Ethics Committee Telecon	
Date:	**20 March 2014**
Event:	**Ethics Committee Telecon**
Time:	15.00 – 16.00
Place:	Teleconference
Participants:	Bob Douglas (BD)
	Bernadette Rogers (BR)
	Catherine Ayland (CA)
	Christine Mai (CM)
	Georgina Butcher (GB)
	Karen Giorgi Vigo (KGV)
	Roni DasGupta (RDG)
	Solvea Lamarina (SL)
	Xander Raijmakers (XR)
Distribution List:	Participants
Apologies:	Peter Eichhorn (PE), Piergiorgio Rossi (PR)
Minutes by:	Bernadette Rogers (BR)

ACTION POINTS			
No.	**Action**	**Timeline**	**Responsibility**
1.1	Ask CM regarding response from ASOCS re Loi Bertrand		CA
	Draft plan regarding the fostering of relationships with the German, French and Italian local MR and pharma' industry associations to allow more effective communications and lobbying.		BR/CA (& BD)
1.2	Follow up with Monica Ganwani in India to check on her progress. Advise Monica Ganwani of the acknowledgement procedure.		BD
	Follow up with China contact. Advise them of the acknowledgement procedure.		BR
2.1	Forward the AER Project Brief to the EC to allow specific members (GB, SL, XR) to follow up with internal connections to assess potential for and request support for the work.		BR GB, SL, XR
3.1	Talk to/survey full members about the draft proposal.		CA
8.1	Draft outline approach to Ethics Approval initiative for the Board.		CA

[The number above relates to the items below]

MINUTES		
No.	**Topic**	**Comment**
1	**Code of Conduct**	**1.1 Ongoing Issues** **France, Loi Bertrand.** Many of the questions that members asked have now been addressed and an FAQ has been posted on the website. A second set of FAQs are due to be published shortly. There is confusion between Loi Bertrand and Loi

Anti-Cadeaux. It was asked if anyone was lobbying on anyone's behalf on this, are EphMRA actively involved in this process, or local associations? The local associations, ASOCS and SYNTEC have lobbied on the issue, without much success. ESOMAR have asked the European Parliament questions in respect of data protection. EphMRA are talking to a French organisation called EuroSante via Sarah May Hall of ZESTE who has actively engaged in trying to work out the implications of Loi Bertrand and Loi Anti-Cadeaux. EuroSante provide legal support for the healthcare industry in a specific region of France, and they have some interesting contacts. EphMRA are currently talking to EuroSante about drafting a joint proposition explaining the difficulties and the issues this causes, to gain a possible route to getting an amendment on the law through.
A broader issue is how we deal with local associations and legislation affecting our industry with no consultation. Is there more we can do to proactively foster relationships with the right associations; particularly in France and Germany, and perhaps Italy? As an example, the BHBIA have a very good relationship with the ABPI and it would certainly help EphMRA if there are initial steps we could take to get close working relationships with these local pharma associations. The more we can help them to understand who we are and what we do, the more we are likely to be able to influence. It was mentioned what EphMRA have been able to achieve this at the German chapter meetings. These have been quite helpful in raising EphMRA's profile with the ADM in Germany for example. It was suggested a plan be put together for these 3 countries and see what comes from this plan. It was suggested that making use of the National Advisors Network would be helpful. Also, there are full members who have contacts in these countries and we could benefit from them and their varied connections.
Germany, Dienstherrengenehmigung/Employer permission. We haven't heard of any more progress on this subject. There is a German chapter meeting in early April, so we will revisit this at the next meeting.
Europe, EFPIA Disclosure Code. EFPIA have provided draft feedback to a series of questions and asked EphMRA whether their questions have been answered satisfactorily. What we have seen so far is encouraging. EphMRA have asked another question to them, which needs addressing. We hope to have information available for an update within the next few months. As part of our lobbying, the clearer we can be about what market research is and isn't and the firmer we can draw the boundaries the better for the industry. It was suggested that EphMRA provide EFPIA with their definitions drawing distinctions between MR, NIS and PSPs.
1.2 Extensions underway - update.

