



EPHMRA Adverse Event Reporting Guidelines

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CODE
OF
CONDUCT

SECTION 1: INTRODUCTION

1.1 Purpose

The EPHMRA Adverse Event Reporting (AER) guidelines provide advice for all parties involved in global healthcare market research on the collection and reporting of information about Adverse Events arising during a market research study where the company commissioning the research is the Marketing Authorisation Holder (MAH) or Certificate Holder (CH) of the medicine, vaccine, medical device or diagnostic.

Note: 'Adverse Events' is an umbrella term used throughout the guidelines for Adverse Events (AE), Special Reporting Situations (SRS), and Product Quality Complaints (PQC) (refer Appendix A - Definitions & Terminology.)

1.2 Scope of Application

These guidelines apply to MAH/CH functions including global, regional, and local market research, Commercial and Marketing, Medical Affairs, Health Economics & Outcomes Research (HEOR), Market Access, and all others involved in market research activities. They equally apply to market research Agencies (MRAs) including their subcontractors, i.e., fieldwork agencies, analysts, recruiters, interviewers, etc.

1.3 Regulatory Context

These guidelines reflect current Pharmacovigilance (PV) requirements as set out in the European Medicines Agency's (EMA) Guidelines on Good PV Practice (Module VI)⁽ⁱ⁾. Also, with reference to the US Federal Drug Agency (FDA) Guidance for Industry Good PV Practices⁽ⁱⁱ⁾ and Medical Device Reporting⁽ⁱⁱⁱ⁾, UK Medicines & Healthcare products Regulatory Agency (MHRA) Guidance on PV procedures^(iv) and post-market surveillance requirements for medical devices^(v), and other applicable regional or local PV guidelines.

1.4 Interpreting Requirements

Throughout this document, the word **"must"** indicates a mandatory requirement. The word **"should"** denotes recommended best practice.

Disclaimer: EPHMRA AER Guidelines are not intended as regulatory or legal advice, nor as a comprehensive guide for healthcare market research. You should seek appropriate legal counsel in the appropriate jurisdiction for your own situation. Every effort has been made in the preparation and editing of this document, but it may contain errors and EPHMRA do not accept responsibility for the consequences that may arise.

SECTION 2: FOUNDATIONAL CONCEPTS

2.1: Pharmacovigilance

Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicines and vaccines may also have side effects, some of which may be undesirable and/or unexpected. Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine related problem (as defined by World Health Organization^(vi)), with monitoring of Adverse Events relating to medical devices and diagnostics also in scope. It is a critical activity contributing to the protection of patients and public health.

SECTION 3: ESTABLISHING RESPONSIBILITIES

3.1 Marketing Authorisation Holder (MAH)/Certificate Holder (CH) Responsibilities

3.1.1 Legal and regulatory responsibility: The MAH or CH bears the legal and regulatory obligation to monitor, collect, report, and manage Adverse Events associated with medical products, vaccines, medical devices, and diagnostics for human use. This obligation includes Adverse Events arising during market research where the commissioning company holds the marketing authorisation for the product in scope.

3.1.2 Reporting Adverse Events: The MAH/CH must take appropriate measures to manage all reports of suspected Adverse Events associated with their medicines, vaccines, medical devices, or diagnostics for human use, whether from solicited or unsolicited sources (refer Appendix A - Definitions and Terminology).

3.1.3 Organisational Coverage: MAH/CH employees across all functions - including market research, business intelligence/insights, marketing, commercial, medical, market access, and sales - as well as all their subcontractors, representatives, and third parties, are subject to these reporting obligations.

3.1.4 Follow-up of Adverse Events: The MAH's/CH's PV function is accountable for all follow-up actions arising from reported Adverse Events, for determining the severity of each Adverse Event, and for assessing causality. Please check for country exceptions, i.e., in Germany the manufacturer must not know the identity of the participant and follow up of Adverse Event reports should be done via the MRA or its subcontractors. It is not the role of the MRA or its subcontractors (e.g., fieldwork agencies) to determine severity or causality of Adverse Events arising from a market research study.

3.1.5 Contractual Requirements: The MAH/CH must include in contracts with third parties performing PV activities, such as market research Agencies (MRAs) and their subcontractors (i.e., fieldwork agencies) the obligation to report Adverse Events arising during market research studies. The contract must clearly define roles, responsibilities, data exchange, audit, and inspection obligations to meet PV requirements (refer Appendix D - Regulation (EU) 2025/1466).

