REAL WORLD TESTING PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). 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 to develop 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 for 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 which 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. 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 would expect 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. 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 – Coming Soon
- 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) (**Century Cures final rule**)
  - ↳ *Section VII.B.5 — "Real World Testing"*

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: Modernizing Medicine Podiatry Systems, Inc.

Product Name(s): TRAKnet

Version Number(s): 3.1.1

Certified Health IT Product List (CHPL) ID(s): 15.04.04.3003.TRAK.31.02.1.191231

Developer Real World Testing Page URL: https://www.nemohealth.com/wp-content/uploads/2021/11/RWT_Test_Plan_ModMed_Traknet_final.pdf

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 generating 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 a successful implementation of a given certified capability in a real-world setting.

Interactive testing will be used to demonstrate conformance to requirements where the adoption rate of a given certified capability is low and to demonstrate ongoing compliance with updated standards and code sets (SVAP). Interactive tests will require a live test as opposed to examining historical usage statistics. The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

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

Modernizing Medicine has not updated TRAKnet to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of the 2022 Real World Test.

CARE SETTINGS

TRAKnet is marketed exclusively to Podiatry providers.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Care setting(s) that are addressed
- ✓ 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.

None of the following criteria were updated to the Cures Update version of criteria prior to August 31, 2021. As a result, all testing is scheduled to be conducted against the 2015 Edition version of the criteria.

Criterion	Metric	Care Setting	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 edge protocols 3) Number of CCDAs received via edge protocols	Podiatry	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. 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	Podiatry	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 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed	Podiatry	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)(6) Data export	Over a 90-day period: 1) Number of times a data export was performed for a patient 2) Number of times a data export was performed for multiple patients in a single transaction 3) Number of times a data export was performed for all patients in a single transaction	Podiatry	This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCDA format according to specified standards and vocabulary code sets. 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. Therefore, we intend to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be very low utilization by providers with a high success rate.
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) Number of QRDA Category 3 aggregate report(s) created over the period	Podiatry	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 must 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 must 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 that, at the time of testing, there will not be sufficient adoption of this certified capability by our users to perform a satisfactory test, 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 pending wider adoption.

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 using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using encrypted method	Podiatry	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	Podiatry	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 that, at the time of testing, there will not be sufficient adoption of this certified capability by our users to perform a satisfactory test, 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 pending wider adoption.
170.315(f)(7) Transmission to public health agencies — health care surveys	Over 3 separate unique 10-day periods within a 90-day window: 2) Total number of health care surveys created and submitted	Podiatry	This criterion requires the ability of a certified Health IT module to transmit health care survey information to a registry using a specified format. We intend to record the frequency that health care survey 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 that, at the time of testing, there will not be sufficient adoption of this certified capability by our users to perform a satisfactory test, 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 pending wider adoption.

170.315(g)(7) Application access — patient selection	3) Number of requests for a patient ID or token 4) Number of requests that provided sufficient information to provide a valid response 5) Number of follow-up requests made using the provided patient ID or token	Podiatry	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. We intend to record the frequency that patient ID requests are received by providers via API 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(g)(8) Application access — data category request	1) Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token 2) Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token for a specific date range	Podiatry	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request patient data by category from the certified Health IT module. We intend to record the frequency that patient data requests by category are received by providers and fulfilled via API 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(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	Podiatry	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API 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(h)(1) Direct Project	1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received 4) Number of Delivery Notifications sent	Podiatry	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 the following criteria where metrics are not available:

- 170.315(c)(1-3) Clinical Quality Measures
- 170.315(f)(1) Transmission to immunization registry
- 170.315(f)7) Transmission to Public Health Agencies - Health Care Surveys

High Level Interactive Test Plan:

- **Care Settings**: TRAKnet is currently used in the Podiatry care setting.
- **Test Environment:** All interactive testing will be performed in a mirror backup of a provider's Real-World production environment in order to reduce the risk of disruption to the Provider's practice.
    - TRAKnet will use a recorded videoconference to perform these tests and keep the evidence of the results in the event that the ONC will want to verify the results report.
    - The plan for interactive testing the criteria described below in the real world will be to partner with a Podiatry practice where the certified Health IT module is deployed as a representative example to show that this certified capability works in the real world and that it works the same way in all podiatry practices.
- **Test Data**: Interactive testing will be performed using test patient data in the mirrored production environment in order to be as representative as possible of real-world deployments without disrupting the provider's day to day business operations or exposing PHI. Precautions will be taken to reduce the risk of exposure of PHI.

Criterion	Interactive Test Plan	Justification and Expected Outcome
170.315 (c)(1-3): Clinical Quality (CQM)s	Modernizing Medicine will partner with 1 Podiatry customer provider to demonstrate over a recorded session that they are able to perform the following functions: • Enter test patients that qualify for the eCQM measure and export their QRDA file • Select and generate eCQMs and export them in a production setting • Import QRDA files and calculate aggregate reports • Generate QRDA I and QRDA III reports	**Justification:** TRAKnet providers are all Podiatry clinics who tend to use MIPS CQMs for reporting and not CMS eCQMs The majority of the TRAKnet provider reporting is done either by MIPS CQMs to a registry or directly as Medicare claims-based reporting rather than reporting using eCQMs. **Expected outcomes**: • Visual inspection will confirm that the data required to record the certified CQM can be denoted within the patient record. • Exported CQMs contain data as expected • QRDA files are able to be imported and calculations run as expected • QRDA I and QRDA III reports are generated correctly

170.315(f)(1) Transmission to immunization registry	Modernizing Medicine will partner with 1 podiatry practice to create 2 test patients with representative test patient data that includes representative data for children of the of the ages who would normally receive vaccines and an adult who will receive an influenza vaccination. TRAKnet will send a request for immunization history for each of the test patients and use the HL7 context free NIST H7 Immunization 2.5.1 IG Release 1.5 Tool to verify message conformance. TRAKnet will receive a response from the HL7 context free NIST H7 Immunization 2.5.1 IG Release 1.5 Tool with history and forecast. TRAKnet will send immunization records to the HL7 context free NIST H7 Immunization 2.5.1 IG Release 1.5 Tool to verify message conformance.	**Justification**: Patients typically don't go to their Podiatrist for immunizations, so this functionality is rarely used. **Expected Outcomes:** ○ Immunization history can be requested for both children and adult patients and conform the HL7 Immunization 2.5.2 IG Release 1.5 Z44message. ○ Visual inspection that the TRAKnet system can receive the History and Forecast from the context-free NIST Tool (the content will not relate to the patient data that was requested, it will be the default message from the NIST tool). ○ Immunization messages can be transmitted for both children and adult patients and conform the HL7 Immunization 2.5.2 IG Release 1.5 Z22 VXU^V04 message.
170.315 (f)(7): Transmission to Public Health Agencies - Health Care Surveys	Modernizing Medicine will partner with 1 Podiatry customer practice to create 2 test patients and generate a Health Care Survey in an Outpatient Setting CCDA document for each patient.	**Justification**: There is not yet a specified registry for healthcare surveys for the Podiatry setting. Modernizing Medicine does not anticipate adoption of this certified criterion until a registry is set up for this purpose. **Expected Outcomes:** • Visual inspection will be used to confirm that each of the CCDA documents that is generated contains all the expected information per the National Health Care Surveys standards.

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2022. Each phase is expected to take 90-days to complete, with report writing to occur end of 2022/early 2023.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Podiatry	90-days
Data collection	Podiatry	90-days
Review and collate data	Podiatry	90-days
Writing report	Podiatry	90-days

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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