Model-Driven Health Tools (MDHT)
CDA Tools Overview

http://mdht.projects.openhealthtools.org

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CDA Tools Objectives

- Accelerate and lower cost of adopting CDAr2 standard
- Define new CDA templates and implementation guides in UML
- Complete MDA lifecycle from UML to Java code
- Open source reference implementation with EPL license

- Author template constraints and implementation guides (IG)
  - UML structure and OCL constraints
- Reuse templates
  - As parent template with additional constraints
  - Include within new document or section templates
- Generate complete application-ready Java libraries
- Generate IG specification documentation (future)

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Generate Java APIs for CDA

- Transform UML and OCL to EMF Ecore models
- Generate complete application-ready Java libraries
  - Generate developer-friendly, domain-specific Java APIs
  - Design simplified “façade” API for application use cases
- Programmatic creation of CDA documents that conform to IG templates
  - e.g., EMR system adapters that export or import CDA
- Save CDA XML document
  - Template Java class (CCD ProblemAct) mapped to templateId via registry
- Parse/load CDA documents
  - templateId mapped to Java class, e.g. ProblemObservation, Medication
- Validate CDA document for template compliance
  - Goal: complete validation via Java, generated from UML, equivalent to current NIST schematron rules

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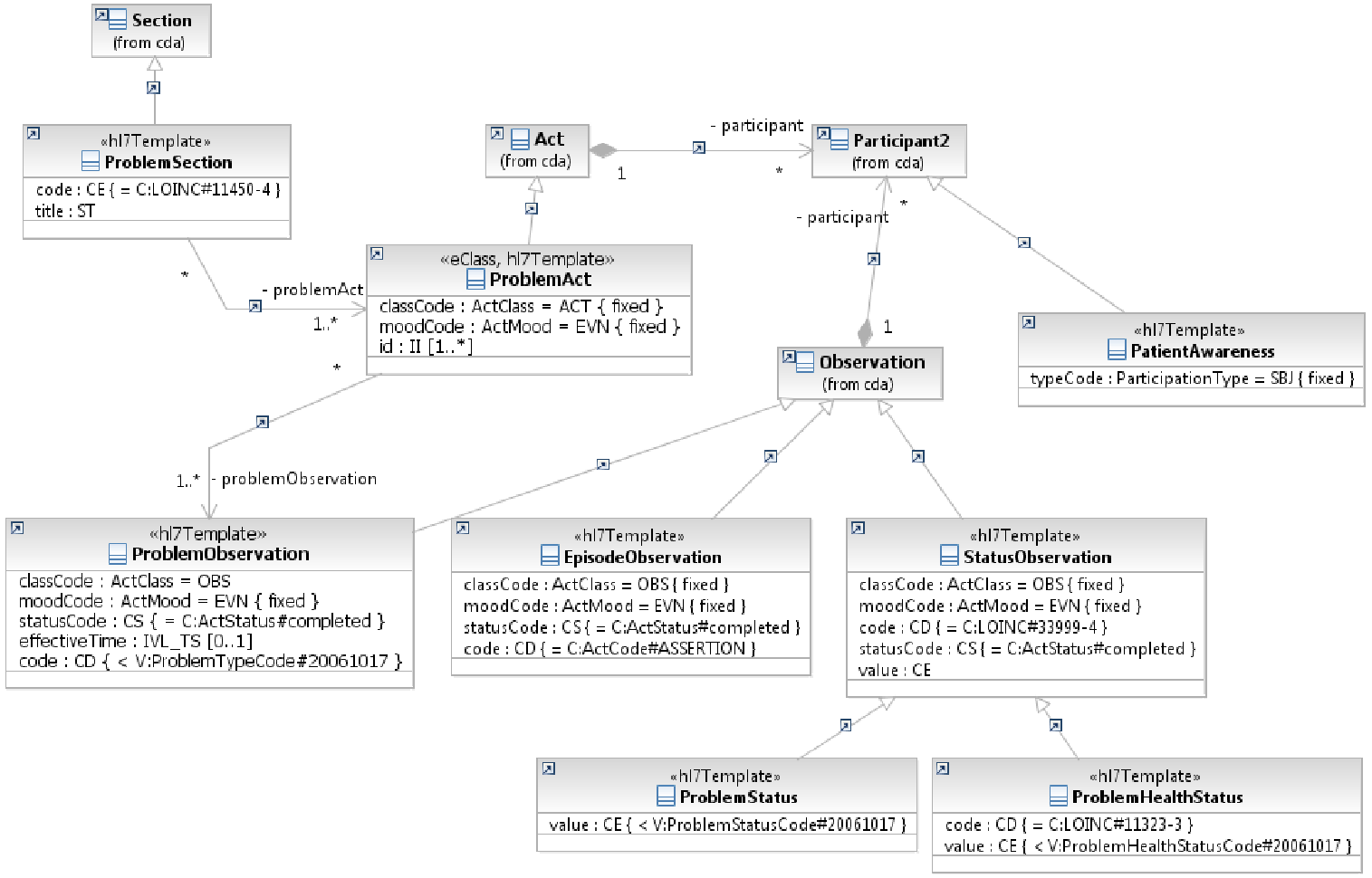
CCD Template Model for Problems Section



