

# REAL WORLD TESTING PLAN 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.

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”

## 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: \_\_\_\_\_

Developer Name: [AaNeel Infotech](#)

Product Name(s): [My Health EHR – By AaNeel Care](#)

Version Number(s): [10.8.2.2](#)

Certified Health IT Product List (CHPL) Product Number(s): [15.07.07.3107.MY02.01.00.0.220429](#)

Developer Real World Testing Plan Page URL: <https://www.aaneel.com/2022/06/16/aaneel-nc-ehr-certification/>

## 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.<sup>1</sup>*

*At this time AaNeel does not have clients utilizing this EHR functionality and therefore does not have real/live data to utilize for RWT; as such, AaNeel shall conduct RWT with test data until such time real client data is available to utilize for RWT milestones.*

### **AaNeel RWT process utilizing test data:**

1. Firstly, we import the patients in the system through backend process and from that data we find the patients who fall under the measure definition.
2. According to the criteria required for the specific measure, the system assigns the member(s)/patient(s) in different status/buckets such as Numerator, Denominator, eligible, etc.
3. Once it is done, we show the member count on screen which gives the end user total count with all the buckets' status.
4. When the user clicks on the counts, we show the list of patients with the basic information under that status/bucket.
5. Every time the provider updates the clinical data for any patient, then system automatically updates member/patient status so individual(s) fall under the respective bucket accordingly.
6. Will generate export data files per standard file format (2022 CMS QRDA I (Updated November 2021)).
7. File export will be reviewed for data integrity and confirmation of meeting file specification requirements.
  1. Results shall be documented by quality assurance Team.
    1. Any discrepancies will be noted, reported as required (both internally and externally), monitored, and addressed.
      1. RWT process shall be conducted again after discrepancies noted are addressed to confirm successful completion of required.
        1. In the event the testing results are not successful, Team shall repeat actions under #7 until success is achieved.

*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.*

**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 Product Number 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?

<b>Standard (and version)</b>	§ 170.205(h)(3) CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020
<b>Updated certification criteria and associated product</b>	C3 Cures
<b>CHPL Product Number</b>	15.07.07.3107.MY02.01.00.0.220429
<b>Method used for standard update</b>	Tested Directly
<b>Date of ONC ACB notification</b>	04/29/2022
<b>Date of customer notification (SVAP only)</b>	N/A
<b>Conformance measure</b>	<i>CMS69v9</i> <i>CMS117v9</i> § 170.315(c)(1) Clinical quality measures - record and export § 170.315 (c)(2) Clinical quality measures - import and calculate § 170.315(c)(3) Clinical quality measures - report
<b>USCDI updated certification criteria (and USCDI version)</b>	N/A

## 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
<a href="#">§ 170.315(c)(1) Clinical quality measures - record and export</a>	<p>For this Measure, AaNeel shall review and conduct validation on the number of measures successfully recorded in <i>My Health EHR</i> for the audit period or those that failed, and shall review and conduct validation on the number of successful or failed QRDA files exported and formatted as per Interoperability Standards Advisory (ISA) requirements (<a href="#">170.205(h)(2)</a>).</p> <p><i>Note: In the event no real-world data is available in My Health EHR, AaNeel shall use test data available to conduct validation, additionally, AaNeel may conduct reporting/extraction events to test effectiveness and compliance of requirements and measures as appropriate and applicable.</i></p>
<a href="#">§ 170.315 (c)(2) Clinical quality measures - import and calculate</a>	<p>For this Measure, AaNeel shall review and conduct validation on the number of measures successfully imported into <i>My Health EHR</i> for the audit period or those that failed and shall review and conduct validation on the number of successful or failed calculations for measure data received/recorded.</p> <p><i>Note: In the event no real-world data is available in My Health EHR, AaNeel shall use test data available to conduct validation; additionally, AaNeel may conduct activities for importing and triggering calculation events to test effectiveness and compliance of required import and calculation activities as appropriate and applicable.</i></p>
<a href="#">§ 170.315(c)(3) Clinical quality measures - report</a>	<p>For this Measure, AaNeel shall conduct validation on the number of measures successfully reported by <i>My Health EHR</i> for the audit period or those that failed, by reviewing the number of successful or failed attempts for generation of electronically created data files for the transmission of clinical quality measurement data per QRDA Interoperability Standards Advisory (ISA) requirements (<a href="#">170.205</a>).</p> <p><i>Note: In the event no real-world data is available in My Health EHR, AaNeel shall use test data available to conduct validation as may be required.</i></p>

**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.

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
N/A	N/A	N/A

**Justification for Selected Measurement/Metric**

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

Measurement/Metric	Justification
<a href="#">CMS69v9</a>	Given that AaNeel has no real-world data available at this time, AaNeel shall use test data for biannual testing of the success/failure rates for capturing and reporting on documentation of BMI for patients 18yrs and older during eligible encounter(s) within the measurement period, and documented follow-up plan if most recent BMI was outside of normal parameters shall demonstrate ongoing interoperability.
<a href="#">CMS117v9</a>	Given that AaNeel has no real-world data available at this time, AaNeel shall use test data for biannual testing of the success/failure rates for capturing and reporting the documentation of recommended vaccine administration, history of illness, or test results indicating antigen as appropriate from birth to age two, for children who turn 2yrs old within the measurement period shall demonstrate ongoing interoperability.

