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February 2023

User's Guide to the Trusted Exchange Framework and Common Agreement – TEFCA

TEFCA User's Guide – Version 1.1
Originally Published January 2022

This informational resource describes select aspects of the TEFCA but is not an official statement of any policy. Please refer to the official versions of referenced documents.

Visit RCE.SequoiaProject.org to view the Common Agreement Version 1.

Version History

Version 1.1 released on 2/28/2023: Corrections or edits made in Version 1.1 to slides 5 (correcting release date), slide 21 (reference to new resource), slide 22 (to link to website location of all Standard Operating Procedures and update examples), slide 25 (reference to Cybersecurity Council), slide 32 (to more clearly describe FHIR Roadmap process and remove dated graphic), slide 35 (to reference Exchange Purposes SOP), slide 36 (to more clearly describe the Public Health Exchange Purpose), slide 38 (to reference Exchange Purposes SOP), slides 49 and 50 (to correct the numbers on mislabeled arrows), slide 60 (to more clearly describe RCE supports), slide 61 (to better reflect the application process), and slide 63 (to reflect updates to the timeline).

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General Disclaimers

- The information in this presentation is based on the Common Agreement Version 1, the Qualified Health Information Network (QHIN) Technical Framework Version 1, and the Standard Operating Procedures as of January 2023.

- While every effort has been made to ensure accuracy, this presentation is not a legal document.

- Examples are merely illustrative and may be simplified for ease of discussion.

- Readers should consult the latest versions of the Common Agreement, the QHIN Technical Framework, and Standard Operating Procedures for the definitive requirements.

- This communication is produced and disseminated at U.S. taxpayer expense.

Why do we need TEFCA?

*"[T]he National Coordinator shall convene appropriate public and private stakeholders to **develop or support** a **trusted exchange framework** for trust policies and practices and for a **common agreement** for exchange between health information networks."*
[emphasis added]

Proliferation of Agreements

While there has been growth in national networks, many organizations must join multiple Health Information Networks (HINs)*, and many HINs do not share data with each other.

The COVID pandemic also underscored the need to share information for care and public health purposes.

Health data exchange must be simplified in order to scale.
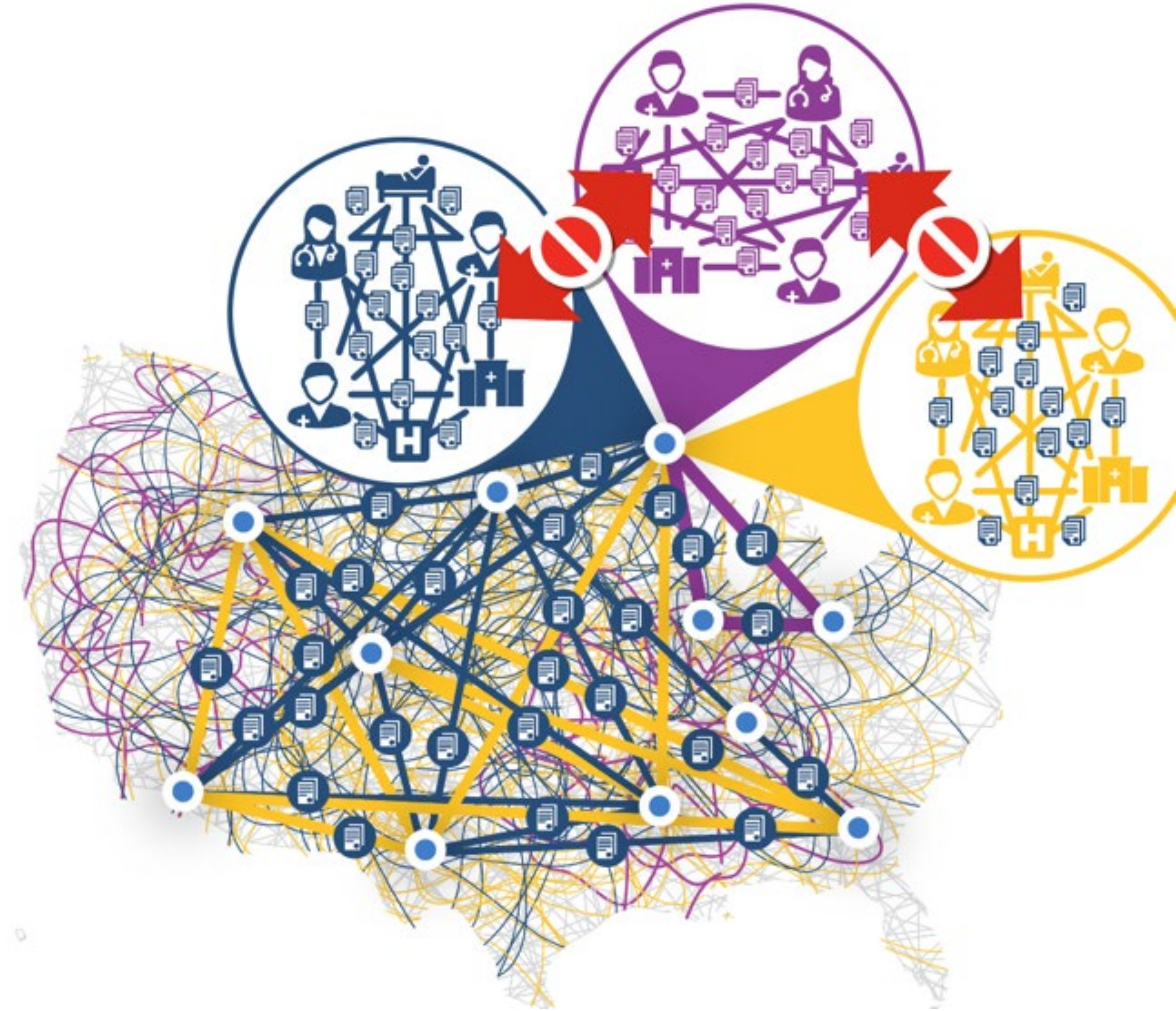
*Capitalized terms have the definitions set forth in the Common Agreement Version 1.

TEFCA Will Create Market Efficiencies

Healthcare organizations are currently burdened with creating many costly, point-to-point interfaces between organizations.

TEFCA **would reduce the need for duplicative network connectivity interfaces**, which are costly, complex to create and maintain, and an inefficient use of provider and health IT developer resources.

## Proliferation of Interoperability Methods

A nationally representative survey by the American Hospital Association found:

- The average number of electronic methods hospitals use to send, receive, and find (or query) health information has increased.[1]
- On average, hospitals used about three different electronic methods for sending (3.59) and receiving (2.90) summary of care records in 2019. [2]
- In addition, 7 in 10 hospitals face at least one challenge in reporting to public health using electronic means.[3]

[1] Johnson C. & Pylypchuk Y. (February 2021). Use of Certified Health IT and Methods to Enable Interoperability by U.S. Non-Federal Acute Care Hospitals, 2019. ONC Data Brief, no.54. Office of the National Coordinator for Health Information Technology: Washington DC. Available at https://www.healthit.gov/sites/default/files/page/2021-03/Hospital%20Use%20of%20Certified%20HIT_Interop%20v10_1.pdf.
[2] ibid.
[3] Richwine C., Marshall, C., Johnson C., & Patel, V. (September 2021). Challenges to Public Health Reporting Experienced by Non-Federal Acute Care Hospitals, 2019. ONC Data Brief, no.56. Office of the National Coordinator for Health Information Technology: Washington DC. Available at https://www.healthit.gov/sites/default/files/page/2021-09/Challenges-to-PH-Reporting.pdf.
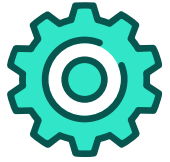
GOAL 1

Establish a universal policy and technical floor for nationwide interoperability

GOAL 2

Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value

GOAL 3

Enable individuals to gather their health care information

Benefits of TEFCA

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Relevant, trusted information from nationwide sources for:

Individuals
Use an app to access their own records from TEFCA-connected sources located across the nation.

Providers and Health Systems
Improve care, coordination and population health by obtaining a more informed picture of care across settings through fewer connection points.

Public Health
Improve quality, reduce costs, and expand public health interoperability.

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

Health Information Networks
Enhance the value of network participation and lower the cost of connecting with other networks.

