September 17, 2024

RCE™ Monthly Information Call

Zoe Barber, RCE Policy Director
Johnathan Coleman, RCE CISO
Didi Davis, RCE Conformance Testing
Dawn Van Dyke, RCE Communications Lead
Lindsey Elkind, RCE Legal SME
Kathryn Lucia, RCE Policy Analyst
Dave Pyke, RCE Technical SME
Steve "Sully" Sullivan, RCE Program Operations
Alan Swenson, RCE Program Operations Lead
Erin Whaley, RCE Legal SME
Chantal Worzala, RCE Stakeholder Engagement
Mariann Yeager, RCE Lead

Agenda

- **Welcome**
- **TEFCA^{TM} Exchange Basics**
- **TEFCA Timeline Review**
- **Spotlight: TEFCA on FHIR**
  - » TEFCA FHIR History
  - » TEFCA FHIR Timeline
  - » Basic FHIR Requirements
  - » FHIR Registration, Authentication and Authorization (auth[x]) Roadmap
  - » Scope Negotiation
  - » FHIR Implementation Advisory Group
- **Educational Resources and FAQs**
- **Questions & Answers (Q&A)**

HL7® FHIR®

TEFCA is Ramping Up and Looking to the Future with FHIR!

TEFCA Exchange Basics

6,977 entries in the RCE Directory:

- 1,123 total organizations are live
  - 7 QHINs
  - 97 Participants
  - 1,019 Subparticipants
- 5,854 Child entries (parts of the above, not individual organizations with Framework Agreements)

