EPHMRA Adverse Event Reporting Guidelines

Revised September 2025

Applicability of EPHMRA's AER Guidelines

EPHMRA Adverse Event Reporting (AER) Guidelines have been written to provide guidance for those engaged in global healthcare market research on collecting and reporting information on an Adverse Event (AE), Product Complaint (PC) or Special Reporting Situation (SRS) 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 and/or medical device (please refer to Terms and Definitions section.)

These guidelines apply to MAH/CH functions, e.g., global/regional/local market researchers, commercial/marketing, medical, health economics & outcomes research (HEOR), Market Access and others involved in MR activities and MRAs, including subcontractors, fieldwork agencies, analysts, interviewers.

These guidelines reflect current Pharmacovigilance (PV) requirements but are not meant to be regulatory or legal advice, or as a comprehensive guide for healthcare market research.

Please note that throughout this document the word "must" indicates a mandatory requirement, whilst "should" is used to denote recommended best practice.

TERMS AND DEFINITIONS

Adverse Event (AE):
Is an unintended and unfavourable response to a medicine, whether considered to be related to the medicine or medical device (i.e., causal relationship).

Where it is reasonable to assume a causal relationship with a medicinal product this is referred to as an Adverse Reaction (AR). The Marketing Authorisation Holder or Certificate Holder's Pharmacovigilance (PV) will assess to determine if there might be a causal relationship or not for the purpose of AE reporting. It is not the role for market research to do this.

Artificial Intelligence (AI):
"'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and 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;". The use of the term "AI" assumes the guidance applies to any of the technologies that fall into the above definition.

Certificate Holder (CH):
Organisation that is legally responsible for a medicine or medical device; includes the CH contracting third party organisations who commission market research.

Diagnostics:
Diagnostic services are used for the prevention, screening, diagnosis, management, monitoring and treatment or surveillance of communicable, noncommunicable, rare diseases, injuries and disabilities. The term diagnostics includes medical devices used for in vitro and in vivo determination of physiological status or presence and characteristics of a disease.

Examples: In vitro diagnostics include laboratory tests (e.g., blood or urine tests); in vivo diagnostics include imaging tests (e.g., chest radiography, mammography or pelvic ultrasound) and other type of tests such as thermometer, electrocardiogram, pulse oximeters, endoscopes or blood pressure measurement devices.

Healthcare Professional (HCP):
Any licensed member of the medical, dental, pharmacy or nursing professions or any other person who, during their professional activities, may administer, prescribe, purchase, recommend or supply a medicine and/or medical device. It may include a payer who is an HCP with budgetary responsibilities.

Marketing Authorisation Holder (MAH):
Organisation that is legally responsible for a medicine or medical device; includes the MAH contracting third party organisations who commission market research.

Market Research (MR):
Its purpose is to gain insight through understanding and knowledge of customers, products, competitors, channels, and markets, to provide input or support decision-making.

It involves the systematic collection, analysis, interpretation, and use of information about individuals, organisations or markets using the information gathering and analytical methods and techniques of the applied social, behavioural and data sciences, statistical principles, and theory.

MR continues to evolve and adopt new methods, including usability testing, digital and social media sources; and evolving methods using Artificial Intelligence (AI/GenAI).

Market Research Agency (MRA):
Company that is commissioned to conduct market research on behalf of the MAH/CH; includes all subcontractors, fieldworkers, analysts, and interviewers engaged by the MRA.

Medical devices[1]:
Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations; and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
  For example, a blood glucose meter, contact lenses, pregnancy or other types of tests, wheelchair, etc.

Non-Healthcare Professional (Non-HCP):
A patient, sufferer, carer, family member or member of the public. It may include a payer who is not an HCP.

Participant:
Participant - or respondent or data subject - is any individual whose personal data is used for Market Research.

Patient:
Characterised by at least one of the following qualifying parameters: initials, data of birth, age/age group, or gender/sex.

Pharmacovigilance:
Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem (see WHO14).