Technology Developers
Provide a scalable policy and technical ecosystem for innovation.
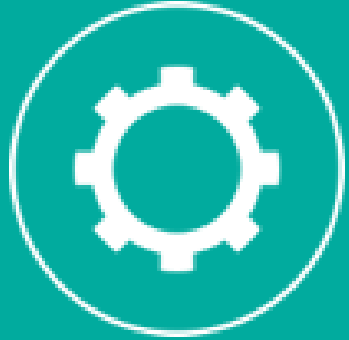
Researchers (Future)
Improve quality, reduce costs, and expand participation in clinical research.

For more detail on the benefits of TEFCA for stakeholders, see factsheets at: https://rce.sequoiaproject.org/tefca-and-rce-resources/

How will exchange work under TEFCA?

How will exchange work under TEFCA?
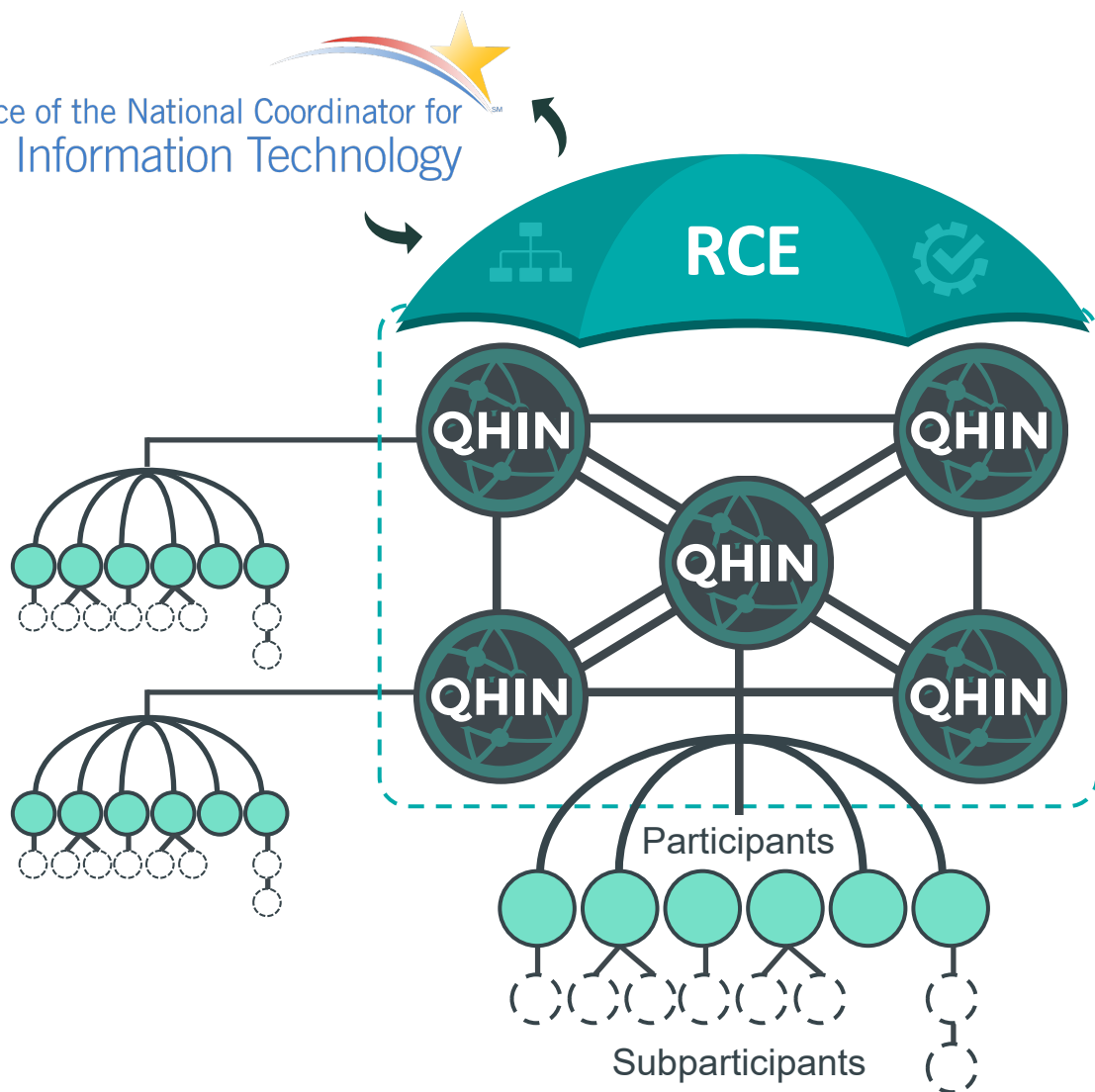
ONC defines overall policy and certain governance requirements.

RCE provides oversight and governing approach for QHINs.

Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.

Each QHIN connects Participants, which connect Subparticipants.

The Role of the Recognized Coordinating Entity (RCE)

RCE

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

- Modify and update the Qualified Health Information Network Technical Framework (QTF).

- 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.

The Role of a Qualified Health Information Network

QHIN Example
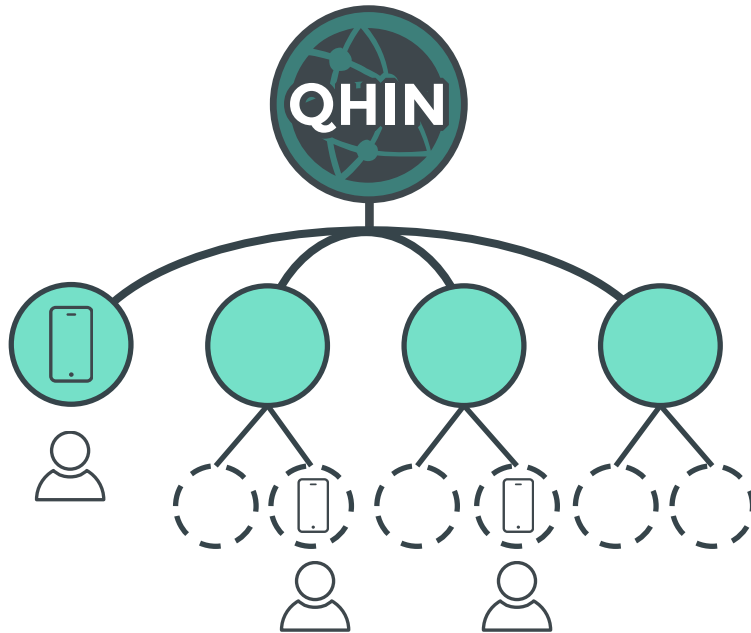
Legend:
- Participant
- Subparticipant
- Consumer App offered by Participant or Subparticipant
- Individual

A **QHIN** is an entity with the technical capabilities and organizational attributes to connect health information networks on a nationwide scale.

- High volume
- High reliability
- Abides by the Common Agreement
- Adheres to the QHIN Technical Framework

Participants and Subparticipants will be able to choose their QHIN based on the services provided and fees charged.

Participants and Subparticipants will be able to share information with all other connected entities regardless of which QHIN they choose.

QHINs may not charge fees to other QHINs for any exchange of information under the Common Agreement.

Framework Agreement Flow-Down Provisions

Common Agreement

Each QHIN shall voluntarily enter into a contractual agreement with the RCE by signing the Common Agreement, making all QHINs parties to the Common Agreement. The Common Agreement includes flow-down clauses for the QHIN's agreements with its Participants and each Participant's agreements with its Subparticipants.

