

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:	<u>https://www.elekta.com/products/oncology-informatics/mosaiq-</u> 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. Realworld error rates will be established for each of those functionalities.

10/12/2022



Milestones

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

Measures used in Overall Approach

Description of Measurement/Metric

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



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

Associated Certification Criteria

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

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	Transmitting patients' health information via unencrypted
email)	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)

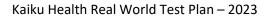
Care Settings

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.

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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.

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