Project Scope Statement 2015 Version Release 1

HL7 Project Management Office
Project Services Work Group

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http://www.hl7.org/Special/committees/projectServices/leadership.cfm

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URL to download document:
http://www.hl7.org/permalink/?ProjectScopeStatement

For prior versions of this document refer to:

http://www.hl7.org/Special/committees/projectServices/docs.cfm

The objective of this document is to communicate the type of activities a group is undertaking to achieve specific objectives or to produce specific work products. It's intended for projects to produce standards or Implementation Guides as well as infrastructure projects.

Template Usage Information:

- Replace `Highlighted Courier New` text with appropriate content.
- To use Track Changes, turn off "protection" by clicking on Tools > Unprotect Document; in Word 2010, select Review>Track Changes
- For assistance in completing each section, refer to Appendix A.
- Information on the Project Approval Process is documented in Appendix B.
- For FAQs (Frequently Asked Questions), refer to Appendix C
- Submit template change requests to PMO@HL7.org

1. Project Name and ID

Click here to go to Appendix A for more information regarding this section.

An ID will be assigned by Project Insight

Consumer Mobile Health Application Functional Framework	Project ID:
☐ TSC Notification Informative/DSTU to Normative Date :	

2. Sponsoring Group(s) / Project Team

Click here to go to Appendix A for more information regarding this section.

Primary Sponsor/Work Group (**1 Mandatory**)	**Mobile Health Work Group**
Co-Sponsor Work Group(s)	**EHR Work Group**
Co-Sponsor Group Approval Date	Co-Sponsor Approval Date CCYY-MM-DD
Indicate the level of involvement that the co-sponsor will have for this project: ☒ Request formal content review prior to ballot ☒ Request periodic project updates. Specify period: ☒ Other Involvement. Specify details here:	Monthly update on EHR Work Group calls. Encourage participation by EHR Work Group members who are not also members of the Mobile Health Work Group In addition, while not formal sponsors, both the Security and Devices Work Groups have agreed to provide input to this project.

Project Team:	
Project facilitator (**1 Mandatory**)	**Tim McKay**(Tim.A.Mckay@kp.org)
Other interested parties and their roles	Mobile Health Co-Chairs: Gora Data (gora@cal2cal.com), Matthew Graham (mgraham@mayo.edu), Nathan Botts(nathan.botts@gmail.com), Harry Rhodes(Harry.Rhodes@AHIMA.org); EHR Work Group Co-Chairs: John Ritter (johnritter1@verizon.net), Gary Dickerson(gary.dickinson@ehr-standards.com), Pat Van Dyke(patricia.vandyke@modahealth.com), Reed Gelzer(rgelzer@provider-resources.com), Diana Warner (Diana.Warner@AHIMA.org).
Multi-disciplinary project team (recommended)	
Modeling facilitator	Gora Datta
Publishing facilitator	Harry Rhodes (Harry.Rhodes@AHIMA.org)
Vocabulary facilitator	Sandra Stuart(Sandra.Stuart@kp.org)
Domain expert rep	Gora Datta, Tim McKay
Business requirement analyst	Tim McKay
Conformance facilitator (for IG projects)	
Other facilitators (SOA, etc)	

Implementers **(2 Mandatory** for DSTU projects)
FHIR Project Note: *The implementer requirement will be handled by the "balloting" project. Therefore work groups do not fill out the above*

1)
2)

3. Project Definition

3.a. Project Scope

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

```
This project will define security, privacy and data standards for secure mobile
health applications (apps). The intent is to provide industry guidance and common
methods to enable the development of mobile health smartphone apps targeted to
consumers/citizens that use protected health information (PHI) and personally
identifiable information (PII). These standards will not address the content of
such apps, but will provide a framework for security, privacy and trusted
integration of data generated from apps into Personal Health Record (PHR) and
Electronic Health Record (EHR) systems as well as into other types of data
repositories (e.g., personal data stores, population care systems).

This project will reuse conformance criteria already available within the HL7 PHR-S
and EHR-S Functional Models, augmenting with new conformance criteria specific to
mobile platforms (e.g., use of geolocation services, accelerometers, cameras,
microphones).

In particular, standards will address the following areas:
    • Privacy policy, terms of use, and in-app disclaimers
    • User, device, and cross-system authentication
    • Authorization to content and features
    • Proxy designations
    • Use of location services, camera, accelerometers and other smartphone
      services
    • Security of data at rest (local and cloud)
    • Security of data in transit (wired and wireless)
    • Minimum data standards for device generated and device transmitted
      information
    • Record system reliability; record authenticity (it is what it represents to
      be)
    • Data provenance
    • Audit
    • Standards related to discontinuation of use of an app
```

