



April 6-9, 2019 • Rome, Italy
Radisson Blu es. Hotel



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

Sponsored by



DIEP/Lazio
Department of Epidemiology
Lazio Regional Health
Service, Italy



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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*

REGISTRATION FEES (US Dollars)

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

ADVANCE DEADLINE MARCH 1, 2019 CHECK BOX	Sunday, April 7/8am-12pm Intro to Pharmacoepi		Sunday, April 7/1:30pm-5:30pm Adv. Topics in Pharmacoepi		Monday, April 8/8:30am-6pm Tuesday, April 9/9am-1:15pm Symposium*	
	Advance by Mar. 1	On-site After Mar. 1	Advance by Mar. 1	On-site After Mar. 1	Advance by Mar. 1	On-site After Mar. 1
ISPE Member						
Industry/Service Provider	<input type="checkbox"/> \$325	<input type="checkbox"/> \$375	<input type="checkbox"/> \$325	<input type="checkbox"/> \$375	<input type="checkbox"/> \$550	<input type="checkbox"/> \$600
Academic	<input type="checkbox"/> \$200	<input type="checkbox"/> \$250	<input type="checkbox"/> \$200	<input type="checkbox"/> \$250	<input type="checkbox"/> \$350	<input type="checkbox"/> \$400
Government	<input type="checkbox"/> \$200	<input type="checkbox"/> \$250	<input type="checkbox"/> \$200	<input type="checkbox"/> \$250	<input type="checkbox"/> \$350	<input type="checkbox"/> \$400
Retired	<input type="checkbox"/> \$55	<input type="checkbox"/> \$105	<input type="checkbox"/> \$55	<input type="checkbox"/> \$105	<input type="checkbox"/> \$135	<input type="checkbox"/> \$185
Special*	<input type="checkbox"/> \$55	<input type="checkbox"/> \$105	<input type="checkbox"/> \$55	<input type="checkbox"/> \$105	<input type="checkbox"/> \$135	<input type="checkbox"/> \$185
Student/Recent Graduate**	<input type="checkbox"/> \$55	<input type="checkbox"/> \$105	<input type="checkbox"/> \$55	<input type="checkbox"/> \$105	<input type="checkbox"/> \$135	<input type="checkbox"/> \$185
Non-Member						
Industry/Service Provider	<input type="checkbox"/> \$375	<input type="checkbox"/> \$425	<input type="checkbox"/> \$375	<input type="checkbox"/> \$425	<input type="checkbox"/> \$625	<input type="checkbox"/> \$675
Academic	<input type="checkbox"/> \$255	<input type="checkbox"/> \$305	<input type="checkbox"/> \$255	<input type="checkbox"/> \$305	<input type="checkbox"/> \$440	<input type="checkbox"/> \$465
Government	<input type="checkbox"/> \$255	<input type="checkbox"/> \$305	<input type="checkbox"/> \$255	<input type="checkbox"/> \$305	<input type="checkbox"/> \$440	<input type="checkbox"/> \$465
Retired	<input type="checkbox"/> \$65	<input type="checkbox"/> \$115	<input type="checkbox"/> \$65	<input type="checkbox"/> \$115	<input type="checkbox"/> \$150	<input type="checkbox"/> \$200
Special*	<input type="checkbox"/> \$65	<input type="checkbox"/> \$115	<input type="checkbox"/> \$65	<input type="checkbox"/> \$115	<input type="checkbox"/> \$150	<input type="checkbox"/> \$200
Student/Recent Graduate**	<input type="checkbox"/> \$65	<input type="checkbox"/> \$115	<input type="checkbox"/> \$65	<input type="checkbox"/> \$115	<input type="checkbox"/> \$150	<input type="checkbox"/> \$200

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 = \$ _____)

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.

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) _____

REGISTER BY

MAIL ISPE 2019 Mid-Year Meeting
 5272 River Road, Suite 500
 Bethesda, MD USA 20816

WEB pharmacoepi.org

FAX Registration form with credit card information to the ISPE Office at 301.656.0989

ISPE Federal Tax ID: 41-1688677

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.



