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ISoP International Society of Pharmacovigilance
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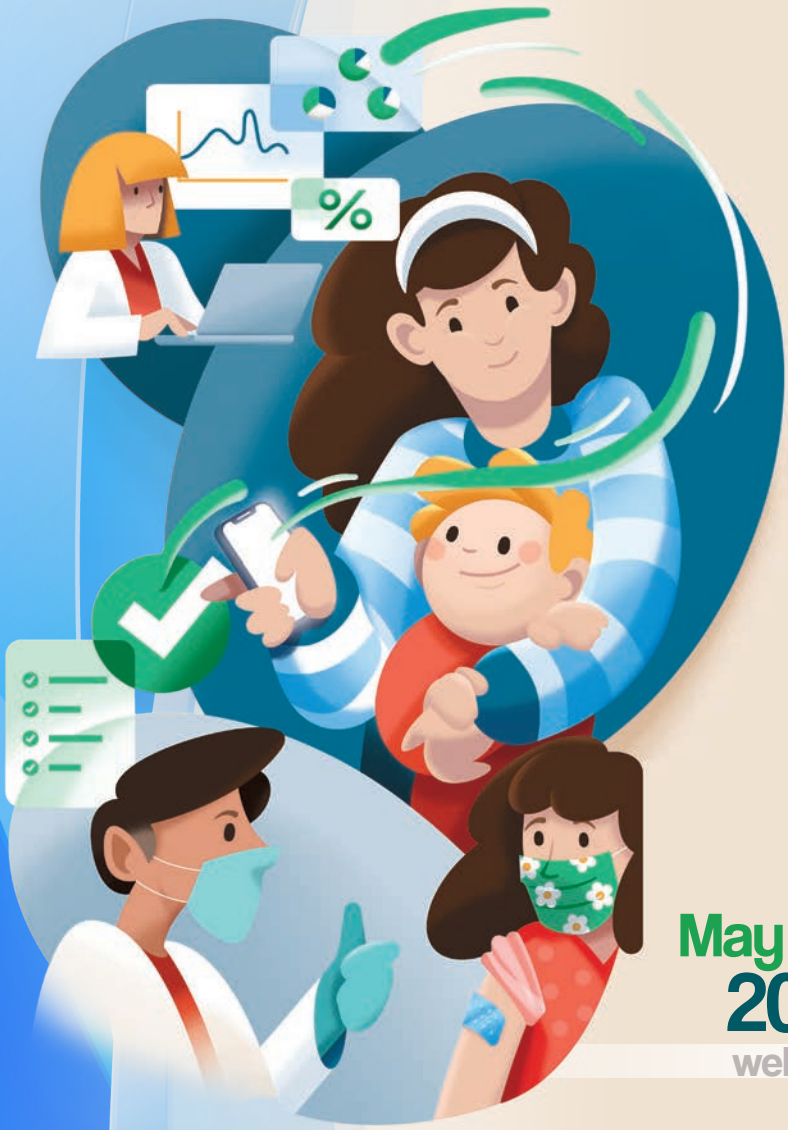
Post-marketing surveillance of vaccines against COVID-19: where do we stand?



May 28, 2021
webinar

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DI FARMACOLOGIA

Post-marketing surveillance of vaccines against COVID-19: where do we stand?

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Four COVID-19 vaccines have been marketed in Europe since December 2020. This has happened incredibly fast as a result of a collective effort by regulatory agencies, pharmaceutical companies and the scientific community.

Other vaccines are currently being reviewed by the European Medicine Agency (EMA) and will soon be authorized for use.

However, all the vaccines have been approved for the market on the basis of the so-called conditional approval. This was granted as post-marketing data on the efficacy and safety of COVID19 vaccines were provided to EMA by the pharmaceutical companies to re-evaluate more accurately the risk-benefit profile of such vaccines.

In this regard, numerous post-marketing surveillance programs for COVID19 vaccines have been funded both nationally and internationally and new evidence on the comparative risk- benefit profile of the different vaccines will soon be available.

The aim of this international webinar is to provide an update on effectiveness and safety of the different COVID19 vaccines authorized in the EU, highlighting the evidence that has been generated until now and the areas of uncertainty that requires further investigation.