Product Quality Complaint (PQC):
A product quality complaint is an alleged failure of a medicine, medical device or diagnostic, and is specific to the medicine, device or diagnostic or its packaging. Examples include suspected failure of a medicine, damaged, missing, incorrect strength or colour of medicine, damaged packaging, missing patient information leaflet, broken or damaged needle or syringe, counterfeit medicine, etc.

Reporter:
Participant (respondent / data subject) characterised by their qualification, e.g., physician, pharmacist, or patient, name or initials, address (e.g., organisation, department, street, city, zip or postcode, country), email or telephone/cell/mobile number.

Special Reporting Situations (SRS):
The following are examples of special reporting situations (SRS):

- Overdose or Lower dose: use per administration or cumulatively above the recommended authorised maximum dose.
- Off-label use: intentionally used for a purpose not within the intended use or authorisation for the medicine.
- Misuse: intentional and inappropriate use outside of the marketing authorisation for the medicine.
- Abuse: persistent or sporadic, intentional excessive use of a medicine accompanied by harmful physical or psychological effects [DIR Art 1(16)].
- Occupational exposure: contact with a medicine because of professional or non-professional occupation, e.g., splitting or cutting capsules and tablets.
- Medication error: includes dispensing errors, accidental exposure, maladministration.
- Lack of, or unexpected, therapeutic effect: where an additional benefit not previously known is reported.
- Drug or drug-food interactions: effectiveness or toxicity of one medication is altered by the administration of another medicine(s), foods interfering with medication, e.g., grapefruit or grapefruit juice with some statins and other medicines.

Note: *MAH/CH PV and the MRA should agree prior to the start of a MR study if additional SRSs are to be included in AERs, e.g., hospitalisation, pregnancy, breast feeding, transmission of infective agent, etc.*

Syndicated Market Research:
Market Research shared - both the findings and the costs - by a number of clients, however the data is owned by the Market Research agency.

Synthetic Data:
Synthetic data is artificially created from original data and models that are trained to reproduce the characteristics and structure of the original data producing similar results to the original data.

1. INTRODUCTION

1.1 What is Pharmacovigilance?

Pharmacovigilance is *'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem'.* Pharmacovigilance is therefore an activity contributing to the protection of patients' and public health[2].

Please refer European Medicine Agency's (EMA) Guidelines on Good Pharmacovigilance (PV) Practice (Module VI, 2017), US FDA Guidance for Industry Good Pharmacovigilance Practices (2025) and regional or local PV guidelines for further information.

1.2 Basis of EPHMRA's AER Guidelines

These guidelines are to help those involved with healthcare market research, whether working for an MAH/CH or MRA or related contractors.

The guidelines offer best practice for an MAH/CH or an MRA or related contractors on collecting, forwarding, and managing "Adverse Events" (refer Note (i) below) for medicines and medical devices and diagnostics.

The following types of MR relating to medicines, medical devices or diagnostics where the commissioning company has responsibilities as a MAH/CH are in scope of these guidelines:

Primary Market Research (PMR): collected directly for the first time from the participant (refer Note (ii) below) to address a specific business issue or question.

Syndicated Research: research funded by a MRA and where the results are made available to anyone who wishes to purchase it. **Note:** an MAH/CH who purchases syndicated research data is responsible for reporting to the relevant regulatory body any AEs identified from the results that are associated with its medicines, medical devices or diagnostics.

Situations where AE arising during MR where it is not applicable to report to the MAH/CH include:

- In-licensing opportunities;
- When the commissioning client is not the MAH/CH for a medicine or diagnostic or medical device;
- Clinical trials.

Notes on terms used throughout these guidelines:

Note (i): **'Adverse Events'** is an umbrella term that covers Adverse Events (AE), Special Reporting Situations (SRS), and Product Quality Complaints (PQC). Refer Definitions.

Note (ii): **'Participant'** is a person, either classed as an HCP or Non-HCP, who participates in a MR interview.

