ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

April 16, 2024

RCE™ Monthly Informational Call

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Agenda

- Trusted Exchange Framework and Common Agreement^{SM} (TEFCA^{SM}) Basics

- Common Agreement Version 2.0 and Participant/Subparticipant Terms of Participation (ToP) Updates and Timeline

- Draft TEFCA Explainer

- Educational Resources and Upcoming Events
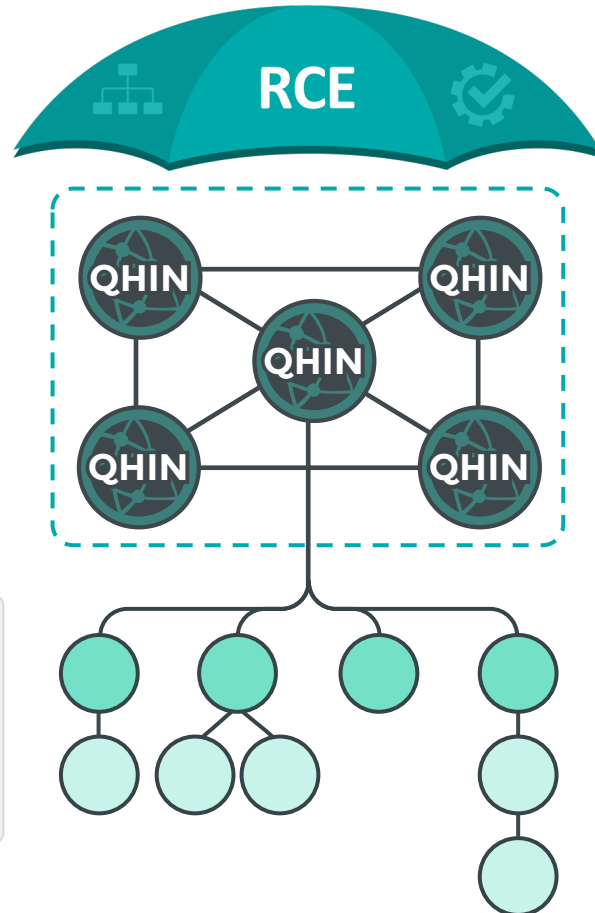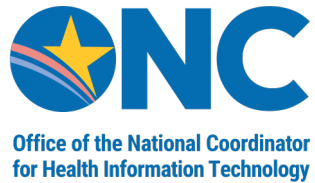
- Questions and Answers

TEFCA is Live and Looking to the Future with FHIR®!

TEFCA Basics

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

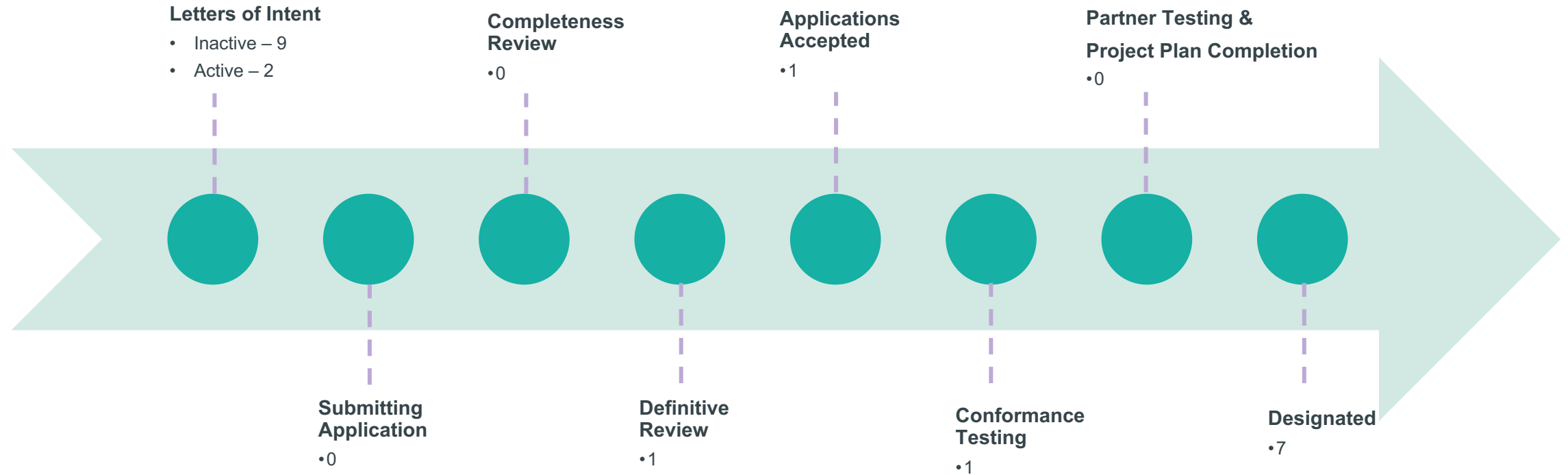Candidate QHINs include eClinicalWorks and Surescripts Health Information Network.

