

# HL7 EHR – Immunization Functional Profile (IFP) Project

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Mark Janczewski, MD  
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# Introduction

- This is an open project
  - All are welcome!
  - International input invited!
- Team meets most Mondays 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:
  - Contributors, Contributions and Readiness
  - Reference Materials
  - Functional Models and Profiles
  - Federal Health Information Model (Immunization)
  - Tools
  - Meeting Notes
- [http://wiki.hl7.org/index.php?title=EHR\\_Immunization\\_Functional\\_Profile](http://wiki.hl7.org/index.php?title=EHR_Immunization_Functional_Profile)

### Collaborative End-to-End Immunization Project Contributions - Immunization FP Contributions - 29 August 2016

Contributor/Participant	Status	Contribution	Readiness	Individual(s)	Tool
Health Level Seven (HL7) Electronic Health Record (EHR) Work Group	HL7 Sponsor	ISO/HL7 10781 EHR System Functional Model R2	Ready	Brody, Dickinson, Gelzer, Janczewski, Ritter, Warner	HL7 FM/FP Tool (EA), UCAT
		ISO/HL7 16527 PHR System Functional Model R1	Ready		
		HL7 EHR-S Public Health Functional Profiles x 9 Joint w/HL7 Public Health/Emergency Response WG	Ready	John Ritter, Hetty Khan, Michelle Williamson	HL7 FM/FP Tool (EA)
		EHR-S Immunization Functional Profile (IFP)	In Progress	Gary Dickinson Mark Janczewski MD	
		EHR-S FM/FP Developer Tool in Enterprise Architect (EA)	Ready	Anneke Goosen Michael Van Der Zel	
HL7 Public Health/ Emergency Response (PHER) WG	Interested	Immunization Domain Analysis Model (IDAM) • Story Boards, Use Case Scenarios, Events, Actions, Actors/Roles, Data Requirements	Ready	John Roberts	
		Immunization History Conformance Profile	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	Matthew Gereke	
US Office of National Coordinator	Observer	Standards & Interoperability (S&I) Framework • Use Case Methodology	Ready	Steve Posnack	
		S&I Use Case Requirements Template	Ready		UCAT, MS Word
Federal Health Information Model (FHIM)	Confirmed	FHIM Immunization Model(s) • Immunization Data Requirements	Ready	Galen Mulrooney	FHIM Tool
S&I Simplification WG	Confirmed	S&I Simplification Core Matrix v3.4	Ready	Gary Dickinson	UCAT, MS Excel
		Use Case Exchange Format	Ready	Steve Hufnagel Ed Larsen	UCAT → UCAT, → NIST, → USHIK
National Institute for Standards and Technology (NIST)	Confirmed	Immunization Test Cases	Ready	Kevin Brady Rob Snelick	NIST IZ Tool
		Implementation Guide Authoring & Management Tool	Ready		NIST IGAMT
		Test Case Authoring & Management Tool	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	UCAT (EA)
Prometheus	Observer	Beacon Use Case Authoring Tool (UCAT)	Ready	Art Greisser	UCAT (Beacon)
US Agency for Health Research and Quality (AHRQ)	Invited	US Health Information Knowledgebase (USHIK)	Ready	Matthew Chudy Chuck Penozza	USHIK Tool
US Centers for Disease Control and Prevention (CDC) Immunization Team	Observer	Immunization Integration Program (IIP) Immunization Test Cases	Ready	Craig Newman	NIST IZ Tool NIST TCAMT
Chickasaw Nation Industries (CNI)	Interested	Immunization Integration Program (IIP) • Use Case Scenarios, Work Flows • Immunization Data Requirements	Ready	Floyd Eisenberg MD	
HIMSS	Invited			Joyce Sensmeier	
ICSA Labs (HIMSS Testing Partner)	Interested			David Tao Michelle Knighton	

