



HITSP

Healthcare Information Technology Standards Panel

Report from the Tiger Teams

July 8, 2009

Presented by:

HITSP Tiger Team Co-Chairs

Tiger Team Leadership

□ EHR Centric Interoperability Specification – 131 members

- Manick Rajendran, eZe Care LLC
- Corey Spears, McKesson Health Solutions
- Michael Nusbaum, Staff Co-chair

□ Harmonization Framework and Information Exchange Architecture – 98 members

- Steve Hufnagel, PhD, DoD/Medical Health System (MHS)
- Ed Larsen, Staff Co-chair



Tiger Team Leadership

❑ Data Architecture (Element, Template and Value Set) – 135 members

- Keith Boone, GE Healthcare
- Don Bechtel, Siemens Medical Solutions
- Don Van Syckle, Staff Co-chair

❑ Security, Privacy & Infrastructure - 124 members

- Glen Marshall, Grok-A-Lot, LLC
- John Moehrke, GE Healthcare
- Johnathan Coleman, Staff Co-chair



Tiger Team Leadership

☐ Quality Measures - 121 members

- Floyd Eisenberg, MD, MPH, National Quality Forum
- Eileen Koski, M. Phil
- Lori Reed-Fourquet, Staff Co-chair

☐ Clinical Research - 169 members

- Walter Suarez, MD, Institute for HIPAA/HIT Education and Research
- Gene Ginther, Staff Co-chair

Total Tiger Team Membership – 402 individuals

HITSP Tiger Team Statistics – ARRA effort

* Face to Face Mtg

	Apr 15th - May 12th	5/12/09	5/20/09	5/27/09	6/1/09	6/17/09*	6/24/09	7/1/09	TOTAL
Tiger Teams	6	6	6	6	6	6	6	6	
Work Groups	4	10	15	15	15	15	15	15	
Volunteers by Team	432	576	576	661	689	768	783	778	
Total Individual Volunteers	102	232	232	288	299	404	415	402	
Organizations	66	66	66	96	100	102	102	102	
Companies	103	103	103	109	112	120	120	120	
Total Entities	169	169	169	205	212	222	222	222	
Weekly calls / meetings	38	18	24	27	27	19	14	11	
Weekly calls / meeting hrs	70	32	32	53	53	182	23	20	
Total Volunteer hrs/week	1197	842	977	1793	1921	5908	915	530	14083

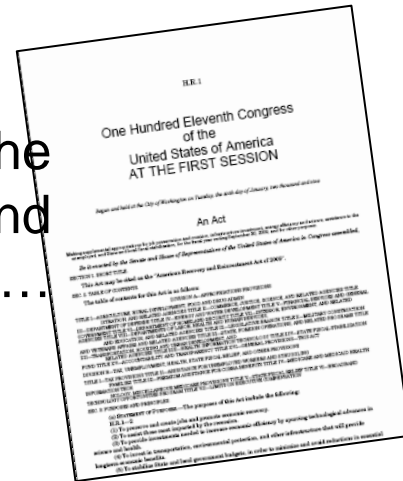
Objective of the EHR-Centric Interoperability Specification Tiger Team

Utilizing the 13 recognized/accepted (as of 13Feb09)
HITSP Interoperability Specifications...



...to produce an
EHR-Centric IS...

...in the context of the
American Recovery and
Reinvestment Act (2009)...



...that is:

- simplified
- easily understood
- applicable beyond limitations of initiating use cases
- implementable
- leverages existing work

Approach

- ❑ Utilized a “tiger team” approach that is:
 - Focused
 - Engages HITSP members
 - Volunteer and Staff Leadership
 - SME’s, facilitators, writers
 - Very time-constrained

Approach (continued)

- ❑ Informed by ONC, HITSP Program Management, HITSP IRT
- ❑ Highly dependent on the work of other Tiger Teams
- ❑ Evolving context, requiring continual flexibility in approach:
 - HIT Policy Committee
 - HIT Standards Committee
 - ONC input and refinements

Results

- Introduction of several new concepts:
 - Capabilities
 - Service Collaborations
 - Orchestration of multiple Capabilities and/or Service Collaborations

- Simplify, reduce redundancy, increase usability and re-usability

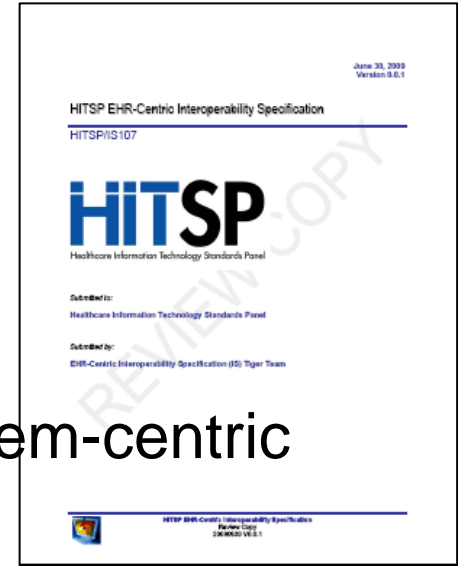
Deliverables

□ IS107: EHR-Centric IS

- The first of a number of potential system-centric interoperability *perspectives*
- A *menu* of specification components that can be assembled to meet varied implementation needs
- All ARRA requirements met by at least one IS but gaps / enhancements were identified for future HITSP work

□ Follow-Ups (internal document)

- IS inconsistencies, errors, omissions, suggestions



A HITSP “Capability”...

- ❑ ...defines a business service that supports an information exchange involving an EHR system
- ❑ 26 Capabilities identified for the EHR-Centric IS

Capability ID	Capability Name	Capability Description
HITSP/CAP118	Communicate Hospital Prescription	This capability addresses interoperability requirements that support electronic prescribing for inpatient orders that can occur within an organization or between organizations. The capability supports the transmittal of a new or modified prescription from a Hospital to an internal or external pharmacy. It also includes the optionality to access formulary and benefit information.
HITSP/CAP121	Communicate Clinical Referral Request	This capability addresses interoperability requirements that support provider-to-provider (clinical) referral request interaction. It allows the bundling of the referral request document with other relevant clinical documents of interest by referencing such documents as shared by other capabilities such as: CAP119 Communicate Structured Document; CAP120 Communicate Unstructured Document; or CAP133 Communicate Immunization Summary.

A Capability

- ❑ ...can be found across one or more of the 13 existing IS documents
- ❑ ...can be combined with other Capabilities to address more inclusive requirements or to support a particular implementation

Capabilities were mapped to ARRA requirements - where appropriate, gaps were identified to inform future HITSP work

HITSP Capabilities

CAP 140	CAP 141	CAP 142	CAP 143	CAP 117	CAP 118	CAP 119	CAP 120	CAP 211	CAP 212	CAP 213	CAP 214	CAP 215	CAP 216	CAP 217	CAP 218	CAP 129	CAP 130	CAP 311	CAP 312	CAP 313	CAP 315	CAP 316	CAP 137	CAP 318	CAP 139			
ADMINISTRATIVE and FINANCIAL				Medication Management	Exchange of Clinical Data				Exchange of Laboratory and Imaging Data				Quality Management		Immunization		Case Reporting and Bio-surveillance		Emergency		CLINICAL OPERATIONS (Care Delivery, Emergency Responder and Consumer Empowerment)				CLINICAL QUALITY AND PUBLIC HEALTH			

HITSP Document Description

Provider Perspective

			•																							IS 01 - Electronic Health Record (EHR) Laboratory Results Reporting
•	•	•	•			•	•	•														•	•		•	IS 04 - Emergency Responder Electronic Health Record (ER-EHR)
•	•	•	•			•	•		•					•	•	•										IS 08 - Personalized Healthcare
•	•	•	•			•	•	•						•	•	•						•				IS 09 - Consultations and Transfers of Care

Population Perspective

			•			•									•	•	•				•		•	•	•	IS 02 - Biosurveillance
			•			•				•					•	•										IS 06 - Quality
		•	•			•	•		•	•						•	•	•				•		•		IS 10 - Immunizations and Response Management
		•	•			•	•		•	•					•	•	•					•	•	•	•	IS 11 - Public Health Case Reporting

Consumer Perspective

			•			•	•		•						•											IS 03 - Consumer Empowerment
			•			•	•		•																	IS 05 - Consumer Empowerment and Access to Clinical Information via Media
•			•	•	•	•																				IS 07 - Medication Management
			•			•																				IS 12 - Patient – Provider Secure Messaging
•	•		•			•																				IS 77 - Remote Monitoring

Service Collaborations

- ❑ Developed by the Security/Privacy/Infrastructure Tiger Team
- ❑ Reusable workflow, greatly simplifies infrastructure constructs

SC #	Service Collaboration Name	Definition
SC108	Access Control	The HITSP Access Control Service Collaboration provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control, entity based access control, context based access control, and the execution of consent directives.

SC #	Service Collaboration Title	Interfaces	Primary Associated Constructs	Integrated S&P Constructs/SCs
HITSP/SC108	Access Control	Request Access Control	HITSP/TP20, HITSP/TP30, HITSP/C19, HITSP/T17	

In the EHR-Centric IS, each capability is described by:

- Detailed description
- Design specification
 - Interacting Systems
 - Constraints & Assumptions
 - List of constructs (incl. Service Collaborations)
 - Specified Interfaces (mapped to construct/content)
 - Interface Conditions & content Optionality
 - UML diagram
 - Capability options (content subsets and transport options)

Requested changes prior to Publication

Section	Description	Content
3.13 CAP128	Typographical Error	Remove extra underscore in table entry Retrieve Images [RAD-16] (HITSP/TP89)_
3.4 CAP119	Correction of document types specific to subsets	Re-statement of these document consumer options being correctly reflected as "T/SC/Content Optionality" entries for each of the specific document types vs as individual subsets for these document types
3.2-3.27	Constraint Language	To be expressed according to RFC 2119 recommendations but limited to terms SHALL, SHOULD, SHALL NOT, SHOULD NOT and MAY

