

Clinical Research, EHR Secondary Use

➤ Meaningful Use, NHIN, HITSP and You

DVHIMSS Meaningful Use Conference, CHOP
February 28, 2010



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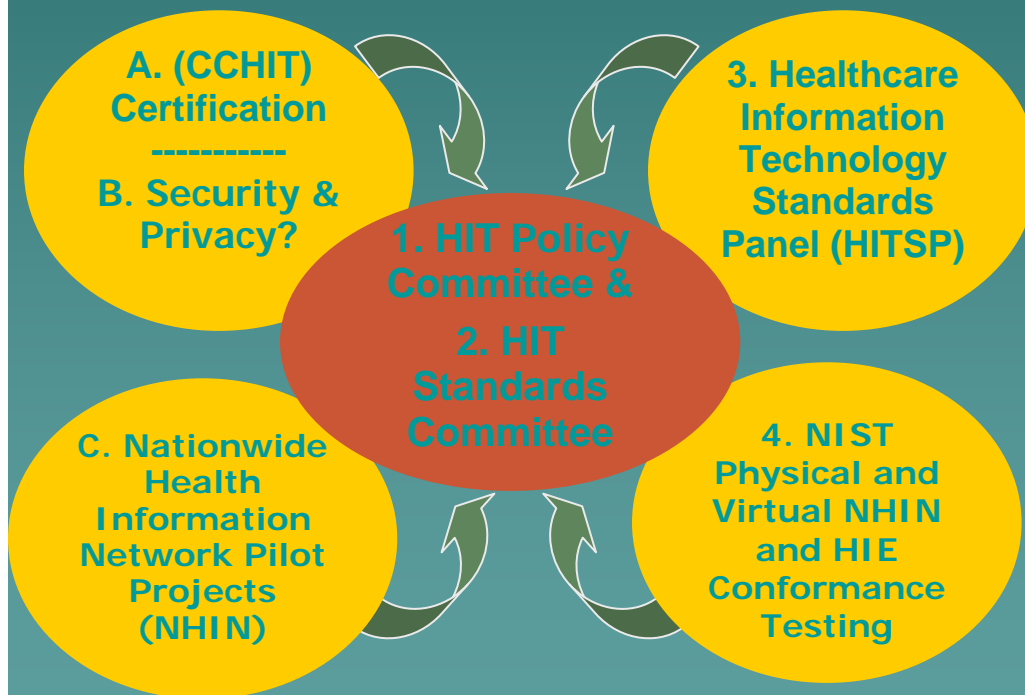
Overview

- ◆ **A Context:**
 - ARRA, Meaningful Use, HITSP, and NHIN
- ◆ **The Clinical Research “Tiger Team” work product: the January, 2010**
 - *“HITSP/IS158 Clinical Research Interoperability Specification”*

A Context

- ◆ To understand the Clinical Research Tiger Team and its efforts, we need a framework
 - The Nationwide Information Network Architecture, and its role in ARRA
 - The ANSI Healthcare Information Technology Standards Panel (HITSP), and its place in the HIT Standards world
 - The general HITSP architecture and terminology, and, then,
 - The Clinical Research Integration Specification that fits within the HITSP and NHIN framework

HHS/ONCHIT's 2009 Health IT Strategy *rapidly* redefined and created the 2010- 2013 NHIN



1. The HIT Policy Committee advises ONC on needed policies and priorities to deliver EHRs by 2014¹.
2. The HIT Standards Committee recommends HIT standards for national NHIN/HIE deployment
3. HITSP brings all stakeholders together to select and integrate the "right" HIT standards
4. NIST has been funded to create expandable conformance testing for NHINS and HIEs
 - A. CCHIT may NOT regain their role as the leading mechanism for health care IT product certification
 - B. HISPC addressed business policy and state laws that affect privacy and security; final report in 12/09?
 - C. NHIN focused on interoperability demo pilots each year; \$60M funding?