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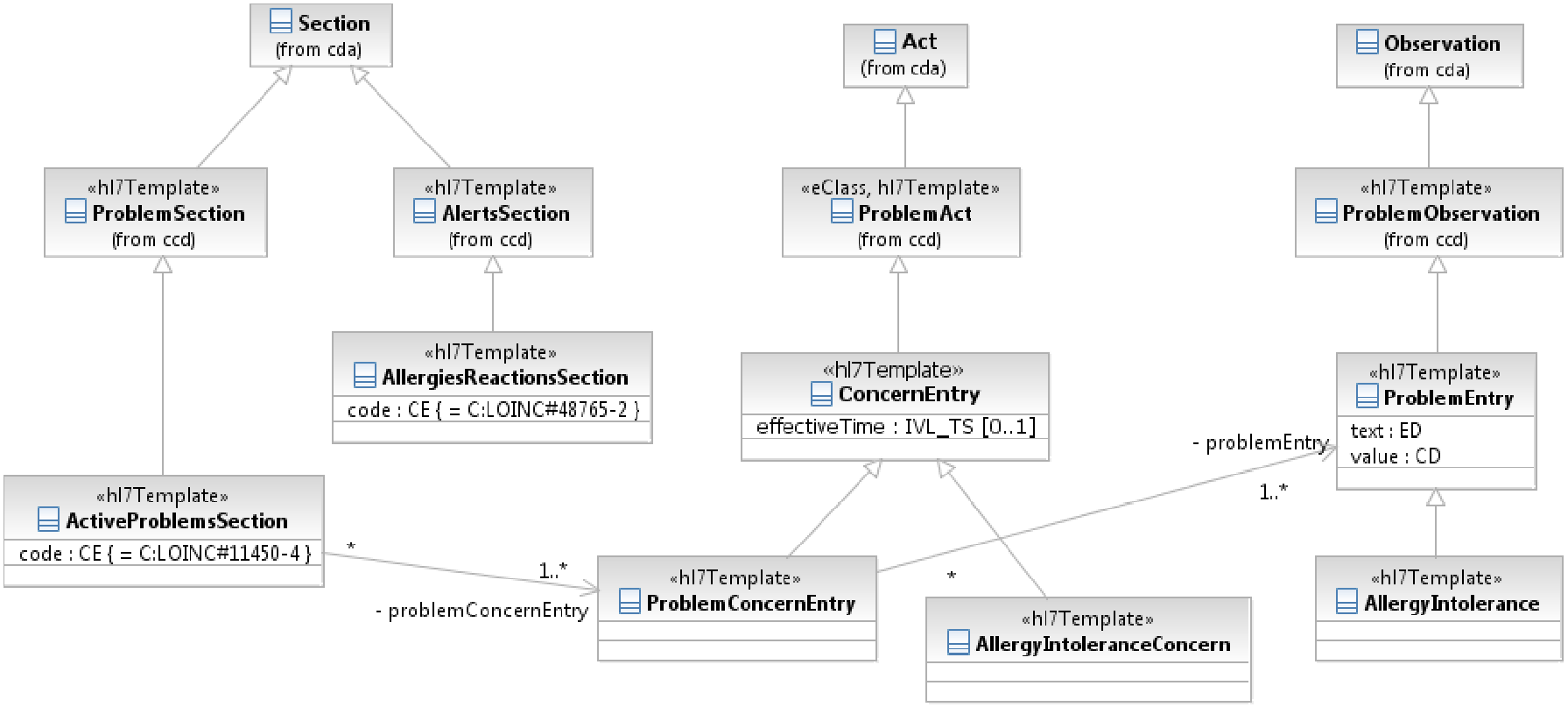
IHE Template Model (subset)



