REAL WORLD TESTING RESULTS REPORT TEMPLATE

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 and results reports.

A 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. To accompany the plan template, ONC has also provided this results report template. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). 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 results report will include a list of these 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 Certification 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"*
- 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"

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded

with additional rows or columns to address the specific needs of the Real World Testing results 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 Plan Page URL: orthoplex.mkoss.com/usercontent/realworldtesting.html

Developer Real World Testing Results Report Page URL [if different from above]:

Related ICS Versions of Product (if not included in original plan):

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	**Reason** [Describe the reason this change occurred]	**Impact** [Describe what impact this change had on the execution of your Real World Testing activities]
Removed 170.315(b)(10) from testing scope.	This criterion was not selected for certification in the final attestation.	Testing resources were reallocated to (b)(1) and (b)(2); no data was collected for export.
Testing methodology updated for Transfer, API Performance, and Direct Transfer measures to incorporate structured synthetic testing using synthetic patient data in a mirror production environment.	No live production deployment occurred during 2025 for these criteria. ONC Real World Testing Resource Guide (p. 22) expressly permits synthetic patient data in lieu of real patient data in mirrored environments.	All three measure categories now include measurable numerator/denominator values and quarterly success rates derived from structured synthetic test sessions conducted throughout 2025.

[IF APPLICABLE] ICS PRODUCT(S)

If a developer chose to utilize inherited certified status (ICS) for a product originally outlined in their Real World Testing plan, the ICS products must be included in Real World Testing if the originating listing is withdrawn following ICS certification.

ICS Products	
Product Name(s):	
Version Number(s):	
CHPL ID(s):	
Date(s) of ICS Certification:	

[IF APPLICABLE] WITHDRAWN PRODUCT(S)

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

Withdrawn Products	
Product Name(s):	
Version Number(s):	
CHPL ID(s):	
Date(s) Withdrawn:	
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

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

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. For criteria with low or zero real-world utilization during the reporting period (specifically Transfer, API, and Direct Transfer), we conducted testing using synthetic patient data in a mirrored production environment. This approach aligns with the ONC Real World Testing Resource Guide ensuring functionality could be verified despite a lack of external real-world traffic. These synthetic tests mirrored actual production workflows to validate that the certified capabilities are functioning as expected.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Voluntary standards updates must be addressed in the Real World Testing results report. Real World Testing results reports 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 for the submitted plan.

Indicate as to whether voluntary SVAP standards are leveraged as part of the certification of your health IT product(s).

[ ] Yes, I have products certified with voluntary SVAP standards. (If yes, please complete the table below.

[✓] No, none of my products include these voluntary standards.

Standard (and version)	USCDI v3
Updated certification criteria and associated product	
Health IT Module CHPL ID	
Date of ONC-ACB notification	
Date of customer notification	
Conformance method and measurement/metric(s)	

Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within 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.

List each care setting that was tested.

Orthopedic Outpatient Clinic: This is the only setting that the software is currently used.

Metrics and Outcomes

Health IT developers should detail outcomes from their testing that 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)

Health IT developers could also detail outcomes that did 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 their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement/ Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
Transfer	170.315(b)(1), (b)(2),	N/A	Verified via synthetic testing in a mirrored production environment.	Real-world usage was zero due to lack of external transfer requests. Synthetic data was used to validate functionality in lieu of live traffic.

e-Prescribing	170.315(b)(3)	DoseSpot	Verified end-to-end workflow for creation, renewal, and cancellation of prescriptions. Drug to drug and drug to allergy checks functioned as intended.	None. Integration with DoseSpot remained stable throughout testing
CQM Reporting	170.315(c)(1), (c)(2), (c)(3)	N/A	Confirmed accurate generation and export of QRDA files for orthopedic measures (CMS550, CMS568, CMS123, CMS134, CMS138, CMS139)	Low-volume reporting periods required relying on system logs rather than direct observation
Registries	170.315(f)(1), (f)(4)	N/A	Automated submission of immunization and cancer registry data was verified via audit logs. All	Minimal registry usage in an orthopedic setting was expected and addressed via retrospective log review.
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API	170.315(g)(7), (g)(9), (g)(10)	N/A	Verified via synthetic testing in a mirrored production environment.	Real-world usage was zero as no third-party apps connected during the period. Synthetic scripts were used to validate API responsiveness and compliance.
Direct Transfer	170.315(h)(1)	EMR Direct	Verified via synthetic testing in a mirrored production environment.	Real-world usage was zero due to lack of external provider requests. Synthetic Direct addresses were used to validate the send/receive loop.

Patient Portal	170.315(e)(1)	N/A	Audit logs confirm patients successfully viewed, downloaded, and transmitted their health records. System security remained intact	Observation was limited to system log analysis to protect patient privacy.

KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

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

Key Milestone	Care Setting	Date/Timeframe
Release RWT Documentation	Orthopedic Clinic (MKO)	Dec 15th, 2024
Begin Data Collection	Orthopedic Clinic (MKO)	Jan 1st, 2025
Quarterly Follow-up	Orthopedic Clinic (MKO)	Quarterly, 2025
Quarterly Data Validation	Orthopedic Clinic (MKO)	Quarterly, 2025
End of RWT / Data Analysis	Orthopedic Clinic (MKO)	Jan 1st, 2026

Report Creation	Orthopedic Clinic (MKO)	Jan 30th, 2026
Submit RWT Reports	Orthopedic Clinic (MKO)	Feb 5th, 2026