

# ISO EN 13606 TECHNICAL REVISION

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# EN ISO 13606

## EHR Communications

- \* A means to exchange part or all of a patients EHR
  - \* *between heterogeneous systems*
  - \* *within a federation of distributed EHR systems*



# The 5 parts of EN ISO 13606

- \* Part 1: Reference Model

- \* *comprehensive, generic model for communicating part or all of an EHR*

- \* Part 2: Archetype Specification

- \* *constraint-based approach for defining clinical models that are built from the Reference Model - adopted from openEHR*

- \* Part 3: Reference Archetypes and Term Lists

- \* *initial set of archetypes mapping to other relevant standards*
  - \* *vocabularies for the Part 1 model*

- \* Part 4: Security

- \* *measures to support access control, consent and auditability of EHR communications*

- \* Part 5: Interface specification

- \* *message and service interfaces to enable EHR and archetype communication*



# Key points about the revision

- \* All five parts being revised together
- \* No change in scope for any of the parts
- \* Need to work out concurrent use with some (newer) standards e.g. Requirements 18308, 10781), ContSys, HISA, DCM, Purposes of use...
- \* Part 1: modify data types to align with ISO 21090, determine what alignment is appropriate with HL7 CDA, openEHR
- \* Part 2: determine best course of action on ADL (version 1.5?), determine what alignment is appropriate with CIMI
- \* Part 3: determine what archetype / DCM patterns to include
- \* Part 4: target an IS and not a TC (note: it is an EN)



# ISO 18308 EHR architecture requirements

ISO/TS 18308

**4 EHR ARCHITECTURAL REQUIREMENTS .....**

**4.1 BUSINESS REQUIREMENTS .....**

    4.1.1 *Health system requirements .....*

    4.1.2 *Clinical practice requirements .....*

    4.1.3 *Citizen inclusion requirements .....*

**4.2 REQUIREMENTS FOR THE REPRESENTATION OF CLINICAL INFORMATION .....**

    4.2.1 *Kinds of health record entries .....*

    4.2.2 *Structure of health record entries .....*

    4.2.3 *The representation of context within health record entries .....*

    4.2.4 *Intra-record links .....*

    4.2.5 *The representation of data values within health record entries .....*

    4.2.6 *EHR data retrieval and views .....*

    4.2.7 *Representation and support of clinical process and workflow .....*

**4.3 COMMUNICATION AND INTEROPERABILITY REQUIREMENTS .....**

**4.4 ETHICAL AND LEGAL REQUIREMENTS .....**

    4.4.1 *Support for legal requirements .....*

    4.4.2 *Subject of care .....*

    4.4.3 *Identification and authentication .....*

    4.4.4 *Health care locations .....*

    4.4.5 *Dates and times .....*

    4.4.6 *Version management .....*

**4.5 CONFIDENTIALITY REQUIREMENTS .....**

    3.40.1 *Subject access .....*

    3.40.2 *Access policies .....*

    3.40.3 *Policy over-ride .....*

    3.40.4 *Audit trails .....*

    3.40.5 *Consents .....*

The EHR shall preserve any explicitly defined relationships between different parts of the record, such as links between treatments and subsequent complications and outcomes.

The EHR shall preserve the original data values within an EHR entry including code systems and measurement units used at the time the data were originally committed to an EHR system.

The EHR shall be able to include the values of reference ranges used to interpret particular data values.

The EHR shall be able to represent or reference the calculations, and/or formula(e) by which data have been derived.

The EHR architecture shall enable the retrieval of part or all of the information in the EHR that was present at any particular historic date and time.

The EHR shall enable the maintenance of an audit trail of the creation of, amendment of, and access to health record entries.

Requirements for an Electronic Health Record

This document is not an ISO International Standard without notice and may not be referred to as an International Standard.

Recipients of this document are invited to submit comments to the ISO Central Secretariat, which they are aware and to provide supporting comments.

Document type: Technical Specification  
Document subtype:  
Document stage: Final Draft  
Document language: E



# Contextual building blocks of the EHR

## EHR Extract

Part or all of the electronic health record for one person, being communicated

## Folders

High-level organisation of the EHR  
e.g. per episode, per clinical speciality

## Compositions

Set of entries comprising a clinical care session or document e.g. test result, letter

## Sections

Headings reflecting the flow of information gathering, or organising data for readability

## Entries

Clinical “statements” about Observations, Evaluations, and Instructions

## Clusters

Multipart entries, tables, time series,  
e.g. test batteries, blood pressure, blood count

