EphMRA Committee Meeting Minutes & Actions

13 December 2017 2pm to 3.30pm (UK time) - Teleconference

Participants:	ABC	Anne- Beatrice Clidassou
	AR	Analia Revaux
	BB	Bettina Brust
	CA	Catherine Ayland
	GB	Georgina Butcher – Chair
	JB	Jayne Blanchard
	JS	Jessica Santos
	KB	Kate Barber
	MC	Matteo Cappai
	MB	Mattias Blomgren
	RDG	Roni DasGupta
	SMH	Sarah May Hall
	XR	Xander Raijmakers
Apologies	BR	Bernadette Rogers
	CM	Christine Mai
	PR	Piergiorgio Rossi

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

A note to all Committee members

In the interests of using our time efficiently and as a courtesy to your fellow Committee members, contributions to discussions need to be:

- Clear and concise
- Focussed on strategic issues – generally avoiding national/tactical, issues specific to your organisation/business

MINUTES & ACTIONS			
No	**Item/Issue ACTIONS highlighted in red**	**By**	**Date**
	New members Jayne Blanshard and Kate Barber, both of Roche were warmly welcomed and it was announced that Karen Giorgi-Vigo, now of Takeda will re-join the EC at the beginning of 2018.		
1	**Engagement Plan** Those leading the engagement initiatives updated the EC on their tasks, timelines and progress <u>Feedback:</u> **UK** No further progress, Georgina and Jessica to follow up by TC before end Dec, with written updated by 5th January. **France** Sarah-May and Analia have recently been in discussion with CNOM about the requirements surrounding whether MR could be considered an 'accessory activity' or not – the advice from CNOM is that all MR that falls within the criteria defined for the standardised annual submission does not have to meet any additional requirements. However MR that falls outside this does not to show evidence of employer permission i.e. the permission has to be documented but it's not yet clear if it needs to be project specific or could it be an annual permission. Sarah-May and Analia will provide further feedback on the CNOM discussions. Zeste are currently working with 2 different legal consultants who might be willing to provide support to EphMRA with regard to lobbying (gratis). . Sarah-May and Analia will advise further. Sarah-May and Analia have drafted a letter to send to SYNTEC (broadly speaking the French MR association) to request their involvement in getting clarification on the accessory activity requirement but until the discussion and advice from CNOM is reviewed this letter should not be sent. **Germany** A letter to encourage the ADM to become involved in lobbying on employer permission and incentive caps will be drafted by Bettina & Mattias and sent by Bernadette. A letter raising the issue of the MR regulation in Germany that prohibits transfer of information that could identify a respondent to a commissioning client company has been drafted for EphMRA to send to ESOMAR. **Italy** Piergiorgio was not available to update. Piergiorgio is asked to provide a written update in early Jan before the next EC call	JS/GB SMH/AR SMH/AR BB/MB CA/BR PG	Jan Jan TBC Jan/Feb Jan Jan

	Korea No further progress as KPRIA contacts are needed – could all EC members including Bernadette forward any Korea contacts that might be in a position to provide a KPRIA contact to Matteo by 12 January. Georgina and Matteo to follow up by TC/email early Jan to develop plan	All/MC	Jan
2	**Changes to EphMRA AER Guidelines** There was strong agreement across the EC from both client and agency side members of the Committee that EphMRA's AER Guidelines should be revised to include the collection of consumer/patient contact data (when consent is given) on the AE report form so that PV can follow up directly with consumers/patients. This is considered necessary for a range of reasons - in view of EMA guidance, in view of the ABPI/BHBIA change, an ethical obligation to provide better quality data. It was also appreciated that this change will have significant practical implications, in terms of the: – Potential to impact on recruitment – Consents required – Additional security requirements – PV workload In view of the fact that the ABPI & BHBIA are progressing this change and working on both the new wording and any additional guidance on the practical implications, it was suggested by Xander and generally agreed that the most pragmatic approach to development of EphMRA would be to liaise with the BHBIA and adopt as far as possible their guidance adapting it if necessary to accommodate country differences. Another lead could be taken from those working in and reporting AEs for OTC products (from consumers/patients), so we will talk to those dealing with this data already and reach out to the OTC Committee to ask if they have any practical advice to offer. – Catherine/Bernadette to follow up with BHBIA to agree sharing of their working guidance with EC early Jan-18 – although there may not be anything to share at this stage – EC to review guidance and provide Catherine with comments, i.e. if acceptable, what changes needed for local use, deadline dependent on receipt of any drafts – Matteo to provide an overview of how OTC companies manage Adverse Event reporting for consumer MR w/c 22 Jan – Bernadette to see if EphMRA have any OTC/Consumer Health contacts that could input on AE reporting to EC by 12 Jan – Review any available guidance and information relating to this topic at February meeting	 CA/BR All MC BR All	 Jan TBC Jan Jan Feb

3	**GDPR/privacy** ▪ Review of progress - Legal Bases Guide is available in draft form and feedback has been provided by Matteo, Jessica and Xander. The guidance will be revised to take account of the feedback and circulated as soon as practical but marked to make it clear this is guidance for MR only and not AER (so does not discuss the legal basis of public interest), this can be added at a later date. Country derogations - all EC members to forward any known national variations to the GDPR.	CA All	Dec Ongoing
4	**Secondary Data Code Addendum** It was decided in June that we should consider preparing some form of addendum to the Code of Conduct highlighting key issues of relevance to the use and management of secondary data. GDPR initiatives are currently taking priority so there is no further progress on this at present.		
7	**Date of forthcoming meetings – suggested schedule** Jan 2018 – w/c 22 (Progress review) – Catherine to send next TC meeting invite before 22/12 The EC could hold a face to face meeting on 26 February 2018 in London (prior to the EphMRA UK one day meeting on 27 February, details of which are available at http://www.ephmra.org/event/EphMRA-one-day-meeting-in-UK-27-February-2018) So far 7 EC members have said they would attend and there are 3 maybes and 1 no, this information will be passed to Bernadette who will check availability and confirm if a face to face meeting will take place on 26 February. Apr 2018 – w/c 16 (Progress and pre-planning meeting planning) Jun 2018 – w/c 18 (Planning meeting) Sep 2018 – w/c 10 (Planning & progress review) Nov 2018 – w/c 12 (Progress review)	BR	Dec