Management of ongoing changes

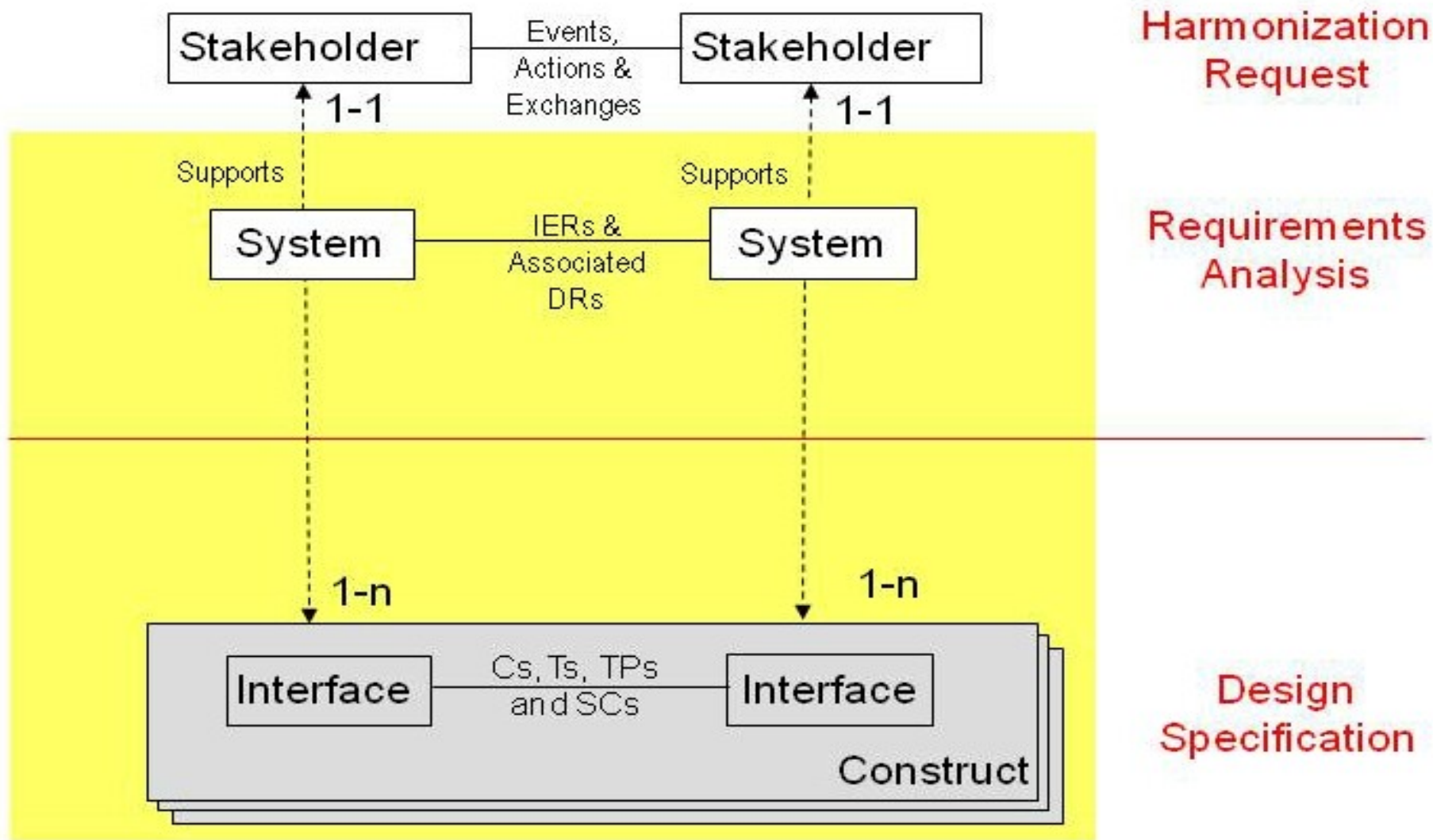
- ❑ Use of the HITSP Comment Tracking System
<http://members.ansi.org/sites/hitsp/Lists/HITSP%20Comment%20Tracking%20System%20Version%2020/active.aspx>
- ❑ Most changes are related to inconsistencies in the underlying IS's that were uncovered as we looked horizontally across them to create IS107
- ❑ The Tiger Team decided to not perpetuate these errors or inconsistencies in approach in the IS107 document, but rather publish IS107 staying true to the source documents, and then correct the underlying IS's in a parallel process

Report from the Harmonization Framework and Information Exchange Architecture Tiger Team

- ❑ HITSP Framework defines Terms
- ❑ HITSP Framework models Relationships
- ❑ HITSP Exchange Architecture demonstrates Topologies

- The *Harmonization Framework* defines the terms, concepts and their relationships within a:
 - HITSP Interoperability Specification and within
 - HITSP Component (C), Transaction (T), Transaction Package (TP) and Service Collaboration (SC) constructs.

- The *Exchange Architecture* defines the fundamental topologies that can be used in implementing the HITSP Interoperability Specifications in systems.
 - EHR systems connected to independent Health Information Exchanges (HIEs),
 - HIEs connected to the NHIN or directly connected.



The figure shows how Stakeholders, Systems, Interfaces, Information Exchange Requirements (IERs), Data Requirements (DRs), and HITSP Interoperability Specification (IS), Component (C), Transaction (T) and Transaction Package (TP) constructs inter-relate.

Fundamental Relationships

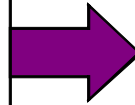
Harmonization Request

Identifies interoperability business needs

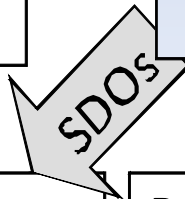
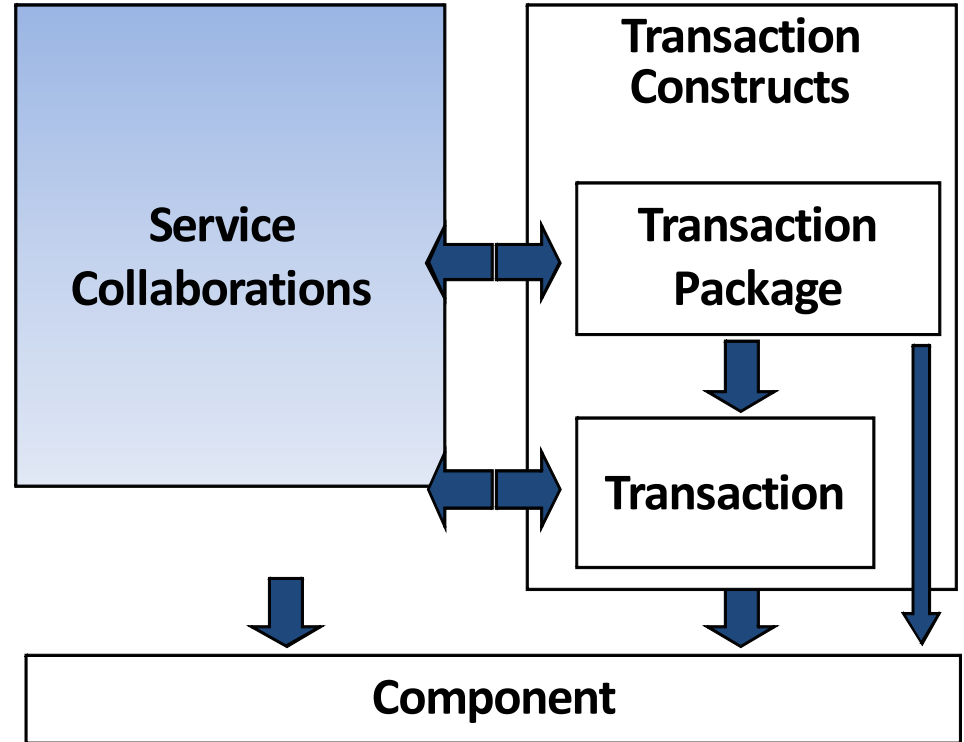


Interoperability Specification

- Identifies what HITSP lower-level constructs to integrate to meet Business Needs
- Defines Requirements, Context and Constraints for those constructs



HITSP Capabilities



Base Standard #1

Base Standard #2

Base Standard #...

Base Standard #n

Composite Standard #1

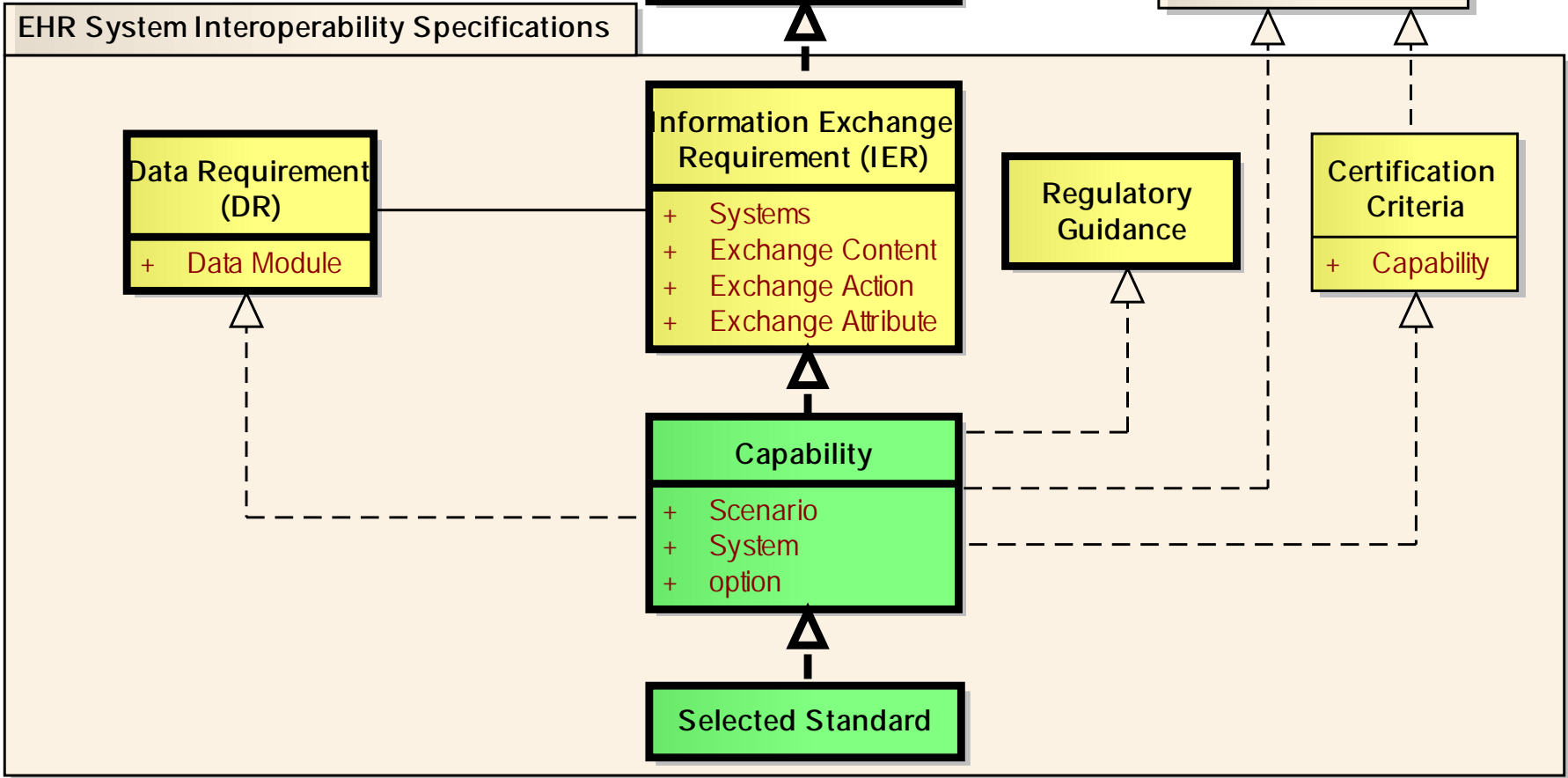
Composite Standard #...