3.1.6 Information Provision: The MAH/CH must provide the MRA and any subcontractors with the relevant PV contact details - email address, fax number, or other secure electronic transfer method - for forwarding Adverse Event reports to their PV function. Country-level privacy rules for the transfer of personal information must be observed. The commissioning MAH/CH should also provide the MRA and any subcontractors with a list of the brand and generic names of its medicines, medical devices, or diagnostics for which they hold marketing authorisation in the countries involved in the market research.

3.2 Market Research Agency (MRA) and its Subcontractors' Responsibilities

3.2.1 Pre-Fieldwork Agreements: Adverse Event reporting requirements associated with medicines and vaccines where the commissioning company is the MAH/CH must be agreed with the MRA and its subcontractors at the start of the market research study, before commencing recruitment and fieldwork. Reporting obligations for medical devices or diagnostics must also be agreed at study commencement, as requirements may differ from those applicable to medicines and vaccines.

3.2.2 Reporting Scope: The MRA or its subcontractors must report Adverse Events arising during market research where the commissioning company is the MAH/CH for the medicine, vaccine, medical device, or diagnostic mentioned by its brand (trademark) name or its generic (International Non-proprietary Name/INN). The MRA or its subcontractors is not required to report Adverse Events cited for products where the commissioning client is not the MAH/CH.

3.2.3 Comprehensive Reporting: The MRA or its subcontractors must report any type of Adverse Event arising during the market research, regardless of whether they are classified as serious or severe, and regardless of whether research participant has already notified the relevant regulatory authority or MAH/CH directly.

3.2.3 Personal Data Transfer: The MRA or its subcontractors must only provide contact details of the participant - whether healthcare professional or non-healthcare professional - to the MAH/CH if there is a lawful basis under relevant data protection legislation. Different lawful bases may apply depending on jurisdiction, and other restrictions may apply - please refer to the EPHMRA Code of Conduct for further information. Given that personal data may be transferred between independent data controllers and across different jurisdictions, consent is typically the most appropriate lawful basis, though not the only option.

3.2.4 Participant Notification: The MRA or its subcontractors must inform participants at appropriate stages of the market research activity of the obligation to report Adverse Events to the MAH's/CH's PV function.

3.2.5 Co-Promotion and Co-Marketing: In co-promotion or co-marketing situations, the MRA should agree with the commissioning company (i.e., MAH/CH) the process for Adverse Event reporting of a medicine, medical device, or diagnostic.

SECTION 4: MARKET RESEARCH STUDY STAGES

4.1 Before Fieldwork

The MAH/CH and MRA must agree the Adverse Event reporting process before recruitment and fieldwork starts. This includes confirming the MAH/CH product lists, reporting formats, reconciliation procedures, training requirements, and relevant PV contact details (e.g., email, fax number, etc).

4.1.2 Informing Research Participants:

The MRA or its subcontractors must inform the research participant during recruitment (i.e., before starting research) of the obligation to report Adverse Events that may arise during the market research interview. Where appropriate, it is good practice to remind participants at the start of interviews, for example in qualitative interviews.

4.1.3 Training

PV training requirements for the Adverse Event reporting process should be agreed between the MAH/CH and MRA before the start of the market research. All individuals from the MRA and its subcontractors assigned Adverse Event reporting responsibilities should complete the PV training to ensure they understand the requirements and actions required.

4.2 During Fieldwork

4.2.1 Completing the Adverse Event Report

The Adverse Event report must be completed at the end of the market research interview - there is no need to interrupt the interview to do this. The person collecting the information and completing the reporting form is responsible for signing the form before it is forwarded to the MAH's/CH's PV function. The Adverse Event report must be completed at the end of recruitment if screening questions are likely to solicit an event, although this should be an exception (refer Appendix C for link to Screener Design & Best Practice).

This is applicable to qualitative studies as the process may differ for quantitative studies, which should be agreed with the MAH/CH before the start of the study.

4.2.2 Information Quality

As much detail as possible should be provided to complete the information required for Adverse Event reporting, preferably completing the form with the assistance of the research participant. Care must be taken to ensure that information included does not raise data protection issues, such as including reporter details without prior consent.

4.2.3 Reporting Timeline

Adverse Events must be reported to the MAH's/CH's PV function **within one business day** of the MRA or its subcontractors **becoming aware of the event**. Please note that some MAH's/CH's PV functions may have a stricter definition of "Day 0" that should be considered for reporting purposes. Where AI is used in a market research study, e.g., AI-moderation, synthetic data or personas, the MAH/CH PV and MRA should agree the reporting timeline for Adverse Events, where applicable.