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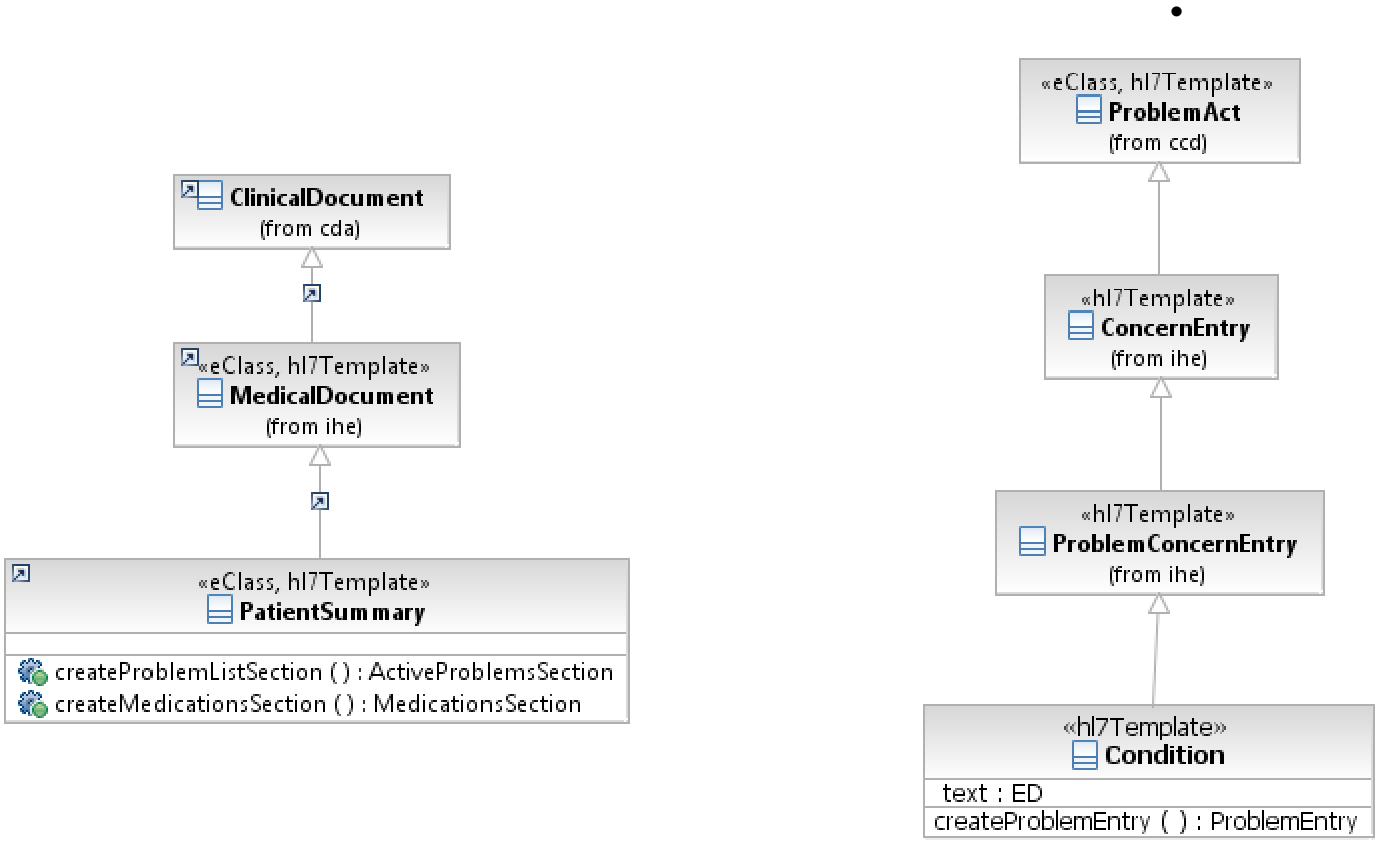
HITSP Template Model (C32 and C83)



Domain Specific Java APIs for Templates

```
PatientSummary doc = HitspFactory.eINSTANCE.createPatientSummary().init();
II id = DatatypesFactory.eINSTANCE.createII("2.16.840.1.113883.3.72",
                    "CCD_HITSP_C32v2.4_16SectionsWithEntries_Rev6_Notes");
doc.setId(id);

ActiveProblemsSection problemList = doc.createProblemListSection();

Condition condition = HitspFactory.eINSTANCE.createCondition().init();
problemList.addAct(condition);

ProblemObservation obs =
    CCDFactory.eINSTANCE.createProblemObservation().init();
condition.addObservation(obs);

ProblemHealthStatus healthStatus =
    CCDFactory.eINSTANCE.createProblemHealthStatus().init();
obs.addObservation(healthStatus);
CE healthStatusValue = DatatypesFactory.eINSTANCE.createCE("xyz",
    "2.16.840.1.113883.1.11.20.12", "ProblemHealthStatusCode", null);
healthStatus.getValue().add(healthStatusValue);
```

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MDHT Project Benefits for CDA

- Standards organizations
  - Formalize representation of CDA implementation guide conformance rules
    - Replace current practice of using MS Word for specification development
    - UML specification is testable for consistency and use of best practices
    - Enables automated model-driven development and code-generation
  - Automate publication of implementation guides in multiple formats (PDF and XHTML) and alternative content structure (ballot document vs. implementer view)
  - Automate generation of CDA instance validator from specification model (using Java and OCL)
- Business Analysts
  - Consistent format of published implementation guide between different standards organizations (HL7, IHE, and HITSP)
  - Cross-referenced, hyperlinked reference material accelerates analysis and EHR mapping
  - Publish a “developer view” of implementation guide that combines conformance rules from all inherited templates and base CDA type
- Java Implementers
  - Reduce Development Cost: Time and resources for analysis and implementation of CDA content and conformance rules
  - Reduce Maintenance Cost: High quality, domain-specific API for programmatic access to CDA content, and validating conformance with standard implementation guide rules (e.g. CCD and HITSP C32/C83)
  - Future support possible for non-Java implementation languages

