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Pharmaco-vigilance

WI.175/EQL, Ed.A/Rev. 2

Apa itu Farmakovigilans?

- Pengumpulan data terkait dengan deteksi, penilaian, pemahaman, dan pencegahan efek samping obat

- Mengidentifikasi informasi baru tentang bahaya yang terkait dengan obat, untuk mencegah bahaya pada pasien

Definisi

Definition

Adverse Event (AE)

Adverse Event (AE) atau Kejadian Tidak Diinginkan (KTD) merujuk pada setiap peristiwa medis yang tidak diharapkan pada seorang pasien atau subjek penelitian uji klinik yang sedang menerima pengobatan (obat atau alat kesehatan penelitian, dll). Peristiwa ini tidak selalu memiliki hubungan sebab-akibat dalam pengobatan tersebut.

Adverse Drug Reaction (ADR)

- In **pre-approval clinical experience** (a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established), ADR is all noxious and unintended responses to a medicinal product (a causal relationship between a medicinal product and an adverse event is **at least a reasonable possibility**) **related to any dose.**
- Regarding **marketed medicinal products**, ADR is a response to a drug that is noxious and unintended and that **occurs at doses normally used** in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function

Serious Adverse Event (SAE)

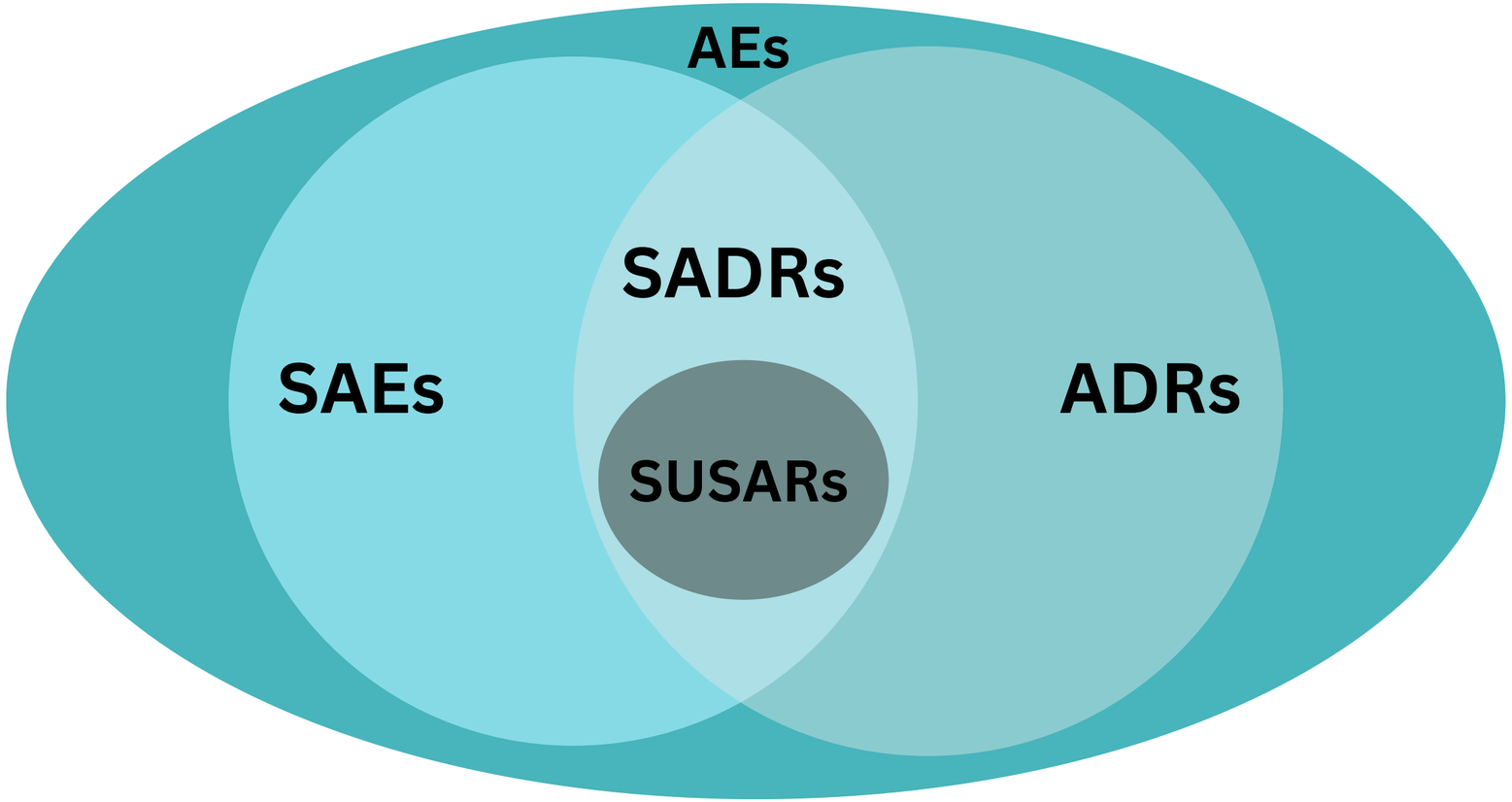
Serious Adverse Event (SAE) is an adverse event which:

- Results in death
- Is life-threatening
- Requires hospitalization, or prolongation of existing inpatients' hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly or birth defect
- Any events that are considered serious, according to the investigator’s judgment

