Federal Institute for Drugs and Medical Devices

Transition – Safety Reporting

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Submission of ASR when CTs ongoing as of Directive 2001/20 & CT Regulation 536/2014

Sponsor are asked to

- Submit Annual Safety Report to the database specified for CTR
- Name all MSs concerned* for all ongoing CTs in EU/EEA within Directive as well as Clinical Trials Regulation
- Fullfill obligation of Directive 2001/20/EC (CT3)
  - Submit ASRs to Ethics Committees according to national legislations in MSs with ongoing clinical trials
  - Inform investigators of any new safety data or change in benefit-risk evaluation

SaMS need to

- Include all MSs concerned (CTR and Dir) in the assessment procedure/workflow [adhoc workflow might be needed here]

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*Best by using a table listing MSC and EudraCT numbers of concerned CTs

Submission of SUSARs when CTs ongoing as of Directive 2001/20 & CT Regulation 536/2014

Sponsor need to

- Report SUSARs to the EV database (EV CTM module)
- Double reporting is to be avoided, unless the NCA has had a national requirement for direct reporting of SUSARs
- Obligations as of CT-3 still need to be respected, especially
  - Reporting to Ethics Committees according to national legislations in MSs for all IMPs/CTs within Directive 2001/20/EC
  - Reporting to investigators (CT-3 Article 109)

SaMS tbd

SUSAR screening and assessment process/methodology under discussion, transition situation to be discussed

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Thank you very much for your attention!

Contact

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