4.2.4 Medicines/Vaccines - Four Minimum Criteria

Four minimum criteria required for Adverse Event reporting:

- one or more identifiable reporters (participants),
- an identifiable patient or group of patients,
- one or more suspected medicines, vaccines, medical devices or diagnostics,
- a suspected Adverse Event (including serious and non-serious AEs, Special Reporting Situations, and Product Quality Complaints).

4.2.5 Medical Devices - reporting criteria

The main reporting criteria for HCPs and non-HCPs who experience Serious Adverse Events associated with a medical device include, device malfunctions, use errors, product quality issues, therapeutic failure, life threatening events, or serious deterioration of a patient's or user's health, or death. (See references for EU, US FDA, and UK MHRA medical device guidelines.). The term 'Adverse Events' includes serious Adverse Events for the purpose of these guidelines.

Note on synthetic respondents or data:

At present, PV frameworks are based on Adverse Events real individuals or data systems involving real subjects (e.g., social media). Synthetic respondents or data introduces uncertainty around the origins of Adverse Events and risk tarnishing safety information based on real individuals. Currently it is not recommended to include synthetic respondents or data in Adverse Event reporting unless explicitly agreed with the MAH/CH. If synthetic respondents or data are used, it should be kept separate from real individual's data, clearly identified and labelled.

4.2.6 Exceptions to Immediate Reporting:

The only exceptions to standard reporting timelines are syndicated studies where data are collected independently and available for purchase, in which case the purchasing MAH/CH is responsible for reporting unsolicited Adverse Events identified from purchased data. Longitudinal patient databases are out of scope of Adverse Event reporting.

4.3 End of Study

4.3.1 Reconciliation Requirement: Confirmation and reconciliation of Adverse Events is a mandatory requirement upon completion of the market research study. A summary of all Adverse Events identified during the research must be reconciled with or checked against those forwarded to the MAH's/CH's PV function to ensure all events are accounted for.

4.3.2 Mandatory Submission: The Adverse Event reconciliation must be submitted to the MAH's/CH's PV function even if no Adverse Events were reported. In such cases, the reconciliation should be reported as "N/A" or "0".

4.3.3 Process Agreement: The MRA and/or subcontractors should agree the reconciliation process with the MAH/CH before the start of data processing (i.e., fieldwork), as requirements may vary depending on the reporting format used, timing requirements, and the type of system used by the MAH's/CH's PV function.

4.3.4 Reconciliation Content: The reconciliation form should include, for each country where market research was undertaken, the number of Adverse Events identified (not merely reported), and a summary by each Adverse Event of the participant's ID, the medicine, vaccine or medical device or diagnostic involved, and the details of the Adverse Event.

4.3.5 Reconciliation Timing: The timing for submission of the reconciliation typically depends on the type of study. For one-off short studies, submission is usually at the end of fieldwork. For longer studies involving multiple waves of the same survey, reconciliation might be submitted at the end of each wave, or on a weekly, monthly, or quarterly basis. Timings should be agreed at the start of the study, especially for longer studies.

SECTION 5: REPORTING FORMATS AND PROCEDURES

5.1 Adverse Event Reporting Formats

5.1.1 Two Common Formats:

The two common formats for reporting Adverse Events in market research are:

5.1.2 Adverse Event Report Form

An Adverse Event Report form is used for collecting information during market research interviews, whether personal or group interviews, at the end. There is no need to interrupt the flow of the interview. The form is used to collect relevant details of the Adverse Event to fulfil the minimum reporting criteria. The MRA or its subcontractor collecting the information and completing the reporting form is responsible for signing the Adverse Event report form before it is forwarded to the MAH's/CH's PV function.

5.1.3 Tabulation of Aggregated Data

This format is typically used where aggregated, or a large volume of Adverse Events is anticipated. This includes both structured and semi-structured studies, such as large online surveys collecting data on prescribing behaviour or conjoint studies. Tabulations should include the number of participants where an Adverse Event was cited and the question base (the number of participants who answered the question). The format should be agreed with the MAH/CH in advance of data processing.

5.1.4 Directing Queries

Market Research Agencies should direct queries relating to the Adverse Event reporting process to the MAH's/ CH's PV function, or to the relevant contact at the MAH/CH, e.g., the market researcher or study owner, for guidance

SECTION 6: QUALITY MANAGEMENT AND TRAINING

6.1: Operating Procedures

The MAH/CH and MRA must agree and put in place clear and comprehensive processes for the collection, forwarding, and management of Adverse Events arising during market research studies. These processes must address data collected using traditional methodologies as well as social media, AI, and other novel or developing methods.

