The use of HL7 in the domain of Medical Devices

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Outline

✓ Objective
✓ State of the art on Medical Devices (MD)
✓ MEDIS system design
  ✓ Clinical Investigation business process
  ✓ Domain Analysis Model
  ✓ Relational Database
✓ Conclusion and future works
Objective

Design and development of an **interoperable** system managing information on Clinical Investigations on MDs supporting:

- Processes of notification and evaluation
- Distribution and exchange of information on current clinical trials

**Issues:**

Identify a common language that:

- Facilitates the integration with other systems
- Gives a standard representation of MDs in the context of Clinical Investigation
State of the art

Regulation:

- **European directives**: 2007/47
- **National laws (IT)**: 37/2010
- **Standards and guidelines**: ISO 14155, MEDDEV 2.x, etc…

Registries:

- **European level**: EUDAMED collects data on MDs and foresees also information on clinical investigations
- **Country level**: development of local systems (i.e. DIMDI)
State of the art

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- **Country level**: IT: MEDIS system (i.e. DIMDI)
What is MEDIS system

The core of MEDIS is composed by:

- registry of data and content repository of documents exchanged between applicants and National Competent Authority during the whole Clinical Investigation lifecycle
Clinical Investigation business process

[Diagram showing the business process of Clinical Investigation, including steps such as Applicant submission, Evaluation, Investigation, and Communication with various parties like NCA, National/International Registries, and CDMS/CTMS.]
MEDIS Domain Analysis Model

MEDIS DAM design has been based on the analysis of the already balloted HL7 domains and, in particular, the BRIDG project.

However, these domains do not entirely cover MEDIS purposes.

<table>
<thead>
<tr>
<th>CIV lifecycle considered</th>
<th>BRIDG</th>
<th>MEDIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focuses on the process of CIV capturing data from the clinical protocol</td>
<td>Considers the whole process from a national competent authority point of view</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product description</th>
<th>Different types (pharmaceutical, MD, …)</th>
<th>Only MD</th>
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</table>

| MD description | Focuses on the investigational product | Considers all the products involved in the CIV and their different functions |
MEDIS Relational Database

Issue: extract information from the database and map them into a message information model, as well as *vice versa*.

- Task very complicated due to the heterogeneity of data models as well as the necessity of identify multiple relationship that link HL7 classes
- Mapping techniques performed by automatic and semi-automatic tools
MEDIS Relational Database

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Propose a method that can make the message construction and interpretation straightforward.

- Database design based on the MEDIS DAM
- Use of the Hibernate framework to map Java objects into a relational database
MEDIS Relational Database
MEDIS Relational Database
Conclusion

• Designing and developing an interoperable system is important considering that the interoperability is going to be fundamental in this domain

• The application of the HL7 RIM in the MD context allows us to describe the MD characteristics highlighting the different artifacts as well as their functions in the process of CIV

• The design of the relational database starting from the HL7 DAM can facilitates the construction and interpretation of message content
Conclusion

Despite these benefits, some limits appear evident in respect of the complexities of the overall database schema realized:

• Complex queries
• Computational costs of the query execution
State of the art and future works

- The HL7 Domain Message Information Model is under construction and will be proposed to the HL7 group for balloting.
- Starting from the RMIM data types and attributes based on the RIM will be included in the relational database.
- At the moment the system is under a testing phase.
Thank you for your attention

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