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PRELIMINARY AGENDA



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 Pharmacoeconomics**
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 Pharmacoeconomics**
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*
Samy Suissa, McGill University, *The Prevalent New-User Design in Pharmacoeconomics*

5:30pm – 7:00pm | **Welcome Reception**

MONDAY, APRIL 8

7:30am – 5:00pm | **Registration**

7:30am – 8:15am | **Exhibits/Poster Viewing/Refreshments**

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 and Industry Perspectives**
Moderators: **Patrizia Popoli**, President of the Scientific Committee of the Italian Medicines Agency (tbc), Italian National Health Institute
June Raine, Medicines and Healthcare Products Regulatory Agency, London, UK

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 | **The Industry's Perspective**, EFPIA

10:45am – 11:00am | **Discussion**

11:00am – 11:30am | **Coffee Break/Exhibits/Poster Viewing**

11:30am – 1:15pm | **Perspectives from Scientific Societies on Biologic and Biosimilar Use**

Moderators: **Alessandro Mugelli**, University of Florence
Sebastian Schneeweiss, FISPE, Harvard Medical School/Brigham & Women's Hospital

11:30am – 12:00pm | **Gionata Fiorino**, European Crohn's and Colitis Organization (ECCO)

*Additional registration required

Save \$50! Register by March 1st

Register Online
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International Society for Pharmacoepidemiology

5272 River Road, Suite 500

Bethesda, MD 20816 USA

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PRELIMINARY AGENDA *(Continued)*

MONDAY, APRIL 8 *(Continued)*

-
- 12:00pm – 12:30pm | **Gary Lyman**, American Society of Clinical Oncology (ASCO)
-
- 12:30pm – 1:00pm | **Tore K. Kvien**, University of Oslo, European League Against Rheumatism (EULAR)
-
- 1:00pm – 1:15pm | **Discussion**
-
- 1:15pm – 2:15pm | **Lunch/Exhibits/Poster Viewing**
-
- 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 Trifiro, University of Messina
-
- 5:45pm – 6:00pm | **Closing Remarks**
-
- 6:00pm – 7:30pm | **Student/Early Career Professionals Meet & Greet**

TUESDAY, APRIL 9

-
- 8:00am – 12:00pm | **Registration**
-
- 8:00am – 9:00am | **Exhibits/Poster Viewing/Refreshments**
-
- 9:00am – 10:45am | **Interchangeability of Originators and Biosimilars**
Moderators: **Jaclyn Bosco**, IQVIA
Gianni Corrao, University Milano Bicocca

-
- 9:00am – 9:30am | **Kristine Moll Harboe**, Danish Medicines Agency, Interchangeability of Reference Product and Biosimilars: Where Do We Stand?
-
- 9:30am – 10:00am | **Bente Glintborg**, DANBIO, Disease Registries
-
- 10:00am – 10:30am | **Francesco Trotta**, Italian Medicines Agency, The Role of Observational Studies: An Example from the Italian Bio-Network
-
- 10:30am – 10:45am | **Discussion**
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- 10:45am – 11:15am | **Coffee Break/Exhibits/Poster Viewing**
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- 11:15am – 1:15pm | **Infrastructure for RWE on Biologics and Biosimilars**
Moderators: **Marina Davoli**, Department of Epidemiology, Lazio Region
Jesper Hallas, FISPE, University of Southern Denmark
-
- 11:15am – 11:45am | **Jeffery Brown**, Harvard Medical School/Harvard Pilgrim Health Institute, Experiences from Networks in the US
-
- 11:45am – 12:15pm | **Andrew Bate**, Pfizer, Global Real-World Data-Based Strategies for Biologics/Biosimilar Postmarketing Surveillance?
-
- 12:15pm – 12:45pm | **Nello Martini**, Drugs & Health, Real World Data on Biologics and Biosimilars for Informed Regulatory Decision Making
-
- 12:45pm – 1:15pm | **Discussion**
-
- 1:15pm – 1:30pm | **Closing Remarks & Adjournment**
Gianluca Trifiro, Co-Chair, ISPE 2019 Mid-Year Meeting Planning Committee
Ursula Kirchmayer, Co-Chair, ISPE 2019 Mid-Year Meeting Planning Committee