Health IT Advisory Committee (HITAC) – TEFCA Task Force, Meeting 1

Arien Malec, Co-Chair
John Kansky, Co-Chair

May 9, 2019

Agenda

- Call to Order/Roll Call

- Opening Remarks – Task Force Charge and Membership

- Review of MRTCs and Major Updates from TEF Draft 1

- Discussion of QHIN Definition, Application, Onboarding, and Designation

- Public Comment

- Homework and Adjourn

Hour 1

Task Force Charge

- **Overarching charge:** The Trusted Exchange Framework and Common Agreement (TEFCA) Task Force will develop and advance recommendations on the TEFCA Draft 2 to inform development of the final Common Agreement.

- **Detailed charge:** Make specific recommendations on the Minimum Required Terms and Conditions and the Qualified Health Information Network (QHIN) Technical Framework (QTF) —

  » **Definition, Structure, and Application Process for QHINs:** Recommendations for further clarifying the eligibility requirements and application process for becoming a QHIN.

  » **Exchange Purposes and Modalities:** Recommendations on enhancing or clarifying the seven (7) exchange purposes and three (3) exchange modalities proposed in the MRTCs, as well as provisions regarding EHI reciprocity and permitted and future uses of EHI.

  » **Privacy:** Recommendations on privacy requirements for participating entities, including Meaningful Choice, Written Privacy Summary, Summary of Disclosures, and Breach Notifications

  » **Security:** Recommendations on security requirements for participating entities, including minimum security requirements, identity proofing, authorization, and authentication.