SCIENTIFIC SECRETARIAT

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Course schedule

09:00 **Introduction**
G. Racagni (President of the Italian Society of Pharmacology)
R. Chandler (Vice-President of the International Society of Pharmacovigilance)
G. Trifirò/A. Capuano (GdL 3F & RWE – SIF)

Chair: Ugo Moretti (University of Verona) and Marco Tuccori (Academic Hospital of Pisa)

09:15 **Available vaccines against COVID19 and emerging safety signals from PRAC**
Amelia Cupelli (AIFA)

09:45 **COVID19 vaccine safety: an European regulatory perspective**
Sabine Straus (PRAC EMA)

10:15 **Large scale program for COVID-19 vaccine monitoring in Europe: from event cohort monitoring to healthcare database networks**
Miriam Sturkenboom (University of Utrecht)

10:45–11:00 *Break*

Chair: A. Capuano (University of Campania) and G. Trifirò (University of Verona)

11:00–12:30 **Round table – COVID-19 and vaccinovigilance: state of the art (in italian)**
E. Coscioni (Agenas); C. Cricelli (Italian Society of General Medicine & Primary Care); P. Popoli (Italian National Institute of Health); A.R. Marra (Post Marketing Surveillance Department - AIFA); M. Cattani (Farmindustria - Association of Pharmaceutical Companies); G. Scroccaro (Veneto Region); S. Tonolo (National Association of patients with rheumatic diseases).

12.30-12.45 **Questions and answer**

12.45-13.00 **Concluding remarks**
Prof. G. Racagni (President of the Italian Society of Pharmacology)
Prof. Gianluca Trifirò (Chair of 3F & RWE working group - SIF)

ITALIAN CME CREDITS
The webinar gives the possibility to acquire CME credits for all italian health professions. The course will be carried out remotely by connecting to a multimedia platform, which allows the total tracking of the activity of the individual participant.

For register please click here
https://www.sifweb.org/eventi/eventi_SIF/webinar-post-marketing-surveillance-of-vaccines-against-covid-19-where-do-we-stand-2021-05-28

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Scientific Committee

- **Giorgio Racagni**
  President of the Italian Society of Pharmacology (SIF)
- **Gianluca Trifirò**
  Full Professor of Pharmacology of the Department of Diagnostics and Public Health, University of Verona, Verona, Italy; Chair of 3F and RWE working group - SIF
- **Annalisa Capuano**
  Full Professor of applied technical and medical sciences at Department of Experimental Medicine - University of Campania "Vanvitelli", Naples, Italy and Head of Campania Regional Pharmacovigilance Centre
- **Ugo Moretti**
  Associate Professor of Pharmacology, Department of Diagnostics and Public Health, University of Verona, Verona, Italy and Head of Veneto Regional Pharmacovigilance Centre
- **Marco Tuccori**
  Head of Pharmacovigilance of the Unit of Adverse Drug Reactions Monitoring, Pisa University Hospital, Pisa, Italy

Faculty

- **Rebecca Chandler**
  Vice-President of International Society of Pharmacovigilance
- **Sabine Straus**
  Chair of the Pharmacovigilance Risk Assessment Committee (PRAC), European Medicines Agency (EMA)
- **Amelia Cupelli**
  Italian Medicines Agency (AIFA) – Italian referent member of PRAC
- **Miriam Sturkenboom**
  Professor of Observational Data Analysis of the Department of Biostatistics and Research Support, University of Utrecht, Utrecht, The Netherlands
- **Enrico Coscioni**
  President of National Agency for Regional Health Services (Agenas)
- **Claudio Cricelli**
  President of Italian Society of General Medicine & Primary Care (SIMG)
- **Patrizia Popoli**
  Head of the National center for drug research and evaluation - Italian National Institute of Health (ISS)
- **Anna Rosa Marra**
  Head of Post Marketing Surveillance Department – Italian Drug Agency (AIFA)
- **Marcello Cattani**
  Italian Association of Pharmaceutical Companies (Farmindustria) advisory board component
- **Giovanna Scroccaro**
  Head of Pharmaceutical Department, Veneto Region, Venezia, Italy
- **Silvia Tonolo**
  President of National Association of patients with rheumatic diseases (ANMAR)