EphMRA Committee Meeting Minutes & Actions

26 June 2018 12 noon to 2.30pm - Basel

Participants:	ABC	Anne-Beatrice Clidassou – joined via Skype
	BB	Bettina Brust
	CA	Catherine Ayland
	CM	Christine Mai – joined via Skype
	GB	Georgina Butcher – Chair
	JS	Jessica Santos
	KGV	Karen Giorgi-Vigo
	MB	Mattias Blomgren – joined via Skype
	MC	Matteo Cappai
	PR	Piergiorgio Rossi
	RDG	Roni DasGupta – joined via Skype
	SMH	Sarah-May Hall
	XR	Xander Raijmakers
Apologies:	BR	Bernadette Rogers
	JB	Jayne Blanshard
	KB	Kate Barber

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

Ethics Committee TC Meeting – 26 June 2018

Chair – Georgina Butcher

MINUTES & ACTIONS

<table>
<tr><th>No</th><th>Item/Issue ACTIONS highlighted in red</th><th>By</th><th>Date</th></tr>
<tr><td>1</td><td>GDPR – Georgina and Catherine

<u>Defining and naming data controller</u>
The issue of ‘Defining the data controller and naming the end client’ was discussed and it was agreed that a further update for members should be a priority to get out in July. The communication needs to make sure that the information reaches as many people as possible (consider different channels of communication) and to reassure members that EphMRA are working on this with other international and national MR associations to address the concerns of their respective membership and MR industry in general. The update should be clear and concise to stress the next steps and what can be done (i.e. what is at the end of the first update).

<u>Further GDPR support for members</u>

• The EC would like to see a GDPR ‘information warehouse’ built on the EphMRA website that pulls together:
– GDPR updates/guidelines
– An FAQ
– Opinion pieces
– News articles
– News from other organisations

• Further guidance should be provided – What it means For each of the key areas of the Code that have been updated with GDPR guidance to provide a separate short guides to explain ‘what it means’ practice, e.g. examples and case studies. For example:

<table><tr><th>C of C GDPR Guidance</th><th>What it means . . .</th></tr><tr><td>Consent agreements
- quote Code paragraphs</td><td>Examples and case studies</td></tr><tr><td>Using customer lists
- quote Code paragraphs</td><td>Examples and case studies</td></tr><tr><td>Etc.</td><td>Etc.</td></tr></table>
Key areas to be covered include:
– Use of different legal bases</td><td>BR

BR

BR</td><td>July

Sep/ Oct

Jun-Sep</td></tr>
</table>

	– Consent agreements and privacy notices – DPIAs – Using customer lists – Use of patient data – Viewing fieldwork – Digital listening – AE reporting – Appending data to lists – Record keeping – Safe-guarding - Sarah-May to provide a link to a CNIL guide that may prove helpful in this area. In addition to regular clear communications and updates on lobbying (where possible), EC to promote engagement between clients and agencies, e.g. develop case studies, draw on real-life experience to share best practice. Action to follow up September meeting and define actions needed Via email follow up Mattias also suggested including: – How to handle New Business / Product Development MR that is highly confidential and commercially sensitive, e.g. evaluating licensing opportunities etc. Naming client will not be possible without a confidentiality agreement on top. Georgina pointed out (via email follow up) that this should be possible but it will be very challenging for the clients. The commercial sensitivity and confidential for company's own pipeline but also assessing in-licensing opportunities creates additional risks for the company/ies. NDA is one option but this has to be worked through with clear examples or case studies. – Providing a contact list to agency for purpose of only analysis (target customer matching or alike) – same rules apply – end client has to be named if data is passed for other purpose than recruiting? – From supplier perspective, also important to understand that they might have to follow different approaches for same MR, if we leave it up to end client to determine how to consider end client as data controller or not. This approach to be extended to the issue of defining the role of the client and agency in terms of whether they are a joint controller, sole data controller, data processor (or even sub-processor). The goal is to list tasks/activities that will help determine whether organisations (company or agency) are involved in determining the purpose and/or means of the data processing which in turn will determine who is or is not a data controller. The Fieldwork Forum are also exploring further guidance and may well be producing content/guidelines that will overlap. So the potential for and areas of overlap would have to be identified and managed.	SMH	July

