

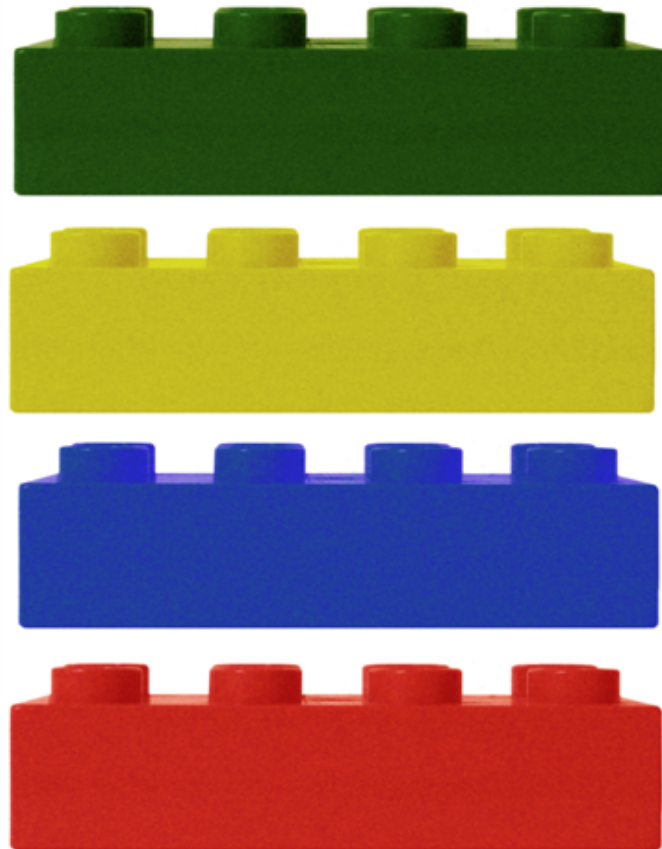
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HL7 RIM

An introduction for Non-technical Professionals

Jörg Dillert
Consulting Solution Director
Oracle Health Sciences



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Let's talk about

- CDISC, HL7, FDA and how it fits together
- Key concepts of HL7 V3 methodology
- HL7 Reference Information model

HL7



Why do we talk about HL7?

SDTM

Exchange Report

Exchange

Update

Ballot

Tools

→ **FDA Endorses SDTM**

At the end of May 2008, the FDA published the final version of the [PDUFA IV Information Technology Plan](#). This document contains explicit reference to multiple CDISC projects including the CDISC Content to HL7 Message Project.

In particular, the document states an anticipated publication date for the proposed rule for **Submission of Standardized Electronic Study Data from Clinical Studies Evaluating Human Drugs and Biologics** as being September 2008. Additionally it clearly states that SDTM will be the foundation for standardized clinical content. Further details are contained in [these extracts](#) from the PDUFA IV Information Technology Plan.



BRIDG Model
<http://www.bridgmodel.org>

Release 2.1 Readme

Biomedical Research Integrated Domain Group (BRIDG)

prepared by
BRIDG Technical Harmonization Committee (THC)

Becky Angeles (ScenPro/NCI)
 Julie Evans (CDISC/HL7 RCRIM)
 Smita Hastak (ScenPro/NCI/HL7 RCRIM)
 Jonathan (Jay) Levine (U.S. FDA)
 Charlie Mead (Booz Allen Hamilton/NCI/HL7 RCRIM)
 Saurin Mehta (Novartis/CDISC)
 Steven Sandberg (Mayo Clinic/NCI)
 Wendy Ver Hoef (ScenPro/NCI)

23 October 2008

forms)

- information about the product
- Contact Information

As of January 1, 2008 CDER only accepts electronic submissions in the eCTD format. To facilitate the transition to the CTD format FDA will start accept CTD submissions based on the RPS standard for a limited set of submissions. These submissions have been part of a paper submission with the electronic

SDTM version 3.1.1 submissions are accepted by FDA. A draft implementation guide for SDTM 3.1.2 is currently under review by CDISC and FDA. FDA and CDISC are in the process of forming a communications team that will ensure SDTM meets FDA's scientific requirements.

CDISC - HL7 Project - The FDA plans to transition to HL7 exchange messages for submission of all study data. This initiative is based on the outcomes of the CDISC Content to HL7 Message Exploratory Project. The objective of the Exploratory Project was to;

- Harmonize the SDTM into the BRIDG model (see below).
- To identify HL7 exchange message content for submission to a regulatory authority that addresses: a) study summary (clinical trial registry), b) eligibility criteria, c) trial design (including parts I and II: arms, elements visits, planned assessments, and planned intervention(s)), d) statistical analysis plan, e) collected data/study data tabulations and f) derived data/analysis datasets, all of which are currently defined by the CDISC standard.

CDISC Content to Message Project initiation was approved by the HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee 11/2007.

The FDA is proposing the development of four messages that map to content areas identified above.

Study Design
 Study Participation
 Subject Data
 Individual Case Safety Reporting (ICSR)

This process also includes the completion of the BRIDG Model

Message development is underway in HL7. Plan is to go to DSTU (draft standard for trial use) ballot at the end of 3rd Quarter, 2008 and to test the messages as part of the Janus phase 3 pilot (see Janus Initiative). Additional milestones:

3rd Quarter, 2008

- HL7 DSTU Ballot

2008 – 2009

- Testing

3rd Quarter, 2009

- HL7 Normative Ballot

2009-2012

- FDA accepts both CDISC-HL7 XML and SAS transport files

2013 and Beyond

- FDA accepts only CDISC-HL7 XML



PDUFA IV Information Technology Plan

Specific Activities associated with Standards Development:

- Interaction with standards development and standards maintenance organizations
- Exchange standards development
 - Data standards requirements gathering / use case development
 - Modeling requirements and use cases (e.g., modeling to HL7 Reference Information Model)
 - Testing model against requirements and use cases to include development of visualization tools (e.g., stylesheets, XForm) documentation and coordination assistance
 - Balloting (e.g., ballot preparation, presentation and reconciliation)
 - Accreditation
 - Conformance specifications (implementation guide)
- Terminology standards development
- Format standards development
- Standards maintenance (e.g. Unique Ingredient Identifier (UNII), NCI Enterprise Vocabulary Services, ongoing evaluation and updating)
- Training and implementation support
 - Support for training or other related IT development activities associated with standards adoption and implementation (e.g. data type specification, message instance examples or data standards harmonization)
 - Communication strategy and stakeholder engagement

Development, User Acceptance Testing, and Adoption

FDA first attempts to identify an existing standard that will meet the business need. standards that adhere to the principles described previously. If a standard is not already begins development activity. FDA identifies and works with a well recognized Standard Organization (SDO), when appropriate to develop and adopt a standard. Priority is consensus-based standards recognized by the American National Standards Institute (ANSI) such as the International Organization for Standardization (ISO), Health Level Seven (HL7) and National Council for Prescription Drug Programs (NCPDP).

