

General Information

Plan Report ID Number: **FOR Drummond Use**

Developer Name: Elekta Inc

Product Name: MOSAIQ

Version Numbers: 2.7, 2.81, 2.82, 2.83, 2.84

Certified Health IT 15.04.04.1420.MOSA.28.03.1.201231

Product list (CHPL) IDs: 15.04.04.1420.MOSA.28.01.1.190625

15.04.04.1420.MOSA.28.02.1.200413

15.04.04.1420.MOSA.28.03.1.201231

15.04.04.1420.MOSA.28.04.1.220630

Developer Real World

Testing page: <https://www.elekta.com/products/oncology-informatics/mosaiq-real-world-testing/>

Justification for Real World Testing Approach

MOSAIQ is a certified health information system that manages the treatment of cancer patients in both the medical oncology and radiation oncology healthcare setting. While managing cancer treatment, patient documentation is coordinated between healthcare providers, patients, and ancillary services within and outside the healthcare organization. The shared documentation includes transition of care documents, electronic prescriptions, healthcare summaries, immunization records and information provided to patients through a portal.

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 is included in this test plan:

- § 170.315(b)(1) Transitions of care
- § 170.315(b)(2) Clinical information reconciliation and incorporation
- § 170.315(b)(3) Electronic prescribing
- § 170.315(b)(6) Data export
- § 170.315(b)(7) Security tags - summary of care - send
- § 170.315(b)(8) Security tags - summary of care - receive
- § 170.315(e)(1) View, download, and transmit to 3rd party
- § 170.315(f)(1) Transmission to immunization registries
- § 170.315(g)(7) Application access— patient selection
- § 170.315(g)(8) Application access— data category request

§ 170.315(g)(9) Application access— all data request

§ 170.315(h)(1) Direct Project

Overall Approach

The test plan consists of 4 user stories that reflect the general workflow of MOSAIQ users as it pertains to the certified criteria and standard data. Within each user story there are one or more certification criteria that are used to share data among providers, patients and services that will be tested and measured for use and success.

Several measurements will be taken for each user story which demonstrate the real-world use of the criteria.

The user stories include:

1. Patient consultation visit
2. Patient treatment
3. Treatment complete
4. Patient Electronic Health Information (EHI) export

The goal of this approach is to demonstrate how the interoperability and conformance capabilities of MOSAIQ meet the needs of clinicians and patients in use in the real world.

Testing grid

| Criteria | User story | Care settings | Versions |
|---|------------|--|--|
| § 170.315(b)(1) Transitions of care | #3 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(b)(2) Clinical information reconciliation and incorporation | #1 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(b)(3) Electronic prescribing | #2 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(b)(6) Data export | #4 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(b)(7) Security tags - summary of care - send | #3a | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(b)(8) Security tags - summary of care - receive | #1a | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(e)(1) View, download, and transmit to 3rd party | #1 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(f)(1) Transmission to immunization registries | #2 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(g)(7) Application access— patient selection | #2 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(g)(8) Application access— data category request | #2 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(g)(9) Application access— all data request | #3 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |
| § 170.315(h)(1) Direct Project | #1 #3 | Radiation Oncology Medical Oncology | MOSAIQ 2.7 MOSAIQ 2.81 MOSAIQ 2.82 MOSAIQ 2.83 MOSAIQ 2.84 |

Care Settings

Elekta markets its products in the Radiation Oncology and Medical Oncology care settings. Each user story in the test plan is applicable to both care settings.

Milestones

| Milestone | Care Setting | Timeframe |
|--|--|------------------------|
| Development of candidate list of providers to assist with Real World Testing | Radiation Oncology Medical Oncology | January 31, 2023 |
| Development of software and/or SQL queries to be used for data analysis | Radiation Oncology Medical Oncology | February 28, 2023 |
| Confirm participation of providers to assist with Real World Testing | Radiation Oncology Medical Oncology | April 30, 2023 |
| Begin collection of information as laid out by plan | Radiation Oncology Medical Oncology | June, 2023 |
| Completion of collection of information | Radiation Oncology Medical Oncology | January 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 |

User Story #1. Patient consultation visit

A patient arrives for a consultation visit where a decision to treat is made by the healthcare staff and patient. A patient summary is received and incorporated from the referring provider, patient information is collected from the patient and diagnostic services and orders are entered to collect additional diagnostics and prepare for treatment, either chemotherapy and/or radiation. The patient establishes a portal account and views their clinical summary on the patient portal.

User story 1a Privacy indicator

This is a variation of user story 1 where the patient is designated as a private/VIP patient by the referring provider restricting the users ability to see the clinical summary.