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

commonwell®
HEALTH ALLIANCE

eHealth Exchange™

Epic
Nexus

HEALTH®
GORILLA

Kno2®

KONZA
NATIONAL NETWORK

MedAllies

Learn More: https://rce.sequoiaproject.org/designated-qhins/

5

QHIN Application and Onboarding & Designation

Letters of Intent
- Inactive – 10
- Active – 3

Completeness Review
- 0

Applications Accepted
- 1

Partner Testing & Project Plan Completion
- 0

Submitting Application
- 0

Definitive Review
- 0

Conformance Testing
- 2

Designated
- 7
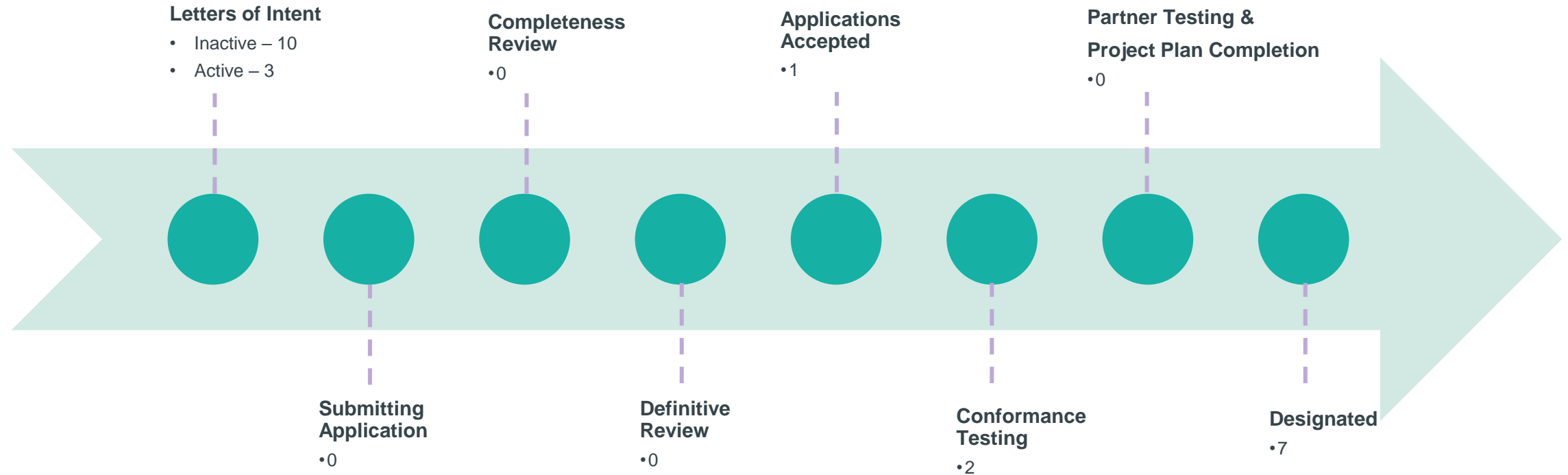
TEFCA Components

Framework Agreements

Standard Operating Procedures

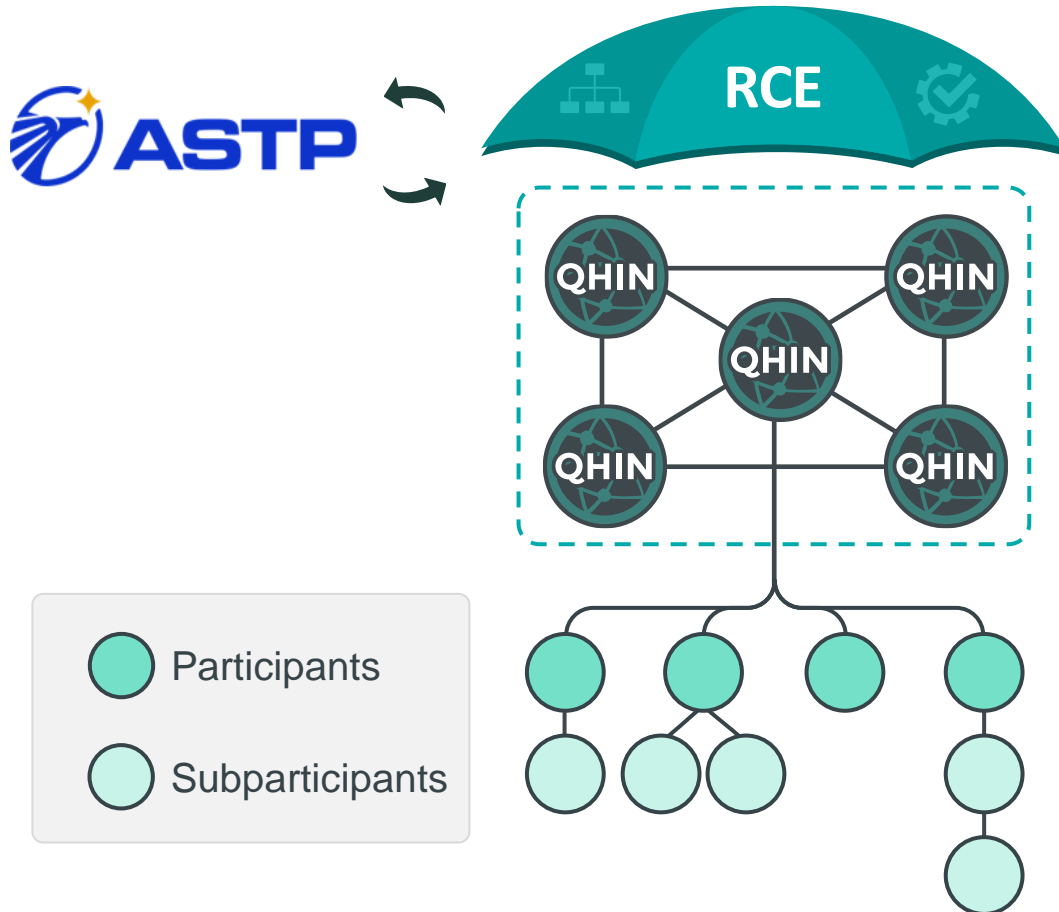**Technical Requirements**

RCE Directory

Oversight & Compliance

Governance

Exchange Under TEFCA

ONC defines overall policy and certain governance requirements

RCE provides oversight and governing approach for QHINs

QHINs connect directly to each other to facilitate nationwide interoperability

Each QHIN connects Participants, which connect Subparticipants

Participants and Subparticipants connect to each other through TEFCA Exchange

- Participants contract directly with a QHIN and may choose to also provide connectivity to others (Subparticipants), creating an expanded network of networks

- Participants and Subparticipants sign the same Terms of Participation and can generally participate in TEFCA Exchange in the same manner

