Cerner Corporation Certified Health IT 2024 Real World Testing Plan

Cerner Corporation, a wholly-owned subsidiary of Oracle, is proud to offer software that is certified under the Office of the National Coordinator (ONC) for Health Information Technology (HIT) Health IT Certification Program. Contained within is Cerner’s calendar year 2024 Real World Testing Plan for all 2015 Cures Update Edition certification criteria subject to the Real World Testing Condition & Maintenance of Certification requirements at 45 CFR 170.405 that were certified as of August 31, 2023.

Individual Real World Testing plans are organized by certification criterion with identification of each Certified Health IT Module under which the criteria are certified on the ONC’s Certified Health IT Product List (CHPL). In some instances, testing plans have been combined for efficiency to account for multiple Certified Health IT Modules or certification criteria. Unless otherwise noted, testing plans account for all active certified versions of the identified Certified Health IT Module(s).

Please note, several Real World Testing plans involve the use of production activity data from real world use of Cerner’s Certified Health IT Modules. This production activity data is aggregated across customers and no protected health information (as defined under HIPAA) or customer-specific identifiable information is used or contained in the information provided for Real World Testing results.

Cerner affirms that 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 Cerner’s Real World Testing requirements.

Mike Hourigan, Sr. Director, Product Regulatory Strategy
mike.hourigan@oracle.com | 816-201-1924

October 23, 2023
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### Real World Testing Methodologies

Real World Testing (RWT) of the Transitions of Care certified capabilities is best performed by tracking customer use for sending a conformant HL7® CDA® Consolidated Clinical Document Architecture (C-CDA) document upon patient discharge from inpatient or emergency department encounters, or upon referral between ambulatory providers. The C-CDA documents are created per applicable U.S. Core Data for Interoperability (USCDI) and HL7 CDA C-CDA R2.1 Implementation Guide (IG) specifications cited as standard for the Transitions of Care criterion from a combination of clinical data recorded directly by end users in the patient record, reconciled and incorporated from external C-CDA documents received inbound, and/or interfaced through HL7 V2 transactions.

The Continuity of Care Document (CCD), Referral Note, and Discharge Summary C-CDA document templates created in Millennium (Clinical) are generated locally and exchanged through Direct Messaging and Integrating the Healthcare Enterprise (IHE) query-based document exchange methodologies. Cerner will track and report on the real world production activity of three distinct components of capabilities supported under the Transitions of Care criterion across our customer base. This real world production activity tracking is achieved via the use of a Cerner cross-database analytics tool which provides near real-time activity tracking of active production environment use.

### Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

Implementation in Acute, Ambulatory, Emergency department, as well as Pediatric and Behavioral health-specific care settings are represented in the aggregate metric reporting.

### Standards Updates

N/A

### Real World Testing Milestones

1. Complete actual RWT activities execution (includes execution of monthly report): end of Q3 2024
2. Complete assessment of RWT data for results and outcomes compilation: end of year 2024

### Real World Testing Expected Outcomes

The expected outcomes for C-CDA document creation and exchange tracking will be observance of extremely high volumes of successful document generation and exchange reaching the tens of millions on a monthly basis. This is due to the broad customer base actively utilizing these certified capabilities in production environments and reflects the overall success of our certified capabilities in the real world.

The expected outcomes for the C-CDA display component will be consistent usage in month-to-month tracking indicating successful utilization of the certified capabilities without drop-off in volumes.

The expected outcomes for the C-CDA validation component will be very low usage with somewhat scattered numbers on a month-to-month basis. This reflects our experience where the value of the conformance validation error visibility to end-users is very low as their focus is the content of the documents they are viewing and the ability to effectively reconcile data into the local record (a capability that is part of the 170.315(b)(2) Clinical Information Reconciliation and Incorporation criterion).

### Real World Testing Metrics

1. Number of standards-conformant C-CDA documents created per month by C-CDA document template (CCD, Referral Note, Discharge Summary)
2. Number of times per month a C-CDA document was opened and viewed utilizing the certified C-CDA viewer capability
<table>
<thead>
<tr>
<th>3. Number of times per month the C-CDA validator capability was leveraged to assess the standards conformance of a C-CDA being viewed</th>
</tr>
</thead>
</table>

### Justification for Real World Testing Approach

We selected the methodology of tracking production activity for the three identified components across our U.S. customer base as this reflects the actual real world use of the certified capabilities in the provision of healthcare for their intended purposes. This is in stark contrast to testing of manufactured care scenarios in production environments or non-production environment activity and aligns closely with the Office of the National Coordinator for Health IT’s (ONC) stated intent and purpose of RWT. It also provides a direct view of active use of certified software on a day-to-day basis across all applicable live care settings to avoid exclusion of particular settings or implementations.

For the tracking of C-CDA documents created and transmitted, isolating to the specific certified C-CDA document templates ensures that the testing is exclusively assessing use of standards-conformant C-CDA documents. The methodology also accounts for inclusion of all pertinent patient records in production systems. The production activity being tracked and reported on assesses workflows available to all user roles and assigned by each customer based on their processes and needs. The system does not limit the number of users in these workflows.
Real World Testing Methodologies
Real World Testing (RWT) of the Transitions of Care certified capabilities for Soarian Clinicals is best performed by tracking customer use for sending a conformant HL7® CDA® Consolidated Clinical Document Architecture (C-CDA) document upon patient discharge from inpatient or emergency department encounters, or upon referral between ambulatory providers. The C-CDA documents are created per HL7 CDA C-CDA R2.1 Implementation Guide (IG) specifications cited as standard for the Transitions of Care criterion from a combination of clinical data recorded directly by end users in the patient record, reconciled and incorporated from external C-CDA documents received inbound, and/or interfaced through HL7 V2 transactions.

The Continuity of Care Document (CCD), Referral Note, and Discharge Summary documents created in Soarian Clinicals are transmitted through Cerner's Document Management product. The method for tracking the sending of C-CDA documents will be counted by two sending workflows: automatic physician-based routing and manual sending. The data will be collected through a file in Document Management per customer and sent to Cerner’s Healthcare Intelligence analytics product for cross-customer production reporting. This file also collects the type of C-CDA documents sent per patient.

This reporting approach aligns with needs for RWT as it excludes irrelevant C-CDA workflows such as Automated Document Routing to patient portals for patient access use-cases. The report per customer will also contain the number of C-CDA documents received as part of transitioning the patient into a care setting and will be evidence for Transition of Care receive capabilities. Additionally, we capture metrics on invalid C-CDA documents received inbound that will be used to demonstrate real world counts of C-CDAs that do not meet the minimum required specifications as defined by the Office of the National Coordinator for Health IT (ONC). Lastly, we will demonstrate real world value of allowing the quantity and order of C-CDA sections displayed when viewing a document via reporting on a system setting that users can apply to establish viewing preferences.

Care Settings for Real World Testing
- Acute
- Emergency Department

With this criterion, we will be testing Acute (Inpatient setting) and Emergency Department care settings as applicable to the certification of Soarian Clinicals as a certified HIT module. Soarian Clinicals is not certified or marketed beyond the Acute and Emergency Department care settings.

Standards Updates
N/A

Real World Testing Milestones
1. Complete identification of target customer participants: end of January 2024
2. Complete readiness for customer query execution: end of Q2 2024
3. Complete actual Real World Testing activities execution (includes execution of monthly report): end of Q3 2024
4. Complete assessment of Real World Testing data to compile results and outcomes: end of year 2024

Real World Testing Expected Outcomes
The expected outcomes will be measured using a monthly report derived from Cerner's Healthcare Intelligence analytics product for the sending and receiving of C-CDA document and will provide successful active engagement in the sample of customer production environments.

For the validation criteria, the outcomes will be measured by a unique monthly report that reflects across all customers the count of C-CDAs that are in error.

For the display criteria, the outcomes will be measured by a unique monthly report derived from the Advanced Interoperability Service (AIS) that reflects the instances of customers that have modified their preferences. Overall,
outcomes anticipated are high volumes of utilization of the certified capabilities reflecting successful implementation and use of certified software in the real world.

<table>
<thead>
<tr>
<th>Real World Testing Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. For the sending and receiving of C-CDA documents, number of patient visits for which a C-CDA document was either received or sent (target 50%+)</td>
</tr>
<tr>
<td>2. For the validation of C-CDA documents, the rate of C-CDA documents received inbound with any error (target less than 25%)</td>
</tr>
<tr>
<td>3. For the validation capabilities system settings, number of customers who have changed their display settings during the measurement period (target less than 5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Justification for Real World Testing Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerner selected the methodology of using the Document Management reporting file as this reflects the actual real world use of sending and receiving C-CDA documents as part of patient care transitions. When C-CDA validation is enabled, the reporting provided captures outcomes of validation of C-CDA documents. The validation reports accurately reflect whether the C-CDA document meets conformance specifications.</td>
</tr>
</tbody>
</table>

For end-user display of C-CDA documents, the evidence of customers modifying their system settings shows real world use of certified C-CDA viewing capabilities in varying sequences and views. This RWT and measurement accounts for all Soarian Clinicals customers using certified software across relevant care settings and implementations, rather than narrowing to particular settings and implementations. Importantly, all the metrics that are being reported on are derived from active customer installed and live production environments, which aligns with the intent and purpose of RWT. The methodology also accounts for all patient records in production systems and all relevant workflows for leveraging the certified capabilities.
# 170.315(b)(2) Clinical Information Reconciliation and Incorporation

**Certified Health IT Module(s):** Millennium (Clinical)

**CHPL Product Numbers:** 15.04.04.1221.Mill.18.06.1.221107

**Relied Upon Software:** N/A

## Real World Testing Methodologies

Real World Testing (RWT) for Clinical Information Reconciliation and Incorporation for Millennium (Clinical) will utilize reporting derived from a Cerner cross-database analytics tool to provide near real-time activity tracking of active production environment use of the relevant certified capabilities. With these reports, Cerner is able to measure and report real world adoption of these certified capabilities by tracking discrete actions taken on the data extracted from HL7® CDA® Consolidated Clinical Document Architecture (C-CDA) documents received inbound from external sources. Specific actions tracked and reported on will be as follows:

- Problems added
- Problems rejected
- Allergies added
- Allergies rejected
- Home Medications added
- Home Medications rejected

These measurements will provide supporting evidence that clinical data reconciliation is being actively utilized by Cerner customers at the point of care. Reconciled data was received from either manually matched C-CDA documents that were received inbound from Direct Messaging exchange, or automated patient matching from Integrating the Healthcare Enterprise (IHE) query-based exchange.

## Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

The Millennium (Clinical) certified HIT module supports workflows for all defined care settings above. Clinical data reconciliation is a clinical end-user function and configuration that is consistent across care settings and enabled based on user role. Data from all defined care settings is tracked in the RWT metrics for this testing plan.

