

Data Access for Research - Phase 3

To access the PDF version of the DAF Phase 3 charter page, [click here](#).
Phase 3 Pilot information can be [found here](#).

Introduction

The nation is reaching a critical mass of HealthIT systems (EHRs, Data Warehouses etc) that comply with data and vocabulary standards. The wide deployment of HealthIT systems has created unique opportunities for providers, provider support teams, healthcare professionals and organizations etc. to access and use the patient data that is already collected during clinical workflows. In order to enable access to data, DAF Phase 1 and Phase 2 focused on identifying standard Application Programming Interfaces (APIs) for accessing data within an organization (also called as Local DAF) and from trusted external organizations (also called as Targeted DAF) for treatment and payment purposes. DAF Phase 1 and Phase 2 activities and artifacts can be accessed [here](#).

DAF Phase 3 on the other hand will focus on enabling researchers to access data from multiple organizations in the context of Learning Health System (LHS). The capabilities created as part of DAF Phase 3 are intended to be leveraged to build our nation's data infrastructure for a Learning Health System. DAF Phase 3 will leverage work that has been completed in DAF Phase 1 and Phase 2 as appropriate.

Learning Health System (LHS) and DAF

The Institute of Medicine (IOM) defines a Learning Health System as “one that is designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care.” IOM has conducted a series of workshops on Learning Health System and published a number of resources which are listed below.

- <http://iom.nationalacademies.org/~media/Files/Activity%20Files/Quality/VSRT/Core%20Documents/LearningHealthSystem.pdf>
- <http://iom.nationalacademies.org/reports/2011/digital-infrastructure-for-a-learning-health-system.aspx>
- <http://iom.nationalacademies.org/reports/2011/engineering-a-learning-healthcare-system.aspx>
- <http://iom.edu/Reports/2011/Clinical-Data-as-the-Basic-Staple-for-Health-Learning.aspx>
- <http://nam.edu/perspectives-2013-making-the-case-for-continuous-learning-from-routinely-collected-data/>

Fundamental to the LHS vision is a data infrastructure that allows definition, collection, access and use of health data from one or more data sources with the appropriate privacy and security safeguards. DAF aims to provide some of the building blocks necessary to build the LHS data infrastructure.

Patient Centered Outcome Research Institute (PCORI), PCORNet and DAF

PCORI is an independent nonprofit, nongovernmental organization authorized by Congress in 2010 to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers and policy makers make informed health decisions. Specifically, PCORI funds comparative clinical effectiveness research or CER as well as support work that will improve the methods used to conduct such studies. PCORnet, the National Patient-Centered Clinical Research Network is an innovative initiative of PCORI. PCORnet will transform clinical research by engaging patients, care providers and health systems in collaborative partnerships that leverage health data to advance medical knowledge and improve healthcare. PCORnet will bring together health research and healthcare delivery, which have been largely separate endeavors. By doing so, this national health data network will allow us to explore the questions about conditions, care and outcomes that matter most to patients and their families. PCORnet integrates health data for studies and catalyzes research partnerships among two types of networks: [Clinical Data Research Networks \(CDRNs\)](#), which are based in healthcare systems such as hospitals and health centers, and [Patient-Powered Research Networks \(PPRNs\)](#), which are run by groups of patients and their partners who are focused on one or more specific conditions or communities, and who are interested in sharing health information and participating in research. Their efforts are supported by a Coordinating Center.

Collaboratively with PCORI and PCORnet the role of DAF Phase 3 is to identify capabilities (standards, tools, and policies) that can enable PCORI and PCORnet to implement their vision at a national scale. DAF Phase 3 intends to pilot identified capabilities within the PCORnet environment before finalizing the capabilities as building blocks for a national data infrastructure.

Potential DAF Phase 3 Capabilities

This section identifies a set of potential capabilities that could improve the ability of PCORI/PCORnet researchers to access data. Each of these capabilities need to be pilot-ed and then standardized to realize the benefit on a national scale. In order to outline the potential capabilities and their benefits we first examine an abstract model describing how PCORnet functions currently which is shown in the graphic below.



Step 1: Creation of Data Marts within CDRN's and PPRN's

1. ETL's (Extract, Transform and Load Utilities) are written to extract data from one or more data sources and loaded into a data mart to be queried by researchers
 - a. Data Marts are currently following a common implementation data model called PCORnet Common Data Model (PCORnet CDM)

Step 2-5: Researcher submitting a query and examining the query results

2. Researcher composes a query to be submitted to various data marts (permissions and access controls determine who can query what data, at what time, and for what purpose)
3. Queries are distributed to various sites depending on access controls, frequency, date, time, orchestration pattern, etc.
4. Queries are executed and results computed on the data marts, optionally reviewed by the local site
5. Query results are released by the networks to the researcher along with data disclosure policies

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Based on the above PCORnet abstract model and the current industry momentum in implementing the HL7 Fast Healthcare Interoperability Resources (FHIR) specifications, the following are a potential list of capabilities along with their benefits that can be developed as part of DAF Phase 3.

