EphMRA Committee Meeting Actions		
Date:	21 June 2016	
Event:	**Ethics Committee - Extended Face to Face Meeting**	
Time:	1 – 3.30 pm (CET)	
Place:	Frankfurt, Germany	
Participants:	BB	Bettina Brust
	CA	Catherine Ayland
	CM	Christine Mai
	GB	Georgina Butcher - Chair
	JA	Julian Alexandra
	PR	Piergiorgio Rossi
	RDG	Roni DasGupta
	SMH	Sarah-May Hall
	XR	Xander Raijmakers
Apologies	BR	Bernadette Rogers
	DS	Daniel Stults
	IB	Ian Barker
	KJ	Katie Joyner
	MB	Mattias Blomgren

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**
1	**Alert Session** Following the Alert Session, these actions were agreed: ▪ Provide members with a GDPR and Privacy Shield update as soon as possible ▪ Keep a watch for the introduction of centralised AE reporting in 2017 and monitor for any impact on MR ▪ Use the detail within Xander's presentation to develop a 'thought piece' for an Ethics Update, that will also draw upon the impact of new technologies (their positive and negative impacts) and the pressures that impact MR, complimented by issues raised by Piergiorgio and Bettina ▪ Deliver a clear, strong EphMRA compliance message to external stakeholders with extensive reach (wide distribution), particularly to consultancies that work on the fringes of MR and to non-pharma/healthcare agencies that only very occasionally work in the field ▪ Provide members with an update on the new simplified CNOM reporting process in France ▪ Provide more supporting detail to distinguish MR and marketing, taking into account how the arrival of new technologies impact what we consider MR to be or not to be ▪ Monitor EFPIA to see if there are any changes to Disclosure requirements following the first period of reporting to provide an early alert and guidance to Members ▪ Include additional USA Sunshine Act sources in Code update ▪ Scheduling of the updates to avoid receipt on the same day and overloading members with information	 CA JA XR/PG /BB/BR BR/CA /GB CA/CM /SMH CA CA/BR CA BR	 1 July Ongoing September Ongoing 1 July October Ongoing December July
2	**GDPR – Impact, communications and training** ▪ To provide members with a GDPR and EU-US Privacy Shield update as soon as possible and by 1 July if practical ▪ To provide members with updates on an as needed basis but reasonably regularly so that we keep in touch and keep them up to date and prepared for any developments, next update likely to be September ▪ Include a GDPR training/update in the 2017 ethics webinar series	 CA/IB CA/IB BR	 1 July Ongoing 2017
3	**Training – 2017 Plans** **Webinars** proposed for 2017: ▪ Country & Regional Differences Update ▪ GDPR ▪ Distinguishing MR (Defining and clearly differentiating MR from other activities) ▪ BR is asked to advise the EC on resource and practicality of providing the **Country Differences Guide** in an alternative additional format – by issue,	 BR	 September

	rather than by country		
4	**AER Training** ▪ Discussion postponed due to lack of time, additional TC dedicated to AER training to be scheduled w/c 18 July	CA	w/c 18 July
5	**Changes in France** **CNOM Update and implications** ▪ An update to members would be prepared and circulated as soon as possible ▪ At present the wording (in French) of the 4 'conventions' are not available for EphMRA to issue or provide a link to members, CM to advise as soon as these are available (hopefully within 2 to 3 weeks). ▪ A translation of the Conventions from French to English, will be required **CNIL requirements in France** Discussion postponed due to lack of time, this item will be added to the agenda for the September 2016 TC meeting.	CA CM BR CA	1 July ASAP ASAP w/c 18 July
	Date of next EC TC meeting w/c 18 July 2016, invite and agenda to be sent	CA	

