

General Information

Plan Report ID Number:
[For Drummond use only]

Developer Name: Elekta Inc.

Product Name: Kaiku Health

Version Number: 7

CHPL Product Number: 15.04.04.1420.Kaik.07.00.1.211015

Developer RWT Plan Page URL: <https://www.elekta.com/products/oncology-informatics/mosaig-plaza/kaiku-real-world-testing>

Justification for Real World Testing Approach

Kaiku Health is a certified health information system that provides care teams with several tools for digital health interventions including a set of oncology-specific patient portal features that the certification focuses on. Combined with health information capture through patient-reported outcomes (PROs) and secure messaging, patients are provided timely access to view, download, and transmit their records.

This test plan is designed to test the functionality certified by the ONC Health IT Certification program as it is used in the real world. The following criteria are in the scope of this plan:

- § 170.315(e)(1) View, Download and Transmit to 3rd party

Overall Approach

Kaiku Health is a cloud-hosted health information system that is currently sold to Radiation Oncology and Medical Oncology care settings. Cloud hosting enables telemetry connectivity for all sold instances of the health information system. This provides remote event tracking capability which will be used for real world testing of the criterion which is in scope of this plan. This ensures testing results accurately reflect the real-world performance of the health information system.

The tested criterion requires that patients can view, download and transmit their health information. Remote tracking will therefore focus on patients' attempts to view, download, and transmit, their health information using the health information system. Additionally, patients need to be able to view the activity log, showing how their health information was accessed for view, download and transmit. Real-world error rates will be established for each of those functionalities.

Milestones

Milestone	Care Setting	Timeframe
Development and testing of remote event and error tracking capabilities completed	Radiation Oncology Medical Oncology	January 15, 2023
Baseline error rate collection period	Radiation Oncology Medical Oncology	January 16 – February 28, 2023
Error rate tracking period	Radiation Oncology Medical Oncology	March 1 – December 31, 2023
Analysis and report creation	Radiation Oncology Medical Oncology	January – February, 2024
Submit Real World Testing report to ACB per instructions	Radiation Oncology Medical Oncology	February 15, 2024

Measures used in Overall Approach
Description of Measurement/Metric

Measurement/Metric	Description
Error rate for View	<p>Total number of errors observed in ‘View’ functionality, divided by total number of attempts for the ‘View’ functionality, expressed in %.</p> <p>Baseline error rate will be measured during a baseline collection period (see Milestones). Error rate will be tracked continuously after the baseline collection period.</p>
Error rate for Download	<p>Total number of errors observed in ‘Download’ functionality, divided by total number of attempts for the ‘Download’ functionality, expressed in %.</p> <p>Baseline error rate will be measured during a baseline collection period (see Milestones). Error rate will be tracked continuously after the baseline collection period.</p>

Measurement/Metric	Description
Error rate for Transmit (unencrypted email)	<p>Total number of errors observed in ‘Transmit (unencrypted email)’ functionality, divided by total number of attempts for the ‘Transmit (unencrypted email)’ functionality, expressed in %.</p> <p>Baseline error rate will be measured during a baseline collection period (see Milestones). Error rate will be tracked continuously after the baseline collection period.</p>
Error rate for Transmit (secure)	<p>Total number of errors observed in ‘Transmit (secure)’ functionality, divided by total number of attempts for the ‘Transmit (secure)’ functionality, expressed in %.</p> <p>Baseline error rate will be measured during a baseline collection period (see Milestones). Error rate will be tracked continuously after the baseline collection period.</p>
Error rate for View Activity Log	<p>Total number of errors observed in ‘View Activity Log’ functionality, divided by total number of attempts for the ‘View Activity Log’ functionality, expressed in %.</p> <p>Baseline error rate will be measured during a baseline collection period (see Milestones). Error rate will be tracked continuously after the baseline collection period.</p>

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software
Error rate for View	170.315(e)(1): View, Download and Transmit to 3 rd Party	MOSAIQ 2.82 (or higher)
Error rate for Download	170.315(e)(1): View, Download and Transmit to 3 rd Party	MOSAIQ 2.82 (or higher)
Error rate for Transmit (unencrypted email)	170.315(e)(1): View, Download and Transmit to 3 rd Party	MOSAIQ 2.82 (or higher)
Error rate for Transmit (secure)	170.315(e)(1): View, Download and Transmit to 3 rd Party	MOSAIQ 2.82 (or higher)
Error rate for View Activity Log	170.315(e)(1): View, Download and Transmit to 3 rd Party	MOSAIQ 2.82 (or higher)

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Error rate for View	Viewing patients' health information is required in §170.315(e)(1)(i)(A)
Error rate for Download	Downloading patients' health information is required in §170.315(e)(1)(i)(B)(1)
Error rate for Transmit (unencrypted email)	Transmitting patients' health information via unencrypted email is required in §170.315(e)(1) (i)(C)(1)(i)
Error rate for Transmit (secure)	Transmitting patients' health information via a secure channel is required in §170.315(e)(1) (i)(C)(1)(ii)
Error rate for View Activity Log	Viewing the Activity Log for access to patients' health information is required in §170.315(e)(1)(ii)(A)

Care Settings

Elekta markets its products in the Radiation Oncology and Medical Oncology care settings. The measurements which are part of this plan will be tracked on all instances of Kaiku Health sold in the United States. This includes both care settings.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Error rate for View	Baseline error rate is expected to be low. Tracking error rate is expected to be comparable or lower than baseline error rate.
Error rate for Download	Baseline error rate is expected to be low. Tracking error rate is expected to be comparable or lower than baseline error rate.
Error rate for Transmit (unencrypted email)	Baseline error rate is expected to be low. Tracking error rate is expected to be comparable or lower than baseline error rate.
Error rate for Transmit (secure)	Baseline error rate is expected to be low. Tracking error rate is expected to be comparable or lower than baseline error rate.
Error rate for View Activity Log	Baseline error rate is expected to be low. Tracking error rate is expected to be comparable or lower than baseline error rate.

Attestation

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in the plan is up to date and fully addresses the health IT developer’s Real World Testing requirements.

Authorized Representative Name: Lauri Sippola

Authorized Representative Email: lauri.sippola@elekta.com

Authorized Representative Phone: +358 40 661 7170

Authorized Representative Signature: 

Date: 10 / 13 / 2022

TITLE	ONC Kaiku Health Real World Test Plan 2023
FILE NAME	Kaiku Health Real...st Plan 2023.docx
DOCUMENT ID	08a297de22739474dc9990acfa53f1173b1bda85
AUDIT TRAIL DATE FORMAT	MM / DD / YYYY
STATUS	● Signed

Document history



SENT

10 / 13 / 2022

09:41:25 UTC

Sent for signature to Lauri Sippola
 (lauri.sippola@elekta.com) from martin.deppe@kaikuhealth.com
 IP: 62.165.128.226



VIEWED

10 / 13 / 2022

12:06:54 UTC

Viewed by Lauri Sippola (lauri.sippola@elekta.com)
 IP: 188.190.122.36



SIGNED

10 / 13 / 2022

12:07:30 UTC

Signed by Lauri Sippola (lauri.sippola@elekta.com)
 IP: 62.165.128.210



COMPLETED

10 / 13 / 2022

12:07:30 UTC

The document has been completed.