Data quality framework for Adverse Drug Reaction reporting - Clinical Trials

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Safety in Clinical Trials

Goal - Responsibilities

- **Sponsor** to ensure participants **positive benefit risk** continuously (CTR 536 Art 28, 1a)
  - Identify potential safety signals and adequate risk minimization/management
  - **Safety reporting requirements** as of CTR 536/2014 :

    Suspected Unexpected Serios Adverse Reactions *SUSAR* , *Annual Safety Report* *ASR*, *notifications*

    (Art 41, 42, 43, 52-54, 38, Reference Safety Information RSI : Annex I)
  - **Investigator** to record and report to sponsor : CTR Art 41 exemptions as of protocol

- **Member States** cooperate in assessment of safety reports (CTR Art44, IR 2022/20)

  'safety surveillance' *: adequate risk management*

- **Characterisation of the safety profile** of the active substance / medical product in the respective population - **in a controlled setting**

- **Impact of data quality :** **Safety of participants in the Clinical Trials**

  Balanced benefit/risk in authorised setting

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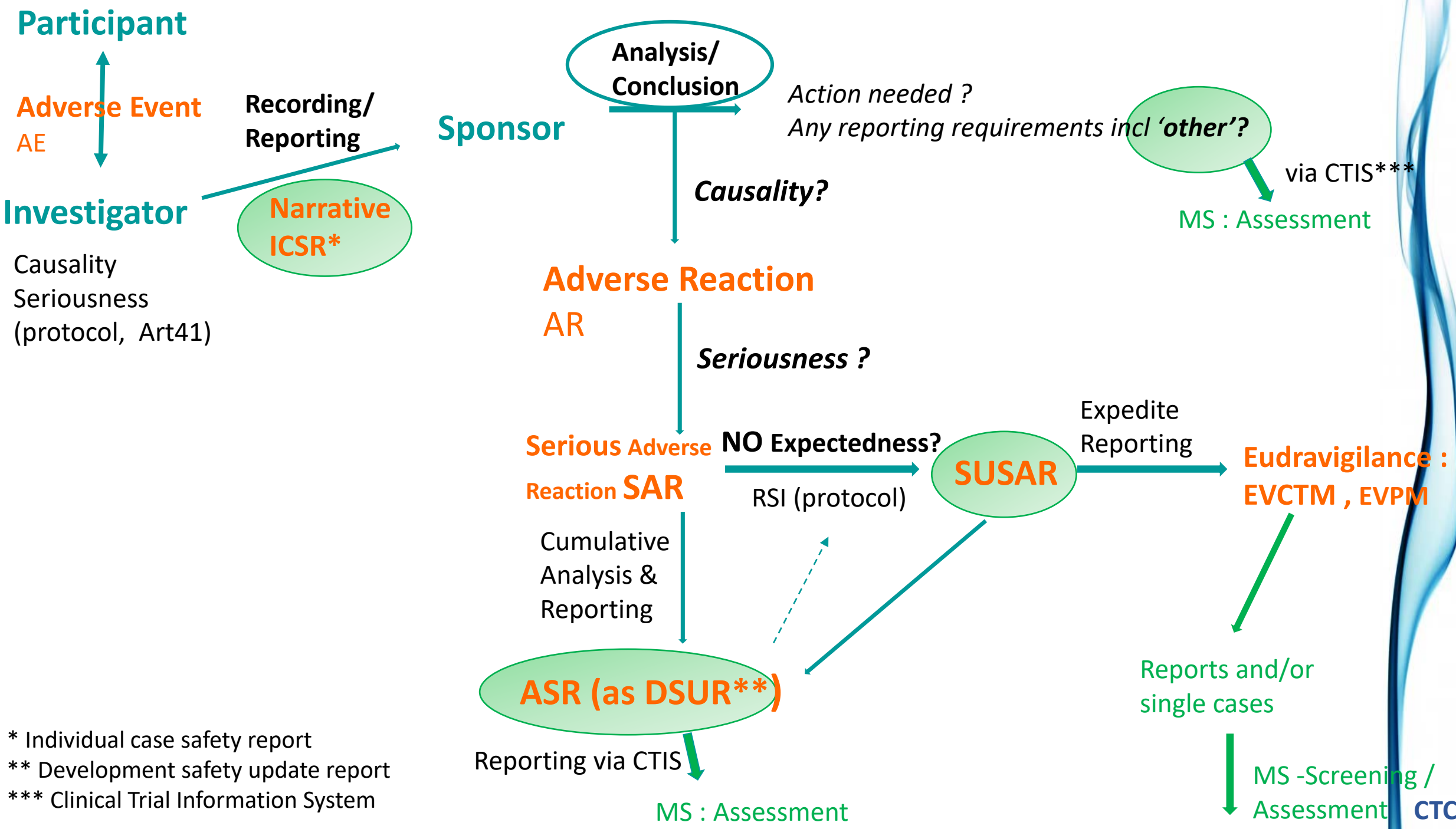
Participant
Adverse Event
AE
Recording/
Reporting
Investigator
Narrative
ICSR*
Causality
Seriousness
(protocol, Art41)
Sponsor
Analysis/
Conclusion
Action needed ?
Any reporting requirements incl 'other'?
via CTIS***
MS : Assessment
Causality?
Adverse Reaction
AR
Seriousness ?
Serious Adverse
Reaction SAR
NO Expectedness?
RSI (protocol)
SUSAR
Expedite
Reporting
Eudravigilance :
EVCTM , EVPM
Cumulative
Analysis &
Reporting
ASR (as DSUR**)
Reports and/or
single cases
Reporting via CTIS
MS : Assessment
MS -Screening /
Assessment
* Individual case safety report
** Development safety update report
*** Clinical Trial Information System
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Analysis of safety reports in Clinical Trials

ASR

- Identify any changes of the safety profile within the reporting period:
  - Changes of frequencies, seriousness, issue (Preferred Term)
  - Known or new potential safety issues and adequate risk management and its follow up
  - Justification for closure of potential safety issue
  - Cumulative tables for SAE/SAR

SUSAR

- Dig out the new information : need of risk management ?
  - UN-expectedness : as of RSI?
  - Causality : neither due to disease (differential diagnosis) nor comedication only
  - Being a new case, not a Follow-Up or merged one
  - Clear category of the issue (Preferred Term)
  - ➢ Good quality structured data to get good reports for primary analysis
  - Clear, complete case description (narrative → sufficient detailed to analyse*)
  - May get intense to analyse marketed active substances used in Clinical Trials

➢ **High quality of importance to analyse safety reports and further use → Basis of the Safety Profile**