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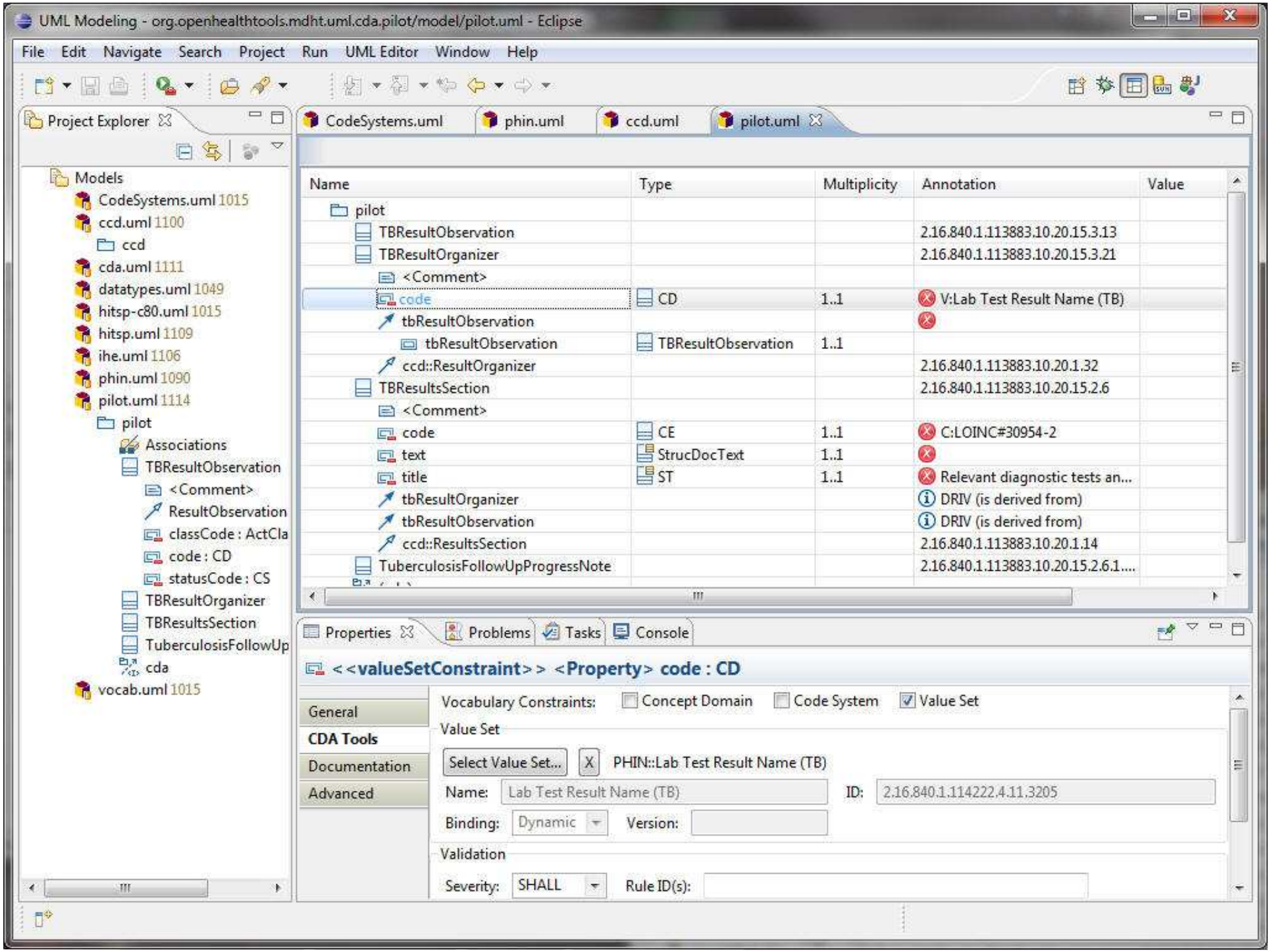
Authoring CDA Templates

- We created a UML class for each template and specified all conformance rules using property redefinitions, directed associations, or using OCL expressions (for only one rule).
- We found that the most intuitive and efficient editor for template definitions is a spreadsheet-style table editor. This editor directly modifies the underlying UML model, but with a different interface from the typical class diagram.
- UML class diagrams may also be created as views of the model, or used as an alternative design interface.

- A separate model was created for CCD, and those template classes were referenced as base types in a new implementation guide model: the Tuberculosis follow up progress note


