2025 REAL WORLD TEST PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Certification Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist Health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. **While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide
- Real World Testing Certification Companion Guide

Health IT Developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
  - ↳ *Section VII.B.5 — "Real World Testing"*
- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, 89 FR 1192 (March 11, 2024) (**HTI-1 Final Rule**)
  - ↳ *Section III.E — "Real World Testing"*

GENERAL INFORMATION

- Plan Report ID Number: **[For ONC-Authorized Certification Body use only]**
- Developer Name: **MedConnect, Inc.**
- Product Name(s): **MedConnectHealth**
- Version Number(s): **3.0**
- Certified Health IT Product List (CHPL) ID(s): **15.04.04.1889.MedC.03.00.0.171212**
- Developer Real World Testing Page URL: **https://www.medconnecthealth.com/realworldtestplan/**

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to ***perform as intended by conducting and measuring observations of interoperability and data exchange***", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

We are using a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing

Adoption rate will be used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might indicate a potential problem, of which there could be several different causes. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted by running reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of the successful implementation of a given certified capability in a real-world setting.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

All criteria listed in the MedconnectHealth Real-World Test Plan will follow the standards referenced in the 2015 Edition Cures Update.

CARE SETTINGS

MedConnectHealth is marketed primarily to primary care providers. The overwhelming majority of our users are comprised of family medicine, internal medicine, and pediatrics.

Care Setting	Justification
Primary Care	Primary care providers make up close to 95% of our customer base. We do not market to any particular care setting or specialty.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric.
- ✓ Associated certification criteria.
- ✓ Relied Upon Software (if applicable).
- ✓ Justification for selected measurement/metric.
- ✓ Expected Outcomes.

ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of licensed installs/users of EHR • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of EHR	Identify the total number of ***active*** installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed separately	Identify which certified capabilities are licensed separately from the base EHR license. Examples may include eRx, CQMs, public health, etc.
Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of ***active*** installs/users of a given certified capability.

SUMMATIVE ASSESSMENT METRICS

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine "success" via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

Criterion	Metric	Relied Upon Software (if applicable)	Justification and Expected Outcome
170.315(b)(1) Transitions of care	Over a 90-day period: 1. Number of CCDAs created. 2. Number of CCDAs sent via HISP. 3. Number of CCDAs received via HISP		This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. In our case, we connect to our HISP via API and not Edge protocols and will track that usage instead. Our expectation is there will be moderate utilization by providers with a high success rate.

170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1. Number of times a user reconciled medication list data from a received CCDA 2. Number of times a user reconciled allergies and intolerance list data from a received CCDA 3. Number of times a user reconciled problem list data from a received CCDA		This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.
170.315(b)(3) Electronic prescribing	Over a 90-day period: 1. Number of prescriptions created. (NewRx). 2. Number of prescriptions changed. (RxChangeResponse). 3. Number of prescriptions canceled. (CancelRx). 4. Number of prescriptions renewed. (RxRenewalResponse).	***Relied Upon Software:*** Partnered with SureScripts	This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be high utilization by providers with a high success rate.
170.315(b)(10) Electronic Health Information Export	1. Number of Single patient electronic health information exports.		This criterion requires the ability of a certified Health IT module to create an EHI export of health information when requested by a patient. The measurements produced will include results of attempted and completed (both successful and errors) by the EHR module for a given timeframe. We intend to demonstrate the certified capability is available and effective, regardless of the frequency it is used. MedConnect will run audit logs to display the Real-World utilization of this criterion.
170.315(c)(1-3) Clinical quality measures (CQMs)	Over a 90-day period: 1. Number of measures recorded during the period. 2. Number of QRDA Category 1 files exported. 3. Number of QRDA Category 1 files imported (if applicable) 4. Number of QRDA Category 3 aggregate report(s) created over the period		These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format. C2 requires a certified Health IT module to be able to import data from a QRDA Category 1 formatted file and calculate the CQMs based on that data. C3 requires a certified Health IT module to be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.
170.315(e)(1) View, download, and transmit to 3rd party	Over a 90-day period: 1. Number of views of health information by a patient or authorized representative 2. Number of downloads of health information by a patient or authorized representative 3. Number of transmissions of health information by a patient or authorized representative, whether via encrypted or unencrypted method		This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.

