



ISoP 2021 Annual Meeting - Post-Conference Course III – 18 November
Making and Assessing Periodic Benefit-Risk Evaluation Reports (PSUR/PBRERs)
 Organised in collaboration with the WHO

Training III	Ottawa	GMT	Prague	Oman	Beijing	Canberra
	UTC-5	UTC	UTC+1	UTC+4	UTC+8	UTC+11
Session A start	02:00	07:00	08:00	11:00	15:00	18:00
Session A end	04:00	09:00	10:00	13:00	17:00	20:00
30'						
Session B start	04:30	09:30	10:30	13:30	17:30	20:30
Session B end	06:00	11:00	12:00	15:00	19:00	22:00
30'						
Session C start	06:30	11:30	12:30	15:30	19:30	22:30
Session C end	08:30	13:30	14:30	17:30	20:30	00:30+1

PBRER Making and Assessment

Final agenda

Thursday 18 November

Session	Session Title	Speakers	Timing
III-A	Event introduction by Event Chairpersons: Jean-Christophe Delumeau (ISoP EC, Bayer), Hiiti Baran Sillo (WHO-RSS), Noha Iessa (WHO-PVG) and Manal Younus (ISoP AB, Iraqi PVC)		
III-A.0	<ul style="list-style-type: none"> Welcoming participants by the chairpersons of the Event Introductory presentation emphasising the challenges faced for scheduling, making, and assessing PBRERs in a global context and the objectives of this event 		20'
III-A	Assessing Benefits versus Risks and Uncertainties: Methods and Practices Chairpersons : Manal Younus & Jean-Christophe Delumeau		
	Introducing Session-A presenters	Session Chairpersons	5'
III-A.1	Benefit vs Risk assessment I: Concepts and Principles	Jan Petracek (IPV)	20'
III-A.2	Benefit vs Risk assessment II: EMA's method	John Joseph Borg (EMA)	20'
III-A.3	Benefit vs Risk assessment III: Industry practice	Dawn Ren (Bayer)	20'
III-A.4	Panel discussion responding to question from the Audience. Panelists: Jan Petracek, John Joseph Borg, Dawn Ren, Helen Ndagije-Byomire and Jean-Christophe Delumeau		35'
	<i>Total Sessions III-O + III-A = 120 minutes.</i>		<i>Intermission</i> 30'

Session	Session Title	Speakers	Timing
III-B	PBRER concept, making and global distribution Chairpersons: Jan Petracek & John-Joseph Borg		
	Introducing Session-B presenters	Session Chairpersons	5'
III-B.1	ICH-E2C(R2) guideline and PBRER template: concept, principles, and regulators' expectations.	Shabnam Sharan (TGA)	20'
III-B.2	PBRER making process: MAH practice.	Dawn Ren (Bayer)	20'
III-B.3	Dealing with the lack of global harmonisation of PBRER submission schedule: Industry experience.	Michal Borawski (Sanofi)	20'

III-B.4	Panel discussion responding to question from the Audience. Panelists: TBD, TBD, Dawn Ren, and Jan Petracek.	25'
	<i>Total Sessions III-B = 90 minutes.</i>	<i>Intermission</i>
		30'

<i>Session</i>	<i>Session Title</i>	<i>Speakers</i>	<i>Timing</i>
III-C	PBRER Assessment Chairpersons: Manal Younus & Helen Ndagije-Byomire		
	Introducing Session-C presenters	<i>Session Chairpersons</i>	5'
III-C.1	PBRER assessment methods and practices at the EMA	John-Joseph Borg (Medicines Authority, Malta, EMA PRAC)	20'
III-C.2	Challenges faced by NRAs starting to request reviewing PBRERs. Prioritisation. Taking advantage from reliance and work-sharing	Victoria Nambasa (NDA, Uganda)	20'
III-C.3	PBRER assessment at Health Canada. Reliance and work sharing across Latin America	Gloria Giraldo (Health Canada)	20'
III-C.4	Transferring PBRER review know-how to NRA starting to request reviewing them. How to facilitate, support, take advantage from reliance and work-sharing. Panelists: Hiito Hiiti Baran Sillo, Noha Iessa, Manal Younus, Helen Ndagije-Byomire, John Joseph Borg, Shabnam Sharan, Gloria Giraldo, Victoria Nambasa, WHO representatives and Jean-Christophe Delumeau		50'
	Closing remarks by Event Chairpersons		5'
	<i>Total Sessions III-C = 120+minutes.</i>	<i>End of meeting</i>	