ARRA/HITECH Strategic Roadmap

Strategic

Practice Enhancement
Quality Optimization

Phase 4: Active Quality Reporting
and Health Surveillance

Phase 3: Clinical Decision Support and
Advanced Access Control

Tactical

Phase 2: Diagnostic Results and
Therapeutic Information

Phase 1: Share Care Status Information

Process/Practice Automation

Quality improvement

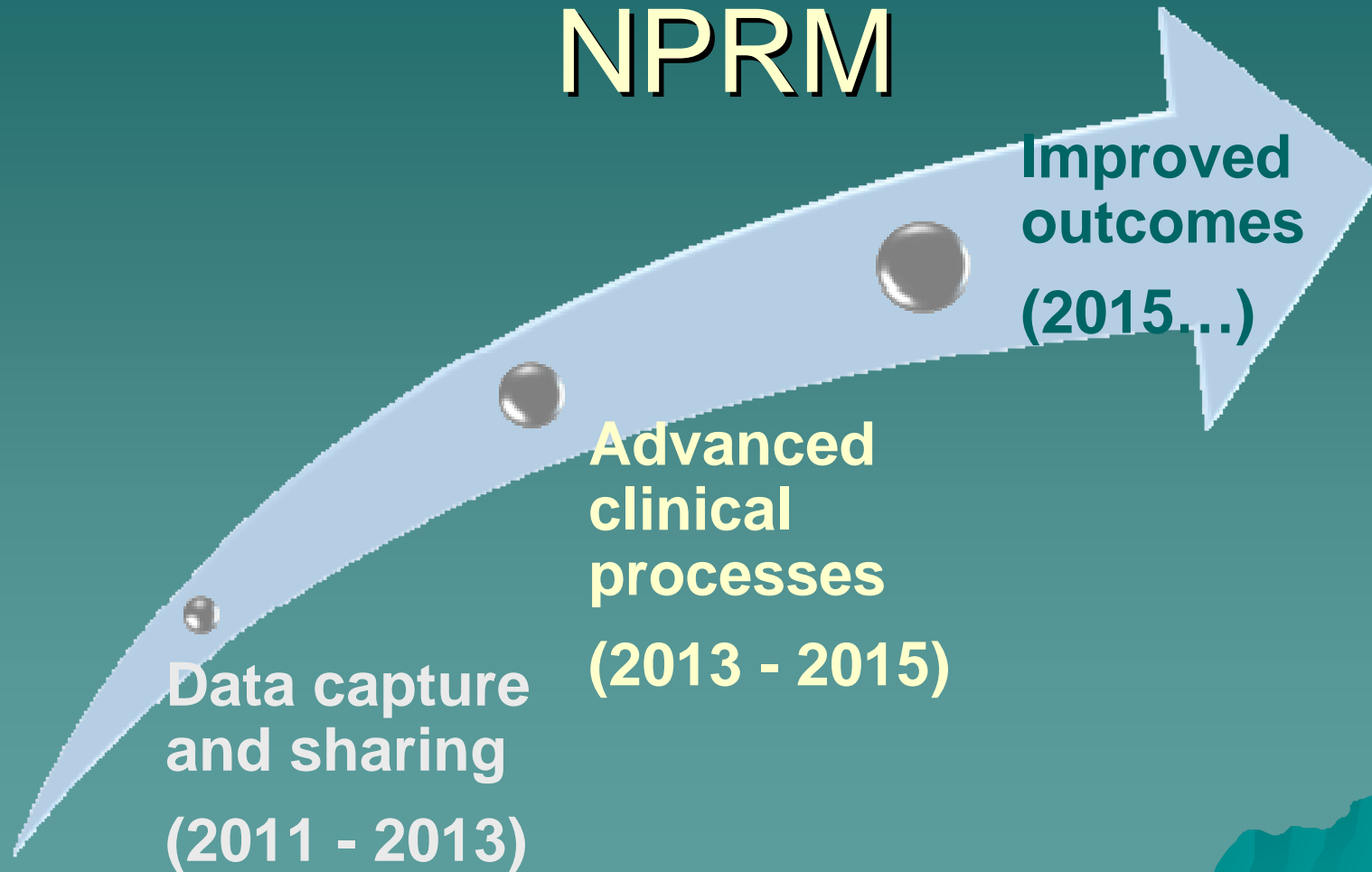
+ 2YRs
and
beyond

2014+

+ 6 mos to
1 yr
2012

Available
2011

Meaningful Use, as articulated in the 12/30/2009 IFR and NPRM



The NHIN?

- ◆ The Nationwide Healthcare Information Network is a conceptual framework for organizing the nation's health data
- ◆ NHIN becomes physical as it is manifested through state, regional, and federal pilot projects
- ◆ The following 5 slides were presented by our partner Vish Sankaran, Director of the Federal Health Architecture at the HIMSS co-hosted "IHE Connectathon" that I moderated in Chicago on January 12

Why information exchange ?



**Continuity of Care:
Wounded Warrior Scenario**



Afghanistan

Washington, D.C.

