit Clinical Trial: Duties and Responsibilities for the Research Team

Cenna Rosita, S.C. Oncoematologia Pediatrica, Presidio Infantile Regina Margherita – A.O:U: Città della salute e della Scienza di Torino, Italy

P355 Safety of Bempedoic Acid: Post-marketing Analysis of the FDA Adverse Event Reporting System

Raschi Emanuel, Alma Mater Studiorum – University of Bologna, Italy

P356 Marketing Authorization Holders: The Pharmacovigilance Performance Pattern According to their Geographic Classification

Arafah Amal, Saudi Food and Drug Authority, Saudi Arabia

P357 Exploring Subpopulation Signal Detection Methods on Spontaneous Adverse Event Reporting Databases

Candore Gianmario, Bayer, Germany

P358 Pharmacovigilance Capacity Building in Indonesia 2017–2021: Overview and Impact Trend Analysis

Wangge Grace, Monash University Indonesia, Indonesia

P359 Drug Safety in Geriatric Patients and the Need for a New ISoP Special Interest Group

D'souza Joan, Institute of Pharmacovigilance, Switzerland

P360 Developing Training Material for Community Health Workers on Adverse Drug Reaction Reporting: A Pilot Project

Viljoen Michelle, University of the Western Cape, South Africa

P362 **Pediatric Drug Safety Surveillance: A Ten-years Analysis of Adverse Drug Reaction Reporting Data in Calabria, Southern Italy**
Leporini Christian, "Magna Graecia" University of Catanzaro, Italy

P363 **Educational Interventions to Improve the Report, Attitude, and Knowledge of Adverse Drug Reactions in Healthcare Professionals: Systematic Review and Meta-Analysis**
Cervantes-Arellano Monica, Universidad Nacional Autónoma de México (UNAM), Mexico

P364 **International Harmonization of Good Pharmacovigilance Practices: Impact on Brazil**
Capucho Helaine, Brazilian, Brazil

P365 **Use of Psychotropic Medications before and after Self-Harm in a Regional Cohort of Older Adults Aged 75+**
Hedna Khedidja, University of Gothenburg, Sweden

P366 **Interdisciplinary Collaboration for Benefit-Risk Assessment Planning During the Medical Product Lifecycle: Results from a Survey**
Edwards Brian, Husoteria Ltd, United Kingdom

P368 **Pharmacovigilance Challenges in Cannabis Medicinal Products – A Narrative Review**
Matos Cristiano, Instituto Politécnico De Coimbra, ESTESC-Coimbra Health School, Portugal

P369 **Occurrence and Characteristics of Linezolid Toxicity in Clinical Practice: Interim Analysis of a Prospective Multicentric Study**
Thirot Helene, UClouvain, Belgium

P370 **Developing Practical Pharmacovigilance Skills at a Distance: Description and Evaluation of UMC's Instructor-Led Online Learning**
Jastrebova Nadja, Uppsala Monitoring Centre, Sweden
Elki Sollenbring, Uppsala Monitoring Centre, Sweden

P372 **An Exceptional DRESS syndrome to Potaba with Positive Patch Test**
Lakhoua Ghozlane, Université Tunis el Manar Faculté de médecine de Tunis / Unité de recherche UR17ES12, Tunisia

P373 **Has Piperine a Role to Play Against Breast Cancer?**
Joaquim João José, University of Salamanca, Portugal

P374 **Is There an Important Role Played by Thiamine (Vit B1) in Alzheimer's Disease?**
Joaquim João José, University of Salamanca, Portugal

P376 A System for Reporting Adverse Drug Reactions to Emergency: Pilot Project
Donadu Matthew Gavino, Sassari University Hospital, Italy

P377 What's up in Celiac Disease Treatment?
Joaquim João José, University of Salamanca, Portugal

P378 Current Pharmacovigilance Outsourcing Practices in Arab Countries
Abdeldayem Ibrahim, Arriello s. r. o, Egypt