UML Modeling - org.openhealthtools.mdht.uml.cda.pilot/model/pilot.uml - Eclipse
File Edit Navigate Search Project Run UML Editor Window Help
Project Explorer
Models
CodeSystems.uml 1015
ccd.uml 1100
ccd
cda.uml 1111
datatypes.uml 1049
hitsp-c80.uml 1015
hitsp.uml 1109
ihe.uml 1106
phin.uml 1090
pilot.uml 1114
pilot
Associations
TBResultObservation
<Comment>
ResultObservation
classCode : ActCla
code : CD
statusCode : CS
TBResultOrganizer
TBResultsSection
TuberculosisFollowUp
cda
vocab.uml 1015
CodeSystems.uml
phin.uml
ccd.uml
pilot.uml
Name
Type
Multiplicity
Annotation
Value
pilot
TBResultObservation
2.16.840.1.113883.10.20.15.3.13
TBResultOrganizer
2.16.840.1.113883.10.20.15.3.21
<Comment>
code
CD
1..1
V:Lab Test Result Name (TB)
tbResultObservation
tbResultObservation
TBResultObservation
1..1
ccd::ResultOrganizer
2.16.840.1.113883.10.20.1.32
TBResultsSection
2.16.840.1.113883.10.20.15.2.6
<Comment>
code
CE
1..1
C:LOINC#30954-2
text
StrucDocText
1..1
title
ST
1..1
Relevant diagnostic tests an...
tbResultOrganizer
DRIV (is derived from)
tbResultObservation
DRIV (is derived from)
ccd::ResultsSection
2.16.840.1.113883.10.20.1.14
TuberculosisFollowUpProgressNote
2.16.840.1.113883.10.20.15.2.6.1....
Properties
Problems
Tasks
Console
<<valueSetConstraint>> <Property> code : CD
General
CDA Tools
Documentation
Advanced
Vocabulary Constraints:
Concept Domain
Code System
Value Set
Value Set
Select Value Set...
X
PHIN::Lab Test Result Name (TB)
Name:
Lab Test Result Name (TB)
ID:
2.16.840.1.114222.4.11.3205
Binding:
Dynamic
Version:
Validation
Severity:
SHALL
Rule ID(s):

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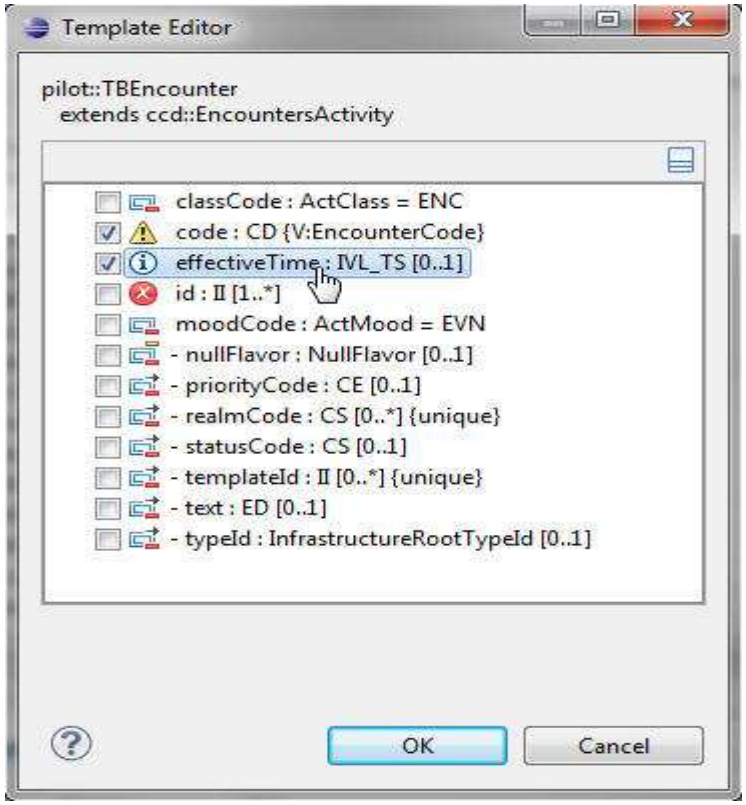
Add a new Template



- **Easy reuse and reference to templates in other IG models.**
- **Dialog wizard to create a new template that conforms to another base template.**
- **For example:**
  - **Add: TB Encounter**
  - **Select base: CCD Encounters Activity**
  - **Check off inherited attributes that will be restricted**
  - **Then use Table editor to refine the new constraints.**