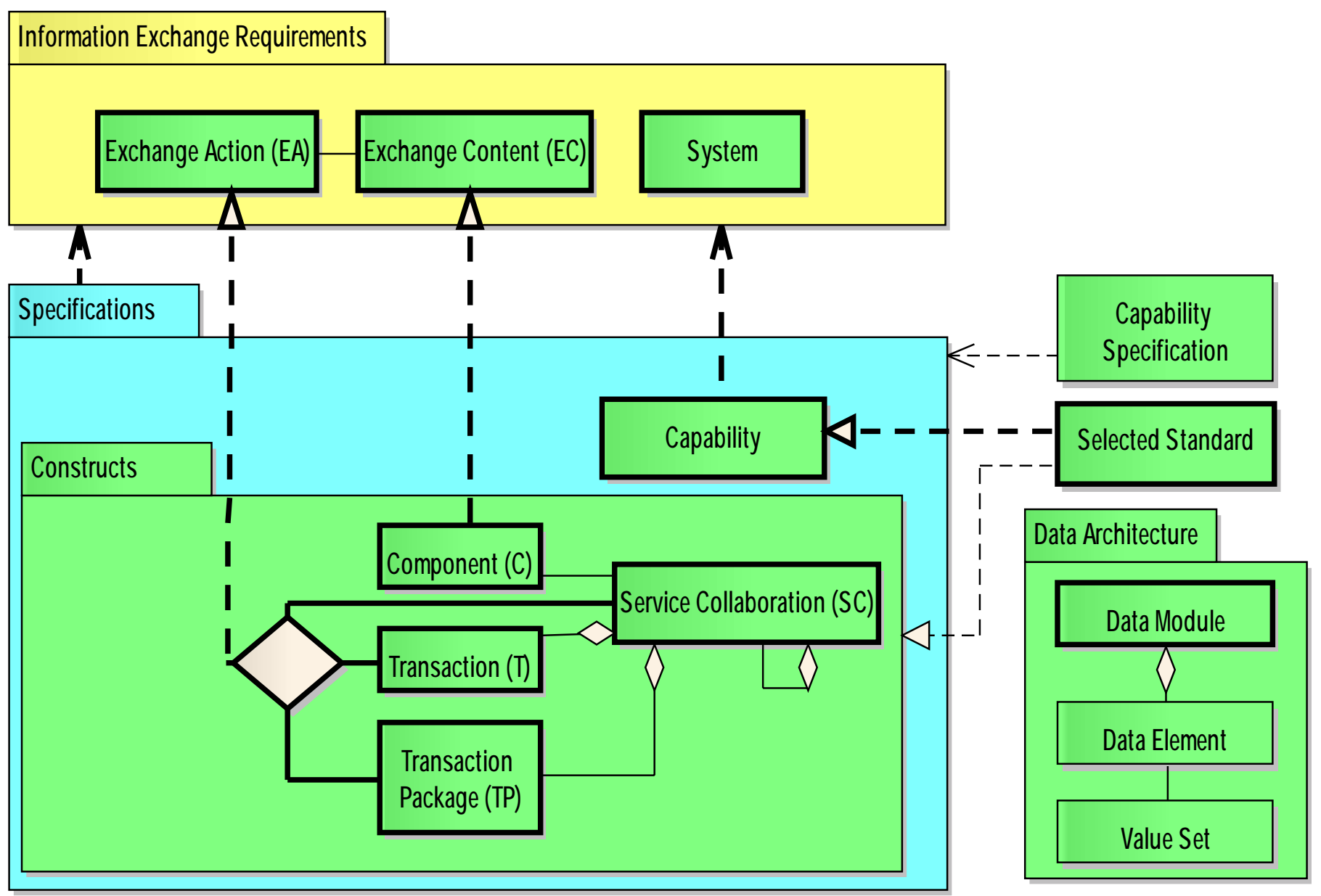
Composite Standard #m

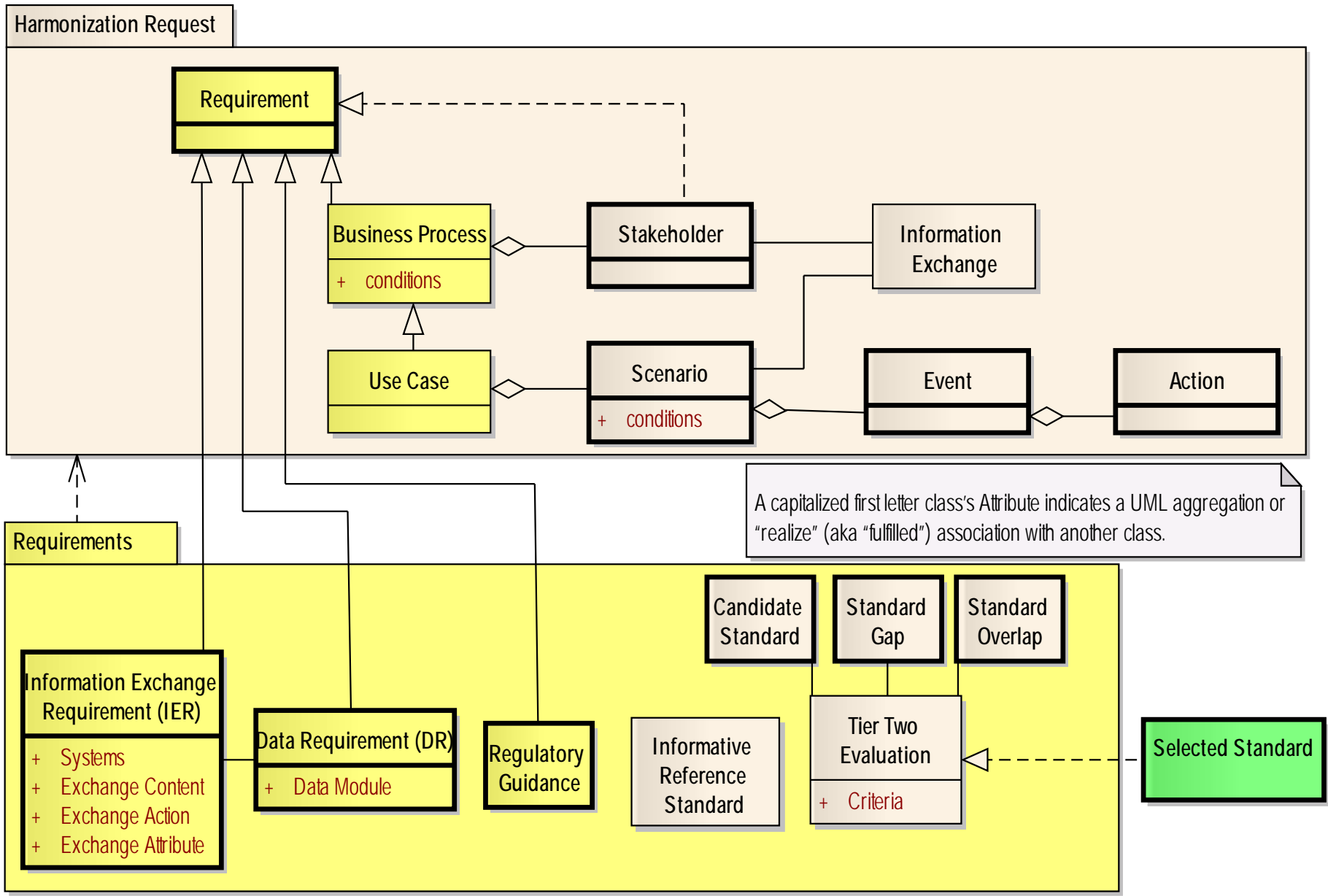
Legend

- reusable element
- requirements
- specifications
- in a HITSP IS table

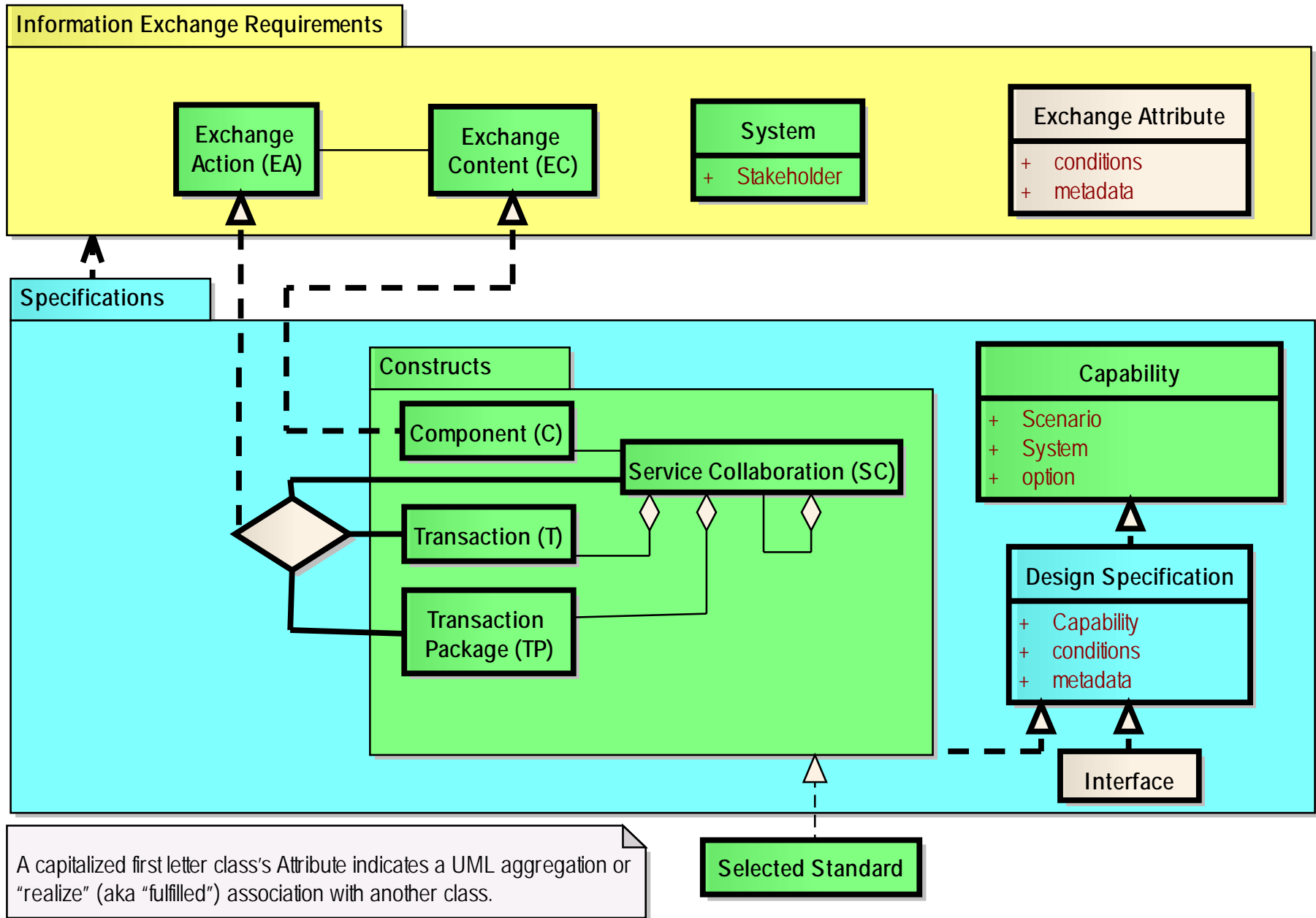
— in a HITSP IS Table



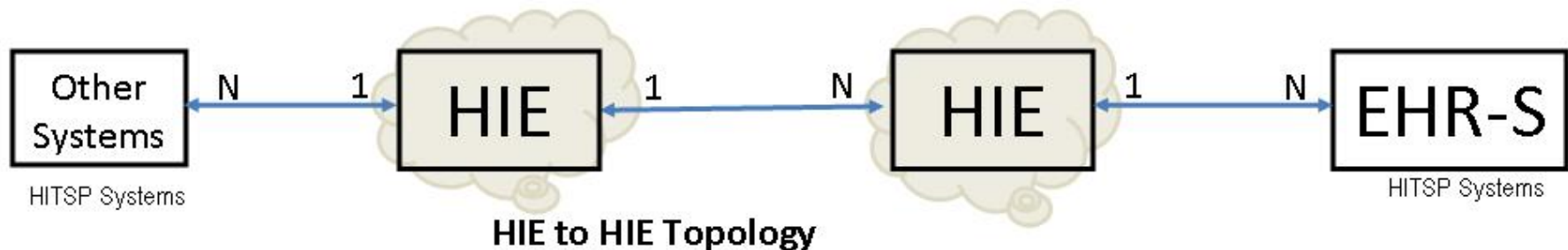
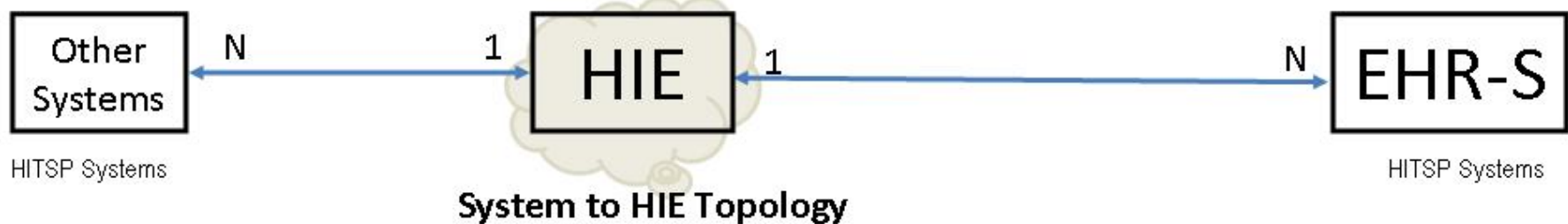
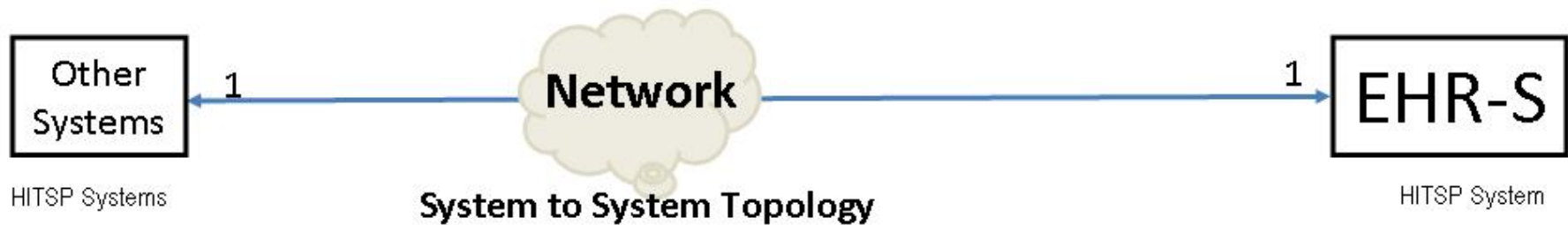