## Elements

Element entries: leaf nodes with values  
e.g. reason for encounter, body weight

## Data values

Date types for instance values  
e.g. coded terms, measurements with units



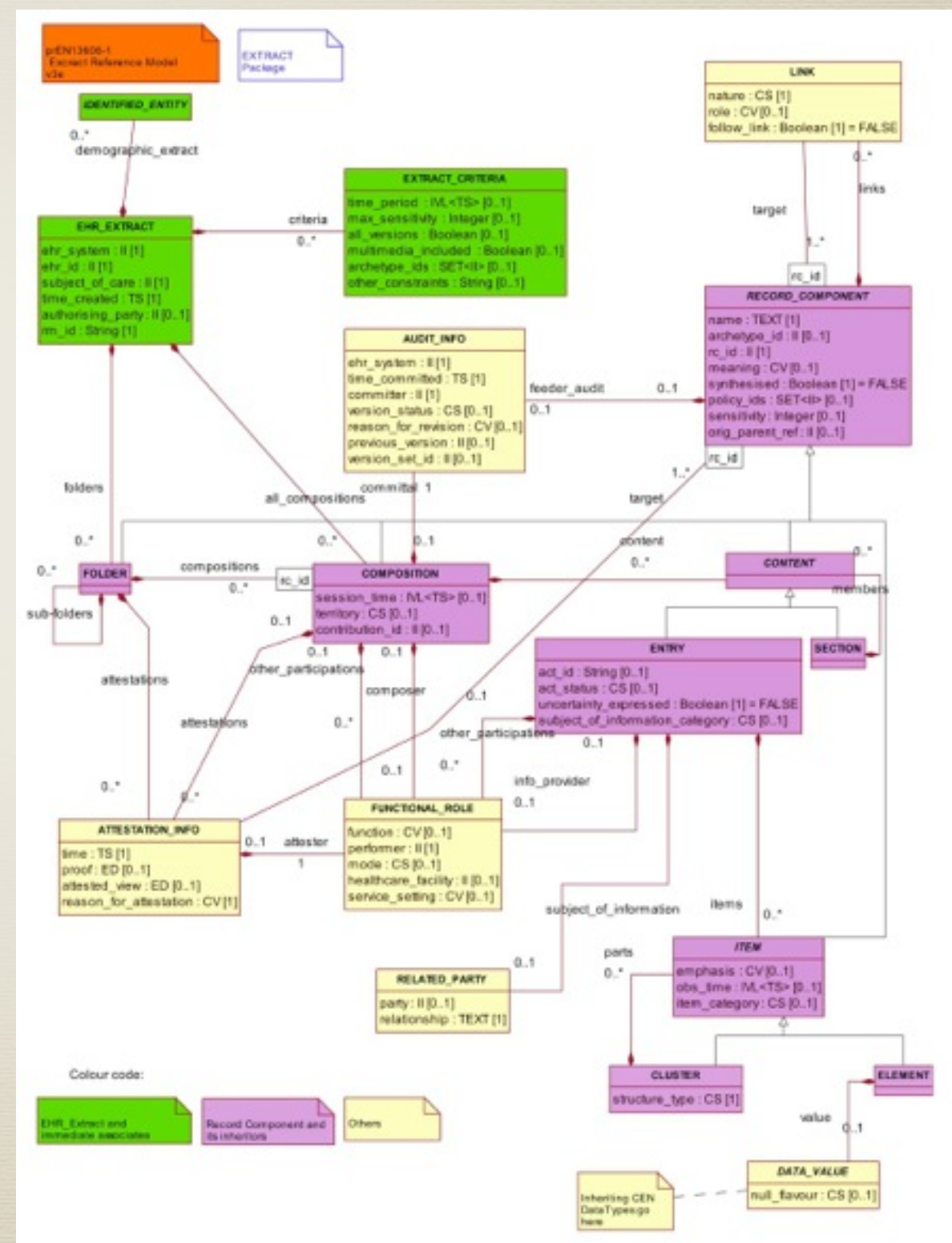
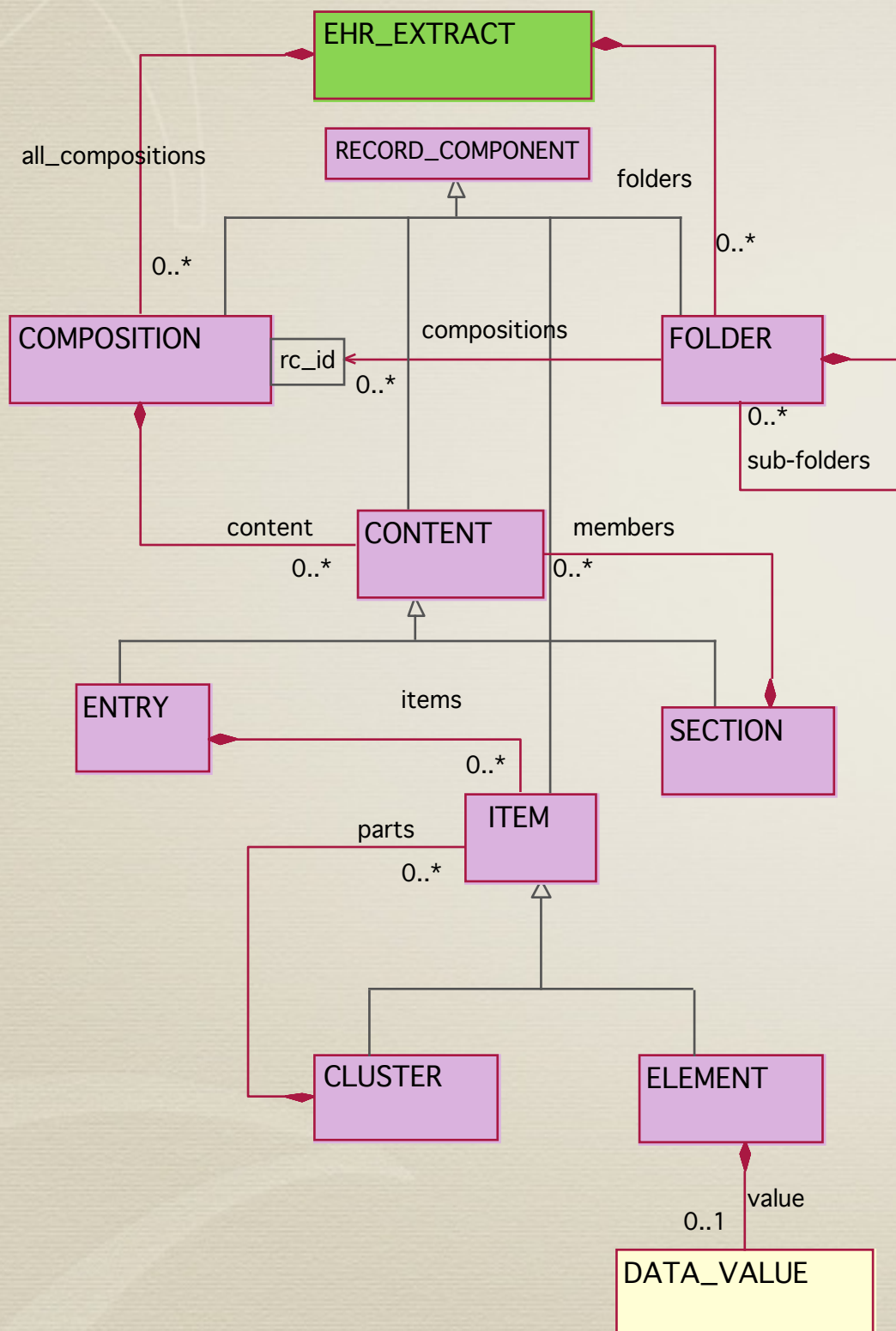
# Core properties of the EHR Reference Model

