EphMRA Committee Meeting Actions

TC Meeting 5 April 2017, 2 to 3pm (GMT)

Participants:	AR	Analia Revaux (acting for Sarah-May Hall)
	BB	Bettina Brust
	BR	Bernadette Rogers
	CA	Catherine Ayland
	GB	Georgina Butcher – Chair
	HH	Holly Hahn
	JA	Julian Alexandra
	JS	Jessica Santos
	MC	Matteo Cappai
	RDG	Roni DasGupta
	XR	Xander Raijmakers
Apologies	CM	Christine Mai
	MB	Mattias Blomgren
	PR	Piergiorgio Rossi

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

ACTIONS			
No	**Item/Issue**	**By**	**Date**
2	**Adverse Event Reporting Guidelines – UK Changes Anticipated** The EC will be provided with a further update at the June meeting and depending on the action decided upon by the ABPI and BHBIA and in light of the EMA's 2014 Guidance will consider the implications for EphMRA's AER guidance. This item will be added to the agenda for the June EC meeting.	CA	20 Jun
3	**June Ethics Committee meeting in Amsterdam** Draft agenda for the June meeting was agreed, Catherine to prepare and circulate beforehand. It was agreed that all members would be involved in a 'Horizon Scanning' initiative and would prepare material (ideally a single slide) for discussion at the meeting a Catherine to provide the template. Topics for discussion: ▪ Catherine – GDPR ▪ Julian – PV/AE reporting ▪ Xander – ? Big Data ▪ Bettina & Mattias - Germany ▪ Christine & Analia – France ▪ Piergiorgio – Italy ▪ Jessica & Matteo – UK ▪ Roni & Holly – USA & Privacy Shield Other items for the agenda will include: ▪ **GDPR/privacy** This will include: – Review of progress (Catherine) – Discussion of any country derogations (i.e. exceptions) – country feedback on derogations to be prepared prior to the meeting by all members of the EC (All) ▪ **PV** – discussion and agreement on changes to EphMRA – feedback on UK decision and agreement on any EphMRA action required.	CA All CA CA All	19 May 9 Jun 19 May 19 May 19 May
4	**GDPR – Comms. & Training Plan 2017** ▪ It was agreed that a GDPR sub team will be formed to provide support for the development of GDPR updates. Holly, Jessica, Matteo, Xander volunteered to join the sub-team. Bettina volunteered to be involved with the topic of consents when this is addressed. Holly also volunteered to share in-house materials when practical. The GDPR Team's first task is to review the first	CA/HH/ JS/MC/	21 Apr

	update within the agreed series. This will be circulated shortly after the meeting.	XR	
5	**National Issues** **France – new decree** It was agreed that the Code would be updated with this information for the next update but that there is no need for an interim update. Analia to forward to Catherine the March 2017 decree for information. **Germany – employers permission** An email will be sent to recent Chapter meeting attendees to get feedback on the impact of the employers' permission requirement by Bernadette. **USA – Privacy Shield** It was agreed that no update is required until there is 'hard' news to report.	 CA AR BR	 Jul Apr Apr/May
6	**Ongoing Actions** **Ethics Requests from the Fieldwork Forum (FF)** We have contacted the FF to ask what particular issues/circumstances were driving their issues and what further support or information would they need/envisage. The FF does not meet again until the end of April so there is no further news, Bernadette will feed back after their meeting. **Ethics Requests from the Devices and Diagnostics (D&D) Group** The D&D Group when asked what they need with regard to guidance on MR involving devices and diagnostics have replied that it would helpful to know which parts of the Code apply equally to devices as much as pharma and which parts of the Code do not apply to devices. Catherine will address this question. **Code Extensions 2017** EC members were reminded that we need a contact based in Portugal that is knowledgeable about legal and ethical requirements in Portugal to help us extend the Code of Conduct to this country. Please contact Bernadette or Catherine if you can suggest anyone.	 BR CA All	 May May Apr/May
	Date of forthcoming meetings – suggested schedule 20 Jun 2017 (Planning meeting) Sep 2017 – w/c 11 (Planning and progress review) Nov 2017 – w/c 13 (Progress review)		