IER # (Local to IS)	IER Name (Local to IS)	Exchange Action	Exchange Content	What System initiates this exchange?	What System (s) responds to this exchange?	Exchange Attribute
IER015	Blood Report	Send	Blood Lab Report	Laboratory Information System	<ol style="list-style-type: none"> 1. PHR System 2. EHR System 3. Public Health Information (PHI) System 	Pseudonymize to PHI System
IER016	Specimen Report	Send	Specimen Lab Report	Laboratory Information System	<ol style="list-style-type: none"> 1. PHR System 2. EHR System 3. Public Health Information (PHI) System 	Pseudonymize to PHI System



A capitalized first letter class's Attribute indicates a UML aggregation or "realize" (aka "fulfilled") association with another class.

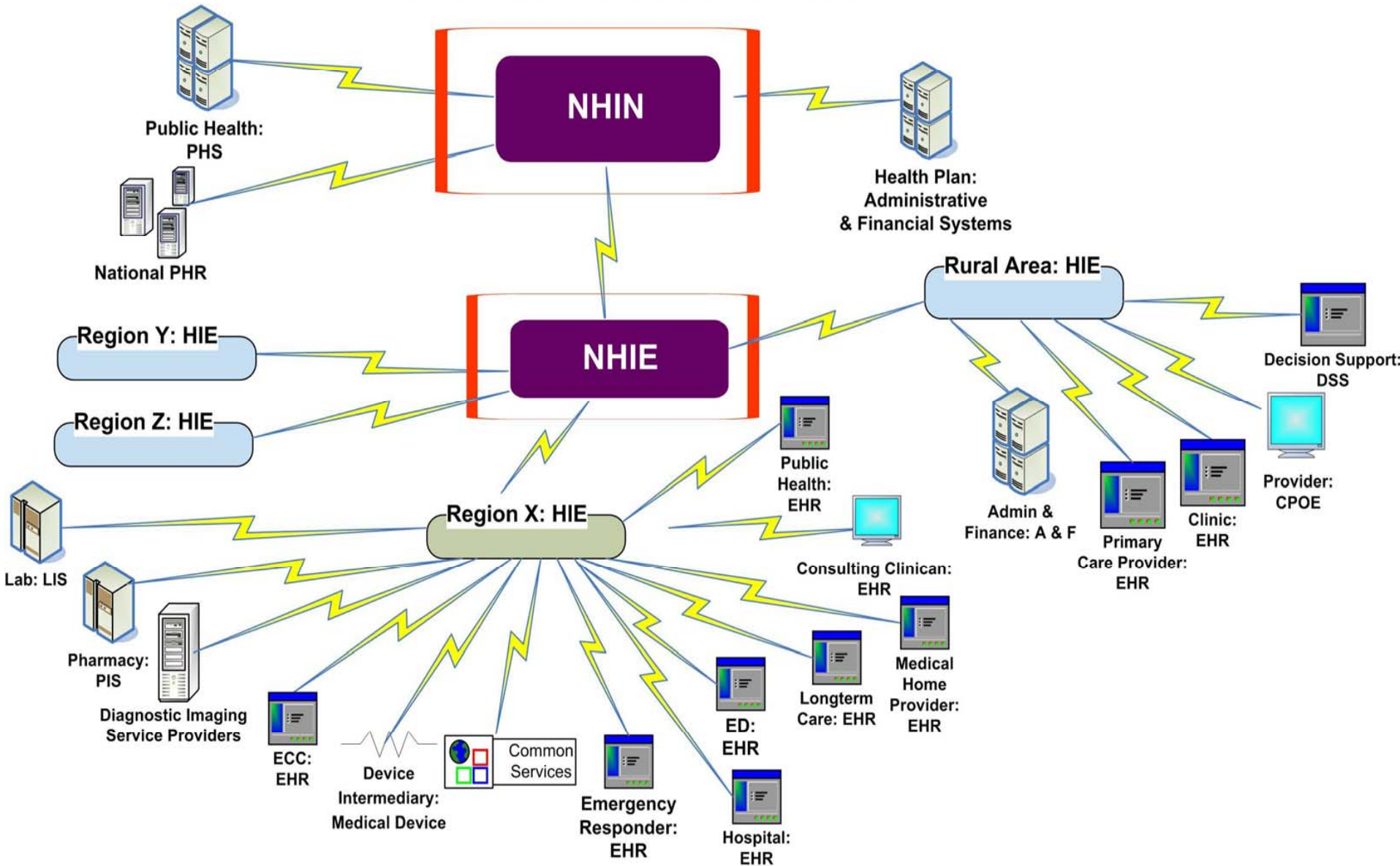


NOTE: HITSP Interoperability Specifications apply across business boundaries. An associated business agreement defines the business boundaries of EHRs, other systems and HIEs.

HITSP ISs apply to information exchanges indicated by the arrows in the figure.

Notional Exchange Architecture Topologies

CALIFORNIA HIE HARMONIZATION



Example Exchange Architecture

Report from the Data Architecture (Element, Template, and Value Set) Tiger Team

DA TT High Level Deliverables

- Ensure Data Element Consistency Across HITSP Specifications
- Provide Data Architecture Design for Use of Data Element, Value Sets and Templates Used Within HITSP
- Support Meta-Data Registries
- Develop Data Architecture Technical Note – TN903
- Address Care Management and Health Records Domain Committee (CMHR) Public Comments

HITSP Constructs Modified by Data Arch. TT

Modified Constructs

- ❑ C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES)
- ❑ C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)
- ❑ C34 - Patient Level Quality Data Message
- ❑ C39 – Encounter Message
- ❑ C41 – Radiology Results Message
- ❑ C48 – Encounter Document using IHE Medical Summary (XDS-MS)
- ❑ C70 - Immunization Query and Response
- ❑ C72 - Immunization Message
- ❑ C78 - Immunization Content
- ❑ C80 - Clinical Document & Message Terminology
- ❑ C83 - CDA Content Modules
- ❑ C84 - Consultation, History and Physical Document
- ❑ TP22 – Patient ID Cross-Referencing
- ❑ T23 – Patient Demographics Query

New Technical Note

- ❑ TN903 – Data Architecture

Ensure Data Element Consistency Across HITSP Specifications

- ❑ Mapped Data Elements, Modules, Value Sets
(for HITSP constrained data)
 - Internal spreadsheet for all clinical/business constructs
 - Documented HITSP constrained Data Elements
 - Does not address implementation guides, integration profiles and base standard constraints

- ❑ HITSP Constrained Value Sets Inconsistencies
 - Document that conveys Data Elements Constrained by Value Sets that are inconsistent between HITSP constructs
 - Provides harmonization recommendations
 - Minor changes made this release, others to be addressed

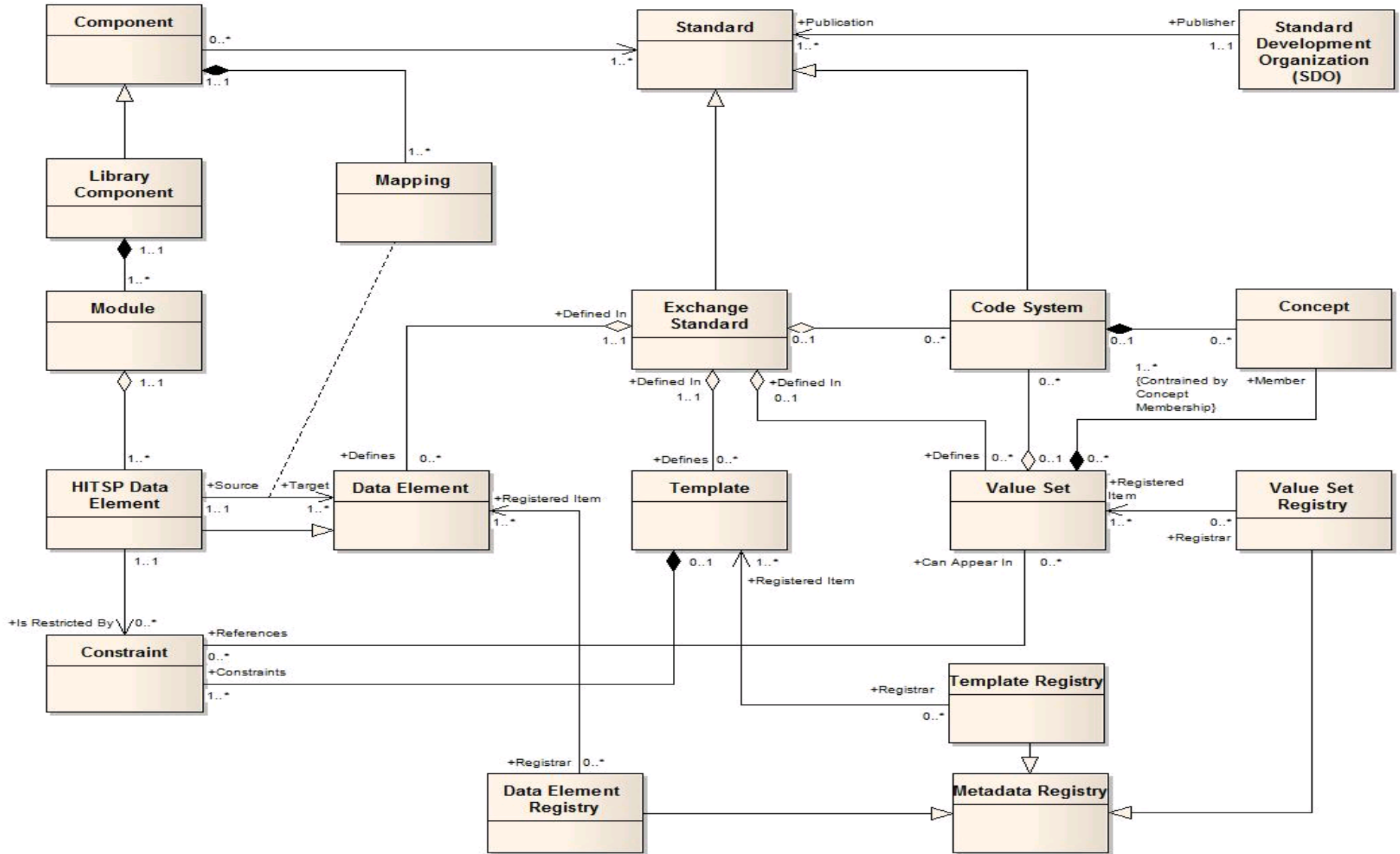
- ❑ HITSP Constructs Modified
 - C34, C39, C41, C70, C72, TP22, T23

Simple Example of Recommendations

HITSP Data Element ID (per C83)	Effort	Pri	Data Element Name (C83 or Others)	Standard's Constrained and HITSP Construct	HITSP Constructs	Value Set Inconsistencies	Recommend Resolution
2.01	L	#1	Language	HL7 CDA (C83) Therefore many related CDA based constructs	HL7 CDA (C83) Therefore many related CDA based constructs	The value set is defined by Internet RFC 4646 (replacing RFC 3066) see http://www.ietf.org/rfc/rfc4646.txt	The RFC 4646 is consistent with HL70296, therefore, we recommend using RFC 4646 in all HITSP constructs. Ramifications of not making this change would be the unnecessary proliferation of multiple vocabularies used to convey language in HITSP specifications.
	L	#1	PID-15 Language	HL7 V2.5 messages	C70, C72	HL7V2 requires HL7v2.3.1 Language Table (HL70296)	We note that this is very easy to accomplish and has little technical impact on implementers, and provides greater consistency in HITSP documents.