Membership

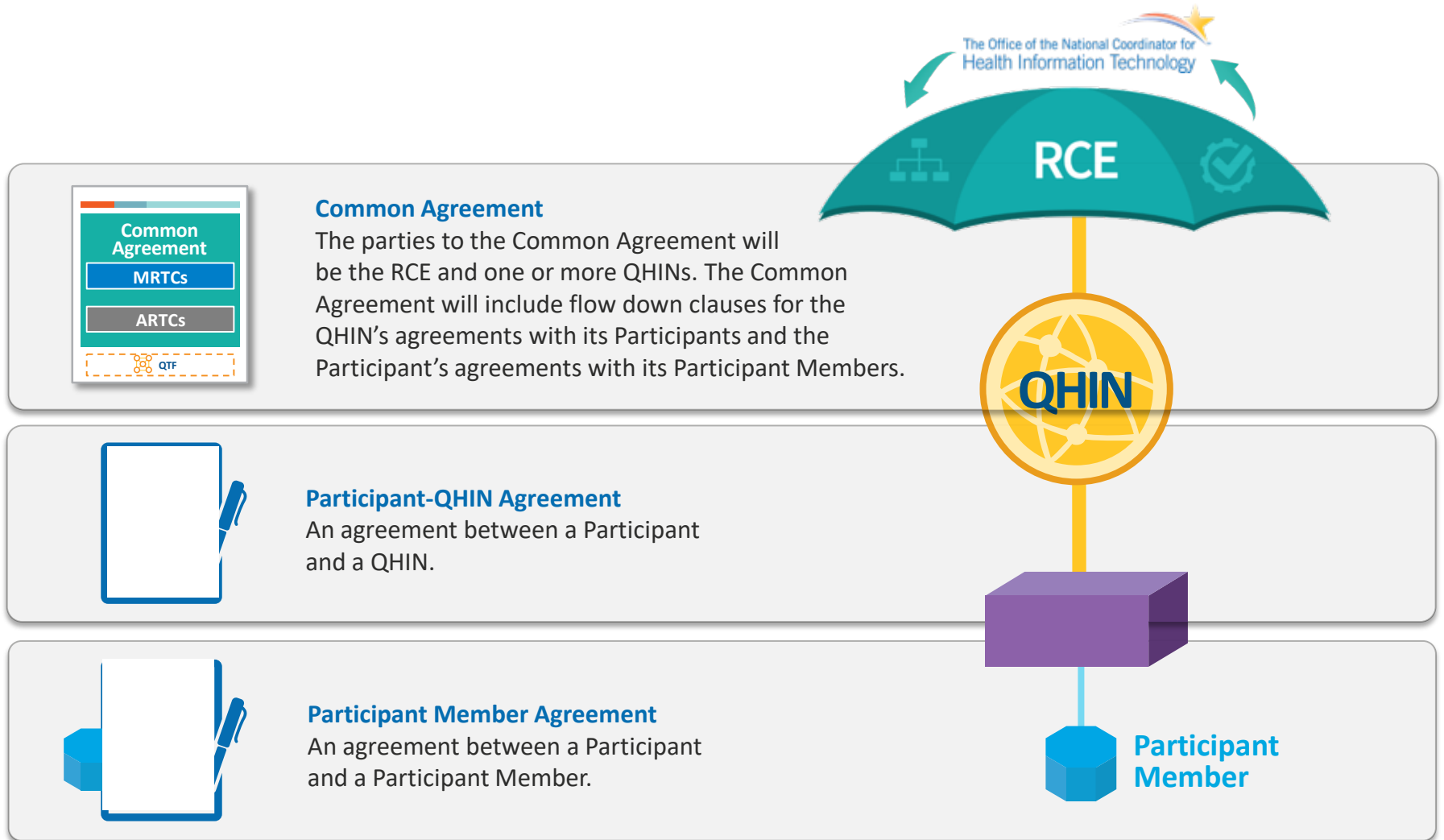| Membership	Organization	Role
Arien Malec	Change Healthcare	Co-Chair
John Kansky	Indiana Health Information Exchange	Co-Chair
Andrew Truscott	Accenture LLP	HITAC Committee Member
Anil Jan	IBM Watson	HITAC Committee Member
Carolyn Petersen	Individual	HITAC Committee Member
Aaron Miri	University of TX, Austin Dell Medical School & UT Health Austin	HITAC Committee Member
Denise Webb	Individual	HITAC Committee Member
Sheryl Turney	Anthem Blue Cross Blue Shield	HITAC Committee Member
Sasha TerMaat	Epic	HITAC Committee Member
Steve Ready	Norton HealthCare	HITAC Committee Member
Cynthia Fisher	WaterRev, LLC	HITAC Committee Member
Kate Goodrich	CMS	HITAC Committee Member
David McCallie	Individual	Public Member
Mark Savage	UC San Francisco	Public Member
Noam Arzt	HLN Consulting	Public Member
Grace Terrell	Envision Genomics	Public Member
Zoe Barber	ONC	ONC Staff Lead
Kimberly Tavernia	ONC	ONC Co-Lead
Michael Berry	ONC	SME, RCE
Alex Kontur	ONC	SME, Technical
Morris Landau	ONC	SME, HIPAA and Privacy/Security

MRTCs Table of Contents

- **Section 1:** Definitions

- **Sections 2-6:** QHINs

  » Section 2: Initial Application, Onboarding, Designation, and Operation of QHINs

  » Section 3: Data Quality and Minimum Necessary

  » Section 4: Transparency

  » Section 5: Cooperation and Non-Discrimination

  » Section 6: Privacy, Security, and Patient Safety

- **Section 7:** Participant Minimum Obligations

- **Section 8:** Participant Member Minimum Obligations

- **Section 9:** Individual Rights and Obligations

Common Terms and Definitions

- Framework Agreements

  » Common Agreement

  » Participant-QHIN Agreement

  » Participant Member Agreement

- QHIN Exchange Network

- Qualified Health Information Network (QHIN), Participant, Participant Member

- Individual and Individual User

- Direct Relationship

- Electronic Health Information (EHI)

- Trusted Exchange Framework (TEF), Minimum Required Terms and Conditions (MRTCs), QHIN Technical Framework (QTF)

- Use and Disclosure

Framework Agreement Flow-Down

Common Agreement
MRTCs
ARTCs
QTF

Common Agreement
The parties to the Common Agreement will be the RCE and one or more QHINs. The Common Agreement will include flow down clauses for the QHIN's agreements with its Participants and the Participant's agreements with its Participant Members.