**Walter
Reed**

Missouri



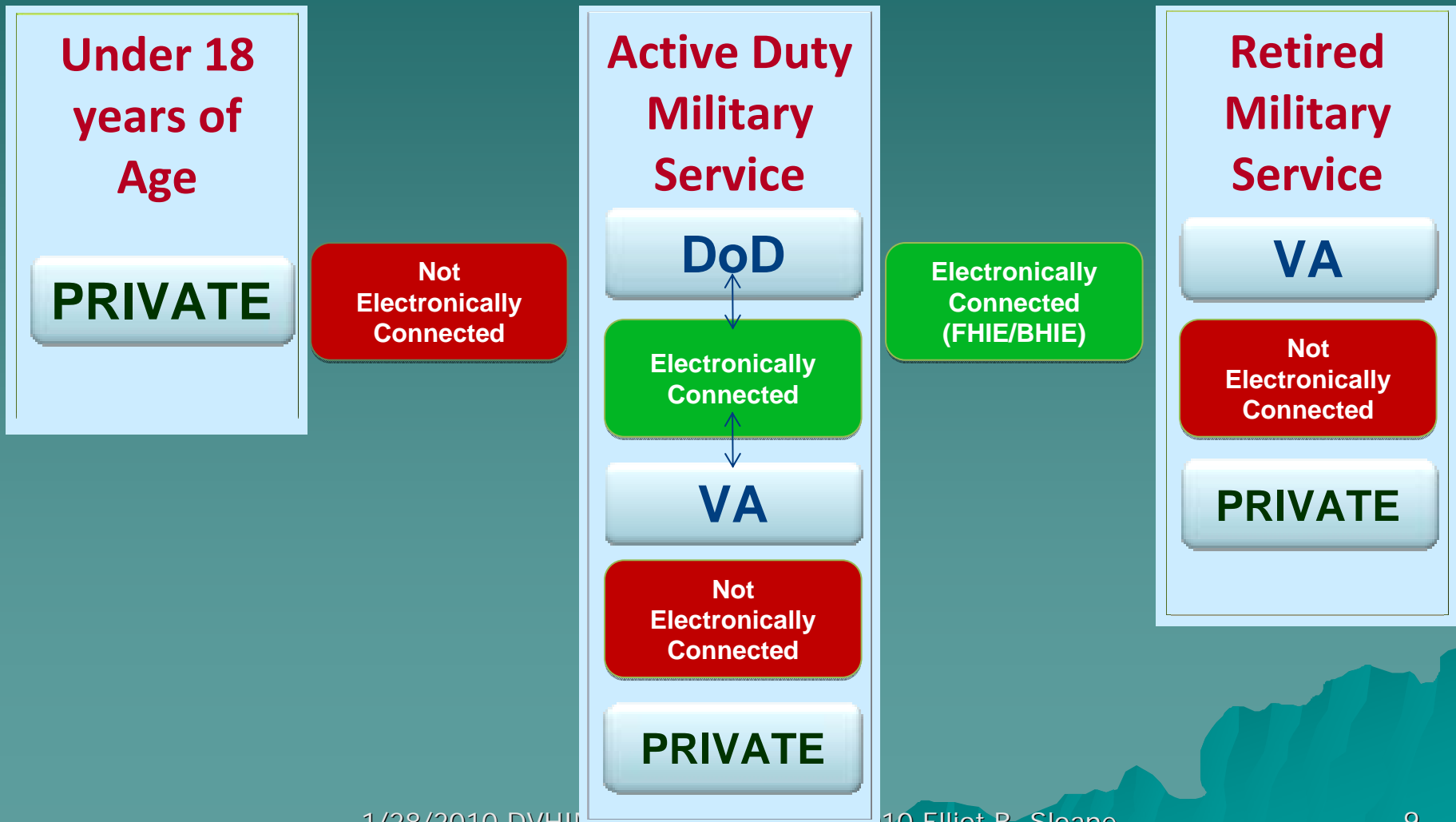
Durham VA

**North Carolina
Private sector**

North Carolina



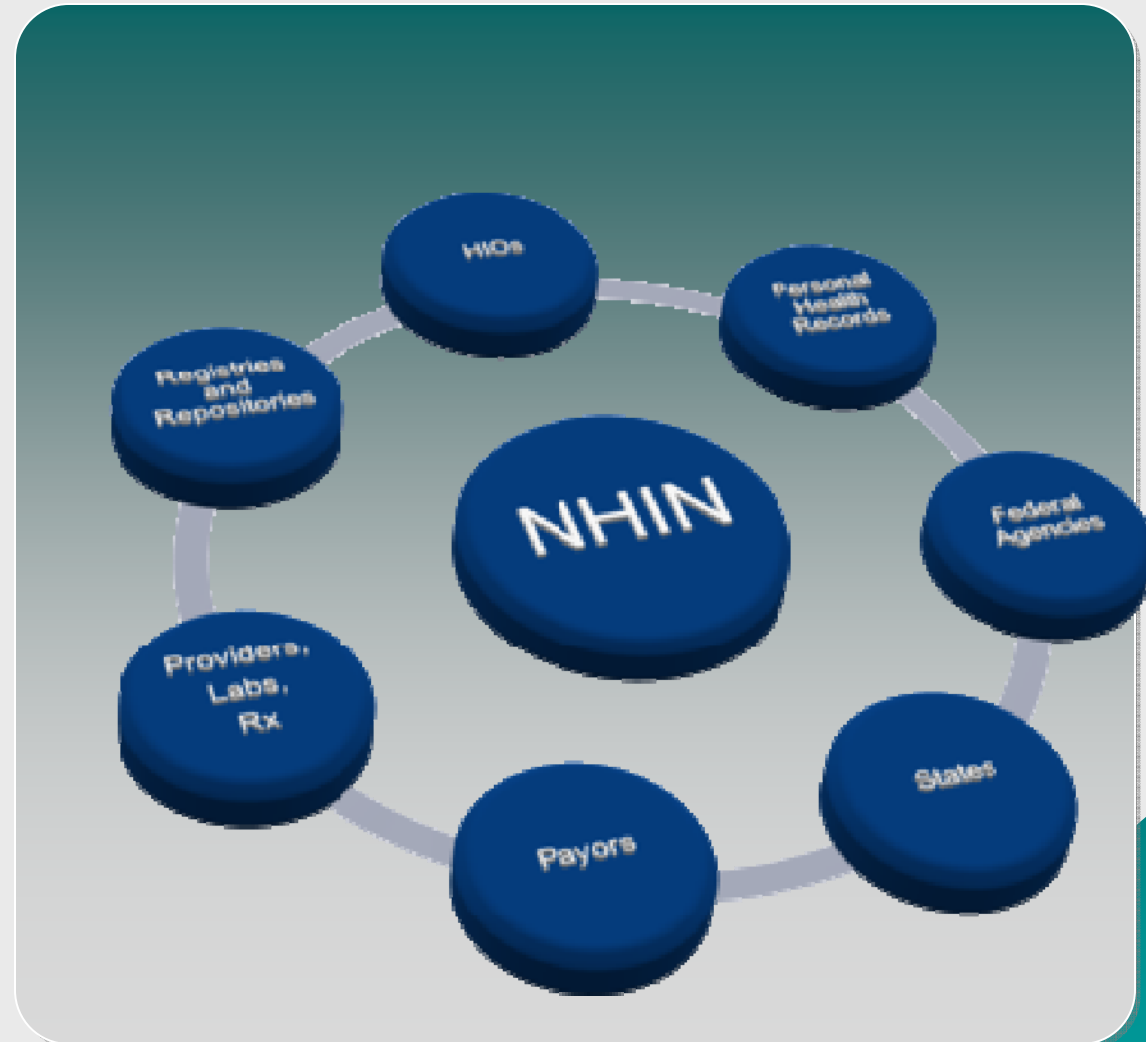
CURRENT - Healthcare provided by multiple entities are NOT connected



The Nationwide Health Information Network

The NHIN:

- ◆ Network of interconnected standards based HIT systems
- ◆ Provides a platform to participate for all health stakeholders
- ◆ Offers technology and trust tools for implementation
- ◆ Supports both the local and nationwide secure exchange of health information.