P379 Outsourcing of Pharmacovigilance Activities for Pharmaceutical Industries in Brazil
Lauton Letícia, Safety One Specialized Services in Pharmacovigilance, Brazil

P380 Safety of Antiangiogenic Drugs in Pediatric Patients with Solid Tumors: A Systematic Review and Meta-analysis
Spini Andrea, Azienda Ospedaliera Universitaria Senese, Italy

P381 Pharmacovigilance in Hospital: Monitoring Reports of Adverse Drugs and Vaccines Reactions Collected in an Active Pharmacovigilance Project
Impagliatelli Rosa, University of Pisa, Italy

P382 Drug Use in Patients before and after Starting Chronic Dialysis, Lazio Regional Dialysis and Transplant Registry, 2008–2020
Kirchmayer Ursula, Lazio Regional Health Service, ASL Roma1, Italy

P383 ICSR and Pharmacovigilance Data: Challenges for Pharmaceutical Companies
Lorenzi Silvia, PQE Group, Italy

P385 Real-World Efficacy and Safety of Off-Label Use of Immune Checkpoint Inhibitors (ICI) in Cancer: A Retrospective Cohort Study in Qatar
Abaza Seif, Hamad Medical Corporation, Qatar

P388 Pharmacovigilance Funding Landscape in Africa – A Survey
Isah Ambrose, University of Benin / University of Benin Teaching Hospital, Nigeria

P389 Characterization of Factors Associated with Long-Term Prescription Opioid Use in Support of Risk Mitigation Strategies in the Non-Cancer Population
Castillon Genaro, YolaRX Consultants, Canada

P390 Post-Marketing Safety of Innovative Drugs: Analysis of Pembrolizumab Related ADRs in a University Hospital
Impagliatelli Rosa, University of Pisa, Italy

P391 Analysis of the Reports of Suspected Adverse Drugs Reactions of 2021 in a Tuscan University Hospital
Impagliatelli Rosa, University of Pisa, Italy

P392	Knowledge, Attitude, and Practice Regarding Pharmacovigilance among Health Care Professionals of Nepal: A Cross-Sectional Study **Gyanwali Pradip,** Nepal Health Research Council, Nepal
P394	Developing Kidney-Specific Causality Assessment Tool **Gülmez Sinem Ezgi,** Koç University School of Medicine, Turkey

Flash Presentation listing

On-Site No. / Poster No. / Time / Paper Title / **Presenter**

SESSION 1 POSTER FLASH PRESENTATION WEDNESDAY 21 SEPTEMBER

FP2	P039 / 12:50–12:55 Smart Safety Surveillance of Vaccines in Mass Immunization Campaigns: Eritrea's Evolving Experience in a Nutshell **Debesai Merhawi,** Eritrean Pharmacovigilance Centre, National Medicines and Food Administration, Ministry of Health, Eritrea
FP4	P091 / 12:55–13:00 Association between SARS-CoV-2 Vaccines and Myo- and Pericarditis; a Large Observational Study Using Electronic Healthcare Data from Four European Countries **Riera-Arnau Judit,** Hospital Universitari Vall Hebron, Spain
FP6	P092 / 13:00–13:05 Covid-Vaccine-Monitor: a Cohort Event Monitoring Safety Study of COVID-19 Vaccines in Twelve European Countries **Riefolo Fabio,** Teamit Institute S.L., Spain
FP8	P093 / 13:05–13:10 How the United States' Vaccine Adverse Event Reporting System (VAERS) Database Has Been Used to Study SARS-CoV-2 Vaccine Safety **Weiss Sheila,** Exponent, USA
FP10	P094 / 13:10–13:15 Real-life Safety of Oral Antivirals for COVID19: a Retrospective Cohort Study **Pivato Lisa,** University Hospital of Padova, Italy

