

HL7 EHR – Immunization Functional Profile Project

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Introduction

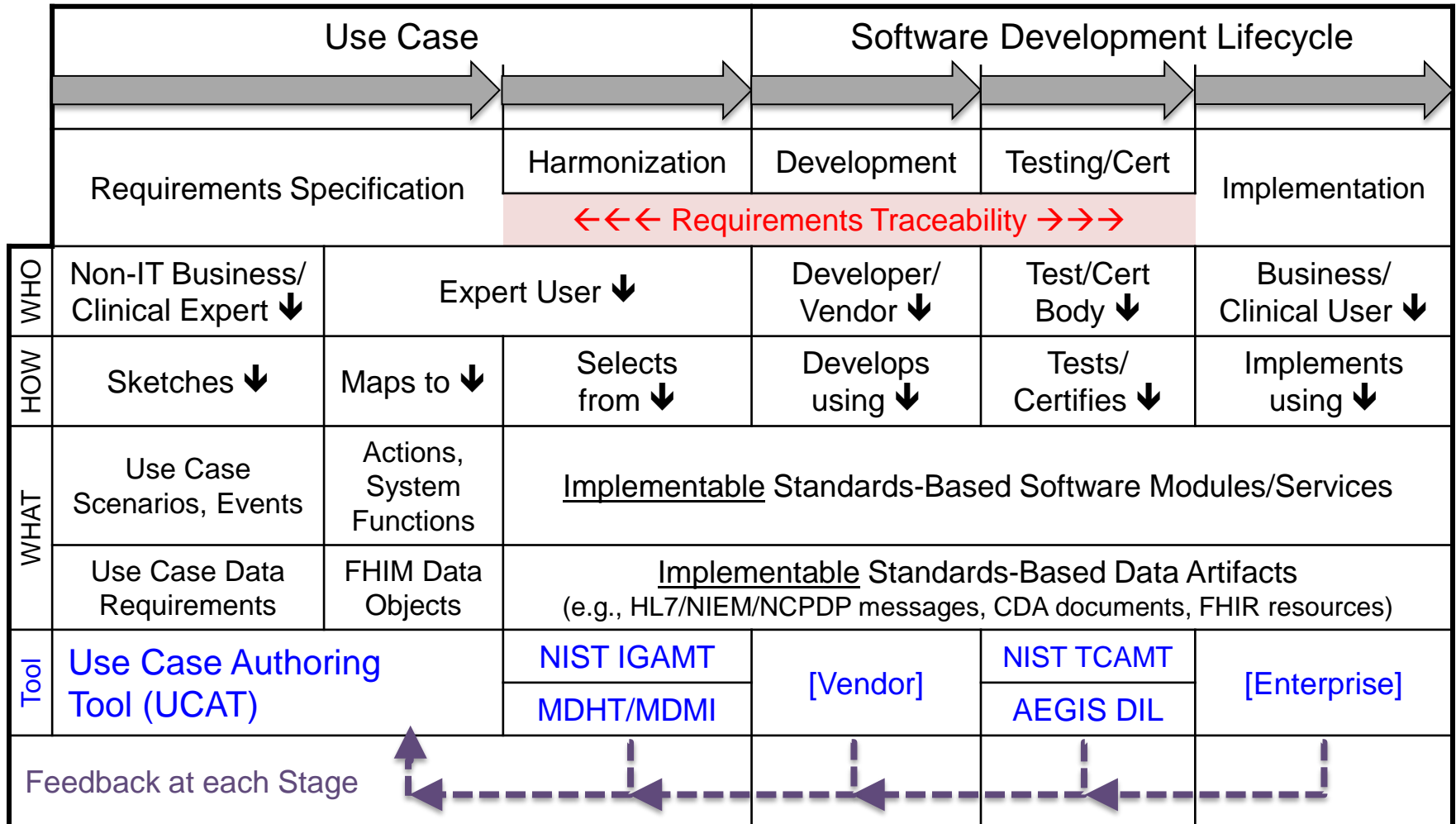
- This is an open project
 - All are welcome!
 - International input invited!
- Team meets each Monday at 11AM US ET
 - <https://global.gotomeeting.com/join/597758325>
 - +1 (571) 317-3122 Access Code: 597-758-325

