REAL WORLD TESTING RESULTS REPORT

GENERAL INFORMATION

Report ID Number	20231206end
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]
EndoSoft added the 2024 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, was represented as a task for the participants to execute in a	Unable to Identify a client that was actively using any of the RWT criteria in our EndoSoft EndoVault EHR. So we opted to use synthetic data and participants in the EndoSoft office that best represents our client's environment.	Negative impact: The number of participants in the test was reduced which could cause the useability results to be slightly less accurate. Positive impacts: Because our customers do not utilize the criteria, our support participants gained valuable experience with this functionality and provided helpful feedback even though the test was not done in a clinical setting..

useability test scenario. 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. 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.		

WITHDRAWN PRODUCTS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Date(s) Withdrawn:	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:

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.

During the usability test, the 4 participants interacted with the EndoVault 3.2 EHR by completing a series of 14 tasks. Each task representing a specific RWT criteria. All users were provided with the same instructions. The exercises were 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

The Data Analysis approach on the relied upon software criteria was to confirm that the product is exchanging EHI securely in the care and practice settings for which it is marketed and used. This was accomplished by physical data analysis of the results of exercising the criteria.

Key Findings:

Use Case Testing

EFFECTIVENESS

The results of the testing performed indicated the application was quite effective in providing medical practices with what they need and what the medical professionals require., The task success rate for all participants for the 14 tasks was 100 % with each of the mean task times at or below the optimum times.

EFFICIENCY

According to the data collected during the usability test it seems that the application was quite efficient overall. No participants had deviations from the optimal path, most users navigated through the optimal paths easily and the 14 tasks were accomplished at or below the allotted time for each of the tasks.

SATISFACTION

Based on a mean System Usability Scale of 54.3 and the mean User Rating of 4.3 out of 5 for the tasks, overall the satisfaction with the EHR was high.

Data Analysis

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

MAJOR FINDINGS

Based on the data provided by the participants, the application seemed to be easy to use and simple for the users and contains functionality which is very customizable allowing clinical sites of any size to use it. Most of the participants were able to navigate quite efficiently. There was a participant who commented that they had some difficulties navigating or entering data with some of the tasks. But others said it was easy to navigate and each participant commented that they would recommend this system.

During the Data Analysis tests we found that that there were 4 different criteria that failed testing.

170.315 (c)(1) Clinical Quality Measures – Record and Export

170.315 (c)(2) Clinical Quality Measures - Import and Calculate

170.315(c)(3) Clinical Quality Measures - Report

170.315 (b)(1) Transitions of care CDA(C-CDA), CCD

170.315 (c)(1) Clinical Quality Measures – Record and Export, 170.315 (c)(2) Clinical Quality Measures - Import and Calculate; 170.315(c)(3) Clinical Quality Measures – Report Failed when connecting to the relied upon software (Pop Health). Determining the connection error is difficult because POP Health has now gone end of life and is difficult to get support for the investigation.

170.315 (b)(1) Transitions of care CDA(C-CDA),CCD Failed the negative tests with MaxMD. EndoSoft has

engaged with MaxMD and they are providing support to troubleshoot the negative tests.

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AREAS FOR IMPROVEMENT

Comments from participants:

It can be slow at times

Some buttons are confusing

The nested tabs take some getting used to.

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 and/or USCDI, are leveraged as part of the certification of your health IT product(s).

__X__ Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below).
____ No, none of my products include these voluntary standards

Standard (and version)	USCDI v1
Updated certification criteria and associated product	b1, b2, e1, f5, g9 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 client within a care setting who's workflow utilized any of the certification criteria with the EndoSoft EndoVault EHR. The testing was done in house by 4 recently hired technical support personnel in training using synthetic clinical data. Use Case criteria which needed relied upon software was completed and analyzed by the EndoSoft software development team.

Metrics and Outcomes

Measurement/Metric	Description
Use Case/Relied Upon SW §170.315(b)(2), § 170.315(b)(3), /SureScripts §170.315(b)(7), § 170.315(b)(8), § 170.315(b)(9), § 170.315(b)(10), § 170.315(e)(1) /MaxMD § 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),	**Description** 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)/ MaxMD § 170.315(g)(7), N/A § 170.315(g)(9), N/A § 170.315(g)(10), N/A § 170.315(h)(1). MaxMD	**Description** The user will be asked to create a data file and transmit a specific data flow from EndoVault to a registry where EndoSoft can perform the data analysis to evaluate for associated criteria compliance.

