ONC Real World Testing Plan

Contents

GENERAL INFORMATION

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Plan Report ID Number: [For ONC-Authorized Certification Body use only]	
Developer Name:	Remarkable Health, LLC
Product Name(s):	remarkable.me
Version Number(s):	V1.0
Certified Health IT Product List (CHPL) ID(s):	15.04.04.3000.rema.01.00.1.190915
Developer Real World Testing Page URL:	https://remarkable-me.rhoneapp.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.

At this time, remarkable.me is provided in an ambulatory setting. For this reason, the Real-World Testing plan will apply to this care setting.   The criteria for which remarkable.me has been certified will be tested, specifically §170.315.e.1 (View, download and transmit to a 3rd party). Verification of the created patient record export requires interaction with a system external to the organization, DIRECT email.

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)	All standards versions are those specified in the test measurements listed below. The developer plans to use SVAP to update its (e)(1) module to support the new version of the Direct transport protocol (now known as Secure Health Transport) during the testing period.
Updated certification criteria and associated product	
Health IT Module CHPL ID	15.04.04.3000.rema.01.00.1.190915
Method used for standard update	SVAP
Date of ONC ACB notification	Not applicable
Date of customer notification (SVAP only)	Not applicable
Conformance measure	
USCDI updated certification criteria (and USCDI version)	The plan documents the support of all USCDI v1 data elements.
WCAG 2.0	All standards versions are those specified in the test measurements listed below.

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 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 Care Setting	The remarkable.me system supports the deployment and tracking of documentation within and outside of the ambulatory setting.

Overall 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.

Expected Outcomes
- Real-World Testing will demonstrate that remarkable.me is conformant to the following certification criteria: §170.315.e.1 (View, download and transmit to a 3rd party)   - Real-World Testing will demonstrate that the Health IT Module supports SVAP for Direct.

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	Date/Timeframe
Release of documentation for the Real-World Testing to be provided to Drummond (per their instructions).	11/15/2021
Collection of information and detailed test steps as laid out by the plan for the period.	11/30/2021
Execute test cases.	12/1/2021 - 12/31/2021
End of Real-World Testing period/final collection of all data for analysis.	1/15/2022
Analysis and report creation.	1/1/2022 - 1/31/2022
Submit Real World Testing report to Drummond (per their instructions).	2/1/2022
Add chpl link of Remarkable Health test results to the website.	3/15/2022

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/Metrics

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

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the sharing of EHI (§ 170.315(e)(1)).

Measurement/Metric	Description
Measure 1: View Patient CCD Document	This measure will assess functionality used to view EHI for a single patient for a single date or a range of dates.
Measure 2: Download Patient EHI to a CCD Document file	This measure will assess functionality used to download EHI for a single patient.
Measure 3: Email Patient CCD Document – password-protected zip file	This measure will assess functionality used to export EHI for a single patient and send it as a password-protected attachment via email.
Measure 4: Email Patient CCD Document – DIRECT email	This measure will assess functionality used to export EHI for a single patient and send it as an attachment using encrypted DIRECT email.
Measure 5: View Proxy List	This measure will assess functionality to allow the patient to view the list of people the patient has assigned as a proxy, as well as deactivate a proxy.
Measure 6: Proxy View Patient CCD Document	This measure will assess functionality to view a single patient's EHI for a single date or a range of dates while logged in as the patient's proxy.
Measure 7: Proxy Download Patient CCD Document to a file	This measure will assess functionality used to download EHI for a single patient while logged in as the patient's proxy.
Measure 8: Proxy Email Patient CCD Document – password-protected zip file	This measure will assess functionality used to export EHI for a single patient and send it as a password-protected attachment via email while logged in as the patient's proxy.
Measure 9: Proxy email Patient CCD Document – DIRECT email	This measure will assess functionality used to export EHI for a single patient and send it as an attachment using encrypted DIRECT email while logged in as the patient's proxy.

Measure 10: View Activity Log	This measure will assess functionality used to access information regarding the action (view, download, transmit) that occurred, when it occurred, and who did it.
Measure 11: Proxy View Activity Log	This measure will assess functionality used by the authorized representative/proxy to access patient information regarding the action (view, download, transmit) that occurred, when it occurred, and who did it.