Immunization Functional Profile Project

Wiki

- Links and documents:
 - Contributions/Contributors List
 - Reference Materials
 - Functional Models and Profiles
 - Federal Health Information Model (Immunization)
 - Tools
- http://wiki.hl7.org/index.php?title=EHR_Immunization_Functional_Profile

From Sketch to Implementation



Collaborative End-to-End Immunization Project Contributions - Immunization FP Contributions - 1 August 2016

Organization	Status	Contribution	Readiness	Individual(s)	Tool
Health Level Seven (HL7) Electronic Health Record (EHR) Work Group	HL7 Sponsor	EHR System Functional Model R2	Ready	HL7 EHR WG Co-Chairs	HL7 EA-based EHR-S FM/FP Tool
		PHR System Functional Model R1	Ready		
		EHR-S Public Health Functional Profiles x 9	Ready	John Ritter, Hetty Khan	
		EHR-S Immunization Functional Profile	Preliminary	Gary Dickinson Mark Janzcewski MD	
HL7 Public Health/ Emergency Response (PHER) WG	Interested	EHR-S FM/FP Developer Tool in Enterprise Architect (EA)	Ready	Anneke Goosen Michael Van Der Zel	
		Immunization Domain Analysis Model (DAM)	Ready	John Roberts	
		Immunization History Conformance Profile • User Story, Use Case Scenario, Events, Actions, Actors/Roles, Data Requirements	Ready		
HL7 Clinical Information Modeling Initiative (CIMI) WG	Confirmed	CIMI Immunization Clinical Model(s)	Ready?	Galen Mulrooney Steve Hufnagel	
AEGIS (HL7 Testing Partner)	Confirmed	Immunization Test Cases	Ready	Mario Hyland	AEGIS DIL
		Developers Integration Lab (DIL)	Ready		
US Office of National Coordinator	Observer	Standards & Interoperability (S&I) Framework Use Case Methodology	Ready	Steve Posnack	
		Use Case Requirements Template (blank)	Ready		MS Word
Federal Health Information Model (FHIM)	Confirmed	FHIM Immunization Model(s) • Immunization Data Requirements	Ready	Galen Mulrooney	FHIM
S&I Simplification WG	Confirmed	S&I Simplification Core Matrix v3.4	Ready	Gary Dickinson, Steve Hufnagel, Ed Larsen	MS Excel
		Use Case Exchange Format	Ready		UCAT output
National Institute for Standards and Technology (NIST)	Confirmed	Immunization Test Cases	Ready	Kevin Brady Rob Snelick	NIST IZ Tool
		Implementation Guide Authoring and Management Tool (IGAMT)	Ready		NIST IGAMT
		Test Case Authoring and Management Tool (TCAMT)	Ready		NIST TCAMT
Results4Care	Confirmed	Detailed Clinical Models (DCMs) for Immunization	Ready	William Goosen	
Sparx Systems	Confirmed	EA-based Use Case Authoring Tool (UCAT)	Ready	J.D. Baker	EA (UCAT)
Prometheus	Observer	Beacon Use Case Authoring Tool (UCAT)	Ready	Art Greisser	Beacon (UCAT)
US Agency for Health Research and Quality (AHRQ)	Invited	US Health Information Knowledgebase (USHIK)	Ready	Matthew Chudy Chuck Penozza	USHIK
US Centers for Disease Control and Prevention (CDC) Immunization Team	Observer	Immunization Integration Program Immunization Test Cases (and much more...)	Ready	TBD	
Chickasaw Nation Industries (CNI)	Interested	Immunization Integration Program Use Cases, Work Flows, Data Requirements	Ready	Floyd Eisenberg, MD	NIST IZ Tool
HIMSS	Invited			Joyce Sensmeier	NIST TCAMT
ICSA Labs (HIMSS Testing Partner)	Interested			David Tao	

