Elements of the Common Agreement and the QHIN Technical Framework: Presentation to the HITAC

October 13, 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

- Common Agreement
  - Overview
  - Exchange purposes
  - Individual Access Services
  - Eligibility criteria
  - Privacy and security
  - Fees
  - Possible expanded use cases (e.g. research)

- QHIN Technical Framework
  - Overview
  - Message delivery
  - RCE directory
  - FHIR road map
  - Ways in which the TEFCA standards can support patient matching

- Discussion

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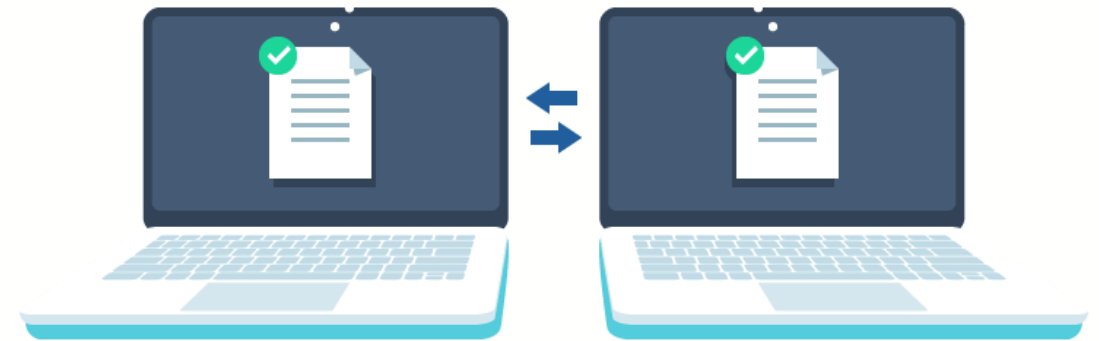
Meet the RCE Team

Mariann Yeager
CEO
The Sequoia Project

Alan Swenson
Executive Director
Carequality

Steve Gravely
Founder & CEO
Gravely Group

Cait Riccobono
Attorney
Gravely Group

Chantal Worzala
Principal
Alazro Consulting

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CURES Act and TEFCA: A Brief History

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Why do we need the Trusted Exchange Framework and Common Agreement (TEFCA)?

COMPLEXITY OF PROLIFERATION OF AGREEMENTS

Many organizations have to join multiple Health Information Networks (HINs), and most HINs do not share data with each other.

Trusted exchange must be simplified in order to scale.

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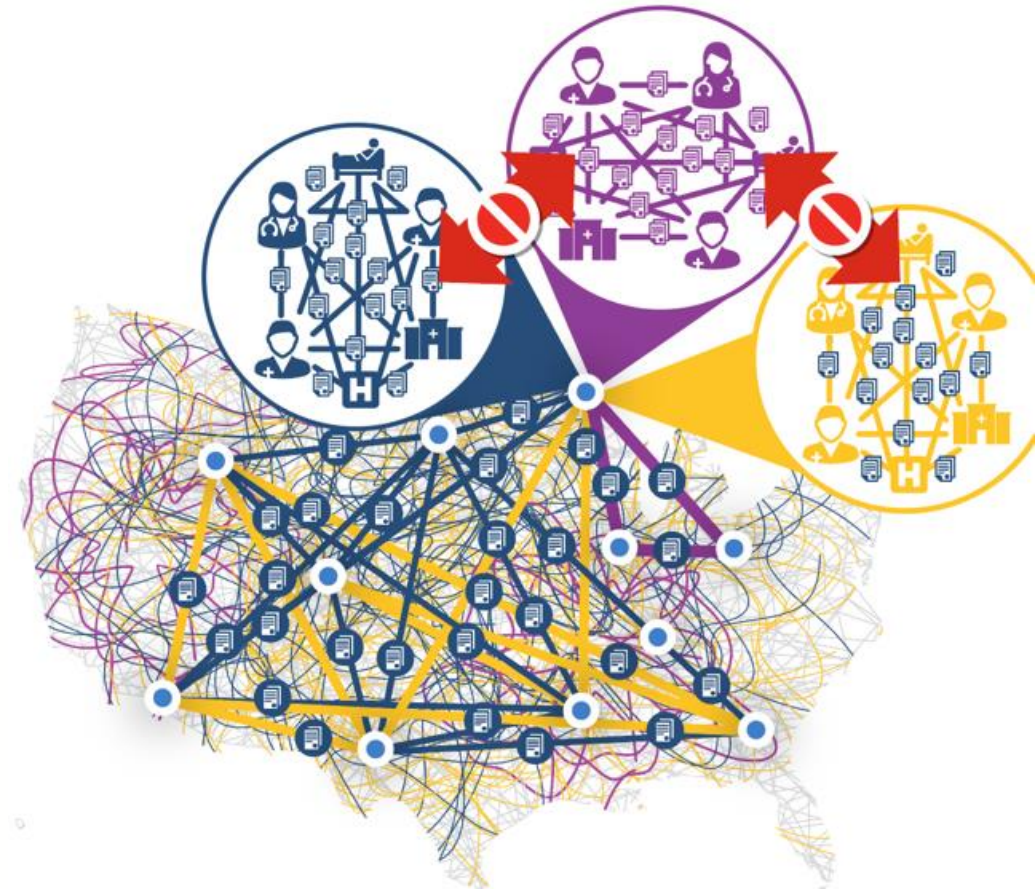
21st Century Cures Section 4003(b)