Required Flow-Downs Will Address:

- Cooperation and Nondiscrimination
- Confidentiality
- Utilization of the RCE Directory Service
- Uses, Disclosures, and Responses
- Individual Access Services

- Privacy
- Security
- Special Legal Requirements
- TEFCA Information Outside the U.S.
- Other General Obligations

Entities may connect into exchange at any level, but must abide by the flow-down provisions, which create common "rules of the road."
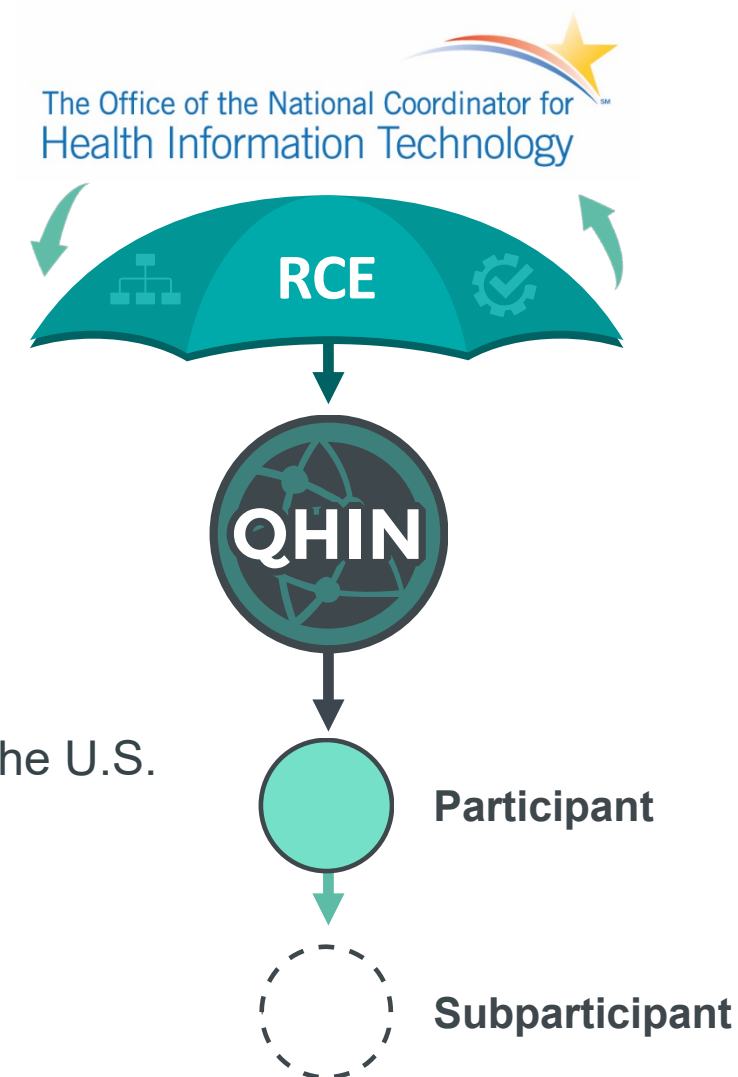
Example of QHIN, Participants, and Subparticipants
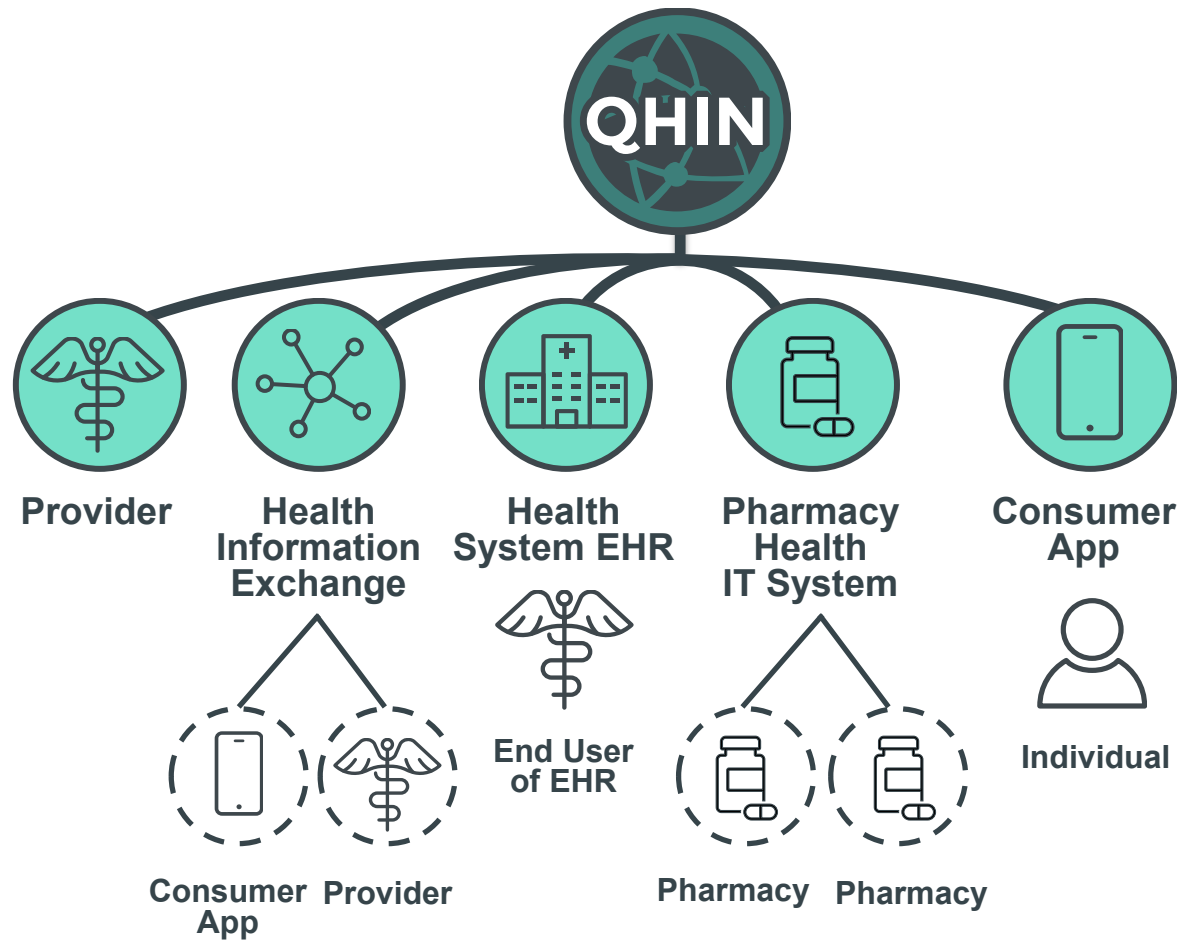
In this example, the QHIN supports a broad range of different Participants, including a provider, a health information exchange (HIE), an Electronic Health Record (EHR) system, a pharmacy health information technology (IT) system, and a consumer application that is an Individual Access Services (IAS) Provider.

The members of the HIE and the pharmacy health IT system are Subparticipants.

Individuals can connect to QHINs, Participants, and Subparticipants that choose to be IAS Providers. In this example, one consumer app is a Participant of the QHIN and another consumer app is a Subparticipant of the HIE.

What are the components of TEFCA?

TEFCA Components

Trusted Exchange Framework

Common Agreement

Standard Operating Procedures

QHIN Technical Framework

QHIN Onboarding

Metrics

Governing Approach

Trusted Exchange Framework

The **TEF** describes a common set of non-binding, foundational principles for policies and practices to facilitate data sharing among health information networks.

Broad industry alignment with these principles can help entities enter into more uniform contractual relationships that are required for improved electronic flow of health information where and when it is needed.

The TEF includes seven principles:

Standardization

Openness and Transparency

Cooperation and Non-Discrimination

Privacy, Security, and Safety

Access

Equity

Public Health

The Common Agreement

- The **Common Agreement** establishes the infrastructure model and governing approach for users in different health information networks to securely share clinical information with each other.

- The Common Agreement is a legal contract that both the RCE signs and a QHIN signs.

  » The latter becomes a Qualified Health Information Network (QHIN) once fully onboarded and designated by the RCE.

- Some provisions of the Common Agreement will flow down to entities in a QHIN's network via other agreements.

  » TEFCA Flow-Down Resource available

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

Standard Operating Procedures

The RCE has developed SOPs on topics such as:

- Advisory Groups
- Conflicts of Interest
- Dispute Resolution Process
- Exchange Purposes
- Governing Council

- QHIN Security of TEFCA Information
- QHIN Cybersecurity Insurance
- QHIN Application
- QHIN Onboarding and Designation
- QHIN Security Requirements for the Protection of TEFCA Information

Additional SOPs will be made available over time. All current SOPs are available at https://rce.sequoiaproject.org/tefca-and-rce-resources/.

What is a Standard Operating Procedure? An SOP is a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into this 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. Each SOP identifies the relevant group(s) to which the SOP applies, including whether Participants and/or Subparticipants are required to comply with a given SOP. An SOP shall be deemed in effect when adopted pursuant to Section 5.3 of this Common Agreement and listed on a public website.

What is the QHIN Technical Framework?

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

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

There are some requirements that must be enforced at the Participant and Subparticipant level.

The QTF is available at RCE.SequoiaProject.org

QHIN Eligibility Criteria, Onboarding, and Designation

- TEFCA includes QHIN eligibility criteria that generally address:
  - » The ability to perform the required functions of a QHIN, per the QTF.
  - » The legal structure and governing approach for a QHIN.
  - » Demonstrated resources and infrastructure to support a reliable and trusted network.

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

- The RCE will conduct extensive education for candidate QHINs on the application and onboarding processes.

- Only the RCE designates QHINs.