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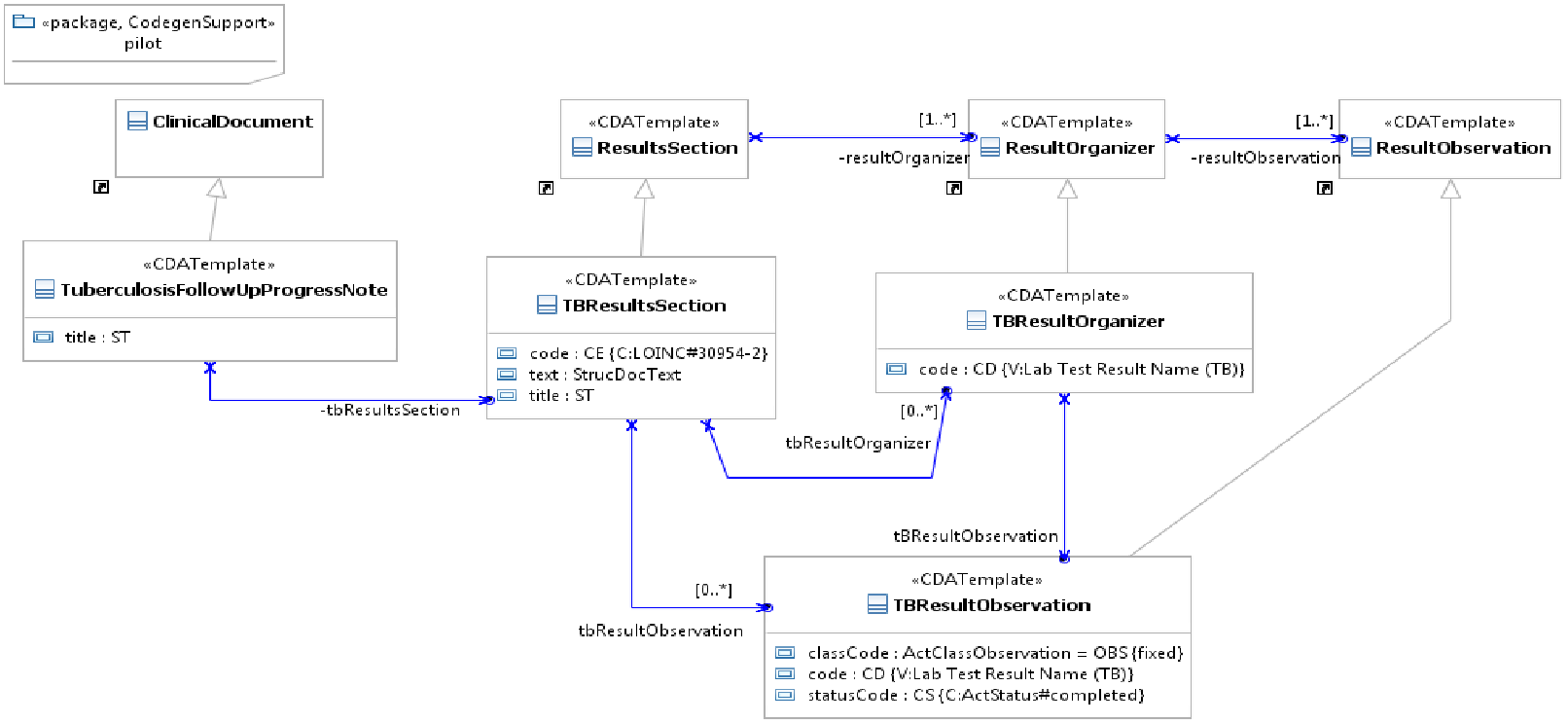
Class Diagrams

We are working on integrating an open source UML class diagram editor provided by the Eclipse UML2Tools project, but it is not yet ready for end-users. When templates are created using the table editor, one or more class diagrams may be created as views of the model.



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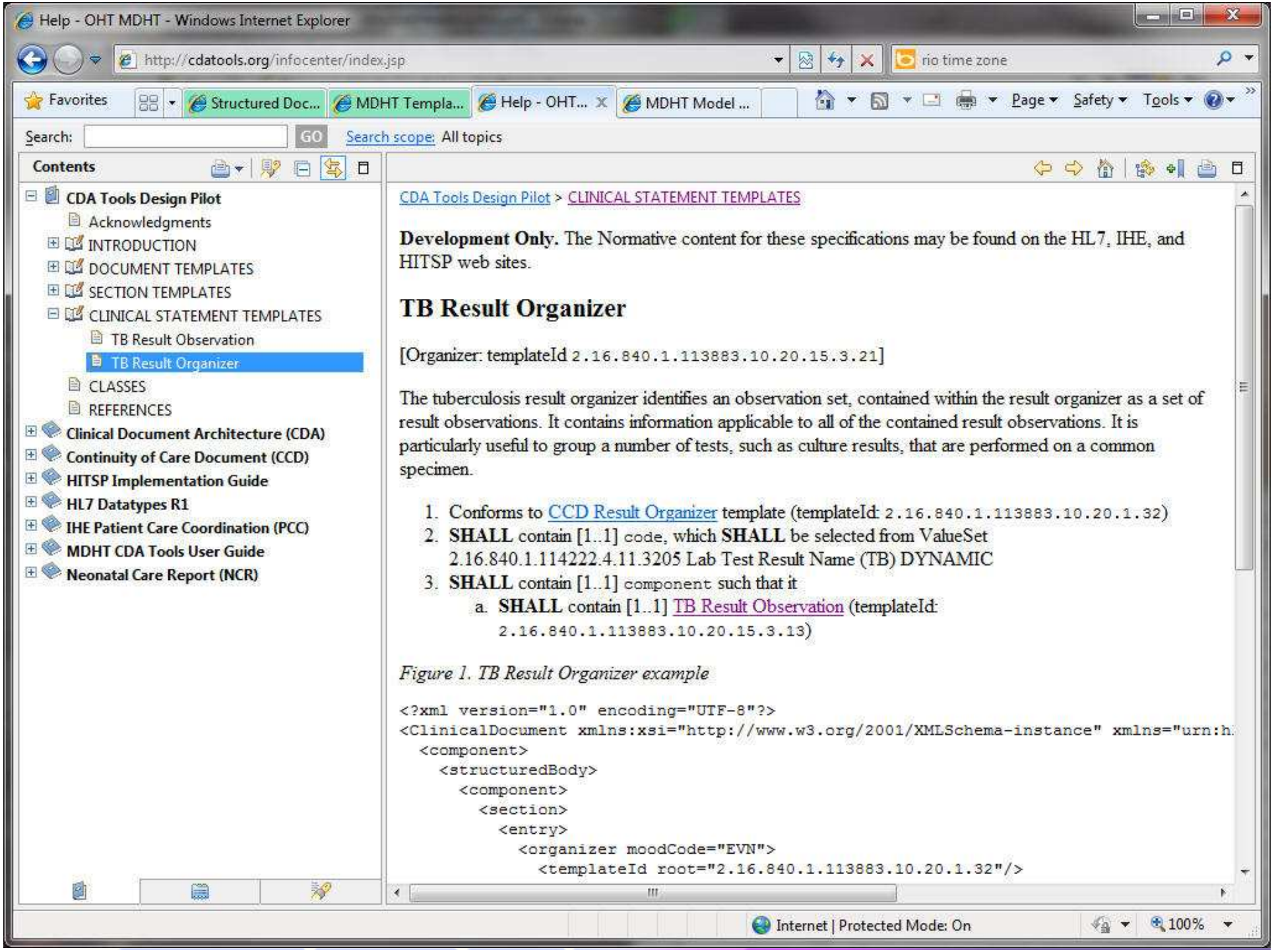
Publishing IGs