170.315(f)(1) Transmission to immunization registries	Over 3 separate unique 10-day periods within a 90-day window: 1. Number (or percentage) of immunization records submitted to the immunization record		This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.
170.315(f)(2) Transmission to public health agencies — syndromic surveillance	Over 3 separate unique 10-day periods within a 90-day window: 1. Total number of syndromic surveillance events created and submitted		This criterion requires the ability of a certified Health IT module to transmit syndrome-based public health surveillance data to a registry using a specified format. We intend to record the frequency that syndromic surveillance data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(f)(4) Transmission to cancer registries	Over 3 separate unique 10-day periods within a 90-day window: 1. Total number of cancer registry data records created and submitted		This criterion requires the ability of a certified Health IT module to transmit cancer case information to a registry using a specified format. We intend to record the frequency that cancer case information is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(g)(7) Application access — patient selection	1. Number of requests for a patient ID or token 2. Number of requests that provided sufficient information to provide a valid response. 3. Number of follow-up requests made using the provided patient ID or token	***Relied Upon Software:*** Dynamic Health IT ConnectEHR +BulkFHIR (Version FHIR4-B)	This criterion requires the certified Health IT module to provide a standardized FHIR-based API that supports bulk data requests to provide patients, providers and niche specialty applications to consume patient data enabling improved interoperability, improved patient care and better overall population health. Our expectation is there will be limited adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(g)(9) Application access — all data request	1. Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token. 2. Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token for a specific date range	***Relied Upon Software:*** Dynamic Health IT ConnectEHR +BulkFHIR (Version FHIR4-B)	This criterion requires the certified Health IT module to provide a standardized FHIR-based API that supports bulk data requests to provide patients, providers and niche specialty applications to consume patient data enabling improved interoperability, improved patient care and better overall population health. Our expectation is there will be limited adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(g)(10) Standardized API for patient and population services	Over a 90 Day Period 1. Number of authorized Patient Applications. 2. Number of authorized Provider Applications. 3. Number of authorized Bulk Applications. 4. Number of patient data requests.	***Relied Upon Software:*** Dynamic Health IT ConnectEHR +BulkFHIR (Version FHIR4-B)	This criterion requires the ability of a certified Health IT module to respond to requests for patient data through FHIR standards from authorized/registered applications. We intend to record the frequency that data is requested through FHIR applications to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization with a high success rate.

170.315(h)(1) Direct Project	Over a 90 Day Period 1. Number of Direct Messages sent. 2. Number of Delivery Notifications received. 3. Number of Direct Messages received. 4. Number of Delivery Notifications sent.	***Relied Upon Software:*** Data Motion	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available because there is limited adoption to date of these criteria in Real World deployments. The justifications for why each criterion have had low adoption are outlined in the table below.

MedConnect will leverage interactive testing for the following criteria:

- §170.315 (f)(2) Transmission to public health agencies – syndromic surveillance
- §170.315(f)(4) Transmission to cancer registries
- § 170.315(g)(7) Application access—patient selection
- § 170.315(g)(9) Application access — all data request
- § 170.315(g)(10) Standardized API for patient and population services

High Level Interactive Test Plan

- **Care Settings**: All interactive testing will be performed to represent the Real-World context of Primary Care practices in the ambulatory space.
- **Test Environment:** All interactive testing will be performed in a live, production environment unless otherwise specified in the table below.
    - Developer will use a recorded teleconference session to capture the results of the interactive test.
    - The plan for interactive testing the criteria described below in the real world will be to engage with a Clinician in a Primary Care practice where the certified Health IT module is deployed as a representative sample to show that this certified capability is deployed in the real world and that it works the same way in all Primary Care practices.
- **Test Data**: Interactive testing will be performed using specially developed test patient data in the live production environment. Test patients will be created using the data that is typically used by MedConnect providers in their day-to-day practice to be as representative as possible of real-world patients. MedConnect will ensure that the test data entered for each patient includes the minimum necessary to meet the data requirements for each criterion being tested using the interactive testing method.