## Standards Updates

N/A

## Real World Testing Milestones

1. Retrieve customer production activity tracking data reports: **first week of Q4 2024**
2. Complete assessment of production activity tracking data reports: **mid-Q4 2024**
3. Complete compilation of RWT results from production activity tracking data reports assessment: **end of year 2024**

## Real World Testing Expected Outcomes

Expected outcomes include general consistency across months throughout the year for overall reconciliation actions (including both add and reject actions). This provides assurances that the certified capabilities are serving our customers’ needs on a day-to-day basis without significant issues and/or interruptions. We also expect to observe higher volumes of reconciliation actions for Problems and Medications than for Allergies. This is expected as most patients are more likely to have a higher number of Medications and Problems than they would have Allergies, which will naturally result in more actions for those concepts.

## Real World Testing Metrics

1. Total number of Problems added and rejected per month
2. Total number of Allergies added and rejected per month
3. Total number of Home Medications added and rejected per month
Note: all reconciliation actions being tracked are taken on external data parsed from HL7 CDA C-CDA documents received inbound.

<table>
<thead>
<tr>
<th>Justification for Real World Testing Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>The RWT metrics selected are directly sourced from U.S. customer production activity for the workflows and actions enabled by the certified capabilities. These metrics provide the best possible view of real world use of the certified capabilities and ensure representation of all identified applicable care settings in the data.</td>
</tr>
</tbody>
</table>
170.315(b)(2) Clinical Information Reconciliation and Incorporation

Certified Health IT Module(s): Soarian Clinicals

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Relied Upon Software: First Data Bank (FDB) Interoperability Module

Real World Testing Methodologies
Real World Testing (RWT) of Clinical Information Reconciliation and Incorporation certified capabilities is best evidenced by tracking actual customer use of the Soarian Clinicals workflows in which an HL7® CDA® C-CDA document received inbound was matched to a patient and reconciled into the local record. This shows correct patient matching and incorporation of data provided by the externally sourced C-CDA documents.

The data provided by the C-CDA documents are accessed by clinicians through three clinical information reconciliation workflows: Allergy Reconciliation, Problem Reconciliation, and Medication Reconciliation. Cerner’s testing methodology will leverage customer production environment tracking via our Healthcare Intelligence analytics product with a report which will count only when each of the reconciliation actions occurs with a C-CDA document for the pertinent workflows.

Care Settings for Real World Testing
- Acute
- Emergency Department

With this RWT plan, Cerner will be testing Acute (Inpatient setting) and Emergency Department care settings as applicable to the certification of Soarian Clinicals as a certified HIT module. Soarian Clinicals is not certified or marketed beyond the Acute and Emergency Department care settings.

Standards Updates
N/A

Real World Testing Milestones
1. Complete identification of target customer participants: end of January 2024
2. Complete technical readiness for customer query execution: end of Q2 2024
3. Complete actual RWT activities execution (includes monthly report execution): end of Q3 2024
4. Complete assessment of RWT data for results and outcomes compilation: end of year 2024

Real World Testing Expected Outcomes
The overall expected outcome for the RWT plan will be high volumes of reconciliation actions across the sampled customer base. This provides indication of active customer engagement with and use of Clinical Information Reconciliation and Incorporation capabilities in the real world.

Real World Testing Metrics
1. Number of patient visits during the measurement period with at least one reconciliation workflow performed (target = 50%+)

Justification for Real World Testing Approach
The RWT methodology described above leverages data from actual customer use across a representative sampling of production environments. This demonstrates use of each of the three reconciliation workflows while specifically focusing metrics on reconciling with an imported C-CDA document that was matched to a patient. It also aligns directly with the intent and purpose of RWT, as opposed to relying on manufactured tests and scenarios. Furthermore, the plan does not include failures or exceptions as consideration in the evaluation of the outcomes as the data represents the end-user’s true experience reconciling data from a C-CDA document.

The methodology also accounts for both the full scope of the Clinical Information Reconciliation and Incorporation criterion and also all applicable care settings for which the certified capabilities are marketed.
170.315(b)(3) Electronic Prescribing

Certified Health IT Module(s): Millennium (Clinical); PowerChart Touch

CHPL Product Numbers: 15.04.04.1221.Mill.18.06.1.221107; 15.04.04.1221.Powe.03.02.1.210308

Relied Upon Software: N/A

Real World Testing Methodologies
In order to demonstrate successful Real World Testing (RWT) of certified ePrescribing capabilities, the live transactions within customer production environments will be queried to show that all services in use are functional across various applicable care settings. Transactions will be reviewed based on the applicable care settings for at least 30 days from the calendar year to demonstrate continued successful use over time while ensuring applicable transaction data is still available for reporting.

Some components of the full ePrescribing criterion will be excluded due to lack of active real world use. As the industry adopts use-cases for those particular components, additional tracking for will be included for future RWT as appropriate. Additionally, to account for RWT of the leading/trailing zeros and oral liquid metric dosing requirements under the ePrescribing criterion, implementation testing processes executed when enabling ePrescribing at a customer site will include functional requirements for these capabilities.

Care Settings for Real World Testing
- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

Some of the capabilities covered under the ePrescribing criterion apply to all care settings while others are specifically targeted at a subset of care settings. Those associations are outlined below by specific capability. In addition, the RxFill transaction has no adoption at this time and cannot be tracked as part of the RWT plan. Additional tracking for RxFill will be added when applicable in future RWT plans.

- Create new prescriptions (NewRx): All care settings
- Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse): Ambulatory care setting
- Request and respond to cancel prescriptions (CancelRx, CancelRxResponse): All care settings
- Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse): Ambulatory care setting
- Receive fill status notifications (RxFill): Current adoption too low to track (not industry supported until release on 2017071 and pharmacy adoption has not increased since release)
- Request and receive medication history (RxHistoryRequest, RxHistoryResponse): All care settings
- Relay acceptance of a transaction back to the sender (Status): All care settings
- Respond that there was a problem with the transaction (Error): All care settings

Standards Updates
N/A

Real World Testing Milestones
1. Complete identification of target customer participants: end of January 2024
2. Complete review and updates to reports used for tracking real world use of the applicable certified capabilities: end of Q2 2024
3. Complete actual RWT activities execution: end of Q3 2024
4. Complete assessment of RWT data for results and outcomes compilation: end of year 2024

Real World Testing Expected Outcomes
The expected outcomes for the RWT activities for ePrescribing certified capabilities center on observing a large volume of each transaction across the supported care settings with a high rate of success. This will demonstrate that all certified capabilities are working as expected in all care settings where they are intended to be used.

Real World Testing Metrics
<table>
<thead>
<tr>
<th>1. Success rate across all prescription transactions (including renewal and change requests) routed electronically for the measurement period (target = 90%+)</th>
</tr>
</thead>
</table>

### Justification for Real World Testing Approach

By monitoring transactions within actual customer production environments, it is possible to show use and the successful processing of transactions by both sending and receiving parties. This guarantees that we test actual real world use of the certified ePrescribing capabilities and not a simulation of use. These queries can also be run in any environment, so selection of organizations to be monitored can account for the variety of care settings that our certified capabilities support.

Standards conformance of the transactions being tracked is also assured as only successful transactions will be processed by the receiving entity. Multiple queries will be used to account for the different components of the ePrescribing criterion and ensure all related transactions are accounted for in tracking as applicable.

Additionally, the RWT methodology accounts for multiple care settings at which the certified capabilities are deployed by identifying the user and encounter associated to the transaction being monitored. This allows Cerner to understand the user’s position within the domain as well as the type of encounter that the patient has which will indicate which care setting is related to the specific transaction and ensure that all applicable care settings are appropriately represented.

Finally, our configuration and process for generating ePrescribing transactions in the required NCPDP SCRIPT Version 2017071 standard are consistent regardless of where the message will be sent or what particular product/application it originated from. This means that our chosen methodology accurately accounts for all identified certified HIT modules/versions and all potential variances in implementation in a single RWT plan.
Real World Testing Methodologies
In order to demonstrate successful Real World Testing (RWT), the live ePrescribing transactions within customer environments will be queried to show that all services in use are functional across various care settings. Transactions will be reviewed based on the applicable care settings for at least 30 days to demonstrate continued successful uses over time while ensuring applicable transaction data is still available.

Some components will be exempt as there is no real world use today. Additional tracking for those components will be included as the industry adopts those use cases. Cerner will leverage customer production environment tracking via existing processes which involve retrieval of summarized, non-PHI volume statistics from the system via process monitoring operations. Reports will be compiled using this production activity monitoring data and volumes will be subtotaled by success/failure status (where applicable), and by visit type of Inpatient (IP) and Emergency Department (EOP).

Regarding methodology for the leading/trailing zeros and oral liquid metric dosing requirements, mandating inclusion of functional requirements as part of implementation testing processes when enabling ePrescribing at customer sites will guarantee that we test real world use of these capabilities.

Care Settings for Real World Testing
- Acute
- Emergency Department

Some of the capabilities covered under the ePrescribing criterion apply to all care settings while others are specifically targeted at a subset of care settings. Those associations are outlined below by specific capability. In addition, the RxFill transaction has no adoption at this time and cannot be tracked as part of the Real World Testing plan. Additional tracking for RxFill will be added when applicable in future Real World Testing plans.

- Create new prescriptions (NewRx): All care settings
- Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse): All care settings
- Request and respond to cancel prescriptions (CancelRx, CancelRxResponse): All care settings
- Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse): Not applicable to Soarian Clinicals’s supported care settings
- Receive fill status notifications (RxFill). Current adoption too low to track (not industry supported until release on 2017071 and pharmacy adoption has not increased since release)
- Request and receive medication history (RxHistoryRequest, RxHistoryResponse): All care settings
- Relay acceptance of a transaction back to the sender (Status): All care settings
- Respond that there was a problem with the transaction (Error): All care settings

Standards Updates
N/A

Real World Testing Milestones
1. Complete identification of target customer participants: end of Q2 2024
2. Complete actual RWT activities execution: end of Q3 2024
3. Complete assessment of RWT data for results and outcomes compilation: end of year 2024

Real World Testing Expected Outcomes
The expected outcomes for the RWT plan is the ability to show a large volume of each transaction across the supported care settings with a high rate of success. This will demonstrate that all certified capabilities are working as expected in all care settings where they are intended to be used.

Real World Testing Metrics
1. Success rate across all prescription transactions (including renewal and change requests) routed electronically for the measurement period (target = 90%+)

Justification for Real World Testing Approach
This RWT plan keys on tracking the majority of transactions related to this criterion and showing that they are overwhelmingly successful in real world use related to actual patient care. Not all prescriptions will be able to be processed for various reasons such as pharmacy or intermediary downtimes, missing information required for standards conformance, or connection issues, which is why the target for the identified metric is less than 100%.

