Medicare Beneficiary Data Donation

National Institutes of Health (NIH) and Centers for Medicare & Medicaid Services (CMS) Inter-Agency Agreement

CMS Blue Button – Sync for Science (S4S)

Final Project Summary

November 19, 2021

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1. Overview 3
2. Background 4
S4S 4
CMS BB 4
3. Objectives and Tasks 5
Task 1: Develop Support for Payer Data 5
Task 2: Enhance Technical Infrastructure 5
Task 3: Develop Data Acquisition and Return-of-Data Viewer Apps 5
Task 4: Streamline App Registration 5
4. Project Deliverables 6
Task 1: Developed Support for Payer Data 6
Accessing Deliverables 6
Task 2: Enhanced Technical Infrastructure 7
Accessing Deliverables 7
Task 3: Developed Data Acquisition and Return-of-Data Viewer Apps 8
S4S Procure App 8
Accessing Deliverables 8
Exhibit 1: S4S Procure App 9
S4S Discovery App 10
Accessing Deliverables 10
Exhibit 2: S4S Discovery App 11
Task 4: Streamlined App Registration 12
5. Project Summation 13
Project Recap 13
Trends Affecting Researchers 13

1. Overview

The Medicare Beneficiary Data Donation Project was undertaken by the National Institutes of Health (NIH) and the Centers for Medicare & Medicaid Services (CMS) over the period of September 2017 to August 2020. The intent of the project was to work toward aligning the NIH-funded Sync for Science (S4S) project and the CMS Blue Button (BB) 2.0 program to serve the needs of the research community.

The research use cases motivating this project included patient-centered outcomes research (PCOR) and comparative effectiveness research (CER). Research of this type often investigates characteristics, outcomes, and costs of hospitalized patients suffering from specific diseases[1] or seeks to identify unintended consequences of payment decisions, highlighting the need for further clinical studies to demonstrate effectiveness of device technologies.[2] Studies of both types benefit from linking clinical to payer data. To this end, it was hoped that this project could capacitate a common approach for research participants to donate their clinical and claims data from one or more providers and payers, which could be used to build out more completely research participants' longitudinal medical histories or, when necessary, use claims data to fill in gaps in clinical data or vice versa.

At the outset of this project, the data standard adopted by S4S for enabling research participants to share their electronic health records (EHRs) was the Health Level 7 (HL7) Fast Health Interoperability Resource (FHIR) standard. CMS had already developed its BB solution, which is used by Medicare beneficiaries to connect their Medicare claims to third-party applications and services. Blue Button went live in March 2018 with a fully functional FHIR standard (STU3) and application programming interface (API) service. As of July 1, 2021, the BB API supports FHIR R4 in addition to FHIR STU3. The specific intent of this project was to align the new CMS effort to the S4S approach on several fronts—participant-facing workflow, data quality testing, app registration, and private-payer adoption consistent with CMS, with reference apps to demonstrate the combined use of S4S and BB—and then conduct a pilot test of the claims donation solution with the NIH *All of Us* Research Program.

[1] Cooper et al. "Differences in health care use and outcomes by the timing of in-hospital worsening heart failure" Am Heart J. 2015 Dec;170(6).

[2] Jones et al. "Trends in Settings for Peripheral Vascular Intervention and the Effect of Changes in the Outpatient Prospective Payment System" J Am Coll Cardiol. 2015 Mar 10;65(9).

2. Background

S4S

S4S is an NIH-funded project that developed and coordinated the first use of HL7 FHIR technology for enabling self-provisioning by individuals to donate their EHR information data to biomedical research studies.

The S4S workflow uses a patient-facing digital approval process that is compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Using a HIPAA- compliant provider patient portal, patients can approve sharing their data to a research or consumer health app. The patient can authorize sharing some or all of the Common Clinical Data Set (CCDS), the most common clinical structured data, and the technical follow-through makes use of the FHIR API to send FHIR-formatted data payloads of the patient's choice.

The S4S team developed reference implementations used by several EHR vendors who collaborated in developing the whole process. The team also worked with several volunteer health care providers to pilot it within the *All of Us* Research Program, the NIH-funded national research study aiming to enroll one million or more research participants in a long-term observational study and which needs to capture many types of data, including participant EHR data.

