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Massoud Toussi

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Generating real world evidence for regulators: the past, the present and the future

This keynote session will be divided into three sections: In the first part, a review of post authorization safety studies (PASS) from EU-PAS Register will be conducted. The characteristics of PASS in terms of the objectives (investigation of safety concerns, study of drug utilization, assessment of risk minimization measures, etc), the design (longitudinal, cross sectional), the data sources (primary, secondary), and the endpoints will be presented and compared between PASS registered from 2012 to 2015 and those conducted from 2015 to 2020. In a second part, an unpublished study of the interactions with the Pharmacovigilance Risk Assessment Committee (PRAC) over the protocol of 12 studies measuring risk minimization measures (RMMs) will be presented and the strategies for interacting with PRAC will be discussed. In the last part, the trends and perspectives for future of PASS will be presented and brief insights about these perspectives will be provided ot the audience. These include more involvement of different stakeholders, especially patients, in defining research questions, more systematic use of secondary data and data landscaping, increased integration of automation and common data models in evidence generation, and enhanced transparency requirements.

Biography

Dr Massoud Toussi is the global offering lead for post authorization safety and effectiveness studies. He has more than 20 years of experience in the design, development and conduct of studies. He conducted as principal investigator or epidemiologist more than 300 studies, including clinical trials, post authorization safety (PASS), and outcomes research (OR) studies using both primary and secondary data. He is medical doctor and PhD in Pharmacoepidemiology. He is a member of the editorial board of the Methodological Standards Guide of the European Network of Centers of Pharmacoepidemiology and Pharmacovigilance (ENCePP), Chair of the Real World Evidence and Artificial Intelligence in Health Technology Assessment International (HTAi), member of the Transparency Steering Committee of the International Society of Outcomes Research (ISPOR) and member of the Board of directors of EU2P. He is also the Editor-in-Chief of Epidemiology Open Access and co-author of several articles and books including The PASS Book.