FHIR® Roadmap for TEFCA Exchange
Version 2.0

CONTENTS

INTRODUCTION

The 21st Century Cures Act (Cures Act) calls on ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."[1] Starting in 2019, The Sequoia Project has served as the Trusted Exchange Framework and Common Agreement^SM (TEFCA^SM) Recognized Coordinating Entity® (RCE^TM) to administer a network-of-networks pursuant to the Cures Act.

Version 2 of the FHIR® Roadmap for TEFCA Exchange (the FHIR Roadmap) completely supplants Version 1. Requirements and definitions of the stages have been re-specified based on feedback from the candidate Qualified Health Information Networks^TM (QHINs^TM), industry, and other interested parties to better align with the market needs and technical capabilities of participating entities.

Current exchange of clinical information through health information networks often relies on established standards including Integrating the Healthcare Enterprise (IHE®) profiles and HL7® Consolidated Clinical Document Architecture (C-CDA). ONC and the RCE's initial work on TEFCA has sought to build upon existing infrastructure by starting with such IHE-based exchange of C-CDA content. This is in alignment with the Cures Act direction to "avoid the disruption of existing exchanges."[2]

However, the healthcare information technology landscape continues to evolve and TEFCA will have to evolve with it to continue to add value to the market and help advance industry progress. The Health Level Seven (HL7®) Fast Healthcare Interoperability Resources® (FHIR) standard uses a modern approach to standards and interoperability and has already gained wide support in the United States[3]. We expect to accelerate adoption as FHIR APIs for general use are now required in all ONC-certified EHR systems as of the end of CY 2022[4] and in patient access APIs by CMS-regulated payers[5], and are proposed for provider access, payer-payer exchange, and prior authorization APIs by CMS-regulated payers[6].

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[1] See https://www.congress.gov/bill/114th-congress/house-bill/34

[2] See https://www.congress.gov/bill/114th-congress/house-bill/34

[3] See https://www.healthit.gov/buzz-blog/health-it/the-heat-is-on-us-caught-fhir-in-2019

[4] The 2020 ONC Cures Act Final Rule requires use of application programming interfaces as part of the ONC health IT certification program. This has been codified within the certification criterion adopted at 45 CFR 170.315(g)(10), Standardized API for Patient and Population Services, which names FHIR Release 4 via references to 45 CFR 170.215(a)(1). Also, as required by the API Condition and Maintenance of Certification at 45 CFR 170.404(b)(3), software developers with health IT previously certified for technical API conformance must provide all customers with upgraded API technology certified to this new certification criterion by no later than December 31, 2022.

[5] https://www.cms.gov/priorities/key-initiatives/burden-reduction/policies-and-regulations/cms-interoperability-and-patient-access-final-rule-cms-9115-f

[6] https://www.cms.gov/priorities/key-initiatives/burden-reduction/policies-and-regulations/cms-advancing-interoperability-and-improving-prior-authorization-proposed-rule-cms-0057-p

While healthcare organizations are in the process of implementing FHIR, it is not being widely used in multi-networked environments in standardized ways. The initial versions of the Common Agreement and the QHIN Technical Framework (QTF) did not explicitly incorporate FHIR-based exchange because standards to support FHIR exchange in a multi-network environment were still maturing when those versions were released. TEFCA can be a strong catalyst for such standards development and maturation. We are therefore releasing this FHIR Roadmap to help align and accelerate FHIR adoption across the industry based on learnings from the past year.

NETWORK SUPPORT FOR FHIR EXCHANGE

The industry's embrace of FHIR makes it imperative that TEFCA include a deliberate strategy to add FHIR-based exchange. Most FHIR implementation activity in the market has focused on point-to-point exchange of FHIR resources via FHIR APIs without network intermediaries. However, some networks have leveraged their infrastructure to support FHIR in various ways. For example, a few nationwide and state/regional networks use existing IHE-based brokering infrastructure to exchange FHIR payloads. In addition, early pilot work has begun to use network infrastructure to support FHIR API Exchange between endpoints and some networks are planning to offer brokered FHIR API exchange.

This roadmap envisions four stages of progressive support for FHIR exchange in TEFCA, as detailed below, to provide continuity for the FHIR activities in the market today and allow TEFCA policy and technical infrastructure to accelerate FHIR adoption into the future. It also bridges network-based exchange communities and the users of FHIR APIs via ONC-certified EHRs and CMS required APIs, which have been operating in parallel up until now. We believe that both patterns of exchange will be important in the future and that use of FHIR APIs in TEFCA can help make these patterns complementary and finally deliver on the promise of a modern, digital health care system.

