Doctorsoft
Innovating Electronic Health Records

REAL WORLD TESTING PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. **While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide – Coming Soon
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - *Section VII.B.5 — "Real World Testing"*

INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan. Each section provides a field for submitting responses and explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: Doctorsoft Corporation

Product Name: Doctorsoft EHR

Version Number(s): v3.0

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1365.Doct.03.00.1.181231

Developer Real World Testing Page URL: https://doctorsoft.com/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing.

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

As per the ONCs recommendation for "Real World Testing" the Doctorsoft EHR is adhering to all the criterions that are mentioned in this plan. Doctorsoft EHR has capability of send and receive transition of care referral summaries to providers (§170.315(b)(1)). It supports documentation & reconciliation of clinical information like medical history, surgery details, allergies, medications and many more (§170.315(b)(2)) also the application has feature of exporting the data based on the provider or patient need (§170.315(b)(6)) (§170.315(c)(1)). This application is integrated to 3rd party application for prescribing the medications for patients electronically (§170.315(b)(3). The Doctorsoft EHR has user friendly main exam page which allows provider to look in to most of the details in one-page view (§ 170.315(g)(7)), (§ 170.315(g)(8)) this page also consists of images, Lab/Rad tests, procedures etc. (§ 170.315(g)(9)).

The goal of this plan is to demonstrate that both the interoperability and conformance capabilities of the Doctorsoft EHR satisfies all the mentioned certification criterion. This will be done through the test scenarios justifications included in the plan.

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.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✔ *Identify standard versions*
- ✔ *Indicate what certification criteria in which product(s) has been updated*
- ✔ *If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products*
- ✔ *CHPL ID for each Health IT Module*
- ✔ *Method used for standard update (e.g., SVAP)*
- ✔ *Date notification sent to ONC-ACB*
- ✔ *If SVAP, date notification sent to customers*
- ✔ *Measure used to demonstrate conformance with updated standard(s)*
- ✔ *Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?*

Standard (and version)	Not Applicable
Updated certification criteria and associated product	Not Applicable
Health IT Module CHPL ID	Not Applicable
Method used for standard update	Not Applicable
Date of ONC ACB notification	Not Applicable
Date of customer notification (SVAP only)	Not Applicable
Conformance measure	Not Applicable
USCDI updated certification criteria (and USCDI version)	Not Applicable

MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen meet the intent and purpose of Real World Testing.

For each measurement/metric, describe the elements below:

- ✔ Description of the measurement/metric
- ✔ Associated certification criteria
- ✔ Justification for selected measurement/metric
- ✔ Care setting(s) that is addressed
- ✔ Expected outcomes

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Criteria	Measurement/Metric	Description
Referrals (§170.315(b)(1))	Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	As part of Real-World Testing, we will be evaluating outpatient: 170.315(b)(1) criteria. Our goal is to enhance patient care by providing secure information to referrals.
Clinical information reconciliation export (§170.315(b)(2))	Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA	The Doctorsoft EHR supports all kinds of Clinical information reconciliation and incorporation criteria which can be demonstrated by exporting the patient information on a regular basis which adheres to the C-CDA standards. Clinical information data export like medical history, Surgical history, allergies etc. over 3 months will demonstrate this measure. Data will be verified manually
Electronic prescribing (§ 170.315(b)(3))	Over a 90-day period: 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed	This measure will provide us the count of electronic prescriptions for selected providers (all options are available) for the entire Practice from the specified period (3 months) (using PI report from Doctorsoft). This measure will also give us details of prescriptions (route/SIG/medications etc.).