Measure 1: View Patient CCD Document:

This measure will assess functionality used to view EHI for a single patient.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(i)(A) View the CCD Document information for the patient.

Justification

The viewing of EHI associated with a patient allows the patient to review and verify their own full patient record.

Test Methodology

1. Load a CCD Document for the patient.
2. Log in as the patient in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page.
4. Review the My Health page to confirm the information displayed matches the source CCD Document data for the patient.
5. Retrieve patient data for a single date.
6. Retrieve patient data for a date range.

Expected Outcome(s)

It is expected that the patient's information on the My Health page matches the data loaded from the CCD Document. See **Appendix A** for data metrics that will be evaluated.

It is expected that the patient's information displayed falls within the date range specified by the date filters, if any are applied. Date filters are filtering on Visit Date.

Measure 2: Download Patient EHI to a CCD Document file:

This measure will assess functionality used to download EHI for a single patient.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1) EHI download– Single patient EHI download	(i)(B) Execute at any time Create a CCD Document following the CCD Document template Must also be in human readable format. (html)

Justification

The download of EHI associated with a patient is another way to share information with an external organization. Download is typically used when there is a need for a full patient record.

Test Methodology

1. Load a CCD Document for the patient.
2. Log in as the patient in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page.
4. Click the Save Copy button
5. Select the files to download by clicking the links
   a. xml
   b. html
   c. zip

Expected Outcome(s)

It is expected that the patient's information on the xml file downloaded matches the data loaded from the CCD Document.

It is expected that the patient's information on the html file matches the My Health page.

It is expected that the zip file contains an xml file and an html file that meet the above expected outcomes.

See **Appendix A** for data metrics that will be evaluated.

Measure 3: Email Patient CCD Document – password protected zip file:

This measure will assess functionality used to export EHI for a single patient and send it as an attachment on a password-protected email.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(i)(C) Transmit a CCD Summary document via email to an email address.

Justification

The transmission of EHI associated with a patient via email provides patients with a readily understood and convenient option to receive their health information.

Test Methodology

1. Load a CCD Document for the patient.
2. Log in as the patient in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page.
4. Click the Send button
5. Fill out the required fields – email, subject, message
6. Click Send

Expected Outcome(s)

It is expected that the email recipient receives a zip file containing an xml file and an html file that matches the data loaded from the CCD Document.

It is expected that the email recipient receives a second email containing a password to access the zip file from the first email.

It is expected that opening the zip file prompts for the password from the second email.

It is expected that the patient's information on the xml file downloaded matches the data loaded from the CCD Document.

It is expected that the patient's information on the html file matches the My Health page.

See **Appendix A** for data metrics that will be evaluated.

Measure 4: Email Patient CCD Document – DIRECT email:

This measure will assess functionality used to export EHI for a single patient and send it as an attachment using encrypted DIRECT email.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(i)(C) Transmit a CCD Summary document via DIRECT email.

Justification

The transmission of EHI associated with a patient via DIRECT email provides patients with a readily understood and convenient option to receive their health information via an encrypted transmission.

Test Methodology

1. Load a CCD Document for the patient
2. Log in as the patient in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page
4. Click the Send button
5. Fill out the required fields – email, subject, message and checking the Send via DIRECT checkbox
6. Click Send

Expected Outcome(s)

It is expected that the DIRECT email recipient receives a zip file containing an xml file and an html file that matches the data loaded from the CCD Document.

It is expected that the patient's information on the xml file downloaded matches the data loaded from the CCD Document.

It is expected that the patient's information on the html file matches the My Health page.

See **Appendix A** for data metrics that will be evaluated.

Measure 5: View Proxy List:

This measure will assess functionality to allow the patient to view the list of people the patient has assigned as an authorized representative (proxy).

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	The patient can view who is an authorized representative to view/download/transmit their EHI.

Justification

The patient needs to know who their authorized representatives are as well as be able to deactivate/expire the representative (proxy).

Test Methodology

1. Log in as the patient
2. Click on Profile & Settings
3. Select Add Proxy User
4. Verify the list of Authorized Representatives (proxies) for the patient
5. Allow the user to deactivate the proxy

Expected Outcome(s)

It is expected that the patient can view who is assigned as an authorized representative (proxy).