Adding new medical data such as payer data and imaging data, is consistent with how S4S envisioned a unified way to capture clinical and clinical grade data. Working with CMS to add such payer data would be the first instance of adding data beyond the CCDS.

CMS BB

BB 2.0 is a developer-friendly, standards-based API that enables Medicare beneficiaries to connect their claims data to secure applications and services. The BB API contains more than seven years of Medicare Parts A, B, and D data for more than 60 million Medicare beneficiaries. Beneficiaries have full control over how their data can be used and by whom, with identification and authorization controlled by Medicare.gov.

Adding API access to the Medicare beneficiary claims data in a manner compliant with S4S was envisioned as a way for CMS to contribute to a consistent way for patient-mediated data sharing to be operationalized for researchers.

3. Objectives and Tasks

The CMS/NIH project to align BB and S4S set out three high-level objectives:

1. Provide a safe and secure mechanism for Medicare beneficiaries to donate their individual Medicare Parts A, B, and D claims data to research studies using the S4S workflow and FHIR standard.
2. Add S4S access to the Medicare beneficiary claims portal to test inclusion of beneficiary-directed donation of their Medicare claims data through the CMS BB API in research studies, including the *All of Us* Research Program.
3. Share lessons learned through this pilot phase that could be applied to future efforts that enable individuals to donate their Medicare claims data to the larger medical research community to support a wide range of health care studies.

These objectives were mapped into four tasks.

Task 1: Develop Support for Payer Data

Undertake standards development work with CMS to generalize the CMS BB specification for all payers.

Task 2: Enhance Technical Infrastructure

Migrate the original S4S Test Suite, including interim CMS specification, to the Office of the National Coordinator for Health Information Technology (ONC)–funded MITRE Inferno Testing Tool.

Task 3: Develop Data Acquisition and Return-of-Data Viewer Apps

Develop open source web apps for acquisition of clinical and payer FHIR data and a way to present the data visually to research participants.

Task 4: Streamline App Registration

Develop a specification to support asymmetric client secrets for connecting both clinical and payer apps to FHIR API endpoints.

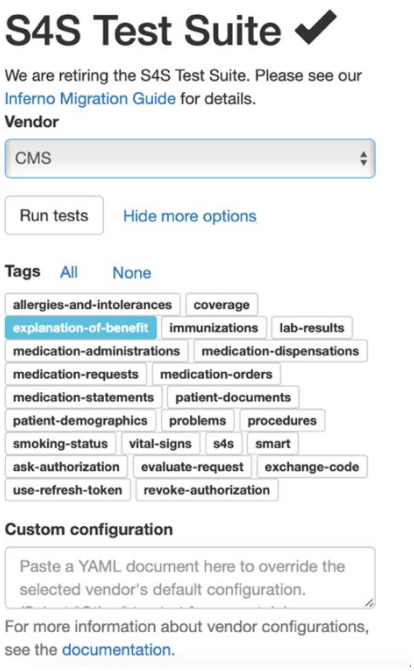
4. Project Deliverables

S4S work unfolded over three years in collaborations with the CMS BB team, HL7 FHIR working groups (Argonaut and the CARIN [Creating Access to Real-time Information Now] Alliance), and the MITRE Corporation and covered a diverse set of activities as set out in the four tasks, including resource and profile specification work for payer data, infrastructure work to migrate testing tools developing during the earlier S4S pilot, open source reference software development to incorporate data sourced from multiple providers, and development of a full specification to address client app registration. Major deliverables by task area are set out below.

Task 1: Developed Support for Payer Data

Task 1 consisted of standards development work with CMS to generalize the CMS BB specification for all payers. The task resulted in two deliverables, the audience for which was technical staff of the CMS BB team, the MITRE Corporation (see Task 2), and members of the CARIN Alliance (as well as the larger HL7 FHIR community).

Deliverable 1. The S4S team worked with the CMS BB 2.0 release of early 2018, providing technical feedback to CMS regarding its BB 2.0 implementation as well as answering CMS team questions about the S4S specification. As part of this process, the S4S team added the CMS Explanation of Benefits (EOB) resource and profiles (CMS payer resource profiles included the patient profile, carrier profile, durable medical equipment (DME), home health agency (HHA), hospice, inpatient, outpatient, Part D event, and skilled nursing facility (SNF) to the S4S Test Suite. The work also involved testing the CMS BB API to be sure S4S permissions, API calls data, and Open Authorization (OAuth) calls were compatible by running the S4S Test Suite against the CMS portal (image on right). All results were shared with the CMS BB team.



