
***Creating excellence in professional standards and practices to enable Healthcare market researchers to become highly valued business partners***

E*ph*MRA *Vision*

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European Pharmaceutical Market Research Association

# EMA Workshop on Patient Support Programmes and Market Research Programmes

## Understanding the diversity of such programmes and the management of safety information

7 June 2013

## Spectrum of market research programmes

## Type of safety data collected

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# European Pharmaceutical Market Research Association

EphMRA is an industry association representing those engaged in multi-country healthcare market research in Europe

Purpose of the Association is to develop and improve standards and techniques in Europe for market research in the field of health and healthcare

40 Pharmaceutical manufacturer members
150+ Market Research agency members

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# Market Research

. . . . is the systematic gathering and interpretation of information about individuals or organisations using the statistical and analytical methods and techniques of the applied social sciences to gain insight or support decision making. The identity of respondents will not be revealed to the user of the information without explicit consent and no sales approach will be made to them as a direct result of their having provided information.

*ICC/ESOMAR International Code 2007*

The goal of market research is to provide objective and sound business intelligence that that will inform commercial decision making. Information is collected systematically to assess (qualitatively or quantitatively) the opinions, attitudes and behaviours of the population being studied. Market research is not a commercial communication or a selling opportunity nor is it non-interventional clinical research.

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# Market Research takes many forms . . . . .

Medium

- Face to face
- Telephone
- Online
- Mobile

Approach/structure

- Fully structured – all closed questions (quantitative)
- Semi-structured – mix of open & closed questions
- Not structured/depth – all open questions (qualitative)

Face to face and telephone work require the presence of an interviewer online or mobile work may not

Closed questions allow anticipation of the type of responses, open questions don't

In some studies there is an opportunity to identify an AE during fieldwork in others this can only be done after fieldwork

In some studies it is possible to anticipate whether AEs will or will not be cited and in other studies this is not possible

Which means that when it comes to collecting AEs from MR studies we have to cater for a wide variety of collection scenarios

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# Can be a complex process involving many parties

Chain of sub-contractors often involved in the process

- Commissioning Client Company
- International MR Agency
- National/local MR Agencies and/or
- National/local Fieldwork Agencies
- National/local freelance recruiters & interviewers
- Coders
- Analysts

Within each link in the chain there are different types of researchers involved from extremely highly qualified and experienced researchers to part-time freelancers with limited experience

