Safety Reporting Flowchart - Clinical Trials

Adverse Event

→ Not Serious → Adverse Event/Reaction/Effect → Keep detailed records of all adverse events

→ Serious → Serious Adverse Event/Reaction/Effect → Complete and submit '*Safety Report - Clinical Trial*' to La Trobe University HREC

Serious Adverse Event/Reaction/Effect →

- Related to IMP *(Investigational Medicinal Product)* and Unexpected → SUSAR *(Suspected Unexpected Serious Adverse Reaction)*
- Related to IMD *(Investigational Medical Device)* and Unanticipated → USADE *(Unexpected Serious Adverse Device Effect)*

→ If trial is registered with TGA report:
- fatal/death or life threatening - no later than 7 calendar days
- other - no later than 15 calendar days

Significant Safety Issue

→ Complete and submit '*Safety Report – Clinical Trial*' to La Trobe University HREC

→ Report to TGA *(if registered):*
- urgent safety measure - within 72 hours
- amendments/temporary halt/early termination - no later than 15 calendar days

Breach of Good Clinical Practice / Protocol

→ Complete and submit '*Breach_Good Clinical Practice_Protocol_Report - Clinical Trial*' to La Trobe University HREC within 7 calendar days

→ Report breach to TGA *(if registered)* when the breach:
- leads to the closure of the site
- involves a defective product that may have wider implications for the supply chain for that marketed product

Note. All trials must annually complete and submit the '*Annual Safety Report – Clinical Trial*' to the La Trobe University HREC

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All kinds of clever