June 18, 2024

RCE™ Monthly Informational Call

Zoe Barber, RCE Policy Director
Johnathan Coleman, RCE CISO
Didi Davis, RCE Conformance Testing
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

- Trusted Exchange Framework and Common Agreement™ (TEFCA™) Basics

- Timeline

- Fast Healthcare Interoperability Resource (FHIR®) Approach

- Treatment

- TEFCA Governance

- Questions and Answers

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

TEFCA Basics

TEFCA is Live!

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

QHIN Application and Onboarding & Designation

Letters of Intent
- Inactive – 9
- 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
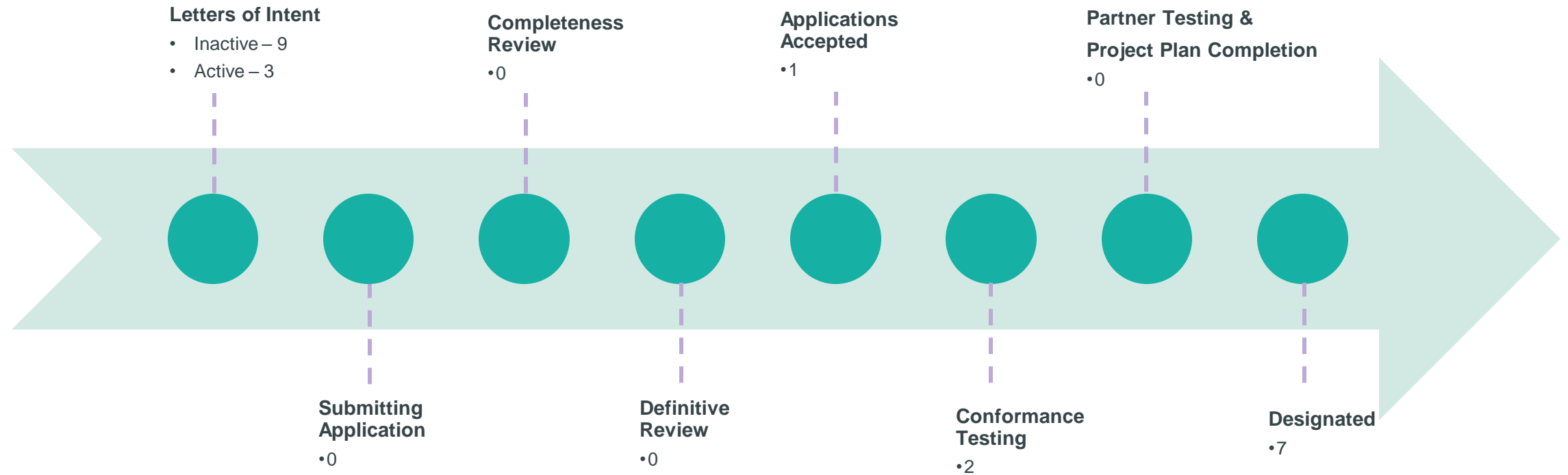
TEFCA Components

Framework Agreements

Standard Operating Procedures

Technical Requirements

RCE Directory
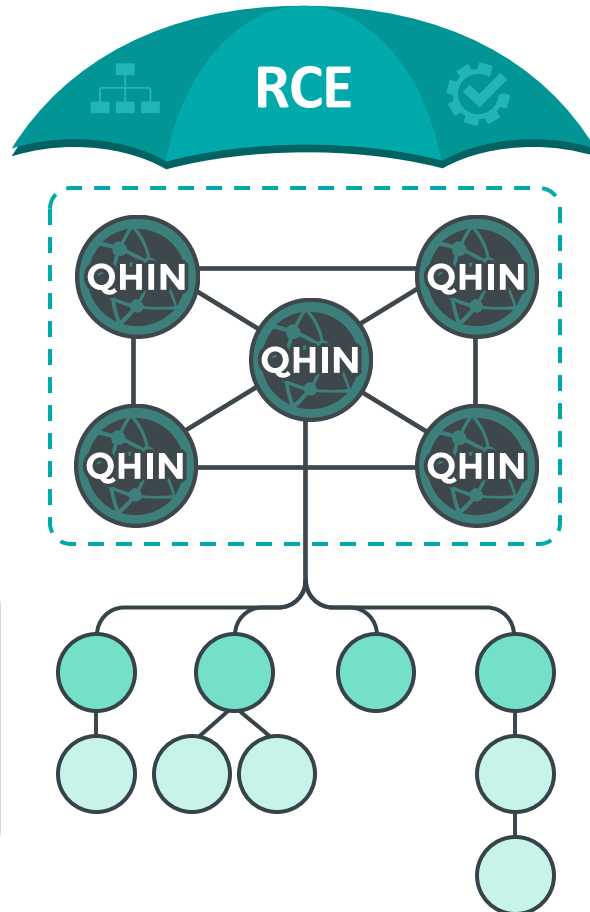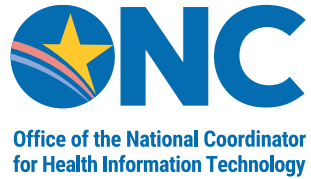
Oversight & Compliance