Capability	Details	Benefits
C1: Standardize data extraction mechanism from clinical data sources to populate data marts. (Impacts Step 1 of the PCORnet Abstract Model)	- Leverage the DAF FHIR profiles from Phase 1 and create an ETL Implementation Guide to extract data from clinical systems using standards - Create a Mapping between DAF FHIR profiles and PCORnet CDM to help populate the Data Mart	- Reduces the CDRN, PPRN data source onboarding time - Reduces the burden of maintaining ETL's and customary data mappings for each data source
C2: Standardize metadata about data marts, CDRN's, PPRN's and data sources. (Impacts Step 2 of the PCORnet Abstract Model)	Leverage the existing PCORnet data mart definitions allowing for appropriate modifications and publish them as existing or new FHIR resources.	- Provides dynamic capability to researchers to determine data characteristics of a data source, data mart or a network. - Aids in researcher decision making in terms of CDRN/PPRN/research activity selection along with needed outreach

C3: Standardize Query Distribution mechanism (Impacts Step 3 of the PCORnet Abstract Model)	• Leverage the existing PCORnet query distribution mechanism allowing for appropriate modifications and publish them as existing or new FHIR resources	• Provides researcher ability to query CDRNs, PPRNs which may be using different vendor implementations • CDRNs/PPRNs can participate in multiple research networks simultaneously • Enables use of common security and privacy controls across networks
C4: Standardize Query Results for returning aggregate data. (Impacts Step 5 of the PCORnet Abstract Model)	• Leverage the existing PCORnet query results mechanism allowing for appropriate modifications and publish them as existing or new FHIR resources	• Provides researcher ability to consume results from CDRNs, PPRNs which may be using different vendor implementations • CDRNs/PPRNs can participate in multiple research networks simultaneously • Enables use of common security and privacy controls across networks • Enables use of the data marts for multiple purposes such as quality reporting, bio-surveillance, population health etc. • Enables a platform to develop Visualization and Analytical tools
C5: Standardize Query Results for returning de-identified or identified patient data (Impacts Step 5 of the PCORnet Abstract Model)	• Leverage the existing PCORnet query results mechanism allowing for appropriate modifications and publish them as existing or new FHIR resources	• Provides researcher ability to consume results from CDRNs, PPRNs which may be using different vendor implementations • CDRNs/PPRNs can participate in multiple research networks simultaneously • Enables use of common security and privacy controls across networks • Enables use of the data marts for multiple purposes such as quality reporting, bio-surveillance, population health, public health etc. • Enables a platform to develop Visualization and Analytical tools
C6: Standardize Query Structure and Queries for identifying cohorts/populations (Impacts Step 4 of the PCORnet Abstract Model)	• Use Queries based on DAF Phase 1 and Phase 2 FHIR profiles to promote standardized queries for common use cases	• Ability to execute the common use cases with pre-approved standard queries • Provides researcher ability to query different CDRNs, PPRNs which may be using different vendor implementations • CDRNs/PPRNs can participate in multiple research networks simultaneously • Enables use of common security and privacy controls across networks

DAF Phase 3 Policy Considerations

As part of the DAF Phase 3 activities, various policy issues need to be addressed. In order to address the various policy issues, a work group dedicated to addressing policy issues will be setup with close coordination with the ONC Office of the Chief Privacy Office (OCPO). The work group is expected to perform the following activities

- Capture policy guidance required to operationalize capabilities C1 through C6 specifically in the following areas
 - Patient identity matching
 - Patient consent and data donation
 - Patient privacy and data disclosure
 - Shared or Centralized IRB approaches to facilitate data access across multiple sites for research purposes
 - Trust establishment and endpoint discovery