Deliverable 2. The second S4S activity involved team members who participated in the HL7-affiliated CARIN Alliance (https://www.hl7.org/carin/), whose members set about (among other things) developing mappings of claims data to FHIR resources that would match BB 2.0 profiles for the then-upcoming FHIR R4 release. The specification work covered a 24-month period, culminating in January 2019 in its inclusion in the official FHIR R4 release.

Accessing Deliverables

- The now-deprecated S4S Test Suite with BB additions is at https://tests.demo.syncfor.science.
- The CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) specification is at http://build.fhir.org/ig/HL7/carin-bb/.

Task 2: Enhanced Technical Infrastructure

Patient-mediated data access and sharing was the use for which the open source S4S Test Suite was developed in 2016. However, major use cases for testing FHIR include clinical SMART (Substitutable Medical Apps, Reusable Technology) on FHIR apps and FHIR Bulk Data, among others. In the intervening period, ONC funded MITRE's Inferno Testing Tool to provide a sustainable, unified, open source testing infrastructure for all use cases of FHIR, including SMART on FHIR apps and FHIR bulk data.

Task 2 therefore consisted of migrating the S4S Test Suite (with CMS additions as developed in Task 1) to the ONC-funded MITRE Inferno Testing Tool. Migration would add the original S4S Test Suite CMS profile in Task 1 (patient profile, carrier profile, DME, HHA, hospice, inpatient, outpatient, Part D event, and SNF) and other FHIR STU3 resource and profile additions. The S4S team also ensured that all of the S4S Test Suite features ran within MITRE's Inferno Testing Tool, for both FHIR R2 and R4 resources. The S4S team also contributed extensions to Inferno to clone functionality of S4S Test Suite's automated authentication. Lastly, the S4S team developed an S4S Test Suite Migration Guide for any users of the original S4S work.

Task 2 activities were completed toward the end of March 2020. The audience for Task 2 was the MITRE Inferno team and EHR vendors who had been using the S4S Test Suite.

Accessing Deliverables

- The S4S Test Suite migration guide to Inferno is at https://github.com/sync-for-science/test-suite/wiki/Inferno-Migration-Guide.
- The Inferno open source code base is at https://github.com/onc-healthit/inferno.
- The ONC-hosted community edition of Inferno is at https://inferno.healthit.gov/community.
- The ONC-hosted Inferno Program Edition of Inferno is at https://inferno.healthit.gov/inferno/.

Task 3: Developed Data Acquisition and Return-of-Data Viewer Apps

Task 3 addressed two aspects of leveraging the emerging FHIR standard to empower patients and researchers by developing two open source reference apps, the S4S Procure App and S4S Discovery App. Each app explored the implications and opportunities an individual patient or research participant would have as a result of their ability to retrieve data from one or more providers and payers as the result of ready access from standardized APIs.

In the context of research, the role of the S4S Procure App was to explore how to operationalize access to provider and systems app and offer the user a set of follow-on capabilities, one of which was to share the fetched data with a research project, whereas the role of the S4S Discovery App was to explore how to organize and present the fetched data in a way that would allow an individual to see and make sense of it.

S4S Procure App

The design of Procure had four objectives:

- Enable research participants and patients to retrieve computable copies of their clinical or financial data from health care providers or payers
- Allow individuals to share their data in FHIR format with a research study
- Allow individuals to back up their health care information or forward it to other apps or perform analyses or charting
- Allow developers (including researchers) to incorporate Procure in whole or part, including portions of the workflow (and interface) or code

A key value of the Procure App for researchers is that it can be integrated with only some features, making it faster and cheaper for a research app to operationalize patient-mediated data sharing. Alternatively, researchers could use Procure's source code to guide development of their own code to operationalize their patient-mediated data sharing. For example, after the project ended, the *All of Us* Research Program was able to make use of Procure's source code to assist in preparing the *All of Us* Participant Portal to access Medicare data.

