Università degli Studi di Trieste

Corso di Laurea Magistrale in
INGEGNERIA CLINICA

HEALTH INFORMATICS STANDARD

Corso di Informatica Medica

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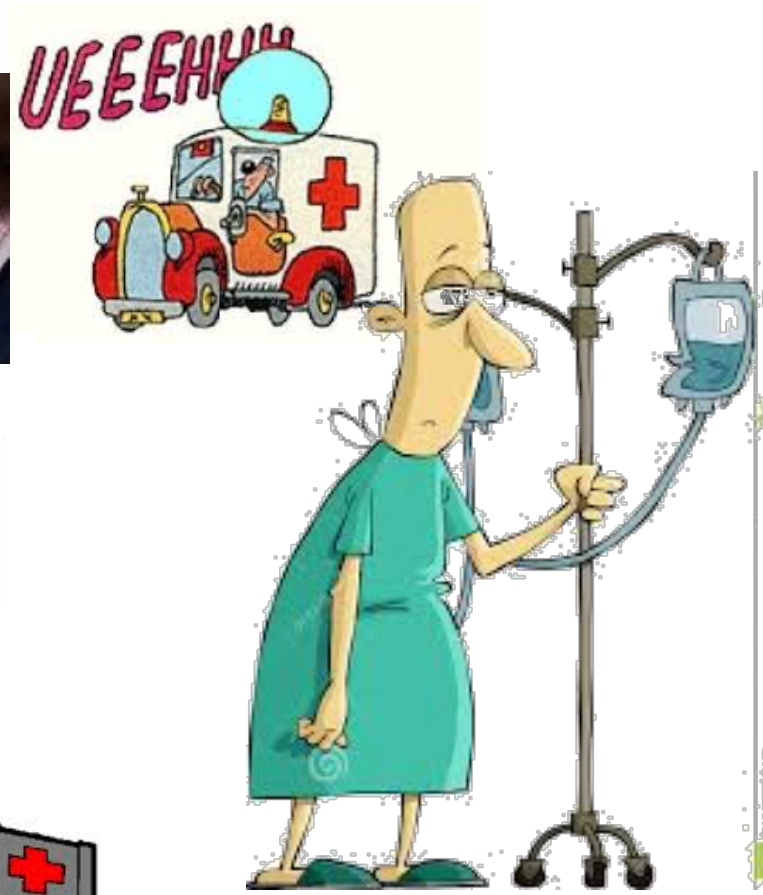
The healthcare heterogeneous scenario



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Interoperability

Ability of different systems to work cooperatively allowing different users to share information and resources

Why standards?

INTEROPERABILITY TYPE	HOW TO ADDRESS IT
Technological	Technological Standards
Structural	Communication Standards
Semantic	Terminologies and ontologies
Organizational	Processi
Governance	Frameworks and agreements
Legal	International legislation

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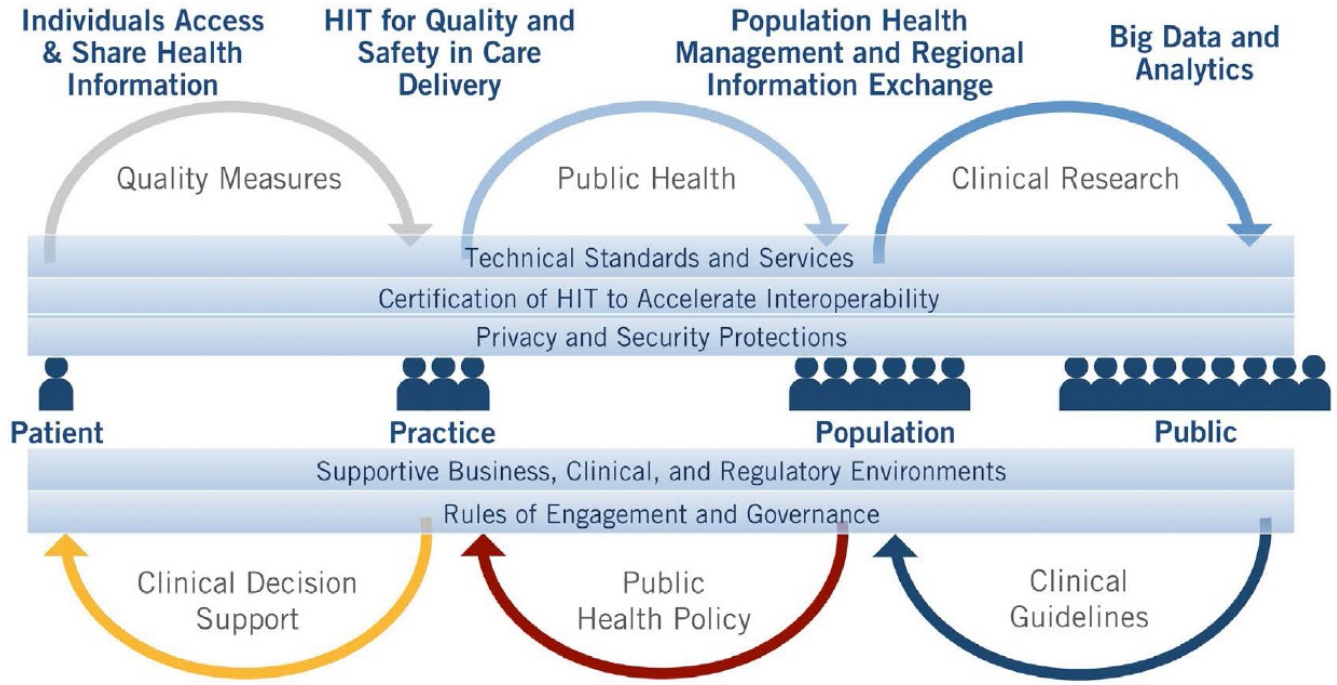
Health Information Exchange

According to healthit.gov, the official US site for Health IT information:

"Electronic health information exchange (HIE) allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care"

HIE =



From: "Connecting Health and Care for the Nation: A Ten Year Vision to Achieve Interoperable Health IT Infrastructure" – ONC 2014

HIE expected scenario

- Exchange data among providers
- Provide secure access to healthcare documents for patients
- **Based on interoperability (technology/standards and semantic/archetypes-terminologies)**

Standards: definition and scopes

•Set of rules and definitions that specify how to carry out a process or produce a product

- 1987 Technical report from the International Standards Organization → "Any **meaningful exchange of utterances** depends upon the prior existence of an **agreed** upon set of **semantic and syntactic rules**"
- Standards →
  - created and used to **make things or processes work** more easily and economically (sometimes, to work at all)
  - permit two or more disassociated people/parts to **work** in some **cooperative** way

Computers and standards

- The first computers were built without standards

- Hardware and software standards were quicly developed for humans who need a more readable language →

  - standard character sets (ASCII, EBCDIC)
  - first standard computer language (COBOL)
  - hardware components depend on standards for exchanging information

The standards development process: methods

Ad hoc method

- A group of interested people and organizations agree on a standard specification.
- These specifications are informal and are accepted as standards through mutual agreement of the participating groups.
- Example: DICOM standard for medical imaging (American College of Radiology/National Electrical Manufacturers Association, ACR/NEMA)

De facto method

- A single vendor controls a large enough portion of the market to make its product the market standard.
- Example: Microsoft Windows.

Government-mandate method

- A government agency creates a standard and legislates its use.
- Example is HCFA's UB92 insurance-claim form.

Consensus method

- A group of volunteers representing interested parties work in an open process to create a standard.
- Example: Health Level 7 (HL7) standard for clinical-data interchange.

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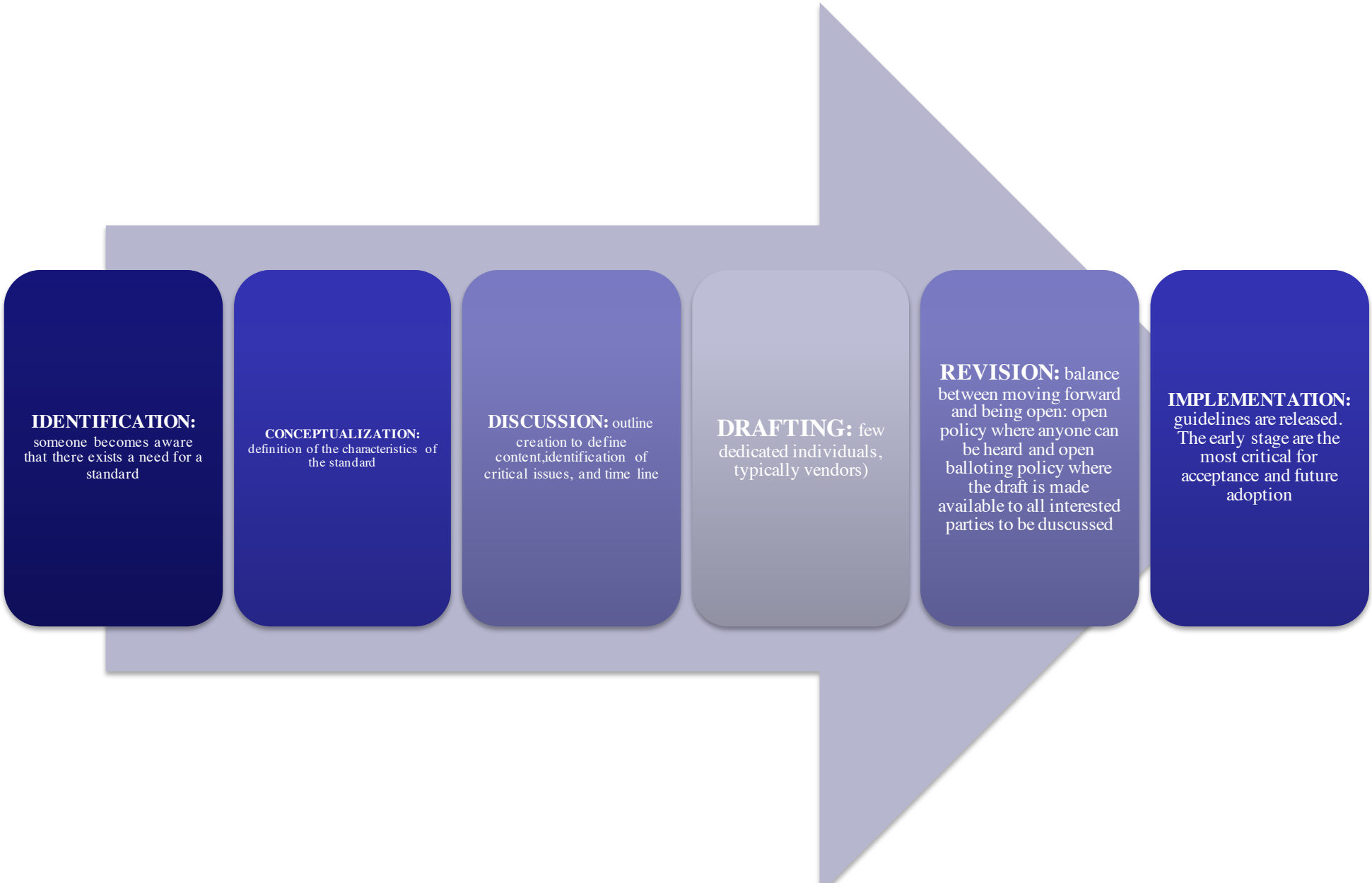
The development process



Conformance and Certification

CONFORMANCE

- Compliance with the standard
- Specific agreements among users of the standard who affirm specific rules will be followed.
- The conformance document identifies specifically what rules are followed in the process/system implementaion

CERTIFICATION

- A neutral body certifies that a vendor's product in fact does comply and conform with the standard.
- There is a verification stage that provides a "certificate"

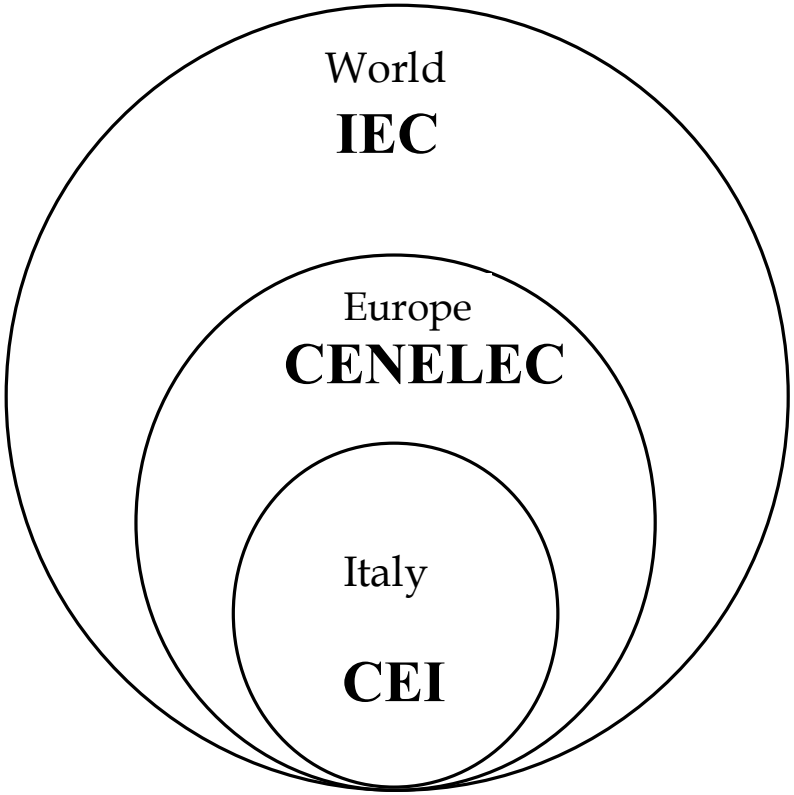
Standards characteristics

- The standard definition process ensures that:

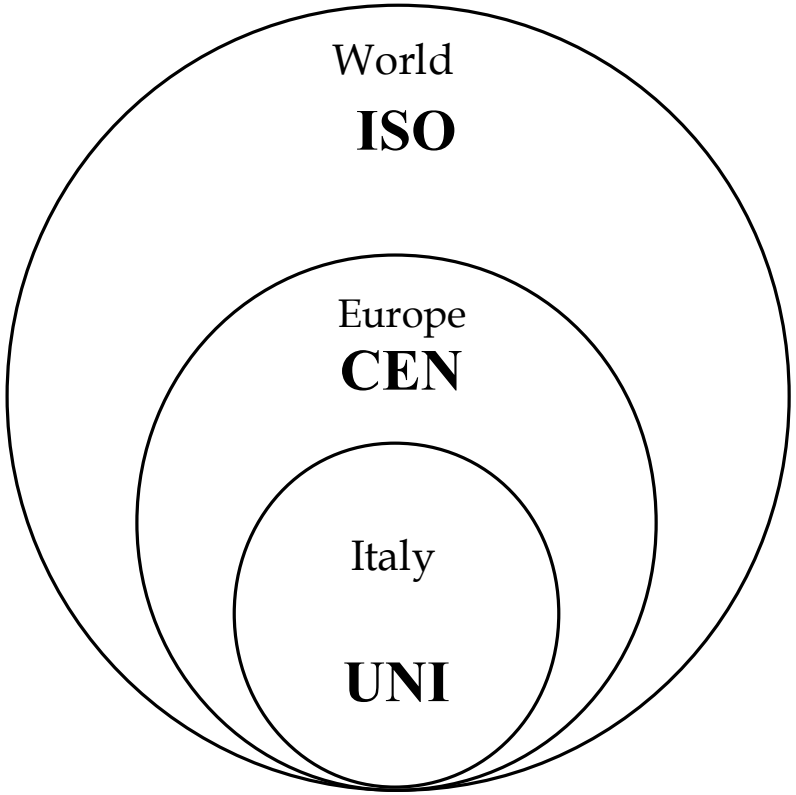
- AGREEMENT → Standards are created upon agreement because there was a consensus among who participated to the working group.
- DEMOCRACY → all the interested stakeholders can participate to the working groups and make observations and suggestions
- TRANSPARENCY → standardization bodies make the process and the diffreent steps avaiable to the poublic who is interested
- VOLUNTARY→ Norms atre a reference that the interested stakeholders voluntary adopt.