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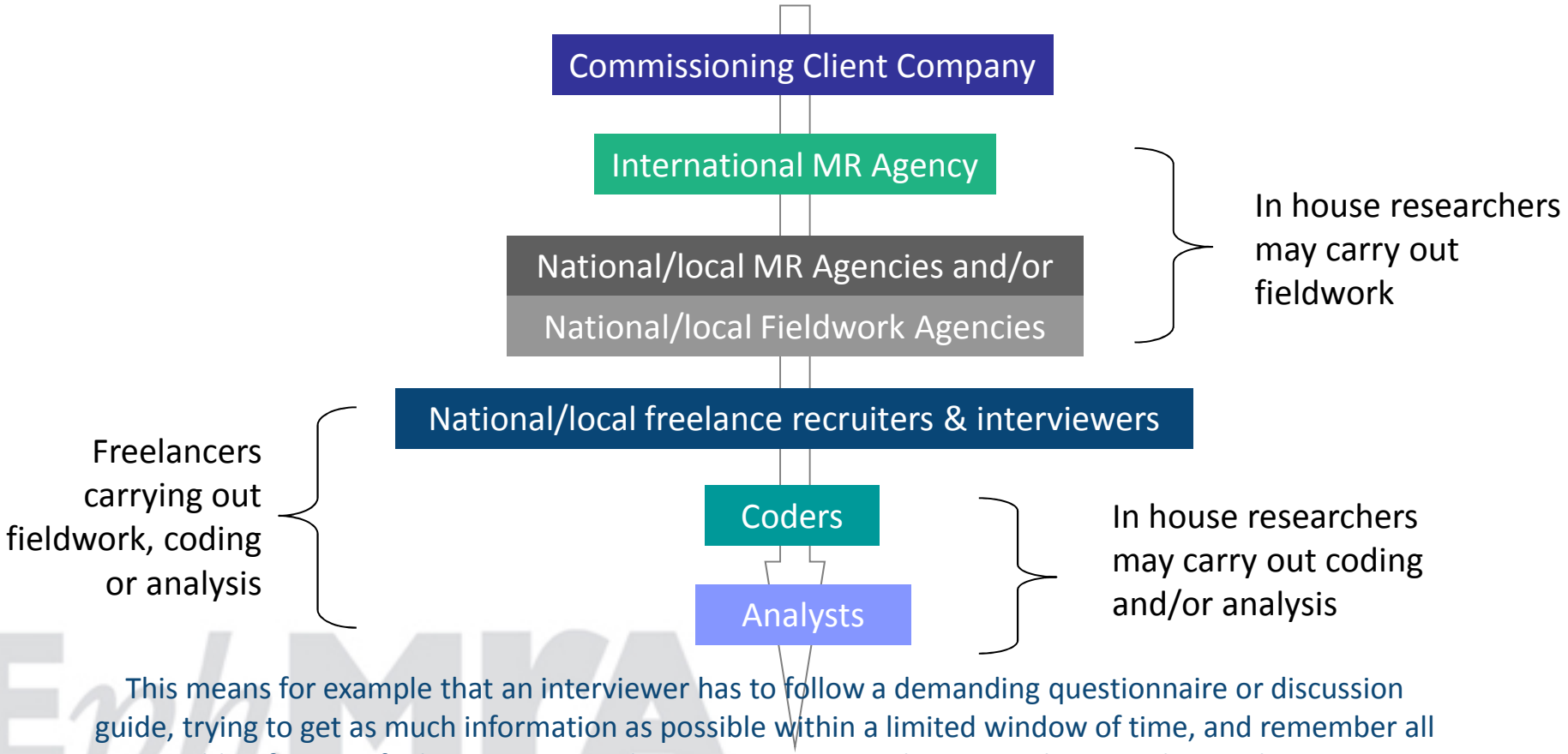
# Opportunities to identify AEs can occur at different points in the process and involve different types of professionals




This means for example that an interviewer has to follow a demanding questionnaire or discussion guide, trying to get as much information as possible within a limited window of time, and remember all possible of types of adverse events, adverse reactions, products complaints and special reporting situations, plus the company's products – brand and generic names and their indications

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- MR is further complicated by the need for researchers to observe legal and ethical guidelines to protect respondents rights and data integrity
- EphMRA provides its members with two sets of compliance guidelines:
  - Code of Conduct
  - Adverse Event Reporting Guidelines
- EphMRA liaises closely with other associations, particularly national healthcare MR associations such as the BHBIA in the UK and the ADM in Germany

BHBIA

adm

efpia

European Federation of Pharmaceutical Industries and Associations

aedemo

asociación española de estudios de mercado, marketing y opinión

ASSIRM

WORLD ESOMAR RESEARCH

LIF

SYNTEC Etudes Marketing & Opinion

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# Type of Safety Data Collected

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# Minimum reporting criteria for an AE are:

- Suspected medicinal product
- Suspected adverse event

For market researchers there will also always be

- Reporter
- Patient or patients

INTERIM

- If potential AE is mentioned in context of group of patients it is essential to establish that the patients do exist i.e. they are/were real patients actually seen:
  - Reporters should be able to state how many patients have been impacted if it is suggested there is more than one
  - If this information is not available, the AE does not need to be forwarded
- Researchers should identify AEs based on cited information

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# Minimum reporting criteria for an AE :