Participant-QHIN Agreement
An agreement between a Participant and a QHIN.

Participant Member Agreement
An agreement between a Participant and a Participant Member.

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RCE

QHIN

Participant Member

Summary of Key Changes

QHIN Technical Framework Added

Addressed the technical requirements for exchange among QHINs through development of the QHIN Technical Framework – Draft 1.

Exchange Purposes Updated

Adopted a subset of payment and health care operations purposes, as defined in HIPAA.

QHIN Message Delivery (Push) Added

Included sending a patient's electronic health information (EHI) to a specific Qualified Health Information Network (QHIN) for delivery.

Fees

Fee proposal was modified to reflect zero-cost fees between QHINs for Individual Access Services only.

QHIN Definition Broadened

Application process added that allows a broader set of HINs to apply to be a QHIN.

Privacy and Security

Expanded privacy and security protections for all participating entities. Added requirement that QHINs must abide by HIPAA Privacy and Security Rule as if it applies to EHI.

QHIN Technical Framework

The QHIN Technical Framework (QTF) describes the technical and functional requirements for EHI exchange among QHINs
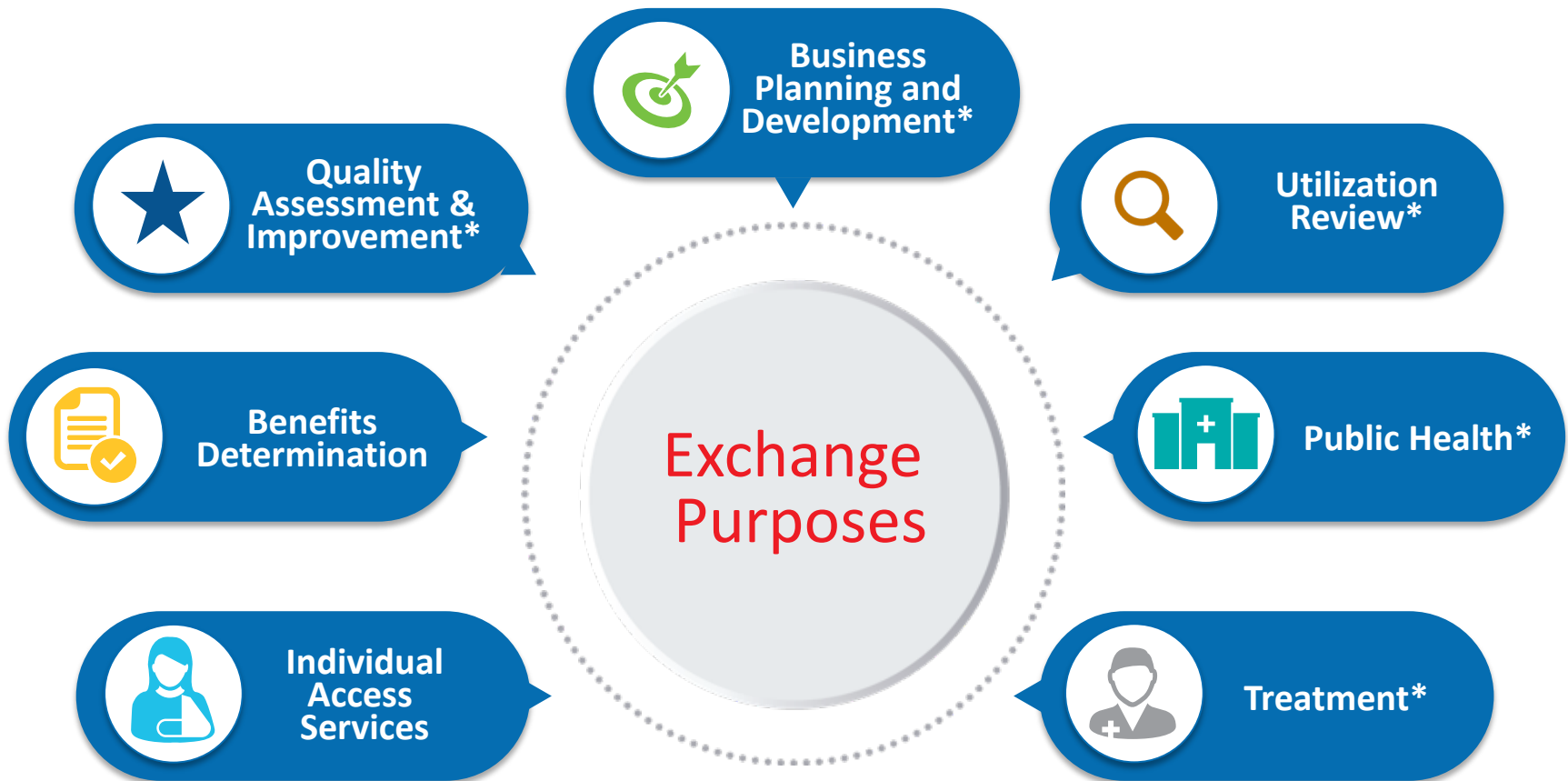
QHIN Technical Framework

