

REAL WORLD TESTING RESULTS REPORT

GENERAL INFORMATION

Report ID Number	20241202end01
Developer Name	EndoSoft LLC
Product Name(s)	EndoVault
Version Number(s)	3.2
Certified Health IT Product List (CHPL) ID(s)	15.02.05.2721.ENDV.01.01.1.220310
Developer Real World Testing PLAN Page URL	https://www.endosoft.com/endosoft_rwt_plans/
Developer Real World Testing RESULTS Page URL	https://www.endosoft.com/endosoft_rwt_plans/

CHANGES TO ORIGINAL PLAN

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	Reason [Describe the reason this change occurred]	Impact [Describe what impact this change had on the execution of your Real World Testing activities]
1. EndoSoft added the 2025 Real World test criteria to the training documentation as an exercise for 4 recently hired technical support personnel. The participants equipment and EHR application was pointed to EndoSoft's EndoAccess in-house server, which contains the synthetic data that represented the data within a customer's production server. Each RWT criteria in the original plan that did not require relied upon software,	Unable to Identify a client that was actively using any of the RWT criteria in our EndoSoft EndoVault EHR. EndoSoft opted to use synthetic data and engage participants in the EndoSoft office that best represents our client's environment.	The number of participants in the test was reduced which could cause the useability results to be less accurate. Our support participants gained valuable experience with this functionality and provided helpful feedback even though it was not a clinical setting.

	was represented as a task for the participants to execute in a useability test scenario. 170.315(b)(11) was an addition to the task list that was not included in the original plan. During the testing, the participants user performance data was collected to evaluate effectiveness, efficiency and user satisfaction. Screen shots of user results were also collected to show successful functionality of the criteria.		
2.	Real World testing criteria that did require a 3rd party (Relied Upon) software to execute was tested and verified internally by the development team using data analysis in the same manner that was used for the original certification.	The criteria that functioned with relied upon software required Data Analysis to be completed by the software development team because the personnel doing the Use Case method did not have access to the tools to perform the data analysis	The software development participants provided helpful feedback regarding the usage of the relied upon software .
3.	170.315(b)(1),170.315(c)(1), 170.315(g)(7),170.315(g)(9), 170.315(g)(10), were tested by using the Data Analysis method rather than Use Case Method.	There was an error in the Description in the Measurement/Metric section of the original plan that listed 170.315(b)(1) 170.315(c)(1) being tested by the Use Case method and did no depend on relied upon software. 170.315(b)(1) and 170.315(c)(1) do depend on relied upon software (RUS) so these were tested using the Data Analysis Method. 170.315(g)(7), 170.315(g)(9), and 170.315(g)(10) were tested using the Data Analysis because only the technical personnel doing the Data Analysis method had the the tools to perform the evaluate the expected outcome data.	No impact on testing activities or expected outcome

WITHDRAWN PRODUCTS

Product Name(s):	N/A
Version Number(s):	
CHPL ID(s):	
Date(s) Withdrawn:	
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Summary of Testing Methods:

Use Case

The objective of the Use Case testing was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test serves as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

In usability testing, the participants interacted with the EndoVault 3.2 EHR by completing a series of 15 tasks. Each task representing a specific RWT criteria. All users are provided with the same instructions. The exercises are evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed without assistance
- Number and types of errors
- Path deviations
- Participants' verbalizations (comments)
- Participants' satisfaction ratings of the system

Data Analysis

The Data Analysis approach was to confirm that the product is exchanging EHI securely in the care and practice settings for which it is marketed and used. The user creates a data file and transmits a specific data flow from EndoVault to a registry where EndoSoft can perform the data analysis to evaluate for associated criteria compliance. This was accomplished by EndoVault technical personnel exercising the criteria then performing physical data analysis of the results of exercising the criteria and comparing with the expected outcomes.

Key Findings:

Criteria tests and Data analysis were completed in July 2025 by 2 of the EndoSoft /EndoVault technical personnel.