Enti di normazione: scenario interna

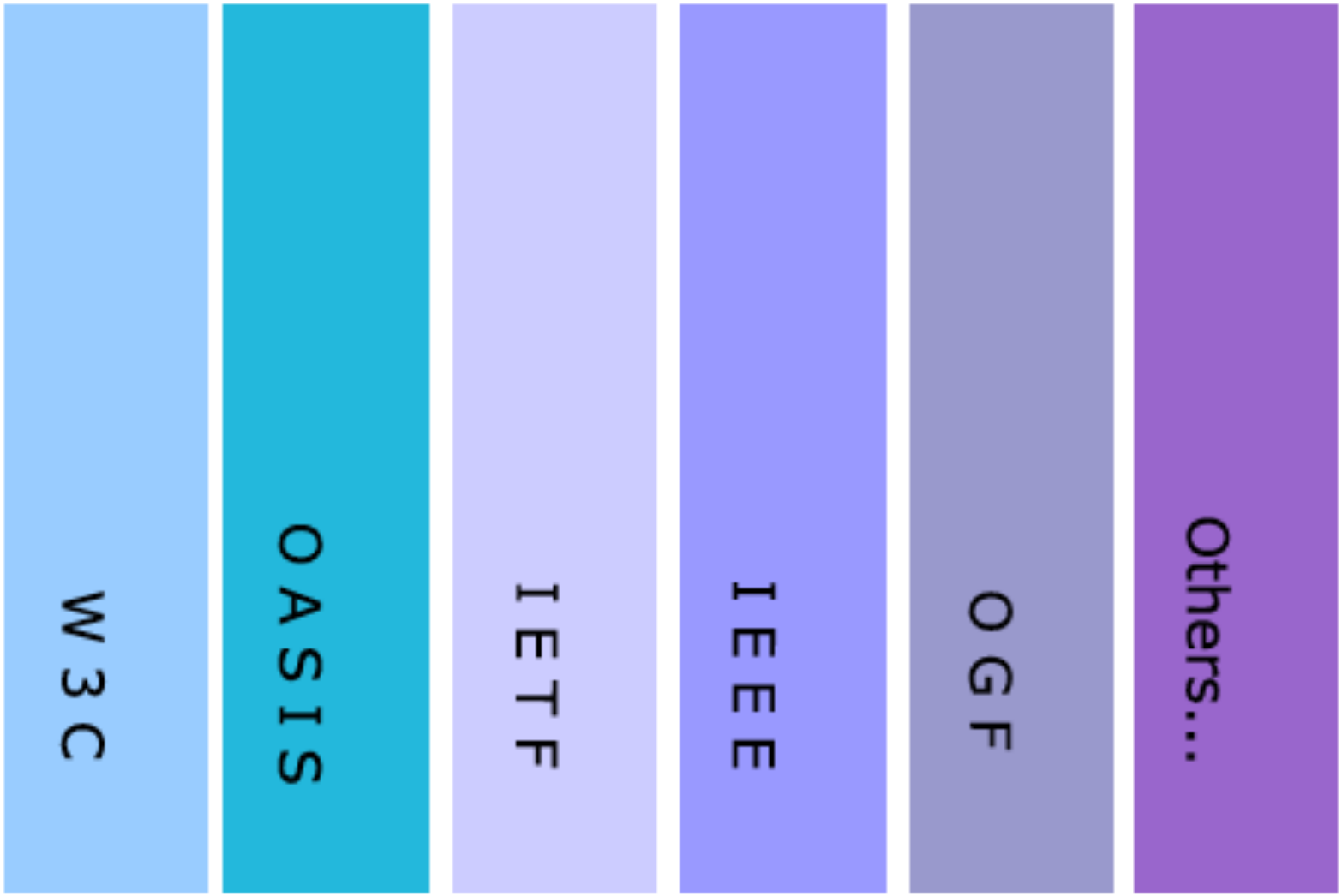
ELECTRICAL AREA



OTHER AREAS



Standardization bodies for ICT



Standardization bodies for Medical Informatics

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INTERNAZIONAL LEVEL

- **CDISC** - Clinical Data Interchange Standards Consortium
- **CEN TC 251** – Health Informatics
- **GS-1** - Supply chain standards system
- **HL7** – Health level 7
- **IHTSDO** - Not-for-profit association that owns and maintains SNOMED CT
- **ISO TC215** – Health Informatics

NATIONAL LEVEL

"**UNINFO** è una libera Associazione a carattere tecnico-scientifico e divulgativo senza fine di lucro (diretto o indiretto) che si prefigge di promuovere, realizzare e diffondere la normazione tecnica nel settore delle tecnologie dell'informazione e delle comunicazioni (in breve ICT) e delle loro applicazioni, sia a livello nazionale che europeo ed internazionale."

HIPAA: a first law on standard adoption in medical informatics

- 1996 → Health Insurance Portability and Accountability Act (HIPAA)

- Signed into law → HIPAA requires that the Secretary of Health and Human Services (HHS) adopt standards for the electronic transmission of specific administrative transactions.

- These standards will apply to health plans, health-care clearinghouses, and health-care providers who transmit any health information in electronic form;

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Health Level 7 (HL7)

Health Level Seven International

www.hl7.org

Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a **comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information** that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare.

What is HL7

Health Level Seven (HL7)

- An international standard development organization established more than 20 years ago
- Enables interoperability of healthcare information
- Creates standards for the exchange, management, and integration of electronic healthcare information
- Develops specifications, e.g., a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data

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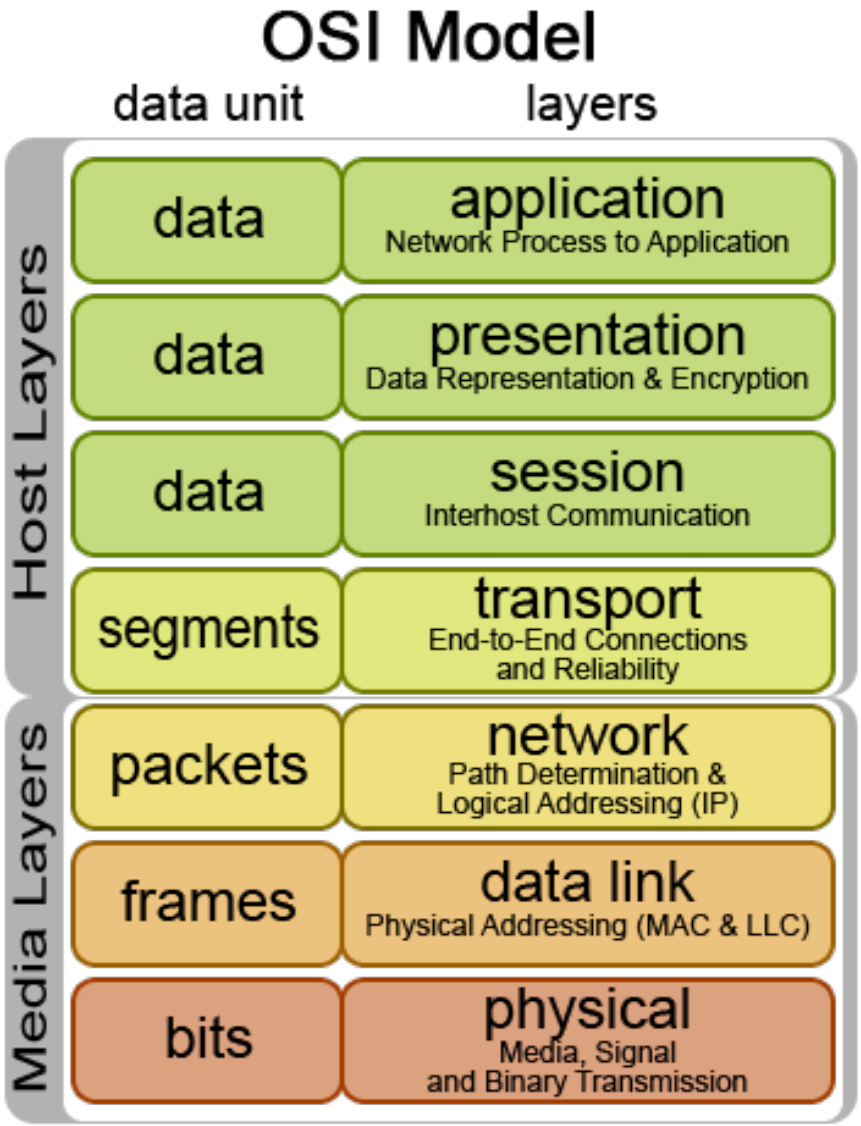
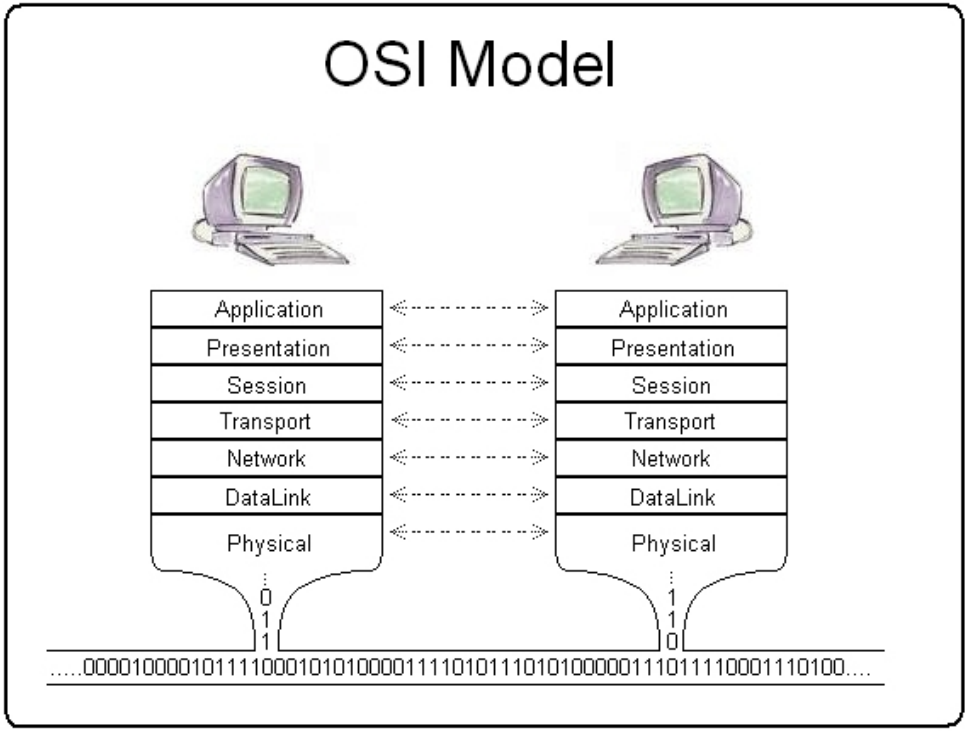
HL7: meaning





"Level 7" refers to the ISO-OSI application level (Open System Interconnection)

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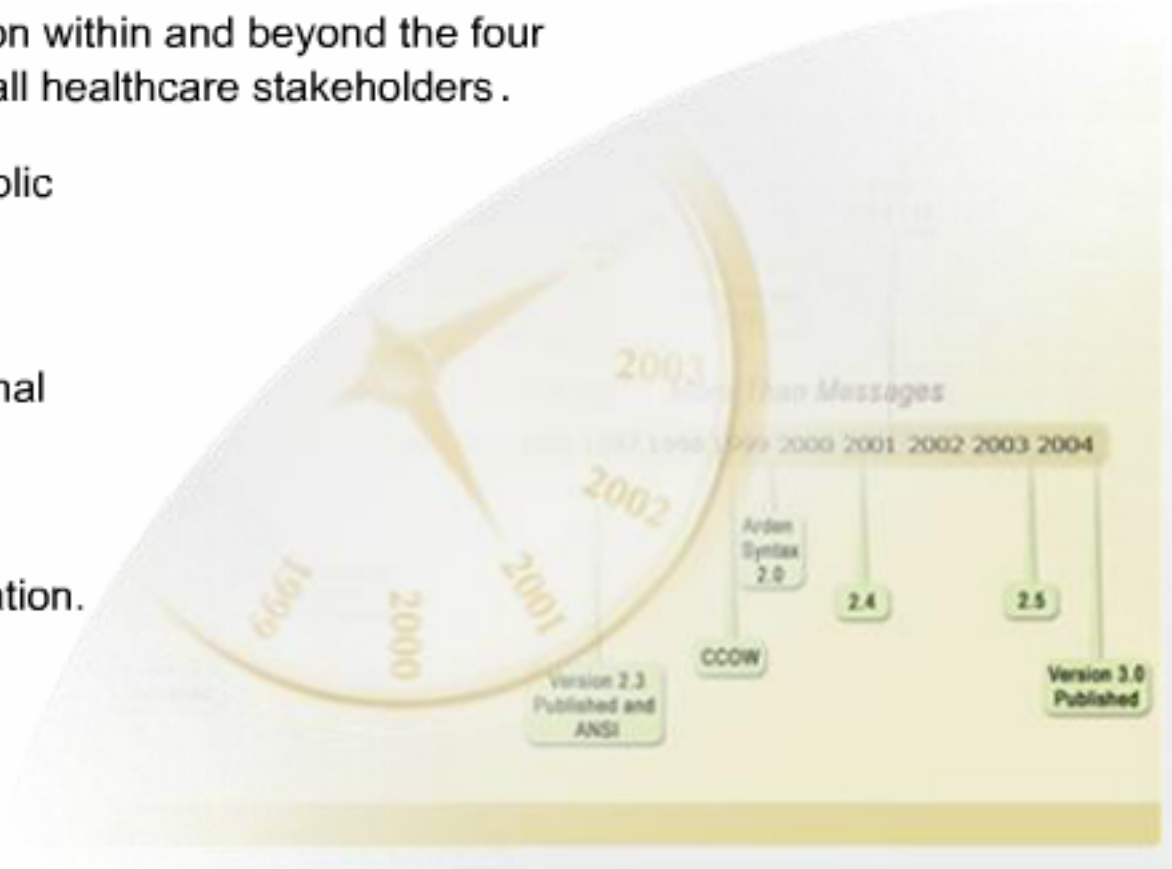
HL7 standard aims (1/2)

HL7 creates healthcare standards to enable interoperability of healthcare information.

- Messages and documents move healthcare information in a standardized way to the point of patient care.
- Standards assist in moving information within and beyond the four walls of hospitals and clinics among all healthcare stakeholders.
- Standards assist in the sharing of public health information.
- Standards help enable the electronic health record and creation of a National Health Information Network.
- HL7 assists in using genomic data in conjunction with other clinical information.



HL7 standard aims (2/2)

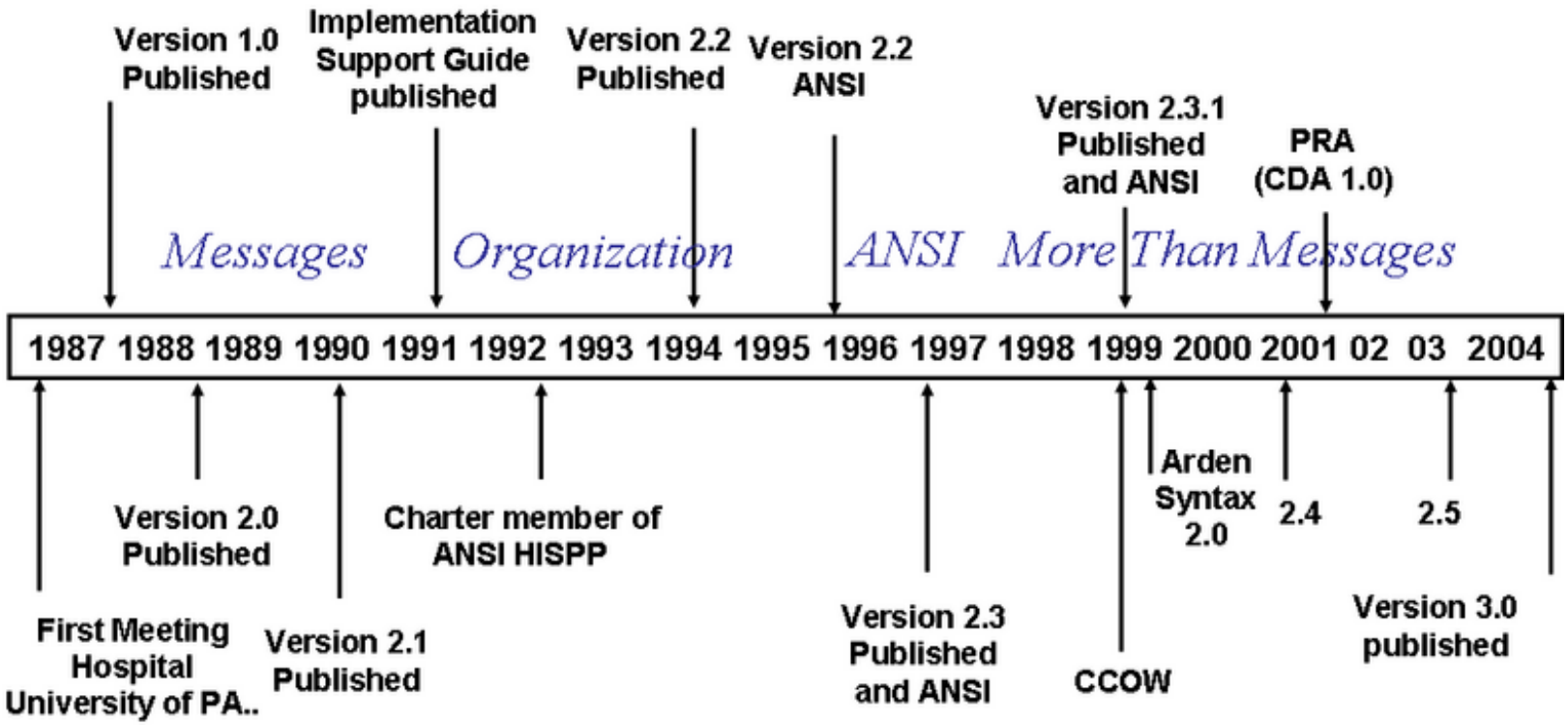
HL7 does not create or provide any sort of software. It does provide healthcare organizations with specifications for making their systems interoperable.

HL7 adopted strategies to develop specifications for making healthcare systems interoperable.