For new health information exchange standards, the FDA works within HL7. The FDA also encourages other stakeholders, such as the healthcare community, Clinical Data Interchange Standards Consortium (CDISC), International Conference on Harmonization (ICH), other government agencies, and international regulatory

PDUFA IV IT Plan Update

March 2011

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Recent FDA announcement (September 2013)

2. Study Data Exchange Standards Currently Under Development

The following resources support ongoing FDA study data exchange standards research and development activities within HL7. These standards are currently not utilized for regulatory submissions of study data.

The purpose of the study data standards is to exchange data between researchers and FDA. The human and animal study data will be stored in the Janus data warehouse, a repository, which allows users to generate views for analysis with different end-user tools.

One of the important goals of FDA in the development and adoption of standards based on Health Level Seven (HL7) Reference Information Model (RIM) is to support meaningful information representation and exchange between systems in use by clinical researchers, FDA (Janus data warehouse) and health care providers (electronic health record systems).

Since 2007, FDA has collaborated with CDISC and other stakeholders within the HL7 Regulated Clinical Research Information Management (RCRIM) Workgroup on the development of study data exchange standards based on HL7 version 3. General RCRIM Workgroup information is available at <http://www.hl7.org/Special/committees/rcrim/index.cfm>.

Highlights on study data exchange standards development activities are available below.

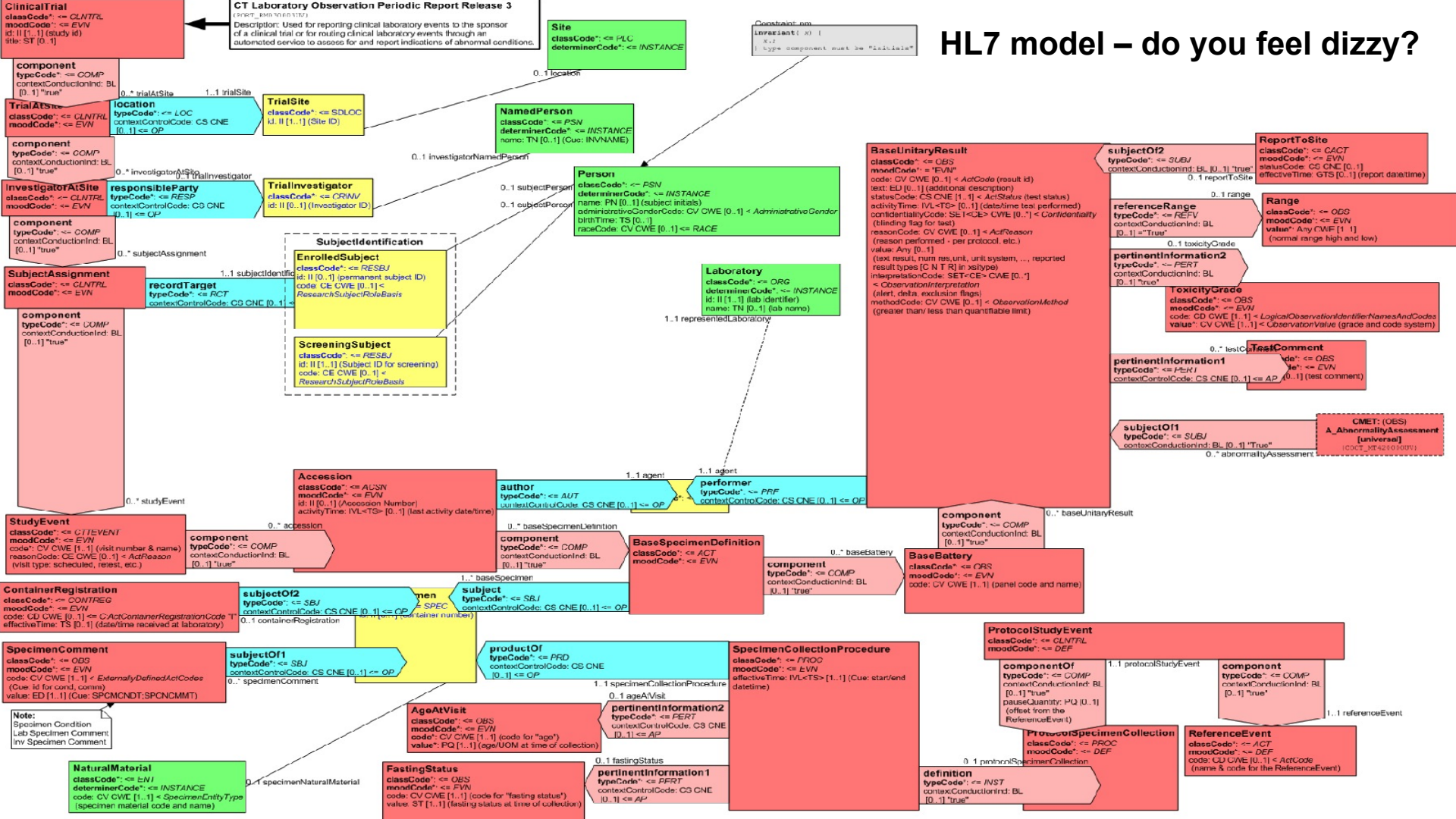
The Study Design, Study Participation and Subject Data exchange standards passed the HL7 September 2009 ballot cycle as Draft Standard for Trial Use (DSTU). The Individual Case Safety Report release 2 is being balloted as a joint ISO/HL7/CEN ballot