- \* the compositional record hierarchy e.g. the document level, headings and the structure of finer grained entries
- \* the representation of persons, such as the record subject, authorship, signatories, information providers
- \* the definition of dates and times, both real world times when events occurred and the time-stamping of when details were recorded
- \* instance identifiers and version management properties
- \* data types to represent coded terms, quantities, dates and times, images etc. consistently
- \* a role based access control approach, supporting jurisdictional profiles of these

but, deliberately, no clinical domain knowledge



# Part 1 Extract





# Key proposed changes (1/2)

- \* Remove EXTACT\_CRITERIA - not needed
- \* Replace sub-Folder nesting with a tag property for FOLDER, data type CD
- \* Remove name: no longer variable to share EHR data with free text node names (make meaning mandatory, so that whether archetypes are used or not the coded node name is always provided)
- \* Remove contribution\_id - does not correspond to information in source systems
- \* Remove synthesised
- \* Remove uncertainty\_expressed
- \* Remove act\_id
- \* Remove structure\_type
- \* Remove: original\_parent\_ref (replace with LINK terms: copied\_from and copied\_to)
- \* Move null\_flavour to ELEMENT
- \* Add subject of care identifier to COMPOSITION, in case the model is later used for multi-patient records (e.g. family records)
- \* Make LINK target association 1:1 instead of 1:\* , to make implementation easier
- \* Remove follow\_link - not practical to implement, not used in source systems