MINUTES	
No	**Item/Issue**
1	**Welcome to new members – Analia, Holly, Jessica, Matteo** ▪ Analia Revaux, Compliance Manager of Zeste Research – replacing Sarah-May whilst she is on maternity leave. ▪ Holly Hahn, Senior Manager, Business Intelligence at AbbVie – replacing Dan Stults (in the short term at least) ▪ Jessica Santos, Global Compliance and Quality Director, Kantar Health ▪ Matteo Cappai, Compliance Officer, Ipsos Healthcare
2	**Adverse Event Reporting Guidelines – UK Changes Anticipated** The EC were briefed on the following possible changes to the ABPI/BHBIA's AER Guidelines : The BHBIA have informed EphMRA that following recent talks with the ABPI, it is likely they will to need to change the BHBIA adverse event/product complaint reporting guidance when AEs are collected directly from patients or consumers. To meet their EMA obligations (2014) for follow up, PV need to collect sufficient information to enable follow up with the patient/consumer that reported the event (whilst still meeting data protection requirements). The 2014 EMA guidance can be found within section *VI.B.3. Follow-up of reports of the Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products (Rev 1) 8 September 2014 EMA/873138/2011 Rev 1*.* In the light of the 2014 EMA guidance when information relating to an AE is received directly from a consumer/patient during MR it will be necessary to obtain consent from the consumer/patient to collect and forward their contact data along with the details of the event to the MAH's PV department for follow up. Full information as to how the data will be used and who will have access to it, will need to be provided to ensure informed consent. Individual MAH's PV departments will determine which events require follow up. It is anticipated consumers will no longer be asked to provide their HCP's (as well as their own) contact details in relation to the AE cited. In the light of data protection requirements for informed consent it is not appropriate for this consent to be obtained by an intermediary (the market researcher) when the user of the data (the MAH) is able and better placed to obtain it. If HCP details are required for further follow up when the patient/consumer is the reporter, the proposal is that PV will request these directly from the consumer and seek the appropriate consent to follow up with their HCP. **ABPI consultation** Members of the ABPI Pharmacovigilance Expert Network are being asked for their feedback. **Data protection and privacy implications** The BHBIA have highlighted and discussed (with the ABPI) the fact that any change involving the collection of sensitive personal data will have significant data protection and privacy implications. These will be properly explored and advice provided before any changes are made.

When will the possible change be made?
As the EMA are currently reviewing GVP, changes to the BHBIA/ABPI's Guidance notes on the collection of adverse events and product complaints from market research programmes (April 2013) and BHBIA's online training and competency certification programmes will not be put into effect until the EMA's 2017 revisions are themselves finalised. This is not likely to be until quarter 4 this year.

The EC will be provided with a further update at the June meeting and depending on the action decided upon by the ABPI and BHBIA and in light of the EMA's 2014 Guidance will consider the implications for EphMRA's AER guidance. This item will be added to the agenda for the June EC meeting.

June Ethics Committee meeting in Amsterdam

The following potential topics for the June meeting's agenda were discussed:

- **Horizon Scanning**
  It was agreed that for each country/issue listed below, EC members would develop and provide 1 slide before the meeting. The aim is to highlight future developments likely in 2018 in the area – THIS IS A FORWARD LOOKING SESSION TO INCLUDE FUTURE RATHER THAN ONGOING ISSUES – the future refers to the next 1 to 2 years.

