REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20241202end01

Developer Name: EndoSoft LLC

Product Name(s): EndoVault

Version Number(s): 3.2

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

Developer Real World Testing Page URL:

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

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

The EndoVault EMR system is a specialty-based application used in out-patient settings with the clients being surgery centers, clinics, and hospitals around the country. The EndoVault EMR's primary use is in the GI and Pulmonary fields. The EndoSoft Real World Testing plan will be applied to those settings. Specifically, elements of Care Coordination; Clinical Quality Measures; Patient Engagement; Public Health; Utilization; and Optional Care Coordination workflows 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 EndoVault EMR in real world settings and scenarios and will also validate that each of the elements is compliant with the certification criteria standards.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP)

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
Date of ONC ACB notification	12/07/2022

Date of customer notification	5/10/2023
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)(1), §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(c)(1), § 170.315(e)(1), § 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), § 170.315(g)(7), § 170.315(g)(9), § 170.315(g)(10), § 170.315(h)(1)	**Description** Data is gathered by observing the actions of a clinical 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.
Data Analysis/ § 170.315(c)(2), § 170.315(c)(3)	**Description** The clinical 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.

ASSOCIATED CERTIFICATION CRITERIA

Certification Criteria	Requirement
§ 170.315(b)(1) Transitions of care CDA (C-CDA),CCD, Discharge Summary	(b)(1)(i) - Send and Receive via Edge Protocol Technology must be able to: (A) Send transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a); and (B) Receive transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a)(2). (C) XDM processing. Receive and make available the contents of a XDM

	package formatted in accordance with the standard adopted in § 170.205(p)(1) when the technology is also being certified using an SMTP-based edge protocol. §170.205(p)(1) XDM package processing. IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) (incorporated by reference in § 170.299).
§ 170.315(b)(2) Clinical information reconciliation and incorporation-	(i) General Requirements Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (for inpatient setting only) Discharge Summary document templates. (ii) Correct Patient Upon receipt of a transition of care/referral summary formatted according to the standards adopted at § 170.205(a)(3) and § 170.205(a)(4), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient. (iii) Reconciliation Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type: (A) Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date; (B) Enable a user to create a single reconciled list of medications, medication allergies, or problems; (C) Enable a user to review and validate the accuracy of a final set of data; and (D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s): (1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(3); (2) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(3); and (3) Problems. At a minimum, the version of the standard specified in § 170.207(a)(4). (iv) System Verification Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard adopted at § 170.205(a)(4) using the Continuity of Care Document template.
§ 170.315(b)(3) Electronic prescribing-	(i) Enable a user to perform all the following prescription-related electronic transactions in accordance with the standards specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows: (A) Create new prescriptions (NEWRX) (B) Change prescriptions (RXCHG, CHGRES)

	(C) Cancel prescriptions (CANRX, CANRES) (D) Refill prescriptions (REFREQ, REFRES) (E) Receive fill status notifications (RXFILL) (F) Request and receive medication history information (RXHREQ, RXHRES). (ii) Transmit and receive the reason for the prescription. Evaluate the Health IT Module's ability to transmit and receive the reason for the prescription for each transaction listed in paragraph (b)(3)(i) of this section using the Diagnosis elements in DRU Segment. (iii) Optional For each transition listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment. (iv) Evaluate the Health IT Module's ability to enable a user to prescribe all oral liquid medications in only metric standard units, i.e mL (v) Evaluate the Health IT Module's ability to always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.
§ 170.315(b)(7) Security tags - Summary of care –Send	Enable a user to create a summary record formatted in accordance with the standard adopted in §170.205(a)(4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted at §170.205(o)(1).
§ 170.315(b)(8) Security tags - summary of care – Receive	(i) Enable a user to receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) that is document-level tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1). (ii) Sequester the document -level tagged document from other documents received (iii) View the restricted document without incorporating any of the data from the document.
§ 170.315(b)(9) Care plan-	(b)(9)(i) - Enable a User to Record, Change, Access, Create, and Receive Care Plan Enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified at §170.205(a)(4).
§ 170.315(b)(10) Electronic Health Information export	(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. (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. (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.

