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# ***Draft* QHIN Onboarding & Designation SOP**

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# Section I: Eligibility Requirements



1. **“Signatory must demonstrate that it meets the definition of a U.S. Entity and is not owned or controlled by any non-U.S. person(s) or entity(-ies). The specific, required means to demonstrate this are set forth in an SOP.”**
  - a) Signatory must provide a copy of its charter or equivalent document issued by the Secretary of State, or similar government agency, for the jurisdiction in which the Signatory is legally organized or incorporated. Signatory shall provide its principal place of business, which shall be within the United States. *(Application Question 2.1)*
  - b) Signatory must provide a certificate of good standing, or similar document, issued by the relevant governmental authority for the jurisdiction in which Signatory is domiciled and dated within ninety (90) calendar days of the date of Signatory’s QHIN application. *(Application Q2.2)*
  - c) Signatory must provide a current copy of its organizing documents, such as Articles of Incorporation and Bylaws for a corporation or Articles of Organization and Operating Agreement for a limited liability company. These documents must be attested to by the Secretary of the organization or another officer of the organization if there is no Secretary. *(Application Q5)*



- d) Signatory must provide a list of its current officers and members of its governing body/ies, including their full names, business addresses, and their terms. (*Application Q6*)
  - i. Signatory shall also attest that none of the individuals below are listed on the Specially Designated Nationals and Blocked Persons list published by the United States Department of Treasury Office of Foreign Asset Control or the list of Excluded Individuals published by the U.S. Department of Health and Human Services, Office of the Inspector General: (*Application Q7 & Q8*)
    1. All owners with a 5% or greater ownership interest in the Signatory, if any;
    2. Officers of the legal entity that is the Signatory;
    3. Governing body members of the legal entity that is the Signatory;
    4. Members of the executive management of Signatory.
- e) Signatory must attest that Signatory is not owned or controlled by any non-U.S. person(s) or entity(-ies) except to the extent that the foreign ownership fully complies with the requirements of the Means to Demonstrate U.S. Ownership and Control of a QHIN SOP. (*Application Q9*)



- 2. “Signatory is able to exchange Required Information, as defined in this Common Agreement. The specific, required means to demonstrate this are set forth in an SOP.”**
- a) Signatory must meet the following: (*Application Q12 & Q13*)
    - i. Be capable of the exchange of Required Information for all Exchange Purposes. Signatory must describe the purposes for exchange that are currently permitted on its network;
    - ii. Be capable of conducting exchange with unaffiliated organizations. Signatory must describe entities participating in its network, including their affiliation or non-affiliation with one another;
    - iii. Signatory must describe how it currently facilitates exchange of health information (e.g., query, push, other exchange modality); and
    - iv. Signatory shall indicate the length of time that it has experience with (i).
  - b) Signatory must submit the number and type of organizations that utilize its exchange services in order to demonstrate that it is engaged in the exchange of Required Information. Signatory shall specify if it limits the types of organizations that can participate in its network or if its network is specialized in any manner (e.g., by geography, exchange purposes, type of information exchanged). (*Application Q15 & Q16*)
  - c) Signatory must submit copies of its data sharing agreements, operating policies and procedures, and other legal agreements and related documents that govern the operation of its health information network. (*Application Q17*)



- 3. “Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by this Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and Designate Signatory under a provisional status, subject to additional monitoring as further provided in the Onboarding & Designation SOP, including additional review during a provisional period.”**
- a) It is anticipated that QHINs may process tens of millions of transactions each day. Signatory must, therefore, demonstrate that it has the ability to successfully process a high number of transactions through a high performing, reliable environment. The following performance measures must be provided to the RCE as part of Signatory’s application:
- i. Average monthly transaction volumes;
  - ii. Average annual transaction volumes.