Framework Agreements and TEFCA connections

Common Agreement
Each QHIN voluntarily enters into the same contractual agreement with the RCE by signing the Common Agreement

Participant/Subparticipant Terms of Participation
All Participants and Subparticipants voluntarily agree to the Terms of Participation without modification as part of their agreements with their TEFCA connector
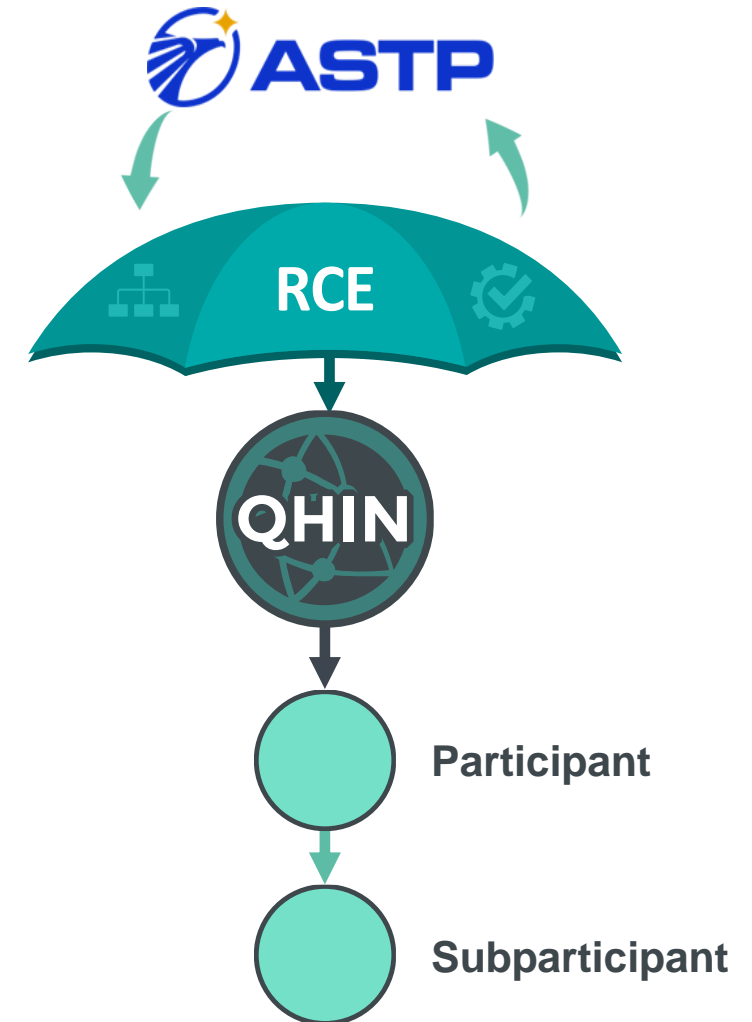
TEFCA connector
A QHIN, Participant, or Subparticipant that offers services to connect into TEFCA exchange

TEFCA connected entity
A QHIN, Participant, or Subparticipant that has signed a Framework Agreement

Entities may connect into exchange at any level

Standard Operating Procedures (SOP)

What is an SOP?

- An SOP is a written procedure or other provision that is incorporated by reference into the Framework Agreements to provide detailed information or requirements related to TEFCA Exchange

- SOPs address, among other things, governance, privacy and security requirements, RCE directory services, and QHIN application and designation

- Each SOP identifies the parties to which it applies (QHINs, Participants, Subparticipants)

What is the Exchange Purposes (XPs) SOP?

The XPs SOP details specifications relevant to when and how information can be requested or shared through TEFCA Exchange

What is an Exchange Purpose (XP) Implementation SOP?

XP Implementation SOPs provide additional details for specific use cases, as needed

Why SOPs?