6.2: Training Requirements

6.2.1 Training process: The MAH/CH and MRA should agree the PV training requirements for the Adverse Event reporting process before the start of the market research study.

6.2.2 Who completes training: All individuals from the MRA and its subcontractors directly involved in the market research study should complete the MAH/CH PV training for Adverse Event reporting study to ensure they fully understand what is required of them.

6.2.3 Adverse Event Reporting and Reconciliation Forms: The MAH/CH should supply their Adverse Event reporting and Reconciliation form(s), if available. The **EPHMRA Adverse Event Reporting Form** and **Adverse Event Reconciliation Form Templates** are available to use (refer [Code of Conduct / AER | EPHMRA](#)).

SECTION 7: DATA RETENTION

7.1 Responsibilities and Requirements

7.1.1. MAH/CH Responsibility: The MAH/CH is responsible for retaining PV data and documents, including Adverse Events arising from market research, relating to individual authorised products. Data and documents should be retained as long as the product is authorised and for a period after marketing authorisation has ceased (i.e., at least 10 years). However, documentation retention may be for a longer period where regional or national law requires it.

7.1.2 Agreement on Retention: The MAH/CH and MRA, including its subcontractors, should agree on data retention periods for all relevant Adverse Event data and materials before recruitment starts. This agreement should include measures to be followed at the end of the agreed retention period, specifically whether data should be deleted or transferred to the MAH/CH if longer retention is required.

7.1.3 Minimising Personal Data Processing: It is recommended that appropriate technological or operational measures are taken to minimise the risk of processing personal data for longer periods than strictly necessary and to ensure compliance with relevant data protection legislation.

7.1.4 Anonymisation and Pseudonymisation: Where possible, the MAH/CH and MRA should agree that relevant Adverse Event data and documentation is either anonymised or pseudonymised at the earliest opportunity.

Note on Anonymisation and Pseudonymisation:

Please refer to the EPHMRA Code of Conduct for further information on Data Protection. Also, it is important to check local data protection and privacy regulations as requirements and interpretation may differ.

Anonymisation: specific meaning under data protection law where anonymous information is data that does not relate to an identified or identifiable person (i.e. data that is not personal data). Data protection law does not apply to anonymous information.

Pseudonymisation: refers to techniques that replace, or transform personal information that identifies people, and keep that information separate. This has benefits as a way of reducing risks and improving security, and for better use of data for research purposes and analysis. Pseudonymisation is in scope of data protection law (i.e., it is not a way of transforming personal data in that the law no longer applies).

SECTION 8: SPECIAL SITUATIONS AND METHODOLOGIES

8.1 Syndicated Studies

8.1.1 Definition: Syndicated market research is data originated, owned, and funded by the MRA and where multiple clients may purchase the results from the MRA.

8.1.2 MRA Responsibility: There is no requirement for the MRA funding and conducting independent syndicated studies (whether primary, secondary, or combined) to report Adverse Events for a medicine, medical device, or diagnostic to companies purchasing the research findings.

8.1.3 MAH/CH Responsibility: The MAH/CH is responsible for reporting Adverse Events to their PV function if such events are identified in the results of purchased syndicated data.

8.1.4 Exception for Proprietary Questions: Where MAH/CH confidential or proprietary questions are included in a syndicated survey, any Adverse Events arising from data collected through those questions must be treated in the same manner as market research commissioned directly by the MAH/CH. The MRA must therefore forward such Adverse Events to the MAH's/CH's PV function.

8.2 Longitudinal Patient Databases

Longitudinal patient databases, e.g., MRA owned longitudinal patient databases, such as the UK's General Practice Research Database (GPRD), are out of scope of these guidelines.

The Council for International Organisation of Medicinal Sciences (CIOMS) suggests that there is no obligation to search through such databases for individual Adverse Events, as this approach may give rise to spurious signals and conclusions. However, if Adverse Events are found in such databases, whether deliberately or coincidentally, they should be forwarded to the MAH/CH.

Data from longitudinal patient databases differ from tabular Adverse Event summaries collected from market research because they have not arisen from a defined market research study and are available to multiple users.

SECTION 9: ONLINE PLATFORMS FOR SOCIAL MEDIA OR RELATED TECHNIQUES IN MARKET RESEARCH

9.1 Mandatory Process: An appropriate Adverse Event reporting process must be in place for market research using online platforms for social media or social media-associated techniques, such as online communities. The MAH/CH and MRA should agree the process for collecting and reporting Adverse Events associated with their medicines, vaccines, medical devices, or diagnostics before the study commences.

