

Enabling a healthier world

PHYSICAL ACTIVITY ALLIANCE

HL7® BALLOTING PROCESS

Recommendation and Roadmap

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1 Purpose

This document was created to help the Physical Activity Alliance (PAA) plan an engagement with HL7® to complement and support other activities envisioned in the PAA's Action Plan – Physical Activity Assessment, Prescription and Referral in Health Care. It identifies objectives for HL7® engagement to standardize measures and related information needed to establish physical activity assessment, prescription and referral as a standard of practice for delivery of care across the healthcare system. The recommended approach and roadmap include high level activities for three streams of work to achieve the objectives with a rough order of magnitude estimate of costs.

2 Business context

2.1 Importance of physical activity

Being physically active is one of the most important lifestyle behaviors people can engage in to maintain physical and mental health and well-being.¹ Regular physical activity (PA) is both health-promoting and important for disease prevention and treatment with numerous benefits that contribute to a disability-free lifespan.² It also contributes to social connectedness, quality of life, and environmental sustainability.³

Currently in the US, only 26 percent of men, 19 percent of women, and 20 percent of adolescents, report sufficient activity to meet the relevant aerobic and muscle-strengthening PA guidelines.¹ The current levels of physical inactivity in the US population create \$117 billion in annual healthcare costs⁴ and contribute about 10 percent of premature mortality.¹ Even so, current population PA levels avert 3.9 million premature deaths globally and 140,200 premature deaths in the US on an annual basis.⁵

2.2 Opportunity

Numerous guidelines and recommendations, including the Physical Activity Guidelines for Americans,¹ the US Preventive Services Task Force⁶, the Healthy People 2030 Framework⁷, and the US National Physical Activity Plan⁸ promote the importance of PA assessment, prescription and referral as a standard of care in clinical practice to help individual patients realize the benefits of more physically active lifestyles. Exercise

¹ Services UDoHaH. Physical Activity Guidelines for Americans, 2nd edition. 2018.

² Wen CP and Wu X. Stressing harms of physical inactivity to promote exercise. Lancet. 2012;380:192-3.

³ Global Advocacy Council for Physical Activity International Society for Physical A and Health. The Toronto Charter for Physical Activity: A Global Call for Action. J Phys Act Health. 2010;7 Suppl 3:S370-85.

⁴ Carlson SA, Fulton JE, Pratt M, Yang Z and Adams EK. Inadequate physical activity and health care expenditures in the United States. Prog Cardiovasc Dis. 2015;57:315-23.

 ⁵ Strain T, Brage, S., Sharp, SJ., Richards, J., Tainio, M., Ding, D., Benichou, J., Kelly, P. Use of the prevented fraction for the population to determine deaths averted by existing prevalence of physical activity: a descriptive study. Lancet Global Health. 2020;8:e920-30.
 ⁶ Force UPST. Draft Recommendation Statement on Behavioral Counseling to Promote a Healthy Lifestyle in Adults with Cardiovascular Risk Factors. 2020.

⁷ Promotion OoDPaH. Healthy People 2030 Framework. 2020.

⁸ National Physical Activity Plan. 2016.



is Medicine® has been a global health initiative to make PA assessment and promotion a standard in clinical care.⁹

Research into the benefits of PA promotion in clinical practice demonstrate that healthcare provider counselling of adult patients on PA is effective at increasing patient activity levels¹⁰ while improving patient quality of life.¹¹ Study of the downstream impacts to population health and associated healthcare costs are ongoing.

2.3 Challenge

Despite an abundance of evidence that a physically active lifestyle can be as or more effective than other health interventions in preventing and managing chronic health conditions and that counseling is effective at increasing patient activity levels, adoption of PA related assessment, prescription and referral as a standard of practice is inhibited by barriers including: 1) lack of consensus about what PA related information (e.g. which measures of physical activity) should be collected in a patient's health record; 2) definition of PA related professional roles and scope of practice (e.g. who is qualified to provide PA related counselling); and 3) lack of funding for PA related activities.

3 Objectives for engagement with HL7

The mission of the Physical Activity Alliance (PAA) is to lead efforts to create, support, and advocate for policy and system changes that enable all Americans to enjoy physically active lives. In the healthcare domain, the PAA has established a Physical Activity Assessment, Prescription and Referral Working Group that is pursuing an action plan that includes activities on several different fronts to establish PA related assessment, prescription, and referral as a standard of practice in healthcare with well-defined roles and funding mechanisms.

Within the Action Plan, engagement with HL7® is anticipated with the goal of tapping into ongoing healthcare data modernization efforts to standardize PA measures and related information that could be captured in electronic health records (EHR) systems and then most importantly used to support PA assessment, prescription, and referral by healthcare providers while also generating timely, accurate and actionable information to support secondary uses including research, population based care and public health surveillance.

Realizing the goals of the initiative will require both the establishment of the new standards and their adoption by software vendors and their users. These two objectives are explored in more detail in the sections that follow.

⁹ Lobelo F, Stoutenberg M and Hutber A. The Exercise is Medicine Global Health Initiative: a 2014 update. Br J Sports Med. 2014;48:1627-33.

¹⁰ Grandes G, Sanchez A, Sanchez-Pinilla RO, et al. Effectiveness of Physical Activity Advice and Prescription by Physicians in Routine Primary Care: A Cluster Randomized Trial. Arch Intern Med. 2009;169(7):694–701. doi:10.1001/archinternmed.2009.23

¹¹ Elley C Raina, Kerse Ngaire, Arroll Bruce, Robinson Elizabeth. Effectiveness of counselling patients on physical activity in general practice: cluster randomized controlled trial BMJ 2003; 326 :793



3.1 Standardize PA related data captured in the EHR

Standardizing PA related information in EHR systems can allow the information to be collected, shared, and used for a range of different purposes, including:

- to help providers (clinicians and community-based health and fitness professionals):
 - identify patients at health risk due to a sedentary lifestyle,
 - intervene to encourage patients to adopt more physically active lifestyles, and
 - monitor and reinforce patient behavior changes;
- to enable information flows that close the loop on PA interventions prescribed by providers by associating any activities that occur in response to a patient referral back to the order;
- to generate real world evidence to support the establishment of PA related standards of practice; and
- to provide information needed to support:
 - reimbursement for services provided by PA professionals,
 - population health initiatives aimed at moving upstream of chronic disease and reducing the total cost of healthcare, and
 - public health surveillance of physical activity.

To meet these goals, unambiguous definitions of and standard specifications for PA measures and other related information will be needed to allow the developers and implementers of EHRs and other systems to collect, share, interpret and use PA related information in a consistent way.

Information that could potentially be standardized to support PAA objectives include:

PA Measures e.g., PAVS Score, objective measures from wearable technologies	Standard measures of PA are needed to help healthcare providers monitor patient activity levels, encourage patients to stay active, promote personal health and well-being, and manage and prevent disease by monitoring changes in patient PA levels that occur over time or as an outcome of health interventions prescribed and taken.
Screening and Assessment Instruments e.g., PAVS Questions, other validated questionnaires	Standard questions and questionnaires will typically be used by healthcare and service providers to collect information about patient PA levels and to evaluate a patient's readiness for change.
Clinical Findings e.g., 415510005 Sedentary lifestyle	Patient health problems that are actively being managed by a provider are typically tracked on a problem list to support continuity of care across patient visits. Using consistent terminology to encode PA related findings in an EHR makes it easier to specify criteria for these systems to use to identify patients with care gaps and remind their providers to take action or to identify populations for quality measurement, research, and other secondary uses.



