EphMRA Committee Meeting Actions		
Date:	16 March 2016	
Event:	**Ethics Committee Interim Meeting AER Issues & Record Keeping Requirements**	
Time:	2 – 3 pm (UK time)	
Place:	Teleconference	
Participants:	BB	Bettina Brust
	CA	Catherine Ayland
	CM	Christine Mai
	DS	Daniel Stults
	IB	Ian Barker – Chair
	JA	Julian Alexandra
	MB	Mattias Blomgren
	PR	Piergiorgio Rossi
	RDG	Roni DasGupta
	SMH	Sarah-May Hall
	XR	Xander Raijmakers
Apologies	BR	Bernadette Rogers
	GB	Georgina Butcher
	KJ	Katie Joyner

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
1a	**AER Requirements** ▪ EphMRA to provide a single one page checklist of the information that companies need to provide to agencies for AER ▪ EphMRA to find out from pharma company members if: – In principle EphMRA AER training would be acceptable or not to companies (PV) if it was: □ Endorsed by the EMA □ Endorsed by EFPIA □ It is not endorsed □ And if it would not be acceptable, to find out why not – what barriers stand in the way? – They would be willing to share their AER training so that EphMRA could develop a single harmonised training programme ▪ EphMRA to explore the development of a single training programme recognised by the EMA and other competent authorities and acceptable to member pharma companies	IB/CA IB/GB/ BR/CA TBC	April April/May TBC
1b	**AER Record Keeping** • EphMRA to provide a single one page checklist of the AER data that should be stored by agencies and by pharma companies • A regulator view on what should be stored by whom and for how long should be sought from the MHRA, the request for guidance would include the information that the international MR standard for record keeping is 2 years	IB/CA IB/GB/ BR	April April-May
	Date of next EC TC meeting 26 April 2016, invite sent.		

MINUTES

No	Item/Issue
	Following discussion at the January EC meeting with regard to concerns surrounding AER requirements and whether EphMRA could further support members in this area it was decided that more time for discussion of this issue was needed. The meeting today was therefore dedicated to discussing: **1. AER Requirements** To find out what AER issues (from pharma company and agency perspectives) are of concern or difficult to manage in order to see what can be done to iron out inconsistencies in AER

	requirements. **2. AE Record Keeping Requirements** To identify common areas that EphMRA might use to develop guidance to FMs and AMs
1a	**AER Requirements** The following points were raised during the course of the discussion: ▪ Pharma companies were asked – what could be changed to make the process smoother, to '*sensibalise*' it? ▪ Agencies need pharma companies to supply training in the local languages ▪ Pharma companies need to know exactly what country differences exist, it was pointed out that PV requirements consistent country to country however data protection/privacy law can impact the process ▪ AE definitions are generally consistent/universal and this is not the major issue ▪ Training is however a major issue as many pharma companies require agencies to take their own ▪ EphMRA training that is not endorsed/approved by either the EMA or EFPIA and ideally both is unlikely to be acceptable instead of pharma company-specific training, although it was acknowledged that this would be an ambitious goal and it was pointed out that regulators generally know little of the MR process and how it can practically accommodate AER The following actions were suggested and agreed: ▪ EphMRA to provide a single one page checklist of the information that pharma companies need to provide to agencies for AER ▪ EphMRA to find out from pharma company members if: – In principle EphMRA AER training would be acceptable or not to pharma companies (PV) if it was: □ Endorsed by the EMA □ Endorsed by EFPIA □ It is not endorsed □ And if it would not be acceptable, to find out why not – what barriers stand in the way? – They would be willing to share their AER training so that EphMRA could develop a single harmonised training programme ▪ EphMRA to explore the development of a single training programme recognised by the EMA and other competent authorities and acceptable to member pharma companies, this would offer the following benefits: – Would streamline the training process and save costs for all – Reduce inconsistencies and the potential for mistakes these introduce
1b	**AER Record Keeping**

	The following points were raised during the course of the discussion: ▪ The need for duplicate record keeping (by agencies and pharma companies) was raised, it was suggested that this need arises because of audit requirements ▪ Pharma company requirements in terms of length of storage do not appear to have a legal basis to support them and even when a time limit is agreed permission to destroy must still be sought and granted ▪ Length of storage requirements appear contrary to current data protection requirements and are likely to be contrary to the GDPR too The following actions were suggested and agreed: ▪ EphMRA to provide a single one page checklist of the AER data that should be stored by agencies and by pharma companies ▪ A regulator view on what should be stored by whom and for how long should be sought from the MHRA; MHRA guidance is considered demanding and so adequate (rather than the EMA), the request for guidance would include the information that the international MR standard for record keeping is 2 years
Date of next teleconference 26 April 2016, 2-3pm (UK time)	

Appendix

Ethics Committee Information Gathering Exercise

Adverse Event Reporting

Introduction

Members of the Ethics Committee (EC) both pharma company and agency, were asked to provide an insight into their views on adverse event reporting (AER) and training requirements with particular reference to issues that are of concern. This information will be used to:

- Inform further discussion at the next EC call
- Help the EC consider if further EphMRA AER support for members is appropriate
- Help us engage productively with EMA.

