ADR & Periodic safety update reports (PSUR)

methods

⇒ ADR reporting is the process of reporting an ADR that occurs due to the use of medicines or vaccines.

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Process:

(1) Identification -
A HCP, patient or consumers identifies a suspected ADR after taking a medicine or vaccine.
The ADR may be known/unknown, serious/non-serious or freq/rare

(2) Documentation -
The reporter documents the relevant info about ADR such as pt's detail, med. history, concomitant meds, onset & durdn of rxn, outcome & trt of rxn.

(3) Submission -
Reporter submits the ADR to the designated authority. Some countries have online portals & mobile apps while some require mailing or faxing of the Dox.

(4) Reciept and Validation -

- Authority recieves and validate the ADR for its completeness and quality of info provided in the report and assigns a unique identification no. for it.

(5) Assessment and analysis.

- Authority does so to evaluate the causality, severity, frequency & preventability of ADR and its impact on public health and product safety.

(6) communicat & feedback :

- Authority does so and shares the report to different authorities, researchers, manufacturers and other HCPs for further investigation.

(7) Action & follow up :

- Authority takes action such as updating product info, issuing safety alerts or warning or recalling or suspending

the product or changing the prescribing guidelines.

PSUR

- It is a Pvigilance document which is used to summarize the safety data of a medicinal product over a defined period of time.

PSUR development → (Data collection & analysis of safety profile of product.)

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Internal review process → (Review by internal teams like, PV/RA/QA).

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PSUR submission → (submit to RA like EMEA/FDA)

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Review by RA → (Reviews PSUR & raise questions or request more info.)

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communicate with internal team → (Address queries or changes from RA & collaborate.)

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RSUR resubmission → (Resubmit updated PSUR after addressing queries.)

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Final regulatory decision → (Regulatory authority makes final decision.)

↳ Communicate decision

Data safety & Monitoring board

- DSMB is a group of individuals w pertinent experience, that reviews on a regular basis, the accumulating data of the angaing clinical trial.
- It is generally appointed by the sponsor.
- Mainly used for RCTs.

Functions

(1) Protect the rights and safety of the trial subjects.

(2) Identify high rates of ineligibility after randomization.

(3) Identify any violations of protocol & suggest changes.

(4) Identify unexpected high drop out rates that alter the ability of CT to produce credible results

(5) Ensure validity of the trial

(6) Ensure credibility of trial results

(7) Advise the sponsor to continuing safety of trial subjects.

DSMB has been established for:

(a) Large randomized multisite studies that evaluate treatment intended for prolonged life or reduced risk of a major Adverse event.

(b) Any controlled trial for any size that compares the rate of mortality or morbidity.

Composition:

- The DSMB / Trial steering committee is generally appointed by the sponsor.

- It includes

(1) clinicians, with expertise in relevant clinical specialities.

(2) At least one biostatistician who is knowledgeable about the statistics of the study & sequential analyses of trial data.

(3) A medical ethicist who knows about the design, conduct & interpretation of results.

Some trials may require participation of.

(4) Toxicologists

(5) Epidemiologists

(6) Pharmacologists

(7) One non-scientist individual to bring the perspectives of the subjects under study.

(8) One representative from regional subset in case of international trials.

Responsibilities:

(1) Interim responsibilities.

(a) Monitoring for effectiveness.

(b) " " safety

(c) " " study conduct

(d) consideration for external data

(e) studies for less serious outcomes.

(2) Early studies.

(3) Other responsibility

(a) Making recommendation

(c) Maintaining meeting records.

Meetings.

- It will be held atleast once annually or as per the timing of protocol.

- They will review the status of CT including toxicity, efficacy, outcomes etc.

- Review of each trial has 3 parts

Open session	Closed session	Closed session
↓	↓	↓
PI will tell the status of CT	DSMB memb. only & STSCs to discuss outcome of results	DSMB meme. will discuss outcomes & results.