Network exchange is essential to business-to-business (B2B) clinical interoperability supporting simple, high-volume, high-reliability, high-trust exchange patterns. Adding FHIR-based exchange to network exchange enables the use of existing trusted, scalable, secure, and well-established network architecture to be leveraged by the FHIR APIs to bring the best solution to the users of the TEFCA infrastructure.

Many elements in TEFCA were built to support existing network exchange that can also be used to address some of the pain points associated with implementing scalable FHIR API exchange. TEFCA components such as endpoint directories, record location services, and security certificate infrastructure can dramatically enhance the scalability of currently deployed FHIR APIs to meet the demands of the network exchange built on TEFCA.

Unbrokered or QHIN-Facilitated FHIR Exchange using FHIR APIs is the dominant mode of FHIR adoption in the market today, especially for business-to-consumer (B2C) use cases. However,

discovering and connecting with FHIR endpoints often requires substantial manual effort, negotiation, and configuration. Many elements in TEFCA that were built to support existing network exchange can also be used to address some of the pain points associated with implementing scalable QHIN-Facilitated FHIR Exchange. TEFCA components such as endpoint directories, record location services, and security certificate infrastructure can dramatically enhance scalability of currently deployed FHIR APIs to meet the demands of the network exchange built on TEFCA.

This version of the FHIR Roadmap redefines what was previously called "Brokered FHIR Exchange" to now be called "QHIN-to-QHIN FHIR Exchange." This provides needed flexibility to QHINs to move to FHIR-based exchange for exchange between QHINs while continuing to support non-FHIR approaches for their internal networks. This also provides a way for QHINs to be responsive to their members while still providing the benefits of FHIR exchange to the broader TEFCA community.

This version of the FHIR Roadmap also creates a new term called "End-to-End FHIR Exchange." This term covers FHIR-based exchange that occurs directly between TEFCA members via the QHINs, including when QHINs broker FHIR payloads via routing FHIR API transactions between Participants and Subparticipants from different QHINs. This method has significant technical requirements and will be the focus of future research.

While the initial versions of the Common Agreement and QTF do not explicitly incorporate FHIR, they also do not prohibit use of FHIR within the required policy and technical architecture. For example, a QHIN may utilize FHIR for exchange within their own networks. Furthermore, the QTF allows for the exchange of FHIR payloads (e.g., FHIR resources and documents) between QHINs using required IHE-based transport. We anticipate that some QHINs will immediately support and use FHIR within their own networks or may support QHIN-Facilitated FHIR Exchange where the Participants or Subparticipants are able to accept FHIR transactions.

This FHIR Roadmap is a plan for the explicit incorporation of FHIR in TEFCA through achievable, incremental steps. The RCE has launched working groups to update the QTF and further develop the use of FHIR for data exchange under the Common Agreement for QHIN-Facilitated, QHIN-to-QHIN, and End-to-End FHIR Exchange. Experience gained regarding standards, workflows, implementation/operations, and market needs will inform any necessary future adjustments to the timeline detailed later in this document.

As standards leveraged for exchange under the Common Agreement move forward to include FHIR, updates to the Common Agreement and QTF will be released in stages to enable full policy and technical support for QHIN-Facilitated, QHIN-to-QHIN, and End-to-End FHIR Exchange. The TEFCA approach to governance, oversight, and QHIN-based architecture will remain as foundational pillars to steward this evolution going forward.

PLANNED STAGES OF FHIR AVAILABILITY IN TEFCA

The roadmap envisions four stages of FHIR exchange in TEFCA. Requirements for each stage build on the previous stage:

- Stage 1: FHIR Content Support
    - Included as part of the initial launch of TEFCA.
    - QHIN-brokered IHE exchange of FHIR payloads between QHINs available.

- Stage 2: QHIN-Facilitated FHIR Exchange
    - QHIN support for facilitated FHIR API exchange required.
    - Participant and Subparticipant exchange via FHIR APIs available.

- Stage 3: QHIN-to-QHIN FHIR Exchange
    - Support for exchange between QHINs via FHIR APIs required.

