Elements of the Common Agreement: Closer Look # 3

October 14, 2021

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This project is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under 90AX0026/01-00 Trusted Exchange Framework and Common Agreement (TEFCA) Recognized Coordinating Entity (RCE) Cooperative Agreement. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.

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Agenda

- Welcome and Brief Overview
- Closer Look #3 Topic: QHIN Designation and Eligibility Criteria
- Opportunities for Stakeholder Feedback
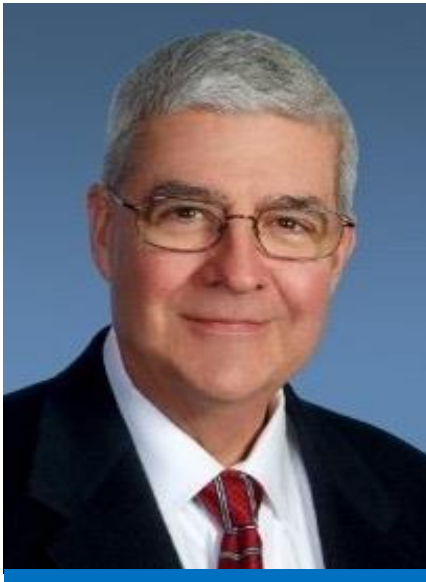- Questions and Answers
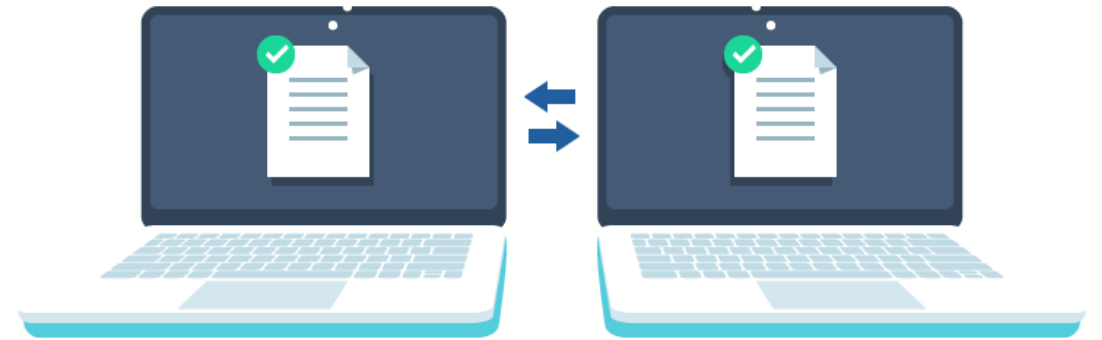
Meet the RCE Team

Mariann Yeager
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Gravely Group

Cait Riccobono
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TEFCA Goals

GOAL 1
Establish a floor of universal interoperability across the country

GOAL 2
Create simplified nationwide connectivity

GOAL 3
Provide the infrastructure to allow individuals to gather their data

Simplified connectivity for individuals, health care providers, health plans, public health agencies, and other stakeholders.

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The Value Proposition for TEFCA

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

Timeline to Operationalize TEFCA

Summer/Fall/Winter 2021
- Public engagement webinars.
- Common Agreement (CA) Work Group sessions.
- RCE and ONC use feedback to finalize CA V1 and QHIN Technical Framework (QTF) V1.

Calendar Q1 of 2022
- Release Final Trusted Exchange Framework, CA V1 Final, and QTF V1 Final.

During 2022
- QHINs begin signing Common Agreement.
- QHINs selected, onboarded, and begin sharing data on rolling basis.
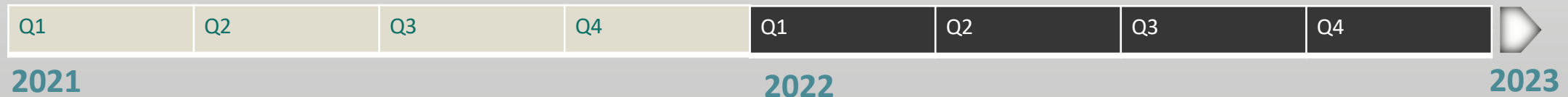
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