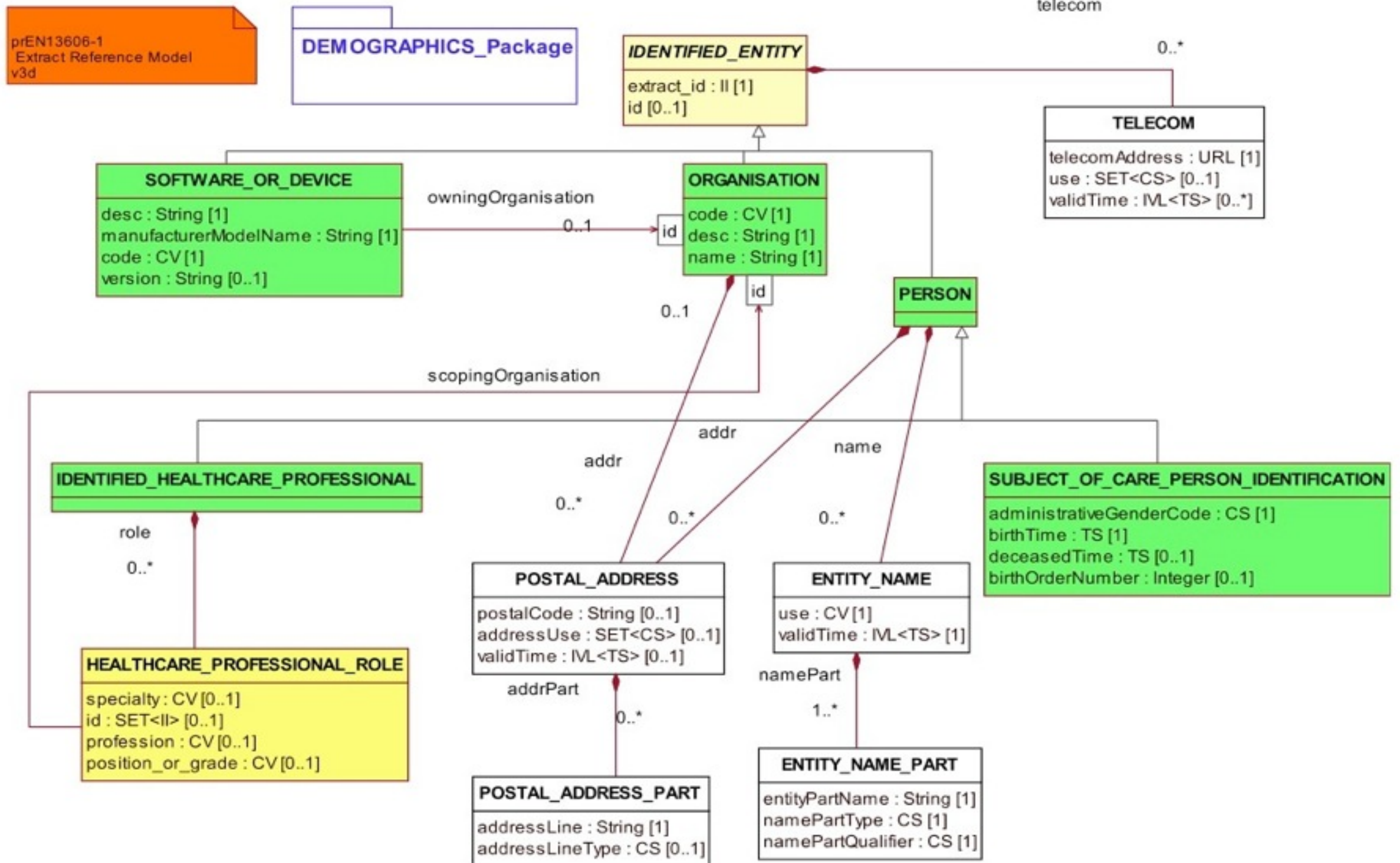


# Key proposed changes (1/2)

- \* Discuss if LINK source and target should be limited to ENTRY and above in the model
- \* Broaden containment of ATTESTATION\_INFO to any RECORD\_COMPONENT
- \* Discuss how to use ATTESTATION\_INFO, to communicate digitally signed data
- \* Discuss removing feeder\_audit association, or remove the committal association
- \* Discuss location of session\_time: COMPOSITION and ENTRY?
- \* Discuss moving sensitivity to COMPOSITION, to avoid multi-sensitivity documents which make communication and revision very difficult to manage safely
- \* Discuss if policy\_ids should be removed (but how else to model “sticky policies”?)
- \* Discuss if we should merge the FunctionalRole and RelatedParty classes?
- \* Re-examine the values needed for the function property