FP12	P095 / 13:15–13:20 Allergic History and Anaphylaxis in COVID-19 Vaccines: A Disproportionality Analysis in the FDA Vaccine Adverse Event Reporting System Giunchi Valentina, University of Bologna, Italy
FP14	P096 / 13:20–13:25 Role of Background Incidence in Signal Detection; Observed/Expected Analysis of Classical Thromboembolism with COVID 19 Vaccines in The Netherlands Van Eekeren Rike, Netherlands Pharmacovigilance Centre Lareb, Netherlands
FP16	P098 / 13:25–13:30 Adverse Events of Special Interests (AESIs) Reported in Pediatrics with Pfizer Biontech COVID-19 Vaccine: Insights from VAERS Database Alsalamat Husam, Al-Balqa Applied University, Jordan
FP18	P211 / 13:30-13:35 Healthcare Utilization Databases for Medical Product Safety Surveillance: a Pilot Analysis from Lombardy Franchi Matteo, University of Milano-Bicocca, Italy
FP20	P212 / 13:35–13:40 Use of ICD-10 Codes for Tracking Adverse Drug Events (ADEs): a Computational Approach to Searching Large Health Databases in Brazil Arrais Paulo Sérgio Dourado, Universidade Federal do Ceará, Brazil
FP22	P213 / 13:40–13:45 Cohort Event Monitoring on Adverse Reactions to COVID-19 Vaccines in Seven European Countries: Pooled Results on First Dose Raethke Monika, Netherlands Pharmacovigilance Centre Lareb, Netherlands
FP24	P214 / 13:45–13:50 Cohort Event Monitoring of COVID-19 Vaccine Safety in Special Cohorts in Italy Ciccimarra Francesco, University of Verona, Italy

SESSION 2 POSTER FLASH PRESENTATION
THURSDAY 22 SEPTEMBER

FP2	P248 / 12:20–12:25 Impact of 2018 EU Risk Minimisation Measures and Revised Pregnancy Prevention Programme on Utilisation and Prescribing Trends of Valproates Abtahi Shahab, Utrecht University, Netherlands
FP4	P299 / 12:25–12:30 Inter-Year Comparison of Adverse Reactions Associated with Legal Cannabis Products Reported to Health Canada, 2018–2019 to 2021 Jack Stephanie, Health Canada, Canada
FP6	P312 / 12:30–12:35 Diarrhea and Apixaban; Using Combined Data from Spontaneous Reporting and Cohort Event Monitoring for Signal Detection in Pharmacovigilance Von Kreijfelt Gabriëlla, The Netherlands Pharmacovigilance Centre Lareb, Netherlands
FP8	P313 / 12:35–12:40 "VigiNetWork: a Community Pharmacists-Network on Pharmacovigilance in Emilia-Romagna and Veneto Region" Stano Marilisa, University of Verona, Italy
FP10	P326 / 12:40–12:45 Acquired Hemophilia A and COVID19 Vaccines: a Possible Safety Signal or a Notoriety/Detection Bias? Ferraro Sara, University of Pisa, Italy
FP12	P327 / 12:45–12:50 Safety and Tolerability Profile of Paliperidone Palmitate: An Analysis on Publicly Accessible EudraVigilance Data Cicala Giuseppe, University of Messina, Italy
FP14	P384 / 12:50–12:55 Is Pegylation of Drugs Associated to Hypersensitivity Reactions? An Analysis of The Italian National Spontaneous Adverse Drug Reaction Reporting System Crisafulli Salvatore, University of Verona, Italy