Data Architecture UML

class Data Architecture Domain Model



Data Architecture for Data Elements

- ❑ Data Elements are defined for consistent use of the data elements across different information exchanges
 - Usable for both document and message exchange standards such as HL7 V3 CDA, HL7 V2, NCPDP, ASC X12, etc.
- ❑ Similar data elements from the different standards are identified as the same HITSP data element
 - To help ensure maximum interoperability
 - Constraints are applied to each data element to facilitate the use of it across a wide variety of standards
- ❑ HITSP Data Elements are identified in C83 – CDA Content Modules
 - Plan to move the HITSP Data Dictionary out of HITSP/C83 and create new construct in the future as Data Dictionary applies to ALL HITSP data elements

HITSP Data Dictionary

- ❑ Each Data Element given a HITSP:
 - Identifier, Name, Definition and possible Constraints
- ❑ Unique Constraint IDs provided for each Data Element constraint to ensure consistency and traceability

Table 2-9 Healthcare Providers Data Mapping Table – Definitions: Provider

Identifier	Name	Definition	Constraints
4.01	Date Range	The period over which this provider has provided healthcare services to the patient	
4.02	Provider Role Coded	Provider role uses a coded value to classify providers according to the role they play in the healthcare of the patient and comes from a very limited set of values. The purpose of this data element is to express the information often required during patient registration, identifying the patient's primary care provider, the referring physician or other consultant involved in the care of the patient	C83-[DE-4.02-1] Provider role SHALL be coded as specified in HITSP/C80 section 2.2.3.8.1 Provider Role
4.03	Provider Role Free Text	This unstructured text classifies providers according to the role they play in the healthcare of the patient	

Data Elements are Grouped into Modules

- ❑ Data elements are organized categorically into modules by their clinical purpose
 - (e.g., problems, medications, allergies, immunizations, etc.)
- ❑ New data elements are placed into existing modules or require the creation of a new module

Module Category	Description
Personal Information	The personal information includes name, address, contact information, personal identification information, ethnic and racial affiliation and marital status of a person.
Healthcare providers	This includes a list of the healthcare providers and organizations that provide or have provided care to the patient.
Insurance Providers and Payers	Insurance providers include data about the organizations or individuals who may pay for a patient's healthcare, and the relationships, demographics and identifiers of those individuals with respect to the payer. Such organizations or individuals may be health insurance plans, other payers, guarantors, parties with financial responsibility, some combination of payers or the patient directly.
Allergies and Drug Sensitivities	This includes the allergy or intolerance conditions, severity and associated adverse reactions suffered by the patient.
Conditions	This includes relevant clinical problems and conditions for which the patient is receiving care, including information about onset, severity, and providers treating the condition. Conditions are broader than, but include diagnoses.
Medications	This includes the patient's prescription or non-prescription medications and medication history, and may include prescriptions, fulfillments and medication administration activities.
Immunizations	This includes data describing the patient's immunization history.
Others.....	Others.....

Data Elements Documented in Constructs

- ❑ Link SDO data element to HITSP data Element
- ❑ Provide SDO Data element, optionality and constraints
- ❑ Updated CDA base documents and will update HL7 V2, NCPDP, ASC X12 based constructs

CDA Data Location	HITSP Data Element Identifier and Name	O/R	Additional Specification
/cda:ClinicalDocument/cda:documentationOf/ cda:serviceEvent/cda:performer	Provider	R2/Y	2.2.2.4.1
cda:time	4.01 -	R/N	
cda:functionCode	4.02 - Provider Role Coded	R2/N	2.2.2.4.3
cda:originalText	4.03 - Provider Role Free Text	R2/N	2.2.2.4.3
cda:assignedEntity	Provider Entity	R/Y	
cda:code	4.04 - Provider Type	R2/N	2.2.2.4.4
cda:addr	4.05 - Provider Address	R2/Y	
cda:telecom	4.06 - Provider Phone / Email / URL	R2/Y	
cda:assignedPerson/cda:name	4.07 - Provider Name	R2/N	
cda:representedOrganization/cda:name	4.08 - Provider's Organization Name	R2/Y	
sdtc:patient/sdtk:id	4.09 - Provider's Patient ID	R2/N	

Data Architecture for Value Sets

- ❑ Data elements may be constrained to a specific value set
- ❑ HITSP/C80 - Clinical Document & Message Terminology identifies value sets selected or created by HITSP
- ❑ Data element value set consistency effort (discussed earlier) ensures that all data elements make use of consistently defined value sets
 - Example, the value set used to describe problems in a HITSP Specification is the VA/Kaiser Permanente subset of SNOMED CT in almost all components that need to exchange problems
- ❑ HITSP specifications may select standards that require the use of different Code Systems for the same Data Element
 - All attempts will be made to ensure that the value sets required in the different exchanges can be mapped

Value Set Meta-data

Meta-data defined for each Value Set selected in HITSP/C80

Element	Description
Identifier	This is the unique identifier of the value set
Name	This is the name of the value set
Source	This is the source of the value set, identifying the originator or publisher of the information
URL	A URL referencing the value set members or its definition at the time of publication
Purpose	Brief description about the general purpose of value set
Definition	A text definition formally describing how concepts in the value set are (intensional) or were (extensional) selected
Version	This row contains a string identifying, where necessary, the specific version of the value set
Type	Extensional (Enumerated) or Intensional (Criteria-based)
Binding	Static or Dynamic
Status	Active (Current) or Inactive (Retired)
Effective Date	The date when the value set is expected to be effective
Expiration Date	The date when the value set is no longer expected to be used
Creation Date	The date of creation of the value set
Revision Date	The date of revision of the value set
Code System Source	This row identifies the source for the code system
Code System Name	This row provides the name of the code system associated with the value set

Code Set Meta-Data

- ❑ Value sets may contain codes from one or more code systems
- ❑ Additional metadata describing a value set or code set may be present in the data registries, such as:
 - the relationships between different value sets
 - links to places where the code system may be downloaded

Element	Description
Source	This row identifies the source for the code system
Name	This row provides the name of the code system associated with the value set
URL	This row identifies the URL for the code system
Identifier	This is the identifier for a code system from which the value set is drawn
Version	This row contains a string identifying, where necessary, the specific version of the code system used
HL7 Identifier	The identifier used to identify this code system in HL7 Version 2.X messages

Data Architecture for Templates

- ❑ A template is a formal collection of constraints (business rules) that are applied to the content of the exchange
- ❑ Templates are used by HL7 V3 CDA to provide a mechanism to express conformance rules
- ❑ Templates can be applied to components, modules used in a component, or to specific data elements or even parts of a data element
- ❑ HITSP uses templates from base and composite standards, such as Integrating the Healthcare Enterprise (IHE) and HL7
- ❑ Templates can be inherited
- ❑ A unique property of templates is that an information exchange complying with a template asserts conformance to its business rule, allowing for easier validation of conformance
- ❑ Templates are defined in HITSP/C83 – CDA Content Modules

Template Meta-data

Element	Description	HITSP Template Metadata
Identifier	This is the identifier of the template	TemplateId
Name	This is the name of the template	templateName
Source	This row identifies the source of the template, the originator or publisher of it.	originatingAuthorEntityID publisher
URL	A URL pointing to an online resource defining the template	templateRepositoryIdentifier
Purpose	A brief description of the purpose for the template	intention
Definition	Brief description of the template	templateDescription
Inherited Templates	Templates may require the use of other templates for the artifact to which this template is applied. This entry indicates which templates must be used	<i>Not Available</i>
Templates Used	Templates may require the use of other templates in artifacts that are subordinate to the artifact to which this template applies. This entry indicates which of these templates are required or optional	<i>Not Available</i>
Version	This row contains a string identifying, where necessary, the specific version of the template	version
Effective Date	The date that the template becomes effective	effectiveDate
Expiration Date	The date after which the template should no longer be used	supersededDate
Status	Active (Current) or Inactive (Retired)	publicationStatus
Creation Date	The date of the creation of the template when available	creation History
Revision Date	The date of the revision of the template when available	revision History

Support Meta-Data Registries

- ❑ Relationship between HITSP and registries (such as AHRQ-USHIK, CDC-PHIN-VADS, and others) play a key role in the success of the understanding and implementation of HITSP specifications and Quality Measures effort
- ❑ HITSP does not re-document the composite or base standards, thus in order to understand the full extent of the HITSP specifications, implementers and users need easy access to the full set of information
- ❑ Registries facilitate access to the complete information as they register HITSP information, but also information from the composite and base standards, value sets, and templates

Support Meta-Data Registries

- ❑ Registries provide data mining tools to browse, search, query, compare, and gather information for review and analysis
- ❑ DA TT has identified several key issues with respect to governance and access to registry information
 - Rights to Information, Lack of Barriers and Ease of Access, Maintenance, Versioning
- ❑ DA TT developing Meta-Data Registry Requirements Document
- ❑ Both AHRQ and CDC have been very active in ARRA effort

TN903 - Data Architecture Technical Note

- ❑ Describes HITSP Data Architecture and related processes used to identify the data elements, templates and value sets. It explains how within HITSP Specifications:
 - base and composite standards are related to the data architecture
 - data elements are harmonized across various standards
 - constraints are applied within HITSP Specifications and uniquely identified
 - metadata registries support development and implementation

TN903 - Data Architecture Technical Note

□ Technical Note main sections:

- Introduction
- Executive Summary – Summarizes the Technical Note
- Background – Provides an overview of healthcare related standards and how they relate to the data architecture, and explains how these are used in HITSP Specifications
- HITSP Data Architecture – Defines key concepts used in this document, and describes the HITSP Harmonization Framework
- Use of Metadata Registries – Describes a metadata registry, and how these are used to support navigation of the selected standards and HITSP Specifications

Care Management and Health Records (CMHR) Domain TC Public Comment Updates

- ❑ Addressed outstanding public comments related to CMHR tasks
- ❑ Most comments related to HITSP/C83 – CDA Content Modules
- ❑ Comments based upon implementations and testing/validation efforts
- ❑ Public comments addressed:
 - 7071, 7078, 7079, 7080, 7081, 7086, 7089, 7090, 7091, 7094, 7096, 7097, 7098, 7112, 7116, 7117, 7118, 7126, 7122

HITSP Constructs Modified by Data Arch. TT for Approval

Data Element Consistency

- C34 – Patient Level Quality Data Message
- C39 – Encounter Message
- C41 – Radiology Results Message
- C70 - Immunization Query and Response
- C72 – Immunization Message
- TP22 – Patient ID Cross-Referencing
- T23 – Patient Demographics Query

Unique Constraint IDs

(for CDA based documents)

- C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES)
- C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)
- C48 – Encounter Document using IHE Medical Summary (XDS-MS)
- C78 - Immunization Content
- C84 - Consultation, History and Physical Document

HITSP Constructs Modified by Data Arch. TT for Approval

Value Set/Code Systems Meta-Data

- HITSP/C80 - Clinical Document & Message Terminology

HITSP Data Dictionary, CDA Document Constraints, Public Comments

- HITSP/C83 – CDA Content Modules

New Technical Note

- HITSP/TN903 – Data Architecture

Report from the Security, Privacy and Infrastructure (SPI) Tiger Team

- ❑ Task 1: ARRA Requirement Analysis
- ❑ Task 2: Develop Service Collaboration Suites
- ❑ Task 3: Update 29 SPI constructs to new format, including minor changes/corrections where needed

SPI Task 1: ARRA Requirements Analysis

- ❑ Identified requirements from ARRA applicable to HITSP Security, Privacy and Infrastructure.
- ❑ Identified and Catalogued construct characteristics from existing 29 SPI constructs.
- ❑ Performed Gap Analysis of construct characteristics against ARRA requirements.
- ❑ Met with representatives from ONC on June 5th, to discuss gaps and recommendations.