170.315(g)(7) Application Access-patient selection

170.315 (g)(9) Application Access all data request

170.315(g)(10), Standardized API for patient and population services

The EndoVault RESTful API is a service developed at EndoSoft for accessing the patient's data. Representational State Transfer (REST) is a style of software architecture for distributed hypermedia systems such as the World Wide Web. REST-style architectures consist of clients and servers. Clients initiate requests to servers; servers process requests and return appropriate responses. Requests and responses are built around the transfer of "representations" of "resources". A resource can be essentially any coherent and meaningful concept that may be addressed. A representation of a resource is typically a document that captures the current or intended state of a resource.

The EndoVault RESTful API is a simple service implemented using HTTPS and can be thought of as a collection of resources, specified as URLs. Some characteristics of the EndoVault RESTful web API:

- The base URL for the web service is https://< service url>
- The service can return the data in CCD XML format.
- The service only supports HTTPS method POST, since it is designed to retrieve patient's data.

Clients of the EndoVault RESTful API can be any applications that support HTTPS POST.

Secure channel can be tested from any web browser such as Internet Explorer, Google Chrome or Firefox etc

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Indicate as to whether optional standards, via SVAP are leveraged as part of the certification of your health IT product(s).

☒ Yes, I have products certified with voluntary SVAP standards. (If yes, please complete the table below).

☐ No, none of my products include these voluntary standards

Standard (and version)	170.215(b)(1)(i) 5.0.1 HL7® FHIR® US Core Implementation Guide STU 5.0.1, June 2022 170.215(c)(2) HL7® FHIR® SMART Application Launch Framework Implementation Guide HL7® FHIR® Bulk Data Access (Flat FHIR®) (v2.0.0: STU 2), November 26, 2021
Updated certification criteria and associated product	g(10) for EndoVault
Health IT Module CHPL ID	15.02.05.2721.ENDV.01.01.1.220310
Conformance measure	Use Case

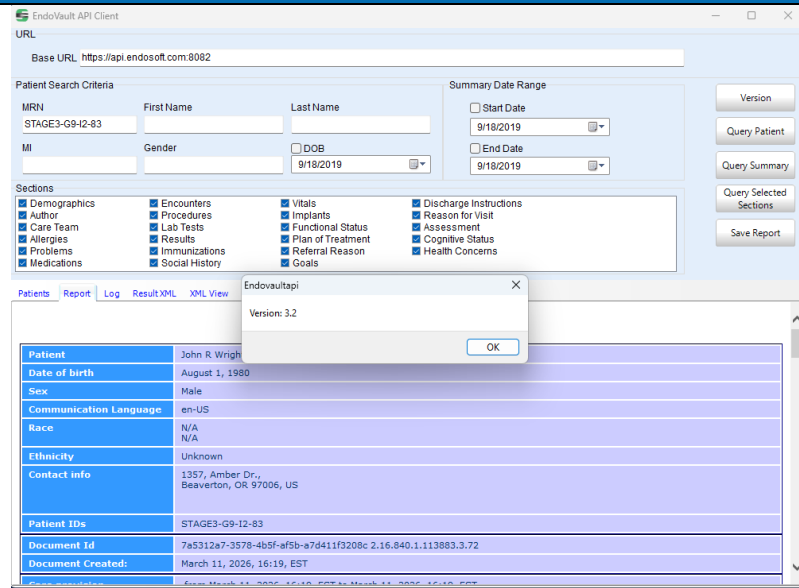
Care Setting(s)

Unable to identify a willing client within a care setting who's workflow utilized any of the certification criteria with the EndoSoft EndoVault EHR.
The criteria testing was done in house by technical support personnel using synthetic clinical data.

Metrics and Outcomes

(from 85 FR 25766)

Measurement/Metric	Description
Use Case/ §170.315(b)(2), § 170.315(b)(3), §170.315(b)(7), § 170.315(b)(8), § 170.315(b)(9), § 170.315(b)(10), § 170.315(f)(1), § 170.315(f)(2), § 170.315(f)(3), § 170.315(f)(4), § 170.315(f)(5), § 170.315(f)(6), § 170.315(f)(7),	<u>Test Description</u> Data is gathered by recording the actions of a user during execution of specific EHR application module workflows. The EHR data is then formatted and tabulated to review for criteria compliance, effectiveness, and efficiency and satisfaction. -Number of tasks successfully completed without assistance -Number and types of errors -Path deviations -Participants' verbalizations (comments) -Participants' satisfaction ratings of the system
Data Analysis/ Relied upon SW § 170.315(c)(1) / Pop Health § 170.315(c)(2)/ Pop Health § 170.315(c)(3)/Pop Health § 170.315(b)(1)/Max MD § 170.315(e)(1)/Max MD § 170.315(h)(1)/ Max MD	<u>Test Description</u> The user creates a data file and transmits a specific data flow from EndoVault to a registry where EndoSoft can perform the data analysis to evaluate for associated criteria compliance.
Data Analysis / No Relied upon SW	170.315(g)(7-10) Data Analysis Outcomes
§ 170.315(g)(7), Application Access-patient selection Standardized API for patient and population services / API	The health IT can 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. (See Figure 1-g(7) for outcome of test



