The U.S. Department of Health and Humans Services' Office of the National Coordinator for Health Information Technology (ONC)

Data Access Framework (DAF)

Initiative Summary—March 2017

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Executive Summary

Challenge: The nation-wide deployment of Health Information Technology systems (Electronic Health Records-EHRs, Data Warehouses, etc.) have created both opportunities and challenges in accessing patient data. While Health IT systems provide many access paths through their pre-defined interactions between a user and the system, they offer limited support in directly querying data, Application Programming Interfaces (APIs), or for other services to access data as needed.

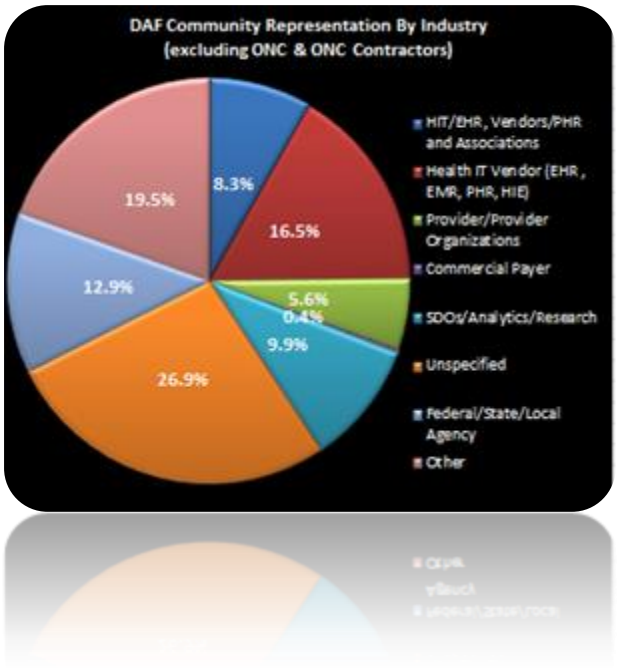
To address these challenges and to expand on opportunities, the Office of the National Coordinator for Health Information Technology (ONC) launched the Data Access Framework (DAF) Initiative with the following goals:

- reduce barriers in extracting granular data and documents from clinical data sources
- simplify data mapping challenges
- enable researchers to access data extracted from clinical data sources using standard mechanisms;
- enable development of third party applications using the data access APIs to add value for clinical and research activities
- enable access to both patient level and population level data using modular, substitutable standards controlled by appropriate privacy and security controls

Methodology: To achieve the goals above, the DAF initiative used a phased approach that included the following:

- **Local data access** *via intra organization query* (phase 1)
- **Targeted data access** *via inter organization query* (phase 2)
- **Data access for researchers** (phase 3) to access multiple patients' data from *multiple organizations* in the context of a Learning Health System

The DAF initiative formed a community of participants, representing a wide array of industry stakeholders to create standardized data access to individual patient encounter documentation and discrete data elements. The work of the DAF team and its community members ultimately led to the development of three implementation guides (IG), which include the following:



1. **Integrating the Healthcare Enterprise (IHE) Data Access Framework (DAF) Document Metadata Based Access Implementation Guide (IG)**: A US National Extension to provide requirements and guidance on accessing clinical documents created during clinical workflows using IHE profiles.
2. **Health Level Seven (HL7) FHIR® US Core Implementation Guide (IG) Release 1 (*formerly known as DAF Core):*** An IG that specifies a set of APIs to access patient level data both within an organization and from a targeted external organization.

3. **Health Level Seven (HL7) FHIR® DAF for Research Implementation Guide (IG) Release 1:** An IG built on top of the FHIR US Core IG to enable researchers to access data from multiple organizations within a research network, such as the National Patient-Centered Clinical Research Network (PCORnet).

Pilots and Lessons Learned: In order to provide experience with actual implementations, the DAF IGs were tested or piloted by multiple organizations. The Argonaut Project implemented the FHIR US Core IG (addressing Fast Healthcare Interoperability Resources—FHIR API based data element access in DAF phase 1 and 2) while several PCORnet organizations implemented the DAF for Research IG (phase 3). Lessons learned included but were not limited to the following:

- It is necessary to work closely and collaboratively with partnering Standards Development Organizations, vendor developers and implementers to create standards and facilitate adoption of those standards in the real world, as that is a lengthy, time-consuming process requiring industry consensus.

- Wider adoption of the IGs requires a trust framework implementing industry standard security and privacy mechanisms and policies.

- The FHIR based IGs (US-Core and DAF-Research) depend heavily on the native adoption of FHIR APIs by health IT system vendors to reach full potential for data access.

- DAF for Research requires further development to support patient level query and response; however, it was seamlessly integrated into existing PCORnet environments as it was an overlay using standards and provided significant value in data source on-boarding and interoperability within and across networks.

Conclusion: Through the development of the aforementioned IG's, DAF successfully created a modular and substitutable framework, enabling local and targeted data access using the various data query methods (document based—The IHE DAF Document Metadata Based Access IG; data element based—The US Core IG; quality measure based; etc.). This enables providers to more readily assemble a patient's complete information to better provide coordinated care in a timely manner and without extra cost.

Additionally, the development of the DAF for Research IG allows researchers to access multiple patients' data using standards for data extraction, query composition, query distribution and result aggregation using APIs and services. This allows the researchers to derive value from complex data using multiple sources without having to rely on existing access paths. Once established, these workflows can be automated to refresh the data at regular intervals, saving researcher's invaluable time. This will advance research efforts to develop an interoperable data network infrastructure maximizing efficiency, advancing research opportunities, and improving future health policies as part of a Learning Health System.

Background

Challenge

The wide deployment of Health Information Technology (IT) systems (Electronic Health Records-EHRs, Data Warehouses, etc.) has created unique opportunities and challenges for healthcare professionals and organizations to access and use the patient data that is actively collected during clinical workflows. While the Health IT systems provide many access paths through their pre-defined interactions between a user and the system, they offer limited support for directly querying data, Application Programming Interfaces (APIs), or services to access data as needed. Increasing support for this class of data access, by leveraging industry standards, would enable applications to expand the ability of users to create value out of their data without having to rely on the predefined , often propriety access paths. Allowing access to this data can enable a provider to better understand a patient's overall health, the health of a provider's collective patient population, and use the data to power innovative new applications and tools for better patient and population care.

Data Access Framework (DAF)

In July 2013, the Data Access Framework (DAF) initiative was launched to expand access to individual patient data for multiple use cases that include ***Local data access*** via intra-organization query, ***Targeted data access*** via inter-organization query, and ***Data access for researchers*** to access multiple patients' data from multiple organizations in the context of a Learning Health System (LHS).[1]

This framework was expected to reduce barriers in extracting data from clinical data sources (EMRs, lab systems, warehouses, etc.), simplify data mappings (specifically around vocabularies, semantic meanings, etc.), expand data access for researchers, create standards for query and query results, and specify modular standards for transport, security, query structure, query results, and information models that could be replaced as Health IT standards evolve. DAF recognized solving these various challenges would require a query stack that is composed of modular and substitutable standards (see Figure 1 below).

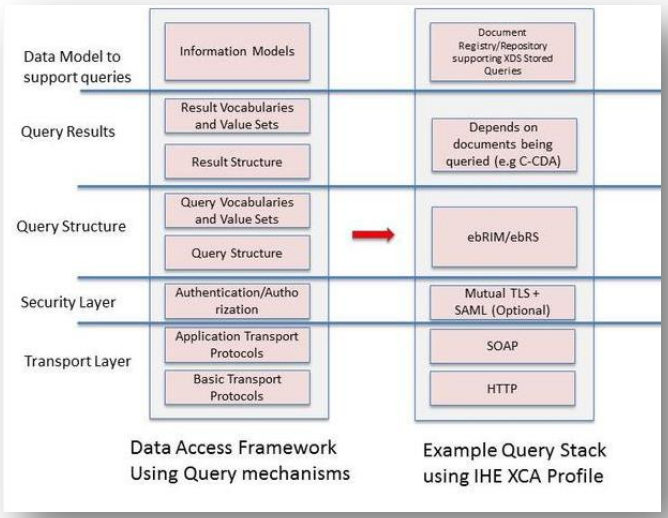


Figure 1: DAF Query Stack

Modularity *is the ability to keep the various layers of standards independent of each other (e.g., Transport Layer standards should be independent of query structure standards which should be independent of query result standards).*

Substitutability *is the ability to replace a particular standard without affecting the other layers of the query stack (e.g., depending on the business requirements the query structure might be best represented using ebRIM/ebRS or HL7 FHIR or HL7*

[1] Grossmann, C., Powers, B., & McGinnis, J. M. (2011). Digital infrastructure for the learning health system: the foundation for continuous improvement in health and health care: workshop series summary. Washington, D.C. National Academies Press.

