Office of the National Coordinator for Health Information Technology

# Accelerating Application Programming Interfaces for Scientific Discovery:

# App Developer and Data Integrator Perspectives

**PREPARED BY**

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# Table of Contents

# Introduction

With the recent proliferation of applications (apps) that collect, display, and use many types of health data, including those connected to remote monitoring devices, fitness trackers, survey tools, and electronic health records (EHRs), there are growing needs and opportunities for data to be available in a standardized format for health care and health research. Application programming interfaces (APIs) can be used to exchange these data, and apps can support clinical decisions and administrative functions, such as billing, condition management, research, population health, and more. APIs allow disparate systems, health care organizations, and stakeholders to share external data. By increasing the quantity and quality of data from source systems, researchers and clinicians may use additional health data to support their efforts.

The use of APIs and apps to exchange data between systems is not new to health care. Many private APIs that use proprietary and developer-specific mechanisms to access data have been used for years to share data across disparate systems and organizations. However, government and industry support for increased health data interoperability provided a catalyst for development of standardized approaches to collect and share data between systems without the need for costly and time-consuming software development. Standardized APIs are key drivers for greater interoperability of systems to achieve a more pro-competitive and transparent health care ecosystem, where data can be shared securely between patients, systems, and organizations.

In March 2020, the Office of the National Coordinator for Health Information Technology (ONC) released the Cures Act Final Rule,[1] which requires certain developers of certified health IT to adopt secure, standards-based APIs with the Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) data exchange standard, and to provide specific business and technical documentation necessary to interact with the certified API technology. Together with CMS Promoting Interoperability Programs,[2] health IT developers are encouraged to support a more interoperable health IT ecosystem. These new federal requirements seek to accelerate the shift to enable consumers to store, aggregate, use, and share electronic health information (EHI) using APIs and third-party apps of their choice.

## SHIFT TOWARDS GREATER INTEROPERABILITY

Standard APIs required under the Cures Act Final Rule include FHIR Release v4.0.1 (R4)[3] standard for individual-level health data, and the FHIR Bulk Data Access API (Flat FHIR v1.0.1: STU 1)[4] for population-level health data. While the Cures Act Final Rule applies to certified API developers, it does not apply to third-party companies that specialize in data integration (hereafter referred to as “data integrators”). Their products include integration services, solutions and platforms to interoperate between health IT systems and third-party software (including apps) and exchange data between health care organizations.

The app development experience has traditionally been a time and resource-intensive, costly, and arduous process for both experienced companies and those new to the health care industry. App developers and data integrators work with varied quantity and quality of technical documentation, requirements, and administrative processes to complete the testing and approval cycles for their solutions. As a result, the product life cycle, from development through implementation, is often mired with confusing guidance, uncertain structures and fees, lengthy timeframes, and established customer prerequisites. This prevents entry into the health app marketplace from all but the most prominent or well-funded companies.

The recent updates to regulatory requirements for health IT developers and providers to avoid information blocking and make EHI more readily available through the use of standardized APIs can lower barriers to entry and create a more level playing field. Both app developers and integrators will benefit from improved access to technical requirements, documentation, and testing processes, positioning them to bring innovative solutions to the health care marketplace.

Understanding app developers' and data integrators' perspectives is crucial to achieving a more seamless approach to developing, testing, and deploying health apps. This document describes app developer and data integrator needs and presents challenges, barriers, and opportunities as the health care industry continues to evolve in its use of standardized APIs and apps for health care and research.

## METHODOLOGY

To better understand the needs of app developers and data integrators, as they use FHIR® and FHIR Bulk Data Access APIs, ONC contracted with Clinovations Government + Health to conduct key stakeholder discussions with nine (9) organizations involved in the development, deployment, and integration of APIs and apps across the health care industry. Participants were app developers, data integrators, or key stakeholders who support the app developer and data integrator community, including app consultants. Discussion participants were selected to provide relevant insights and perspectives based upon their expertise or roles in developing health apps or data integrating solutions with health IT systems or products. Data integrators included in these discussions were experienced in working with health IT developers and app developers to implement various types of health care apps using both provider-facing and patient-facing APIs. App developers included in these discussions were most experienced in building patient-facing apps, such as platforms and portals for billing, appointment scheduling, and access to EHR data. Discussions held for this analysis were conducted between November 2021 and September 2021, prior to Cures Act Final Rule compliance deadlines. Therefore, there may be perspectives shared in this report that reflect opinions of discussion participants based on the timing of the discussions and prior to certain changes being implemented by certain health IT developers.

Discussions explored the experience, methods, and approaches by which app developers and data integrators develop, test, and implement solutions to access data within health IT products (e.g., EHRs, medical devices, clinical databases). This report summarizes their needs, challenges and barriers, and areas for improvement that, if addressed, would aid app developers and data integrators as they seek to create novel solutions for the health care industry, researchers, and consumers.

Before each discussion, the contractor distributed background information regarding the project's scope and preliminary discussion topics to the app developers and data integrators. Specific topics addressed during the discussions were:

- Knowledge of the regulations and certification requirements for use of APIs;
- App development processes and experiences with various health IT developers;
- Level of experience with different health IT systems and products;
- Opportunities to improve the app development and integration process; and
- Privacy and security issues associated with APIs and apps.

A facilitator led the discussions and an analysis team documented each discussion, organized the information collected, and assisted in identifying and analyzing key themes and findings using grounded theory techniques.[5] This report summarizes common themes, findings, challenges and barriers, and opportunities detailed during the discussions.

The organizations included in this report and their respective discussion participants are listed in Table 1.