The screenshot shows the EndoVault API Client interface. At the top, there's a 'Base URL' field set to 'https://api.endosoft.com:8082'. Below this is the 'Patient Search Criteria' section with fields for MRN (STAGE3-G9-12-83), First Name, Last Name, MI, Gender, and DOB (9/18/2019). To the right is the 'Summary Date Range' section with 'Start Date' and 'End Date' both set to 9/18/2019. On the far right are buttons for 'Version', 'Query Patient', 'Query Summary', 'Query Selected Sections', and 'Save Report'. Below the search criteria is a 'Sections' section with a grid of checkboxes for various data categories like Demographics, Encounters, Vitals, Discharge Instructions, etc. At the bottom, there's a 'Patients' tab and a 'Report' tab. The 'Report' tab is active, showing a table of patient data. A small 'Endovaultapi' dialog box is open over the table, displaying 'Version: 3.2' and an 'OK' button.

Patient	John R. Wright
Date of birth	August 1, 1980
Sex	Male
Communication Language	en-US
Race	N/A
Ethnicity	Unknown
Contact info	1357, Amber Dr., Beaverton, OR 97006, US
Patient IDs	STAGE3-G9-12-83
Document Id	7a5312a7-3578-4b5f-af5b-e7d411f3208c 2.16.840.1.113883.3.72
Document Created:	March 11, 2026, 16:19, EST

Figure 1 – g(7)

- The API includes accompanying documentation and the Hyperlink for the API and is publicly accessible. See the following links.

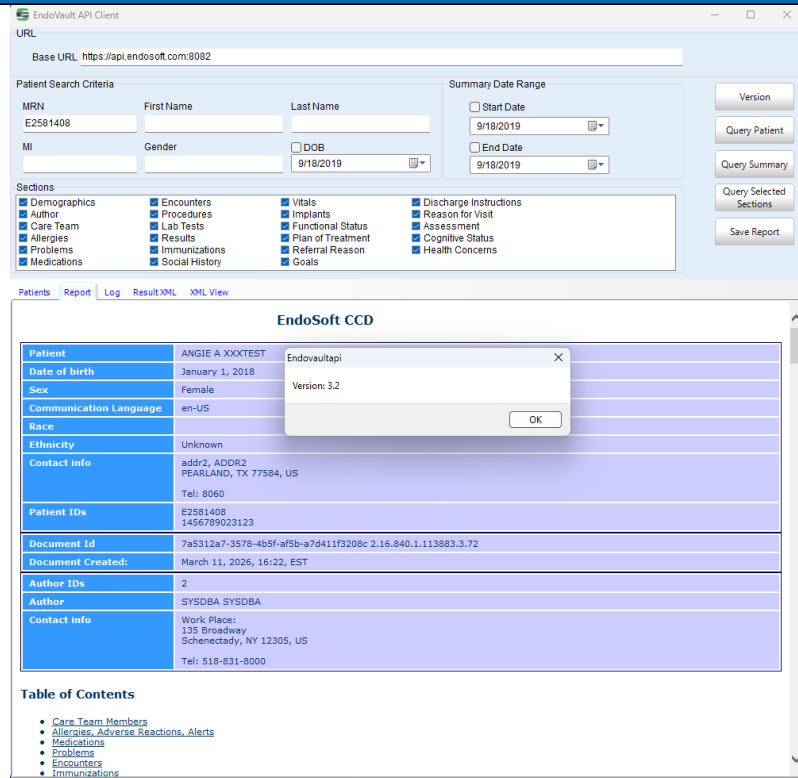
[170_315_g8_g9_applicationaccess.pdf](#)

[Secure Patient Data Access | EndoSoft® FHIR API](#)

fhirapi.endosoft.com/apiendpoints.json

§ 170.315(g)(9) Application Access all data request/API

- The API responds to requests for patient data associated with a specific date as well as with a specific date range. (Figure 2 – g(9) for outcome of test.