It is expected that the patient can deactivate an authorized representative (proxy).

Measure 6: Proxy View Patient CCD Document:

This measure will assess functionality to view a single patient's EHI while logged in as the patient's authorized representative/proxy.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(i)(A) View the CCD Document information for the patient as the patient's authorized representative/proxy.

Justification

The viewing of EHI associated with a patient allows the patient's authorized representative/proxy to review and verify the patient's full patient record.

Test Methodology

1. Load a CCD Document for the patient
2. Log in as the patient's authorized representative/proxy in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page
4. Review the My Health page to confirm the information displayed matches the source CCD Document data for the patient
5. As the authorized representative, retrieve the patient data for a single date
6. As the authorized representative, retrieve the patient data for a date range

Expected Outcome(s)

It is expected that the patient's information on the My Health page matches the data loaded from the CCD Document when accessed as the patient's authorized representative/proxy. See **Appendix A** for data metrics that will be evaluated.

It is expected that the patient's information displayed falls within the date range specified by the date filters, if any are applied. Date filters are filtering on Visit Date.

Measure 7: Proxy Download Patient CCD Document to a file:

This measure will assess functionality used to download EHI for a single patient while logged in as the patient's authorized representative/proxy.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1) EHI download– Single patient EHI download	(i)(B) As the patient's authorized representative/proxy, • Execute at any time • Create a CCD Document following the CCD Document template • Must also be in human readable format. (html)

Justification

The download of EHI associated with a patient is another way for the patient's authorized representative/proxy to share information with an external organization. Download is typically used when there is a need for a full patient record.

Test Methodology

1. Load a CCD Document for the patient
2. Log in as the patient's authorized representative/proxy in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page
4. Click the Save Copy button
5. Select the files to download by clicking the links
   a. xml
   b. html
   c. zip

Expected Outcome(s)

It is expected that the patient's information on the xml file downloaded matches the data loaded from the CCD Document.

It is expected that the patient's information on the html file matches the My Health page.

It is expected that the zip file contains an xml file and an html file that meet the above expected outcomes.

See **Appendix A** for data metrics that will be evaluated.

Measure 8: Proxy Email Patient CCD Document – password-protected zip file:

This measure will assess functionality used to export EHI for a single patient and send it as an attachment on a password-protected email while logged in as the patient's proxy.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(i)(C) As the patient's authorized representative/proxy, Transmit a CCD Summary document via email to any email address.

Justification

The transmission of EHI associated with a patient via email provides the patient's authorized representative/proxy with a readily understood and convenient option to receive their health information.

Test Methodology

1. Load a CCD Document for the patient
2. Log in as the patient's authorized representative/proxy in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page
4. Click the Send button
5. Fill out the required fields – email, subject, message
6. Click Send

Expected Outcome(s)

It is expected that the email recipient receives a zip file containing an xml file and an html file that matches the data loaded from the CCD Document.

It is expected that the email recipient receives a second email containing a password to access the zip file from the first email.

It is expected that opening the zip file prompts for the password from the second email.

It is expected that the patient's information on the xml file downloaded matches the data loaded from the CCD Document.

It is expected that the patient's information on the html file matches the My Health page.

See **Appendix A** for data metrics that will be evaluated.

Measure 9: Proxy email Patient CCD Document – DIRECT email:

This measure will assess functionality used to export EHI for a single patient and send it as an attachment using encrypted DIRECT email while logged in as the patient's authorized representative/proxy.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(i)(C) As the patient's authorized representative/proxy, Transmit a CCD Summary document via DIRECT email.

Justification

The transmission of EHI associated with a patient via DIRECT email provides the patient's authorized representative/proxy with a readily understood and convenient option to receive their health information via an encrypted transmission.

Test Methodology

1. Load a CCD Document for the patient
2. Log in as the patient's authorized representative/proxy in remarkable.me
3. Select the record that corresponds to the CCD Document data for the patient on the My Health page
4. Click the Send button
5. Fill out the required fields – email, subject, message and checking the Send via DIRECT checkbox
6. Click Send

Expected Outcome(s)

It is expected that the DIRECT email recipient receives a zip file containing an xml file and an html file that matches the data loaded from the CCD Document.