Interventions

active lifestyle include a range of services provided by clinicians and e.g., "Counseling about physical community-based health and fitness professionals. Documenting activity", "Referral to physical and encoding PA related procedures, orders, and referrals activity program" consistently in an EHR will make it easier to specify criteria for the systems to use to notify providers of patients with care gaps, to help identify services eligible for reimbursement as well as to reuse information for research, quality measurement and other secondary uses. Goals Coded goals allow providers to document objectives set with a patient and then monitor the patient's progress toward those e.g., "To do 150 minutes of objectives. Goals are used to help manage patient care over time, as moderate physical activity per well as to help evaluate the efficacy of interventions taken. week"

Interventions that can help a patient assume a more physically

Care Plans Care plans tie together goals, planned interventions and actual interventions taken and provide a shared view of the 'plan' of care - including objectives, current activity and planned future steps - for providers, patients, and caregivers.

3.2 Build awareness and desire to adopt the PA measures

To achieve the objectives of standardizing the information above, the standards produced through engagement with HL7® must be adopted (implemented and used) by software vendors and their users in a manner that aligns with and supports other objectives and activities within PAA's Action Plan.

To realize this goal, the HL7® engagement must be undertaken in a manner that brings together different stakeholders within the PAA and HL7® communities – including clinicians, community based health and fitness professionals, software vendors, payers, researchers and regulators – in a manner that ensures that the specifications and standards produced to address PA requirements are implementable within systems, are useable, and are seen as providing value to different communities of stakeholders and users who must adopt them.

To minimize barriers to adoption and minimize costs, the approach taken to standardize PA information should align with data capture and sharing patterns already in use or development by the relevant software vendors.



4 Recommended approach

In the short term, Gevity recommends that the PAA:

- join HL7® and begin to engage with the community to gain knowledge of its work groups, projects and group dynamics while building the relationships that will be necessary to realize its goals;
- create software that uses existing HL7[®] standards to show members of the PAA and HL7[®] communities how PA measures can be captured, viewed, and used to identify at risk patients in an EHR; and
- design an engagement with HL7® that will deliver quick wins by leveraging and building upon the work of existing projects and standards that have shared objectives and existing momentum and/or stakeholders that complement other activities in the PAA action plan.

Over time, the PAA should engage with HL7® to build and iterate upon existing standards work to incorporate PA requirements, community feedback and implementation experience. It should aim to increase PA service provider engagement in the standards community and support the rollout of standards-compliant technology solutions to providers incentivized by payer reimbursement and/or regulation.

This approach is provided in more detail in the sections that follow.

4.1 Leverage the HL7 standards process and community

Joining HL7® will provide the PAA with an opportunity to engage a community of stakeholders who are interested in information driven healthcare transformation – including clinicians, software vendors, payers, researchers, and regulators – in discussions about the PAA's objectives, requirements, and ways to realize them through the use of EHR systems and HL7® standards.

The PAA should begin to engage with the community by having project members attend conference calls and monitor relevant forum discussions¹² to gain an understanding of the HL7® standards process¹³, different work groups¹⁴ and projects¹⁵ as well as group dynamics. Once its project members understand the lay of the land, the PAA should seek out opportunities to discuss PA requirements and use cases with relevant work groups and projects to build an understanding of and support for the PAA's objectives and upcoming work among key members of the community.

¹² See <u>http://chat.FHIR®.org</u> accessed Nov 1, 2020.

¹³ See <u>https://confluence.hl7.org/display/HL7/Understanding+the+Standards+Process</u> accessed Nov 1, 2020.

¹⁴ See <u>http://www.hl7.org/special/committees/index.cfm</u> accessed Nov 1, 2020.

¹⁵ See <u>https://www.hl7.org/about/FHIR®-accelerator/</u> accessed Nov 1, 2020.



Key early goals are for the PAA to build the foundational knowledge and relationships it needs to gain sponsorship for and to smooth delivery of its work while also gaining visibility into related projects and activities that are relevant to and support its mission.

Over time, the PAA should work to increase its visibility among stakeholders relevant to its mission including the EHR vendors, payers and regulators who will, in the end, need to support the implementation and adoption of the standards the PAA hopes to develop while contributing to other related standards work.

4.2 Prove the concept using SMART-on-FHIR app(s)

Proof-of-concept and reference implementations are often used by software developers to demonstrate design ideas or appropriate use of a technical standard for a given use case to other implementers. Existing projects, including the Gravity¹⁶ and Argonaut¹⁷ accelerator projects have specified HL7® standards that are a close fit the PAA's objectives for PA assessment, evaluation and prescribing and that can be used to show members of the PAA and HL7® communities how PA measures could be captured, viewed, and used to identify at risk patients in an EHR.

The SMART-on-FHIR¹⁸ standard provides a way for third parties to build software applications that can run 'inside' EHR systems. These apps can also run in web browsers to allow authorized providers as well as patients and caregivers to access and manipulate information within an EHR system. Such apps can be written once and be used with multiple independent EHRs. Major EHR vendors such as Epic, Cerner and Allscripts all have SMART support, and many smaller vendors are following suit.

The PAA should pursue the creation one or more proof of concept SMART-on-FHIR apps. These apps would serve several functions:

- They would allow the PAA to experiment with different types of metrics (e.g., PAVS), different styles of presentation and different types of provider-facing and patient-facing user interfaces to get a sense of what is most effective in driving desired provider and patient behavior. As PAA-controlled software, they could be iterated quickly based on feedback and could even provide differing interfaces to different users to allow comparative evaluation of differing approaches.
- They would allow demonstration and potentially early release of PA-based functionality to the community, allowing PA stakeholder feedback and metrics on effectiveness to be gathered sooner than would be possible with implementations by EHR and other software vendors. There would be no need to wait for formal standards approval before software development could begin.
- They would demonstrate the feasibility of and best practices for software vendors considering enabling PA functionality within their own applications.

¹⁶ See <u>https://www.hl7.org/gravity/</u> accessed Nov 1, 2020.

¹⁷ See <u>https://argonautwiki.hl7.org/Main_Page</u> accessed Nov 1, 2020.

¹⁸ See <u>https://docs.smarthealthit.org</u> accessed Nov 1, 2020.



• As HL7® standardization efforts mature, these apps would provide an interoperability testing platform for applications that are developing their own solutions, ensuring that early adopters always have at least one independently created partner system to share data with.

There are three main types of apps that could be developed, listed below in the recommended order of development, based on both community readiness and interdependency:

- 1. An app that runs inside an EHR to allow its users to capture PA measures and metrics and to see existing PA data, including support for trending, comparison with target benchmarks based on age and gender, etc. Viewable data would include data recorded by the app as well as PA information in the EHR captured from other sources including other apps. Many EHRs can support this functionality right now. In the future, the app could be expanded to support authoring and managing referrals related to PA and/or developing and managing PA-related care plans. The ability to manage referrals with external agents is an area in early development but not generally available in most production EHR systems as yet.
- 2. An app that runs in a web browser or on a mobile device that allows patients to view and record PA measures and metrics inside the providers EHRs. Recent US regulation mandates that patients have view access and most EHRs (though not always most healthcare system policies) allow patient recording of observational data directly into the EHR. Such an app could share device-based PA metrics (e.g., step counts, heart rates) as well as questionnaire-based answers. The app could also provide guidance on strategies to increase PA levels, benchmarking based on gender, age, or past activity. In the future, this app could be expanded to gain read access to active PA-related referrals as well as to read and write access to PA-related care plans.
- 3. An app that runs in a web browser or on a mobile device that allows PA service providers to access or record information PA information about a patient and to access and manage PA-related referrals and care plans. Deployment of this app would be dependent on availability of PA referral capabilities in EHR systems (or EHR apps).