- In particular distinguishing between AEs in groups of patients and generalisations about events based upon feelings, hearsay or general reputation has proved difficult - particularly when market research interviewing is carried out by junior researchers

- It is also important to remember that information is very largely based on recall without the aid of patient notes, memories are often vague when it comes to precise detail

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# AE Reporting Form

- Generally used when responses generated/analysed on a respondent by respondent basis
- Collect as much detail as possible
- EphMRA provides a template
- Different companies use different forms and this in itself is a problem
- In a MR setting when time is very short and respondents are recalling detail from memory – which accounts for the vast majority of occasions – respondents willingness and ability to provide detail is limited

| EphMRA Adverse Event Reporting Form – TEMPLATE | | | |
|---|---|---|---|
| **MR Agency Information** | | | |
| Agency name | | | |
| Telephone number | | | |
| Researchers name | | | |
| Date aware of Adverse Event | | | |
| Project title/reference number | | | |
| Respondent ID/AE number | | | |
| **Patient Information** | | | |
| Number of patients | | | |
| Availability of patient information | YES | NO | |
| Age and Gender | AGE | FEMALE | MALE |
| Pregnant | YES | NO | |
| Patient's initials | | | |
| **Drug and Event Information** | | | |
| Drug name | | | |
| Description of Adverse Event | | | |
| Indication/condition for which drug prescribed | | | |
| Daily Dose | | DON'T KNOW | |
| Lot/batch number. | | DON'T KNOW | |
| Frequency | | DON'T KNOW | |
| Route of administration/form | | DON'T KNOW | |
| Reported to local regulator | YES | NO | DON'T KNOW |
| Does reporter think drug caused event | YES | NO | DON'T KNOW |
| **Respondent/Reporter details** | | | |
| Reporter/respondent name | | | |
| Reporter type (E.g. doctor, patient) | | | |
| Respondent's address/contact information if willing to provide | | | |
| | NOT WILLING TO PROVIDE | | |
| Willing to be contacted for follow up | YES | NO | |
| | SIGNATURE | | |
| Doctor's name & address if patient is a respondent/reporter | | | |

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## Tabulations of Aggregate Data

- Appropriate when AE data only reviewed in aggregate
  - E.g. an online survey when the respondent completes it alone (without interviewer support) and the information given is automatically data processed
  - So AEs only detected at point of coding or analysis at intervals during fieldwork or at the end of data collection
- Tabulation should show
  - No. respondents citing the AE
  - Question base

Reporting format should be agreed between the MAH/commissioning client company and the MR agency at start of project

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*When transfer of PV data occurs within an organisation or between organisations having concluded contractual agreements, the mechanism should be such that there is confidence that all notifications are received; in that, a confirmation and/or reconciliation process should be undertaken*

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Reconciliation

- Reconciliation = production of a summary of all AEs
  - Even if no AEs recorded
- Summary to include:
  - No. of AEs identified
  - Summary of each AE
- Summary to be produced at end of study – not at end of fieldwork

Finally in terms of data collected and forwarded from MR studies the EMA recommends 'reconciliation' at the end of a study, so EphMRA advises that it takes place

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# Current challenges

# Proposals to move forward

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# Current Challenges

1. **Passing on contact/personal data** – MR is in part defined by the fact that it has no interest in the individual identity of respondents and one of the basic tenets of MR is that respondents must be offered confidentiality and anonymity – this can appear to conflict with the request for AE reporter contact details and confuse respondents
   - MR respondents will not always allow their contact details to be passed back to the MAH for follow up even after repeated requests
     - EU data protection legislation prohibits the transfer of personal data without the fully informed consent of the individual concerned
   - In Germany MR industry guidelines prohibit requesting personal data to pass to the client company.
     - So it is suggested that the MR agency facilitates follow up between the MAH's PV department and the reporter by allowing questions and answers to be passed via the agency with no personal data passed to the MAH

