

Questions and Answers that relate to AE Reporting for Marketing Researchers in both Pharma Companies and MR Agencies.

Question	Answer
<p>1. Why does MR have to become involved in AE reporting?</p>	<p>A MR agency is, when asked to become involved in custom research project, acting as an agent for the Pharma Company, however they are not necessarily bound to report AE's as part of their contract unless this is specified.</p> <p>Some Pharmacovigilance personnel require anyone working for the company to report any AE that is mentioned, where the AE is directly linked to an individual patient, which means that MR agencies along with other similarly employed organizations (Ad. agencies; CRO's etc) have to act in accordance with the legally enforceable rules of the Pharma Company.</p> <p>However, there are several Pharma Companies that appear to feel that as the information collected via MR interviews is not based on any scientific clinical investigations and that the information provided is "soft". Not all feel there is a need to involve MR agencies in such types of reporting. This is why several different points of view exist.</p>
<p>2. What should I do if senior staff in a Pharma Company ask that only physicians who consent to allow their names to be passed on to the company if an AE linked to a patient for the company's product is mentioned?</p>	<p>EphMRA along with many other including the BHBIA as and the ABPI in the UK all believe that it is unnecessary to adhere to such a request.</p> <p>It should be pointed out that many Pharma Company Pharmacovigilance directors also believe that if a doctor that has been interviewed and a relevant AE has been mentioned in an interview, should the doctor refuse to allow his/her name to be passed onto the company, it is sufficient to report the event without naming the physician. This is still a reportable event and can be submitted to the FDA or other relevant body. In Germany it is not possible to pass on the name of the respondent to any third party for any reason. (See ADM market research guidelines)</p> <p>If the company insists on such a procedure, it would be up to the agency to decide either to comply or to refuse the project. The EphMRA Guidelines cannot be regarded as legally binding.</p>
<p>3. In Germany, the ADM and BVA has indicated that Physician confidentiality is sacrosanct and studies that require the physician's name to be passed onto a Pharma Company in the event of an AE having to be reported should not be undertaken by a German MR agency or fieldwork organization. What can be done in this situation?</p>	<p>The Pharma Company will need to be advised of this situation. They can decide either to drop Germany from the range of countries to be examined, or they can be informed that a statement similar to the one in the EphMRA Guidelines will be shown to the Physicians advising them of their obligation to report such an event to the Pharma Company's Drug Safety department. If this is acceptable then the study could proceed, if not the study may not be feasible in Germany.</p>

Question	Answer
<p>4. What AE information has to be reported?</p>	<p>If the following 4 criteria are met:</p> <ul style="list-style-type: none"> i) The ADR/AE is identified as being linked to a specific drug ii) The ADR/AE is a clearly identifiable reaction iii) The ADR/AE is provided by an identifiable reporter (physician/patient) iv) The ADR/AE is linked to a specific patient. (named or referred to by age and or gender) <p>-then either the physician should be asked to report the AE to the client Pharma Company or in the UK the agency should ask the physician's permission to pass on their information for possible follow up. In the event of this being refused the agency should still report the AE. In the case of the patient, the patient should be asked to mention the AE with their physician or in the UK, a similar procedure to physicians needs to be put in place.</p>
<p>5. If an agency is asked to conduct a multi-country study, what procedure on AE reporting should there be given that there is a difference between the EphMRA Guidelines and those of the BHBIA /ABPI in the UK?</p>	<p>In all countries, unless otherwise directed by the client, the EphMRA Guidelines should be followed. The UK Guidelines should only be followed if directed to by the client. Following the EphMRA Guidelines, this means that in the event of an AE occurring that should be reported, physicians should be asked to get in touch with the client's Drug Safety department within 24hrs. A patient should be asked to speak to their physician within 24hrs.</p>
<p>6. Is there a difference in the time that should be allowed to report an AE depending on how long the product has been available on the market?</p>	<p>Yes: Pharmacovigilance personnel have indicated that if the product has been on the market up to three years then the Pharma Company has only 15 days to submit a report to the Authorities. This means that a MR agency would need to provide the information to the Pharma Company very quickly, often in 24 - 48 hours of the AE being mentioned in a face to face or telephone interview. Some companies insist that it should be reported in 24hrs regardless.</p> <p>If the product has been available for longer than three years then the Pharma Company has to provide a quarterly report for such products and hence timing may not be so critical. It will be important for the MR Agency to establish the Company's policy, but they could ask for more time in the event of an older product being mentioned.</p>
<p>7. Is there a difference between what might be regarded as a "serious" AE and once that is not "serious"?</p>	<p>Yes. However, a timeframe for reporting an AE should be given. The pharma company has defined rules on how quickly it needs to respond to a reported AE (e.g. 7 days for a life-threatening AE), and during that time the pharma company needs to assess the level of danger associated with that AE. The clock starts for this as soon as the AE is reported (i.e. by the patient or physician to, in this case, the MR interviewer). Therefore the interviewer needs guidance to report an AE immediately after an interview, it is not something to be put off until a later date. (Also see answer above) It should be within 24hrs. EphMRA's advice is that while differences do exist between what constitutes a serious and a less serious AE, it should be left to the DS /Pharmacovigilance team to determine what is or is not a serious AE. Thus once such an issue that is linked to a clearly identifiable named patient occurs then the report should be sent within the timeframe outlined.</p>