Collaborative End-to-End Immunization Project

End-to-End

What	Who	How (Tools)
Immunization Functional Profile, based on EHR-S FM R2	HL7 EHR WG	HL7 EHR-S FM/FP Tool
Immunization Use Case(s) <ul style="list-style-type: none"> • User Stories • Scenarios, Events, Actions • Actors and Roles 	HL7 PHER WG CNI/HIMSS IIP NIST	UCAT(s)
Data Requirements	FHIM/CIMI	FHIM Tools
Implementation Guides	NIST	IGAMT (NIST)
Software Development	(Vendors, developers)	(various)
Test Cases	NIST, CDC, AEGIS	TCAMT (NIST)
Testing (then Certification)	AEGIS, ICSA	DIL (AEGIS)
Implementation	(Providers, users)	

Immunization Functional Profile Project

Planning and Tasks

Focus	Tasks	Who
1. Environmental Scan	<ul style="list-style-type: none">• Identify Sources for Review, Analysis, Inclusion or Reference<ul style="list-style-type: none">• Functional Models and Profiles<ul style="list-style-type: none">• EHR and PHR System• Conformance Profiles• Domain Analysis Models• FHIM, CIMI (and RIM?) Immunization Information Models• Implementation Guides• Use Cases	All
2. MU FP 2015 Edition (DRAFT)	<ul style="list-style-type: none">• Review Functions and Criteria in Section §170.315(f)(1), “Transmission to Immunization Registries” and Sections (f)(2) through (f)(7)• Add/modify functions/criteria as needed	John Roberts, Noam Arzt and...

Planning and Tasks

Focus	Tasks	Who
3. Use Cases	<ul style="list-style-type: none">• Identify Sources:<ul style="list-style-type: none">• HL7 Immunization DAM• CNI/HIMSS Immunization Integration Program (IIP) and others• For each scenario, extract use case scenarios and events, including:<ul style="list-style-type: none">• Event steps, event description, actor, roles, inputs and outputs• Fill out Use Case Scenario Worksheet• Later: determine actions taken (within each event) and link to EHR-S FM functions and related criteria• Add/modify functions/criteria as needed	Gary Dickinson and...

Using S&I Use Case Basic Flow

Use Case Scenario Worksheet

Start: Capture Use Case Scenarios and Event Steps and for each Step - Actor, Role, Event, Input and Output (Col A-F)

Later: Determine Actions Taken (ultimately linked to EHR-S FM functions and conformance criteria) (Col G)

Event Step	Actor	Actor Role	Event	Data Requirements		Functional Requirements
				Input(s)	Output(s)	Action(s)
1-N	Organization, individual or software/device	(at this step)	Description	Data/records required to initiate or inform Event	Data/records originated or updated during Event	Task, act or process step(s) undertaken during Event
Scenario 1 [follows]						
1						
2						
3						
4						
5						
6						
7						
...						
Scenario 2 [follows]						

Immunization Functional Profile Project

Planning and Tasks

Focus	Tasks	Who
4. EHR-S FM	<ul style="list-style-type: none">• Review Immunization Related Functions, Names, Statements, Descriptions and Conformance Criteria including Sections CP.6.2 and CPS.6.2• Add/modify functions/criteria as needed	
5. EHR-S FM	<ul style="list-style-type: none">• Review ALL sections, functions and conformance criteria relevant to immunizations<ul style="list-style-type: none">• CP – Care Provision• CPS – Care Provision Support• AS – Administrative Support• POP – Population Health Support• RI – Record Infrastructure• TI – Trust Infrastructure• Add/modify functions/criteria as needed	