Functions included: Certificate Policy, Secure Channel, Mutual QHIN Server Authentication, User Authentication, Authorization & Exchange Purpose, Query, Message Delivery, Patient Identity Resolution, Record Location, Directory Service, Individual Privacy Preferences, Auditing, and Error Handling.

Technical detail: Focuses directly on information exchange between QHINs; for most interactions within a QHIN's network, the QHIN may determine how best to implement its responsibilities.

Functions enable: QHIN Broadcast Query, QHIN Targeted Query, and QHIN Message Delivery.

Exchange Purposes

- Business Planning and Development*
- Quality Assessment & Improvement*
- Utilization Review*
- Benefits Determination
- Public Health*
- Individual Access Services
- Treatment*

Exchange Purposes

Only applies to HIPAA covered entities and business associates

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Individual Access Services (IAS)

- **Individual Access Services:** with respect to the Exchange Purposes definition, the services provided to satisfy an Individual's right to access and to obtain a copy of the Individual's EHI and to direct that it be sent to a third party pursuant to:
  - » Applicable Law;
  - » Any of the Framework Agreements;
  - » 45 CFR §164.524(a) as if it applied to all EHI;
  - » 45 CFR §164.524(c)(2) as if it applied to all EHI; and
  - » 45 CFR §164.524(c)(3)(ii) if the Individual wants the EHI sent to a third party.

- Participating entities must respond to queries for IAS whether or not the request was prompted by a Covered Entity or Business Associate, provided the Individual has satisfied the requirements at 45 CFR 164.(c)(3)(ii) if it wants EHI send to a third party. (Section 2.2.4(ii), 7.4(ii), 8.4(ii)).

- Participating entities must respond to queries for all Exchange Purposes with the EHI they have available. However, if a Participant or Participant Member provides IAS only, they are only required to respond to requests for IAS (Sections 7.1(ii) and 8.1(ii)).

- Participating entities must respond to queries for IAS whether or not the request was prompted by the Individual User or by a QHIN, Participant, or Participant Member who is making the request on behalf of the Individual User. (Sections 2.2.4 (iv), 7.4(iv), and 8.4 (iv)).

- Once EHI is received by a QHIN, Participant, or Participant Member for IAS, the QHIN, Participant, or PM may only exchange, retain, aggregate, Use, and Disclose that EHI for IAS.