SPI Task 1: ARRA Requirements Analysis (cont.)

- Developed Gaps & Recommended Resolution document:
 - 12 ARRA requirements (grouped into three key categories) identified as in-scope for SPI, yet not fully addressed by existing constructs:
 - 1) Requirements for Accounting of Disclosures
 - 2) Requirements for protection of data at rest
 - 3) Requirements pending clarification (e.g. meaningful use)

Task 2: SPI Service Collaboration Suite

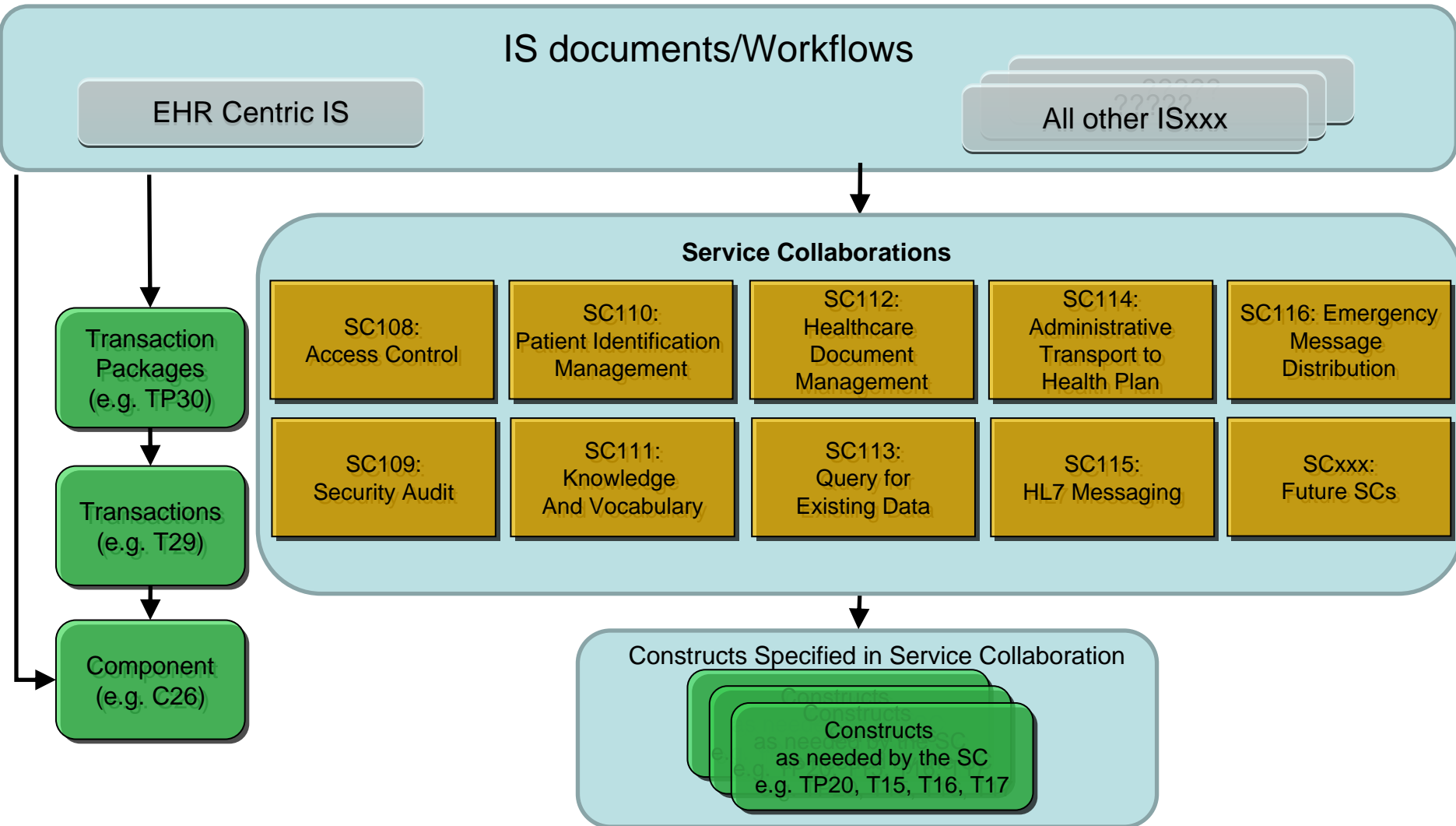
Service Collaboration Definition:

A service collaboration is a composition of constructs into a reusable workflow.

Task 2: SPI Service Collaboration Suite (cont.)

- ❑ A Service Collaboration (SC) is the composition of HITSP Transaction Package, Transaction, Component, or other SC constructs into a reusable workflow, primarily at the infrastructure level.
- ❑ Service Collaborations do not contain content, i.e., Data Elements.
- ❑ Service Collaborations are organized into an external view, i.e., outward facing interfaces, and an internal view that includes inward facing interfaces. Inward facing interfaces may call upon other constructs.
- ❑ Each Service Collaboration document illustrates one internal view diagram and sequence table for each service interface. The internal view diagrams are descriptive and the associated sequences are not mandatory. They may be affected by policy, chosen architecture, and implementation details.
- ❑ Security and privacy constructs are incorporated into the infrastructure Service Collaborations as appropriate.

Task 2: SPI Service Collaboration Suite (cont.)



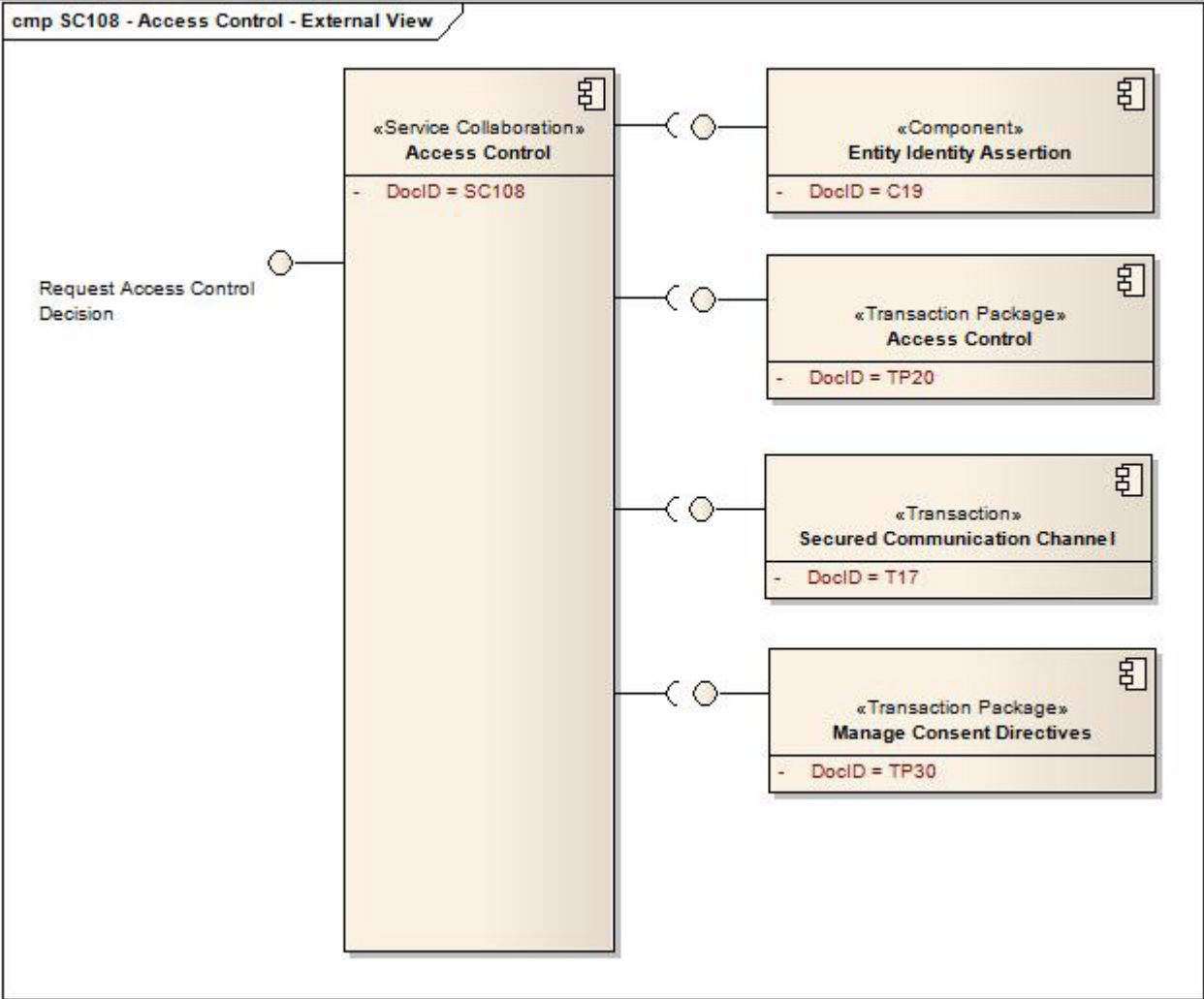
Task 2: SPI Service Collaboration Suite (cont.)

SC #	Service Collaboration Title	Interfaces	Primary Associated Constructs	Integrated S&P Constructs/ SCs
SC108	Access Control	<ul style="list-style-type: none"> Request Access Control 	TP20, TP30, C19, T17	
SC109	Security Audit	<ul style="list-style-type: none"> Send Security Audit Event 	T15, T16	
SC110	Patient Identification Management	<ul style="list-style-type: none"> Request Patient Identification 	T23, TP22, T24	SC108, SC109, T17
SC111	Knowledge and Vocabulary	<ul style="list-style-type: none"> Request Medical Knowledge Respond Medical Knowledge Request Value-Set Respond Value-Set 	T81 and T66	T17
SC112	Healthcare Document Management	<ul style="list-style-type: none"> Send Documents (dynamically choose method) <ul style="list-style-type: none"> Send Documents Directly Send Documents through email Publish Documents through Media Send Documents through Share Publish Documents through Share Receive Documents (dynamically choose method) <ul style="list-style-type: none"> Receive Documents Directly Receive Documents through email Consume Documents through Media Receive Documents through Share Consume Documents through Share 	TP13, T31, T33, T29	SC108, SC110, SC109, T17, T64