# Part 1 Demographics



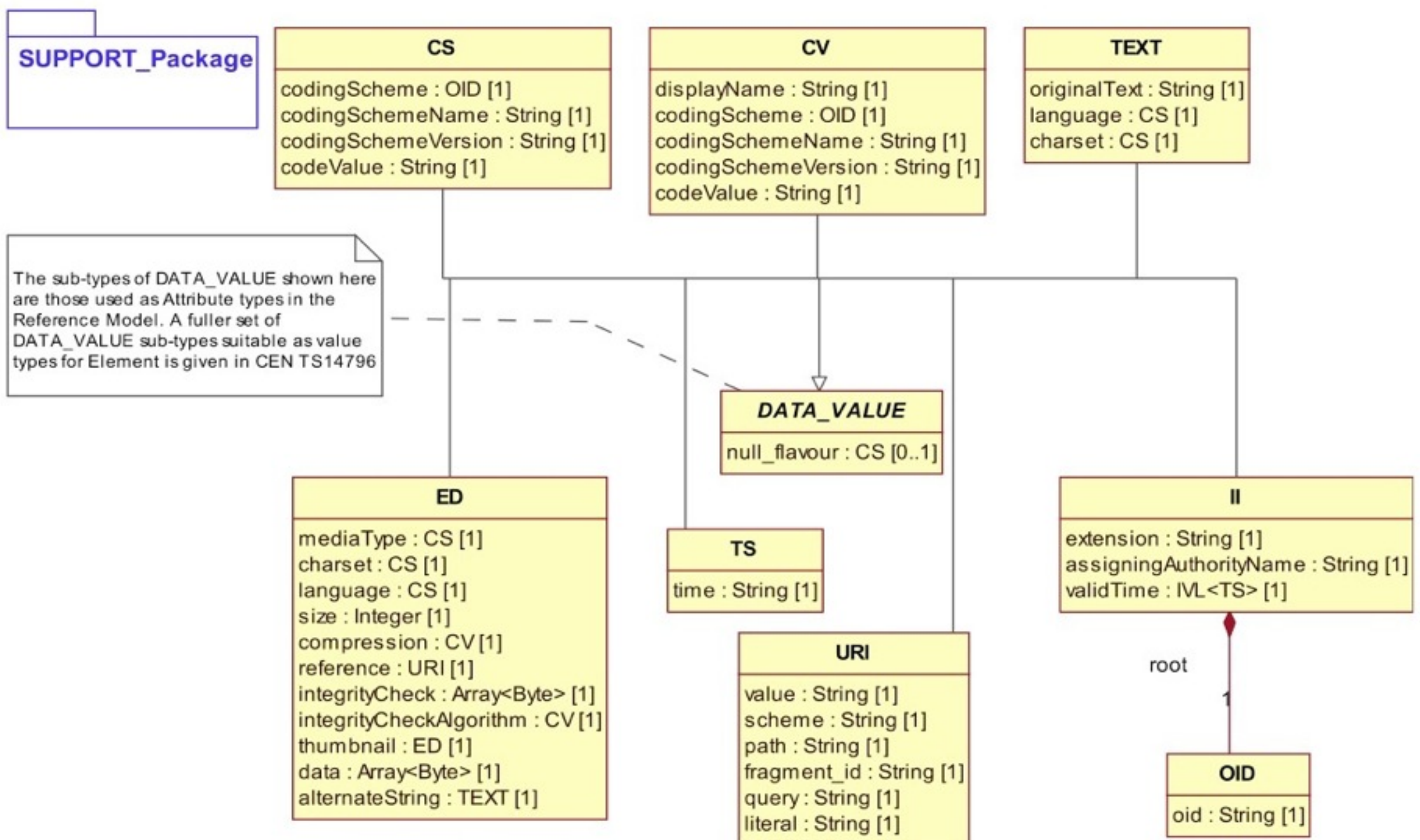


# Demographics

- \* Originally based on the CEN HL7 GPIC standard
- \* Some refactoring of this model was desirable to respondents, but differences in suggested approach
- \* Not good enough to represent roles and relationships: needs to be richer
- \* “The separation of clinical and demographic data must be preserved, to ease the anonymisation of EHR Extracts.” - Spain
- \* Include a subject of care identifier at Composition level, to cater for multi-patient extracts
- \* “Remove demographic model and represent as semantic patterns in Part 3.” - Netherlands

