22nd September 2021

Webinar

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?

Rational

In recent years, healthcare databases have become increasingly important because of their potential to rapidly conduct analyses aimed at evaluating the pattern of use and the benefit-risk profile of drugs through data from clinical practice. Scientific evidence on potential benefits and risks of drugs, derived from the analysis of Real World Data and therefore relating to the use of drugs in the real-world setting, is known as *Real World Evidence* and it is fundamental to integrate pre-marketing evidence on drugs generated by clinical trials. If Real World Evidence is based on the analysis of good-quality data and on the correct interpretation of the results, it constitutes a valid support for regulatory decision-making. Many experiences have been conducted in order to optimize the use of Big Data and to apply artificial intelligence in several areas of medicine, including pharmacovigilance.

In Italy, data infrastructures have been created from clinical practice, by integrating claims data with data from clinical registries of local networks and data collected during active surveillances. Clinical registries have been also used in several European countries to conduct post-marketing studies on the safety of drugs used for the treatment of immune-mediated inflammatory diseases (IMID). Furthermore, in the United States, the Biologic and Biosimilar Collective Intelligence Consortium (BBCIC) was established in 2015. It is a non-profit research network with the aim of conducting observational analysis on the safety and efficacy of biological drugs.

All these infrastructures play a key role in the evaluation of the risk-benefit profiles of biological drugs. Biological drugs have revolutionized the treatment of IMID in different therapeutic areas, especially in the dermatology, rheumatology, gastroenterology and onco-hematology setting. However, the use of these drugs has been associated with the onset of several safety issues, including hypersensitivity and immunogenicity reactions, infections and malignancies. Moreover, with the current pandemic caused by SARS-CoV-2, there is uncertainty about the prognosis of COVID-19 in patients chronically treated with biological drugs. Because of these issues, it is necessary to monitor biological drugs, facing challenges related to data infrastructure, in order to obtain useful and updated large-scale clinical data relating to the safety of biological drugs.

The sixth edition of this symposium aims at comparing the needs and priorities of the institutional/regulatory world and the scientific experience of national and international research groups on the generation of Real World Evidence, in order to conduct post-marketing evaluations on the benefit-risk profile of biological drugs.

Agenda:

22nd September 2021

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 - 1:45 pm – Italian Experience *(in Italian)*

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

  Gianluigi Bajocchi – *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*
  Enrica Tornielli – *Egualia Industrie Farmaci Accessibili*
  Giovanna Scroccaro –*Pharmaceutical and Medical Device Department, Veneto Region*
  Anna Rosa Marra –*Post-Marketing surveillance Department – Italian Medicines Agency (AIFA)*

Anna Maria Porrini – *Farmindustria*

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*

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

- 4.10 pm - 4.30 pm – **Discussion**

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

SCIENTIFIC COMMITTEE

Trifirò Gianluca *– Full Professor of Pharmacology, Department of Diagnostics and Public Health, University of Verona, Italy*
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FACULTY
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Porrini Anna Maria *– Farmindustria, Italy*
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