2021 **2022** **2023**

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How Will TEFCA Work?
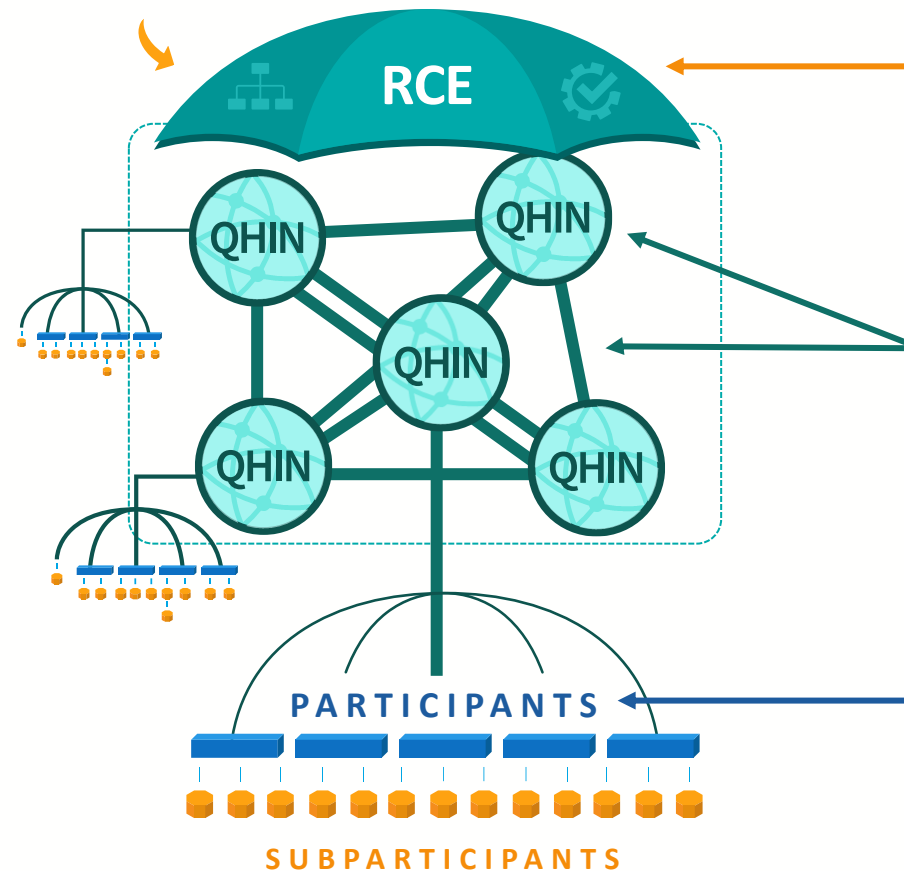
RCE provides oversight and governance for QHINs.

QHINs connect directly to each other to facilitate nationwide interoperability.

Each QHIN represents a variety of Participants that they connect, serving a wide range of Subparticipants.

TEFCA Elements

| Common Agreement | Standard Operating Procedures | QHIN Technical Framework | QHIN Onboarding | Metrics | Governing Approach |

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The Common Agreement

- The **Common Agreement** would establish the infrastructure model and governing approach for users in different information exchange networks to securely share clinical information with each other—all under commonly agreed-to expectations and rules, regardless of which network they happen to be in.

- The Common Agreement will be a legal document that each QHIN signs with the RCE.

- Some provisions of the Common Agreement will flow down to other entities (Participants and Subparticipants) via other agreements.

- The Common Agreement will incorporate the QHIN Technical Framework and the Standard Operating Procedures (SOPs).

The RCE welcomes stakeholder feedback.

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Standard Operating Procedures

To provide more specificity on particular issues, the RCE will also develop SOPs on topics such as:

Dispute Resolution Process

Governing Approach (Governing Council, Transitional Council, Advisory Groups)

Conflicts of Interest

QHIN Eligibility Criteria, Onboarding, and Designation

QHIN Security Requirements for the Protection of TEFCA Information

Standard Operating Procedure(s) or **SOP(s):** a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into the Common Agreement to provide detailed information or requirements related to the exchange activities under the Common Agreement, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. SOPs will be adopted to address the application process, the Onboarding process, and other operational processes.

Closer Look #3: QHIN Designation and Eligibility Criteria

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QHIN Designation and Eligibility Criteria - Overview

- Only the RCE would be able to designate a QHIN

- Application, assessment, testing and on-boarding processes are under development

- QHINs will be expected to provide ongoing reporting on metrics and other information needed to monitor performance over time

- The Common Agreement would include specific QHIN eligibility criteria that generally address:

  — The ability to perform all of the required functions of a QHIN, as identified in the QTF;

  — The legal structure and governing approach for the QHIN; and

  — Demonstrated resources and infrastructure necessary to support a reliable and trusted network.