Governing Approach

- QHINs, Participants, and Subparticipants shall have the opportunity to engage in governance under the Common Agreement.

- The Common Agreement creates a Governing Council that:
  - » Reviews amendments to the Common Agreement, QTF, and SOPs.
  - » Serves as a resource to the RCE and forum for discussion.
  - » Provides oversight for resolution of disputes.

- A Transitional Council serves during TEFCA's first year.

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

GOVERNING COUNCIL

- QHIN CAUCUS
- PARTICIPANT/ SUBPARTICIPANT CAUCUS
- ADVISORY GROUPS
- CYBERSECURITY COUNCIL

Cooperation and Non-Discrimination
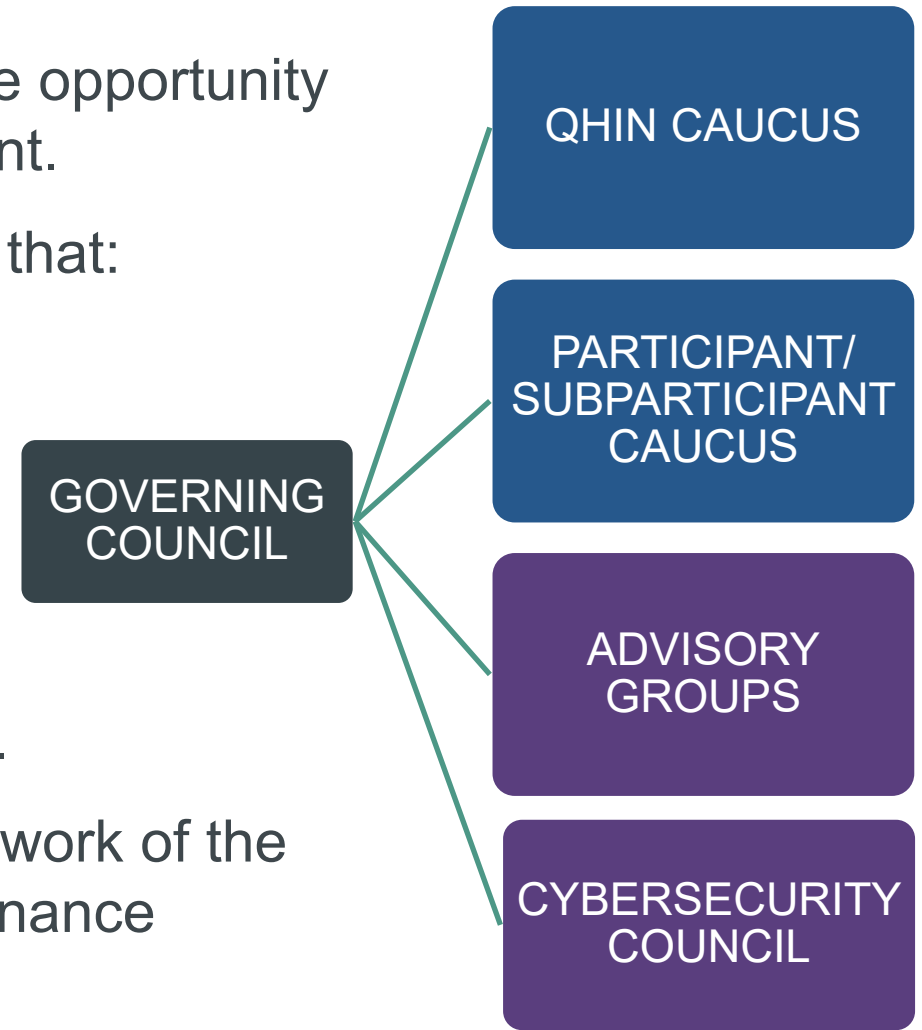
- The Common Agreement specifies expectations of QHINs, Participants, and Subparticipants to ensure that all parties cooperate in certain aspects of exchange such as:

    » Timely responses to inquiries.
    » Notification of persistent and widespread connectivity failures.
    » Support in resolving issues.
    » Sharing information regarding cybersecurity risks.

- QHINs, Participants, and Subparticipants are prohibited from limiting interoperability with others in a discriminatory manner.
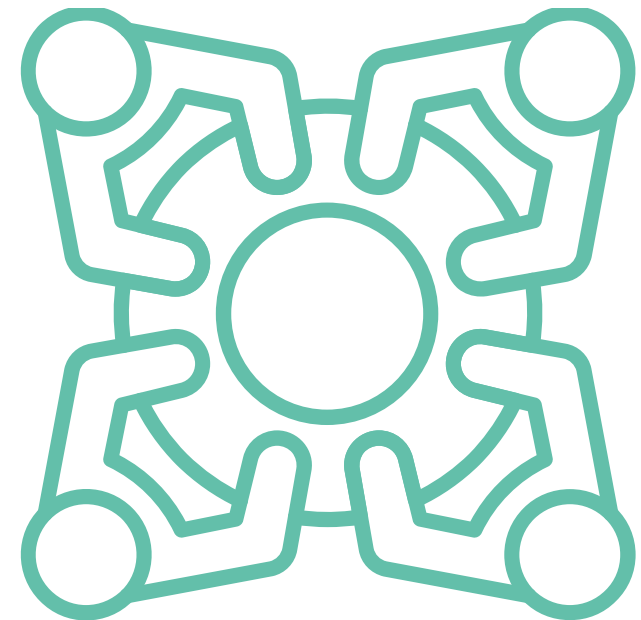
What are the technical aspects of TEFCA?

Components of the QHIN Technical Framework

Supported Information Flows:

- Patient Discovery
- Document Query
- Message Delivery

Data Exchanged (Query):

- Available electronic health information in C-CDA 2.1, including the United States Core Data for Interoperability (USCDI) V1

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

Exchange Modalities

Query
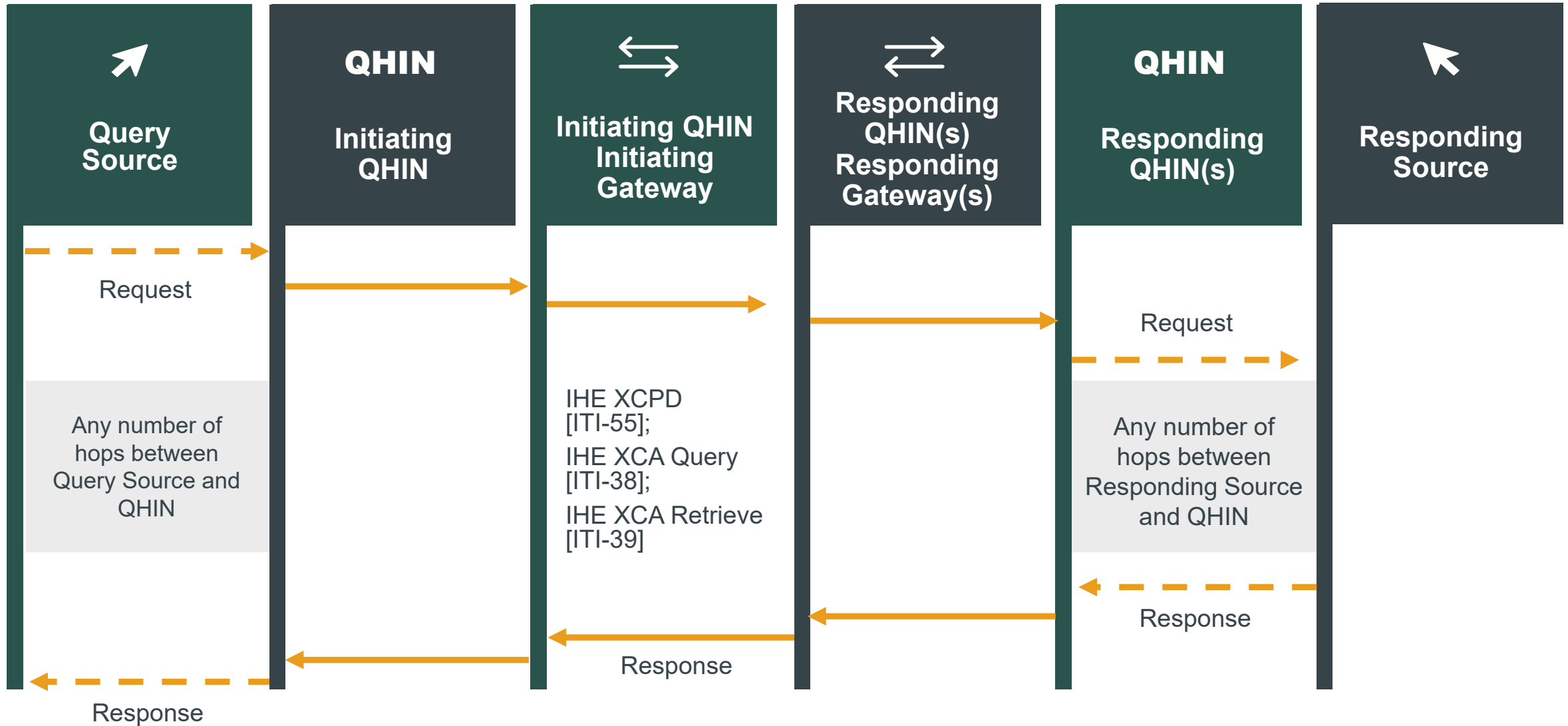- o Patient Query
- o Document Query
- o Document Retrieve

Message Delivery

Note: Entities within a QHIN's network must respond to queries for Exchange Purposes in accordance with the Common Agreement and applicable law, but do not have to be able to receive data sent to them using message delivery.