Previously discussion amongst EC members had made clear that:

- Different pharma companies do have largely similar but occasionally different AE reporting and training requirements and that inter country variations although limited can exist
- The logistics/practical processes can vary from company to company

Four pharma company and four agency EC members responded to the request for information.

Key points

Key points raised within the feedback from EC members were inconsistencies in and the demanding nature of the process – both common causes of concern for both agencies and pharma companies.

Inconsistencies

- Inconsistencies can occur in four areas – defining AEs, reporting requirements, training and country to country variations.
- Defining AEs – particularly 'lack of efficacy'
- Reporting forms:
  - Can vary both company to company and within company, country to country
  - Some require accompanying instructions that are not provided
  - Some require 24 hour reporting and monthly reconciliation
  - The EphMRA and BHBIA templates aren't always used.
- Training
  - Each pharma company that responded had their own in-house training
  - One pharma company referred to their training detailing EMA requirements and company needs
  - Pharma company training can vary from the BHBIA training but the differences were not made clear
  - One agency suggested the need for specific AER training on each project

    - One agency said it was hard to keep up to date with certificate renewal
    - One pharma company requires annual renewal of their company's training
- Country variations
    - Need to be spelt out for agencies
    - May include reporting routes i.e. the means and addresses to which AE reports should be sent
- Intra-company differences exist too between regional and national requirements

Other difficulties raised included:

- Providing product information (even a seemingly simple short product summary) can be very time consuming for a company to prepare
- Lack of awareness in PV about the MR process and why it may not be practical to supply all the required AE information
- Requirement to follow up AE reports and re-interview respondents to get additional AE data
- Post project audits
- Couriering of AE material

Demanding process

- For both agencies and companies AER is a demanding process – time consuming and difficult, and it is absorbing increasing amounts of time
- Not all those entering data recognise the importance of accurate and up to date detail
- Case studies and examples to illustrate the benefits of AER would be helpful
- Training is very time-consuming for agencies
- Pharma company requirements aren't always made clear
- Translators may need to do AE training although there is no obligation for them to report AEs
- Materials may not be user-friendly

Suggestions made

- A common process – definitions, reporting and training – was suggested by some companies
- Country-specific legal requirements for training, reporting, program approval and material review
- EphMRA to recommend one training and one form

Ethics Committee Information Gathering Exercise

Adverse Event Reporting & Record Keeping Requirements

Members of the Ethics Committee (EC) both pharma company and agency, were also asked to provide their views on adverse event record keeping in order to help the EC decide whether EphMRA should provide guidance on AER record keeping.

Four pharma company and four agency EC members responded to the request for information.

Issues

- Agencies - Uncertainty and differing views exist with regard to how long personal data can and should be stored for:
  - In Germany it was suggested that primary data must be stored for 10 years but that this conflicts with ADM/BVM guideline to destroy records at the end of the project
  - One agency stores data for up to 2 years, one that it has been asked to store for 20 years
  - Length of storage is specified in vendor agreement
  - MSA requires that copies of AEs are stored for 5 years (or an alternative agreed period) and that before any data is destroyed it must be offered to the company for longer term storage
  - Permission to destroy may be requested (as well as time period)
  - Requirements are evolving – the goal posts move and storage times are extending
  - Secure electronic storage is expensive
  - Clients have been known to audit storage on site
- Pharma companies – National/local drug safety department is responsible for record retention

Data stored

- Project content, copies of AE reports, receipts and correspondence (Agency)
- Report form and anonymised primary data(Company request of agency)
- Sometimes paper and electronic copies (Agency)
- Training records, AE reports and reconciliation forms (Pharma company)
- One company referred to auditing MR suppliers annually and checking record keeping
- Reference was made to secure electronic storage system and secure server use for storage
- Intra-company differences in storage between national affiliates

Suggestions

- Guidance on record keeping would be a great help
- Guidance on what personal data can be passed on would be helpful (record sharing)
- Guidance on what the local/national vs what the international agency should store would be helpful