	Action – EC to be provided with feedback from Fieldwork Forum • The EC identified a need to reach out to non-EU based EphMRA members (in particular US based members) and provide them with guidance on implementing GDPR on projects that are managed or commissioned by a non-EU based organisations but that must meet GDPR requirements because they have a EU based data controller, processor or data subject. It was suggested that this may involve liaising with Intellus. • Karen has volunteered to share a guide that she has in development, (six) steps to protecting privacy. A small scale guide with clear sections, titling and lots of examples was requested. • EphMRA to reach out to EFPIA and discuss whether the impact of GDPR is going to be accommodated within the guidance on promotion to healthcare professionals. It would be useful if EFPIA guidance included reference to the GDPR requirement to name end clients (on different occasions for different reasons) within MR projects. It would be useful to have an acknowledgement that naming the end client because of legal requirements will not on its own lead to a complaint that the MR is disguised promotion. N.B. It is important to ensure that industry guidance is balanced and proportionate, and avoiding over-reaction e.g. in the form of a regulation that states that the end client should always be named.	GB/BR KGV BR	Sep-Oct July Sep/ Oct
2	**Data Protection/Privacy in the USA** – Karen & Roni Please see slides – EphMRA US Data Protection <u>Sunshine Acts</u> – Karen drew attention to changing Sunshine Act requirements at the state level. In response to a question about whether a single accessible source of up to date information on state Sunshine Acts/requirements is available, it was stated that there is no single website source for the latest information. <u>Privacy Shield</u> – This appear to be under an ongoing threat but that threat does not appear to be imminent. It was felt that lots of US based organisations that transfer personal data in and out of the USA do not have adequate safeguards in place. <u>California Consumer Privacy Act</u> – Please see document (attachment to email) – 'Drastic Privacy Initiative on California State Ballot This Fall: The California Consumer Privacy Act' issued by the Insights Association. *"An initiative on the California ballot this fall would dramatically expand privacy regulations in California law and drive litigation risks and costs through the roof for marketing research and data analytics companies"*		

	There was very limited time available to discuss the details and implications of the Act or any actions that EphMRA should take. However it was agreed that EphMRA members should be alerted and those that are based in California encouraged to lobby on this issue (as we did on the California Senate Bill S.B. 790 in July 2017. It was also suggested that EphMRA liaise with Insights Association to offer support and keep in touch on the issue. Contacting Howard Fienberg, Director of Government Affairs (Roni provided an introduction in October 2017).	BR	July
3	**UK withdrawal from the EU** – Georgina and Jessica Please see slides – EphMRA Ethics UK Update JSGB 26 June 2018 <u>Impact on Pharmacovigilance</u> - The EMA is thought to be preparing for a 'hard' Brexit, with the UK classified and treated as a third country, the consequences of which could potentially mean that there would need to be: – Two filings made to the Eudravigilance database, assuming the UK can still access this database directly. – Two QPPVs (Qualified Person Responsible For Pharmacovigilance) – one based in the UK and one in the EU No actions were noted other than a need to monitor and feedback on any further news/developments. Alert EC if anything significant changes that will impact on healthcare MR	GB/JS	On-going
4	**Engagement Plan Update** <u>France Sarah-May & Christine</u> Zeste's DPO has said that AER forms can be kept for a period of 10 years (on the basis that an audit might be required within this timeframe). Accessory activity – It has been confirmed that classification of an activity as 'accessory' is not to do with fees but is based on the time the activity takes. It is understood from CNOM that all hospital based doctors wold have to have written permission from their hospital and possibly also from another internal authority. This is not required if the project is covered by the parameters of CNOM's Simplified Reporting System. It was also confirmed that an active 'go-ahead' will be provided (in the past no response was a go-ahead'. 2016 Act – Has raised questions about the status of MR carried out with patients and whether this requires Ethics approval or not. Sarah-May to keep the EC updated on this issue.	SMH	On-going

	Germany – Bettina There has been no reply yet from the ADM following Bernadette's approach and this will be followed up. Italy – Piergiorgio A healthcare orientated sub-group has been formed within ASSIRM. The ASSIRM Privacy Code will be updated and made GDPR-ready. There is a new 'Do Not Contact' Regulation in Italy which requires that organisations send their lists of individuals to the DNC Registry who for a fee review this list against their data base and you are then informed which individuals may not be contacted. The Regulation divides activity into 2 camps one of which is tele-marketing, at present it would appear that MR falls within this camp and consequently will be vulnerable to far more DNCs. Arguments have been made and lobbying by ASSIRM will continue in order to change this classification. Korea – Matteo & Georgina No further news. No further actions (other than the one for Germany) were noted other than a need to monitor and feedback on any further developments.	BR MC/GB	July On-going
5	**Change in ethics support** It was announced that Catherine is stepping down from her role as EphMRA's Ethics Consultant (effective the end of June 2018) and although the EphMRA Board had been made aware of this some time ago, the announcement had been postponed until a plan for ethics cover had been put in place. EphMRA will be supported in ethics by MRS/EFAMRO, with Dr Michelle Goddard providing support to the EC. Bernadette will provide Ethics Committee support in Catherine's place for the next year. Catherine was thanked for her work and in turn thanked all the EC for their support over the years. A gift of thanks was presented and gratefully received.		
6	**Date of forthcoming meetings – suggested schedule** Dates to be sent out for the next three meetings Sep 2018 – w/c 10 (Planning & progress review) Nov 2018 – w/c 12 (Progress review) Jan 2019 – w/c 28 (Progress review)	BR	July
	No other business was raised		