*"[T]he National Coordinator shall convene appropria[te] public and private stakeholders to **develop or suppor[t a] trusted exchange framework** for trust policies and practices and for a **common agreement** for exchang[e] between health information networks."* [emphasis added]
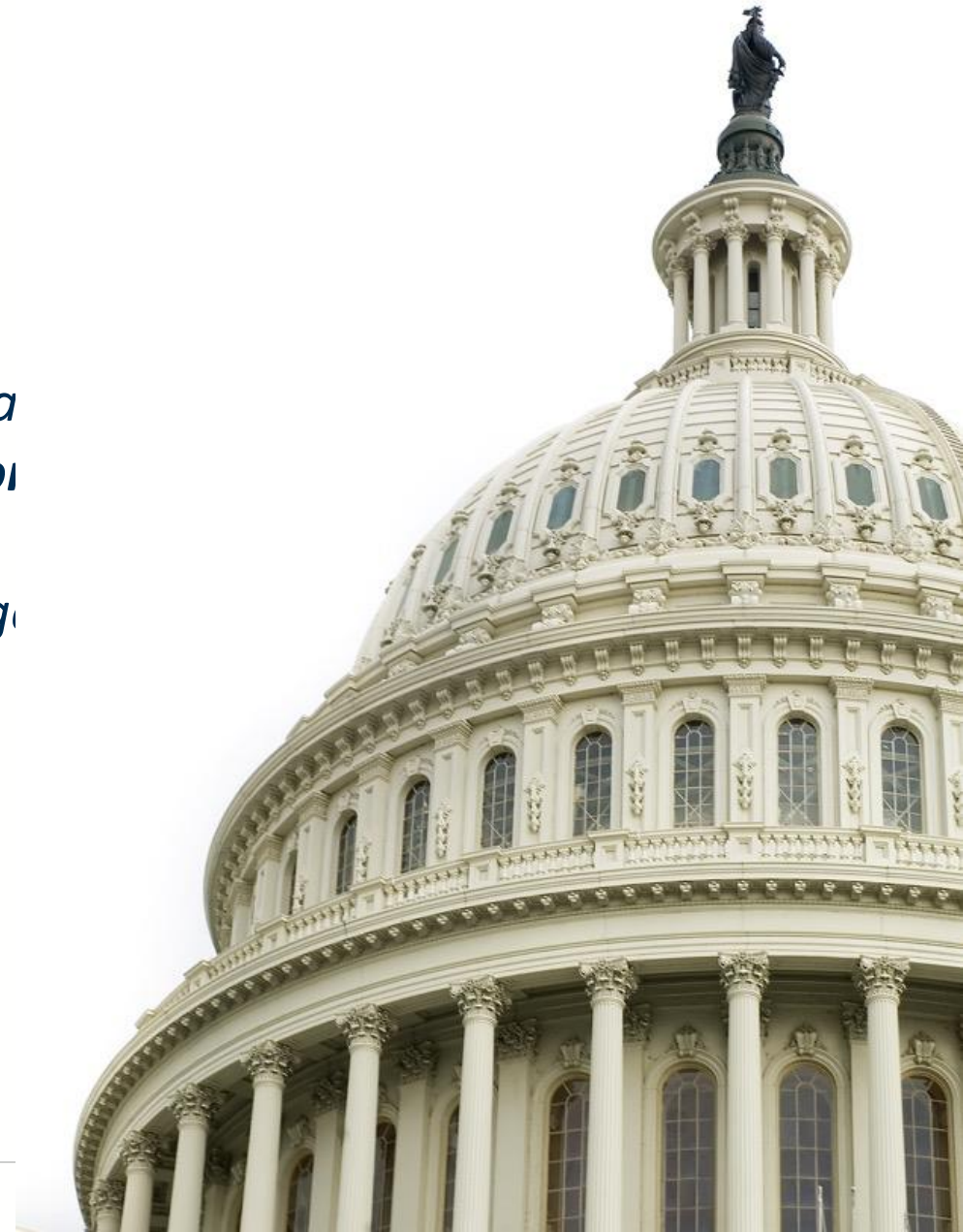
# Timeline to Operationalize TEFCA