- Develop coherent, extendible standards and a formal methodology.
- Collaborate with healthcare information users and other standards development organizations.
- Promote the use of HL7 standards worldwide.
- Educate the healthcare industry and policy makers.
- Enable domain experts from the healthcare industry to develop healthcare information standards in their areas

HL7 history

History of HL7



Designed by David Marotta

HL7 reference categories

HL7 standards are grouped into reference categories:

Section 1: Primary Standards - Primary standards are considered the most popular standards integral for system integrations, inter-operability and compliance. Our most frequently used and in-demand standards are in this category.

Section 2: Foundational Standards - Foundational standards define the fundamental tools and building blocks used to build the standards, and the technology infrastructure that implementers of HL7 standards must manage.

Section 3: Clinical and Administrative Domains - Messaging and document standards for clinical specialties and groups are found in this section. These standards are usually implemented once primary standards for the organization are in place.

Section 4: EHR Profiles - These standards provide functional models and profiles that enable the constructs for management of electronic health records.

Section 5: Implementation Guides - This section is for implementation guides and/or support documents created to be used in conjunction with an existing standard. All documents in this section serve as supplemental material for a parent standard.

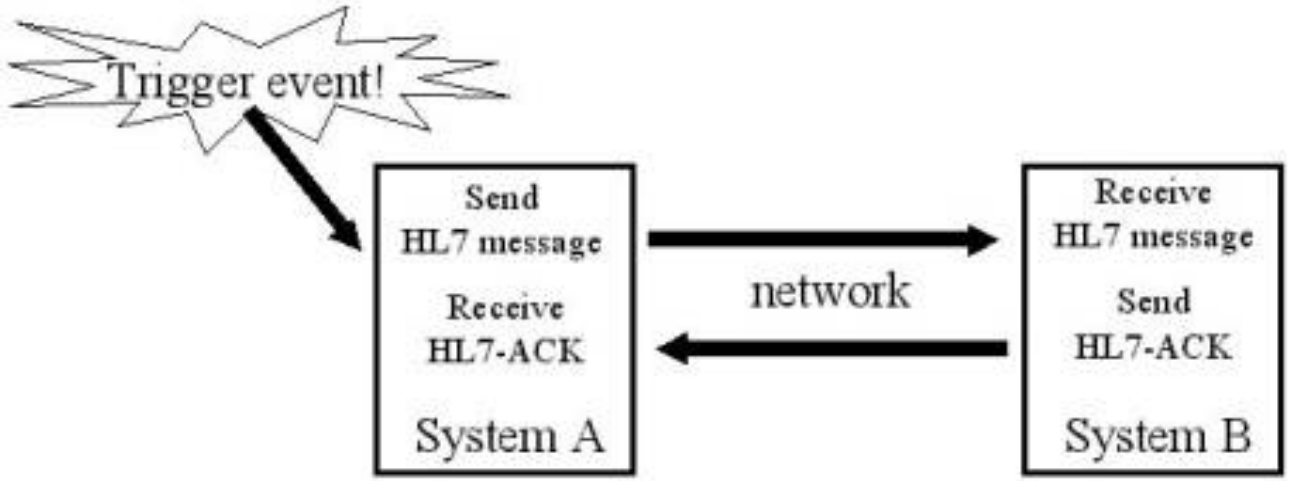
Section 6: Rules and References - Technical specifications, programming structures and guidelines for software and standards development.

Section 7: Education & Awareness - Find HL7's Draft Standards for Trial Use (DSTUs) and current projects here, as well as helpful resources and tools to further supplement understanding and adoption of HL7 standards.

HL7 v2: communication workflow

- The data exchange protocol is based on ASCII-coded messages delimited by “separators”;
- Two actors (sender and receiver) communicate throgh the exchange of bi-directional messages;
- The message content is validated by a parser before the transmission: first, the parser adds missing parts, then the message is transmitted;
- The receiver decodes the message accoridng to the protocol rules and interprets the data type extracting all the relevant information from the message;
- Messages are independent from the system implementations → heterogeneous systems can communicate withouth knowing each other;
- The receiver always sends an Acknowledge (ACK) message to confirm the reception.

Trigger events



- The HL7 vs communication workflow is activated by a **trigger event: an explicit set of conditions that initiate the transfer of information between system components (real world event)**
- Examples: the placing of a laboratory order or drug order.
- The Trigger Event may be caused by one of the following reasons:
  - User Request Based (the trigger event that prompts a system to send all accumulated data to a tracking system every 12 hours; a user pressing a button in a user-interface)
  - State Transition (the trigger for canceling a document)
  - Interaction Based (the response to a query)

HL7 v2 message structure

- **Message →**
  - Delimited ASCII text
  - Composed by one or more **Segments**.

- **Segment →**
  - Text line delimited by the carriage-return (hexadecimal 0D).
  - Can be optional
  - Composed by one or more **Fields** delmited by the pipe character "|".

- **Fields →**
  - Composed by data or strings separated by "^".
  - They can be empty
  - The NULL value is the empty string "".

HL7 v2 message separators

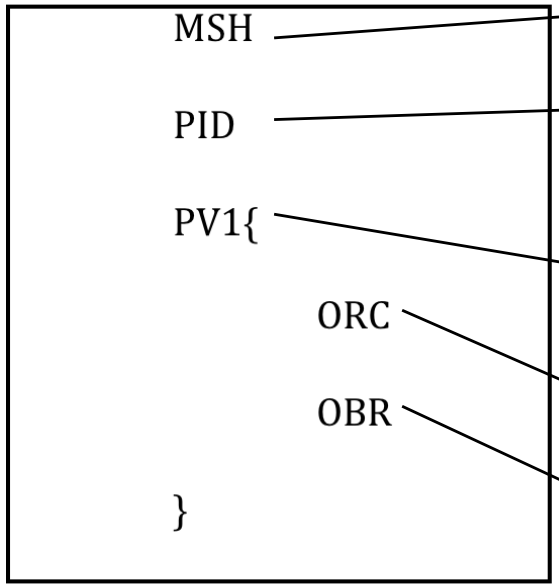
(x0D)		Segment separator
|		Field separator, aka pipe
^		Component separator, aka hat
&		Sub-component separator
~		Field repeat separator
\		Escape character

HL7 vs message example: order placer

ORM^O01 New Order

```
MSH|^~\&|RIS|SIEMENS|SCREENING|DEDALUS|20131001134643||ORM^O01|20240061|P|2.3.1||||||8859/1<c
r>
PID||59530^^^RIS|""||ROSSI^MARIA||19540101<cr>
PV1||O|||||||||||||||SCR2013156803
ORC|SC|00000000000034466^DEDALUS|4399598^RA2000||CM
OBR||||4399598|||20131001131042
```

Segment desciption



MSH: message header (sender, receiver, timestamp, message type)

PID: patient identification information (name, address, gender, UID)

PV1: information regarding the institution (division, operative unit, director, etc.).

ORC: order to be activated through the message

OBR: information on the medical procedure to apply

HL7 vs message example: Acknowledge


```
MSH|^~\&|RIS|SIEMENS|EUROSOFT|EU|20131001134643||ACK^O01|MSGID12345678|P|2.3.
1<cr>
MSA|AA|MSGID12345678
```

Acknowledge message

- Composed by two segments→ **MSH** e **MSA**
- **MSH:** message header
- **MSA** →
  - ID of the message that is acknowledged;
  - A code describing the result of the message→
    - AA (Application Accept): success;
    - AE (Application Error): rejected for application error;
    - AR (Application Reject): rejected ffor data error.

HL7 v3

- Change in the HL7 philosophy → from message definition to data exchange model definition

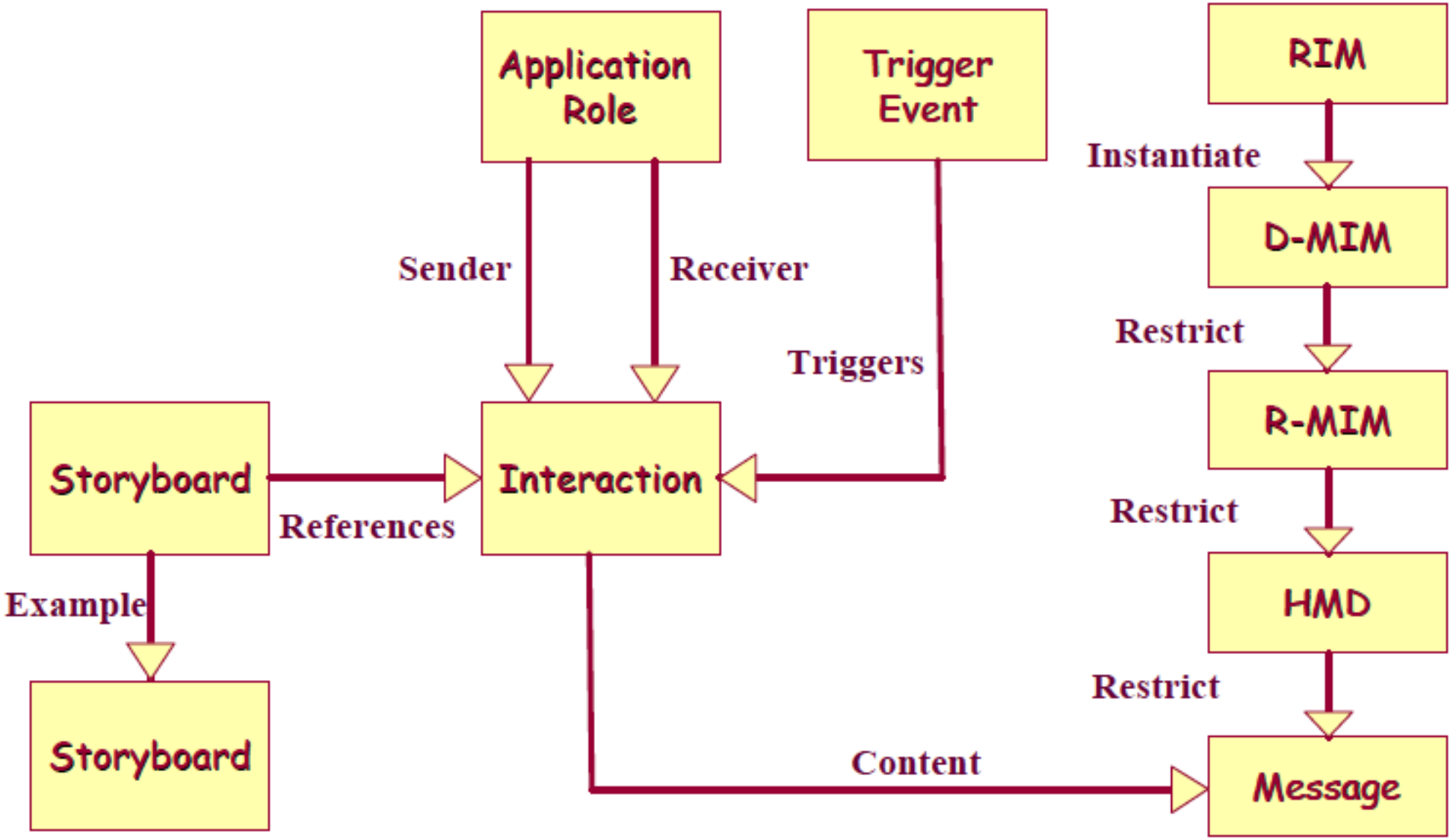
- Creation of the **HL7 Reference Information Model (RIM)** – data model
  - Object oriented (attributes and methods)
  - In 2006 the RIM became the standard ISO/HL7 21731;

- Data format → from ASCII-delimited messages to XML messages.

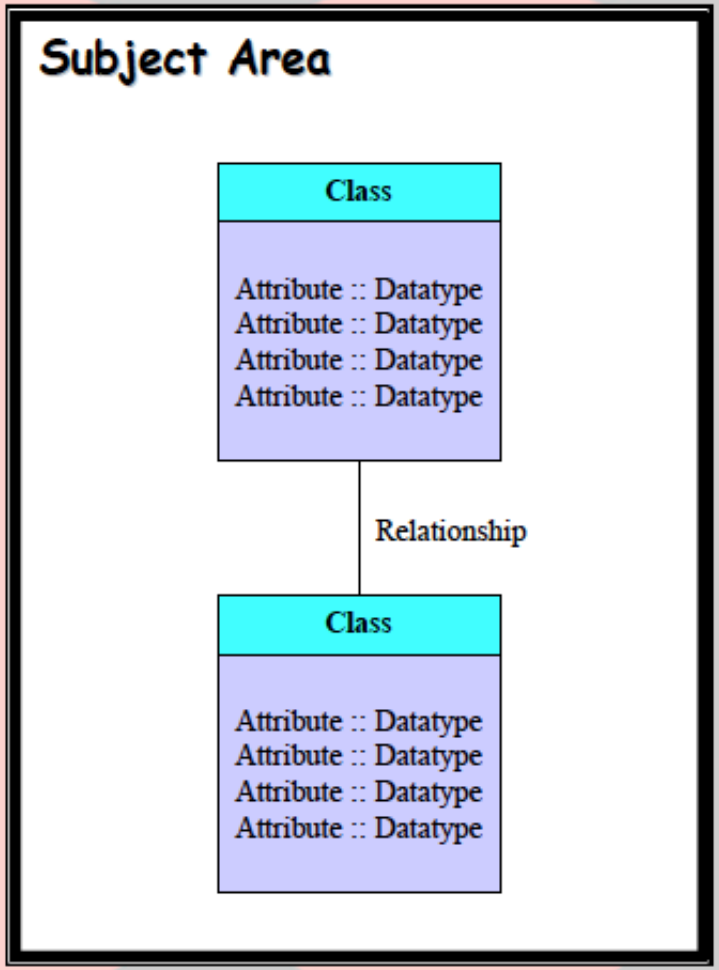
HL7 v3-based system implementation pathway (1/2)

1. Define a consensus Reference Information Model (RIM)
2. Assemble the terminology/vocabulary and data types necessary to express the attributes of the RIM
3. Design the technology to implement the interactions (XML)
4. Develop supporting structures (Storyboards, Trigger events, application roles) that reflect the business model in healthcare
5. Apply the RIM, Vocabulary and Data Types and supporting information to define interactions
6. Publish, Verify, Localize and Implement

HL7 v3-based system implementation pathway (2/2)



RIM components



Subject Area: a major partition of a information model.

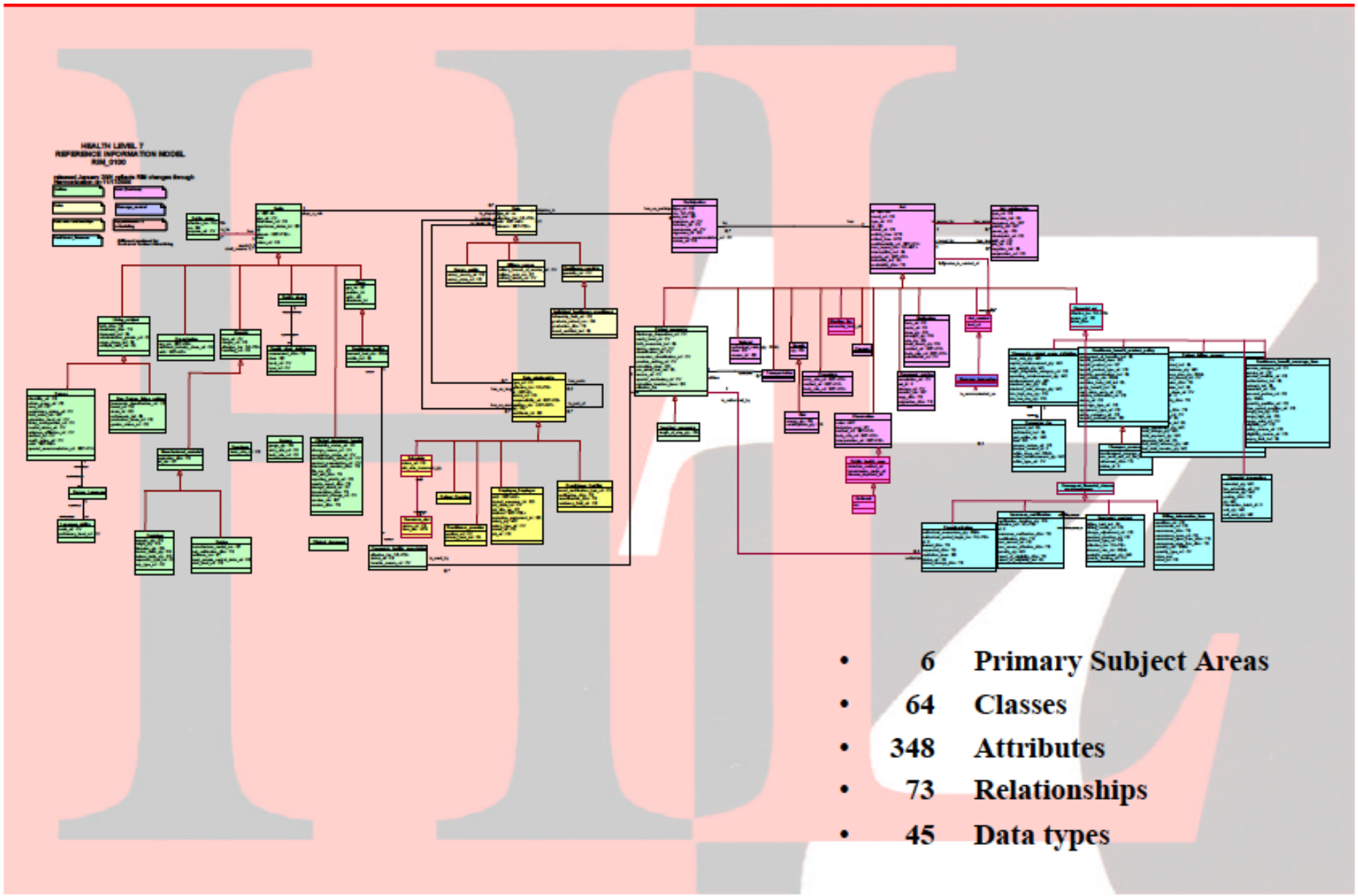
Class: something about which information is collected.