***Table 1. App Developer and Data Integrator Perspectives: Discussion Participants***

| Stakeholder | Organization | Role | Discussion Participant |
|---|---|---|---|
| **Data Integrator** | 1upHealth | **Chief Executive Officer and Co-founder** | **Ricky Sahu** |
| **Data Integrator** | 1upHealth | **Chief Products Officer** | **Doug Williams** |
| **App Developer** | Apple | **Clinical and Health Informatics Lead** | **Ricky Bloomfield** |
| **App Developer** | Bridge Patient Portal | **Chief Executive Officer** | **Josh Deutsch** |
| **App Developer** | Bridge Patient Portal | **Chief Technology Officer** | **Josh Orueta** |
| **App Developer** | Common Project | **Chief Product Officer** | **JP Pollak** |
| **App Developer** | Navimize | **Co-Founder and Chief Technology Officer** | **Kavita Mangal** |
| **App Developer** | Navimize | **Senior Software Architect** | **Alex Harvey** |
| **Data Integrator** | Redox | **President and Co-Founder** | **Niko Skievaski** |
| **App Developer** | Rx.Health | **Founding Chief Executive Officer** | **Ashish Atreja** |
| **App Developer** | Rx.Health | **Chief Executive Officer** | **Richard Strobridge** |
| **App Developer** | Rx.Health | **Chief Solutions Architect** | **Sarthak Kakkar** |
| **App Consultant** | SMART Health IT | **Senior Technical Lead** | **Dan Gottlieb** |
| **Data Integrator** | Zus Health | **Product Manager** | **Brendan Keeler** |

# Findings

## CURRENT STATE OF ADOPTION AND USE

While the use of proprietary APIs, standardized APIs (such as FHIR® and FHIR Bulk Data Access APIs), and apps by patients and providers are still emerging, discussion participants described an evolving landscape with steady progress towards greater adoption and use of APIs and apps. Many health care providers are beginning to leverage digital health technologies as part of their strategic initiatives to engage patients and promote interoperability of health IT systems across their enterprise. As a result, discussion participants emphasized the move towards more patient-centered care and described many use cases for APIs and apps that would assist in clinical workflows and enhance patient care processes.

While the availability of standards-based API solutions in the marketplace remains low, there has been significant progress over the last three years. Initially FHIR was used primarily in research settings and over the last year FHIR-based APIs have been used in a growing number of widely available patient-access apps and some research apps. The landscape for API-based solutions will need to continue to evolve to meet the needs of key stakeholders in health care and research. When asked to describe the current motivators for the adoption and use of standards-based APIs and apps by providers and patients, discussion participants expressed the following key themes:

- Standardized workflows and processes will promote further innovation for digital health and mobile app solutions.
- Use of interoperable data across multiple EHRs and health systems remains a strong motivator of using standardized APIs and apps.
- Regulations and certification requirements (Cures Act Final Rule, Centers for Medicare and Medicaid Services (CMS) Interoperability and Patient Access Final Rule) motivate health IT developers, providers, and payers to implement interoperable solutions and provide greater access to EHI.
- The potential for “plug and play”, seamless connections to multiple systems will help drive a “self-service” model at lower costs, with fewer resources, and a shorter development life cycle.

### Motivators for Use of Standardized APIs

The Cures Act Final Rule requires FHIR APIs and specific business and technical documentation necessary to interact with the certified API technology. Furthermore, the Cures Act Final Rule requires the adoption of the United States Core Data for Interoperability version 1 (USCDI v1) standard, with future versions of the USCDI voluntary.[6,7] USCDI v1 provides a standardized but limited set of data classes that promote interoperable data exchange, including patient demographics, clinical notes, vital signs, allergies and intolerances, immunizations, and procedures. ONC provides avenues to add additional data classes through the ONC New Data Element and Class (ONDEC) submission system, with USCDI revisions reviewed and finalized by the following July. USCDI v2 was released in July 2021 and USCDI v3 is already under development. Several discussion participants provided feedback during the USCDI public comment period and assisted in identifying and justifying additional data classes and elements.

As a part of the Merit-based Incentive Payment System (MIPS) under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[8] using certified EHR technology (CEHRT) may aid with MIPS reporting in three out of the four grading categories (quality, promoting interoperability, and improvement activities) and qualify providers for a MIPS payment adjustment (positive, negative, or neutral). As a result, providers are increasingly adopting technologies and digital health tools that may help them qualify for MIPS payments. With these important business drivers and regulations, app developers and data integrators will have additional building blocks and incentives to create and develop apps for providers, researchers, and patients using standardized APIs.

Outside of policy-led initiatives to increase standardization of technologies within digital health, all discussion participants described beneficial aspects to standardization. One discussion participant noted that standardized APIs helped foster greater sharing of data between health care organizations. Another discussion participant believed the USCDI data set is a significant step forward, as it offers well-organized and usable data for app development. Another discussion participant noted negligible software development cost and resource burden when using standardized APIs because the apps require little ongoing maintenance. Recent experiences using standards-based APIs prompted several discussion participants to articulate a vision of generally available API gateways that enable seamless integration of their apps into a large ecosystem of multi-vendor health IT systems and products.

## Expanded Data Sets and Use Cases

While discussion participants described significant progress using standards-based APIs, they called for additional data sets and listed several expanded use cases for standardized APIs and apps. Most applications developed using existing standards-based APIs supported patient access to their health information contained in EHRs and offered basic data aggregation capabilities. Apps that offered additional capabilities depended upon proprietary or private APIs or working with a data integrator that had already completed integration with certain EHRs to obtain larger data sets.

When asked about future expansion of standardized APIs in the provider setting, one discussion participant prioritized two scenarios that currently use proprietary write-back APIs: appointment scheduling and patient payment processing using a patient portal on their mobile device or personal computer. In both use cases, manual reconciliation is still required to ensure data quality and accuracy, but as standardized APIs become more available and sophisticated, automatic reconciliation of data may be possible.