The Path to Meaningful Use: Communities CONNECTing to the NHIN



- ◆ Roughly 5,000 square feet of demonstrations within the Interoperability Showcase
- ◆ Participants include feds, states, providers, payers, health IT vendors, and others

45 organizations will demonstrate progress toward meaningful use in the areas of:

- *Quality Measurement Reporting*
- *Pharmacy Transactions*
- *Diagnostics*
- *Administrative Efficiency*
- *Consumer*
- *Improving Care Coordination*
- *Improving Population and Public Health*

New Regulations Created by the HITECH Act (summarized by Vish Sankaran)

Meaningful Use Notice of Proposed Rule-Making
Published December 30, 2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 412, 413, 422, and 405
CMS-9033-P
RIN 0938-AP03
Medicare and Medicaid Programs; Electronic Health Record Incentive Program
AGENCY: Centers for Medicare & Medicaid Services (CMS), 2009.
ACTION: Proposed rule.
SUMMARY: This proposed rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. The proposed rule would specify the initial criteria an EP and eligible hospital must meet in order to qualify for the incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs and eligible hospitals failing to meaningfully use certified EHR technology; and other program participation requirements. Also, as required by ARRA, the Office of the National Coordinator for Health Information Technology (ONC) will be issuing a closely related interim final rule that specifies the Secretary's adoption of an initial set of standards, implementation specifications, and certification criteria for electronic health records. ONC will also be issuing a notice of proposed rulemaking on the process for organizations to conduct the certification of EHR technology.

◆ Proposed phase 1 criteria for Medicare- and Medicaid-participating providers and hospitals to receive incentives for using electronic health records (EHRs) in a meaningful manner

◆ Now in 60 day comment period

http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PI.pdf

BILLING CODE: 410-45-P
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
42 CFR Part 170
RIN 0991-AB08
Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology
AGENCY: Office of the National Coordinator for Health Information Technology; Department of Health and Human Services.
ACTION: Interim final rule.
SUMMARY: The Department of Health and Human Services (DHHS) is issuing this interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 1003(d)(1) of the Public Health Service Act. This interim final rule represents the first step in an incremental approach to adopting standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology and to support its meaningful use. The certification criteria adopted in this initial set establish the capabilities and related standards that certified electronic health record (EHR) technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use (Stage 1) beginning in 2011 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Program.

Page 1 of 106

Interim final regulation for certification criteria and standards
Published December 30, 2009

◆ An initial set of standards, implementation specifications, and certification criteria for EHRs

◆ Now in 60 day comment period

http://www.federalregister.gov/OFRUpload/OFRData/2009-31216_PI.pdf

HITSP and the NHIN

- ◆ The ANSI/Health Information Technology Standards Panel (HITSP) was created by HHS in 2005 to select the BEST health information standards and assemble them into orchestrated “interoperability framework” for the US NHIN and Certification programs to use

ALL HITSP documentation is **FREE, as in FREE!**

Welcome to www.HITSP.org

The **Healthcare Information Technology Standards Panel (HITSP)** is a cooperative partnership between the public and private sectors. The Panel was formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems.