- SOPs create the flexibility for TEFCA to evolve and expand over time

- SOPs will be created and modified as needed and finalized through a defined change management process

- Access the SOPs on the RCE website

Principal/Delegate Relationship

A TEFCA connected entity may authorize a Delegate to share information on their behalf through a Principal/Delegate relationship

- ## What is a Principal?
  - » A QHIN, Participant, or Subparticipant that is acting as a Covered Entity, Government Health Care Entity, Non-HIPAA Entity (NHE) Health Care Provider, a Public Health Authority, a government agency that makes a Government Benefits Determination, or an IAS Provider (as authorized by an Individual) when engaging in TEFCA Exchange

- ## What is a Delegate?
  - » Delegate means a **First Tier Delegate** or **Downstream Delegate.**

  - » **First Tier Delegate:** a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a Principal authorizing the First Tier Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of the Principal. For purposes of this definition, a "written agreement" shall be deemed to include a documented grant of authority from a government agency.

  - » **Downstream Delegate:** a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a First Tier Delegate or another Downstream Delegate authorizing the respective Downstream Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of a Principal.

TEFCA Timeline Review

Transition from Version 1.1 to Version 2.0

- **TEFCA is currently live on Common Agreement Version 2.0 for QHINs**
- Applicable Flow-Down provisions are applied to Participants and Subparticipants
- There is a transition period to allow for adoption of the new Framework Agreements by those who are already live
  - o 60 days for the Common Agreement
  - o 180 days for the Terms of Participation
- During the transition, all TEFCA connected entities can engage in TEFCA Exchange for approved Exchange Purposes
- QHINs are responsible for adding new TEFCA connected entities to the RCE Directory as they sign the Terms of Participation

May 2024	June/July 2024	Summer/Fall 2024	December 2024
• May 1: Common Agreement and Terms of Participation published in Federal Register	• July 1: Common Agreement 2.0 is effective for QHINs (60 days after publication) • RCE and newly designated QHINs sign version 2.0 • Final QTF version 2.0 published and expected to be in production • Facilitated FHIR SOP expected to be published and in production • New Participants and Subparticipants sign the Terms of Participation	• Additional SOPs are released on a rolling basis	• Dec 27: Terms of Participation compliance date for any Participant / Subparticipant that signed a flow down agreement prior to June 30th

https://www.federalregister.gov/documents/2024/05/01/2024-09476/notice-of-publication-of-common-agreement-for-nationwide-health-information-interoperability-common).

Expected SOP Batch Release

Published July 1, 2024	Published August 6th	Expected Fall 2024
• QHIN Technical Framework (QTF) Version 2.0 • Facilitated FHIR Implementation SOP • Individual Access Services (IAS) Provider Requirements • Governance Approach SOP • Delegation of Authority SOP • Expectations for Cooperation SOP • Exchange Purposes SOP • RCE Directory Service Requirements Policy SOP • Security Incident Reporting SOP • XP Implementation SOP: Treatment	• Public Health Exchange Purpose (XP) Implementation SOP • Health Care Operations XP Implementation SOP • Individual Access Services XP Implementation SOP (updated) • Exchange Purposes (XP) SOP (updated) • QHIN Security for the Protection of TEFCA Information (updated)	• Participant/Subparticipant Additional Security Requirements SOP • QHIN Onboarding & Designation SOP • QHIN Application SOP • Updated TEFCA Governance SOP

TEFCA on FHIR

Christopher Muir, Director, Network & Scalability Division
Avinash Shanbhag, Associate Deputy Assistant Secretary for Technology Policy

Agenda

- TEFCA FHIR History

- TEFCA FHIR Timeline

- Basic FHIR Requirements

- FHIR Registration, Authentication and Authorization (auth[x]) Roadmap

- Scope Negotiation

Support of FHIR and Updated Roadmap

TEFCA will expand support of FHIR over time, in four stages:

1. FHIR Content Support
   - Included as part of the initial launch of TEFCA
   - QHIN-brokered IHE exchange of FHIR payloads between QHINs available

