The Office of the National Coordinator for Health Information Technology

Sync for Science Pilot Project: Participants' Experiences

Prepared by: Clinovations Government + Health for the Office of the National Coordinator for Health Information Technology

Contract No. HHSP233201600030I/75P00120F37004

November 2020

BACKGROUND AND PURPOSE

Sync for Science[1] (S4S) was launched in February 2016 as a public-private collaboration between the Office of the National Coordinator for Health Information Technology (ONC), the National Institutes of Health (NIH), and Harvard Medical School's Department of Biomedical Informatics with the initial goal of enabling patients to share their electronic health record (EHR) data with researchers in support of the Precision Medicine Initiative[2] (PMI). A cornerstone of PMI, the NIH *All of Us* Research Program[3] (*All of Us*) was launched in 2016 with the goal of building a diverse research cohort of one million or more volunteers to participate in a longitudinal, long-term research effort to transform the understanding of factors contributing to individual health and disease. The 21st Century Cures Act[4] (Cures Act), signed into law in December 2016, authorized $1.5 billion over 10 years for *All of Us* and provides support for development of tools and resources to accelerate medical product development, advance biomedical research, and bring new innovations and advances to patients who need them faster and more efficiently.

The S4S pilot project supported health IT developers and provider organizations in advancing and building capabilities to enable patient-directed data sharing using third-party applications (apps) through standards-based application programming interfaces (APIs). By participating in the pilot project, provider organizations and health IT developers more quickly connected EHRs to *All of Us*. The S4S pilot project demonstrated how individuals can share their health data with researchers via API technology, and how individuals who elect to participate in research (direct volunteers) can submit their health data to *All of Us*.

The S4S pilot project engaged leading health IT developers and was initiated with commitments from seven developers. By the end of the pilot project period, four health IT developers, Allscripts (FollowMyHealth), Cerner, eClinicalWorks, and Epic, were actively participating. The four participating health IT developers recruited 11 provider sites to participate in the S4S pilot project, 6 of which successfully launched with connectivity to *All of Us*:

- Cedars-Sinai Health System
- Cerner Healthe Clinic
- Duke University Health System
- Partners HealthCare
- Rush University Medical Center
- University of Missouri Health Care

ONC assessed the experiences of S4S pilot project participants to identify lessons learned and understand barriers and facilitators to broader adoption of patient-directed data sharing using established industry standards for authenticating and exchanging data in certified health IT products with third-parties. S4S used the Health Level Seven International (HL7®) Substitutable Medical Apps, Reusable Technology (SMART®) on Fast Healthcare Interoperability Resources[5] (FHIR®) and OAuth 2.0 Authorization Framework[6] (OAuth 2.0)

[1] https://www.healthit.gov/topic/sync-science [Accessed October 2020]
[2] https://obamawhitehouse.archives.gov/precision-medicine [Accessed October 2020]
[3] https://allofus.nih.gov/news-events/press-kit/all-us-research-program-backgrounder [Accessed October 2020]
[4] https://www.congress.gov/bill/114th-congress/house-bill/34/text [Accessed October 2020]
[5] http://hl7.org/fhir/smart-app-launch/ [Accessed October 2020)
[6] https://auth0.com/docs/protocols/protocol-oauth2 [Accessed October 2020]

standards, which are the same standards and technical provisions within the ONC Cures Act Final Rule[7] released in March 2020.

The assessment aimed to understand the approaches taken by the S4S team, health IT developers, and provider sites to inform future expansion of S4S and support ONC and its federal partners in expanding opportunities to use SMART® on FHIR® standard APIs and third-party apps by patients. The assessment reviewed the S4S pilot project's history, structure, and operational support provided by *All of Us* partners, the S4S team, and NIH. The following *All of Us* partner organizations participated in the assessment:

- S4S Team (NIH, ONC, and Harvard Medical School Department of Biomedical Informatics)
- DXC Technology (*All of Us* Support Center)
- Vanderbilt University Medical Center (*All of Us* Data and Research Center)
- Vibrent Health (*All of Us* Participant Technology Systems Center)
- Scripps Research Institute (*All of Us* Participant Center)

This assessment of the lessons learned from health IT developers, provider sites, *All of Us* partners, and other key stakeholders inform future considerations for S4S expansion, *All of Us* coordination, and advancement of ONC's *National Health IT Priorities for Research: A Policy and Development Agenda*.[8]