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QHIN Designation and Eligibility Criteria – U.S. Entity

1. **Signatory must demonstrate that it meets the definition of U.S. Entity.**
   - Provide a copy of charter, principal place of business, certificate of good standing, organizing documents, and list of current officers and members of governing body/bodies.
   - Foreign ownership considerations

QHIN Designation and Eligibility Criteria – Exchange Capabilities

2. **Signatory is able to exchange Required Information, as defined in this Common Agreement.**

- Be capable of the exchange of Required Information for all Exchange Purposes.
- Describe the exchange purposes that are permitted on its network;
- Be capable of conducting exchange with unaffiliated organizations. Signatory must describe entities participating in its network, including their affiliation or non-affiliation with one another
- Describe how it currently facilitates exchange of health information (e.g. query, push, other exchange modality), and length of time with this experience
- Submit data on number and type of organizations that utilize its exchange services and whether it limits participation or is specialized in any manner
- Submit copies of data sharing agreements, operating policies and procedures, and other legal agreements and related documents that govern the operation of its health information network.

3. **Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE.** Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and **Designate the Signatory as a provisional QHIN** as further provided in the QHIN Designation SOP, including additional review during a provisional period and the potential to have the provisional status removed if Signatory achieves a predetermined level of technical competency.

QHIN Designation and Eligibility Criteria – Required Functions

- Demonstrated ability to successfully process a high number of transactions through a high performing, reliable environment – tens of millions of transactions each day. Provide:
  - Average monthly transaction volumes
  - Average annual transaction volumes.

- Provide specific information regarding its architecture and an attestation of its ability to expand the volume of data transactions through its network. This information shall include the ability to add technology capacity, staff, and other needed resources. Signatory must provide specific evidence of having been in operation and supporting the query functionality as outlined in the QTF for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN. RCE can also consider other evidence.

- Signatory must identify any gaps between its current technical infrastructure and the requirements of the QTF and identify its plan to address these gaps so that Signatory will be able to fully comply with the QTF once Signatory is Designated as a QHIN.

QHIN Designation and Eligibility Criteria – Provisional QHINs

- The RCE can designate Signatory as a QHIN, assuming Signatory satisfies all other requirements, on a provisional basis if the RCE determines that Signatory can reasonably support the query functionality as outlined in the QTF for a specified period of time in production, exchange with other QHINs and otherwise complies with the requirements of the Common Agreement. The RCE will consider the following when making this determination:

    - Evidence to show that Signatory has been engaged in the transmission of Required Information using a different but functionally comparable exchange method to the QTF in a live production environment for at least twelve (12) consecutive months during the twelve (12) months immediately preceding its application to the RCE.

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QHIN Designation and Eligibility Criteria – Provisional QHINs
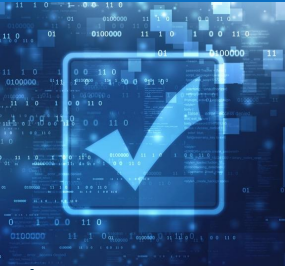
- A "Provisional QHIN" is an organization that the RCE Designates as a QHIN on a provisional basis ("Provisional Status") based on a determination that the organization: (1) does not, at the time of its application, satisfy all of the eligibility criteria, but (2) demonstrates the likelihood of being able to satisfy all such criteria during the course of the Provisional Status. The Provisional Status is a 12-month period in which a Provisional QHIN has the opportunity to demonstrate the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, QTF, and applicable SOPs.

- The RCE may impose such limitations on Signatory during its Provisional Status as the RCE deems reasonably necessary to allow the RCE to monitor Signatory's performance. This may include, but is not limited to, requiring Signatory to provide information about the type and volume of exchange activity, any problems that Signatory or its Participants or Subparticipants experience with exchange activity, participation in meetings with the RCE to discuss Signatory's performance during the Provisional Status, and any other matters that the RCE determines to be necessary. The Provisional Status shall continue for a time period of twelve (12) months following the RCE Designating Signatory as a Provisional QHIN; provided, however, that the RCE has the right to suspend (and toll) or terminate Signatory's Provisional Status at any point if the RCE determines that Signatory is in non-compliance with the requirements and obligations that are applicable to Provisional QHINs, as more fully set forth in the applicable SOP.

QHIN Organizational Infrastructure, Legal Authority, and Functional and Technical Ability

4. Signatory must demonstrate that it has in place, at the time of its application to be Designated as a QHIN, the organizational infrastructure and legal authority to comply with the obligations of the Common information and a functioning system to govern its health information network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network.