Query – Technical Data Flow Diagram

Message Delivery – Technical Data Flow Diagram
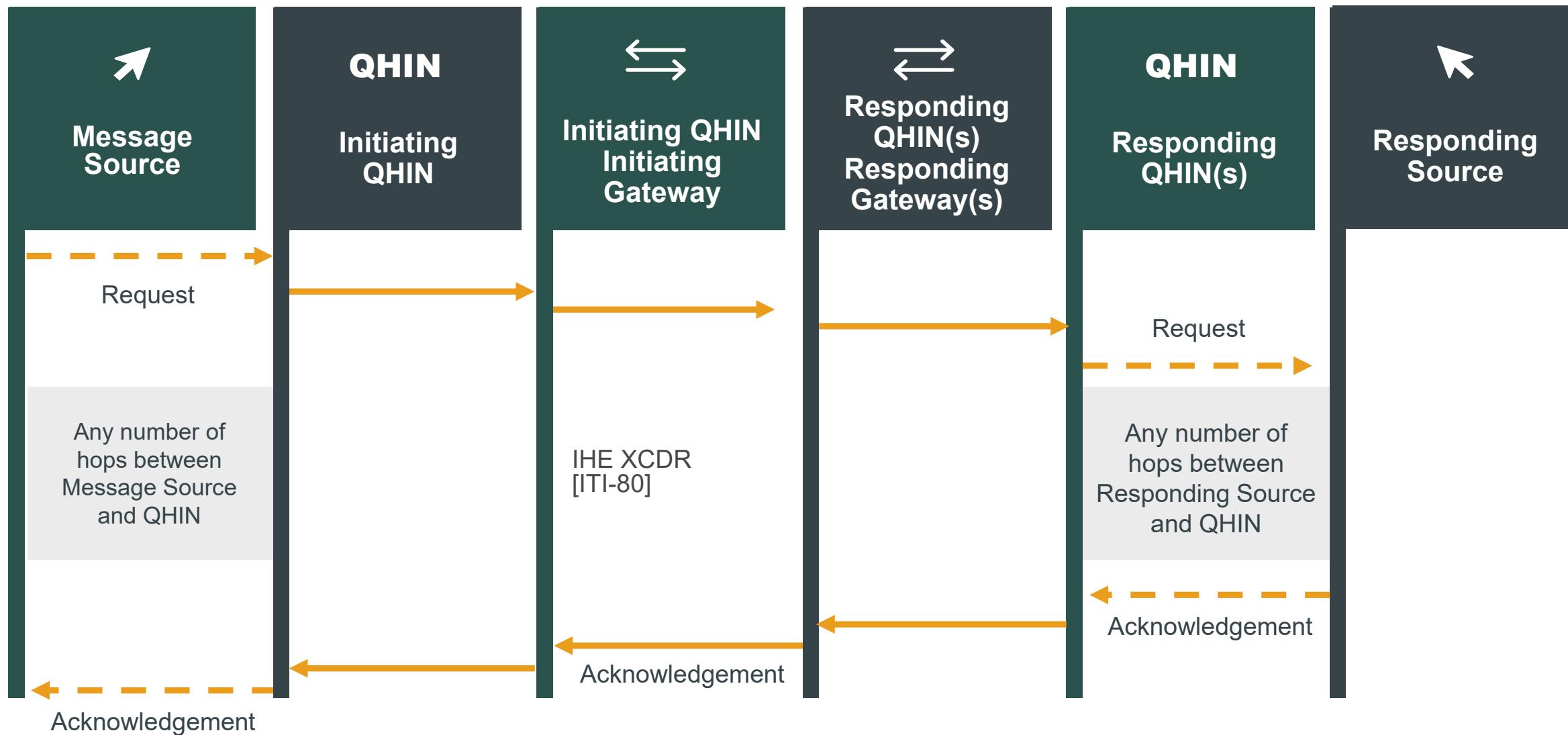
- ONC and the RCE have published the "FHIR® Roadmap for TEFCA Exchange – Version 1."

- Evolving health IT landscape requires TEFCA to rapidly include approaches that support FHIR.

  » Approach leverages current state of FHIR today and allows TEFCA policy and technical infrastructure to accelerate FHIR adoption into the future.

  » The RCE will develop the use of FHIR for both QHIN-brokered and facilitated FHIR exchange.

Planned Stages of FHIR Availability in TEFCA:

Stage 1: FHIR Content Support
- FHIR exchange possible within QHINs' own networks
- IHE exchange of FHIR payloads between QHINs *is possible with* *"out-of-band" coordination*.

Stage 2: Network-Facilitated FHIR Exchange
- QHIN-facilitated FHIR-based exchange available as an *option* under TEFCA.

Stage 3: Network-Brokered FHIR Exchange
- QHIN-facilitated FHIR-based exchange *required* under TEFCA
- QHIN-brokered FHIR API exchange *optionally* available.

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

- The Common Agreement identifies the rights and limits of use of 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.

What are the Exchange Purposes under TEFCA and how do they work?

- The Exchange Purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange.

- Only these six Exchange Purposes are authorized under the Common Agreement.

- The Exchange Purposes SOP specifies that Treatment and Individual Access Services (IAS) require Responses.

- Eventually, the other four Exchange Purposes will require Responses in conformance with forthcoming implementation SOPs. These will be rolled out with adequate time for stakeholders to prepare.

- Additional Exchange Purposes may be added over time, including whether they require Responses.

Permitted Exchange Purposes

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

Exchange Purposes

- **"Treatment," "Payment," and "Health Care Operations"** generally have the same meanings as they have under the HIPAA Privacy Rule and apply to all TEFCA Information, regardless of whether the parties to exchange are HIPAA Covered Entities or Business Associates.

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

- The **Government Benefits Determination** Exchange Purpose supports 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**.

- TEFCA **Requests** will be transmitted via a QHIN-to-QHIN exchange and consistent with the requirements of the Common Agreement.

  » Only QHINs and certain Participants or Subparticipants can make Requests for each Exchange Purpose.

- **Uses and Disclosures** must adhere to the privacy and security requirements in the Common Agreement, any privacy and security notices, and any requirements of applicable law.

As specified in the Exchange Purposes SOP, Requests for Treatment and Individual Access Services are the first types of Exchange Purposes to which TEFCA entities are required to Respond.

Responses would not be required if providing the information is prohibited by Applicable Law or the Common Agreement permits but does not require a Response (see the Common Agreement Section 9.4.1, Exceptions to Required Responses).
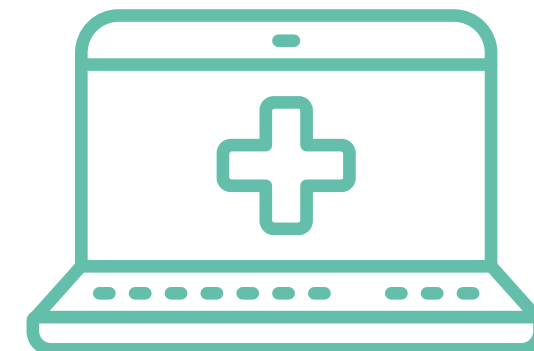
The following entities are permitted, but not required, to Respond to Requests:

- Public Health Authorities.

- Users of Government Benefits Determination Exchange Purpose.

- Federal agencies, to the extent that the requested Disclosure of Required Information is not permitted under Applicable Law.