3.b. Project Need

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

```
Industry is in need of privacy and data standards in order to create consumer
smartphone health apps which are secure, private, and that allow for data generated
from and through these apps to be used in other health care contexts (e.g.,
personal data tracking, integration into a person's record of care, clinical
decision making). While the HL7 PHR-S FM expresses many of these functional
requirements, it is not possible to use the PHR-S FM as-is to create mobile
application standards.  Mobile apps are generally not comprehensive in scope and,
as such, mobile app standards cannot be extracted as PHR system profiles as it is
impossible for most apps to adhere to all the SHALL statements within the PHR-S FM.
```

3.c. Success Criteria

```
Creation of the functional framework
```

3.d. Project Risks

Risk Description:	**This product intends to use the Sparx Systems 'Enterprise Architect' Profile Designer Tool for documentation and publishing and is dependent on personnel with EA expertise to be available to work on the project.**
Impact:	☐ Critical ☐ Serious ☒ Significant ☐ Low
Likelihood:	☐ High ☒ Med ☐ Low
Risk Type:	☐ Requirements ☒ Resources ☐ Social-Political ☐ Technology
Risk To HL7:	☒ Internal to HL7 ☐ External to HL7
Mitigation Plan:	**Have at least two people on the project team trained to use the EA Profile Designer Tool. Rely on ad-hoc consulting with current implementers within the EHR Work Group for troubleshooting and support.**

3.e. Security Risks

Will this project produce executable(s), for example, schemas, transforms, stylesheets, executable program, etc. If so the project must review and document security risks.	☐ Yes	☒ No	☐ Unknown

3.f. External Drivers

```
No external drivers are known at this time.
```

3.g. Project Objectives / Deliverables / Target Dates

Within each row, enter the explicit work product(s) / objective(s). Indicate their target date at the right in WGM/Ballot Cycle format. Include the project end date as the last objective (for standards projects, the end date will be the projected ANSI approval date). *Click here for further information, FHIR project instructions, and an EXAMPLE*	**Target Date** *(in WGM or ballot cycle format, e.g. '2010 Sept WGM' or '2010 Jan Ballot')*
Submit Framework for Comment Only Ballot(First Ballot Cycle)	2015 September Ballot
Complete consideration of comments	2016 January WGM
Submit for DSTU Ballot (1)	2016 May Ballot
DSTU Period – 12 months; complete reconciliation of comments	2017 May WGM
Submit for Normative Ballot	2017 May
Complete Normative Reconciliation	2017 Sep WGM
Submit Publication Request	2017 October
Receive ANSI Approval	2018 January
Project End Date (all objectives have been met)* *consideration will be given to beginning new project for V2 of the framework dependent on the continued evolution of consumer mobile devices and applications	2018 January

3.h. Common Names / Keywords / Aliases

```
Mobile Health Framework; Consumer Health Mobile Framework
```

3.i. Lineage

```
While this is a new product, it will draw conformance criteria from both the EHR-S FM Release 2 and the PHR-S FM Release 1.
```

3.j. Project Requirements

```
TBD
```

3.k. Project Dependencies

```
None
```

3.l. Project Document Repository Location

```
TBD
```

3.m.   Backwards Compatibility

Are the items being produced by this project backward compatible?	☐ Yes	☐ No	☐ Unknown	☒ N/A

For V3, are you using the current data types? (Refer to TSC position statement on new projects using R2B for more information on the current V3 data types)	☐ Yes	☐ No	N/A
If you check 'No' please explain the reason:			

3.n. External Vocabularies

Will this project include/reference external vocabularies?	☐ Yes	☒ No	☐ Unknown	☐ N/A
If yes, please list the vocabularies:				

4. Products

☐ Non Product Project- (Educ. Marketing, Elec. Services, etc.)	☐ V3 Domain Information Model (DIM / DMIM)
☐ Arden Syntax	☐ V3 Documents – Administrative (e.g., SPL)
☐ Clinical Context Object Workgroup (CCOW)	☐ V3 Documents – Clinical (e.g. CDA)
☐ Domain Analysis Model (DAM)	☐ V3 Documents - Knowledge
☐ Electronic Health Record (EHR) Functional Profile	☐ V3 Foundation – RIM
☐ Logical Model	☐ V3 Foundation – Vocab Domains & Value Sets
☐ V2 Messages – Administrative	☐ V3 Messages - Administrative
☐ V2 Messages - Clinical	☐ V3 Messages - Clinical
☐ V2 Messages - Departmental	☐ V3 Messages - Departmental
☐ V2 Messages – Infrastructure	☐ V3 Messages - Infrastructure
☐ FHIR Resources	☐ V3 Rules - GELLO
☐ FHIR Profiles	☐ V3 Services – Java Services (ITS Work Group)
☐ New/Modified/HL7 Policy/Procedure/Process	☐ V3 Services – Web Services (SOA)
☒ New Product Definition	
☐ New Product Family	

```
This is a variation/extension of the EHR-S and PHR-S functional models.
```

