REAL WORLD TESTING RESULTS REPORT

GENERAL INFORMATION

Report ID Number	20230417END
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]
The test plan was changed to perform a Usability Test on the single criteria for § 170.315(b)(1) Transitions of care CDA (C-CDA),CCD, Discharge Summary	Unable to Identify a willing client that was actively using any of the other certification criteria within our EndoVault EHR. EndoSoft eventually identified 1 existing client that was utilizing the EndoVault interface used for § 170.315(b)(1) Transitions of care CDA (C-CDA),CCD, Discharge Summary.	Very much limited the usage data that could be acquired.
Ultimately unable to execute any portion of the § 170.315(b)(1) Transitions of care CDA (C-CDA),CCD, Discharge Summary	During the rollout of the planned test we found that the identified client was utilizing the EndoVault EHR CCD interface in their workflow but only to pull the patient pre-procedure	Failed to rollout/perform usability test at the customer site. No criterion in the secondary plan was tested.

usability test.	information from their main Epic EHR to complete EndoSoft's pre-procedure form within the EndoVault EHR.	

WITHDRAWN PRODUCTS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Date(s) Withdrawn:	
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products.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

Overall, the objective of this usability test 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 was to serve 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, participants were to interact with the EndoVault 3.2 EHR. Each participant was to use the EndoVault 3.2 under the supervision of the site administrator. The Usability test was to be conducted in a clinical setting with specialties in the GI and Pulmonary fields. All users would have been provided with the same instructions. The criteria was to be 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 Use Case approach was to confirm that the product is exchanging EHI securely and in the care and practice settings for which it is marketed and used.

Our attempt at the updated test resulted in a lack of findings. During the rollout of the planned test we found that the identified client was utilizing the EndoVault EHR CCD interface in their workflow but only to pull the patient pre-procedure information from their main Epic EHR to complete EndoSoft's pre-procedure form

within the EndoVault EHR.

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).

____ 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)	No
Updated certification criteria and associated product	
Health IT Module CHPL ID	
Conformance measure	

Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use.

List each care setting that was tested.

Attempted the testing at Suburban Gastroenterology Midwest Endoscopy Center

Metrics and Outcomes

Health IT developers should detail outcomes from their testing that successfully demonstrate that the certified health IT:

1. is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;

2. is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
3. EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Health IT developers could also detail outcomes that did not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
Use Case/ § 170.315(b)(1)	§ 170.315(b)(1)	No	EndoSoft was not able to perform test plan. Failed to rollout/perform usability test at the customer site. No criterion in the secondary plan was tested.	During the rollout of the planned test we found that the identified client was utilizing the EndoVault EHR CCD interface in their workflow but only to pull the patient pre-procedure information from their main Epic EHR to complete EndoSoft's pre-procedure form within the EndoVault EHR.

KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe
Possible client using criteria identified and test plan updated	Clinical Center	Jan 2023

Client workflow understood and found that the identified client was utilizing the EndoVault EHR CCD interface in their workflow but only to pull the patient pre-procedure information from their main Epic EHR to complete EndoSoft's pre-procedure form within the EndoVault EHR n	Clinical Center	April 2023