In addition, the PAA may want to consider developing a CDS Hooks¹⁹ service that could evaluate information in a patient's health record and identify whether they were a suitable candidate for a PA intervention, optionally providing a linkage to specific recommended interventions, patient literature, evidence supporting intervention or other clinician supports that would increase the likelihood, improve the consistency and/or streamline the use of PA interventions. The patient-view hook is the most mature and is starting to be rolled out in existing EHRs, though infrastructure around registering external hook services is still in its early stages.

4.3 Align with high visibility projects

The HL7® Accelerator Program¹⁵ is composed of projects that are actively being driven forward by healthcare providers, software vendors, payers and government agencies who have come together with an interest in using FHIR® to address common objectives and use cases. Each of these initiatives include

¹⁹ See <u>https://cds-hooks.hl7.org</u> accessed Nov 1, 2020.



formally funded projects with a broad set of stakeholders looking to leverage the HL7® FHIR® standard to improve interoperability and meet specific industry needs.

The Argonaut Project ²⁰	What it is: The Argonaut Project is a US-centric private sector initiated and funded implementation community comprised of leading technology vendors and provider organizations that came together to advance industry adoption of modern, open interoperability standards.		
	Relevance to PAA objectives: The Argonaut Project informs and supports the development of the US Core Implementation Guide (IG) that specifies minimum conformance requirements for systems accessing and manipulating patient data in the US. Support for these standards is mandated for EHRs and payers in recent ONC and CMS regulations.		
The Gravity Project ¹³	What it is: The Gravity Project was initiated in November 2018 by SIREN with funding from the Robert Wood Johnson Foundation to convene broad stakeholder groups in identifying and harmonizing social risk factor data for interoperable electronic health information exchange.		
	Relevance to PAA objectives: The Gravity Project has convened a large community of committed members to develop a technical framework to support objectives very similar to PAA.		
The Da Vinci Project ²¹	What it is: Da Vinci stakeholders are industry leaders (payers and providers) and health IT technical experts who are working together to accelerate the adoption of FHIR® as the standard to support and integrate value-based care data exchange across communities.		
	Relevance to PAA objectives: Payers, providers and EHR vendors on the Da Vinci Project are developing a technical framework to allow healthcare providers to determine whether a service will be covered by a patient's payer at the time it is ordered.		

Alignment with existing initiatives being undertaken by the PA community is also highly recommended, especially where existing work products can be leveraged to provide a starting point for standards development work or existing implementers overlap with stakeholder groups that participate in the HL7® community. The Exercise is Medicine® (EIM) initiative managed by the American College of Sports Medicine (ACSM) is an example of an initiative that has produced collateral (user stories, use cases, measures, assessment tools, etc.) that are used by provider organizations that participate within the HL7® community.

²⁰ See <u>https://argonautwiki.hl7.org/Main_Page</u> accessed Nov 1, 2020.

²¹ See <u>https://www.hl7.org/about/davinci/</u> accessed Nov 2, 2020.



4.4 Follow and elaborate upon existing patterns

The Gravity Project is developing specifications to support use cases that align very closely with PA evaluation, prescription, referral and secondary use requirements while the Da Vinci project is developing specifications to support health coverage requirements discovery and prior authorization for services ordered by providers at the point of care. These specifications can be readily used to evaluate PA requirements for, and potential uses of PA measures and related information in the context of well-defined workflows.

Leveraging and elaborating upon existing specifications that are familiar with Gravity and Da Vinci stakeholders will provide PAA with starting point to define PA specific specifications and, perhaps more importantly, workflows and data exchange scenarios that are familiar to other stakeholders to use to discuss PA requirements. Gevity recommends that PAA leverage and build upon the following Gravity and Da Vinci use cases to define PA use cases that illustrate how PA measures and other information can be collected and used:

Gravity Use Case 1: Document SDOH Data in Conjunction with a Patient Encounter	What it is: This use case describes how coded social determinants of health (SDOH) data are captured in a health care system and how data are shared with other systems. SDOH data are documented either as part of screening or assessment/diagnosis activities and may provide a reason for ordering care activities.		
	Relevance to PAA objectives: The use case provides a technical framework and workflow for collecting user reported data using instruments like the PAVS and recording observations and clinical findings in the patient's chart. The flows are readily adaptable to the PA instruments to show how PA related data could be collected and used at the point of care.		
Gravity Use Case 2: Document and Track SDOH Related Interventions to Completion	What it is: This use case describes how interventions planned or completed in response to data collected about social risks and social needs in electronic health information systems. Actions can include counseling, education, consults, referrals, case management, care planning, and modifications to treatment.		
	Relevance to PAA objectives: The use case illustrates how interventions ordered by a provider can be sent to another for completion. The flows provide a starting point for examining how information exchange with PA providers could work when discussing the capabilities of systems and data requirements.		
Da Vinci Coverage Requirements Discovery (CRD)	What it is: These use cases describe how systems can give providers real-time access to payer approval requirements, documentation, and rules and then request prior authorization for services ordered		



and Prior Authorization Support (PAS) Use Cases	at the point of service with the objective to reduce provider burden and support treatment planning.			
	Relevance to PAA objectives: These use cases provide a technical framework and workflow to allow providers to identify covered services and patient out of pocket costs when referring patients to PA related services. This is a starting point for examining payer requirements for PA related measures, interventions, and related data.			
Gravity Use Case 3: Gather and Aggregate SDOH Data for Uses Beyond Point of Care	What it is: This use case describes how patient-level social risk information documented and shared in the above use cases can be aggregated and analyzed to support clinical, system, and community activities, including but not limited to panel and population health management, risk adjustment, value-based payment, community health improvement and public health surveillance.			
	Relevance to PAA objectives: This use case provides a technical framework and workflow for population-based data aggregation and secondary use. This is a starting point for examining the requirements payers, researchers, public health, and other users of population-based data.			
Da Vinci Data Exchange for Quality Measures (DEQM) Use Case	What it is: Defines standards for both defining and submitting data in support of evaluating healthcare quality measures from EHRs and other clinical systems to payers and government agencies			
	Relevance to PAA objectives: For patients covered under a capitated care model, would allow reporting of formal measures related to PA level in patients as well a level of PA intervention undertaken. Such measures can be used by payers and/or regulators to incentivize improvements in PA intervention.			

4.5 Progress iteratively

Engagement with the standards community will be a long-term exercise. The time from project inception to publication of an official "trial use" standard will be a minimum of 18 months. Implementation and rollout to the community typically takes at least a year but often 2 or 3 after that.

Implementers often develop new capabilities within their systems in stages where 'easier' functionality and/or requirements are taken on in early releases, while more complex capabilities are deferred to future releases to allow for iterative design, testing and vetting of the use-case by users and target market. For this reason, the time to progress to a normative standard will be 4-5 years or more.