Source: <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>

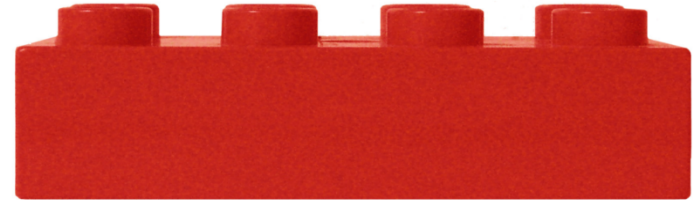
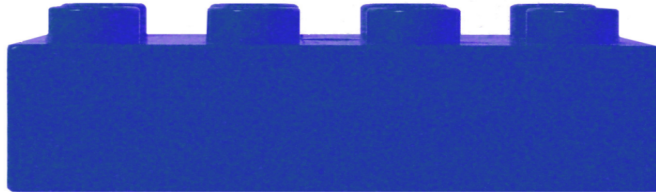
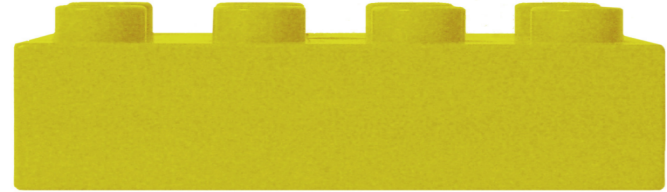
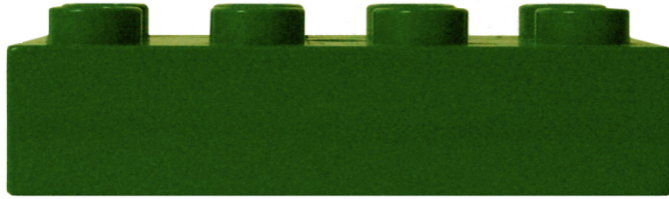
HL7 versions and models and abbreviations

- V2
- V3
 - Internationalization & localization
 - Key concepts
 - Unified Modeling Language (UML)
 - Reference Information Model (RIM)
 - Domain Message Information Model (D-MIM)
 - Refined Message InformationModel (R-MIM)
 - Hierarchical Message Description (HMD)
 - Message type

HL7 model – do you feel dizzy?



Nice toy or?



HL7 RIM stands for

- Reference Information Model
- HL7 – „Metadata model“ for all other models
- HL7 creates / defines and sends „messages“

Green - Entity

- Person A
- Person B
- Organisation
- Device
- Material
- Creature
- Animal

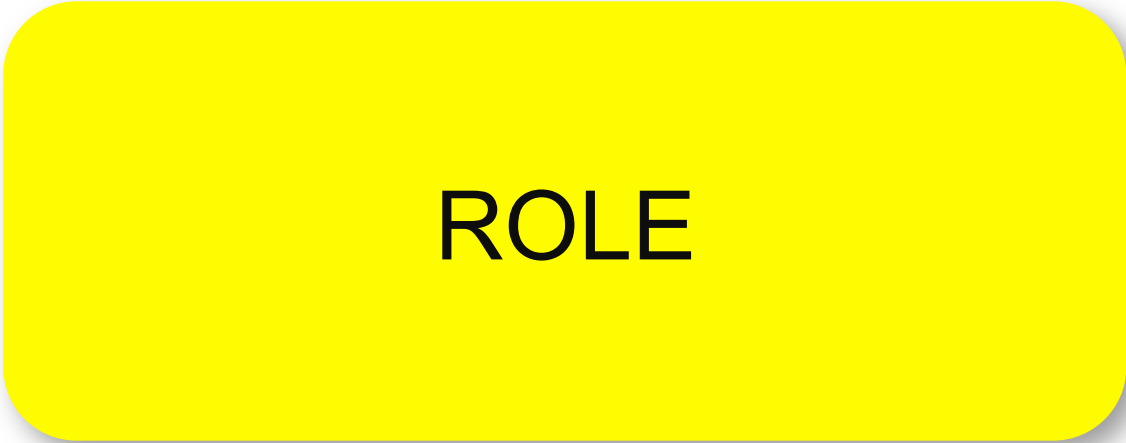


ENTITY

Represents the physical things and beings that are of interest to and take part in health care

Yellow - Role

- Patient
- Investigator
- Nurse
- CEO



ROLE

Establishes the roles that entities play as they participate in health care acts

Blue - Participation

- Hospitalizer
- Author
- „Destination“
Object



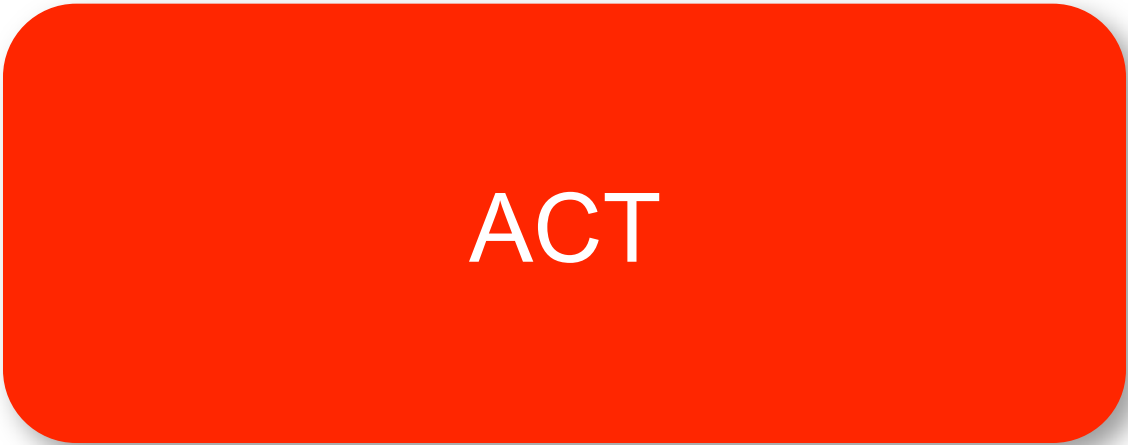
PARTICIPATION

Expresses the context for an act in terms such as who performed it, for whom it was done, where it was done, etc.