MINUTES	
No	**Item/Issue**
	Alert Session - Changes to the Ethics Environment Each Committee Member provided a brief update highlighting future developments likely in the next 1 to 2 years. Each of the updates are detailed from page 6 onwards, the following actions were agreed: ▪ GDPR & EU-US Privacy Shield (Ian/Catherine) – To provide members with an update as soon as possible, by 1 July (CA) ▪ Pharmacovigilance/AE reporting (Julian) – To keep a watch for the introduction of centralised reporting (JA) ▪ Impact of new technologies (Xander) – To use this detail to develop a 'thought piece' for an Ethics Update, that will also draw upon common issues raised by Piergiorgio and Bettina (XR/PG/BB/BR) – To get our compliance message out as far and wide as possible, particularly to consultancies that work on the fringes of MR and to non-pharma/healthcare agencies that only very occasionally work in the field (BR/CA/GB) ▪ Germany (Bettina & Mattias) – To include mention of the problem areas (which reflect pressures on MR) within the proposed 'thought piece' for an Ethics Update ▪ France (Sarah-May & Christine) – To provide members with an update by 1 July (CA/CM/SMH) ▪ Italy (Piergiorgio)

	- To provide more supporting detail to distinguish MR and marketing, this also ties in with points raised in Xander's session (how does the arrival of new technologies impact what we consider MR to be or not to be) (CA) ▪ UK (Katie) - To monitor EFPIA to see if there are any changes to Disclosure requirements following the first period of reporting (CA/BR) ▪ USA (Daniel & Roni) - To include additional Sunshine Act sources in Code update (CA)
2	**GDPR – Impact, communications and training** In view of the changes that GDPR will bring, the EC discussed the best way/ways to keep members up to date and help them to understand its implications and agreed on the following: ▪ To provide members with a GDPR and EU-US Privacy Shield update as soon as possible and by 1 July if practical ▪ To provide members with updates on an as needed basis but reasonably regularly so that we keep in touch and keep them u to date with any developments, next update in September 2016 ▪ Include a GDPR training/update in the 2017 ethics webinar series
3	**Training – 2017 Plans** **Webinars** proposed for 2017, scheduling was not discussed: ▪ Country & Regional Differences Update ▪ GDPR ▪ Distinguishing MR (Defining and ring-fencing MR) ▪ The suggestion was made to provide the **Country Differences Guide** in an alternative additional format – by issue, rather than by country however this is not considered a high priority and BR is asked to advise the EC on resource and practicality. It was agreed that whilst an interactive tool would be ideal, this could not be justified over other priorities and would not be suggested/progressed.
4	**AER Training** ▪ Discussion postponed due to lack of time, an additional TC dedicated to AER training to be scheduled w/c 18 July
5	**Changes in France** **CNOM Update and implications** ▪ Following a detailed update on the new simplified CNOM reporting procedures by CM & SMH it was agreed that an update to members would be prepared and circulated as soon as possible and ideally by 1 July. ▪ At present the wording (in French) of the 4 'conventions' are not available for EphMRA to issue or provide a link to members, CM to advise as soon as these are available (hopefully within 2-3 weeks). ▪ A translation of the Conventions from French to English, will be required **CNIL requirements in France** ▪ Discussion postponed due to lack of time, this item will be added to the agenda for the September

	2016 TC meeting.
6	**Dates of forthcoming meetings** Suggested schedule was approved Jul 2016 – w/c 18 – Additional TC meeting dedicated to AER Sep 2016 – w/c 12 (Planning & progress review) Nov 2016 – w/c 14 (Progress review) Jan 2017 – w/c 23 (Progress review) Apr 2017 – w/c 3 or 24 (Progress and pre-planning meeting planning) Jun 2017 – w/c 19 (Planning meeting) Sep 2017 – w/c 11 Nov 2017 – w/c 13

GDPR & EU-US Privacy Shield (Ian/Catherine)

General Data Protection Regulation (GDPR)