Although the use of FHIR® Bulk Data Access APIs is still emerging in the market, two participants discussed the rapid uptake of this API, primarily by CMS. CMS is using FHIR Bulk Data Access APIs in multiple pilots, driving use of this API by providers, drug plans, and Accountable Care Organizations (ACOs). The bulk data API is either available or being implemented in many FHIR server platforms including those offered by Amazon, Google, IBM, and Microsoft

Discussion participants shared the USCDI data set is a critical and necessary step forward in API and FHIR integration. However, there are challenges when implementing APIs, particularly for research-specific use cases or in commercial settings. One challenge described was that sometimes in conducting novel research there may be one or two data elements missing that aren't available through the FHIR interface, or there may be a need to write-back a specific data element that is not available. In those cases, developers or researchers will create workarounds to gather slightly more data then needed and filter it down in the app. Consequently, when data elements are missing or a particular FHIR® resource type can't be written back,

developers will move to the native APIs. This increases the cost, resources, and maintenance associated with integration because the app may need to work differently with each different vendor and/or platform.

In academic and commercial research settings, non-standardized and standardized APIs and apps are emerging as pathways for gathering critical research data. For example, several discussion participants described the development of apps to streamline the patient or volunteer enrollment process for clinical trials. Once enrolled, APIs are used to gather the enrollee's data and share it with the organization's data warehouse or project database. Two discussion participants highlighted interest in the market to create apps using FHIR Bulk Data Access APIs to pull large quantities of patient or volunteer data from pre-existing data warehouses. One discussion participant noted that this is most commonly achieved today by using direct database queries using Structured Query Language (SQL) or another programming language. However, the discussion participant stated the goal for the future is to at least partially transition to using the FHIR Bulk Data Access APIs for this process.

As consumers continue to embrace digital health solutions, software companies have increasingly invested in API and app technologies that aid in developing these products and solutions. Cloud computing platforms offer many services that are of value to many app developers, including Software-as-a-Service (SaaS), cloud storage, and data backup capabilities.[9] With the large platform vendors developing FHIR servers that support FHIR Bulk Data Access APIs, participants described advanced analytic capabilities from cloud computing platforms as a driver for use and adoption of FHIR Bulk Data Access APIs. While bulk data APIs may be needed as a mechanism to obtain data across different EHRs, these FHIR server platforms are implementing secure, standards-based APIs to support data access to their platform by third-party apps as a method to hold data temporarily or permanently in their application data store before transferring it to the end-user (e.g., provider, patient, researcher).

## Mobile Platform Integrations

With government policy encouraging the use of standards to promote interoperability, lower cost, and enable greater data exchange, native mobile platform app developers have championed and committed to developing health apps that conform to standards-based and non-proprietary technologies. This has greatly contributed to increased access to health data by patients and other key stakeholders. As of September 2021, the Apple Health iOS app is connected to nearly 400 health care institutions. Eight health IT developers, the Veterans Administration (VA), and two national laboratories support either FHIR DSTU2 or FHIR R4 connections to the Apple Health app in the United States.[10] CommonHealth, the Android equivalent of the iOS-based Apple Health app, allows Android users to collect and manage their personal electronic health data. As of September 2021, nearly 400 health care institutions are connected to the CommonHealth app. At least four health IT developers, the Veterans Administration (VA), and two national laboratories support either FHIR DSTU2 or FHIR R4 connections to the CommonHealth app in the United States.[11]

With both Apple Health and CommonHealth apps, users can share their data with health services, organizations, and third-party health care apps that they trust. For third-party app developers, the CommonHealth app provides them with a FHIR testing sandbox suite and a framework to build their apps. By enforcing a commitment to interoperability and use of standards, Apple and the Commons Project have accelerated a market that drives health IT developers, app developers, health systems, and providers to adopting FHIR® APIs if they want to participate in the Apple Health and CommonHealth app network.

## Developer Tools and Resources

While discussion participants agreed there is promise and reward for the development, deployment, and integration of apps built using standardized APIs, they described some of the key barriers and challenges encountered when developing these apps, especially when integrating their app(s) with an existing EHR. Overall, the app developer and data integrator discussion participants expressed the following key themes when describing their experience working with various health IT developers:

- Health IT developers are inconsistent at making app development resources and documentation (FHIR resources, access points, endpoints, etc.) available on public-facing websites.
- Health IT developers generally grant access to the required APIs and data sets but may not provide enough sample data to thoroughly test their app functionality.
- App developers/data integrators generally do not have policy or standards specialists that understand government policies (Cures Act Final Rule, etc.) and/or technology standards (FHIR R4, FHIR Bulk Data Access) – especially the smaller app developers who may not be informed regarding policy and/or the ONC's Health IT Certification Program.
- Cost barriers and lack of resources continue to be challenges for app developers, data integrators, and health systems when developing or implementing standardized APIs and health care apps, despite policies aimed at reducing overall cost.