Relationship: an affiliation between two classes.

Attribute: information about a class.

Data Type: a specification of the format of an attribute.

RIM class diagram



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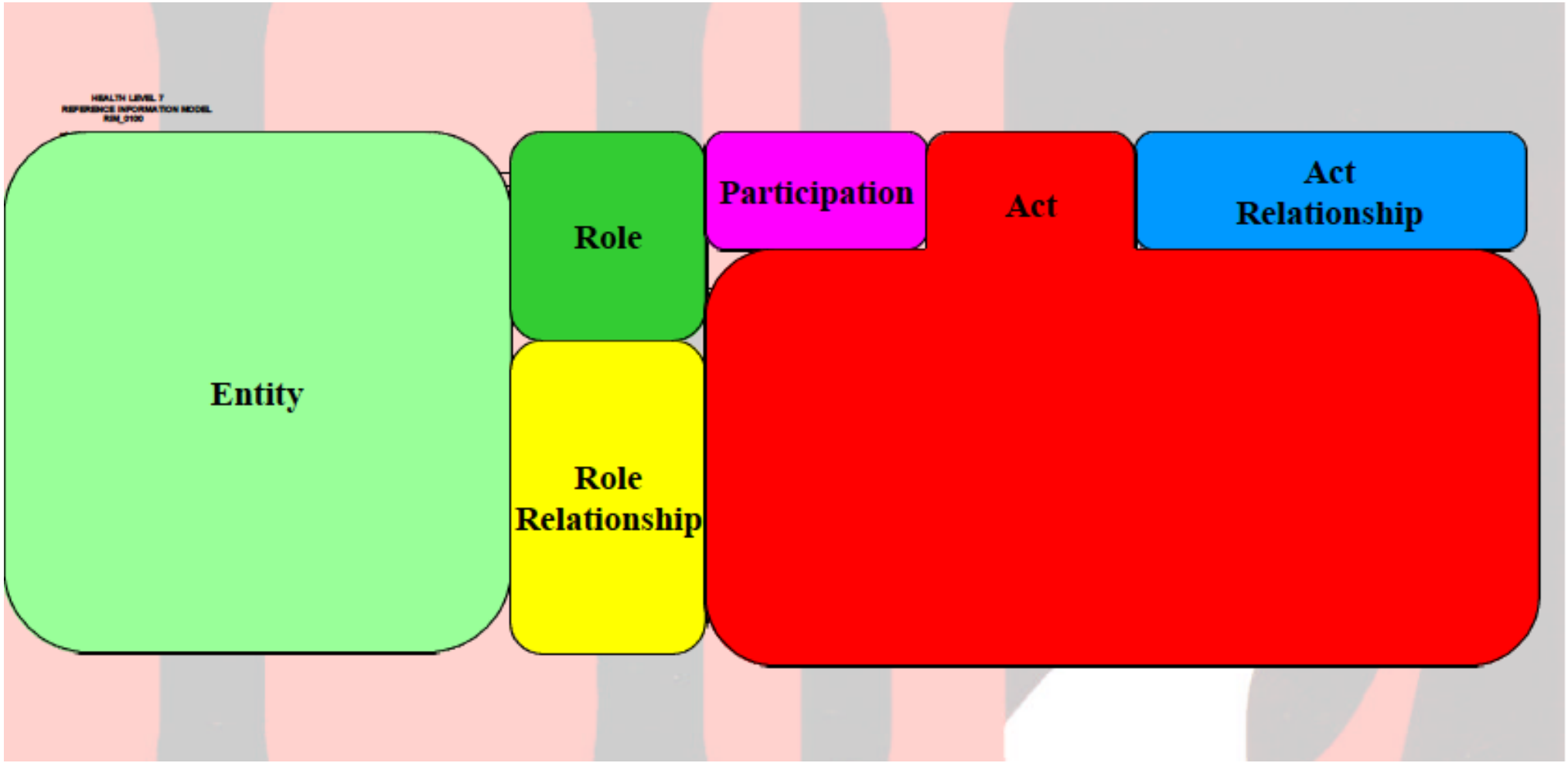
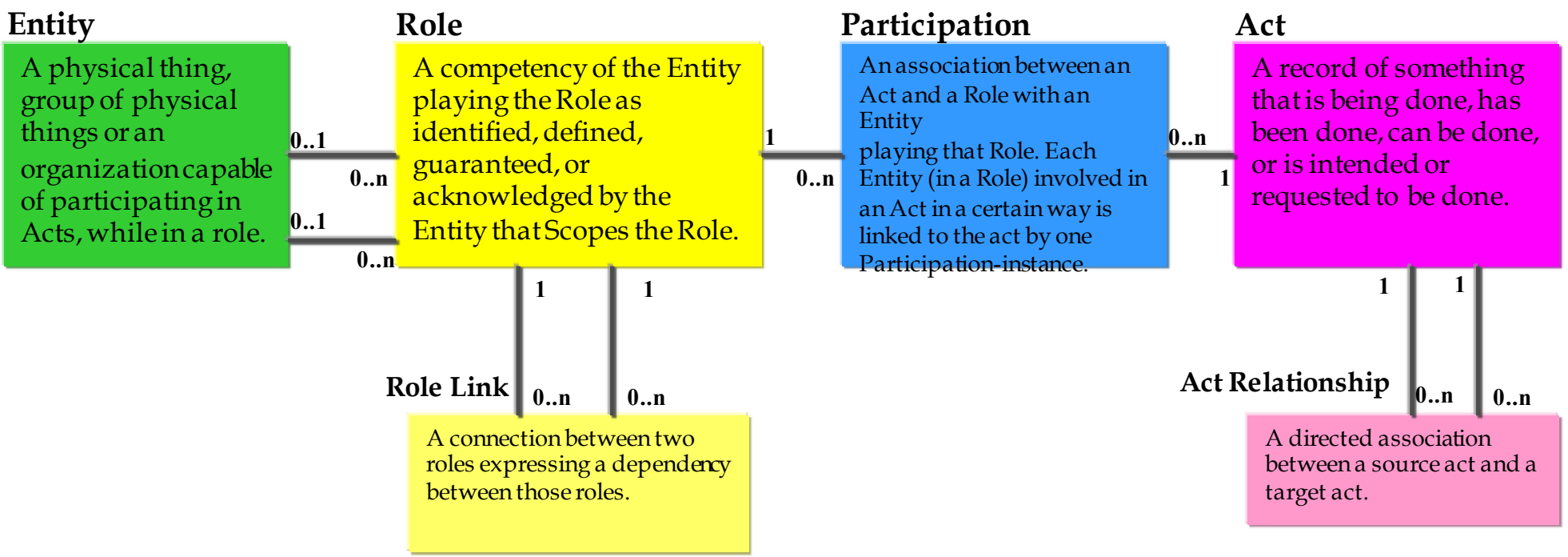
Primary subject areas



RIM Core classes



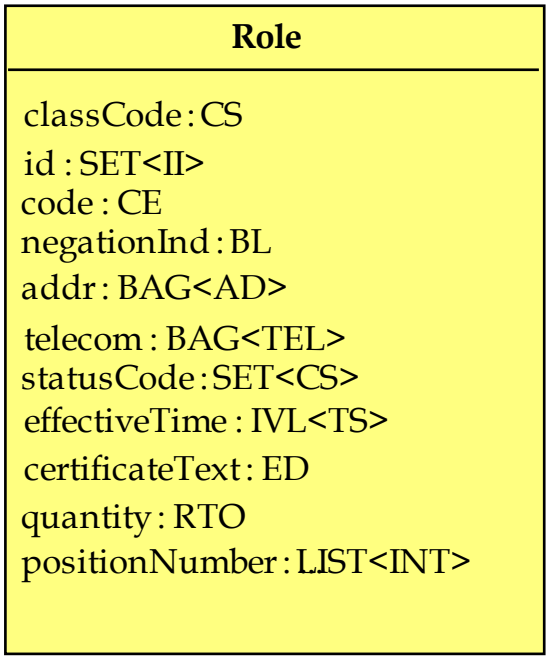
Entity

Entity
classCode : CS determinerCode : CS id : SET<II> code : CE quantity : SET<PQ> name : BAG<EN> desc : ED statusCode : SET<CS> existenceTime : IVL<TS> telecom : BAG<TEL> riskCode : CE handlingCode : CE

Entity: a person, animal, organization or thing
A collection of classes related to the Entity class, its specializations and related qualifying classes. The classes represent health care stakeholders and other things of interest to health care.

Entity has the following sub-classes:
Container
Device
LanguageCommunication
LivingSubject
ManufacturedMaterial
Material
NonPersonLivingSubject
Organization
Person
Place

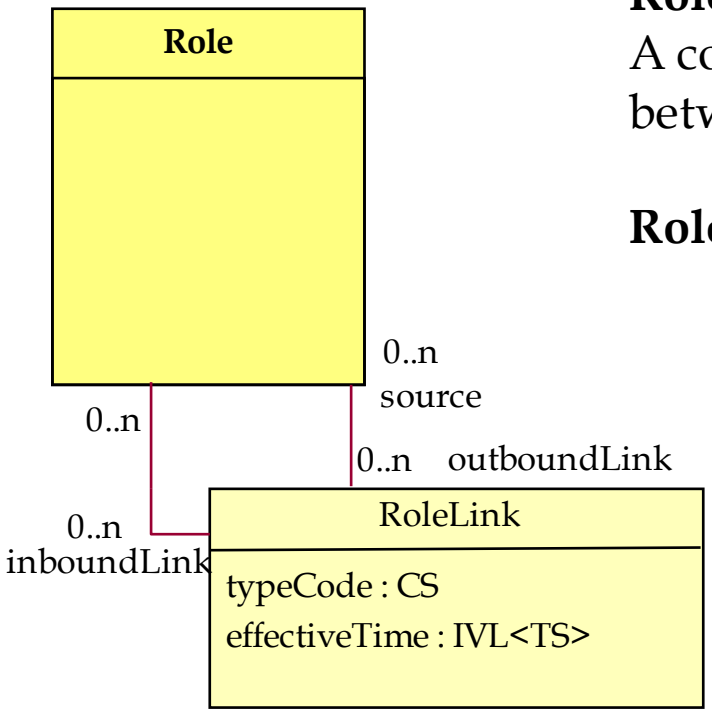
Role



Roles:
A responsibility or part played by an entity (e.g. Person in a role of patient, employee, etc.) – different faces of an Entity
A collection of classes related to the Role class and its specializations. These classes focus on the roles participants may play in health care.

Role has the following sub-classes:
Access
Employee
LicensedEntity
Patient

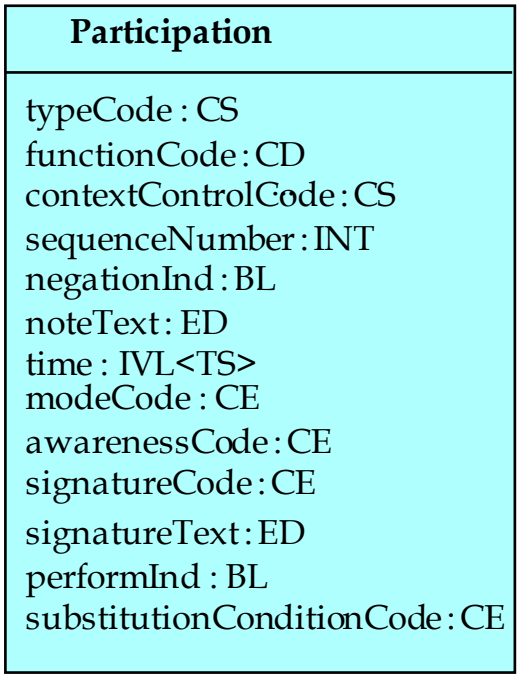
RoleLink



RoleLink:
A connection between two roles expressing a dependency between those roles.

RoleLink has no sub-classes.

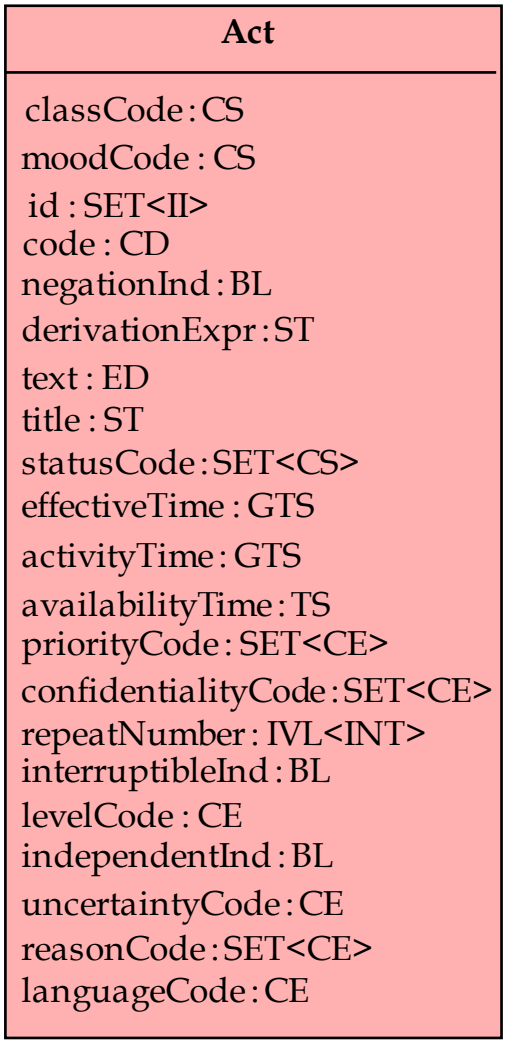
Participation



Participation:
An association between an Act and a Role with an Entity playing that Role.

Participation has the following sub-class:
ManagedParticipation

Act

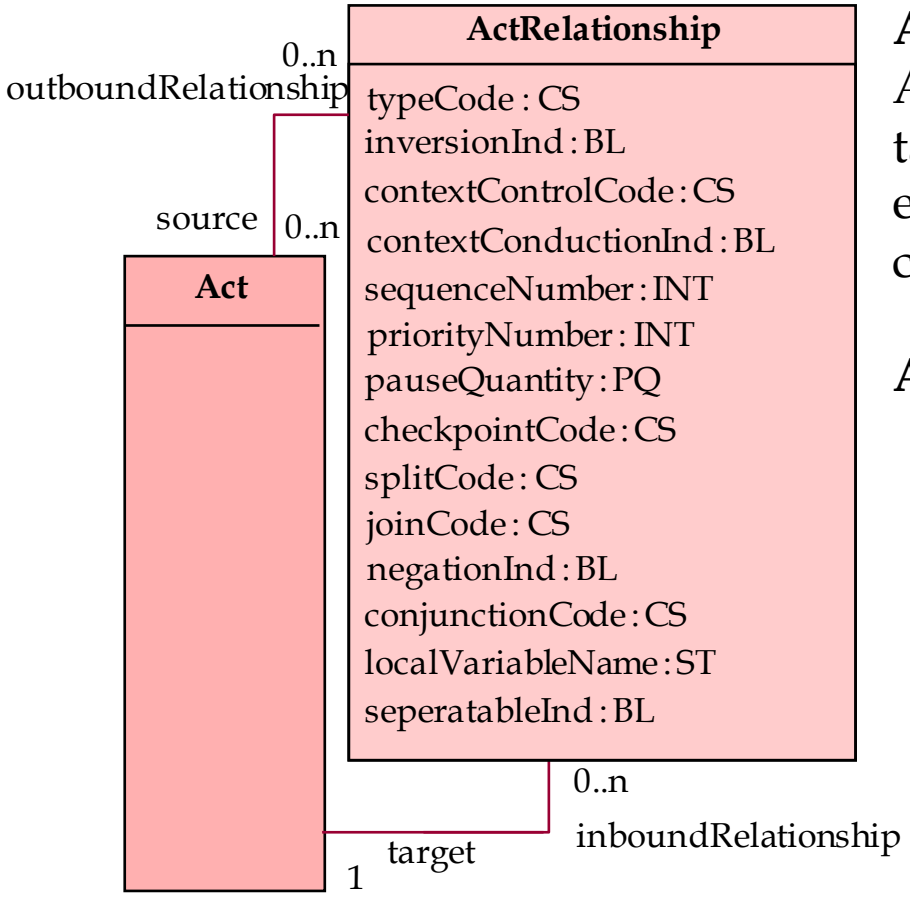


Act:
A collection of classes including the Act class and its specializations. These relate to the actions and events that constitute health care services. A record of something that is being done, has been done, can be done, or is intended or requested to be done.