## 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"> <li>• User Stories</li> <li>• Scenarios, Events, Actions</li> <li>• Actors and Roles</li> </ul>	HL7 PHER WG IIP Partners? NIST	UCAT(s)
Data Requirements	FHIM/CIMI, PHER, CNI	UCAT, FHIM
Implementation Guides	NIST	IGAMT (NIST)
Software Development	(Vendors, developers)	(various)
Test Cases	NIST, CDC, AEGIS	TCAMT (NIST)
Testing (then Certification)	AEGIS, ICESA	DIL (AEGIS)
Implementation	(Providers, users)	

## Immunization Functional Profile Project

# Planning and Tasks

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

## Immunization Functional Profile Project

# Planning and Tasks

Focus	Tasks	Who
3. Use Cases	<ul style="list-style-type: none"><li>• Identify Sources:<ul style="list-style-type: none"><li>• HL7 Immunization DAM use cases</li><li>• CDC/CNI/HIMSS/ICSA Immunization Integration Program (IIP) work flows</li><li>• Others, as discovered or submitted</li></ul></li><li>• For each scenario, extract use case scenarios and events, including:<ul style="list-style-type: none"><li>• Event steps, event description, actor, roles, inputs and outputs</li></ul></li><li>• Follow pattern described in Use Case Scenario Worksheet</li><li>• Link to EHR-S FM functions and related criteria</li><li>• Add/modify functions/criteria as needed</li></ul>	Gary Dickinson Julia Chan ...

## Immunization Functional Profile Project

# Planning and Tasks

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



## Immunization Functional Profile Project

# Planning and Tasks

Focus	Tasks	Who
6. PHR-S FM (FUTURE)	<ul style="list-style-type: none"><li>• Review Immunization Related Functions and Criteria</li><li>• Add/modify functions/criteria as needed</li></ul>	John Ritter, HL7 PHR WG
7. Data Objects and Elements	<ul style="list-style-type: none"><li>• Identify Sources: FHIM (CLIM), CIMI, FHIR, HL7 Immunization DAM and IG, IIP</li><li>• <b>Map IIP Data Requirements to FHIM (CLIM)</b></li></ul>	<b>Galen Mulrooney?</b> <b>Steve Hufnagel?</b>
8. Testing	<ul style="list-style-type: none"><li>• Recommend characteristics of testable criteria</li></ul>	Mario Hyland, David Tao
9. EHR-S & Registries	<ul style="list-style-type: none"><li>• Establish functional requirements for general purpose registry</li></ul>	CIC WG

## Immunization Functional Profile Project

# Planning and Tasks

Focus	Tasks	Who
10. FM/FP Tool	<ul style="list-style-type: none"><li>• Capture selected functions in (EA-based) EHR-S FM/FP Profiling Tool to <u>create initial IFP</u> [EA = Enterprise Architect]</li></ul>	Anneke Goossen? William Goossen? Michael Van Der Zel?
11. UCAT	<ul style="list-style-type: none"><li>• Capture IDAM/IFP Scenarios in (EA-based) Use Case Authoring Tool (UCAT)</li></ul>	J.D. Baker

# Contact

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  - Co-Chair, HL7 EHR Work Group
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  - Co-Chair, HL7 EHR Work Group
  - [mark.janczewski@verizon.net](mailto:mark.janczewski@verizon.net)

