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 170.556 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 1qmade 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: HCA Physician Services Group

Product Name(s): M.A.P.

Version Number(s): 5.0

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.1557.MAP5.05.00.0.181031

Developer Real World Testing Page URL: https://hcahealthcare.com/util/documents/onc-certification/2021-map-rwt-plan.pdf

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.

M.A.P. is a pure calculation engine with relied upon technology from the select EHRs where the raw data to be calculated is drawn from. Its function is to calculate performance across electronic quality metrics such as electronic clinical quality measures (eCQMs) published and updated annually through the Electronic Clinical Quality Improvement Resource Center and the Promoting Interoperability measures as updated by the final Physician Fee schedule and annual measure specifications.[1][2][3] None of the certified criteria used to calculate Promoting Interoperability are subject to Real World testing requirements.[4] Thus the only certified functionalities of M.A.P. subject to real world testing are the calculation functions c(1) – c(3).

The real world testing of M.A.P.'s CEHRT module functionality will be conducted via a demonstration of the daily calculations of PSG clinician performance across selected eCQMs. As the M.A.P. module is a calculation engine only, it is not appropriate to demonstrate it in a care setting. Rather the certified functionality will be real world tested by a live demonstration of the daily refresh of data for quality measure (QM) 130 (eCQM CMS 68v10 for 2021). This test will show the data being imported into the calculation engine, processed, and then calculated with the result of the calculation appearing on the front-end dashboard of the module.

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

[1] Eligible Professional/Eligible Clinician eCQMs, Electronic Clinical Quality Improvement Resource Center, published May 2020, downloaded references May 2020.

[2] CY 2021 Physician Fee Schedule, Fed. Reg. Vol. 85, No. 248, Dec. 28, 2020, page 84865.

[3] 2021 Promoting Interoperability measure specifications, QPP Resource, February 3, 2021, All specifications.

[4] Id and the Applicable Real World Testing Certification Criteria, hyperlink, (9/23/2021 at 11:40 AM).

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?*

M.A.P. is a single module and its CHPL ID is 15.04.04.1557.MAP5.05.00.0.181031. The product is certified to the following criteria – c(1), c(2), c(3), c(4), d(1), d(2), d(3), d(5), g(2), g(4), and g(6). Of those criteria, c(3), d(2), and d(3) required 21st Century Cures Act-related updates, which PSG has completed and attested to per ONC's requirements.

The only applicable standards updates for M.A.P. are annual updates to measure specifications for the eCQMs, and the QRDA3 specifications for eligible clinicians and eligible professionals.[5] Standard updates occur annually and PSG sends notice upon their completion to the ONC-ACB Drummond Group in the relevant quarterly report. The exact date of the notification varies annually. Updates are completed by changing the measure calculation logic to reflect published changes in the measure specifications on the eCQI Resource center website for Eligible Professional/Eligible Clinician eCQMs pages and the QRDA Implementation Guide for Eligible Clinicians and Professionals published by the Centers for Medicare and Medicaid Services (CMS).[6] PSG will demonstrate with QM 130 as it is a measure that is calculated for every encounter and will reliably have sufficient data for a real world test.

Per review of ONC resources and discussions with certification body Drummond Group, SVAP is not appropriate for use in a calculation engine as the relevant measure specifications apply only to a single and specific program year and updates on this progress are required to be sent to the ONC-ACB Drummond Group. USCDI changes are not applicable for a pure calculation engine such as M.A.P.

MEASURES USED IN OVERALL APPROACH

[5] Eligible Professional/Eligible Clinician eCQMs and Resources, Hyperlink, (9/23/2021 at 11:04 AM).

[6] Id.

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 are addressed*
- ✓ *Expected Outcomes*

PSG will record the instances of the use of the certified functionality of the M.A.P. calculation engine during the Real World Test Plan (RWT Plan) date range. PSG anticipates collecting counts of both scheduled and ad hoc instances of import, record, export, calculation, report, and access of the calculations. PSG will also record the error rate for these metrics.

As a pure calculation engine, M.A.P., certified to c(1), c(2), and c(3), is not appropriate for any patient care setting and thus will be demonstrated in a review of quality performance setting. Live data received from the relied upon technology EHR will be used to demonstrate the real world functionality of the calculation engine. The expected outcome is to demonstrate appropriate logic to import, record, export, calculation, and report real world data as it is received daily and then display correctly calculated data on the front end dashboard that is in use currently.