List of Chairpersons and Speakers

Bahri Priya, Chair of the Risk Communication SIG (Netherlands)
Bate Andrew, GSK (UK)
Bégaud Bernard, Emeritus Professor in the Department of Health of the University of Bordeaux (France) and chair of the EPIPHARE scientific committee
Benabdallah Ghita, Centre Anti Poison et de Pharmacovigilance du Maroc (CAPM) (Morocco)
Bullman Alix, ECAMET Alliance, (Belgium)
Burn Edward, University of Oxford (UK)
Candore Gianmario, Bayer (Germany)
Capuano Annalisa, PRAC Member – University of Naples (Italy)
Caputi Achille P., former President of the Italian Society of Pharmacology (Italy)
Caro Rojas Angela, Scientific Chair ISoP 2022, Pontificia Universidad Javeriana (Colombia)
Chandler Rebecca, ISoP Vice-President, Coalition for Epidemic Preparedness Innovations (Sweden)
De Bernardi Barbara, Pfizer (Italy)
Edwards Brian, Chair of the Medication Error SIG, Husoteria Ltd (UK)
Edwards Ralph, former Director of Uppsala Monitoring Centre (Sweden)
Giezen Thijs, member of EMA Biosimilar working party (Netherlands)
Gini Rosa, Agenzia regionale di sanità della Toscana (Italy)
Goedecke Tomas, European Medicines Agency – EMA (Netherlands)
Grundmark Birgitta, Norwegian Medicines Agency (Norway)
Hagemann Ulrich, ISoP (Germany)
Härmark Linda, The Netherlands Pharmacovigilance Centre Lareb (Netherlands)
Harrison-Woolrych Mira, President of ISoP (New Zealand)
Hartigan-Go Kenneth, Asian Institute of Management (Philippines)
Ilic Katarina, Takeda (USA)
Ingrasciotta Ylenia, University of Verona (Italy)
Jew Rita, Institute for Safe Medication Practices (ISMP) (USA)
Kant Agnes, The Netherlands Pharmacovigilance Centre Lareb (Netherlands)
Lane Samantha, Drug Safety Research Unit (DSRU) (UK)
Laporte Joan Ramon, Autonomous University of Barcelona (Spain)
Leone Roberto, University of Verona (Italy)
Lino Maria Maddalena, Pfizer (Italy)
Lucenteforte Ersilia, University of Pisa (Italy)
Marchione Pasquale, Agenzia Italiana del Farmaco (AIFA) (Italy)
Mazzaglia Giampiero, Milano Bicocca university (Italy)
McCarthy Deirdre, ISoP Executive member, Gates MRI (USA)

Meldau Eva-Lisa, Uppsala Monitoring Centre (Sweden)
Menniti Ippolito Francesca, Italian National Health Institute and Chair of herbal remedies monitoring (Italy)
Moretti Ugo, University of Verona (Italy)
Nocini Pierfrancesco, University of Verona (Italy)
Pariente Antoine, University of Bordeaux (France)
Petracek Jan, ISoP Board member, Institute of Pharmacovigilance (Czech Republic)
Popoli Patrizia, President of Scientific Technical Committee of the Italian Drug Agency (Italy)
Racagni Giorgio, President of the Italian Society of Pharmacology (Italy)
Raschi Emanuel, University of Bologna (Italy)
Salvo Francesco, University of Bordeaux (France)
Sefiani Houda, Moroccan Pharmacovigilance Centre, Rabat WHO Collaborating Centre (Morocco)
Segec Andrej, European Medicines Agency – EMA (Netherlands)
Shakir Saad, Drug Safety Research Unit – DSRU (UK)
Skalli Souad, Chair of ISoP Herbal and Traditional Medicines SIG, Mohammed V University (Morocco)
Sturkenboom Miriam, University of Utrecht (Netherlands)
Tacconeli Evelina, University of Verona (Italy)
Tarapués Mónica, ISoP Board member, Central University of (Ecuador)
Toh Darren, Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute (USA)
Top Karina, Canadian Center for Vaccinology Dalhousie University, IWK Health Centre (Canada)
Tregunno Phil, Medicines and Healthcare products Regulatory Agency – MHRA (UK)
Trifirò Gianluca, Local Chair ISoP 2022, University of Verona (Italy)
Tuccori Marco, University of Pisa (Italy)
Van Puijenbroek Eugène, The Netherlands Pharmacovigilance Centre Lareb (Netherlands)
Wilkinson John, University of York (UK)
Yue Qun-Ying, Chair of the Pharmacogenomics SIG, Uppsala Monitoring Centre (Sweden)
Zaccaria Cosimo, European Medicines Agency – EMA (Netherlands)

Networking

Welcome Reception

Tuesday 20 September, 19:30–21:00

Venue: Cloister of San Francesco

Open to all ISoP 2022 delegates (badge required).