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# Current Challenges

1. Continued . . . . .

- Consequently there may appear to be a conflict between pharmacovigilence and market research or between PV legislation and data protection legislation.
- It is critical to the integrity of market research that the data protection rights of respondents are clear and respected
- In Germany whilst it is not ideal to ask the MR agency to take up this role, it is EphMRA's understanding that in Germany MR industry regulations are accepted by the courts as the standard of professional diligence required for market and social researchers so they carry weight
  - There is a view held by some but contested by others that consent from MR respondents to pass their personal data to the MAH can be sought in Germany when a higher order of safety is at risk and drug safety reporting is a higher order or safety than data protection
- One of the things we are aware of is that there are differences in the interpretation and demands of local PV regulators – another layer of complexity
- Market researchers need consistency

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# Current Challenges

2. **Defining a 'patient'** in a format that is recognizable for all those involved in the market research chain
   - Market research responses come in many, many different forms
     - *I've seen several patients who experienced rash on [Drug X] (physician)*
     - *Patients can get really constipated on [Drug X] (physician)*
     - *Fatigue is common in these types of patients on [Drug X] (physician)*

3. **Duplication** - physicians sometimes report that they have already advised the appropriate party/body and it can be a source of significant irritation to be asked to do the same task twice, when physicians are engaged for MR, they don't always have the time or patience for what they see as additional AE reporting, there is anecdotal evidence of physicians self-censoring AEs out of MR

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# Current Challenges

4. **Incomplete or vague information** – concerns expressed that because AE reporting from MR is almost always from memory and rushed it is also often poor quality
    - Significant feedback from some drug safety/PV departments to their in-house MR colleagues suggests that AEs reported from MR sources are not good quality and can cloud the true picture (diluting signals) so they do not serve the patients' best interests
5. **Off-label use** – there is significant concern about the requirement to report off-label use when it is not associated with an AE, this is of particular concern in specific therapeutic areas – CNS, oncology – it could increase the number of reports many-fold without providing useful information on AEs – is this what is required?
    - E.G. In schizophrenia, where physicians may be reluctant to apply diagnostic labels – concern that reporting the use of anti-psychotic drugs in non-labelled schizophrenics may be inappropriate for AE reporting

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# Current Challenges

6. **Providing clear, precise and workable guidelines** suitable for all those involved in the market research chain down to part-time freelance interviewers and coders
   - MR study can take many forms and involve several different parties, AE reporting in all potential scenarios and from all sources must be catered for, we struggle to provide clear and simple guidelines that will work for the least qualified interviewer working in the field under immense time pressure, trying to ensure that everyone can understand what does and doesn't qualify as an AE to be forwarded is truly a challenge

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# Proposals to move forward

## Liaison & communication

- Liaison with EMA on EphMRA AER Guidelines
- Enquiry service – means by which MR AER questions can be addressed

## Guidelines support

- Definitions and guidelines that are simple and clear for all those in the MR chain to follow

EphMRA would welcome a close working relationship with the EMA so that we can consult readily on EMA Guideline implications to ensure our understanding and interpretation is correct and at the same time we would like to be able to access informed support by which we mean support that understands the MR context in which we operate so that when we have enquires we are able to get timely tailored responses

We would welcome input that helps us to provide clear, simple and precise guidelines that all levels of market researcher can put into practise

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# Proposals to move forward

**Information to be forwarded**

- Adverse event reporting requirements tailored to the market research context
  - Market researchers can be strongly criticised for providing AE reports that are vague, poor quality and unhelpful but it's hardly surprising given that a demanding AE reporting process has been overlaid on a what is already a complex and pressured process

**Duplication**

- Avoid duplication of reporting by only reporting AEs not already reported via other channels
  - We would like an approach that ensures that only necessary demands are placed on market researchers – is it possible that if MR respondents provide confirmation that an AE cited in a MR setting has been reported through another channel already, it does not need to be duplicated?

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