	(b)(10)(i)(D) The export files(s) created must be electronic and in a computable format. (b)(10)(i)(E) The export files(s) created must be electronic and in a computable format. (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. (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.
§ 170.315(c)(1) Record and Export-	(i) For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."
§ 170.315(c)(2) Import and Calculate-	(i) Import. Enable a user to import a data file in accordance with the standard specified in § 170.205(h)(2) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. (ii) (ii) Calculate. Calculate each and every clinical quality measure for which it is presented for certification.
§ 170.315(c)(3) Report-	(i) Report. Enable a user to electronically create a data file for transmission of clinical quality measurement data: At a minimum, in accordance with the standards specified in § 170.205(h)(2) and § 170.205(k)(1) and (2).
§ 170.315(e)(1) View, download and transmit CCD documents to third party-	(e)(1)(i) View, Download, and Transmit to a Third Party Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the following standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2). (A) View Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data: (1) The Common Clinical Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set). (2) Ambulatory setting only: Provider's name and office contact information. (3) Inpatient setting only: Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

	(4) Laboratory test report(s). Laboratory test report(s), including: (i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7) (ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d) (iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2) (5) Diagnostic image report(s) (B) Download. (1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats: (i) Human readable format, and (ii) The format specified in accordance to the standard specified in § 170.205(a)(4) following the CCD document template. (2) When downloaded according to the standard specified in§ 170.205(a)(4) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set): (i) Ambulatory setting only: All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5). (ii) Inpatient setting only: All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5). (3) Inpatient setting only: Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section). (C) Transmit (1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with both of the following ways: (i) Email transmission to any email address (ii) An encrypted method of electronic transmission (2) Inpatient setting only: Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by (e)(1)(i)(B)(3)) of this section selected by the patient (or their authorized representative) in both of the ways referenced (e)(1)(i)(C)(1)(i) and (ii) of this section) (D) Timeframe Selection Patients (and their authorized representatives) must be able to: (1) Select data associated with a specific date (to be viewed, downloaded, or transmitted) (2) Select data within an identified date range (to be viewed, downloaded, or transmitted)

§ 170.315(f)(1) Transmission to immunization registries-	(i) Create immunization information for electronic transmission in accordance with: (A) The standard and applicable implementation specifications specified in § 170.205(e)(4); (B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and (C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines (ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).
§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance-	Create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).
§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results-	Create reportable laboratory tests and values/results for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(g); (ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2)Electronically Create Reportable Laboratory Tests and Values/Results for Transmission
§ 170.315(f)(4) Transmission to cancer registries-	Create cancer case information for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in §170.205(i)(2) (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3)
§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting-	(i) Consume and maintain a table of trigger codes to determine which encounters may be reportable. (ii) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table. (iii) Case report creation. Create a case report for electronic transmission: (A) Based on a matched trigger from paragraph (f)(5)(ii); (B) That includes, at a minimum, (1) The Common Clinical Data Set (2) Encounter diagnoses Formatted according to at least one of the following standards: (i) The standard specified in § 170.207(i) (ii) At a minimum, the version of the standard specified in § 170.207(a)(4); (3) The provider's name, office contact information, and reason for visit (4) An identifier representing the row and version of the trigger

	table that triggered the case report.
§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting-	Create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).
§ 170.315(f)(7) Transmission to public health agencies — health care surveys –	Create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1)
§ 170.315(g)(7) Application access— patient selection-	(i) Functional requirement - 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. (ii) Documentation (A) The API must include accompanying documentation that contains, at a minimum: (1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. (2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s). (3) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements. (B) The documentation to meet paragraph (g)(7)(ii)(A) of this section must be available via a public all accessible hyperlink.
§ 170.315(g)(9) Application access— all data request	(i) Functional requirements (A) Respond to requests for patient data 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 adopted at § 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. (ii) Documentation (A) The API must include accompanying documentation that contains, at a minimum: (1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. (2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully

	interact with the API and process its response(s). (3) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements. (B) The documentation used to meet paragraph (g)(9)(ii)(A) of this section must be available via a publicly accessible hyperlink.
§ 170.315(g)(10) Standardized API for patient and population services	(g)(10)(i)(A) Respond to requests for a single patient's data according to the standard adopted in § 170.215(a)(1) and implementation specification adopted in § 170.215(a)(2), including the mandatory capabilities described in "US Core Server CapabilityStatement," for each of the data included in the standard adopted in § 170.213. All data elements indicated as "mandatory" and "must support" by the standards and implementation specifications must be supported. (g)(10)(i)(B) Respond to requests for multiple patients' data as a group according to the standard adopted in § 170.215(a)(1), and implementation specifications adopted in § 170.215(a)(2) and (4), for each of the data included in the standard adopted in § 170.213. All data elements indicated as "mandatory" and "must support" by the standards and implementation specifications must be supported. (g)(10)(ii)(A) Respond to search requests for a single patient's data consistent with the search criteria included in the implementation specification adopted in § 170.215(a)(2), specifically the mandatory capabilities described in "US Core Server CapabilityStatement". (g)(10)(ii)(B) Respond to search requests for multiple patients' data consistent with the search criteria included in the implementation specification adopted in § 170.215(a)(4). (g)(10)(iv) Enable an application to register with the Health IT Module's "authorization server. (g)(10)(v)(A)(1) Establish a secure and trusted connection with an application that requests data for patient and user scopes in accordance with the implementation specifications adopted in § 170.215(a)(2) and (3). (B) Establish a secure and trusted connection with an application that requests data for system scopes in accordance with the implementation specification adopted in § 170.215(a)(4). (g)(10)(v)(A)(1) For first time connections, authentication and authorization must occur during the process of granting access to patient data in accordance with the implementation specification adopted in § 170.215(a)(3) and standard adopted in § 170.215(b). Additionally, a Health IT Module's authorization server must issue a refresh token valid for a period of no less than three months to applications capable of storing a client secret. Finally, a Health IT Module's authorization server must issue a refresh token for a period of no less than

	three months to native applications capable of securing a refresh token. (g)(10)(v)(A)(2) For subsequent connections, access must be granted to patient data in accordance with the implementation specification adopted in § 170.215(a)(3) without requiring re-authorization and re-authentication when a valid refresh token is supplied by the application. Additionally, a Health IT Module's authorization server must issue a refresh token valid for a new period of no less than three months to applications capable of storing a client secret. (g)(10)(v)(B)(Authentication and authorization must occur during the process of granting an application access to patient data in accordance with the "SMART Backend Services: Authorization Guide" section of the implementation specification adopted in § 170.215(a)(4) and the application must be issued a valid access token. (g)(10)(vi) A Health IT Module's authorization server must be able to revoke an authorized application's access at a patient's direction. (g)(10)(vii) A Health IT Module's authorization server must be able to receive and validate tokens it has issued. (g)(10)(vii)(A) The API(s) must include complete accompanying documentation that contains, at a minimum: (1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns; (2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s); and (3) All applicable technical requirements and attributes necessary for an application to be registered with a Health IT Module's authorization server. (g)(10)(vii)(B) The documentation used to meet paragraph (g)(10)(viii)(A) of this section must be available via a publicly accessible hyperlink without any preconditions or additional steps.
§ 170.315(h)(1) <u>Direct Project-</u>	(i) Applicability Statement for Secure Health Transport Able to send and receive health information in accordance with the standards specified in § 170.202(a)(2),including formatted only as a "wrapped" message. (ii) Delivery Notification in Direct Able to send and receive health information in accordance with the standard specified in § 170.202(e)(1). Required Enhanced Testing The Health IT Module submits evidence of multi-partner testing with three different and unrelated partner HISPs using Direct v1.2 (in accordance with the standard specified at §170.202(a)(2): Applicability Statement for Secure Health

	Transport v1.2, formatted only as a "wrapped" message.