Drinks and canapés will be served.

We would like to invite all participants to join us for the official conference reception which will take place at the University of Verona, Cloister of San Francesco.

Attendees will have the opportunity to network with friends, colleagues and industry partners in a relaxed atmosphere whilst enjoying refreshments.

Student Meet and Greet

Wednesday 21 September, 18:00–19:30

Venue: Cloister of San Francesco.

Conference Dinner

Thursday 22 September, 19:30 – Midnight

Venue: Giardino e Palazzo dei Conti Giusti

Giardino e Palazzo dei Conti Giusti.

Dress code: Smart casual

Open to all ISoP 2022 delegates (badge required).

How to get there: The venue is 5-minute walk from the University of Verona.

Transfer from the ISoP 2022 venue is not provided.

The conference dinner will be held at the historical Giardino e Palazzo dei Conti Giusti. Attendees will enjoy welcome drinks and a dinner in a casual atmosphere, which will allow them to network and meet.

Verona

Verona, in the Veneto region of north-east Italy, is one of Italy's loveliest towns, famous for its summer opera season. This has been a thriving town for most of its history, and today smart shops and cafes fill the attractive medieval lanes of the historic centre. Verona is a popular day-trip from Lake Garda, and an appealing destination for weekend breaks or longer stays. There's a lot to see here, from Roman ruins to the so-called 'Juliet's balcony', and the town is also well-connected for exploring the surrounding area, including destinations like Lake Garda, Vicenza, Padua and Venice.

Points of interest:

- Castelvecchio and Ponte Scaligero
- Arena di Verona (Roman Amphitheater)
- Casa di Giulietta
- Basilica of San Zeno Maggiore
- Piazza delle Erbe
- Piazza dei Signori and Loggia del Consiglio
- Duomo di Santa Maria Matricolare (Cathedral)
- Giardino Giusti
- San Fermo Maggiore

Moving around

The historic center of Verona covers an area of about 3 square kilometers and can therefore be easily visited on foot. Some of the main monuments are very close to each other, such as the Arena, Castel San Pietro, and the Castelvecchio Bridge. The center is full of interesting shops and boutiques, as well as great restaurants and nightclubs where you can have fun late into the night. For longer journeys, Verona offers an excellent transport service, both by public and private transport such as the Verona public transport service, managed by the ATV, Verona Transport Company. The bus lines cover the entire city and neighboring municipalities.
Verona is a safe and well-equipped city for those who love to move around by bicycle, with many cycle paths in and out of the historic center.
The municipality runs a bike-sharing service called Verona Bike. To use it just register on the website. Registration for 24 hours costs € 2. The first 30 minutes of use are free and then the cost is € 0.50 every half hour.

Language

The official language is Italian but most of the restaurants and coffee staff speak English and German.

Weather and time

Verona is located in the north-east part of Italy, and it is 59 meters above sea level so the city experiences hot summers and cold, humid winters, even though tempered by Garda Lake's influence. In September, the Italian local time is UTC (GMT) + 2.

Taxes and tips

In Italy all the services and goods are usually subject to VAT tax which is 22 % of the value of the goods. In all restaurants, bars, taxis VAT is 10 % and is usually already included in the bill.

Hospitals

Ospedale Civile Maggiore
Piazzale A. Stefani, 1 – Verona
Policlinico G. Rossi Piazzale L.A. Scuro, 10 – Verona

Pharmacies

www.farmacieverona.it
Pharmacies are easy to recognize by a bright green cross. They are open: Monday–Friday, from 9:00 am to 12:00 am and from 4:00 pm to 7:00 pm.