Data analysis Criteria Outcomes

The outcome of exercising 170.315(g)(10), Standardized API and displaying the proper fields for 170.315(g)(7) Application Access-patient selection and 170.315 (g)(9) Application Access all data request for patient and population services and 170.315(h)(1) Direct Project; while performing the data analysis method, indicated that EHI is transmitted/received and formatted in compliance with the certification requirements.

When 170.315 (c)(1) Clinical Quality Measures – Record and Export, 170.315 (c)(2) Clinical Quality Measures - Import and Calculate; 170.315(c)(3) Clinical Quality Measures – Report, and 170.315 (b)(1) Transitions of care CDA(C-CDA),CCD were tested the outcome for each was a failure to meet the certification requirements. (c)(1) (c)(2) and (c)(3) and (b)(1) require relied upon software to meet the certification requirements.

EndoVault's (c)(1) (c)(2) and (c)(3) criteria have been updated since initial testing with the relied upon SW resulting in

some incompatibilities with the initial verified version of the relied upon SW.

When (b1) was last tested successfully, MaxMD, partnered with EndoSoft and was used to validate, through MaxMD logs, the correct execution of secure messaging interoperability. To determine the exact cause of the failure EndoSoft will again collaborate with MaxMD to determine root cause of the messaging failure.

Use Case Criteria Outcomes

Table 1 contains the Use Case results for each of the 4 participant's 14 tasks that were performed and details of how those tasks were measured.

Measure / Task	N	Task Success (%)	Path Deviation (steps)	Task Time (Seconds)		Errors (%)	Task Ratings (Likert Scale) 5=Very Easy
	#	Mean (SD)	Deviations (Observed/Optimal)	Mean (SD)	Dev (Obs /Opt)	Mean (SD)	Mean
Task 2: Reconcile and incorporate clinical information § 170.315(b)(2)	4	4/4 100% 1 (0)	0/4	15 (4)	15/20	0 (0)	4.8 (.6)
Task 3: Send a Prescription § 170.315(b)(3)	4	4/4 100% 1 (0)	0/4	16 (6)	16/20	0 (0)	5 (0)
Task 4: Export the summary of care document with security tag § 170.315(b)(7)	4	4/4 100% 1 (0)	0/4	22 (11)	22/20	0 (0)	4 (0)
Task 5: Import summary of care document § 170.315(b)(8)	4	4/4 100% 1 (0)	0/4	20 (16)	20/10	0 (0)	4.3 (.5)
Task 6: Treatment plan(recommendation) 170.315(b)(9)	4	4/4 100% 1 (0)	0/4	18 (5)	18/15	0 (0)	4.7 (.5)
Task 7: Export the summary of care document without security tag § 170.315(b)(10)	4	4/4 100% 1 (0)	0/4	19 (5)	19/25	0 (0)	4.7 (.5)

Task 8: View, download and transmit CCD documents to third party using patient portal § 170.315(e)(1)	4	4/4 100% 1 (0)	0/4	21 (12)	21/20	0 (0)	4.3 (.7)
Task 9: Transmission to immunization registries § 170.315(f)(1)	4	4/4 100% 1 (0)	0/4	20 (2)	20/20	0 (0)	4.8 (0)
Task 10: Transmission to public health agencies (surveillance) § 170.315(f)(2)	4	4/4 100% 1 (0)	0/4	17 (5)	17/20	0 (0)	4.8 (.6)
Task 11: Transmission to public health agencies — reportable laboratory tests and value/results § 170.315(f)(3)	4	4/4 100% 1 (0)	0/4	31 (11)	31/40	0 (0)	4 (0)
Task 12: Transmission to cancer registries § 170.315(f)(4)	4	4/4 100% 1 (0)	0/4	19 (3)	19/20	0 (0)	4.5 (.5)
Task 13: Transmission to public health agencies — electronic case reporting § 170.315(f)(5)	4	4/4 100% 1 (0)	0/4	17 (4)	17/20	0 (0)	4.8 (.6)
Task 14: Transmission to public health agencies — antimicrobial use and resistance reporting § 170.315(f)(6)		4/4 100% 1 (0)	0/4	15 (4)	15/20	0 (0)	4.8 (.6)
Task 15: Transmission to public health agencies —health care surveys § 170.315(f)(7)		4/4 100% 1 (0)	0/4	17 (8)	17/20	0 (0)	5 (0)

Table 1- Results and Measures of the Use Case Criteria

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.	Onsite- EndoSoft headquarters	06/23/25-07/11/25