This metric also tracks all transactions under the criterion with the exception of RxHistory requests and responses. These transactions are more difficult to account for success due to requirements placed on the application by third parties communicating the information bi-directionally. Often, multiple requests will be triggered prior to receiving a response and cause the success rates to be unreliable. By tracking the success rates of all other transactions, we can validate that they were received whenever possible and conformed to the NCPDP SCRIPT Version 2017071 standard cited for the ePrescribing criterion. If they were not formatted properly then they would be returned as failures.
Clinical Quality Measures (CQMs) – 170.315(c)(1)-(3)

Certified Health IT Module(s): Millennium (CQMs)

CHPL Product Numbers: 15.04.04.1221.Mill.18.04.1.220101

Relied Upon Software: Cerner Quality Reporting (all criteria)

Real World Testing Methodologies

The CQM – record and export criterion at 170.315(c)(1) enables the customer/user to record all of the data that would be required to calculate eCQMs and allows the customer/user to export a data file conforming to the applicable release of the HL7® CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category 1 (QRDA I) specifications at any time. The CQM – import and calculate criterion at 170.315(c)(2) enables the customer to import and calculate every CQM used for reporting purposes utilizing the same HL7 CDA QRDA I specification. The CQM – report criterion at 170.315(c)(3) enables a user to electronically create a data file conformant with the applicable annual release of the Category I and Category III CMS Implementation Guides for Quality Reporting Document Architecture (QRDA) for transmission of clinical quality measurement data.

In order to demonstrate successful Real World Testing (RWT) for the CQM – record and export and CQM – report criteria, we will track data submissions to Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) for a sample of Cerner Millennium® customers that have used Cerner’s Millennium (CQMs) certified capabilities to record and process the eCQM data through the Cerner Quality Clearinghouse portal for their CMS and TJC submissions. The following EH measures will be used during the testing: ED-2, VTE-1, STK-2 and Safe Use of Opioids. Additionally, CMS-165 and CMS-122 will be included as these are applicable to the Ambulatory Care setting.

For the CQM – import and calculate criterion, we will demonstrate successful real world use by coordinating with a customer that requires the import of QRDA data files from an external third-party source system to Cerner Millennium system and observe the successful use of our certified capabilities to import the data.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

Cerner has identified the above care settings as those supported by our certified eCQM capabilities. These applicable care settings are derived directly from the care settings which the actual eCQMs that the Millennium (CQMs) certified HIT module is certified for. All of the measures under the Eligible Hospital (EH)/Critical Access Hospital (CAH) eCQMs can be mapped to Acute or Emergency Department care settings, while all of the measures under the Eligible Clinician (EC) eCQMs can be mapped to Ambulatory Care setting.

Standards Updates

HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, STU Release 5.3 with errata - US Realm, December 2022

- Method used for standard update: SVAP
- Date notification sent to ONC-ACB: October 23, 2023
- Date notification sent to customers: October 18, 2023
- Measure used to demonstrate conformance with updated standard: Metric #1 from this RWT plan demonstrates conformance to the new standard via tracking of successful generation of QRDA files using the updated conformance standard


- Method used for standard update: SVAP
- Date notification sent to ONC-ACB: October 23, 2023
- Date notification sent to customers: October 18, 2023
- Measure used to demonstrate conformance with updated standard: Metric #3 from this RWT plan demonstrates conformance to the new standard via tracking of successful submission for CMS and TJC reporting using the new standard


- Method used for standard update: SVAP
- Date notification sent to ONC-ACB: October 23, 2023
- Date notification sent to customers: October 18, 2023
- Measure used to demonstrate conformance with updated standard: Metric #3 from this RWT plan demonstrates conformance to the new standard via tracking of successful submission for CMS and TJC reporting using the new standard

**Real World Testing Milestones**

1. Complete identification of target customers for testing (EH and EC): **end of Q1 2024**
2. Complete execution of RWT activities: **end of Q2 2024**
3. Complete assessment of RWT data for results and outcomes compilation: **end of year 2024**

**Real World Testing Expected Outcomes**

RWT outcomes for the Millennium (CQMs) certified HIT module will consist of successful QRDA file submission to CMS and TJC across the tracked customers. More specifically, for Eligible Hospitals, Cerner reports display the measure outcomes for each qualifying encounter and the aggregated outcome count for the quarter. The encounter could have an outcome assigned of Initial Population, Denominator, Denominator Exclusion, Numerator, or Exception. The aggregated count will include a total for each of the outcomes. These counts should match CMS/TJC submission reports.

For Eligible Clinician measures, the QRDA III Cerner audit report matches the submission detail report generated by the Cerner Quality Clearinghouse. The following outcomes are evaluated: Patient population, Denominator, Denominator Exclusion, Numerator, Exception, Performance rate, Medicare Population (Denominator), and Tax Identification Number (TIN) counts. The validation of the expected outcome correlates to successful real world use of the certified capabilities.

**Real World Testing Metrics**

1. CQM – record and export criterion: percentage of selected patients for whom QRDA files are successfully generated (target = 100%)
2. CQM – import and calculate: percentage of patient data successfully imported (target = 90%)
3. CQM – report criterion: percentage of successful QRDA file submissions to CMS/TJC with less than 10% outcome mismatches against Cerner reporting (target = 95%)

**Justification for Real World Testing Approach**

A customer’s ability to successfully submit eCQM data to CMS/TJC for the Hospital Inpatient Quality Reporting (IQR), Joint Commission Accreditation, and Merit-based Incentive Payment System (MIPS) Quality Measurement Category directly correlates to the customer’s actual real world use of the CQM – record and export and CQM - report criteria certified capabilities. Likewise, ability to import and submit QRDA data files for a customer that has transitioned from a third-party EHR to Cerner Millennium correlates with a customer’s real-world use of CQM – import and calculate criterion.

Our RWT methodology is designed directly around tracking successful submissions for these real world programs which represent the ultimate purpose for which these certification criteria exist. Additionally, the workflows utilized for the eCQMs remain the same for all of the care settings applicable for the CQM certified capabilities. Thus, the methodology appropriately accounts for all care settings. This is verifiable via the output file (QRDA) which includes data identifying the source care setting.

Similarly, Cerner eCQM Reporting is consistent across all organizations regardless of size or type and Cerner’s Quality Clearinghouse can cater to numerous providers for different quarters and/or for a full year evaluation. This is irrespective of the large volumes of patients which can be sourced from the Cerner Millennium EHR. Accordingly, the selected methodologies also appropriately account for potential variances in implementations at different sizes and types of organizations.
Clinical Quality Measures (CQMs) – 170.315(c)(1)-(3)

Certified Health IT Module(s): Soarian Clinicals

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Relied Upon Software: Health Services Analytics (all criteria)

Real World Testing Methodologies

The methodology for Real World Testing (RWT) of the Soarian Clinicals CQM certified capabilities under the CQM – record and export (170.315(c)(1)) and CQM – report (170.315(c)(3)) criteria will make use of the real world generation of certified Quality Reporting Document Architecture (QRDA) files by customers and their subsequent successful submission of that data to the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) for eCQM reporting programs.

We will utilize a customer pool that represents an appropriate sampling of different hospital settings, workflows, and processes that are used in the real world for the certified capabilities. As part of the methodology, reports will be systematically validated by utilizing various queries and Soarian Clinicals eCQM reports. These reports will be compared with the reports provided by the regulatory agencies (CMS/TJC) after submission to determine the success rate of these criteria. The following Eligible Hospital measures will be used during the testing: Admit Decision Time to ED Departure for Admitted ED Patients (CMS111), Venous Thromboembolism Prophylaxis (eVTE-1), Discharged on Antithrombotic Therapy (CMS104), and Safe Use of Opioids (CMS506).

For the CQM – import and calculate criterion (170.315(c)(2)), the methodology will make use of test scripts and the actual mock testing scenario execution will be performed on the testing EHR environment that appropriately mirrors real world use and conditions. A set of mock data will be imported into Cerner’s Healthcare Intelligence eMeasure application and will be used to generate the QRDA files.

Care Settings for Real World Testing

- Acute
- Emergency Department

We have identified the above care settings as those supported by the Soarian Clinicals eCQM certified capabilities and the same workflows are utilized across both. All of the measures under the Eligible Hospitals (EH)/Critical Access Hospital (CAH) eCQMs which Soarian Clinicals are certified for can be mapped to Acute or Emergency Department care settings.

Standards Updates

<table>
<thead>
<tr>
<th>Implementation Guide</th>
<th>Method used for standard update</th>
<th>Date notification sent to ONC-ACB</th>
<th>Date notification sent to customers</th>
<th>Measure used to demonstrate conformance with updated standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, STU Release 5.3 with errata - US Realm, December 2022</td>
<td>SVAP</td>
<td>October 23, 2023</td>
<td>October 18, 2023</td>
<td>Metric #1 from this RWT plan demonstrates conformance to the new standard via tracking of successful generation of QRDA files using the updated conformance standard</td>
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</table>


- SVAP
- October 23, 2023
- October 18, 2023
- Metric #3 from this RWT plan demonstrates conformance to the new standard via tracking of successful submission for CMS and TJC reporting using the new standard

- Method used for standard update: SVAP
- Date notification sent to ONC-ACB: October 23, 2023
- Date notification sent to customers: October 18, 2023
- Measure used to demonstrate conformance with updated standard: Metric #3 from this RWT plan demonstrates conformance to the new standard via tracking of successful submission for CMS and TJC reporting using the new standard

### Real World Testing Milestones

1. Complete identification of target customers (EH) for CQM – record and export and CQM – report criteria: **end of Q1 2024**
2. Complete setup of testing EHR environment that replicates CQM – import and calculate criterion usage in the real world: **end of Q1 2024**
3. Complete actual RWT activities for CQM – record and export and CQM – report criteria: **end of Q1 2024**
4. Complete actual RWT activities for CQM – import and calculate criterion: **end of Q2 2024**
5. Complete assessment of RWT data for results and outcomes compilation: **end of year 2024**

### Real World Testing Expected Outcomes

The expected outcomes for the Soarian Clinicals CQM Real World Testing will consist primarily of the observations outlined in the RWT metrics. For Eligible Hospitals, Soarian Clinicals eCQM reports display the measure outcomes for each qualifying encounter and the aggregated outcome count for the quarter. These counts should match with the relevant population in CMS/TJC submission reports. The various population counts for the selected measures and calendar quarter will be compared with values in Soarian Clinicals eCQM reports and justified with the results returned using Database queries.

### Real World Testing Metrics

1. CQM – record and export: Percentage of successful QRDA file generation for export for patients qualified according to the measure logic (target = 100%)
2. CQM – report: Percentage of successful QRDA file submissions to CMS/TJC with less than 10% outcome mismatches against Cerner reporting (target = 95%)
3. CQM – import and calculate: Percentage of successfully imported QRDA files from the testing (target = 100%)

### Justification for Real World Testing Approach

Our methodologies appropriately account for all applicable care settings for the certified capabilities, which is traceable via data in the output file (QRDA) identifying the care setting from which the encounter originated. Tracing of the appropriate care settings can also be attained by dissecting the data in the customer database for the data elements which is traversed from Soarian Clinicals to the eMeasure application. Furthermore, Soarian Clinicals eCQM reporting is consistent for all hospitals, regardless of their size or type.