Signatory must show that it is currently processing successful transactions in order for the RCE to have any means by which to evaluate the ability of Signatory to process transactions at the anticipated scale and expected reliability of a QHIN. (*Application Q12, Q13, Q22*)

# Common Agreement Criterion 3

- b) Signatory must provide specific information regarding its architecture and an attestation of its ability to expand the volume of data transactions through its network. This information shall include the ability to add technology capacity, staff, and other needed resources. Signatory should provide specific evidence of having been in operation and supporting the query functionality as outlined in the QTF for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN.  
*(Application Q13, Q22)*
- c) The RCE can Designate Signatory as a QHIN, assuming Signatory satisfies all other requirements, on a provisional basis if the RCE determines that Signatory can reasonably support the query functionality as outlined in the QTF in production, exchange with other QHINs, and otherwise comply with the requirements of the Common Agreement. When making this determination, the RCE will require evidence to show that Signatory has been engaged in the transmission of Required Information using a different but functionally comparable exchange method to the QTF in a live production environment for at least the twelve (12) consecutive calendar months immediately preceding its application to the RCE.  
*(Application Q12, Q13)*

If Signatory cannot demonstrate at least twelve (12) consecutive calendar months of operating history with query functionality as outlined in the QTF, the RCE can consider other evidence that Signatory is capable of a functionally comparable exchange method (provisional status).





Provisional status for organizations that do not satisfy all of the requirements of this eligibility criterion at the time of application:

- (i) The RCE may Designate an organization as a QHIN on a provisional basis (“Provisional Status”) based on a determination that the organization: (1) does not, at the time of its application, satisfy all of the requirements of this eligibility criterion, but (2) demonstrates the likelihood of being able to satisfy all such requirements during the course of the Provisional Status. The Provisional Status is a 12-month period in which a QHIN has the opportunity to demonstrate the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, QTF, and applicable SOPs.
- (ii) The RCE may impose such limitations on Signatory during its Provisional Status as the RCE deems reasonably necessary to allow the RCE to monitor Signatory’s performance. This may include, but is not limited to, requiring Signatory to provide information about the type and volume of exchange activity, any problems that Signatory or its Participants or Subparticipants experience with exchange activity, participation in meetings with the RCE to discuss Signatory’s performance during the Provisional Status, and any other matters that the RCE determines to be necessary. The Provisional Status shall continue for a time period of twelve (12) calendar months following the RCE Designating Signatory as a QHIN in Provisional Status; provided, however, that the RCE has the right to suspend (and toll) or terminate Signatory’s Designation at any point if the RCE determines that Signatory is not in compliance with the requirements and obligations that are applicable to QHINs, as more fully set forth in the applicable SOP.

A QHIN in Provisional Status is a Designated QHIN that is subject to additional monitoring by the RCE for purposes of assuring the RCE that the QHIN is fully meeting the requirements of being a QHIN. QHINs may not discriminate against any QHIN, including those in Provisional Status, and all QHINs must exchange with one another as required by the Common Agreement, the SOPs, and the QTF.



- d) Signatory must identify any gaps between its current technical infrastructure and the requirements of the QTF and identify its plan to address these gaps so that Signatory will be able to fully comply with the QTF once Signatory is Designated as a QHIN. (*Application Q12, Q13, Q21, Q22*)
- e) Signatory must provide evidence of compliance with the QTF, including but not limited to any required conformance, interoperability, or partner testing as specified in this SOP and/or in the separate QHIN Testing Process document(s). (*Application Q12, Q13, Q18, Q22*)



4. **“Signatory must demonstrate that it has in place, at the time of its application to be Designated, the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its Health Information Network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network. The specific, required means to demonstrate this are set forth in an SOP.”**
- a) Signatory must have network governance. This governance must include the following:
    - i. Network governance must include representatives of entities that participate in Signatory’s network. Signatory must describe the eligibility criteria for becoming a representative in its network governance, including any criteria related to ensuring the diversity of those participating in Signatory’s network are represented. Signatory must provide the number (or range) of individuals that participate in the body responsible for its network governance, as well as their affiliations. *(Application Q6, Q11, Q14, Q15)*
    - ii. Network governance must provide for participation by network participants. The body responsible for network governance, which must include network participants, must have the ability to make decisions regarding Signatory’s network. As an indicum of having representative and participatory network governance, Signatory must state the minimum frequency with which meetings of the governing body are required to take place (e.g., monthly, quarterly, etc.) and attest that these meetings are attended by the number of acting representatives necessary to establish a quorum. *(Application Q10, Q11, Q14, Q15)*



- iii. Network governance must be codified through written means. Signatory must provide a copy of the document(s) that memorialize(s) the body's authority to govern the network. (*Application Q10*)
- iv. The rules of network governance must be communicated to members of Signatory's network. Signatory must describe how network governance rules are communicated (e.g., via contract terms, policies, or some other written form?). (*Application Q14*)
- v. Network requirements must be enforced, including for onboarding entities to the network. Signatory must describe how Signatory evaluates organizations to decide that they have the necessary technical, legal, and operational capability to participate in Signatory's network. (*Application Q14*)