Red - Act

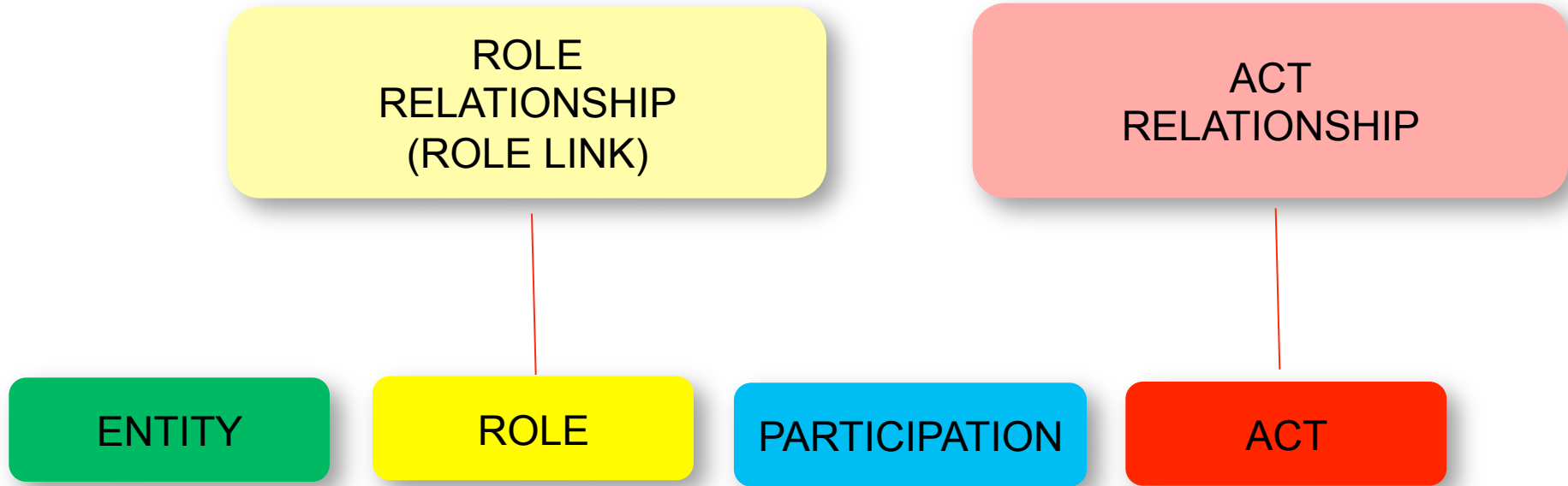
- Procedure
- Transport
- Episode
- Financial activities
- Monitoring
- Observation

Represents the actions that are executed and must be documented as health care is managed and provided

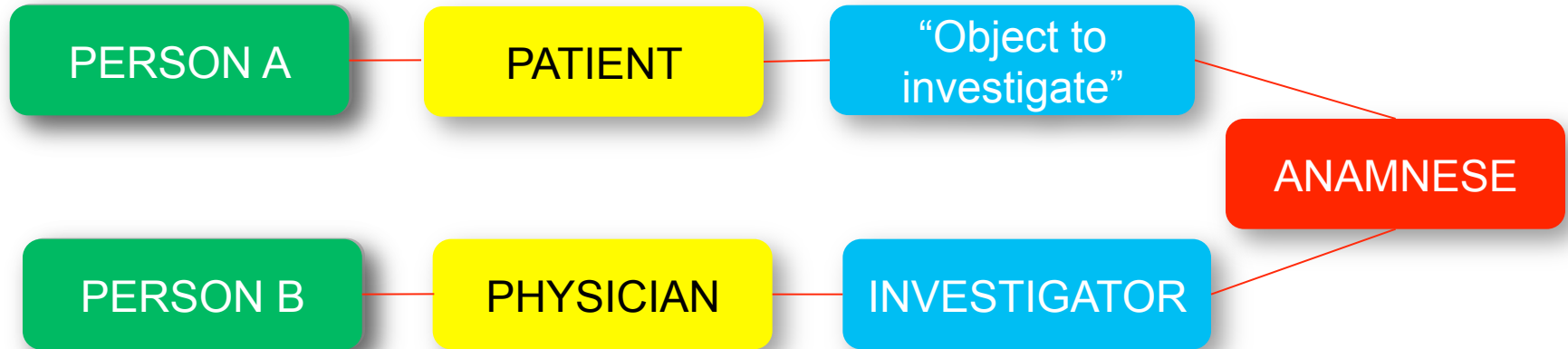


ACT

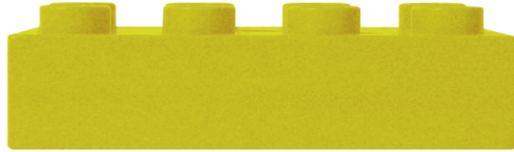
2 help „colors“



A first example



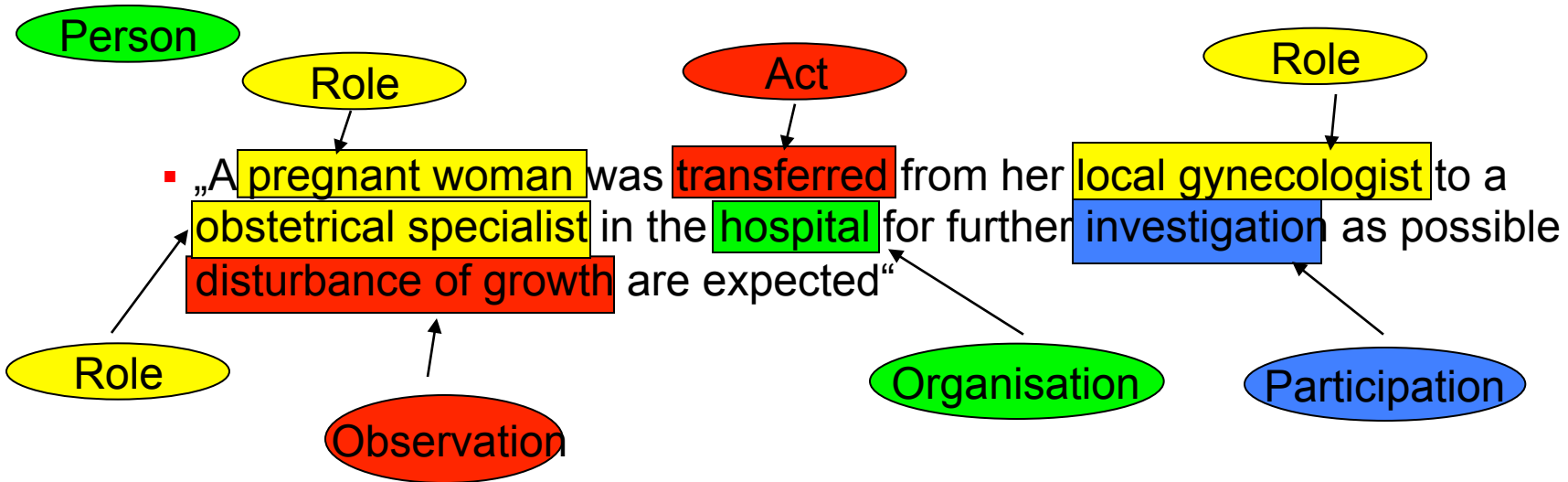
Play with them....