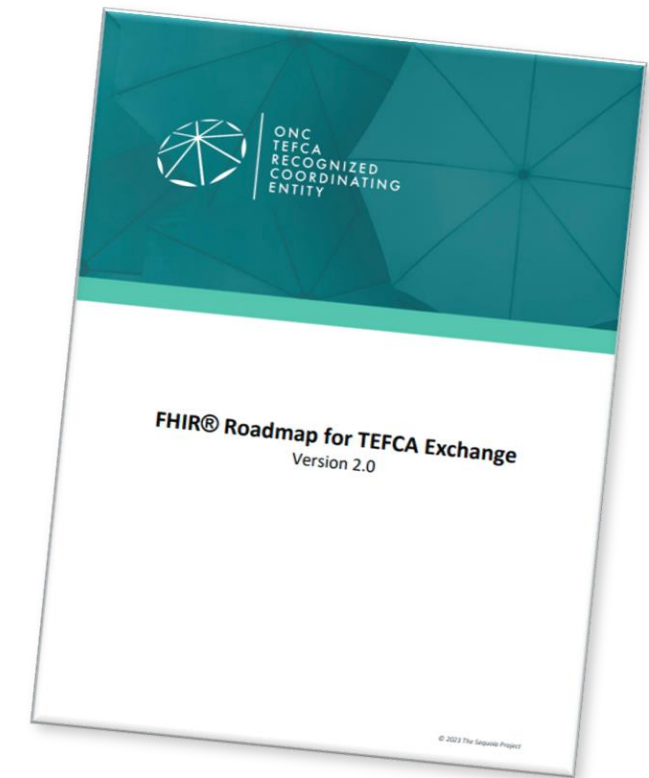2. QHIN-Facilitated FHIR Exchange
   - QHIN support for facilitated FHIR API exchange required
   - Participant and Subparticipant exchange via FHIR application programming interfaces (APIs) available

3. QHIN-to-QHIN FHIR Exchange
   - Support for exchange between QHINs via FHIR APIs

4. End-to-End FHIR Exchange
   - Support for QHIN-brokered FHIR Exchange between Participants and Subparticipants

Access the FHIR® Roadmap for TEFCA Exchange Version 2 on the RCE website.

TEFCA FHIR HISTORY

QTF V1.0

QTF V2 and Facilitated FHIR SOP

Dec. 2022

Aug. 2024

Jan. 2022

July 2024

Facilitated FHIR released for Pilot testing in December 2022

Public Health and HCO SOPs that reference the Facilitated FHIR Implementation SOP
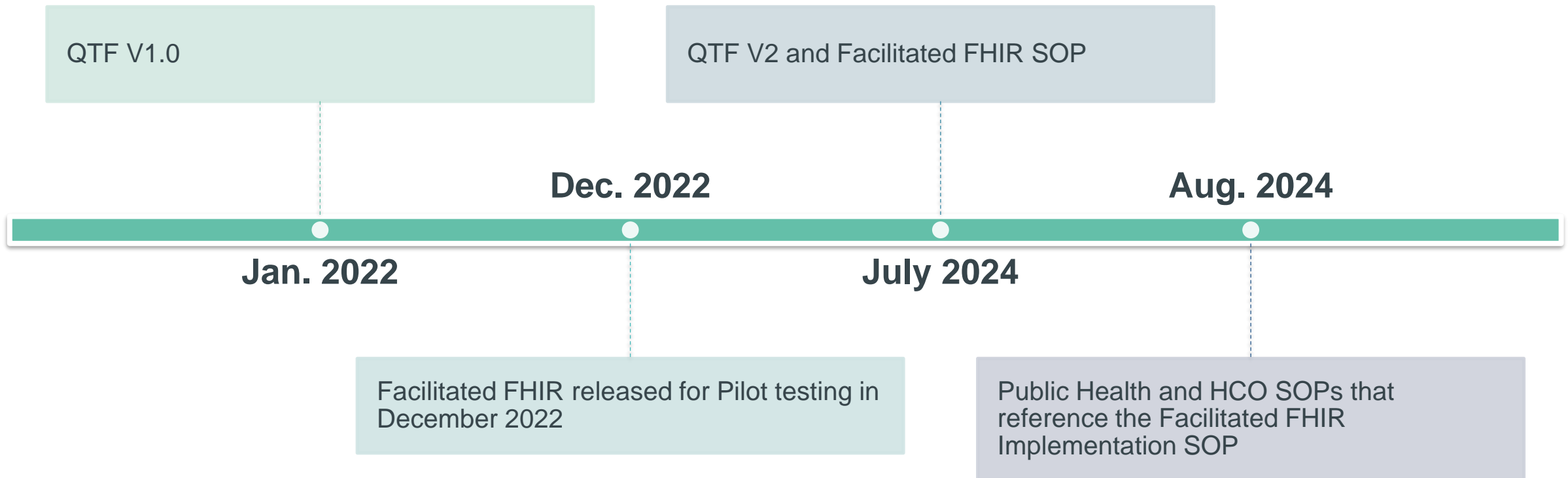
Facilitated FHIR Exchange