The RWT methodologies for CQM – record and export and CQM – report criteria correlate to the actual use of the certified capabilities in the real world through the tracking of customer data submissions to CMS or TJC that are performed using our certified capabilities. This aligns well with the intent of RWT and will provide reliable evidence of the certified capabilities’ real world usability post-certification.

For the CQM – import and calculate criterion, the current Soarian Clinicals customer base does not have an identifiable real-world use case for import functionality. Thus, tracking of real world use will be infeasible and the functionalities pertaining to the criterion can only be tested in an internal mock testing environment that will closely mirror a customer production environment.
Real World Testing Methodologies
To perform Real World Testing (RWT) for the View, Download, and Transmit to 3rd Party (VDT) criterion, Cerner will track real world use of the HealtheLife patient portal by consumers credentialed for access to their health information by our customers across a 3-month measurement period. This data will be aggregated, de-identified, and shared via a report from the patient portal environments used by our customers.

Reports will be specifically designed to home-in on use of particular capabilities that closely align with the requirements of the VDT criterion, which is reflected by the associated metrics defined for RWT plan. The description of the data set used in the report will outline the number of HealtheLife portals based in the U.S. that contributed to the data.

Care Settings for Real World Testing
- Acute
- Ambulatory
- Emergency Department

The selected care settings are representative of the primary care settings of the provider organizations which currently utilize HealtheLife as a patient portal.

Standards Updates
N/A

Real World Testing Milestones
1. Complete planning and estimates for requirements to carry out the defined RWT plan: **end of Q1 2024**
2. Establish operational processes allowing retrieval of data for defined metrics needed for submission of RWT results: **end of Q3 2024**
3. Complete execution of the established operational processes and a draft report of the RWT results: **end of November 2024**

Real World Testing Expected Outcomes
The outcomes Cerner expects to observe from the HealtheLife RWT plan include high volume of frequently used VDT capabilities within the product. The volume of unique users will reflect the number of persons that were enabled to interact with the electronic health data for themselves and others within a given timeframe.

Volume for the events of viewing is expected to be greater than the events for downloading and transmitting health records as view actions are considered primary use of HealtheLife and more accessible/user-friendly functions. Download and transmit features in HealtheLife are accessed less frequently and thus will have a lower volume of events.

Real World Testing Metrics
1. Number of unique HealtheLife users that viewed an element of the health record during the measurement period
2. Number of total combined viewing events of the health record during the measurement period
3. Number of unique HealtheLife users that downloaded or transmitted an HL7® CDA® C-CDA Continuity of Care Document (CCD) during the measurement period
4. Number of unique HealtheLife users that viewed Access Logs during the measurement period
5. Number of total viewing events of Access Logs during the measurement period

Justification for Real World Testing Approach
Viewing health information through the HealtheLife patient portal is the primary purpose of the product. Each view of the health record portion of HealtheLife will represent a user navigating the portal and accessing their health information. When referenced against the # of unique users that viewed health information, a larger picture can be developed of the effectiveness of HealtheLife and its real-world capabilities to enable access to health information.
Furthermore, the tracking of actual live production activity (as opposed to manufactured testing scenarios in mock environments) provides a true representation of the real-world use of the product. This makes for ideal alignment with ONC’s intent for RWT.
# 170.315(e)(1) View, Download, and Transmit to 3rd Party

**Certified Health IT Module(s):** Patient Portal – MMD  
**CHPL Product Numbers:** 15.07.04.1221.Pati.MM.01.0.180720  
**Relied Upon Software:** N/A

## Real World Testing Methodologies

Cerner’s elected methodology for the Real World Testing (RWT) of the View, Download, and Transmit to 3rd Party (VDT) criterion for the Patient Portal – MMD certified HIT module consists of specialized reports that capture data on both the reportable usage of the VDT capabilities in specific care settings, as well as gauging items such as a patients’ or proxies’ experience accessing their healthcare information. This includes, among other items, accessibility and ease of searching for their information to ensure that the full scope of the certified capabilities are accounted for.

A report will be generated from Patient Portal – MMD customers’ production environments on a bi-annual basis that shows the usage of the following VDT capabilities per care setting and selected date range:

- Discharged patients had access to the Patient Portal on time
- Discharged patients had access to their C-CDA on time
- New patients being provisioned to the Patient Portal (In addition to counting new user account creations per quarter, also count how many of those discharged in the quarter already had access prior to the visit, versus new patients without a prior portal account.)
- Patients or their proxies logging in to the Patient Portal
- Patients or proxies viewed their C-CDA’s
- Patients or proxies downloaded their C-CDA’s
- Patients or proxies transmitted their C-CDA’s (both securely and via unsecured email)
- Patients accessed their audit log

An additional Patient Portal – MMD user report will be generated from the customers’ production environments on a bi-annual basis that shows the usage of the following VDT capabilities per de-identified user and selected date range:

- Number of logins
- Number of total documents viewed
- Number of total C-CDA’s viewed
- Number of dashboard (parsed C-CDA aggregated views)
- Number of Acute visits • Number of Ambulatory visits
- Number of Emergency visits

Activity tracking in these reports will be designed to account for various available methods of access provision, including: manual (a system component), rapid ADT (an integration), Experian (an integration), and validation code entry (a system component)

## Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

Patient Portal – MMD is used by healthcare providers in Acute, Emergency Department, and Ambulatory care settings to provide their patients electronic access to their health information.

## Standards Updates

N/A

## Real World Testing Milestones

1. Complete actual RWT activities execution: **mid-Q4 2024**
2. Assess data and compile RWT results: **end of Q2 and Q4 2024**
Real World Testing Expected Outcomes

2022 and 2023 RWT observed outcomes provided a baseline for expected outcomes for 2024. We anticipate active participation especially among the Inpatient population of the VDT criteria. Some of the VDT events will not have much activity across all Care Centers, but viewing health information will be a popular event. We also expect new patients to continually gain access to the Patient Portal throughout the observed measurement periods.

Real World Testing Metrics

1. Success rate for patients being provided access to their health information during the measurement periods (target = 90%)
2. Percentage of patients or proxies who have created a username when offered to exercise ability to access their health information on the patient portal during the measurement periods (target = 60%)
3. Success rate for HL7® CDA® Consolidated Clinical Document Architecture (C-CDA) documents received on time in the patient portal during the measurement periods (target = 98%)

Justification for Real World Testing Approach

Overall, the selected metrics are the best options for providing evidence of the certified capabilities being successfully leveraged for their intended purpose (i.e., enabling fast, secure, and reliable access to health information electronically). Measuring the success rate for patients being provided access to their health information and patients (or their proxies) actually creating accounts/usernames to exercise their access addresses the root of the upstream source of enabling use of the Patient Portal – MMD certified HIT module and is a reflection of our customers’ confidence in the value of the capabilities for their intended purpose.

The 90% and 60% target success rates in the identified metrics account for the following circumstances:

- Patient does not have an email address (required to be provisioned)
- Patient does not desire access (conscious declination)
- Patient does not have electronic device and/or internet access
- Errors due to incorrect ADT Rapid Provisioning (RAP) segment

Measuring the success rate of HL7 CDA C-CDA documents containing patients’ structured health information being received on time in the patient portal is critical to ensure that the data patients (and their proxies) are seeking is actually available in a timely manner. The 98% success target accounts for rare occurrences of transmission failures or potential downtimes.
### 170.315(f)(1) Transmission to Immunization Registries

**Certified Health IT Module(s): Millennium (Immunizations)**

<table>
<thead>
<tr>
<th>CHPL Product Numbers: 15.04.04.1221.Mill.03.1.220101</th>
</tr>
</thead>
</table>

**Relied Upon Software:** Cerner Medication Administration Record (MAR); Vaccinations Outgoing Interface OR Cerner Hub - Immunizations

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**Real World Testing Methodologies**

For the Transmission to Immunization Registries criterion as certified under the Millennium (Immunizations) certified HIT module, Cerner’s Real World Testing (RWT) methodology will consist of monitoring real world production use of the certified capabilities over a 30-day measurement period. The specific system activities tracked will include the following:

- User or system-initiated queries to Immunization Information Systems (IIS) for patient immunization history
- Reconciliation of immunization history data to update the local patient record and EHR immunization forecast
- Administration of vaccines (whether via automated scanning or manual entry, or historical documentation where applicable) to initiate submission of the vaccination records to an IIS

Cerner will accomplish this production activity tracking via the use of a cross-database analytics tool which provides near real-time activity tracking of active production environment use. Additionally, Cerner’s new, more advanced certified capability for immunizations reporting under the certified HIT module enables monitoring of deeper details for immunization history query and reconciliation, such as failure reasons and discrete data volumes accepted or rejected into the local patient record.

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**Care Settings for Real World Testing**

- Acute
- Ambulatory
- Emergency Department
- Pediatrics

The applicable care settings include any setting where vaccinations may be administered or managed for a patient. This includes Acute venues who often administer pneumococcal and influenza vaccines to deficient patients and the hepatitis B birth doses to newborns. This also includes the Emergency Department who often administer Tdap shots for patients who may have come in contact with a rusty object. Of course, Pediatrics and Ambulatory also administer routine vaccines to patients according to Advisory Committee on Immunization Practices (ACIP) recommendations, which is where the majority of vaccine administrations occur.

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**Standards Updates**

N/A

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**Real World Testing Milestones**

1. Complete compilation of plan for specific data to measure: **end of 2023**
2. Execute data reporting of RWT activities for identified timeframe: **end of Q3 2024**
3. Complete assessment of RWT data for results and outcomes compilation: **end of year 2024**

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**Real World Testing Expected Outcomes**

Through the identified RWT methodology, we anticipate observing high volume daily use of certified capabilities in production environments by our customers. We also anticipate that the success rates of transactions for both the submission and query capabilities will indicate that immunizations data is being successfully exchanged on a consistent basis with a broad range of partner IIS registries.

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**Real World Testing Metrics**

1. Estimated number of production domains live with query and reporting capabilities to any IIS during the measurement period
2. Volume of successful queries (QBPs) initiated to an IIS over the measurement period
3. Success rate for submissions (VXUs) to any valid endpoint using our certified standards-conformant HL7® v2.5.1 messaging interface over the measurement period (target = 90%)
Note: 10% failure rate for metric #3 accounts for intermittent failures beyond the system’s control, such as:
- Registration staff did not accurately capture patient demographics, or patient was unwilling/unable to provide information necessary to successfully match a patient during query (e.g., mother’s maiden name)
- Clinician misdocuments vaccine details during administration (e.g., incorrect lot number)
- Network connectivity issues or failures on the endpoint’s end resulting in inability to accept valid requests

**Justification for Real World Testing Approach**

We believe tracking the estimated number of production environments with live connections to at least one IIS will accurately represent our market base and care settings actively using the certified functionality. A high volume of active connections also provides a reliable indication of the value of our certified capabilities to our customer base.