Exchange Modalities

QHIN Broadcast Query

A QHIN's electronic request for an Individual's EHI in the context of the Common Agreement that requests EHI from all other QHINs to the extent permitted by the Common Agreement and Applicable Law.

QHIN Targeted Query

A QHIN's electronic request for an Individual's EHI (sometimes referred to as a "pull") from specific QHINs in the context of the Common Agreement to the extent permitted by the Common Agreement and Applicable Law. .

QHIN Message Delivery (Push)

The electronic action of a QHIN to deliver an Individual's EHI to one or more QHINs without an obligation to further transmit it, or to send EHI to one or more QHINs for delivery to one or more Participants or Individuals (sometimes referred to as a "push"). Notwithstanding the foregoing, QHIN Message Delivery does not include responses to any QHIN Query.

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Fees

- QHINs must use reasonable and non-discriminatory criteria if it charges any fees to another QHIN.

- QHINs *may not* charge another QHIN any amount to exchange EHI for *Individual Access Services.*

- QHINs *may not* impose any other fee on the Use or further Disclosure of the EHI once it is accessed by another QHIN.

- Any additional requirements around fees will be specified in the ARTCs, which will be developed by the RCE and approved by ONC.

QHIN Application Process

Step 1: RCE solicits, collects, and evaluates QHIN Applications from HINs who wish to receive QHIN Designation. In order to apply for QHIN Designation, a HIN must meet certain prerequisites:

i. The HIN already operates a network that provides the ability to locate and transmit EHI between multiple persons and/or entities electronically, on demand or pursuant to one or more automated processes.

ii. Such persons and/or entities are already exchanging EHI in a live clinical environment using the network.

iii. The HIN has provided reasonable evidence that exchange of EHI using its network is occurring in accordance with Applicable Law and the privacy, security and patient safety requirements in the MRTCs.

iv. The HIN has provided a reasonable plan in writing of how it will achieve within the required period all of the applicable requirements of the Common Agreement and the QHIN Technical Framework.

Step 2: After receipt of a completed QHIN Application, the RCE approves or rejects each QHIN Application in writing and within a stated period.

QHIN Application Process

Step 3: If approved, the HIN and RCE must both execute the Common Agreement and the HIN receives Provisional QHIN status.

Step 4: The RCE assigns the Provisional QHIN to a Cohort which has an applicable deadline by which the Provisional QHIN must become a Designated QHIN or be terminated from the Cohort.

> A Cohort is a group of one or more Provisional QHINs that are attempting to be Designated by the RCE as QHINs. They have been assigned the same deadline for completing all required actions to be Designated a QHIN.

Step 5: The Provisional QHIN asserts, and the RCE confirms that all applicable requirements of the Common Agreement and QHIN Technical Framework have been met.

Step 6: RCE provides written notice to the Provisional QHIN that it has been Designated a QHIN. The RCE also provides notice to ONC.

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Privacy

- **Breach Notification Requirements (6.1.1, 6.1.2, 7.12, 7.13, 8.12, 8.13)**—Included requirement that QHINs, Participants, and Participant Members comply with the Breach notification requirements pursuant to the HIPAA Breach Notification Rule at 45 CFR §164.400-414, regardless of whether or not they are a Covered Entity or Business Associate. Further, each QHIN shall notify the RCE, as well as other QHINs, Participants, Participant Members, and Individual Users who may have been affected by the Breach without unreasonable delay and in accordance with Applicable Law.

- **Meaningful Choice (2.2.3, 7.3, 8.3)**—QHINs, Participants, and Participant Members must provide Individuals with whom they have a Direct Relationship the opportunity to exercise Meaningful Choice to request that their EHI not be Used or Disclosed via the Common Agreement, except as required by Applicable Law. Participants and Participant Members are responsible for communicating this Meaningful Choice up to the QHIN who must then communicate the choice to all other QHINs.