At various stages of Procure's development, the S4S team presented Procure to data providers, consumers, and researchers in a number of venues, including the CARIN Alliance to support FHIR R4 profiles for claims data (2019), the CMS FHIR Connectathon and the ONC Annual Meeting (2020), and the Digital Technology in Clinical Trials Conference (2020). The team also held conversations with researchers about both legal and technical aspects of Procure.

The development of Procure also informed the early concept work for research support tools to provide data analysis of FHIR records. Two such tools, the S4S A3 Prototype and the S4S Data Census Tool, were developed after the end of the project (see the Discussion section).

After the CMS Project, Harvard Medical School was able to configure Procure in Research Wizard mode to operationalize patient-mediated data sharing into its People-Powered Medicine project platform.

➤ **Exhibit 1** (next page) depicts the Procure App's workflow and key features

Accessing Deliverables

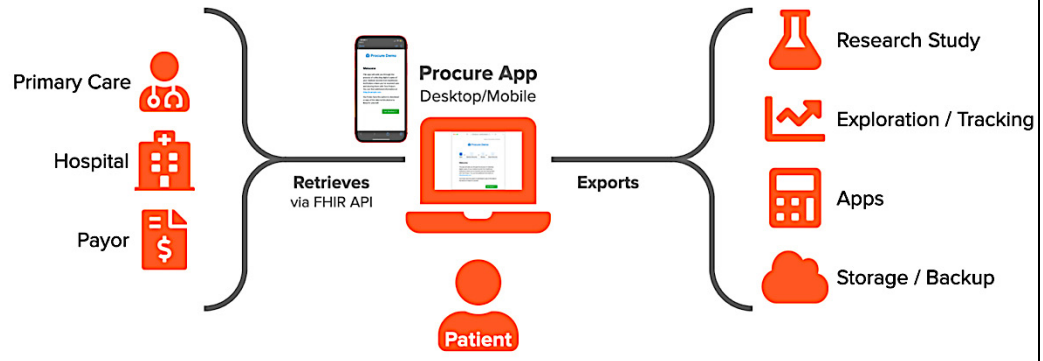
➤ **Read.me**: https://github.com/sync-for-science/procure-wip/blob/master/README.md

➤ **Source code**: https://github.com/sync-for-science/procure-wip

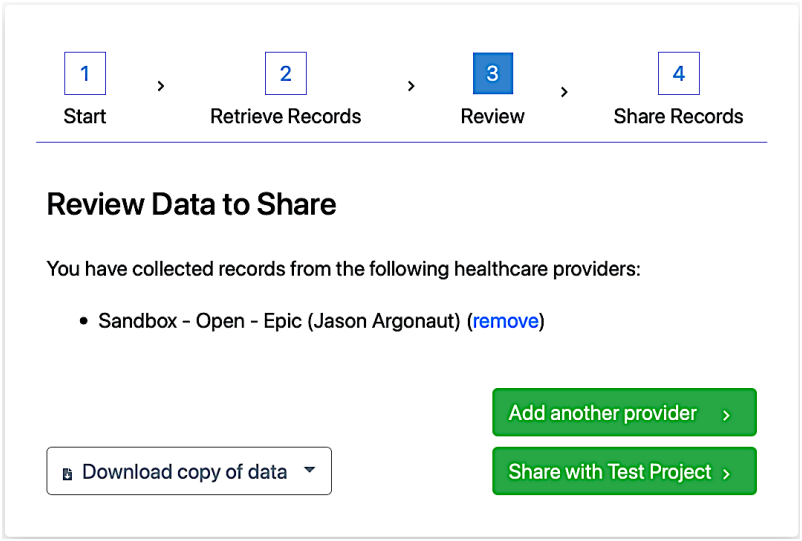
➤ **Run-time demo**: http://syncfor.science/procure-wip/?wizard=true (showing Wizard UI workflow)

Exhibit 1: S4S Procure App

Functional Concept



Research Wizard User Interface



App Feature List

- Secure retrieval of structured clinical data and unstructured clinical documents
- User interface to filter, navigate, and review raw data from multiple providers
- Retrieval of payer data, including through the CMS Medicare Portal
- Downloading of data in FHIR format
- Export of data subsets in Excel and CSV format for analytics
- Integration of a provider site list and support for custom site configurations
- Uploading of raw data to public or private GitHub repositories
- Export and import of user-selected provider site lists
- Default query profiles for Epic, Cerner, and Argonaut FHIR servers
- Configuration of the provider directory, customization of query profiles by vendor/site, and export of mappings
- Integrated ability for research participants to upload data to a study web service
- Streamlined research wizard interface for data collection and upload by participant
- Sample back-end components for research studies to collect historical clinical data
- Prototypes of data loading and user interface to back-end data analysis tools