Since query failures are generally out of our system’s control (patient match errors, uptime connectivity, etc. are controlled by the IIS), we chose to track query volumes overall instead of a % success or fail. High volumes of successful queries also demonstrates real world interoperability of the certified capabilities in lieu of a success rate metric. Additionally, keying on successful queries ensures conformance to the HL7 2.5.1 Implementation Guide (IG) for Immunization Messaging, Release 1.5 specifications as conformance is a standard condition of acceptance by the IIS.

Finally, tracking success rates for submissions is the ideal metric for ensuring that certified capabilities are actively and successfully used for interoperability purposes. Further, similar to the query tracking, a successful VXU message provides indication of conformance to the HL7 2.5.1 Implementation Guide (IG) for Immunization Messaging, Release 1.5 specifications as the submissions would not otherwise be accepted.
170.315(f)(1) Transmission to Immunization Registries

Certified Health IT Module(s): Soarian Clinicals

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Relied Upon Software: N/A

Real World Testing Methodologies
Soarian Clinicals Transmission to Immunization Registries Real World Testing (RWT) methodology consists of a combination of production activity tracking via transaction results from connected state Immunization Information Systems (IIS) where available, along with a compilation of internal transaction results compiled from our customer base. The tracking will be conducted over the full Q3 of the calendar year to provide a broad representative sample of production activity.

In collaborating with each state IIS, we have discovered that not all discretely track transmission results or have them available only in raw data transactions. As such, data obtained directly from state IISs is supplemented with data from querying customer databases directly for query and submission evidence. The methodology was also designed to account for all applicable care settings and sizes and types of organizations. The immunization query and submission workflows available in Soarian Clinicals are consistent across care settings as a common user interface (UI) service component is shared whether it is called from Acute or Emergency Department care settings.

Care Settings for Real World Testing
- Acute
- Emergency Department

Soarian Clinicals is an Acute care solution with an integrated EDIS. Immunization records will be submitted the same regardless of the patient care settings to the appropriate state IISs upon patient discharge.

Standards Updates
N/A

Real World Testing Milestones
1. Complete actual RWT activities execution for the target customers: end of Q3 2024
2. Complete assessment of RWT data for results and outcomes compilation: end of year 2024

Real World Testing Expected Outcomes
Expected outcomes from conducting the RWT activities will be observance of high volumes of daily use of certified immunization query and reporting capabilities in production by customers qualified for the relatively small Soarian Clinicals installed customer base. Reporting on the discrete data will allow us to continue establishing and revising baselines for volumes and further expectations for future RWT activities.

Real World Testing Metrics
1. Total transactions from state IIS data across the measurement period
2. Number of successful messages from state IIS data across the measurement period
3. Number of failure messages from state IIS data across the measurement period
4. Success rate for submissions and queries with state IISs across the measurement period (target = 90%+)
5. Total transactions from internal customer transaction data across the measurement period
6. Number of successful messages from internal customer transaction data across the measurement period
7. Number of failure messages from internal customer transaction data across the measurement period
8. Success rate for submissions and queries from internal customer transaction data across the measurement period (target = 90%+)

Justification for Real World Testing Approach
Reporting on production activity tracking data from state IISs as well as querying customer production databases provides a baseline to monitor activity for immunization data exchange. Target success rates of 90%+ would indicate an acceptable and productive use of the capabilities as we realize there are some failures outside of the certified capabilities’ control, such as timeouts due to network outages, data corruption in payload, etc.

Additionally, by monitoring both overall transaction volumes and success rates we can provide a more complete picture of overall real world interoperability of the certified capabilities while also tracking abnormalities for resolution. This is because a stable network traffic and instance should not deviate from the established threshold.
Real World Testing Methodologies
The objective of this Real World Testing (RWT) plan is to provide evidence of the successful and conformant reporting of syndromic surveillance information to target public health agencies (typically state departments of health (DOH)) from the Cerner Syndromic Surveillance and HealthSentry certified HIT modules.

We will provide evidence of successful creation and transmission of the required PHIN Messaging Guide for Syndromic Surveillance, Release 2.0 specification transactions for ED encounters to target public health agencies. The plan is to engage a representative sample of customers actively transmitting syndromic surveillance information to their respective DOH and capture submission logs and transactions for an appropriate 30-day period to show evidence of ongoing transmission of the following Admission, Discharge, and Transfer (ADT) HL7® transactions:
- A01 – Admissions
- A04 – Emergency Department (ED)
- A03 – Discharge
- A08 – Revise Patient Information

Care Settings for Real World Testing
- Acute
- Emergency Department

Cerner Syndromic Surveillance and HealthSentry are standalone applications which process and format ED encounter transactions received from Cerner Millennium® EHR systems.

Real World Testing Milestones
1. Establish target customers for test sample: end of Q1 2024
2. Gather sample customer submission logs: end of Q1 2024
3. Prepare summary RWT results report: end of Q2 2024

Real World Testing Expected Outcomes
The results of the RWT plan will indicate the successful ongoing transmission of the HL7 transactions to the target DOH. It shall demonstrate the test sample customers actively and successfully generate and send information for their ED patients during the test period. This includes admissions (A01), discharges (A03), and ED registrations (A04), as well as any update transactions (A08) specific to data reported for syndromic surveillance for the patients included in the reporting test period.

This approach will show successful “active engagement” with public health registries as required for customers who rely on the certified capabilities as part of measurement under the Centers for Medicare and Medicaid Services’ (CMS) Promoting Interoperability programs.

Real World Testing Metrics
1. Percentage of successful daily syndromic surveillance transactions (A01, A04 – ED, A03, A08) for sample customers across the 30-day selected measurement period (target = 85%+)

Justification for Real World Testing Approach
Cerner’s Syndromic Surveillance and HealthSentry certified HIT modules are designed to provide standardized HL7 transmission of required patient and clinical information to public health agencies. As part of the certification process, Cerner demonstrated Syndromic Surveillance and HealthSentry generate the appropriate outbound messages as admissions, ED registrations, discharges and patient updates are saved within the products. Messages are generated near real-time and submitted to public health authorities per their specified timeliness requirements.
Demonstrating the 85% or higher percentage of successful daily submissions provides evidence the required HL7 transactions were successfully created and transmitted from Cerner Syndromic Surveillance and HealthSentry to the DOH on a consistent basis. Using 85% as a target for the metric allows for occasional unanticipated networking errors or interruptions outside of control of the certified capabilities.

Furthermore, the chosen metric directly tracks data indicative of sustained successful utilization of the certified capabilities for their real world purpose. By selecting a specific target subset of active customers for the RWT activities, we are able to ensure that the data appropriately accounts for various sizes and types of organizations utilizing the certified capabilities.
**170.315(f)(2) Transmission to Public Health Agencies — Syndromic Surveillance**

**Certified Health IT Module(s):** Soarian Clinicals

**CHPL Product Numbers:** 15.04.04.1221.Soar.15.01.1.210331

**Relied Upon Software:** Cerner OPENLink

**Real World Testing Methodologies**
The objective of this Real World Testing (RWT) plan is to provide evidence of ongoing (near real-time), successful reporting of syndromic surveillance information to target public health agencies. The RWT plan methodology consists of two components as summarized below:

1. Collect audit data from the production database of a representative sample of customers actively transmitting syndromic surveillance information to their respective Department of Health (DOH) jurisdiction. The auditing will show evidence of ongoing (near real-time) events that generate the following ADT HL7® transactions for Syndromic Surveillance reporting of Acute (Inpatient), Emergency Department (ED) and any customer-designated Urgent Care encounters: A01 – Inpatient Admissions, A04 – Emergency Department (ED)/Urgent Care Registrations, A03 – Discharge (Inpatient/ED/UrgentCare), A08 – Revise Patient Information (Inpatient/ED/Urgent Care). Audit data will be collected for a 2-week testing period within the reporting year and the total (aggregate) number of ADT message events (A01, A04, A03, A08) will be provided for each 2-week sample of audit data. The numbers will show totals for the 2-week test period as well as daily breakdown/averaging to demonstrate ongoing (near real-time) message generation.

2. Monitor Soarian Clinicals issue reporting and tracking tools for any issues specific to the syndromic surveillance certified capabilities to support that they are functioning as expected and customers submitting data to their respective DOH jurisdiction are not encountering issues with the successful transmission/receipt of the supported HL7 ADT transactions.

**Care Settings for Real World Testing**
- Acute
- Emergency Department

Soarian Clinicals is an integrated Acute care solution with an integrated Emergency Department (ED) Information System.

**Standards Updates**
N/A

**Real World Testing Milestones**
1. Monitor for reported issues: **initiate Q1 2024 and continue through Q4 2024**
2. Identify representative test customer sample and test period for audit data collection: **end of Q2 2024**
3. Gather audit data from sample customer production data for test period: **end of Q3 2024**
4. Prepare summary report: **end of year 2024**

**Real World Testing Expected Outcomes**
The results of the RWT will indicate with confidence the ongoing and successful creation of the supported Syndromic Surveillance ADT HL7 transactions. It shall substantiate that the sample customers generate and send information for their Acute Inpatient, ED and designated Urgent Care patients during the measurement period. This includes A01, A03, A04, and A08 transactions specific to Syndromic Surveillance for qualifying patients/encounters included in the reporting test period. These results coupled with minimal (if any) reported issues specific to syndromic surveillance reporting will further show successful "active engagement" with public health registries (as defined for CMS Promoting Interoperability programs) by Soarian Clinicals customers.

**Real World Testing Metrics**
1. Aggregate successful submission volume of the supported messages across the selected 2-week measurement period.

While specific numbers cannot be set as the timing and type of message generated will depend on customer configuration, patient activity, and documentation practices, the aggregate data will show generation of the supported messages throughout each 24-hour period within the 2-week test period. Additionally, monitoring for
customer reported issues affecting syndromic surveillance reporting will further substantiate the conformant
transactions are successfully transmitted (and received) on a sustained ongoing basis to target public health
agencies where the information is available for the intended use in trending and analysis of public health.

Justification for Real World Testing Approach

As part of the certification process, Cerner demonstrated that Soarian Clinicals generates the appropriate outbound
messages as Inpatient Admissions, ED and Urgent Care registrations, Discharges, and Patient Updates are saved in
Soarian Clinicals. Messages are generated near real-time. Each HL7 message was certified to be conformant to
required content and format. Customers who subsequently pursued implementation of these capabilities for
“active engagement” with DOH as part of Centers’ for Medicare and Medicaid Services’ (CMS) Promoting
Interoperability programs completed an onboarding/verification process with their respective DOH jurisdiction to
assure information was being successfully transmitted and received prior to full implementation of their Production
data.