Justification for Real World Testing Approach

This user story is a typical workflow for the incorporation of a new patient, designating a specific cancer diagnosis and arrival at a decision between the physician and patient to commence treatment. Within this workflow there are several criteria that can demonstrate real-world use simultaneously, namely *§170.315(h)(1) Direct Project* to receive the clinical summary, *§170.315(b)(2) Clinical information reconciliation and incorporation* to incorporate the received information, *§170.315 § 170.315(e)(1) View, download, and transmit to 3rd party* allowing the patient to view their healthcare information on their portal and (*§170.315(b)(8) Security tags - summary of care - receive* to restrict access to the clinical summary.

Standards and Updates

| Version | CHPL ID | Standards |
|-------------|-----------------------------------|--|
| MOSAIQ 2.7 | 15.04.04.1420.MOSA.28.03.1.201231 | All standards versions are those specified in the Common Clinical Data Set |
| MOSAIQ 2.81 | 15.04.04.1420.MOSA.28.01.1.190625 | As above |
| MOSAIQ 2.82 | 15.04.04.1420.MOSA.28.02.1.200413 | As above |
| MOSAIQ 2.83 | 15.04.04.1420.MOSA.28.03.1.201231 | As above |
| MOSAIQ 2.84 | 15.04.04.1420.MOSA.28.04.1.220630 | As above |

Overall Expected outcomes

Real World Testing will show that MOSAIQ is interoperable as specified by §170.315(h)(1) using DIRECT to receive health care summaries.

Real World Testing will show that MOSAIQ can be used to receive, reconcile and incorporate health care summaries as specified by §170.315(b)(2).

Real World testing will show that a patient can view, download, and transmit their clinical summary through their portal as specified by §170.315(e)(1).

Real World Testing will show that MOSAIQ can receive clinical summaries with a privacy indicator and restrict viewing rights to authorized users, prohibiting the view of such summaries to unauthorized users as specified by §170.315(b)(8).

Measures – User Story #1

| §170.315(h)(1) | Receive health summary using DIRECT |
|---------------------|---|
| Methodology | Log files will be used to track the frequency of DIRECT to receive health information. |
| Justification | Demonstrates real-world use of DIRECT messaging to receive clinical summaries sent by referring providers |
| Expected outcome(s) | It is expected that health care providers will receive clinical summaries using the DIRECT protocol. |

| §170.315(b)(2) | Create a single reconciled list of medications, medication allergies, or problems from received summary and active patient record |
|----------------|--|
| Methodology | Reports will be used to calculate the number of times that medications, problems and allergies are incorporated into a medical record compared to the number of referrals into a clinic. |
| Justification | Demonstrates real-world use of DIRECT messaging to receive, incorporate, and reconcile clinical summaries sent by referring providers |

| | |
|---------------------|--|
| Expected outcome(s) | It is expected that a high percentage of new patients and incoming referrals with clinical summaries are incorporated into the new patient records. The test will report the frequency of use of MOSAIQ to receive, reconcile, and incorporate clinical summaries. |
|---------------------|--|

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|---------------------|---|
| §170.315(e)(1) | View, download and transmit to a third party |
| Methodology | SQL queries will be run to track the frequency of patient views, downloads and transmissions to third parties |
| Justification | Demonstrates real-world patient use and frequency of the patient portal to view, download and/or transmit their health information. |
| Expected outcome(s) | Numbers of patient views, downloads and transmissions |

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|---------------------|--|
| §170.315(b)(8) | Security tags - summary of care - send |
| Methodology | SQL queries will be run to ascertain the frequency of clinical summaries received with a privacy indicator. A test CCDA with a privacy indicator will be imported by a) an unauthorized user and b) an authorized user. |
| Justification | Demonstrates real-world use of the privacy indicator in incoming clinical summaries and verifies that only authorized users can view those clinical summaries. |
| Expected outcome(s) | Numbers that reflect the frequency of received clinical summaries with a privacy indicator and a positive test of the restriction of viewing rights of a summary with a privacy indicator to authorized users. |

User Story #2. Patient treatment

The patient arrives for radiation simulation and setup (radiation care setting) and receives an immunization shot. Outpatient medications are ePrescribed to mitigate possible treatment side effects and appointments are scheduled for multiple instances of treatment and in-treatment consultations. On treatment days, vital signs, lab tests and other information are captured and treatment is delivered. During treatment, the patient views their current lab tests via a Patient Access API.

