



14 November 2023
EMA/296352/2023

Agenda – 18th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

22 November 2023, 13:00-16:30, Virtual meeting

Co-Chairs: Sabine Straus and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome and matters arising - Sabine Straus and Evdokia Korakianiti	13:00-13:10 10 min
2.	Artificial Intelligence in Pharmacovigilance - EMA update: Julie Durand (EMA) - Application in small patient populations / orphan indications: Peter De Veene (EUCOPE) Q&A (All)	13:10-13:40 10 min 10 min 10 min
3.	Good Pharmacovigilance Practices (EU-GVP) – Update - Priya Bahri (EMA) Q&A (All)	13:40-14:05 15 min 10 min
4.	Risk Management Plans - EMA transparency measures: Emil Cochino (EMA), Q&A (All) - Guideline on Specific Adverse Reaction Follow-up questionnaires, Specific AR FUQ: Viola Sarinic Macolic (EMA) Q&A (All)	14:05-14:40 15 min 10 min 10 min



	Coffee break	14:40-14:55 <i>15 min</i>
5.	PASS update - EMA/HMA catalogue of non-interventional studies (EU PAS Register) - new functionality: <i>Ana Cochino (EMA)</i> - PASS Category 3 study process FU: <i>Carla Jonker (EMA)</i> Q&A (<i>All</i>)	14:55-15:20 <i>10 min</i> <i>5 min</i> <i>10 min</i>
6.	EudraVigilance update - Proposals to reduce ICSR replication issues on EudraVigilance and within MAH PV systems: <i>David Lewis (EFPIA)</i> - International transfers of personal (health) data in ICSRs originating from EudraVigilance, <i>Sabine Brosch (EMA)</i> - New developments in EudraVigilance: <i>Rodrigo Postigo (EMA)</i> Q&A (<i>All</i>)	15:20-16:00 10 min 10 min 10 min 10 min
7.	Summary and follow-up items Close of meeting - Sabine Straus and Evdokia Korakianiti END	16:00-16:20 <i>20 min</i>

Participants List

EMA	EMA scientific committees and working parties
Evdokia Korakianiti Georgy Genov Viola Sarinic Macolic Marie-Helene Pinheiro Agnieszka Szmigiel Priya Bahri Thomas Goedecke Satta Maria Giovanna Amaouche Nadia Emil Cochino Ana Cochino Julie Durand Rodrigo Postigo Luis Pinheiro Tom Paternoster-Howe Sabine Brosch Carla Jonker	Sabine Straus Kora Doorduijn-van der Stoep Martin Huber
Industry	
AESGP Christelle Anquez-Traxler Wendy Booth Stephanie Pick Stephan Köhler EFPIA Juergen Zohn Achint Kumar Birgit Van de Vliet Vicki Edwards Guy Demol David Lewis Katarina Nedog EUCOPE Peter De Veene Sigrid Lang Cecile Beden Liliana Hansen Marie Caby-Tosi Andrea Rau	EuropaBio Tsambika Fuchs Barbara de Bernardi Michelle Grimes Europharm Parminder Kaur Divyaja Mogarala Graeme Ladds Medicines for Europe Klaudija Marijanovic Barac Sebastian Horn Torsten Hero Augusto Eugénio Filipe Marina Couva Mohamed Ali Kotal Jean Kilgour-Christie Alexandra Vaz