5 Scope of a PA Implementation Guide

A FHIR®²² Implementation Guide (IG)²³ for PA should be developed and used to seek formal HL7® community endorsement of PA data standards and exchange workflows for PA. Once accepted by HL7®, the IG would become available for regulatory reference by CMS and/or ONC and would also serve as the foundation for software development by EHR and PA service provider systems.

To support the HL7® balloting process and future use by implementers, a FHIR® IG for PA should be built using a standard FHIR® IG template to provide business context, use cases, formal technical specifications, computable artifacts, and examples in a standard format. Wherever appropriate, existing specifications should be referenced and elaborated upon to increase compatibility with other solutions and to reduce unnecessary development effort for vendors that could become a barrier to adoption.

5.1 Existing specifications to reference

Existing technical artifacts (FHIR® profiles) from existing projects and IGs would be leveraged by a FHIR® IG for PA. These would include:

- **US Core**²⁴: Patient, Practitioner, PractitionerRole, Organization, Observation, and potentially others.
- Structured Data Capture (SDC): Questionnaire, QuestionnaireResponse
- Da Vinci: Coverage
- Gravity: ServiceRequest, Task, Condition, CarePlan, Goal, Procedure, Condition

5.2 New specifications required for PA information

Several new technical artifacts will be need to be created for a FHIR® IG for PA, including:

- Profiles on the FHIR® Observation resource to standardize how specific PA measures and metrics of interest will be captured and shared. These new profiles will align with the US Core and possibly Gravity profiles on the Observation resource.
- SDC-conformant instances of the FHIR® Questionnaire resource to standardize the instruments or forms used to collect PA information from patients and/or providers (e.g., PAVS Questions) along with example instances of the FHIR® QuestionnaireResponse resource. Where possible, these will also align with Gravity profiles.

²² See <u>https://www.hl7.org/FHIR/overview.html</u> accessed Nov 1, 2020.

²³ See <u>https://www.hl7.org/FHIR/implementationguide.html</u> accessed Nov 1, 2020.

²⁴ See <u>http://hl7.org/FHIR/us/core/</u> accessed Nov 1, 2020.



- Profiles on the FHIR® ServiceRequest resource to show how information needed to order and/or authorize PA services will be collected and used to define and manage care related to PA. These profiles will be based on profiles developed by the Gravity project with the vocabulary and other constraints changed to focus on PA rather than social determinants of health (SDOH) requirements. Where Gravity profiles are not SDOH-specific, they will be leveraged directly. (As part of this work, PAA should encourage Gravity to make their 'framework' parent IG not overly SDOH-specific to maximize opportunities for other projects to use directly.)
- Vocabularies for PA observations and interventions which may involve requesting new LOINC®²⁵ codes for the former and new CPT® codes for the latter requiring engagement with payers and American Medical Association. It may also be necessary to define new SNOMED CT®²⁶ codes in this space. (US Core requires ordering using SNOMED CT® while billing uses CPT®.) As part of the standards process, the HL7® Terminology Authority can assist with engaging external organizations (at least LOINC® & SNOMED CT®) in defining codes.

Finally, the IG will need to provide documentation describing the use-case, business objectives, considerations around workflow, security & privacy principles, etc. Much of the latter will align with, or directly reference, the Gravity base IG²⁷.

²⁵ See <u>https://loinc.org</u> (EVS example <u>https://loinc.org/89574-8/</u>) accessed Nov 1, 2020.

²⁶ See <u>http://www.snomed.org/snomed-ct/five-step-briefing</u> accessed Nov 1, 2020.

²⁷ See <u>http://build.FHIR®.org/ig/HL7/FHIR®-sdoh-clinicalcare/</u> accessed Nov 1, 2020.



6 Roadmap

The following sections propose a roadmap for realization of a FHIR® IG for PA that is consistent with the Recommended Approach.

6.1 Streams of work

The objective of PAA's engagement with HL7® will be to standardize PA measures and other related information to be captured within and flow between software applications used by clinicians, community-based health and fitness professionals, payers, healthcare consumers and others. Three streams of work are proposed to meet this objective.

S1: Core Stream

A significant part of the work required to meet the objective will be to establish and maintain consensus on a set of PA requirements that will progressively be harmonized with the work of other projects, formalized into technical specifications, implemented within software, and published as a standard – first for trial use and, over time, as a normative standard. It will be a journey of several years. Requirements, technical specifications, and the published standard will evolve along the way.

The focus of the Core Stream would be on the long running activities needed to establish and maintain stakeholder relationships and consensus on the requirements for and content of the standards produced over the course of the PAA's engagement with HL7®. This can be accomplished by a small team with responsibility for:

- managing and overseeing the work of all streams to ensure that all requirements, specifications, standards, issues (etc.) are appropriately managed and that project commitments, including timelines and budgets, are achieved;
- ensuring regular and ongoing engagement with stakeholders within both the PA and HL7® communities by resourcing and managing:
 - a secretariat function to ensure that items that require input from the PA community are directed to the PAA Physical Activity Assessment, Prescription and Referral Working Group (or subgroup) and as needed, other PA stakeholders for their input and approval, and
 - an HL7® engagement function to ensure that approved PA requirements, issues, (etc.) are addressed through engagement with the appropriate HL7® work groups, monitoring related projects for work items and specification changes that could impact PA requirements and for attaining necessary approvals to move through the various milestones and activities that are part of the HL7® process; and



• providing continuity of relationships and institutional knowledge by providing continuity of resources and effective management of project deliverables and commitments.

As the group that 'owns' the PAA's relationship with different stakeholder groups as well as commitments made to them, resources on the Core Stream would have primary responsibility for the content of the standards deliverables, leading efforts to establish consensus with stakeholders through the PA workgroup and the HL7® balloting and issue resolution process.

To ensure consistency and continuity, the Core Stream should be resourced by PAA staff with visibility into activities beyond the HL7® engagement. Support from a subject matter expert with existing relationships to draw upon is recommended to help initiate and support PAA's engagement with the HL7® community.

S2: FHIR IG Development

The FHIR® IG Development stream represents a set of intermittent IG authoring and editing activities that must be performed by resources with specialized knowledge and skills. These activities should be planned and managed as a time bound projects overseen by the Core Stream where:

- development of the initial IG would occur over a period of a few weeks starting after PAA's requirements and the HL7® project have been approved and ending with the HL7® sponsoring workgroup's approval to proceed to ballot;
- revisions to the initial IG would be applied over a short period of time after feedback received through the HL7® balloting process has been resolved through the Core Stream's engagement with the HL7© community and PA stakeholders; and where
- subsequent versions would follow a similar development and revision process.

Development of a FHIR® IG for PA will require engagement of a subject matter expert familiar with HL7®'s FHIR® IG templates, publishing tools, and editing of technical artifacts to create and edit the guide.

S3: POC App Development (optional)

The POC App development stream represents any software development projects that the PAA may undertake to create SMART-on-FHIR apps to demonstrate collection and use of PA measures and related information to PA and HL7® stakeholders. Like the work in the IG Development stream, software development and testing should be managed as time bound projects.