2. RESPONSIBILITES FOR AE REPORTING IN MR STUDIES

The MAH/CH has a legal and regulatory obligation to monitor, collect, report, and manage AEs associated with medicinal products (medicines), including prescription and non-prescription e.g., over the counter (OTC), or medical devices or diagnostics for human use. This includes the obligation to report AEs arising during market research (ref. 1.2 above) where the commissioning company is the MAH/CH for the medicine, medical device or diagnostic in scope of the study.

The MAH/CH and MRA should consider likely implications for AE reporting where there is any use of AI as part of the MR study (refer also the EPHMRA Checklist for AI in Healthcare Market Research).

2.1 MAH/CH Responsibilities

- MAHs should take appropriate measures to manage all reports of suspected AEs associated with medicinal products for human use originating from unsolicited or solicited sources (see definitions).
- All MAH/CH employees - all functions, e.g., market research, business intelligence/information, marketing/commercial, sales, etc), contractors and MAH/CH's representatives and third parties.
- Where a MAH/CH engages an MRA to provide services, it should require that the MRA reports AEs to the MAH/CH via appropriate contract.
- The MAH/CH must provide the MRA or its sub-contractors with the relevant PV contact details, i.e., email, fax number or other secure electronic method for transfer of data, to forward AERs. Note: Country level privacy rules for transfer of personal information should apply.
- The MAH/CH's PV department is responsible for all associated follow-up actions, if appropriate.
- The MAH/CH's PV department is responsible for determining the severity of the AE and any causality.
- The commissioning MAH/CH should provide the MRA with a list of the brand and generic names of the medicines or medical devices or diagnostics for which they hold the marketing authorisation for the countries involved in the MR at the start of the study.

2.2 MRA Responsibilities

- Adverse Event reporting requirements associated with medicines where the commissioning company is the MAH/CH should be agreed at the start of the MR before commencing recruitment and fieldwork.
- AE reporting obligations for medical devices or diagnostics where the commissioning company is the MAH/CH should be agreed at the start of the study as the requirements, if applicable, may differ compared to medicines.
- AEs arising during MR where the commissioning company is the MAH/CH of the medicine or medical device or diagnostic is mentioned by brand (trademark) name or its generic (International Non-proprietary Name /INN) should be reported.
- You are not required to report AEs cited for a medicine or medical device or diagnostic where the commissioning client is not the MAH/CH.
- You must report any type of AE arising during the MR whether they are serious or severe, or if they have already been reported.

- You should only provide the contact details of the participant, whether a healthcare professional (HCP) or non-HCP to the MAH/CH if there is a lawful basis for this under the relevant data protection legislation.
- There may be different legal basis to process personal data depending on jurisdictions. Market research studies most commonly use consent as a lawful basis for the transfer of personal data, but this is not the only option.
- If consent is used as the lawful basis for the transfer of personal data, this is a separate data processing operation and requires the participant's consent, whether an HCP or Non-HCP.
- The MRAs must inform the participant both at recruitment and at the start of the interview of the obligation to report AEs to the MAH / CH's PV that may arise during the MR interview.
- Where the MRA subcontracts its MR obligations to a third party, e.g., a fieldwork agency, it should ensure the subcontractor undertakes AE reporting to comply with all legal, regulatory, and contractual requirements in general (refer above points).
- In a co-promotion or co-marketing situation, the MRA should agree with the commissioning company the process for AE reporting of a medicine, medical device or diagnostic.

3. BEFORE FIELDWORK AND DURING FIELDWORK

3.1 The MRA, or third party if sub-contracting, must inform the participant of the obligation to report AEs arising during the MR interview at recruitment and at the start of the interview.

3.2 Completing AERs

- The AER must be completed at the end of recruitment or the MR interview - there is no need to interrupt the interview to do this.
- You must ensure that information required (refer criteria below) to report an AE to the MAH/CH PV does not include personal data included that raises Data Protection issues, e.g., including the reporter details without their prior consent.
- You should provide as much detail as possible to complete the information required for AE reporting, preferably completing it with the help of the participants.
- AEs must be reported to the MAH/CH within **one business day** of the MRA or their subcontractor becoming aware of it.
- The only exceptions are:
    - Syndicated studies (either based on primary and/or secondary MR) where data are collected independently of individual companies and are available for purchase by multiple Healthcare companies. It is the MAH/CH's responsibility to report unsolicited AEs identified from the research purchased (refer Section 3.5 Unsolicited).
    - Longitudinal patient databases.