PROGRAM OF WORK

View by Topic

View by Status

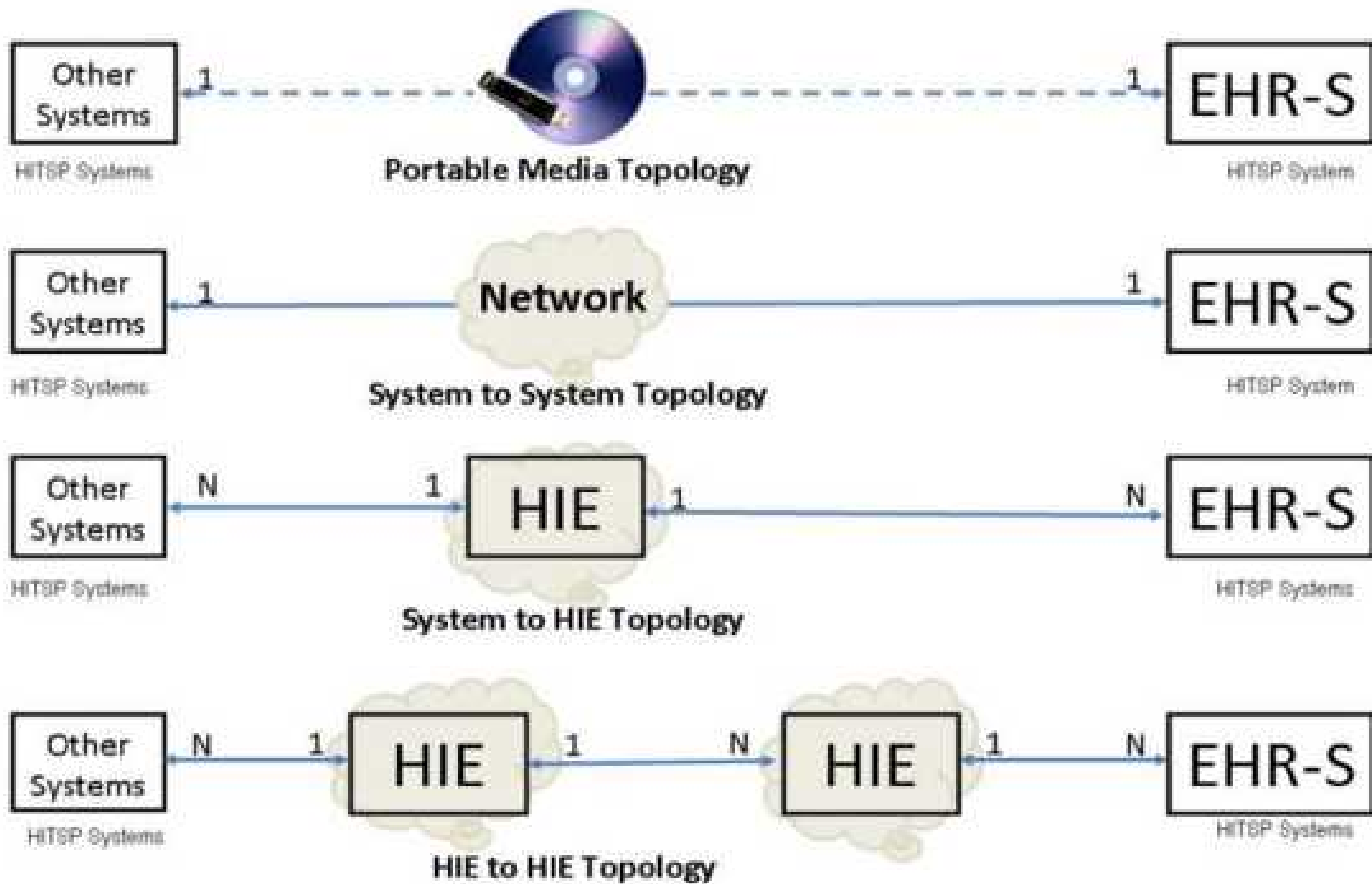
View Complete Library

- Interoperability Specification
- Capability
- Service Collaboration
- Transaction Package
- Transaction
- Component
- **Technical Note**
- Requirements Design and Standards Selection
- Reference

Quick HITSP Roadmap

- ◆ From Base Standards to YOUR EHR
 - Value Proposition/Use Case