HQMF).

Goals of DAF

The goals for the DAF initiative include the following:

- Enabling queries for individual patient's data, through Local and Targeted data access, using various data access mechanisms (document based, data element based, quality measure based, etc.)
- Expanding and building on Targeted data access mechanisms to support queries for multiple patients' data to support researchers and other secondary uses
- Identifying the privacy, security and necessary metadata requirements to support the various data access mechanisms
- Building the query stack in modular layers (transport, query structure, query results, authentication, etc.) and allow for substitutability at each layer of the query stack. The extent of the modularity and substitutability that can be achieved will be determined by working with the community experts and experimenting with real-world technical feasibility.
- Identifying the set of modular components and industry standards that could be assembled together as valid combinations to promote interoperability for the various business requirements of the community

Methodology

Scope

The Data Access Framework was built incrementally by first focusing on Local Access via Intra-Organization query *(known as Phase 1),* then Targeted Access via Inter-Organization query *(known as Phase 2),* and lastly, to enhance technical capabilities enabling the research community to access multiple patients' data from different organizations and data sources within a Learning Health System (LHS) infrastructure *(known as Phase 3*).

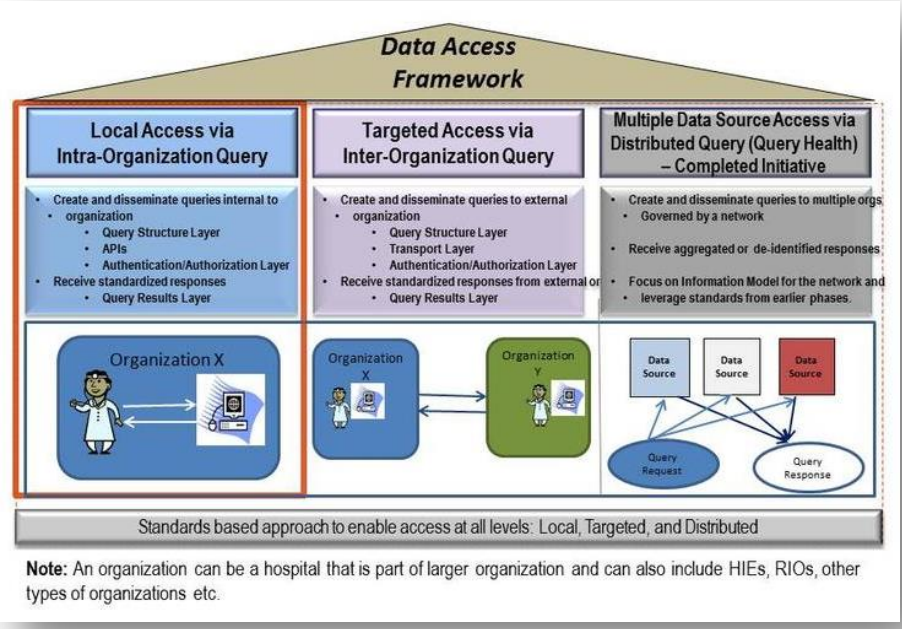


Figure 2: DAF Initiative Approach

Requirements and Design

Phase 1 (Local Data Access) and Phase 2 (Targeted Data Access)

Local Data Access (Phase 1)

Obtaining a complete view of a patient's health information within a Health IT system's multiple applications (i.e. EHRs, labs, data warehouses, etc.) can often be a challenge. Health IT systems are limited in their support of queries for patient data, through standard interfaces, APIs, and services to access data sets as needed. As a result, the Local Data Access Framework provides a standardized and simplified approach to querying for documents and data across disparate applications within a single healthcare organization, by utilizing a coordinated stack of interoperability standards.

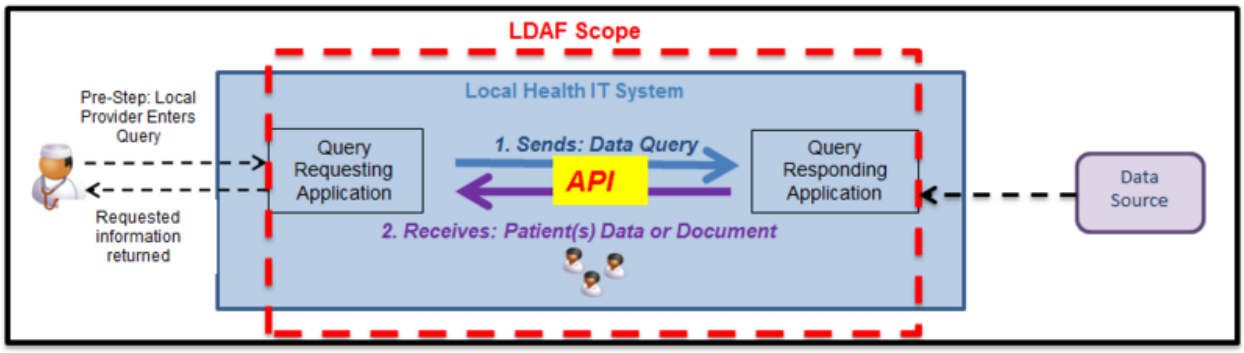


Figure 3: Local Use Case Diagram

Local DAF enables an integrated healthcare organization to gather and share documents and data from different internal systems for coordinating individual patient care and for collecting such data for analysis of multiple patients. Local DAF interfaces are built on existing document registries and repositories and the emerging HL7 Fast Healthcare Interoperability Resources (FHIR®)[2] standard for exchanging healthcare information electronically. The use of such query standards enables automation of data sharing without the expense and efforts of developing non-standard interfaces for proprietary systems or manual workarounds. Allowing access to a patient's data enables a provider to further analyze the collected data. This analysis is critical to better understanding a patient's overall health and, with aggregation of multiple queries, the health of a provider's collective patient population. The liberated data can be used to power innovative new applications and tools to enhancing the health and care of patients and patient populations.

Note: The implementation of Local DAF standards, particularly to access HL7 FHIR® resources, supports the build-out of data interoperability in subsequent phases.

Targeted Data Access (Phase 2)

Healthcare organizations are rapidly adopting electronic health records (EHR) systems to manage patient records; however, providers are often faced with the need to access patient information from multiple healthcare organizations where the patient may have received healthcare services. Accessing patient data

[2] Health Level Seven Fast Healthcare Interoperability Resources DTU3 (May 15, 2016). Retrieved from http://hl7.org/fhir/index.html.

from external organizations increases security and privacy risks, requiring common trust frameworks and risk-mitigation strategies among organizations. The Targeted Data Access Framework enables standardization of data access between organizations willing to exchange health information.

Targeted DAF enables one healthcare organization to query and share documents and data from different healthcare organizations involved in the care of individual patients. Extending the use of the document and data sharing standards described under Local DAF to these external providers enables the host organization to coordinate and deliver care based on complete patient records without manual workflow steps, such as phone calls and faxes.

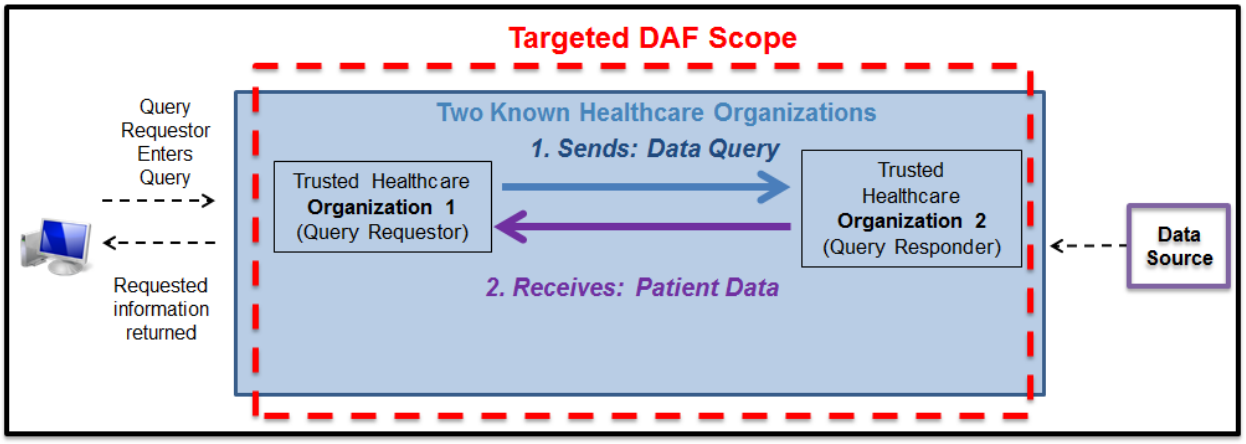


Figure 4: Targeted Use Case Diagram

The increasing support for data access using industry standards enables providers to access targeted individual patient health documents and data between trusted organizations without having to rely on predefined access paths. Accessing all of a patient's data from known healthcare organizations ensures better care coordination and reconciliation of patient health data.

