



ENCePP plenary meeting – 30th November 2022

Collaboration between ENCePP and ISOP (International Society of Pharmacovigilance)

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ISoP 2022 21st Annual Meeting

A New Era of Pharmacovigilance: Challenges and Opportunities



To keep PV community updated on emerging topics in PV!

THURSDAY 22 SEPTEMBER 2022

Plenary Session 2A

08:30 – 10:10
Room T2/T3

Big Data for PV - are we delivering on the promises?

Chairs: Gianmario Candore (Bayer, Germany) and Deirdre McCarthy (ISoP EC member, Gates MRI, USA)

08:30 09:00 **2A1:**
Big data vs. smart data for post-marketing surveillance of drugs/vaccines
Gianluca Trifirò (Department of Diagnostics and Public Health - University of Verona, Italy)

09:00 09:30 **2A2:**
How big data support post marketing surveillance in USA: the Sentinel initiative
Darren Toh (Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute, USA)

09:30 10:00 **2A3:**
Data Analysis and Real World Interrogation Network (DARWIN EU®)
Andrej Šegec (European Medicines Agency – EMA, Netherlands)

10:00 10:10 **Q&A**



Educational activities

- ISOP pre-conference course
- Joint webinar/workshop



Scientific collaboration

ISOP Big Data and RWE SIG:

To develop methodological papers on how SRS and RWE should complement with each other and more in general on the role of RWE/big data in all the stages of signal management process, with a special focus on signal detection;

A mapping exercise of all the ongoing initiatives concerning signal detection using large scale distributed database networks.