Real World Testing Plan

2023

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Executive Summary

As per ONC Health IT Certification Program, Health IT developers are required to conduct Real World Testing of their Certified Health IT ((45 CFR 170.556 and 170.523(i)). This document defines the plan to execute the requirement.

Vericle as a practice management software, is working with the small to medium sized clinics. We market ourselves primarily to the Physical Medicine and the Mental Health care setups. Our existing ONC certified version is 5.0. This document is a combined real world testing plan-year 2023 for all the applicable criteria listed under Vericle certification.

The real-world testing aims towards identifying the interoperability and usability when the system functions within real-world scenarios. This will not only help us establish the continued conformance to the certified criteria but also, identify the practicality of the system features so that the software is implemented for the optimal use at the client site. This document includes test plans for the 12 criteria Vericle has CHPL listing for. We have defined subsequent final testing measurements and metrics for each of these criteria separately. Along with that, justification for the approach, Key Milestones as of today and relied upon softwares are also mentioned in the plan.

System data will be captured and analysed for the measurement reporting at the end of the testing milestone and based on these calculations, we will be able to report the system's continued compliance with the criteria requirements under this RWT Plan. As described in the resource guide published by ONC, the participants or the sample of users performing RWT depends upon the usage of a particular functionality by the clients. We have decided to collect the data from 3 of our users who belong to different specialties to make a heterogenous sample.

The schedule for the key milestones planned for this project is mentioned as a separate section of the document and the events based on the plan will be timely recorded and reported at the end of testing. We are currently working on USCDI data elements updates in the CCDAs and will be including that to the testing result report for the coming year.

Our signed attestation of compliance with the real-world testing requirements is at the end of this documentation.

Justification for Real World Testing Approach

This RWT plan is defined to establish the interoperability and the usability of the features, functions implemented by Vericle which are certified with ONC. The justifications and the expected outcomes for all the applicable criteria are observed to be the same for both the care settings we market ourselves in, i.e., Physical Medicine and Mental Health care. Hence, the testing plans address both these settings without any significant change to the measures or to the outcomes. Participant sample has been chosen in order to capture almost all of the use cases we can have and to get a sufficient amount of data to analyse the interoperability and usability of the product in both the care settings.

We are applying two folded approaches for testing:

1. Adoption Rate metrics- To get overview of the certified functionalities used by the clients. This metric will be applicable to only the functionalities which require separate subscription.
2. Summative Assessment metric- The following metrics will be measured by looking at audit logs and reporting systems available to track the behaviour of the certified Health IT module during a given time frame.

System data will be captured and analysed for the measurement reporting at the end of the testing milestone and based on these calculations, we will be able to report the system's continued compliance with the criteria requirements under this RWT Plan. The measures defined in the plan are to provide the quantitative analysis of the usage and working of the functionality. They will be capturing the data on if the functionality is being used in the real world and the success rate of the workflow.

General Information

Plan Report ID Number: VERP24E25S26

Developer Name: Erez Lirov

Product Name(s): Vericle

Version Number(s): 5.0

Applicable Certified Health IT Criteria:

1. 170.315(b)(1) Transitions of care
2. 170.315(b)(2) Clinical information reconciliation and incorporation
3. 170.315(b)(6) Data export
4. 170.315(c)(1) CQM - record and export
5. 170.315(c)(2) CQM - import and calculate
6. 170.315(c)(3) CQM - report CQM report
7. 170.315(e)(1) View, download and transmit to 3rd party
8. 170.315(g)(7) Application access – patient Selection
9. 170.315(g)(8) Application access – data category request
10. 170.315(g)(9) Application access – all data request
11. 170.315(h)(1) Direct project
12. 170.315(f)(1) Transmission to immunization registries

Product List (CHPL) ID(s): 15.07.04.2500.VERI.05.01.1.210101

Developer Real World Testing Page URL: https://www.vericle.net/real-world-testing

Schedule of Key Milestones

Key Milestone	Date/Time Frame
Communicate with the client and confirm participants in the real-world testing. Release of RWT document which includes specific instructions on what to look for, how to record the issues encountered, and Customer Agreements	January 1, 2023-April 1, 2023
The real-word testing will be performed. Timely follow-up with the client on their findings. Any non-conformities found will be reported to ONC-ACB	April 2, 2023-September 1, 2023
Planned System USCDI updates and work starts on the RWT Plan for 2023	September, 2023
RWT Plan for 2023 will be completed and will be submitted to ONC-ACB as per their due date	October, 2023
End of Real-World Testing period/final collection of all data for analysis	January 1, 2024
Submit Real World Testing report to ACB (per their instructions)	February 1, 2024

Adoption Rate Metrics

The following metrics are applicable to the criteria that are licensed separately from base license 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 number of users who are using the feature that we have. However, this usage will help us direct the next approach of testing.