To demonstrate real world use of the feature, the focus of the methodology is to provide evidence that Soarian
Clinicals is raising the required events for creation of the supported ADT HL7 transactions for syndromic
surveillance on a continuous basis (over a 2-week testing period) rather than on a scripted occurrence as
demonstrated during the certification process. Focusing on actual submission activity is the best indication of
successful real world use for the intended purposes. The methodology also leverages Cerner’s existing mechanism
for tracking Soarian Clinicals issues related to Office of the National Coordinator for Health IT (ONC) certification
requirements. If there are issues with the successful generation and receipt/acceptance of the supported
syndromic surveillance ADT HL7 messages, the customer would report an issue for investigation. Minimal (or no)
reported issues will support that the feature is working as expected.

Finally, the RWT methodology will include a representative sample of facilities that are actively submitting
syndromic surveillance data for applicable care settings to ensure all are appropriately accounted for in the testing
data and metrics.
## 170.315(f)(3) Transmission to Public Health Agencies — Reportable Laboratory Tests and Value/Results

**Certified Health IT Module(s):** Electronic Lab Results; HealthSentry

<table>
<thead>
<tr>
<th>CHPL Product Numbers:</th>
<th>15.04.04.1221.Heal.23.06.1.230331; 15.04.04.1221.Elec.23.06.1.230331</th>
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**Relied Upon Software:** N/A

### Real World Testing Methodologies

The objective of this Real World Testing (RWT) plan is to provide evidence of the successful and conformant reporting of reportable laboratory results information to target public health agencies via utilization of the Cerner Electronic Lab Results and HealthSentry certified HIT modules. The target public health agencies are typically state departments of health (DOH). The RWT methodology will consist of evidence of successful creation and transmission of the required HL7® 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 transactions for reportable laboratory results to target public health agencies. The strategy is to engage a representative sample of customers actively transmitting reportable lab information to their respective DOH and capture submission logs and transactions for a 30-day period during the calendar year to show evidence of ongoing successful real world use of the certified capabilities.

### Care Settings for Real World Testing

- Acute

Electronic Lab Results and HealthSentry are both standalone products that perform processing and formatting of reportable laboratory result transactions received from Cerner Millennium® EHR systems. These capabilities are exclusively intended for the Acute care venue.

### Standards Updates

N/A

### Real World Testing Milestones

1. Establish target customers for test sample: **end of Q1 2024**  
2. Gather sample customer submission logs: **end of Q1 2024**  
3. Prepare summary report: **end of Q2 2024**

### Real World Testing Expected Outcomes

The expected outcomes of the RWT plan will be that the test sample customers generate and transmit information for their reportable laboratory results successfully on a daily-basis during the test period. This will provide proof of “active engagement” with public health registries as required for customers who rely on the certified capabilities as part of measurement under the Centers’ for Medicare and Medicaid Services’ (CMS) Promoting Interoperability programs.

### Real World Testing Metrics

1. Percentage of successful daily reportable laboratory results transactions for sample customers across the 30-day selected measurement period (target = 85%+)

### Justification for Real World Testing Approach

Electronic Lab Results and HealthSentry are designed to provide standardized HL7 transmission of required patient and clinical information to public health agencies. These certified HIT modules provide the information on the specified outbound HL7 transactions according to the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 specifications. As part of the certification process, Cerner demonstrated Electronic Lab Results and HealthSentry generate the appropriate outbound messages containing all required message segments. Messages originating from Electronic Lab Results are generated near real-time and submitted to public health authorities per their specified timeliness requirements, while those originating from HealthSentry are generated in a batch file and submitted to public health authorities daily.

To demonstrate real world implementation/use of this feature, the plan will show successful transmission of the required HL7® transactions to the target public health agency on an ongoing basis (over a 30-day test period) rather than on a scripted occurrence as demonstrated during the certification process. The testing will gather submission logs for the sample customers who will be strategically selected to ensure coverage of all appropriate...
care settings served by the certified HIT modules. Since message formatting and submission processing is consistent for all users of the certified HIT modules, the plan also appropriately accounts for any unique implementations or potential variances between different sizes or types of organizations.

Showing the 85% or higher percentage of successful daily submissions provides evidence the required HL7 transactions were successfully created and transmitted from Cerner Electronic Lab Results and HealthSentry to the DOH. This target also accounts for occasional unanticipated networking errors or interruptions outside of control of the certified Electronic Lab Results and/or HealthSentry processing.
## 170.315(f)(3) Transmission to Public Health Agencies — Reportable Laboratory Tests and Value/Results

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<td>CHPL Product Numbers:</td>
<td>15.07.04.1221.NOVI.NO.01.0.180720</td>
</tr>
<tr>
<td>Relied Upon Software:</td>
<td>N/A</td>
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### Real World Testing Methodologies

The Real World Testing (RWT) methodology for NOVIUS Lab Reportable Laboratory Tests and Values/Results certified capabilities will consist of a combination of customer production database and outbound transaction queries to identify unique public health transactions that have been generated by our customers to report real world laboratory results to public health departments.

The queries will be compiled into a report to demonstrate that transactions are successfully transmitted by NOVIUS Lab and received by the customers’ public health department on an ongoing basis. Additionally, NOVIUS Lab will attempt to partner with the customers’ represented Department of Health (DOH) to obtain a record of the “active engagement” as part of Centers’ for Medicare and Medicaid Services’ (CMS) Promoting Interoperability programs. This additional element of the plan will provide supplemental assurances that the certified capabilities are serving their intended real world purpose for our customers.

If partnering with the DOHs proves infeasible for this purpose, we will use our existing internal surveillance report which is generated on a monthly basis to track and respond to any issues identified by customers related to use of the certified capabilities. Having no active issues during the measurement period related to NOVIUS Lab’s Reportable Laboratory Testing and Values/Results certified capabilities will also provide supplemental assurances that customers are achieving “active engagement” as expected and that submissions are conformant.

### Care Settings for Real World Testing

- Acute
- Emergency Department

NOVIUS Lab is utilized to process laboratory samples that are received for analysis from the Acute and Emergency Department care settings. The samples are processed within the lab based on sample type and not on individual care setting. Each state DOH determines result values that are required to be sent regardless of the care setting where the sample is collected. NOVIUS Lab is marketed exclusively to Acute care hospitals.

### Standards Updates

N/A

### Real World Testing Milestones

1. Complete Identification of target NOVIUS Lab customers (those who have their systems configured to electronically send results to their public health department) and their reportable result transactions to public health: end of Q1 2024
2. Execute the reports/queries on identified customer production databases (we will execute the report/query on a daily basis for a single calendar quarter): end of Q2 2024
3. Attempt to work with identified state DOHs and obtain a report showing customers are actively sending results and in active engagement (if engaging the DOHs is not successful by this time, we will generate and include the surveillance report for the test period as an alternative to the partnership with the DOHs): end of Q2 2024
4. Generate final RWT result report: end of Q3 2024

### Real World Testing Expected Outcomes

For targeted customers who have NOVIUS Lab configured to send outbound result transactions to their state DOH, it is expected that NOVIUS Lab will consistently provide successful submission of the desired data for purposes of lab result reporting. This will specifically be identified by monitoring the status of the transactions providing indication of successful delivery and receipt. Generally, we anticipate that results will show submission frequencies varying from daily to once or twice per week across the individual target customers. This is due to the differing sizes of and ranges of reportable specimens supported by the facilities being measured.
### Real World Testing Metrics

1. Volume of Reportable Laboratory Tests and Values/Results successfully generated and transmitted to the appropriate state DOH per customer within a single calendar quarter testing period to include targeted amount of data (target = at least 10)

### Justification for Real World Testing Approach

Measuring successful submissions of data to state DOHs is the best approach for providing a metric that assures successful real world use of the certified capabilities. Due to the small customer base for NOVIUS Lab, the expected volumes will be relatively low. Therefore, showing successful transactions from at least one customer should be attainable. The targets for the metric also take into account any possible issues beyond the control of the certified capabilities (e.g., networking issues, customer configuration, etc.).

The transactions that are reported on via the selected methodology will also be obtained from the full scope of applicable care settings for the RWT plan to ensure proper coverage. This is achieved by using a “Patient Class” identifier on the transactions which indicates the source care setting for the results being transmitted. NOVIUS Lab also determined that due to the small customer base of NOVIUS Lab and consistency in the implementation model, there is no additional variability to account for that is not already covered inherently with the chosen methodology.
### 170.315 (f)(5) Transmission to Public Health Agencies – Electronic Case Reporting

**Certified Health IT Module(s):** Electronic Case Reporting  
CHPL Product Numbers: 15.04.04.1221.1.12.00.1.211229  
Relied Upon Software: Cerner PowerChart; eCR Now FHIR App

**Real World Testing Methodologies**

To demonstrate Real World Testing (RWT) of the Electronic Case Reporting certified HIT module, we will leverage an analytics dashboard which displays the amount of standardized HL7® CDA® R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1–US Realm the Electronic Initial Case Report (eICR) documents and Reportability Responses (RRs) that have been successfully transmitted in live production environments for customers actively using the product.

This methodology reflects activity between the Electronic Case Reporting product and the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform which is the standard pathway for eICR to reach its final destination at the state/local Department of Health (DOH) level. We will then compare this data to an extract from live customer environments which provides the count of cases for which an eICR should have been triggered and transmitted per reportability specifications. This comparison will be done for a full calendar month during 2024 and will provide an indication of the success rate of eICR transmissions in real world use.

The Electronic Case Reporting certified HIT module is a cloud-based product that is implemented and used consistently by all. However, in order to appropriately account for various different sizes and types of customers using the product in the testing activities, we will strategically select target customers by choosing representatives from various applicable market segments and care settings.

**Care Settings for Real World Testing**
- Acute
- Ambulatory

Electronic Case Reporting is centered on locations that diagnose and treat the list of reportable conditions based on the Reportable Conditions Knowledge Management System (RCKMS) conditions list curated by the Council of State and Territorial Epidemiologists (CSTE). These are required for Acute and Ambulatory care sites.

**Standards Updates**
- N/A

**Real World Testing Milestones**

1. Identify target customer subset on which to perform RWT activities: **end of Q1 2024**
2. Contact customers and AIMS for any assistance, if needed: **end of Q2 2024**
3. Complete comparison of successfully transmitted eICRs to records of cases that should have been triggered: **end of Q3 2024**
4. Complete analysis and documentation of RWT findings and outcomes: **end of Q4 2024**

**Real World Testing Expected Outcomes**

Through RWT of the Electronic Case Reporting certified HIT module, we expect to observe a high frequency and volume of overall conditions reported to AIMS given the real-time submission capabilities in play. Additionally, we anticipate testing will show actual conditions/cases reported are well aligned to the count of reportable conditions observed in the system. This indicates an overall highly functioning product for the real world purpose of its certification.