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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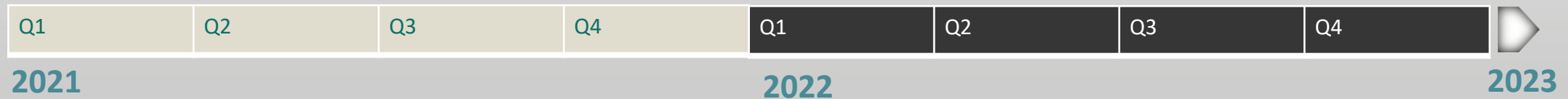
TEFCA Goals

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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Benefits of TEFCA

Relevant, trusted information from nationwide sources

Consumers
Access their own records from sources located across the nation.

Providers and health systems
Obtain complete picture of care across settings to improve care and coordination with fewer connection points.

State programs and public health
Enhance understanding of health metrics, reduce cost of public health reporting and program management.

Payers
Get and share data needed for care management, value-based care, etc.

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The Value Proposition for TEFCA

How Will TEFCA Work?

The Office of the National Coordinator for Health Information Technology

RCE

QHIN

QHIN

QHIN

QHIN

QHIN

PARTICIPANTS
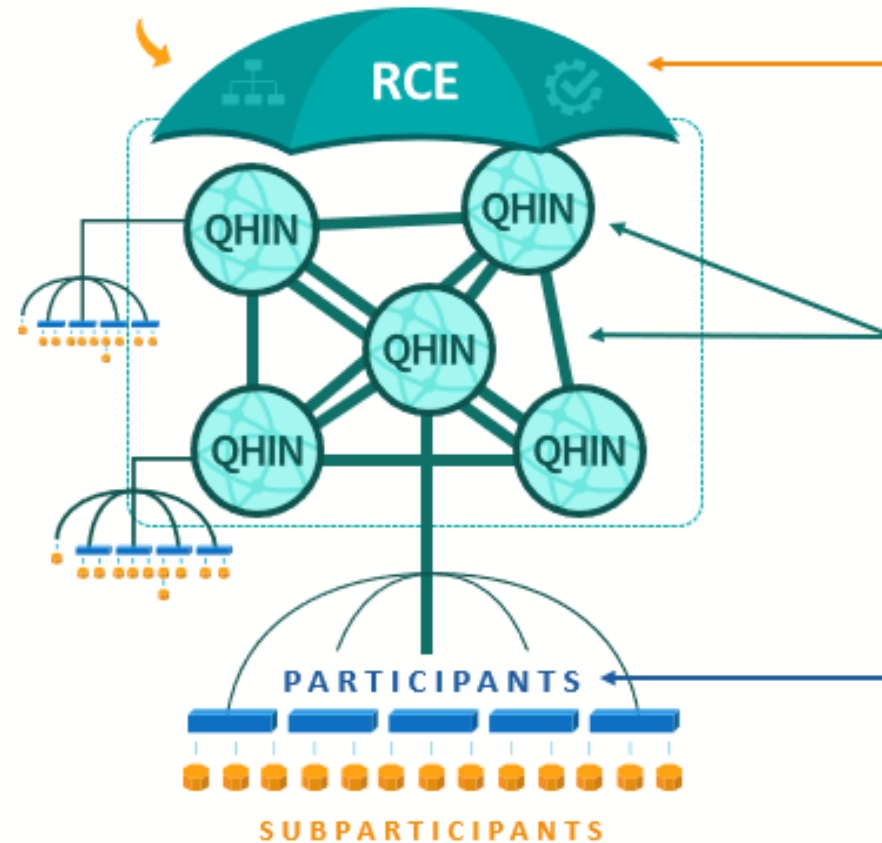
SUBPARTICIPANTS

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.

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Recognized Coordinating Entity (RCE)

- Develop, update, implement, and maintain the Common Agreement.

- Modify and update the QHIN Technical Framework.

- Virtually convene public stakeholder feedback sessions.

- Identify, designate, and monitor Qualified Health Information Networks (QHINs).

- Develop and maintain a process for adjudicating QHIN noncompliance.

- Propose strategies to sustain the Common Agreement at a national level.

Elements of the Common Agreement

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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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Cooperation and Non-Discrimination

- The Common Agreement would specify expectations of QHINs Participants and Subparticipants that would ensure that all par cooperate in certain aspects of exchange such as:
  - Timely responses to inquiries
  - Notification of persistent and widespread connectivity failu
  - Support in resolving issues
  - Sharing information regarding cybersecurity risks.

- QHINs, Participants, and Subparticipants would be prohibited limiting interoperability with any other QHIN, Participant, Subparticipant or Individual in a discriminatory manner.

