ONC TEFCA RECOGNIZED COORDINATING ENTITY

FHIR® Roadmap for TEFCA Exchange

Version 1

January 2022

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Introduction

The 21st Century Cures Act of 2016 calls on ONC to "develop or support a trusted exchange framework, including a common agreement [TEFCA] among health information networks nationally." In August 2019, ONC awarded a cooperative agreement to The Sequoia Project to be the Recognized Coordinating Entity (RCE) to administer the Common Agreement and govern network-to-network connections by health information networks.

Current exchange of clinical information through health information networks often relies on established standards including Integrating the Healthcare Enterprise (IHE®) profiles and Health Level Seven (HL7®) Consolidated Clinical Document Architecture (C-CDA). In order to meet the industry where it is today, ease the transition to the TEFCA governance and operational model, and fulfill the Cures Act direction to "avoid the disruption of existing exchanges between participants of health information networks", the Common Agreement Version 1 and Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1, both published concurrently with this document, build upon existing work by adding the use of QHIN-brokered IHE exchange.

However, the healthcare information technology landscape continues to evolve and TEFCA will have to evolve with it in order to continue to add value and, more important, to avoid holding back industry progress. The HL7 Fast Healthcare Interoperability Resource (FHIR®) standard uses a modern approach to standards and interoperability and has already gained wide support in the United States[1]. We expect to accelerate adoption as FHIR Application Programming Interfaces (APIs) for general use become required in all ONC-certified Electronic Health Record (EHR) systems by the end of CY 2022[2].

While healthcare organizations have begun 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 QTF do not explicitly incorporate FHIR-based exchange because network enablement of FHIR is still maturing in key areas. TEFCA can be a strong catalyst for such maturation. We are therefore releasing this three-year FHIR Roadmap to help align and accelerate FHIR adoption across the industry.

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

[2] 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.

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 unbrokered, point-to-point FHIR API exchange. Finally, there are some networks who are planning to offer brokered FHIR API exchange.

This roadmap envisions two paths for supporting FHIR exchange in TEFCA:

1) *Facilitated FHIR exchange*: QHINs provide network infrastructure support to facilitate unbrokered FHIR API-based exchange between Participants and Subparticipants from different QHINs
2) *Brokered FHIR exchange*: QHINs broker FHIR payloads by routing FHIR APIs transactions between Participants and Subparticipants from different QHINs

This approach provides continuity for the FHIR activities in the market today and allows TEFCA policy and technical infrastructure to accelerate FHIR adoption into the future. It also bridges network-based exchange communities and the emerging open API community, which have been operating in parallel up until now. This separation has created a false dichotomy suggesting that the industry will ultimately choose between brokered networks and open APIs. We believe that both patterns of exchange will be important in the future and TEFCA can help to make these patterns complementary rather than competitive and synergize scalability of FHIR implementation overall.

Network exchange is the workhorse of business-to-business (B2B) clinical interoperability supporting simple, high-volume, high-reliability, high-trust exchange patterns. Adding FHIR to network exchange allows the use of existing policy and network architecture to ease adoption of new FHIR standards. It also creates the opportunity for value-added network services, such as adaptors for conversion between FHIR API and transport standards, and the ability to conduct data-level exchange at scale.

Unbrokered exchange using FHIR APIs is the dominant mode of FHIR adoption in the market today, especially for business-to-consumer (B2C) use cases. However, connecting FHIR endpoints often requires manual coordination, negotiation, and configuration. Many elements built to support existing network exchange can also be used to address some of the pain points associated with implementing scalable FHIR API exchange. Key network components such as endpoint directories and individual identity services can enhance scalability of FHIR APIs, as was noted by the multi-stakeholder FHIR at Scale Taskforce.[3] Indeed,

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[3] For more details, see the 2021 FAST Action Plan - ONC Tech Lab Standards Coordination - Confluence (healthit.gov)

in the absence of such network services, the high friction of manual, point-to-point coordination between exchange partners will likely hamper growth of FHIR API-based exchange across the industry.

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, there are no restrictions on how QHINs enable exchange within their own networks. Furthermore, the QTF does not prohibit 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 and will convert to the appropriate IHE standards when communicating with other QHINs.