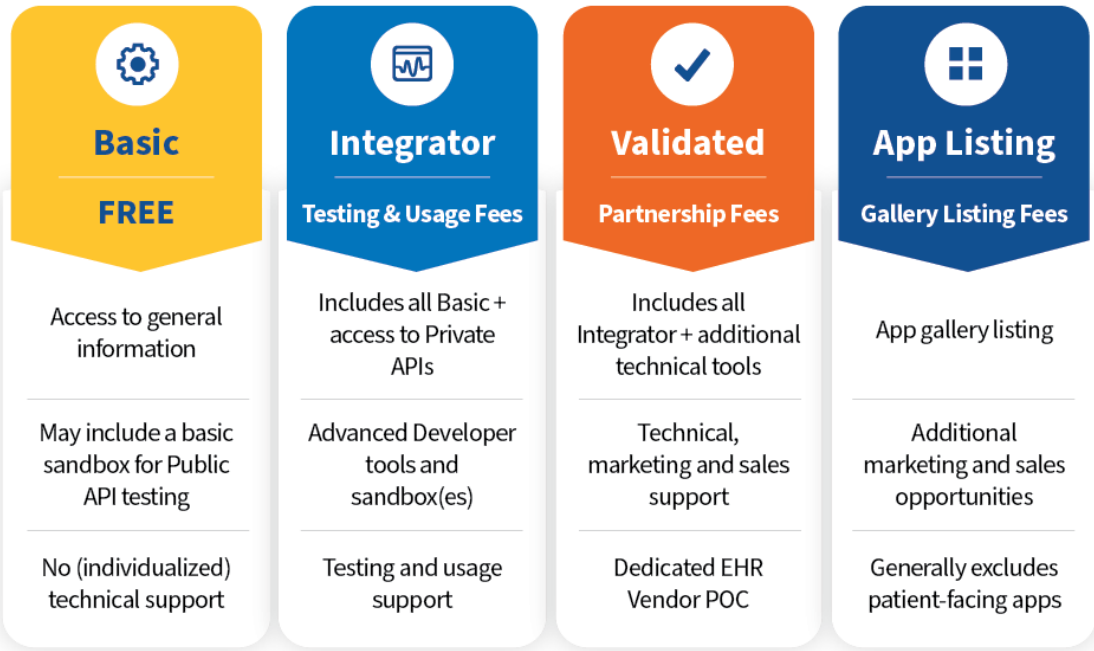
Discussion participants highlighted the lack of support and the minimal availability of developmental resources (i.e., documentation, APIs, sandboxes, etc.) from health IT developers as major bottlenecks for the development and testing process. One discussion participant reported difficulties gaining access to a FHIR API because the health IT developer knew that the API would be used to connect with a competing product. While some health IT developers provide easy access to development and testing resources, two discussion participants stated that they encountered a series of challenges with others. In some current instances, the health IT developer requires app developers to have a fully FHIR-compliant app before testing. In other cases, the health IT developer requires the app developer to have a pre-existing customer before testing. Sometimes, the health IT developer requires that both requisite conditions are met.

These barriers create dilemmas for app developers and data integrators. For example, an app developer or integrator cannot gain access to test FHIR resources or development sandboxes to create a FHIR-compliant app because they do not have a customer, but they cannot get a customer because they do not have a fully functioning and integrated app. A few health IT developers offer an alternative method to provide access to their resources (i.e., documentation, APIs, sandboxes, etc.) and testing sandboxes by setting a fee that app developers and integrators must pay (see Figure 1). Often, app developers and integrators do not have the required funds unless they have secured a third-party funder (i.e., venture funds, grants, customers, etc.). Furthermore, one discussion participant described the legal documentation and consent that third-party app developers often must obtain before developing and connecting an app to a health system's EHR.

> **"We're a lot closer than we used to be but I don't think we're at the stage where somebody can come up with an innovative app in their garage and actually deploy it to the healthcare system."**

Examples of these legal documents include data source agreements, data use agreements, connectivity agreements, agreements to use personalization, and IT support agreements.

**Figure 1: App Development Resource Access Tiers**




Discussion participants claimed that many health IT developers are not FHIR®-enabled and that many of the FHIR-enabled health IT developers do not offer the APIs that many app developers and data integrators need to develop their apps. One discussion participant acknowledged that FHIR-enabled health IT developers granted them access to the required APIs and data sets (C-CDAs, etc.), but these required APIs and data sets do not contain enough data elements or are not those that app developers and data integrators need for their apps. The participant stated that app developers want patient-facing APIs that enable capabilities, such as self-scheduling, bi-directional bill-pay, and messaging with providers. As a result, one discussion participant stated that their company was moving away from standardized APIs due to numerous limitations and indicated that it will be easier to create proprietary APIs or interfaces.

One discussion participant posited that the gap would remain in available data classes and data elements, resulting in limited FHIR API (R4) access to data classes and data elements that app developers and data integrators need. The same discussion participant argued that additional data classes and elements should be required since large data sets with various data classes and data elements can always be managed with filters. Another discussion participant explained that the FHIR standard has the capability to contain a larger amount of data in the raw specifications compared to other data standards and specifications, such as the Observational Medical Partnership (OMOP) Common Data Model. The same discussion participant stated that FHIR supports a greater amount of data classes and data elements than what is typically found in the EHR. Even though app developers and integrators may get access to a broader selection of data classes and elements by using standards-based FHIR R4 APIs, they may still encounter challenges

developing and integrating apps into different health IT products and health systems, due to the variances in data element terminologies, mappings, and standards used by health IT product end-users.

## IMPLEMENTATION AND INTEGRATION CHALLENGES

When asked to describe the process of integrating their apps with various health IT systems and products, including EHRs, discussion participants described several challenges and barriers. One discussion participant asserted that there are no business incentives for health IT developers to decrease implementation burden and suggested that disincentives may exist. The participant stated that in many cases, there is a lack of access and transparency to each health IT developers' FHIR® API developmental resources (e.g., documentation, APIs, sandboxes), creating unnecessary burden on the app developer.

Discussion participants reported that some health IT developers provide easy access to quality documentation, while others do not. Often it is difficult for app developers and data integrators to gain access to these relevant resources due to unknown endpoints (i.e., FHIR, private health IT developer-specific APIs, custom APIs, data source endpoints) and integration times based on the health IT developer's customer priority and support team's bandwidth. In addition, three participants commented that health IT developers often give priority access to resources and support staff to app developers who have brand recognition.

Confusion often arises in scenarios where there may be one endpoint for multiple provider organizations, and the app developer needs to discern which client they are attempting to test their app. For example, in a heavily concentrated geographic region, such as New York City, many health systems use the same EHR product and share an endpoint, though they are separate organizations. This creates confusion because app developers may not be aware of the different organizational entities and who is affiliated with the same institution. To alleviate these burdens, two discussion participants suggested creating public directories that document health IT developers' APIs and endpoints that app developers and integrators can access if they receive prior approval from each health IT developer.

Other common challenges and barriers described by discussion participants included:

- Custom/proprietary (non-standardized) APIs are often required to connect to EHRs because 1) the standardized APIs are not available in all versions of the software product(s), 2) the standardized APIs do not extract enough data, or 3) the customer wants to perform functions (such as write-back) that cannot be accomplished with the current version of their EHR.
- Data mappings may vary across systems or organizations, making it difficult to exchange data without curating and manipulating source data.
- Support from health IT developers has been inconsistent, creating undue burden and project delays for both app developers and provider organizations.
- APIs are not always forward and backward compatible and may result in rework; users will need to ensure that data [mappings] are not lost when versions are updated.