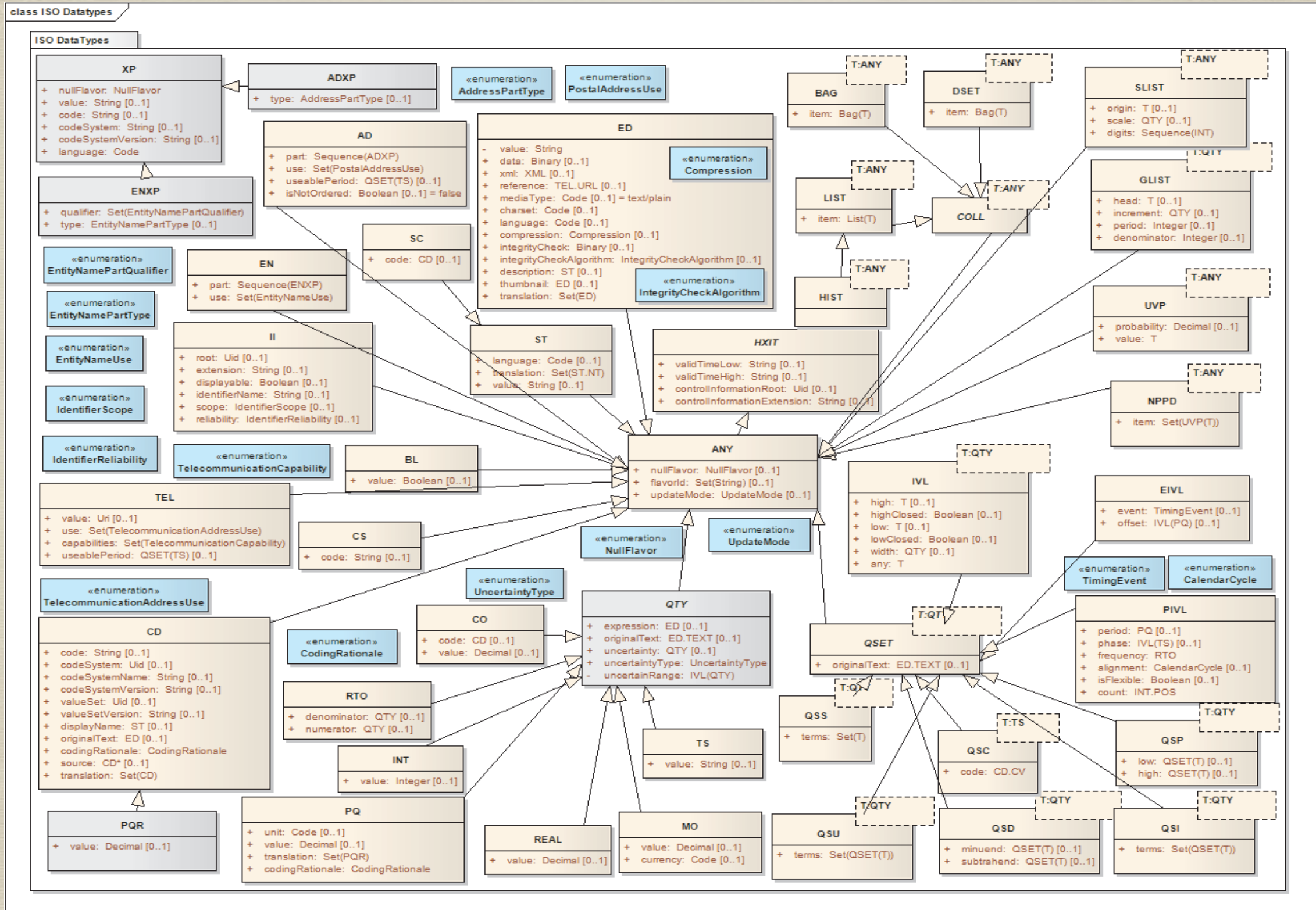


# Part 1 Data Types





# ISO 21090 Data Types



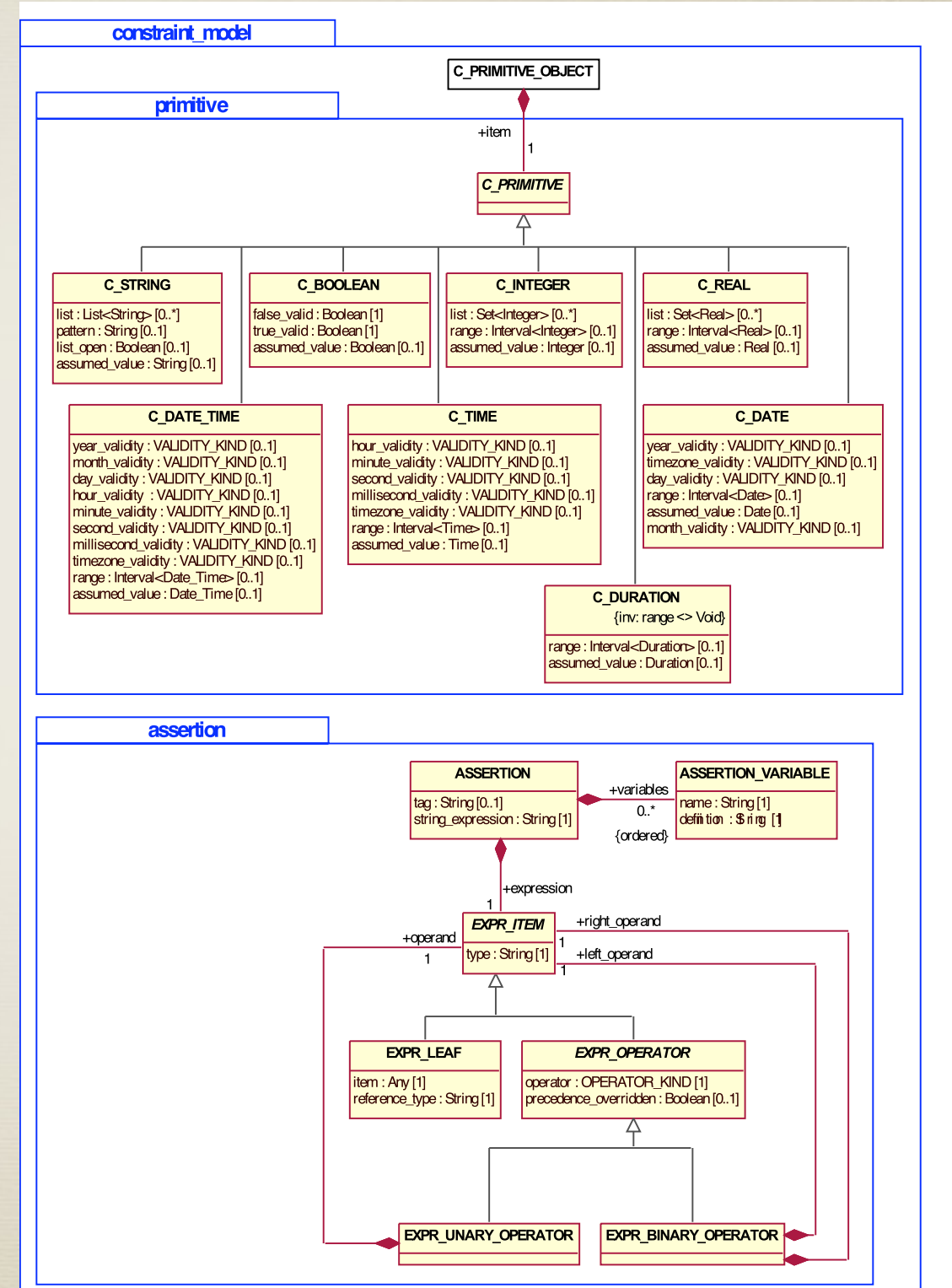
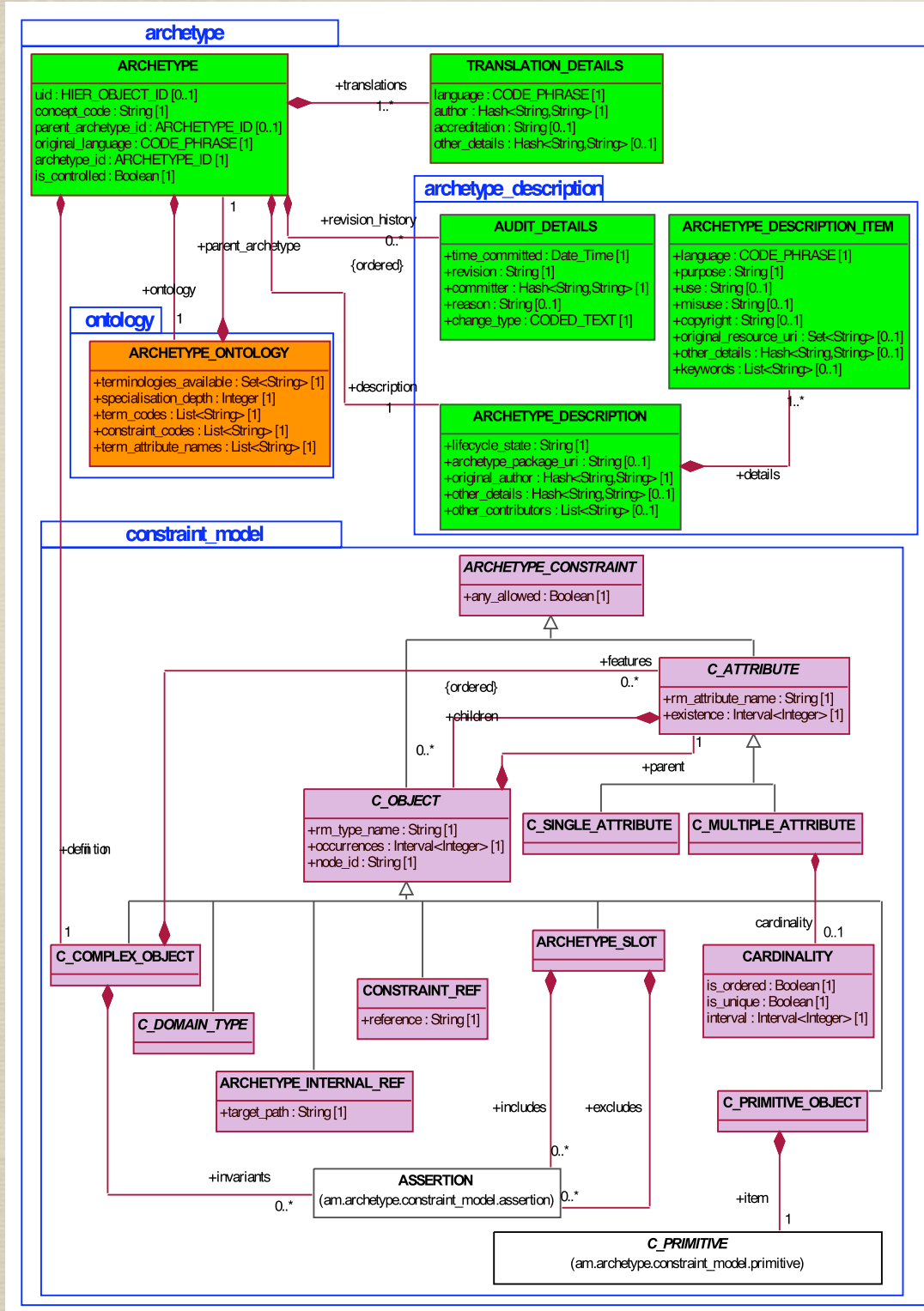