3.3 AE Reporting Criteria

The MAH/CH's PV is responsible for managing and reporting valid Individual Case Safety Reports (ICSR) of suspected AEs to the relevant regulatory authorities.

The MAH/CH's PV is expected to follow-up AERs where information is missing. Please check for country exceptions, i.e., in Germany the manufacturer must not know the identity of the participant and follow up of AERs should be done via the MRA or its sub-contractor.

3.4 Four minimum criteria are required:

I. One or more identifiable reporter(s), i.e., participant(s),

II. Identifiable patient or group of patients,

III. One or more suspected medicinal product(s) or diagnostic(s) or medical device(s),

IV. Suspected Adverse Event (includes serious and non-serious AEs, SRSs and PQCs).

3.5 Sources for AEs

The two types of AEs that may arise for medicinal products or devices or diagnostics are classified as either **'solicited'** or **'unsolicited'** (see below). Both solicited and unsolicited AEs during MR interviews with HCPs or non-HCPs should be reported to the MAH/CH's PV department.

- **Solicited:** includes AEs "derived from organised data collection systems, including surveys of patients or healthcare professionals", e.g., personal/telephone/web-based interviews, surveys (paper, online, etc).
- **Unsolicited:** "not related to any organised data collection systems" e.g., European Medicines Agency (EMA) include internet or digital sources, including social media, as 'unsolicited'. This includes unsolicited AEs associated with the MAH/CH's medicinal products or devices or diagnostics identified in reports purchased as part of syndicated studies (including either primary and/or secondary MR).

4. CONSENT AND AE REPORTING

4.1 Transfer of personal information in AERs

Consent is the most used lawful basis for the transfer of personal data, but this is not the only option (refer EU/UK GDPR, or other applicable data protection legislation). The participant's personal information, e.g., name, contact details, can only be forwarded to the MAH/CH PV if the participant has provided consent or there is an alternative lawful basis in place. You should check for country exceptions, for example in Germany the requirement of anonymity cannot be overturned, and personal information must not be forwarded to the MAH/CH PV.

- If consent is being used this must be provided before any data are transferred by the MRA to the MAH/CH PV.
- Measures should be put in place to ensure the use of AI is compliant with relevant regional, national or sub-national (e.g. US states) data protection regulations in relation to requirements for AE reporting, if applicable, for a MR study.
- Measures should be in place to mitigate the risk of non-human respondent input to data collection - either by uneventfully or intentionally - where AEs arise, e.g., use of bots or "ants" or use of "synthetic" data for a MR study.
- Personal information must not be forwarded to the MAH/CH PV if consent has not been given, or an alternative lawful basis has been used, e.g. legitimate interest (supported by Legitimate Interest Assessment) although the participant may still take part in the MR. Under these circumstances the AE must be forwarded to the MAH/CH PV as an anonymous report.
- AEs must still be reported to the MAH/CH PV even if the participant has already notified the relevant regulatory authority.
- When relying on consent for receiving and transferring personal data the sponsoring company could be named when personal information is obtained during MR (ref. EU GDPR). For very specific studies, such as in-licensing or requirement of local codes, e.g., Denmark, the sponsoring company should not be identified. The participant should provide their consent to participate on this basis (preferably documented) or decline.
- Consent for processing personal data for AE reporting purposes may be obtained at the start or end of the interview, as it is not essential for participating in MR.
- AE information about an individual when reported by the individual's carer, relative, or friend must be reported to the MAH/CH PV **without** including personal details of the individual involved, as they have not consented to share their information.

4.2 Patient 'special category' personal data

- Personal data that is especially sensitive is classed as **'special category'** and requires additional security.

- 'Special category' personal data (EU/UK GDPR) includes race or ethnicity, sexual orientation, biometric or genetic data, religious beliefs, data on health problems.
- Patients must provide explicit consent if they are providing 'special category' personal data.

