

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. 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: Lightning Step Technologies

Product Name(s): Lightning Step

Version Number(s): 1.0

Certified Health IT Product List (CHPL) ID(s): 15.04.04.3183.Ligh.01.00.1.231228

Developer Real World Testing Plan Page URL: <https://lightningstep.com/onc-certification>

Justification for Real World Testing Approach

Consistent with the ONC’s recommendation to “verify that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange,” this Real World Testing Plan is designed to document and validate the performance of certified capabilities in active use. This plan emphasizes the collection of real-world evidence, tracking the number of instances in which certified capabilities are utilized successfully within healthcare settings. In cases where adoption is limited or evidence capture is challenging, Lightning Step will conduct controlled demonstrations to simulate real-world deployment as closely as possible.

Real World Testing serves as an essential verification step in the Health IT Certification program, complementing but not duplicating the initial certification testing. Rather than revisiting previously demonstrated compliance, this plan aims to ensure that certified functionalities are effectively integrated and utilized by healthcare providers in actual clinical environments.

To verify real-world implementation and performance, our approach is structured around three main components:

1. **Adoption Rate:** This metric tracks usage rates of certified capabilities, providing insights into their practical value and relevance across different care settings. A high adoption rate indicates that the functionality is valuable and practical, whereas lower rates may prompt further investigation to understand usage patterns.
2. **Summative Testing:** By examining reports and audit logs, Lightning Step assesses the frequency and success of certified capabilities over specific time periods. High success rates from these assessments will serve as evidence of effective real-world implementation.
3. **Interactive Testing:** In instances where adoption rates are low or where updates to standards are required, live, interactive tests will validate the ongoing compliance and utility of the certified capabilities.

Through this methodology, Lightning Step aims to demonstrate both the reliability and value of our certified capabilities in supporting healthcare providers across various care settings.

Measurements/Metrics 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

- **Description of the Measurement/Metric:**
 - The adoption rate measures the frequency and consistency of the certified capability's use within healthcare settings. This metric reflects how widely the feature is adopted by users, providing insights into its relevance, ease of use, and value in real-world clinical workflows.
- **Associated Certification Criteria:**
 - This metric aligns with the ONC certification criterion for interoperability and data exchange, ensuring that the certified capability is utilized across

different healthcare environments. Certification criteria relevant here may include electronic health information (EHI) exchange standards and patient data access provisions.

- Care Setting(s) Addressed:
 - This measurement will apply across behavioral health settings, including outpatient clinics, addiction treatment centers, and other specialized care environments where certified EHR capabilities are critical to daily operations.
- Justification for Selected Measurement/Metric:
 - Adoption rate is a key indicator of the utility and practicality of certified capabilities. A high adoption rate suggests successful integration and alignment with user needs, while a lower rate may indicate potential usability barriers or need for additional support. This metric will help highlight care settings where the certified capabilities are most and least utilized
- Expected Outcomes:
 - Identify care settings with high adoption, affirming the capability's value.
 - Identify settings with lower adoption, prompting further analysis.
 - Overall, we expect to see moderate to high adoption rates across primary care settings, demonstrating effective deployment of certified features.

Summative Testing

- Description of the Measurement/Metric:
 - Summative testing involves generating periodic reports and reviewing audit logs to assess the frequency of certified capability usage. This testing method tracks specific actions within the certified EHR over defined timeframes, allowing for assessment of feature use and success rates.
- Associated Certification Criteria:
 - Summative testing aligns with criteria around data capture, documentation standards, and performance tracking to confirm that features are not only used but also effective in capturing necessary clinical information. These criteria help demonstrate that certified functionalities support interoperability and meet ONC compliance for accurate data recording
- Care Setting(s) Addressed:



- Behavioral health settings where structured data capture and record-keeping are essential, including addiction treatment and mental health facilities.
- Justification for Selected Measurement/Metric:
 - Summative testing provides quantifiable evidence of certified capability usage in real-world settings. By tracking successful versus unsuccessful actions, this metric can help identify operational challenges and confirm the capability's reliability across care settings.
- Expected Outcomes:
 - Expected outcomes include identifying frequent and successful usage patterns, indicating a smooth deployment.
 - Areas with low successful usage may suggest training or integration issues.
 - High success rates would indicate effective functionality that meets clinical needs.