  This slide would include:
  - Developments expected (including any assumptions made)
  - The implications for MR
  - The risks for MR
  - Can EphMRA influence this change
  - What, if anything, EphMRA should do about this

  Our goal is to identify and prioritise issues that need follow up and action for next Code update or by the EC

  Issues/countries:
  - Catherine – GDPR
  - Julian – PV/AE reporting
  - Xander – ? Possibly big data – Xander to consider
  - Bettina & Mattias - Germany
  - Christine & Analia – France
  - Piergiorgio – Italy
  - Jessica & Matteo – UK
  - Roni & Holly – USA & Privacy Shield

In addition, it was agreed the following items would be included on the agenda:

- **GDPR/privacy** – This will include a review of progress by Catherine and discussion of any country derogations (i.e. exceptions) – country feedback on derogations to be prepared prior to the meeting by all.

- **PV** – The EC will be provided with an update on the UK decision at the June meeting and depending on the action decided upon by the ABPI and BHBIA and in light of the EMA's

	2014 Guidance will consider the implications for EphMRA's AER guidance. This item will be added to the agenda for the June EC meeting. It was also pointed out that the potential change to AER guidance would impact the blinding of consumer respondents.
4	**GDPR Guidance** A draft framework (based on the MR process we use in the Code of Conduct and the EphMRA Managing a Research Project) has been agreed - to provide a means to organise and deliver information on the impact of the GDPR. See the Framework in appendix 1 on page 5 of the EC report attached within the agenda for the April EC TC. The need for support for the development and review of GDPR updates was discussed and it was agreed that a sub team would be formed to provide this input. Holly, Jessica, Matteo, Xander volunteered to join the sub-team. Bettina volunteered to be involved with the topic of consents when this is addressed. Holy also volunteered to share in-house materials when practical. All offers of support were gratefully received. The GDPR Team's first task is to review the first update within the agreed series. This will be circulated shortly after the meeting.
5	**National Issues** The following national issues were discussed: **France – new decree** Decree no. 1939 of 28 December 2016 regarding the public declaration of interests provided for in Article L. 1451-1 of the public health code and the transparency of benefits - reporting deadlines has been moved to Sep 1 for Jan to Jun data, and to Mar 1 for Jul to Dec data, changes will be enforced starting July 2017 The ordinance modifying the "anti-gift" law was published in the Official Journal the 20th of January 2017 and takes effect from July 2018. The major impacts are as follows : – Enlargement of target groups receiving benefits: – Osteopaths and chiropractors are now included, declaration to be sent to the appropriate regional health authority (ARS - Agence Régional de la Santé). – State civil servants and administrative officers – Associations (such as learned societies of physicians – However patient associations are NOT included. – Higher criminal sanctions for those who donate "gifts" - 150,000€ penalty and up to 2 years of imprisonment. Analia let us know that there is also another new decree published March 2017 but this simply clarifies how to publish information. Analia to forward to Catherine for information. It was agreed that the Code would be updated with this information for the next update but that there is no need for an interim update. **Germany – employers permission**

	An email will be sent to recent Chapter meeting attendees to get feedback on the impact of the employers' permission requirement by Bernadette. **USA – Privacy Shield** Press reports suggest that the Trump administration and/or a challenge to the Privacy Shield in the European Courts may impact it but at present this is speculation. It was agreed that no update is required until there is 'hard' news to report.
	Ongoing Actions **Ethics Requests from Other EphMRA Groups** **From the Fieldwork Forum (FF)** We have contacted the FF and provided them with the current guidance on dealing with vulnerable patients and ask what particular issues/circumstances were driving their concerns and what further support or information would they need/envisage. The group does not meet again until the end of April so there is no further news. **From Devices and Diagnostics (D&D) Group** We have contacted the D&D Group and asked them for more detail upon what they need with regard to guidance on MR involving devices and diagnostics and if they have any sources/references that could be of help in shaping any potential additional guidance. They replied that it would helpful to know which parts of the Code apply equally to devices as much as pharma and which parts of the Code do not apply to devices. Catherine will address this question. **Code Extensions 2017** EC members were reminded that we need a contact based in Portugal that is knowledgeable about legal and ethical requirements in Portugal to help us extend the Code of Conduct to this country. Please contact Bernadette or Catherine if you can suggest anyone.