**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
Healthcare Provider(s)	My Health EHR - By AaNeelCare is a system developed for healthcare providers to utilize wherever the Provider practices and has system access (internet access).

**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
CMS69v9	Successful results for importing/exporting functions, recording of all data required, calculating CQMs, and reporting of measure by creating data file for transmission in accordance with CMS QRDA standards.
CMS117v9	
<a href="#">§ 170.315(c)(1) Clinical quality measures - record and export</a>	<ol style="list-style-type: none"> <li>1. <b>Record.</b> <ol style="list-style-type: none"> <li>a) Validate <i>My Health EHR</i> records all of the data that would be necessary to calculate each CQM.</li> </ol> </li> <li>2. <b>Export.</b> A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:           <ol style="list-style-type: none"> <li>a) Formatted in accordance with the standard specified in § 170.205(h)(2);</li> <li>b) Ranging from one to multiple patients; and</li> <li>c) That includes all of the data captured for each clinical quality measure under certification.</li> </ol> </li> </ol>
<a href="#">§ 170.315 (c)(2) Clinical quality measures - import and calculate</a>	<ol style="list-style-type: none"> <li>1. <b>Import.</b> Validate <i>My Health EHR</i> user may import a data file in accordance with the standard specified in § 170.205(h)(2) for one or multiple patients and use such data to perform the specifications of this section.           <ol style="list-style-type: none"> <li>a) User must be able to execute this capability at any time without subsequent developer assistance to operate.</li> </ol> </li> <li>2. <b>Calculate.</b> Validate <i>My Health EHR</i> accurately calculates clinical quality measures under certification.</li> </ol>

Measurement/Metric	Expected Outcomes
<a href="#">§ 170.315(c)(3) Clinical quality measures - report</a>	<p><b>Report.</b> Validate <i>My Health EHR</i> enables users to electronically create a data file for transmission of clinical quality measurement data:</p> <ul style="list-style-type: none"> <li>(i) In accordance with the applicable implementation specifications specified by the CMS implementation guides for Quality Reporting Document Architecture (QRDA), category I, for inpatient measures in § 170.205(h)(3) and CMS implementation guide for QRDA, category III for ambulatory measures in § 170.205 (k)(3); or</li> <li>(ii) In accordance with the standards specified in § 170.205(h)(2) and § 170.205(k)(1) and (2) for the period until December 31, 2022.</li> </ul>

### 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
Biannual Test (CMS69v9/CMS117v9) – Conduct RWT	Healthcare Provide(s) web-based	1 <sup>st</sup> Annual Test (due by 6/30/2023)
Begin collection of information as laid out by the plan.		June 2, 2023
Conduct review and validation of successful record data required for calculation of CQM captured in <i>My Health EHR</i> .		June 9, 2023
Conduct export to validate functionality.		June 9, 2023
Conduct import ad hoc to validate functionality.		June 9, 2023
Conduct review and analysis of calculation functions required for Certified CQMs.		June 9-30, 2023
Conduct report generation activities to validate functionality.		June 9-30, 2023
Submit RWT results report to the required internal and external entities, as applicable.		As Instructed
Biannual Test (CMS69v9/CMS117v9) – Conduct RWT	Healthcare Provide(s) web-based	2 <sup>nd</sup> Annual Test (due by 12/31/2023)
Begin collection of information as laid out by the plan.		December 1, 2023
Conduct review and validation of successful record data required for calculation of CQM captured in <i>My Health EHR</i> .		December 8, 2023
Conduct export to validate functionality.		December 8, 2023
Conduct import ad hoc to validate functionality.		December 8, 2023
Conduct review and analysis of calculation functions required for Certified CQMs.		December 8, 2023
Conduct report generation activities to validate functionality.		December 29, 2023
Submit RWT results report to the required internal and external entities, as applicable.		As Instructed

## ATTESTATION

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

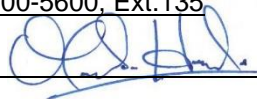
*Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.<sup>ii</sup>*

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: Mercedes Howle

Authorized Representative Email: [mercedes.howle@aaneel.com](mailto:mercedes.howle@aaneel.com)

Authorized Representative Phone: (813) 200-5600, Ext.135

Authorized Representative Signature:  \_\_\_\_\_

Date: 11/22/2022

<sup>i</sup> 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)

<sup>ii</sup> <https://www.federalregister.gov/d/2020-07419/p-3582>