Among Act sub-classes:

Account	Observation
ControlAct	Participation
DeviceTask	PatientEncounter
DiagnosticImage	Procedure
Diet	PublicHealthCase
FinancialContract	SubstanceAdministration
FinancialTransaction	Supply
InvoiceElement	WorkingList

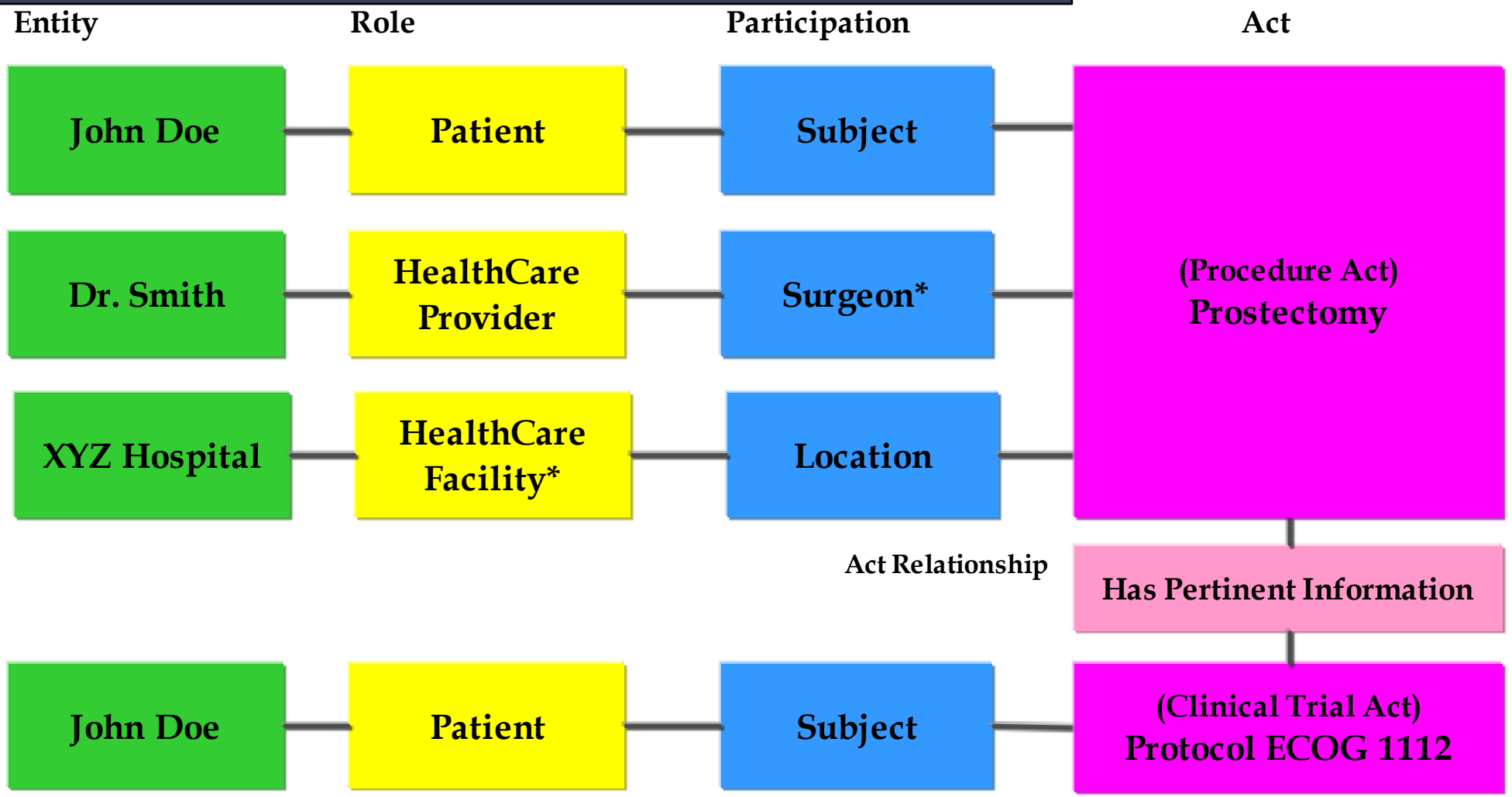
ActRelationship



ActRelationship:
A directed association between a source Act and a target Act. A point from a later instance to a earlier instance OR point from collector instance to component instance.

ActRelationship has no sub-classes.

HL7 RIM instance example



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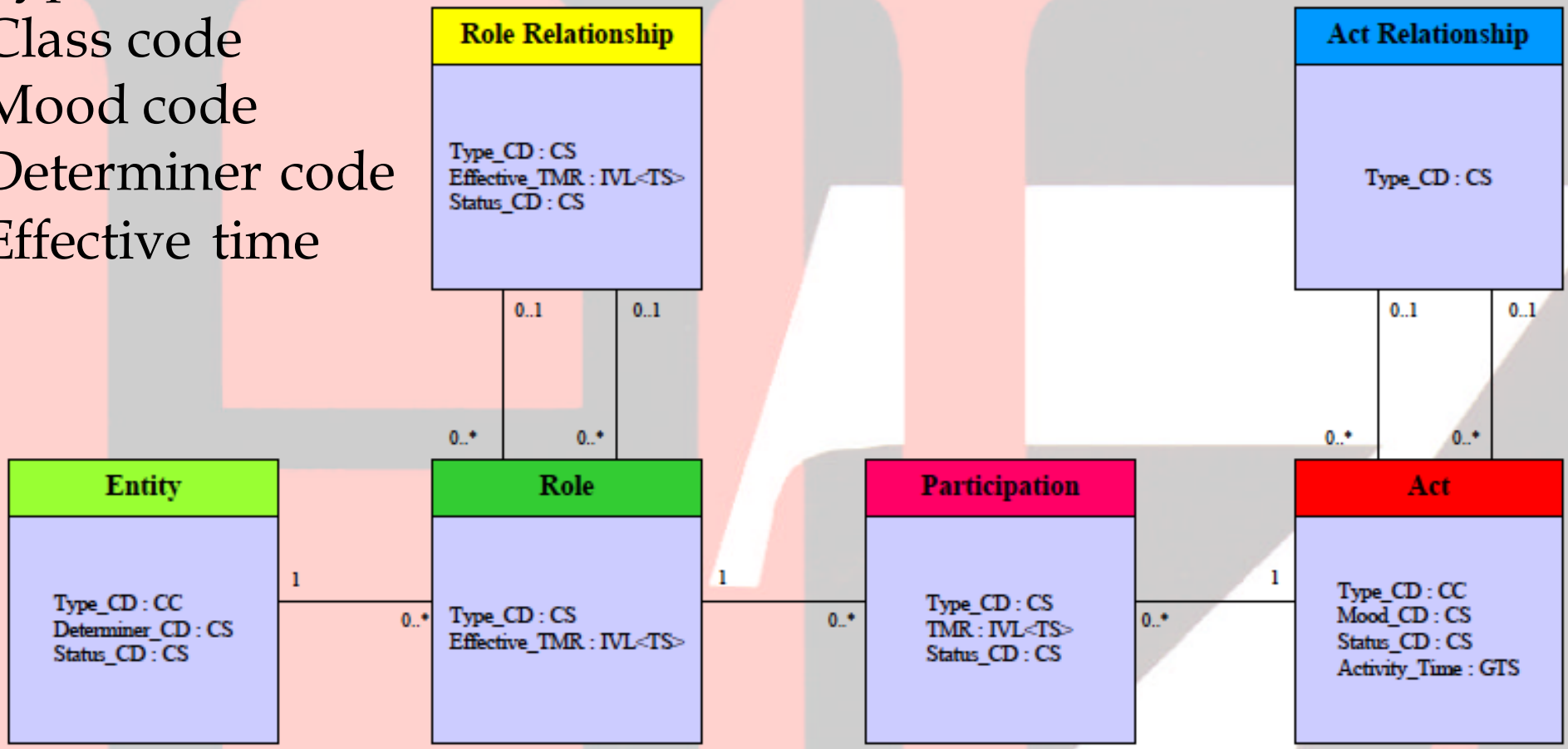
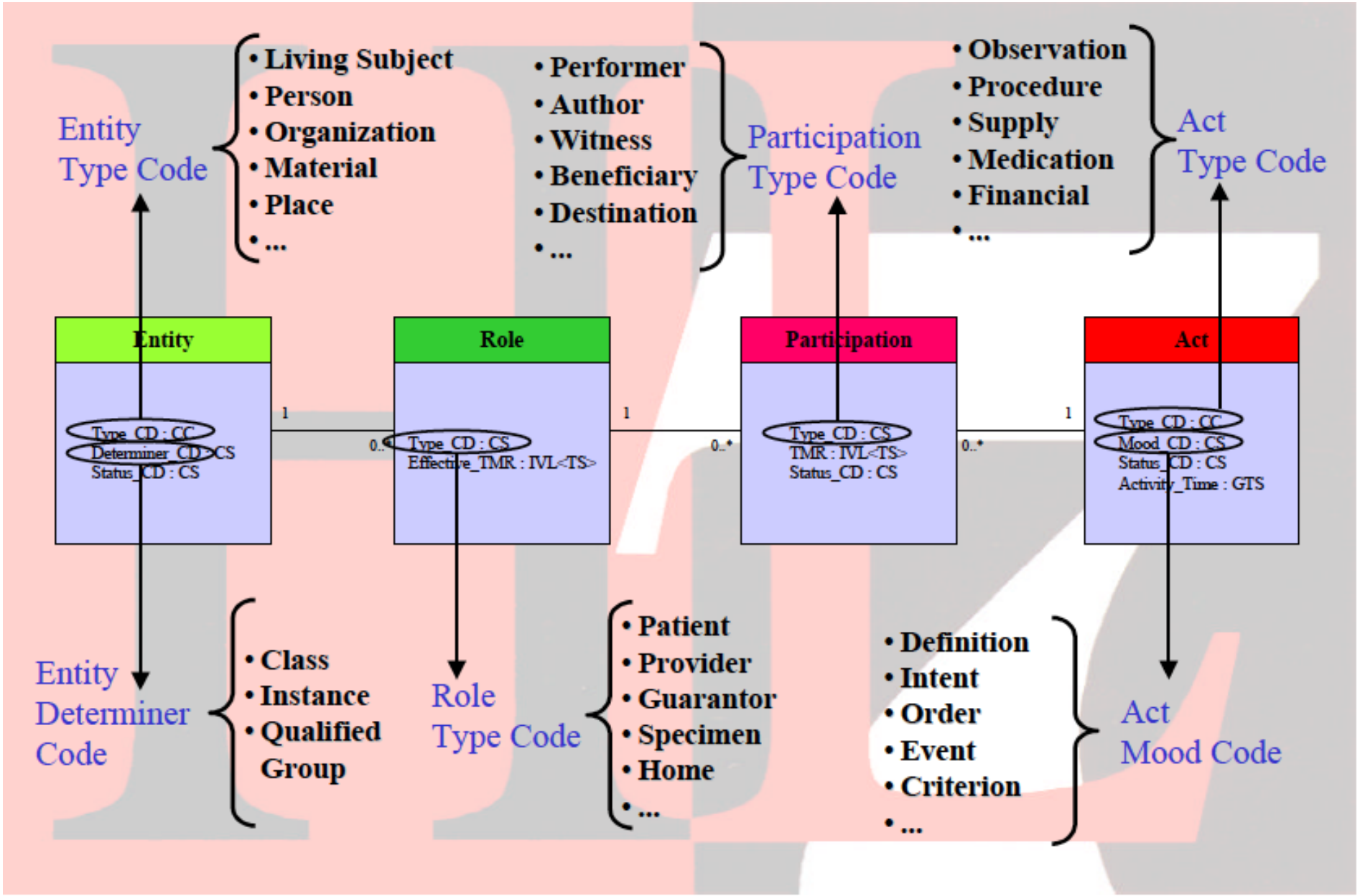
Core attributes

Type code
Class code
Mood code
Determiner code
Effective time



Core attributes value set



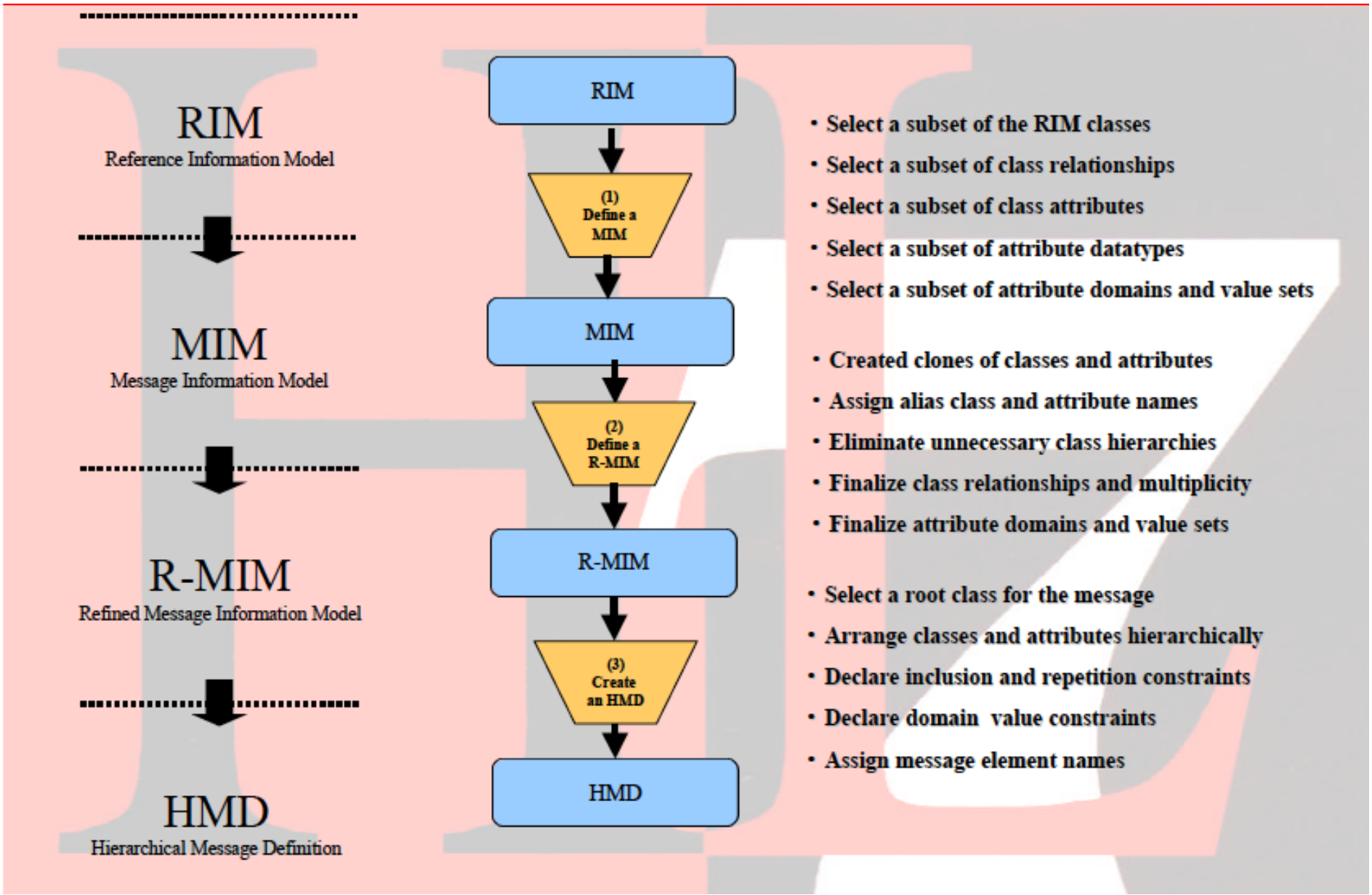
The "mood codes"

- Proposal (PRP)
  - Why don't you clean your room today?
- Order (ORD)
  - Clean your room!
- Intent (INT)
  - I promise to clean my room
- Event (EVN)
  - The room is cleaned
- Definition (DEF)
  - "Cleaning your room" means make the bed, put toys away…
- Event Criterion (EVN.CRT)
  - If you want ice cream you must clean your room

Vocabulary domains and codes

- Coded attributes in the RIM must be associated with one and only one Vocabulary Domain prior to being used in a message specification.
- A vocabulary domain is "The set of all concepts that can be taken as valid values in an instance of a coded field or attribute."
- Each concept in the vocabulary domain is represented using a code from a specific vocabulary.
- A vocabulary is a defined set of coded concepts.
- A vocabulary may be specified as an enumerated list of coded concepts (HL7 defined) or as a reference to an externally maintained list of coded concepts (e.g., SNOMED, LOINC, CPT, . . .).