- b. Signatory's network governance must include the following functions:
- i. Oversight of the technical framework that enables the exchange of Required Information through its network. If Signatory uses a third-party technology vendor for its network, explain how Signatory conducts oversight of the third party and how Signatory will assure the third party's compliance with the Common Agreement and QTF. *(Application Q24)*
  - ii. Signatory must describe and demonstrate the legal means that it uses to enforce the policy, technical, and legal requirements of its network with its participants. If Signatory does not have a network legal agreement, the burden is on Signatory to demonstrate that it does have a legally enforceable approach. *(Application Q14 & Q17)*
  - iii. A formalized structure, resources, and controls to satisfy the privacy and security requirements of the Common Agreement and related SOPs, as well as evidence of compliance as specified in related SOPs. *(Application Q25-Q34)*
  - iv. A formalized process to advance cooperation or resolve disputes regarding use of Signatory's network. Signatory shall provide a detailed description of: (1) all disputes that have been processed through the dispute resolution process during the twenty-four (24) calendar months immediately preceding the submission of Signatory's application; (2) any disputes that are pending at the time Signatory submits its application; and (3) any legal claims filed during the twenty-four (24) calendar months immediately preceding the submission of Signatory's application that arose out of a dispute that was first brought to Signatory's dispute resolution process or that was permitted to bypass such process (e.g., a petition for injunctive relief), to the extent Signatory knows of any such legal claims. *(Application Q19)*

# Common Agreement Criterion 4



- v. A formalized process to manage any data breach involving Signatory's network. (*Application Q26*)
  - vi. A formalized process to impose sanctions on any network participant that violates the rules of Signatory's network, including the suspension or termination of said participant's ability to use the network. (*Application Q14 & Q17*)
  - vii. A formalized process to implement changes to any of the above. (*Application Q14, Q17*)
- c. Signatory must have the requisite financial and personnel resources to support its obligations as a QHIN. This includes but is not limited to the following:
- i. Signatory shall provide an attestation of the organization's financial health to assure continuity of QHIN operations. This includes an attestation that Signatory has available a minimum amount of cash, or cash equivalents, and availability of borrowing arrangements (e.g., a line of credit) equal to 6 calendar months of operating reserves, as well as copies of its audited financials for the prior two years. (*Application Q3*)
  - ii. Signatory shall describe the organizational structure and personnel who support the QHIN, including how these individuals work with the network governing body. (*Application Q23*)
  - iii. Signatory shall provide evidence of one of the following: (1) a certificate of insurance demonstrating that Signatory has current cyber-liability coverage that meets the requirements set forth in the applicable SOP; (2) that Signatory has applied for cyber-liability coverage that meets the requirements set forth in the applicable SOP, including an attestation that Signatory will obtain the coverage prior to Signatory being Designated; or (3) available internal funds, separate from those attested to in 4(c)(i), to self-insure against a cyber-incident in at least the amount required by the applicable SOP. (*Application Q4*)



## d. Security (*Application Q25-Q34*)

- i. Trusted Network. Signatory must provide evidence that it has been certified under a nationally recognized security framework from a list of pre-approved certifications/certifying bodies developed by the RCE, as required by the QHIN Security Requirements for the Protection of TI SOP. (*Application Q27*)
- ii. Chief Information Security Officer. Signatory must have a Chief Information Security Officer and provide evidence that the CISO has executive-level responsibility for overseeing the security of Signatory's network. (*Application Q33*)

Signatory must provide detailed information about any HIPAA reportable breaches of ePHI over the past 3 years, including the nature of the breach, the number of individuals affected by the breach, the remediation measures undertaken by Signatory, and the amount of any fines or penalties. (*Application Q26*)



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# Section II: Application Process



# QHIN Application Process



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## Pre-application Activities



Prospective QHIN reviews the Common Agreement, QTF, and SOPs.

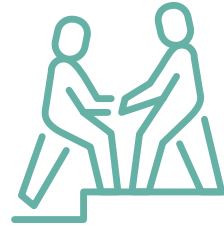
Prospective QHIN participates in educational sessions.



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

The RCE makes an eligibility determination.