- In the QHIN-Facilitated Exchange model, QHINs will make available network services to enhance the use of FHIR APIs among TEFCA connected entities to share individual-level data

- Services could include: FHIR Endpoint directory, patient matching, Record Locator Services, identification verification services, issuing certificates, dynamic client registration, and other potential services

Requester

Requester uses services of its TEFCA connector to support FHIR Exchange

Responder

Responder returns requested information, or a notification that no records were found through its API

FHIR Endpoint and Patient Discovery

Requester submits request directly to Responder's API using FHIR standards and protocols to retrieve available FHIR Resources, including those aligned with USCDI

QHIN

QHIN

Facilitated FHIR SOP History and Development

- Technical approach tested at four Connectathons (IHE and HL7) in 2023 with much feedback and refinement

- Discussions on Scope Negotiations came from issues during Connectathon testing
  - » An HL7 WGM Birds of a Feather started the discussions and an informal workgroup was created to refine the recommendations
- Sent out for Public Comment in January of 2024
  - » Many refinements based on comments

- Reviewed through Policy and Technical Advisory Group discussions

- Now being reviewed and refined by the FHIR Implementation Advisory Group review and discussions

TEFCA Basic FHIR Requirements

- All exchange MUST be according to FHIR R4 (v4.0.1)

- All data exchange MUST follow the US Core FHIR IG requirements (which is negotiable before Jan 1, 2026 and then V6.1). In addition, the following FHIR Implementation Guides SHOULD be supported:
  - » Bulk Data Access IG v2.0.0
  - » Mobile access to Health Documents (MHD) v4.2.1
    - – Specifically: Find Document References [ITI-67] and Retrieve Document [ITI-68]
  - » Da Vinci Payer Data Exchange v1.0.0
  - » Da Vinci Clinical Data Exchange v2.0.0

- All requesters using a valid TEFCA certificate and Purpose of Use must be given access according to the Common Agreement

- Where data is transformed from other formats, a Provenance resource must be available to show where and how the transformation is done.

TEFCA Basic FHIR Requirements

- Endpoint and Patient discovery MUST be through a QHIN Patient Discovery Query

- Servers MUST have at least CapabilityStatement and Patient resources available

- Servers MUST have a CapabilityStatement at each published endpoint
  - » CapabilityStatements MUST list all FHIR IG operations supported and SHOULD list all FHIR IGs supported

- Servers MUST support $match – demographics-based matching.
  - » Servers SHOULD have the capability to return more than one potential patient match when a patient search yields more than one match
    - – Except when such action could be a violation of HIPAA or other Applicable Law
  - » Responding Nodes MUST NOT require more than all US Core Patient Resource demographics before returning a patient list Response

TEFCA Basic FHIR Requirements

- All data created or captured and sent on or after December 31, 2024, should conform to the appropriate data classes, data elements, and vocabulary requirements from the United States Core Data for Interoperability (USCDI) v1, when such data are maintained.

- Beginning January 1, 2026, all data created or captured and sent must conform to USCDI v3 data classes, data elements, and vocabulary requirements.

- This aligns with the use of US Core Version 3.1.1/4.0 (or later) for 2026 exchange prior to 2026 and US Core Version 6.1 for exchange on or after January 1, 2026.

- The RCE will advance FHIR standards in alignment with ASTP/ONC regulatory requirements and effective dates. For example, later versions of US Core and other FHIR Implementation Guides mandated by ASTP/ONC regulations will be adopted into the FHIR SOP and/or the QHIN Technical Framework.