This FHIR Roadmap is a plan for the explicit incorporation of FHIR in TEFCA through achievable, incremental steps. Initially, data exchange under the Common Agreement and QTF will use IHE profiles, including Cross Community Patient Discovery (XCPD), Cross Community Access (XCA), and Cross Community Document Reliable Interchange (XCDR). TEFCA will also use the HL7 Consolidated Clinical Document Architecture (C-CDA 2.1) document format to ensure interoperability for the widest number of systems.

However, early in 2022, the RCE will launch working groups to initiate development of the use of FHIR for data exchange under the Common Agreement for both brokered and facilitated FHIR exchange. The goal is to include FHIR as an optional, additional standard in the QTF in CY 2023 for those ready to use it, and to gradually make it a required, additional capability during CY 2024. Experience gained regarding standards, workflows, implementation/operations, and market needs will inform any necessary future adjustments to this timeline.

As standards leveraged for exchange under the Common Agreement move forward to include FHIR, updates to the QTF and Common Agreement will be released in stages to enable full policy and technical support for brokered and facilitated 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 three stages of FHIR exchange in TEFCA:

- Stage 1: FHIR Content Support
  - QHIN-brokered IHE exchange of FHIR payloads between QHINs available
- Stage 2: Network-Facilitated FHIR Exchange
  - Optional QHIN-facilitated FHIR API exchange between Participants and Subparticipants available
- Stage 3: Network-Brokered FHIR Exchange
  - QHIN-brokered FHIR API exchange between QHINs available
  - QHIN-facilitated FHIR exchange required

Each stage will be supported by a new version of the QTF and managed via the change management process defined by the Common Agreement. QHINs are expected to have six months to adopt the new QTF before the previous version is deprecated.

FHIR Roadmap Timeline (preliminary)
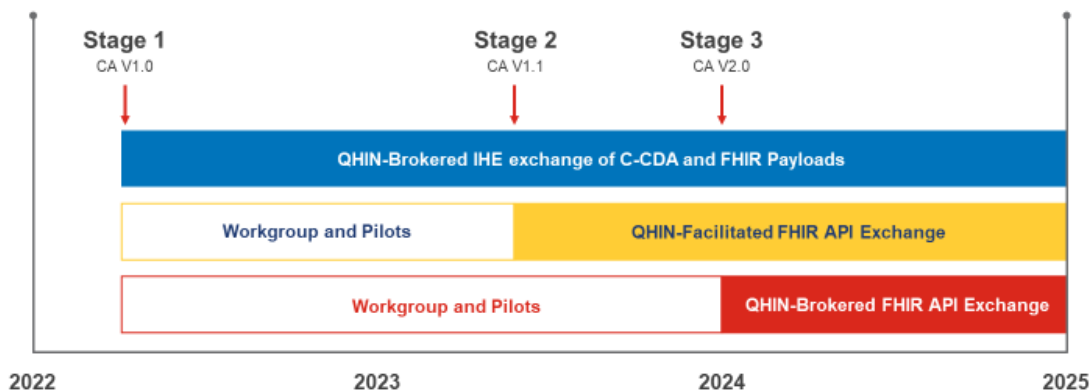
The preliminary timeline provides approximate expectations for key milestones. It is fully expected that this timeline will be adjusted and refined based on implementation experience and stakeholder input.

STAGE 1: COMMON AGREEMENT V1.0 – FHIR CONTENT EXCHANGE

QTF V1.0 is based on the IHE profiles with C-CDA 2.1 documents as the content format. As noted earlier, the IHE profiles support other document and data formats as well, such as FHIR documents[4] and FHIR resources[5], which organizations can make available for specific purposes and use cases. Therefore, organizations may request or send specific payload types, including FHIR-formatted content.

Stage 1: FHIR Content Exchange

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: COMMON AGREEMENT V1.1 – NETWORK-FACILITATED FHIR EXCHANGE

ONC certification requirements for FHIR APIs in certified EHRs by the end of CY 2022 will add significantly to the installed base of FHIR APIs. Stage 2 is designed to align with this timing to provide a significant boost to adoption and use of what will be broadly available, standards-based FHIR capabilities across the health care delivery system.