RIM implementation process



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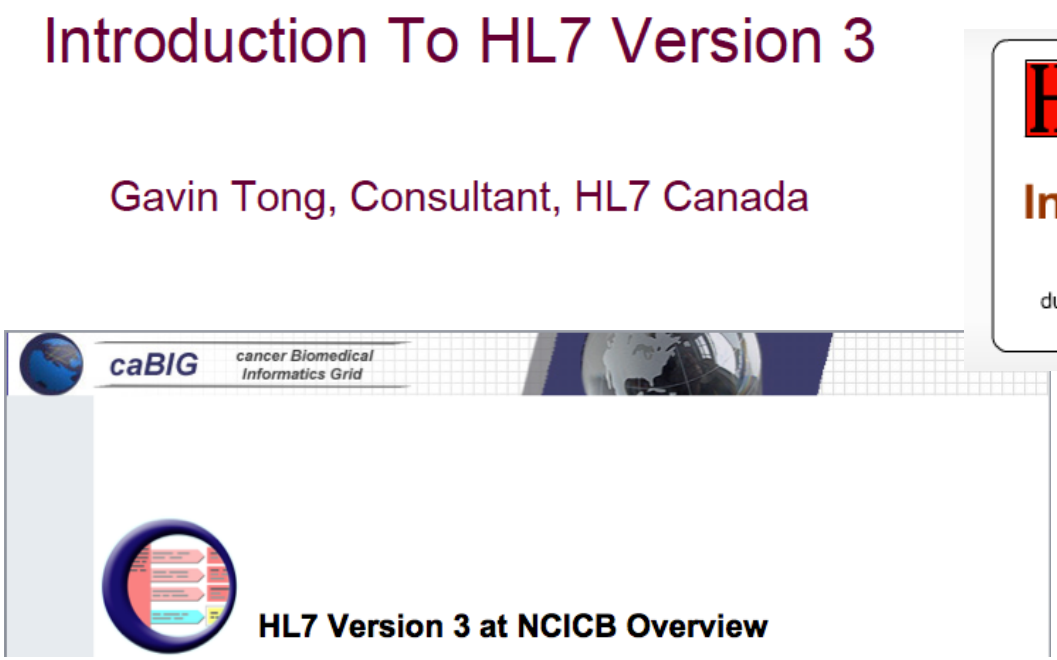
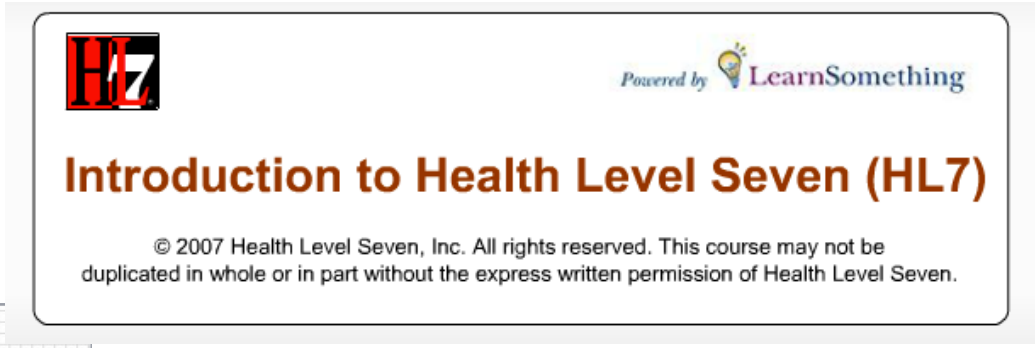
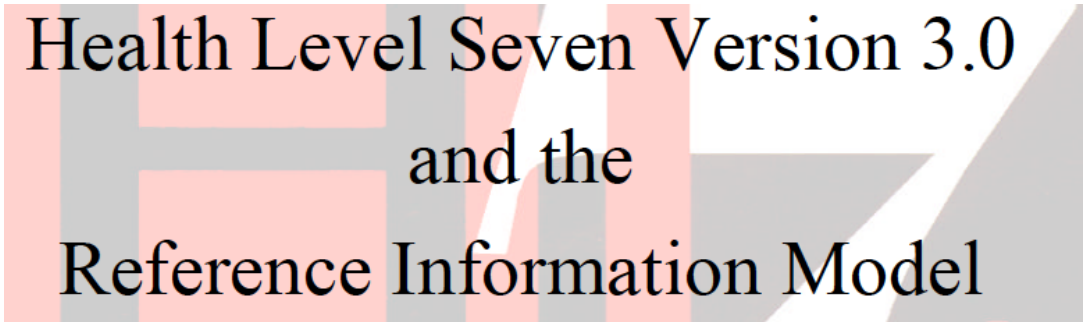
HL7 - references





www.hl7.org



IHE Integrating the Healthcare Enterprise

Integrating the Healthcare Enterprises

IHE is **an initiative by healthcare professionals and industry** to improve the way computer systems in healthcare share information. IHE **promotes the coordinated use of established standards such as DICOM and HL7** to address specific clinical needs in support of optimal patient care**. Systems** developed in accordance with IHE **communicate with one another better**, are easier to implement, and enable care providers to use information more effectively.

IHE aims

- Born in 1998 in USA from *Radiological Society of North America* (RSNA) e *Healthcare Information and Management Systems Society* (HIMSS)

- IHE is not a communication standard → it has the aim to define how the available standards have to be used in practice to implement system integration:
  - To facilitate health information integration;
  - To provide support functionalities for EHRs;
  - To boost standard adoption;
  - To promote the communication aming vendors;
  - To improve efficacy and efficiency in clinical practice;
  - To improve ICT security and privacy;

- Interoperability → definition of an information exchange process known as **profile.**

IHE domains

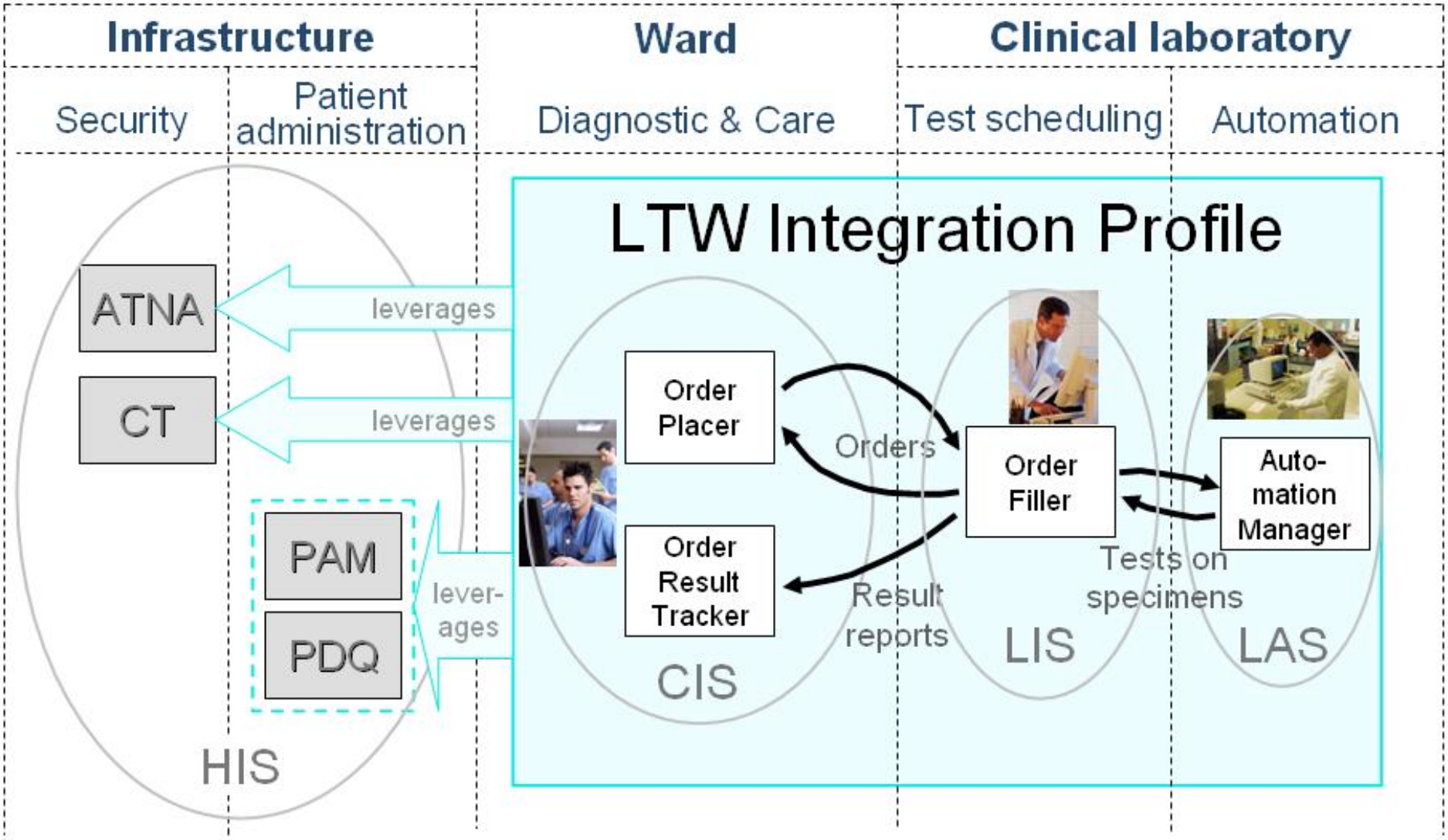
- IHE is organized by clinical and operational domains.
- In each domain users with clinical and operational experience identify integration and information sharing priorities and vendors develop consensus, standards-based solutions to address them.
- Each domain includes a technical committee, whose primary task is developing and documenting the solutions (= integration profiles).
- Each domain includes a planning committee → long-term scope planning and organizing deployment activities.
- Each domain develops and maintains its own set of Technical Framework documents.

IHE profiles

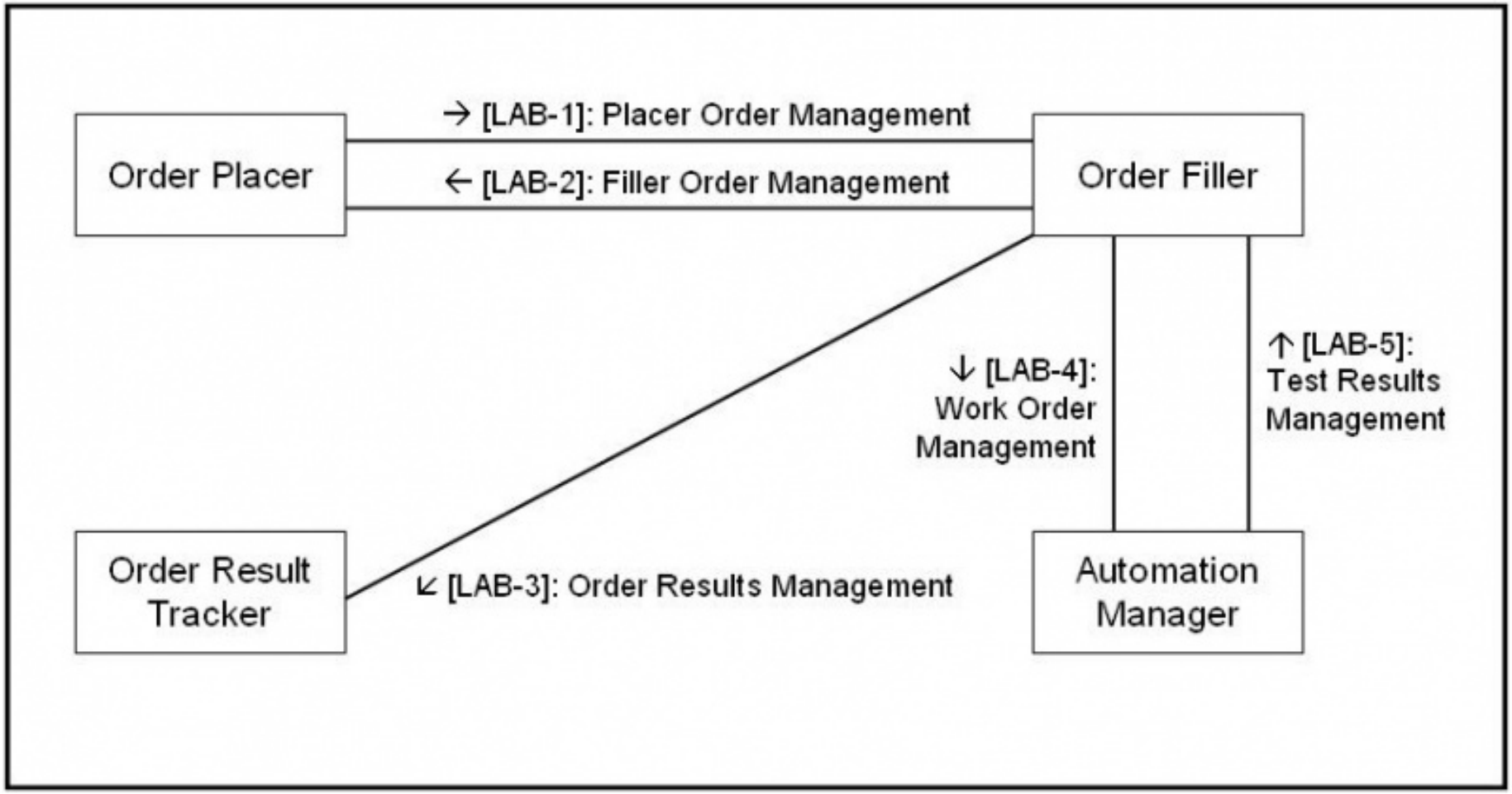
- A **profile** is an abstract representation of the real world that defines the implementaion specifications of one or more “use cases”:
- Communication processes
- Type of information exchanges
- Actions to be done when the information is received

- Each profile is characterized by:
- **ACTORS**: healthcare information systems that mange the communication activities (es. ADT, Order Placer, Order Filler, etc.);
- **TRANSITIONS**: standard-based information exchange among actors (ex. HL7). Each transaction is characterized by the refernce standard and other information.
- In each profile, a **table** lists the actors and the transactions of the specific case.

Example: the Laboratory Testing Workflow (LTW) overview



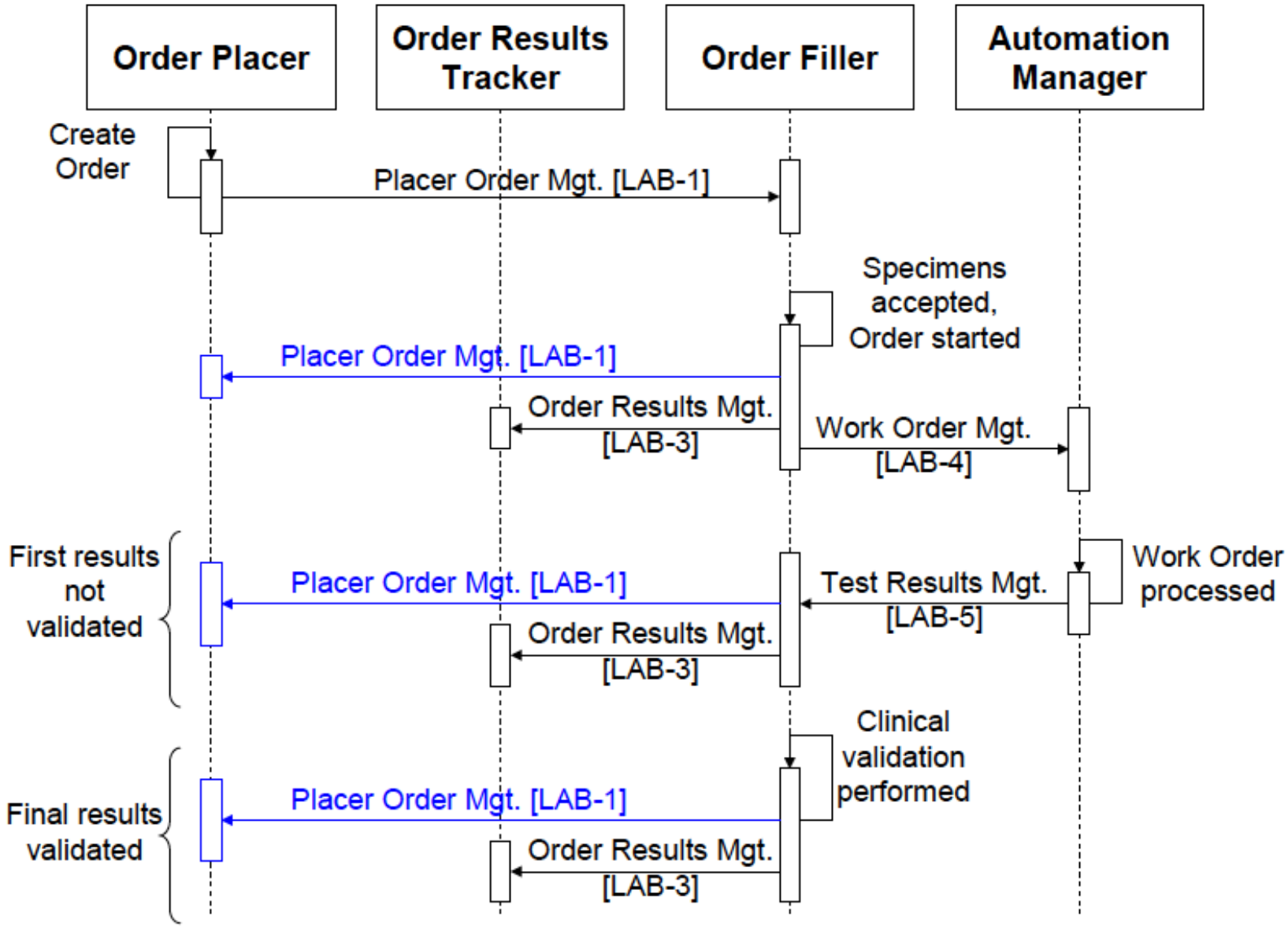
Example: LTW actors and transactions



Example: LTW actors and transactions reference messages

Actors	Transactions	Optionality	Section in Vol. 2
Order Placer	Placer Order management [LAB-1]	R	LAB TF-2a: 3.1
	Filler Order Management [LAB-2]	R	LAB TF-2a: 3.2
Order Filler	Placer Order management [LAB-1]	R	LAB TF-2a: 3.1
	Filler Order Management [LAB-2]	R	LAB TF-2a: 3.2
	Order Results management [LAB-3]	R	LAB TF-2a: 3.3
	Work Order Management [LAB-4]	R	LAB TF-2a: 3.4
	Test Results Management [LAB-5]	R	LAB TF-2a: 3.5
Automation Manager	Work Order Management [LAB-4]	R	LAB TF-2a: 3.4
	Test Results Management [LAB-5]	R	LAB TF-2a: 3.5

