REAL WORLD TESTING PLAN TEMPLATE

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 170.405). 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 – 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) (**ONC Cures Act Final Rule**)
  - *Section VII.B.5 — "Real World Testing"*

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan.

Each section provides a field for submitting responses and/or explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

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

Developer Name: Mendelson Kornblum Orthopedic & Spine Specialists

Product Name(s): OrthoplexEMR

Version Number(s): v1

Certified Health IT Product List (CHPL) ID(s): 15.04.04.3014.Orth.01.00.1.180101

Developer Real World Testing Page URL:

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing[i].

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

The Orthoplex EMR is used in an Orthopedic Clinic setting. Most of the features were specifically designed to accommodate Orthopedic Specialties and their sphere of use. Currently the EMR is only used by one Clinic Group (MKO), therefore the testing will be related directly to their current procedures. The real word testing plan tracks user actions directly related to ONC certification criteria. When possible, testing is done by a test proctor recording the results of users in a real world environment performing regular duties in a non-controlled setting, in conjunction with Audit and System Log reviews. The purpose of this approach is to record results without interfering with the real world clinic work flow process, as to not influence the results of testing. Testing intends to demonstrate continued compliance with ONC regulations within the use of the Orthoplex EMR.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ *Identify standard versions*
- ✓ *Indicate what certification criteria in which product(s) has been updated*
- ✓ *If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products*
- ✓ *CHPL ID for each Health IT Module*
- ✓ *Method used for standard update (e.g., SVAP)*
- ✓ *Date notification sent to ONC-ACB*
- ✓ *If SVAP, date notification sent to customers*
- ✓ *Measure used to demonstrate conformance with updated standard(s)*
- ✓ *Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?*

Standard (and version)	All standards versions are those specified in USCDI v1.
Updated certification criteria and associated product	None
Health IT Module CHPL ID	Not applicable
Method used for standard update	Not applicable
Date of ONC ACB notification	Not applicable
Date of customer notification (SVAP only)	Not applicable
Conformance measure	Not applicable
USCDI updated certification criteria (and USCDI version)	None

MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen meet the intent and purpose of Real World Testing.

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
Transfer	This measurement will review the administrative staff and provider usage of the transfer of patients to/from external sources and their incorporation of these patients into the existing patient database.
e-Prescribing	This measurement will test the e-prescribing functions incorporated into the EMR and it's relation to patient care.
CQM Reporting	This measurement will test the administrative staff's usage of the integrated CQM reporting system. It will follow through the complete process tracking the steps to submission.
Registries	This measurement will review the effectiveness of the software to report on the immunization and cancer data entered by staff members.
API	This measurement will track the performance of the software's API system. Tracking timing, usage, and errors.
Direct Transfer	This measurement will test the staff usage of the direct transfer procedure to send/receive of C-CDA data of patients.
Patient Portal	This measurement will track the patient usage of the portal functions. Reporting on activity, timing, and errors.

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your Real World Testing plan for any metrics that would involve use of that software in testing.

Measuremen	Associated Certification Criteria	
Transfer	170.315(b)(1) Transitions of Care, 170.315(b)(2) Clinical Information Reconciliation and Incorporation, 170.315(b)(10) Electronic Health Information export	
e-Prescribing	170.315(b)(3) Electronic Prescribing	DoseSpot
CQM Reporting	170.315(c)(1) CQMs - Record and Export, 170.315(c)(2) CQMs - Import and Calculate, 170.315(c)(3) CQMs - Electronic Submission	
Registries	170.315(f)(1) Immunization Registries, 170.315(f)(4) Cancer Registries	
API	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	
Direct Transfer	170.315(h)(1) Direct Project	EMR Direct
Patient Portal	170.315(e)(1) View, download, transmit to 3rd party	

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification
Transfer	The EMR has the ability to send/receive and incorporate patient information from external sources using the edge protocol (SMTP) as well as CCDA exports/Imports. This measurement will track the feature's operation throughout the different stages of use and the results. Due to the nature of external initiation and low usage of this feature, testing will be done by tracking the Audit/System Logs.
e-Prescribing	The ability to prescribe medications through the EMR's interface is a daily function of the EMR. Providers use a 3rd party screen-in e-Prescribing software. Testing methodology includes proctor onsite monitoring of the randomly selected providers to monitor the prescribing process. Tracking the process through observation of events and recording results.
CQM Reporting	CQM reporting feature is available for the office staff to use to track CQM 550, CM568, CMS123, CMS134, CMS138, and CMS139. This reporting is conducted by the office staff on regular intervals for compliance reporting. Due to the routine nature of this procedure a test proctor will be present during an agreed upon time to monitor the process and track the results.