- Stage 4: End-to-End FHIR Exchange
    - Support for QHIN-brokered FHIR Exchange between Participants and Subparticipants.

Each stage will be supported by a new version of the QTF and managed via the change management process in the Common Agreement.

FHIR Roadmap Timeline
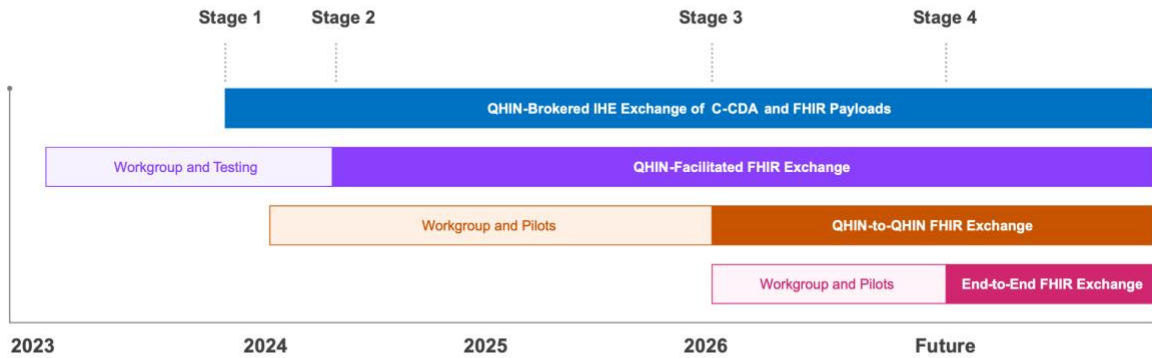
The timeline provides approximate expectations for key milestones. It is fully expected that this timeline will be adjusted and refined based on implementation experience and stakeholder input.
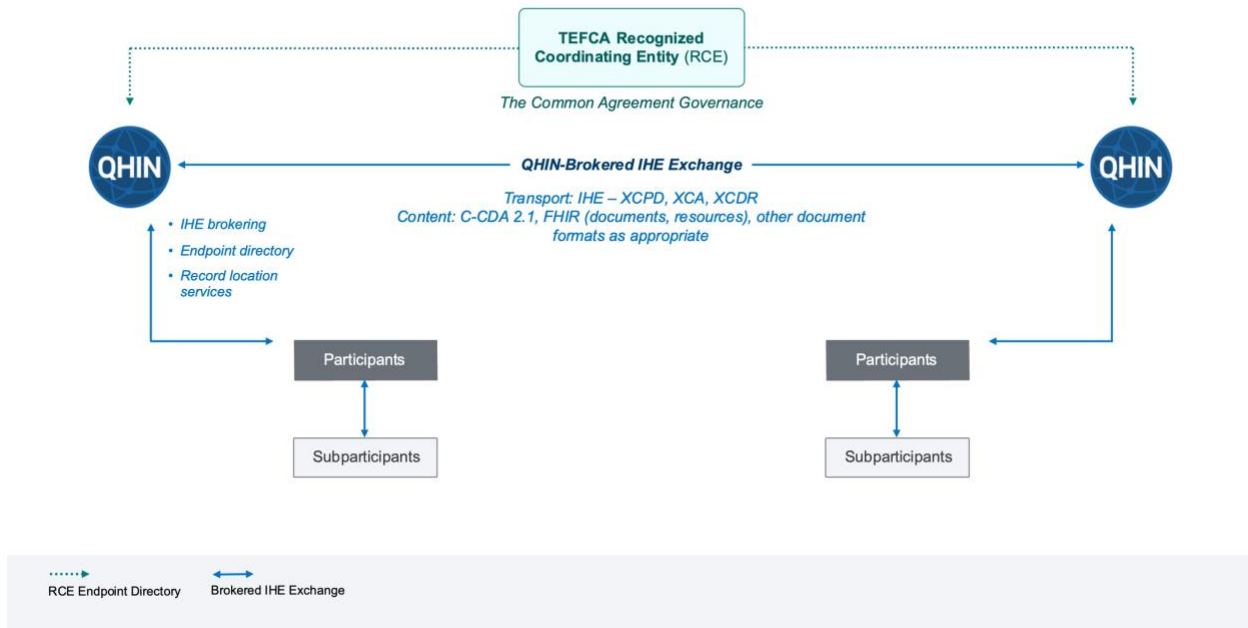
Stage 1: FHIR Content Support

QTF Version 1.0 and 1.1 were based on the IHE profiles with HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm (C-CDA 2.1) documents as the primary content format. As noted earlier, the IHE profiles support other document and data formats as well, such as FHIR documents[7] and FHIR resources[8], which organizations can make available for specific purposes and use cases. Therefore, organizations may request or send specific payload types, including FHIR-formatted content.