API STANDARDS IMPLEMENTATION

Over the course of the S4S pilot project period, three versions of the HL7® FHIR® standard specification were released:

- Draft Standards for Trial Use version 1.0.2 (DSTU 2)[9]
- Standards for Trial Use version 3.0.2 (STU 3)[10]
- Release version 4.0.1 (R4)[11]

Initially, the health IT developers participating in the pilot project, Allscripts (FollowMyHealth), Cerner, eClinicalWorks, and Epic implemented DSTU 2, as it was released in 2015 and the most recent standard available at the start of the pilot. All four health IT developers indicated their efforts for implementing the ONC 2015 Edition Health IT certification API requirement aligned with S4S, though the 2015 Edition requirement did not specify a particular standard. As DSTU 2 was the predominant standard at the time of the launch of the pilot, three of the health IT developers had implemented DSTU 2, while one health IT developer implemented STU 3 in its core EHR system production environments for customers. Because there was no requirement to use a specific API standard at the time, health IT developers made decisions on which APIs to support based on their own general release and upgrade schedules. Some health IT developers maintained several versions of the FHIR® standard, while others only used one. Ultimately, the S4S integration with *All of Us* only allowed for the use of the DSTU 2 standard. This presented a challenge during the pilot project for one health IT developer who struggled to maintain two production environments for their EHR to support both their general

[7] https://www.healthit.gov/curesrule/ [Accessed October 2020]
[8] https://www.healthit.gov/topic/scientific-initiatives/national-health-it-priorities-research-policy-and-development-agenda [Accessed October 2020]
[9] https://www.hl7.org/fhir/DSTU2/ [Accessed October 2020]
[10] https://www.hl7.org/fhir/STU3/ [Accessed October 2020]
[11] https://www.hl7.org/fhir/R4/ [Accessed October 2020]

customers on STU 3 and provider organizations participating in S4S on DSTU 2. While a FHIR® standard is in the "Draft" and "Standard" Trial Use version, the HL7® standards development process states that these versions are not necessarily backwards compatible; this was the case with DSTU 2 and STU 3.[12] Provider sites with EHR software using STU 3 were unable to connect and participate in *All of Us* via S4S.

The four participating health IT developers indicated that SMART® on FHIR® API, OAuth 2.0, and Argonaut Data Query Implementation Guide[13] development required minimal additional effort, as development using these standards was already planned based upon industry standards, adoption trends, and anticipated future certification requirements.

API Testing

Health IT developers reported that while API development was straightforward, evaluating API performance using test cases that mirrored the rich complexity of real-world patient data was time-consuming. The S4S pilot project focused on exchange of 11 data elements required within the 2015 Edition Health IT Certification Criteria[14] and associated Common Clinical Data Set[15] (CCDS). Implementations of APIs following the S4S pilot project that use more recent standards (i.e., FHIR® R4, United States Core Data for Interoperability [USCDI]) include additional data elements.

Provider sites indicated that testing and validation activities were more resource-intensive than development activities. While testing was not considered to be burdensome for health IT developers, they did require provider resources to conduct localized testing using valid test cases representing the characteristics and complexity of the patients they served. Provider-site specific EHR data mapping to exchange data using the FHIR® standard specification was a challenge because some data elements did not map properly, such as inpatient medication data. Half of the provider sites required a special upgrade to their EHR software before testing the FHIR® standard API since this capability was not part of the generally available version of their EHR software at the time.

Provider sites worked with their health IT developers to test the new API to ensure successful authorization, authentication, and transmission of correct data to the *All of Us* application. The sites also tested new *All of Us* patient portal functionality used by patients to enable data sharing. Provider sites with prior experience implementing API connectivity to third-party apps (e.g., Apple Health) required less testing and reported a more seamless implementation experience.

Once the development and testing of the HL7® FHIR® standard API was complete, developers needed to implement the new security profiles at each provider site, which required additional configuration and testing within specific instances of their EHR environments.