- **Minimum Necessary (3.3, 7.19, 8.19)**—QHINs, Participants, and Participant Members shall satisfy the Minimum Necessary Requirements at 45 CFR § 164.514(d) as if they applied to EHI.

- **Other Legal Requirements (6.1.4, 7.4, 8.4)**—QHINs, Participants, and Participant Members with a Direct Relationship with an Individual shall obtain and maintain copies of the Individual's consent, approval or other documentation when required by Applicable Law. The participating entity may make it available electronically to any other Participant, QHIN, or Participant Member upon request to the extent permitted by Applicable Law.

- **Written Privacy Summary (6.1.5, 7.6, 8.6)**—QHINs, Participants, and Participant Members must publish and make publically available a written notice describing their privacy practices regarding the access, exchange, Use, and Disclosure of EHI. This notice should mirror ONC's Model Privacy Notice and include information explaining how an Individual can exercise their Meaningful Choice and who they may contact for more information about the entity's privacy practices.

- **Summary of Disclosures (6.1.6, 7.20, 8.20, 9.5)**—Individuals shall have the right to receive a summary of Disclosures of EHI for applicable Exchange Purposes in the context of the Framework Agreements for up to a period of six (6) years immediately prior to the date on which the summary of Disclosures is requested. For Covered Entities, this obligation may be met by complying with the requirements of 45 CFR § 164.528.

Security

- **Minimum Security Requirements (6.2, 7.7, 8.7)—**All QHINs shall comply with the HIPAA Privacy and Security Rules as if they applied to EHI. Participants and Participant Members must comply with the HIPAA Rules when applicable. However, regardless of whether they are a Covered Entity or Business Associate, Participants and Participant Members must take reasonable steps to promote the confidentiality, integrity, and availability of EHI.

- **NIST SP 800-171 (6.2.1)—**QHINs must evaluate their security program for the protection of Controlled Unclassified Information (CUI), and develop and implement an action plan to comply with the security requirements of the most recently published version of the NIST Special Publication 800-171 (Protecting Controlled Unclassified Information in Non-federal Information Systems and Organizations).

- **No EHI Used or Disclosed outside the US (2.2.11)—**QHINs shall not Use or Disclose EHI outside the US, except as required by Applicable Law and to the extent an Individual User requires their EHI to be Used or Disclosed outside the US. QHINs may only utilize cloud-based services that are physically located within the US.

- **Data Integrity (6.2.2, 7.16, 8.16)—**QHINs, Participants, and Participant Members shall include procedures to promote data integrity with respect to the Exchange Purposes it performs.

- **Authorization (6.2.3, 7.8, 8.8)—**QHINs, Participants, and Participant Members security policy shall include written authorization procedures to confirm that any entities requesting access to system functions or EHI possess the appropriate credentials (e.g., granted and provisioned in security and privacy management).

- **Identity Proofing (6.2.4, 7.9, 8.9)—**QHINS, Participants, and Participant Members shall be identity proofed at a minimum of IAL 2 and require proof of identity for Individual Users at a minimum of IAL2 prior to issuance of credentials.

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Security, continued

- **User Authentication (6.2.5, 7.10, 8.10)—**QHINS, Participants, and Participant Members shall be authenticated at AAL2 (with support for FAL2) and require Individual Users be authenticated at a minimum of AAL2 prior to issuance of credentials.

- **Transport Security (6.2.6, 7.17, 8.17)—**QHINs, Participants, and Participant Members' security policies shall include written policies and procedures to ensure a secure channel for communications between Participants and QHINs and between Participants and Participant Members.

- **Auditable Events (6.2.8, 7.11, 8.11)—**QHINs, Participants, and Participant Members shall abide by the auditable events requirements described in the QHIN Technical Framework with respect to the Exchange Purposes it performs.

- **Certificate Policies (6.2.7)—**Each QHIN's security policy shall require that all Participant cryptographic certificates meet or exceed the applicable criteria in the QHIN Technical Framework.