   – Network governance

   – Financial and personnel resources

   – Security, including certification under a nationally recognized security framework and CISO

   – Detailed information about any HIPAA reportable breaches of ePHI over the past three years

5. Signatory has the functional and technical ability to comply with the QHIN Technical Framework.

   – Signatory must provide evidence of compliance with the QHIN Technical Framework, including but not limited to any required conformance, interoperability, or partner testing as specified in the *RCE QHIN Testing and Onboarding Process*.

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Cybersecurity Insurance

Signatory shall provide evidence of one of the following:

(1) a certificate of insurance demonstrating that Signatory has current cyber-liability coverage that meets the requirements set forth in the applicable SOP;

(2) that Signatory has applied for cyber-liability coverage that meets the requirements set forth in the applicable SOP, including an attestation that Signatory will obtain the coverage prior to Signatory being Designated; or

(3) available internal funds, separate from those attested to in 4(c)(i), to self-insure against a cyber-incident up to the amount required by the applicable SOP.

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Opportunities for Stakeholder Feedback

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Opportunities for Stakeholder Feedback on Elements of the Common Agreement

Webinar Series:

- Overview; Cooperation and Nondiscrimination; Exchange Purposes and Related Definitions (September 21)

- Closer Look Topics #1: Permitted Requests, Uses, and Disclosures; Required Responses and Required Information (including Consent); Privacy and Security (September 29)

- Closer Look Topics #2: Individual Access Services; Governing Approach; Change Management; RCE Directory Service; Fees (October 5)

- Closer Look Topics #3: QHIN Designation and Eligibility Criteria (October 14)

Common Agreement feedback form on the RCE website open until October 21

https://rce.sequoiaproject.org/common-agreement-elements-feedback-form/
or email us at rce@sequoiaproject.org
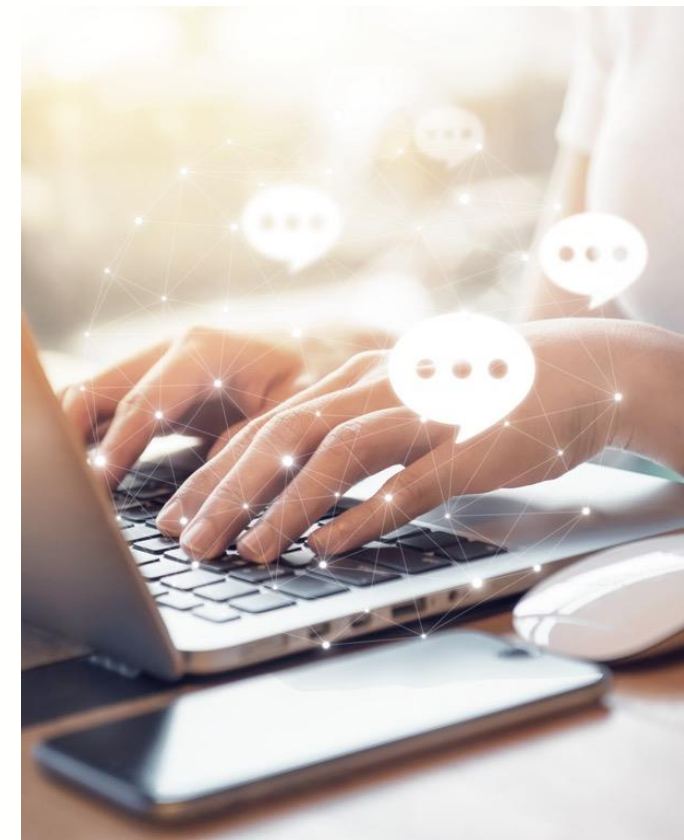
All feedback submitted to the RCE will be made publicly available on the RCE's and/or ONC's website, including any personally identifiable or confidential business information that you include in your feedback. **Please do not include anything in your feedback submission that you do not wish to share with the general public.**

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Opportunities for Stakeholder Feedback

General Sessions:

- Presentation to the Health IT Advisory Committee (October 13)
- October 19 Monthly Informational call

QHIN Technical Framework (Recorded webinars):
- QHIN Technical Framework Overview
- Essential Elements of QTF: A Technical Overview

Sign up for webinars at:
https://rce.sequoiaproject.org/

Questions?
Email us at rce@sequoiaproject.org

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Questions & Answers