Provider sites worked collaboratively with their health IT developers and the S4S team in early phases of the project. Provider sites reported that:

[12] https://www.hl7.org/fhir/STU3/versions.html [Accessed October 2020]
[13] https://www.fhir.org/guides/argonaut/r2/ [Accessed October 2020]
[14] https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base [Accessed October 2020]
[15] https://www.healthit.gov/sites/default/files/ccds_reference_document_v1_1.pdf [Accessed October 2020]

- Implementing the first HL7® FHIR® standard API required configuration and mapping changes of the CCDS and related data to appear to S4S (or any app) via the API. Provider sites that had already implemented the HL7® FHIR® standard API connectivity to other third-party apps reported minimal additional configuration and testing efforts to integrate with S4S. Those provider sites who had not yet implemented the API had to begin with the initial lengthy configuration and testing effort.
- Their process for allowing connectivity to third-party apps was generally restricted to those authorized and tested by the provider organization, including apps that utilize the same APIs.
- Pilot project activities helped prepare provider organizations to easily deploy other emerging third-party apps that use the HL7® FHIR® standard APIs.

Using APIs for Research

The S4S pilot project demonstrated how research requirements, such as institutional review board (IRB) review and approval and research protocols can impact the ability to rapidly test innovative technical solutions in real-world settings such as the adoption of APIs and third-party apps for research.

The IRB application submission and approval timeframe and process created project delays for onboarding both health IT developers and provider sites, which caused a loss of momentum and engagement for some provider sites. IRB requirements that restrict or specify user interface or technical architecture requirements can limit the flexibility to incorporate pilot feedback or updates to the technology.

Similarly, IRB requirements regarding outreach and communications that are overly prescriptive create challenges for provider organizations as they implement local operational guidelines and procedures. Provider sites struggled to use the generic IRB-approved communications materials to adequately engage patients in the S4S pilot project and wished to tailor them to their own organizations and patient populations and address varying levels of digital health and technology literacy.

Some provider sites, out of concern that participation in the S4S pilot project constituted "research," conducted their own internal IRB approval process to review the NIH IRB protocol, and adopt it for their participation. This was not considered to be necessary in the pilot design, as sharing patient data with researchers is not considered to be research in and of itself, and all participants consented to participate with *All of Us*. Offering patients a way to send their data to an app of their choice is covered under Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule "right of access," regardless of the third-party the data is shared with, such as researchers.[16] Nevertheless, provider sites would not fully commit to participating in the pilot project until internal administrative and IRB approvals were complete.

API and App Expansion

The S4S pilot project assessment provided a wealth of information and insight from four health IT developers, five provider sites, and *All of Us* partners on the successes, challenges, barriers, and lessons learned from the initial phase of this collaboration. Additional considerations for future expansion of the use of third-party apps for research include:

- Develop a formal governance structure, project management, and testing plans in advance of pilot launches and define clear lines of communication and program management expectations.

[16] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html [Accessed October 2020]

- Establish a coordinated and formal governance structure and project management methodology to coordinate across program partners and private sector partners.
- Conduct user testing and validation to improve the user experience. Provider sites were concerned that the *All of Us* enrollment and consent processes could be time-consuming and cumbersome for prospective participants.
- Develop tailored communications for each type of user that explains how to use an application and articulates potential next steps and actions.
- Provide educational materials for provider site staff to help them understand and explain the value of API technology, *All of Us*, HIPAA Privacy Rule right of access, and S4S.
- Provide clear documentation for health IT developers and provider sites on how to continue support beyond the initial API launch at their organizations.
- Develop and disseminate benchmarks that provider sites can use to compare enrollment numbers and improve outreach activities post go-live.
- Consider development of apps that are installed directly on mobile devices using the device's own operating system (i.e., iOS, Android) and not browser-based and require apps to be open-source, reusable, or customizable by others.
- Assess where IRB requirements for mobile user interfaces or technical architecture may limit opportunities to incorporate pilot project feedback or responsively update technology.
- Evaluate IRB requirements for outreach and messaging that may be overly prescriptive and limit the ability to adapt to local provider site guidelines and procedures.

CONCLUSION

As a result of the ONC Cures Act Final Rule, certified health IT developers and provider organizations are now actively implementing the required patient-facing standards-based API that will enable patients to direct their health information to the third-party app of their choice. The S4S pilot project established early efforts to support patient-directed sharing of health information with research. As *All of Us* expands enrollment of direct volunteers who want to join *All of Us* but do not have access to participating health care provider organizations (HPOs),[17] insights gained from the S4S pilot project assessment provide opportunities to support increased patient-directed sharing of health information.

[17] https://www.joinallofus.org/health-care-provider-organizations [Accessed October 2020]