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[7] See https://www.hl7.org/fhir/documents.html for the definition and structure of a FHIR Document
[8] See https://www.hl7.org/fhir/resource.html for the definition and information about FHIR Resources

Stage 1: FHIR Content Support

Although transactions using FHIR-formatted content are possible under Stage 1, the QTF does not explicitly support FHIR exchange, and thus, organizations choosing to exchange FHIR content in this manner will need to coordinate out-of-band with trading partners to determine format requirements (e.g., common value sets, data element constraints, FHIR versions, etc.) to ensure interoperability.

Stage 2: QHIN-Facilitated FHIR Exchange

ONC requirements for FHIR APIs in certified EHRs by the end of CY 2022[9] added significantly to the installed base of FHIR APIs in EHRs. Stage 2 is designed to align with this timing to enable use of broadly available FHIR API exchange capabilities across the health care delivery system.

In 2023, the RCE initiated work to extend the QTF to allow QHINs to leverage their current infrastructure to provide QHIN-Facilitated FHIR Exchange to support FHIR API-based exchange among Participants and Subparticipants across different QHINs. Such FHIR API-based exchanges is already occurring in the market today, however, discovery of FHIR API endpoints and scalability of FHIR API exchange can be bolstered using QHIN policy and technical components such as:

- FHIR endpoint directory
- Record location services
- Security certificate infrastructure

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[9] https://www.healthit.gov/buzz-blog/health-it/achieving-a-major-milestone-health-it-developers-certify-to-cures-update

- Uniform contracting
- Transparent rules-of-the-road

The QHIN-Facilitated Exchange model provides the opportunity for QHINs to make available selected network services to enhance Participants' and Subparticipants' use of FHIR APIs among themselves. This model will also provide the opportunity for QHINs to provide additional value-added services to FHIR API users such as scalable registration, authentication, and authorization[10].

The RCE launched a workgroup of TEFCA candidate QHINs to develop a model for services that QHINs will need to support QHIN-Facilitated FHIR Exchange. The RCE participated in a series of IHE and HL7 connectathons to test the QHIN-Facilitated FHIR Exchange model. The results of the connectathons will inform the development of Common Agreement Version 2.0, QTF Version 2.0, and associated Implementation Guides (IGs) to support full production availability in CY 2024.

Stage 2: QHIN-Facilitated FHIR Exchange
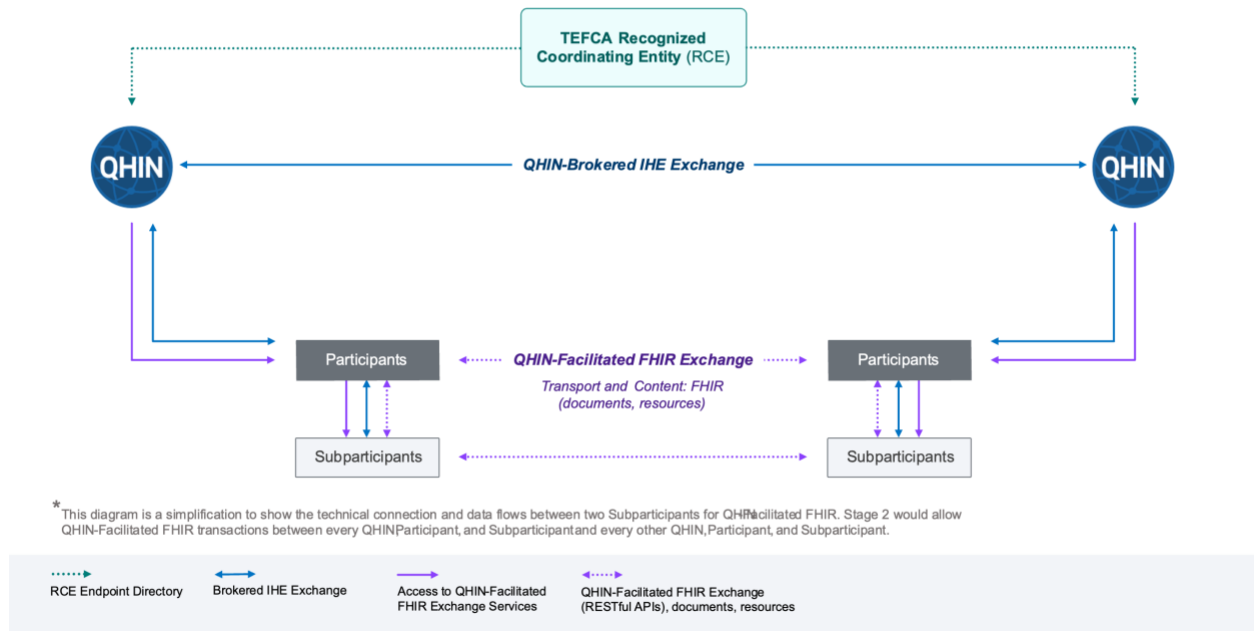
QHINs will be required to support IHE exchange and QHIN-Facilitated FHIR Exchange. All Participants and Subparticipants will be covered by the Common Agreement.