Planning and Tasks

Focus	Tasks	Who
6. PHR-S FM	<ul style="list-style-type: none"> • Review Immunization Related Functions and Criteria • Add/modify functions/criteria as needed 	John Ritter, HL7 PHR WG
7. Data Objects and Elements	<ul style="list-style-type: none"> • Identify Sources: FHIM, CIMI, FHIR, Immunization DAM, IIP • Specify data requirements by reference 	
8. Testing	<ul style="list-style-type: none"> • Establish characteristics of testable criteria 	Mario Hyland, David Tao and...
9. EHR-S & Registries	<ul style="list-style-type: none"> • Establish functional requirements for general purpose registry 	Floyd Eisenberg MD

Issues and Discussion Points

- Normative or DSTU?
- US (specific) or International (more general)?
- Filling EHR-S Functionality Gap as US MU has ventured more toward “interoperability”
- PHR-S FM Profile?
- Relationship with Other Projects
 - CIC: EHR-S and Any Registry
- Data requirements: How best to reference?
 - Specify SHALL/SHOULD/MAY at data element level?

Contact

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Related Materials follow

Overarching

OV.1
Overarching

OV.2
Manage User
Help

EHR System Functional Model – Release 2

Care Provision

CP1
Manage Clinical
History

CP2
Render Externally
Sourced Info

CP3
Manage Clinical
Documentation

CP4
Manage Orders

CP5
Manage Results

CP6
Manage Treatment
Administration

CP7
Manage Future Care

CP8
Manage Patient Ed. And
Communication

CP9
Manage Care Coord.
and Reporting

Care Provision Support

CPS1
Record Management

CPS2
Support Externally
Sourced Info

CPS3
Support Clinical
Documentation

CPS4
Support Orders

CPS5
Support Results

CPS6
Support Treatment
Administration

CPS7
Support Future Care

CPS8
Support Patient
Education and
Communication

CPS9
Support Care
Coordination and
Reporting

CPS10
Manage User Help

Administrative Support

AS1
Manage Provider
Information

AS2
Manage Pt
Demographics
Location,
Synchronization

AS3
Manage Personal
Health Record
Interaction

AS4
Manage Communica-
tion

AS5
Manage Clinical
Workflow/Tasking

AS6
Manage Resource
Availability

AS7
Support Encounter,
Episode of Care
Mgmt.

AS8
Manage Info. Access for
Supplemental Use

AS9
Manage Administrative
Transaction
Processing

Population Health Support

Pop1
Health Maint.
Prevention and
Wellness

Pop2
Support Pop-Based
Epidemiologic
Investigation

Pop3
Support for Notification
and Response

Pop4
Monitoring/Response
Notifications, Patient
Specific

Pop5
Donor Management
Support

Pop6
Measurement,
Analysis, Research &
Reports

Pop7
Public Health Related
Updates

Pop8
Deidentified Data
Request Management

Pop9
Consistent HC
Management of Patient
Groups or Populations

Pop10
Population
Health Study-Related
Identifiers

Record Infrastructure

RI1
Record Lifecycle and
Lifespan

RI2
Record Synchroniza-

RI3
Record Archive and
Restore

Trust Infrastructure

TI1
Security

TI2
Audit

TI3
Registry and Directory
Services

TI4
Standard Terminology
& Terminology
Services

TI5
Standards Based
Interoperability

TI6
Business Rules
Management

TI7
Workflow
Management

TI8
Database Backup and
Recovery

TI9
System Management
Operations and
Performance

Broad-Based Core Functionality

- Facilitates software-enabled support for individual health and provision of healthcare
- Across care settings: acute, ambulatory, emergent, same day, long-term/post acute, home health...
- Supports both business and clinical domains
 - Describes capture/management of provider business and clinical record
- Enables implementation of policy and best practice
- Specifies functions for safety, security and privacy

EHR-S FM R2

- Captures core functions/criteria from EHR-S FM R1-based FPs
- R2 Record Infrastructure captures RM-ES FP R1
- R2 profiled for Meaningful Use 2011 and 2014
 - 2015 Edition in development

Focused Functionality = Profile

Whereas the Functional Model (FM) specifies EHR system functions across many domains, a Functional Profile (FP):

- Is based on requirements of a particular domain, region, service/specialty or care setting supported by EHR systems;
- Extends and specializes EHR-S functions and conformance criteria;
- May be tailored to US and/or international realm requirements.
- See Functional Profile List.