Other

- Demo mode and interactive online demo
- Open source code, documentation, and overview on GitHub

S4S Discovery App

The S4S Discovery App was developed to explore the potential to assemble and view longitudinal medical records using the patient-mediated workflow to access data from EHR patient portals. The access method, which was informally called the S4S method before its official naming as the Patient Access API in the ONC 21st Century Cures Final Rule regulations, is one use case for SMART on FHIR, the HL7 standard for consumer, clinical, bulk health, and payer data.

The S4S Discovery App was developed to explore the following patient (consumer) uses:

- See both clinical and beneficiary data in a single user-facing app
- Select which data to see—by provider, data type, or time
- Try different views of the data—namely, one summary view and three detailed views that offer distinct data juxtapositions for exploring user responses:
    - Summary View
    - Catalog View
    - Compare View
    - Timeline View
- Access sandbox (synthetic) data sources having synthetic data from multiple health care providers, as well as CMS Medicare data

The version of the S4S Discovery App created during the CMS performance period is a web app that was written for a landscape orientation best viewed on a desktop or laptop browser (although also it also works on mobile tablet browsers).

After the end of the CMS Project, the S4S team completed a user evaluation of the Discovery to identify the next stage of work, which included a significantly revised and simplified user interface for native mobile use on iOS and Android smartphones and tablets.

➤ **Exhibit 2** (next page) depicts the Discovery App's key screens and features

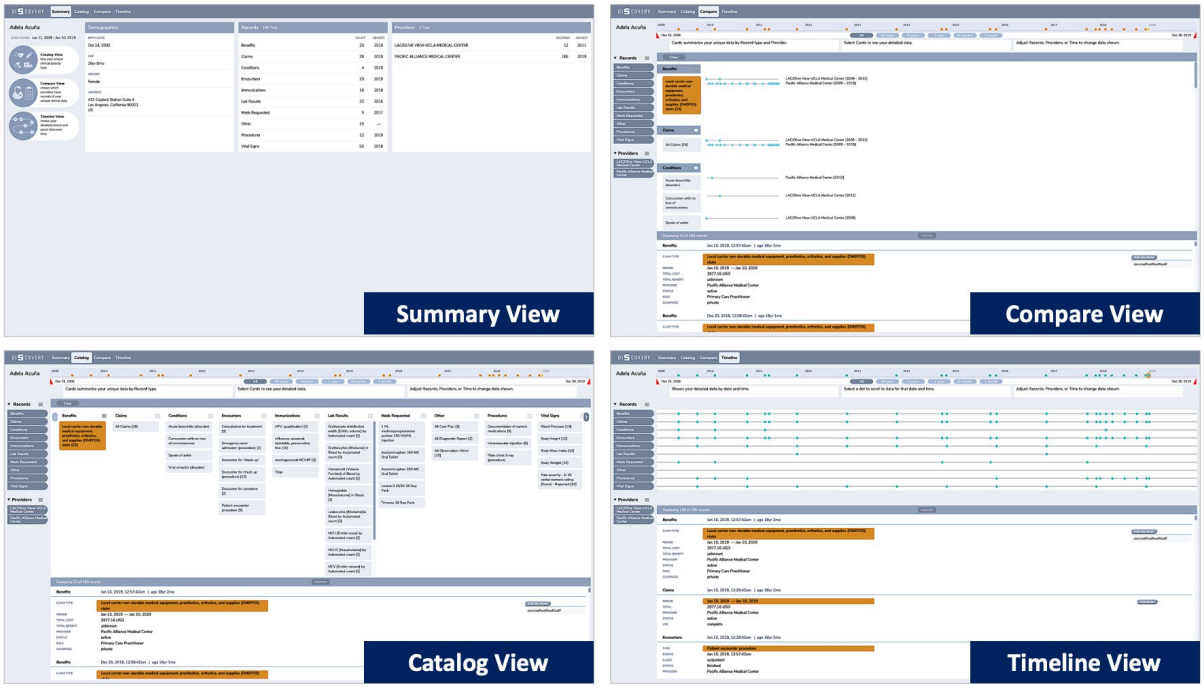
Accessing Deliverables

➤ **Read.me**: https://github.com/sync-for-science/discovery-web-ui/blob/master/README.md