Governance

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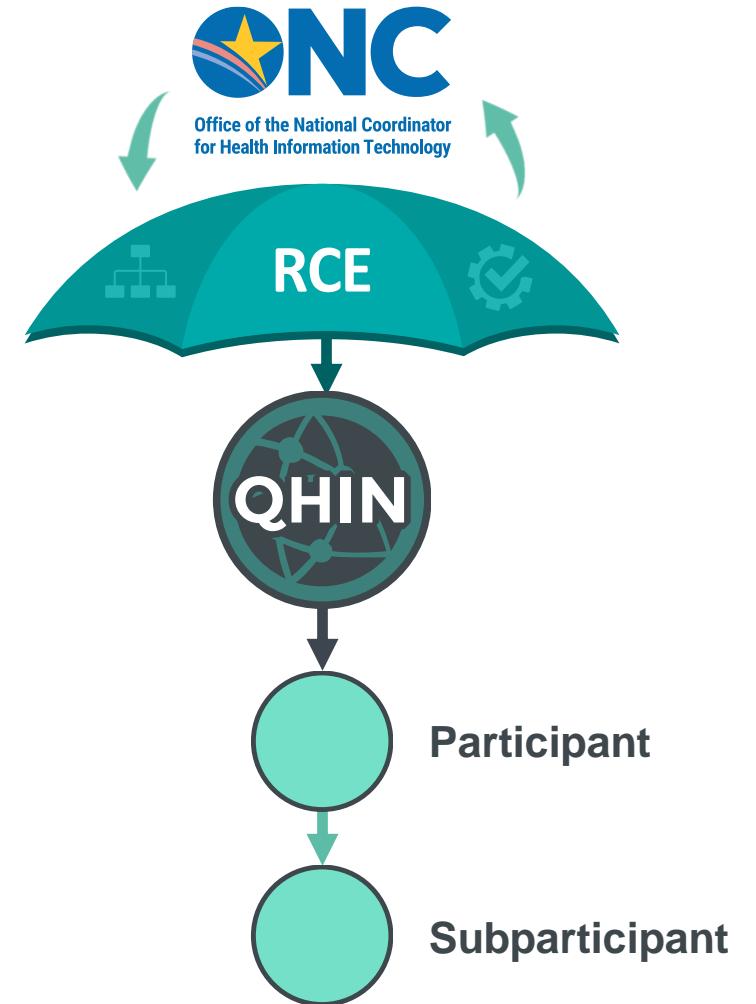
TEFCA connector
A QHIN, Participant, or Subparticipant that offers services to connect into TEFCA exchange

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

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

May 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

Expected SOP Batch Release

May 1st, 2024: Common Agreement Version 2.0 and Terms of Participation (ToP) Published in the Federal Register

Publish by July 1, 2024	Publish Summer 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: IAS Demographic Matched • XP Implementation SOP: Public Health • XP Implementation SOP: Health Care Operations • QHIN Security for the Protection of TEFCA Information (TI) • Dispute Resolution • QHIN Security for the Protection of TEFCA Information • Participant/Subparticipant Additional Security Requirements SOP • QHIN Onboarding & Designation/Application SOP • QHIN Application SOP • Updated Governance SOPs

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

May 2024	June/July 2024	Summer 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).

FHIR

Approach to Standardized FHIR Authorization

1. Requirements for registration, authentication, and authorization of FHIR clients MUST follow these requirements:

   a. **Prior to January 1, 2026**:

      i. All FHIR Adopters MAY follow the requirements of HL7 FAST Security IG 1.0.0 (SSRAA) Registration process

         1. Manual registration requests MUST be resolved within 5 days where sufficient information has been provided. Information requirements MUST NOT exceed those of SSRAA and this SOP.

      ii. All FHIR adopters MUST use one of the following:

         1. SSRAA Authentication and Authorization sections

         2. SMART Release 1.0.0; or

         3. Another authentication and authorization framework that adheres to QTF requirements and based on out-of-band agreements between exchange partners.

   b. **Beginning January 1, 2026**, all FHIR Adopters MUST follow SSRAA for registration, authentication and authorization

Provisional FHIR Implementation Advisory Group

Purpose

- A FHIR Implementation Advisory Group will be established to collect and document learnings and progress towards adoption of a network-wide approach to Facilitated FHIR, including assessing adoption and implementation of the HL7 Security for Scalable Registration, Authentication, and Authorization (HL7 SSRAA) FHIR Implementation Guide (IG).