9.2 Monitoring Period: Monitoring for Adverse Events during fieldwork - defined by the start and end dates for data collection using social media or related techniques - applies to public and private sites, passive and active approaches, and to both company-sponsored and non-company-sponsored websites.

9.3 Listening and Scraping Activities: If a MAH/CH chooses to listen in to or “scrape” from non-company-sponsored sites, whether public or private (with consent), it is recommended that the pages being monitored should be routinely checked for Adverse Events for the duration of the listening activity only.

9.4 No Routine Monitoring Obligation: There is no obligation for researchers (either MRA or its subcontractors and/or MAH/CH) to monitor non-company-sponsored sites routinely for Adverse Events if those sites are not being used for market research purposes.

SECTION 10: DATA PROTECTION AND CONSENT

10.1 General Principle: The research participant's personal information, including name and contact details, can only be forwarded to the MAH's/CH's PV function if the participant has provided consent, or an alternative lawful basis is in place under applicable data protection legislation. Please refer to relevant regional or local data protection and privacy regulations, e.g. EU/UK GDPR, US State privacy regulations, Brazil's LGPD data privacy law, etc.

10.2 Consent as Primary Basis: Consent is the most used lawful basis to operationalise the transferring of personal data between independent data controllers and across jurisdictions in market research. Consent for processing personal data for Adverse Event reporting purposes may be obtained at the start or end of the interview, as it is not essential for participating in market research studies.

10.3 Consent for Transferring Personal Data: Where consent is the lawful basis for transferring personal data in connection with Adverse Event reporting, the MAH/CH could be identified to the participant depending on jurisdictions. Exceptions include in-licensing opportunities where the MAH/CH is not the marketing authorisation holder of the product(s) and Adverse Event reporting is not required. Also, where local codes require that the MAH/CH should not be identified, for example Denmark. In such cases, participants should provide their consent to participate on this basis (preferably documented) or decline. If in doubt, please consult your Privacy Officer.

10.4 Naming the commissioning company: Naming the commissioning company is mandatory when transparency obligation require it; for example, under GDPR the identity of the data controller must be disclosed or consent is the lawful basis for transferring personal data in connection with Adverse Event reporting (e.g., EU, UK, Brazil, etc). Refer 10.3 for examples of where exceptions may apply or consult your Privacy Officer.

10.5 Anonymous Reporting: If consent has not been given or an alternative lawful basis has not been established, personal information must not be forwarded to the MAH's/CH's PV function. Under these circumstances, the participant may still take part in the market research, and the Adverse Event must be forwarded as an anonymous report.

10.6 Country-Specific Requirements: Certain jurisdictions impose specific requirements. In Germany, for example, the requirement of anonymity cannot be overturned, and personal information must not be forwarded to the MAH's/CH's PV function. Any follow-up of Adverse Event reports in Germany should be conducted via the MRA or its subcontractor(s). Please check local regulations for further information if necessary.

10.7 International data transfer: When personal data is transferred across national borders, appropriate safeguards must be in place to ensure adequate protection travels with the data. Data protection regulations vary by jurisdiction and may impose specific requirements for cross-border transfers, including approved transfer mechanisms, contractual safeguards, or regulatory authorisations. Before commencing fieldwork, verify the applicable data protection requirements in all countries within scope of the market research, including any restrictions or conditions on international transfers. Note that these requirements apply regardless of transfer method, including cloud-based systems, AI tools, or other technological means.

10.8 Third-Party Reports: The MRA or its subcontractors should only provide the contact details of the participant, whether a healthcare professional (HCP) or non-HCP (e.g., patient, carer) to the MAH's/CH's PV function if there is a lawful basis for this under the relevant data protection legislation. Adverse Event information about an individual reported by the individual's carer, relative, or friend must be reported to the MAH's/CH's PV function without including personal details of the individual involved, as they have not consented to share their information.

Note: Please refer to the EPHMRA Code of Conduct, or relevant regional or local regulations and codes, for further information on Data Protection and Privacy requirements. If in doubt, please consult your data protection officer.

10.9 Lawful Basis for Personal Data Transfer

10.9.1 General Principle: The participant's personal information, including name and contact details, can only be forwarded to the MAH's/CH's PV function if the participant has provided consent or an alternative lawful basis is in place under applicable data protection legislation such as EU/UK GDPR, US State privacy regulations, or other relevant regional or local regulations.

10.9.2 International data transfer: When personal data is transferred across national borders, appropriate safeguards must be in place to ensure adequate protection travels with the data. Data protection regulations vary by jurisdiction and may impose specific requirements for cross-border transfers, including approved transfer mechanisms, contractual safeguards, or regulatory authorisations. Before commencing fieldwork, verify the applicable data protection requirements in all countries within scope of the market research, including any restrictions or conditions on international transfers. Note that these requirements apply regardless of transfer method, including cloud-based systems, AI tools, or other technological means.