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Measurement/Metric	Justification and Expected Outcome
Use Case	**Justification-** When assessing the EndoVault system, a specialty based clinical application used by 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. **Methodology-** EndoSoft will provide the steps to perform each requirement of the criteria and score the results based on a predetermined rationale. **Expected outcome of use case testing-** 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)

Associated criteria that will be tested by Use Case

§ 170.315(b)(1) Transitions of care CDA (C-CDA), CCD, Discharge Summary- Relied Upon SW = NA

§ 170.315(b)(2) Clinical information reconciliation and incorporation- Relied Upon SW = NA

§ 170.315(b)(3) Electronic prescribing- Relied Upon SW = Surescripts

§ 170.315(b)(7) Security tags - summary of care –Send- Relied Upon SW = NA

§ 170.315(b)(8)
Security tags - summary of care –Receive Relied Upon SW = NA

§ 170.315(b)(9) Care plan- Relied Upon SW = NA

§ 170.315(b)(10) Electronic Health Information export- Relied Upon SW = NA

§ 170.315(c)(1) Record and Export- Relied Upon SW = Pop Health

§ 170.315(e)(1) View, download and transmit CCD documents to third party- Relied Upon SW = MaxMD

§ 170.315(f)(1)
Transmission to immunization registries- Relied Upon SW = NA

§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance- Relied Upon SW = NA

§ 170.315(f)(3)
Transmission to public health agencies — reportable laboratory tests and value/results- Relied Upon SW = NA

§ 170.315(f)(4) Transmission to cancer registries- Relied Upon SW = NA

§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting- Relied Upon SW = NA

§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting- Relied Upon SW = NA

§ 170.315(f)(7) Transmission to public health agencies — health care surveys – Relied Upon SW = NA

§ 170.315(g)(7) Application access— patient selection- Relied Upon SW = NA

§ 170.315(g)(9) Application access— all data request- Relied Upon SW = NA

§ 170.315(g)(10) Standardized API for patient and population services- Relied Upon SW = NA

§ 170.315(h)(1) Direct Project- Relied Upon SW = MaxMD

Measurement/Metric	Justification and Expected Outcome
Data Analysis	**Justification** EndoVault builds the analytical reports for the hospital administration team. This is a data file that is only created electronically by software. EndoSoft will use data analysis to validate the data prepared for transmission and submission of the clinical quality measurement data to a federal registry. **Methodology-** List Data analysis **Expected outcome of the data analysis-** An analytical report transmitted from EndoVault application to a predefined registry. Validation errors will be tracked and trended over time to insure they

	are conformant to the required measure with less than 1% error rate.
Associated criteria that will be tested by Data Analysis § 170.315(c)(2) Import and Calculate- Relied Upon SW = Pop Health § 170.315(c)(3) Report- Relied Upon SW = Pop Health	

CARE SETTING(S)

Care Setting	Justification
Out-patient (Ambulatory) settings with the clients being Mid to Large Hospitals, Clinics, and Surgery Centers	EndoSoft LLC markets its EndoVault EHR, a specialty-based product, to clients (physicians and clinicians) of Mid to Large hospitals, 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 EndoVault is marketed and utilized. The typical size of an organization using the application is 30 users with daily patient numbers ranging from 30 to 50. Where feasible, EndoSoft will incorporate real patient data and real environments. Focus of the Real-World Testing will occur within these environments.

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 EndoVault will be conformant to the required measure with less than 1% error rate

EndoVault 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.

Only reconciled data will be imported into the EndoVault application.

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

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

EndoVault 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.

The data analysis approach will show that a user can import a data file formatted in accordance with HL7 QRDA Category I Release 3 or the corresponding version of the QRDA standard.

The data analysis approach will show that a user can successfully send an analytical report transmitted from EndoVault application to a predefined registry.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Candidate list established	Surgery Centers, Clinics and Hospitals	January, 2025
The documentation for the Real-World Testing will be provided along with the customer agreements.	Surgery Centers, Clinics and Hospitals	End February, 2025
Test start, Data Collection begins	Surgery Centers, Clinics and Hospitals	Begin 2nd quarter, April, 2025
Follow-up with client on a monthly basis to understand any issues arising with the data collection	Surgery Centers, Clinics and Hospitals	2nd and 3rd quarter, 2025
End of Real-World Testing. Collect all data and create final report.	Surgery Centers, Clinics and Hospitals	End 4th quarter, 2025
Submit Testing Report.	Surgery Centers, Clinics and Hospitals	January 2026

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.

Authorized Representative Name: Michael L Shaffer

Authorized Representative Email: mshaffer@endosoft.com

Authorized Representative Phone: 518-831-8086

Authorized Representative Signature: Michael L Shaffer

Date: 10-10-24