Example: LTW process flow for placer ordering



Example: OML^O21 message for the LAB-1 transaction in LTW

Table 3.1.5.3-1: OML^O21 static definition for transaction LAB-1

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	RE	[0..1]	
PID	Patient Identification	R	[1..1]	3
[PV1]	Patient Visit	RE	[0..1]	3
]	--- PATIENT end			
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[TQ1]	Timing Quantity	RE	[0..1]	4
	--- OBSERVATION REQUEST begin	R	[1..1]	
OBR	Observation Request	R	[1..1]	4
{[NTE]}	Notes and Comments	O	[0..*]	2
[{	--- OBSERVATION begin	O	[0..*]	
OBX	Observation Result	R	[1..1]	7
[{NTE}]	Comment of the result	C	[0..*]	2
}]	--- OBSERVATION end			
[{	--- SPECIMEN begin	O	[0..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Container	C	[0..*]	13
}]	--- SPECIMEN end			
[{	--- PRIOR_RESULT begin	O	[0..*]	
PV1	Patient Visit – previous result	R	[1..1]	3
{	--- ORDER_PRIOR begin	R	[1..*]	

Connectathon

Annual plenary session among all the vendors and clinical and operational experts that test the profile implementations to define the integration level

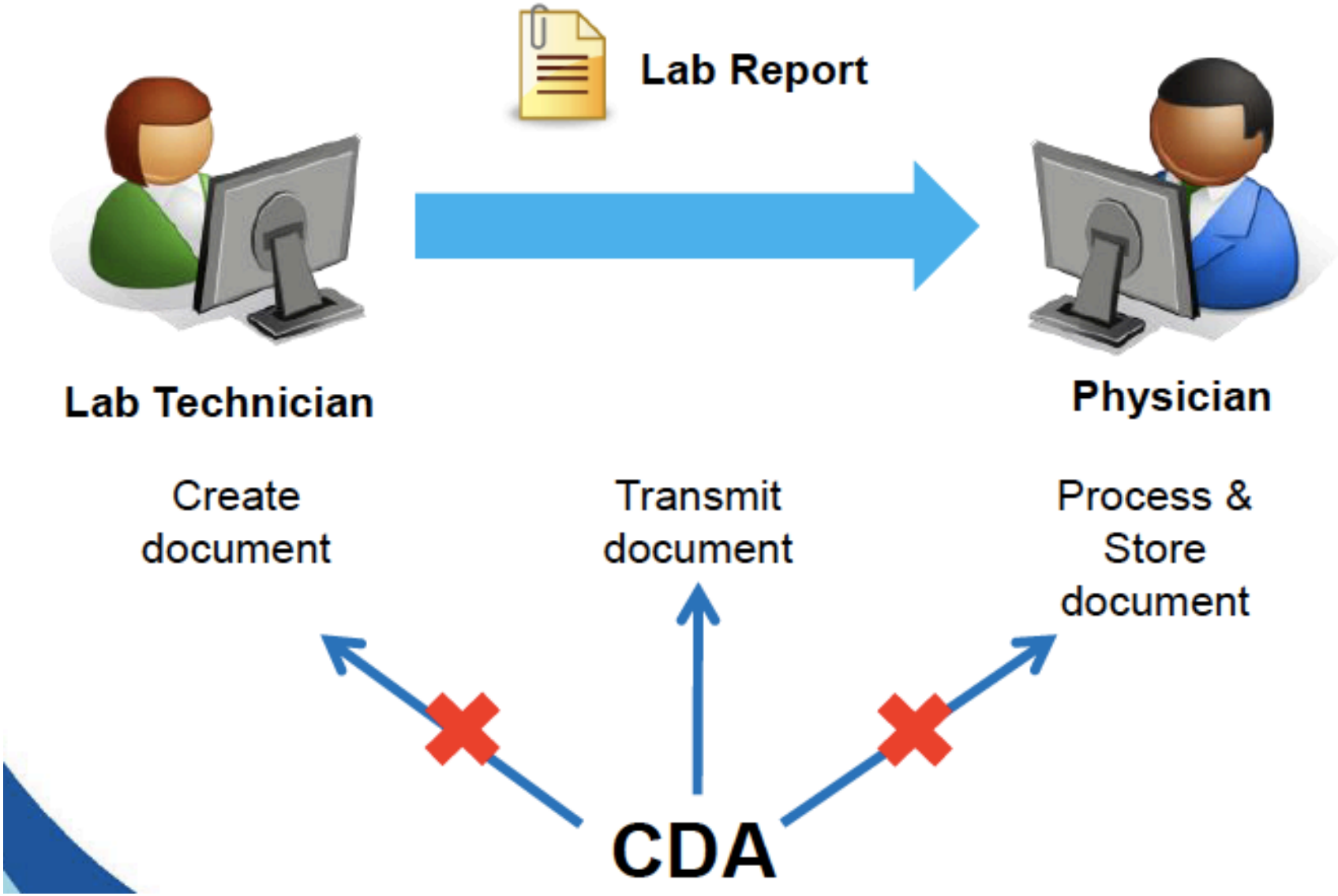

CDA
Clinical
Document
Architecture

WHAT IS THE CDA

- **The HL7 CDA is a document markup standard that specifies the structure and semantics of a clinical document (such as a discharge summary, progress note, procedure report) for the purpose of exchange.**

- Defined and complete information object that can include text, images, sounds, and other multimedia content.
- It can be transferred within a message, and can exist independently, outside the transferring message.
- CDAdocuments are encoded in Extensible Markup Language (XML).
- CDA documents incorporate concepts from standard coding systems such as Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC).

SCOPE OF THE CDA



XML

- XML is Extensible Markup Language (www.w3c.org)
- In XML, structure and format are conveyed by markup which is embedded into the information

<markup>text</markup>

```
<section>
 <title>Hospital Course</title>
 <text> The patient was admitted and started on Lovenox and
        nitroglycerin paste. The patient had serial cardiac
        enzymes and was ruled out for myocardial infarction.
        The patient underwent a dual isotope stress test.
        There was no evidence of reversible ischemia on the
        Cardiolite scan. The patient has been ambulated.
 </text>
</section>
```

HL7 DOCUMENT vs HL7 MESSAGE

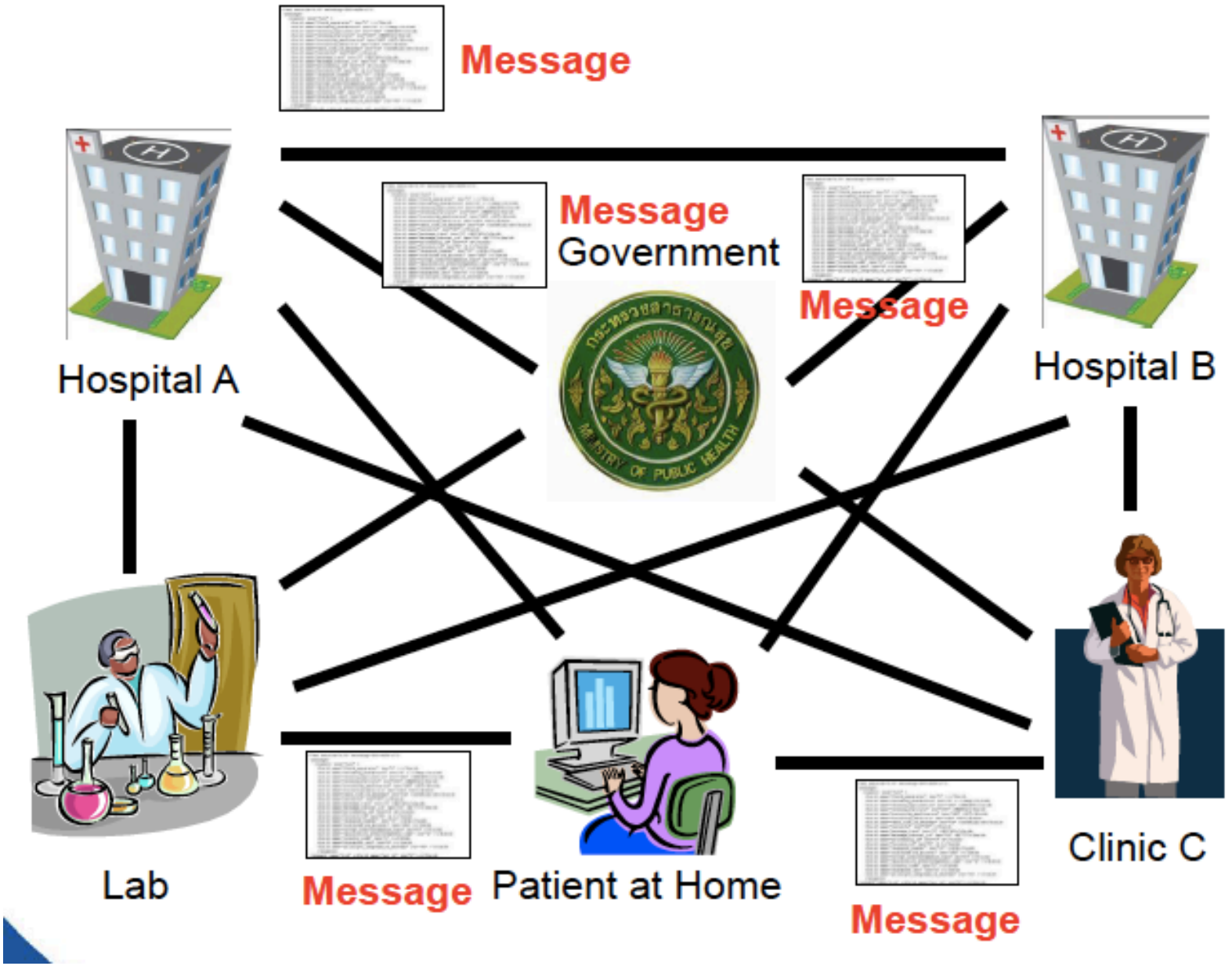
HL7 MESSAGE

- Transient
- Trigger-based - there are events that induce the message creation
- Non-persistent - Once received, the message can be deleted

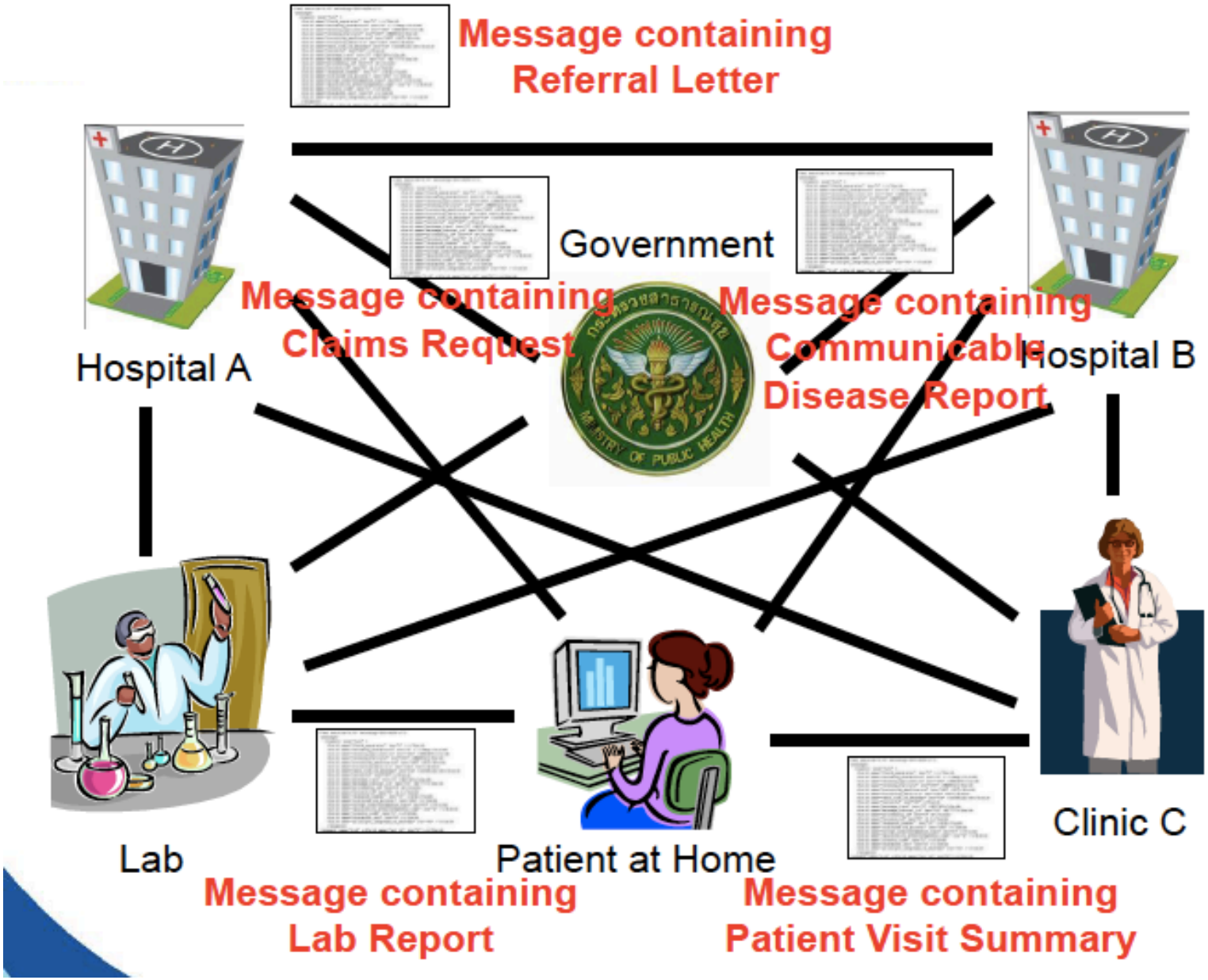
HL7 DOCUMENT

- Persistence –A clinical document continues to exist in an unaltered state, for a time period
- Stewardship –A clinical document is maintained by an organization entrusted with its care
- Potential for authentication -A clinical document is an assemblage of information that is intended to be legally authenticated
- Context -A clinical document establishes the default context for its contents
- Wholeness -Authentication of a clinical document applies to the whole
- Human readability –A clinical document is human readable

EXCHANGING MESSAGES



EXCHANGING DOCUMENTS



CDA-2 DOCUMENT EXCHANGE

- **CDA documents can be exchanged in HL7 messages or exchanged using other transport solutions.**
- To exchange a CDA Document:
  - All components of a CDA document that are integral to its state of wholeness (such as attested multimedia) can be **exchanged as a unit**;
  - Content needing to be rendered or additional files associated with a CDA document (such as a style sheet) can be included in the exchange package;
  - There is **no need to change any of the references** (e.g., a reference to attested multimedia in a separate file) within the base CDA document when creating or extracting the exchange package (indeed, they cannot be changed);
  - There are **no restrictions on the directory structure used by receivers**—receivers can place the components of the CDA document into directories of their choosing;
  - Critical metadata about the CDA instance needed for document management (e.g., document state, document archival status) must be included in the exchange package.

CDA-2 EXTENSIBILITY

- Locally defined markup can be used to extend CDA when local semantics have no corresponding representation in the CDA specification.
- To support local extensibility requirements, it is permitted to include additional XML elements and attributes that are not included in the CDA schema.
- These extensions should not change the meaning of any of the standard data items, and receivers must be able to safely ignore these elements.
- Document recipients must be able to faithfully render the CDA document while ignoring extensions.