The MRA should check applicable local and regional data protection requirements and agree with the MAH/CH PV how this should be managed at the start of the MR. This should apply to the full data management process and be documented (e.g., contract, PV instructions on AERs).

5. REPORTING FORMATS

The two common AE reporting formats are:

- **AER Form:** collecting information during a MR interview, e.g., personal or group interviews. There is no need to interrupt the flow of the interview as the form can be completed at the end. Collect as many details as possible for minimum reporting criteria. The MRA or the third party collecting the information and completing the reporting form is responsible to sign the AE reporting form before it is forwarded to the MAH/CH PV.
- **Tabulation of aggregate data:** this format is used where information is provided in tables when a large volume of AEs is anticipated, including both structured and semi-structured surveys. For example, large online surveys, collecting data on prescribing behaviour or conjoint studies.

5.1 Tabulation of aggregated AE data

AE Reporting tabulations should include:

- The number of participants where an AE was cited.
- The question base, i.e., the number of participants who answered the question.

The **format** should be agreed with the MAH/CH in **advance of data processing.**

Refer EPHMRA AE Reporting Form template.

5.2 AE Reconciliation Process

Confirmation and/or reconciliation of AEs is a requirement upon completion of the MR study.

A summary of all AEs identified during the MR must be 'reconciled' with or checked against AEs forwarded to the MAH/CH's PV during the MR to ensure all AEs are accounted for. The reconciliation process applies where information is collected using either an AE Report Form or tabulation format for aggregated AE data.

The AER Reconciliation form should include for each country where MR was undertaken, the number of AEs identified (not just reported), summary by each AE of participant's ID, the medicine or medical device or diagnostic, and the details of the AE (including SRS and PQC).

The timing to submit the AE reconciliation typically depends on the type of study, for example submission for:

- One-off short study usually at the end of the research (fieldwork).
- For longer studies, e.g., multiple waves of the same survey, might be at the end of each wave, or a weekly or monthly basis.

AE Reconciliation must be submitted to the MAH/CH's PV even if no AEs were reported: usually reported as "N/A" or "0".

The MRA and/or subcontractor should agree the reconciliation process before the start of data processing (i.e., fieldwork) as the process may vary depending on requirements for AE reporting format, timing to submit the AE reconciliation and the type of system used by the MAH/CH's PV to process the AEs.

5.3 Syndicated Studies (refer to 1.2)

There is no requirement for the MRA funding and conducting independent syndicated studies (primary and/or secondary) and purchased by multiple clients to report AEs for a medicine, medical device or diagnostic relating to the company purchasing the findings of the research. The MAH/CH is responsible to report AEs to their PV if identified in results of purchased syndicated data. AEs arising from data collected by the inclusion of

MAH/CH confidential or proprietary questions in a syndicated survey must be treated in the same way as MR commissioned by the MAH/CH, i.e., the MRA must forward AEs to the MAH/CH's PV.

5.4 Longitudinal Patient Databases

Longitudinal patient databases e.g., GPRD (General Practice Research Database) are out of scope.

The Council for International Organisation of Medicinal Sciences (CIOMS) suggests that there is no obligation to search through such databases for individual AEs as this will give rise to spurious signals and conclusions however if they are found (deliberately or co-incidentally), they should be forwarded to the MAH/CH.

Data from longitudinal patient databases are different to tabular AE summaries collected from MR as they have not arisen from a defined project and are for multiple users, not just acquired by an MAH/CH for internal use (unlike commissioned MR).

5.5 AE reporting where social media is used in MR

- An appropriate AE reporting process must be in place for MR using social media, or social media associated techniques (e.g., online communities). The MAH/CH and MRA should agree the process for collecting and reporting AEs associated with their medicinal products or medical devices or diagnostics before the start of the study.
- Monitoring for AEs during fieldwork (i.e., 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 company sponsored and non-company sponsored websites.
- If a company chooses to listen-in to or 'scrape' from non-company sponsored sites, whether public or private (with consent) it is recommended that the 'listened' to pages should be monitored for AEs for the period of the listening-in activity only.
- There is no obligation for researchers to monitor non-company sponsored sites routinely for AEs if they are not being used for a MR purpose.