- Requirements surrounding the registration and auth[x] of a FHIR client to a Responding Node MUST follow these requirements:
  - » Prior to January 1, 2026:
    - – All FHIR Adopters MAY use the Security for Scalable Registration, Authentication, and Authorization (SSRAA) Registration Requirements
      - If not, Manual registration requests resolved within 5 business days where sufficient information has been provided.
      - Information requirements MUST NOT exceed those in Section 3 of HL7 SSRAA and this SOP.

    - – All FHIR adopters MUST use one of the following:
      - HL7 SSRAA US Sections 4 and 5;
      - SMART Release 1.0.0; or
      - Some other auth[x] framework that adheres to the QTF, based on out-of-band agreements between exchange partners.

  - » As of January 1, 2026, all FHIR Adopters must use HL7 SSRAA for all Registration and auth[x]

TEFCA Basic Auth[x] Requirements

- Authorization Servers SHOULD issue access tokens with a lifetime no longer than 60 minutes.

- An Authorization Server MAY issue a refresh token to an application using the Authorization Code Grant type if the Authorization Server issues a refresh token to an application that has requested and has been authorized to use the "offline_access".

- All implementations MUST support RS256, and SHOULD support ES256, ES384 and RS384.

- The scopes_supported metadata MUST be present in the .well-known/smart-configuration or .well-known/udap object, as applicable, and MUST list all scopes supported <u>including all supported wildcard scopes.</u>

- A client may only request a wildcard scope if wildcards are specified in the scopes_supported metadata list.

- If a wildcard scope is specified and the server supports wildcards, the server SHOULD respond with either the wildcard or with an exploded list of scopes that the client has been granted.

TEFCA Scope Negotiation

- A server MAY respond with more, fewer or different scopes than requested.

- An application SHOULD be able to receive a superset of the scopes requested.

- A server SHOULD only respond with "invalid scope" if the wildcard is requested and not supported, or if none of the requested scopes are supported and/or not part of the scopes requested during registration.

- The FHIR Implementation Advisory Group was established to ensure consistent adoption of a scalable approach to Facilitated FHIR across TEFCA and began meeting in Summer of 2024.

- Representatives include FHIR SMEs from the QHINs and their Participants/Subparticipants, as well as outside industry and federal expertise appointed by ASTP.

- The group will collect and document learnings and progress towards this goal, including assessing adoption and implementation of the HL7 Security for Scalable Registration, Authentication, and Authorization (HL7 SSRAA) FHIR Implementation Guide (IG).

- The group will provide regular updates to the TEFCA Transitional Council or the Governing Council (as applicable) in progress, and informed by that progress, will have the authority to recommend changes to the dates in the FHIR Security Roadmap and/or conformance statements in applicable SOPs for approval by ASTP and the RCE.

Educational Resources and Upcoming Events

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

Fact Sheets

- FHIR Roadmap for TEFCA Exchange Version 2.0
- TEFCA Cross Reference Resource
- TEFCA Glossary
- Questions to ask your QHIN or other TEFCA connectors
- TEFCA for Executives
- TEFCA on FHIR
- TEFCA for Individuals
- Benefits for Health Information Networks (HINs)
- Benefits for State Governments and Public Health
- Benefits for Patients and Consumers
- Benefits for the Payer Community
- Benefits for Health Care Providers Across the Continuum

These Frequently Asked Questions address common questions and will be updated regularly.

- **What is TEFCA?**
- **How Does TEFCA Work?**
- **How Do I Participate in TEFCA Exchange?**
- **How is TEFCA Governed?**
- **How are QHINs Designated?**

https://rce.sequoiaproject.org/rce/faqs/

RCE Resource Library

TEFCA is a multifaceted, living framework that enables seamless and secure nationwide exchange of health information.

GETTING STARTED
↓

Below is a guide to the Common Agreement, Standard Operating Procedures (SOPs), technical documents, and other resources that make up TEFCA's rules of the road. Start your journey to next generation interoperability here.

https://rce.sequoiaproject.org/tefca-and-rce-resources/

Additional Resources:
https://www.healthit.gov/tefca

All Events Registration and Recordings:

https://rce.sequoiaproject.org/community-engagement/

Upcoming RCE Monthly Info Calls:
October 15th, 12:00pm ET (60 minutes)

Questions & Answers

For more information:
rce.sequoiaproject.org