Note: As with Phase 1, implementation of Targeted DAF standards, particularly HL7 FHIR® resources, supports the build-out of data interoperability in subsequent phases.

Phase 3 (Data Access for Research)

DAF for Research extends Targeted DAF to access aggregated data and in a later phase (*see Recommendations section of this document)* detailed data elements for multiple patients from multiple healthcare organizations. The initial focus of the phase was to support researchers' queries for comparative effectiveness research and the Learning Health System. However, the underlying HL7 Fast Healthcare Interoperability Resources (FHIR®) standard, when supported by electronic health record (EHR) systems and intermediate data marts, can be profiled to support diverse population health data requirements. Many healthcare organizations operate distributed health care delivery systems with the inherent challenge of collecting and analyzing process and outcomes data across their patient population. DAF for Research provides a way for healthcare organizations to participate in the growing National Patient-Centered Clinical Research Network (PCORnet)[3] initiatives,

[3] PCORnet, the national patient-centered clinical research network. (2017, January 13). Retrieved from http://pcornet.org/

supporting management oversight to benchmark their performance.

Note: The implementation of DAF standards, particularly HL7 FHIR® resources, supports the build-out of data interoperability in subsequent phases.

Accessing patient data in a structured manner helps advance research efforts to develop a comprehensive, interoperable and sustainable data network infrastructure that will maximize efficiency, protect patients' privacy, advance research opportunities and improve future health policies.

Note: to learn more about DAF's privacy and security approaches, please visit Appendix C of this document.

Implementation Specifications

During this step, the DAF Support team worked with the pilot community and the participating standards development organizations (SDO) to develop draft implementation specifications and related profiles to meet the technical requirements.

Phase 1 and 2 (Local and Targeted DAF)

DAF developed two implementation guides (IGs) to create standardized data access for encounter documentation and for discrete data elements both *within* a Health IT organization's systems and *between* known Health IT organizations' systems.

1. The Health Level Seven (HL7) FHIR® US Core Implementation Guide (IG) Release 1[4] *(formerly known as DAF Core)* is a US-realm specific implementation guide that defines the minimum mandatory requirements for recording, searching for, and fetching patient information. It defines the minimum conformance requirements for accessing patient data as defined by the Argonaut pilot implementations and the ONC 2015 Edition Common Clinical Data Set (CCDS)[5]. The IG defines standard APIs to access discrete data elements such as Patient Demographics, Problems, Medications, and Procedures for a Patient. The IG also contains specifics on transport, security, privacy, query structure, query results, information models and metadata.

2. Under the Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Committee, DAF published The Data Access Framework (DAF) Document Metadata Based Access Implementation Guide[6] as a US National Extension to provide requirements and guidance on accessing clinical documents created during clinical workflows using IHE profile. This implementation guide further constrains IHE profiles used for clinical document management and exchange.

   This IG further defines access to encounter documentation such as a Discharge Summary, History & Physical, CCD, etc., using standard APIs. Additionally the IG outlines API access using RESTful resources based on HL7 FHIR® and the more traditional Simple Object Access Protocol (SOAP) based IHE Profiles.

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[4] Bashyam, N., Haas, E., Marquard, B., DAF-Core Implementation Guide. Health Level Seven (2016) Available from http://hl7.org/fhir/us/core/

[5] 2015 Edition Common Clinical Data Set, § 45 CFR 170.102 (10/21/2016).

[6] Integrating the Healthcare Enterprise. The Data Access Framework (DAF) Document Metadata Based Access Implementation Guide (September 24, 2015). Retrieved from http://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_IG_DAF_National-Extension.pdf

The IG also contains specifics on transport, security, privacy, query structure, query results, information models and metadata.

Phase 3 (DAF for Research)

The DAF team and pilot community developed a new IG titled Health Level Seven (HL7) FHIR® DAF for Research Implementation Guide (IG) Release 1[7]. This Research IG defines the conformance requirements for capabilities used by researchers to access data about multiple patients in multiple data sources. These requirements have been developed based on the National Patient-Centered Clinical Research Network (PCORnet)[8] research activities. The DAF Research IG has also leveraged the work from the US Core IG.

Over 80% of the DAF data element needs are covered in the existing FHIR DSTU and US Core profiles. However, a small number of additional FHIR resources and profiles were developed to enable researcher workflows for PCORnet activities and this work has been completed in mapping existing PCORnet data models. This IG standardizes access to these data from multiple patients and sources by using APIs in the Extract, Transform, and Load (ETL) processes. The IG defines supporting metadata used by researchers to compose queries. The IG specifies methods to distribute query packages to multiple sources and to return aggregated data to researchers.

Standards Development Support and Standards Development Organization (SDO) Engagement

Pre-Discovery and Candidate Standards List

During the Pre-Discovery efforts, a list of potential standards was identified and listed on the Candidate Standards List for DAF. The purpose of this exercise was two-fold. First, the effort was a thought exercise to help community members brainstorm on the potential tools that could be brought to bear on the problem DAF was solving. Second, this effort allowed the DAF team to analyze the likely SDO stakeholders for DAF and to construct a communications plan and an SDO engagement strategy that encompassed this group(s). The Candidate Standards List is a comprehensive scan of all standards and related artifacts mentioned and in consideration across what was then all S&I Framework Initiatives.

DAF identified existing standards modifying or utilizing them in an IG, to solve basic data access issues faced by providers within their own organization and across organizations in a modular and substitutable fashion. DAF focused on enabling providers, their tools, and applications to access their patient's data. The standards were then evaluated for their representation of the content within the use case, functional requirements and harmonized concepts. They were also evaluated against other adopted standards in the S&I Framework, to ensure cross-initiative consistency and interoperability.

IHE Engagement

During the 2013/2014 Integrating the Healthcare Enterprise (IHE) annual Call for Proposals, DAF approached the Patient Care Coordination (PCC) domain with a Brief Proposal and Detailed Proposal to leverage existing IHE profiles and identify gaps and potential new profiles for ubiquitous data access. The PCC domain accepted

[8] PCORnet, the national patient-centered clinical research network. (2017, January 13). Retrieved from http://pcornet.org/

the work as a project to develop white paper technical documentation which would provide guidance on the DAF Framework. The final white paper was published to the IHE website as a resource of the PCC domain in July 2014. The DAF team then participated in the IHE Connectathon from January 25-30, 2015 in Cleveland, Ohio where DAF tested as a defined implementation of the IHE MHD profile. Based on the publication of the IHE DAF white paper, IHE Connectathon results, and the start of the 2014/2015 IHE cycle in September 2014, a brief and detailed proposal for a DAF Document Metadata Based Access IG was submitted and reviewed with IHE PCC domain and IHE USA. After approval and through a joint effort of the DAF project team, IHE USA and IHE PCC work began on drafting content for the IG. On September 24, 2015, the IEH PCC Technical Committee and IHE USA published The DAF Document Metadata Based Access Implementation Guide. This US National Extension provided requirements and guidance on accessing clinical documents created during clinical workflows. The guide accomplished this using RESTful resources based on HL7 FHIR® and the more traditional SOAP based IHE Profiles. There were some efforts to again participate in the IHE Connectathon in January 2016; however, several participants signed up had to pull out of testing DAF due to competing priorities.

