

HL7 RIM - An Introduction for Non-technical Professionals

Jörg Dillert, Oracle, Potsdam, Germany

ABSTRACT

The FDA (Food and Drug Administration) announced the development of HL7 (Health Level 7) messages, based on the HL7 RIM (Reference Information Model) model, which may act as the transport device for all electronic submission in the future. Also in other working areas in the life science industry, HL7 and CDISC (Clinical Data Interchange Standards Consortium) are often seen together as stakeholders in projects.

HL7 RIM contains many new elements and mostly understood only by technicians.

This presentation will provide a comprehensive introduction for non-technical practitioners and decision makers, helping to demystify the many of the vagaries of HL7.

INTRODUCTION

HL7 is an ANSI (American National Standards Institute)-accredited Standards Development Organization operating in the healthcare arena. HL7 also has co-operation agreements with International Standards Organization (ISO) and with ECN, the European Standards Body.

HL7 is the leading standard for the electronic interchange of healthcare information. Over the past decade, Version 2 of the HL7 standard has been widely implemented in over 20 countries. Following new possibilities in technology improvement, Version 3 of the standard has been developed to address and solve more complex requirements in the healthcare world today.

The new Version 3 reflects the trend in systems interoperability and removes optionality as far as possible. Also, it includes international requirements from its earliest stages. Multiple advantages are the result compared with the Version 2 keeping the compatibility with version 2.

Since last year, HL7 standards are published for free and everybody can study the related documentation. However, the integration of these standards into IT systems requires an HL7 membership.

HL7 VERSION 3 KEY CONCEPTS

HL7 introduced with Version 3 new main concepts:

- Unified Modeling Language (UML)
- Reference Information Model (RIM)
- Domain Message Information Model (D-MIM)
- Refined Message Information Model (R-MIM)
- Hierarchical Message Description
- Message Type

This presentation will focus on the HL7 Reference Information Model (RIM) as it is the fundamental model from which all other HL7 models are derived. The RIM is populated by classes and their relationships to each other, topped with attributes. All models have as source six core classes. To avoid re-inventing the wheel, more than 70 generic healthcare classes defined. We will focus on the first 6 classes.

WHY DO WE TALK ABOUT FDA, CDISC AND HL7

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Historically, HL7 was focused on the data exchange of healthcare data, where CDISC standards are mainly interested in data exchange as part of clinical trials and a standardized data structure for regulatory (drug) submissions.

With acceptance of CDISC standards through the FDA a partnership was established, where HL7 became a stakeholder of certain CDISC model development like the CDISC BRIDG (Biomedical Research Integrated Domain Group) model (www.bridgmodel.org). Beside, the FDA implemented HL7 standard development into their PDUFA IV – IT plan (Prescription Drug User Fee Act) update, which states the ‘modeling to HL7 Reference Information Model’ and that the ‘new health information exchange standards development, the FDA works within HL7’.

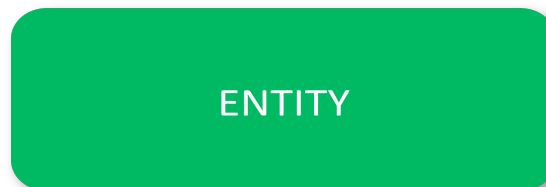
There is another touch point between HL7 and CDISC, which is the integration of Electronic Health Records (EHR) data into the set of clinical trial data for running clinical trials.

THE HL7 RIM MODEL

The HL7 Reference Information Model (RIM) is the metadata model for all other models in the world of HL7. As a result it creates and defines ‘HL7 messages’ as part of a D-MIM/R-MIM creation – which is technically an XML file which contains all required data for the particular D-MIM/R-MIM model.

The HL7 RIM contains 4 generic classes and 2 “helper” classes, where all classes are represented through different colors.

ENTITY - GREEN



An entity represents physical ‘things and beings’ that is of interest to and take part in healthcare.

This can be a person, an organization, a device, materials, creatures, animals etc.

The Entity is colored green in HL7 models.

ROLE - YELLOW

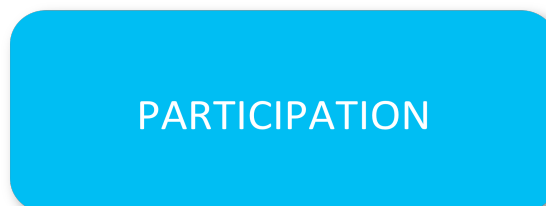


The role definition establishes how entities play as they participate in health care acts.

For example, the definition of a patient, an investigator, a nurse or a Chief Executive Office (CEO) is a classified as a role.

The Role class is colored in yellow.