QHIN Application and Onboarding & Designation

Letters of Intent
- Inactive – 9
- Active – 2

Submitting Application
- •0

Completeness Review
- •0

Definitive Review
- •1

Applications Accepted
- •1

Conformance Testing
- •1

Partner Testing & Project Plan Completion
- •0

Designated
- •7

TEFCA Components

Framework Agreements

Standard Operating Procedures

Technical Requirements

RCE Directory

Oversight & Compliance

Governance

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
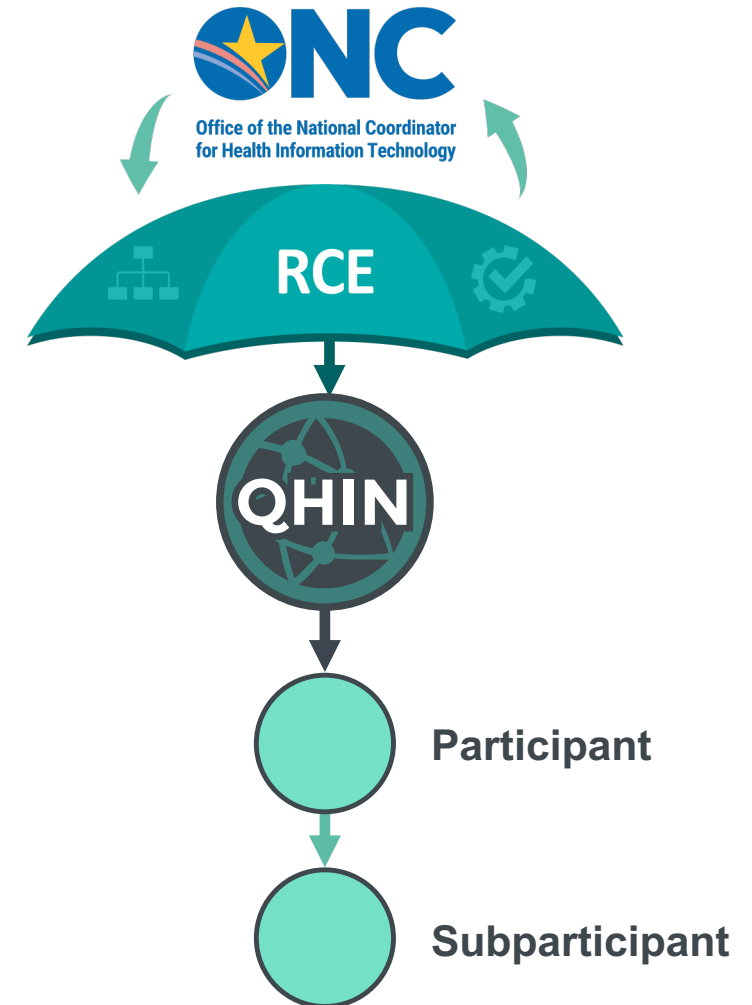
TEFCA connector
A QHIN, Participant, or Subparticipant that offers services to connect into TEFCA exchange

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

Entities may connect into exchange at any level

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?
- A QHIN, Participant, or Subparticipant that is not acting as a Principal and has a written agreement, directly or indirectly, with a Principal authorizing the Delegate to conduct TEFCA Exchange activities 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.