 - Requirement Document (RDS)
 - HITSP Constructs, or building blocks, which are FREE specification documents at HITSP.org (i.e., Transactions, Transaction Packages, Capabilities, and Service Collaborations)
 - HITSP Technical Notes, which are FREE (implementation “builders notes”)

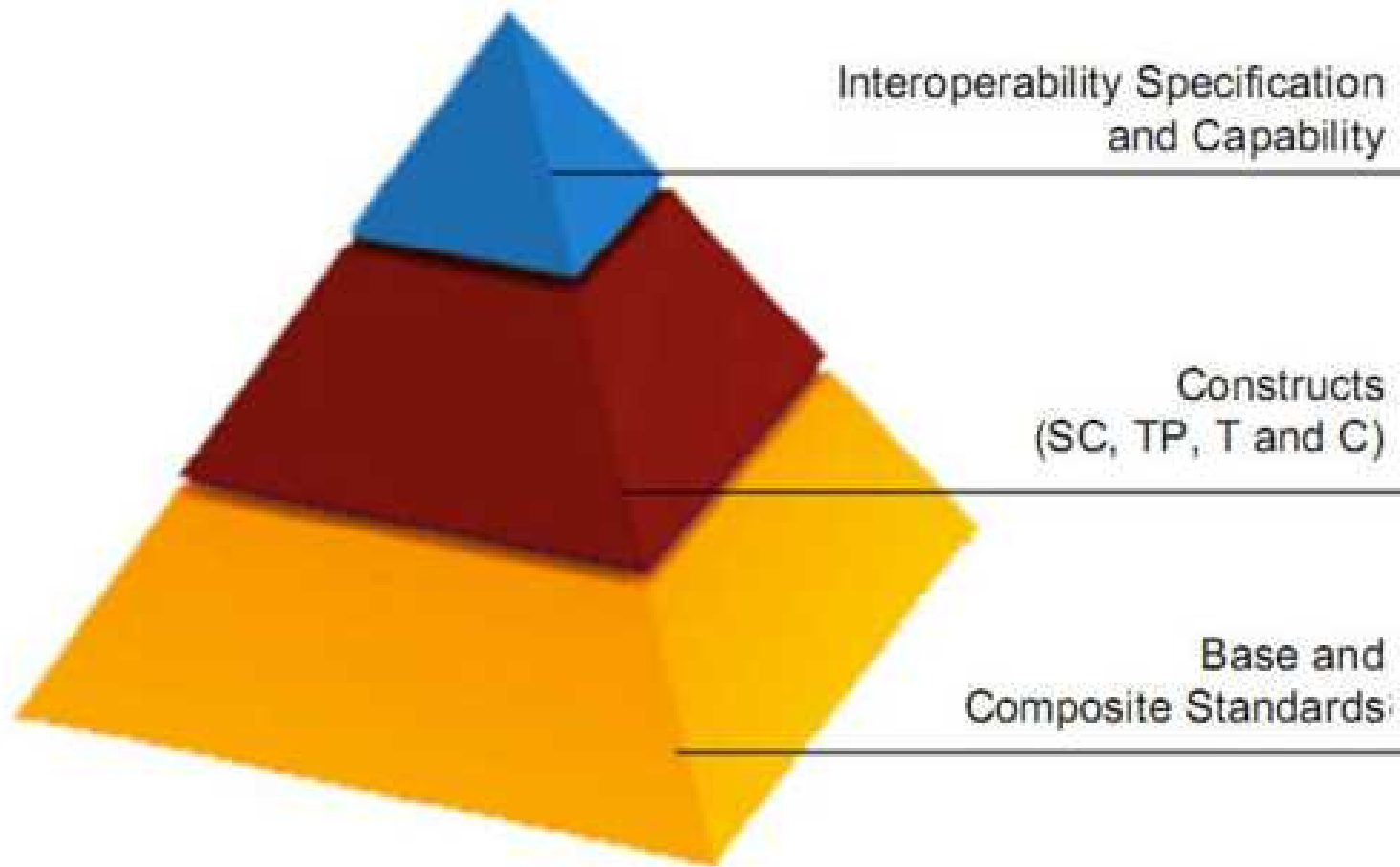
Figure 3-6 Notional Exchange Architecture Topologies