- Cooperation and nondiscrimination are foundational values of TEFCA.

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Exchange Purposes

- The term Exchange Purposes identifies the reasons for which information could be requested and shared through QHIN-to-QHIN exchange

- At this time, only the six Exchange Purposes described above would be allowed under the Common Agreement

- The RCE plans to work with stakeholders to identify additional Exchange Purposes over time

- QHINs must support all Exchanges Purposes

Permitted Exchange Purposes

	Treatment
	Payment
	Health Care Operations
	Public Health
	Benefits Determination
	Individual Access Services

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Exchange Purposes

- For the purposes of QHIN-to-QHIN exchange, the terms **"Treatment," "Payment," and "Health Care Operations"** generally would have the same meaning as they do under the HIPAA Privacy Rule and would apply to all TEFCA Information, regardless of whether or not the parties to exchange are HIPAA Covered Entities or Business Associates.

- The **Public Health** Exchange Purpose would include requests for Uses and Disclosures of information by Public Health Authorities that are consistent with the HIPAA Privacy Rule and other Applicable Law.

- The **Benefits Determination** Exchange Purpose would support governmental agencies that need information to determine whether a person qualifies for non-health government benefits in a manner that is consistent with the HIPAA Privacy Rule and other Applicable Law.

- The Common Agreement anticipates the use of consumer-facing applications that would assist Individuals in obtaining access to their health information. This Exchange Purpose is called **Individual Access Services**. To the extent permitted by law, Individuals could use an account with a connected consumer-facing application or platform, prove who they are, and request their health information from entities connected via QHIN-to-QHIN exchange.

- Entities will not need to respond to **Individual Access Services** data requests if they meet an exception, which will include, for example, if they are themselves a Non-HIPAA Entity provider of Individual Access Services, or if they are prohibited from doing so by law.

