



REAL WORLD TESTING PLAN TEMPLATE

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”

TEMPLATE 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/or 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 ReportID Number: [For ONC-Authorized Certification Body use only]

Developer Name: InPracSys

Product Name(s): InPracSys EHR

Version Number(s): 9.0

Product List (CHPL) ID(s): 15.05.05.2762.INPS.01.00.1.191206

Developer Real World Testing Page URL: <https://www.inpracsys.com/rwt/>

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 Testing¹.

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.

We plan on beginning real work testing using 1 representative clinic that agrees to all criteria that are included in the requirement list for RWT. If some criteria or criterion remain unused by the testing clinic, InPracSys will perform that part of the test at InPracSys Lab.

The tests will be performed on real data using data queries and dynamically presented as counts of successes and failure or screen available to authorized users. The data presented will also be benchmarked against InPracSys internal benchmark for expected results and acceptable failure rates to ensure continuing success. All failures will be documented and used for process improvement and/or training of clinic staff.

All tests will be carefully aligned to meet criteria's requirements and technical outcomes. E.g., B(1) can the IT detect valid vs invalid ToC referral summaries.

If, for any reason, the test clinic has not used one or more functions, for their own reasons, e.g. Transmission to Public health agencies, we plan on running the tests manually a few times during the calendar year(s) to ensure continuing functionality thru the year(s) of the unused functions.

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



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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)	All Standards are the 2015 Versions
Updated certification criteria and associated product	NA
Health IT Module CHPL ID	NA
Method used for standard update	NA
Date of ONC-ACB notification	NA
Date of customer notification (SVAP only)	NA
Conformance measure	NA
USCDI-updated certification criteria (and USCDI version)	NA

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 (Ambulatory Medical Clinic)
- ✓ Expected outcomes

DESCRIPTION OF MEASUREMENT/METRIC –

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

Measurement/Metric	Description
Transitions of Care as CCDA – Create	Using data query, Count of C-CDA referral summaries created, formatted to release 2.1, during the measurement period
Transitions of Care CCDA - Conformance	Use CMS validator API to Automatically test a Random sampling of messages created during the measurement period to ensure at a minimum that messages meet the Release, content and PT matching criteria
Transitions of Care CCDA Receive	Using data query, Count of C-CDA referral summaries received during the measurement period grouped by status (valid/invalid) AND “grouped by” containing XDM package
Transitions of Care CCDA Display	Using data query, count of referral summaries received and successfully displayed, during the measurement period, “grouped by” CCD release (1.1, 1.2)
Transitions of Care CCDA Display section order	Using data query, count of referral summaries displayed where the display order was changed by the user
Clinical information reconciliation and incorporation	Using data query, Count of reconciliations, during the measurement period, where the auto-matched PT flag is set to true, and occurred from the side-by-side display page
Electronic prescribing	Count of prescriptions successfully transmitted, during the measurement period, where the units are in mL and where the Qty is set to 0.XX where XX is any numeric value
Data export	Using data query, Count of summaries created by the user where a user entered single date or date range and destination locations are saved in database in the appropriate fields, during the measurement period.
Clinical quality measures (CQMs) - record and export	Using data query, count of patients, in measurement period, where the criteria is met or where the patients fall in exclusions, with coded exclusion reason, for all certified CQMs, and where data was successfully exported