Criterion	Interactive Test Plan	Justification and Expected Outcome
§170.315 (f)(2) Transmission to public health agencies – syndromic surveillance	MedConnect will pair with a Provider within the Primary Care setting to demonstrate Syndromic Surveillance. MedConnect will create 3 patients with data that qualifies for syndromic reporting and then send the reports but catch them on the backend before they go to the registry and use visual inspection to validate that the ADT message is correctly formed. Urgent Care will be one of the Primary Care settings used to demonstrate the PHIN messaging guide for Urgent Care sent to Alabama Department of Public Health.	**Justification:** The providers who were expecting to use the Syndromic surveillance reporting certified capability were not eligible for this program because their taxonomy was not emergency care focused enough to qualify for claims for their Department of Health. As a result, usage metrics are not available for this certified capability because messages are not currently being sent out. If a MedConnect client does qualify for Syndromic Surveillance, the messages will be able to be sent out. **Expected Outcome:** Both Provider systems will send an ADT message that is well formed for each patient.
§170.315(f)(4) Transmission to cancer registries	MedConnect will create 3 different patients with Cancer diagnoses and their representative data in the MedConnect production system. These test patients will include a test patient with a Cancer diagnosis with no treatment, as well as 2 patients with Cancer diagnoses with different prescribed treatments. MedConnect will walk through the EHR, mimicking the intended workflow of a Primary Care Clinician following up after an Oncology referral and use the manual generation feature to generate 3 Cancer CCDA documents, then use visual inspection to confirm that the documents include all the expected content for each patient and uses SNOMED and LOINC value sets per the required standard.	**Justification:** There are very few customers currently using this certified capability in the field. MedConnect providers who were expecting to use the Cancer reporting ended up not being eligible in their state and as a result did not use the certified capability for Cancer reporting. MedConnect providers typically refer out the diagnoses that are reportable to Cancer Registries. If a provider were to perform a diagnosis that qualifies, this capability is available in their EHR and would be able to send the report to the registry per the expectations of the Criterion **Expected Outcome:** The CCDA documents will be generated for each patient and will include the correct value sets.
170.315 (g)(7): Application Access - Patient Selection (g)(9): Application Access - All Data Request (g)(10): Application Access – Standardized API for Patient and Population Services	MedConnect will work with a Primary Care Provider clinic to run through the following high-level steps using MedConnect patients in the provider's deployment of the MedConnect API. Test patients will be used, they will be set up in each provider's EHR in advance. Encounters are created and visually confirmed and transmitted to Dynamic Health IT ConnectEHR +BulkFHIR (Version FHIR4-B) MedConnect will leverage the ONC Inferno Testing tool to capture proper FHIR data.	**Justification:** MedConnect will use interactive testing using the ONC Inferno test tool to demonstrate that API capabilities are present and available for use in Real-World customer deployments. Most patients and providers just use the portal features to get their data since it is available, and it works and there are no apps out there. **Expected outcomes:** • Patient ID is accepted, and token is returned for authentication and data requests. • Patient FHIR data is retrieved and validated via visual inspection to contain USCDI data elements.

SCHEDULE OF KEY MILESTONES

Key Milestone	Date/Timeframe
Submit Final 2025 Real World Testing Plans to Drummond Group	November 1, 2024
Post approved Real World Testing Plan to External URL	December 2024
Data Collection (will vary per measure)	Quarterly – March, June, September, December 2025
Analysis of Data Collected (will vary per measure)	Quarterly – March, June, September, December 2025
Design 2025 Real World Testing Results Report.	January 2026
Submit Final 2025 Real World Testing Results to Drummond Group	March 2026

ATTESTATION

This Real-World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the Health IT Developer's Real World Testing requirements.

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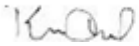
Authorized Representative Signature: 

Date: ***October 17, 2024***