

10.00-11.30 in the Mallarme Room, Pullman Montparnasse Hotel, Paris

<b>Present</b>	<b>BB</b>	<b>Bettina Brust</b>
	<b>BD</b>	<b>Bob Douglas – Group Chair</b>
	<b>BR</b>	<b>Bernadette Rogers – Present for part of meeting</b>
	<b>CA</b>	<b>Catherine Ayland (TC)</b>
	<b>GB</b>	<b>Georgina Butcher (TC)</b>
	<b>HF</b>	<b>Henri Farina</b>
	<b>JB</b>	<b>Jeremy Brody (TC)</b>
	<b>PR</b>	<b>Piergiorgio Rossi</b>
<b>Apologies</b>	<b>IM</b>	<b>Ignacio Macías</b>
	<b>KG</b>	<b>Kim Gray</b>

## ACTIONS

### 1. Code of Conduct Update

- a. 2012 Draft
  - Content
    - AER in D – issue to be discussed with ADM and any amends to the Code made following this, it is anticipated this will be practical within the next 2 weeks. CA
    - Observation & Recording Guidelines and naming of client company – guidelines to remain unchanged until further legal guidance on the implications of Data Protection legislation has been obtained. CA to provide legal information to Thomas Hein of Bayer and asked for Bayer legal interpretation and continue discussions with ESOMAR CA
    - AER in Italy guideline to be checked (paragraph 12.3) CA & PR
  - Russia input now available and to be included CA
  - Draft Code to be circulated to Ethics Group for review and feedback CA & ALL
  - Revised Code will be available online once the AER in D issue is clarified, Russia Included and feedback from the Ethics Group received CA
  - Revised 2012 Code will not be published (in booklet form) until questions about observation and recording guidelines are resolved

### 2. News/developments in Ethics Group territories

- New Transparency Law in France – no further news, HF to keep the EG informed of any developments HF
- Market research (MR) has been included within a telephone do not contact service/list intended to protect individuals from unwelcome direct marketing approaches, ASSIRM are working to get MR removed, PR to keep the EG informed of any developments PR

### **3. Moving to mandatory Code of Conduct – Next Steps**

- Next steps agreed following Executive Board and Ethics Group discussion of the White Paper:
  - A series of full member companies are to be approached and discussions held about the move to mandatory Code adoption, company barriers and options in July & August, who will hold these discussions has yet to be decided
  - Interim measures also to be considered e.g. default opt-out commitment to abide by the Code for members
  - EG to review output from these discussion and input to the Executive Board in September
  - Feedback from EG to executive Board in October
- Move to a far less detailed Code that would refer only to abiding by the relevant laws and not explain their practical implications was rejected

### **4. Code of Conduct Enquiries**

- No actions arising

### **5. Training**

- Online training and competency test to be updated once the revised 2012 Code is fully finalised CA

### **6. Beijing Conference**

- No immediate actions arising but format and content still to be agreed BR & BD

### **7. New pharmacovigilance legislation and implications for Adverse Event Reporting**

- At time of the meeting Implementation Guidelines had not been released
- Guidelines since released, Steering Group and Ethics Group to follow up on the implications for the Code of Conduct EG

### **8. AER Foundation Project Update**

- Proposal for AER Study not yet reviewed by Executive Board due to lack to time, decision by end of July anticipated
- EG will be kept informed of progress BD
- The EG hope to liaise with the Foundation Committee with regard to focus of the study to ensure that the focus of any work undertaken is useful from an ethics perspective BD/EG

### **9. Any other business**

- No other business raised

Catherine Ayland  
2 July 2012