## Implementation and Testing Sandboxes

To work around implementation and integration barriers, some app developers and data integrators use public sandboxes to develop and test their apps without integrating them into a health IT developer's product. In many instances, these public test sandboxes may not offer an accurate or relevant test environment. One discussion participant noted that they have seen many examples of app developers testing their app in a public test sandbox that contains a larger number of APIs, data classes, or data elements compared to what a health IT developer may offer, making it more challenging to integrate into a health IT developer's product. The complications usually stem from privacy concerns, security concerns, and integration with other pre-existing infrastructure, such as the health IT developer's codebase, data fields, and data elements. In many cases, these apps are not deployable in a real-world client organization.

When asked if provider organizations understand the app development, integration, and deployment process, several discussion participants believed that most providers, especially clinicians, do not understand the standard processes required for apps developed using sandbox environments to be successfully deployed in health systems for patient care. One discussion participant discussed this gap by highlighting two examples that occur frequently. In the first example, clinicians with research projects or algorithms that they want to build often test them using public FHIR® sandboxes and testing tools (e.g., InterSystems, Logica Health, Inferno). These sandboxes support a much broader set of APIs and data than are available at most health care organizations, resulting in the research project or algorithm not being deployable at their health system. They described a second example which involved clinicians who built provider-facing apps using functionality that is not yet readily available on the market. Examples include Clinical Decision Support (CDS) Hooks and certain SMART (Substitutable Medical Applications, Reusable Technologies) on FHIR functionalities (write-back capabilities, access to all data elements, etc.). For provider-facing apps that do get deployed, they often require a back-end integration engine or private APIs because there are often data elements needed that are not available through FHIR.

## Proprietary APIs and Custom Integration

Many discussion participants stated that, if a standardized API is not available to gain access to a particular data element in the health IT developer's product, they need to either use custom and/or proprietary APIs or create workarounds using different standards and methods. Custom and/or proprietary APIs may not be problematic if an app developer or data integrator only creates or integrates an app for one health IT product. However, many app developers and data integrators would need to change out substantial portions of their software to adapt their codebase to integrate their apps into other health IT products. Two discussion participants noted that if an app developer or data integrator creates a workaround, they typically use HL7®v2 standards and direct database connections.

> **"You have HL7 being still the primary method of connecting for Cerner and Epic, let alone the 91 EHRs [that] we've connected to as you go down the long tail."**

> **"A fair assumption that with any vendor that we would typically work with on the mid-market space that has an API, probably three quarters of the endpoints are created through HL7 and direct database connections."**

These limitations caused one discussion participant to move his company away from using standardized APIs to using customized APIs and connecting directly into a customer's database. Another discussion participant described attempting to emulate the FHIR® Bulk Data Access APIs because they were not yet readily available in the market. In this example, the discussion participant integrated into the provider organization's EHR using the available set of APIs (FHIR, private, public). The data was extracted and stored in a standard format and mapped and stored in a separate SQL database, allowing the end-user to manipulate and partition the data similarly to the FHIR Bulk Data Access APIs. Even with health IT developers implementing their FHIR Bulk Data Access APIs in response to the Cures Act Final Rule, one discussion participant speculated that it would take months or even years to implement them fully, due to the difficulties and challenges of mapping pre-existing data sources and standards into the new standards and specifications.

## Data Mapping and Data Integrity

While federal regulations require health IT developers, health systems, and health plans to support FHIR APIs, several discussion participants agreed that mapping data into usable formats, mapping errors, and data integrity are still major pain points when integrating an app with a health IT product. The adherence to using certain data standards (e.g., SNOMED CT, ICD-10, DICOM, NCPDP) is a critical factor in determining how successful a new app integration will be. However, discussion participants also agreed that the use of specific data formats and standards might vary depending on the data owner and does not guarantee an easy integration. The lack of seamless, automated mapping between standard codes, such as SNOMED CT and ICD-10, erodes the benefit of using APIs to exchange data between systems. Because these two standards differ in purpose and structure, integrating disparate systems may prove difficult if an app developer or data integrator is trying to map codes between the two.

For example, while SNOMED CT and ICD-10 document clinical diagnoses, both code sets have different organizational structures and varying levels of specificity. A clinician can select a diagnosis code from a set of 254 different SNOMED CT codes for a stroke patient. In comparison, an administrator or researcher can only select from a set of 102 different ICD-10 codes for the same diagnosis.[12,13] As a result, an app developer or data integrator must be mindful of how the data formats and standards are mapped so that data are pulled correctly from the source system into their app. The same is true when an app developer or data integrator sends data back into a health system's health IT product. When done incorrectly, the data will likely be unusable, and further complications and consequences may arise when apps attempt to pull the same data in the future.

A different pain point for some app developers and data integrators is the process of mapping data elements from legacy EHR systems using old standards and specifications to data sets and models that are more common today. However, one discussion participant claimed they do not experience mapping difficulties because they simply keep the data in its native format once it is pulled from the EHR. Two discussion participants discussed the challenge of migrating from previous versions of FHIR (such as DSTU2) to the most recent version (R4) and reported that it is not a seamless process and data elements are not represented 1:1. To complicate this further, some data elements, such as medications, were renamed (i.e., "medication order" was renamed "medication request"). Additionally, some data elements were combined to create a net new data element, while others were separated to create more granular data elements. In certain instances, some health IT developers have a different FHIR ID or resource ID that uniquely identifies a piece of data.

Using the same example, if the app still contained data in FHIR® DSTU2, locally (i.e., on the app user's phone), one discussion participant discussed the complicated decision tree app developers and data integrators must go through to determine what happens with the data in the outdated standard.