Mapping / Use Case: Form Mapping to Message

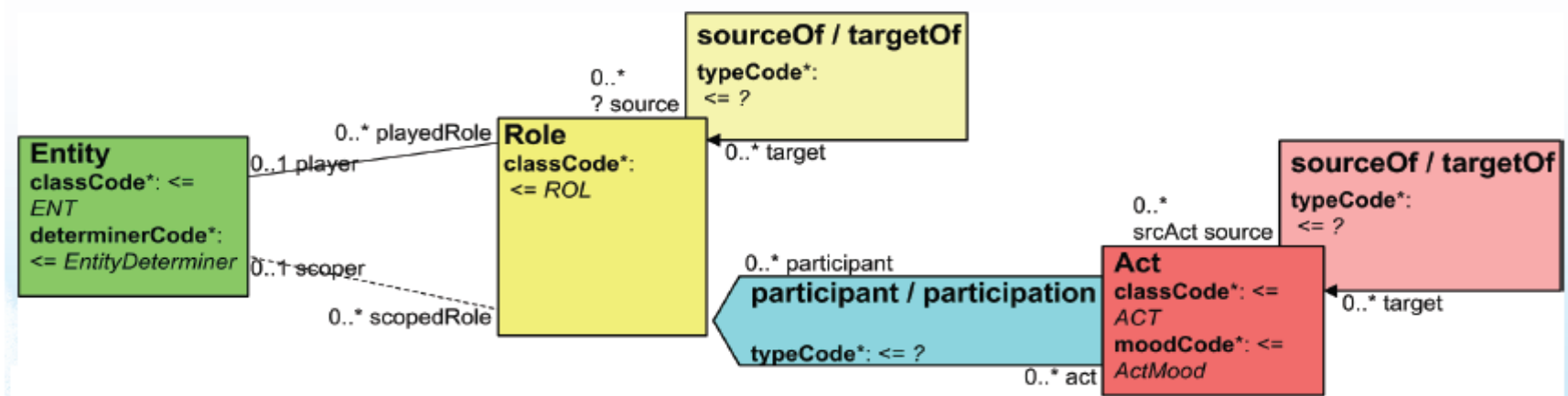
- Domain experts describe their communication scenario / message:

Storyboard:

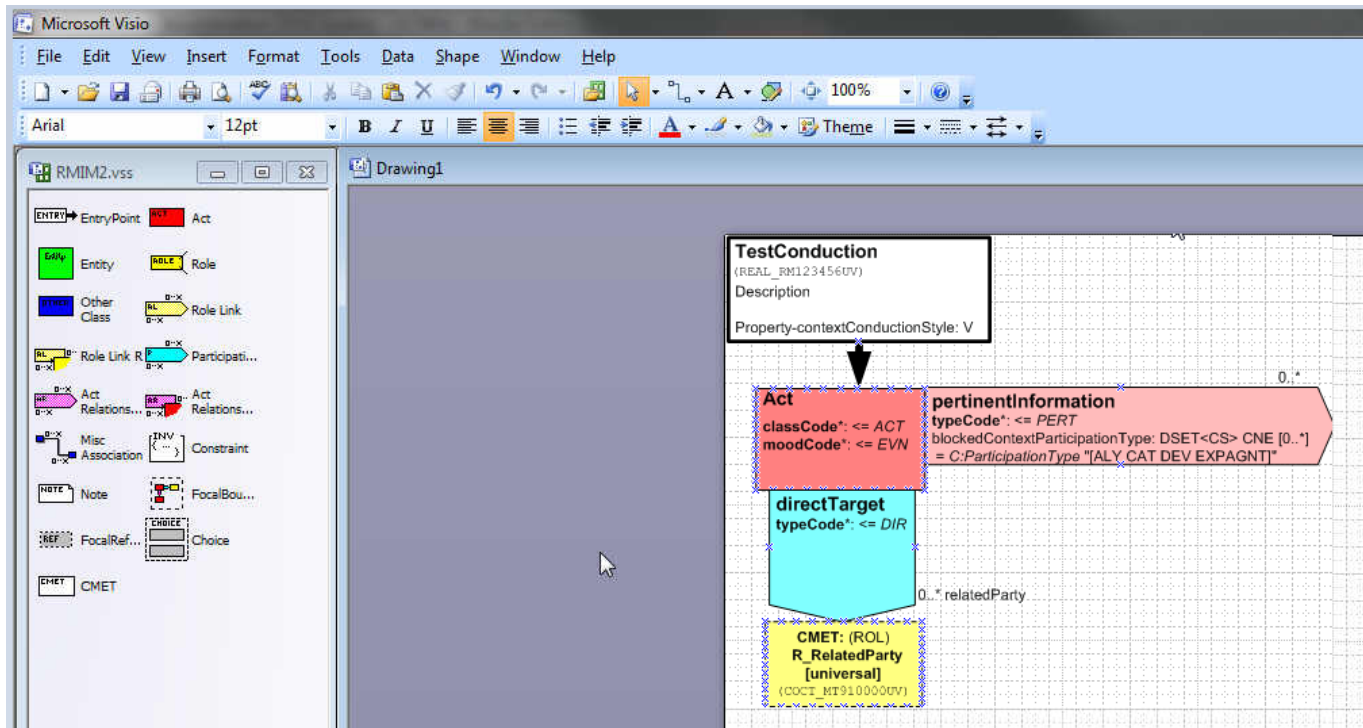


Modelling with Tools

- good way to explain the ‚things‘ – even understandable for domain experts



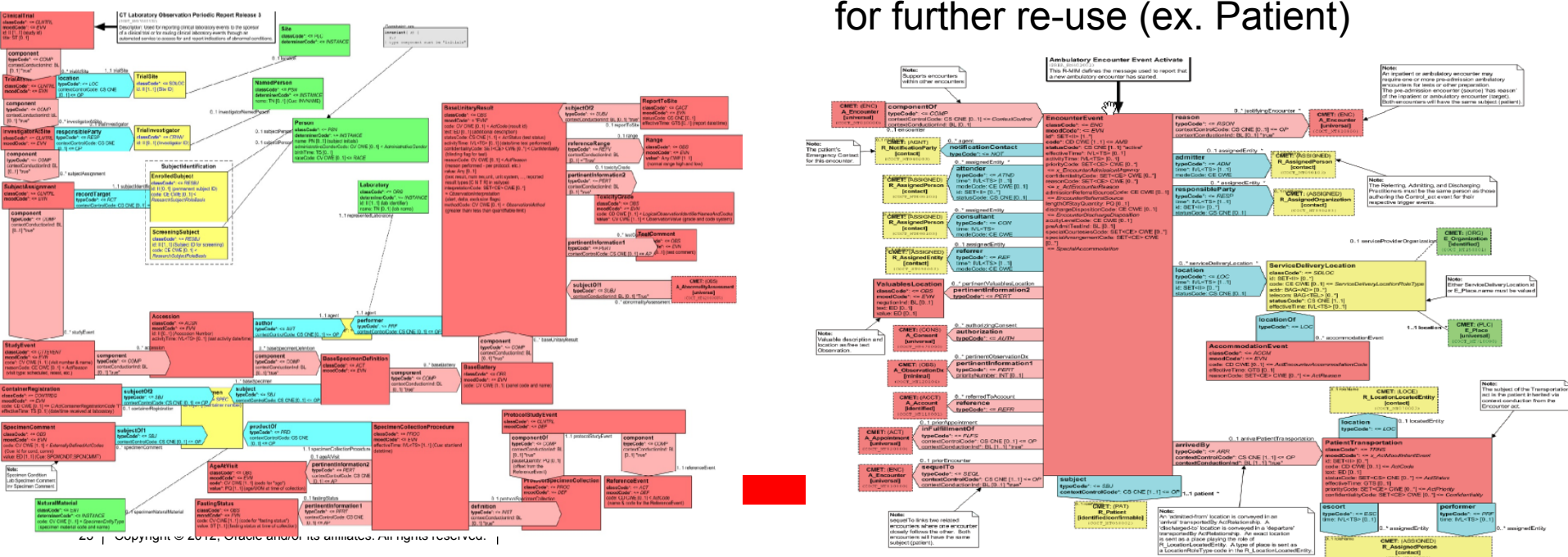
Design the model



D-MIM vs. R-MIM

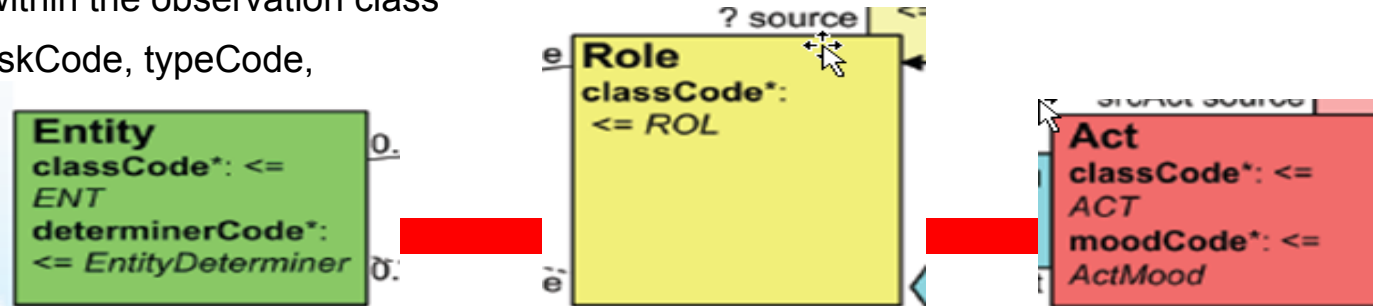
- D=Domain

- R=Refined
- Special subset/categories of interaction
- And further, special form (CMET-Common Message Element Types) for further re-use (ex. Patient)



Attributes and Cardinality Codes in Act, Entity and Role

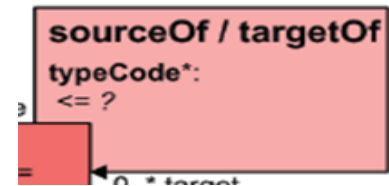
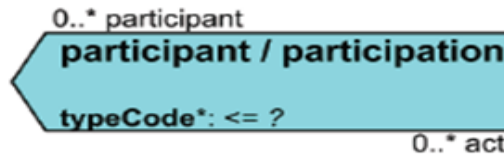
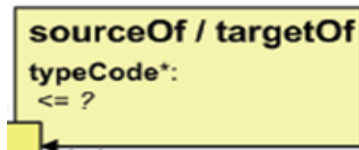
- ClassCode (in Act, Entity, Role)
 - Represents the exact class or concept intended, whether or not that class is represented as a class in the RIM hierarchy
- MoodCode (in Act) and DeterminerCode (in Entity)
 - An attribute that distinguishes whether the class represents an instance or a kind of Act or Entity. If the class is a specialization of Act then moodCode further delineates the instance as an occurrence of intent
- Code (in Act, Entity, Role)
 - Provides further classification within a particular classCode value such as a particular type of observation within the observation class
 - Examples: taskCode, typeCode,



Attributes and Cardinality (2)

Codes in Participation, ActRelationship and RoleLink

- typeCode (in Participation, ActRelationship and RoleLink)
 - Represents a variety of concepts (different forms of participation / different kinds of relationships between acts)
 - typeCode is the attribute for this distinctions for each of these classes.



Daily example for mood code

- Proposal (PRP)
 - „Why you are not clean up your room?“
- Order (ORD)
 - „Clean your room!“
- Intent (INT)
 - „I swear, I will clean my room“
- Event (EVN)
 - „My room is clean!“
- Definition (DEF)
 - „Clean the room means: toys on the right place, bed is ok, always fun 😊
- Event Criterion (EVN.CRT)
 - „You want an ice cream, clean up your room.“