10.9.3 Consent as Primary Basis: Consent is the most used lawful basis to **operationalise the transferring of personal data between independent data controllers and across jurisdictions in market research.**

10.9.4 Timing of Consent: Consent for personal data transfer for Adverse Event reporting is a separate data processing operation from consent to participate in the market research. Participants may consent to participate in the research while declining consent for personal data transfer; in such cases, any Adverse Events are reported anonymously. When consent is being used as the lawful basis, it must be provided before any personal data are transferred by the MRA or its subcontractors to the MAH's/CH's PV function; in this case, for consent to be considered informed, thus valid, the individuals whose personal data is being processed must be informed of the identity of the MAH/CH both as the recipient and data controller of the personal data prior to any transfer. Where the MAH/CH identity cannot be disclosed at the start of the interview, consent for AE-related personal data transfer should be obtained at the end of the interview once disclosure is possible.

10.9.5 Anonymous Reporting: If consent has not been given or an alternative lawful basis has not been established, personal information must not be forwarded to the MAH's/CH's PV function. Under these circumstances, the participant may still take part in the market research, and the Adverse Event must be forwarded as an anonymous report.

10.9.6 Country-Specific Requirements: Certain jurisdictions impose specific requirements. In Germany, for example, the requirement of anonymity cannot be overturned, and personal information must not be forwarded to the MAH's/CH's PV function. Any follow-up of Adverse Event reports in Germany should be conducted via the MRA or its subcontractor(s).

10.9.7 Third-Party Reports: The MRA/subcontractors should only provide the contact details of the participant, whether a healthcare professional (HCP) or non-HCP (e.g., patient, carer) to the MAH's/CH's PV function if there is a lawful basis for this under the relevant data protection legislation. Adverse Event information about an individual reported by the individual's carer, relative, or friend must be reported to the MAH's/CH's PV function without including personal details of the individual involved, as they have not consented to share their information.

10.10 Special Category Personal Data

10.10.1 Definition: There is no single global definition, but under EU/UK GDPR personal data that is especially sensitive is classified as "special category" and requires additional security measures. Other jurisdictions may use slightly different terms, e.g., "sensitive data" is used in various US state laws or 'sensitive personal information' in China. Special category/sensitive personal information includes characteristics such as race or ethnicity, sexual orientation, biometric or genetic data, religious beliefs, disability, and data concerning health problems.

10.10.2 Explicit Consent Requirement: Patients must provide explicit consent if they are providing special category or sensitive personal data as part of Adverse Event reporting.

10.10.3 Process Agreement: The MRA should check applicable local and regional data protection requirements and agree with the MAH's/CH's PV function how special category/sensitive personal data should be managed at the start of the market research. This agreement should apply to the full data management process and be documented in the contract or PV instructions on Adverse Event reports.

SECTION 11: TRANSFER OF VALUE DISCLOSURES

11.1: Disclosure Requirements

11.1.1 General Position: Disclosure of ToV is not applicable for market research conducted with Healthcare Professionals where the identity of the research participant is not known to the end commissioning client, i.e., MAH or CH. This applies to Adverse Events arising during market research. Where disclosure of ToV applies it is for the entire market research study. Refer EFPIA Code of Practice^(vii), US Physicians Payment Sunshine Act^(viii), Insights Association advisory comments^(ix).

11.1.2 Rationale: These reports are considered solicited Adverse Event reports. The Healthcare Professional's personal data is provided to the MAH's/CH's PV function for the purpose of Adverse Event reporting only, and transfer is dependent upon the Healthcare Professional's consent to pass the information.

SECTION 12: ARTIFICIAL INTELLIGENCE (AI) IN MARKET RESEARCH

12.1 Artificial Intelligence (AI) Considerations: The MAH/CH and MRA should consider the implications for Adverse Event reporting where there is any use of AI as part of a market research study. The MAH/CH should include any additional Adverse Event reporting requirements relating to the use of AI in the appropriate contract with the MRA and its subcontractors, if appropriate. Please refer Appendix A for the definition of AI used in these Guidelines.

Any use of AI to perform Adverse Event-related activities, such as checking large volumes of survey data, should be agreed between the MAH/CH and MRA and its subcontractors (or other third parties if applicable) before the market research study commences.