- The FHIR Implementation Advisory Group will provide regular updates to the TEFCA Transitional Council or the Governing Council (as applicable) on progress, and informed by that progress

- The FHIR Implementation Advisory Group will have the authority to recommend changes to the dates in the FHIR Security Roadmap detailed in Section 4.4 of the Facilitated FHIR SOP and/or conformance statements throughout the SOP for approval by ONC and the RCE.

Treatment

Treatment Implementation SOP

- "Treatment" is an Exchange Purpose (XP) under Common Agreement Version 1.1
- TEFCA currently allows Health Care Providers to send Queries for Treatment purposes
- Currently, there is no Treatment Implementation SOP, but we have received feedback asking for more granularity in the Treatment XP
- A feedback form was circulated to PTAG members on use cases that are believed to meet the definition of "Health Care Providers" and "Treatment" and those that do not

"Health Care Provider" is defined in the Common Agreement Version 2.0 as meeting the definition of such term in either 45 CFR § 171.102 or in the HIPAA Rules at 45 CFR § 160.103.

"Treatment" has the meaning assigned to such term at 45 CFR § 164.501, which is "the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another."
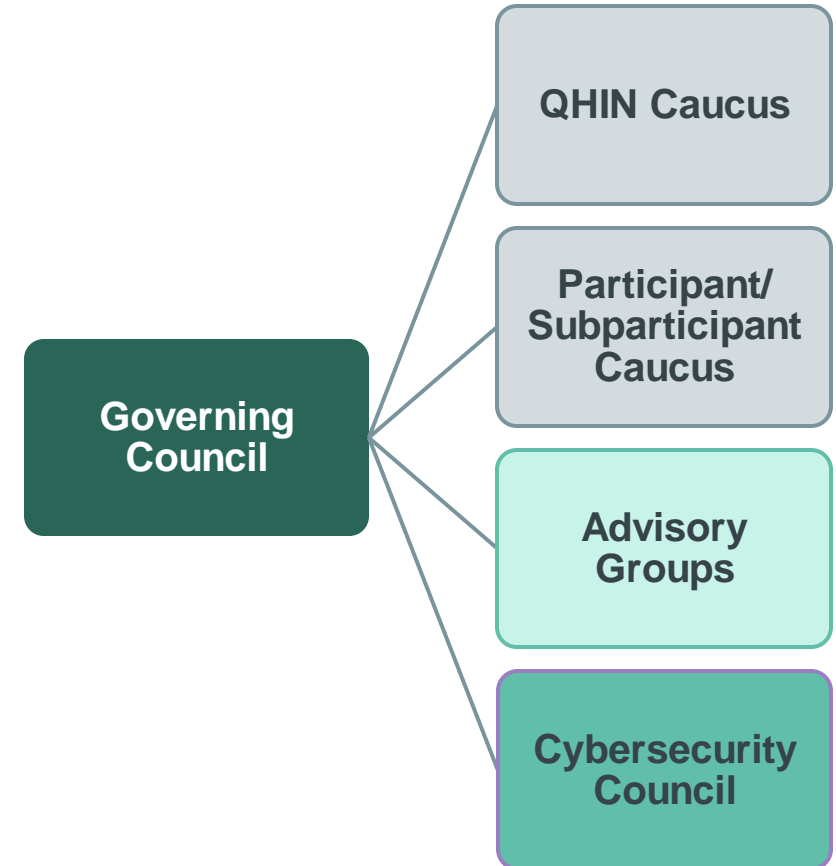
https://forms.microsoft.com/r/ZZicptZs1W

Governance

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

Governing Approach

- 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**

Governance SOP Approach

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

Goal: To create one Governance SOP that governs the Governing Council, the Caucuses, and the Advisory Groups by Fall of 2024

Phase 1 (May - July):

- Review SOPs key governance topics and draft updates *(e.g., composition, duration, leadership, conduct, etc.)*

Phase 2: (July - September):

