

REAL WORLD TESTING PLAN

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: 20241030bec

Developer Name: Becton Dickinson and Company

Product Name(s): HealthSight Advisors

Version Number(s): 4

Certified Health IT Product List (CHPL) ID(s): [15.02.05.3024.BEDC.01.01.0.220125](#)

Developer Real World Testing Plan Page URL: <https://www.bd.com/en-us/resource-and-education/documentation-landing-page/promotional-articles/honors-recognition-healthsight-medmined-earns-mu3-certification>

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

By leveraging data from a hospital's electronic medical record, physician order entry, laboratory and pathology systems to monitor patients for adverse drug events and interactions, BD HealthSight™ Clinical Advisor and Infection Advisor with MedMined™ Insights can alert clinicians and pharmacists and identify opportunities for antimicrobial stewardship across the continuum of care.

The AUR Reporting Module enables clinicians to submit AUR data into the NHSN platform, thereby benchmarking their antibiotic usage and organism resistance data nationally to target areas for improvement.

Our approach for Real World Testing involves measuring our ability to successfully deliver our clients' AUR reports to NHSN.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Standard (and version)	N/A
Updated certification criteria and associated product	(No applicable standard updates)
Health IT Module CHPL ID	N/A
Date of ONC ACB notification	N/A
Date of customer notification	N/A
Conformance method and measurement/metric(s)	N/A

MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

Description of Measurement/Metric

Describe the measurement(s)/metric(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
Report Submissions	The total number of AUR files generated by BD for client submissions to NHSN
Electronic Health Information (EHI) Export	Export EHI for a single patient and multi-patient

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Report Submissions	170.315 (f)(6): Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting	N/A
Electronic Health Information (EHI) Export	170.315(b)(10): EHI Export criterion	N/A

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Report Submissions	This metric reveals that our clients can use our software for purpose of AUR reporting.
Electronic Health Information (EHI) Export	This metric will reveal that our clients will be able to export electronic health information securely and in a timely-manner.

Care Setting(s)

Care Setting	Justification
Infection Preventionist (IP)	BD HealthSight™ Infection Advisor with MedMined™ Insights (formerly MedMined™ Surveillance Advisor) standardizes the identification of all NHSN-reportable events and streamlines electronic submission through auto-populated NHSN Clinical Document Architecture (CDA). Our SmartForms improve the speed and accuracy of NHSN reporting by reducing the risk of manual data entry errors.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Report Submissions	By measuring successful report submissions, we are demonstrating that the electronic information exchanged is compliant and accepted by NHSN. We expect this number to be higher in certain months when higher submissions are required. In the event of an unsuccessful submission, our team will assist clients in correcting their data. From month to month, we will analyze our success rate and intervene accordingly.
Electronic Health Information (EHI) Export	By exporting electronic health information for a single patient, and multi patient, we are demonstrating that this electronic information can be exported successfully in a secure and timely manner.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Collection of test data begins	IP	01/01/2025
Collection of test data ends	IP	12/31/2025
Results submitted and publicly posted	IP	02/01/2026

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.ⁱⁱ

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: Ramya Mehta

Authorized Representative Email: Ramya.mehta@bd.com

Authorized Representative Phone: 1-858-617-1019

Authorized Representative Signature: Ramya Mehta

Date: 10/14/2024

ⁱ 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)

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