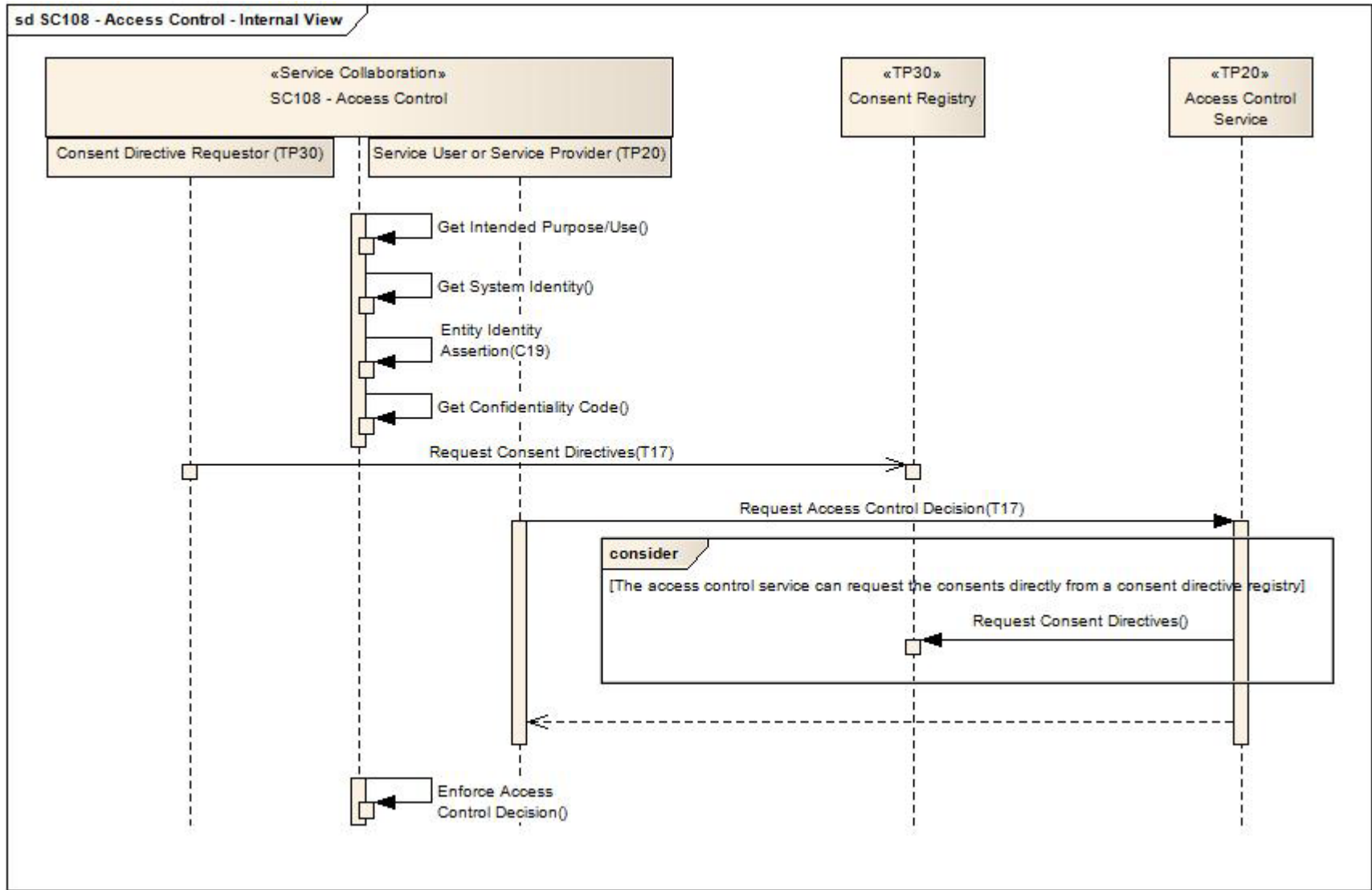
Task 2: SPI Service Collaboration Suite (cont.)

SC #	Service Collaboration Title	Interfaces	Primary Associated Constructs	Integrated S&P Constructs/SCs
SC113	Query for Existing Data	<ul style="list-style-type: none"> Request Existing Patient Data Respond Existing Patient Data 	TP21	SC108, SC110, SC109, T17
SC114	Administrative Transport to Health Plan	<ul style="list-style-type: none"> Request Administrative Response to Health Plan Respond to Administrative Response to Health Plan 	T85	SC108, SC110, SC109, T17
SC115	HL7 Messaging	<ul style="list-style-type: none"> Request HL7 Message Respond to HL7 Message 	HL7 v2.x MLLP	SC108, SC109, T17
SC116	Emergency Message Distribution Element	<ul style="list-style-type: none"> Send Emergency Message Distribution Element 	T63	SC108, SC109, T17

SC108: Access Control – External View



SC108: Request Access Control: Internal View



Not likely to be the focus of Service Collaborations (remain as stand-alone constructs)

- ❑ HITSP/T16 - Consistent Time
- ❑ HITSP/T17 – Secured Communication Channel
- ❑ HITSP/C19 – Entity Identify Assertion
- ❑ HITSP/C26 - Non-Repudiation
- ❑ HITSP/C25, C87, C88 – Anonymization
- ❑ HITSP/C44 – Secure Web Connection
- ❑ HITSP/T64 – Identify Communication Recipients
- ❑ HITSP/C62 - Unstructured Document
- ❑ HITSP/C82 – Emergency Common Alerting Protocol
- ❑ HITSP/TP30 – Manage Consent Directives
- ❑ HITSP/T29 – Notification of Document Availability
- ❑ HITSP/TP50 – Retrieve Form for Data Capture
- ❑ HITSP/T67 - Clinical Referral Request Transport

Task 3: SPI Construct Updates

- ❑ HITSP/TN900: Security and Privacy Technical Note:
 - Updated to reflect addition of SC108 (Access Control) and SC109 (Security Audit) Service Collaborations
 - Duplicative information from underlying constructs removed
 - Editorial updates for additional clarity
- ❑ HITSP/TP20: Access Control
 - Updated to reflect minor typographical error and incorporate “beautified” UML diagrams
- ❑ HITSP/TP30: Manage Consent Directives
 - Technical Actor names corrected
 - UML diagrams updated
 - Added optionality for supporting T31 (Document Reliable Interchange) and T33 (Transfer of Document Sets on Media)
 - Editorial updates for additional clarity
- ❑ HITSP/T15: Collect and Communicate Audit Trail
 - Per public comment, removed Secure Node from being a required pre-condition.

Task 3: SPI Construct Updates

- ❑ HITSP/T23: Patient Demographics Query:
 - Updated race data element components to reference C80 vocabulary for Race and Ethnicity
 - Minor editorial changes were made
- ❑ HITSP/TP22: Patient ID Cross-Referencing:
 - Based on Public Comment, “PIX Transaction” was updated to the correct term “PIX Query Transaction” throughout the document.
 - Minor editorial changes were made
- ❑ HITSP/T85: Administrative Transport to Health Plan:
 - Replaced CAQH CORE 270 Phase II Connectivity Rule v2.0.0 with v2.0. CAQH does not introduce new underlying standards at the x.x.x (i.e., 2.0.x) level, but only makes minor technical corrections (see CORE Phase 2 Policies and Operating Rules Manual v2.0.0). This change does therefore not allow for the inheritance of new underlying standards.
 - Unnecessary references to HITSP/C44 have been removed.
 - Minor editorial changes were made
- ❑ Remaining SPI Constructs:
 - Updated to new construct template only

Next Steps

- ❑ Address items deferred back to the Technical Committee
 - Major updates to constructs (incorporation of new standards through Tier 2 etc.)
- ❑ Address Gaps
- ❑ Develop new Service Collaborations and other constructs as needed to support 2009 Technical Committee Statement of Work
 - Includes Common Data Transport Use Case

Report from the Quality Measures Tiger Team

- ❑ Assessment of Data Elements supporting Quality Measures
- ❑ Value Set Development
- ❑ Value Set Support for Quality Measures in USHIK
- ❑ Establish Construct for Measure Specification Communication
- ❑ Establish Construct for Patient-level and aggregate-level reporting (QRDA)
- ❑ Update HITSP/IS06 Quality
- ❑ Establish Model for representing the Electronic Quality Specifications manual CMS quality measures
- ❑ Technical Note

Quality Measure Tiger Team

Data Elements Supporting Quality Measures

- ❑ Identify set of value sets needed and associated HITSP selected taxonomies. Created an internal spreadsheet for all clinical/business constructs
- ❑ Identify the mapping of data elements to EHR CDA or Message attributes and associated issues
- ❑ Identify issues with the data elements supporting the quality measures
- ❑ Identify Policy requirements needed to support the electronic capture of the data elements supporting the quality measures

Quality Measure Tiger Team

Value Set Development

- ❑ Identify attributes required for each value set
- ❑ Identify rules / methodology for creation of value sets
- ❑ Identify (initial) list of coded values for each value set
- ❑ Review (initial) list of coded values with the measure developer
- ❑ Identify Issues and recommendations for value set creation and maintenance
- ❑ Establish Quality Measure representation to include value sets

Terminology Experts

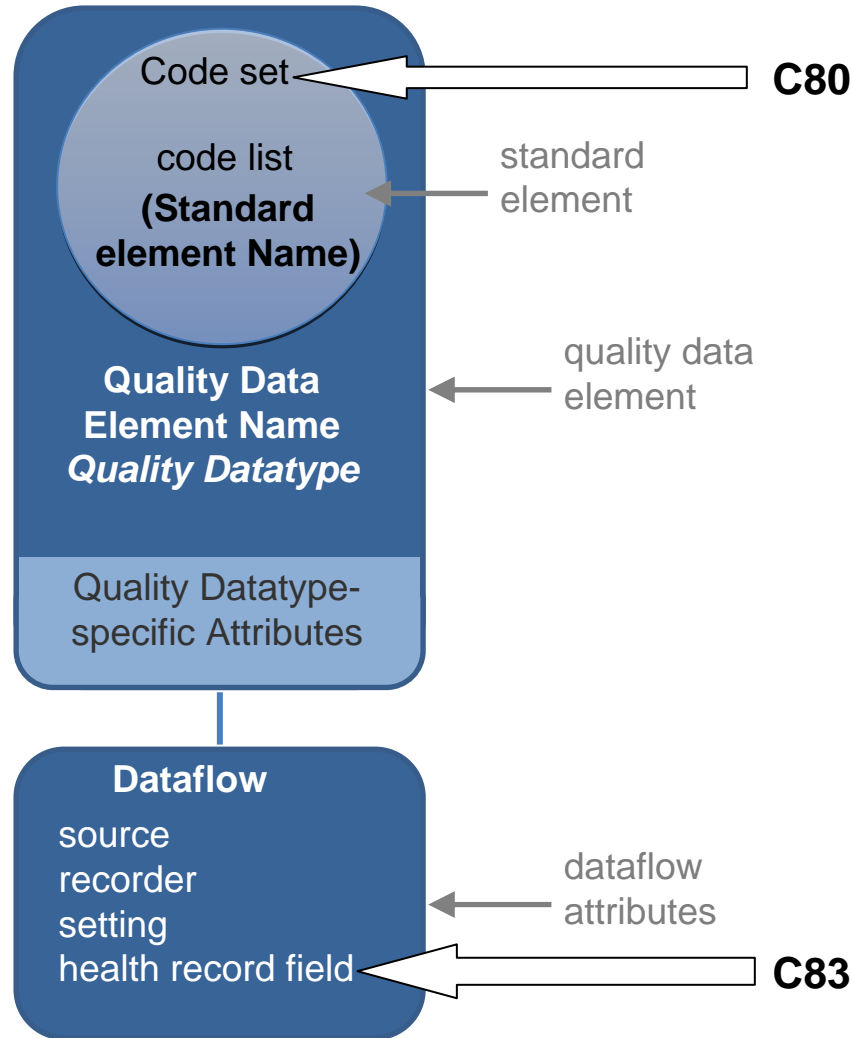
- Lisa Lang, et. al. (NLM)
- Rob McClure (Apelon)
- John Carter (Apelon)
- James Shalaby (Consultant)
- Sundak Ganesan (CDC)
- Cecil Lynch (CDC Consultant)
- Noah Stromer, Robin Barnes (USHIK)
- Debra Konicek (SNOMED)
- Gerry Wade (Consultant)
- Many Others

Measure Developer/User Community

- The Joint Commission
- CMS
- Intermountain Healthcare
- Oklahoma Foundation for Medical Care