Privacy

- Most connected entities will likely be HIPAA Covered Entities or Business Associates of Covered Entities, and thus already be required to comply with HIPAA privacy and security requirements.
- The Common Agreement would require health care provider non-HIPAA entities to protect TEFCA Information that is individually identifiable in substantially the same manner as HIPAA Covered Entities protect PHI, including having to comply with the HIPAA Security Rule and most provisions of the HIPAA Privacy Rule

- Discussion question: How should **other** non-HIPAA entities (such as IAS Providers) protect the privacy of TEFCA information?

TEFCA will promote strong privacy protections.

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Security

- QHINs will be expected to meet a high bar for security, including:
  - Third-party certification to an industry-recognized cybersecurity framework
  - Annual security assessments
- Flow-down contract provisions for all Participants and Subparticipants:
  - At a minimum, security measures that align with the HIPAA Security Rule, even if they are not HIPAA Covered Entities or Business Associates

- Security incident notifications affecting QHIN-to-QHIN exchange
  - Apply to QHINs
  - Flow down to Participants and Subparticipants
- Generally designed to avoid conflict with Applicable and duplicative notification requirements
- The RCE would actively facilitate security activities, with the support of a Cybersecurity Council drawn from participating QHINs

TEFCA will promote strong security protections.

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Requests, Uses and Disclosures, and Responses

- TEFCA **requests** would be transmitted via a QHIN's Connectivity Services and consistent with the requirements of the QTF.

- Only certain QHINs, Participants, or Subparticipants could make requests for each Exchange Purpose. Specifically, **a QHIN, Participant, or Subparticipant may only request, Use, or Disclose TEFCA Information for a specific Exchange Purpose if the QHIN, Participant, or Subparticipant is the type of person or entity that is described in the definition of the applicable Exchange Purpose.**

- **Uses and Disclosures** would adhere to the Common Agreement privacy and security requirements and any applicable privacy notices.

- **In most cases, QHINs, Participants, and Subparticipants would be required to respond** to a request for certain health information for any of the Exchange Purposes.

  - Responses would not be required by the Common Agreement if providing the information is prohibited by Applicable Law or the Common Agreement.

  - There would be six **specific exceptions** where a response is permitted but not required by the Common Agreement (such as Public Health Agency or Non-HIPAA Entity provider of Individual Access Services)

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QHIN Designation and Eligibility Criteria (1)

- 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 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 (2)

1. Signatory must demonstrate that it meets the definition of U.S. Entity.

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

QHIN Designation and Eligibility Criteria (3)
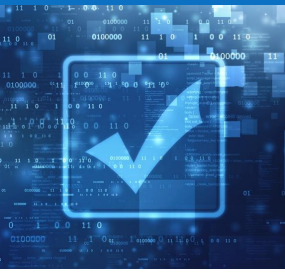
3. Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. Signatory can demonstrate this by having been in operation and supporting the query 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 (4)

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 Agreement 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.

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

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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RCE Directory Service

- The RCE would maintain an RCE Directory Service to support exchange of information between and among QHINs, Participants, and Subparticipants.

- The Common Agreement would identify the rights and limits of use to the RCE Directory Service. For example, the information contained in the RCE Directory Service is prohibited from being used for marketing purposes unless that marketing is merely incidental to an effort to expand or improve connectivity via the Common Agreement.

- The QTF specifies expectations for QHINs to access and contribute to the RCE Directory Service.

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Individual Access Services (IAS)

- IAS would be the services any QHIN, Participant, or Subparticipant provide to an Individual to satisfy that Individual's request to access, inspect, or obtain a copy of that Individual's TI that is then maintained by any QHIN, Participant, or Subparticipant.

- A QHIN, Participant or Subparticipant would be allowed but not required to offer Individual Access Services to Individuals with whom they have a Direct Relationship.