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.

Figure 3-1 Interoperability Specification Framework



Interoperability Specification (Complete Set)

Figure 3-2 Fundamental Relationships depicts the interrelationships of the requirements and design sections of the IS. Stakeholders' Information Exchange Requirements (IERs) are met with System software Capabilities (CAP).

Figure 3-2 Fundamental Relationships

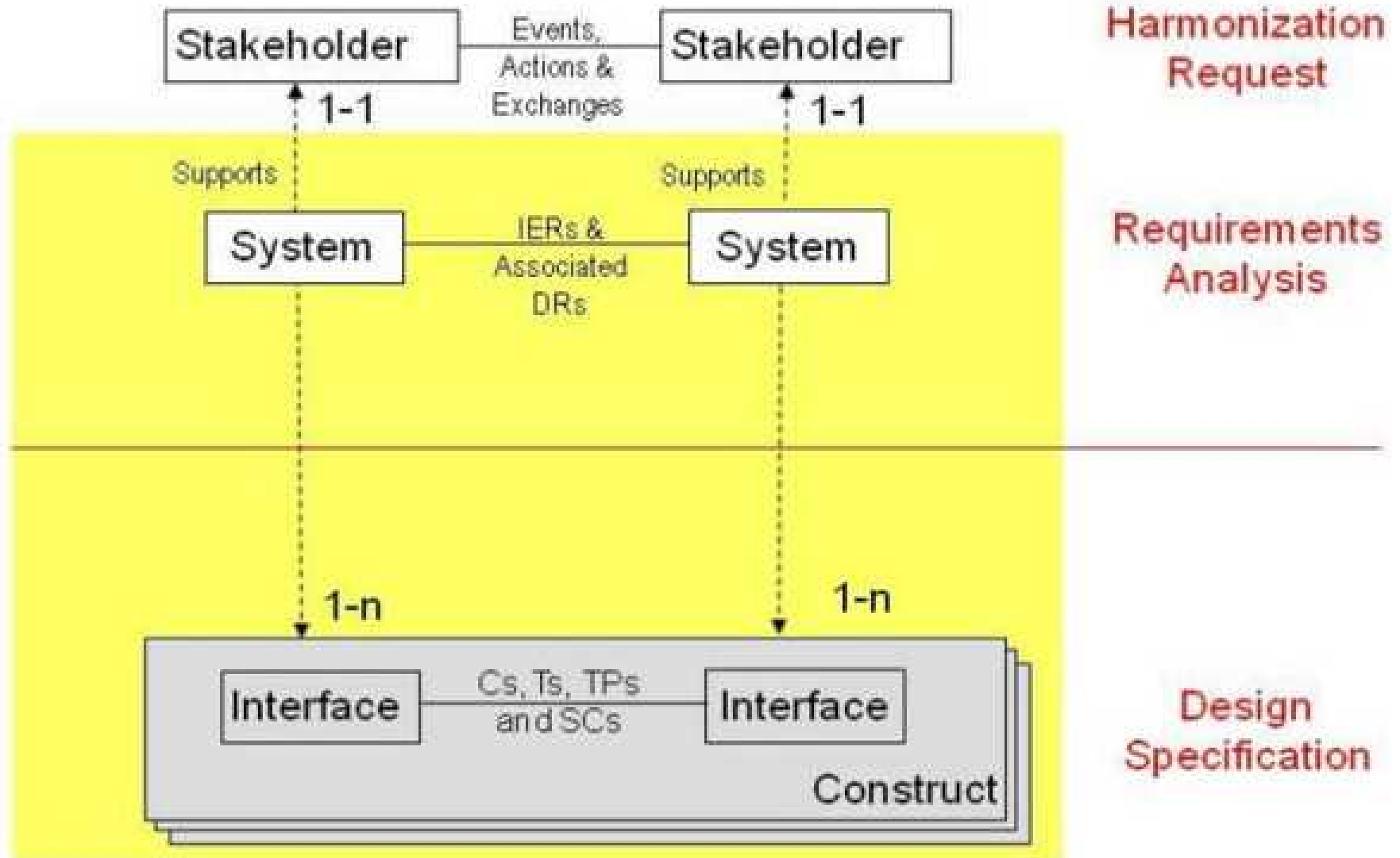
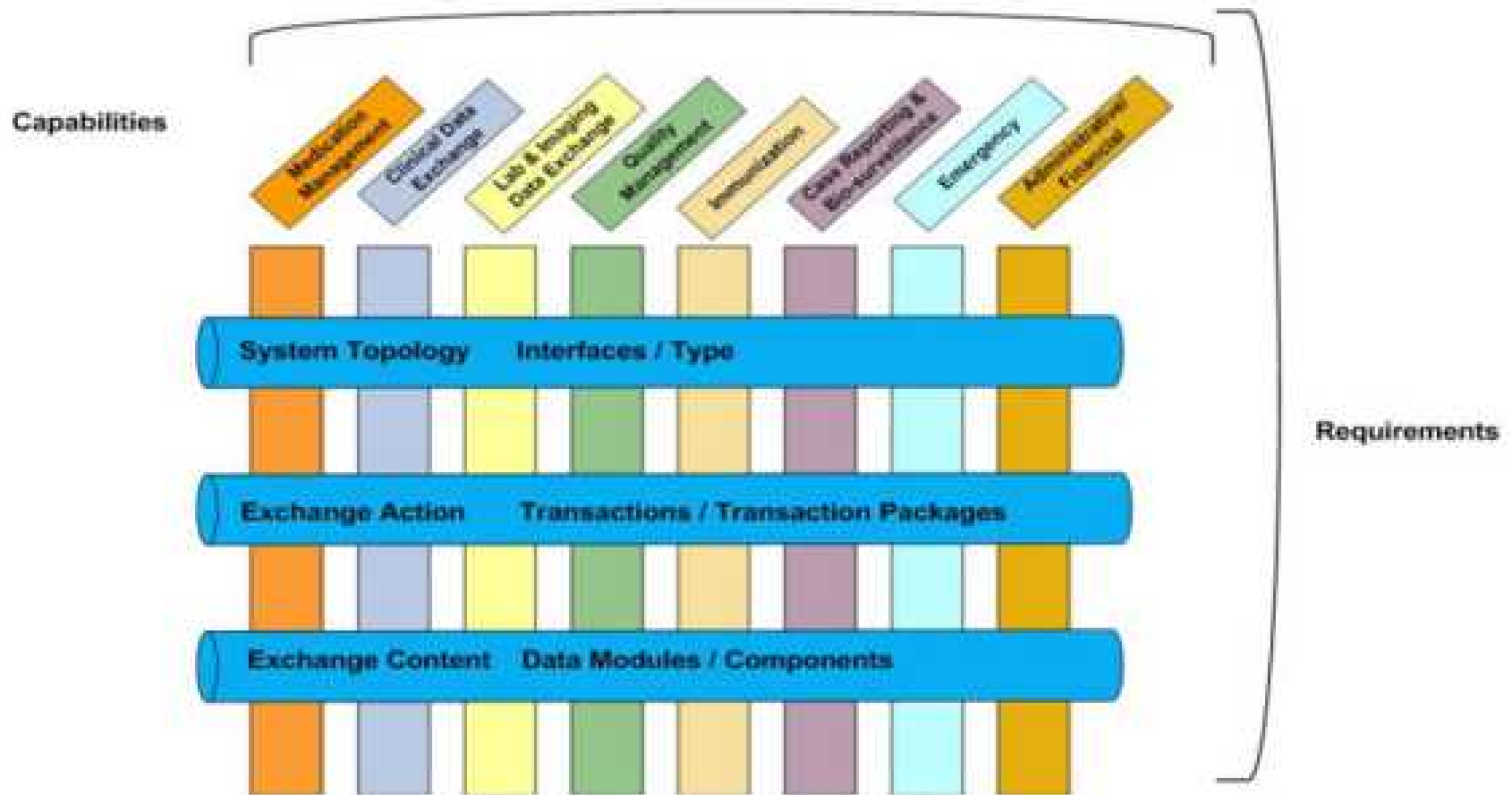