- GDPR finally agreed by the European Council, Parliament and Commission.
- The final text published in Official Journal in May 2016 and so it will be enforceable in May 2018 – giving us a two year window to prepare.
- Compromise solution - does not completely satisfy either privacy advocacy or commercial interests.
- Creating new and strengthens existing individual rights, requires greater business accountability and focuses on privacy.
- Key - compliance is not a bolt-on and must be an integral part of market research, privacy is built in by design and default.
- It will impact on the activities of all researchers working in the EU as well as those operating further afield.
- Personal health data continues to be treated as sensitive personal data requiring explicit consent.
- Processing sensitive data is prohibited unless allowed by member states who are also allowed to introduce further conditions around the processing of biometric, genetic or health data. This could be an area of inconsistency across the EU.
- Pseudonymised data – is explicitly recognised as a type of personal data, the GDPR makes it clear that this should be the default in research projects.
- Increased territorial scope - GDPR applies to all persons handling the personal data of EU residents wherever the data handler (i.e. controller or processor) is located. Those without a physical presence should appoint a Representative in an EU Member State. For example if you are exporting personal data from the UK to Japan, your Japan based partner would have to have a representative based in the UK to act as a point of contact for regulators and data subjects.
- Penalties for non-compliance are significant with fines of up to 4% of worldwide turnover or €20 million/£15 million.
- Strong internal accountability mechanisms will be required, such as record-keeping and self-regulation initiatives, allowing data controllers and processors to rely on approved codes and certifications for demonstrating compliance. More guidance required from grouping of 28 European Data Protection Regulations on this.
- More information must be provided to data subjects such as on retention periods or criteria and actively promote awareness of rights to individuals. Information has to be provided in an intelligible form using clear and plain language.
- Greater accountability and more detailed compliance responsibilities on Data Processors and Data Controllers.
- Current requirements to notify DPA of data processing (e.g. in UK) have been removed but in its place is a risk-based accountability scheme with obligations to: keep very detailed internal records of processing activities; complete privacy impact assessments (DPIA's) that provide a framework for

identifying, assessing and reducing the data protection risks of your project; and appoint a Data Protection Officer (DPO). Some of these requirements will be mandatory for those involved in riskier or large scale processing of sensitive data such as health data.

- New requirements on Data Processors (DP) and Data Controllers (DC) wider responsibilities now placed directly on data processors.
  - GDPR will place obligations directly on processors and enforcement action can be taken directly against them.
  - There are new mandatory terms to be included in contracts between DC and DP so that DP must seek approval to appoint sub-processors and to transfer personal data out of the EEA.
  - DC have a right to audit DP in the legislation.
  - Set up demonstrable processes to ensure accountability
- Legal grounds for processing personal data under the GDPR reflect the existing position and informed consent will continue to be key. Consent must be specific, informed with clear affirmative action. Explicit consent is required from the individual to process their health data this must be distinct from other T's and C's. Consent must be as easy to withdraw as it is to give. You also need to be able to provide evidence that you obtained consent from specific data subjects, which may require different/better record keeping and the use of clearer language in privacy policies/notices.
- The GDPR provides an exemption for "scientific research" which can be used where it is impossible to conduct research otherwise.
  - Researchers can get a broad consent for research including healthcare research.
  - GDPR recognises that it is unrealistic to require scientists to list all purposes in consent form at time data collected.
  - Personal data can be repurposed without getting further consent once individuals have given their consent to certain areas.
  - Member States will need to specifically introduce this in national legislation. So that whilst previously the ICO seems to have accepted that market research falls within research exemptions this view may not be shared across the EU member states
- Review policies and contracts, may need to strengthen and design new compliance policies, make sure:
  - Methods of obtaining consent and data breach notification are sufficient.
  - Only necessary personal data is collected, pseudonymise or anonymise as soon as possible.
  - Systems can cope technically with new rights of data portability, right to be forgotten, record objections or withdrawal.
  - Supply chain all meet the new standards
- Implement privacy impact assessment for risk management. Have processes in place to assess risk of MR projects and the use of personal data. There will be a need to identify the privacy and related risks; and then identify and evaluate the privacy solutions.
- May need to appoint a DPO - the DPO is required to act independently and report to the highest level of management – but this position can be outsourced to a competent firm or individual.
- Reforms will impact on us in the UK regardless of the Remain or Leave decision made on 23rd June 2016 as we still need to have a data protection regime in place that meets EU standards of adequacy. Experts in the UK appear to be suggesting that in the event the UK left the EU it would enact any changes necessary to comply with the GDPR in order to maintain adequacy. Although