➤ **Source code**: https://github.com/sync-for-science/discovery

➤ **Run-time demo**: http://discovery-fhir.eba-az3mg9m9.us-east-1.elasticbeanstalk.com/participant/3001

Exhibit 2: S4S Discovery App



Discovery's Four Views: Summary, Compare, Catalog, and Timeline

App Feature List

- User filters for record types, provider sources, and time frame
- Views of patient data:
  - **Summary** View shows demographics and data by type and provider
  - **Catalog** View shows clinical data by type in cards
  - **Compare** View shows clinical data by type in cards by provider
  - **Timeline** View shows clinical and payer data over time
- Retrieval of structured clinical data from multiple FHIR servers or via the Procure App
- Annotation-enabled for users to create/edit/remove notes for each data record
- Validated scripts to install Discovery executables on FHIR servers with sample data

Other

- Run-time demo with synthetic patient data
- Open source code, documentation, and overview on GitHub

Task 4: Streamlined App Registration

Task 4 tackled development of a standards-based specification to support asymmetric client secrets for connecting both clinical and payer apps to FHIR API endpoints, a front-end specification for patient access SMART apps. The technical work related to this task included dynamic app registration and was collaborated on with CMS BB team members.

All of the standards development work envisioned and accomplished for this task was designed to be candidates for prioritization by the Argonaut Project, which selects projects annually. The Argonaut Project is an HL7-affiliated implementation community of leading technology vendors and provider organizations focused on accelerating the use of FHIR and OAuth in health care information exchange, both of which are the core standards for S4S.

The S4S team's Task 4 project work first found its way into two project proposals for consideration for the Argonaut Project Year 2018. The effort that addressed back-end client-to-FHIR server registration for FHIR bulk data services was accepted. As a result, the S4S team published that work as a Standard for Trial Use, Version 1 (STU1) for SMART Backend Services specification in March 2020. The HL7 FHIR community completed the standardization work, incorporating it into the HL7 SMART Backend Services: Authorization Guide (https://hl7.org/fhir/uv/bulkdata/authorization/index.html). The bulk data specification became part of the ONC 21st Century Cures Act Final Rule, requiring that it must be supported by all ONC-certified EHR system vendors no later than the end of 2020.

The initial intent for Task 4, however, was to address support for token introspection and asymmetric client authentication for user-facing SMART apps and was intended to ease the burden of both consumer and clinical app registration, including allowing for multiple FHIR resource servers to follow a single patient access approval. Indeed, the front-end proposal shared the same techniques the S4S team developed for the FHIR Bulk Data API proposals, and it would have advanced vendor-neutral registration protocols for such apps. Unfortunately, the proposal did not make the Argonaut Project Year 2018, 2019, or 2020 short lists, though it may do so in subsequent years. Accordingly, the S4S team did not proceed to develop a full specification of this.

5. Project Summation

Project Recap

The goal of this project was to explore providing an operational framework for Medicare beneficiaries to donate their individual Medicare Parts A, B, and D claims data to research studies. To this end, CMS and NIH collaborated in this project on exploring how to align the BB and S4S technical approaches for supporting patient-mediated data sharing to third-party apps from health care provider EHR systems and payer systems (such as CMS) to third-party apps using the HL7 FHIR standard.

The S4S team worked collaboratively with the CMS BB team, as well as other key actors in the FHIR interoperability landscape, including HL7, MITRE, and the CARIN Alliance, to develop both FHIR resource and profile specifications; implementation guides, including migrating the S4S Test Suite to MITRE's Inferno Tool (the ONC's open source FHIR testing platform); and the Argonaut Project to address vendor-neutral third-party application registration to FHIR endpoints.

The S4S team also developed two open source reference web apps, Procure and Discovery. Both apps explore how the emerging FHIR standard for patient-mediated data access to clinical and payer data can be used by researchers to collect medical data from multiple sources and viewed by research participants.

