NOTE: To use Track Changes, turn off "protection" by clicking on (pre-MS Word 2007) Tools > Unprotect Document or (MS Word 2007 and higher) Review > Protect Document.

PSS-Lite/Investigative Projects: Sections surrounded by a <u>BOLD OUTLINE</u> must be completed for approval of "Investigative Projects" (a.k.a PSS-Lite).

1. Project Name and ID

`Enter the name of the project here. Patient Reported Outcomes`	Project ID:

TSC Notification Informative/STU to Normative	Date :

`Check this box when the project proceeds from Informative to Normative or STU to Normative status.  Forward to the TSC for notification, as this triggers American National Standards Institute (ANSI) Project Initiation Notification (PINS) submission.`

Investigative Project	Date :

`Check this box when the project is investigative or exploratory in nature, which allows limited project scope definition.  Sections in bold outline are mandatory for project approval of an investigative project; all other sections are optional.`
`Sections 1-Project Name and Scope, 2-Sponsoring Group(s)/Project Team, 3a-Project Scope, 3b-Project Need, 3g-Project Objective, 3i-Project Document Repository, 6b-[Realm, if known], and 6d-[applicable Approval Dates] are required.`
`Investigative Project specific instructions are highlighted in yellow.`
`An investigative project must advance in two WGM cycles, requiring a full scope statement.  Otherwise the project will be closed.`

2. Sponsoring Group(s) / Project Team

2.a. Primary Sponsor/Work Group

Primary Sponsor/Work Group **(1 (And Only 1) Allowed)**	`FHIR-Infrastructure`

2.b. Co-sponsor Work Group(s)

Co-sponsor Work Group(s) (Enter co-sponsor approval dates in Section 6.d Project Approval Dates)	`Patient Care`
	`BR&R`
	`O&O – Interested Party`

Indicate the level of involvement that the co-sponsor will have for this project:
X Request formal content review prior to ballot
X Request periodic project updates. Specify period: <mark>Monthly, at WGMs, etc</mark>.
Other Involvement. Specify details here: <mark>Enter other involvement here</mark>

2.c. Project Team

All names should have confirmed their role in the project prior to submission to the TSC.

Project facilitator (**1 Mandatory**)	**Nagesh Bashyam / Brett Marquard**
Other interested parties and their roles	
Multi-disciplinary project team (recommended)	
Modeling facilitator	**Nagesh Bashyam**
Publishing facilitator	**FHIR**
Vocabulary facilitator	`RobMcClure`
Domain expert rep	`pSCANNER / ReachNet pilot sites`
Business requirement analyst	`Nagesh Bashyam`
Conformance facilitator (for IG projects)	
Other facilitators (SOA, etc)	

Implementers (**2 Mandatory** for STU projects)

1)	pSCANNER
2)	REACHnet

3. Project Definition

3.a. Project Scope

Describe the project; Patient Reported Outcomes (PROs) can be used to inform the clinical management of individuals, shared decision-making, patient self-management, care planning, goal setting and attainment, and to inform patient-centered outcomes research. However, health systems have historically been slow to utilize this data. The aim of this project is to standardize electronic capture and exchange or PRO data in clinical and research settings. Specifically the project will develop and/or improve profiles for the following FHIR Resources

- Questionnaire
- Questionnaire Response
- Other US Core profiles required to capture/exchange PRO responses.

The profiles will likely be used for administering PROs for Physical Function status measures as part of the pilots using standard FHIR APIs.
Any extensions that may be necessary for the project will be part of the overall profiles developed.
Also as part of the projects value sets for structured capturing of the PRO data will be developed for Physical Function measures.

For other clinical data that may be used for auto-population or exchanging PRO data within the context of EHRs the US Core FHIR profiles will be reused.

3.b. Project Need

A landscape analysis on the use of PROs in clinical care and research settings were conducted the outcomes of which have identified the lack of standardization in the creation, administration and sharing of PRO data even if they would help with the outcome for patients. In order to improve the use of PRO data in the clinical workflow the following needs have been identified for standardization
- **Need to identify relevant PROMs for each domain using defined data elements and vocabularies**
- **Need to enable PROM administration within EMRs**
- **Need to enable PROM administration using apps outside of EMRs**
- **Need to share PROM responses to clinicians, researchers and care managers.**

3.c. Security Risks

Will this project produce executable(s), for example, schemas, transforms, style sheets, executable program, etc. If so the project must review and document security risks. Refer to the Cookbook for Security Considerations for additional guidance, including sample spreadsheets that may be used to conduct the security risk assessment.	☐ **Yes** ☐ **No** ☒ **Unknown**

3.d. External Drivers

AHRQ intends to run pilots in calendar year 2018-19 using technical implementation guidance created by this project.

3.e. Project Objectives / Deliverables / Target Dates

	Target Date
Submit for STU Comment Only Ballot	2018 May Ballot

Complete Comment Only Ballot Reconciliation	2018 May WGM
Submit for STU Ballot in September	2018 Sep Ballot
Complete STU Ballot Reconciliation	2018 Sep WGM
Submit for STU publication	2018 Dec – 2019 Jan
STU Period	2019 Jan – 2020 Jan
Project End Date (all objectives have been met) Note: For PSS-Lite/Investigative Project, End date must be no more than two WGM cycles, e.g. project initiated at January WGM must complete investigation by September WGM.	2019 September

3.f. Common Names / Keywords / Aliases

PRO IG, Patient Reported Outcomes IG

3.g. Lineage

If your project creates a Post-Release 1 version; indicate the name of the prior product and if it is supplanting, replacing or coexisting with a previous release.