## QHIN onboarding



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](http://www.RCE.SequoiaProject.org).

# Beginning the Application Process



- The entity seeking to be Designated as a QHIN must inform the RCE of its intent to apply by submitting written communication to **QHINApplications@sequoiaproject.org** or **via other appropriate method advertised by the RCE (e.g., web portal)**.
- The RCE will provide the entity with the Onboarding process documents to become a QHIN and schedule a virtual consultation with the entity to review the Eligibility Requirements, Onboarding process documents, and answer any clarifying questions.
- The Onboarding process documents that the RCE provides to the entity shall be the following: (1) this Onboarding & Designation SOP, (2) a copy of the Common Agreement for signature, and (3) QHIN Application. The Common Agreement and QHIN Application are to be completed and returned in their entirety to the RCE representative for review.



- Upon receipt of an application, the RCE will review the application to determine if the applicant has responded to all of the application's questions and provided supporting documents.
- If the application is not complete, **the RCE will notify the applicant within thirty (30) calendar days of receipt of the application what information is required to make the application complete.** The RCE may extend this time period.
- Once the RCE has determined that the application is complete, **the RCE will notify the applicant in writing that its application has been accepted for review.**
  - » The acceptance of an application for review does not mean that the applicant will be Designated as a QHIN; the applicant must demonstrate that it meets all of the requirements to be Designated as a QHIN.



- Once the RCE determines that the application is complete, it will begin its review of the application to determine whether the applicant meets the Eligibility Criteria to be Designated as a QHIN.
- The RCE will complete its review **within sixty (60) calendar days** of notifying the applicant that its application is “complete.”
  - » The RCE may extend this time period.
- The RCE may contact the applicant with questions as the RCE reviews the application.
  - » The applicant will have **ten (10) business days to respond with answers to questions** from the RCE. It is important that the applicant respond to the RCE promptly so that the RCE can complete its review within the sixty- (60-) calendar day timeframe.
  - » **If the applicant fails to respond with satisfactory answers to the RCE’s questions within ten (10) business days, then the application shall be deemed to have been withdrawn by the applicant without any further action by the RCE.** The effect of this withdrawal is to end all review by the RCE.



- If an application is deemed to have been withdrawn, the applicant can reapply **no sooner than six (6) calendar months after the date on which its previous application was submitted** with a new application that includes all required information and that specifically addresses the question(s) to which the applicant previously failed to respond and an explanation as to why no response was previously provided within the required timeframe.
  - » The RCE will review a re-application solely on the basis of what is included in the re-application; the applicant cannot rely upon information or documents that were previously submitted to the RCE.



- The application contains several different sections that require the applicant to demonstrate its ability to comply with the different Eligibility Criteria. The RCE will have different sections of the application reviewed by different RCE team members depending upon each team member's expertise.
  - » During the review of the application by the team members, if the RCE determines that the applicant has failed to demonstrate that it satisfies any Eligibility Criterion or other requirement, the RCE will stop its review and deny the application.
- If the RCE denies an application, it will notify the applicant of the denial and will identify why the application was denied. Applicants should understand that there may be additional failures to comply that the RCE has not yet identified at the time that it identifies non-compliance and denies the application.
  - » Due to limited resources, the RCE is not in a position to review an application once the RCE has determined that the application should be denied. If an application is denied, the applicant has two options:



- **Re-application:** If an application is denied, the applicant can reapply six (6) calendar months after the date shown on the notice of denial with a new application that includes all required information and that specifically addresses the deficiencies noted as the basis for denial of the applicant's previous application.
  - » The applicant must make it very clear in its reapplication how it has addressed the reason(s) for denial that the RCE listed in its notice of denial for the first application. The RCE will review a re-application solely on the basis of what is included in the re-application; the applicant cannot rely upon information or documents that were previously submitted to the RCE.
- **Appeal of denial:** An applicant may appeal the denial of its application **only** for one or more of the following reasons:
  - » The reason(s) for denial identified by the RCE is/are objectively incorrect due to an inadvertent error(s) by the RCE;
  - » The RCE failed to follow the procedures set forth in this SOP, and this failure materially interfered with the applicant's ability to demonstrate that the applicant does satisfy the Eligibility Criteria. This would include, by way of example only, if the RCE failed to provide applicant with ten (10) business days to respond to questions from the RCE;
  - » There is reasonable evidence that the RCE has not applied the Eligibility Criteria in a consistent manner across all applicants;
  - » There is evidence that the RCE discriminated against the applicant in the RCE's review of the application;
  - » The RCE based its denial on something other than the Eligibility Criteria or other requirements imposed on QHINs by the Common Agreement, SOPs, or the QTF.