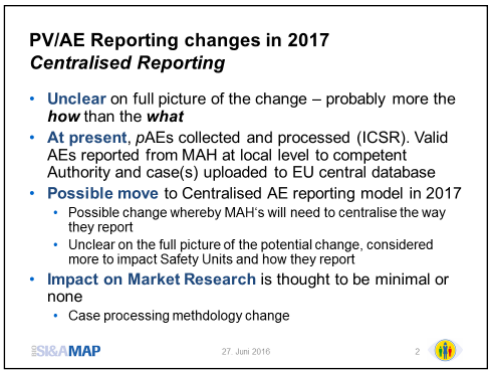
some legal commentators are already arguing the current UK Data Protection Act is sufficient for an adequacy finding if the UK did leave the EU. The reality is it's a guessing game!

EU-US Privacy Shield

- The adequacy decision on the EU-US Privacy Shield to replace the Safe Harbor scheme is ongoing and fraught with continued legal uncertainty in light of the decision of the Article 29 Working Party (group of EU data protection authorities) that the EU-US Privacy Shield is not yet fit for purpose. Despite this the Commission has indicated that it expects to issue an adequacy decision on the Shield by June 2016.

Action: To provide members with an update as soon as possible, by 1 July.

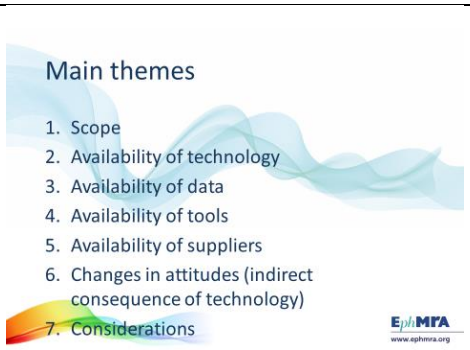
Pharmacovigilance/AE reporting (Julian)



At this stage centralised reporting isn't likely to have implications for MR or the Code of Conduct. However increased visibility of processing could lead to increased focus on detail which in turn could lead to more auditing of MR agencies.

Action: To keep a watch for the introduction of centralised reporting.

Impact of new technologies (Xander)



Scope

- Company perspective
- Focus on risk, not on how this may impact our function

Availability of technology

- Desk Top, Lap Top, Tablet, Phablet, Smart Phone, Wearable…
- Are we catching up quick enough or are tech companies better at this?
- Enthusiasm beats prudence
  - Privacy
  - Data owners/Respondents' rights
  - Damage to the reputation of MR via poor analysis as well as questionable results
  - AE reporting concerns
  - Intellectual property

Availability of data (II)

- Over-research -> Under-response
  - We're killing the goose with the golden eggs
- Over-research driven by the opportunity: smart phone, tablet, PC…., we can reach anyone anytime, anywhere
- Any web site you look at for more than 0.5 of a second ….

Availability of data (II)

- Over-research -> Under-response
  - We're killing the goose with the golden eggs
- Over-research driven by the opportunity: smart phone, tablet, PC…., we can reach anyone anytime, anywhere
- Any web site you look at for more than 0.5 of a second ….

Availability of tools

- Survey Monkey, Google Analytics…
- You don't need MR for this!
- (Knowledge is a handicap)
- Enthusiasm beats prudence
  - Privacy
  - Respondents' rights
  - Damage to the reputation of MR via poor analysis as well as questionable results
  - AE reporting concerns
  - Intellectual property

Availability of techniques

- Neuroscience, Behavioral Economics, Big Data, Social Media are promising as well as being hyped…..
- "It's not market research" (and even if it is, there are risks)
- *More data, less Insight (DRIP)*
- Enthusiasm beats prudence
  - Privacy
  - Respondents' rights
  - Damage to the reputation of MR via poor analysis as well as questionable results
  - AE reporting concerns