In early 2022, the RCE will initiate work to extend the QTF to allow QHINs to leverage their current infrastructure to optionally provide network-facilitated exchange to support point-to-point FHIR API

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

transactions among Participants and Sub-participants across different QHINs. Such FHIR API transactions are already occurring in the market today, however, scalability of FHIR API exchange can be bolstered using QHIN policy and technical components such as:

- FHIR end-point directory
- Record location services
- Security certificate infrastructure
- Uniform contracting
- Transparent rules-of-the-road

QHINs will not be expected to manage FHIR APIs used by Participants and Subparticipants. The network-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 identity verification services, Unified Data Access Profiles (UDAP) dynamic client registration and tiered Open Authorization (OAuth) profiles, and FHIR at Scale Taskforce (FAST) solutions for scalable FHIR capabilities.

Stage 2: Network-Facilitated FHIR Exchange
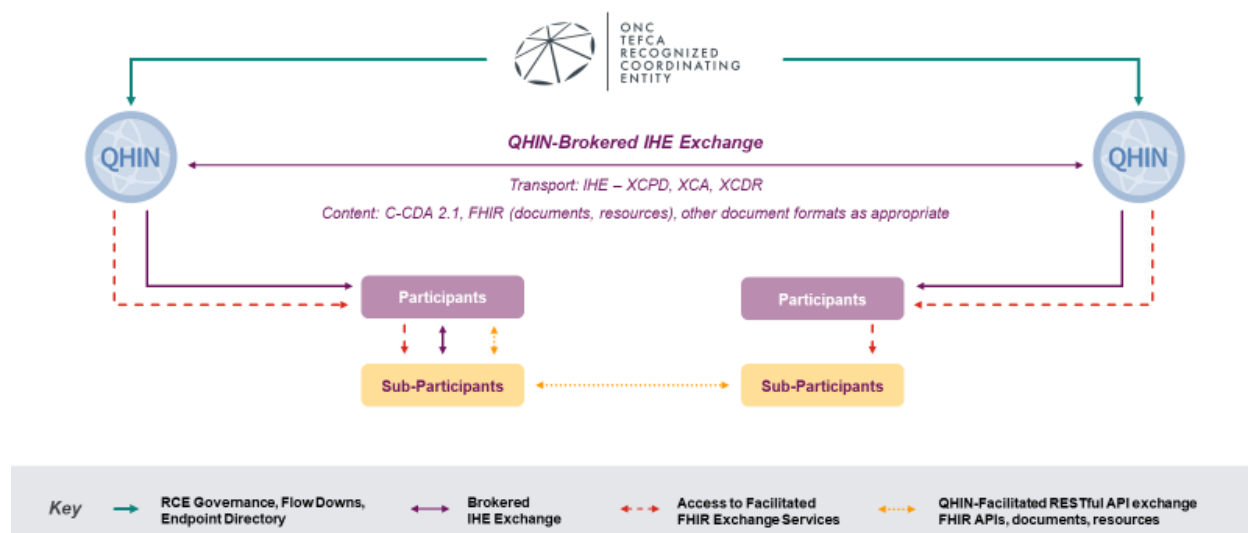
QHINs will be required to support network-brokered IHE exchange and may optionally support network-facilitated FHIR API exchange. QHINs may offer network-facilitated FHIR exchange as a stand-alone service or bundled with network-brokered IHE exchange services. However, all Participants and Subparticipants will still be required to be covered by the Common Agreement.

The Common Agreement V1.1 and QTF V1.1 will provide any adjustments needed to support participation in FHIR API network-facilitated exchange and additional technical specifications for accessing QHIN network infrastructure and services.

The RCE will launch a workgroup of TEFCA stakeholders to develop a model for services that QHINs may offer to support network-facilitated FHIR exchange. The RCE will also coordinate a pilot to test the facilitated FHIR exchange model for Individual Access Services (IAS) and at least one other use case. This pilot is expected to include at least a QHIN, a provider, a payer, and an IAS provider. The results of the pilot will be published by the end of CY 2022 to support publication of the Common Agreement V1.1 and associated Implementation Guides (IGs), as needed, to support full production availability in the first half of CY 2023.