- If an applicant wishes to appeal the denial of its application, the applicant must file with the RCE **a written appeal within fifteen (15) business days of the date shown on the notice of denial.**
  - » The appeal must set forth which of the **five grounds** for appeal the applicant is asserting and the evidence or information that the applicant is relying upon to support these grounds.
  - » The appeal must be signed by an executive, officer, or director of the applicant who has the express authority to legally bind the applicant.
  - » The RCE will review the appeal and prepare a **summary of the appeal allegations within fifteen (15) business days of receiving the appeal from the applicant.**
  - » The RCE will brief the Governing Council or the Transitional Council by providing it with a copy of the summary of the appeal, unless the appeal occurs prior to the formation of the Transitional Council.
    - This summary will be labeled as confidential and shall not be further disclosed by any member of the Governing Council or the Transitional Council unless specifically directed to do so by the RCE.





- The RCE will seek input from the Governing Council or the Transitional Council about the merits of the appeal unless the appeal occurs prior to the formation of the Transitional Council.
  - » The RCE will determine what input to seek and how best to obtain this input, but neither the Governing Council nor the Transitional Council will actually vote on the merits of any appeal.
  - » The RCE will inform ONC that an appeal has been filed and share the summary with ONC on a confidential basis.
  - » The RCE will consider any input that ONC provides on the merits of the appeal, but the decision on any appeal will be made by the RCE.
  - » In the event an applicant appeals a denial prior to the formation of the Transitional Council, the RCE will inform ONC that an appeal has been filed and share the summary with ONC on a confidential basis.



- The RCE will **make a decision on the appeal within seventy (70) calendar days of the appeal** being filed with the RCE. The RCE may extend this time period.
- The RCE can deny the appeal or grant the appeal.
  - » The decision of the RCE is final, subject to Signatory's right to escalate certain Disputes to ONC, as set forth in Section 15.6.1 of the Common Agreement, and the ONC's right to review the RCE's conduct, as set forth in Section 3.1 of the Common Agreement.
  - » **If the RCE denies the appeal, the applicant cannot file a new application to be Designated as a QHIN until six (6) calendar months after the date of the denial of the appeal** unless, subject to Section 15.6.1 or Section 3.1 of the Common Agreement, ONC specifies a shorter timeframe.
  - » Any new application must address how the applicant has addressed the reason(s) that applicant's application was previously denied. If the RCE grants the appeal, then the applicant shall be allowed to proceed to the next step in the Onboarding process as set forth in this SOP.



- By applying to be Designated as a QHIN and beginning the technical testing process outlined in the next section, the applicant asserts that the system or systems used are compliant with the technical specifications outlined in the QTF.
- Applicants must register for the testing platform identified in Section III of this SOP and should successfully pass testing via that platform prior to submitting their application.



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# Section III: Pre-Production Testing Process



- **QHIN Onboarding**
  - » Onboarding begins when a prospective QHIN has signed the CA and received approval of their QHIN Application.
- **QHIN Onboarding Process**
  - » During the Onboarding Process, the applicant will have regular check-ins with its RCE contact to denote the progress on any outstanding requirements and coordination of technical testing.
- **Testing Overview**
  - » This section outlines the steps that prospective QHINs must take in order to demonstrate that their network can connect to those of other QHINs.
  - » The testing and connectivity validation approach outlined in these sections relies on QHINs serving as testing and validation partners for prospective QHINs. All QHINs have an obligation to serve as testing and validation partners at the request of other QHINs or the RCE on behalf of other QHINs or applicants. QHINs and applicants are strongly encouraged to coordinate with one another to distribute the effort of serving as testing and validation partners among the community of QHINs and applicants.
  - » As detailed below, prospective QHINs will be required to complete:
    - 1- Conformance Testing Process
    - 2- Non-Production Partner Testing
    - 3- Production Connectivity Validation



