CHALLENGES IN POSTMARKETING STUDIES OF BIOLOGICAL DRUGS IN THE ERA OF BIOSIMILARS

Sponsored by
# ISPE’s 2019 Mid-Year Meeting

**April 6-9, 2019 | Radisson Blu ES Hotel | Rome, Italy**

## Registration Form

Use one form per person; use photocopies for additional registrations

First/Given Name ___________________________ Last/Family Name ___________________________

Position/Title ___________________________ Company/Institution/Affiliation ___________________________

Street Address ______________________________________________________________________________

City ___________________________ State/Province ___________ Zip/Postal Code ___________________________

Country _________________________________________ Email _____________________________________________________

Office Phone (_______)_____________________________________ Cell (_______)______________________________________

*Special Dietary/Accessibility Requirements __________________________________________________________

*Please describe in detail

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## Registration Fees (US Dollars)

**ISPE: Mid-Year Symposium registration includes admission to welcome reception, food functions, and meeting materials.**

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<th>ISPE Member</th>
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## New ISPE Membership (NOT for Dues Renewal)

- Regular ☐ $275 Retired ☐ $85
- Special* ☐ $25 **Membership will expire June 30, 2020.**
- Student/Recent Graduate** ☐ $85

**TOTAL** (REGISTRATION + NEW MEMBERSHIP = $ _______ )

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### Notes:

* Individual must be a citizen and resident of a country classified as High, Medium or Low Human Development as identified by the United Nations (Source: Human Development Report 2016)

** Students/recent graduates must provide ISPE with 1) Documentation of Full-Time Status OR 2) Proof of recent graduation, within 3 years of meeting dates via email info@pharmacoepi.org or fax 301.656.0989.

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**PAYMENT**

Payment by credit card (US DOLLARS)

☐ American Express ☐ Visa ☐ Master Card

Please Print

- Account Number
- Security Code
- Name Exactly as it Appears on Card
- Expiration Date (Month/Year)

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### Cancellation/Refund Policy

To cancel your registration for any reason, ISPE must receive written notification by March 1, 2019. Refunds will be issued, less a 20% administrative fee, after the meeting. No refunds will be issued for cancellation received after March 1, 2019.
CHALLENGES IN POSTMARKETING STUDIES OF BIOLOGICAL DRUGS IN THE ERA OF BIOSIMILARS

SATURDAY - APRIL 6
8:30am – Noon | ISPE Strategic Planning Committee
1:00pm – 5:00pm | ISPE Board of Directors Meeting
ISPE members are encouraged to contact staff if interested in attending the Board meeting

SUNDAY, APRIL 7
7:00am – 6:00pm | Registration
8:00am – Noon | Pre-conference Course* | Introduction to Pharmacoepidemiology
Almut Winterstein, FISPE, College of Pharmacy, University of Florida, Cohort Studies
Anton Pottegård, Clinical Pharmacology and Pharmacy, University of Southern Denmark, Case-Control
Tobias Gerhard, FISPE, Ernest Mario School of Pharmacy, Rutgers University, Bias & Confounding
8:30am – Noon | 2019 Scientific Program Committee Meeting
Noon – 1:30pm | Lunch on your own
1:30pm – 5:30pm | Pre-conference Course* | Advanced Topics in Pharmacoepidemiology
Miriam Sturkenboom, FISPE, University Medical Center Utrecht
Innovative Approaches in Vaccine Post-Marketing Surveillance
Stephen Evans, FISPE, London School of Hygiene and Tropical Medicine – Signal Detection: Where Do We Stand?
Nicholas Tatonetti, Institute for Genomic Medicine, Columbia University – Observational Data for Biomedical Discovery
5:30pm – 7:00pm | Welcome Reception

MONDAY, APRIL 8
7:30am – 5:00pm | Registration
7:30am – 8:15am | Exhibits/Poster Viewing/Refreshments