- **Certificate Authority Backup and Recovery (6.2.9)—**Each QHIN who is an issuer of certificates shall maintain backup copies of system, databases, and private keys in order to rebuild the certificate authorities' capability in the event of software and/or data corruption.

- **Security Labeling (Introduction)—**ONC requests comment on inclusion of a new requirement regarding the use of confidentiality codes and security tags and/or reasonable alternatives that would ultimately promote the ability to exchange sensitive data under the Common Agreement.

Draft Work Plan

Meeting Date	Discussion Items
Thursday May 9th	• **Welcome, review of TEFCA, and review of Task Force project plan and schedule of meetings** • **Begin Discussion of QHIN Definition, Application, Onboarding, and Designation** **MRTCs Definitions:** QHIN, QHIN Application, Onboarding, Designation, Cohort, Provisional QHIN **MRTCs Provisions:** 2.1
Tuesday May 14th	**QHIN Exchange Purposes, Exchange Modalities, EHI Reciprocity, and Permitted and Future Uses of EHI** **MRTCs Definitions**: Benefits Determination, Business Planning and Development, Connectivity Services, Individual Access Services, Public Health, Utilization Review, Quality Assessment and Improvement, Treatment, QHIN Broadcast Query, QHIN Message Delivery, QHIN Targeted Query, Use, Disclosure, Minimum Information, Direct Relationship, QHIN Technical Framework, Individual, Individual User **MRTCs Provisions:** 2.2.1, 2.2.2, 2.2.4, 7.1, 7.2, 7.14, 8.1, 8.2, 8.14 **QTF:** Example QHIN Exchange Scenarios and Functions and Technology to Support Exchange
Thursday May 16th	**Continue discussion of QHIN Exchange Purposes, Exchange Modalities, EHI Reciprocity, and Permitted and Future Uses of EHI**
Wednesday May 22nd	**Present update to full HITAC**
Thursday May 23rd	**Privacy- Meaningful Choice, Minimum Necessary, Written Privacy Summary, Breach, Summary of Disclosures** **MRTCs Definitions:** Meaningful Choice, Minimum Necessary, Breach, Summary of Disclosures, United States **MRTCs Provisions:** 2.2.3, 2.2.11, 3.3, 6.1.1, 6.1.2, 6.1.3, 6.1.4, 6.1.5, 6.1.6, 7.3, 7.4, 7.6, 7.12, 7.13, 7.28, 7.19, 7.20, 8.3, 8.4, 8.6, 8.12, 8.13, 8.18., 8.19, 8.20, 9.5 **QTF:** Individual Privacy Preferences

Draft Work Plan, continued

Meeting Date	Discussion Items
Friday May 24th	• **Continue discussion on Privacy** • **Begin Security discussion if time allows**
Tuesday May 28th	**Security- Minimum Security Requirements, ID Proofing, Authentication, Authorization, Data integrity, Transport Security, Certificate Policies, Auditable Events, No EHI Outside the US** MRTCs Provisions: 2.2.11, All of 6.2, 7.7, 7.8, 7.9, 7.10, 7.11, 7.16, 7.17, 8.7, 8.8, 8.9, 8.10, 8.11, 8.16, 8.17, 9.3, 9.4 QTF: Certificate Policy, Secure Channel, Mutual QHIN Server Authentication, User Authentication, Authorization, Auditing, Error Handling
Monday June 3rd	**Data Quality, Transparency, Fees, Cooperation and Non-Discrimination, Timelines** MRTCs Provisions: 2.2.5, 2.2.6, 2.2.7, 2.2.8, 2.2.9, 2.2.10, Sections 3, 4, and 5; 7.5, 7.22., 7.23, 7.24, 8.5, 8.15
Tuesday June 4th	**Draft recommendations**
Tuesday June 11th	**Finalize recommendations**
Thursday June 13th	**Present Final Recommendations to HITAC**

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Health IT Advisory Committee

Hour 2

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Definitions

- **Qualified Health Information Network (QHIN):** a Health Information Network that is a party to a Common Agreement signed by the RCE and has been Designated a QHIN by the RCE after satisfying all the conditions of the Common Agreement and the QHIN Technical Framework.

