Real World Testing Plan
2025

Executive Summary

This executive summary presents Clinicmind's Real-World Testing Plan, developed to assess our Electronic Health Records (EHR) system's adherence to the standards specified by the Office of the National Coordinator for Health IT (ONC). This plan focuses on evaluating the system's capabilities in interoperability, data accuracy, clinical quality measurement, patient engagement, and integration with external entities as required by the following certified criteria:

- **170.315(b)(1) Transitions of Care:** Assesses the system's ability to support seamless patient information exchange during transitions of care.
- **170.315(b)(2) Clinical Information Reconciliation and Incorporation:** Evaluates the accuracy and consistency of clinical data reconciliation and integration into patient records.
- **170.315(b)(10) Electronic Health Information Export:** Verifies the EHR's ability to export patient data in a standardized format to support interoperability and data portability.
- **170.315(c)(1) CQM - Record and Export:** Confirms accurate recording and exporting of Clinical Quality Measures (CQMs) for reporting and analysis.
- **170.315(c)(2) CQM - Import and Calculate:** Assesses the system's effectiveness in importing and calculating CQMs from external sources to enhance data quality and reporting.
- **170.315(e)(1) View, Download, and Transmit to 3rd Party:** Examines functionality enabling patients to view, download, and securely transmit their health information to third-party applications.
- **170.315(f)(1) Transmission to Immunization Registries:** Validates the EHR's ability to transmit immunization data to registries accurately and promptly.
- **170.315(g)(7) Application Access – Patient Selection:** Evaluates application access for healthcare providers with a focus on patient selection and information retrieval.
- **170.315(g)(9) Application Access – All Data Request:** Confirms the system's capability to respond to comprehensive data requests from authorized applications, ensuring access to complete patient information.
- **170.315(h)(1) Direct Project:** Ensures compliance with Direct Project standards to support secure and standardized health information exchange via Direct Messaging.

The Real-World Testing Plan includes comprehensive testing scenarios and metrics to thoroughly assess the EHR system's compliance with each criterion. Findings will guide any necessary enhancements to optimize performance, interoperability, and efficiency. Clinicmind remains committed to meeting high standards in health IT and improving patient care and outcomes through robust electronic health data management. A signed attestation of compliance with the real-world testing requirements is included at the end of this document.

Justification for Real World Testing Approach

This Real-World Testing (RWT) plan is designed to assess the interoperability and usability of Clinic Mind's certified features in line with ONC standards. Testing will cover criteria relevant to both Physical Medicine and Mental Health settings, ensuring consistent justification and outcomes for each. We aim to select participants from practices in these specialties with high patient volumes, detailed documentation, and the capacity to generate ample data for a comprehensive analysis of product interoperability and usability across our client network.

Summative Assessment Metrics: This phase involves evaluating metrics from audit logs and reporting tools that track the certified Health IT module's performance over time. We will measure and analyze system data to ensure compliance with the specified criteria outlined in this RWT Plan. At the end of each testing milestone, we will capture and thoroughly examine system data to document adherence to these criteria, offering quantitative insights into the functionality, usage, and effectiveness in real-world scenarios. These metrics will provide an overview of real-world utilization and workflow success rates, enabling a robust assessment of the system's compliance with RWT criteria.

Testing for the §170.315(b)(10) criterion will be conducted independently, utilizing MeldRx by Darena to access and export data files. This testing will encompass both single and bulk data requests for all criteria. The metrics and descriptions detailed in this plan will apply to the independently tested §170.315(b)(10) criterion. RWT sessions will take place via Zoom, with participants using a production environment and actual patient data. Upon completion, we will validate the certified technology's capability to successfully export EHI data for §170.315(b)(10).

General Information

Plan Report ID Number: CM05Y25

Developer Name: Erez Lirov

Product Name(s): Clinicmind

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)(10) Electronic Health Information Export
4. 170.315(c)(1) CQM - record and export
5. 170.315(c)(2) CQM - import and calculate
6. 170.315(e)(1) View, download and transmit to 3rd party
7. 170.315(f)(1) Transmission to immunization registries
8. 170.315(g)(7) Application access – patient Selection
9. 170.315(g)(9) Application access – all data request
10. 170.315(h)(1) Direct project

Product List (CHPL) Number: 15.07.04.2500.VERI.05.02.1.221230

ONC-ACB CERTIFICATION ID: 15.07.04.2500.VERI.05.02.1.221230

Developer Real World Testing Page URL: https://www.clinicmind.com/real-world-testing/