**Real World Testing Metrics**

1. Success rate of reportable conditions for the applicable state/local DOH for which an eICR document is successfully submitted to the AIMS Platform during the measurement period (target 95%+)

Note: The 5% buffer in the target success rate is to account for replays and network latency beyond the control of the certified product. state/local DPH is defined as the state's accepted conditions list which may be a subsection of the full RCKMS conditions list.
**Justification for Real World Testing Approach**

This RWT plan provides evidence that the certified capabilities are actively reporting on conditions identified as reportable based on state/local DOH specifications. The number comparison derived in the identified metric will demonstrate that reportable conditions are not being missed and that the product is ultimately serving its intended purpose in the real world.

Furthermore, the approach ensures that we are appropriately accounting for the range of care settings and various different types and sizes of organizations using the product through strategic selection of target customers for the testing activities as defined as milestone #1 for the testing (e.g., selecting representative customers from applicable market segments).

Finally, although the Electronic Case Reporting criterion does not require a particular standard, the methodology demonstrates proof of conformance to the recognized best practice standard in the industry (i.e., the HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1–US Realm the Electronic Initial Case Report (eICR)) as all submissions to the AIMS Platform must conform to be accepted and receive an Reportability Response.
### 170.315 (f)(5) Transmission to Public Health Agencies – Electronic Case Reporting

| Certified Health IT Module(s): Soarian Clinicals |
| CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331 |
| Relied Upon Software: N/A |

#### Real World Testing Methodologies

The Real World Testing (RWT) methodology employed for the Soarian Clinicals Electronic Case Reporting (eCR) certified capabilities will involve production-like activity testing and tracking for verification of use of the capabilities in the real world. Cerner will specifically be tracking customer-like data to verify reporting activity of sending an HL7® CDA® R2 Implementation Guide: Public Health Case Report, Release 2 STU Release 1.1–US Realm the Electronic Initial Case Report (eICR) document.

To execute the methodology, testing will be executed in a production-like environment with Advanced Interoperability Services (AIS) to test the eCR workflow with sending of the eICR document. We will not be using customer production environments for this testing as there will not be Soarian Clinicals customers live in production with the certified capabilities during the 2024 calendar year.

#### Care Settings for Real World Testing

- Acute
- Emergency Department

With this criteria, we will be testing Acute (Inpatient) and Emergency Department care settings as applicable to the certification of Soarian Clinicals as a certified HIT module. Soarian Clinicals is not certified or marketed beyond the Acute and Emergency Department care settings.

#### Standards Updates

N/A

#### Real World Testing Milestones

1. Complete production-like environment for testing with end-to-end connections, including AIS: end of Q2 2024
2. Complete actual RWT activities execution: end of Q3 2024
3. Complete assessment of RWT activities and outcomes: end of year 2024

#### Real World Testing Expected Outcomes

Although there is no specific content exchange standard for eCR, the eICR document is the standard being adopted across the industry. Accordingly, we expect to observe the RWT activities demonstrate that the certified capabilities enable successful Electronic Case Reporting in alignment with real world industry best practices so that the capabilities could be successfully utilized in the real world by customers, if implemented.

#### Real World Testing Metrics

1. Success rate of eICR document test transmissions processed via AIS (target = 100%)

#### Justification for Real World Testing Approach

The RWT plan for Soarian Clinicals Electronic Case Reporting will be focused on assessing successful generation of the eICR document based on relevant condition triggers in production-like environment and conditions. By successfully sending this document type in production-like environments/conditions, this prepares the Soarian Clinicals customer base for real world use when/if eventually adopted in their live production environments. Additionally, setting up a new production-like environment will mimic the setup for production environments, thus testing all the components for the full end-to-end execution.

Collectively, this plan provides the best possible approach to prove out support for the certified capabilities in the real world in lieu of active real world implementations.
Real World Testing Methodologies

The Real World Testing (RWT) methodology for the Antimicrobial Usage and Resistance (AUR) Reporting certified HIT module will involve observing production use of the certified capabilities through activity trackers embedded in the software. These trackers can be used to determine when customers are generating the AUR reports for subsequent submission to the National Health Safety Network (NHSN). This data can be used to reliably determine which customers are actively utilizing the reports and how often. However, it will not provide proof that they were able to successfully upload the data to the NHSN, which is important to understand as an assurance that the ultimate purpose of these certified capabilities in the real world (i.e., submission to the NHSN's AUR Module) is being served for the users of the certified HIT module.

To account for this final element of the full successful use of the certified capabilities, Cerner engaged with the NHSN requesting information confirming rates of successful submission by participating organizations using Cerner software. However, the report NHSN provides does not contain adequate information to confirm that facilities are successfully submitting AUR data to NHSN. Accordingly, Cerner will leverage a backup option of requesting direct confirmation from customers who have been identified as actively utilizing the Antimicrobial Usage and Resistance Reporting certified HIT module in production of their successful submissions. Customers will be able to confirm this based on the immediate response received within the NHSN upload application affirming success or failure of a submission.

Care Settings for Real World Testing

- Acute
- Emergency Department
- Pediatrics

AUR Reporting is specific to adult and pediatric Inpatient and Emergency Department locations based on the NHSN protocols.

Standards Updates

N/A

Real World Testing Milestones

1. Identify target customers actively using AUR Reporting in production for the 2024 reporting year: end of Q3 2024
2. Complete execution of reports for production activity tracking data and retrieval of NHSN submission evidence from partner customers: end of Q3 2024
3. Compile data for RWT results submission: end of Q4 2024

Real World Testing Expected Outcomes

The expected outcomes of the Antimicrobial Usage and Resistance Reporting RWT plan will consist of observing successful generation of AUR reports across installed customers, along with positive affirmation of successful submission to the NHSN for the vast majority of our customers responding to Cerner's request for confirmation of successful submission.

Real World Testing Metrics

1. Total number of successfully generated Antimicrobial Use (AU) reports over the Q1 and Q2 2024 submission periods
2. Total number of successfully generated Antimicrobial Resistance (AR) reports over the Q1 and Q2 2024 submission periods

Justification for Real World Testing Approach
The selected RWT methodology will demonstrate that the AUR reports are providing the means to submit the required data to the NHSN, which is the ultimate purpose of the certified capabilities in the real world. The NHSN has specific protocols for how the data should be generated and submitted. Cerner followed NHSN protocols during development of AUR reports and has been through the NHSN SDS validation for Antimicrobial Use and Antimicrobial Resistance. Therefore, reports successfully generated from our certified software have a reasonable certainty of conforming to standards for the criterion and associated NHSN protocols. Any evidence of conformance failures would also be identified through our additional testing methodology of obtaining confirmation of subsequent successful submission by customers.

Furthermore, the approach of identifying the target customers for the RWT activities via tracking of real world use of the certified capabilities ensures that the data reflects the full set of customers accounting for all care settings and sizes/types of organizations.
### Real World Testing Methodologies

The methodology employed for the Soarian Clinicals Antimicrobial Use and Resistance (AUR) Reporting certified capabilities will involve production activity tracking for use of the capabilities in the real world. Soarian Clinicals will specifically be tracking customer transactional data to determine our customers’ AUR reporting activity to the NHSN. To execute the methodology, each month our support teams will upload customer transactional file generation activity to correlate with customers submitting the reports to the National Health Safety Network (NHSN).

To account for the actual successful submission of the generated reports as part of the Real World Testing (RWT) plan, Soarian Clinicals engaged with the NHSN requesting information confirming rates of successful submission by participating organizations utilizing Soarian Clinicals software.

### Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is an Acute care solution with an integrated EDIS. AUR Reporting is applicable to Acute and Emergency Department care settings based on the NHSN protocols.

### Standards Updates

N/A

### Real World Testing Milestones

1. Complete actual monthly file generation by our targeted customer base: **end of Q3 2024**
2. Complete assessment of RWT data for results and outcomes compilation: **end of year 2024**

### Real World Testing Expected Outcomes

RWT outcomes for Soarian Clinicals AUR Reporting are expected to be comprised of successful ongoing generation of AUR reports in production environments, along with successful subsequent submission of those reports to the NHSN.

### Real World Testing Metrics

1. Total number of successfully generated Antimicrobial Use (AU) reports over the Q3 2024 submission period
2. Total number of successfully generated Antimicrobial Resistance (AR) reports over the Q3 2024 submission period

### Justification for Real World Testing Approach

The selected RWT metrics will display that the AUR reports are providing the means to submit the required data to the NHSN, which is the ultimate purpose of the certified capabilities in the real world. This is in contrast to mock testing which may not appropriately represent real world customer use, even if conducted in production-like environments.

Since the NHSN does not allow this data to be manually entered into their website, the only way the data can be successfully submitted is through file generation and upload. The NHSN has specific protocols for how the data should be generated and submitted. Soarian Clinicals followed NHSN protocols during development of AUR reports and has been through the NHSN SDS validation for Antimicrobial Use. Therefore, reports successfully generated from our certified software have a reasonable certainty of conforming to standards for the criterion and associated NHSN protocols. Any evidence of conformance failures would also be identified through our additional testing methodology of obtaining confirmation of subsequent successful submission.
By also testing success rates of customers’ reporting submissions to the NHSN the methodology ensures that the full scope of the AUR Reporting criterion and associated HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1 specification conformance are accounted for. AUR Reporting in Soarian Clinicals is consistent across all organizations regardless of size, type, or care setting and does not deviate from customer-to-customer. Therefore, the methodology is also suitable for all possible users and system variations as the tracking takes into account activity from all sources.
## Real World Testing Methodologies

National Health Care Surveys (NHCS) is a sample-based public health registry with providers/facilities being selected by the Office of National Statistics, a division of the Centers for Disease Control and Prevention (CDC). Providers/facilities sign up to participate in the NHCS registry and are notified throughout the year if they have been sampled and are required to submit data. The CDC and their contractor communicate a project plan and engage with the provider/facility (and their developer, if requested) to review procedures and specifications for data submission, including the applicable date ranges for their survey.

Cerner and other developers are not provided access to the list of participating providers/facilities, which limits the ability to positively identify the customers surveyed for the registry. Accordingly, Cerner’s Real World Testing (RWT) methodology for the Millennium (Health Care Surveys) certified HIT module will consist of working in unison with the NHCS registry representatives on a quarterly basis to track Cerner customer surveyed participants’ submission status. This includes confirmation that the certified capabilities being utilized by these participants are fulfilling the submission requirements in accordance with the mandatory HL7® CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 DSTU Release 1.2 - US Realm standard.

### Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

The care settings supported by Millennium (Health Care Surveys) certified HIT modules directly correlate to those involved in the various NHCS survey types as described in the Methodology section above.

