SAE / SUSAR reporting

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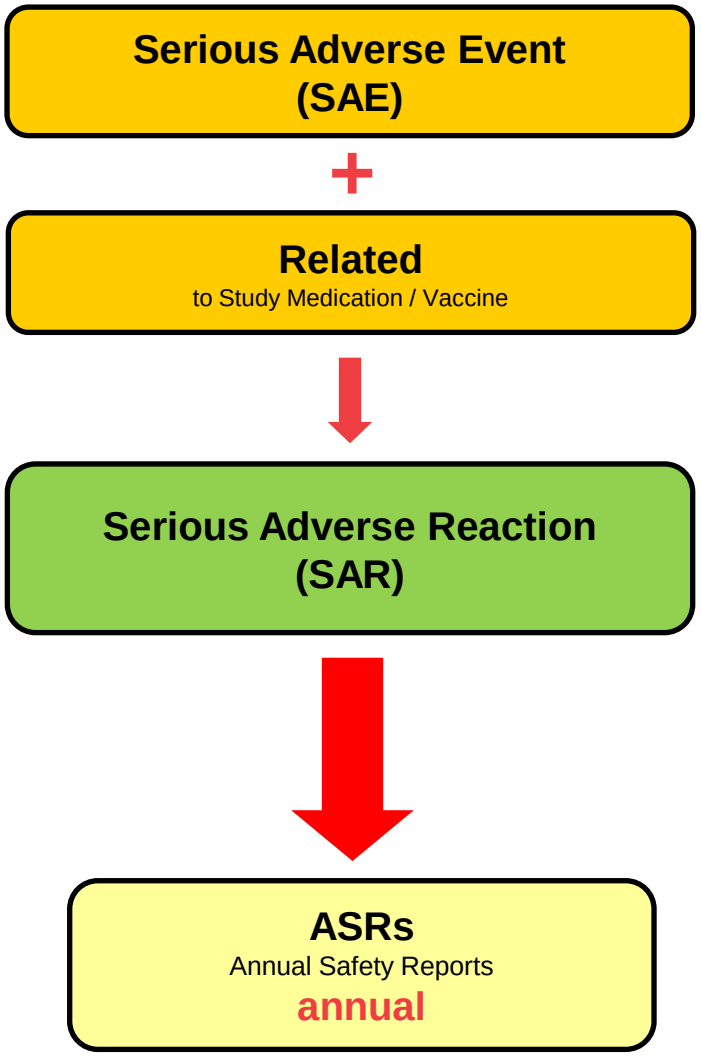
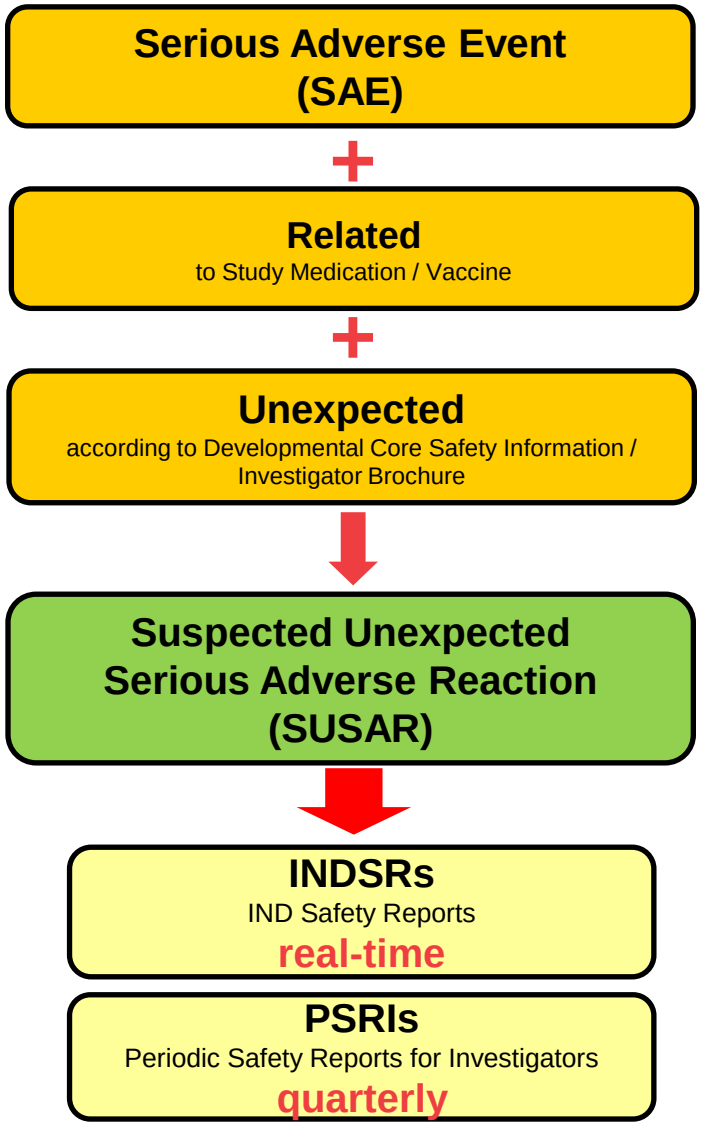
Friday, 24 June 2011

Terminology: Investigator Safety Reports





Prior to Study Start: IBs, Safety Reports, Distribution Lists

- Sponsor provides
  - Investigator Brochure (IB) plus
  - INDSRs and
  - PSRIs generated after the IB specified data cut-off date
- Once site has been provided an IB,
  - The investigator is added to
  - INDSR (if applicable) and
  - PSRI distribution lists
- Australian sites added to the Annual Safety Report (ASR) distribution list

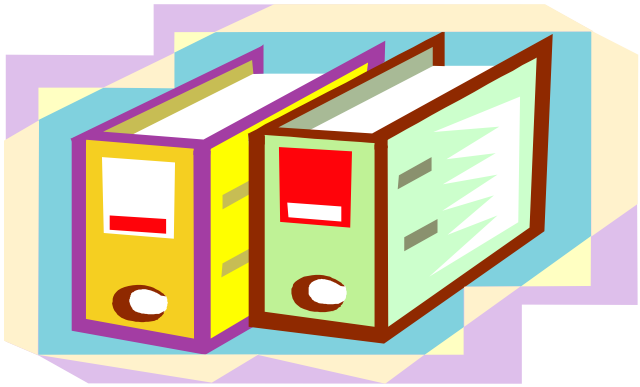
Monitoring during the Study: Investigator Safety Reports

- Ensure that INDSR (if applicable) and PSRI distribution lists are current
- When monitoring, ensure Investigator Safety Reports (INDSRs, PSRIs, ASRs, DIL*s) have been received and submitted to ethics committees, as required.

- *DIL = Dear Investigator Letter
- For this presentation purpose SAE/AE reporting is out of scope, need to follow institution guidance

Background of Changes to 21 CFR 312.32, 320.31

- FDA issued regulation changes and draft guidance 30September2010



- Effective date 28March2011

- FDA's stated objective

  "…to improve the utility of IND safety reports (INDSR), reduce the number of reports that do not contribute in a meaningful way to the developing safety profile of the drug, expedite FDA's review of critical safety information and better protect human subjects enrolled in clinical trials…"

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Thank you Dr Suzanne Hasthorpe and Dr Campbell Simpson
and the
Coordinating Office for Human Research Ethics

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