- The UML model created with template definitions is automatically transformed to DITA XML (OASIS standard), which is then published to PDF and Eclipse Help HTML format using the open source DITA-OT toolkit.
- Automatic generation of example XML instance snippets for each template, included in the published IG.

- Separate developer documentation: Includes the complete aggregate list of all inherited elements and conformance rules. Thus, a developer does not need to "follow the breadcrumbs" of template conformance references. Example provided in PDF output.


Help - OHT MDHT - Windows Internet Explorer
http://cdatools.org/infocenter/index.jsp
rio time zone
Favorites
Structured Doc...
MDHT Templa...
Help - OHT...
MDHT Model ...
Page
Safety
Tools
Search:
GO
Search scope: All topics
Contents
CDA Tools Design Pilot
Acknowledgments
INTRODUCTION
DOCUMENT TEMPLATES
SECTION TEMPLATES
CLINICAL STATEMENT TEMPLATES
TB Result Observation
TB Result Organizer
CLASSES
REFERENCES
Clinical Document Architecture (CDA)
Continuity of Care Document (CCD)
HITSP Implementation Guide
HL7 Datatypes R1
IHE Patient Care Coordination (PCC)
MDHT CDA Tools User Guide
Neonatal Care Report (NCR)
CDA Tools Design Pilot > CLINICAL STATEMENT TEMPLATES
Development Only. The Normative content for these specifications may be found on the HL7, IHE, and HITSP web sites.
TB Result Organizer
[Organizer: templateId 2.16.840.1.113883.10.20.15.3.21]
The tuberculosis result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen.
1. Conforms to CCD Result Organizer template (templateId: 2.16.840.1.113883.10.20.1.32)
2. SHALL contain [1..1] code, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
3. SHALL contain [1..1] component such that it
a. SHALL contain [1..1] TB Result Observation (templateId: 2.16.840.1.113883.10.20.15.3.13)
Figure 1. TB Result Organizer example
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h
<component>
<structuredBody>
<component>
<section>
<entry>
<organizer moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.1.32"/>
Internet | Protected Mode: On
100%