# Data Types

- \* *“The usage of standard data types is a critical issue that is not solved by using the new ISO 21090 standard.” - Germany*
- \* *“Add an implementable profile of 21090 data types...” - Netherlands*
- \* *“Unfortunately the ISO replacement is excessively large and does not recognise features already provided in the ISO EN-13606 extract model.” - GB*
- \* *“About practical deployment the profile about the ISO21090 was highly beneficial.” - Spain*



# Part 2





# Part 2 - general comments

- \* No conformance clause
- \* Archetype requirements useful but statements should all be independent of the model
- \* Better define archetype metadata (requirements)
- \* AOM complex, hard to understand, but some feedback that it is important to retain
- \* Would like to also use archetypes in XML, semantic web
- \* Limited usable content: need many many more archetypes before an archetype approach can be widely adopted



# Archetype Object Model

- \* Maybe many classes not needed as only constraining one RM - relationship between Parts 1 and 2 not clear
- \* Archetype id syntax needs to be clarified
- \* Concern about uniqueness of AT codes when archetypes are embedded in other archetypes
- \* "Ontology" section not helpful: use a CTS2 like approach for terminology binding



# ADL

- \* Less confidence in retaining ADL in particular
  - \* *“Update AOM/ADL 1.4 if needed.” - Netherlands*
  - \* *“...the main new features of ADL 1.5 such as groups and the new specialisation semantics should be rejected.” - Spain*
  - \* *“The whole structure of ADL is implemented and practiced [by us] using Java Technology. The Archetype structure can be parsed into XML-based structure...” - Iran*
  - \* *“ADL does not have a canonical (unique) representation and therefore it is even impossible to decide about two ADL specifications.” - Germany*
  - \* *“[We recommend] being able to work with archetypes in XML format.” - Spain*
  - \* *“[Feels strongly about retaining] AOM and the ADL formalism.” - Brazil*



# Part 3

- \* **SUBJECT\_CATEGORY:** ENTRY.subject\_of\_information\_category
- \* **ITEM\_CATEGORY:** ITEM.item\_category
- \* **VERSION\_STATUS:** AUDIT\_INFO.version\_status
- \* **MODE:** FUNCTIONAL\_ROLE.mode
- \* **ACT\_STATUS:** ENTRY.act\_status
- \* **STRUCTURE\_TYPE:** CLUSTER.structure\_type
- \* **LINK\_NATURE:** LINK.nature
- \* **LINK\_ROLE:** Optional term list for LINK attribute



# Part 3

- \* “On several occasions in the standard a code is described as having a CS type but only two of the four necessary parts of the CS are provided by part 3 (and part 4). This is usually a value and a human-readable portion.” - GB
- \* “The terminological tables cannot be referenced properly from the reference model data instances due to the lack of an OID identifier of Part 2.” - Spain
- \* STRUCTURE\_TYPE redundant?
  - \* *“The set of contents of a CLUSTER howsoever transmitted amounts to a list in any case and on that basis a table would simply be a repetition of it and a tree a nested repetition.” - GB*
- \* Reason for revision should be extended to cater for code mapping versions of a document: "derived"



# Part 3 - semantic patterns

- \* Better mapping support is needed to openEHR and to CDA - maybe move to a separate technical annex, or publish separately (for easier maintenance)
- \* Add semantic patterns, e.g. from CIMI that provide high level base patterns for archetypes