3.h. Project Dependencies

FHIR Release 4 publication.

3.i. Project Document Repository Location

ONC Tech Lab Page URL **https://www.healthit.gov/techlab/standards_coordination.html**

3.j. Backwards Compatibility

Are the items being produced by this project backward compatible?	☐	Yes	☐	No	☐	Unknown	☒ N/A
If you check 'Yes' please indicate the earliest prior release and/or version to which the compatibility applies:							

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	☐	Unknown	☒ N/A
If you check 'No' please explain the reason:							

If desired, enter additional information regarding Backwards Compatibility.

3.k. External Vocabularies

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

4. Products (check all that apply)

	Arden Syntax		V2 Messages – Administrative
	Clinical Context Object Workgroup (CCOW)		V2 Messages – Clinical
	Domain Analysis Model (DAM)		V2 Messages – Departmental
	Electronic Health Record (EHR) Functional Profile		V2 Messages – Infrastructure
X	FHIR Extensions		V3 Domain Information Model (DIM / DMIM)
X	FHIR Implementation Guide		V3 Documents – Administrative (e.g. SPL)
X	FHIR Profiles		V3 Documents – Clinical (e.g. CDA)
X	FHIR Resources		V3 Documents – Knowledge
	Guidance (e.g. Companion Guide, Cookbook, etc)		V3 Foundation – RIM
	Logical Model		V3 Foundation – Vocab Domains & Value Sets
	New/Modified/HL7 Policy/Procedure/Process		V3 Messages – Administrative
	New Product Definition (please define below)		V3 Messages – Clinical
	New Product Family (please define below)		V3 Messages – Departmental
	Non Product Project - (Educ. Marketing, Elec. Services, etc.)		V3 Messages – Infrastructure
	White Paper		V3 Rules – GELLO

	Creating/Using a tool not listed in the HL7 Tool Inventory		V3 Services – Java Services (ITS Work Group)
			V3 Services – Web Services (SOA)

If you checked New Product Definition or New Product Family, please define below:

5. Project Intent (check all that apply)

	Create new standard		Supplement to a current standard
	Revise current standard (see text box below)	X	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):
	White Paper (select one):		Adopted - OR - Endorsed
	Balloted Informative OR Non-balloted WG White Paper		N/A (Project not directly related to an HL7 Standard)

If revising a current standard, indicate the following:
  – Name of the standard being revised
  – Date it was published (or request for publication, or ANSI designation date)
  – Rationale for revision
  – The relationship between the new standard and the current standard (is it designed to replace the current standard, a supplement to the current standard, etc.)

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

X	Comment (aka Comment-Only)		Joint Ballot (with other SDOs)
	Informative		N/A (project won't go through ballot)
X	STU to Normative - OR - Normative (no STU)		

If necessary, add any additional ballot information here. If artifacts will be jointly balloted with other SDOs, list the other groups.

5.b. Joint Copyright

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?		Yes	X	No

6. Project Logistics

6.a. External Project Collaboration

Include SDOs or other external entities you are collaborating with, including government agencies as well as any industry outreach. Indicate the nature and status of the Memorandum of Understanding (MOU) if applicable. ONC, AHRQ, NLM ?	
For projects that have some of their content already developed:	
How much content for this project is already developed?	**40%**
Was the content externally developed (Y/N)?	**No, SDC FHIR IG.**
Is this a hosted (externally funded) project? (not asking for amount just if funded)	Yes No

6.b. Realm

	Universal - OR -	**X**	Realm Specific
			Check here if this standard balloted or was previously approved as realm specific standard
	U.S Realm		

6.c. Stakeholders / Vendors / Providers

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	X	EHR, PHR		Emergency Services
X	Quality Reporting Agencies		Equipment		Local and State Departments of Health
X	Regulatory Agency	X	Health Care IT		Medical Imaging Service
X	Standards Development Organizations (SDOs)		Clinical Decision Support Systems	X	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: Indicate other stakeholders, vendors or providers not listed above.

6.d. Project Approval Dates

Affiliate Approval Date (for Affiliate Specific Projects):	**Affiliate Approval Date CCYY-MM-DD or indicate "N/A"**
US Realm Steering Committee Approval Date (for US Realm Specific Projects):	**USRSC Approval Date CCYY-MM-DD or indicate "N/A"**
Sponsoring Work Group Approval Date:	**WG Approval Date CCYY-MM-DD**
Co-Sponsor Group Approval Date (Copy this entire row for each co-sponsor; indicate the specific cosponsor that issued approval)	**Co-Sponsor Approval Date CCYY-MM-DD**
FHIR Project: FHIR Management Group Approval Date:	**FMG Approval Date CCYY-MM-DD or "N/A"**
Architectural Review Board Approval Date: (required for externally developed content)	**ARB Approval Date CCYY-MM-DD or "N/A"**
Steering Division (of Primary Sponsor WG) Approval Date:	**SD Approval Date CCYY-MM-DD**
Last PBS Metrics Score:	☐ Green ☐ Yellow ☐ Red
PBS Metrics Reviewed? (required for SD Approval if not green)	☐ Yes ☐ No
Technical Steering Committee Approval Date:	**TSC Approval Date CCYY-MM-DD**

TSC has received a Copyright/Distribution Agreement (containing the verbiage outlined within the SOU), signed by both parties.	☐ Yes ☐ No ☐ N/A