Common Agreement Version 2.0 and QTF Version 2.0 will provide any adjustments needed to support participation in QHIN-Facilitated FHIR Exchange and additional technical specifications

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[10] https://hl7.org/fhir/us/udap-security/

for accessing QHIN network infrastructure and services. It will also address requirements for QHIN FHIR API security infrastructure and the overall trust model. It will address required services QHINs will offer including the FHIR endpoint directory, patient matching, record locator services, identification verification services, issuing certificates, dynamic client registration, and other potential services.

Stage 3: QHIN-to-QHIN FHIR Exchange

Stage 3 will build on Stage 2 and will introduce brokered FHIR-based exchange between QHINs. QHIN-to-QHIN FHIR Exchange will enable QHINs to leverage FHIR-based exchange for exchange between QHINs while continuing to support non-FHIR approaches within the QHINs' internal networks. QHINs will be required to continue to support QHIN-Facilitated FHIR Exchange.

The QHIN-to-QHIN FHIR Exchange approach is expected to require an update to the QTF.

Stage 3: QHIN-to-QHIN FHIR Exchange
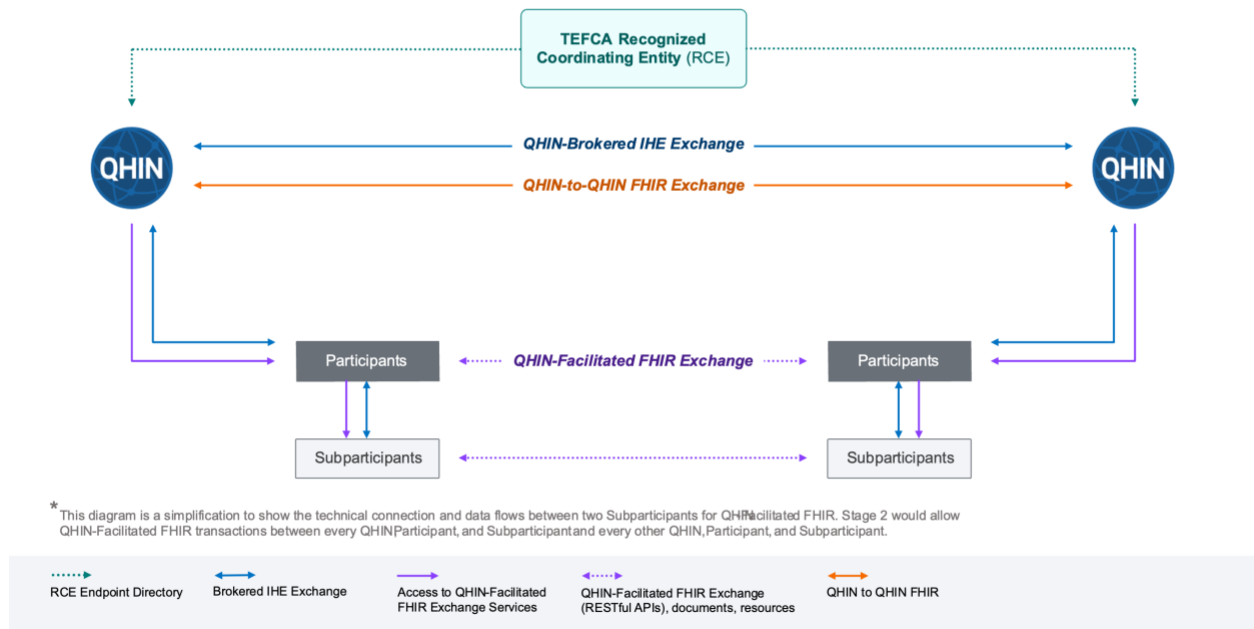
QHIN-to-QHIN FHIR Exchange is expected to begin to be piloted in CY 2025. It is anticipated that implementation specifications for QHIN-to-QHIN FHIR Exchange will be developed soon after the pilots are completed.

