REAL WORLD TESTING RESULTS REPORT TEMPLATE

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (Certification 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 and results reports.

A 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. To accompany the plan template, ONC has also provided this results report template.

While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). 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 results report will include a list of these 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 Certification Program requirements referenced in this resource.

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide
- 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 Certification 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 results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

GENERAL INFORMATION

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

Product Name(s): TheraDoc

Version Number(s): 5.0.0, 5.0.1, 5.1.0, 5.2.0, 5.3.0

Certified Health IT Product List (CHPL) Product Number(s): 170021R07, 170021R08, 170021R09, 170021R10 (15.07.04.3033.TH52.11.11.0.230111), 170021R11 (15.07.04.3033.TH03.05.12.0.221224)

Developer Real World Testing Plan Page URL: https://www.theradoc.com/certifications/2022-real-world-testing-plan-and-results/

Developer Real World Testing Results Report Page URL [if different from above]:

Same as above

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

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]
After the original plan was submitted and before testing began, an adjustment was needed to our metric methodology.	To account for submission failures unrelated to document content, such as DirectCDA outages, we are reporting a de-duplicated count of successful and failed submissions for each AUR document type in a monthly reporting period.	If a given numerator or denominator record was unsuccessfully submitted 2 times before being accepted, it is counted as 1 successful submission for the relevant reporting period. Similarly, if a given numerator or denominator record was unsuccessfully submitted 2 times and never successfully submitted, it is counted as 1 failed submission for the relevant reporting period.

[OPTIONAL] WITHDRAWN PRODUCTS

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

Product Name(s):	TheraDoc
Version Number(s):	5.0.0, 5.0.1, 5.1.0
CHPL Product Number(s):	170021R07, 170021R08, 170021R09
Date(s) Withdrawn:	3/15/2022, 6/10/2022, 10/6/2022
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.]	Data was captured while withdrawn products were in use. Because TheraDoc uses both on-premesis and cloud-based installation models, it is not feasible to differentiate the specific version used to report specific data in the results report.

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

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

The objective of 170.315(f)(6) is electronic transmission of Antimicrobial Use and Resistance (AUR) data to NHSN. Our testing approach evaluated this objective by counting the net (i.e., de-duplicated) number of successful and failed monthly CDA document submissions for TheraDoc customers who report AUR data to NHSN. As noted earlier, we revised our plan before data submission began due to the challenges presented by the number of reporting failures unrelated to document content, such as DirectCDA outages and errors in facilities' NHSN configuration, including omissions in monthly reporting plans and incorrect location type definitions.

The results shared in this report demonstrate real-world interoperability in that they reflect predictable volumes of reporting activity, including slightly lower numbers for October-December in advance of many states' Q4 reporting deadlines, as well as explainable variances in pass/fail submission counts and percentages across months. We learned that submission counts do not stabilize for several months, as different states have different submission deadlines, so success/failure numbers may be in flux for some time. As expected, the top reasons for submission failures included AU/AR reporting not being included in a facility's monthly AUR reporting plan; attempts to report against new NHSN business rules using an old version of TheraDoc; and attempts to report data for locations not mapped as eligible NHSN AUR location types. To address submissions that failed due to a TheraDoc usability issue, we are implementing a product enhancement in an upcoming release.

For details on monthly record counts and averages, plus a breakdown of submission failure reasons, see Page 6 in this report.

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)	
Updated certification criteria and associated product	
CHPL Product Number	
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.