*Additional registration required

8:30am – 9:15am | Opening Remarks
Alison Bourke, FISPE, ISPE President
Gianluca Trifirò, Co-Chair, ISPE 2019 Mid-Year Planning Committee
Ursula Kirchmayer, Co-Chair, ISPE 2019 Mid-Year Planning Committee
Welcome address: Italian Minister of Health
Director, Italian Medicines Agency
9:15am – 11:00am | Regulatory Perspectives
TBA
9:15am – 9:45am | Thijs Giezen, Biosimilar Medicinal Products Working Party, European Medicines Agency
9:45am – 10:15am | Gerald Dal Pan, US Food & Drug Administration
10:15am – 10:45am | TBA, Japanese Pharmaceuticals and Medical Devices Agency
10:45am – 11:00am | Discussion
11:00am – 1:15pm | Scientific Perspectives on Biologic and Biosimilar Use
Moderators: Alessandro Mugelli, University of Florence
Sebastian Schneeweiss, FISPE, Harvard Medical School/Brigham & Women's Hospital
Johannes W.J. Bijlsma, University Medical Center Utrecht, Rheumatology
1:00pm – 1:15pm | Discussion
1:15pm – 2:15pm | Lunch/Exhibits/Poster Viewing

Save $50! Register by March 1st
Register Online
PHARMACOEPI.ORG Today!
MONDAY, APRIL 8 (Continued)

2:15pm – 3:45pm | Student Oral Session I (6 Talks)
Moderators: Lindsay Wong, Chair, ISPE Student Council, University of Toronto
            Ursula Kirchmayer, Department of Epidemiology, Lazio Region

3:45pm – 4:15pm | Refreshment Break/Exhibits/Poster Viewing

4:15pm – 5:45pm | Student Oral Session II (6 Talks)
Moderators: Caroline Walsh, Co-Chair, ISPE Student Council, Royal College of Surgeons in Ireland
            Gianluca Trifirò, University of Messina & Erasmus University Medical Center

5:45pm – 6:00pm | Closing Remarks

6:00pm – 7:30pm | Student/Early Career Professionals Meet & Greet

TUESDAY, APRIL 9

8:00am – Noon | Registration
8:00am – 9:00am | Exhibits/Poster Viewing/Refreshments
9:00am – 10:40am | Interchangeability of Originators and Biosimilars: Pre- vs. Post-Marketing Evidence
Moderators: Jaclyn Bosco, IQVIA
            Gianni Corrao, University Milano Bicocca

9:00am – 10:00am | Tore K. Kvien, University of Oslo, The NOR-SWITCH Study – An Example for RCTs

10:00am – 10:30am | Francesco Trotta, Italian Medicines Agency, The Role of Observational Studies: An Example from the Italian Bio-Network

10:30am – 10:40am | Discussion

10:40am – 11:00am | Coffee Break/Exhibits/Poster Viewing

11:10am – 1:20pm | Infrastructure for RWE on Biologics and Biosimilars: Specific Issues
Moderators: Marina Davoli, Department of Epidemiology, Lazio Region
            Jesper Hallas, FISPE, University of Southern Denmark

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11:10am – 11:40am | Bente Glintborg, DANBIO, Disease Registries

11:40am – 12:10pm | TBA, The Industry’s Perspective

12:10pm – 12:40pm | Jeffrey Brown, Harvard Medical School/ Harvard Pilgrim Health Institute, Experiences from Networks in the US

12:40pm – 1:10pm | Nello Martini, Drugs & Health, Real World Data in Research on Biologics and Biosimilars for Informed Decisions Regulation Making

1:10pm – 1:20pm | Discussion

1:20pm – 1:30pm | Closing Remarks & Adjournment

Gianluca Trifirò, Co-Chair, ISPE 2019 Mid-Year Meeting Planning Committee
Ursula Kirchmayr, Co-Chair, ISPE 2019 Mid-Year Meeting Planning Committee