VDT - View	Using data query count of patients who viewed their data including complete common clinical data set, lab reports and Dx reports, containing provider name/contact, in human readable format, for one or more date ranges during the measurement period.
VDT - download and Transmit	Using data query count of patients who downloaded or transmitted their data including complete common clinical data set, lab reports and Dx reports containing provider name/contact, for one or more date ranges, during the measurement period.
VDT - Activity Logging	Using data query generate a list of top 10 patients/rep who, during the measurement period, viewed, downloaded, and/or transmitted their data including the user (patient/rep) who performed the action and NTP timestamp when the action was performed
Creation of syndromic surveillance messages	Using data query, count of Syndromic Surveillance messages created by staff as needed, per HL7 2.5.1 standard, during the measurement period.
Transmission to public health agencies	Using data query count eligible cases when a trigger is matched in accordance with provision (f)(5)(ii), where the Health IT Module created a case report with only the required subset of CCDS data elements, during the measurement period
Application access — patient selection (Success)	Using data queries, count the number of successful requests for patient data, where the request resulted in successful generation of a token and data exchange, during the measurement period
Application access — patient selection (failure)	Using data queries, count the number of failed requests for patient data during the measurement period, where a successful token was not issued and no data was exchanged.
Application access — data category request	Using data queries count individual data categories requested, during the measurement period, where the request resulted in successful generation of a token and subsequent data exchange
Application access — all data request	Using data queries count of data requests specifying all categories. requested during the measurement period, where the request resulted in successful generation of a token and subsequent data exchange.
Direct Project – Stored addresses	Using data query, count the direct addresses entered and stored in the health IT module, grouped by binding (domain/Address) and hosting (DNS and LDAP), during the measurement period
Direct Project – Wrapped message success	Using data query, count the wrapped messages successfully transmitted to third parties during the measurement period

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
Transitions of Care as CCDA	170.315(b)(1) Transitions of Care



– Create	
Transitions of Care CCDA - Conformance	170.315(b)(1) Transitions of Care
Transitions of Care CCDA Receive	170.315(b)(1) Transitions of Care
Transitions of Care CCDA Display	170.315(b)(1) Transitions of Care
Transitions of Care CCDA Display section order	170.315(b)(1) Transitions of Care
Clinical information reconciliation and incorporation	170.315 (b)(2) Clinical information reconciliation and incorporation
Electronic prescribing	170.315 (b)(3) Electronic prescribing
Data export	170.315 (b)(6) Data export
Clinical quality measures (CQMs) — record and export	<i>170.315(c)(1) Clinical quality measures (CQMs) — record and export</i>
VDT- View	<i>170.315(e)(1) View, download, and transmit to 3rd party</i>
VDT- download and transmit	<i>170.315(e)(1) View, download, and transmit to 3rd party</i>
VDT - Activity Logging	<i>170.315(e)(1) View, download, and transmit to 3rd party</i>
Creation of syndromic surveillance messages	<i>170.315(f)(2) Transmission to public health agencies — syndromic surveillance</i>
Transmission to public health agencies	<i>170.315(f)(5) Transmission to public health agencies — electronic case reporting</i>
Application access — patient selection Success	<i>170.315(g)(7) Application access — patient selection</i>
Application access — patient selection failed	<i>170.315(g)(7) Application access — patient selection</i>
Application access — data category request	<i>170.315(g)(8) Application access — data category request</i>
Application access — all data request	<i>170.315(g)(9) Application access — all data request</i>
Direct Project – Stored addresses	<i>170.315(h)(1) Direct Project</i>
Direct Project – Wrapped message success	<i>170.315(h)(1) Direct Project</i>

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

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

Measurement/Metric	Justification
Transitions of Care as CCDAs – Create	Counts of valid CCDAs created during the measurement period, demonstrates that the Health IT is working as expected and certified to create CCDs
Transitions of Care CCDAs - Conformance	Counts of conforming CCDAs created during the measurement period, demonstrates that the Health IT is working as expected and certified
Transitions of Care CCDAs Receive	Counts of invalid and /or valid CCDAs received during the measurement period, demonstrates the ability of the IT to detect valid/invalid CCDAs
Transitions of Care CCDAs Display	Counts of CCDAs grouped by R1.1 and R2.1 demonstrates the ability of the IT to handle both releases
Transitions of Care CCDAs Display section order	Our technology is able to save the display preferences of the application. Counting the number of times this activity took place, during the measurement period demonstrates functionality
Clinical information reconciliation and incorporation	Our technology automatically matches the patient to the ToC and has the user verify the match and sets the auto-match flag true. Counting cases that the flag is set to true, and the page the action was performed on, during the measurement period, demonstrates that the product is working as expected.
Electronic prescribing	Getting counts of prescriptions, during the measurement period, that were successfully received by the service provider and not rejected, that contained units in mL as well as quantity, demonstrates this function.
Data export	Our application allows the user to choose the instances, date range and location of the destination of the export. Therefore reporting counts of summaries created, grouped by date range and destination demonstrates this function.
Clinical quality measures (CQMs) — record and export	Reports of patients by the CQM including status (Met, Unmet and Exclusion, with reason medical, Patient, System) demonstrates that the Health IT is working as expected and certified for this function.
VDT - View	Counts of occurrence(s) during the measurement period demonstrate that the function is working as expected for viewing data.
VDT - download and Transmit	Counts of occurrence(s) during the measurement period demonstrate that the function is working as expected for downloading or transmitting data
VDT - Activity Logging	Counts of occurrence(s) during the measurement period demonstrate that NTP time stamp and user activity logging is working.
Creation of syndromic surveillance messages	Since our technology validates messages on creation, getting counts demonstrates that the function is working.
Transmission to public health agencies	Counts of eligible cases generated and transmitted during the measurement period illustrates that this function is working.
Application access — patient selection Success	If we receive, validate the request, issue a token that is used subsequently for data exchange, we demonstrate that this function is working and our documentation is on point.
Application access — patient selection failed	If we receive, validate the request, do not issue a token if the request is not to syntax, we demonstrate that this function is working and documentation is on point, but the requester made an error.
Application access — data category request	If we receive, validate the request, issue a token that is used subsequently for data exchange, we demonstrate that this function is working and documentation is on point.