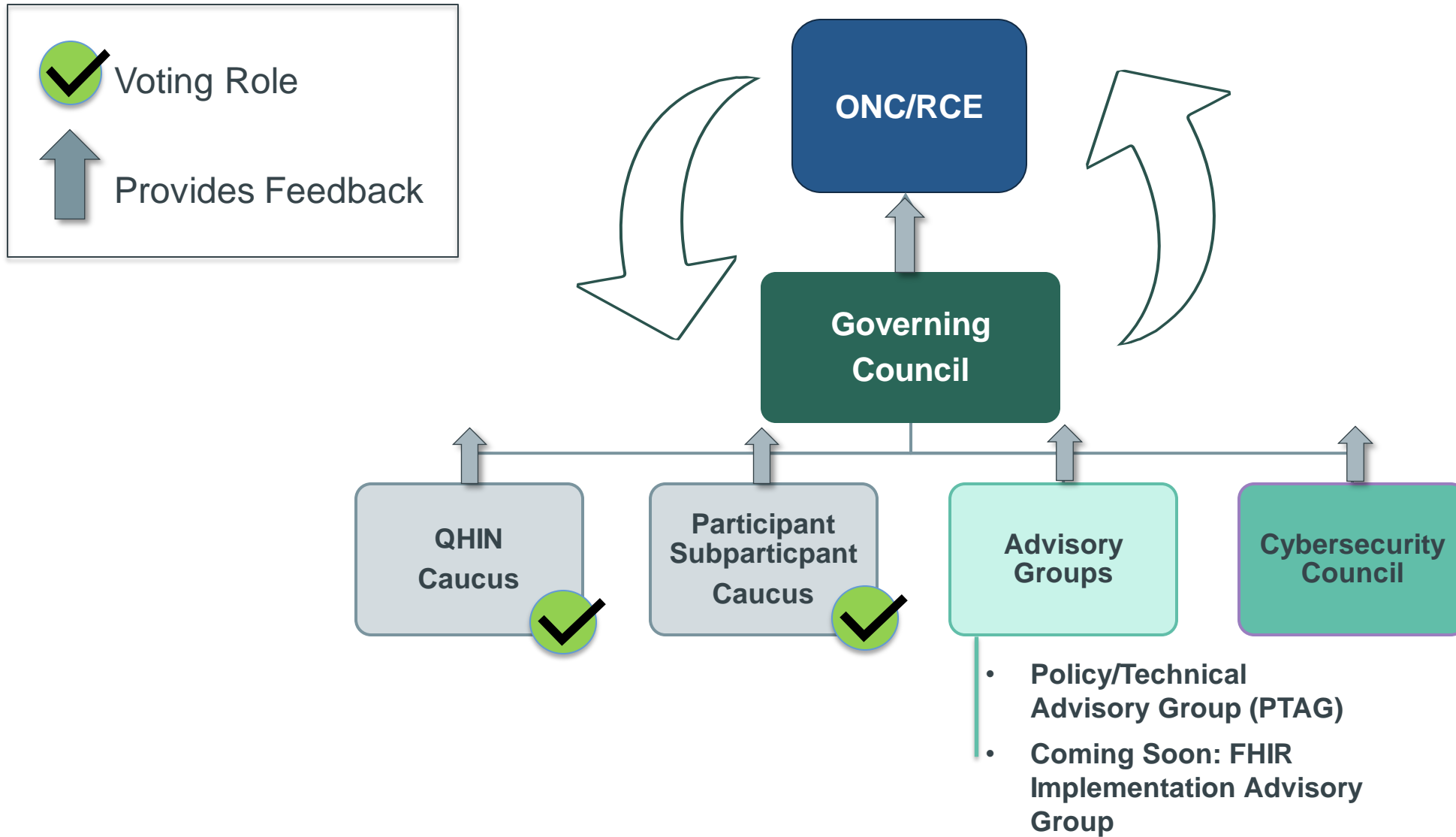- Incorporate draft updates with current language and draft combined SOP

Phase 3: (July - September):

- Present new Governance SOP to the PTAG, incorporate feedback, and publish new Governance SOP

Governance Roles & Voting Responsibilities

✔ Voting Role

⬆ Provides Feedback

ONC/RCE

Governing Council

QHIN Caucus ✔

Participant Subparticpant Caucus ✔

Advisory Groups

Cybersecurity Council

- **Policy/Technical Advisory Group (PTAG)**
- **Coming Soon: FHIR Implementation Advisory Group**

Voting Roles and Responsibilities

	ONC	RCE	Governing Council (GC)	QHIN Caucus	Participant/ Subparticipant Caucus	Advisory Groups	Cybersecurity Council
Advises and Recommends Amendments to SOPs, CA, and QTF	✔	✔	✔	✔	✔	✔	✔
Approves or Vetoes Amendments for Vote	✔						
Provides initial feedback on amendments, including recommendations for additional feedback			✔	✔	✔	✔	✔
Recommends Establishment of Advisory Groups			✔				
Establishes Advisory Groups		✔					
Votes on amendments with material impact on Participants/Subparticipants				✔	✔		
Votes on amendments with NO material impact on Participants/Subparticipants				✔			

May 2024 Q&A

May Q&A Categories	Connections
	Delegates
	Directory
	Fees
	FHIR
	Onboarding

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

Questions & Answers

For more information:
rce.sequoiaproject.org

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 Events:

- **July 16 Monthly Information Call**
- **HSRA Panel**