NHSN-defined inpatient locations and select outpatient acute care settings as specified in the NHSN AUR protocol (https://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf)

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)
AR submissions to NHSN	170.315(f)(6)	N/A	See details on page 6	N/A
AU submissions to NHSN	170.315(f)(6)	N/A	See details on page 6	N/A

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
Begin collection of data as specified in plan	NHSN-defined inpatient locations and select outpatient acute care settings	January 1, 2022
Data collection and review	NHSN-defined inpatient locations and select outpatient acute care settings	Monthly, 2022
End of Real World Testing period/final collection of all data for analysis	NHSN-defined inpatient locations and select outpatient acute care settings	January 2023

Reporting Year-Month	Antimicrobial Utilization (AU)					Antimicrobial Resistance (AR) Numerator					Antimicrobial Resistance (AR) Denominator					Facility Count
	Successful	Failed	Total	% Success	% Fail	Successful	Failed	Total	% Success	% Fail	Successful	Failed	Total	% Success	% Fail	
22-Jan	2,579	407	2,986	86.4	13.6	15,132	6,310	21,442	70.6	29.4	248	104	352	70.5	29.5	210
22-Feb	2,280	506	2,786	81.8	18.2	11,929	2,487	14,416	82.7	17.3	221	53	274	80.7	19.3	212
22-Mar	2,305	452	2,757	83.6	16.4	13,668	2,456	16,124	84.8	15.2	261	57	318	82.1	17.9	207
22-Apr	2,281	278	2,559	89.1	10.9	12,901	1,095	13,996	92.2	7.8	225	26	251	89.6	10.4	208
22-May	2,378	210	2,588	91.9	8.1	11,591	1,603	13,194	87.9	12.1	211	33	244	86.5	13.5	203
22-Jun	2,432	185	2,617	92.9	7.1	11,490	2,646	14,136	81.3	18.7	203	41	244	83.2	16.8	203
22-Jul	2,410	276	2,686	89.7	10.3	11,818	2,858	14,676	80.5	19.5	217	56	273	79.5	20.5	204
22-Aug	2,406	242	2,648	90.9	9.1	14,960	1,300	16,260	92.0	8.0	248	29	277	89.5	10.5	205
22-Sep	2,359	354	2,713	87.0	13.0	11,741	1,696	13,437	87.4	12.6	205	51	256	80.1	19.9	191
22-Oct	1,952	190	2,142	91.1	8.9	8,922	940	9,862	90.5	9.5	178	19	197	90.4	9.6	161
22-Nov	2,123	260	2,383	89.1	10.9	6,471	1,279	7,750	83.5	16.5	134	23	157	85.4	14.6	160
22-Dec	1,112	321	1,433	77.6	22.4	1,814	274	2,088	86.9	13.1	29	6	35	82.9	17.1	108
Average	2,125	280	2,405	81.1	10.5	10,885	2,056	12,941	77.8	13.9	196	41	237	76.4	15.2	180

Results identify the number (count) and percentage of successful and failed monthly CDA submissions for AU, AR numerator, and AR denominator reporting.
Average numbers and percentages are included for the 12-month reporting period.
The total number of unique facilities from which data was reported is included for each month.
Successful submissions demonstrate that TheraDoc is compliant with AUR certification criteria and exchanging EHI in the care settings for which it is marketed for use.
Failed submissions likewise demonstrate that TheraDoc AUR data is being exchanged with NHSN and vetted against NHSN business rules.

An analysis of failed AU submissions identified the following most responsible reasons, in order of frequency:

53% AU reporting not in facility's NHSN monthly reporting plan
25% AU data submitted before facility installed TheraDoc version supporting new NHSN business rules
9% AU data submitted for location facility did not have mapped as eligible NHSN AU location type
8% TheraDoc usability issue that prevented users from recognizing previous DirectCDA submission and caused unnecessary resubmission attempts
5% NHSN issue with AU summary record identification

An analysis of failed AR submissions identified the following most responsible reasons, in order of frequency:

72% AR reporting not in facility's NHSN monthly reporting plan
16% AR data submitted before facility installed TheraDoc release supporting new NHSN business rules
7% TheraDoc usability issue that prevented users from recognizing previous DirectCDA submission and caused unnecessary resubmission attempts
5% AR data submitted for location facility did not have mapped as eligible NHSN AR location type

The TheraDoc usability issue will be addressed in an enhancement in an upcoming release. The majority of other failures can be prevented with proper end-user training and awareness.