- An applicant must successfully complete the Conformance Testing Process and the Non-Production Partner Testing (collectively, “Pre-Production Testing”) **within twelve (12) calendar months** of approval of its application by the RCE.
  - » If the applicant fails to do so, the applicant will not be Designated, **unless the applicant provides the RCE with factual and verifiable information that supports providing the applicant with additional time to complete the testing on the basis of relevant testing circumstances that render it impossible for the applicant to complete testing within the twelve- (12-) calendar month timeframe through no fault of the applicant, AND the RCE agrees to grant applicant an extension.**
  - » The RCE is under **no obligation to provide an applicant with additional time beyond twelve (12) calendar months. Neither the applicant’s non-Designation for failure to complete Pre-Production Testing within twelve (12) calendar months nor the RCE’s denial of a request for an extension are appealable.** The applicant is responsible for keeping the RCE informed about any material developments that may delay the applicant from completing testing.



- An applicant that **fails to complete Pre-Production Testing within twelve (12) calendar months or within the timeframe of any extension granted by the RCE will receive a written Designation** determination from the RCE notifying the applicant that it is **not Designated** as a QHIN.
  - » An applicant that receives a determination that it has been denied Designation **cannot file a new application to be Designated as a QHIN until twelve (12) calendar months** after the date of the Designation determination. If an applicant is denied on the basis of its failure to complete Pre-Production Testing within the required timeframe and decides to later re-apply, the applicant must submit with its new application clear evidence that it has addressed the reason(s) the applicant was unable to successfully complete these testing phases following its previous application.
  - » The RCE will review a re-application solely on the basis of what is included in the re-application; the applicant cannot rely upon information or documents that were previously submitted to the RCE.



- This section describes the scope, approach, and testing process for verifying that an applicant complies with the QTF requirements, which are defined in the QHIN Testing Process documents.
  - » The Conformance Testing Process is intended to be a largely automated process augmented by minimal manual review to verify conformance of systems and technology used by applicants. The process will leverage an automated **testing environment known as the Sequoia Interoperability Testing Platform (“ITP”)**. The ITP environment automates the tests and enables applicants and vendors to conduct practice testing on a self-service basis, with real-time feedback regarding issues of non-conformance.
- To begin the Conformance Testing Process, **applicants must submit a testing application package**, which denotes specific configuration information required to onboard the system under test to the Sequoia ITP and information related to users who need to have accounts provisioned to access the tooling. Testing is self-service and is facilitated by the applicant.
  - » Once testing is completed, the RCE will complete any manual testing required to verify all test results and generate a final test report. Systems that successfully complete the program and pass all testing will be eligible to continue the Onboarding process for the specific version of the system that was validated.



# Non-Production Partner Testing



- Prior to implementing production connectivity, **each prospective QHIN will complete a series of non-production tests against the test instances of other QHIN gateways (“Test Ecosystem”)**. The Test Ecosystem will include an RCE Directory instance with which QHINs and prospective QHINs can interact to obtain and update test gateway information. Test Ecosystem gateways and transactions will be secured using valid, non-production RCE certificates.
- Prospective QHINs are responsible for conducting partner tests with all other QHINs.
- The non-production partner tests will consist of successfully completing each of the required transactions.
- Test partners must NOT report success until each transaction has been completed and data returned to the other party in that transaction. Specifically, for QHIN Query transactions, matching patients must be found, at least one document must be available, and one or more documents must be retrieved. Data should be coordinated among the test partners such that patient matching is successful. For QHIN Message Delivery, a successful acknowledgement must be received from the responding QHIN.



- **Prospective QHINs are required to achieve 100% transaction success with all in-production QHINs participating in the Test Ecosystem.** The RCE recognizes that for the initial group of QHIN applicants, there will not be any in-production QHINs against which an applicant can test. **For this initial group of applicants only, each applicant is required to achieve 100% transaction success with at least one other QHIN applicant.** After the initial group of QHINs are Designated by the RCE, these QHINs will be the in-production QHINs for purposes of the testing requirement of achieving 100% transaction success.
  - » Once an applicant is Designated, it must assist future QHIN applicants with their testing by maintaining a suitable test environment as further described below.
- QHINs that have received an RCE Directory Read/Write API key are required to add an entry into the Non-Production Test Ecosystem Directory that is available for testing at any time. QHINs are required to maintain entries in this directory that reasonably represent their production environment. QHINs MAY add additional entries to the Test Ecosystem Directory beyond the minimal list if they so choose.



