CTFG Best Practices (BPs) in Safety Surveillance in Clinical Trials

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Project Overview: CTFG best practice (BP) in Safety Surveillance in Clinical Trials

Scope of project: To cooperate in safety surveillance and keep/increase quality of safety data in clinical trials and marketing authorization (safety IR objective)

harmonize safety assessment between EU/EEA MSs in order to obtain added value of safety oversight and avoid duplication of safety assessment by workshare.

Deliverables:

1) CTFG produces BPs with clear and detailed procedural descriptions to guide assessors on how to perform safety evaluation (using the tools developed by EMA).

2) CTFG supports implementation of the best practices to built trust and ensure an environment where we learn from each other.

Clinical Trial Safety Surveillance Best Practice – 5+ parts:

1) Introduction to BP including summary of roles and responsibilities and saMS selection
2) CTFG best practice on the use of the safety sheet and IT tools e.g. SharePoint
3) CTFG best practice on coordinated SUSAR screening and assessment
4) CTFG best practice on coordinated ASR assessment
5) CTFG best practice on coordinated assessment of Any Safety Issue
6) CTFG best practice on RSI assessment

The BP documents are in the format of "SOPs" with tips and tricks for the safety assessors on how to perform safety assessment within the IT tools

→ Confidential and will not be publicly available