Questions included:

- Should the app preserve all the data elements between two standard formats? If so:
  - How does the app present the data in a simple way?
  - How does the app ensure there are no duplicate data?
  - How does the app display accurate and valid information?

Data collection, sharing, and presentation must be evaluated, so the app user's data are protected and securely maintained within the newly updated app. In the above example, the discussion participant highlighted the importance of both backward and forward compatibility. Once an app developer or integrator successfully updates their health IT product's codebase and maps the data to FHIR R4, it must be re-integrated into the health IT ecosystem.

While many of the difficulties app developers and data integrators experience with data mapping are due to technical specifications (e.g., conversion of outdated code, creation of new code, removal of legacy code, conversion of data in legacy or outdated formats), others can be attributed to data integrity challenges at the health system level. As EHR solutions by design tend to support localization and organization-specific workflows, app developers indicate that their apps present the data as it is provided. If there are mapping issues at the health system level, it is not a problem with the standard, but the varied implementation and mapping across organizations that can cause the data to appear in unexpected FHIR resources. One discussion participant described three major types of data and data integrity errors that may result from mapping errors:

1) Data mapped to incorrect fields (e.g., glucose level readings in the heart rate field, full narrative report text in a short text or positive/negative results field);
2) Variation in the taxonomy or nomenclature used between different health IT systems; and
3) Data fields with the same name that do not represent the same field.

These examples highlight the need for education for care team members that emphasizes the importance of careful data entry, data taxonomy or nomenclature uniformity, and data entry workflow standardization.

## API PROCESS IMPROVEMENT OPPORTUNITIES

When asked about the availability of resources for third-party app developers and data integrators, several discussion participants agreed there should be an increase in the number of available resources to address the app development and integration processes, such as implementation guides and health IT developer-specific guides. Discussion participants also suggested various types of resources that would be beneficial to their experience but also their capability to develop and integrate third-party health care apps.

Key considerations and suggestions from all discussion participants included:

- App users who work with app developers/data integrators need more education on the standards and app development lifecycle.
- App developers and data integrators may benefit from a centralized repository of educational materials, information forums, tools, and resources.
- A public directory of health IT developer APIs, endpoints, and access points may be a helpful addition to the developer-specific public-facing websites.
- A central app directory where end users can find apps relevant to them organized by their participating provider(s) may be a helpful tool to promote more adoption and use of APIs and health apps.

## Centralized Tools and Resources

From a regulatory perspective, one discussion participant discussed the need for a centralized resource that reviews and highlights the regulatory requirement updates from previous editions (i.e., 2015 Edition Health IT Certification Criteria). Two discussion participants expressed the need to conduct in-depth evaluation and discovery phases just to stay current with new technologies (e.g., exchange mechanisms, exchange standards, data standards, data sets).

The discussion participant provided examples of helpful tools, such as timelines that indicate when new regulations must be implemented, documentation of what technologies are required, and documentation specific for each stakeholder type (e.g., health IT developers, third-party app developers, health care providers, end-users). These centralized resources will help third-party app developers better understand new government regulations and technology standards. Several discussion participants indicated that app developers often are confused by at least one facet of newly released regulations. In some cases, resources are centralized, but stakeholders do not know where to find them.

Many discussion participants discussed the need for centralized documentation of FHIR® resources (DSTU2, STU3, and R4) for all health IT developers and other app development and integration resources, such as published lists of health IT developer endpoints, which is currently under development. They also described the desire to understand different health IT developers' registration and integration processes and the required standards and data sets that must be supported by third-party health care apps per government regulations and policies. For health IT developers who do not have published endpoints, app developers must often call individual health IT developers to access their FHIR endpoints and/or understand their registration process.

Several discussion participants noted the lack of access and transparency to each health IT developer's FHIR resources, resulting in additional barriers and challenges for the small third-party app developer trying to develop, integrate, and deploy their health app into health care organizations. Some discussion participants noted that many health IT developers do not provide the resources to support many methods of exchange, and claimed that out of 100 health IT developers, only two published their FHIR resources publicly. To alleviate these burdens, one discussion participant proposed creating a public directory of health IT developer APIs, resources, registration processes, and health care organization-specific endpoints.

## Industry Education and Collaboration

When asked about the current availability of public forums (e.g., web-boards, conferences) for third-party app developers to ask questions, exchange information, and collaborate, discussion participants agreed that the forums are limited in availability, do not convene regularly, or do not exist. One discussion participant stated there are very few places to ask questions for smaller to mid-market health IT developers.

Third-party app developers may have limited opportunities to educate themselves through professional organizations such as the Healthcare Information and Management Systems Society (HIMSS) Electronic Health Record Association (EHRA), as these often require costly memberships. Another discussion participant claimed that the market is fiercely competitive and lacks collaboration between health IT and app developers. Furthermore, the discussion participant stated that there is conflicting technical documentation and implementation guidance across several different online sources, making it difficult to determine the real source of truth. Key drivers for data integrators' business models are to simplify the process and help educate app developers in working with different health IT developers. Data integrators are beginning to develop educational materials (e.g., blog posts, podcasts, videos, webinars) for app developers and provider organizations).

> **"Knowledge is one of our greatest assets, to be quite honest - of processes, of EHRs, and what it's like. That is absolutely one of those unspoken benefits that we [data integrators] provide."**

In addition to providing educational materials, data integrators often provide app developers with a suite of testing tools. One discussion participant described their testing tools as robust, health IT developer agnostic, and presenting relevant and realistic testing scenarios. Another discussion participant acknowledged using data integrators provides the easiest path to developing, integrating, and deploying apps. Subsequently, data integrators have been a valuable resource for not only app developers but also for provider organizations who are trying to implement apps into their environments.

Furthermore, discussion participants highlighted the importance of hiring app developers with prior real-world experience since there are many nuances and health IT developer-specific APIs that are complex. By understanding the third-party health care app development, integration, and deployment process, provider organizations may mitigate some of these risks and challenges. However, discussion participants noted that there is more demand for app developers with health apps development experience than there is available supply.