Metric	Description
Certified capabilities that are licensed separately	We will identify which certified capabilities are licensed separately from the base EHR license in the results report. Examples may include Direct Messaging, CQMs, Public Health, etc.
Number of installs/ users who licensed a certified capability	Where applicable, we will identify the number of licensed installs/users of a given certified capability in the results report.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, we will identify the number of active installs/users of a given certified capability in the results report.

Summative Assessment Metrics

The following metrics will be measured by looking at audit logs and reporting systems available to track the behaviour 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 capability being used.

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 the successful attempt was made where no error was received from the destination system or its intermediaries.

We are currently working on USCDI V1 updates and will be including that in our results report. We are not planning for SVAP while drafting this plan.

Certification Criteria	Measures	Justification and Expected Outcome	Relied upon software
§ 170.315(b)(1) Transition of Care § 170.315(h)(1) Direct Project	CCDAs are successfully sent via direct messaging.	The above measure is created to analyse the system's ability to send the encrypted and edge protocol supported messages to a 3rd party provider in the real-world setup. The system records logs for the attempts to send the direct messages. The CCDA documents that are failed to send are also logged and these exceptions will be investigated at the end of testing for the underlying cause and will be reported. In order to capture the "success" in case of the inability to capture the completion of the transaction, we will capture logs for attempts made to send the CCDAs via direct messaging. The standardized format of the CCDA document as per the template and inclusion of specific data elements will also be verified under this measure as the system does not allow users to generate and send the CCDA which does not follow the standard formatting. These transactions will establish the usability of the function i.e., how frequently this interoperability feature is being used by the clients. Users will successfully send the patient CCDAs to another provider via direct messaging. This	NewCrop Core v13.05.s19-22-2_22.10.18.1-63705

		transaction will be logged under the PHI audit log.	
§ 170.315(b)(2) Clinical information reconciliation	System successfully reconciles the imported CCDA documents.	This measure is created to measure the success of the rate of the reconciliations performed on the system. System throws validations if the imported document does not support the C-CDA templates, which will also be tested under this measure. The updated CCDAs can be verified to check if it includes the reconciled information. The PHI audit log records the reconciliation. Vericle has an inbuilt bug reporting tool which can be used by the physicians to report any exceptions to the action. These exceptions will also be analysed and reported at the end of RWT. Imported CCDAs will be successfully reconciled to the existing PHI and the audit log will show the entries for the attempts started, successful and failed attempts of these reconciliation actions.	NewCrop Core v13.05.s19-22-2_22.10.18.1-63705
§ 170.315(b)(6) Data Export	Export summaries are created successfully	Vericle has specified privileges for the export summary creation, timeframe configuration and location configuration functions. The user who has been assigned these privileges can generate the export summaries. These summaries then get stored in the location specified under the location configuration which is also accessible by the privileged users. The above measure has been created to calculate the success rate of attempts made to create export summary. The frequency of the use of this function will also be checked. Alongside, the system's ability to limit the number of users who can create the export summaries, will be indirectly tested. When a user out of this set tries to access the configuration and to create an export summary, the system will generate an error validation. The export summary generation is logged under the PHI audit log. The flow of the execution of the scenario will also check if the user who has access to the configurations can define the timeframe and location configuration. User successfully generated the export summary for the selected patient. PHI audit log	N/A