Who Can Conduct Exchange Pursuant to an Exchange Purpose?

A QHIN, Participant, or Subparticipant may only Request information under TEFCA for a specific Exchange Purpose if it is the type of person or entity that is described in the definition of the applicable Exchange Purpose.

For example, only a Health Care Provider as defined in the HIPAA Rules or the information blocking regulations (or a Business Associate, agent, or contractor acting on that Health Care Provider's behalf) may Request information for the Exchange Purpose of Treatment.

- A provider of social services that is not a health care provider would generally not be able to request data for Treatment, Payment, or Health Care Operations.

- Such providers of social services could request information if they did so as an Individual Access Services Provider or if they were serving as a contractor to a health care provider, for example.

Individual Access Services (IAS)

What is IAS?
IAS is, with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant.

In general, entities are <u>required to Respond</u> to Requests for information for the purpose of Individual Access Services.

What is an IAS Provider?
Each QHIN, Participant, and Subparticipant that offers Individual Access Services.

It is <u>optional to be an IAS Provider</u>.

Individuals will be able to access their own information from all connected entities through an IAS Provider.

Patient Matching

- QHINs must be capable of accurately resolving requests to match patient demographic information with patient identities.

- QHINs, Participants, and Subparticipants can choose patient matching techniques that meet their business needs, if they satisfy the functional requirement to accurately match patients and locate their records. Examples include Enterprise Master Patient Index (eMPI), a Record Locator Service, or other means.

- To help support accurate patient matching, the Query or Message Delivery source is required by the QTF to include all available demographic information to facilitate a positive match.

- Patient matching can be centralized (a QHIN function) or distributed (a Participant function).

- The RCE is actively participating in the national dialogue to improve patient matching work and will work with QHINs to develop matching recommendations and/or requirements in the future.

TEFCA Information (TI): any information that is exchanged between QHINs for one or more of the Exchange Purposes pursuant to any of the Framework Agreements. As a matter of general policy, once TI is received by a QHIN, Participant, or Subparticipant that is a Covered Entity or Business Associate and is incorporated into such recipient's system of records, the information is no longer TI and is governed by the HIPAA Rules and other Applicable Law.

Framework Agreement(s): any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.

Required Information (RI): Electronic information maintained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement:
> (i) that would be electronic protected health information (ePHI) if maintained by a Covered Entity or a Business Associate; and
> (ii) regardless of whether the information is or has already been transmitted via QHIN-to-QHIN exchange.
Notwithstanding the foregoing, the following types of information are not Required Information:
> (a) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; or
> (b) psychotherapy notes (as defined in the HIPAA Privacy Rule (45 CFR 164.501)).

ePHI and PHI: have the meanings assigned to such terms in the HIPAA Privacy Rule (45 CFR § 160.103).

What are some examples of use cases that leverage the Exchange Purposes?

Context for Example Use Cases

> The following slides are examples of potential current and future use cases that leverage the TEFCA Exchange Purposes.

> The examples show simplified versions of the steps involved in exchange.

> Some of the detailed steps are not depicted or are abstracted.

> Several of the examples leverage Exchange Purposes that are authorized under TEFCA, but do not require response to queries.

Exchange Purpose Example – Treatment

Use Case: Referral using Message Delivery.

PCP

Health System A **QHIN A** QHIN Message Delivery **QHIN B** **Dermatologist** **Health System B**
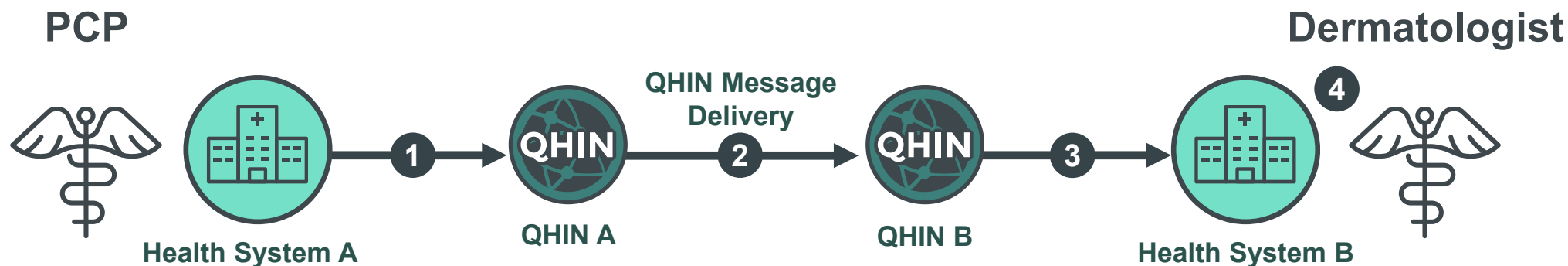
1 Primary care provider (PCP) is an end user of Health System A's EHR (Health System A is a Participant). PCP creates and sends a referral to a dermatologist for Treatment. Health System A sends care summary to its QHIN A.

2 QHIN A initiates QHIN Message Delivery to send the care summary to QHIN B.

3 QHIN B sends care summary to the appropriate Participant, in this case Health System B.

4 Dermatologist (end user of Health System B's EHR) can access the referral within Health System B's EHR.

Exchange Purpose Example – Payment*

Use Case: Sharing a documentation for reimbursement using Message Delivery.

1 An Accountable Care Organization (a Participant of QHIN A) needs to send documentation of quality metrics to a health plan, consistent with its contract, to satisfy a reimbursement requirement. ACO sends documentation of quality metrics to QHIN A.

2 QHIN A executes QHIN Message Delivery to QHIN B.

3 QHIN B delivers the documentation of quality metrics to the health plan (Participant of QHIN B).

*Payment is an authorized Exchange Purpose under the Common Agreement but response to a query for this Exchange Purpose is not required as of February 2023.

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Use Case: Quality improvement activity using Query.
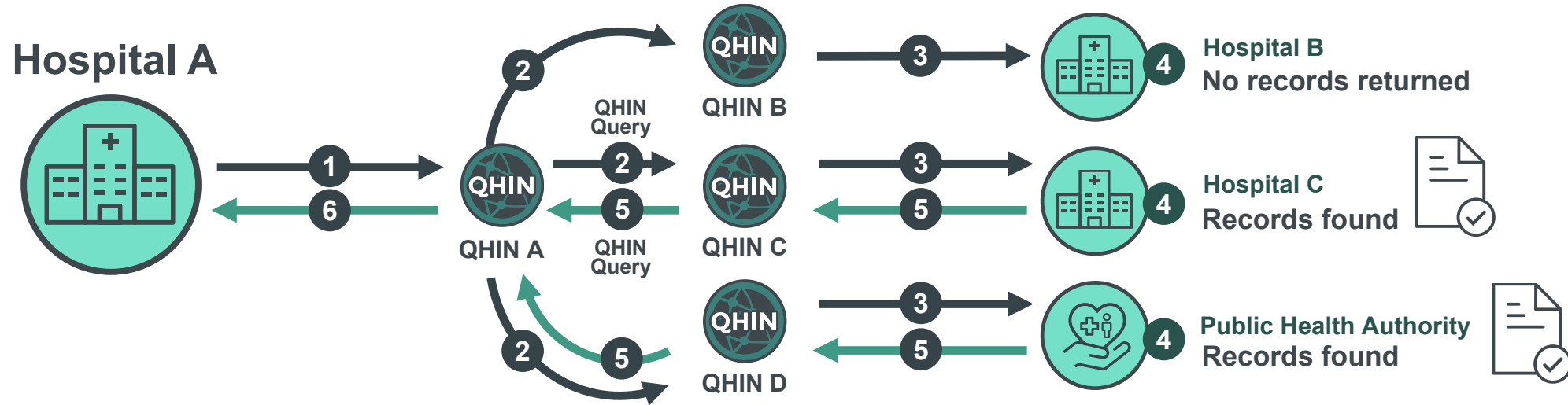
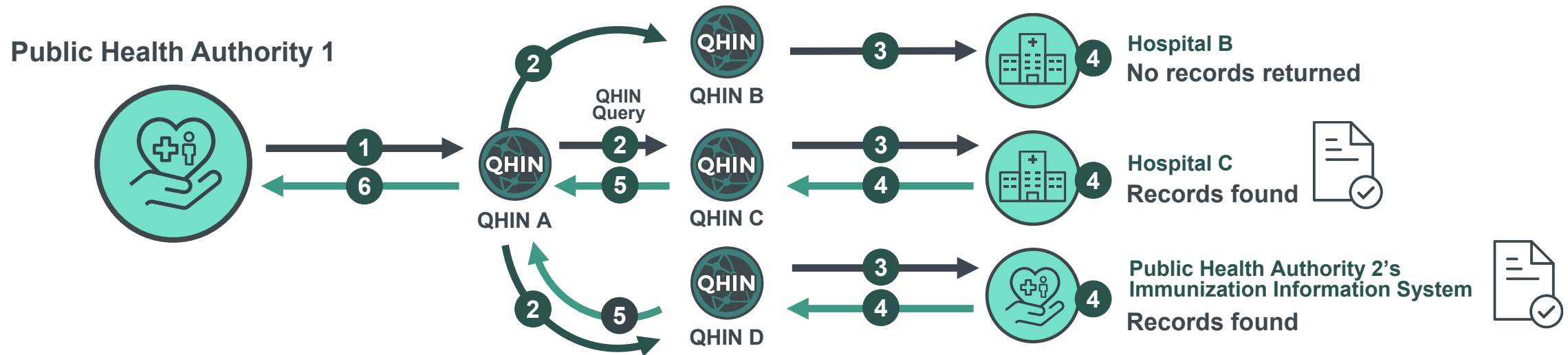1. Hospital A (Participant) sends a request for medical records to QHIN A for quality improvement, which is a Health Care Operations Exchange Purpose.