Justification for Real World Testing Approach

This user story is a typical workflow for the setup and process for ongoing cancer treatment. In this use case the patient is administered an immunization in one visit which is transmitted to public health demonstrating §170.315(f)(1) *Transmission to immunization registries* and an order is sent to a local pharmacy demonstrating §170.315(b)(3) *Electronic prescribing*. Additionally, a patient uses an API application to retrieve their clinical data using §170.315(g)(7) *Application access— patient selection* and §170.315(g)(8) *Application access— data category request*. The test metrics describe the real-world use of these interoperability capabilities.

Standards and Updates

| Version | CHPL ID | Standards |
|-------------|-----------------------------------|--|
| MOSAIQ 2.7 | 15.04.04.1420.MOSA.28.03.1.201231 | All standards versions are those specified in the Common Clinical Data Set |
| MOSAIQ 2.81 | 15.04.04.1420.MOSA.28.01.1.190625 | As above with the addition of NCPDP SCRIPT Version 2017071 |
| MOSAIQ 2.82 | 15.04.04.1420.MOSA.28.02.1.200413 | As above |
| MOSAIQ 2.83 | 15.04.04.1420.MOSA.28.03.1.201231 | As above |
| MOSAIQ 2.84 | 15.04.04.1420.MOSA.28.04.1.220630 | As above |

| Standards updates | |
|---|--|
| Standard and version | NCPDP SCRIPT Version 2017071 |
| Updated certification criteria and associated product | § 170.315(b)(3) Electronic prescribing MOSAIQ 2.81, 2.82, 2.83, 2.84 |
| CHPL ID | 15.04.04.1420.MOSA.28.01.1.190625 15.04.04.1420.MOSA.28.02.1.200413 15.04.04.1420.MOSA.28.03.1.201231 15.04.04.1420.MOSA.28.04.1.220630 |
| Method used for standard update | Required - Cures |
| Measure used to demonstrate conformance | ePrescribing |
| Customer notification | May 31, 2019 |

Overall Expected outcomes

Real World testing will show that MOSAIQ will successfully transmit electronic prescriptions as specified in §170.315(b)(3).

Real World testing will show that MOSAIQ will successfully collect immunization information and transmit the data to immunization registries as specified in §170.315(f)(1).

Real World testing will show that the MOSAIQ Patient Access API can receive search parameters and identify a patient ID from an API application as specified in §170.315(g)(7) and can receive search parameters for a specific category of patient data and return the data as specified in §170.315(g)(8).

Measures – User Story #2

| §170.315(b)(3) | Electronic prescribing |
|---------------------|--|
| Methodology | SQL queries will be run to determine the frequency of ePrescribing messages and the number of errors during transmission |
| Justification | Demonstrates the real-world use of ePrescribing to manage patient prescriptions with outpatient pharmacies. |
| Expected outcome(s) | Clinicians will be able to manage outpatient prescriptions with local pharmacies with few errors. Less than 1% of errors are expected. |

| | |
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| §170.315(f)(1) Transmission to immunization registries | |
| Methodology | Interface logs will be scanned and de-identified to determine the use of the immunization interface message transmissions. |
| Justification | The test will illustrate the real-world use of immunization data transmission to public health registries. |
| Expected outcome(s) | It is expected that clinics are able to transmit their immunization information successfully. Error rates will be tracked. |

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|--|--|
| §170.315(g)(7) Application access— patient selection | |
| Methodology | Interface logs will be reviewed to determine the number of API applications registered and the number of patient selection API transactions over time. |
| Justification | This test will demonstrate the real-world frequency of use of the Patient Access API for patients to retrieve their clinical information. |
| Expected outcome(s) | API applications will be able to receive properly-authorized patient ID's. |

| | |
|--|---|
| §170.315(g)(8) Application access— data category request | |
| Methodology | Interface logs will be reviewed to measure the volume of patient laboratory results retrievals. |
| Justification | This will test the use of an API application to access patient data for a patient residing in a real-world data base. |
| Expected outcome(s) | The patient lab results will be retrieved in full and without error. |

User Story #3. Treatment complete

After the final treatment, the physician documents a treatment summary and sends the summary via DIRECT to the referring physician. The referring physician reviews and incorporates the clinical summary.

User Story 3a Privacy indicator

This is a variation of user story 3 where the clinical summary is designated as restricted to users with high privacy user rights.

Justification for Real World Testing Approach

This user story is a typical workflow for the completion of a cancer treatment episode. The clinician summarizes the treatment episode and a clinical summary is sent to the original referring provider demonstrating §170.315(b)(1) *Transitions of care* and §170.315(h)(1) *Send health summary using DIRECT*. In a variation of that clinical summary, the document is sent with a privacy indicator demonstrating §170.315(b)(7) *Security tags - summary of care – send*. Later the patient views the clinical summary using an API application using §170.315(g)(9) *Application access— all data request*.