12.2 Measures to Mitigate Risks: Where AI is to be used in any aspect of the market research study, measures should be agreed and implemented before fieldwork to ensure compliance with all relevant regional and local data protection and AI regulations, (including but not limited to the EU GDPR and AI Act, and US state privacy and AI regulations, etc.). Measures should also be in place to mitigate the risks where an Adverse Event might arise with the use of AI, including but not limited to:

- non-human participant data input, e.g., AI-bots, "ants," synthetic data or humans using AI to complete surveys or interviews.
- AI-moderators, and/or AI transcription and AI translation tools.
- AI in surveys, including AI transcription and translation tools.

12.3 Synthetic Respondents and Data: At present, PV frameworks are based on Adverse Events or data systems (e.g., social media) involving real individuals (i.e., humans). Synthetic respondents and data introduce uncertainty around the origins of Adverse Events and risk corrupting safety information based on real individuals. Currently it is not recommended to include synthetic respondents or data in Adverse Event reporting unless explicitly agreed with the MAH/CH and their PV function at the start of the market research study. If synthetic respondents or data are used, it should be kept separate from real individual's data and clearly identified and labelled as 'synthetic' data.

12.4 Quality Verification: Where AI is used to generate any outputs based on primary market research data, such as translations, transcriptions, or content analysis of source data, the MRA and its subcontractors (or other relevant third parties) should have appropriate processes or procedures to verify and validate the quality and accuracy of the those outputs if they are included in Adverse Event reporting.

12.5 Human Oversight: When using AI in market research, it is essential that human oversight is incorporated within agreed Adverse Event reporting process to mitigate risks, such as AI-moderators not reporting Adverse Events or hallucinations, as well as for transparency and good governance.

APPENDICES

Appendix A: Definitions and Terminology

Adverse Event (AE): An unintended and unfavourable response to a medicine or medical device, whether a causal relationship is established. When a causal relationship with a medicinal product is assumed, this is referred to as an Adverse Reaction (AR). The determination of causality is the responsibility of the MAH's/CH's PV function and is not within the scope of market research activities.

Product Quality Complaint (PQC): An alleged failure of a medicine, medical device, or diagnostic specific to the product or its packaging. Examples include suspected product failure, damaged or missing components, incorrect strength or colour, damaged packaging, missing patient information leaflets, broken or damaged delivery devices, and counterfeit products.

Special Reporting Situations (SRS): Circumstances requiring reporting that may or may not involve a traditional adverse event. These include overdose or lower dose usage, off-label use, misuse, abuse, occupational exposure, medication errors, lack of or unexpected therapeutic effect, and drug or drug-food interactions. The MAH/CH PV and MRA should agree prior to study commencement if additional Special Reporting Situations are to be included, such as hospitalisation, pregnancy, breastfeeding, or transmission of infective agents.

Marketing Authorisation Holder (MAH)/Certificate Holder (CH): The organisation legally responsible for a medicine or medical device, including when contracting third-party organisations to commission market research.

Market Research Agency (MRA): The company commissioned to conduct market research on behalf of the MAH/CH, encompassing all subcontractors, fieldwork agencies, analysts, and interviewers engaged by the MRA.

Healthcare Professional (HCP): Any licensed member of the medical, dental, pharmacy, or nursing professions, or any other person who may administer, prescribe, purchase, recommend, or supply medicines or medical devices during their professional activities.

Non-Healthcare Professional (Non-HCP): A patient, caregiver, family member, or member of the public.

Participant: Any individual whose personal data is used for market research purposes, also referred to as respondent or data subject.

Patient: An individual who is ill or receiving medical care for a condition and, for market research purposes, is characterised by at least one identifying parameter: initials, date of birth, age or age group, or gender/sex.

Reporter: A participant characterised by their qualification (physician, pharmacist, patient, etc.), and where compliant with relevant data protection legislation, name, or initials, and contact information (organisation, address, email, telephone).

Solicited Adverse Events: Those derived from organised data collection systems, including surveys of patients or healthcare professionals, personal, telephone, or web-based interviews, and paper or online surveys.

Unsolicited Adverse Events: Those not related to organised data collection systems, including reports from internet or digital sources, social media, and those identified in syndicated study results purchased by the MAH/CH.

Artificial Intelligence (AI): An AI system is a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment (OECD definition^(x)).

Synthetic Data: Artificially created from original data and models trained to reproduce the characteristics and structure of original data, producing similar results. Refers to data created to mimic the properties and patterns of real-world data. It maintains the statistical properties, relationships, and distributions of that original data, often with some corrections or modifications that make it beneficial in the development and adaptation of large language models (LLMs).