Example: An Accountable Care Organization (ACO) has a written agreement with a Health Care Provider authorizing the ACO to conduct TEFCA Exchange for the Health Care Provider. The Health Care Provider acts as the Principal and the ACO acts as the Delegate. They are both connected to TEFCA.

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

QHIN Technical Framework

- The QHIN Technical Framework (QTF) outlines the technical, functional, privacy, and security requirements necessary for QHINs to exchange data

- The QTF primarily addresses TEFCA transactions, and is generally silent on how the necessary functional outcomes are achieved within a QHIN

- Some requirements in the QTF must be enforced at the Participant and Subparticipant level

Access the QTF on the RCE website

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Trusted Exchange Framework and Common Agreement^SM

Qualified Health Information Network™ (QHIN™) Technical Framework (QTF)

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RCE Directory Service

- The RCE maintains the RCE Directory Service to support exchange of information between and among TEFCA connected entities

- This key component of TEFCA Exchange enables access to the electronic endpoints and other necessary information about all entities that participate in TEFCA Exchange

- RCE Directory information is consistently kept up to date to ensure that all information flows to the right destination no matter how the network changes

- TEFCA connected entities can share across trusted endpoints without having to know electronic addresses in advance

- QHINs play a key role in maintaining entries in the RCE Directory Service

RCE Oversight Activities

- **QHIN Designation:** Reviews applications from Health Information Networks (HINs) seeking QHIN status and administers a rigorous testing and onboarding process before Designation as a QHIN

- **Collaboration:** Collaborates with ONC and the TEFCA community to update policies and expand use cases over time

- **Adjudication of Noncompliance:** Adjudicates instances of noncompliance, ensuring adherence to established standards, policies, and the Common Agreement

- **Monitoring of Network Performance:** Collects, reviews, and analyzes metrics reported by QHINs regarding network performance

- **Development and Oversight of Governance:** Establishes and supports TEFCA Governing Council and other governing bodies

Common Agreement Version 2.0 and Terms of Participation (ToP) Timeline

Common Agreement Versions At-A-Glance

January 2022

Common Agreement — v1

The Common Agreement version 1 was the initial version of the Common Agreement and reflected policies developed with extensive public input.

Related QTF Version: 1
Related FHIR Roadmap Version: 1

December 2023

Common Agreement — v1.1

The Common Agreement version 1.1 included changes required by HHS prior to TEFCA exchange going live. *This is the version in operation as of the official launch of TEFCA exchange.*

Related QTF Version: 1.1
Related FHIR Roadmap Version: 2

April 2024

Common Agreement — v2

The Common Agreement version 2.0 includes enhancements and updates to support HL7 FHIR® based transactions.

Related QTF Version: 2 – DRAFT
Related FHIR Roadmap Version: 2

Status of TEFCA Policy and Technical Documents

Applicable Law
(federal, state, local, territorial, etc.)