HL7 Engagement

HL7 International Working Group Meetings (WGM) are held three times per year at varying locations. The purpose of these meetings is to give the HL7 WG's a chance to meet face-to-face to work on the standards as well as the opportunity to network with industry leaders from around the world and to provide an invaluable educational resource for the healthcare IT community. DAF presented for the first time on its work efforts and interest in FHIR at the September 2013 WGM. Then at the September 2014 WGM that the DAF team members drafted the DAF FHIR IG Project Scope Statement (PSS), producing the first Draft for Comment Ballot in January 2015 ballot cycle. The work was refined and moved on to Draft Standard for Trial Use (DSTU) in the next ballot cycle in May 2015 WGM. In the September 2015 HL7 WGM discussions centered on expanding the DAF FHIR IG PSS to support updates from pilot implementation, such as Argonaut, updates to account for FHIR DSTU 2 changes, and any additional guidance from the common clinical data set. During the May 2016 WGM, a PSS was approved for updates to the DAF FHIR IG as well as creation of the DAF Research IG. There was a desire and subsequent approval amongst the members of the HL7 US Realm Board Committee to rename the DAF FHIR IG work to FHIR US Core IG. On the other side of the DAF FHIR work was the DAF Research IG which defined the conformance requirements for capabilities used by researchers to access data about multiple patients. These requirements were developed based on the National Patient-Centered Clinical Research Network (PCORnet) research activities. The DAF Research IG also leveraged the work from the FHIR US Core IG. Over 80% of the DAF data element needs are covered in the existing FHIR DSTU and FHIR US Core IG profiles. However, a small number of additional FHIR resources and profiles were developed to enable researcher workflows for PCORnet activities and this work has been completed in mapping existing PCORnet data models. This IG standardizes access to data from multiple patients and sources by using APIs in the Extract, Transform, and Load (ETL) processes. HL7 engagement continued in January 2017 in San Antonio TX, with Standard for Trial Use (STU) ballot for the DAF Research IG. The FHIR US Core IG has been officially transferred in ownership to HL7 US Realm Board Committee for future work efforts and refinement.

Pilot Activity Results

Phase 1 and 2 (Local and Targeted DAF)

Successful real world implementations of the FHIR® US Core IG have been demonstrated through the Argonaut Project[9], a private sector initiative comprised of Health IT vendors and healthcare organizations working to accelerate development of a FHIR API and FHIR® US Core Data.

The Argonaut data element query IGs[10] were created for each 2015 Edition Common Clinical Data Set and where applicable, they are based on the HL7 FHIR® US Core IG; however, the Argonaut use case and requirements per resource are a subset of those of the HL7 FHIR® US Core IG. Test scripts for the HL7 FHIR® US Core IG were developed and tested by vendors from the Argonaut Projects (*see Appendices for test results).*

Phase 3 (DAF for Research)

In collaboration with the PCORnet community, the role of DAF Phase 3 was to identify capabilities that could enable PCORI[11] and PCORnet to implement their vision at a national scale. Three PCORnet sites took part as DAF for Research pilot participants and they included:

- **Lincoln Peak Partners (LPP):** the developers of the PopMedNet software for the PCORnet community and many others that include the FDA Sentinel post-market surveillance network, the NIH Collaboratory basic research network, and many Clinical Data Research Networks (CDRNs).[12]

- **Patient-centered SCALable National Network for Effectiveness Research (pSCANNER)** and **Research Action for Health Network (REACHnet)** are both part of the PCORnet CDRNs which are sites comprised of many different types of health systems who are partnering to conduct research as a network.

Using the PCORI/PCORnet abstract model, these three pilots implemented the capabilities listed below:

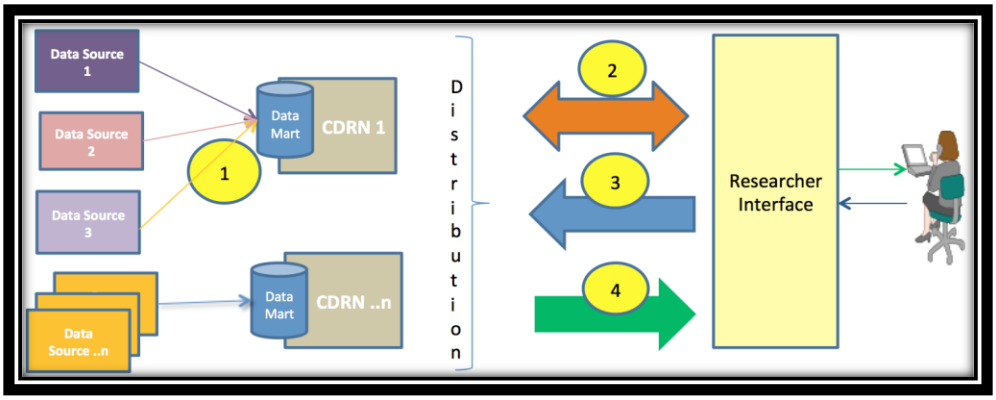

Figure 5: PCORnet Abstract Model

[9] The Argonaut Project. Health Level Seven. (2015). Retrieved from http://argonautwiki.hl7.org/index.php?title=Main_Page

[10] Argonaut Data Query Implementation Guide. Health Level Seven (2017). Available from: http://www.fhir.org/guides/argonaut/r2/index.html

[11] PCORI, Patient-Centered Outcomes Research Institute (n.d). Retrieved from http://www.pcori.org/

[12] Clinical Data Research Networks. (November 26, 2016). In PCORnet, the national patient-centered clinical research network. Retrieved from http://pcornet.org/clinical-data-research-networks/

DAF for Research Capabilities:

Capability	Description:
C1	Standardize data extraction mechanism from clinical data sources to populate data marts. *Impacts Step 1 of the PCORnet Abstract Model*
C2	Standardize metadata about data marts, CDRN's, PPRN's and data sources. *Impacts Step 2 of the PCORnet Abstract Model*
C3	Standardize Query Distribution mechanism. *Impacts Step 3 of the PCORnet Abstract Model*
C4	Standardize Query Results for returning aggregate data. *Impacts Step 5 of the PCORnet Abstract Model*
C5	Standardize Query Results for returning de-identified or identified patient data. *Impacts Step 5 of the PCORnet Abstract Model*
C6	Standardize Query Structure and Queries for identifying cohorts/populations. *Impacts Step 4 of the PCORnet Abstract Model*

Figure 6: DAF Phase 3 Capabilities

Note: C5 and C6 are deferred until C1-C4 pilot activities had been sufficiently completed and the FHIR API implementations were evaluated. It is recommended below that C5 and C6 be addressed in a future phase of DAF.

DAF Pilot Sites	Capabilities Piloted
Lincoln Peak Partners (LPP)	**C2, C3, C4**
patient-centered SCAlable National Network for Effectiveness Research (pSCANNER)	**C1, C2**
Research Action for Health Network (REACHnet)	**C1, C2, C3, C4**

Figure 7: Capabilities Piloted by DAF Phase 3 Pilots

Three PCORnet sites successfully demonstrated the use of FHIR API in ETL process in conformance with the FHIR DAF for Research Profiles and IGs. The pilots successfully mapped these data against Clinical Data Models (CDM) and Observational Medical Outcomes Partnership (OMOP) data models. Lastly, queries were composed and distributed, using standardized metadata, and standard FHIR resources, tasks, and operations in conformance with the DAF Research IG.

Pilots Results

Metrics	LPP	pSCANNER	REACHnet
Capability 1: Standardize data extraction mechanism from clinical data sources to populate data marts.	N/A	Pass	Pass
Capability 2: Standardize metadata about data marts, CDRN's, PPRN's and data sources.	Pass	Pass	Pass
Capability 3: Standardize Query Distribution mechanism.	Pass	N/A	Pass
Capability 4: Standardize Query Results for returning aggregate data.	Pass	N/A	Pass

Figure 8: Pass/Fail Results of DAF Phase 3 Pilots

Pilots Success Metrics

<table>
<tr><th>Pilot Site</th><th>Metrics</th></tr>
<tr><td>LPP</td><td>

Onboarding new DataMarts into networks is a very time consuming and costly process. An organization needs to both understand the target data model as well as data mappings from their data repository (EHR system), and then develop an ETL process to build the DataMart database. This process can take up from 3 to 12 person months depending on the complexity of the model, data, and environment. Through the use of a DAF implementation guide that determines the data mapping, standard interfaces to the data sources (both the source and target), and potentially shared ETL code source, this process will be reduced substantially, perhaps as much as 70% reduction in cost and time to prepare quality DataMarts. Add to this the use of standardized testing and quality testing services, this time could be reduced further by minimizing errors and defects in the process. Reductions in the effort to onboard DataMarts in various data model formats is perhaps the most critical factor in the success and sustainability of distributed research networks.
Standardizing query and result API's and data formats against widely used data models within a distributed research network allows heterogeneous technologies and platforms to participate within existing networks. While this hasn't be en a priority in the networks we've developed and support, we expect this to become a requirement in the future as networks gain popularity and use for clinical research. Enabling the use of heterogeneous technologies to interoperate with existing networks removes barriers to entry and reduces/eliminates costs to migrate and support technologies required to join networks. This process will also help spawn innovation in new query engines and data sources thus expanding the use and value to clinical and other application domains. It's difficult to estimate the cost/benefit of pursuing this initiative without examining real world use cases where such as strategy can be measured.