- Entries in the Test Ecosystem Directory, and the gateway(s) behind them, should behave substantially similarly to the production environment without access to Production data. Specifically, test partners should expect that the same query that yielded a successful test with entries in the Test Ecosystem Directory would yield a non-errored query response in production. These test entries must **ONLY** return information consisting of synthetic patient data, including demographics and retrievable files.
  - » **No production clinical data should be available via gateways published in the Test Ecosystem Directory.** QHINs **MUST** ensure that their test gateway is active and ready to reply to test queries. Failure to repair these test entries in a timely manner may result in punitive actions from the RCE which may include, but are not limited to, a denial of access to the RCE Directory read/write privileges.



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# Section IV: Designation and Post- Production Testing



- After completing the non-production partner testing, attesting that any necessary system changes to complete non-production partner testing have been moved into the Production environment, satisfying all requirements of the QHIN Application Process section of this SOP, and countersigning the Common Agreement, the RCE will provide the applicant with the RCE's written Designation determination indicating that the applicant has been Designated by the RCE, and the QHIN may configure its production system for connectivity.
  - » **Until the validation process described in this Section is successfully completed, other QHINs are not obligated to engage in exchange activities with the QHIN, other than those required for the connectivity validation as described in this Section.**
- QHINs must initiate a Patient Discovery transaction to all other QHINs and must successfully receive a “No Matching Patient Found” response for all of these transactions. Such a response is “successful” if it is received and processed without error by the initiating system.



- While general experience shows that receiving the “No Matching Patient Found” response for a non-production test patient is a reasonable method for establishing that connectivity will likely be successful between two parties, it does not guarantee that there is not a configuration issue related to the other required transactions. Therefore, all QHINs must complete testing with a Production Validation Partner. A QHIN must coordinate data with its Production Validation Partner such that connectivity can be confirmed for all required transactions for that QHIN.
- Validation with a Production Validation Partner may use data from an actual shared patient as long as any appropriate access policy requirements are met. If it is not possible to do so under policy constraints, coordinated non-production test patient data can be used.
- Upon completion of the validation to the Production Validation Partner’s satisfaction, the Production Validation Partner will independently inform the RCE that the QHIN’s production partner validation was successfully completed.



- **Within thirty (30) calendar days of having its entry in the RCE Directory, each QHIN must demonstrate that it has completed a successful transaction with all other in-production QHINs.**
  - » If a QHIN is unable to complete Production Connectivity Validation within the thirty (30) day-period provided, the QHIN must provide to the RCE, no later than day thirty (30), an explanation as to why the QHIN is unable to complete this validation process within the allotted time and include a detailed plan and timeline for completion of this validation process.
  - » **The RCE will review and approve or reject the QHIN's plan for completing Production Connectivity Validation within five (5) business days of receipt.**



- A QHIN’s **failure to complete Production Connectivity Validation within thirty (30) calendar days may result in the RCE imposing sanctions against the QHIN**, including, but not limited to: identification of the QHIN as “Not in Good Standing”; suspension of the QHIN’s representation in any of the Deliberative Bodies (as defined in the Standard Operating Procedure: “Conflicts of Interest”), including suspension of any voting rights therein while the QHIN remains “Not in Good Standing”; suspension from use of the Connectivity Services; and/or termination of the Common Agreement, thereby terminating the QHIN’s Designation status.
  - » The RCE retains the right to determine, in its sole discretion, which sanctions to impose.
  - » The RCE’s imposition of any sanctions under this Section, *other than* termination, is final and not appealable.
  - » A QHIN that has its Designation terminated under this Section may dispute such termination through the Dispute Resolution Process but shall be suspended from all QHIN activities and identified as “Inactive” during the pendency of the Dispute Resolution Process.





- **A QHIN that has its Designation terminated for failure to complete Production Connectivity Validation within thirty (30) calendar days or within the period of an extension, if any, granted by the RCE may not reapply to be Designated as a QHIN until at least twelve (12) calendar months after the date of such termination.**
- The new application must include clear and compelling evidence that the applicant has addressed the reason(s) it was unable to successfully complete this testing phase during the applicant's prior Designation.
  - » The RCE will review a re-application solely on the basis of what is included in the re-application; the applicant cannot rely upon information or documents that were previously submitted to the RCE.
  - » An applicant that has previously had its Designation terminated for failure to complete Production Connectivity Validation **does not have the right to appeal a denial of its re-application.**