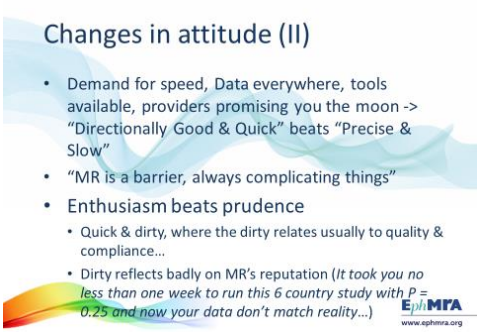
Availability of new providers (I)

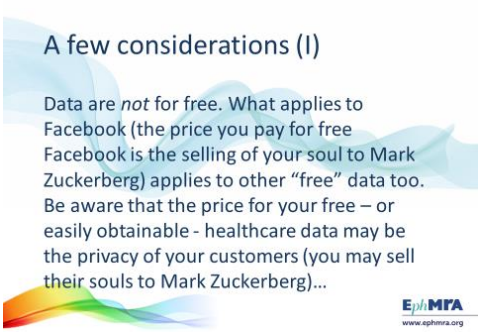
- Google Health, Apple Health, Microsoft..
- "No, we don't do market research. We're just gonna ask some questions…"
- They talk to other people than we do, so we're out of the loop
- Enthusiasm beats prudence
  - Privacy
  - Respondents' rights
  - AE reporting concerns

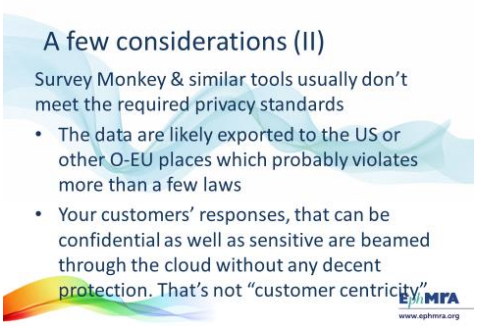
Changes in attitude (I)

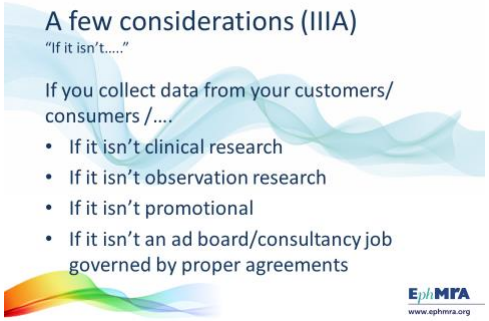
Our internal customers change:

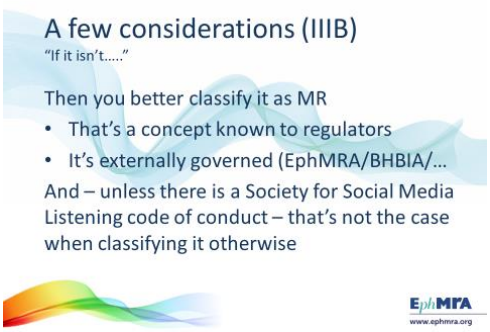
- From market research-> plan-> execute to a **constant flow of customer learnings, interactions and adjustments**
- From shotgun approach to targeted messaging
- From one way sending to communicating
- From messaging to **customer experience** where each interaction is a piece of marketing
- **Speed is crucial**

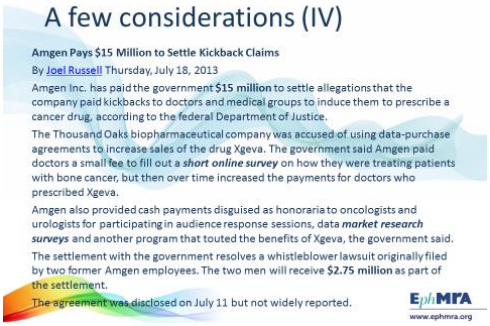












Action: To use this detail to develop a 'thought piece' for an Ethics Update, that will also draw upon common issues raised by Piergiorgio and Bettina.

To get our compliance message out as far and wide as possible, particularly to consultancies that work on the fringes of MR and to non-pharma/healthcare agencies that only very occasionally work in the field.