DESCRIPTION OF MEASUREMENT/METRIC

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

PSG will demonstrate the certified criteria c(1), c(2), and c(3) through the end to end calculation of certified electronic clinical quality measures for the time period of July 1, 2022 to September 24, 2022.

In real world testing of c(1), PSG will import data daily from an EHR (eClinicalWorks) into the PSG Electronic Data Warehouse. PSG expects this to occur 83 times in the date range of July 1 through September 24, 2022, which excludes the 3rd Saturday of each month when the EDW undergoes regular maintenance. If a divesture of a practice occurs within the date range of July 1 through September 24, 2022 occurs and the practice requests it, PSG will export patient data for that practice. PSG will track such divestures and requests for reporting to Drummond in addition to success or failure on those occasions export is requested.

In real world testing of c(2) PSG will calculate the certified eCQMs daily with the new data from the daily import. PSG expects this to occur 83 times in the date range of July 1 through September 24, 2022, which excludes the 3rd Saturday of each month when the EDW undergoes its regular maintenance. If an acquisition of a practice with an EHR capable of exporting CQM data occurs within the date range of July 1 through September 24, 2022, PSG will import a batch of data for CQM calculation from the acquired practice's former EHR. PSG will track such acquisitions and availability of imports for reporting to Drummond in addition to success or failure on those occasions import is available.

In real world testing of c(3), PSG will generate a minimum of 1 test QRDA3 file as part of the annual update to the QRDA3 file structure in accordance with the eCQI. PSG expects this to occur 1 time in the date range of July 1 through September 24, 2022. This will be submitted through the Cypress validation tool.

In summation, per discussion with Drummond Group PSG's RWT Plan metric looks at the day-to-day cycling of the import, recording, export, calculation and reporting of live data into the calculation engine and reporting if there are any failures thereof or instances where it requires intervention beyond standard maintenance or updating process.

ASSOCIATED CERTIFICATION CRITERIA

List certification criteria associated with the measure and if updated to 2015 Edition Cures Update criteria.

Certification criteria c(1), c(2), and c(3) are associated with the above plans for import, recording, exporting, calculating, and reporting CQM data. Only c(3) has 2015 Edition Cures Update – PSG has updated and attested to the update per the 21st Century Cures Act requirements.

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

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

The daily import, recording, and calculating of data for eCQMs is a regular and scheduled task for the M.A.P. module. Exporting and reporting data from and to other EHRs does not occur on a regular basis and thus there is limited opportunity to test that metric.

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
Provider review of performance on eCQMs during RWT date range.	M.A.P., as a single CEHRT module, is used solely for the calculation of metrics for CMS's Quality Payment Program (QPP). M.A.P. is not marketed to any clinician, it is only available for use by clinicians employed by HCA Healthcare; clinicians are not charged for the use of M.A.P. PSG providers check their performance through eCQM calculations routinely during the date range of the RWT.

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 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 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.

PSG expects 83 instances of the daily processes for import, recording, and calculation working. Additionally, PSG will include a count of the ad hoc processes of export, reporting, and the access of the dashboard providers use to monitor quality performance. Finally, we'll prepare a summary of these results at the conclusion of the real world testing.

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
PSG demonstrates data in live tables for the import and calculation processes, the QRDA3 export process, and the front-end dashboard.	PSG EDW	Screenshots of this occurring throughout the RWT date range
PSG begins recording count of imports, recording, export, calculations, reporting, and access of dashboard.	PSG EDW and PSG hosted dashboard	July 1, 2022
PSG ends count of imports, recording, export, calculations, reporting, and access of dashboard.	PSG EDW and PSG hosted dashboard	September 24, 2022
PSG reports count of imports, recording, export, calculations, reporting, and access of dashboard to Drummond.	Drummond reporting functionality.	Q4 of 2022

ATTESTATION

The Real World Testing plan must include the following attestation signed by the Health IT Developer Authorized representative.

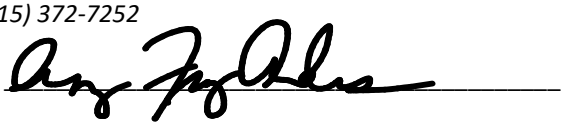
Note: The plan must be approved by a Health IT Developer authorized representative capable of binding the Health IT Developer for execution of the plan and include the representative's contact information. [ii]

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: *Amy Frye-Anderson*

Authorized Representative Email: *Amy.FryeAnderson@hcahealthcare.com*

Authorized Representative Phone: *(615) 372-7252*

Authorized Representative Signature: 

Date: 12/06/2021

[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