The intention to pilot Medicare beneficiary claims data sharing with the *All of Us* Research Program could not be achieved before the project ended in August 2020 due to competing programmatic, regulatory, and COVID-19 challenges. However, in the following half-year, *All of Us* funded a separate project to complete integration of patient-mediated sharing of payer data into the *All of Us* Participant Portal, leveraging the S4S Procure App reference implementation to guide integration, achieving technical readiness in February 2021. Live launch will require revisions to the participant consent, other communications materials, and training of operations and support center staff.

This project reached beyond operationalizing donations of claims data for research. It tackled several other prerequisites for advancing the FHIR-based, patient-mediated data sharing ecosystem, including app registration and reference apps to demonstrate participant use of claims and clinical data for self-investigation—as both Procure and Discovery were designed to explore. As the interoperability ecosystem for patient access to provider and payer data continues to mature, there will be opportunities to stimulate novel work in data visualization and integration of standardized data through other CMS and NIH initiatives, including challenges, code-a-thons, and other targeted collaborations.

Trends Affecting Researchers

The overall trend for researchers to use FHIR will continue over the next few years, as a result of CMS and ONC regulations (CMS's May 2020 Interoperability and Patient Access Final Rule and ONC's May 2020 21st Century Cures Act Final Rule, respectively). EHR systems will be required to adopt FHIR and the FHIR API to support patient-mediated sharing of the data by December 2022. Moreover, the minimum scope of API-accessible data will be the U.S. Core Data for Interoperability (USCDI), a set of data that adds clinical notes, provenance, and specific pediatric data to the earlier minimum data list, the CCDS. FHIR API-based access to free-text clinical notes, in particular, will markedly increase the value of standardized data access for researchers, including those engaged in PCOR and CER efforts.

The research community can also contribute to the evolution of the scope of USCDI by participating in the annual ONC New Data Element and Class (ONDEC) Submission System for adding new data types and classes to the USCDI. Imaging data would not likely be added to USCDI for EHR systems, but organization boundaries and incentives, rather than technical barriers or deficiencies in standards coverage, will determine whether imaging data can become a mandatory part of the patient sharing ecosystem.

No matter how stepwise data expansion progresses, patient-mediated access to FHIR-based clinical and claims data will introduce new opportunities for researchers. When it is adopted by payers and other health care IT vendors, the supply of data that researchers can get will widen, improve in sample size and currency of their data, and gradually extend to nontraditional sources, such as patient-generated health data (PGHD) for passive (sensor) and active (questionnaire) data, leading to more ways for researchers to finely phenotype patients.

The economics of standardized access to clinical and payer data may also increase the overall speed and quality of PCOR and CER research studies. Researchers may no longer need to hire staff, spend research funds, and incur the long lead times to create and maintain custom data linkages to clinical data providers and payers. Instead, they could propose more PCOR and CER studies that can acquire more complete longitudinal medical and payer data and ask more—and more nuanced—questions. With such access and reach, researchers should be able to generate more precise conclusions and have higher degrees of confidence in them. For example, researchers could conduct longer passive follow-up to clinical trials or behavioral intervention research studies to assess longer-term benefits or harms of new medications.

The one near-term limiting factor on the use of standardized data is the uncertainty about the quality and comparability of data obtained from sources that have just begun to deliver FHIR data. On the one hand, researchers will not need to invest in custom data linkages and highly customized curation. On the other, they may need to validate and curate FHIR payloads. In particular, new tooling will be necessary to perform a spot check on the quality of data to know whether a source delivers good or poor data. Downstream of that, other FHIR tooling may be needed to do more elaborate data analytics (following what has been done for the Observational Medical Outcomes Partnership [OMOP] and Informatics for Integrating Biology & the Bedside [i2b2]). In fact, the S4S team, which created the S4S Test Suite to test consistency of syntax and semantics of individual FHIR payloads, has more recently created a FHIR spot check tool (the Data Census tool) and an annotation-for-analytics toolkit (the A3 Annotation Toolkit) to assist in inspecting and performing some basic types of automated (nondestructive) curation on native FHIR datasets. Investing in tools like these will likely be necessary if current health care IT investments in FHIR are to produce truly accelerated payoffs for researchers.