# Part 4

Functional role	RECORD_COMPONENT sensitivity				
	Care management	Clinical management	Clinical care	Privileged care	Personal care
Subject of care	Y	Y	Y	Y	Y
Subject of care agent	Y	Y	Y	Y	Y
Personal healthcare professional	Y	Y	Y	Y	Y
Privileged healthcare professional	Y	Y	Y	Y+	++
Healthcare professional	Y	Y	Y	—	—
Health-related professional	Y	Y	—	—	—
Administrator	Y	—	—	—	—

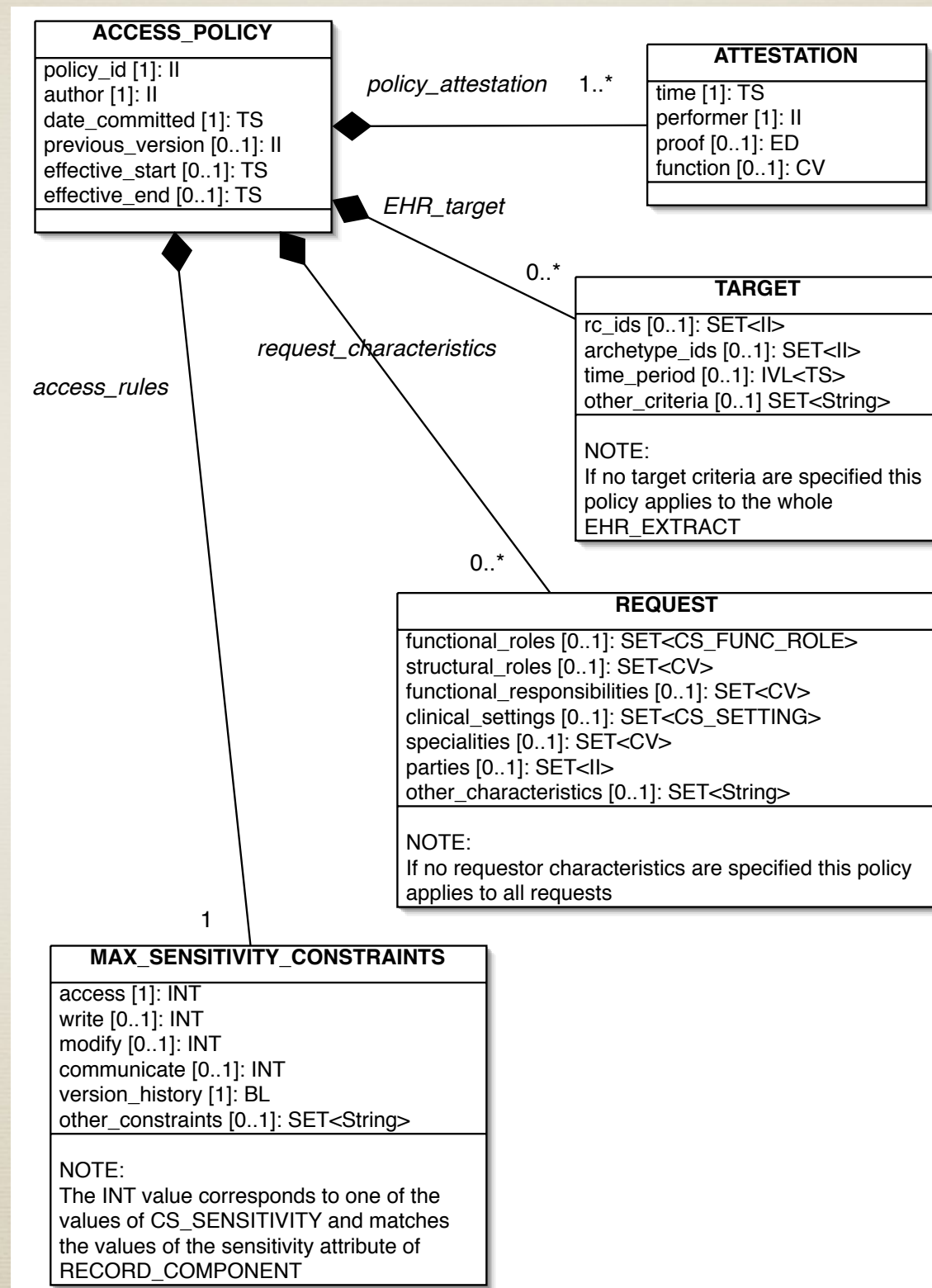
Y Indicates that access will be granted to RECORD\_COMPONENTs of this sensitivity unless otherwise dictated by other policy constraints, as specified according to Clause 7.

+ Indicates that access will be granted if the EHR recipient is a member of the same speciality or clinical service as that in which the RECORD\_COMPONENT was created, e.g. sexual health clinic, prison health service [as specified in the service\_setting attribute for the composer of the COMPOSITION in the reference model (ISO 13606-1)]. This access may also be granted in healthcare emergency situations if so authorized.

++ Indicates that access to personal care information may sometimes be granted by mandate to privileged healthcare professionals in some care settings, such as in the armed forces of some countries.



# Part 4





# Part 5 - general comments

- \* Overlaps with distributed computing technical architectures: how much of the content is really needed
- \* Interface better with IHE (XDS profile?), WSDL
- \* Should support archetype based queries
- \* Not clear if the Request Archetypes interface is needed
- \* Not clear how to establish conformance
- \* Needs APIs for clinical research scenarios, more query options
- \* Support EHR updates and deletions