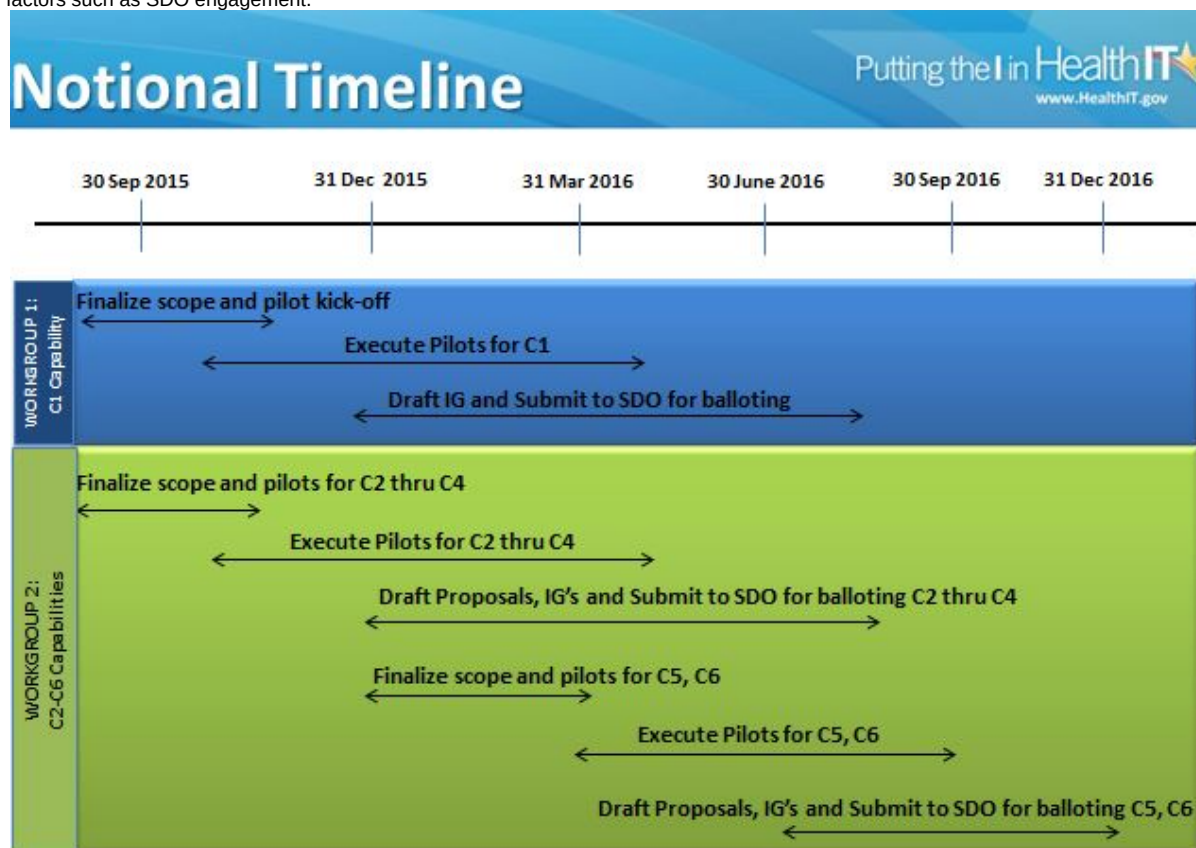
DAF Phase 3 Execution Process

For DAF Phase 3 execution the following process steps will be performed

- Finalization of Project Charter for Phase 3
- Recruitment of pilots for each capability C1 through C6 or potential new capabilities
- Execute pilots (Includes activities such as Finalize Technical Requirements, Prototyping, Pilot operations, Production operations Metrics gathering etc)
- Create Implementation Guides/Enhance existing Standards using SDO specific process

DAF Phase 3 Notional Timeline

A notional timeline for the DAF Phase 3 activities are as shown below. These timelines will be refined depending on the pilots and other contributing factors such as SDO engagement.



DAF Phase 3 SDO Engagement

DAF Phase 3 activities are planning to leverage HL7 FHIR standard for the capabilities C1 through C6. In order to accomplish these tasks effective engagement with the HL7 SDO and the FHIR Management Group and other work groups dealing with FHIR resources will be planned in advance and project proposals submitted to identify potential work groups for shepherding, balloting and publishing any standards and implementation guide related artifacts.

[1] IOM is a division of the National Academies of Sciences, Engineering, and Medicine . The Academies are private, nonprofit institutions that provide independent, objective analysis and advice to the nation to solve complex problems and inform public policy decisions related to science, technology, and medicine.

[2] <http://www.pcori.org>

[3] <http://www.pcornet.org>

Reference Materials

Document Name	Description
	General Reference
DAF Project Charter	The document describes the overall DAF project charter, including the challenge statement, scope, deliverables and timelines.
DAF/QH/SDC /CQF Comparison Slides	This presentation provides a comparison and contrast of DAF to the previous and current ONC initiatives: Query Health (QH), Structured Data Capture (SDC), and the Clinical Quality Framework (CQF).
DAF Terminology	This wiki page describes the terminology that will be used by the community to discuss DAF standards.
Use Case Parking Lot Items	This page highlights any items identified as parking lot items for both the Local and Targeted DAF workstreams.
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)
	Local Access Reference
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).
	Targeted Access Reference
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).
	Data Access for Research Reference
Phase 3 Pilot Requirements	The minimum set of requirements needed to become a DAF Phase 3 pilot.
	DAF IHE Artifacts
DAF IHE White Paper	This DAF IHE White Paper provides a framework of integration profiles that shows how IHE enables data access for a wide variety of use cases, by encouraging standards based integration, both within and across enterprises (published 10/24/2014).
DAF Document Metadata Based Access IG	This IHE US National Extension implementation guide provides requirements and guidance on accessing clinical documents using RESTful resources based on HL7 FHIR® and the more traditional SOAP based IHE Profiles (published 9/24/2015).
	DAF HL7 Artifacts
DAF FHIR IG	This DAF FHIR IG DSTU is a US-realm specific implementation guide that 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 (published 9/23/2015).
DAF Data Elements-based Query FHIR Profiles	This provides a list of all the DAF profiles that are a part of FHIR DSTU 2.