REAL WORLD TESTING PLAN

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: Infomedika, Inc.

Product Name(s): Evolution EHR

Version Number(s): 3

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1684.Evol.08.00.1.181221

Developer Real World Testing Page URL: https://www.infomedika.com/certifications

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to ***perform as intended by conducting and measuring observations of interoperability and data exchange***", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

We are using a pair of methods to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing

Adoption rate will be used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might indicate a potential problem, of which there could be several different causes. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted by generating reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

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

Infomedika has not updated Evolution EHR to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of the 2025 Real World Test.

CARE SETTINGS

Evolution EHR is a certified technology that addresses the needs of the Inpatient Acute Care Setting for small and medium size hospitals and the Ambulatory ER Clinics Setting available for the Puerto Rico, Latin America and the USA market.

Care Setting	Justification
Inpatient acute care hospitals	Inpatient acute care hospitals comprise roughly half our user base.
Ambulatory centers with ER services	Ambulatory centers with ER services comprise roughly half our user base.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of licensed installs/users of EHR • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of EHR	Identify the total number of ***active*** installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed separately	Identify which certified capabilities are licensed separately from the base EHR license. Examples may include Predictive DSI, eRx, CQMs, public health, etc. Relied Upon Software: 1) Zimbra Desktop - b(1) 2) eCQM Solutions - c(1), c(2), c(3) 3) SecureHit - H(1) 4) MeldRx AI - B(11)
Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of ***active*** installs/users of a given certified capability.

SUMMATIVE ASSESSMENT METRICS

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine "success" via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(b)(1) Transitions of care	Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies and intolerance list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

170.315(b)(10) Electronic Health Information Export	Over a 90-day period: 1) Number of times an EHI data export was performed for a patient. 2) Number of times an EHI data export was performed for multiple patients in a single transaction. 3) Number of times an EHI data export was performed for all patients in a single transaction	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the capability of a certified Health IT module to export all of the patient's electronic health information (EHI) in an electronic and computable format. However, it is not possible to consistently and reliably demonstrate that all required EHI has been exported, as the quantity and variety of EHI can vary depending on the environment and healthcare system. Therefore, our goal is to demonstrate that the certified capability is available and effective, regardless of the frequency of use. We expect there to be low utilization by providers, but with a high success rate in exporting the EHI.
170.315(c)(1-3) Clinical quality measures (CQMs)	Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA Category 1 files exported 3) Number of QRDA Category 1 files imported (if applicable) 4) Number of QRDA Category 3 aggregate report(s) created over the period	• Inpatient acute care hospitals • Ambulatory centers with ER services	These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format. C2 requires a certified Health IT module must be able to import data from a QRDA Category 1 formatted file and calculate the CQMs based on that data. C3 requires a certified Health IT module must be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.
170.315(f)(1) Transmission to immunization registries	Over 3 separate unique 10-day periods within a 90-day window: 1) Total Number of immunization records submitted to the immunization record.	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of reportable laboratory results created and submitted	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the ability of a certified Health IT module to transmit reportable laboratory tests and values/results to a registry using a specified format. We intend to record the frequency that reportable laboratory tests and values/results is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.
170.315(f)(5) Transmission to public health agencies — electronic case reporting	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of electronic case reports created and submitted	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the ability of a certified Health IT module to identify which encounters may be reportable and then create an electronic case report for transmission to a registry using a specified format. We intend to record the frequency that electronic case reports are created and submitted by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.
170.315(h)(1) Direct Project	1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received 4) Number of Delivery Notifications sent	• Inpatient acute care hospitals • Ambulatory centers with ER services	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in the first quarter of 2025. Each phase is expected to take 90-days to complete, with report writing to occur end of 2025/early 2026.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	• Inpatient acute care hospitals • Ambulatory centers with ER services	90-days
Data collection	• Inpatient acute care hospitals • Ambulatory centers with ER services	90-days
Review and collate data	• Inpatient acute care hospitals • Ambulatory centers with ER services	90-days
Writing report	• Inpatient acute care hospitals • Ambulatory centers with ER services	90-days

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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Date: 10/28/2024