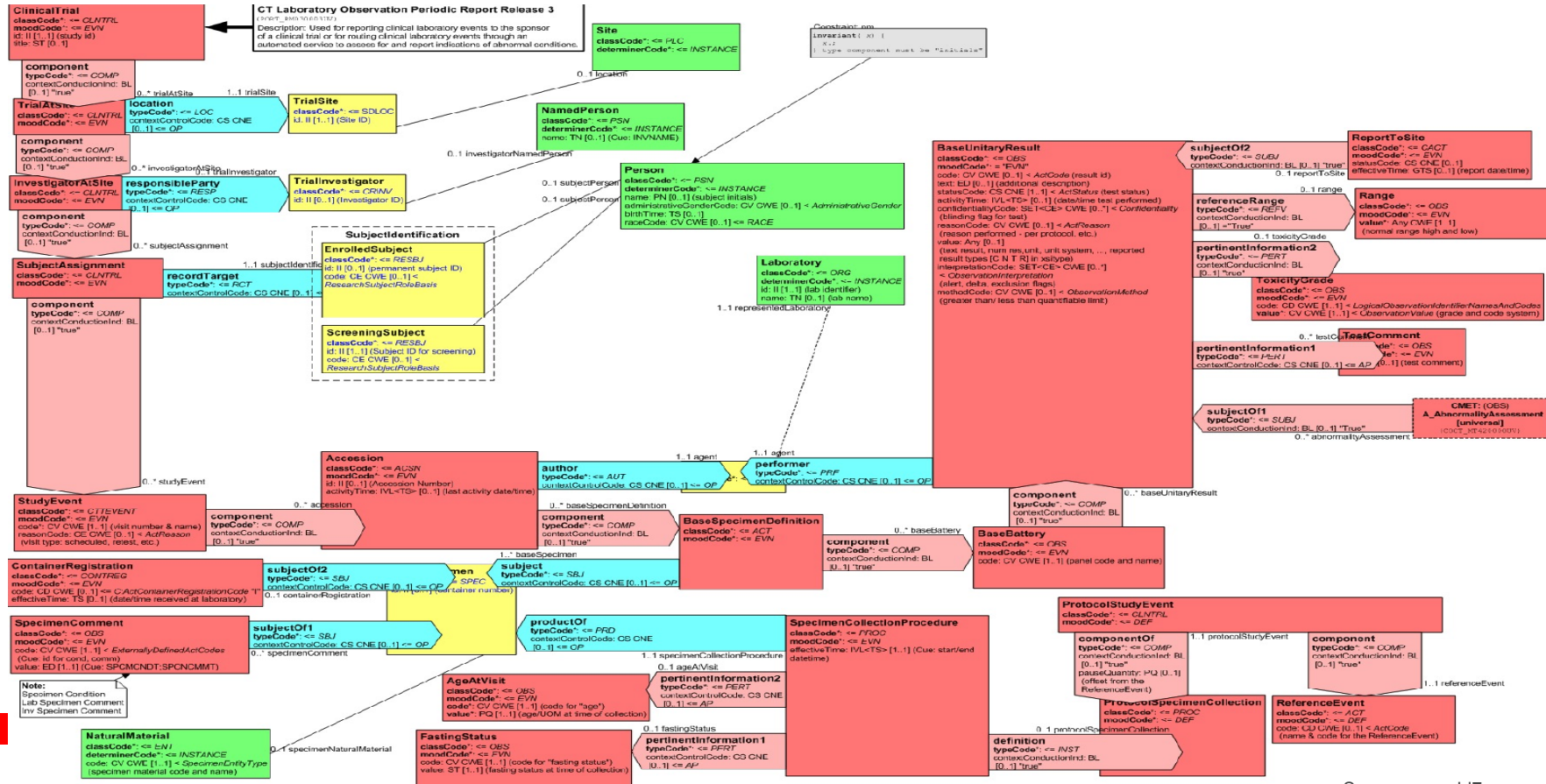
In Clinical:

- DEF - Definition of an X-Ray
- EVN - Visit executed
- APT – Visit planned
-

There is much more

- ... but would extend „an introduction“
- Things like:
 - Trigger and application role
 - More status codes / transition statuses / state machines
 - „Hundreds“ of class attributes
 - Ex: Financial transaction
 - creditExchangeRateQuantity
 - Person
 - maritalStatus
 - raceCode
 - HL7 Data types
 - DataValue = ANY
 - Boolean = BL

HL7 Lab (CDISC) model = „One message“



Content Last Edited: 2008-11-11T15:42:01

4.1 Storyboards

[Go To Top](#)

▼ Storyboards (Sorted by Title)

- CT Laboratory Test Result Abnormality Assessment(PORT_ST030002UV)
- Periodic Reporting of CT Laboratory Results(PORT_ST030001UV)

▼ Storyboards (Sorted by Structured Sort Name)

- Ctlabrthree_01(PORT_ST030001UV)
- Ctlabrthree Test Result Abnormality Assessment(PORT_ST030002UV)

▼ Storyboards (Sorted by Display Order)

- CT Laboratory Test Result Abnormality Assessment(PORT_ST030002UV)
- Periodic Reporting of CT Laboratory Results(PORT_ST030001UV)

4.1 Storyboards

4.2 Application Roles

4.3 Trigger Events

4.4 Refined Message Information Models

4.5 Hierarchical Message Descriptions

4.6 Interactions

4.2 Application Roles

▼ Application Roles (Sorted by Artifact Code)

- CTLaboratory Observation Event Global Informer (PORT_AR030001UV01)
- ClinicalTrial Observation Order Global Placer (PORT_AR030002UV)
- Abnormality Assessment Observation Fulfiller (PORT_AR030003UV)
- ClinicalTrial Observation Event Global Tracker (PORT_AR030004UV)

▼ Application Roles (Sorted by Structured Sort Name)

- Ctlabrthree Event Fulfiller (PORT_AR030003UV)
- Ctlabrthree Event Informer (PORT_AR030001UV01)
- Ctlabrthree Event Tracker (PORT_AR030004UV)
- Ctlabrthree Order Placer (PORT_AR030002UV)

▼ Application Roles (Sorted by Display Order)

- ClinicalTrial Observation Order Global Placer(PORT_AR030002UV)
- Abnormality Assessment Observation Fulfiller(PORT_AR030003UV)
- CTLaboratory Observation Event Global Informer(PORT_AR030001UV01)
- ClinicalTrial Observation Event Global Tracker(PORT_AR030004UV)

4.3 Trigger Events

▼ Trigger Events (Sorted by Title)

- Agreed Transmission Criterion Attained - CT(PORT_TE010001UV01)

▼ Trigger Events (Sorted by Structured Sort Name)

- Ctlabrthree Event Agreed Transmission Criterion Met(PORT_TE010001UV01)

▼ Trigger Events (Sorted by Display Order)

- Agreed Transmission Criterion Attained - CT(PORT_TE010001UV01)

4.4 Refined Message Information Models

▼ Refined Message Information Models (Sorted by Title)

- CTLaboratory Observation(PORT_RM030002UV)
- CTLaboratory Observation Periodic Report(PORT_RM030003UV)

▼ Refined Message Information Models (Sorted by Structured Sort Name)

- Ctlabrthree(PORT_RM030002UV)
- Ctlabrthree Event Observation Periodic Report(PORT_RM030003UV)

▼ Refined Message Information Models (Sorted by Display Order)

- CTLaboratory Observation Periodic Report(PORT_RM030003UV)
- CTLaboratory Observation(PORT_RM030002UV)

4.5 Hierarchical Message Descriptions

▼ Hierarchical Message Descriptions (Sorted by Title)