Data export (§170.315(b)(6))	Over a 90-day period: 1) Number of times a data export was performed for a patient 2) Number of times a data export was performed for multiple patients in a single transaction 3) Number of times a data export was performed for all patients in a single transaction	The Doctorsoft EHR has implemented an export utility using C-CDA standards for exporting IRIS registry related data that will have all the clinical information and patient details. There is also an export utility for referral notes as well. All the IRIS registry related data from 03/01/2022 through 05/30/2022 (3 months) will be extracted and the date will be validated in the application.
record and export §170.315(c)(1)	Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA files exported & imported	Clinicians record all data necessary to successfully calculate clinical quality measures (CQMs). It also gives the ability to download/export the data for CQMs so that it can be evaluated for specific CQMs. This measure will provide us the count as well as frequency to indicate how often this interoperability feature is being used. We will provide data for 3 months to demonstrate this measure.
Patient Engagement (§170.315(e)(1))	Over a 90-day period: 1) Number of views of health information by a patient or authorized representative 2) Number of downloads of health information by a patient or authorized representative 3) Number of transmissions of health information by a patient or authorized representative using email	This measure is tracking and counting how many patients are successfully logged into and accessed their patient portal account as well as email transmissions from the portal over the course of a given interval (3 months). The goal of the approach for Patient Engagement is to demonstrate and validate the patient activities through logs which will give us details about how many patients make use of patient engagement functionality through the patient portal. This data will be provided for 3 months.
Application access—patient selection § 170.315(g)(7)	1) Number of requests for a patient ID 2) Number of requests that provided sufficient information 3) Number of follow-up requests made using the provided patient ID	As part of the Real World Testing, we will be evaluating the 170.315(g)(7) Application access - patient selection criteria and test if the Doctorsoft application should be able to show selected patient's information, about demographics data, visit history, disease history, surgeries done, prescribed medicine, allergies.
Application access—data category request § 170.315(g)(8)	1) Number of requests for a patient's data made by an application via a data category request using a valid patient ID 2) Number of requests for a patient's data made by an application via a data category request using a valid patient ID for a specific date range	As part of the Real World Testing, We will be evaluating the patient data under each category (170.315(g)(8)) for a valid patient
Application access—	1) Number of requests for a	As part of the Real World Testing, We will be

all data request § 170.315(g)(9)	patient's Summary Record made by an application via an all data category request using a valid patient ID 2) Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID for a specific date range	evaluating the 170.315(g)(9) criteria and test the patient's Summary Record, if the Data is coming as desired.

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
Care Coordination	§170.315(b)(1) Transitions of care
Care Coordination	§170.315(b)(2) Clinical information reconciliation and incorporation
Care Coordination	§170.315(b)(3) Electronic prescribing
Care Coordination	§170.315(b)(6) Data export
Clinical Quality Measures	§170.315(c)(1) - record and export
Patient Engagement	§170.315(e)(1) View, download, and transmit to 3rd party
Application Programming Interfaces	§ 170.315(g)(7) Application access— patient selection
Application Programming Interfaces	§ 170.315(g)(8) Application access— data category request
Application Programming Interfaces	§ 170.315(g)(9) Application access— all data request

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Criteria	Justification
Transitions of care (§170.315(b)(1))	This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards. However, it is not possible to consistently and reliably demonstrate that all required standards were used because not all CCDAs created in a real-world setting contain all the necessary data elements. We intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
Clinical information reconciliation export	This criterion requires the ability of a certified Health IT module to take

(§170.315(b)(2))	a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. We intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective.
Electronic prescribing (§ 170.315(b)(3))	This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. We intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that the transactions are successfully received by the eRx clearinghouse.
Data export §170.315(b)(6)	The implemented export utility in Doctorsoft application follows C-CDA standards for exporting the patient data & Clinical information that can be exported manually or through scheduled jobs. This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCDA format according to specified standards. We intend to demonstrate the certified capability is available and effective. Our expectation is there will be very low utilization by providers with a high success rate.
record and export §170.315(c)(1)	These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format. Doctorsoft intends to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective. Metrics for CQMs will be focused on the Ophthalmic care setting. Usage of these features is predominantly leveraged by Ophthalmic providers in the Advantage program. As part of the Real world testing Doctorsoft ability to record and export clinical quality measures, by generating a QRDA 1 File will be evaluated.
Patient Engagement (§170.315(e)(1))	This use case has three metrics which measure real world interoperability actions of patients and their secure portals. This measure will provide a numeric value to indicate both how often patients log into their patient portal to view, download, or transmit their health data. These activities show how patients commonly utilize a patient portal as well as the breadths of its use with other health care entities.
Interoperability and Data Exchange (§ 170.315(g)(7))	Doctorsoft provides access to specific patient data through the edgeMed or eRx interfaces, this will provide a metric on the use of APIs to access patient data. This will be verified through the review of the log files. We intend to record the frequency that patient ID requests are received by providers via API to demonstrate the certified capability is available and effective.
Application access— data category request § 170.315(g)(8)	This requires doctorsoft module to provide an API and supporting documentation that enable external applications to request patient data by category from the certified Health IT module. We intend to record the frequency that patient data requests by category are received by

	providers and fulfilled via API to demonstrate the certified capability is available and effective. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature
Application access— all data request § 170.315(g)(9)	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature

Care Setting(s)

The expectation is that a developer's Real World Testing plan will address 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. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Ophthalmology care - Doctorsoft is a cloud based EHR for ophthalmology	Doctorsoft is a cloud based EHR that has been designed for ophthalmology specialty and it has one-page exam view EHR (Electronic Health Records) design for ophthalmologists. This is integrated with multiple 3rd party software to provide cost effective patient care.