Germany (Bettina & Mattias)

Key points:

- No major changes expected.
- Trends and emphasis likely to be on increased accountability and increased auditing.
- Incentives caps continue to be a problem area.

Action: To include mention of the problem areas (which reflect pressures on MR) within the proposed 'thought piece' for an Ethics Update.

France (Sarah-May & Christine)

Conventions for simplified CNOM declaration in accordance with Art. R4113-107 of the "Code de la santé publique" (public health regulation)
Executed between CNOM – ASOCS – SYNTEC
Summary

4 conventions executed on May 5 2016

- Convention n° 2016-0001 in application to Art. R4113-107 of the "Code de la santé publique" relative to hospitality and honoraria provided in the context of focus groups
- Convention n° 2016-0002 in application to Art. R4113-107 of the "Code de la santé publique" relative to honoraria provided in the context of qualitative IDIs (face to face, telephone, on-line)
- Convention n° 2016-0003 in application to Art. R4113-107 of the "Code de la santé publique" relative to honoraria provided in the context of quantitative questionnaires (face to face)
- Convention n° 2016-0004 in application to Art. R4113-107 of the "Code de la santé publique" relative to honoraria provided in the context of quantitative questionnaires excluding face to face: email, mail, on-line, telephone

References for the conventions are
Art.L4113-6 of the "code de la santé publique » (control of the advantages distributed to HCPs)
Art.R4113-107-II allowing simplified protocols between CNOM and representative professional organizations
ESOMAR Code

Scope

- **For the 4 conventions**
    - Payment by market research agencies of the expenses and honoraria relative to the participation to focus groups/interviews/questionnaires by physicians who (are granted?) have the authorization to practice in France
    - Convention signed with the physician reminds about the obligation to participate according to the medical code of ethics, and for full time employed by a Government hospital their obligation to have the authorization to participate*

- **Convention n° 2016-0001** in application to Art. R4113-107 of the "Code de la santé publique" relative to hospitality and honoraria provided in the context of **focus groups**
    - 3 to 12 participants for a 1 up to 4 hour duration
    - Hospitality cost is 40 € maximum

- Honoraria are 150€ ex VAT per hour maximum
- Travel time are not paid
- Travel cost might be reimbursed (receipt necessary)

- **Convention n° 2016-0002** in application to Art. R4113-107 of the "Code de la santé publique" relative to honoraria provided in the context of **qualitative IDIs (face to face, telephone, on-line)**
  - 6 up to 30 GPs and maximum total of 36 specialists for a duration of 30 min up to 2 hours
  - Honoraria are 150€ ex VAT per hour maximum (2,50€ ex VAT per min)

- **Convention n° 2016-0003** in application to Art. R4113-107 of the "Code de la santé publique" relative to honoraria provided in the context of **quantitative questionnaires (face to face)**
  - 30 up to 200 GPs and maximum total of 300 specialists for a duration of 15 min up to 2 hours
  - Honoraria are 2,50€ ex VAT per min; maximum, total 37,5 € ex VAT up to 300 € ex VAT

- **Convention n° 2016-0004** in application to Art. R4113-107 of the "Code de la santé publique" relative to honoraria provided in the context of **quantitative questionnaires excluding face to face: email, mail, on-line, telephone**
  - 30 up to 200 GPs and maximum total of 300 specialists for a duration of 5 min up to 1 hour
  - Honoraria are 150€ ex VAT per hour maximum (2,50€ ex VAT per min)

Duration

These conventions are valid for 1 year – a steering committee is responsible for assessing the impact and practicalities of the simplified process and possibly amend it/ renew it

Process

Agencies will post the declarations on the CNOM platform: IDAHE

To access and use the platform

Agencies must request an access (account) to the CNOM by email: idahe-crea-comptes@cn.medecin.fr or a recorded letter

Signed by the legal representative
Provide a Kbis extract (issued less than 3 months)
With company mail address
First name, last name, contact details of the administrator(s)

Agency will receive User login – password by email from idahe-assistance@cn.medecin.fr