It is expected that the patient's information on the xml file downloaded matches the data loaded from the CCD Document.

It is expected that the patient's information on the html file matches the My Health page.

See **Appendix A** for data metrics that will be evaluated.

Measure 10: View Activity Log:

This measure will assess functionality used to access information regarding the action (view, download, transmit) that occurred, when it occurred, and who did it.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(ii) The patient must be able to access information regarding the action (view, download, or transmit) that occurred, the date and time each action occurred, the user who took the action, and the addressee to whom the summary was transmitted.

Justification

The patient needs to know what actions the patient has done, as well as what actions other people have done as an authorized representative/proxy of the patient.

Test Methodology

1. Log in as the patient
2. Click on Profile & Settings
3. Click on Activity Log

Expected Outcome(s)

It is expected that the patient can view the patient's own actions.

It is expected that the patient can view the patient's authorized representative/proxy actions.

It is expected for any CCD Document that is sent that the patient can view the addressee to whom the summary was transmitted.

Measure 11: Proxy View Activity Log:

This measure will assess functionality used by the authorized representative/proxy to access patient information regarding the action (view, download, transmit) that occurred, when it occurred, and who did it.

Associated Certification Criteria

Associated Certification Criteria	Requirement
§ 170.315(e)(1)	(ii) The patient's authorized representative/proxy must be able to access information regarding the actions for the patient (view, download, or transmit) that occurred, the date and time each action occurred, the user who took the action, and the addressee to whom the summary was transmitted.

Justification

The patient's authorized representative/proxy needs to know what actions the patient has done, as well as what actions other people have done as an authorized representative/proxy of the patient.

Test Methodology

1. Log in as the patient's authorized representative/proxy
2. Click on Profile & Settings
3. Click on Activity Log

Expected Outcome(s)

It is expected that the patient's authorized representative/proxy can view the patient's own actions.

It is expected that the patient's authorized representative/proxy can view the patient's authorized representative/proxy actions.

It is expected for any CCD Document that is sent that the patient's authorized representative/proxy can view the addressee to whom the summary was transmitted.

Appendix A: CCD Document Metrics

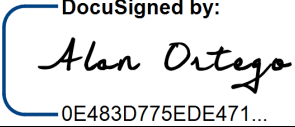| Category	Detail
Demographics	Name Address Date of Birth Ethnicity Sex Home Phone Race Marital Status Preferred Language
Care Team – For each Care Team Member include	Name Phone Address
Facility Contact Information	Facility Name Facility Phone Facility Address
Assessment	Text statement of the Assessment
Care Plan - For each item in the Care Plan include	Planned Care Start Date
Problems – Active and Resolved Concerns – For each include	Problem Name Start Date
Encounters	Encounter Diagnosis Encounter Location Encounter Date
Health Concerns – Observation and Concerns – For each include	Description Status Date
Immunization – For each vaccine include	Vaccine Name Date Status
Lab Values/Results	Lab Location • Lab Name • Address • Phone For each lab result include: • Result Type • Result Value • Relevant Reference Range • Interpretation • Date
Medication Allergies – For each allergy include	Substance Reaction Severity Status Onset Date

Goals – For each goal include	Goal Name
	Value
	Date
Medications – For each medication include	Medication Name and Dosage
	Directions
	Start Date
	End Date
Procedures – For each procedure include	Procedure Name
	Date
	Target Site
	Status
	Performer
Reason for Referral	Text field describing the reason
Smoking Status	Text field describing the smoking status
Social History – For each social history observation include	Social History Observation
	Description
	Date(s) Observed
UDI – For each UDI include	Implanted
	Area
	UDI Identifier
Vitals – For each Vital include	Vital
	Value
	Date/Time

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.

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:	Alan Ortego
Authorized Representative Email:	aortego@remarkablehealth.com
Authorized Representative Phone:	512-496-7574
Authorized Representative Signature:	DocuSigned by: *Alan Ortego* 0E483D775EDE471...
Date:	11/15/2021 | 2:24 PM MST