| Ethics Committee | |
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| **Date:** | **13 November 2014** |
| **Event:** | **Ethics Committee Telecon** |
| **Time:** | 1400 – 1500 |
| **Place:** | Teleconference |
| **Participants:** | Bernadette Rogers (BR) |
| | Catherine Ayland (CA) |
| | Christine Mai (CM) |
| | Georgina Butcher (GB) – Co-Chair |
| | Ian Barker (IB) – Co-Chair |
| | Karen Giorgi Vigo (KGV) |
| | Peter Eichhorn (PE) |
| | Piergiorgio Rossi (PR) |
| | Roni DasGupta (RDG) |
| | Xander Raijmakers (XR) |
| **Distribution List:** | Participants |
| **Apologies:** | Solvea Lamarina (SL) |
| **Minutes by:** | Catherine Ayland |

| ACTION POINTS | | | |
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| **No.** | **Action** | **Timeline** | **Responsibility** |
| 2.1 | Review the 2015 Code of Conduct - changes only | By 28 Nov | ALL |
| 3.1 | Code Certified Count - Voluntary list of AMs<br>– Consider metrics<br>– Discuss metrics, targets and PR approach | 5 Feb | <br>ALL<br>CA/BR |
| 4.1 | Quality of AER – FM EC members to feedback on feasibility of data collection | By 19 Dec | ALL |

[The number above relates to the items below]

| MINUTES | | |
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| **No.** | **Topic** | **Comment** |
| **1** | **Process Adjustments** | 1.1 It was proposed there should be a slight change to the committee process.<br>– A standard response time to be introduced of 2 weeks for EC members to comment or feedback on items. If there are no further comments after this time, it is to be accepted that everyone is happy with an item and to proceed on this basis. A reminder after one week will be sent.<br>– The agenda is to be clearer, showing the priority items and when these have to be achieved by.<br>– Specific Ethics Committee member roles may be allocated, so there would be primary points of contact for communications, code mark, etc.<br>These amendments were agreed by all. |
| **2** | **Code of Conduct** | 2.1 Feedback has been given by many ECmembers as part of the Ethics Advisers Network regarding things that need changing and updating. The Code of Conduct 2015 update has been emailed to committee members asking if they would |

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| | | review the changes only. It is asked that comments be confiendto the content rather than wording of the guidelines. Following comments, a final draft will be prepared1st/2nd December to be sent to the programmer 3rd December with an aim of the release to member's w/c 12th January. It was noted changes are clearly marked so the amount of work should be manageable. |
| **3** | **Code of Conduct Mark** | 3.1 many months of discussion and consultation have led to the clear conclusion that in principle a Code Mark is a very attractive proposition, there are some very real practical problems/fundamental issues in making it work, such as extending ethics knowledge and standards throughout the company and the potential use of sanctions and the need for a complaints. The EC has concluded therefore that it cannot presently produce a code mark that meets all of the essential objectives and this is to be fed back to The Board.<br><br>However, the option to have a voluntary list of associate members, that includes the number of their staff that have the competency certificate. This could boost uptake of the test which in turn could boost knowledge of the code and help drive awareness and standards.<br><br>It was commented the some of the value of this depends on whether or not the full members think it will help them from a due-diligence point of view and if the associate members find it helpful in reducing the burden of dealing with due-diligence. It was also commented it is better than nothing and this is an acceptable compromise.<br><br>The question was asked would it be possible to include the names of individuals that have taken the test. In reply this issue has been discussed with the Compliance Network who had some strong objections. In future, as the list becomes established it might become acceptable to produce a list with names.<br><br>Measurement of the impact of a list was discussed. Given that it will be known how many AMs and how many of their staff are competency certificated and this can be monitored to help the EC judge whether the list appears to be encouraging more AMs to take up competency certified.<br><br>Effort should be put into advertising the list and to watch what happens over the first 6 months and review the impact by the end of a year. We can define targets, set metrics and have longer term goals to develop the list.<br><br>It was decided to set up a voluntary list of the number of AM staff competency certified as a first step, defining the metrics we want to use to measure success and review at intervals over time. |
| **4** | **Adverse Event Reporting** | 4.1 FM EC members - GB, XR and KG-V- reviewed the original 3 questions and fed back. The questions have been changed slightly and a 4th question added. There's a revised brief on page 5 of the agenda documents. FM EC members will now go back to their pharmacovigilance colleagues and ask if it's feasible to collect this information and come back by 19th December to advise if this or some of this can be done. |
| **5** | **PR** | 5.1 Page 6 of the agenda document detailed the overall global stakeholder engagement objectives. BR, CA and the PR company will be working on an initial |

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| | | short-term plan to action these goals over the next few weeks. This plan will use currently available resources and concentrate on the more achievable objectives. The plan will include use of various media; newsletter, Twitter, LinkedIn and email. There has been little ethics-specific PR for some time so a build-up of regular communication will start to build awareness.<br><br>It was commented and noted that the plan would focus in the short term upon internal stakeholders rather than external ones. |
| **6** | **Public Affairs** | 6.1 The goals in terms of communications and liaison with external organisations are acknowledged to be very important but also achievable in small steps. A target list of organisations has been produced and accompanying short, medium and long-term goals defined.<br><br>3 global organisations are targeted; EFPIA, EMA and ESOMAR.<br>- EFPIA - good progress made over the last year and we are definitely on their radar now. We need to build and maintain the relationships that have been started. There is a meeting coming up that we may be able to get ourselves invited to, they know we exist, and that MR exists and they know there is a code and that we need guidance.<br>- EMA - we are undoubtedly further behind. We had contact mid-2013 at a workshop, there are a couple of people in the EMA who know we exist and we need to work harder in developing contacts in order to build relationships and we need to start to try and get them to understand the implications of AER guidelines particularly for MR.<br>- ESOMAR we probably have the best developed relationship. We are now at the stage where we're liaising with ESOMAR and there is talk of another joint webinar, the second in a series. We have been invited in the past to be involved in a joint guidelines development initiative, but this didn't come to fruition. They are aware of us and our ethics expertise and want to take advantage of that.<br><br>We have 3 key countries targeted France, Germany and the USA. The UK is absent as it is not a priority as we have a good existing relationship with the BHBIA. France is a key country particularly because of Loi Bertrand and Loi Anti-Cadeaux. Germany because there are a lot of differences in the guidelines there. We have made some progress, recently developing a second contact within the ADM, and the VfA. In the USA we have made progress with CASRO who have been sending us information recently and BR is developing a relationship with Diane Bowers there. In the short term it is important to get to know the national associations so that we can get our questions answered quickly and efficiently. |
| **7** | **Any Other Business** | None. |
| | **Next Meeting** | 5 February 2015 (Co-Chair Georgina Butcher) |

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