		will keep the entry for the attempts started and attempts to create export summaries.	
§ 170.315(c)(1) Clinical Quality Measures– record and export	The data files with the required information on the selected measure are successfully exported by the user.	The measure is devised to analyse Health IT's conformance with § 170.315(c)(1) Clinical Quality Measures– record and export. The attempted and successful attempts to generate cat 1 file for the selected CQMs will be logged under the PHI audit list. These measures also will validate that the system records all the required data for all the six CQMs Vericle is certified with. The data files are formatted as per the QRDA guidelines for cat 1 files. These data files can be created and exported for more than one patient at a time. System logs the attempts started and successful attempts made to export the cat 1 data files without or minimal errors.	N/A
§ 170.315(c)(2) Clinical Quality Measures– import and calculate	The data files (cat1) are successfully imported to get the CQM statistics.	This measure will help us to establish that Health IT allows users to import the data files with all the CQM(s) related information even in a real-world setting. The imported cat 1 files enable users to generate the statistics on the selected CQMs. The files can be generated for all the six CQMs for multiple patients at a time. All these functions will be verified under this measure. The PHI log entries for the participant users will be collected and studied for the successful import of the cat 1 data files. cat 1 files are successfully imported with the selected CQM data to generate the CQM statistics. System records the entries of the attempts started and attempts completed to import the data files/ cat1 files.	N/A
§ 170.315(c)(3) Clinical Quality Measures– report	System successfully generates the data files of the CQM report for transmission.	The system has a feature to generate the statistics for the selected CQM(s) based on the data files fed into the system. This is done by using the cat 1 data files with all the data components. These cat 1 files are processed to generate the statistics on the CQM(s), the cat 3 files. The above measure is devised to establish that Health IT can create the data file/ cat 3 in compliance with the QRDA format with the ability to transmit it without or with minimum errors. The attempts started and the status of	N/A

		the generation of the CQM report will be logged and will later be reviewed for the calculation of the measurement metric. The defined measure also tests if the file generated is guided by the interoperability and content exchange standards. The data files are successfully created electronically for the transmission without or with less than 1% errors. The action is logged under the PHI audit log.	
§ 170.315(e)(1) View, download and transmit to 3rd party	Vericle allows patients or authorized representatives to download their care summaries without any subsequent assistance.	The above measure will be used to perform a quantitative analysis of Vericle patient portal functions; specially to download patient's care summary. The measure indirectly verifies that the patients can access the portal for their care data and the CCDAs are displayed in human readable format. All the actions on patient care summary such as view, download and transfer are getting logged under the audit log history; on both the portal itself and under the PHI audit log of the physician who had or has an appointment with the patient. System's usability and interoperability will be tested under the use case as patient accesses and downloads the clinical data summary via the internet-based technology. Along with it is reported the system's capability of patient engagement by allowing them to access their real-time care information for the selected timeframe. Audit log that keeps the trail of all the actions performed on the care summary is accessible to the patient or his/her authorized representative, who has access to the portal. Patient successfully downloads the care summary from their patient portal account. This action gets logged on the portal as well as on the PHI audit log records of the physician who has or had an appointment with the patient.	N/A
§ 170.315(g)(7) Application access – patient selection	Vericle successfully receives and responds to the external	This measure has been drafted by the developer to quantitatively measure the system's ability to receive and respond to the external app requests with sufficient information. Successful data responses from	NewCrop Core v13.05.s19-22-2_22.10.18.1-63705

§170.315 (g)(8) Application access – data category request §170.315 (g)(9) Application access – all data request	application requests with sufficient information to identify the patient.	the system are recorded (response code 200). The audit logs under the user who has or has an appointment with the patient, gets the entry for the request and response. We will be getting the data from these logs to calculate the success rate of the above measure. Any exceptions will be treated as failures and we will review them at the end of the testing. The numerical value of this measure will confirm the system's compliance with the interoperability requirement and conformance with the above criteria. Third party app requests with sufficient information are responded successfully (with the response code 200) and it will be captured under the audit logs.	
§ 170.315(f)(1) Transmission to immunization registries	The immunization information created is successfully transmitted to the immunization registry.	The above measure is created in order to check for the usability of this feature and if the system establishes interoperability with the immunization registry. In addition, the standard data classes recorded under the immunization record and the usage of standard codes will also be verified as we will be tracking the successful transmission of the information. We will calculate the success rate attempts made for this transmission alongside the number of times this frequency is being used by the set of providers selected for the RWT. User successfully sends the created immunization record for the patient to the registry. PHI log creates the entry for the attempts made and successful attempts in transmission of this information.	N/A

Attestation

This Real-world testing plan is complete with all the mandatory elements, including a measure defined per applicable criteria addressing the Physical Medicine and Mental Health care setup. All the information in the plan is up to date and completely addresses the real-world testing requirements.

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