It is expected that an updated QTF to support QHIN-to-QHIN FHIR Exchange will result in updated infrastructure deployment by QHINs and the RCE during CY 2026.

Stage 4: End-to-End FHIR Exchange

End-to-End FHIR Exchange requires significant development to ensure security, privacy, and data preservation throughout the exchange process. Use of FHIR through multiple intermediaries creates new challenges regarding privacy, security, and performance.

End-to-End FHIR Exchange will permit a Participant/Subparticipant to seamlessly exchange FHIR data between themselves and other network members through the QHINs and multiple other intermediaries both within a QHINs' network and through the TEFCA-governed network.

Stage 4: End-to-End FHIR Exchange
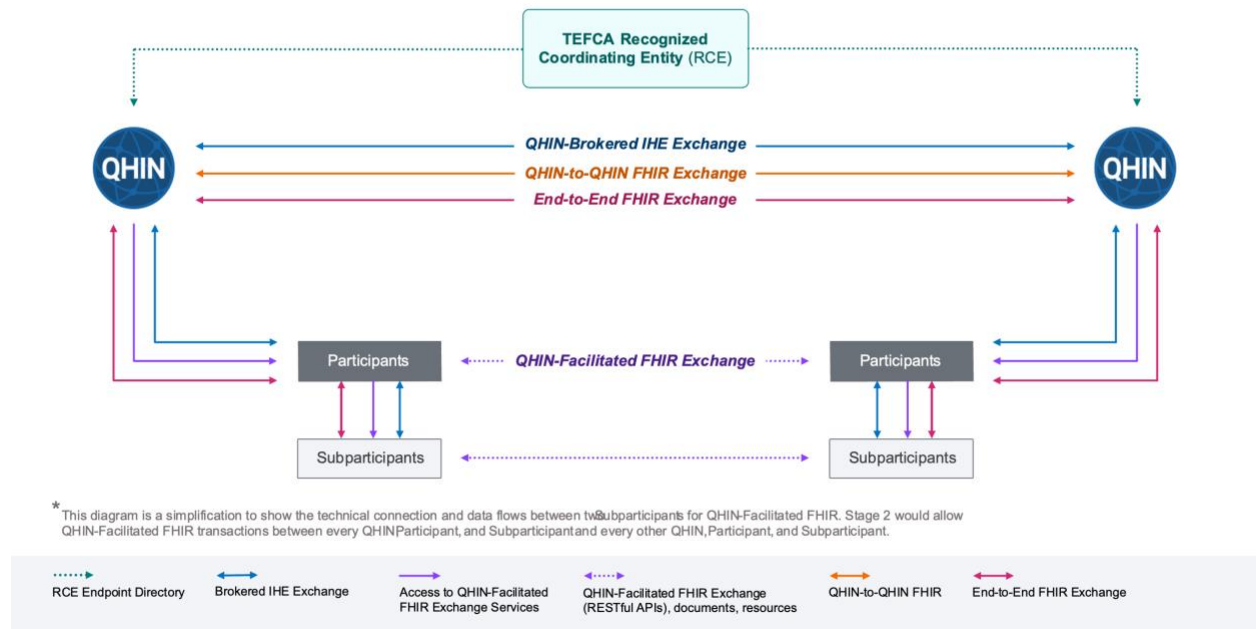
This effort requires further research into optimal methods for secure exchange through the network via the QHINs. When that research is complete, ONC will launch a pilot with TEFCA users to determine how and when that research can be rolled into a production environment. This effort will also be driven by market needs that are not covered by the QHIN-Facilitated and QHIN-to-QHIN FHIR Exchange methods.

The adaptation of the FHIR Roadmap to support future needs will be determined through TEFCA's collaborative participation and governance process.