Medical Devices^(xi): Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer for use in human beings for medical purposes including diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease or injury, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means.

Diagnostics: Services used for prevention, screening, diagnosis, management, monitoring, and treatment or surveillance of diseases, injuries, and disabilities, including both in vitro diagnostics (laboratory tests) and in vivo diagnostics (imaging tests and other assessments).

Appendix B: Quick Reference Checklists

Pre-Fieldwork Checklist

- AE reporting requirements agreed between MAH/CH and MRA
- PV contact details and secure method of data transfer provided by MAH/CH
- Product list (brand and generic names) provided by MAH/CH
- Reporting format agreed (form or tabulation)
- Reconciliation process, form, and timing agreed
- Data retention period agreed between MAH/CH and MRA
- Training completed for all study personnel
- AI-related measures agreed (if applicable)
- Subcontractor compliance including PV activities documented
- Any required PV approvals on MAH/CH side for survey instruments obtained.

During Fieldwork Checklist

- Participant informed of AE reporting at recruitment
- Participant informed of AE reporting at interview start
- AE report completed at end of interview
- Consent obtained before personal data transfer (if applicable)
- AE reported to MAH/CH PV within one business day.

Post-Fieldwork Checklist

- Reconciliation form completed
- All AEs accounted for
- Reconciliation submitted to MAH/CH PV (including nil returns)
- Completion of any required source data verification activities
- Data retention policy followed.

Appendix C: Websites and References

The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI)

<https://www.enli.dk/media/wudd3rrn/promotion-code-version-50-april-2025.pdf>

European Medicines Agency (EMA):

<https://www.ema.europa.eu/en>

European Union (EU) PV Regulation:

[Implementing regulation - EU - 2025/1466 - EN - EUR-Lex](#)

[Rules on international data transfers - European Commission](#)

EPHMRA:

<https://www.ephmra.org/>

EPHMRA Code of Conduct & AER Proformas:

<https://www.ephmra.org/code-conduct-aer>

EPHMRA AI Checklist (Members only)

[2025 AI Checklist - Updated | EPHMRA](#)

UK Government website

[AI Insights: Synthetic Data \(HTML\) - GOV.UK](#)

UK Government Medical devices: post-market surveillance requirements

[Vigilance reporting requirements - GOV.UK](#)

UK Information Commissioner Office (ICO)

[A guide to international transfers | ICO](#)

UK BHBlA guidance on reporting Adverse Events:

[Adverse Event Reporting | BHBlA](#)

UK BHBlA Screener Design & Best Practice Guide (Developed by BHBlA in collaboration with EPHMRA)

[Screener Design & Best Practice | BHBlA](#)

U.S. Centers for Medicare & Medicaid Services website:

<https://www.cms.gov/OpenPayments>

U.S. FDA Medical Device Reporting (MDR): How to Report Medical Device Problems

[Medical Device Reporting \(MDR\): How to Report Medical Device Problems | FDA](#)

REFERENCES

- i EMA Guideline on good PV practices (GVP) - Module VI - Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev. 2)
[Good PV practices \(GVP\) | European Medicines Agency \(EMA\)](#)
- ii U.S. Food and Drug Administration (FDA) Guidance for Industry Good PV Practices
[Good PV Practices and Pharmacovigilance Assessment | FDA](#)
- iii U.S. FDA Medical Device Reporting (MDR): How to Report Medical Device Problems
[Medical Device Reporting \(MDR\): How to Report Medical Device Problems | FDA](#)
- iv UK Government Medicines and Healthcare products Regulatory Agency (MHRA)
[Guidance on PV requirements for UK authorised products from 1 January 2021 – MHRA Inspectorate](#)
- v UK Government Medical devices: post-market surveillance requirements
[Vigilance reporting requirements - GOV.UK](#)
- vi World Health Organization (WHO) definition of PV
<https://www.who.int/teams/regulation-prequalification/regulation-and-safety/PV>
- vii European Federation of Pharmaceutical Industries and Associations (EFPIA)
[The EFPIA Code](#)
- viii U.S. Sunshine Act:
<https://www.congress.gov/bill/111th-congress/senate-bill/301>
- ix U.S. Insights Association:
[The Physician Payments Sunshine Act: The Insights Industry Position - Articles](#)
- x Updated OECD Definition of an AI system - OECD.AI Refer PDF: Explanatory Memorandum on the Updated
[OECD Definition of an AI System: OECD Artificial Intelligence Papers, March 2024 No.8](#)
- xi Guideline on good PV practices (GVP) Annex I - Definitions (Rev 5)
[GVP Annex I Definitions \(pp16-7\)](#)