6.2 Key activities

1)	l) Get Started		Objective: Establish the team that will deliver the core stream and oversee other streams. Establish a foundation for successful engagement with PA and HL7® stakeholders. Get things moving. Stream: S1, Timeline: ~2 months		
	a) Assemble the core team and launch project		(From startup until attainment of HL7® sponsorship for project.) Objective: Bring together the core project team that will work with PA and HL7® stakeholders to build and maintain consensus.		
			Actions:		
			I. Engage project core team		
			II. Confirm project charter & plan		
	b)	Initiate engagement with PA community	Objective: Establish a working group of influential and highly interested stakeholders to represent the needs of different members of the PA community and to support decision making an communication.		
			Actions:		
			 Socialize project with PA community (e.g., PA Assessment, Prescription and Referral Working Group, EIM, other active projects). 		
			II. Identify influential stakeholders who are interested taking a deep dive into workflow, use of systems and data requirements		
			III. Launch PA working group to support requirements gathering and decision making		
	c)	Initiate engagement with the HL7® community	Objective: Get familiar with the goals, objectives and processes of related HL7® activities. Contribute. Build relationships.		
			Actions:		
			I. Sign up for organizational HL7® membership ²⁸		

²⁸ Membership isn't strictly necessary, but it will reduce costs for connectathons & meetings as well as HL7 education and will smooth some of the processes. It also allows the association to vote on HL7 specifications. For professional associations, membership is \$1500 USD/year.



- II. Join work group calls (Patient Care, Clinical Interoperability Council, Orders and Observations, Clinical Quality Information, Healthcare Devices)
- III. Join project conference calls (Gravity, Da Vinci)
- IV. Attend initial HL7® FHIR® Connectathon event²⁹
- V. Attend initial HL7® Working Group Meeting²⁹
- d) Establish requirements, confirm project goals and scope
 d) Dijective: Gather initial requirements for standardization effort and any supporting Proof-of-Concept apps. Confirm goals for and scope of the work ahead.

Actions:

- I. Review and become familiar with relevant FHIR® IGs and project documentation (US Core, Da Vinci IG and Gravity)
- II. Review and become familiar with relevant PA projects, use cases and documentation (e.g., EIM)
- III. Identify relevant use cases, PA measures and information for initial IG and proof-of-concept application development
- IV. Create and document PA use cases (refine existing from Gravity with PA personas, actors, flows and example data)
- V. Identify existing FHIR® resources to reuse and gaps to close
- VI. Draft materials that will be used to socialize the PAA, the project, its goals, and requirements to the HL7® community and other stakeholders. (May overlap with other activities in the PAA Workgroup's Action Plan.)
- VII. Review documentation above with the PA working group to confirm goals and scope of standardization effort / engagement with HL7®, attain agreement to proceed.
- VIII. (Optional) Confirm goals for and scope of proof-of-concept app development to support PA standardization goals, ensure user acceptance of any apps produced, promote and support in scope deployment activities.
- e) Socialize the project
 with HL7® stakeholders and attain sponsorship
 Objective: Build awareness among HL7® community, engage with potential project sponsors, attain sponsorship for project.

Actions:

I. Present project goals and proposed scope to potential sponsors (Patient Care, Orders & Observations, Clinical

²⁹ See: <u>http://www.hl7.org/events/</u>, accessed Nov 12, 2020.



2)

		 [nteroperability Council) and key project groups including Da Vinci and Gravity		
		II. A	Attain sponsorship for FHIR® IG development work from an HL7® work group		
		III. E C	Explore opportunities to piggyback on planned Connectathon activities to demonstrate collection and use of PA information (Da Vinci, Gravity)		
Standardize PA information with stakeholder input		Objectives: Establish and maintain consensus on the requirements for and content of the standards produced through engagement with HL7®. Establish an HL7® Project to produce the FHIR® IG for PA with the sponsor work group and keep it moving. Oversee work in other streams.			
		Stream: S	S1, Timeline: Month 3 – Normative Standard (5+ years)		
a)	Regular, ongoing HL7® engagement	Objectiv projects, establish	e: Contribute to sponsor work group activities, monitor and work items with overlapping scope or requirements, and maintain alignment with other projects.		
		Actions:			
		Actions:	Regularly participate in sponsor work group calls and monitor		
		Actions: I. F II. N	Regularly participate in sponsor work group calls and monitor Monitor the work of related work groups and projects, including Gravity and Da Vinci (calls, forums ³⁰)		
		Actions: I. F II. N i III. A	Regularly participate in sponsor work group calls and monitor Monitor the work of related work groups and projects, ncluding Gravity and Da Vinci (calls, forums ³⁰) Attend HL7® FHIR® Connectathon events (Jan, May, Sept) ³¹		
		Actions: I. F II. N i III. A S IV. A	Regularly participate in sponsor work group calls and monitor Monitor the work of related work groups and projects, ncluding Gravity and Da Vinci (calls, forums ³⁰) Attend HL7® FHIR® Connectathon events (Jan, May, Sept) ³¹ Attend HL7® Working Group Meetings (Jan, May, Sept) ³¹		
		Actions: I. F II. N i III. A V. F V. F	Regularly participate in sponsor work group calls and monitor Monitor the work of related work groups and projects, ncluding Gravity and Da Vinci (calls, forums ³⁰) Attend HL7® FHIR® Connectathon events (Jan, May, Sept) ³¹ Attend HL7® Working Group Meetings (Jan, May, Sept) ³¹ Participate in the balloting of relevant IGs when they come up for review (US Core, Da Vinci and Gravity specifications) ³²		
		Actions: I. F II. N i III. A V. F V. F V. F	Regularly participate in sponsor work group calls and monitor Monitor the work of related work groups and projects, ncluding Gravity and Da Vinci (calls, forums ³⁰) Attend HL7® FHIR® Connectathon events (Jan, May, Sept) ³¹ Attend HL7® Working Group Meetings (Jan, May, Sept) ³¹ Participate in the balloting of relevant IGs when they come up for review (US Core, Da Vinci and Gravity specifications) ³² Direct opportunities and issues that surface to the PA community for input and decision making.		
ь)	Regular, ongoing PA community engagement	Actions: I. F II. N i III. A V. F V. F V. F VI. F Objective for and c and any s	Regularly participate in sponsor work group calls and monitor Monitor the work of related work groups and projects, ncluding Gravity and Da Vinci (calls, forums ³⁰) Attend HL7® FHIR® Connectathon events (Jan, May, Sept) ³¹ Attend HL7® Working Group Meetings (Jan, May, Sept) ³¹ Participate in the balloting of relevant IGs when they come up for review (US Core, Da Vinci and Gravity specifications) ³² Direct opportunities and issues that surface to the PA community for input and decision making. e: Establish and maintain consensus on the requirements content of standards produced by the HL7® engagement supporting Proof-of-Concept apps.		

Actions:

 ³⁰ See: <u>https://chat.FHIR®.org</u>, accessed Nov 12, 2020.
 ³¹ See: <u>http://www.hl7.org/events/</u>, accessed Nov 12, 2020.
 ³² This is an ongoing requirement, items may come up for ballot prior to the January, May or September workgroup meetings.