Schedule of Key Milestones

Key Milestone	Date/Time Frame
Initiation & Verification of logging of data.	January, 2025
Capture real-world testing data and record any identified non-conformities for reporting to ONC-ACB.	January, 2025-October, 2025
Work on Real World Testing Plan 2026	October, 2025
Analyze the real-world testing data and get the measures calculated. Report generation.	November, 2025- December, 2025
Submit the Real World Testing report 2025 to ACB the instructions.	January, 2026
Follow-up & Rectify the submission.	February, 2026

Summative Assessment Metrics

We will evaluate the specified metrics using audit logs and reporting systems that track the performance of the certified Health IT module over a defined period. These metrics are meticulously designed to capture key aspects of the criteria, demonstrating both interoperability and the effectiveness of the certified capabilities in use. For consistency with federal incentive program requirements, we typically select a 90-day period for recording these metrics.

Consistent and measurable utilization of certified features will reflect the successful deployment of the required functionalities, particularly where interoperability with external systems is achieved. In cases where direct confirmation of "success" from a receiving system is not feasible, we will define success as a successful transmission attempt with no errors returned from the destination system or any intermediaries.

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	Description: The above measure is created to analyze 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 transaction will be logged under the PHI audit log.	NewCrop v2

		Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successful exchanges made for transition of care data between certified health IT systems during real-world testing period. ● Denominator: The total number of attempted transition of care data exchanges during real-world testing period.	
§ 170.315(b)(2) Clinical information reconciliation	Clinical Information Reconciliation Success Rate	Description: 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 analyzed 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 Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successful clinical information reconciliation completed during real-world testing period. ● Denominator: The total number of clinical information reconciliation attempts started during real-world testing period.	N/A

§ 170.315(b)(10) Electronic Health Information Export	Count of single patient export files created during a 3-month timeframe. This demonstrates the ability to export single patient files containing all their EHI.	Description: We chose to concentrate on the aspects of this criterion that would: 1) Demonstrate an EHR's ability to export batches of patient data in a straightforward fashion 2) Facilitate interoperability by providing the exported data in the form of valid C-CDA files that conform to the HL7 standards as described in the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm). Additionally, it includes a publicly accessible hyperlink to the export's format. Count of single patient export files created during a 3-month timeframe. This demonstrates the ability to export single patient files containing all their EHI. This metric will also provide information on the demand for this capability. Calculation: The number of single-patient export files generated over a 3-month period will be tracked. Real-world testing will demonstrate the system's ability to create single-patient EHI export files in compliance with the 170.315(b)(10) criterion. The expected outcome is a non-zero count, though we anticipate low numbers since many organizations may continue using their existing methods for exporting single-patient data, such as interoperability tools or manual processes.	MeldRx ver. 2.0
§ 170.315(c)(1) Clinical Quality Measures–record and export	Clinical Quality Measures (CQMs) CAT1 file generation Success Rate	Description: The measure is devised to analyze 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	N/A

		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. Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successful attempts towards cat-1 file generation during real-world testing period. ● Denominator: The total number of attempts made towards cat-1 file generation during real-world testing period.	
§ 170.315(c)(2) Clinical Quality Measures–import and calculate	Clinical Quality Measures (CQMs) Importing CAT1 file Success Rate	Description: 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 enables 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 Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successfully imported cat-1 files during real-world testing period. ● Denominator: The total number of attempts made towards importing	N/A

		cat-1 files during real-world testing period.	
§ 170.315(e)(1) View, download and transmit to 3rd party	Care summaries download Success rate of Patients or authorized representatives without any subsequent assistance.	Description: The above measure will be used to perform a quantitative analysis of Vericle patient portal functions; especially 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. Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successful instances where patients were able to download their health information during real-world testing period. ● Denominator: The total number of instances where patients attempted to download their health information during real-world testing period.	N/A

§ 170.315(g)(7) Application access – patient selection *§170.315 (g)(9) Application access – all data request*	Application Access – Receives and Responds All Data Requests Success Rate	Description: 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 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. Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successful instances where API requests are responded successfully to requirements of § 170.315(g)(7) and § 170.315(g)(9) during real-world testing period. ● Denominator: Total Instances where API requests are received during real-world testing period.	N/A
§ 170.315(f)(1) Transmission to immunization registries	Immunization Registry Data Transmission Success Rate	Description: 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	N/A

		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. Calculation: Success Rate= (Numerator/Denominator) x 100 ● Numerator: The number of successful instances Immunization message successfully to immunization registries during real-world testing period. ● Denominator: The total number of attempted immunization data transmission processes during real-world testing period.	

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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