

REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20241202end02

Developer Name: EndoSoft LLC

Product Name(s): Qlinical

Version Number(s): 1

Product List (CHPL) ID(s): 15.02.05.2721.QLIN.01.01.1.220310

Developer Real World Testing Page URL:

https://www.endosoft.com/endosoft_rwt_plans/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

EndoSoft LLC markets its Qlinical Cloud-Based EHR, a specialty-based product, to clients (physicians and clinicians) of small practice clinics, and surgery centers in an out-patient setting. The Qlinical EMR's use is in the GI and Pulmonary fields. The EndoSoft Real World Testing plan will be applied to those settings. Specifically, the Electronic Health Information export workflow will be tested. This will require interfacing with external EMR systems and other third-party applications. Testing in this manner will demonstrate interoperability and functionality of the Qlinical EMR in real world settings and scenarios and will also validate that the element is compliant with the certification criteria standards.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP)

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	15.02.05.2721.QLIN.01.01.1.220310
Date of ONC ACB notification	N/A
Date of customer notification	N/A
Conformance method and measurement/metric(s)	Use Case

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

Measurement/Metric	Description
Use Case/ § 170.315(b)(10)	<p>Description</p> <p>Data is gathered by observing the actions of a clinical user during execution of this specific EHR application module workflow. The EHR data is then formatted and tabulated to review for criteria compliance, effectiveness, and efficiency.</p>

ASSOCIATED CERTIFICATION CRITERIA

Certification Criteria	Requirement
§ 170.315(b)(10) <u>Electronic Health Information export</u>	<p>(b)(10)(i)(A) Enable a user to timely create an export file(s) with all of a single patient’s electronic health information stored at the time of certification by the product, of which the Health IT Module is a part.</p> <p>(b)(10)(i)(B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.</p> <p>(b)(10)(i)(C) Limit the ability of users who can create export file(s) in at least one of these two ways: (1) To a specific set of identified users (2) As a system administrative function.</p> <p>(b)(10)(i)(D) The export files(s) created must be electronic and in a computable format.</p> <p>(b)(10)(i)(E) The publicly accessible hyperlink of the export’s format must be included with the exported file(s)</p> <p>(b)(10)(ii) Create an export of all the electronic health information that can be stored at the time of certification by product of which the Health IT Module is a part.</p> <p>(b)(10)(iii) The exported format(s) used to support paragraphs (b)(10)(i) and (ii) of this section must be kept up-to-date.</p>

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC



Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

Measurement/Metric	Justification and Expected Outcome
<u>Use Case</u>	<p><u>Justification-</u> When assessing the Qlinical Cloud-Based EHR, a specialty based clinical application used by small practice clinics, and surgery centers as their primary electronic medical record, the Use Case measure is the optimum method to evaluate the workflow in each of the associated criteria for compliance and usability.</p> <p><u>Methodology-</u> EndoSoft will provide the steps to perform each requirement of the criteria and score the results based on a predetermined rationale.</p> <p><u>Expected outcome of use case testing-</u> A user data sheet that includes participant demographics, errors, successes, workflow timing and satisfaction. Findings will be based on Effectiveness (Success/Failure); Efficiency(time to perform) and Satisfaction(ease of use scale)</p>
<u>Associated criteria that will be tested by Use Case</u>	
§ 170.315(b)(10) Electronic Health Information export- Relied Upon SW = NA	

CARE SETTING(S)

Care Setting	Justification
<i>Out-patient (Ambulatory) settings with the clients being small practice Clinics and surgery centers.</i>	EndoSoft LLC markets its Qlinical Cloud-Based EHR, a specialty-based product, to clients (physicians and clinicians) of small practice clinics, and surgery centers in an out-patient setting. The two largest specialties using the EHR are in the GI and Pulmonary medical fields. These two specialties are indicative of all care settings and specialties where Qlinical is marketed and utilized. Where feasible, EndoSoft will incorporate real patient data and real environments. Focus of the Real-World Testing will occur within this environment.

EXPECTED OUTCOMES

The Use Case approach to real world testing will confirm that the product is exchanging EHI securely and in the care and practice settings for which it is marketed and used.

Only a physician can perform specific functions and Qclinical will be conformant to the required measure with less than 1% error rate

Qclinical only provides access to specific patient data. The API will provide a metric to access the rest of the patient PHI. Additionally, the credential required to view PHI is passed through the API so only authorized users will have access to PHI.

Produced documents can be viewed only by the target users. If the clinical tester is not allowed to view a restricted document, Qclinical displays an informational message.

Restricted users are unable to create or send the patient reports.

Qclinical will create data files in(XML/QRDA) format.

The Use Case approach to real world testing will confirm that the output from the functions performed are compliant with the standard's certification criteria.

The Use Case approach to real world testing will demonstrate the interoperability and functionality of the EMR in real world settings and scenarios indicating its Effectiveness (Success/Failure); Efficiency(time to perform) and Satisfaction(ease of use scale)

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Candidate list established	Small practice clinics, and surgery centers	January, 2025
The documentation for the Real-World Testing will be provided along with the customer agreements.	Small practice clinics, and surgery centers	End February, 2025
Test start, Data Collection begins	Small practice clinics, and surgery centers	Begin 2nd quarter, April, 2025
Follow-up with client on a monthly basis to understand any issues arising with the data collection	Small practice clinics, and surgery centers	2nd and 3rd quarter, 2025
End of Real-World Testing. Collect all data and create final report.	Small practice clinics, and surgery centers	End 4th quarter, 2025

Submit Testing Report.	Small practice clinics, and surgery centers	January 2026
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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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