		I.	Discuss opportunities and issues that surface during the HL7® engagement, review impact to requirements and decide on go-forward approach
		II.	Engage PA community in review of project deliverables (e.g., requirements documentation, proof-of-concept app design, app user acceptance testing, FHIR® IG for PA review) to build interest and desire to implement
		III.	Engage PA community in review of related HL7® specification (e.g., participation in balloting of Gravity and Da Vinci specifications) – feedback can be aggregated and submitted by PAA representative
c)	Initiate HL7® project	Object Work (ive: Initiate IG Standardization effort with Sponsor HL7® Group
		Action	5:
		I.	Submit a Project Proposal ³³
		II.	Submit Project Scope Statement ³⁴ (deadline: 16 weeks before target for ballot review) ³⁵
		III.	Attain approvals from the Sponsor Working Group, FHIR Management Group, US Realm Steering Committee, Technical Steering Committee (multiple deadlines: 12 weeks before ballot)
d)	(Optional) Launch and	Obiect	ive: Establish time-bound project(s) to create one or more
,	oversee activity #4 – Build proof-of-concept	proof-c	of-concept applications.
	app(s)	Action	s (for Core Stream):
		I.	Staff, launch and support activity #4 – Build proof-of- concept app(s)
		II.	Align app design activities with FHIR® IG profile and example development activities to minimize redundant effort
		III.	Develop test cases and test data to use to perform quality assurance testing of the app
		IV.	Facilitate discussions through forums, on sponsor work group calls (etc.) to address questions and issues that surface when harmonizing PA requirements with existing work (e.g., from Gravity and Da Vinci)

 ³³ See: <u>https://confluence.hl7.org/display/HL7/How+to+Create+and+Review+a+Project+Proposal</u>, accessed Nov 12, 2020.
 ³⁴ See: <u>https://confluence.hl7.org/display/PSS/Project+Scope+Statement</u>, accessed Nov 12, 2020.
 ³⁵ See: <u>https://confluence.hl7.org/display/HL7/HL7+Calendars</u>, accessed Nov 12, 2020.



		V.	Engage PA community to review and endorse app design and test cases
		VI.	Engage PA community to engage in user acceptance testing
		VII.	Use the application to engage with healthcare organizations, clinicians, payers, and other influencers, by optionally:
			 Aligning app delivery timelines with Connectathon (Target Connectathon ~14 weeks prior to ballot)
			 Going through the app approval processes with one or more of the major EHR vendors, support adoption
e)	Launch and oversee activity #3 - Build FHIR® IG for PA – draft	Object i draft Fl	ve: Establish and support a time-bound project to create the HIR® IG for PA for balloting.
	for balloting	Actions	(for Core Stream):
		I.	Staff, launch and support activity #3 - Build FHIR® IG for PA
		II.	Migrate requirements documentation to HL7® FHIR® IG framework and begin to maintain there
		111.	Facilitate discussions through forums, on sponsor work group calls (etc.) to address questions and issues that surface when harmonizing PA requirements with existing work (e.g., from Gravity and Da Vinci)
		IV.	Engage PA community to review and endorse FHIR® IG content prior to balloting
		V.	Complete initial draft for review by sponsor working group prior to balloting (target: ~4 weeks prior to ballot)
f)	Ballot the FHIR® IG for PA	Object i public b	ve: Gather feedback from HL7® community through formal palloting process ³⁶
		Actions	x ·
		I.	Submit FHIR® IG Proposal (8 weeks prior to ballot), receive necessary approvals (6 weeks prior to ballot)
		II.	Submit Notice of Intent to Ballot (NIB) (6 weeks prior to ballot)
		III.	Support consensus group signup, encourage participation by key stakeholders (4 weeks prior to ballot)
		IV.	Support QA of IG prior to balloting (3 weeks prior to ballot)

³⁶ See: <u>https://confluence.hl7.org/display/HL7/HL7+Balloting</u>, access Nov 12, 2020.



V.	Support sponsor work group approval to ballot (2 weeks
	prior to ballot)

- VI. Finalize IG for balloting (1 week prior to ballot) and submit ballot readiness checklist
- VII. Ballot cycle open (1 month)

g) Reconciliation of
feedbackObjective: Work with sponsor work group to disposition feedbackfrom HL7® community and resolve issues.

Actions:

- I. Review and triage feedback from balloting
- II. Identify what changes, if any, will be made to the specification because of the comment
- III. Prepare blocks for discussion and/or voting
- IV. Facilitate discussions to reach consensus on proposed changes at Working Group Meeting and on regular Sponsor work group calls

(Depending on volume and nature of issues, reconciliation process may take 2-8 months to complete.)

h) Restart and oversee
activity #3 - BuildObjective: Establish and support a time-bound project to apply
changes agreed upon during reconciliation to the FHIR® IG for PA

Actions (for Core Stream):

- I. Staff, launch and support activity (effort and time required will depend on the number and complexity of changes agreed to during reconciliation)
- i) Publish 'trial-use' Objective: Get the "ready to implement" FHIR® IG for PA out there standard for implementers to implement, use and provide feedback on.

Actions:

- I. Work with sponsor work group to submit Publication Request and attain approvals from FMG and TSC
- j) Promote adoption of standard and gather feedback from
 Objective: Continue to engage with implementer community to drive adoption of the IG and to adapt to feedback

Actions:

I. Monitor HL7®'s Jira for IG feedback and work with sponsor committee to resolve issues and apply changes

FHIR® IG for PA -

implementers

revision for publishing



			II.	Continue to participate in HL7® connectathons – and encourage vendors to participate
			III.	Consider developing test cases, additional examples, and reference implementations to support implementers in the rollout process
			IV.	Identify enhancements of interest to the community and incorporate into new release
	k)	Iterate and improve until normative	Objec norma	tive: Multiple cycles of revisions will be required to get to a tive standard
			Actior	s:
			I.	Iterate through steps above starting with 2.e for each new release of the specification. (Number and frequency of revisions will depend on vendors implementing the specification – plan for 18 months per revision cycle.)
3) Build F		ild FHIR® IG for PA	Objec can im	t ive: Produce a FHIR® IG for PA so EHR vendors and others plement PA measures and workflows.
			Stream	ns: S2, overseen and supported by S1
			Timeli submis before	ne: Initial draft 4-5 weeks effort (target to start after PSS ssion, complete prior to notice of intent to ballot – 4 weeks balloting).
	a)	Create Draft IG for balloting	Objec suppo stakeh	t ive: Develop FHIR® IG for PA in shared environment to rt engagement and collaboration with PA and HL7® older groups
			Action	IS:
			I.	Use the FHIR® IG in HL7® continuous integration using the environment to allow collaboration with HL7® stakeholders
			II.	Add business context, use cases, technical artifacts (FHIR® profiles, terminology, examples, etc.) and other content to framework.
			III.	Continuously build to allow PA and HL7® stakeholders to review and provide input on content
			IV.	Fix technical issues and errors and warning identified by IG publisher
			V.	Collaborate with Core Stream to work content issues and complete activities required for balloting



Note: FHIR® profiles and example artifacts (part of 3.a.II) will be needed to support optional app development and testing (4.b), this may require an early start to IG development.

b) Prepare revision for
publicationObjective: Apply changes agreed upon during ballot reconciliation
to prepare the FHIR® IG for PA for publication

Actions:

- I. Apply agreed upon changes to narrative content, technical artifacts (etc.) in the IG
- II. Continuously build to allow PA and HL7® stakeholders to review and provide input on edits
- III. Fix technical issues and errors and warning identified by IG publisher
- **IV.** Collaborate with Core Stream to work content issues and complete activities required for publication
- 4) Proof-of-concept app design and development (Optional)
 4) Objective: Get a proof-of-concept app out into the community to use to demonstrate how PA information can be collected in FHIR® based systems

Stream: S3, overseen and supported by S1

Timeline: Varies with scope and type of app.

