EphMRA Committee Meeting Actions TC Meeting 4 October 2016, 2 to 3pm (GMT)		
Participants:	BR	Bernadette Rogers
	CA	Catherine Ayland
	CM	Christine Mai
	DS	Daniel Stults
	GB	Georgina Butcher – Co-Chair
	IB	Ian Barker – Co-Chair
	MB	Mattias Blomgren
	RDG	Roni DasGupta
	SMH	Sarah-May Hall
	XR	Xander Raijmakers
Apologies	BB	Bettina Brust
	JA	Julian Alexandra
	KJ	Katie Joyner
	PR	Piergiorgio Rossi

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**
1	**2017 Update** ▪ Update to be prepared Sep to Nov 2016 ▪ Further guidance will be added on: - 'Definition' of MR will be added, this will not change the basic definition but will provide additional detail on when the following are/are not MR: - Digital listening - Observational studies - Advisory boards - Patient consent when conducting PRFs	CA	End November
2	**Code Extensions 2017** ▪ It was agreed that the following countries would be added to next year's update, in order of priority: 1 Australia – Ian, Dan & Sarah-May all have local contacts that may be able to help 2 Saudi Arabia - Dan has a local contact that may be able to help 3 Portugal -	CA to liaise with IB, DS & SMH	January 2017
3	**Training Platform Update** ▪ All members of the EC are welcome to try the new training platform, feedback is very welcome	All	October
4	**CNIL requirements in France** ▪ A Country News update on the requirement in France for permission to process sensitive personal data from the national data protection regulator will be prepared and added to the website. ▪ Reference to the need to adhere to national data protection requirements will be added to the Code.	CA CA	October November
5	**AER Guidelines Training - Update** ▪ EphMRA will liaise with the EMA to ask that they acknowledge and reference EphMRA's AER Guidelines, which may involve their review of them.	BR	Oct 2016 to Mar 2017
	Date of next EC TC meeting ▪ 24 Nov 2016, invite and agenda to be sent ▪ The main topic on the agenda will be how to inform members about the GDPR and its implications	CA GB to chair	November

MINUTES	
No	**Item/Issue**

1	**2017 Update**
	All EC members were asked for input in terms of topics for guidance or clarification. The following topics were raised:
	- 'Definition' of MR will be added, this will not change the basic definition but will provide additional detail on when the following are/are not MR:
	  - Digital listening
	  - Observational studies
	  - Advisory boards
	- Patient consent when conducting PRFs.
	In addition, disguised promotion was mentioned however it was pointed out that guidance on disguised promotion had been extended in the 2016 update and at present there is a little further to add.
	New legislation on data security was mentioned but as the legislation is not due to be put in place until 2018, there are no Code updates required in 2017.

2	**Code Extensions 2017**
	▪ It was suggested and agreed that the following countries would be added to next year's update, in order of priority:
	  1 Australia – Ian, Dan & Sarah-May all have local contacts that may be able to help
	  2 Saudi Arabia - Dan has a local contact that may be able to help
	  3 Portugal – local contact required.
	▪ It was decided that Belgium would not be progressed any further at present. In terms of volume sales, the three countries prioritised above would be more appropriate.

3	**Training Platform Update** Bernadette updated the EC on the new training platform. It has been 'soft-launched' and is available to members on the website. As members apply for access to training and competency tests they are being directed to the new platform on the EphMRA website. There have not been any formal announcements yet, the soft launch will continue until the end of October. The soft launch has helped sort out minor issues but there have been limited technical problems and the feedback so far has been positive. Any member that wants to access Code training or competency certification can now do so through the new platform. All competency certificates that are issued now are valid until 30 September 2017. Competency certification now aligns with the membership year.
4	**CNIL requirements in France** EphMRA has become aware that in France permission to process sensitive personal data is required from the national data protection regulator. Although this is not a new requirement, it

	is not currently covered within the Code; It was discussed whether it should be or whether it is better to keep this level of national data protection detail to a country update. It was pointed out that this is a complex area, that it is not 'news' and that EphMRA does not provide detailed and complex guidance on data protection for any other country. It was concluded that the detail should not be included in the Code although reference to the need to adhere to national data protection requirements will be added to the Code and the detail will be made available to members in a country update.
5	**AER Guidelines Training - Update** Georgina outlined the position with regard to one standard AER Guidelines Training programme. In principle many FM companies are in favour of one standard training programme however a lot of companies would not adopt this in practice. A very significant minority (possibly a majority) would require adherence to either their own training or to enough additions or exemptions to the standard as to invalidate it. Previous experience (EphMRA's and the BHBIA's) of trying to persuade pharma companies to use a central single training programme has not proved successful. Given the need to allocate EphMRA's finite resources carefully it is not considered appropriate to progress exploration of a single harmonised training programme at the expense of other initiatives. This was agreed by the EC. It was also agreed that a more gently, 'softly softly' approach would be taken to trying to persuade members to use EphMRA training as their standard. It was also agreed that it is very important to ensure that EphMRA's AER Guidelines are clear, comprehensive and up to date, and well publicised. EphMRA will liaise with the EMA to ask that they acknowledge and reference EphMRA's AER Guidelines, which may involve their review of them.
	Date of forthcoming meetings – suggested schedule 24 Nov 2016 – (Progress review) Jan 2017 – w/c 23 (Progress review) Apr 2017 – w/c 3 or 24 (Progress and pre-planning meeting planning) Jun 2017 – w/c 19 (Planning meeting) Sep 2017 – w/c 11 (Planning and progress review) Nov 2017 – w/c 13 (Progress review)