2. QHIN A initiates QHIN Query, which sends requests to QHIN B, C, and D.

3. QHIN B, C, and D execute queries to request medical records from their Participants, which includes Hospital B, Hospital C, and a Public Health Authority.

4. Hospital B finds no records. Hospital C and the Public Health Authority have a relationship with the patient and find matching medical records.

5. Hospital C and the Public Health Authority send the medical records to QHIN C and D, respectively, and those QHINs send those records back to QHIN A.

6. QHIN A sends the medical records to Hospital A.

*Health Care Operations is an authorized Exchange Purpose under the Common Agreement but response to a query for this Exchange Purpose is not required as of February 2023. 48

Exchange Purpose Example – Public Health*

Use Case: Public Health Authority queries TEFCA for a case investigation.

Public Health Authority 1

QHIN B — Hospital B: **No records returned**

QHIN C — Hospital C: **Records found**

QHIN D — **Public Health Authority 2's Immunization Information System** — **Records found**

1 A Public Health Authority 1 (Participant) is performing a case investigation. It has a public health need and the appropriate authority to understand all previous care provided to a particular patient. It sends a request for medical records to QHIN A for the Exchange Purpose of Public Health.

2 QHIN A initiates QHIN Query to all QHINs.

3 QHIN B, C, D execute their query methodology to request medical records from their Participants.

4 Hospital B finds no records. Hospital C and Public Health Authority 2's Immunization Information System (both Participants) respond to their respective QHINs with medical records.
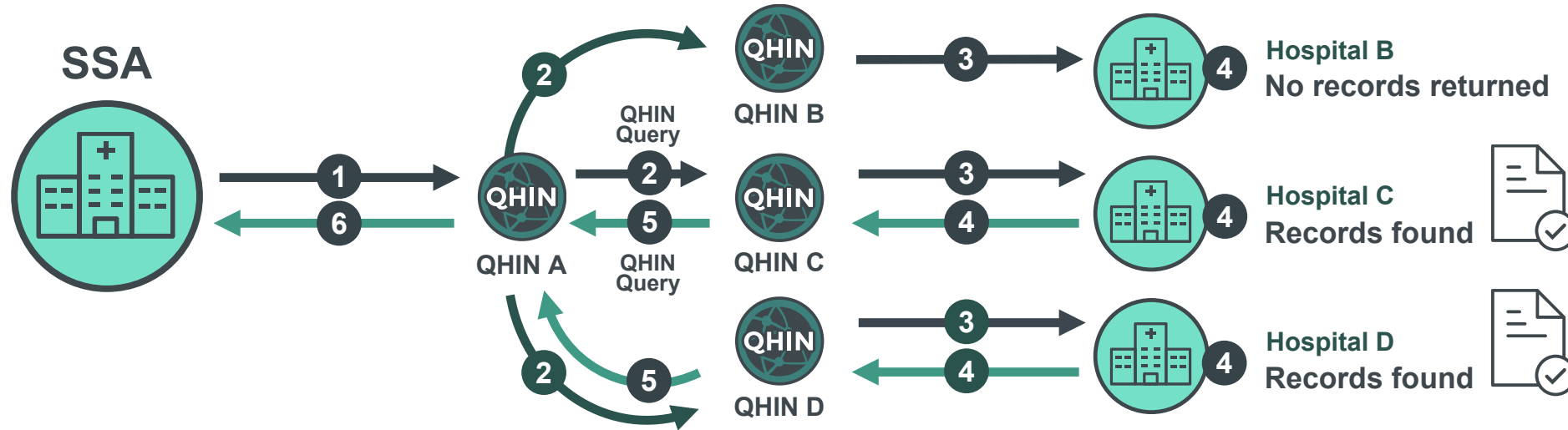
5 QHIN C, D send medical records to QHIN A.

6 QHIN A sends medical records to the Public Health Authority.

*Public Health is an authorized Exchange Purpose under the Common Agreement but response to a query for this Exchange Purpose is not required as of February 2023.

Use Case: SSA Requests records to confirm disability.

1. Social Security Administration (SSA) (Participant) sends a request for medical records to QHIN A for the purpose of Government Benefits Determination.

2. QHIN A initiates QHIN Query to all QHINs.

3. QHIN B, C, D execute their query methodology to request medical records from its Participants.

3.5. <u>NOT DEPICTED</u>: Participants holding the requested records query back to SSA across the network for an authorization to release the records. SSA responds across the network with a copy of the signed authorization.

4. Hospital B finds no records. Hospital C and D (Participants) respond to their respective QHINs with medical records.
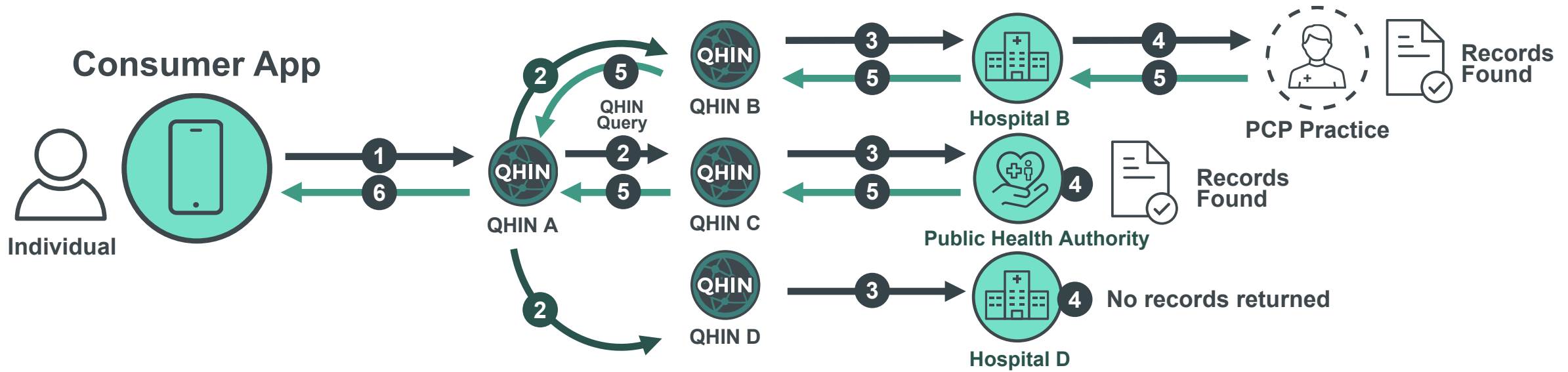
5. QHIN C, D send medical records to QHIN A.

6. QHIN A sends medical records to SSA.

Exchange Purpose Example – Individual Access Services

Use Case: Individual seeks her records from all her providers.

1 Individual verifies her identity with a Consumer App (Participant that is an IAS Provider) then uses it to make an Individual Access Services Request via QHIN A for Individual Access Services.

2 QHIN A initiates QHIN Query to all QHINs.

3 QHINs B, C, D execute their query methodology to request medical records from their Participants.

4 Hospital B queries its Subparticipants, and a standalone PCP Practice (Subparticipant) finds matching medical records. Public Health Authority finds matching records. Hospital D finds no records.