## Guidance for Provider Organizations

Like app developers, provider organizations also require additional information about the processes for implementing APIs and apps. Specifically, provider organizations do not understand the standard processes required to develop, integrate, or deploy a third-party app into their specific organization. Multiple discussion participants believe data integrators provide a valuable niche service as advisors and educators to assist in this process and has driven provider organizations to utilize data integrators rather than manage and connect to apps directly.

One discussion participant discussed common challenges at academic medical centers that seek to leverage FHIR® APIs:

- Clinicians and researchers secure funding for research studies that involve use of a novel app, and may hire an app developer to develop it. However, the custom app requires FHIR® resources or APIs that are not available or exposed through their health system's health IT product.
- The result is a codebase that cannot be easily integrated into the system's health IT product's infrastructure and relies on data formats that cannot be accurately mapped to the organization's health data infrastructure.
- Ultimately, the app is used in the research study, but is never deployed to the organization's live production environment.

In addition to emphasizing the need for provider organizations to understand the app development, integration, and deployment process, multiple discussion participants discussed the need to standardize integration workflows to better inform and improve scalability and reduce the resource-intensive workload. To integrate at scale, three discussion participants believed it is necessary to automate the app registration, onboarding, and integration process. One discussion participant suggested that an automated approval process should be reduced to approximately 24 hours or less.

Most health care provider organizations do not have access to standards expertise in-house and assume that products will be "plug and play". One discussion participant used an example from provider organizations implementing patient engagement solutions to illustrate this challenge:

- A health system attempts to gain a competitive edge or fulfill a regulatory requirement by implementing various patient engagement solutions.
- The health system acquires one health IT product to solve their appointment and scheduling needs, a second product to solve their patient communication needs (e.g., fax, SMS, video chat), and a third product to solve their revenue cycle management needs.
- Ultimately, the organization realizes those three products are not interoperable, and they must then acquire an additional product that will consolidate all three solutions.

The discussion participant concluded by discussing the need for an API implementation roadmap to determine how one health IT product could communicate and exchange data with the other using APIs. Having resources and tools for provider organizations that do not require them to contract for or hire technical expertise can help accelerate adoption and use of standardized APIs and apps.

## PRIVACY AND SECURITY CONSIDERATIONS

As health apps become more prolific in the marketplace, organizations must prioritize strict privacy and security safeguards to protect users' data from breaches. The increase in data breaches of health apps, including the most recent breach of over 61 million records related to fitness trackers and wearables, highlights the need for increased attention to strong cybersecurity practices and policies.[14] In addition, recent changes have been made to breach notification requirements, including the September 21, 2021 Federal Trade Commission (FTC) policy statement emphasizing that health apps and connected device companies must comply with the Health Breach Notification Rule (Rule).[15] The Rule requires vendors that collect sensitive health data to notify consumers when they experience a data breach. The statute directing

the FTC to promulgate the Rule requires that a "personal health record" be an electronic record that can be drawn from multiple sources. The Commission considers apps covered by the Rule if they are capable of drawing information from multiple sources, such as through a combination of consumer inputs and APIs. In addition, the Commission reminds entities offering services covered by the Rule that a "breach" is not limited to cybersecurity intrusions or nefarious behavior. Incidents of unauthorized access, including sharing of covered information without an individual's authorization, triggers notification obligations under the Rule.

Discussion participants agreed that strong privacy and security protections are critical for successful implementation of APIs and health apps in the marketplace. They described the following themes related to the availability and quality of security practices in the development, testing, and deployment of these solutions:

- More granular levels of consent/scope are needed to provide consumers with more transparency on specific data elements and explicit timeframes their data will be shared.
- Lengthy security risk assessments and overly complex approval processes from some health IT developers or provider organizations often cause delays in implementation schedules.
- App developers need to become accustomed to providing a privacy statement to users specifying their commitment to security and the risks of releasing EHI to any third-party.
- More guidance is needed regarding the administrative processes associated with privacy and security requirements, including contracts, data use agreements, Business Associate Agreements, and user consents.

When asked about privacy and security concerns, discussion participants noted that provider organizations often lacked robust security processes and trusted frameworks to manage patient data in third-party apps. Furthermore, many health systems often do not have a governance structure in place to determine the necessary privacy and security workflows and provide security reviews of third-party health apps. There is a link between the lack of a governance structure and the lack of internal stakeholder alignment. There is often not a single point of decision making, but rather many relevant stakeholders. These may include the: Chief Information Officer, Chief Information Security Officer, Information Security professionals, other C-suite level executives, and the clinical staff.[16,17]

## Granular Consent and Workflow

From a technical perspective, two discussion participants noted that current FHIR® APIs allow app users to consent to a granular level exchange of their EHI down to specific data elements. However, extracting health data from the source system (e.g., EHR) to the third-party app or the patient's personal mobile device remains a consent workflow challenge. One discussion participant summarized that FHIR offers a sufficient framework for the development of apps but does not solve other processes, such as privacy, security, and consent. However, initiatives such as the Argonaut Project aim to create more granular consent flows. Two discussion participants discussed their respective app's ability to exchange individual data elements via FHIR APIs (e.g., step counts, heart rate, weight, blood glucose level, medications, problem lists). One discussion participant stated their app allowed users to select the frequency of data exchange, allowing users to decide if they want continuous data exchange or a one-time exchange.

As third-party health apps become more ubiquitous, discussion participants described their desire to empower app users to make their own decisions. Participants also expressed the need to use case-specific

workflows to ensure the privacy and security of health data. One discussion participant expressed concern over the exchange of health data without the ability to filter out trial-specific or patient-sensitive health data. The discussion participant highlighted a nascent HL7® workstream that is focused on building patient-centric privacy flags into FHIR® data models as an attempt to mitigate some of these concerns. This workstream is similar to, but separate from, the HL7 Vulcan Accelerator's work bridging existing gaps from a translational and clinical research stakeholder perspective.