Framework Agreements – Expected April 2024
Common Agreement (QHINs)
Terms of Participation (Participants/Subparticipants)

QHIN Technical Framework
Expected Mid June

Standard Operating Procedures (SOPs)
Expected June - July

Expected SOP Batch Release

Batch 1
Published on ONC website in April (Effective: 60 days after publication in Federal Register)

- Common Agreement Version 2.0
- Terms of Participation (ToP)

Batch 2
(Publish 60 days after publication in Federal Register)

- Governance Approach SOP
- Expectations for Cooperation SOP
- Individual Access Services (IAS) Provider Requirements
- Exchange Purposes SOP
- Delegation of Authority SOP
- RCE Directory Service Policy SOP
- QHIN Technical Framework (QTF) Version 2.0
- *New* Facilitated FHIR Implementation SOP
- Security Incident Reporting SOP

Batch 3
(Publish Summer 2024)

- XP Implementation SOP: IAS Demographic Matched
- XP Implementation SOP: Public Health
- XP Implementation SOP: Health Care Operations
- QHIN Security for the Protection of TEFCA Information (TI)
- Participant/Subparticipnat Additional Security Requirements
- QHIN Onboarding & Designation SOP
- QHIN Application SOP

Batch 4
(Publish Summer - Fall 2024)

- Update SOPs published on website (Dispute Resolution and Means to Demonstrate U.S Ownership and Control of a QHIN)

Transition from Version 1.1 to Version 2.0

- TEFCA is currently live on Common Agreement Version 1.1 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
    - 60 days for the Common Agreement
    - 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

April 2024

- Expected Publish of final Common Agreement and Terms of Participation in Federal Register

June 2024

- Common Agreement 2.0 is effective for QHINs (60 days after publication)
- Final QTF version 2.0 published and expected to be in production
- Facilitated FHIR SOP expected to be published and in production

Summer 2024

- Additional SOPs are released on a rolling basis

December 2024

- Terms of Participation are effective for all Participants and Subparticipants

Key Concepts that have Evolved: Common Agreement Version 1.1 to Version 2.0

Common Agreement and QTF Version 1.1	Proposed Common Agreement and QTF Version 2.0
Fundamental requirements and components of TEFCA mostly included within Common Agreement and QTF Version 1.1	More details moved to SOPs
Model Participant/Subparticipant flow-down terms	Static Participant/Subparticipant Terms of Participation
Exchange only occurs QHIN-to-QHIN via IHE protocols	Facilitated FHIR available between Participants/Subparticipants
Exchange within QHINs not considered TEFCA exchange	TEFCA Exchange identified by unique TEFCA code
Six (6) authorized Exchange Purposes (XPs)	Six (6) authorized Exchange Purposes (XPs) with new sub exchange purposes and implementation guidance
Two (2) XPs require a response: Treatment and Individual Access Services (IAS)	Three (3) XPs require a response: Treatment, IAS, and Health Care Operations SubXP-1 (FHIR only)
All QHINs, Participants, and Subparticipants must respond	Introduction of Principal/Delegate roles and requirements
Participants and Subparticipants may not participate with more than one QHIN	Participants and Subparticipants may conduct TEFCA Exchange in multiple QHINs using multiple Nodes
Privacy/security obligations apply to all	Privacy/security obligations apply to all

