REAL WORLD TESTING PLAN FOR 2024

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 Certification 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"*

GENERAL INFORMATION

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

Developer Name Exscribe, Inc.	**Developer Website** https://www.modmed.com/
Product Name Exscribe EHR	**Version Number** 7
CHPL Product Number 15.04.04.1467.Exsc.07.01.1.221227	**Certification Date** 27 Dec 2022
RWT Plans https://www.exscribe.com/ehr-certification	**RWT Results** https://www.exscribe.com/ehr-certification

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

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 zero 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 UNITED STATES CORE DATA FOR INTEROPERATBILITY (USCDI))

Exscribe certified Exscribe EHR to US Core 3.1.1, USCDI 1.0, SMART App Launch 1.0, and Bulk Data 1.0. Exscribe will not be adopting any newer standards as part of SVAP as of this date nor plan to prior to the execution of the 2024 Real World Test.

Exscribe EHR plans to update to USCDI 3.0 along with US Core 6.1.0 during 2024 but after August 31, 2024 and thus will not be included in the Real World Test Plan for 2024.

Table 1. USCDI

Standard (and version)	USCDI v1
Updated certification criteria and associated product	2015 Cures Update / Exscribe EHR
CHPL Product Number	15.04.04.1467.Exsc.06.00.0.180305
Method used for standard update	N/A
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	Inferno US Core 3.1.1 Test Suite
USCDI updated certification criteria (and USCDI version)	USCDI v1

Table 2. US Core 3.1.1

Standard (and version)	US Core 3.1.1
Updated certification criteria and associated product	2015 Cures Update / Exscribe EHR
CHPL Product Number	15.04.04.1467.Exsc.06.00.0.180305
Method used for standard update	N/A
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	Inferno US Core 3.1.1 Test Suite
USCDI updated certification criteria (and USCDI version)	USCDI v1

Table 3. SMART App Launch 1.0

Standard (and version)	SMART App Launch 1.0
Updated certification criteria and associated product	2015 Cures Update / Exscribe EHR
CHPL Product Number	15.04.04.1467.Exsc.06.00.0.180305
Method used for standard update	N/A
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	Inferno SMART App Launch STU1
USCDI updated certification criteria (and USCDI version)	USCDI v1

Table 4. Bulk Data 1.0

Standard (and version)	Bulk Data 1.0
Updated certification criteria and associated product	2015 Cures Update / Exscribe EHR
CHPL Product Number	15.04.04.1467.Exsc.06.00.0.180305
Method used for standard update	N/A
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	Inferno SMART App Launch STU1
USCDI updated certification criteria (and USCDI version)	USCDI v1

CARE SETTINGS

Exscribe EHR is marketed exclusively to Orthopedic 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).

Measurement/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.

Measurement/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 minimum 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.

All testing is scheduled to be conducted against the 2015 Cures Update Criteria version of the criteria.

Criterion	Measurement/Metric	Care Setting	Justification and Expected Outcome
170.315(a)(9) Clinical Decision Support	Over a 90-day period: 1. Number of drug interaction alerts received by clinicians. 2. Number of preventative care service alerts received by clinicians.	Orthopedics	This criterion requires the ability of a certified Health IT module to support development, adoption, and implementation of CDS to improve health care decision making and better outcomes for patients. The expectation is that this information will help clinicians make informed decisions. We intend to demonstrate the required certified capabilities by demonstrating how often a CDS interaction is triggered and number of times they are acted upon. Interactions may include drug and preventative care alerts.
170.315(b)(1) Transitions of care	Over a 90-day period: 1) Number of CCDAs manually created by providers 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	Orthopedic	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. Relied Upon Software : Secure Exchange Solutions SES HISP
170.315(b)(2) Clinical information reconciliation and incorporation	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 Number of times a data export was performed for all patients in a single transaction	Orthopedic	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.

Criterion	Measurement/Metric	Care Setting	Justification and Expected Outcome
170.315(b)(3) Electronic prescribing	Over a 90-day period: 1) Number of prescriptions created 2) Number of prescriptions renewed	Orthopedic	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. Relied Upon Software: NewCropRx
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	Orthopedic	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 there will be zero 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 Relied Upon Software: Dynamics Healthcare IT (DHIT) CQMSolution
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	Orthopedic	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

Criterion	Measurement/Metric	Care Setting	Justification and Expected Outcome
	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		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. Relied Upon Software : Secure Exchange Solutions SES HISP
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	Orthopedic	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 zero 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.

Criterion	Measurement/Metric	Care Setting	Justification and Expected Outcome
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	Orthopedic	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. No third-party vendors use our API but our mobile application does use the certified API. We will use the interactions between the mobile app and the EHR for this criteria's metrics. The mobile app does not request patient information based upon a date range, a full patient information is used with each interactive session.
170.315 (g)(10) Standardized FHIR Server API for patient and population services	1) Number of requests for a patient's data made by an application via the FHIR server using a valid patient ID or token 2) Number of requests for a patient's data made by an application via the FHIR Server at a data category request using a valid patient ID or token for a specific date range	Orthopedic	This criterion requires the certified Health IT module to provide a FHIR Server API and supporting documentation that enable external applications to request patient data by category from the certified Health IT FHIR Server. We intend to record the frequency that patient data requests by category are received by providers and fulfilled via FHIR Server API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. We have zero adoption of this certified capability by our users but we have implemented CDC eCR Now FHIR app for electronic case reporting which uses FHIR queries to our FHIR server to create eICR CDA documents. We will use this interface for the metrics for (g)(10). We use relied upon software: Dynamics Healthcare IT (DHIT) ConnectEHR +BulkFHIR (Version FHIR4-B).

Criterion	Measurement/Metric	Care Setting	Justification and Expected Outcome
170.315(h)(1) Direct Project	1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received	Orthopedic	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. Relied Upon Software : Data Motion HISP

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in the first quarter of 2024. Each phase is expected to take 90 days to complete, with report writing to occur during first quarter of 2025.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Orthopedic	90-days
Data collection	Orthopedic	90-days
Review and collate data	Orthopedic	90-days
Writing report	Orthopedic	First Quarter 2025

ATTESTATION

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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