STAGE 3: QTF V2.0 - BROKERED FHIR EXCHANGE

Stage 3 will build on Stage 2 by requiring that QHINs support facilitated FHIR exchange, and will introduce as an optional service brokered FHIR-based exchange between QHINs. Brokered FHIR exchange means that QHINs route FHIR API exchange messages and queries as intermediaries on behalf of those who are exchanging data. QHINs will be required to continue to support brokered IHE exchange as well.

These exchange approaches will require updates to the QTF and the Common Agreement. Version 2.0 of the QTF will address how QHINs will execute both facilitated FHIR exchange and brokered FHIR exchange. It will also address requirements for QHIN FHIR API security infrastructure and the overall trust model. For facilitated exchange, it will address required and optional services QHINs may offer including caching the RCE endpoint directory, patient matching, record locator services, identification verification services, issuing certificates, dynamic client registration, and other potential services. It will also address how QHINs may offer the optional service of FHIR-brokered routing of transactions.

Stage 3: Network-Brokered FHIR Exchange
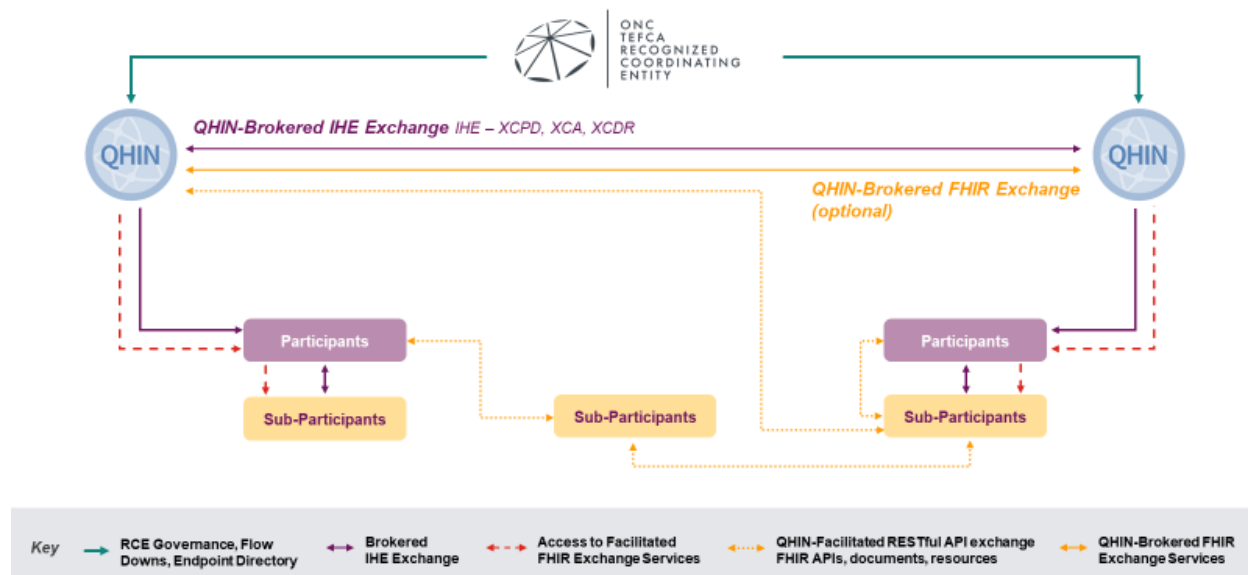
While the facilitated FHIR exchange will be developed, piloted, and have corresponding IGs published by the end of CY 2022, brokered FHIR exchange will begin to be piloted by the second quarter of CY 2023. It is anticipated that implementation specifications for brokered FHIR exchange will also need to be developed soon after the pilots are accomplished. For both facilitated and brokered FHIR exchange, IGs from FAST and other FHIR-related industry initiatives will be used as appropriate to accelerate development activities.

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It is expected that the Common Agreement V2.0 will require facilitated and support optional brokered FHIR exchange by approximately the end of CY 2023 to support production roll-out during CY 2024.

Depending on the maturity and adoption of facilitated and brokered FHIR services and general market developments, brokered IHE exchange could become optional at this or a later stage, introducing the opportunity for FHIR-based as well as IHE-based (and combination) QHINs. The adaptation of the FHIR Roadmap to support market needs will be determined through the TEFCA collaborative participation and governance process.