EphMRA Committee Telephone Meeting: Minutes & Actions 5 December 2019		
Committee members	Jessica Santos	Analia Revaux
	Mattias Blomgren	Matteo Cappai
	Xander Raijmakers	Alex Adams
	Christine May	Anne Beatrice Clidassou
	Chloe Simmons	Matteo Scaringi
	Karen Giorgio Vigo	Piergiorgio Ross
	Roni DasGupta	Bernadette Rogers
Please kindly remember that all EC discussions should remain confidential		

MINUTES & ACTIONS

	Topic	Who?
1	**Introduction and apologies.** Follow up actions from September TC meeting. (refer 5 Dec Agenda - notes)	
2	**<u>Decision Tree</u>** (Refer 5 Dec Agenda for decision tree and comments) Those on the call felt a decision tree makes sense to help determine the role of controller. However, previously aired concerns remain about the commissioning company, i.e. client, role as controller (jointly or sole). XR reiterated that the main concern client-side relates to the requirement of a controller to be named. From a client perspective the risks include perceptions of MR as undisguised promotion, bias, lack of comparability for tracking studies etc. The risks were highlighted from an agency perspective. A key concern is where the client determines the agency as sole controller for the MR project. This puts the risks and additional costs associated with being sole controller, e.g. additional time checking materials, legal input and delays in fieldwork, fully on the agency. XR suggested that agencies communicate the extra burden, including costs, to clients. There is no update on the ESOMAR/EphMRA (GDPR) Code. There isn't a clear timeline when EDPBs will have discussed this. A recent UK ICO meeting indicated new guidelines would be issued soon but did not provide a timeline. Moreover, the ICO strongly implied there wouldn't be any change in GDPR guidance to the wording to determine roles (controller). JS – fewer ad hoc queries raised by clients implying a degree of acceptance of the situation for the moment. As the EDPBs have not provided further clarity the situation remains unchanged. EC agreed to put further development of a Decision Tree on hold until there is additional guidance to determine roles. EphMRA should not provide further updates to members until new information becomes available, e.g. ICO/EDBPs new guidance. **Action: Note to review/modify Decision Tree and EphMRA EC updates as soon as further information available from UK ICO and/or EDBPs.**	BR/EC
3	**<u>AER Guidelines</u>** (Refer attachment with 5 Dec agenda) Update of AER guidelines to make more concise and clearer for users. Draft circulated and feedback received (refer 5 Dec agenda).	

	Roche Drug Safety utilised GPV modules to develop internal training, etc. Chloe offered help to finalise the AER guidelines. XR – more condensed and improved. Noted focus is EMA guidance. Lilly also refers to FDA PV requirements. Concluded that EMA guidance reflects global PV position but that it's an important point that EphMRA guidance should better reflect international perspective. The modified version is easier to follow and not over complicated. Possible error in wording to collect patient AERs. Cross reference to BHBIA as EphMRA aligned with the 2018 changes on patient as reporter.	BR/GB
4	**<u>EphMRA received this enquiry relating to Germany:</u>** (Refer 5 Dec agenda): **feedback from a client: Germany physicians should not be paid more than 67€/hour for participating in market research, defined by GOA for "expert opinion". Germany's ADM does not provide recommendation on this (would raise potential problems under antitrust law).** XR – queried rationale and authority of GOA to defined MR incentives for German physicians. GOA framework is lengthy and very complex offering generic information on payment for experts' views. Point raised that Fair Market Value (FMV) and incentives not the same thing. Incentives are a token of appreciation for time taken to participate in MR, not a fee. (FMV requires a contract for professional services linked to a fee.) EC agreed that reference to GOA to define incentives is not relevant for MR purposes. BR – EphMRA has received several queries about clients insisting that patients included in MR for Italy should not be paid. EC not clear where this came from or the validity of it. GB – previous company local position 'no payment' to patients/consumers for MR in Italy. Based on national clinical research guidelines, not relating to MR studies. **Action: EC check if misunderstandings / confusion around clinical vs. MR guidelines, specifically incentives, is Italy-specific query or wider misconception. Identify if this is an issue EphMRA should address during 2020.**	All
5	**AOB & Close of meeting** No AOB raised	