### Standards Updates

N/A

### Real World Testing Milestones

1. First touchpoint with NHCS: **end of Q1 2024**
2. Second touchpoint with NHCS: **end of Q2 2024**
3. Third touchpoint with NHCS: **end of Q3 2024**
4. Compile data for RWT results from NHCS status reports during CY 2023: **end of Q4 2024**

### Real World Testing Expected Outcomes

Through the RWT methodology for the Millennium (Health Care Surveys) certified HIT module, we expect positive affirmation from the NHCS registry representatives that all sampled providers/facilities utilizing Cerner’s certified capabilities have submitted successfully. We also expect that any data quality issues encountered will be quickly remediated through engagement with the NHCS registry representatives.

### Real World Testing Metrics

1. Success rate of compliance with NHCS reporting submission for sampled Cerner customers (target = 100%)

### Justification for Real World Testing Approach

Since the sole purpose of the Health Care Surveys certification criterion is for supporting submission to the CDC’s NHCS registry, this RWT methodology is ultimately focused on the most direct source of evidence for successful use of the certified capabilities. It also ensures that all applicable care settings are accounted for by selecting a representative sample of customers who have been surveyed for each of the NHCS survey options (NHCS, NAMCS, NHAMCS) which directly correlate back to particular care settings as explained above.

Furthermore, the identified metric for the plan provides confirmation that our customers’ NHCS submissions are satisfying the registry’s requirements consistently.
### Application Access and Standardized API – 170.315(g)(7), (9), (10)

**Certified Health IT Module(s): Millennium (Clinical)**

**CHPL Product Numbers:** 15.04.04.1221.Mill.18.06.1.221107

**Relied Upon Software:** N/A

### Real World Testing Methodologies

The Real World Testing (RWT) methodology for Millennium (Clinical) Application Access and Standardized API certified capabilities will consist of tracking the following live production activity for each aligned certification criterion:

- HL7® FHIR® API requests and responses from registered consumer applications (g10)
- Applications utilizing HL7 FHIR Bulk Data extracts (g10)
- Live production HL7 FHIR API requests for patients' data in an HL7 CDA C-CDA Continuity of Care Document (CCD) format (g9)
- Cumulative access events utilizing an access token for the patient persona (g7)

These items will be tracked through transaction logging in a cross-database analytics tool which provides near real-time activity tracking of active production environment use for analytics purposes.

### Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

The above care settings have been determined as those applicable to the customer base leveraging the certified APIs under the Millennium (Clinical) certified HIT module in the real world.

### Standards Updates

N/A

### Real World Testing Milestones

1. Implement any necessary code changes for new tracking methodologies: **end of Q1 2024**
2. Review current production activity tracking dashboard in-depth to identify any data gaps or issues to be addressed: **end of Q1 2024**
3. Begin data retrieval and follow-up on any "loose ends" discovered in prep activities: **end of Q3 2024**
4. Complete all RWT execution and results compilation for CY 2024: **end of Q4 2024**

### Real World Testing Expected Outcomes

Expected outcomes for the Millennium (Clinical) certified APIs RWT execution will include high volumes of successful API transactions across all of the live production endpoints. This would be observed on a daily basis showing application usage for the certified APIs. Additionally, we anticipate that volumes of transactions will vary widely across individual FHIR resources based on the types of U.S. Core Data for Interoperability (USCDI) data that is more commonly requested by popular apps today. For example, volumes for the Observation resource will be significantly higher than any other resource.

For HL7 FHIR Bulk Data export we anticipate seeing fairly low volumes of overall activity given the general novelty status of the capabilities. Production activity observed will likely be concentrated to a small subset of customer endpoints who are early adopters and innovators in this space.

### Real World Testing Metrics

1. **(g10) Single Patient** – Success rate of HL7 FHIR API transactions observed across all customer production activity for the 2024 calendar year (target = 98%+)
2. **(g10) Bulk Data** – Count of customers completing a HL7 FHIR Bulk Data extraction during the 2024 calendar year (no target)
3. **(g9) C-CDA** – Success rate of events returning a C-CDA document in a HL7 FHIR API response (no target)
4. **(g7)** – Count of successful access events for access token being granted to a patient (no target)
Justification for Real World Testing Approach

Tracking on success rates and counts within the production environment represents direct visibility to real world use of the certified APIs. This directly aligns the selected methodology to the intent of RWT. The production activity tracking also tracks across all customers actively utilizing the certified APIs meaning that all care settings for which the capabilities are marketed and supported are represented equally, instead of picking and choosing only certain care settings or implementations.

A variety of count and success rate measures are being used to display functionality of the various capabilities being reported on across relevant criteria.

- For (g10) Single Patient, discretely tracking the success and failure of the API responses in the real world via HTTP response codes shows the real world use is resulting in successful API calls (not just high volumes with high failure rates). The 98% success rate target accounts for intermittent failures due to occurrences such as bad requests, networking failures, and other expected complexities in the real world that are beyond the control of the certified capabilities.
- Tracking success counts for (g10) FHIR Bulk Data allows us to show the success of the operations while also providing visibility to the adoption of a newer capability.
- Tracking success counts for (g7) Patient Access requests will allow visibility of the total breadth of patients successfully being granted access tokens.
- Tracking counts of successful transactions returning a C-CDA document from a HL7 FHIR API request aligns with the (g9) criterion and shows successful utilization in the real world.
### Application Access and Standardized API – 170.315(g)(7), (9), (10)

**Certified Health IT Module(s): Soarian Clinicals**

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

**Relied Upon Software:** Ignite Soarian API

#### Real World Testing Methodologies

There are two methodologies presented for the Soarian Clinicals Application Access and Standardized API Real World Testing (RWT) plan. The primary methodology and preferred method for RWT involves the collection of API usage statistics from customers’ production environments. Each time a HL7® FHIR® resource is retrieved by an app, the Soarian Clinicals EHR inserts a record in an API activity log that includes the type of resource (Patient, AllergyIntolerance, etc.), patient, and success/failure indicator. Our methodology is to query this log to ensure a positive count of successful retrievals across all resources required for the Application Access and Standardized API criteria.

Soarian Clinicals EHR customers are in the process of migrating to other EHR solutions. Because of this, the number of customers using the Soarian Clinicals EHR is steadily declining. The app developer community is aware of this and as a result has shown less interest in investing in API integration with the Soarian Clinicals EHR than it has with other EHRs. Consumer enthusiasm has also yet to materialize. For these reasons, we define a secondary, fall back method to be used if there is insufficient usage of apps connected to the Soarian Clinicals EHR API among consumers. This secondary method involves an app exercising the same Soarian Clinicals API software on a simulated customer production environment. This environment would be configured to use the same EHR software version, authorization server, and network connectivity as our production hospital customers use to provide as close to a real world production scenario as is feasible.

#### Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is used in Acute and Emergency Department care settings.

#### Standards Updates

N/A

#### Real World Testing Milestones

1. Identify production customer environments for which API usage statistics will be gathered: **end of Q1 2024**
2. Assess need for fallback test method, based on customer API usage. If necessary, set up EHR environment that mirrors real world to implement fallback test method: **end of Q2 2024**
3. Execute RWT activities (primary or secondary methodology): **end of Q3 2024**
4. Complete assessment of RWT data for results and outcomes compilation (primary or secondary methodology): **end of Q4 2024**

#### Real World Testing Expected Outcomes

- **Primary Methodology** – It is expected that the API activity log will reflect relatively low levels of app usage by patients of hospitals that use the Soarian Clinicals API in production. As explained earlier in this test plan, the Soarian Clinicals customer base is relatively small and neither Cerner nor its Soarian Clinicals customers can force app developers to support the Soarian Clinicals API in their products, much less force patients to use those apps that are available. If no usage is indicated by the API activity log, the secondary methodology will be used.
- **Secondary Methodology** – It is expected that the API activity log will reflect the usage of a test client app successfully exercising all of the required API functions in an environment that mirrors a hospital customer’s production environment in EHR software and network configuration.

#### Real World Testing Metrics

1. Number of successful HL7 FHIR API reads by resource type across the testing year (target at least one successful access event via API is recorded in the EHR’s API activity log for each resource type for the USCDI data scope: Provenance, DocumentReference, Patient, Practitioner, Person, Organization, Device,
Justification for Real World Testing Approach
The counts derived from the activity log apply only to successful HL7 FHIR API accesses through the entire pathway from consumer app through networking to the EHR and out. As the counts are broken down by resource type, a positive count for each resource type demonstrates that the API has successfully returned the full USCDI data set. We set the minimum bar of 1 successful read of all covered data resources in a “real world” environment, again bearing in mind our limited adoption by patients and customers across a customer base that is migrating away from the Soarian Clinicals EHR. As mentioned immediately above, the nature of the activity log also tests the full depth and breadth of the API in a real world context.
## 170.315(h)(1) Direct Project

### Certified Health IT Module(s): Millennium (Clinical); Soarian Clinicals

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### Real World Testing Methodologies

The Real World Testing (RWT) methodology for Cerner's Direct Project certified capabilities, which are shared across the Millennium (Clinical) and Soarian Clinicals certified HIT modules, will consist of collecting data on Direct messages that have been sent and received through the Cerner Direct Health Information Service Provider (HISP).

This reporting will include measures for the % of inbound and outbound messages that are processed by the HISP in less than 1 hour and a measure of system uptime using our 27 microservices health check data. All measures will be reported as a monthly percentage meeting the criterion established. Through this reporting, we are able to track data on all Soarian Clinicals and Cerner Millennium® (Millennium (Clinical)) customers live with the Cerner Direct HISP in production environments. This also allows us to reliably track collective success and failure rates of real world transactions through our Direct HISP.

### Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

The above identified care settings have been determined as the full scope of those applicable to users of the Soarian Clinicals and Millennium (Clinical) certified HIT modules.

### Standards Updates

N/A

### Real World Testing Milestones

1. Complete assessment of RWT data for results and outcomes compilation: **end of CY 2024**

### Real World Testing Expected Outcomes

The expected outcomes for our RWT plan are that nearly all messaging activity across the measurement period is successfully processed within an hour. We also expect the system downtime % to be consistently very low indicating high system reliability. Overall, these expected outcomes show that the system works for its intended purposes and provides our customers with a high level of confidence in the capabilities.

### Real World Testing Metrics

1. Percentage of inbound and outbound messages processed in less than 1 hour over the Q1-Q3 2024 measurement period (target >=99.9%)
2. Overall system uptime over the Q1-Q3 2024 measurement period (target >=99.9%)

### Justification for Real World Testing Approach

By measuring the processing time and system uptime of the HISP, we are establishing a confidence in the technology that when a message can or cannot be delivered we are giving feedback in a timely manner, either by providing a success or a failure indication back to the user with as little delay as possible.

Delays in message delivery are possible at many levels, but we are measuring specifically the time it takes our HISP to process the messages either outbound or inbound. It has already been established that Direct messages are flowing successfully, so this RWT plan methodology takes the next step to affirm that they are processing efficiently and effectively. Additionally, our continued strategy of tracking all activity for the HISP (as opposed to picking and choosing particular customers) ensures we are aligning with the intent of RWT to assess all types of care settings, implementations, and sizes/types of organizations using the technology.