5. Project Intent (check all that apply)

☒ Create new standard	☒ Supplement to a current standard
☐ Revise current standard (**see text box below**)	☐ Implementation Guide (IG) will be created/modified
☐ Reaffirmation of a standard	Project is adopting/endorsing an externally developed IG:
☐ New/Modified HL7 Policy/Procedure/Process	Specify external organization in Sec. 6 below;
☐ Withdraw an Informative Document	Externally developed IG is to be (select one):
☐ N/A (Project not directly related to an HL7 Standard)	☐ Adopted - OR - ☐ Endorsed

```
This project will create artifacts which are conceptually related to the PHR-S FM
but directly address the needs of consumer mobile applications.
```

5.a. Ballot Type (check all that apply)

PSS Consumer Mobile Heatlh Standards Framework 20150213-1 rdg.docx	2015 Release	Page **5** of **7**

☒ Comment Only ☐ Informative ☐ DSTU to Normative	☐ Normative (no DSTU) ☐ Joint Ballot (with other SDOs or HL7 Work Groups) ☐ N/A (project won't go through ballot)

Intent is to produce an artifact for comment only balloting in 2015 and to move to a DSTU ballot by mid-2016.

5.b. Joint Copyright

Click here to go to Appendix A for more information regarding this section
Check this box if you will be pursuing a joint copyright. Note that when this box is checked, a Joint Copyright Letter of Agreement must be submitted to the TSC in order for the PSS to receive TSC approval.

☐ Joint Copyrighted Material will be produced

6. Project Logistics

6.a. External Project Collaboration

Click here to go to Appendix A for more information regarding this section and FHIR project instructions.

For projects that have some of their content already developed:	
How much content for this project is already developed?	**Assuming 30% to 50% of material will be derivative from existing conformance criteria from the PHR-S FM and EHR-S FM**
Was the content externally developed (Y/N)?	**NO**
Date of external content review by the ARB?	**N/A**
Is this a hosted (externally funded) project? (not asking for amount just if funded)	☐ Yes ☒ No

6.b. Realm

Click here to go to Appendix A for guidelines regarding choosing Universal or Realm Specific.

☒ Universal	☐ Realm Specific
	☐ Check here if this standard balloted or was previously approved as realm specific standard

6.c. Project Approval Dates

Click here to go to Appendix A for more information regarding this section.

Affiliate/US Realm Task Force Approval Date (for US Realm Specific Projects)	**USRTF Approval Date CCYY-MM-DD**
Sponsoring Work Group Approval Date	**WG Approval Date CCYY-MM-DD**
Steering Division Approval Date	**SD Approval Date CCYY-MM-DD**
PBS Metrics and Work Group Health Reviewed? (required for SD Approval)	☐ Yes ☐ No
FHIR Project: FHIR Management Group Approval Date	**FMG Approval Date CCYY-MM-DD**
Technical Steering Committee Approval Date	**TSC Approval Date CCYY-MM-DD**
TSC has received a Copyright/Distribution Agreement (which contains the verbiage outlined within the SOU), signed by both parties.	☐ Yes ☐ No

6.d. Stakeholders / Vendors / Providers

Click here to go to Appendix A for more information regarding this section
This section must be completed for projects containing items expected to be ANSI approved, as it is an ANSI requirement for all ballots

Stakeholders	Vendors	Providers
☐ Clinical and Public Health Laboratories	☐ Pharmaceutical	☐ Clinical and Public Health Laboratories
☐ Immunization Registries	☒ EHR, PHR	☐ Emergency Services
☐ Quality Reporting Agencies	☐ Equipment	☐ Local and State Departments of Health
☐ Regulatory Agency	☒ Health Care IT	☐ Medical Imaging Service
☐ Standards Development Organizations (SDOs)	☐ Clinical Decision Support Systems	☒ Healthcare Institutions (hospitals, long term care, home care, mental health)

☒ Payors	☐ Lab	☐ Other (specify in text box below)
☒ Other (specify in text box below)	☐ HIS	☐ N/A
☐ N/A	☐ Other (specify below)	
	☐ N/A	

Other: Mobile Health application developers

6.e. Synchronization With Other SDOs / Profilers

Click here *to go to Appendix A for more information regarding this section*

Check all SDO / Profilers which your project deliverable(s) are associated with.		
☐ ASC X12	☐ CHA	☐ LOINC
☐ AHIP	☐ DICOM	☐ NCPDP
☐ ASTM	☐ GS1	☐ NAACCR
☐ BioPharma Association (SAFE)	☐ IEEE	☐ Object Management Group (OMG)
☐ CEN/TC 251	☐ IHE	☐ The Health Story Project
☐ CHCF	☐ IHTSDO	☐ WEDI
☐ CLSI	☐ ISO	☐ Other (specify below)

onsor" dropdown field. The search results will reflect projects which your Work Group is sponsoring and co-sponsoring.