- **QHIN Application:** the written application of a HIN that wishes to become a QHIN that: (a) certifies which of the Common Agreement and QHIN Technical Framework requirements the HIN already satisfies with sufficient detail to allow the RCE to easily confirm such representations, and (b) describes the HIN's plan to satisfy all other requirements of the Common Agreement and the QHIN Technical Framework within a stated period after signing the Common Agreement.

- **Cohort:** a group of one or more Provisional QHINs specified in writing by the RCE that are attempting to be Designated by the RCE as QHINs by the same Cohort Deadline.

- **Cohort Deadline:** the date established by the RCE for a completion of all Onboarding and other actions necessary for the Provisional QHINs in the Cohort to be Designated by the RCE as QHINs.

- **Designation (including its correlative meanings "Designate", "Designated", and "Designating"):** the RCE's written confirmation to ONC that a Provisional QHIN has satisfied all the requirements of both the Common Agreement and the QHIN Technical Framework before the Provisional QHIN may become a QHIN

- **Onboarding:** all implementation and other actions necessary for a QHIN, a Participant, or Participant Member to become operational in the live environment of the Framework Agreements to which it is a party. For a QHIN, the Onboarding requirements shall be set forth in the Common Agreement. For a Participant, the Onboarding requirements shall be set forth in the Participant-QHIN Agreement. For a Participant Member, the Onboarding requirements shall be set forth in the Participant Member Agreement.

- **Provisional QHIN:** a Health Information Network that has signed a Common Agreement that has also been signed by the RCE after approval as described in Section 2 below. A Provisional QHIN has not yet completed all of the requirements of the Common Agreement and the QHIN Technical Framework and has not been Designated by the RCE as a QHIN.

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QHIN Application Process

Step 1: RCE solicits, collects, and evaluates QHIN Applications from HINs who wish to receive QHIN Designation. In order to apply for QHIN Designation, a HIN must meet certain prerequisites:

i.   The HIN already operates a network that provides the ability to locate and transmit EHI between multiple persons and/or entities electronically, on demand or pursuant to one or more automated processes.

ii. Such persons and/or entities are already exchanging EHI in a live clinical environment using the network.

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iv. The HIN has provided a reasonable plan in writing of how it will achieve within the required period all of the applicable requirements of the Common Agreement and the QHIN Technical Framework.

Step 2: After receipt of a completed QHIN Application, the RCE approves or rejects each QHIN Application in writing and within a stated period.

QHIN Application Process

Step 3: If approved, the HIN and RCE must both execute the Common Agreement and the HIN receives Provisional QHIN status.

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Step 6: RCE provides written notice to the Provisional QHIN that it has been Designated a QHIN. The RCE also provides notice to ONC.

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Homework

Please come to the 5/14/19 call prepared to discuss:

QHIN Exchange Purposes, Exchange Modalities, EHI Reciprocity, and Permitted and Future Uses of EHI

MRTCs Definitions: Benefits Determination, Business Planning and Development, Connectivity Services, Individual Access Services, Public Health, Utilization Review, Quality Assessment and Improvement, Treatment, QHIN Broadcast Query, QHIN Message Delivery, QHIN Targeted Query, Use, Disclosure, Minimum Information, Direct Relationship

MRTCs Provisions: 2.2.1, 2.2.2, 2.2.4, 7.1, 7.2, 7.14, 8.1, 8.2, 8.14

QTF: Example QHIN Exchange Scenarios and Functions and Technology to Support Exchange

To make a comment please call:

Dial: 1-877-407-7192

*(once connected, press "***1**" to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
"Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.

Meeting Adjourned

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