Horizontal – EHR-S FM Core Functions

Vertical – Profiles (Built on Base)

Functional Profiles	Ambulatory	Behavioral Health	Child Health	Clinical Research	EHR-S Usability	Emergency Care	Long-Term Care	Laboratory	Meaningful Use	Mobile Health	Nutrition	Pharmacy	Public Health x 9	Immunization	Records Management Evidentiary Support (EHR as Legal Record)	Work/Occupation	and more...	
EHR-S FM R2	<u>Care Provision + Care Provision Support</u>						<u>Population Health Support</u>					<u>Administrative Support</u>						
	<u>Record Infrastructure</u> <i>Describes basics of EHR System managing an EHR Record</i> Record Management, Lifespan, Lifecycle, Audit...																	
	<u>Trust Infrastructure</u> Identity, Accountability, Authorization, Authentication, Access Control, Audit...																	

Functional Profile Development

The FP Development process:

- Identifies discrete EHR-S FM functions and conformance criteria applicable to that domain (immunization);
- Adds specific EHR system functions and conformance criteria where there are identified gaps

Then, the FP:

- Is balloted by HL7 as a US realm or international standard, either informative or normative;
- After approval by consensus ballot, is published;
 - HL7 IP is free to non-members 90 days post publication;
- May be used as the basis for EHR system conformance claims (by vendors, by provider implementers);
- May be used as the basis for criteria in EHR system certification or inspection programs;
- May be promoted for adoption by ISO.

Profile Development Process

Typical steps, some in parallel:

- Identify lead(s), Include FP veterans
- Scope project, Develop HL7 Project Scope Statement and Get project approval (HL7 EHR WG, SSD SD, TSC)
- Schedule teleconferences, Make announcement
- Gather SME team members, including international folks
- Review previous FP(s)
- Do environmental scan, Find sources and references
- Identify functions/criteria not captured in core EHR-S FM
- Develop FP content
- Learn then use the FM/FP tool, Prepare ballot draft
- Consensus ballot, Reconcile, repeat if needed
- Approve, Publish, Publicize

Tooling Support for FMs and FPs

- Based on Sparx Enterprise Architect 10 and up
- Supports EHR-S FM Releases (starting with R2)
 - Develop, ballot, reconcile, publish, maintain
- Supports R2 Functional Profile Development
 - From base FM and from other FPs
 - Develop, ballot, reconcile, publish, maintain
- Supports R2 Language Translation
 - See National Program List
- Next Stage: Capture/manage PHR-S FM R1

Looking Forward

EHR-S FM on FHIR!

- HL7 FHIR = Fast Health Interoperable Resources
 - New, widely-promoted, HL7 “Standard” data container
 - Built on current Web and mobile app technologies
 - Addition (or ultimate successor?) to HL7 Version 2/3 messages, HL7 CDA/CCDA documents (also data containers)
 - Balloted/published as HL7 Draft Standard, 2nd Edition, Sep 2015
 - FHIR Resources are data containers (objects), with elements
 - FHIR Resource instances may be:
 - Transient (single exchange only)
 - Persistent (native) data objects in source (or any) system
 - For exchange, FHIR Resource instances may be:
 - Queried then *pulled* from source system: e.g., via RESTFUL APIs
 - At trigger events, *pushed* to receiver system
- Objective: To show how EHR-S FM R2 requirements are fulfilled in FHIR implementation(s)**
- Starting with R2 Record Infrastructure

