



INSPIRE

Innovative Solutions for medical Prediction
and big data Integration in Real world setting



Webinar
22nd September 2021

6TH SYMPOSIUM ON THE ROLE OF THE REAL WORLD EVIDENCE TO SUPPORT REGULATORY DECISION MAKING:

*Post-marketing surveillance of biologics in real world
setting: which strategies?*

Under the auspices of



International Society
of Pharmacovigilance

AGENDA

10:30-10:45 am - Welcome

Professor Giorgio Racagni – President of the Italian Society of Pharmacology - SIF

Professor Gianluca Trifirò – Full Professor of Pharmacology – Department of Diagnostics and Public Health, University of Verona

Dr. Mira Harrison-Woolrych – President of the International Society of Pharmacovigilance

1st session

10:45 am - 1:30 pm - Italian Experience (in Italian)

Moderators: Francesco Trotta - HTA Division at the Italian Medicines Agency (AIFA) – *Invited (TBC)*

Nello Martini – ReS Foundation

10:45 am - 11:05 am - **The role of registries to conduct post-marketing surveillance: the example of monoclonal antibodies for the treatment of COVID-19**

Pierluigi Russo - Monitoring Registers Office, Italian Medicines Agency (AIFA)

11:05 am – 11:25 am – **From the Italian Network for Monitoring Medication Use During Pregnancy (MoM-Net) to the PsoMother Project**

Valeria Belleudi - Department of Epidemiology, Lazio Regional Health Service

11:25 am - 11:45 am - **A multi-Regional distributed database network for post-marketing surveillance of biological drugs: the VALORE Project**

Ylenia Ingrassiotta – Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

11:45 am - 12:00 pm - **Discussion**

12.00 pm - 1.30 pm - **Round table “Which priorities for the post-marketing monitoring of biological drugs in clinical practice?”**

Moderators: Gianluca Trifirò - Department of Diagnostics and Public Health, University of Verona

Antonio Addis - Department of Epidemiology, Lazio Regional Health Service; Scientific Technical Committee, Italian Medicines Agency

Carlo Salvarani – University of Modena and Reggio Emilia; Unit of Rheumatology - IRCCS “S. Maria Nuova”, Reggio Emilia

Luigi Naldi - Department of Dermatology – San Bortolo Hospital AULSS 8 Berica, Vicenza; GISED Study Center

Stefano Collatina– Equalia Industrie Farmaci Accessibili

Giovanna Scroccaro – Head of Pharmaceutical and Medical Device Department, Veneto Region

Anna Rosa Marra – Head of Post-Marketing surveillance – Italian Medicines Agency (AIFA)

Anna Maria Porrini – Roche – Medical Director – Roche Farmindustria – (TBC)

1:30 pm - 1:45 pm - **Discussion**

1:45 pm - 2:30 pm - **Break**

2nd Session

2:30 pm - 4:30 pm - Overview of research network and international real-world studies for post-marketing surveillance of biological drugs (In English)

Moderators: Jessica Jalbert - Regeneron Pharmaceuticals

Ursula Kirchmayer - Department of Epidemiology, Lazio Regional Health Service

2:30 pm - 2:50 pm - **Post-marketing surveillance of biological drugs: US experience**

Seoyoung C. Kim - Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital and Harvard Medical School, Boston; Division of Rheumatology, Inflammation, and Immunity, Brigham and Women's Hospital and Harvard Medical School, Boston

2:50 pm – 3:10 pm - **Priorities for post-marketing surveillance of biological drugs: regulatory perspective**

Helga Gardarsdottir – Drug Regulatory Sciences at the Division of Pharmacoepidemiology & Clinical Pharmacology, Utrecht University

3:10 pm - 3:30 pm – **The experience of the DANBIO Registry**

Bente Glintborg – The DANBIO Registry Rigshospitalet, and Department of Rheumatology, Gentofte and Herlev University Hospital – *Invited (TBC)*

3:30 pm - 3:50 pm - **The experience of the Biologics & Biosimilars Collective Intelligence Consortium (BBCIC)**

Cate Lockhart - Executive Director, Biologics and Biosimilars Collective Intelligence Consortium- BBCIC

3:50 pm - 4:10 pm – **TheShinISS: a tool for conducting distributed analyses in pharmacoepidemiology studies on biological drugs**

Marco Massari/Stefania Spila Alegiani - Pharmacoepidemiology Unit, National Center for Research and Pre-clinical and Clinical Evaluation of Drugs, National Health Institute

4.10 pm - 4.30 pm – **Discussion**

Conclusion

Gianluca Trifirò - Department of Diagnostics and Public Health, University of Verona



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