NOTE

1. The ***cause*** of the death is the SAE. “Fatal” is the outcome.
2. Life-threatening - an adverse event that immediately endangers the patient's life due to the adverse drug event as it happened.
3. Events that result in or prolong hospitalization - **Report the diagnosis, NOT the procedure**
4. Disability - an AE that substantially disrupts a person’s ability to **conduct normal life functions**
5. **Pregnancy is not an SAE**

AE, ADR & SAE



1 Adverse Event Recording Procedure

1. The investigator records AE that occurred in AE form attached or as a part of the subject's CRF. The information that should be recorded are:
   - Subject identity (subject number, initial)
   - Adverse event experience by the subject
   - Event course (constant, intermittent)
   - Duration of adverse event: date & time of onset and the end of the AE
   - Outcome: resolved, ongoing, or died. If died, complete the SAE Form.
   - Intensity:
     * mild : the symptoms of AE are simply tolerated
     * moderate: the symptoms of AE are adequate incomfort and may cause intervention with normal
     * severe : the symptoms of AE may cause failure to perform normal activities

1 Adverse Event Recording Procedure

- Causality:
  * Definite : If the event is re-confirmed by laboratory data; and/or reaction immediately following drug administration
  * Probable: If the event is temporal correlation with administration; and or recovery on withdrawal of drug if no other drug is withdrawn and no therapy given; and/or uncommon clinical phenomenon associated with the administration of drug in the absence of other factors.
  * Possible : If the event is followed by possible alternative explanation that exists; and/or more than one drug is suspected and/or data are incomplete; and/or recovery follows withdrawal of more than one drug; and/or time relationship is not clear; and/or outcome of the relationship is not recorded; and/or recovery follows therapy in addition to withdrawal of drug

1 Adverse Event Recording Procedure

* Unlikely : If clinical event may be well explained as occurring from factors related to underlying disease, or other non-drug aetiology

* Unrelated: The AE, including laboratory test abnormality, could not medically (pharmacologically/clinically) be attributed to the IP under study in this protocol. This statement should be regarding to reasonable explanation that have to be stated

- Corrective therapy
- Notification that the subject withdrawn from the study or not
- Notification that the event is an SAE or not

2. Resume the AE occurred per study, completed with the information as mentioned in point 1, the information of date and time of IP administration, and information of the oucome of AE

1 Adverse Event Recording Procedure

3. Follow up the AE occurred and record the outcome. If there any medication given, record in the concomitant medication form. And if the AE to be a SAE, record in the SAE form.

4. Attach the summary of AE in the study report (this study report will be submitted to regulatory authority by sponsor), and submit together with the study close out report to Ethical Committee.

5. For AE which is reported by study subject by phone, whoever perosnnel who contacts with this subject (e.g. operator, nurse, study physician, CRO officer, etc) responsible to get the information related to the AE occurred and recorded in the AE form which is provided in each unit of CRO office. The AE report will be given to investigator to be reviewed and followed up.

2 SAE Reporting Procedure

1. If SAE occur, Investigator should report the SAE to sponsor or CRO by telephone/fax within 24 hours after SAE first known by investigator. The minimum information to be reported are: the event to be considered as SAE, subject number, subject initials, age, sex, and onset.
2. Investigator should handle and follow up this SAE, and if any medication is given, it should be recorded as concomitant medication in CRF.
3. Record and complete the information needed into the SAE Form (F.008/EQL):
   - Study information (project code, center no., subject no., drug name, batch no., expiry date, report type
   - AE information (subject/patient initials, date of birth, age, sex, event onset, AE, description, expedited reporting of SAE criteria
   - Suspect study drug information (suspect drug, daily dose, indication, route of administration, therapy date and duration

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2 SAE Reporting Procedure

- Concomitant drugs and history (relevant concomitant drug, action taken by investigator, relevant test/laboratory findings, outcome, causality assessment by investigator)
- Study monitor information (name and address of study monitor, date received by study monitor, date of report)
- Information source (signature, name, address, and telephone number of investigator/person reporting event or CRF, reporting date by Investigator/person reporting experience

4. Quality Assurance should review and check the information about the AE or SAE before inform to the sponsor, Ethic Committee and Regulatory Authority and recorded in the Document Review (F.202/EQL)

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2 SAE Reporting Procedure

5. Send the written report to CRO within 7 calendar days after SAE first known by Investigator
6. Sponsor or CRO should report SAE to Regulatory Authority (BPOM) and Scientific/Ethic Committee within 15 calendar days. Fatal and life threatening SAE should be reported within 7 calendar day.
7. Inform SAE to other study sites of the clinical study.
8. Record SAEs in Serious Adverse Event Log (F.020-CRU/EQL) and documented in Study Master File.
9. Report all ADRs that are both serious and unexpected to Regulatory Authority (BPOM) by completing ADR Report Form (Formulir Pelaporan Efek Samping Obat, D.094/EQL)

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2 SAE Reporting Procedure

10. Send the completed ADR Report Form to the address as below:

Pusat Farmakovigilans/MESO Nasional
c.q. Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Deputi Bidang Pengawasan Obat, Narkotika, Psikotropika, Prekursor, dan Zat Adiktif
Badan Pengawas Obat dan Makanan Republik Indonesia

by:

1. Aplikasi pelaporan farmakovigilans Pusat Farmakovigilans/MESO Nasional (e-meso) dengan alamat https://e-meso.pom.go.id
2. Pos : Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
3. E-mail : pv-center@pom.go.id

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Thank you