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 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: Clinigence Health

Product Name(s): Clinigence Value Improvement Platform (VIP)

Version Number(s): 4.5

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2696.Clin.05.00.0.181231

Developer Real World Testing Page URL: https://clinigencehealth.com/solutions/monitor-report-quality-measures/

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]*.*

We have written three measures which we believe will thoroughly test our capabilities to perform the Quality reporting functions we have certified. The testing will collect data from our actual MIPS reporting cycle using client data, calculate measure scores, and submit the report files to CMS.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND 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.

The standards for §170.315(c)(3) Clinical Quality Measures (CQMs) – Report (Cures) will be followed when we generate the QRDA CAT III reports that we will then upload to the QPP portal for MIPS reporting.

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.

DESCRIPTION OF MEASUREMENT/METRIC

The following outlines the three measures that have been identified to best demonstrate conformance to multiple certification criteria concerning Clinical Quality Measures (170.315 (c)(1): Record and Export, 170.315 (c)(2): Import and Calculate, and 170.315 (c)(3): Report across the use cases demonstrated.

Measure 1: Data Extraction and Import. This measure will demonstrate the ability to use our proprietary data extraction tools to consume data from various sources and formats and import that data into our database.

Measure 2: Calculate and Validate. This measure will demonstrate the ability to use the imported PHI to calculate a specific MIPS eCQM measure *(Probably use the Controlling BP measure)* for the PY 2021 according to that year's measure specifications. An audit process will be completed to validate the scores prior to submission to CMS. Clinigence will use the following audit Processes for the Quality data submission:

- Initial Implementation – accuracy of numerator, denominator and exclusion criteria results are verified after an EP's data is initially loaded, mapped and calculated, working with the practice.
- Nightly Variance Checks - An automated job runs several queries every night checking for unusual variances in report results in the cache tables and a variance report is emailed to the Clinigence support and development teams.
- Quality Data validation Audit Prior to Submission – At least 3% of the TIN/NPIs submitted to CMS (with a minimum of 10 or maximum of 50 TIN/NPIs), with at least 25% of the TIN/NPI's patients (with a minimum 5 patients or maximum sample of 50 patients) for a specific quality measure implemented for 2021. The audit will be performed as soon as all data has been loaded and processed for all of the 2021 quality measures for each TIN/NPI implemented for 2021 submission. (i.e., Results of the data validation/targeted audits, identifying calculation issues, why they occurred and what was done to remediate.)

Measure 3: Submitting Reports to CMS. This measure will demonstrate the ability to submit MIPS scores to CMS. We will generate the required QRDA Cat III files, upload to CMS via the QPP portal, and download the scores and submission ID.

ASSOCIATED CERTIFICATION CRITERIA

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

Certification Criteria	Requirement
§170.315(c)(3) Clinical Quality Measures (CQMs) – Report (Cures)	(c)(3)Generate an aggregate report with calculated summary data for the patient population of the clinical quality measures calculated in the Execute test (§ 170.315(c)(2)), which at a minimum is in accordance with the standard specified in § 170.205(k)(3). CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020 Generate a de-duplicated archive of patient documents in the CMS QRDA Category I IG format of the clinical quality measures calculated in the Execute test (§ 170.315(c)(2)), which at a minimum is in accordance with the standard specified in § 170.205(h)(3). CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020 Submit the quality measurement data file consisting of the data created by the generation of the CMS QRDA Category III IG aggregate report(s) and the de-duplicated CMS QRDA Category I IG report(s) for verification.

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Measure 1 Justification: Health IT needs to be able to record all data necessary to successfully calculate selected clinical quality measures (CQMs). Clinigence's proprietary methodology allows us to extract and/or import data from many different EMRs and import several different file formats, including CCDs, and QRDA CAT I.

Measure 2 Justification: Certain CMS programs require or provide the option for electronic CQM (eCQM) reporting. Each year, CMS issues annual updates to eCQMs (herein referred to as the "CMS annual measure update(s)") which are published on the Electronic Clinical Quality Improvement (eCQI) Resource Center. The audit process described ensures that Clinigence is meeting the measure specifications and has validated the scores prior to submission to CMS.

Measure 3 Justification: A user can export a data file formatted in accordance with HL7 QRDA Category I Release 3 or the corresponding version of the QRDA standard for the CMS annual measure update being certified for one or multiple patients that includes all of the data captured in (c)(1)(i) of this criterion.

CARE SETTING(S)

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

Care Setting	Justification
Group	Clinigence generates and submits one file for all NPIs in The TIN (group). Scores are aggregated in the CAT III file for the entire group.
Individual	Clinigence generates and submits one file for each provider. This can be for a single provider practice or multiple providers under the same TIN. One CAT III file is generated per NPI.

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)

Expected outcomes: It is expected that authorized users will be able to generate measure scores for each EP and generate the files needed to upload to the QPP portal for the yearly MIPS submission. Any errors found will be tracked, analyzed, and corrected so that 100% of the MIPS submissions are accepted by CMS.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Confirm data extraction and import for all EPs who have purchased the MIPS reporting service	All	Jan. 1, 2022 – Mar. 31, 2022
Calculate measure scores for Groups and EPs selected to participate in the RWT	All	Jan. 1, 2022 – Mar. 31, 2022
Validate the measure scores	All	Jan. 1, 2022 – Mar. 31, 2022
Generate the QRDA Cat III files	All	Jan. 1, 2022 – Mar. 31, 2022
Upload QDRA files to QPP portal and download submission reports	All	Jan. 1, 2022 – Mar. 31, 2022
Create RWT report	All	May 31, 2022
Submit RWT report	All	March 15, 2023

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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Authorized Representative Phone:

Authorized Representative Signature:

Date: Oct. 22, 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)