Req'ts Fulfilled in Implementation

EHR-S FM/FP specifies ↓		FHIR specifies ↓
Functional + Data Requirements	Fulfilled in →	Implementable Resources
EHR Record Management: <ul style="list-style-type: none"> • Record Entries – Lifespan, Lifecycle Events • Tracking Who did What When Where and Why 	Fulfilled in →	FHIR <u>AuditEvent</u> + <u>Provenance</u> Resources, starting with Record Entry origination/retention (initial lifecycle event) <u>HL7 FHIR Record Lifecycle Event Implementation Guide</u>
<ul style="list-style-type: none"> • Immunization FP • Long Term Care FP • Behavioral Health FP • Other FPs 	Fulfilled in →	Relevant FHIR Resources such as: <u>Assessment</u> , <u>CarePlan</u> , <u>DiagnosticOrder</u> , <u>Goal</u> , <u>Immunization</u> , <u>ImmunizationRecommendation</u> , <u>Observation</u> , <u>ReferralRequest</u> ...

Known National Programs using EHR-S FM

Nation	Language	Lead(s), if known	Contact	Status/Use
Australia	English	Queensland Health Peter MacIsaac	macisaac.peter@gmail.com	Complete Queensland Ambulatory EHR Adoption Program
Brazil	Portuguese	Beatriz Leao	beatriz.leao@zilics.com.br	R1.1 Translation: Complete R2 Translation: Partial (in progress) EHR Developers Reference
Canada	English	Canada Health Infoway Grant Gillis	ggillis@coachorg.com	On Hold Provincial EHR Adoption Programs
Denmark	Danish	TBD		Preliminary
Finland	Finnish	Juha Mykkanen	juha.mykkanen@uef.fi	Preliminary
France	French	Francois Macary	francois.macary@sante.gouv.fr	R2 Translation: Partial (awaiting resources) National EHR Adoption Program
Italy	Italian	Stephano Lotti Giorgio Cangioli	slotti@invitalia.it giorgio.cangioli@gmail.com	R2 Translation: Complete Regional EHR Adoption Program Underway
Ireland	English	General Practice Information Technology (GPIT) Group Brian O'Mahony	bom@iol.ie	Complete GP EHR System Certification Program
Japan	Japanese	Noriko Inaoka, PhD Hideshige Hasegawa	inaoka@jp.ibm.com hide.hasegawa@mx8.ttcn.ne.jp	R1.1 Translation: Complete R2 Translation: Partial (in progress) EHR System Developers Reference
Korea	Korean	Center for Interoperable EHR (CiEHR) Il Kon Kim	ikkingg@gmail.com	R1 Translation: Complete Public and National University Hospital EHR Framework
Netherlands	Dutch	William & Anneke Goosen Robert Stegway	agoossen@results4care.nl robert.stegwee@capgemini.com	R2 Translation: Partial (in progress) Behavioral Health FP and Others
New Zealand	English	Peter Jordan	peter.jordan@patientsfirst.org.nz	Preliminary National EHR Adoption Program
Norway	Norwegian	Line Saele Andraessen	line.sele@nasjonalikt.no	R2 Translation: Partial (in progress) National EHR Adoption Program
Mexico	Spanish	José Manuel Castañeda Casas Marco Pardavé	castaneda.jmanuel@gmail.com mapardave@gsprogress.us	R1.1 Translation: Complete R2 Translation: Preliminary National EHR Adoption Program
Sweden	Swedish	Helen Broberg	Helen.Broberg@skane.se	R2 Translation: Partial (in progress) Regional EHR Adoption Program
US	English	Various		Original EHR-S Certification Program Basis for CCHIT Certification Criteria

