



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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ROMA 1



REGIONE  
LAZIO



# ISPE'S 2019 MID-YEAR MEETING

APRIL 8-9, 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
<b>ISPE Member</b>						
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
<b>Non-Member</b>						
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"/> \$55	<input type="checkbox"/> \$75	<input type="checkbox"/> \$55	<input type="checkbox"/> \$75	<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*

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

Moderators: **June Raine**, Medicines and Healthcare Products  
Regulatory Agency, London, UK  
**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 – 11:30am | Coffee Break/Exhibits/Poster Viewing

11:30am – 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

11:30am – Noon | **TBA**, European Crohn's and Colitis  
Organisation (ECCO)

Noon – 12:30pm | **TBA**, Oncology

12:30am – 1:00pm | **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 1<sup>st</sup>**

**Register Online**  
**PHARMACOEPI.ORG Today!**

**International Society for Pharmacoepidemiology**

5272 River Road, Suite 500

Bethesda, MD 20816 USA

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## PRELIMINARY AGENDA *(Continued)*

### 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 Trifiro**, 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 – 9:30am | **TBA**, Interchangeability of Reference Product  
and Biosimilars: Where Do We Stand?

9:30am – 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 – 11:10am | **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

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 Regulatory Making

1:10pm – 1:20pm | **Discussion**

1:20pm – 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