**Related Materials follow**

## Related HL7 EHR/PHER Work

# 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

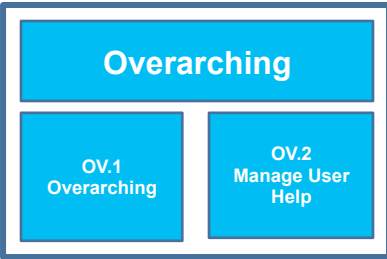
# Broad-Based Core Functionality

- 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

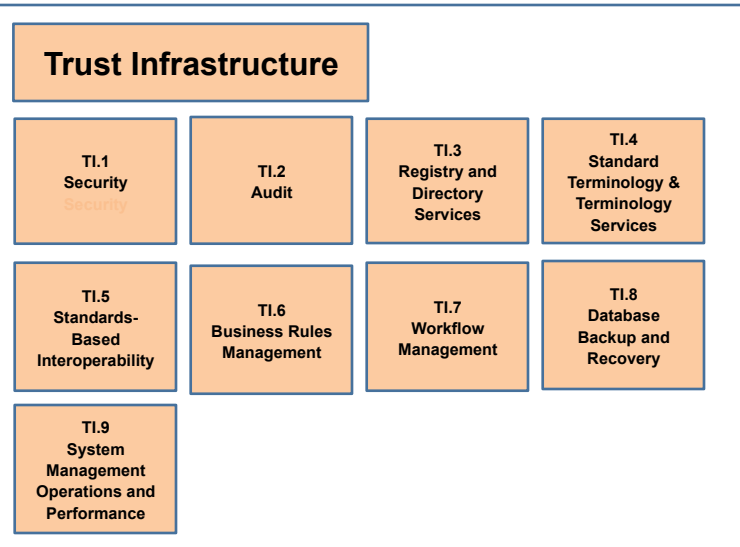
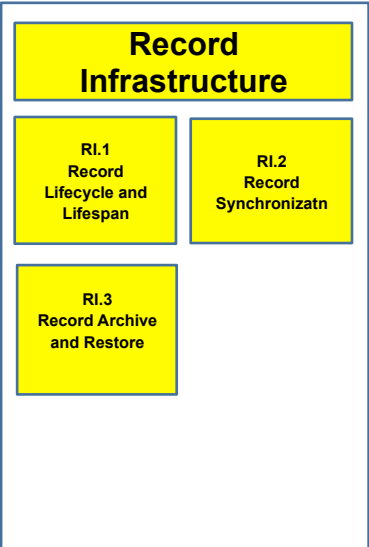
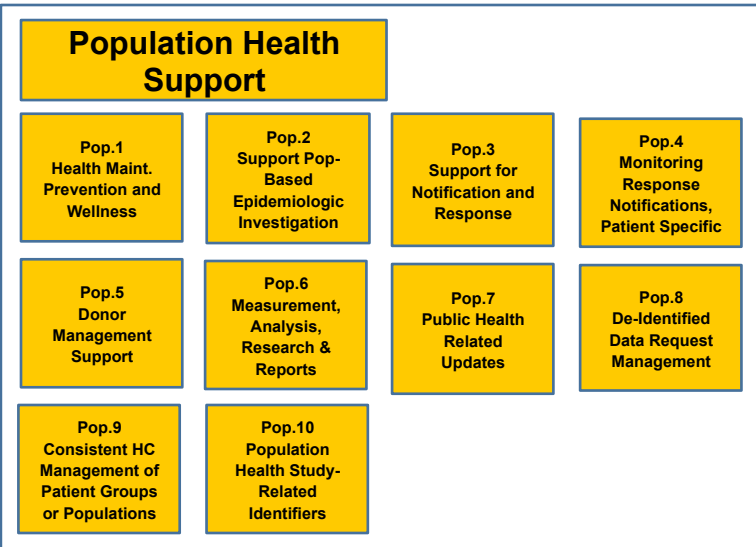
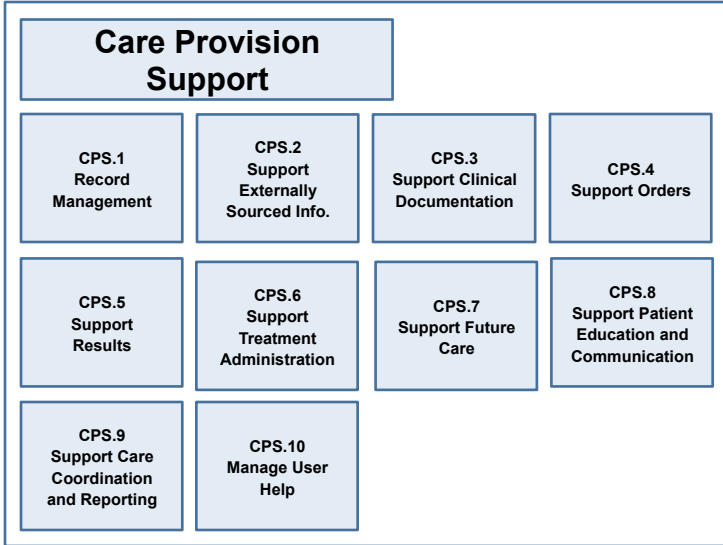
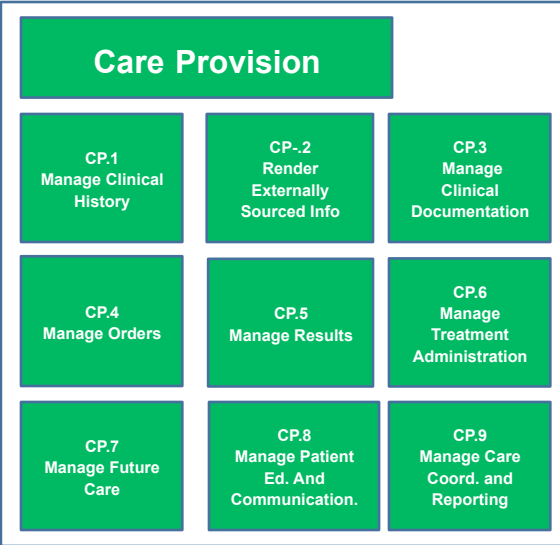
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## **EHR-S FM R2**