(A minimal web-based proof of concept app to use to engage with vendors at Connectathon could take 4-5 weeks to develop. Development of an end-user ready mobile app would be a much more significant undertaking.)

a) Design app Objective: Create a design document and use it to (a) deepen understanding of PA requirements and (b) support application development.

Actions:

- I. Review some of the existing SMART apps from the SMART app registry and other PA-related mobile and web-based applications for ideas³⁷
- II. Create a design document with wire frames and user interface mock-ups to illustrate use of PA data with existing FHIR® resources (US Core, Gravity)

³⁷ Reviewer underscore the importance of understanding the existing landscape of apps that link healthcare (via the EHR) to (community resources before developing POC. Identified two examples: <u>https://www.nowpow.com/</u> <u>https://uniteus.com/</u>



		111.	Collaborate with Core Stream to review design document with the PA work group to discuss PA requirements and deepen the design, incorporate learnings into requirements documentation
		Note: F needed may ree	HIR® profiles and example artifacts (part of 3.a.II) will be to support optional app development and testing (4.b), this quire an early start to IG development.
b)	Develop and test app	Object i collecti vendor	ive: Create the proof-of-concept app to demonstrate on and display of PA information with public test servers or sandbox environments.
		Actions	5:
		I.	Iteratively develop and test initial, proof-of-concept version of the app
		II.	In conjunction with the, work issues identified during design and test process improve understanding of PA requirements and to enhance FHIR® profiles and example artifacts
c)	(Optional) Develop production ready app	Object it adop	ive: Get the app approved for use with EHR systems and get ted by users.
		Actions	5:
		I.	Go through the app approval processes with one or more of the major EHR vendors
		II.	Promote use of the application with healthcare organizations, clinicians, payers, and other influencers

S GEVITY

6.3 Estimated timeline

Creating a normative standard FHIR® IG for PA will be a journey of several years on a timeline with milestones aligned with the HL7® calendar. Figure 1 illustrates the estimated timeline to reach a trial use standard (12-18 months in duration).





6.4 Estimate of associated costs (ROM)

Rough order of magnitude (ROM) cost estimates for three different streams of activity have been provided to help the PAA plan and fund the envisioned work. These estimates reflect current knowledge about market rates for resources as well as prior experience on similar standards projects but are significantly limited by several constraints related to the timing of the estimate and scope of the current engagement.

S1: Core Stream

ROM Cost estimate:

	Cost:	Note:
Year 1	\$150,000	Based on 2020 rates, no escalation
Years 2-3	\$155,000/yr.	Based on 2020 rates, no escalation
Years 4-5	\$110,000/yr.	Based on 2020 rates, no escalation

Basis of Estimate:

<u>Year 1:</u>

	Cost:	Note:
Project Sponsor	N/A	Not included in cost estimate.
PM / Requirements Owner	\$100,000	Full Time Staff Member @ $100,000/yr$. ^{A,B,C,D}
HL7 Support SME	\$45,000	Sr. Consultant, 250hrs @ \$180/hr. ^E
HL7 Membership Fee	\$1,500	Professional Organization, 2020 rate ^F



HL7 Work Group Meetings	\$1,200 - 1,800	3 mtgs x 2 attendees, virtual, 2020 rates ^F
		early bird rate \$200, regular rate \$300
HL7 Connectathon Events	\$900 - 1,500	3 mtgs x 2 attendees, virtual, 2020 rates ^F
		early bird rate \$150, regular rate \$250
HL7 DevDays (US)	\$450 - 700	Virtual, 2020 rates
		early bird rate \$450, regular rate \$700
Years 2&3:		
	Cost:	Note:
Project Sponsor	N/A	Not included in cost estimate.
PM / Requirements Owner	\$100,000	Full Time Staff Member @ \$100,000/yr. ^{A,B,D}
HL7 Support SME	\$45,000	Sr. Consultant, 250hrs @ \$180/hr. ^E
HL7 Membership Fee	\$1,500	Professional Organization, 2020 rate ^F
HL7 Work Group Meetings	\$2,400 - 3,600	3 mtgs x 2 attendees - 2 mtgs virtual + 1 in-person, 2020 rates ^{F,G}
HL7 Connectathon Events	\$1,800 - 3,000	3 mtgs x 2 attendees - 2 mtgs virtual + 1 in-person, 2020 rates ^{F,G}
HL7 DevDays (US)	\$450 - 700	Virtual, 2020 rates
		early bird rate \$450, regular rate \$700
Years 4&5:		
	Cost:	Note:
Project Sponsor	N/A	Not included in cost estimate.
PM / Requirements Owner	\$100,000	Full Time Staff Member @ \$100,000/yr. ^{A,B,D}
HL7 Support SME	N/A	
HL7 Membership Fee:	\$1,500	Professional Association, 2020 rate ³⁸

HL7 Work Group Meetings \$1,200 - 1,800 2 mtgs virtual + 1 in-person, 2020 rates ^G

HL7 Connectathon Events \$750 - 1,095 2 mtgs virtual + 1 in-person, 2020 rates ^G

Virtual, 2020 rates early bird rate \$450, regular rate \$700

Notes and Assumptions:

HL7 DevDays (US)

^A **PM / Requirements Owner** is assumed to be a PAA staff member with responsibility for Project Management, the PA secretariat function, participation in HL7® meetings and events, 'ownership' of the

+ travel

+ travel \$450 - 700

³⁸ See <u>http://www.hl7.org/participate/membership/organizational.cfm?ref=nav#2020pricing</u>, accessed Nov 11, 2020.



PA requirements and standards and performance of other related activities identified in the Action Plan established by the PA Assessment, Prescription and Referral Working Group

^B PM / Requirements Owner base salary provided by PAA, no overheads or escalation added.

^c **PM / Requirements Owner** is expected to be fully utilized on "Get Started" activities identified in section 6.1 for a period of 2 months.

^D **PM / Requirements Owner** utilization on "Standardize PA information with stakeholder input" is estimated at approximately 50% for the remainder of the project, including:

- ¹⁄₂ day per week project management,
- ¹/₂ day per week on requirements management,
- 2 days per month performing PA secretariat function,
- HL7® engagement including:
 - ¹/₂ day per week on working group and project calls,
 - 3 weeks per year at HL7® Connectathon events (Jan, May, and Sept),
 - 3 weeks per year at HL7® Working Group meetings (Jan, May, and Sept).

^E HL7 Support SME resource is included in years 1-3 only. Estimate of 250 hours/yr, includes:

- 5 days during "Get Started" period to support planning, initial engagement, and to attend project socialization meetings
- approximately 50% of **PM / Requirements Owner** HL7® engagement time for the remainder of year 1 to support project approvals, issue resolution, balloting, and ballot issue resolution discussions with HL7® stakeholders and workgroup.

^F Assumes **HL7 Support SME** will register for events and be available to participate in meetings with sponsor work group and others to support PAA Requirements Owner.

^G In-person HL7® meetings are currently expected to resume 1x per year starting in 2022.

