

PSS: Application Data Exchange Assessment Framework and Functional Requirements for Mobile Health

[PSS Help and FAQs](#)

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1a. Project Name	Application Data Exchange Assessment Framework and Functional Requirements for Mobile Health
1b. Project ID	1599
1c. Is Your Project an Investigative Project (aka PSS-Lite)?	No
1d. Is your Project Artifact being Reaffirmed or proceeding to Normative directly after being either Informative or STU?	No
1e. Today's Date	
1f. Name of standard being reaffirmed	
1g. Project Artifact Information	
1h. ISO/IEC Standard to Adopt	
1i. Does the standard include excerpted text from one or more ISO, IEC or ISO/IEC standards, but is not an identical or modified adoption?	
1j. Unit of Measure	
2a. Primary/Sponsor WG	Mobile Health
2b. Co-Sponsor WG	Electronic Health Record
2c. Co-Sponsor Level of Involvement	Request formal content review prior to ballotRequest periodic project updates; specify period in text box below (e.g. 'Monthly', 'At WGMs', etc.)
2c. Co-Sponsor Update Periods	Review prior to publication and at WGMs
2b. Co-Sponsor WG 2	Orders & Observations
2c. Co-Sponsor Level of Involvement	Request formal content review prior to ballotRequest periodic project updates; specify period in text box below (e.g. 'Monthly', 'At WGMs', etc.)
2c. Co-Sponsor 2 Update Periods	Review prior to publication and at WGMs
2b. Co-Sponsor WG 3	Clinical Information Modeling Initiative

2c. Co-Sponsor Level of Involvement	Request formal content review prior to ballotRequest periodic project updates; specify period in text box below (e.g. 'Monthly', 'At WGMS', etc.)
2d. Project Facilitator	Christina Caraballo
2e. Other Interested Parties (and roles)	US Office of the National Coordinator for Health IT US National Institutes of Health, All of Us Research Project Open mHealth
2f. Modeling Facilitator	Keith Boone
2g. Publishing Facilitator	Keith Boone
2h. Vocabulary Facilitator	
2i. Domain Expert Representative	Nathan Botts
2j. Business Requirements Analyst	
2k. Conformance Facilitator	Keith Boone
2l. Other Facilitators	
2m. Implementers	Reliant Medical Open mHealth Audacious Inquiry Health eServices
3a. Project Scope	<p>The scope of this project is to develop the assessment framework and functional requirements for consumer medical devices and applications required to support the exchange of observations and other data in support of consumer health monitoring. We will focus ensuring that devices, apps and infrastructure can support reporting of vital signs (height, weight, blood pressure, O2 saturation, respiration and heart rate), and physical activity based on requirements of implementation guidelines and specifications from HL7 and other sources.</p> <p>The scope of this project is Universal even though current leadership of the project is US based. We have had participation in project efforts from individuals in the US, Europe and Asia, and who serve markets internationally. We welcome greater international participation in this project.</p> <p>This project will produce a FHIR Implementation Guide containing:</p> <ol style="list-style-type: none"> 1. A framework for assessing conformance to the function requirements. (Normative) 2. Functional requirements for Mobile Health Devices and Apps and Supporting infrastructure exchanging health data. (Normative) 3. FHIR resource constraints necessary to support functional requirements in this guide. (Informative) <p>Out of scope items include:</p> <ul style="list-style-type: none"> * Non-functional requirements are covered in other specifications (e.g., CMHAFF) and will be referenced by this document but are otherwise out of scope. * Development of new profiles for the purposes of exchange for the above mentioned content. The profiles included in this guide will be for the purposes of automation of assessments, not for the purposes of exchange.
Attachments	
3b. Project Need	<p>Mobile health devices and apps provide their own APIs and methods for collecting device data that can be communicated to EHR, PHR and research endpoints. Much of this data can (and has been) readily converted to FHIR resources.</p> <p>However, some limits have been encountered which demonstrate that essential data needed to generate, interpret and use the FHIR resources is sometimes missing.</p> <p>The purpose of this project is to develop functional requirements and a framework that can be used to assess mobile health devices, apps and FHIR profiles to ensure that the essential data needed for clinical, patient and research uses is present in communications between applications.</p>
3c. Security Risk	No

3d. External Drivers	All of Us Research program
3e. Objectives/Deliverables and Target Dates	Initial Ballot May 2020 Additional Ballot September 2020
3f. Common Names / Keywords / Aliases:	mHealth ADE Assessment Framework
3g. Lineage	mHealth App Data Exchange investigative project
3h. Project Dependencies	
3i. HL7-Managed Project Document Repository URL:	https://confluence.hl7.org/display/MH/Mobile+Health+App+Data+Exchange+Project
3j. Backwards Compatibility	No
3k. Additional Backwards Compatibility Information (if applicable)	
3l. Using Current V3 Data Types?	N/A
3l. Reason for not using current V3 data types?	
3m. External Vocabularies	Yes
3n. List of Vocabularies	LOINC SNOMED CT IEEE 11073
3o. Earliest prior release and/or version to which the compatibility applies	
4a. Products	FHIR Implementation Guide, FHIR Profiles
4b. For FHIR IGs and FHIR Profiles, what product version(s) will the profiles apply to?	R4
4c. FHIR Profiles Version	R4
4d. Please define your New Product Definition	
4d. Please define your New Product Family	
5a. Project Intent	Implementation Guide (IG) will be created/modified
5a. White Paper Type	
5a. Is the project adopting/endorsing an externally developed IG?	No
5a. Externally developed IG is to be (select one)	
5a. Specify external organization	
5a. Revising Current Standard Info	

5b. Project Ballot Type	STU to Normative
5c. Additional Ballot Info	There are compatibility concerns, given that this specification could be used to assess existing FHIR and other implementation guides (e.g., US Core, Healthcare Devices FHIR IG specifications). However, these concerns are not material to the development of this guide.
5d. Joint Copyright	No
5e. I understand I must submit a Joint Copyright Letter of Agreement to the TSC in order for the PSS to receive TSC approval.	no
6a. External Project Collaboration	Open mHealth IHE Mobile Health App Workgroup
6b. Content Already Developed	5-10%
6c. Content externally developed?	No
6d. List Developers of Externally Developed Content	
6e. Is this a hosted (externally funded) project?	No
6f. Stakeholders	Regulatory Agency, Standards Development Organizations (SDOs)
6f. Other Stakeholders	
6g. Vendors	EHR, PHR, Equipment, Health Care IT
6g. Other Vendors	
6h. Providers	Healthcare Institutions (hospitals, long term care, home care, mental health)
6h. Other Providers	
6i. Realm	Universal
7d. US Realm Approval Date	
7a. Management Group(s) to Review PSS	FHIR
7b. Sponsoring WG Approval Date	Dec 20, 2019
7c. Co-Sponsor Approval Date	Dec 17, 2019
7c. Co-Sponsor 2 Approval Date	
7c. Co-Sponsor 3 Approval Date	
7c. Co-Sponsor 4 Approval Date	
7c. Co-Sponsor 5 Approval Date	
7c. Co-Sponsor 6 Approval Date	
7c. Co-Sponsor 7 Approval Date	

7c. Co-Sponsor 8 Approval Date

7c. Co-Sponsor 9 Approval Date

7c. Co-Sponsor 10 Approval Date

7e. CDA MG Approval Date

7f. FMG Approval Date Jan 22, 2020

7g. V2 MG Approval Date

7h. Architecture Review Board Approval
Date

7i. Steering Division Approval Date Mar 08, 2020

7j. TSC Approval Date Mar 16, 2020