- **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**



# EHR System Functional Model – Release 2



# 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...																	

**HL7 EHR Work Group – Functional Profiles of ISO/HL7 10781 EHR System Functional Model (Limited to HL7 Projects)**  
**Revised: 26 August 2016**

Functional Profile Subject	SDO(s)	Prior Profile Based on	R2 Lead(s)	HL7 WGs	Contributing Organization(s)	R2 Status
Ambulatory Care	HL7	DSTU	TBD	EHR		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, ISO, CEN, CDISC	R1	Mitra Rocca	RCRIM	FDA, CDISC, eClinical Forum	Preliminary
Dental	ADA, HL7	-----	Patrick Cannady	EHR	American Dental Association	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 (S&I LOI/LRI)	HL7	-----	Riki Merrick, Bob Dieterle, Bob Yencha	EHR, Orders/Observations	NIST, ONC S&I (LRI/LOI)	In Progress FP to Come
Long Term/Post-Acute Care	HL7	R1 (LTC)	TBD	EHR	LTPAC HIT Collaborative	Preliminary
Meaningful Use (2011/14 Edition)	HL7	-----	Gary Dickinson, Diana Warner, Michael Brody DPM	EHR	CMS	Published
Meaningful Use (2015 Edition)	HL7	R2				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 Lindsay Hoggle	EHR	American Dietetics Association, Academy of Nutrition & Dietetics	In Progress
Pharmacy/Pharmacist	NCPDP, HL7	R1.1	Sue Thompson	Pharmacy	NCPDP	In Progress
Podiatry	HL7	-----	Michael Brody DPM	EHR		Preliminary
Public Health - Vital Records	HL7	R1.1	Hetty Khan John Ritter Michelle Williamson	EHR, PHER	CDC/NCHS, PHDSC, PHII	Published
Public Health - Early Hearing Detection & Intervention		-----				
Public Health - Chronic Diseases Cancer Surveillance		-----				
Public Health - Lab Interactions (Orders and Results)		-----				
Public Health - Occupational Disease, Injury, and Fatality		-----				
Public Health - Health Statistics		-----				
Public Health - Deep Vein Thrombosis / Pulmonary Embolism		-----				
Public Health - Birth Defects		-----				
Public Health - Adverse Events		-----				
Public Health – Work and Health		HL7				
Public Health – Immunization	HL7	-----	Gary Dickinson Mark Janczewski, MD	EHR	ONC, NIST, CNI, AEGIS, ICESA, Results4Care, Sparx, (CDC?)	In Progress
Quality Indicators	HL7	-----	Floyd Eisenberg MD	CQI		Preliminary
Records Management/Evidentiary Support (RM-ES)	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