Governance Update
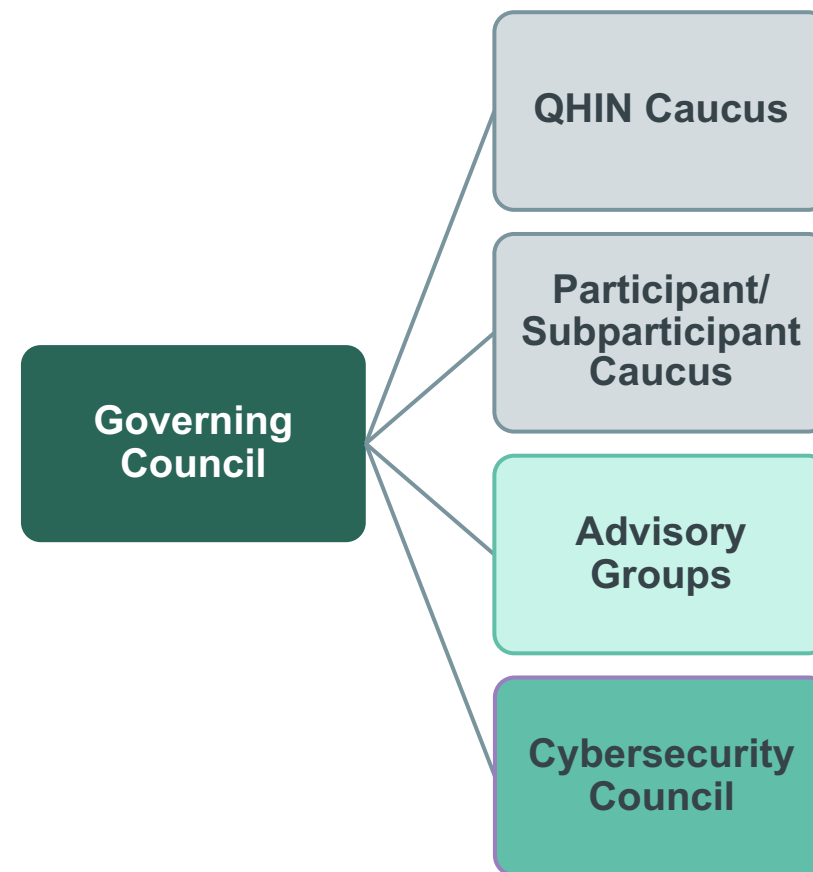
Overview
Current Status

Governance

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Governing Approach

- TEFCA connected entities can engage in governance under the Common Agreement

- The Common Agreement establishes a Governing Council that:

  » Reviews amendments to the Common Agreement, QTF, and SOPs

  » Serves as a resource to the RCE and a forum for discussion

  » Provides oversight for resolution of disputes

- A Transitional Council serves during TEFCA's first year

- ONC oversees the work of the RCE, which has specific obligations to follow the governance procedures set forth in the Common Agreement

- Advisory groups will be formed to provide targeted input from stakeholders

Governing Council

- **QHIN Caucus**
- **Participant/ Subparticipant Caucus**
- **Advisory Groups**
- **Cybersecurity Council**

Transitional Council

The Transitional Council shall serve as the interim governing body for the activities conducted under the Framework Agreements, as more fully described in the Transitional Council SOP.

Transitional Council Composition

- **QHIN Representative:** Each QHIN appoints one individual to serve on the Transitional Council. The individual appointed must be affiliated with the QHIN that appoints them either as an employee or on a contract basis.

- **Participant Representative:** Each QHIN appoints a Participant representative to serve on the Transitional Council. The Participant Representatives shall be individuals who are affiliated, either by employment or on a contract basis, with a Participant.

- **RCE Representative:** The RCE appoints one (1) individual to serve on the Transitional Council and this individual shall serve as the Facilitator of the Transitional Council.

- **Kicked-off in February 2024**
- **Monthly 90-minute meetings**
- **Two Co-Chairpersons, one QHIN Representative and one Participant Representative**

  - Assists RCE with agenda items
  - Helps facilitate meetings to promote efficiency, transparency and inclusiveness of all perspectives on any matter being considered

Transitional Council Overall Responsibilities

The Transitional Council shall be responsible for the following:

i. Serving as a resource to the RCE and a forum for orderly and civil discussion of any issues affecting exchange activities or other issues that may arise under the Common Agreement;

ii. Supporting the RCE in its work to monitor the exchange of TI and other activities under the Common Agreement and serving as a resource to the RCE to identify possible corrective actions for conditions that disrupt exchange activities, including, but not limited to, the following:

   a. Provide advice on issues related to the Onboarding of QHINs;

   b. Assist in evaluating suspected or alleged non-compliance with requirements in this Common Agreement, the SOPs, and the QTF;

   c. Provide input regarding whether to suspend or terminate a QHIN's participation;