Expected Outcomes

Health IT developers should detail how the approaches chosen will 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)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should 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 expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes
Transitions of care (§170.315(b)(1))	It is expected that the user is able to create a CCDA format for patient data transitions with the help of secure access that also includes the reason for referral, and the name and contact information of the provider. It is expected that the user is able to create a Summary Document that also includes the discharge instructions. It is expected that the provider will be able to review the progress. Our expectation is there will be moderate utilization by providers with a high success rate
Clinical information reconciliation export (§170.315(b)(2))	All the Clinical information reconciliation data like medications, medical history, allergy, surgery history etc. can be exported manually without any errors or losing any data. This will make sure that no data has been lost and it is accurate. Our expectation is there will be low utilization by providers with a high success rate.
Electronic Prescribing (§ 170.315(b)(3))	We will access our eRX system to run detailed reports on providers for Prescriber on eRX portal as well as on our EHR portal. We can easily get the number of successful electronic prescriptions over specified duration in detail. If we observe any failed electronic prescriptions, we will investigate and address accordingly. Our expectation is there will be high utilization by providers with a high success rate
Data export	Upon validating the exported data for IRIS registry we can conclude that

§170.315(b)(6)	both the interoperability and conformance capabilities of Clinical information is maintained.
record and export §170.315(c)(1)	QRDA-1 files generated as part of the real world testing will be DE identified and validated for accuracy and conformance with 170.315(c)(1) criteria, with less than 1 percent errors.
Patient Engagement (§170.315(e)(1))	The measurements will produce numeric results over a given time interval of a minimum of three (3) months. We will utilize various reports and audit logs to determine our measure count. For all measures, a successful increment indicates compliance to the underlying ONC criteria. It will show that patients can log into their patient portal to access their patient data and transmit their health data to a 3rd party. We will use the measure counts to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts. Our expectation is there will be moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.
Interoperability and Data Exchange (§ 170.315(g)(7))	Log files obtained during Real World Testing will be identified and used for analysis to validate the proper operation of criteria g(7) with less than 1 percent error rate experienced by users. We have added interactive testing methodology for these capabilities to the test plan to demonstrate the feature is available and functions as expected should any users elect to begin using this feature
Application access— data category request § 170.315(g)(8)	The Data displayed under each category should be successful with less than one percent errors. We have added interactive testing methodology for these capabilities to the test plan to demonstrate the feature is available and functions as expected should any users select to begin using this feature.
Application access— all data request § 170.315(g)(9)	The real world testing will be identified and validated for accuracy and conformance with 170.315(g)(9) criteria, with less than 1 percent errors. We have added interactive testing methodology for these capabilities to the test plan to demonstrate the feature is available and functions as expected should any users select to begin using this feature.

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/time frame during which data will be collected.

Key Milestone	Care Setting	Date/Time Frame
Real World Testing plan submission	Ophthalmology care	November 22, 2021
Begin collection of information as laid out by the plan	Ophthalmology care	March 1 to May 30 2022
Follow-up with providers and authorized representatives to understand any issues arising with the data collection.	Ophthalmology care	Quarterly, 2022

Key Milestone	Care Setting	Date/Time Frame
End of Real World Testing period/final collection of all data for analysis. Analysis and report creation	Ophthalmology care	September 15, 2022
Submit Real World Testing report to ACB (per their instructions)	Ophthalmology care	October 15, 2022

ATTESTATION

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.[ii]

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: Dr. Sanjay Logani

Authorized Representative Email: sanjay.logani@doctorsoft.com

Authorized Representative Phone: 818-886-6700

Authorized Representative Signature: 

Date: 11/22/2021

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i Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

ii https://www.federalregister.gov/d/2020-07419/p-3582