# 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"> <li>• Record Entries – Lifespan, Lifecycle Events</li> <li>• Tracking Who did What When Where and Why</li> </ul>	Fulfilled in →	FHIR <u>AuditEvent</u> + <u>Provenance</u> Resources, starting with Record Entry origination/retention (initial lifecycle event) <a href="http://hl7.org/fhir/2016Sep/ehrsle/ehrsle.html">http://hl7.org/fhir/2016Sep/ehrsle/ehrsle.html</a>
<ul style="list-style-type: none"> <li>• <b>Immunization FP</b></li> <li>• Long Term Care FP</li> <li>• Behavioral Health FP</li> <li>• Other FPs</li> </ul>	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	<a href="mailto:macisaac.peter@gmail.com">macisaac.peter@gmail.com</a>	Complete Queensland Ambulatory EHR Adoption Program
Brazil	Portuguese	Beatriz Leao	<a href="mailto:beatriz.leao@zilics.com.br">beatriz.leao@zilics.com.br</a>	R1.1 Translation: Complete R2 Translation: Partial (in progress) EHR Developers Reference
Canada	English	Canada Health Infoway Grant Gillis	<a href="mailto:ggillis@coachorg.com">ggillis@coachorg.com</a>	On Hold Provincial EHR Adoption Programs
Denmark	Danish	TBD		Preliminary
Finland	Finnish	Juha Mykkanen	<a href="mailto:juha.mykkanen@uef.fi">juha.mykkanen@uef.fi</a>	Preliminary
France	French	Francois Macary	<a href="mailto:francois.macary@sante.gouv.fr">francois.macary@sante.gouv.fr</a>	R2 Translation: Partial (awaiting resources) National EHR Adoption Program
Italy	Italian	Stephano Lotti Giorgio Cangioli	<a href="mailto:slotti@invitalia.it">slotti@invitalia.it</a> <a href="mailto:giorgio.cangioli@gmail.com">giorgio.cangioli@gmail.com</a>	R2 Translation: Complete Regional EHR Adoption Program Underway
Ireland	English	General Practice Information Technology (GPIT) Group Brian O'Mahony	<a href="mailto:bom@iol.ie">bom@iol.ie</a>	Complete GP EHR System Certification Program
Japan	Japanese	Noriko Inaoka, PhD Hideshige Hasegawa	<a href="mailto:inaoka@jp.ibm.com">inaoka@jp.ibm.com</a> <a href="mailto:hide.hasegawa@mx8.ttcn.ne.jp">hide.hasegawa@mx8.ttcn.ne.jp</a>	R1.1 Translation: Complete R2 Translation: Partial (in progress) EHR System Developers Reference
Korea	Korean	Center for Interoperable EHR (CiEHR) Il Kon Kim	<a href="mailto:ikkingg@gmail.com">ikkingg@gmail.com</a>	R1 Translation: Complete Public and National University Hospital EHR Framework
Netherlands	Dutch	William & Anneke Goosen Robert Stegway	<a href="mailto:agoossen@results4care.nl">agoossen@results4care.nl</a> <a href="mailto:robert.stegwee@capgemini.com">robert.stegwee@capgemini.com</a>	R2 Translation: Partial (in progress) Behavioral Health FP and Others
New Zealand	English	Peter Jordan	<a href="mailto:peter.jordan@patientsfirst.org.nz">peter.jordan@patientsfirst.org.nz</a>	Preliminary National EHR Adoption Program
Norway	Norwegian	Line Saele Andraessen	<a href="mailto:line.sele@nasjonalikt.no">line.sele@nasjonalikt.no</a>	R2 Translation: Partial (in progress) National EHR Adoption Program
Mexico	Spanish	José Manuel Castañeda Casas Marco Pardavé	<a href="mailto:castaneda.jmanuel@gmail.com">castaneda.jmanuel@gmail.com</a> <a href="mailto:mapardave@gsprogress.us">mapardave@gsprogress.us</a>	R1.1 Translation: Complete R2 Translation: Preliminary National EHR Adoption Program
Sweden	Swedish	Helen Broberg	<a href="mailto:Helen.Broberg@skane.se">Helen.Broberg@skane.se</a>	R2 Translation: Partial (in progress) Regional EHR Adoption Program
US	English	Various		Original EHR-S Certification Program Basis for CCHIT Certification Criteria



Reference – S&I Simplification

# From Sketch to Implementation