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Generate XML Example

Figure 1. TB Result Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.21"/>
              <id root="35428f7f-f994-44e4-a83c-d6eb374b1982"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"/>
                  <templateId root="2.16.840.1.113883.10.20.15.3.13"/>
                  <id root="b7e48f8f-bda4-4d9c-be57-151c25a655c7"/>
                  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                  <statusCode code="completed"/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <interpretationCode/>
                  <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
```

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Developer Documentation (PDF)

TB Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.15.3.21]

The tuberculosis result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen.

1. Conforms to *CDA Organizer*
2. Conforms to *CCD Result Organizer* template (templateId: 2.16.840.1.113883.10.20.1.32)
3. [CDA] **SHALL** contain [1..1] @classCode, where its data type is x_ActClassDocumentEntryOrganizer
4. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
5. [CDA] **MAY** contain [0..1] @nullFlavor, where its data type is NullFlavor
6. [CDA] **MAY** contain [0..*] realmCode, where its data type is CS
7. [CDA] **MAY** contain [0..1] typeId, where its data type is InfrastructureRootTypeId
8. [CDA] **MAY** contain [0..*] templateId, where its data type is II
9. [CCD] **SHALL** contain [1..*] id
10. [TBPN] **SHALL** contain [1..1] code, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
11. [CCD] **SHALL** contain [1..1] statusCode
12. [CDA] **MAY** contain [0..1] effectiveTime, where its data type is IVL_TS
13. [CDA] **MAY** contain [0..1] subject, where its type is *CDA Subject*
14. [CCD] **SHOULD** contain [1..*] component such that it
    a. **SHALL** contain [1..1] *CDA Specimen*
15. [CDA] **MAY** contain [0..*] performer, where its type is *CDA Performer2*
16. [CDA] **MAY** contain [0..*] author, where its type is *CDA Author*
17. [CDA] **MAY** contain [0..*] informant, where its type is *CDA Informant12*
18. [CDA] **MAY** contain [0..*] participant, where its type is *CDA Participant2*
19. [CDA] **MAY** contain [0..*] reference, where its type is *CDA Reference*
20. [CDA] **MAY** contain [0..*] precondition, where its type is *CDA Precondition*
21. [CDA] **MAY** contain [0..*] component, where its type is *CDA Component4*
22. [CCD] **SHALL** contain [1..*] component such that it
    a. **SHALL** contain [1..1] *CCD Result Observation* (templateId: 2.16.840.1.113883.10.20.1.31)
23. [TBPN] **SHALL** contain [1..1] component such that it
    a. **SHALL** contain [1..1] *TB Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.13)
24. [CCD] **SHOULD** satisfy: The value for 'code' in a result organizer SHOULD be selected from LOINC

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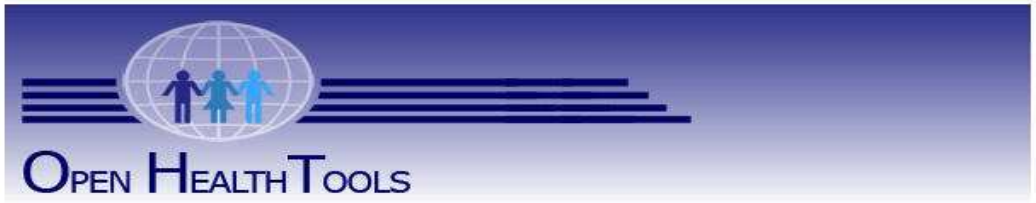
Validating CDA Instances

- The template conformance rules represented in UML are transformed to OCL as part of the automated code generation.
- The resulting Java classes encapsulate all validation rules and may be used to parse and validate a CDA document instance.
- We have created an example web application that may be used to validate CDA documents for implementation guides that we have modeled. See http://cdatools.org
- We are integrating validation from the generated Java libraries into the Eclipse open source XML instance editor. This editor already includes good support for "content assist" and validation based on the CDA.xsd schema. But we have used the Eclipse extension points to also validate CDA instances using the conformance rules that go beyond schema structure.

Validation on a Web Application



MDHT Clinical Document Architecture (CDA) Document Validation Services

The site provides validation services for CDA documents using the MDHT CDA Tooling solution and the complete source code is available on the MDHT Subversion. The web page uses a web service to provide XML validation content which is then rendered using XSLT.

MDHT CDA Diagnostics Service

CDA Document		
		Browse...
CDA Diagnostic Level		Only Error and Warnings Diagnostics
		Validate

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Validation Results on Web

MDHT Clinical Document Architecture (CDA) Document Validation Services

Diagnostics For CDA Document xxx

Total	Errors	Warnings	Information
9	5	4	0

Specification	Severity	Message
/clinicalDocument[1]		
org.eclipse.emf.ecore	error	Diagnosis of org.openhealthtools.mdht.uml.cda.pilot.impl.TuberculosisFollowUpProgressNoteImpl@1098594{urn:hl7-org:v3#//@clinicalDocument}
/clinicalDocument[1]/component[1]/structuredBody[1]/component[2]/section[1]/entry[1]/observation[1]		
org.openhealthtools.mdht.uml.cda.ccd	warning	CCD Result Observation SHOULD satisfy: Contain one or more referenceRange to show the normal range of values for the observation result
org.openhealthtools.mdht.uml.cda.ccd	error	CCD Result Observation SHALL satisfy: Contains one or more sources of information.
org.openhealthtools.mdht.uml.cda.ccd	warning	CCD Result Observation SHOULD contain [0..*] interpretationCode
/clinicalDocument[1]/component[1]/structuredBody[1]/component[2]/section[1]/entry[2]/organizer[1]		
org.openhealthtools.mdht.uml.cda.ccd	error	CCD Result Organizer SHALL satisfy: Contains one or more sources of information.
org.openhealthtools.mdht.uml.cda.pilot	error	TBPN TB Result Organizer SHALL contain [1..1] code, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
/clinicalDocument[1]/component[1]/structuredBody[1]/component[2]/section[1]/entry[2]/organizer[1]/component[1]/observation[1]		
org.openhealthtools.mdht.uml.cda.ccd	warning	CCD Result Observation SHOULD satisfy: Contain one or more referenceRange to show the normal range of values for the observation result
org.openhealthtools.mdht.uml.cda.ccd	error	CCD Result Observation SHALL satisfy: Contains one or more sources of information.
org.openhealthtools.mdht.uml.cda.ccd	warning	CCD Result Observation SHOULD contain [0..*] interpretationCode

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Validation in XML Editor