EphMRA Committee Telephone Meeting: Minutes & Actions 24 September 2020 14:30 – 15:30 BST / 15:30 – 16:30 CET		
Participants	Mattias Blomgren	Camilla Ravazzola
	Matteo Cappai	Analia Revaux
	Florence Chopin	Bernadette Rogers
	Christine May	Jessica Santos
	Xander Raijmakers	
Apologies	Alex Adams	Jeanette Kaufmann
	Anne Beatrice Clidassou	Matteo Scaringi
	Roni DasGupta	Piergiorgio Ross
	Karen Giorgio Vigo	
Please kindly remember that all EC discussions should remain confidential		

MINUTES & ACTIONS

	Topic	Action
1	**Welcome** **AER Guidelines and 2020 Code almost ready to launch**	
2	**<u>Question raised by Mattias (EDPB update)</u>** Refer Agenda - EFAMRO comment Discussion points: Query emanated from company data privacy officer. How should the HC industry respond to the new EDPB guidance? CR: The guidance does not add anything new. It is to clarify and codify the decisions of the European Court of Justice (ECJ). Businesses can take a risk-based approach to determining roles under GDPR, but the jurisprudence of the court is clear and applicable. There is some flexibility to determine who is in responsible at the different stages of each project, rather than defining one role for the entirety of the project (i.e. start to finish). Question the extent of the need to follow article 13 'to the letter' when determining roles, e.g. client and agency are joint controllers but level of risk not naming client? Recognition that GDPR is to provide a solution to the problem of how personal information are currently managed. However, several EC members voiced concern that this blanket approach is a solution applied to a non-problem in HC MR. CR: It is specific in the guidelines of the need to define the obligations and objectives for the client and agency for each stage of the project. Within this is the scope to be clear that the point of contact is the MR agency, not the sponsoring company. Acknowledgement that problems arise where the data subject requests access to their data (amend, delete, etc) to the sponsor company rather than the agency. Potential scenario where the data subject provides more information than needed to the company, e.g. ID to confirm they are who they say they are, and therefore are identifiable. Confidentiality and anonymity are then removed. JS: Two questions. Do both parties need to be named or just one (client and/or agency)? Supply chain usually includes client, MR agency and one or more fieldwork / panel agencies. The agencies at the end of the chain hold personal information, but not passed to the main	

	MR agency or client. Anonymised (or pseudo-anonymised) data goes to MR agency and aggregated, anonymised data reported to client (end user). XR: Pharma companies will consider if other laws take precedence over GDPR/DP regulations, especially anti-bribery / corruption laws. US HC companies, such as Lilly view anti-corruption law as a higher risk vs. GDPR and naming the client during MR. Example: agency and client are named, but payment of a fee for completion of the MR is associated with Pharma company X not the MR agency. This might be construed as an inducement or bribe from the company with resulting consequences from US (or national) corruption laws. FC: France CPA – problems and risk regarding transparency and transfer of value to HCPs. The complexity and problem, which we have known for two years, is the declaration of incentives by HCPs which means s/he is no longer anonymous. MC: We need also to consider other countries' legislation that might affect the rationale for disclosure. For example, the name of the client must not be given if an incentive is offered when conducting research in Russia. It is not feasible to do any MR if an incentive is not offered, but there the agency also needs to comply with GDPR which creates a problem (national laws can trump DP regulations). CR: The responsibility of the controller is not just towards the subject access requests or dealing with the data subjects. The example given is the obligation to disclose the name of the client and not because it is the controller, but because of transfer of data. E.g. To transfer personal data to a third country, such as the US, you must inform the subject that you are doing this. The pharma company can use their discretion to decide where they feel there is the greater risk, but this cannot be codified in EphMRA guidelines. Point raised re: BHBIA and the MRS discussions on addressing the updated EDPB's guidance. Question – could EphMRA be involved? Is it an opportunity for sector-specific guidance? CR: MRS focus is across industry sectors, i.e. general MR rather than HC specific sensitive personal data. The code being developed by EFAMRO and ESOMAR will provide sector-specific guidance. That is more relevant but raising the problem again with the EDPB is also an option. Another angle to consider is initiating discussions with the relevant regulatory parties within the EU to see if a feasible and applicable solution can be identified, rather than 'going against' the EDPB. For example, the EMA or EFPIA as broader regional bodies, rather than attempting to approach separate national regulators / industry associations where differing opinions will arise, i.e. increasing confusion and does not resolve the issues identified.	**EC members**: Provide Camilla with real practical examples of problems arising by naming the client. Not hypothetical or vague examples. Will look at how this can be developed as a discussion document to take to the EDPB. **CR:** following up BHBIA & MRS discussions – what can EphMRA learn from this. Potential to piggy-back.
3	**Plans for EphMRA EC 2020/21** What should the EC plan to focus on for the members?	**BR** follow-up EC via email - discuss next call if needed
4	**Training Developments** 2020/21 new courses: 1. Preparing for Field 2. Code of Conduct for Medical Personnel Reviewing Market Research Would like to develop another offering which includes a competency test. Ideas / suggestions from EC	**BR** follow-up EC via email - discuss next call if needed

5	**<u>Thoughts on an online Ethics and Compliance event in Feb 2021</u>** One day (10:00 – 15:00 h) Topics could include: Review of key elements in the EphMRA Code and discussion on future developments Update on Data Protection and Privacy guidance, including international developments Discussion on what compliance issues EphMRA anticipates over the next 12 – 24 months. Ask delegates for their suggestions and priorities for any new resources the EC should consider preparing to meet future compliance needs. Break-out sessions to discuss key topics Cost for day per member will be Euros 300	**BR** follow-up EC via email - discuss next call if needed
6	**<u>AOB</u>** No further points raised. **Close meeting**	