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Application access — all data request	If we receive, validate the request, issue a token that is used subsequently for data exchange, we demonstrate that this function is working and documentation is on point.
Direct Project – Stored addresses	Storing direct addresses to the database during the measurement period demonstrates this function
Direct Project – Wrapped message success	Counting wrapped messages transmitted during the measurement period demonstrates this function

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
Ambulatory Medical Clinic	Ambulatory Medical Clinic(Urology Clinics) Note: Our application is specific to the practice of Urology

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 as CCDA – Create	That CCDA messages were successfully created with no errors
Transitions of Care CCDA – Conformance	That CCDA messages created conform to B(1) requirements
Transitions of Care CCDAReceive	That the CCDA messages were successfully received, reconciled and data incorporated with no errors
Transitions of Care CCDADisplay	That the CCDA messages were successfully received and displayed
Transitions of Care CCDADisplay section order	That the CCDA messages were successfully received, order of sections displayed with no errors
Clinical information reconciliation and incorporation	That the CCDA messages were successfully reconciled, and data incorporated with no errors.
Electronic prescribing	The prescriptions in the measure were successfully transmitted and acknowledged by the recipient service provider.
Data export	That summaries were successfully exported and transmitted without errors, and final destination recorded.
Clinical quality measures (CQMs) — record and export	Data was successfully exported and error free.
VDT - View	Data was successfully viewed and error free
VDT - Download and Transmit	Data was successfully downloaded or transmitted and error free
VDT - Activity Logging	Data viewed, successfully downloaded or transmitted, contains user and timestamp
Creation of syndromic surveillance messages	Messages were successful created to HL7 2.5.1 standard and there were no errors
Transmission to public health agencies	Messages were successfully transmitted without errors
Application access — patient selection Success	Greater than 99% of the requests made per Health IT's documentation, resulted in successful issue of a token
Application access — patient selection failed	Greater than 99% of the requests made per Health IT's documentation, resulted in successful issue of a token
Application access — data category request	Greater than 99% of the requests made per Health IT's documentation, resulted in successful issue of a token and exchange of data for the requested parameters.
Application access — all data request	Greater than 99% of the requests made per Health IT's documentation, resulted in successful issue of a token and exchange of data for the requested parameters.
Direct Project – Stored addresses	Greater than one each of address and domain bound Direct addresses are stored without errors
Direct Project – Wrapped message success	Messages are successfully sent to third parties



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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/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Complete RWT Development	Ambulatory Medical Clinic	Nov 30 2021
Test RWT plan	Ambulatory Medical Clinic	Dec 15 2021
Implement RWT Plan	Ambulatory Medical Clinic	Jan 2 2022
Report Results to SLI	Ambulatory Medical Clinic	Jan 6 2023

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: Ashu Kataria

Authorized Representative Email: Ashu.Kataria@inpracsys.com

Authorized Representative Phone: 612-455-6789

Authorized Representative Signature: Digitally Signed Ashu Kataria for InPracSys

Date: 10/8/2021

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>