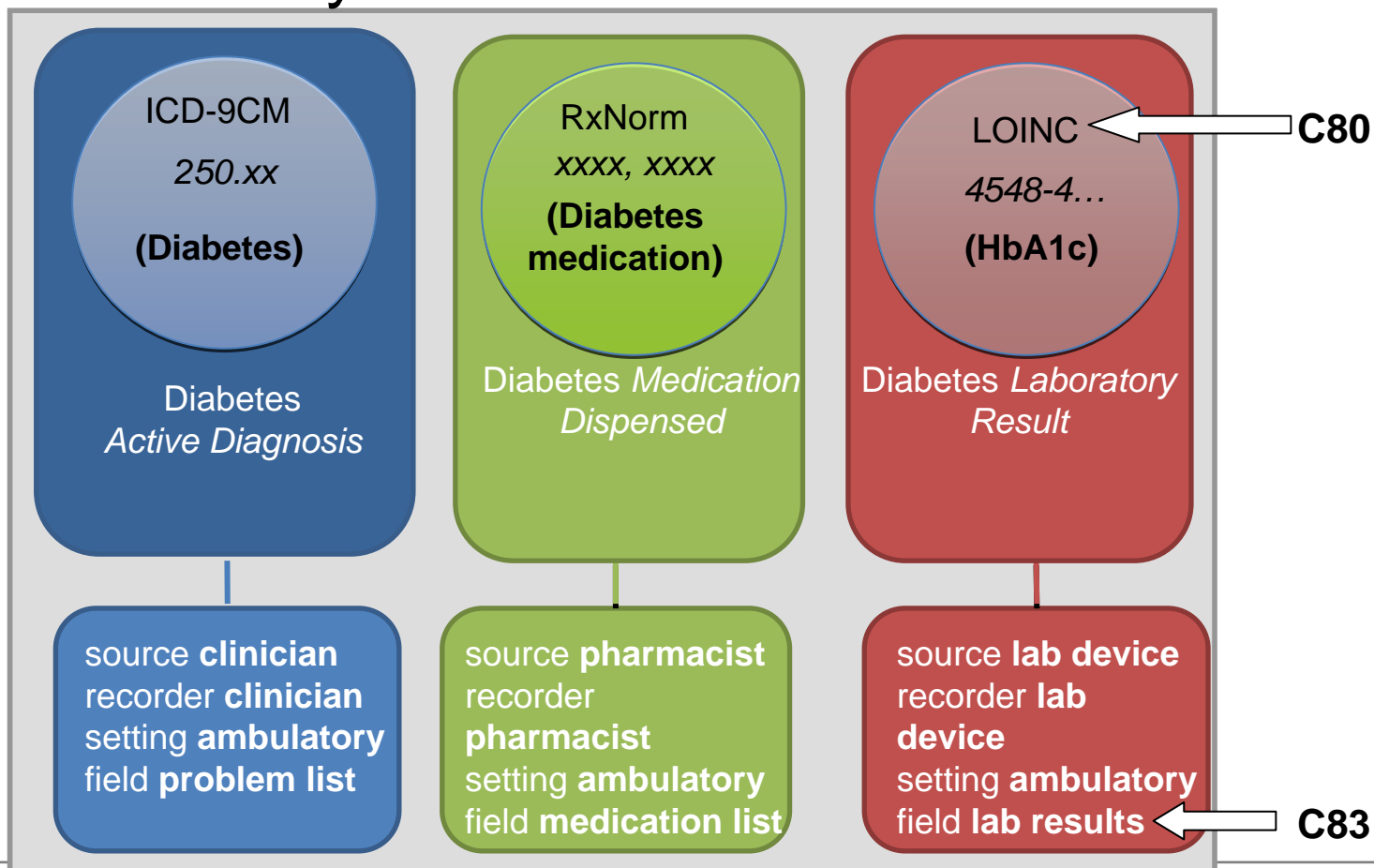
Quality Measure Tiger Team

Preview – Quality Data Set Framework – HITEP



Quality Measure Tiger Team

Preview – Quality Data Set Framework – HITEP



Example Measure Including Quality Data Elements and Dataflow (bottom rounded rectangles). Each quality data element (rounded rectangle) has associated dataflow information (bottom rounded rectangles). These dataflow attributes describe where to find the quality data element electronically.

Quality Measure Tiger Team

USHIK Prototype

- ❑ Establish value set attributes
- ❑ Initial Prototype a USHIK entry of Quality Measure Value Set
 - Data Architecture Infrastructure Technical Note

Quality Tiger Team

HITSP/IS06 Updates

TP 30	Manage Consent Directives Transaction Package	Version 1.2.1
TP 50	Retrieve Form for Data Capture Transaction Package	Version 2.4.1
T 17	Secured Communication Channel Transaction	Version 1.3.1
T 24	Pseudonymize Transaction	Version 2.2.1
T 81	Retrieval of Medical Knowledge Transaction	Version 1.0.1
SC 108	Access Control Service Collaboration	Version 0.0.1
SC 109	Security Audit Service Collaboration	Version 0.0.1
SC 111	Knowledge and Vocabulary Service Collaboration	Version 0.0.1
SC 112	Healthcare Document Management Service Collaboration	Version 0.0.1
SC 115	HL7 Messaging Service Collaboration	Version 0.0.1

Quality Tiger Team

HITSP/IS06 Updates

C 25	Anonymize Component	Version 2.2.1
C 26	Nonrepudiation of Origin Component	Version 1.3.1
C 28	Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES) Component	Version 1.2.1
C 32	Summary Documents Using HL7 Continuity of Care Document (CCD) Component	Version 2.4.1
C 34	Patient Level Quality Data Message Component	Version 1.1.1
C 39	Encounter Message Component	Version 2.2.1
C 48	Encounter Document Using IHE Medical Summary (XDS-MS) Component	Version 2.4.1
C 74	Remote Monitoring Observation Document Component	Version 1.0.1
C 75	Healthcare Associated Infection (HAI) Report Component	Version 1.0.1
C 76	Case Report Pre-Populate Component	Version 1.0.1
C 78	Immunization Document Component	Version 1.0.1

Quality Tiger Team HITSP/IS06 Updates

C 80	Clinical Document and Message Terminology Component	Version 1.0.1
C 83	CDA Content Modules Component	Version 1.0.1
C 84	Consult and History & Physical Note Component	Version 1.0.1
C 105	Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA) Component	Version 0.0.1
C 106	Measurement Criteria Document Component	Version 0.0.1

Quality Tiger Team

Updates in Public Comment

- ❑ Quality Interoperability Specification (IS06) and referenced constructs [HITSP/IS06 Quality](#)
- ❑ Patient Level Quality Data Message (C34) [HITSP/ C34 Patient Level Quality Data Message](#)
- ❑ Patient Level Quality Data Document (C105) [HITSP/C105 Patient Level Quality Data Document](#) (replaces C38)
- ❑ Measurement Criteria Document (C106) [HITSP/C106 Measurement Criteria Document](#)

The public comment period opened **Wednesday July 1, 2009** until **Close of Business, Thursday, July 30, 2009**.

Report from the Clinical Research Tiger Team



Background

- ❑ Clinical research an important priority identified early by AHIC and ONC; in June, 2008 AHIC approved a recommendation to develop a clinical research use case
- ❑ In late 2008 ANSI convened an **EHR Clinical Research Value Case Workgroup**
- ❑ CCHIT added in January, 2009 clinical research to roadmap for EHR certification; HL7 EHR Clinical Research Profile passed ballot
- ❑ Value case anticipated to provide a foundation for future use cases:
 - Patient eligibility and recruitment
 - Pharmacogenomics and biomarkers
 - Safety reporting
 - Compliance reporting
- ❑ Long-term goal: create an infrastructure through which health care advances clinical research which, in turn, informs clinical care

Acknowledgement - EHR Clinical Research Workgroup Members

- ❑ Jonathan Andrus - SCDM
- ❑ Robert Annechiarico - Duke Comprehensive Cancer Center
- ❑ Kate Blenner – Faster Cures
- ❑ Kenneth Buetow – NCI
- ❑ Christopher Chute – Mayo Clinic, CTSA
- ❑ Perry Cohen - Parkinson Pipeline Project
- ❑ Elaine Collier – NCRR
- ❑ Kevin Coonan – Harvard, HL7, Dana Farber
- ❑ Timothy Cromwell - VA
- ❑ Jeffrey David - HIMSS
- ❑ Peggy Devine - Cancer Information and Support Network
- ❑ * **Gregory Downing - HHS**
- ❑ Paul Harris - Vanderbilt University, CTSA
- ❑ Steven Hirschfeld – NICHD
- ❑ Charles Jaffe – HL7
- ❑ Michael Kahn – AMIA, Colorado Children’s
- ❑ Linda King – eClinical Forum, PhRMA, Eli Lilly
- ❑ Judith Kramer – Duke, CTTI
- ❑ * **Rebecca Kush - CDISC**
- ❑ David Leventhal – Pfizer, ASTER
- ❑ Nikolay Lipskiy - CDC
- ❑ Armando Oliva - FDA
- ❑ Rachel Richesson – USF
- ❑ John Speakman – NCI
- ❑ Gary Walker - ACRO

**Co-chairs*

HITSP

Clinical Research Tiger Team



Value Case

- ❑ Workgroup developed initial draft detailed value case and extensions (Nov 2008 – Feb 2009)
- ❑ Draft value case posted for public comment in March 2009
- ❑ Detailed value case completed by end of April, 2009; value case submitted HITSP for development of interoperability specifications
- ❑ Document describes three value scenarios:
 - Scenario 1: Data exchange from EHR to clinical research sponsor for submission to regulatory, public health, and other agencies
 - Scenario 2: Exchange of information from EHR to registries or other databases
 - Scenario 3: Exchange of information from EHR in a distributed research network

Use of Electronic Health Records in Clinical Research: Core
Research Data Element Exchange
Detailed Use Case
April 23rd, 2009

HITSP

Clinical Research Tiger Team



Value of Standards for Clinical Research

- Facilitate investigator/site participation in multicenter studies
- Study data in standard format readily populates reports, publications, registries
- Increase data quality
- Enable data integration into 'knowledge warehouses' to improve science, marketing and safety surveillance
- Improve communication among project teams
- Enable efficient exchange of information among a variety of tools and technologies
- Minimizes customization of EHRs to support research
- Site research data archive helps meet regulatory compliance
- Improve data exchange among partners (e.g. academic institutions, FDA, NLM, IRBs, DSMBs)
- Facilitates regulatory reviews

HITSP Clinical Research Tiger Team



TT Formation

- ❑ HITSP group convened as a 'Tiger Team' in early-May
- ❑ Goal: Perform requirements analysis of the value case through mid-July, while Technical Committees are on temporary hold during the ARRA realignment
- ❑ Outcome to be transferred to appropriate Technical Committee moving forward

HITSP

Clinical Research Tiger Team



TT Leadership, Members

❑ Leadership

- Walter Suarez, MD, Institute for HIPAA/HIT Education & Research, Co-Chair
- Gene Ginther, JBS International, Staff Co-chair
- Landen Bain, CDISC, Technical Writer

❑ Membership

- 165 signed up for the list serve
- Participation on weekly calls from provider organizations, research institutions, federal and state public health government, national research associations and vendors
- Added a large number of new members to HITSP

HITSP

Clinical Research Tiger Team



Terms of Reference

1. Review Use Case, provide feedback to requestor, evaluate scope of effort and develop statement of work for completion.
2. Perform high level design of Interoperability Specification and lower level constructs including requirements analysis and minimum data set identification.
3. Submit for public comment detailed Requirements Analysis and Design documentation
4. Identify Domain Committee(s) for construct development and provide high level design and statements of work.
5. Review and evaluate existing Interoperability Specifications for the selected standards, integrating relevant constructs.
6. Manage overall execution plan/schedule in collaboration with Domain Committees.

HITSP Clinical Research Tiger Team



Focus of RDSS Development

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HITSP Clinical Research Tiger Team



Status

- ❑ Initial meeting held May 14th
- ❑ Requirements Analysis nearly complete
 - ❑ In-depth review of value case scenarios
 - ❑ Completed mapping of value case events, actions, data exchange and data requirements
 - ❑ Wrapping up minimum data set analysis discussions this week

HITSP

Clinical Research Tiger Team



Status

- ❑ 1st Draft of the RDSS to be reviewed by TT next week
 - ❑ Incorporates new Framework concepts of Capabilities and Service Collaborations
 - ❑ Reuses many HITSP constructs
 - ❑ Requires at least one new supporting construct
 - ❑ *Clinical Research Form*
- ❑ Handoff of RDSS for IRT review scheduled for July 23rd
- ❑ RDSS scheduled for released for Public Comment o/a July 30th