</td></tr>
<tr><td>pSCANNER</td><td>

Successful implementation of API on FHIR framework (HAPI) and demonstrate conformance.
Successful mapping from a data model.
Metadata management standards that is consistent with national and international standards (e.g. mapping of Tasks to PROV metadata).

</td></tr>
<tr><td>REACHnet</td><td>

Mapping from EMR to DAF standard stage format : 20 man days
ETL Implementation and validation (assuming no mapping issues): 7 man days
Data load 1 sec/record calculated using observation in full load

Full load record count:

<table>
<tr><td>CDM table</td><td>Record Count</td><td rowspan="9">Time required to completely ingest is approximately 7 days.</td></tr>
<tr><td>Patient</td><td>127000</td></tr>
<tr><td>Condition</td><td>1092595</td></tr>
<tr><td>Diagnosis</td><td>4091105</td></tr>
<tr><td>Encounter</td><td>929527</td></tr>
<tr><td>Lab-results</td><td>13969162</td></tr>
<tr><td>Vitals</td><td>24420817</td></tr>
<tr><td>Procedure</td><td>817732</td></tr>
<tr><td>prescribing</td><td>1672655</td></tr>
</table>
Less than a week would be required to setup the DAF for a new data partner with a known
</td></tr>
</table>

	EDW structure. Although REACHnet does not have the details in hand about what it took other partners using current model, it did take several months. The best case probably at least 3 months. • DAF supports automated refresh which is efficient and faster than compared to manual refresh. DAF made weekly incremental data ingestion possible. The best performing site has only now tried to do a monthly refresh using the current model. REACHnet is still not sure if we will be able to process on a monthly basis using the current processes. Other sites are still taking 3-5 months to process a new load. So, DAF will definitely be a substantial improvement compared to current processes. • REACHnet now ingest files by either receiving a full load or an incremental. These are large flat files. Thus, REACHnet would have to measure how many records are sent and how long it will take to ingest them along with any manual processes involved. It can be done, but it would take some time. • FHIR layer allows conversion of transformation to other data models easier and faster. • Given that an API is placed in the data partner site, the integration of SMART apps or any other applications are possible because of DAF architecture. This is a tremendous advancement as there are many other use cases for clinical data beyond ingestion in data marts for research. For instance, REACHnet is working on a public health reporting App in partnership with the Louisiana Department of Health and Blue Cross Blue Shield. Also, we have a tablet-based App suite that is placed at the point of care to recruit patients in clinical trials that could also benefit from an API and timely access to the clinical data. This is VERY important because we can build it once and it allows for many use cases.

Figure 9: Success Metrics of DAF Phase 3 Pilots

Note: To learn more about the details of pilot activities, review presentations and to view the live demo, please visit Appendix A of this document.

Summary

Value of DAF

Through the development of the US FHIR® Core Standards, DAF successfully created a modular and substitutable framework to enable Local and Targeted data access using the various data query mechanisms (document based, data element based, quality measure based, etc.). This enables providers to more efficiently assemble a patient's complete information in a timelier manner. This efficiency leads to better coordinated care without additional costs.

Through the development of the FHIR® DAF for Research Standards, researchers can now access multiple patients' data using standards for data queries, APIs, or services and derive value from complex data using multiple sources without having to rely on existing and often proprietary access paths. DAF for Research has helped advanced research efforts to develop an interoperable data network infrastructure maximizing efficiency, advancing research opportunities and improving future health policies. By providing standard mappings to and from FHIR profiled resources, DAF for Research reduces the efforts necessary to add new data sources as well as new data mart models.

Benefits to healthcare professionals, healthcare organizations, researchers and research organizations include but are not limited to the following:

- Reducing organizational costs of sharing data to provide better care coordination
- Replacing proprietary systems APIs by utilizing standardize APIs enabling greater access enables simpler ETL and data model mappings
- Bridging future technology with existing healthcare systems
- Providing a common foundation for new applications

Lessons Learned

General

- In order to produce consensus based implementation guides and standards refinement it is necessary to work in collaboration with SDOs (i.e., HL7 and IHE). Participation with those organizations is resource and time consuming. Without work effort sponsorship and committed resources, work is unlikely to succeed in producing timely, effective, and adopted interoperability specifications.
    - During the IHE white paper and profile development process DAF team members participated in 2 complete IHE development cycles (each 18 months in length), multiple face to face meetings, numerous domain calls, and an IHE North America Connectathon.
    - During the HL7 development process the DAF team members participated in two HL7 FHIR based implementation guides and resource development, five FHIR ballot cycles, 9 face-to-face work group meetings, numerous calls, and resolved thousands of ballot comments.
    - In addition, DAF team members help guided selected SDO work-group efforts that support DAF (e.g, the HL7 Security WG, the HL7 Community Based Collaborative Care WG, the IHE IT Infrastructure Domain, OpenID, and HEART-Health Relationship Trust Profile for OAuth 2.0).

Phase 1 and 2 (Local and Targeted DAF)

- To facilitate development of the query/response implementation specifications, certain simplifying assumptions concerning patient consent, privacy and security policy and methods were made. In order for widespread use of Local and Targeted DAF IGs, these assumptions must be fulfilled using standards adopted by industry, Where those standards are insufficient, participation in the relevant SDO work-groups is necessary to help amend the standards and avoid duplication of effort.
- Document metadata based queries have well established underlying IHE profiles, e.g., XCA, that have been adopted and further constrained by Commonwell and Carequality as well as in the Sequoia project. There has been some level of coordination between DAF and these other initiatives. However, in the absence of governance models and supporting organizations it is not clear the DAF IG will be as readily adopted as compared to these other industry efforts.
- If the FHIR US Core IG, based directly on profiles of FHIR resources and demonstrated by the Argonaut initiative, becomes the industry adopted FHIR IG for data element based query it will depend on the widespread adoption of FHIR resources and APIs.
- The DAF experience with each of these IGs shows the importance of close working relationships with the sponsoring SDO/profiler/developer, industry partners and user communities willing to implement the specifications. The industry is currently doing things based on other standards not FHIR, and we were unable to test in those environments due to the fact we were closely tied to FHIR which has yet

to have wide industry adoption. We however believe that in time FHIR will become more widely adopted and our work will be in alignment.

Phase 3 (DAF for Research)

- Drafting a use case for Phase 3 DAF for Research would have been beneficial to outline the roles of the requesters/users, define the actors, outline the purposes for the requested data, determine the types of data that would be accessed, understand the data etc. Developing use case(s) and specific requirements from a broad charter is valuable in both producing specific plans, priorities and phasing but in the process of building community consensus. Time lost in use case development process is offset by time lost debating and rehashing unclear business requirements and scoping.
- Expanding DAF for Research scope to support secondary users of clinical data (e.g. quality measures, public health reporting, etc.) would allow for more stakeholders within the healthcare IT community to implement DAF IG's.
- True success of DAF for Research can only be measured once a mature set of "core" FHIR APIs is adopted by a larger community of EHR vendors, using DAF Research Profiles/Extensions.
- Implementing C5 and C6 are the most significant ways to improve the query and response capability in querying detailed data sets for research and analytics. *(Note: These capabilities were not piloted as part of the DAF for Research Pilot).*
- Recruiting pilots for DAF for Research was challenging because members of the larger DAF community felt the scope was too narrow, focusing only on the PCORnet community, which has specific data models, non-standard security and privacy controls methods for performing complex aggregate queries making it difficult on both a resource and monetary level for those not part of the current PCORnet process. Additional challenges in recruitment include: organizations not having resources to access and implement FHIR as outlined by the pilot requirements; organizations were unable to obtain consensus and sign-off within the organization for participation, and many organizations had competing national HealthIT priorities (certification, MU etc.).
- Understanding an EMR system and mapping it to FHIR is challenging. Source data is not always in structured format and does not follow standard coding systems. Many fields are manually populated; contain plain text and NULL values. Significant efforts are needed to cleanup and put the data into standard format that can be mapped to FHIR APIs. This challenge will be greatly simplified, although not made plug and play, by health IT vendors' adoption of native FHIR API's and resources.
- FHIR resources need to be added extended to accommodate some CDM fields and additional data model maps as these come on line.
- Enumeration in FHIR fields is different than CDM enumeration and a convertor is required to handle this.
- Authentication is enabled at operating system level to avoid anonymous access to the DAF deployed components. More discreet security and privacy protections, based on well-defined risk models and employing industry standards, would address additional vulnerabilities.