- CTLaboratory Observation(PORT_HD030002UV)
- CTLaboratory Observation Periodic Report(PORT_HD030003UV)

▼ Hierarchical Message Descriptions (Sorted by Structured Sort Name)

- Ctlabrthree(PORT_HD030002UV)
- Ctlabrthree Event Observation Periodic Report(PORT_HD030003UV)

▼ Hierarchical Message Descriptions (Sorted by Display Order)

- CTLaboratory Observation Periodic Report(PORT_HD030003UV)
- CTLaboratory Observation(PORT_HD030002UV)

Source: www.hl7.org

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4.6.1 CTLab Test Result Abnormality Assessment Request (PORT_IN030002UV)

Description

Structured Name:  Ctlabrthree Event Test Result Abnormality Assessment Request

This interaction supports communication of clinical trial laboratory test results to an assessment service for evaluation. The interaction is initiated by the central laboratory responsible for the laboratory data, to communicate clinical trial laboratory test results to an assessment service for evaluation. The interaction is used by the central laboratory responsible for the laboratory data, to communicate clinical trial laboratory test results to an assessment service for evaluation.

Trigger Event	Agreed Transmission Criterion Attained - CT	PORT_TE010001UV01
Transmission Wrapper	Send Message Payload	MCCI_MT000100UV01
Control Act Wrapper	Trigger Event Control Act	MCAI_MT700201UV01
Message Type	CT Laboratory Observation Periodic Report	PORT_MT030003UV

Receiver Responsibilities

Reason	Trigger Event	Interaction
Initiate the abnormality assessment response, in order to transmit the preliminary assessment outcome data.	PORT_TE010001UV01	PORT_IN030002UV

Sending and Receiving Roles

Sender	ClinicalTrial Observation Order Global Placer	PORT_AR030002UV
Receiver	Abnormality Assessment Observation Fulfiller	PORT_AR030003UV

4.6.2 CTLaboratory Periodic Report to Sponsor/Agent (PORT_IN030001UV)

Description

Structured Name:  Ctlabrthree Event Periodic Report To Sponsor/agent

This interaction is used by the central laboratory responsible for the laboratory data, to communicate clinical trial laboratory test results to an assessment service for evaluation.

Trigger Event	Agreed Transmission Criterion Attained - CT	PORT_TE010001UV01
Transmission Wrapper	Send Message Payload	MCCI_MT000100UV01
Control Act Wrapper	Trigger Event Control Act	MCAI_MT700201UV01
Message Type	CT Laboratory Observation Periodic Report	PORT_MT030003UV

Sending and Receiving Roles

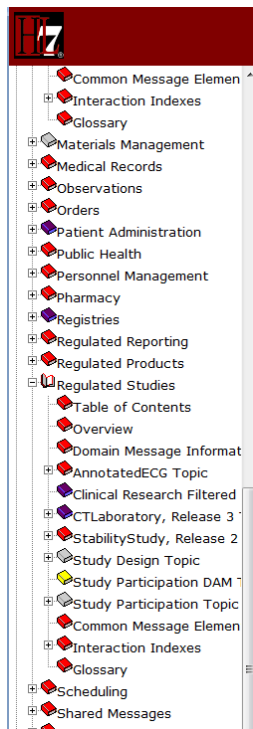
Sender	CTLaboratory Observation Event Global Informer	PORT_AR030001UV01
Receiver	ClinicalTrial Observation Event Global Tracker	PORT_AR030004UV

Source: www.hl7.org

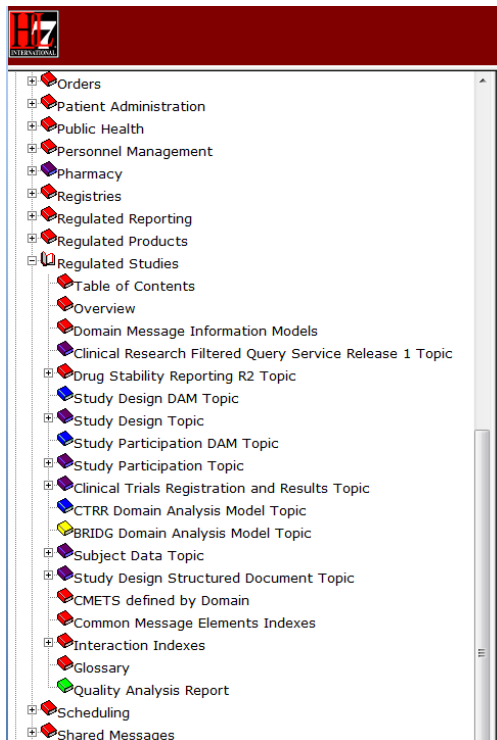
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Ballot sites: example CDISC lab model

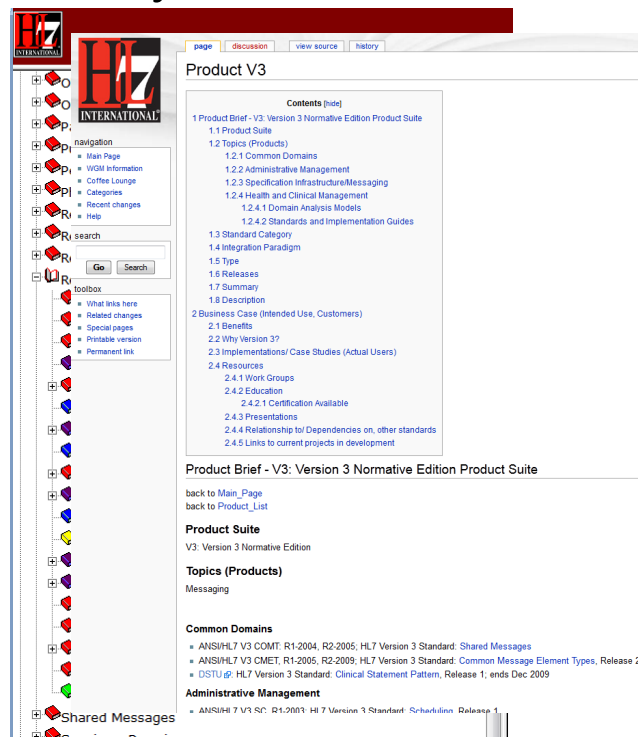
2009



2011



today



Source: www.hl7.org

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Hardware and Software

The Oracle logo, consisting of the word "ORACLE" in white, uppercase, sans-serif font, centered within a solid red rectangular bar.

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