Standards and Updates

| Version | CHPL ID | Standards |
|-------------|-----------------------------------|--|
| MOSAIQ 2.7 | 15.04.04.1420.MOSA.28.03.1.201231 | All standards versions are those specified in the Common Clinical Data Set |
| MOSAIQ 2.81 | 15.04.04.1420.MOSA.28.01.1.190625 | As above |
| MOSAIQ 2.82 | 15.04.04.1420.MOSA.28.02.1.200413 | As above |
| MOSAIQ 2.83 | 15.04.04.1420.MOSA.28.03.1.201231 | As above |
| MOSAIQ 2.84 | 15.04.04.1420.MOSA.28.04.1.220630 | As above |

Overall Expected outcomes

Real-world interoperability is displayed using DIRECT to send the results of healthcare treatment to a referring provider as specified by §170.315(b)(1) Transitions of care.

Real World Testing will show that MOSAIQ can send clinical summaries with a privacy indicator and restrict viewing rights to authorized users, prohibiting the view of such summaries to unauthorized users as specified by §170.315(b)(7).

Real World testing will show that the MOSAIQ Patient Access API can receive a request for a patient clinical summary and provide a complete summary as specified by §170.315(g)(9) Application access— all data request.

Measures – User Story #3

§170.315(h)(1) Send health summary using DIRECT

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|---------------------|--|
| Methodology | Log files will be used to track the frequency of DIRECT to send health information. |
| Justification | Demonstrates real-world use of DIRECT messaging to send clinical summaries to referring providers |
| Expected outcome(s) | It is expected that health care providers will receive clinical summaries using the DIRECT protocol. |

§170.315(b)(1) Transitions of care

| | |
|---------------------|--|
| Methodology | SQL queries will be used to determine the number of clinical summaries sent to providers. |
| Justification | Demonstrates the real-world use of DIRECT interoperability to send health information upon completion of oncology treatment. |
| Expected outcome(s) | It is expected that a high percentage of oncology treatments result in clinical summaries sent to referring providers. |

§170.315(g)(9) Application access— all data request

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|---------------|---|
| Methodology | Logs will be used to measure the volume of All Data Requests |
| Justification | Demonstrates the real-world frequency of this particular API data request |

| | |
|---------------------|--|
| Expected outcome(s) | API applications will be able to request and receive patient’s properly authorized clinical summary data. Error rates will be tracked. |
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| §170.315(b)(7) | Security tags - summary of care - send |
| Methodology | Test CCDA’s with a privacy indicator will be created by a) an unauthorized user and b) an authorized user and visually analyzed. |
| Justification | Demonstrates that a clinical summary can be sent upon a transition of care such that it is viewable only by authorized users. |
| Expected outcome(s) | All CCDA’s designated as “private” by the user will be constrained with the Confidentiality Code in accordance with the standard specified in DS4P R1. |

User Story #4 Patient EHI Export

An external system is brought online with need to populate MOSAIQ patients and their clinical histories. The external system is provided with clinical summaries from multiple selected MOSAIQ patients.

Justification for Real World Testing Approach

This user story is an imagined need to make use of a multiple patient clinical summary export as described in §170.315(b)(6) Data export

Standards and Updates

| Version | CHPL ID | Standards |
|-------------|-----------------------------------|--|
| MOSAIQ 2.7 | 15.04.04.1420.MOSA.28.03.1.201231 | All standards versions are those specified in the Common Clinical Data Set |
| MOSAIQ 2.81 | 15.04.04.1420.MOSA.28.01.1.190625 | As above |
| MOSAIQ 2.82 | 15.04.04.1420.MOSA.28.02.1.200413 | As above |
| MOSAIQ 2.83 | 15.04.04.1420.MOSA.28.03.1.201231 | As above |
| MOSAIQ 2.84 | 15.04.04.1420.MOSA.28.04.1.220630 | As above |

Overall Expected outcomes

Real World Testing will show that MOSAIQ is interoperable as specified by §170.315(b)(6) Data export.

Measures – User Story 4

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|---------------------|---|
| §170.315(b)(6) | Data export |
| Methodology | SQL queries will be used to measure the number of Batch Export instances and CCDA’s per batch. |
| Justification | Demonstrates the real world use of the data export function. |
| Expected outcome(s) | Users will be able to batch export clinical summaries for multiple patients for use by external systems. Error rates will be tracked. |

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: Padmasri Bhetanabhotla
Authorized Representative Email: Padmasri.Bhetanabhotla@elekta.com
Authorized Representative Phone: +1 408 830 8028
Authorized Representative Signature: *Padmasri Bhetanabhotla*
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