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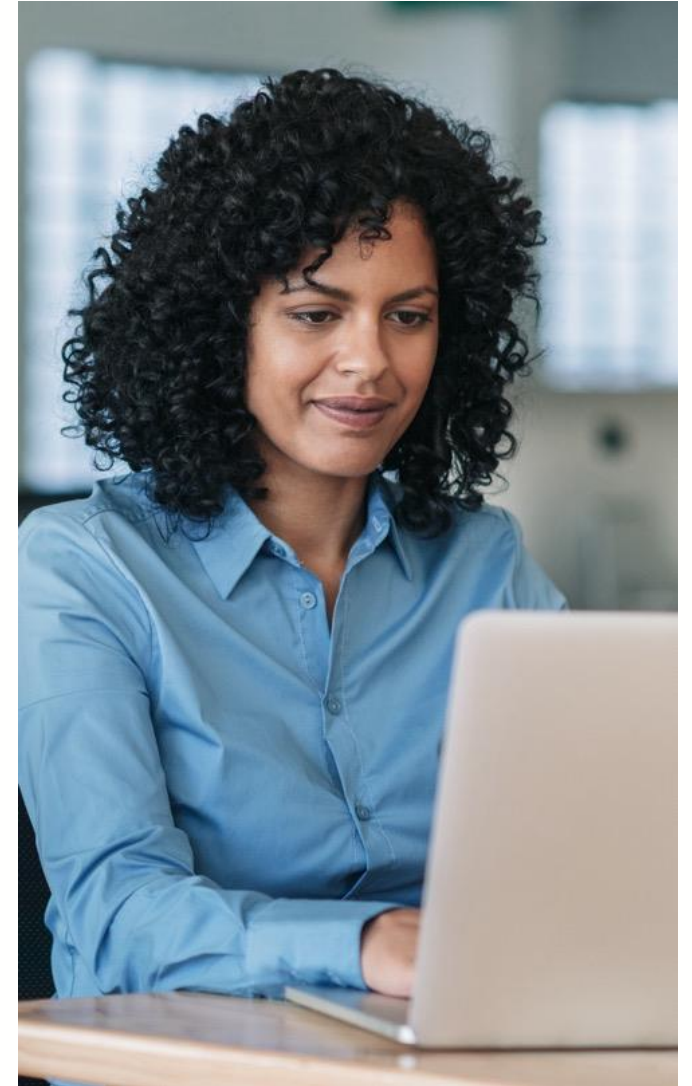
IAS Privacy and Security Requirements

- The Common Agreement would specify the privacy and security requirements that a QHIN, Participant, or Subparticipant would be required to adhere to if it chooses to become an IAS Provider.
  - Includes elements of a written privacy notice for such IAS Providers, which would include a description of the need to obtain express consent from Individuals regarding the way their information will be accessed, exchanged, Used, or Disclosed by the IAS Provider.
- The Common Agreement would specify Individual rights that IAS Providers would need to provide, such as:
  - The Individual's right to have deleted all of their individually identifiable information maintained by an Individual Access Service Provider and
  - The right to obtain an export of their data in a computable format.

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IAS Privacy and Security Requirements (2)

- IAS Providers would need to implement security requirements, including encryption and certain security incident notifications

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Fees

1. The Common Agreement is expected to include a provision that prohibits a QHIN from charging fees to other QHINs with respect to activities under the Common Agreement.

2. QHINs would not be prohibited from charging fees to Participants.

The RCE is specifically seeking input on the issue of fees.

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Questions & Answers

QHIN Technical Framework

What is the QHIN Technical Framework?

The **QHIN Technical Framework (QTF)** outlines the specifications and other technical requirements necessary for QHINs to accomplish exchange

The QTF primarily addresses QHIN-to-QHIN transactions, and where possible we propose to be silent on how the necessary functional outcomes are achieved within a QHIN.

Nonetheless, there are some requirements that must be enforced at the Participant and Subparticipant level.