Registries	Cancer and Immunization registries input and sending have been available for EMR users. User facing forms populate discrete data, used to push through the registries interface automatically. The testing of the measure will be done through the tracking and review of Audit/System Log files for usage and error reporting. Due to the specialization of the only clinic group currently in operation, the usage of these registries is minimal.
API	The API is for external integration, these external sources are approved by Clients to access the Search and Request of patient information in the FHIR standard. The API is implemented for possible integrations into the EMR. Currently there are no active integrations using the API to access patient data. The Measure will be tracked through Log transaction reporting, tracking usage and errors. Due to the external nature of these requests coming from sources at non-specified times.
Direct Transfer	Direct transfer is a procedure manually done by staff members. The initiation is based on external requests from participating providers at external clinics. A test proctor will be on site to record the results of outgoing communication. For inbound communication Audit/System logs will be used to track and report on results, due to their source being external.
Patient Portal	The patient portal allows for individual patients to have the ability to View, download and transmit their information to their preferred location. After validating their identity, the system gives access to perform these tasks. Due to concerns of Patient Privacy and Experience the tracking of this measure will be done through Audit/System Logs of the operations.

Care Setting(s)

The expectation is that a developer's Real World Testing plan will address each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Orthopedic Outpatient Clinic	This is the only setting that the software is currently used.

Expected Outcomes

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes
Transfer	The expected outcome of this test will be to confirm that no current errors are logged during operation of this feature. That all sends/receives of Patient information are done securely and completely. Patient data will have identifying data removed before analysis.
e-Prescribing	The expected outcome of this test will be to track through Create, Update, Cancel, and Renewal of medications. Review notifications, drug to drug, drug to allergy, and other complications. Verification of Patient medication history and current history. Proctor will also record controlled substance prescription to confirm conformance with all authorization requirements. Results of usage, timing and error reporting will be compiled and aggregated without patient identification. The Proctor will conduct these through observation and not through directed action on dates agreed upon by the participating providers.
CQM Reporting	The expected outcome of this test will be to observe the generation of reports verifying the CQM being reported on. The verification will assess the accuracy, usage, and any process errors. This reporting happens at regular intervals for aggregation of results before submission. Importing and submission of the reports will be tracked through the view of Audit/System Logs when identified users report their use of these features. The Logs will be compiled to generate results of usage and errors.

Registries	The expected outcome of this test will be to confirm that no errors are logged during input and submission of the cancer and immunization registries. That all outgoing Patient information are done securely and completely. Log data will have patient identifying data removed before analysis.
API	The expected outcome of this test will be to confirm that no errors are logged in the usage of the API functions (FHIR Standard). That all API response messages were conducted securely and completely. Log data will have patient identifying data removed before analysis.
Direct Transfer	The expected outcome of this test will be to observe the sending of the patient CCDA record through the Direct Transfer method. The proctor will schedule a time with office staff when transfers are being conducted to confirm the accuracy, usage, and any process errors. The receiving of Direct Messages will be reviewed through Audit/System logs, as the source of this communication is from an external source. The Log analysis will confirm patient information was received in compliance with the standard and that no errors occurred. The Logs will be compiled to generate results of usage and errors.
Patient Portal	The expected outcome of this test will be to confirm that no errors are logged during Patient Access, View, Download and transmit. System/Audit logs are setup to track users access through for security reporting. Activity History Log incorporate into the 170.315(e)(1)(iii) requirement will be cross-referenced against audit\system logs. Test plan does not include the intervention of a test proctor interacting with patients. Log data will have patient identifying data removed before analysis.

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Release of documentation for the Real World Testing to be provided to authorized representatives and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	Orthopedic Clinic (MKO)	December 15th, 2024
Begin Data Collection	Orthopedic Clinic (MKO)	January 1st, 2025
Follow Up with Test Proctor to confirm observation testing is being scheduled and reported.	Orthopedic Clinic (MKO)	Quarterly, 2025
Confirm with Authorized Personal that Data/Log collection is being done correctly and reporting is accurate.	Orthopedic Clinic (MKO)	Quarterly, 2025

End of RWT for 2022, de-identification and analysis.	Orthopedic Clinic (MKO)	January, 2026
Report Creation	Orthopedic Clinic (MKO)	January 15th, 2026
Submit RWT Reports	Orthopedic Clinic (MKO)	February 1st, 2026

ATTESTATION

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.[ii]

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.

Authorized Representative Name: Mark Warren

Authorized Representative Email: mwarren@proactivemgmt.com

Authorized Representative Phone: Office 248-731-0071

Cell 248-736-8469

Authorized Representative Signature: 

Date: 10/30/2024

---

[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

[ii] https://www.federalregister.gov/d/2020-07419/p-3582