Note: to explore more "lessons learned" as outlined by Phase 3 pilots, please review the pilot final reports found in Appendix A of this document.

Recommendations

General

- ONC should work to reference the FHIR US Core IG, DAF IGs and Profiles in future iterations of the Interoperability Standards Advisory (ISA).
- Work with SMART on FHIR and HEART to support to allow Smart researcher Apps.
- Incorporate standard security methods, e.g., OAuth2, as referenced by SMART on FHIR.
- Continue to work and coordinate closely with key SDOs, e.g., HL7 FHIR and IHE, to maintain and enhance implementation guides.
- Participate in the relevant SDO work-groups as necessary to help amend supportive standards and avoid duplication of effort, especially for security and privacy.
- Develop dedicated DAF sponsors/participants in ongoing DAF IG support within the SDO(s).
- Consider an ONC sponsored cross SDO US Realm to coordinate US national interoperability interests. This should include some funding for focused development and pilots.

US FHIR® Core IG

- Encourage national profiles of FHIR resources, DAF, SDC and CQF, to use US Core as their foundation.
- Contribute to the HL7 FHIR governance and management efforts to assure success of FHIR standards.
- Encourage industry adoption of FHIR technical specifications and US Core Profiles.

DAF for Research

- Support implementation of DAF by other research and analytic organizations.
- Use existing industry standards for risk analysis and mitigation for security and privacy, simplifying technical interoperability and the related policy work for Institutional Review Boards.
- Support the research subject informed consent requirements in the recently-updated Common Rule (45 CFR Part 46).
- Expand the DataMart Metadata to include additional information discussed in early design meeting such as Data Dictionary, DataMart Environment, Data Governance, etc., as these elements could be key to a truly interoperable research network.
- Continue the design and development of Capability 5 to standardize FHIR Query Results for returning de-identified or identified patient data.
- Continue the design and development of Capability 6 to standardize native FHIR based Query Structure and Queries for patients' level data in cohorts/populations.
- Present DAF for Research as a candidate for the Precision Medicine Initiative (All of US) and other PCORnet CDRNs.
- Encourage adoption by business clients that manage large databases of secondary data that signal convergence between healthcare operations and healthcare research (CMS, Other Payers, Large health systems).

Note: To explore more detailed "recommendations" as outlined by Phase 3 pilots, please review the pilot final reports found in Appendix A of this document.

Appendix A: DAF Project Deliverables

DAF General Reference Materials	
DAF Wikipage	The DAF wiki home page which houses all DAF Initiative artifacts and meetings materials
DAF Initiative Kickoff	This is the slide presentation from the DAF/ONC initiative kickoff from July 16, 2013
DAF Phase 1 (Local) and Phase 2 (Targeted) Project Charter	The document describes the overall DAF project charter, including the challenge statement, scope, deliverables and timelines
DAF Terminology	This wiki page describes the terminology that will be used by the community to discuss DAF standards
FHIR Overview	This presentation provides a high-level overview of API's, the HL7 FHIR Standard (including FHIR Resources, FHIR implementation guides and profiles), along with values sets, security components, and more. (9/17/2015)
DAF Use Case Documents	
DAF Local Access Use Case 1(Phase 1)	This document outlines the scope of the Local Data Access Use Case and defines the requirements for intra-organizational data access (published 12/11/2013)
DAF Targeted Access Use Case 2 (Phase 2)	This document outlines the scope of the Targeted Data Access Use Case and defines the requirements for inter-organizational data access (published 2/5/2014).
DAF Phase 3 Reference Materials	
DAF Phase 3 Technical Overview	An overview of the PCORnet Abstract Model as well as the Proposed Technical abilities.
DAF Phase 3 (DAF for Research) Project Charter	The charter describes the challenge statement, scope, capabilities and of data access for Research.
Phase 3 Pilot Requirements	Information on the minimum technical requirements an organization must meet for Phase 3 piloting.
DAF Phase 3 FAQs	These draft slides address the frequently asked questions for data access for research.
Functional Requirements	Functional Requirements identify the capabilities a system in a role must have in order to enable interoperable exchange of the healthcare data of interest. They provide a detailed breakdown of the requirements in terms of the intended functional behaviors of the application. Tabs (C1-C6) contain information about the Functional Requirements needed for each capability. (4/6/16)
PCORnet Common Data Model (CDM) Specification, Version 3.0 and PCORnet Common Data Model v3.0 – parseable	The Common Data Model (CDM) is a way of organizing data into a standard structure. The approach PCORnet is using to do this mirrors the approaches used by other large national research consortia, including the HMO Research Network and the Mini-Sentinel Network. To learn more click here.
DAF Phase 3 Pilot Deliverables	
Lincoln Peak Partners (LPP)	• Kickoff Presentation *(2/24/16)* • Final Pilot Report-Out Presentation *(11/30/16)*
Patient-centered SCAlable National Network for Effectiveness Research (pSCANNER)	• Kickoff Presentation *(8/24/16)* • C1 and C2 demo • Final Pilot Report-Out Presentation *(10/19/16)*

Research Action for Health Network (REACHnet)	• Kickoff Presentation *(4/6/16)* • C1 demo • C1-C4 demo *(1/23/2016)* • Final Pilot Report-Out Presentation *(1/25/2017)*
DAF Initiative Publications	
DAF FHIR® IG DSTU 1.0	On September 23, 2015, Health Level Seven® International (HL7®) published Release 2 of the HL7 Fast Healthcare Interoperability Resources (FHIR®) Draft Standard for Trial Use (DSTU). Additionally, the DAF FHIR Implementation Guide, a US-realm specific implementation guide, was also published. The DAF FHIR IG identifies and recommends standards for the interoperable representation and transmission of data using the notion of a Query Stack, which modularizes the various layers of the Data Access Framework.
US Core FHIR® IG	On March 22, 2017 HL7® officially released and published FHIR Release 3 (STU). US Core FHIR Implementation Guide (Release 1) officially released its version, based on FHIR Version 3.0.0.The US Core Implementation Guide defines the minimum conformance requirements for accessing patient data as defined by the Argonaut pilot implementations and the ONC 2015 Edition Common Clinical Data Set (CCDS). These profiles are intended to be the foundation for future US Realm FHIR implementation guides. In addition to Argonaut, they are used by DAF-Research, QI-Core, and CIMI. Under the guidance of HL7 and the HL7 US Realm Steering Committee, the content will expand in future versions to meet the needs specific to the US Realm: http://hl7.org/fhir/us/core/
DAF for Research STU1 FHIR® IG	THis is expected for publication on or around March 30, 2017: http://hl7.org/FHIR/us/daf/2016Sep/index.html
DAF Document Metadata Based Access Implementation Guide	On September 24, 2015, the Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Committee published The Data Access Framework (DAF) Document Metadata Based Access Implementation Guide. This US National Extension provides requirements and guidance on accessing clinical documents created during clinical workflows. The guide accomplishes this using RESTful resources based on HL7 FHIR® and the more traditional SOAP based IHE Profiles.
DAF/IHE White Paper	On October 24, 2014, the IHE Patient Care Coordination (PCC) domain has published the DAF White Paper, A Data Access Framework Using IHE Profiles as a resource artifact under the IHE technical framework resources.
HL7 FHIR Connectathon Results	
FHIR Connectathon 14	The US Core IG participated in FHIR Connectathon 14 as an official track proposal from January 14-15, 2017 in San Antonio, TX. Testers included: Servers- Aegis.net, Inc., Cerner, T-System, Inc., Transcend Insights, GE Healthcare Digital. Clients- Aegis.net, Inc. Details on the US Core test track can be found here: https://docs.google.com/spreadsheets/d/1b_zI38TvseYgENOozuVUYPB0fsX-THUm4tRHpJu36kI/edit#gid=0.
FHIR Connectathon 13	The US Core IG participated in FHIR Connectathon 13 in September 2016 in Baltimore, MD. Testers included: Servers: Aegis.net, Inc., Allscripts, Cerner, Epic, Intersystems, T-System, Inc., Mayo Clinic. Clients: Aegis.net, Inc. Cigna, CIOX Health, InterSystems, Medidata Solutions, Philips, Qvera, XMLModeling, VA. Testing Tools: Crucible, Touchstone Details on the US Core test track can be found here:https://docs.google.com/spreadsheets/d/1rrz8yqkG5gHhSEzUvZxP-6_CCFr_6F0FUElFRGmObyw/edit#gid=1058013156

FHIR Connectathon 12	The DAF Core IG (later renamed to US Core IG) participated in FHIR Connectathon 12 from May 7-8, 2016 in Montreal, Canada. Details on the test track can be found here.
FHIR Connectathon 11	The DAF Core IG (later renamed to US Core IG) participated in FHIR Connectathon 11 from January 9-10, 2016 in Orlando, FL. The following vendors formally signed-up to test DAF (additional onsite participants were expected): Cerner, Qvera, Care Evolution, Aegis.net, Inc., InterSystems, McKesson and Transcend Insights.
IHE N.A. Connectathon Results	
IHE N.A. Connectathon 2015	The DAF team participated in the IHE N.A. Connectathon from January 25-30, 2015 in Cleveland, Ohio where DAF tested as a defined implementation of the IHE MHD profile.