Companies Profiles

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Eu2P + Am2P stands for "European and American programs in Pharmacovigilance and Pharmacoepidemiology". It is currently offering an innovative web-based education & training offer in Pharmacovigilance and Pharmacoepidemiology: – Master of Science programme: This curriculum includes mandatory and optional course modules, possibly leading to a Master Specialisation Track – Certificate courses: 29 different course modules to be attended on a single basis during the Master curriculum calendar – Short Courses: 65 bite-sized courses which have been designed out of the Master modules' course material and can be attended at anytime – PhD programme: A 3-years research programme leading to a research thesis and doctoral degree.

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ORGANISER

The International Society of Pharmacovigilance (ISoP) is a global professional, independent, not-for-profit society, open to anyone with an interest in the safe and effective use of medicinal products. ISoP aims to foster science, learning and research in pharmacovigilance in all countries.

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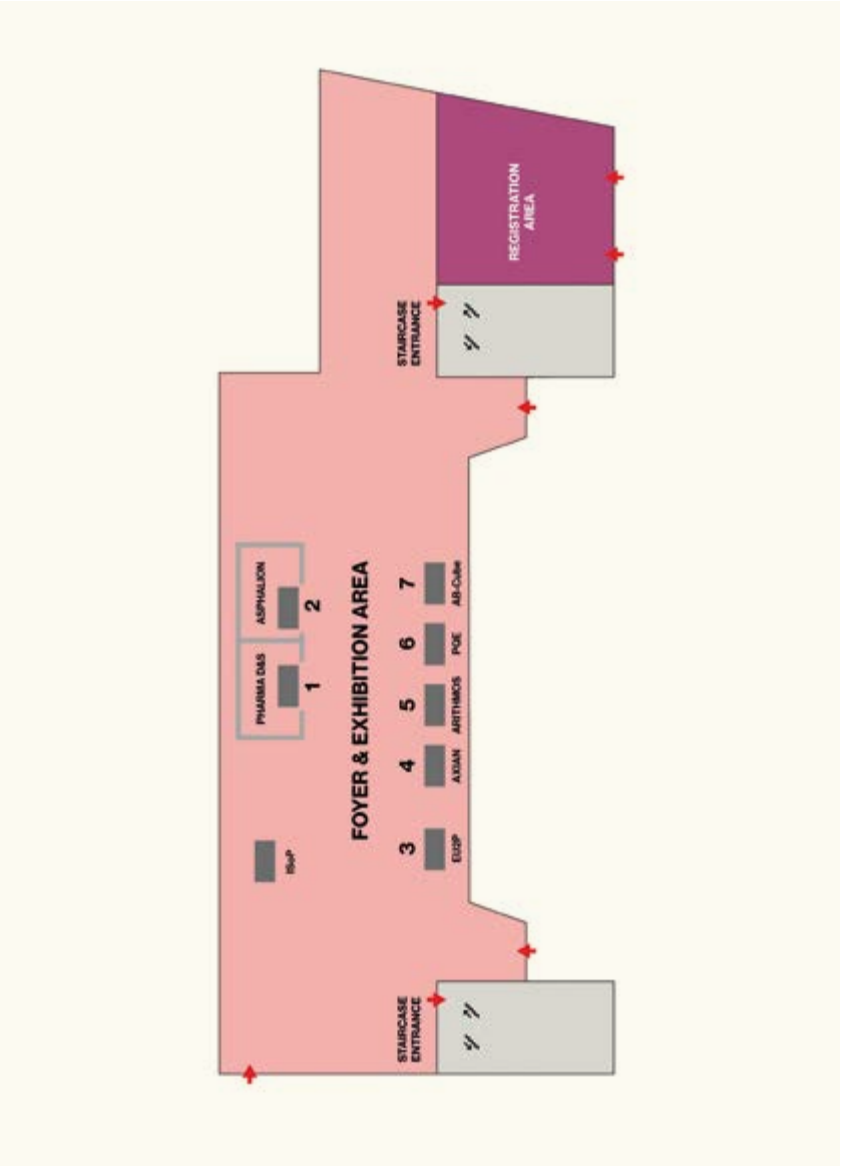
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06–09 November 2023

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2023 Annual Conference Bali, Indonesia

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