The screenshot shows the EndoVault API Client interface. At the top, there's a 'Base URL' field set to 'https://api.endosoft.com:8082'. Below this is a 'Patient Search Criteria' section with fields for MRN (E2581408), First Name, Last Name, MI, Gender, and DOB (9/18/2019). There's also a 'Summary Date Range' section with 'Start Date' and 'End Date' both set to 9/18/2019. A 'Sections' section lists various data categories like Demographics, Encounters, Vitals, Discharge Instructions, etc. On the right, there are buttons for 'Version', 'Query Patient', 'Query Summary', 'Query Selected Sections', and 'Save Report'. Below the search criteria is a 'Patients' tab with a 'Report' button. The main content area displays the 'EndoSoft CCD' for a patient named 'ANGIE A XXXTEST'. The patient's information includes Date of birth (January 1, 2018), Sex (Female), Communication Language (en-US), Race (Unknown), and Contact info (address, phone, etc.). A 'Table of Contents' is also visible at the bottom, listing sections like Care Team Members, Allergies, Adverse Reactions, Alerts, Medications, Problems, Encounters, and Immunizations.

Figure 2 – g(9)

- The API includes accompanying documentation and the Hyperlink for the API and is publicly accessible. See the following links
[170_315_g8_g9_applicationaccess.pdf](#)
[Secure Patient Data Access | EndoSoft® FHIR API](#)
fhirapi.endosoft.com/apiendpoints.json

§ 170.315(g)(10), Standardized API for patient and population services /API

- Application can register with the Health IT Module’s “authorization server.”
- Established a secure and trusted connection with an application that requests data for patient and user scopes
- First time connections, authentication and authorization occur during the process of granting access to patient data.
- Health IT Module’s authorization server is able to revoke and must revoke an authorized application’s access at a patient’s direction within one hour of the request.
- Health IT Module’s authorization server is able to receive and validate tokens it has issued

See Figure 3 g(10) endpoints

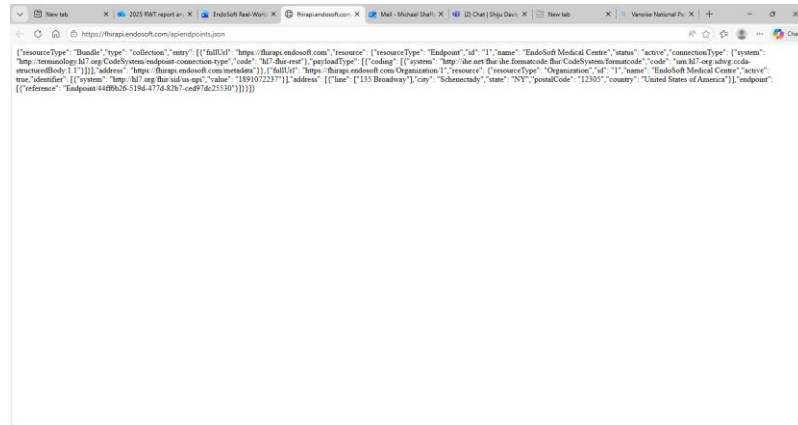


Figure 3 g(10) endpoints

- The API includes accompanying documentation and the Hyperlink for the API and is publicly accessible. See the following links
[170_315_g8_g9_applicationaccess.pdf](#)
[Secure Patient Data Access | EndoSoft® FHIR API](#)
fhirapi.endosoft.com/apiendpoints.json

KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Development and support teams put infrastructure in place to support testing and relied upon SW	Onsite- EndoSoft headquarters	06/02/25 thru 06/09/25
Technical Support trainees perform the series of tasks to exercise the criteria that require Real World Testing	Onsite- EndoSoft headquarters	06/23/25 thru 07/01/25
Development team execute and analyze criteria that require relied upon software	Onsite- EndoSoft headquarters	07/01/25-07/10/25
Organize test data, Analyze test results then provide report.		06/23/25- 07/11/25