Ethics Committee Telecon	
Date:	**26 September 2013**
Event:	**Ethics Committee Telecon**
Time:	1430-1530
Place:	Telecon
Participants:	Bernadette Rogers (BR)
	Catherine Ayland (CA)
	Christine Mai (CM)
	Georgina Butcher (GB)
	Piergiorgio Rossi (PR)
	Roni DasGupta (RDG)
	Robert Seigmund (RS)
Distribution List:	Committee Members
Apologies:	Bob Douglas, Karen Giorgi Vigo, Peter Eichhorn
Minutes by:	Bernadette Rogers (BR)

ACTION POINTS			
No.	**Action**	**Comment?**	**Responsibility**
#1.1	Follow up with France on the question of patient details in the AER form		CM/CA
#1.2	Check with BD regarding discussion on the total number of adverse events and what percentage is coming from market research, and the quality of the data		BR
#1.3	Look into developing EphMRA AER training and certification		BR/BD
#1.4	Obtain a pharma company view on the definition of patient support packages and how to pull these together		GB
#3.1	Disclosure Code – send questions back to EFPIA		BR
	Loi Bertrand – EphMRA to issue a general update	Week comm 30 Sept	BR
#5.2	BHBIA joint test - look at the way forward to implement and test		BR

Minutes		
No.	**Topic**	**Comment**
#1	**Adverse Event Reporting Guidelines & Training**	**1.1 Revisions to EphMRA AER Guidelines.** Feedback has been given; there was nothing that needed complete reconsideration or any dramatic differences. The guidelines are ready to be issued, unless anyone raised any last minute queries. Off label use was queried and was confirmed it is included in the periodic safety update. The use of patient details in the AER form was questioned and will be followed up for France.

		1.2 AER project. Goal to collect data upon volume and quality of AER forwarded from MR : the total number of adverse events what percentage is coming from market research, and the quality of the data from MR The EC will sign off the protocol/proposal for this study and then it will go to the Hot Topics Group for review. The EC will work with an external resource to get the study done. Budget is in place. It was asked how feasible it would be to check what percentage of duplication we have on AER coming from market research, and was concluded it would be difficult to identify. However, qualitative input from the source would be good to have. **1.3 AER Training.** After discussion, it was concluded that EphMRA should look to develop its own AER training and certification to offer members. This it was felt would be an added value benefit to members. **1.4 EMA liaison update**. The question was asked if there are any further comments on the definition of market research. None were given.
#2	**Code Mark**	**2.1 Code Mark** - discussion of proposal following full member consultation exercise. Following lengthy discussion, it was concluded more work and analysis should be done before the next call particularly with regard to sanctions and the requirements of AM. EphMRA has no sanctions procedure in place right now – EphMRA will confer with other organisations to better understand their procedures e.g ESOMAR), legal advice may also be needed.
#3	**Code of Conduct**	**3.1 Ongoing issues.** ○ Observation & recording guidelines – ICO UK recommendation. We are keeping an eye on this, and will go into the updated code. ○ Disclosure Code. We need to put some questions back to EFPIA. ○ Loi Bertrand in France. French associations are the main driving force working on this, to try and get the exclusions necessary for our industry. A general update will be sent out by EphMRA. **3.2 Code Extensions underway.** ○ Argentina, Brazil and The Netherlands are underway. Turkey and India still static. At the China Pharmaceutical Research Group (CphMRA in July), Thomas Hein gave a presentation about the Code of Conduct. There

		was general interest and thought that the CphMRA in the light of some of the bad press and things coming to light regarding bad practice in China, there is a feeling they want to develop their own Code of Conduct based on EphMRA's.
#4	**National News**	**4.1 News from Ethics Advisors Network**. There is no news coming in. **4.2 News from Ethics Committee members.** Breach of patient privacy issue in Germany, there is no further news currently.
#5	**Competency Test Training**	**5.1 Member uptake and the implications.** We can look at this more at the next telecon when a 12 month report on uptake will be available. **5.2 BHBIA - EphMRA joint test certification**. Going ahead – looking at logistics for a 6 month test period. Br to produce a way forward document.
#6	**Compliance Network Update**	**6.1 Data Protection Agencies listing**. It is complete and attached to the minutes
#7	**AOB**	Next call – early November.