   d. Provide advice regarding issues before they become Disputes and are escalated to the formal Dispute Resolution Process; and

   e. Evaluate possible and actual TEFCA Security Incidents, other Threat Conditions, and information and/or recommendations from the Cybersecurity Council

iii. Reviewing proposed amendments to the Common Agreement, the QTF, and SOPs and providing feedback to the RCE on the proposed changes;

iv. Participating in the development of new SOPs and providing feedback to the RCE on the proposed changes

v. Assisting the RCE with the Dispute Resolution Process as set forth in this Common Agreement and the Dispute Resolution SOP;

vi. Informing the RCE on development and updating of the strategic roadmap for exchange activities under the Common Agreement; and

vii. Advocating for the value of the exchange activities under the Common Agreement and promoting their success.

Transitional Council Specific Responsibilities

Transition Plan Development – In addition to the responsibilities listed for participation in governance generally, the Transitional Council shall develop the transition plan to the Governing Council.

Formation of Caucuses – The RCE shall work with the Transitional Council to form the caucuses described in the Common Agreement as part of the transition plan. The caucuses are responsible for identifying individuals to serve on the Governing Council that will be established at the end of the twelve (12) months following the formation of the Transitional Council.

Advisory Groups— The Transitional Council, until such time as the Governing Council is established, has the authority to recommend to the RCE that an Advisory Group should be convened. Any recommendation by the Council shall be made by way of a motion that is duly adopted by the Council in accordance with the SOP: Advisory Groups and requirements in Section 3.5 of the CA v1.1.

Governance SOPs

TEFCA Governing Council SOP

- Provides the specifics for the composition, conduct and other issues for the Governing Council

Draft Governance Approach SOP

- Sets forth the formation, composition, responsibilities and duration of the Transitional Council and Governing Council

Advisory Group SOP

- Sets out the way in which Advisory Groups will be established and the general rules that govern the activity of an Advisory Group

Transitional Council SOP

- Describes the role of the Transitional Council to provide governance support to the RCE and develop a Transition Plan to facilitate an effective transition to the Governing Council

- **Purpose:** Serve as an **Advisory Group** to the Transitional Council to deliberate and review proposed amendments to the Common Agreement v2, the QTF v2, and associated SOPs.

- **Responsibilities:**
  - » Review proposed amendments to the Common Agreement v2, the QTF v2, and associated SOPs and provide feedback to the RCE and ONC on the proposed changes.
    - – The feedback is intended to be advisory only and the RCE and ONC are not required to incorporate any specific feedback into the draft Common Agreement Version 2.0.
  - » Discuss practical and operational implementation questions and considerations that arise from policy and technical requirements across TEFCA.

- **Composition:** Continuation of the Applicant QHIN, QHIN, and Participant/Subparticipant Representative(s) involved in the Policy/Technical Working Group.

- **Timing and cadence:** The group will meet weekly until the formation of the caucuses, at which point we will re-assess timing and cadence.

- **Next Steps**: RCE will distribute draft charter to the Transitional Council for feedback and vote

NEW: DRAFT TEFCA Explainer
(Previously the TEFCA User's Guide)

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- Replaces the TEFCA Users Guide

- Informational resource that describes select aspects of TEFCA

- Tailored towards Participants & Subparticipants

- Offers clarity and insights for those curious about TEFCA

***Draft* TEFCA Explainer**
Updated April 2024

1. Goals and Benefits
2. Exchange Under TEFCA
3. TEFCA Components
4. Technical Aspects
5. Exchange Purposes
6. Example Use Cases
7. Privacy and Security Requirements

Educational Resources and Upcoming Events

RCE Resource Library

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

GETTING STARTED
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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/rce-resources-new/

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

All Events Registration and Recordings:
https://rce.sequoiaproject.org/community-engagement/

Upcoming Events:

- May 21, noon-1pm ET: Monthly Information Call

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Questions & Answers

For more information:
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