

Agenda

4th Swissmedic Roundtable Innovation (RTI)

Real-World-Evidence for Regulatory Decision-making: Promises, Limitations and Challenges

October 18th, 2024, 09:30 - 12:30

Swissmedic, H044, Hallerstrasse 7, Bern

09:30-09:40	Welcome and Introductions Dr. Eveline Trachsel, Head medicinal product authorisation and vigilance
09:40-09:55	Philosophical perspectives Michaela Egli, Philosophy of Medicine, University of Geneva & ELSI project manager SPHN
09:55-10:10	Academic perspectives PD Dr. med. Lars Hemkens, Lead Pragmatic Trials and Real World Evidence, University of Basel
10:10-10:25	Industry perspectives Dr. Gracy Crane, RWD policy and chapter lead, Global Regulatory Science, Roche
10:25-10:55	COFFEE BREAK
10:55-11:10	Regulatory perspectives Lorenzo Hess, Biostatistical Assessor Swissmedic
11:10-11:25	European Regulatory perspectives Dr. Patrice Verpillat, Data Analytics and Methods Task Force (TDA), Head of Real World Evidence (TDA-RWE), EMA
11:25-12:20	Open discussion Moderator: Dr. Eveline Trachsel, Head medicinal product authorisation and vigilance
12:20-12:30	Closing remarks and next steps Dr. Eveline Trachsel, Head medicinal product authorisation and vigilance

End of the Roundtable Innovation