## Data Governance

With the continued development of the health app market, one discussion participant noted a need for a streamlined approach to third-party app integration from a data governance perspective, specifically regarding user consent and health data exchange. During the discussion, the participant provided examples of questions that they believed must be answered to ensure a streamlined approach to data governance:

- How should third-party app developers and apps be introduced into a data exchange ecosystem, whether on an app-level or health system level?
- How should third-party apps and app developers be held accountable for data governance?
- What sort of review processes are required, both from a privacy and security standpoint?
- How will data governance change between commercial third-party apps and research apps?
- How do we help app users understand these nuances as they make their own decisions?

To answer these questions, the participant hosted key stakeholder workshops to gain relevant insights. In addition, the organization continued to collaborate with academic medical centers to iteratively build a data governance model that works for potential app users so that they are comfortable sharing data with third-parties in a sensible and usable manner. That work resulted in a model similar to the model used by Apple in their Apple Health and Apple ResearchKit apps, where the data only resides on the app user's device. The third-party app facilitates a direct connection between its user's mobile device and the health system portal using Argonaut specs and OAuth flows. In this way, the third-party app has no direct control or storage of its users' health data. For example, the Apple Health and CommonHealth apps do not have access patient data and do not collect precise adoption information in terms of users.

Other discussion participants described data governance models where the app user's health information is stored in a data retention layer before it is exchanged with the user's mobile device. Many discussion participants noted the necessity of the data retention layer to enable certain capabilities, such as reconciliation and FHIR Bulk Data Access API substitutes. Furthermore, one discussion participant stated that many business models were built around the aggregation of data. The aggregated data may then be de-identified so that the data can be re-used, re-purposed, or sold.

On a market level, one discussion participant was concerned about the lack of clarity over the governance of third-party apps in the market, specifically the process to remove nefarious and malicious apps from app galleries and app stores. App stores, such as Google Play or Apple's App Store, have general guidelines for security, privacy, and app performance, but these guidelines do not include provisions that support the quality, safety, security, and efficacy of the health information used by the app.[18,19] Furthermore, there is no ongoing surveillance and oversight of health apps, and app stores could remove apps in response to negative user feedback unrelated to the quality or safety of the app.[20]

## Data Security Risks and Liabilities

Discussion participants agreed that standardized FHIR® APIs allow for safe health data exchange between relevant stakeholders (e.g., health systems, health care providers, data warehouses, health IT products, third-party health app users). Although two discussion participants disclosed that their apps do not contain a data retention layer, most discussion participants' apps disclosed storing users' health data in a data retention layer in a cloud or local server. While this enables additional capabilities (e.g., active de-duplicating of data, filtering of health data, building algorithms for new data analysis functions, testing of new apps), aggregation of data within a data retention layer creates additional liabilities or risks for the app developer because of the new endpoint and the associated governance responsibilities.

Discussion participants highlighted the need for app developers to provide ample disclosures to users regarding the future exchange of the user's health data with other third-parties (e.g., other apps, health care providers, researchers). One discussion participant stated that their health data exchange disclosure informs their users that once they share the health data with a third-party app, the third-party health care app's privacy policy governs the health data.

Additional considerations for the implementation and management of APIs in can be found in the ONC publication "*Key Privacy and Security Considerations for Healthcare Application Programming Interfaces (APIs)*."[21] The document describes key privacy and security considerations that include administrative, technical, and organizational controls needed for building a robust data protection program (Table 2).

***Table 2. Key Consideration for Privacy and Security of APIs***

| Privacy Considerations for Implementing APIs | Security Considerations for Implementing APIs |
|---|---|
| • HIPAA right of access<br>• Scope and granularity of patient choice<br>• Methods for revoking sharing permissions<br>• Development of organizational privacy policies | • Encryption of data in transit<br>• Input validation of API calls<br>• Access controls – protecting against unauthorized users<br>• Service provider security<br>• Data integrity protection<br>• Patient portal security<br>• Development of organizational security policies |

# Conclusion

Innovations in the digital health sector through the development and deployment of APIs and apps can enable greater accessibility to, and interoperability of health data. This project sought to understand the perspectives of app developers and data integrators as they work to bring those heath app solutions to the market. In addition, health IT developers continue to make modifications to their software and provide additional documentation and tools to meet ONC Cures Act Final Rule certification requirements, which app developers and data integrators must use to navigate an often cumbersome, costly and time-intensive process.

Discussions with app developers and data integrators focused on their experience interacting with health IT developers' technical documentation, resources, and tools as they worked to develop, test, and implement APIs and apps. The findings provide insight into their challenges and barriers, and opportunities as they continue to push the health app economy forward.

The priorities and needs that emerged support the strategies that ONC established in the Agenda and considerations in realizing the vision of the ONC Cures Act Final Rule. In particular, participants underscored:

- Increased demand for high-quality health data is driving the market to deliver innovative solutions;
- Standardization of APIs may result in benefits including reductions in the time, cost and variation of app development, testing, and implementation processes;
- Integration across disparate health IT systems and organizations often requires the use of private APIs and interfaces when data are not easily obtained through standardized APIs;
- Forwards and backwards compatibility (when old code reads new data, and when new code reads old data, respectively) between versions of FHIR® remains a challenge to accurately map and represent data that are meaningful to end users;
- Data mapping and normalization is needed to produce high-quality data used by apps;
- Access to quality documentation, educational materials, collaboration tools, and support will help app developers and integrators working with health IT developers and third-parties; and
- Trust in APIs and apps will depend largely on having strong privacy and security controls.

Limitations on the information gathered from stakeholder interviews included the small sample size and limited number and type of stakeholder groups represented across the discussion participants. The open-ended nature of the discussions facilitated gathering valuable individual insights that may or may not be able to be aggregated and synthesized across stakeholder groups. Discussions identified potential areas for ONC to consider for future funding of studies, pilots, or policy development. Discussion participants varied in their insights into the broader goals of ONC and national priorities for interoperability and research.

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