Declaration

Two step process

- Preliminary declaration to request a positive opinion
  - For each of the 4 conventions, Market Research agencies declare to the CNOM the expected number of questionnaires/interviews/groups for a given period of time (cannot exceed 12 months)
  - Don't under estimate the number otherwise you will need to do an additional declaration
- "A posteriori" declaration after each individual project

- Market research agency will provide to the CNOM no longer than a month after the operation
    - The file listing the participant names and information according to the formulary
    - The topic covered
    - The actual duration of the questionnaire
    - Honoraria paid to the participant

    If a similar interview is planned in the following 6 months, on the same topic, with the same participants, the market research agency must inform the CNOM and provide with justification

Support: idahe-assistance@cn.medecin.fr
Technical requirement to use the IDAHE platform
Browser
Internet Explorer 7 and more
•Firefox 3 and more
•Safari
•Chrome
Recommended browser
•Firefox up to date

Action: To provide members with an update by 1 July.

Italy (Piergiorgio)

Key Points:

- Developing the distinction between MR and marketing is critical because there is confusion amongst regulators about the difference between direct marketing telephone calls and MR interviews and there is a danger the two will be treated alike and restrictive conditions imposed by regulators.
- With regard to the GDPR, MR is not likely to be classed as 'scientific research'.
- Lobbying activity is important to ensure that an MR voice is heard as GDPR implications that can be worked out nationally in Italy are decided e.g. ensuring that informed consent allows all those who have not opted out to be accessible for MR (i.e. they can opt-out and do not have to opt-in).
- ASSIRM are to produce a leaflet of privacy laws in Italy that it could be helpful to point EphMRA members towards.

Action: To provide more supporting detail to distinguish MR and marketing, this also ties in with points raised in Xander's session (how does the arrival of new technologies impact what we consider MR to be or not to be).

UK (Katie)

1. Possible impact of Brexit on data protection laws and the GDPR:
    - If there's an exit vote the GDPR will not apply to the UK and it's unclear what the UK data protection laws will look like

- However, even if we leave the EU, companies operating in, or targeting EU countries / citizens will still have to abide by the GDPR
- In addition, it's likely that the UK would still need to adopt similar data protection laws to the GDPR in order to continue international data transfers
  - To enable data transfers within the EEA the UK would need to either be a member of the EEA or be granted "safe 3rd country" status by the EU commission, both of which would require the UK data protection legislation to provide a level of protection equivalent to that of the GDPR

2. Brexit is also likely to result in a number of changes and implications for pharma companies – the details of which are largely unknown
   - For example, many pharma companies have their main European PV operations, including the Qualified Person for Pharmacovigilance (QPPV) based in the UK. If the UK doesn't become a member of the EEA then it's likely that many pharma companies will need to revisit their PV operations and decide on what to relocate and to where
     - Whilst this is unlikely to have a direct impact on the code or the way in which MR operates, it does highlight just one example of the uncertainty and upheaval a Brexit vote could have on the industry, and it may impact the PV personnel agencies are dealing with

3. EFPIA Disclosure Code – data is published on 30th June
   - There are likely to be inconsistencies in reporting from company to company and market to market that will become apparent when the data is published at the end of the month. It will take time for these inconsistencies to be ironed out and may result in changing processes for companies
   - In addition, it's likely that many companies have been adopting temporary solutions to meet the EFPIA disclosure deadlines, and that over time more permanent solutions will be established

Action: To monitor EFPIA to see if there are any changes to Disclosure requirements following the first period of reporting.

USA (Daniel & Roni)

- There are no major changes expected other than the Privacy Shield.
- Ongoing issues include regular need to inform clients of the details/implications of the Sunshine Act. Reference articles used to send to agencies and end clients for questions on Sunshine Act. These are all still valid. No updates.
  https://www.casro.org/news/140761/Physician-Payment-Sunshine-Act-FAQs.htm
  https://www.casro.org/news/137727/Physician-Payment-Sunshine-Act-Alert.htm
  http://www.marketingresearch.org/issues-policies/best-practice/physician-payments-sunshine-act

Action: To include additional sources in Code update