A Medical Device Domain Analysis Model based on HL7 RIM

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✓ Objective
✓ Background information on Medical Devices (MDs) and main differences with pharmaceutical product
✓ MEDIS project
✓ Introduction to HL7 standards
✓ MEDIS Domain Analysis Model
✓ Conclusion and future works
Objective

Development of an **interoperable** system managing information on Clinical Trials for MD supporting:

- Process of notification and evaluation
- Distribution and exchange of information on current Clinical Trials and their lifecycle

Challenges:
1. Define a dataset
2. Identify a common language
3. Adopt a suitable standard
# Medical Device: definition

<table>
<thead>
<tr>
<th>MD can be an/a</th>
<th>Used</th>
<th>With</th>
<th>To be used specifically for</th>
<th>Of</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Instrument</td>
<td>• Alone</td>
<td>• Software</td>
<td>• Diagnosis</td>
<td>• Disease</td>
</tr>
<tr>
<td>• Apparatus</td>
<td>• in combination</td>
<td>• Accessories</td>
<td>• Prevention</td>
<td>• Compensation for an injury of handicap</td>
</tr>
<tr>
<td>• Appliance</td>
<td></td>
<td></td>
<td>• Monitoring</td>
<td>• Anatomy or of a physiological process</td>
</tr>
<tr>
<td>• Software</td>
<td></td>
<td></td>
<td>• Treatment</td>
<td>• Conception</td>
</tr>
<tr>
<td>• Materials</td>
<td></td>
<td></td>
<td>• Alleviation</td>
<td></td>
</tr>
<tr>
<td>• Other article</td>
<td></td>
<td></td>
<td>• Investigation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Replacement</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Modification</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Control</td>
<td></td>
</tr>
</tbody>
</table>

*(EU Directive 2007/47/CE)*
Some implantable Medical Devices
Some diagnostic Medical Devices
### Main differences between MDs and drugs

<table>
<thead>
<tr>
<th></th>
<th>Drug</th>
<th>MD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanism of action</strong></td>
<td>chemical</td>
<td>physical</td>
</tr>
<tr>
<td><strong>Production process</strong></td>
<td>discovered</td>
<td>invented</td>
</tr>
<tr>
<td><strong>Development</strong></td>
<td>clinical trial, error process, laboratory test</td>
<td>design, prototyping, production phases</td>
</tr>
<tr>
<td><strong>Scientific evidence</strong></td>
<td>multi-phased trials (I-III phase)</td>
<td>clinical investigation, scientific literature, single confirmatory study</td>
</tr>
<tr>
<td><strong>Trial objectives</strong></td>
<td>safety and efficacy</td>
<td>safety, efficacy, and MD performance</td>
</tr>
<tr>
<td><strong>Interaction with patients</strong></td>
<td>whole body reversible</td>
<td>body parts difficult to remove</td>
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</tbody>
</table>
Clinical investigation (from EU 2007/47/CE): any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.

European Directive
• EU 2007/47/CE

Italian National laws
• D.Lgs. 46/97 (MD)
• D.Lgs. 507/92 (AIMD)
Medical Device regulation

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European Directive
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Italian National laws
• D.Lgs. 46/97 (MD)
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Needing of common language for exchanging data
Medical Device: at initial stage in MD domain

Pharmaceutical: common practice (i.e. CDISC, HL7)
State of the art

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<th>Data standardization</th>
<th>Drug</th>
<th>MD</th>
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<td>Common practice</td>
<td>Initial stage</td>
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<td>Registry in Europe</td>
<td>EUDRACT</td>
<td>EUDAMED: Initial stage Few local registries</td>
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European level: EUDAMED project is planning an information system to exchange data related to MD Clinical Investigation

Country level: development of local systems
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**European level:** EUDAMED project is planning an information system to exchange data related to MD Clinical Investigation

**Country level:**

**ITALY**
MEDIS project
The core of MEDIS is composed by:

- registry of clinical investigation data and content repository of documents exchanged between Clinical Investigation proposer and National Competent Authority during the whole clinical investigation lifecycle
MEDIS project

- **Notification phase**
  - Acquisition of data and documents required by the national and European Directives to obtain the approval for the activation of a Clinical Investigation (CI)

- **Evaluation phase**
  - Communication exchanges
    - between CI proposer and NCA evaluators that manage the requests of further information for assessment as well as the updating of CI data and documents
    - among NCA evaluators that manages the assignments of roles as well as the agenda
Objective

To develop a flexible and interoperable system for sharing information among MD clinical investigation stakeholders

Standardization
Objective

To develop a flexible and interoperable system for sharing information among MD clinical investigation stakeholders

HL7
What is HL7

HL7 provides healthcare standards based on:

• A conceptual model (Reference Information Model, RIM)

• An exchange model for clinical documents (CDA, Clinical Document Architecture)

• A model for messaging exchange (Domain Message Information Model, DMIM)
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• An exchange model for clinical documents (CDA, Clinical Document Architecture)
• A model for messaging exchange (Domain Message Information Model, DMIM)
**HL7 RIM – Definition**

- **Role**: i.e. relation between organizations
- **Link**: i.e. temporal order associations
- **Entity**: people, places and things, nouns
- **Role**: relators
- **Participation**: prepositions
- **Act**: verbs

**Diagram**

- Entity
- Role
- Participation
- Act

Relationships:
- Entity -> Role: Plays
- Role -> Participation: 0..1
- Participation -> Act: 0..*
- Act -> Relationship: 0..*

**Definitions**

- **i.e. relation between organizations**: Role Link
- **i.e. temporal order associations**: Act Relationship

**Terms**

- People
- Places
- Things
- Nouns
- Relators
- Prepositions
- Verbs

**Notes**

- i.e. temporal order
- i.e. relation between organizations
“The manufacturing enterprise Device & Co. submits a notification through its legal representative Mr. Jack Smith”
HL7 RIM – An example

An organization… **Device & Co.**

... plays the role of... **Proposer Environment**

... participates as a ... **Manufacturer**

... at the act **Notification**
HL7 RIM – An example

A person... Mr. Jack Smith

... plays the role of... Proposer

... participates as a... Legal representative

... at the act Notification
HL7 RIM – An example

... plays the role of ... Proposer Mr. Jack Smith

... plays the role of ... Proposer Environment Device & Co.
HL7 RIM – An example

Entity 0..1 0..1

Role 0..* 0..*

Role Link 0..1 0..1

Scopes

Participation 0..*

Act Relationship 0..* 0..*

Act 0..* 0..*

... at the Act Notifying

... at the Act Evaluating

Is followed by
The application of the HL7 RIM in the MD context:

• Has proved to be useful for the representation of Clinical Investigation lifecycle

• Its adoption represents a first step forward for the development of a common standard language

This is particularly important in a domain where standardization is at its initial stage.
State of the art and future works

At the moment the system has been developed and is actually under a testing phase.

The HL7 Domain Message Information Model is under construction and will be proposed to the HL7 group for balloting.
Thank you for your attention

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