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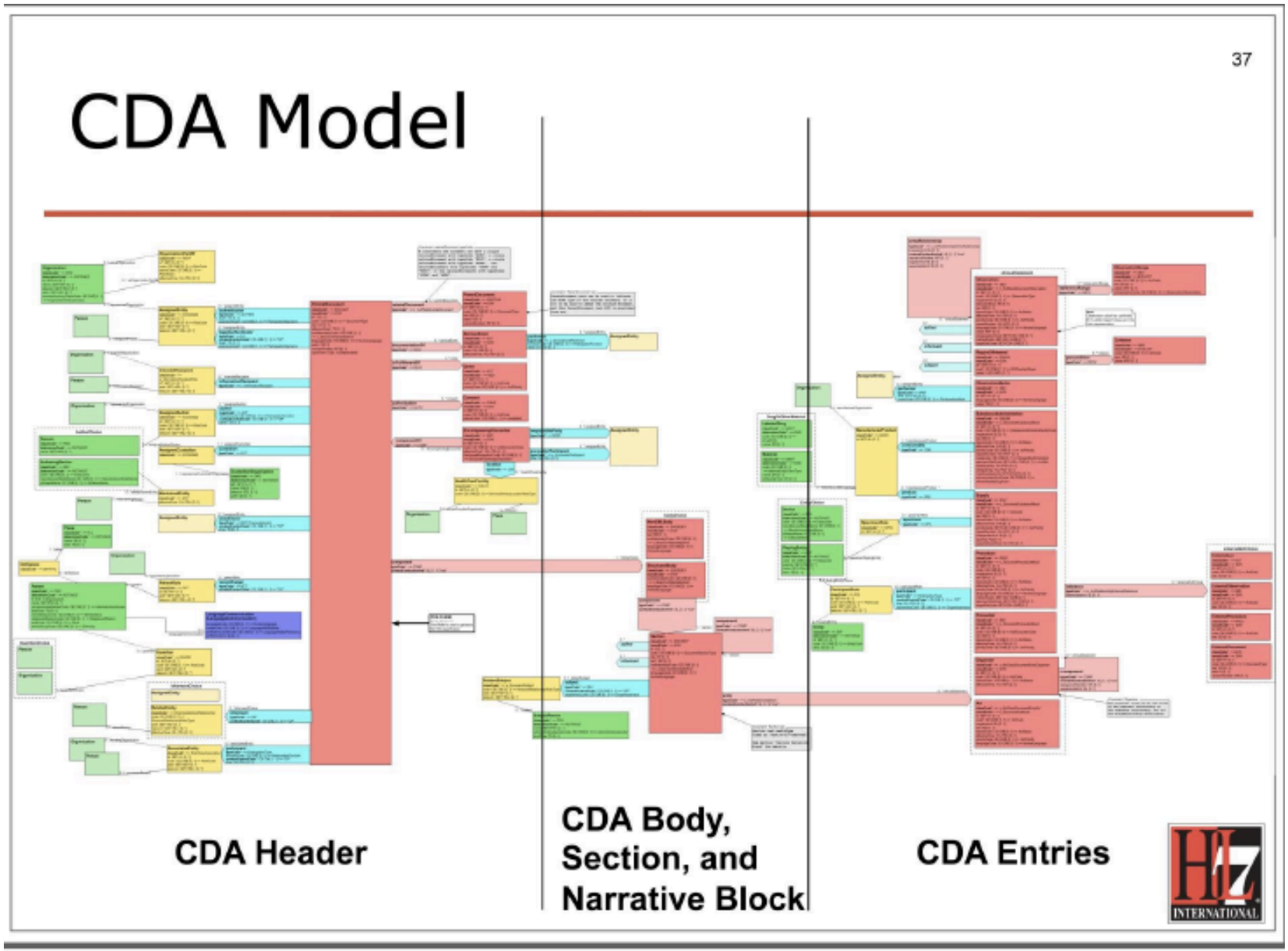
CDA-2 OBJECT MODEL



CDA-2 COMPONENTS

```
<ClinicalDocument>
  ... CDA Header ...
  <structuredBody>
    <section>
      <text>(a.k.a. "narrative block")</text>
      <observation>...</observation>
      <substanceAdministration>
        <supply>...</supply>
      </substanceAdministration>
      <observation>
        <externalObservation>...
        </externalObservation>
      </observation>
    </section>
    <section>
        <section>...</section>
    </section>
  </structuredBody>
</ClinicalDocument>
```

Header

Body

CDA2 HEADER

- Metadata about the document
- Focused on data for:
  - Document Indexing
  - Document authentication
  - Document context
- Supports document management

- id : Identificativo univoco del documento
- code : Codifica LOINC
- effectiveTime : Data di creazione del documento
- author : Persona che valida il documento
- custodian : Struttura che ha generato il referto
- recordTarget : Anagrafica Paziente
- title : Testo d'intestazione del documento
- setId : Identificativo comune ad ogni revisione del documento
- versionNumber : Versione del documento
- legalAuthenticator : Firmatario del referto
- informationRecipient : Unità di consegna
- dataEnterer : Rappresenta la persona che inserisce i dati nel sistema
- responsibleParty : Primario della struttura che ha generato l'atto
- relatedDocument : Collegamento tra due documenti
- documentationOf : Motivo della richiesta di indagine
- inFulfillmentOf : Order Filler
- componentOf : Order Placer e Unità richiedente

CDA-2 HEADER EXAMPLE (1)


```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xsi:schemaLocation="urn:hl7-org:v3 ..\..\..\0.Standards\HL7\CCD\CDASchemas\cda\Schemas\CDA.xsd">
    <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
    <templateId root="2.16.840.1.113883.10.20.9"/>
    <id root="db734647-fc99-424c-a864-7e3cda82e703"/>
    <code code="53576-5" codeSystem="2.16.840.1.113883.6.1"/>
    <title>Good Health Personal Healthcare Monitoring Report</title>
    <effectiveTime value="20080501123333-0500"/>
    <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
    <languageCode code="en-US"/>
```

CDA-2 HEADER EXAMPLE (2)


```
<recordTarget>
    <patientRole>
        <id extension="996-756-495" root="2.16.840.1.113883.19.5"/>
        <!-- The following tag was modified in Release 2-->
        <addr>
            <streetAddressLine>6666 Home Street</streetAddressLine>
            <city>Ann Arbor</city>
            <state>MI</state>
            <postalCode>99999</postalCode>
            <country>USA</country>
        </addr>
        <telecom value="tel:555-555-5001"/>
        <patient>
            <name>
                <given>Ned</given>
                <family>Nuclear</family>
                <suffix/>
            </name>
            <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
            <birthTime value="19320924"/>
        </patient>
    </patientRole>
</recordTarget>
```

CDA BODY

- **Unstructured Body** provides a container for non-XML content

- **Structured Body** that provides both structured human readable narrative as well as machine readable content
  - **Narrative** block that provides the human readable content and represents the authenticated content of the document
  - **Entries** that optionally provide a discrete, machine readable representation of the document content

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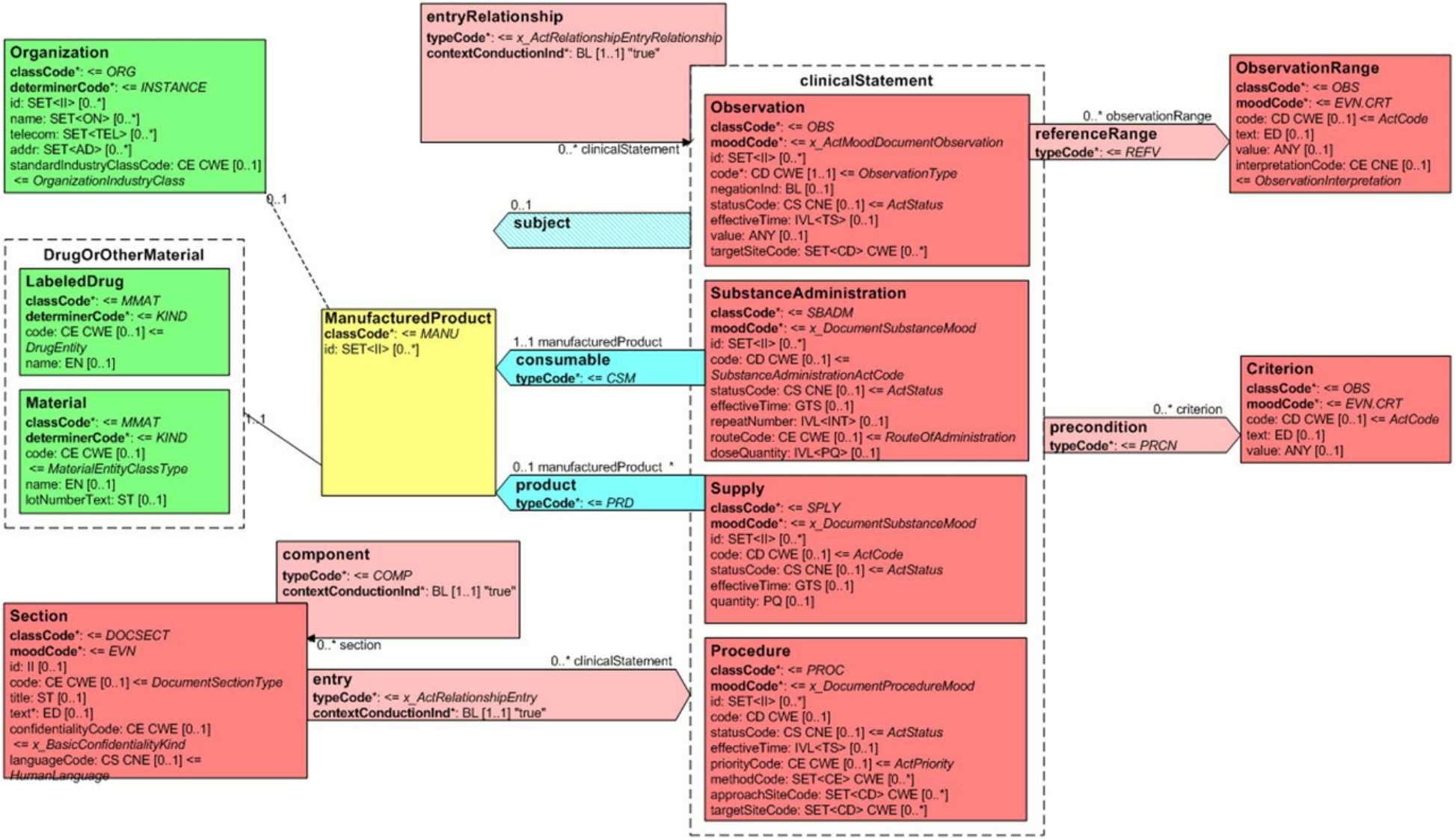
CDA ENTRIES



ENTRY RELATIONSHIP

Table 1 ■ CDA entryRelationship Types

entryRelationship. typeCode	Reasonable Source and Target Acts	Comments
CAUS (is etiology for)	[Act | Observation | Procedure | Substance Administration] **CAUS** [Observation]	Used to show that the source caused the target observation (for instance, source "diabetes mellitus" is the cause of target "kidney disease").
COMP (has component)	[Act | Observation | Procedure | Substance Administration | Supply] **COMP** [Act | Observation | Procedure | Substance Administration | Supply]	Used to show that the target is a component of the source (for instance, "hemoglobin measurement" is a component of a "complete blood count").
GEVL (evaluates (goal))	[Observation] **GEVL** [Observation]	Used to link an observation (intent or actual) to a goal to indicate that the observation evaluates the goal (for instance, a source observation of "walking distance" evaluates a target goal of "adequate walking distance").
MFST (is manifestation of)	[Observation] **MFST** [Observation]	Used to say that the source is a manifestation of the target (for instance, source "hives" is a manifestation of target "penicillin allergy").
RSON (has reason)	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] **RSON** [Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	Used to show the reason or rationale for a service (for instance, source "treadmill test" has reason "chest pain").
SAS (starts after start)	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] **SAS** [Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	The source Act starts after the start of the target Act (for instance, source "diaphoresis" starts after the start of target "chest pain").
SPRT (has support)	[Observation] **SPRT** [Observation | ObservationMedia | RegionOfInterest]	Used to show that the target provides supporting evidence of the source (for instance, source "possible lung tumor" has support target "mass seen on chest -x-ray").

CDA 2 BODY EXAMPLE (1/4)

```
<section>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Vital Signs</title>
  <text>Temperature is 36.9 C</text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Body temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="200004071430"/>
      <value xsi:type="PQ" value="36.9" unit="Cel"/>
    </observation>
  </entry>
</section>
```

Figure 4. An example of a simple observation.

CDA 2 BODY EXAMPLE (2/4)

```
<section>
  <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>History of Present Illness</title>
  <text>Henry Levin, the 7<sup>th</sup> is a 67 year old male
   complaining of disabling <content ID="SX1">osteoarthritis
   of the right knee</content>.
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="396275006" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Osteoarthritis">
        <originalText><reference value="#SX1"/></originalText>
        <qualifier>
          <name code="363698007" codeSystem="2.16.840.1.113883.6.96"
           displayName="finding site"/>
          <value code="6757004" codeSystem="2.16.840.1.113883.6.96"
           displayName="right knee"/>
        </qualifier>
      </code>
    </observation>
  </entry>
</section>
```

Figure 5. An example of a more complex observation.

CDA 2 BODY EXAMPLE (3/4)

```
<section>
  <code code="10157-2" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Family history</title>
  <text>
    <list>
      <item>Father had fatal MI in 1970.</item>
      <item>No cancer or diabetes.</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="22298006" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Myocardial infarction"/>
      <effectiveTime value="1970"/>
      <subject>
        <relatedSubject classCode="PRS">
          <code code="FTH" codeSystem="2.16.840.1.113883.5.111"
           codeSystemName="PersonalRelationshipRoleType"
           displayName="Father"/>
        </relatedSubject>
      </subject>
      <entryRelationship typeCode="CAUS" contextConductionInd="true">
        <observation classCode="OBS" moodCode="EVN">
          <code code="399347008" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT" displayName="death"/>
          <effectiveTime value="1970"/>
        </observation>
      </entryRelationship>
      </observation>
  </entry>
  <entry>
    <observation classCode="OBS" moodCode="EVN" negationInd="true">
      <code code="275937001" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT"
       displayName="Family history of cancer"/>
    </observation>
  </entry>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
     <code code="160274005" codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT"
      displayName="No family history of diabetes"/>
    </observation>
  </entry>
</section>
```

FAMILY HISTORY

CDA 2 BODY EXAMPLE (4/4)

```
<section>
  <code code="101155-0" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Allergies and Adverse Reactions</title>
  <text>
    <list>
      <item>Penicillin - Hives</item>
      <item>Aspirin - Wheezing</item>
      <item>Codeine - Itching and nausea</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="247472004" codeSystem="2.16.840.1.113883.6.96"
       displayName="Hives"/>
      <entryRelationship typeCode="MFST">
        <observation classCode="OBS" moodCode="EVN">
          <code code="91936005" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT" displayName="PCN Allergy"/>
        </observation>
      </entryRelationship>
    </observation>
  </entry>
</section>
```

Figure 7. An example of allergies and adverse reactions.

```
<section>
  <text>Take captopril 25mg PO every 12 hours.</text>
  <entry>
    <substanceAdministration classCode="SBADM" moodCode="RQO">
      <effectiveTime xsi:type="PIVL_TS">
        <period value="12" unit="h"/>
      </effectiveTime>
      <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"
       codeSystemName="RouteOfAdministration"/>
      <doseQuantity value="1"/>
      <consumable>
        <manufacturedProduct>
          <manufacturedLabeledDrug>
            <code code="318821008" codeSystem="2.16.840.1.113883.6.96"
             codeSystemName="SNOMED CT"
             displayName="Captopril 25mg tablet"/>
          </manufacturedLabeledDrug>
        </manufacturedProduct>
      </consumable>
    </substanceAdministration>
  </entry>
</section>
```

Figure 8. An example of a substance administration.

CDA RENDERING (1/3)

```
************************************************************
  History of Present Illness section
************************************************************
-->
                        <component>
                                <section>
                                        <code code="10164-2"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                                        <title>History of Present Illness</title>
                                        <text>
                                                <content styleCode="Bold">Henry Levin,
the 7<sup>th</sup>
                                                </content> is a 67 year old male
referred for further asthma management. Onset of asthma in his <content
revised="delete">twenties</content>
                                                <content
revised="insert">teens</content>. He was hospitalized twice last year, and already
twice this year. He has not been able to be weaned off steroids for the past several
months.
                                        </text>
                                </section>
                        </component>
                        <!--
************************************************************
  Past Medical History section
************************************************************
-->
                        <component>
                                <section>
```

Source: From "What is CDA R2? by Calvin E. Beebe at HL7 Educational Summit in July 2012

CDA RENDERING (2/3)

Good Health Clinic Consultation Note

Patient: Henry Levin , the 7th
Birthdate: September 24, 1932
Consultant: Robert Dolin , MD

MRN: 12345
Sex: Male
Created On: April 7, 2000

History of Present Illness

Henry Levin, the 7th is a 67 year old male referred for further asthma management. Onset of asthma in his teens. He was hospitalized twice last year, and already twice this year. He has not been able to be weaned off steroids for the past several months.

Past Medical History

- Asthma
- Hypertension (see HTN.cda for details)
- Osteoarthritis, right knee

Medications

- Theodur 200mg BID
- Proventil inhaler 2puffs QID PRN

Source: From "What is CDA R2? by Calvin E. Beebe at HL7 Educational Summit in July 2012

CDA RENDERING (3/3)

- Different recipients may use different style sheets to render the same CDA document, and thus may display it differently (but the same content is presented)
- This can help facilitate display of CDA documents with specific preferences or local requirements

CDA TEMPLATES

- Templates and/or implementation guides can be used to constrain the CDA specification within a particular implementation and to provide validating rule sets that check conformance to these constraints.
- Templates → formal definition of a set of constraints on the model
- Templates are set of instructions for a CDA instance of a particular use case

- A template has two parts
  - Metadata → identifier, version, description, etc
  - Body → actual constraints

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379