Question	Answer
8. When the interviewer reminds a doctor of his obligation to report an AE should this be recorded, so that there is a record of this happening?	Yes: This is good practice and is to be recommended as a safeguard for the agency.
9. In relation to the question above, what happens if the study is on-line and the AE information is not discovered until the coding stage as no one will have seen the data until then?	It is obviously not possible to report on something that is not known about until it becomes available. However, once the information comes to light, then it should be treated in the same way as the points made in the previous question. It should be provided to the client within 24 hours of it becoming identified.
10. If I am conducting a MR project for client "A" and an AE that is technically reportable occurs in an interview for a competitive drug, does that have to be reported to Company "B"?	No. It is not necessary to do this. Depending on the nature of the AE (i.e. if serious), you might consider mentioning it to the client company "A" and leave it to the Drug Safety department to consider whether to raise it with Company "B" or not.
11. If an MR agency is involved in conducting syndicated investigations and an AE that is reportable occurs, what does the MR agency do?	In those cases where a MR agency is conducting a syndicated investigation on its own initiative, and is offering the data to any potential Pharma company, as the MR agency is not under any legal obligation to provide details of AE's to the Medical authorities no AE reporting is required. If special questions are asked for individual clients and these lead to an AE being mentioned, then the same guidance as mentioned above for custom MR applies. If one or more Pharma companies collectively request that a MR agency conduct a "shared study" for them then the same rules for custom MR apply. With regard to any other audit undertaken by a MR company if the data collected is able to be purchased by any Pharma company, then as the MR agency is not itself a Pharma company it is not governed by any reporting rules to Medical Agencies involved in Pharmacovigilance. Consequently it is not necessary to prepare any AE reports at this time.
12. Different Pharma clients have slightly different training programs that MR agencies need to agree to examine and follow if they are to be approved for conducting MR for that company, can we not have a standard set of training procedures that all companies can agree we should follow?	All MR Associations are aware of this difficulty. In the UK an agreed training program from an amalgamation of various client companies training programs is about to be implemented by the BHBA/ABPI working Group. This has the backing of the participating companies. Although the Guidelines for the UK are different to those announced by EphMRA the working group is considering how best to get Pharma companies to accept an agreed standard training protocol for MR agencies to follow.

Question	Answer
<p>13. Should we try to prepare questionnaires in such a way to try to reduce any likelihood of an AE occurring during the course of an interview?</p>	<p>No association can dictate what a MR agency or Pharma MR executive should do in this regard. However, it is our view that great care should be taken when preparing a questionnaire so as not to bias any responses provided. If questionnaires are prepared in such a way that they try to avoid asking questions that might give rise to an AE, this might result in an unbalanced set of answers and not provide clients with appropriate “balance” they would normally expect from MR investigations. “The tail should not be allowed to wag the dog.”</p>
<p>14. Do we have to ask Drug Safety personnel to approve our MR questionnaires?</p>	<p>To some extent this may be dictated by the internal Pharma’s own policy. However, such requirements would seem unnecessary and could result in significant timing issues for both Pharma’s management team and the MR agency.</p> <p>It could be advisable to involve systematically DS for a given period of time to establish the link between MR and DS and make sure that both parties understand the issues. Based on this experience, we may not need to involve DS systematically after this period.</p> <p>It might be wise to establish what if any protocols exist prior to starting any study that could involve DS personnel to avoid cancellation fees and conflicts between MR client and MR agency executives.</p> <p>Drug Safety departments may wish to examine the questionnaire to see how much work might be generated for them from follow up calls about AE’s, so this might slow down the timing and initiation of the project.</p>
<p>15. What if any precautions are needed if MR investigations to examine patients on a longitudinal basis are carried out?</p>	<p>If the study is one of audit information or syndicated and hence is not being conducted for a specific client on a customized basis, the same points apply to those cited earlier.</p> <p>However, customized studies of this type could very well lead to a large volume of AE reports being required. For example, it was pointed out by a senior DS executive that:-</p> <p><i>“MR interviews can generate a large number of solicited reports of adverse events which may give the regulating agency a skewed view of the number of real AEs directly resulting from use of a particular drug. E.g. an interviewer may ask a doctor every 6 months if patient X is still using drug Y. The doctor may reply “no, she died last week” which would mean according to the guidelines that this should be reported as an AE, even through there may be no causal link between use of the drug and the death of the patient.”</i></p>