EphMRA Committee Meeting Actions

20 June 2017 Amsterdam 1pm to 3.30pm

Participants:	ABC	Anne- Beatrice Clidassou
	AR	Analia Revaux
	CA	Catherine Ayland
	CM	Christine Mai
	GB	Georgina Butcher – Chair
	JA	Julian Alexandra
	JS	Jessica Santos
	MB	Mattias Blomgren
	MC	Matteo Cappaii
	PR	Piergiorgio Rossi
	RDG	Roni DasGupta
	XR	Xander Raijmakers
Apologies	BB	Bettina Brust
	BR	Bernadette Rogers
	HH	Holly Hahn

COMMITTEE MEMBERS ARE ASKED TO RESPECT THE CONFIDENTIALITY OF THE INFORMATION THAT IS EXCHANGED WITHIN COMMITTEE COMMUNICATIONS – THANK YOU.

ACTIONS			
No	**Item/Issue**	**By**	**Date**
Please see attached file presentation detailing the issues raised and discussed.			
1	**Horizon Scanning - Changes that will impact the Ethics Environment** Committee Members provided the following updates highlighting future developments likely in 2018: – Georgina – Increasing use of secondary data – Bettina & Mattias - Germany – Christine & Analia – France – Piergiorgio – Italy – Jessica & Matteo – UK – Roni & Holly – USA & Privacy Shield – Julian – PV/AE reporting The updates included: – Developments expected – The implications for MR – The risks for MR – Can EphMRA influence this change – What, if anything, EphMRA should do about this From the updates the following actions were agreed: ▪ The EC to develop an 'Engagement Plan' to build relationships, provide leadership and expertise in the area of market research (primary / secondary) and lobby important and influential organisations on key issues., Proposed areas to include: – **Germany – ADM** – provide support to help the ADM present the case for the clear distinction to be drawn between MR and marketing, including conditions/exemptions for MR within data protection legislation – **France – CNOM** – clarify and if appropriate lobby for the exclusion of MR from the category 'accessory activity', i.e. excluding MR from the requirement for employer permission., Analia to provide copies of the decree, the Jan 2017 amendment and the letter (including English translation) to Catherine – **Italy – ASSIRM** – support if and as necessary lobbying on behalf of ASSIRM (via Piergiorgio) for exemptions for MR from the 'do not contact' law, and for the inclusion of commercial MR within the definition of 'research' under the GDPR to allow bona fide market research to be conducted – **UK – MHRA and/or EMA** – EphMRA to understand the implications and impact on country and international healthcare MR with regard to the UK's withdrawal from the EU	Analia	July

	and the relationship with EMEA. (It has been suggested by the EMA that following Brexit the UK will be treated as a 3rd party country)., Identify an appropriate communication and, if appropriate, lobbying strategy is required to address issues arising from this change in the relationship between EU/EMA and the UK, including transfer of personal data for AE reporting purposes from MR – **USA – PMRG/Insights Association** – support their efforts to exempt MR from CA S.B. 790 by: – Sending an EphMRA statement and a request for action to members, including one specifically aimed at those based in California if possible. Roni and Jessica to provide their templates for action for EphMRA use. – A first draft of a position statement has been circulated to EC members – any further feedback is needed ASAP. – EC to consider contacting the AMA and PHMRA to discuss the issue and ask for their support with a MR exemption. – Roni to forward request to Bernadette for EphMRA to consider the request for funding to support lobbying on this issue in the US parliament. . ▪ EC members to review the and prioritise the above actions by end of July ▪ Always include reviewing progress on the Engagement Plan as an EC agenda item ▪ EC to prepare an addendum to the Code of Conduct highlighting key issues of relevance to the use and management of **secondary data**. ▪ Catherine will provide the Sep 2017 changes as soon as practical to Piergiorgio as the EphMRA Code of Conduct is being translated into Italian at present (by ASSIRM).	Roni & Jessica All Bernadette Roni All Catherine Catherine Catherine	Done July 31 July Ongoing August August
2	**GDPR/privacy** The EC reviewed the plan for updating members on the implications of the GDPR was and Catherine reported on progress to date and next steps. The EC confirmed the plan. It was acknowledged that there may be revisions made to the updates as more detail is released. However, it is important to issue guidance in the absence of all the final detail to provide timely guidance to help members prepare for GDPR. There were no country 'derogations' (i.e. exceptions) reported. Action: EC members report any news on derogations in local privacy law.	All	Ongoing

3	**Pharmacovigilance** **Changes to EphMRA AER Guidelines** The ABPI/BHBIA change on consumer/patient AE reporting was discussed briefly and Catherine will circulate a review of the ABPI/BHBIA decision, the basis for it and an outline of the implications of it. EC members will discuss in the next call to decide what changes, if any, should be included in the updated Code. Action for EphMRA to approach the EMA to request their understanding and clarification of the patient/consumer reporting requirement. In addition, QC auditors may be able to provide an understanding of the requirement, Jessica and Christine volunteered to provide contacts that we can approach to ask for their interpretation. **Medical and drug safety review and approval requirements for MR materials – stimulus and instruments** It became clear during discussion of this issue that different pharma' companies have different practices with regard to the internal Medical and drug safety review and approval requirements for MR materials – stimulus and instruments. It was felt that the regulatory position on this issue is not always as well known or understood as it might be. Action: Include an update/position statement highlighting regulator and Code requirements for members.	Catherine All Bernadette /Catherine Jessica & Christine Catherine	July August July August
4	**Date of next meeting** Date for September meeting to be circulated by CA Likely to be w/c 11 September 2017	Catherine	July