Interactive Testing

- Description of the Measurement/Metric:
 - Interactive testing involves live, hands-on testing of certified capabilities, especially for features with low or zero adoption rates. This testing method serves as a real-time validation of ongoing compliance with updated standards and demonstrates functionality under semi-controlled conditions that mimic real-world scenarios.
- Associated Certification Criteria:
 - Interactive testing is aligned with ONC certification criteria for security, standard version advancements (SVAP), and feature compliance updates. These criteria require that certified health IT functionalities be maintained and validated periodically to remain compliant with current standards
- Care Setting(s) Addressed:
 - Interactive testing will be conducted across a selection of settings, including clinics and addiction treatment facilities, to reflect real-world environments where certified functionalities are essential.
- Justification for Selected Measurement/Metric:
 - This metric allows us to verify compliance even when real-world usage is limited, ensuring that certified capabilities are functional and compliant across different care settings. Interactive testing also provides valuable

insights into potential areas where usage is lower, offering opportunities to assess usability in a controlled environment.

- Expected Outcomes:
 - Expected outcomes include confirmed compliance with standards, even in cases of limited real-world usage.
 - The identification of any discrepancies between expected and actual performance, with an opportunity for immediate rectification.
 - Demonstrating continued adherence to updated interoperability and security standards.

Schedule of Key Milestones

1. Adoption Rate Baseline Establishment
 - Care Setting: Outpatient behavioral health clinics and addiction treatment centers
 - Date/Timeframe: Q3 2025
 - Details: Begin tracking the adoption rate of certified capabilities within initial test sites. This baseline data will capture early usage patterns and provide a reference point to compare changes in adoption over the testing period.
 - Data Collection: Monthly reports from usage logs, focusing on the frequency of capability utilization within the setting.
2. Summative Testing for Usage Frequency and Success Rates
 - Care Setting: Outpatient clinics, addiction recovery facilities, and mental health centers
 - Date/Timeframe: Mid-Q3 2025
 - Details: Conduct summative testing to gather data on the total number of successful and unsuccessful actions for certified functionalities. This milestone will also verify initial adoption rates and success rates after six months of testing.
 - Data Collection: Summative reports generated quarterly from audit logs, capturing action frequency and completion status.
3. Interactive Testing for Low-Adoption Capabilities
 - Care Setting: Facilities with low adoption or where usage data is sparse (e.g., smaller or specialized behavioral health centers)
 - Date/Timeframe: Mid-Q3 2025
 - Details: Conduct interactive, live testing for certified capabilities with low or zero adoption rates in select settings. This milestone will confirm

- functionality and compliance for features underrepresented in real-world usage data.
- Data Collection: Real-time interactive testing sessions, documented in reports with evidence of feature performance.
4. Mid-Point Review and Adjustment
- Care Setting: All participating behavioral health facilities
 - Date/Timeframe: End of Q3 2025
 - Details: Review data collected from adoption rates, summative testing, and interactive testing to assess progress and make adjustments to the testing plan as necessary. This checkpoint ensures the testing plan aligns with expected outcomes and identifies any emerging issues.
 - Data Collection: Summary report of all data collected thus far, with actionable insights and adjustments to be implemented in Q4 if needed.
5. Final Summative Testing and Outcome Analysis
- Care Setting: Comprehensive analysis across all participating care settings
 - Date/Timeframe: End of Q4 2025
 - Details: Conduct final summative testing across all sites to measure the cumulative adoption and success rates of certified capabilities over the full testing period. This milestone will confirm compliance, interoperability, and effectiveness of the certified functionalities.
 - Data Collection: Final report summarizing adoption, success rates, and interactive testing outcomes to verify real-world performance and overall impact.

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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