Appendix B: DAF Milestones

DATES	MILESTONES
2013	
July 16, 2013	DAF Initiative launched
August 28, 2013	Project Charter reached consensus
December 11, 2013	Use Case 1-Local DAF reached consensus
2014	
February 5, 2014	Use Case 2-Targeted DAF reached consensus
May 20-August 12, 2014	DAF participated in ONC Joint Initiative Alignment (DAF/SDC/CQF)
June 17, 2014	DAF presented to HITSC
July 10, 2014	DAF presented to FACA HITSC NwHIN Power Team
September 12-December 17, 2014	DAF participated in ONC Cross Initiative Data Modeling Review Tiger Team (DAF/SDC/CQF/DPROV)
October 24, 2014	DAF IHE White Paper published to IHE PCC Domain Resources on IHE website
2015	
December 12-January 12, 2015	DAF FHIR IG (comment only) and Profile Ballot open for comment Negative: 41, No Vote: 39, Affirmative: 26, Abstain: 59, Removed 1—TOTAL 166
January 17-18, 2015	DAF participated in the 8th FHIR Connectathon in San Antonio, TX
January 25-30, 2015	The DAF team participated in the IHE N.A. Connectathon from January 25-30, 2015 in Cleveland, Ohio where DAF tested as a defined implementation of the IHE MHD profile.
February 3, 2015	DAF presented at ONC Annual Meeting in Washington, DC
March 19, 2015	HL7 presented a webinar on Argonaut and referenced they will continue to leverage existing DAF Profiles
April 3, 2015	The deadline to submit comments for the draft ONC Interoperability Roadmap. The roadmap specifically identifies the DAF Initiative and its ability to support query services. DAF encourages the community to provide feedback on the appropriateness of DAF IG's through the online comment form
April 3-May 4, 2015	DAF FHIR IG DSTU 2 and Profile Ballot open for comment Negative: 59, No Vote: 38, Affirmative: 47, Abstain: 74 —TOTAL Approximately ~230 comments by ~20 unique commenters
April 12-16, 2015	HEART demo utilizing DAF components at HIMSS 2015
May 29, 2015	The deadline to submit comments for the draft 2015 Notice of Proposed Rulemaking (NPRM). The DAF Use Cases

	have been identified in the Rule (Objective: Application Access to Common Clinical Data Set - 170.315(g)(7)), although the DAF IG's have not been listed. We encouraged community members to provide feedback on whether the DAF IG's should be included as they become published to certify for the above objective
June 8, 2015	DAF presented to PCOR
June 24, 2015	DAF Presented to the HITSC
June 25, 2015	DAF presented to ONC Interoperability WG
June 29, 2015	DAF and SDC to presented to PCORnet
July 21, 2015	DAF/SDC presented on the PCORnet Best Practices Series https://www.nihcollaboratory.org/Pages/Knowledge-Repository.aspx
September 9, 2015	Phase 3 Launched with DAF S&I Community
September 9, 2015	DAF presented at DoD/VA IPO
September 23, 2015	DAF FHIR IG DSTU PUBLISHED
September 24, 2015	DAF Document Metadata IG PUBLISHED
2016	
January 9-10, 2016	DAF tested at FHIR Connectathon 11
February 24, 2016	Lincoln Peak Pilot Kickoff with DAF/S&I Community
April 6, 2016	REACHnet Pilot Kickoff with DAF/S&I Community
May 7-8, 2016	DAF tested at FHIR Connectathon 12
June 1, 2016	DAF Presents at ONC Annual Meeting
August 24, 2016	pSCANNER Pilot Kickoff with DAF/S&I Community
September 18-23, 2016	HL7 30th Annual Plenary & WG Meeting in Baltimore, MD *DAF Core STU1 (InM and FHIR I)* Affirmative: 27 Negative: 53 Comments: ~119 The name of the IG has been renamed to US Core IG. It was updated to be able to clearly identify the core profiles that US implementations should support and was approved by HL7 US Realm Steering Committee on Thursday 9/22 at the WGM in Baltimore, MD *DAF for Research Comment Only (InM and FHIR I Primary; RCRIM Co-Sponsor)* Affirmative: 27 Negative: 30 Comments: ~90
September 17-18, 2016	DAF tested at HL7 FHIR Connectathon 13

October 19, 2016	pSCANNER Final Pilot Report
November 22, 2016	DAF for Research PSS updated
November 30, 2016	LPP Final Pilot Report
2017	
January 14-15, 2017	DAF tested at HL7 FHIR Connectathon 14
January 16-20, 2017	HL7 31th Annual Plenary & WG Meeting in San Antonio, TX DAF for Research STU 1 96 comments 1 - In person - Clem 8 - Ready for Block Vote 14 - Typos Ready for Block Vote 3 - Publication Related 17 - Move to other ballots - FHIR core, C-CDA on FHIR, US-core 53 - Need additional review and potential discussion at WG or conference call
January 24, 2017	Joint Pilots Demo call with Steve Posnack (OST/ONC)
January 25, 2017	REACHnet Final Pilot Report
January 30, 2017	DAF submitted recommendations for 2017 ISA Task Force
March 20, 2017	FHIR STU3, US Core STU1 and DAF for Research STU1 is expected for publication on or around March 20, 2017.
March 22, 2017	DAF Closing Ceremony

Appendix C: DAF Security and Privacy

Overview

The security and privacy strategy employed by DAF is to leverage existing standards and associated best practices. This maximizes interoperability and minimizes the cost and effort needed to include DAF capabilities in Health IT systems. It includes:

- **Data Transport** using the widely-implemented TLS protocol industry standard for authenticated communication endpoints and encryption
- **User Identification and Authentication** using the widely-implemented OpenID industry standard
- **Access Authorization** using the widely-implemented OAuth 2.0 industry standard, supplemented by patient consent for data access
- **Auditing** using the HL7 FHIR Audit resource and its underlying industry standards
- **Data Authentication** using the HL7 FHIR Provenance resource and, optionally, W3C Digital Signature industry standards
- **Security Labels** for optional fine-grained access control using HL7 FHIR labeling specifications

The DAF implementation guides stress the importance of conformance with HIPAA security and privacy regulations, which include policy-level and risk management. Specifications for these policy and administrative controls are out of scope for DAF.

During the DAF project, SME participation in the HL7 Security and Community Based Collaborative Care (CBCC) work-groups has guided the continued development of the FHIR Security, Auditing, Provenance, and Consent resources. This helps ensure support for DAF implementation requirements. These specifications have been balloted in HL7 at the same time as DAF.

Additionally, SME participation in the OpenID HEART (Health Relationship Trust Profile for OAuth 2.0) work-group has guided development of a user-managed access authorization (UMA) framework to supplement OAuth 2.0 with automated patient consent enforcement. This is a work in progress that may be incorporated in additional DAF work after the current project ends.

Phase 1 and 2 (Local and Targeted DAF)

The DAF HL7 Implementation Guide includes security guidance. This specifies the following:

- Conformance with HIPAA security and privacy regulations for policy and administrative controls
- Common time-base to help assure audit and data provenance integrity
- Auditing using the FHIR AuditEvent resource
- TLS transport authentication and encryption
- Conformance with FHIR communication specifications
- OAuth 2.0 for user identification, authentication and authorization, referencing the SMART on FHIR OAuth 2.0 scopes

- Optional FHIR security labeling for especially sensitive data
- Patient consent for data access per state, local, and institutional policies (The FHIR Consent resource supports this.)
- Optional data provenance tracking using the FHIR Provenance resource
- Optional data authentication using W3C digital signatures
- Cautions for displaying narrative text data that may contain active content such as CSS, XSLT, and external hyperlinks.