EHR-S FM based Functional Profiles

HL7 EHR-S FM Functional Profile	SDO(s)	Prior Profile Based on	R2 Lead(s)	HL7 WGs	Contributing Organization(s)	R2 Status
Ambulatory Care	HL7	DSTU	TBD			TBD
Behavioral Health	HL7	R1	Jim Kretz	CBCC	APA, SAMHSA	Preliminary
Child Health	HL7	R1	Pele Yu, MD ?	Child Health	AHRQ?	Preliminary
Child Health – Developmental Screening	HL7	R2	Pele Yu, MD, Michael Padula, MD	Child Health		In Progress
Clinical Research	HL7, ANSI, ISO, CEN, CDISC	R1	Mitra Rocca	RCRIM	FDA, CDISC, eClinical Forum	Preliminary
Dental	ADA, HL7	—	Patrick Cannady	EHR	American Dental Assoc	Preliminary
EHR System Usability	HL7	—	John Ritter, Mitra Rocca	CIC, CQI, EHR	FDA, HIMSS, VA	In Progress
Emergency Care	HL7	R1	Laura Heerman, RN, James McClay, MD	Emergency Care	DOD	In Progress
Lab Interactions	HL7	—	Riki Merrick, Bob Dieterle,	EHR, Orders/ Observations	NIST, ONC S&I (LRI/LOI)	In Progress FP to Come
(S&I LOI/LRI)			Bob Yench			
Long Term Care	HL7	R1	TBD	EHR	LTPAC HIT Collaborative	Preliminary
Meaningful Use (2011/14)	HL7	—	Gary Dickinson Diana Warner	EHR	CMS	Published
Meaningful Use (2015)	HL7	R2			ONC? CMS?	In Progress
Mobile Health Consumer Framework	HL7	—	Matthew Graham, Gora Datta	Mobile Health		In Parallel
Neonatal	HL7	—	TBD	Child Health		On hold
Nutrition	HL7	R1.1	Kay Howarter, Lee Unangst	EHR	American Dietetics Assoc	In Progress
Pharmacy/Pharmacist	NCPDP, HL7	R1.1	Sue Thompson	Pharmacy	NCPDP	In Progress
Podiatry	HL7	—	Michael Brody, MD	EHR		Preliminary
Public Health Domains	HL7	—	Hetty Khan, John Ritter	EHR, PHER	CDC/NCHS, PHDSC	Published
· Vital Records	HL7	R1.1				
· Early Hearing Detection & Intervention		—				
· Chronic Diseases Cancer Surveillance						
· Public Health Lab Interactions (Orders and Results)						
· Occupational Disease, Injury, and Fatality						
· Health Statistics						
· Deep Vein Thrombosis / Pulmonary Embolism						
· Birth Defects						
· Adverse Events						
Public Health – Work and Health	HL7	—	John Ritter Michael Goldcamp, PhD Genny Luensman, PhD	EHR	CDC, NIOSH	In Progress
Public Health – Immunization	HL7	—	Gary Dickinson Mark Janczewski, MD	EHR	ONC, NIST, CNI, AEGIS, Sparx (CDC?)	In Progress
Quality Indicators	HL7	—	Floyd Eisenberg, MD	CQI		Preliminary
Records Management/ Evidentiary Support	HL7	R1	Reed Gelzer, MD, Diana Warner	EHR	AHIMA	In Progress
S&I Structured Data Capture (SDC)	HL7	—	TBD		FDA? CDISC? ONC?	Preliminary
Unique Device ID (UDI)	HL7	—	TBD	OO	FDA? ONC?	Preliminary

Public Health Functional Profile

- HL7 Public Health Functional Profile Release 2 (PHFP R2)
 - Based on EHR-S FM Release 2
 - Balloted/Published 2015
- Developed as a partnership between CDC NCHS, HL7 EHR WG and PHER Work Groups
- Approved by consensus ballot, with input from the international community
- Includes FPs for nine (9) Public Health Domains:
 - Vital Records
 - Early Hearing Detection and Intervention
 - Chronic Diseases (Cancer Surveillance)
 - Public Health Laboratory Interactions (Orders and Results)
 - Occupational Disease, Injury, and Fatality
 - Health Statistics
 - Deep Vein Thrombosis and Pulmonary Embolism
 - Birth Defects
 - Adverse Events