PARTICIPATION - BLUE



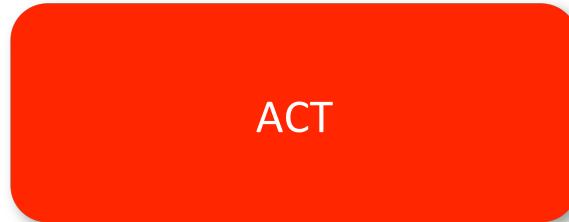
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The participation class expresses the context for an act in terms such as who performed it, for whom was it done, where was it done.

Examples are: Hospitalizer, Author, "Destination Object".

The participation class is blue colored.

ACT - RED

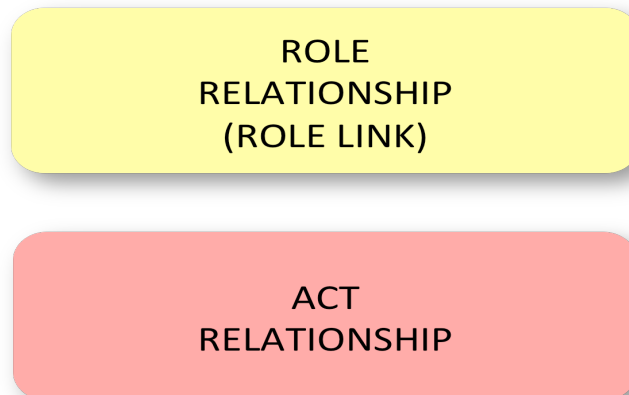


The act represents the action, which is executed and must be documented as health care is managed and provided.

Acts are – procedures, transport, episodes, financial activities, monitoring and observations.

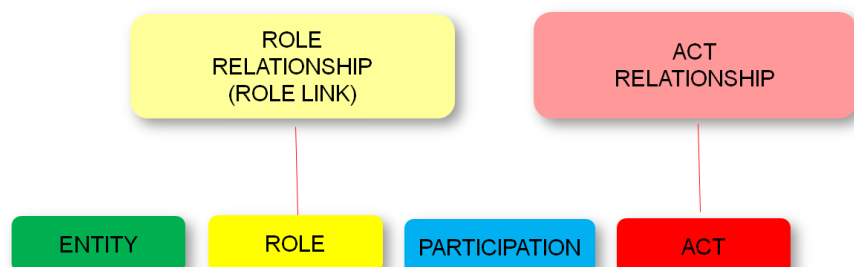
The act is red colored.

2 HELP CLASSES AND COLOR

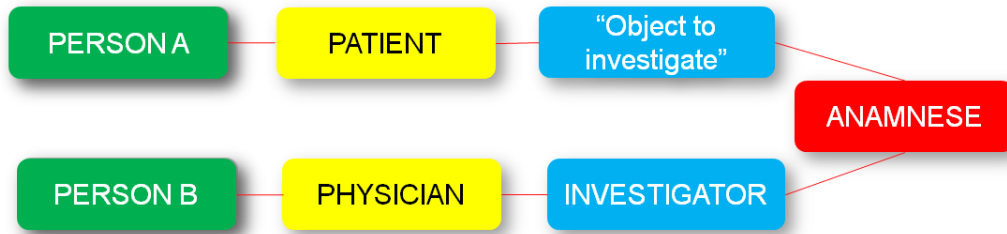


For relations links between roles the role relationship link is implemented. The role relationship link is colored in light yellow.

Also, for acts, which are related together, an act relationship link is part of the model and it's colored in light red.

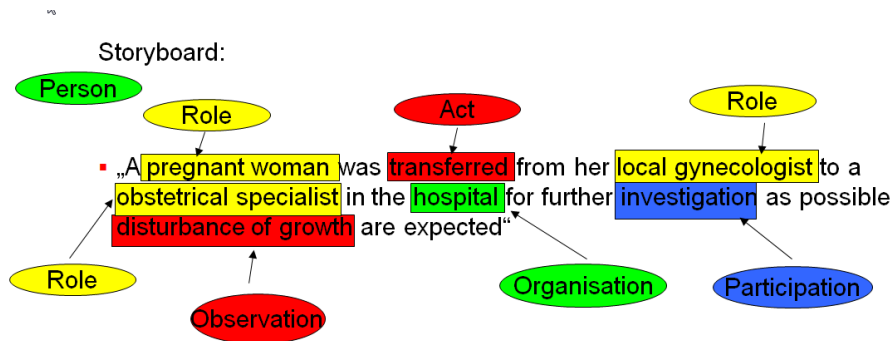


To complete this section, here is a first simple example that is self-explaining:

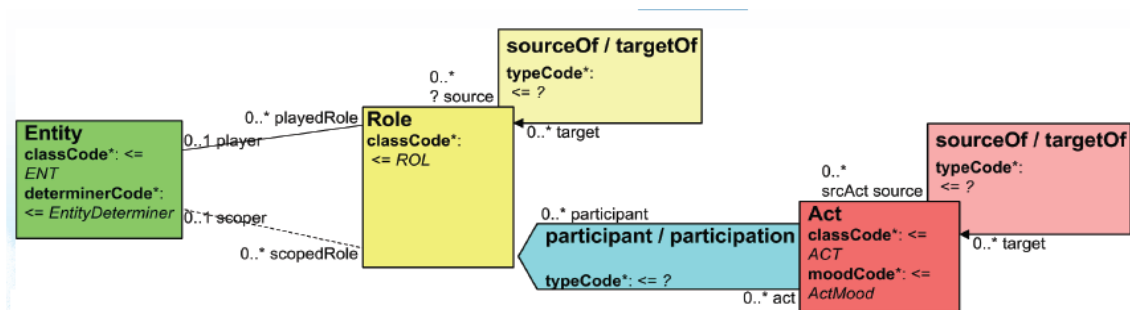


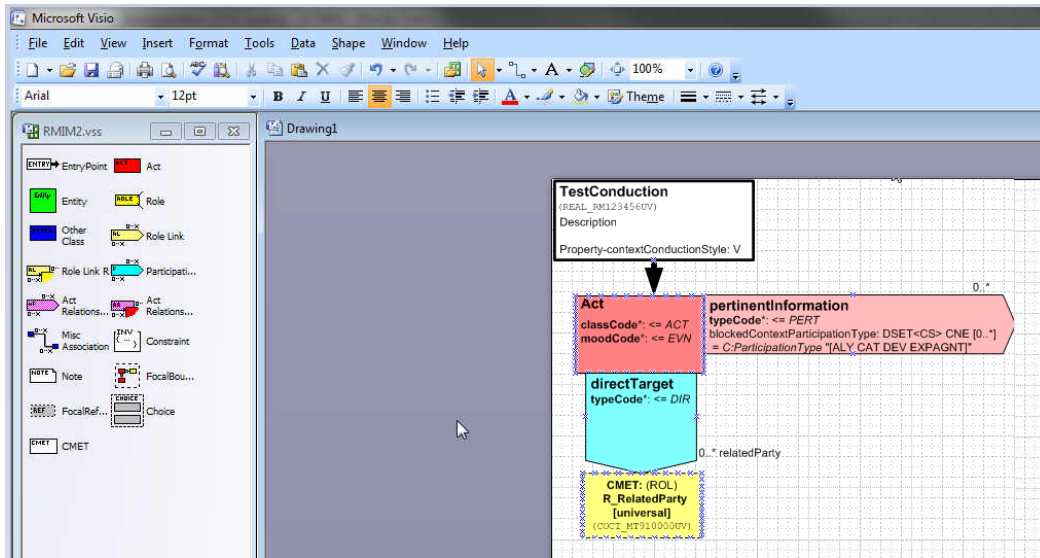
HOW ARE MODELS DEVELOPED?

To come to the model implementation, HL7 starts with the use of a storyboard mechanism, where the use case will be written down and all 'classes' will be determined. An example:

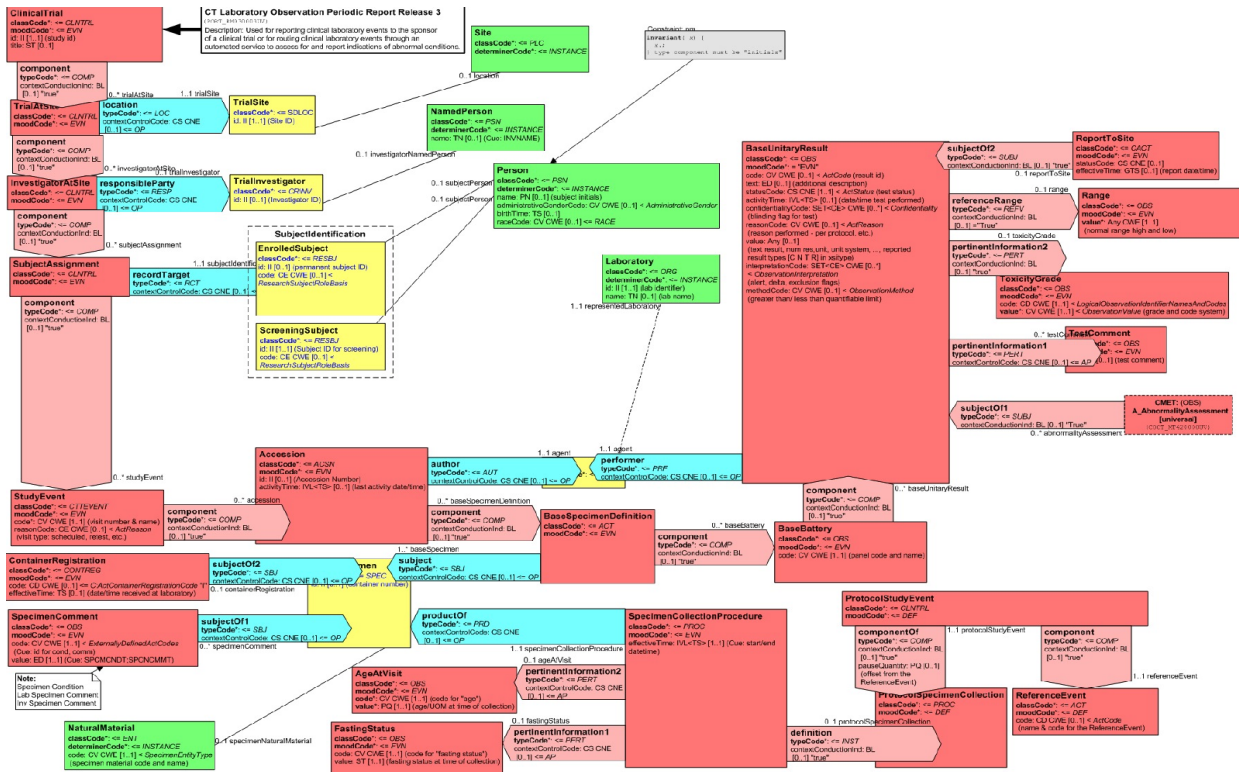


As a next step, using tools (MicroSoft Visio shapes/pencil and macros), this 'colored' storyboard will be transferred into the model:





At the end you get a full colored model, as an example you see the CDISC LAB model that has been moved into HL7 some time ago.



ATTRIBUTES AND CARDINALITY

Every class has attributes; the HL7 world calls them structural attributes. Examples are:

- typeCode (in Participation, ActRelationship and RoleLink)
 - o Represents a variety of concepts (different forms of participation / different kinds of relationships between acts)

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- typeCode is the attribute for this distinctions for each of these classes
- classCode (in Act, Entity, Role)
 - Represents the exact class or concept intended, whether or not that class is represented as a class in the RIM hierarchy
- moodCode (in Act) and determinerCode (in Entity)
 - An attribute that distinguishes whether the class represents an instance or a kind of Act or Entity. If the class is a specialization of Act then moodCode further delineates the instance as an occurrence of intent

In addition there is a cardinality given between the classes. It determines the associations between classes and 'how often they can be available'. A cardinality of "Class A: 1 – 0..* : Class B" says, that you can have one instance of class A which relates to zero up to unlimited instances of class B.

DIVING IN DEEPER INTO THE HL7 RIM

This presentation serves as an introduction into the HL7 RIM and provides a user friendly opportunity to quickly become familiar with the RIM. However, as soon you start diving deeper into something, the more complex things become.

It's the same for the HL7 RIM. Next important topics, which would come up, would be:

- Trigger and application role
- More status / transition status / state machines
- Hundreds of class attributes
- HL7 data types (DataValue = ANY)

CONCLUSION / SUMMARY

HL7 RIM is the 'metadata' model for HL7 model development. It contains 4 main classes with 2 helper classes, containing attributes. The classes are colored to make it easier to 'read' the models also for the domain experts.

HL7 design tools help to 'draw' these models according to written and 'classed' storyboards.

REFERENCES

Andreas Hinchley – Understanding Version 3 – A primer on the HL7 Version 3 Healthcare Interoperability Standard – Normative Edition, Alexander Mönch Publishing, Munich 2007, ISBN 3-933819-21-0

FDA PDUFA IV – IT Plan update March 2011 -

<http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM272334.pdf>

HL7 – www.hl7.org

CDISC – Clinical Data Interchange Standards Consortium – www.cdisc.org

CONTACT INFORMATION (HEADER 1)

Your comments and questions are valued and encouraged. Contact the author at:

Jörg Dillert
Oracle Deutschland B.V. & Co. KG
Schiffbauergasse 14
14467 Potsdam
Work Phone: +49-331 2007388
Email: Joerg.dillert@oracle.com
Web: www.oracle.com

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