EphMRA ETHICS COMMITTEE TC MEETING 12 February 2013 1-2pm GMT

Attending	**BR**	**Bernadette Rogers**	) Chaired the meeting
	CA	**Catherine Ayland**	) in Bob's absence
	GB	**Georgina Butcher**	
	KGV	**Karen Giorgi-Vigo**	
	PE	**Peter Eichhorn**	
	SG	**Steve Grundy**	
Apologies	**BD**	**Bob Douglas – Committee Chair**	
	PR	**Piergiorgio Rossi**	

ACTIONS

1. New Adverse Event Reporting Guidelines

a. EMA endorsement
It was agreed that EphMRA would look to develop a closer working relationship with the EMA with a view to seeking their support on definitions and questions, moving on to asking them to review and then possibly endorse the AER Guidelines at some future stage, all the time building up the profile of market research within the EMA. It was considered a very positive goal to work towards.

b. Outstanding query with EMA – defining what constitutes an identifiable patient or patients
Awaiting EMA feedback which is anticipated in late February or March **CA**

c. AER in Germany
An ADM representative will be attending and speaking at the Germany Chapter meeting on (18th April) after which it is hoped the ADM position on AER will be clearer – currently they advise that it cannot be combined with market research. The issue of passing on reporter contact details for PV follow-up – effectively prohibited in Germany – will also be discussed. In the meantime the AER Guidelines include the suggestion that in Germany (as advised by PE) market researchers are advised to facilitate company PV follow up of reporters/AEs by asking the MR agency to pass a request to the reporter to contact the pharma' company directly to discuss the AE should this be required. MR agencies are reminded that they should include a re-contact question for this purpose.

d. AER Guidelines training – extent of coverage within CofC training
It was agreed that AER training should not be made a separate module but kept within the Code of Conduct training. It was noted that the AER webinar is available on the website and this too is a useful training tool. It was agreed that an FAQ for members would be developed based upon the Webinar Q&A and made available on the website to compliment the Guidelines.
FAQ to be developed by CA. **CA**

This material will also provide Newsletter material too. **BR**

It was also suggested that some form of chat-room or blog is set up to encourage the exchange of information on AER although it was noted that the free to members enquiry service is available to members should they have questions on the AER Guidelines.
BR to look into the possibility of some sort of AER forum. **BR**

2. Code of Conduct Code Mark

The following outline for a Code Mark scheme was presented (in the agenda) by BR

Outline:
The EphMRA Code of Conduct will not be made mandatory. However in order to encourage adherence and further promote it member companies will be invited to sign up to the EphMRA Code Mark scheme (CM). The aim of this is to demonstrate that individual member companies have agreed to adhere to the Code and are striving to achieve best practice when it comes to observing ethical and legal guidelines in pharma market research.

CM focuses on the company agreeing to:
- *abide by the EphMRA Code of Conduct*
- *nominating one person to be the main ethics/compliance contact*
- *nominating one person who will be certified via the Code Competency test*

CM for members will run along the membership year from 1 October to 30 September.

An example of how it could run is as below – depending upon when the scheme will commence.
1. *Membership Invoice issued on 1 October 2013*
2. *Once paid, the member company is asked to:*
   - nominate one person in their company who is the main contact for compliance and ethics
   - have at least one person in the company must take the Code competency test and be certified within 2 months of the membership invoice date
3. *Once certified the person's name, job title, contact details and company name and certification date will be published in a members' area of the web site.*
4. *The company will then be able to use a symbol supplied in jpeg form to demonstrate their company is a member of the CM scheme. This could be the letters CM in a blue circle with the year 2012-2013 at the bottom.*
5. *The logo will expire on 30 September and members will be informed they can only use till 30 November so that there is overlap whilst they are paying the membership invoice again.*

It was confirmed that it is a good idea. The following observations were made:
- Full member companies may need to get their legal departments to agree it
- There may be demonstrable pre-conditions that ought to be set as part of 'entry criteria' e.g. membership of the national MR association, having taken specific training courses, it was recognised that the criteria for full and associate members might have to be different
- Maintaining an identifiable ethics contact might be difficult particularly for full member companies.