The corresponding The Data Access Framework (DAF) Document Metadata Based Access Implementation Guide specifies the many of the same requirements, referencing the relevant IHE profiles. This supports DAF among Health IT systems that have not implemented HL7 FHIR.

The DAF HL7 implementation guide is congruent with the Argonaut project's security and privacy work.

While security and privacy protections are also needed for Health IT systems' databases storage and access, they are out of scope for DAF.

Phase 3 (DAF for Research)

The DAF HL7 Implementation Guide for Research recognizes the current state of research systems that are typically disjointed from Health IT systems. Accordingly:

- C1 security and privacy is standardized when using HL7 FHIR APIs for data acquisition. The DAF HL7 Implementation Guide applies.
- C1 security and privacy is non-standardized when not using 7 FHIR APIs and for C2-C6. DAF recommends the use existing industry standards for risk analysis and mitigation, simplifying technical interoperability and the related policy work for Institutional Review Boards

In health research, security and privacy requirements are specified in the Common Rule (45 CFR Part 46). Institutional Review Boards are the controlling policy bodies, and they are expected to conform to relevant federal, state, local, and institutional regulations.

The particular requirements for patient informed consent differ from those in health IT system environments. Accommodating these differences is a subject of ongoing work within SDOs via the HL7 Community Based Collaborative Care work-group's FHIR Consent resource specification and other vehicles. This is out of scope for DAF.

Appendix D: SDO Engagement Details

IHE Engagement

During the 2013/2014 Integrating the Healthcare Enterprise (IHE) annual Call for Proposals, there were three domains in IHE that were open for new business: Patient Care Coordination (PCC) IT Infrastructure (ITI), and Quality, Research, and Public Health (QRPH). In the organizational chart of each domain, there is a Planning Committee and a Technical Committee, each of which conducts their own face-to-face meetings to review the proposals and vote to move the work forward in their domain of IHE. The first step in the IHE process is to submit a Brief Proposal to the Planning Committee who is responsible for the first pass review. In October 2013 the Brief Proposal meeting was in Oakbrook, IL. Their focus was to review the problem defined in the proposal and ascertain if it is relevant to their domain and IHE as well as to review whether the proposed work is something that IHE already has worked on in the past. If the body of work is accepted by the Planning Committee of that domain, the next step is to submit a detailed proposal to the Technical Committee. In the November 2013 Detailed Proposal meeting, aface-to-face meeting again held in Oakbrook IL, their charge was to conduct a more in depth review focusing on validating if the work is technically possible and the resources needed were available for this work to be completed and published within IHE. At the end of those meetings there was again a vote by that committee to accept the body of work into their IHE domain. DAF approached IHE to leverage existing IHE profiles and identify gaps and potential new profiles for ubiquitous data access and submitted a brief proposal to all three domains. It was accepted by the planning committee and technical committee of the PCC domain as a project to develop white paper technical documentation which would provide guidance on the DAF Framework. On November 25, 2013 the IHE/ S&I Joint Technical Workgroup was launched; Keith Boone (PCC Expert Author) and (Dragon) Nagesh Bashyam, ONC's Technical Support Lead, led the work. In efforts to help support the advancement of the whitepaper to the overall DAF Framework technical solution there was recurring calls every Monday till the deadline of February 3, 2014 at which time it was presented at the IHE Volume One meeting February 2014. A 60 day public comment period followed and then disposition of comments was presented at the IHE Public Comment meeting May 2014 with a final published white paper to the IHE website as a resource of the PCC domain in July 2014. The DAF team then participated in the IHE Connectathon from January 25-30 2015 in Cleveland, Ohio where DAF tested as a defined implementation of the IHE MHD profile. Based on the publication of the IHE DAF white paper, IHE Connectathon results, and the start of the 2014/2015 IHE cycle in September 2014, a brief and detailed proposal for a DAF Document Metadata Based Access IG was submitted and reviewed with IHE PCC domain and IHE USA. After approval and through a joint effort of the DAF project team, IHE USA and IHE PCC work began on drafting content for the IG. On September 24, 2015, the IEH PCC Technical Committee and IHE USA published The DAF Document Metadata Based Access Implementation Guide. This US National Extension provided requirements and guidance on accessing clinical documents created during clinical workflows. The guide accomplished this using RESTful resources based on HL7 FHIR® and the more traditional SOAP based IHE Profiles. There were some efforts to again participate in the IHE Connectathon in January 2016; however, several participants signed up had to pull out of testing DAF due to competing priorities.

HL7 Engagement

HL7 International Working Group Meetings are held three times per year at varying locations. The purpose of these meetings is to give the HL7 WG's a chance to meet face-to-face to work on the standards as well as the opportunity to network with industry leaders from around the world and to provide an invaluable educational resource for the healthcare IT community. The 27th Annual HL7 Plenary & Working Group Meeting (WGM) took place from September 2013 in Cambridge, MA. Data Access Framework presented for the first time at this meeting to the Technical Steering Committee (TSC) and Clinical Quality Improvement (CQI). The feedback from the meetings was positive and there was interest in DAF. TSC commends DAF for bringing this in at the beginning of the process and the conducting an extensive environmental scan for existing standards to leverage. Austin Kessler from the TCS also pointed out the options with FHIR and DAF. At the HL7 WGM in San Antonio, TX in January 2014, more informal discussions continued with TSC members and other workgroups around if the FHIR standard could be a solution. John Feikema, the Initiative Coordinator, presented DAF initiative status and current completed work to date with Infrastructure and Messaging (INM) and Implementable Technology Specifications (ITS) at the May 2014 HL7 WGM in Phoenix, AZ. INM has interest in the work effort, and will conduct WG conference calls to have initial discussions of scope of work and current gaps as identified for possible draft PSS for September 2014 WGM. At the next HL7 WGM in September 2014 in Chicago, IL, the first official HL7 DAF Project Scope Statement (PSS) was introduced and approved by the US Realm Steering Committee, INM WG, Structured Documents WG (SDWG), and Orders and Observations (O&O). In January 2015 DAF produced a Draft for Comment Ballot DAF FHIR IG, getting 166 votes and 289 comments. After ballot reconciliation of the comment only ballot, the work efforts surrounded creating a Draft Standard for Trial Use (DSTU) DAF FHIR IG and then reviewing it at the May 2015 HL7 WGM in Paris France. In the September 2015 HL7 WGM discussions centered on expanding the DAF FHIR IG PSS to support updates from pilot implementation, such as Argonaut, updates to account for FHIR DSTU changes, and any additional guidance from Meaningful Use. By the end of the WGM it was officially approved. By the January 2016 WGM in Orlando FL, the DAF FHIR IG was an official track in FHIR Connectathon 11. Then in the May 2016 WGM in Montreal Quebec Canada, DAF again was an official track in FHIR Connectathon 12. The participation in Connectathon give the IG testing and validation for updates and revisions necessary. Also in May 2016 a PSS was approved thru the FHIR Infrastructure (FHIR-I) WG with co-sponsorship with Regulated Clinical Research Information Management WG (RCRIM) for the creation and continuation of the DAF FHIR IG as well as a DAF Research IG. The DAF FHIR IG was following a path of continued updated from implementations, as well as updated based on regulations as they evolved. There was a desire and subsequent approval amongst the members of the HL7 US Realm Board Committee to rename the DAF FHIR IG work to US Core FHIR IG. On the other side of the DAF FHIR work was the DAF Research IG which defined the conformance requirements for capabilities used by researchers to access data about multiple patients. These requirements were developed based on the National Patient-Centered Clinical Research Network (PCORnet) research activities. The DAF Research IG has also leveraged the work from the US Core IG. Over 80% of the DAF data element needs are covered in the existing FHIR DSTU and US Core profiles. However, a small number of additional FHIR resources and profiles were developed to enable researcher workflows for PCORnet activities and this work has been completed in mapping existing PCORnet data models. This IG standardizes access to data from multiple patients and sources by using APIs in the Extract, Transform, and Load (ETL) processes. In September 2016 in Baltimore MD, US Core FHIR IG participated in FHIR Connectathon 13, with much

success and continued feedback. Also during the September ballot cycle, DAF Research IG participated with a Comment Only ballot. HL7 engagement continued in January 2017 in San Antonio TX, with FHIR Connectathon 14 participation as well as a continued Standard for Trial Use (STU) ballot for the DAF Research IG under the FHIR-I WG. US Core FHIR IG has been officially transferred in ownership to HL7 US Realm Board Committee for future work efforts and refinement.