5.6 Who to Direct Queries To?

MRAs should direct queries relating to the AER process to the MAH/CH PV department, or market researcher or project owner contact person for guidance.

6. DATA RETENTION

6.1 Responsibility for AER Data Retention

- The MAH/CH is responsible for retaining certain types of AE data for as long as necessary.
- The MAH/CH and MRA including third parties should agree on data retention periods for all relevant AE data and material, including measures to be followed at the end of the agreed retention period, i.e., deletion and/or transfer of AE data and material being returned to the MAH/CH if longer retention is required.

6.2 Longer PV retention and Personal Data Processing

- It is recommended that appropriate technological or operational measures are taken to minimise the risk of processing personal data for longer period of times, if not strictly necessary and in compliance with relevant data protection legislation.
- Where possible the MAH/CH and MRA should agree that relevant AE data and documentation is either anonymised or pseudonymised at the earliest opportunity.

7. DISCLOSURES OF TRANSFER OF VALUE (TOV)

In general, disclosure requirements under European Federation of Pharmaceutical Industries and Associations (EFPIA) code, 2019 and the US Physicians Payment Sunshine Act, 2010 relating to Transfer of Value (TOV) do not require MRAs to identify the names of the HCPs who report AEs during MR studies.

These are considered as solicited AE reports. The HCP's personal data are provided to the MAH/CH's PV for the purpose of AE reporting only and is dependent on the HCP's consent to pass the information.

8. QUALITY MANAGEMENT AND TRAINING

- The MAH/CH and MRAs should have clear and comprehensive operating procedures in place for the collection, forwarding and management of Adverse Events, including data collected using social media, AI or other novel and developing methods.
- PV training requirements for the AE reporting process should be agreed between the MAH/CH and MRA before the start of the MR.
- PV training for AE reporting should be undertaken by all individuals directly involved in the MR study to ensure they fully understand the requirements and actions required.

The MAH/CH should supply their AE report form, or the EPHMRA AER template may be used.

9. AI AND ADVERSE EVENT REPORTING

- Any use of AI to perform AE related activities, e.g., to check large volumes of survey data, should be agreed between the MAH/CH and MRA and third parties if applicable before the start of the MR study.
- Measures should be agreed and implemented to ensure the use of AI is compliant with all relevant data protection and AI regulations (e.g. EU GDPR and AI Act, US state privacy and AI regulations).
- Measures should be in place to mitigate the risk of non-human respondent data input where an AE might arise, e.g., bots or "ants" or "synthetic" data.
- Where AI is used to generate any outputs based on PMR data (such as translation, transcriptions, content analysis, etc. of source data), the MRA and any third party should have appropriate processes or procedures to verify and validate quality and accuracy of the generated data outputs if included in AE reporting.
- AER requirements should not apply to any artificial or synthetic data generated by the AI/GenAI tool but always confirm with the MAH/CH PV at the start of the MR study.

RESOURCES - WEBSITES:

- European Medicines Agency: https://www.ema.europa.eu/en
- European Medicines Agency Pharmacovigilance training materials: https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance/pharmacovigilance-training-materials
- EPHMRA (European Pharmaceutical Market Research Association): https://www.ephmra.org/
- EPHMRA Code of Conduct, **AE Guidelines & AER Proformas:** https://www.ephmra.org/code-conduct-aer
- BHBIA (British Healthcare Business Intelligence Association): https://www.bhbia.org.uk/
- Centers for Medicare and Medicaid Services **(CMS)** final rule on the Sunshine Act 02/08/2013 : Federal Register: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests
- **CMS** 42 CFR Parts 402 and 403 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf
- Open Payments Law and Policy | CMS

RESOURCES - REFERENCES:

[1] GVP Annex I Definitions Medical Device (See pages 16-17)

[2] GVP Annex I Definitions Pharmacovigilance (See page 21)