QHIN Technical Framework
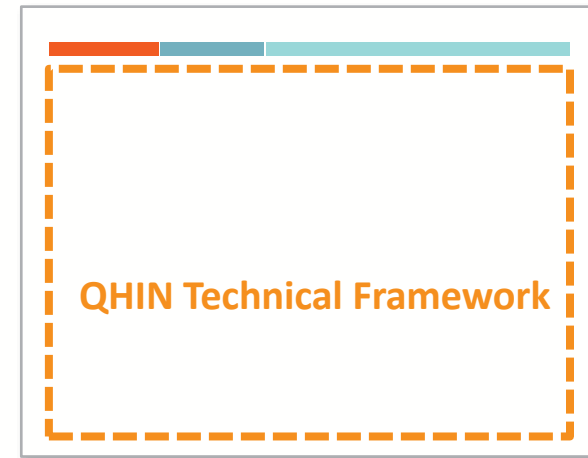
**Draft published by the RCE
for public feedback until 9/17**

https://rce.sequoiaproject.org/qhin-technical-framework-feedback/

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Elements of the QHIN Technical Framework

Supported Information Flows:

- Patient Discovery
- Document Query
- Message Delivery

Functions and Technology to Support Exchange

- Certificate Policy
- Secure Channel
- Mutual QHIN Server Authentication
- User Authentication
- Authorization and Exchange Purpose
- Patient Identity Resolution
- Individual Privacy Preferences
- Directory Services
- Auditing
- Error Handling
- Onboarding and Testing

Approach:

- Build from current capabilities
- Deploy known standards
- Keep an eye toward future approaches

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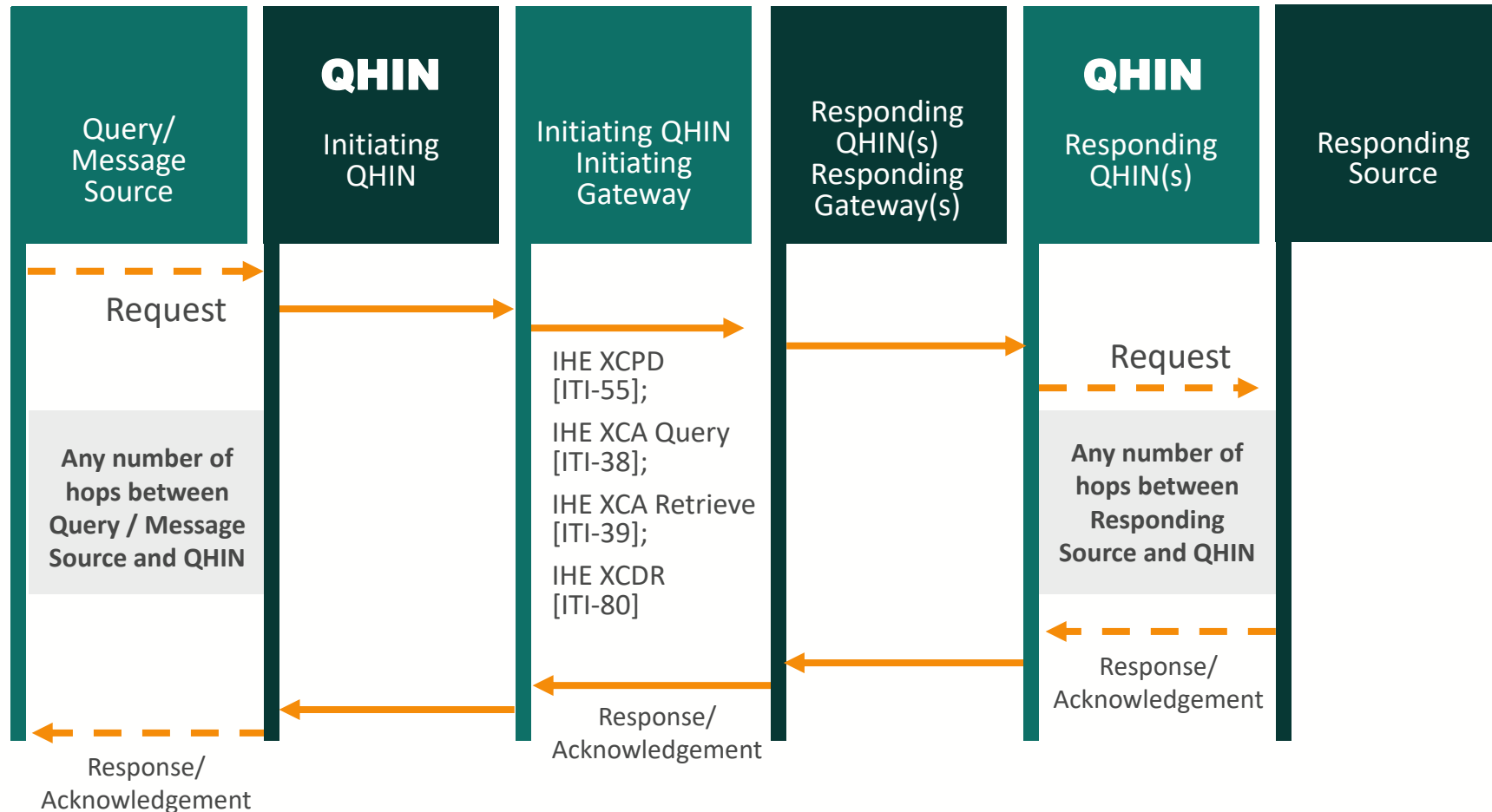COORDINATING
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Exchange Modalities