S2: FHIR® IG Development

ROM Cost estimate:

	Cost:	Note:
Initial draft IG	\$40,000	Input to balloting process
Revised IG	\$10,000 - 20,000	Revisions after balloting, candidate for publishing.
Each subsequent draft	\$10,000 - 40,000	Draft and revisions for each version, pan for 2
Each subsequent revision	\$5,000 - 20,000	subsequent versions at approx. 18-month intervals.



Basis of Estimate:

Initial Draft IG ((for balloting) ^H :
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	Cost:	Note:
IG Author (HL7 Support SME)	\$39,960	Sr. Consultant, 222hrs @ \$180/hr
PM / Requirements Owner	N/A	Full cost of resource in core stream

Revisions to IG (for publishing after reconciliation of ballot feedback)

25-50% of cost initial draft¹

New versions of IG:

25-100% of cost of first version $^{\rm I}$

Notes and Assumptions:

^H The estimate of the Initial Draft IG is built bottom up and reflects the following assumptions:

- approximately 30 technical artifacts will be required in addition to standard narrative content
- use case descriptions will be inherited directly or with minor edits from documents created in 'Get Started' phase of the project
- the HL7 Support SME engaged in the core stream will perform the role of IG Author
- the PM / Requirements Owner will transition requirements documentation to the IG Author, coordinate with HL7® and PA communities to help resolve issues, provide oversight/PM

¹ The range of these top-down estimates reflect that scope of revision required will relate to factors that are impossible to forecast at this point in time, including the volume of feedback from ballot participants and functional scope of new versions. This is a conservative range.

S3: POC App Development (optional)

ROM Cost estimate:

	Cost:	Note:
Development and testing $^{\scriptscriptstyle J}$	\$15,000 - 50,000+	Proof of concept only. Minimum represents single measure.
Register, publish to vendor app store ${}^{\mbox{\tiny K}}$	\$10,000 - 20,000	ROM estimate of cost per app per vendor. Vendor programs, pricing models and fees vary.
Ongoing costs for registered apps ^L	Not estimated	



Notes and Assumptions:

^J Development and testing:

- The low end of the range represents the minimum costs of development and testing of a simple, webbased, proof of concept SMART-on-FHIR app that uses an existing SMART-on-FHIR app framework with an existing sandbox environment (plan to spend more)
- Actual costs of app development will depend on many factors including: the application container (e.g., web browser vs iOS app), availability of appropriate frameworks, number of screens and functions, elegance of user interface, and many other factors.

^K EHR vendors including Allscripts, Cerner, Epic and Meditech have programs and FHIR® platforms to allow app developers to build apps that work with their systems; have them validated for security, reliability, and usability; and presented for access by their users. Costs for participation, support and app usage vary between vendors and bundled services.

^L Ongoing costs include the costs associated with hosting an application on a web server; usage fees for accessing data from EHR systems; development costs for updates, improvements and fixes to the software; costs of supporting end users, etc.



Appendix A: HL7 Event Registration Fees

The following 2020 event registration fees were used to support the estimate.

Virtual events:

WGM: Member 200-300 (early bird vs. regular). Non-member is +150 per person Connectathon 150-250 (early bird vs. regular). Non-member is +100 per person DevDays U.S. 450-700 (early bird vs. regular). Non-member is +250 per person

In person:

WGM: Member 800 - 1200 (early bird vs. regular). Non-member is +400-550 Connectathon: 450-595 (early bird vs. regular). Non-member is +100 per person DevDays U.S.: 1995. Non-member is +300

Note: Current expectation is 2 WGMs and connectathons/year will be virtual; 1 will be in person. In 2021, everything will be virtual. Do not know what DevDays will do in terms of physical vs. virtual past 2021



Appendix B: Glossary

Term (Abbreviation)	Definition
Centers for Medicare and Medicaid Services (CMS)	The agency within the U.S. Department of Health and Human Services that administers the nation's major public healthcare programs. CMS' Health Information and Policy Group helps drive adoption of HL7® standards through policy making including the Interoperability and Patient Access final rule. https://www.cms.gov/About-CMS/Components/HIO/HIO-Landing
Clinical Decision	Clinical decision support provides clinicians, staff, patients or other
Support (CDS)	individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.
	https://www.healthit.gov/topic/safety/clinical-decision-support
CDS Hooks	An HL/® published specification for clinical decision support. https://cds-hooks.hl7.org
Connectathon	HL7® FHIR® Connectathon events provide software implementers and developers with hands-on experience developing FHIR-based solutions by participating in tracks focused on different projects. Testing as part of a connectathon is also a pre-requisite for implementation guides progressing up the FHIR Maturity Model. <u>https://confluence.hl7.org/display/FHIR/FHIR+Connectathon+Track+</u> <u>Process</u>
Current Procedural	A widely accepted medical nomenclature used to report medical,
Terminology (CPT®)	surgical, radiology, laboratory, anesthesiology, genomic sequencing, evaluation and management (E/M) services under public and private health insurance programs in the US. <u>https://www.ama-assn.org/practice-management/cpt/cpt-overview-</u> and-code-approval
Data Modernization	A CDC Initiative to modernize data, technology and workforce capabilities to support public health surveillance, research and decision making. <u>https://www.cdc.gov/surveillance/surveillance-</u> <u>data-strategies/data-IT-transformation.html</u>
Electronic Health	A digital version of a patient's paper chart. EHRs are real-time,
Record (EHR)	patient-centered records that make information available instantly and securely to authorized users.
	<u>An HI 7® specification for exchanging healthcare information</u>
ГПІКШ	electronically.
Health Level Seven	A not-for-profit, ANSI-accredited standards developing organization
International® (HL7®)	dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. https://www.hl7.org/about/
LOINC®	Widely used terminology standard (common set of identifiers, names,
	and codes) for health measurements, observations, and documents. <u>https://loinc.org/get-started/what-loinc-is/</u>



Office of the National Coordinator for Health (ONC)	The principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information including HL7® standards. <u>https://www.healthit.gov/topic/about-onc</u>
Physical Activity (PA)	Any bodily movement produced by skeletal muscles that result in sufficient energy expenditure (i.e., >1.5 METs) including walking, running, biking, lifting objects and other activities of daily living.
Public Health Surveillance	Public health surveillance is the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice. <u>https://www.cdc.gov/publichealth101/surveillance.html</u>
Sedentary Behavior	Any waking behavior characterized by an energy expenditure of <1.5 METs while sitting, reclining, or lying down.
SMART-on-FHIR	An application programming interface (API) standard developed to provide a way for software developers to write software applications that can run anywhere in the healthcare system. https://smarthealthit.org
SNOMED CT®	A comprehensive, multilingual clinical healthcare terminology that enables consistent representation of clinical content in electronic health records. <u>http://www.snomed.org/snomed-ct/five-step-briefing</u>
Social Interventions Research and Evaluation Network (SIREN)	The Social Interventions Research and Evaluation Network (SIREN) at UCSF was launched in the spring of 2016 to synthesize, disseminate, and catalyze rigorous research in the field of social determinants of health. <u>https://sirenetwork.ucsf.edu/about-us</u>
US Core Implementation Guide	A FHIR® implementation guide developed by the HL7® Argonaut project that defines the minimum conformance requirements for accessing patient data using the HL7 FHIR standard in the United States. https://www.hl7.org/fhir/us/core/