- **Turkey** – This is ongoing.
- **India** – There is progress. Monica Ganwani of IPSOS India, has volunteered to coordinate feedback.
- **China** – There is nothing to report. The China contact has been emailed, who replied with 'she would see'. BR to follow up again, and to also mention the acknowledgement if they are able to contribute. GB asked if EphMRA is aware what the barriers are – CMR may prefer to develop their own guidelines. Since then there has been press exposure regarding bribery within the industry, so they have been busy responding to this. However, this

		has made them realise it is more important to have a code for self-regulation. - It was noted that contributors will be acknowledged for their time and commitment. The acknowledgements can be published in the Code or in a separate document alongside the Code. Contributors need to give their written permission to be acknowledged in this way. Everyone apart from Korea have responded with written permission so far. BD to advise Monica Ganwani of the acknowledgement procedure.
2	**Adverse Event Reporting Guidelines & Training**	**2.1 Forward Thinking Project - AER.** A brief outline of who the Forward Thinking Group is and what they do was given to assist XR's understanding. The Forward Thinking Group Chair has sent a note to BD advising they have only managed to speak to one person within a pharma company about the feasibility of collecting useful information around adverse events. Therefore, as this project is proving difficult to progress, is there any support this group can give to at least identify a few people in full member companies who can assist. The full members on the Forward Thinking Group were unable to identify anyone who would want to take part in a pilot interview or exploratory talk. A knee-jerk reaction is they would not want to provide data. There is a project brief, which can be used by this Group to forward to relevant people in their companies. **2.2 AER Training – Update.** There has been a TC with the Compliance Network and also with the AER Training working party to talk about thoughts on scope and objectives for specific AE training. Overall there is positive reaction that it is a good thing to develop both a training module and a test. There was talk about things that have been covered before; there should not be another test, but maybe to align it with other available tests – make it complimentary. Avoid repetition, as there are a few pharma companies, where they've done the BHBIA test, who then don't have to do the training. An outline will be pulled together to look at the way forward. How it is going to be done without introducing into the market another test. Look to align it with other offerings.
3	**Code of Conduct Code Mark**	**3.1** It was previously agreed within this Group, it would be difficult to develop a code mark which was meaningful and really had teeth. The Board asked us to have a rethink. There has been a discussion with the Compliance Network, as they are a group of very experienced market researchers in charge of compliance at major agencies. We talked to them about what a code mark might mean and how it should be set up, and we have pulled the information together into a draft code mark proposal. It has potential ideas for the way a code mark might work. It talks about the purpose, the benefit, how long it will be valid for, qualification criteria, what information would be publicised, would there be an actual mark, what would happen if there was a complaint or a breach, sanctions and resource required. Essentially there is still a concern there is no point EphMRA developing a code mark unless it really means something and brings a worthwhile tangible benefit to full members. EphMRA need to establish a code mark that would be of value, which does offer meaningful benefit and it might make a tangible difference to decision making and behaviour. It was suggested a survey is conducted with a majority of full members to gauge their thoughts on how worthwhile it is considered and then we can tailor our efforts and any initiative accordingly.

4	**EFPIA Disclosure Code**	**4.1** See 1.1
5	**Forward Thinking Project - AER**	**5.1** See 2.1.
6	**Competency Test Training**	**6.1 BHBIA Test.** This was launched at the end of February. There have been 23 requests in the last 3-4 weeks from people wanting to do the joint code.
7	**Ethics Webinars**	**7.1** One has taken place today, aimed at non-market researchers. There were 30 connections over the hour. Two thirds were pharma companies and one third were agencies. There were a range of job functions on the webinar; market researcher, compliance, commercial, medical affairs and regulatory affairs. The next webinar is with ESOMAR at the beginning of April.
8	**AOB**	**8.1** The Board will be looking at some point for an update regarding gaining ethical approval/input into market research studies. The Board are looking for some feedback on some of the issues, some of the things we might be able to cover in the shorter term and some that need a longer and more sustained effort.

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