Serious Adverse Event Reporting in a Medical Devices Information System

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Outline

• Objectives
• State of the art
• MEDIS requirements and methodology
• Adoption of HL7 for SAE in Medical Device domain
• Some remarks in the use of HL7 & Conclusion
Objective

Design and development of a Serious Adverse Event (SAE) reporting tool that:

• Provides a complete and detailed information on SAE related to investigational Medical Devices
• Facilitates monitoring activities by National Competent Authorities
• Facilitates data exchange with other information systems

issues

• Modelling Medical Device characteristics
• Using a standardised sharable dataset

our vision

• SAE module embedded within a CIV information system
• Interoperable
State of the art

Information systems supporting clinical research:
• e-CRF, site management, patient recruitment, protocol authoring, …
• Limited number of SAE reporting and monitoring tools
• … especially in the MD domain

Registries on Medical devices:
• **Country level**: development of local systems (i.e. DIMDI, MEDIS)
• **European level**: EUDAMED, databank on commercialized MDs and information on clinical investigations

Standardization:
• **CIV domain**: common practice in pharmaceutical clinical trials (i.e. CDISC, HL7, BRIDG, …)
• **MD domain**: at initial stage
MEDIS requirements

- **Monitoring**
  - Tracking the entire CIV lifecycle, from proposal submission to the collection of CIV results

- **Secure and consistent data acquisition**
  - Identification of applicants (responsibility) and mandatory data & documents

- **Supporting evaluation and communication**
  - Uniform & collaborative evaluation procedures, tracking communication

- **Interoperable**
  - Data exchange among NCAs, with EUDAMED and other stakeholders

Adoption of HL7 methodology and messaging standards

MIE 2011, 28th – 31st August 2011, Oslo, Norway
SAE Domain Analysis Model
SAE Message Information Model
Main remarks in the use of HL7

The application of HL7 standards has proved to be useful to:

- Represent the CIV lifecycle including the SAE reporting and monitoring processes
- Describe the MD characteristics highlighting the different artifacts as well as their functions in the process of CIV

It presents ambiguity in the concept of Act representing both a structured document and an action.

Its adoption represents a first step forward to develop a common standard language in the MD domain.
Conclusion

The development of a specific module of SAE reporting within a MD information system:

• Supports CIV applicants in the reporting activity of SAEs

• Supports the NCA in monitoring SAEs as well as managing the communications exchanged during the SAE process

• Increases consistency in SAE data, reduces time of reporting and evaluation procedures, facilitates the analysis and the status track of reported events

This is particularly important considering that SAE information represents an important means to test MD efficacy and safety
Thank you for your attention

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Adverse Event definition

**Adverse Device Effect (ADE)**
Related to the use of an investigational MD. It includes: inadequacies in the instructions for use, malfunction, use error or intentional misuse.

**Adverse Event (AE)**
Untoward medical occurrence in subjects, users or other persons whether or not related to the investigational MD.

**Device deficiency**
Inadequacy of a MD relate to its identity, quality, durability, reliability, safety or performance such as malfunction, misuse or use error & inadequate labelling.

**Serious Adverse Event (SAE)**
Led to death, serious deterioration, hospitalization, surgical intervention, fetal distress, fetal death or a congenital abnormality or birth defect.

**Unanticipated Serious Adverse Device Effect (USADE)**
Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
MEDIS system

Authorisation Authentication
- Roles
- Delegation

Notification
- MD
- CIV
- Documents

Communication

CIV Monitoring
- Amendments
- SAE

Evaluation
- Collaborative reporting
Reporting SAE in MEDIS (initial report a)

Administrative & Timing information

MD tracking information

Causality & USADE evaluated by sponsor and/or investigator
Reporting SAE in MEDIS (initial report b)

Subject involved information

SAE description

Led to or might have led to SAE

Subject status related to SAE

Action taken
SAE Domain Analysis Model
SAE Domain Analysis Model