Clinical Data Solutions
Publishers of **The Clinical Manager™**

109 Whitegate Ln., Wayzata, MN 55391
Sales: (847) 948-9600
Support: (847) 948-9604

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"
  - Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, 89 FR 1192 (March 11, 2024) (**HTI-1 Final Rule**)
    - Section III.E — "Real World Testing"

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]	
Developer Name:	Clinical Data Solutions
Product Name(s):	The Clinical Manager
Version Number(s):	2023.01.01
Certified Health IT Product List (CHPL) ID(s):	15.04.04.2932.TheC.23.00.1.230414
Developer Real World Testing Plan Page URL:	https://www.clinicaldata.org/mandatory-disclosures/

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. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

The Clinical Manager is marketed to the Behavioral Health Care industry setting, specifically county governments and Managed Care Organizations (MCOs). The Clinical Manager Real World Testing plan will apply to this specialty care setting. The Clinical Manager is certified to a wide variety of criteria. Clinical Data Solutions has identified a use case and measure for the criteria The Clinical Manager is certified to which falls within the RWT scope, namely § 170.315(b)(10) EHI export.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Clinical Data Solutions has not updated The Clinical Manager to any new standards as part of SVAP criteria as of this date nor plan to prior to the execution of the 2024 Real World Test. Clinical Data Solutions updated to the Cures Update in April 2024.

CARE SETTINGS

The Clinical Manager supports the deployment and tracking of documentation within and outside of the behavioral health care specialty setting. All of our clients using certified technology are doing so in outpatient settings.

EXPECTED OUTCOMES

Real World Testing will demonstrate that The Clinical Manager is conformant to the following certification criteria:

- § 170.315(b)(10) EHI export

MEASURES USED

The following outlines the measures that have been identified to best demonstrate conformance to the certification criteria concerning the sharing of EHI (§ 170.315(b)(10)) across the two use cases demonstrated (single patient and population services).

Use Case 1 (Single Patient) Metrics: As part of the Real World Testing requirements for § 170.315(b)(10), Clinical Data Solutions has developed the following metrics for The Clinical Manager's testing plan:

Measure 1: Sharing. This measure will catalogue the transport mechanisms used to share transitions of care documents and EHI, as well as track usage of the various transport mechanisms. Associated certification criteria for the case management system in a specialty care setting include:

Certification Criteria	Requirement
§ 170.315(b)(10) EHI export – Single patient EHI export	(i)(A) Create an export file
	(i)(B) Execute at any time
	(i)(C) Limit ability of users who can create export
	(i)(D) Electronic and computable format

- Justification: The export of EHI associated with a patient is another way to share information with an external organization. Export is typically used when there is a need for a full patient record. This metric will provide information on the type of data exported for a single patient and the frequency of usage.
- Test Methodology: Case management logs and system logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.
- Expected outcome(s): It is expected that authorized users will be able to share EHI using the export function. Error rates will be tracked and trended over time.

Use Case 2 (Population Services): As part of the Real World Testing requirements for § 170.315(b)(10), Clinical Data Solutions has developed the following metrics for The Clinical Manager's testing plan:

Measure 1: Patient Population Export. This measure will assess the functionality used to export EHI for a patient population. The associated certification criterion is:

Certification Criteria	Requirement
§ 170.315(b)(10) EHI export – Patient population EHI export	(ii)(A) Create an export file

- Justification: The export of the health information associated with a patient population is another way to share health information with an external organization. It is typically used for research or quality purposes to look for specific trends on patient population. Export of a patient population is an administrative function only available to credentialed users. It is assumed that this function will be run as a scheduled activity as it will have significant impact on the Health IT Module. This will provide a metric on the use of the export of EHI for a patient population associated with the Health IT Module.
- Test methodology: Case management logs and system logs will be reviewed to ensure the export function is operating properly and to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.
- Expected outcome(s): It is expected that authorized users will be able to share EHI for a patient population using the export function. Errors in transmission will be tracked and analyzed.

SCHEDULE OF KEY MILESTONES

Key Milestones	Date/Timeframe
Submit Real World Testing Plan documentation to Drummond.	November 1, 2024
Begin Collection of information as laid out by the plan for the period.	January 1, 2025
Follow-up with providers and authorized representatives on a regular basis to understand any issues arising with the data collection.	Quarterly, 2025
End of Real-World Testing period/final collection of all data for analysis.	December 31, 2025
Analysis and report creation.	January 15, 2026
Submit Real World Testing report to ACB (per their instructions)	February 1, 2026

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.

Authorized Representative Name: David Ferri

Authorized Representative Email: david-ferri@clinicaldata.org

Authorized Representative Phone: 847-948-9600

Authorized Representative Signature: 

Date: October 31, 2024