REAL WORLD TESTING PLAN

WellStack fka SymphonyCare - Empower™ Patient Portal & Engagement Suite

October 31, 2022

Background & Instructions

Under the ONC Health IT Certification Program (Program), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). 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 to develop 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 for 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 which 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 would expect that the Real-World Testing results report would include a description of these types of changes, the reasons for them, and how the intended outcomes were more efficiently met as a result. 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.

GENERAL INFORMATION

Plan Report ID Number:	[*For* ONC-Authorized Certification Body use only]
Developer Name:	*WellStack INC. (fka* SymphonyCare, LLC)
Product Name(s):	Empower™ Patient Portal & Engagement Suite
Version Number(s):	6.4
Certified Health IT Product List (CHPL) ID(s):	15.07.07.1681.IN02.03.00.1.191105
Developer Real World Testing Page URL:	https://www.wellstack.ai/onc-certification

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.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for clients to use at their discretion in live settings.

We are using a 2-fold approach to demonstrate successful real-world implementations.

Adoption Rate

Adoption rate will determine if/when a certified capability is being used in the real world and help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but did not by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might indicate a potential problem, of which there could be several different causes. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative Testing

Summative assessments will measure which certified actions were performed at the conclusion of a given time. These will be conducted by running reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

STANDARDS UPDATES

(INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

WellStack (fka SymphonyCare) has not updated Empower™ Patient Portal & Engagement Suite to any new standards as part of SVAP or the Cures Update criteria as of this date.

MEASURES 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

The following metrics are applicable to all criteria 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 participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

> **Metric**: Number of sites with a licensed instance of certified Health IT module.

> **Description**: Identify the total number of licensed sites using the certified Health IT module. Each site may have multiple users.

SUMMATIVE ASSESSMENT METRICS

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given period. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases, we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful when demonstrating interoperability with outside systems. When it is impossible to determine "success" via an explicit confirmation by a receiving system, success is defined as a transmission made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

None of the following criteria was updated to the Cures Update version of the criteria prior to August 31, 2021. As a result, all testing will be conducted against the 2015 Edition version of the criteria.

CARE SETTINGS

Empower™ Patient Portal & Engagement Suite specializes in Inpatient as well as Outpatient / Ambulatory care settings. While the clinical workflow may be different between different care settings, the use of the certified criteria is the same.

Care Setting	Justification
Inpatient	The product is extensively used in this care setting, thereby allowing the performing of real-world testing without any hindrances.
Outpatient / Ambulatory	The product is extensively used in this care setting, thereby allowing the performing of real-world testing without any hindrances.

Associated Certification Criteria

170.315(e)(1) View, download, and transmit to 3rd party

Functional requirement: Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a third party. Such access must be consistent and in accordance with the standard adopted in §170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in §170.204(a)(2).

Metric	Care Setting	Justification and Expected Outcome
1. Number of requests for a patient ID or token 2. Number of requests that provided sufficient information to provide a valid response 3. Number of follow-up requests made using the provided patient ID or token	▪ Inpatient Care ▪ Outpatient / Ambulatory Care	This criterion requires the certified Health IT module to provide Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a third party. We intend to record the frequency Patients (and their authorized representatives) use internet-based technology to view, download, and transmit their health information to a third party to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be high utilization by patients (and their authorized representatives) with a high success rate.

Associated Certification Criteria

170.315(g)(7) Application access — Patient Selection

<u>Functional requirement:</u> The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data.

Metric	Care Setting	Justification and Expected Outcome
1. Number of requests for a patient ID or token 2. Number of requests that provided sufficient information to provide a valid response 3. Number of follow-up requests made using the provided patient ID or token	▪ Inpatient Care ▪ Outpatient / Ambulatory Care	This criterion requires the certified Health IT module to provide an API and supporting documentation that enables external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. We intend to record the frequency that providers receive patient ID requests via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

Associated Certification Criteria

170.315(g)(9) Application Access — All Data Request

Functional requirements:

(A) Respond to requests for patient data (based on an ID or other token) for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard specified in §170.205(a)(4) following the CCD document template.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

Metric	Care Setting	Justification and Expected Outcome
Over a 90-day period: 1. Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token 2. Number of requests for a patient's data made by an application via a data category request using a valid patient ID or token for a specific date range	▪ Inpatient Care ▪ Outpatient / Ambulatory Care	This criterion requires the certified Health IT module to provide an API and supporting documentation that enables external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

Schedule of Key Milestones

Due Date	Description
10/17/2022	WellStack to submit first draft of CY22 RWT plan to ICSA Labs for review
11/14/2022	ICSA Labs to complete review of plans and communicate results to WellStack
12/15/2022	Approved RWT Plans to be submitted by ICSA Labs to the ONC
2/1/2023	WellStack to identify client list for Real World Testing
4/1/2022	WellStack to schedule identified clients for Real World Testing
6/1/2023	WellStack to analyze WRT outcomes with identified clients
8/1/2023	WellStack to submit first draft of CY22 RWT results to ICSA Labs for review
2/16/2024	ICSA Labs to complete review of RWT results and communicate results to WellStack
3/1/2024	WellStack to submit revised records of results if applicable
3/15/2024	Approved RWT results to be submitted by ICSA Labs to the ONC

Attestation

Date: October 31, 2022

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