Query

- Patient Query
- Document Query
- Document Retrieve

Message Delivery

- Message Delivery

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Information Exchange Modalities

When Will TEFCA Have FHIR?

- FHIR roadmap planned for release with the final QTF Version 1.

- Value of FHIR based exchange when using certified health IT

- Need to address concerns based on QHIN-to-QHIN exchange model:

  – Security model with multi-hop.

  – OAuth not designed for multi-hop.

    • Originating user unknown to responder.

  – Routing RESTful transactions over multi-hop

- We are asking for feedback on how to support FHIR-based exchange in the future.

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
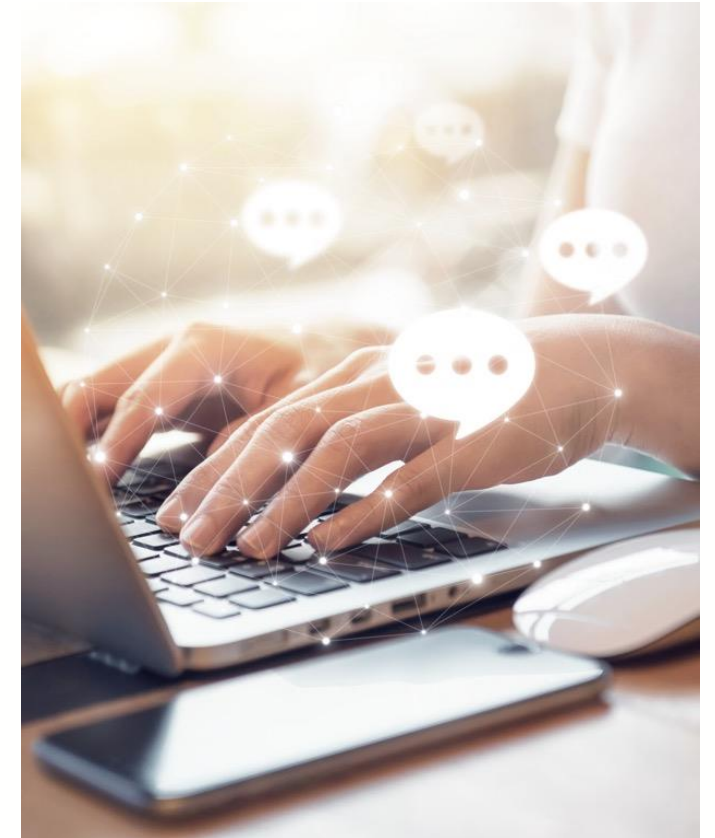
All feedback submitted to the RCE will be made publicly available on the RCE's and/or ONC's website, including any personally identifiable or confidential business information that you include in your feedback. **Please do not include anything in your feedback submission that you do not wish to share 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