5 The standalone PCP responds with the matched medical records to Hospital B, which sends them to QHIN B. The Public Health Authority sends matched records to QHIN C. QHINs B and C send medical records to QHIN A.

6 QHIN A sends medical records to Consumer App, who shares them with the Individual.

What privacy and security requirements are included in TEFCA?

TEFCA will provide strong privacy protections.

- 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.

  » As a matter of general policy, once TEFCA Information (TI) is received by a QHIN, Participant, or Subparticipant that is a Covered Entity or Business Associate and is incorporated into such recipient's system of records, the information is no longer TI and is governed by the HIPAA Rules and other Applicable Law.

- The Common Agreement requires each Non-HIPAA Entity to protect individually identifiable information that it reasonably believes is TEFCA Information in substantially the same manner as HIPAA Covered Entities protect Protected Health Information (PHI), including most provisions of the HIPAA Privacy Rule.

  » This includes, for example, Health Care Providers and IAS Providers that are non-HIPAA Entities.

  » IAS Providers have additional requirements (see later slides).

TEFCA will provide strong security protections.

- QHINs will be expected to meet a high bar for security, including:

  » Third-party certification to industry-recognized cybersecurity standards, in addition to complying with the HIPAA Security Rule.

  » Annual security assessments.

  » Have a Chief Information Security Officer.

  » Have cyber risk coverage.

- Flow-down contract provisions for all Participants and Subparticipants:

  » Non-HIPAA Entities (NHEs) must comply with the HIPAA Security Rule with respect to all individually identifiable information that the entity reasonably believes is TEFCA Information.

- Notice of TEFCA Security Incidents involving or affecting exchange:

  – Are required of QHINs, Participants and Subparticipants.

  – Generally designed to avoid conflict with Applicable Law and duplicative notification requirements.

- All TEFCA entities shall evaluate the risks of any Uses and/or Disclosures of TEFCA Information outside the U.S to evaluate whether they satisfy the HIPAA Security Rule.

- The RCE will actively facilitate security activities, with the support of a Cybersecurity Council drawn from participating QHINs.

TEFCA IAS Providers must, among other requirements:

- Have a written privacy and security notice.

- Obtain express consent from Individuals regarding the way their information will be accessed, exchanged, Used, or Disclosed.

- Provide Individuals with the right to delete their information, with certain exceptions.

- Provide Individuals with the right to obtain an export of their data in a computable format.

- Take the following steps with respect to all individually identifiable information they hold:

  - » Protect such information in accordance with all TEFCA security requirements.

  - » Encrypt all information.
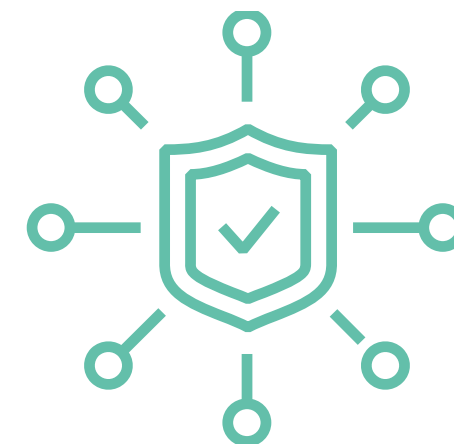
- IAS Providers will need to implement security requirements, including encryption and certain security incident notifications.

- These requirements are in addition to the requirement of abiding by the HIPAA Security Rule.

Consent

- Individual Access Services (IAS) Providers are required to obtain express consent from Individuals.

- TEFCA places no consent requirements on other Participants beyond what is required by applicable law, such as HIPAA.

  » The HIPAA Privacy Rule permits, but does not require, a Covered Entity to obtain patient consent for Uses and Disclosures of Protected Health Information for Treatment, Payment, and Health Care Operations activities.

  » Where HIPAA or other applicable laws require patient authorization or consent, it is also required for TEFCA exchange.

- The QTF includes a mechanism for QHINs, Participants, and Subparticipants to share such electronic consent documents with each other.

Applicable Law and Order of Precedence

- TEFCA will function within the constraints of Applicable Law, including state, local, tribal, and federal law.
- If there is a conflict between Applicable Law and provisions of the Common Agreement, the order of precedence is as follows:
    - i.   Applicable Law;
    - ii.   The Common Agreement including the Required Flow-Down provisions to be included in the agreements between TEFCA Entities;
    - iii.   The QHIN Technical Framework (QTF);
    - iv.   The Dispute Resolution Process, as set forth in the Common Agreement and an SOP;
    - v.   All other SOPs; and
    - vi.   All other attachments, exhibits, and artifacts incorporated into the Common Agreement by reference; and
    - vii. Other RCE plans, documents, or materials made available regarding activities conducted under the Framework Agreements.
- An entity **Disclosing** data must follow the Applicable Law that applies to it for disclosing data.
- An entity **Requesting** data must follow the Applicable Law that applies to it for the actions it takes in making Requests.

How do you become a QHIN?

ONC
TEFCA
RECOGNIZED
COORDINATING
ENTITY

The RCE will provide educational opportunities and a designated point of contact to help prospective QHINs understand:

- ❑ Eligibility criteria in the Common Agreement

- ❑ Application

- ❑ QHIN Onboarding & Designation SOP

For more information on the QHIN application process, visit: www.RCE.SequoiaProject.org.

QHIN Application Process

**Pre-application
Activities**

**QHIN
onboarding**

Prospective QHIN reviews the Common Agreement, QTF, and SOPs.
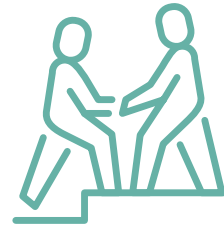
Prospective QHIN participates in educational sessions.

Prospective QHIN signs the Common Agreement and submits QHIN Application package.

The RCE makes an eligibility determination.

If application is accepted, prospective QHIN begins the QHIN onboarding process, including pre-production testing.

If all requirements are met, RCE counter-signs the Common Agreement and designates the applicant as a QHIN.

RCE provides written notice to both the applicant and ONC.*

QHIN is added to RCE Directory and undergoes production connectivity validation.

All relevant materials and resources will be available at www.RCE.SequoiaProject.org.

*The RCE will announce an initial set of QHINs together; additional QHINs will be designated on a rolling basis.

How will TEFCA be operationalized?

Timeline to Operationalize TEFCA

2021
- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Q3/Q4 2022
- Finalize additional SOPs
- QHIN application review
- Prepare for TEFCA FHIR-based exchange pilot

Q3/Q4 2023
- Additional QHIN applications processed
- Continue onboarding of initial QHINs
- Refine Common Agreement, SOPs, and QTF, including to support FHIR-based exchange

| 2021 | Q1/Q2 2022 | Q3/Q4 2022 | Q1/Q2 2023 | Q3/Q4 2023 |
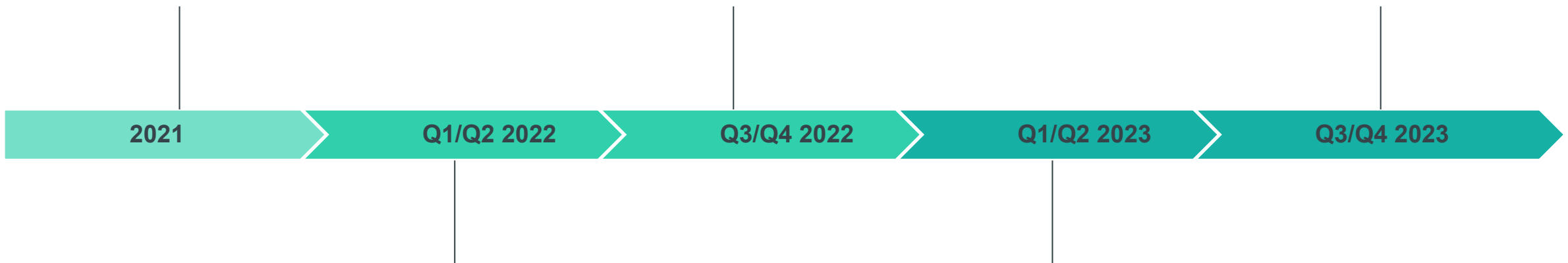
Q1/Q2 of 2022
- Publish Common Agreement Version 1 and initial SOPs
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement

Q1/Q2 of 2023
- **Public announcement: First Approved QHIN Applicants**
- Onboarding of initial QHINs
- Additional QHIN applications processed
- Launch TEFCA FHIR-based exchange pilot

Visit <u>RCE.SequoiaProject.org</u> to view the Common Agreement Version 1.