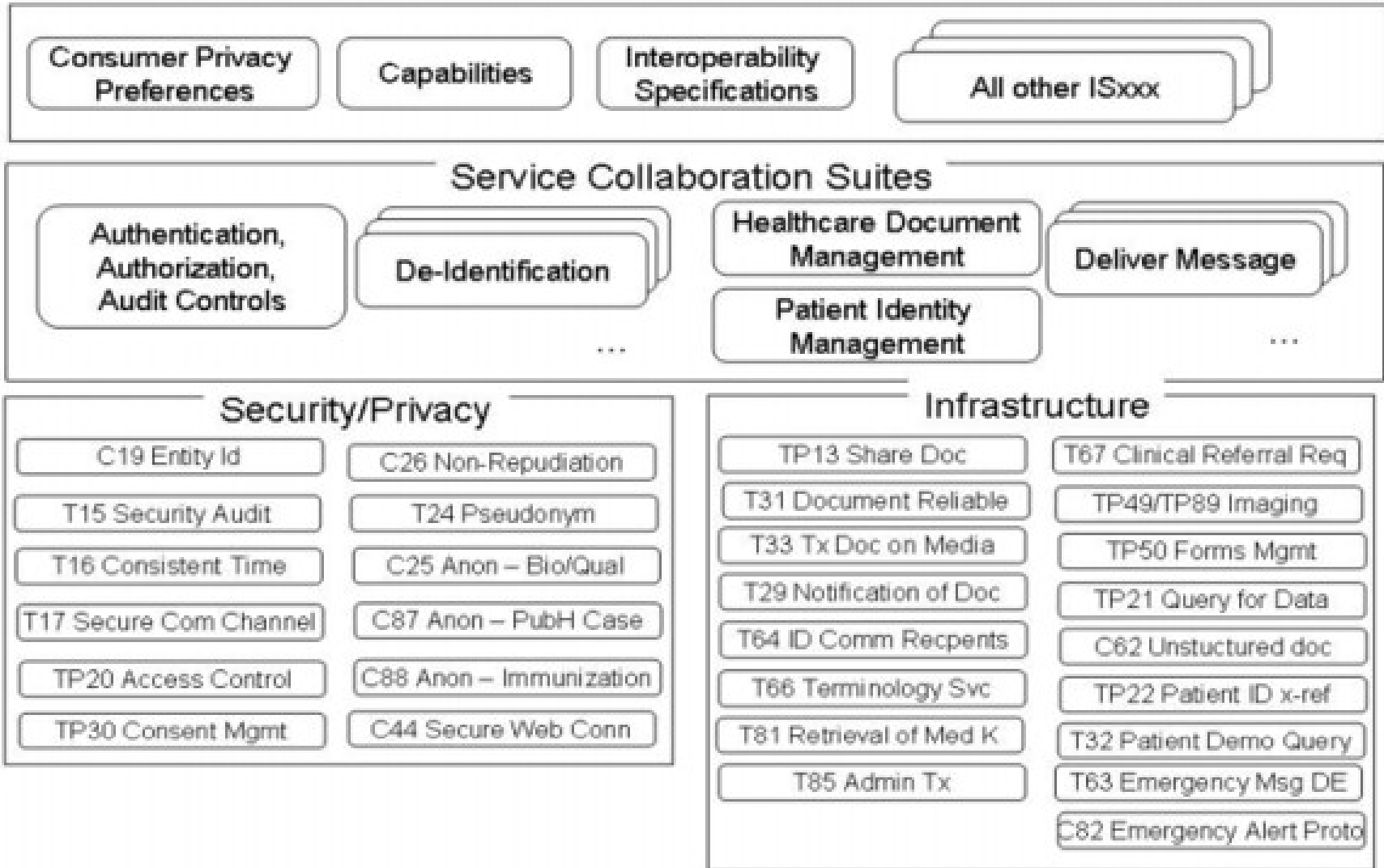
Figure 3-4 HITSP IS Requirements



The following are examples of capabilities:

- CAP117: Communicate Ambulatory and Long Term Prescription
- CAP118: Communicate Hospital Prescription
- CAP119: Communicate Structured Document
- CAP120: Communicate Unstructured Document

Figure 3-5 Security, Privacy and Infrastructure Service Collaborations



July 8, 2009
Version 1.3

HITSP Security and Privacy Technical Note

HITSP/TN900

July 8, 2009
Version 1.0



HITSP Data Architecture Technical Note

HITSP/TN903

July 8, 2009
Version 1.0



HITSP Harmonization Framework and Exchange Architecture Technical Note

HITSP/TN904

Healthcare Information

SO, how did Clinical Research become a NHIN EHR priority?

- ◆ Basically, YOU, the community, asked for it!
- ◆ This HITSP Interoperability Specification is the *ONLY independently funded* project since 2005!
 - Collaborative effort between ANSI, ONC, and CDISC (non-profit Clinical Data Interchange Standards Consortium, www.CDISC.org)



IS 158

Clinical Research

The Clinical Research Interoperability Specification covers clinical research in all its forms as it interoperates with healthcare systems, particularly EHRs. The specification spans two industries, healthcare and clinical research, and incorporates standards from healthcare (HL7 and IHE) and research (CDISC). The design leverages existing HITSP constructs and communication methodologies where applicable, and lays out new constructs as needed. The design also leverages the current players in the clinical research industry such as Electronic Data Capture (EDC) systems and research registries.

IS 158 - Clinical Research

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January 18, 2010
Version 0.0.2

HITSP Clinical Research Interoperability Specification

HITSP/IS158

IS 158 VERSION:0.0.2 Panel Review

Clinical Research (Complete-Set)

IS-158	Clinical Research
CAP 127	Communicate Lab Results
CAP 128	Communicate Imaging Information
CAP 135	Retrieve and Populate Form
CAP 143	Manage Consumer Preference and Consents



Healthcare Information Technology Standards Panel

DOWNLOAD

Version 0.0.2

DOWNLOAD

Version 0.0.2

DOWNLOAD

**FREE, at
www.HITSP.org**

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Let's take you on overview of HITSP

- ◆ I will use the November, 2011 HITSP Webinar slide set
 - Yes, FREE, at www.HITSP.org, along with the narration



November 19, 2009 1:00 – 3:00 PM (Eastern)	Understanding the New HITSP Clinical Research Interoperability Specification and Related Constructs	Audio: (mp3) Presentation: (.pdf)
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http://www.hitsp.org/archived_webinars_09.aspx

Switch to HITSP Webinar

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Thank You!

- ◆ Elliot B. Sloane, PhD, CCE, FHIMSS
 - Drexel University, School of Biomedical Engineering, Science and Health Systems
 - Center for Healthcare Information Research and Policy
 - ◆ Board of Directors, ANSI/HITSP
 - ◆ Co-Chair IHE-International
 - ◆ Board of Directors, DVHIMSS
 - ◆ Board of Directors, IHE USA

All questions cheerfully answered! *FREE!*

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Or just Google™ me!