The following actions were agreed: **BR & CA**

- A few full member companies will be asked for feedback on the idea and how it could be applied

- A list of potential entry criteria is to be collated and discussed with a short series of full and associate members including organisations of differing sizes and feedback gathered on what would be reasonable and practical

3. Code of Conduct

a. Definition of a process for updating the Code of Conduct
   - Frequency of updates – annually was agreed unless a significant change requires an additional ad hoc update
   - Scheduling of the annual update – various suggestions were made:
     - For release at the annual conference
     - At the beginning or end of the calendar year
     - In line with EphMRA's year

     It was agreed that the scheduling of the update should be looked at in the light of the broader EphMRA workload and timetable **BR**
   - Members will be invited to offer input, make suggestions or ask questions prior to the annual update and scheduled accordingly but will not be required to consult on the changes to be made, the Ethics Committee's role with the support of the Ethics Network is to agree the changes to be made
   - It was also suggested that somewhat more frequent EC meetings may need to be convened to ensure that the ethics issues can be addressed in a timely way
   - The process should be clear, structured, scheduled, transparent and made available to members **BR & CA**

b. Outstanding issues - observation & recording guidelines in Germany, the EC was informed that discussions with the ADM, the MRS and the ICO have taken place, EC members were alerted to the fact that their input on this issue may be needed in the near future.

c. Extensions update
   - China – it was suggested that Thomas Hein's help is sought in progressing China as the Head of CPHMRA works for Bayer
   - India – MRSI Board member has been identified and consulted, a copy of EphMRA's CofC has been sent to the MRSI, who were meeting w/c 11 Feb and BR hopes to hear back soon hopefully with a way forward

d. 2013 Extensions – suggestions made included:
   - Brazil
   - Greece
   - A focus on Europe
   - Portugal
   - Ireland
   - Argentina
   - Eastern Europe

   A list of preferred countries will be developed in line with the statement on geography in the strategic plan and it was pointed out that more than one country can be progressed at a time as different countries taken very different lengths of time to include and further feedback on priorities will be asked for to develop an action list. **BR &CA**

e. Translations – need, frequency and cost implications
It was generally agreed that translations are a valuable means by which to make the Code more accessible but it was also recognised that they are an expensive service and that the 4 major European languages – French, German, Italian, and Spanish – are the priorities. The timeline for translation will also have to be worked into the timeline for the production of the annual update.

The following items were not covered as the EC ran out of time and the EC will reconvene on Thursday 28 February 1-2pm (GMT) to carry on the agenda.

4. National news/developments BD & CA

a. Update on Transparency Law/Sunshine Act in France
b. Involvement of patient associations in recruitment in France
c. Transparency Law in Italy
d. News from Ethics Advisors Network
e. Any news from Ethics Committee members?

5. Feedback and suggestions from the Compliance Network

a. Update CA
b. Options for EC consideration – need for and practicality of developing and maintaining to be considered: CA
   - □ Listing of appropriate incentives by country and respondent type including physician type
   - □ Data processing law and requirements by country including registration requirements and data protection agencies
c. Image and status of Code BR & CA

6. AER Foundation Project Update BD

a. Pilot results?

7. Training

a. AER Webinar 31 Jan feedback BD & CA
b. 2013 training suggestions BD & CA
   - □ Further webinar proposed – May – Code Update & Key Issues
   - □ Conference – no training workshop proposed but ethics input to master classes is proposed where this is appropriate to the topic
c. Online Training and Competency Test/Certification take-up (keys used) CA
   - □ To date 420 members have taken the Code Competency Test and a further 250 have completed the online training module
   - □ Online training and competency test to be fully updated once the outstanding Code queries on observation are answered

8. Access to Competency Test & Certification BD & BR

a. Certification for freelance independent market researchers e.g. moderators (now being requested by commissioning companies)

9. Any other business All