ClinNext 10

Real World Test Results 2022

SabiaMed Corporation

GENERAL INFORMATION:

Developer Name:	SabiaMed Corporation
Product Name and Version:	ClinNext 10 v1.0
CHPL Product Number:	15.04.04.2297.Clin.01.00.1.181029
Developer Real World Testing Plan Page URL:	https://www.sabiamed.com/rwtest
Developer Real World Testing Results Report URL:	https://www.sabiamed.com/rwtest

CHANGES TO ORIGINAL PLAN:

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]			**Reason** [Describe the reason this change occurred]	**Impact** [Describe what impact this change had on the execution of your Real World Testing activities]
CRITERIA	**TEST PLAN**	**ACTUAL EXECUTION**		
170.315 (c)(2): Clinical Quality Measures - Import and Calculate	*(Step)* The user will perform a data export for the time range that contains those patients.	*[Step]* The user will perform a QRDA Category III export for the time range that contains those patients.	The correct file that needs to be generated as part of the (c)(2) criteria is a QRDA III file, not a QRDA I as stated in the original test plan.	None (The modified step measures the tested criteria more accurately)
170.315 (c)(2): Clinical Quality Measures - Import and Calculate	*[Step]* The QRDA I files for the patients matching the Cypress data set will be imported back into Cypress for calculations validation.	*[Step]* The QRDA Category III files for the patients matching the Cypress data set will be imported back into Cypress for calculations validation.	The correct file that needs to be generated as part of the (c)(2) criteria is a QRDA III file, not a QRDA I as stated in the original test plan.	None (The modified step measures the tested criteria more accurately)
170.315 (c)(2): Clinical Quality Measures - Import and Calculate	*[Outcome]* The user is able to run a report for the date range that contains the imported data set and observe where those 2 patients fall within the measure populations of each of the 2 selected measures	*[Outcome]* The user is able to run a report for the date range that contains the Imported data set and observe where the patients fall within the measure populations of each of the 2 selected measures	Since this criteria involved the generation of a QRDA III, what was tested was that the QRDA III file reflected the correct populations by measure. Specific patient QRDA I files were out of scope for this test.	None (The modified step measures the tested criteria more accurately)
170.315 (c)(2): Clinical Quality Measures - Import and Calculate	*[Outcome]* The user is able to perform an export containing the QRDA I files for the 4 imported patients within the 2 selected measures	*[Outcome]* The user is able to perform an export containing the QRDA Category III files for the 2 selected measures	The correct file that needs to be exported as part of the (c)(2) criteria is a QRDA III file, not a QRDA I as stated in the original test plan.	None (The modified step measures the tested criteria more accurately)
170.315 (c)(2): Clinical Quality Measures - Import and Calculate	*[Outcome] Cypress validation tool returns no standards compliance errors in any of the 4 imported QRDA I files.*	*[Outcome]* Cypress Validation tool returns no standards compliance errors in any of the imported QRDA Category III files.	The correct file that needs to be validated for compliance using Cypress as part of the (c)(2) criteria is a QRDA III file, not a QRDA I as stated in the original test plan.	None (The modified step measures the tested criteria more accurately)

SUMMARY OF TESTING METHODS AND KEY FINDINGS:

For all tested criteria, a set of real patients was selected in a live facility which currently has the latest version of our product installed. A test date was scheduled with a system user at the selected facility. All testing was performed live while both the facility resource as well as a resource from Sabiamed Corporation observed the entire process. All generated testing artifacts (files and screenshots) were saved for future reference. Participants involved in the tests, facility name, and execution date is provided below for each tested criteria.

A comprehensive multi-level testing and validation approach was used, to ensure maximum coverage and thoroughness of all performed tests, as follows:

- Testing the functionality UI and ensuring no functional defects were uncovered while documenting the data needed to execute the test
- All files specified in the test script were generated and saved for future reference. Screenshots of the process were also generated and saved.
- All criteria that involved calculations (c1, c2, and c3) were validated via Cypress tool, by comparing Cypress calculations with ClinNext 10
- All generated CCDAs were visually inspected for accuracy against the documented clinical data and to ensure no malformations were present
- All generated CCDAs and HL7 files where validated for conformance with the standards by using context-free tools provided by ONC (CCDA Validator, ELR Validator)
- QRDA Category III patient population accuracy was tested using Cypress validation tool
- Both QRDA Category I and III conformance with the standard was validated using Cypress validation tool

After executing all tests outlined in this test script and applying the specified measurements and validation steps, all tested criteria were found to be fully compliant.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)): Yes, I have products certified with voluntary SVAP or USCDI standards.

Standard (and version)	USCDI v1, STU 4.0.0, June 28, 2021
Product Name and Version:	ClinNext 10 v1.0
Criteria:	170.315(g)(10) Standardized API for Patient and Population Services
CHPL Product Number:	15.04.04.2297.Clin.01.00.1.181029
Conformance measure:	Live testing

CARE SETTING: All performed steps and key milestones achieved were executed in an In-Patient setting.

170.315 (b)(1): Transition of Care						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamon **Sending Facility:** Grupo HIMA San Pablo Bayamon **Receiving Facility:** Grupo HIMA San Pablo Caguas **Test Execution Date:** 1/30/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	1 CCDA File tested Visual Inspection Data inspection using SQL Compliance validation using ONC Test tool	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to generate and send the CCDA file to the receiving facility	Y	The user was able to generate the C-CDA for the selected patient. The receiving hospital confirmed the CCDA was received and sent us the print screen of their inbox where the CCDA was viewed and inspected. The C-CDA was visually inspected to be accurate. The C-CDA was compared with the patient data, they matched. The C-CDA was successfully tested for compliance using ONC CDA Validator. The functionality of the criteria was fully validated.
		A date and time will be coordinated with a system user at the selected facility that currently uses the "Send C-CDA" functionality that allows them to send CCDA documents when referring patients to an external facility.	Y	The receiving facility acknowledges having received the C-CDA file	Y	
		In the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the user sending a Referral Summary C-CDA of a patient that requires to be transferred to another facility. The C-CDA will be transferred to the receiving facility via SMTP protocol.	Y	The receiving user is able to download the CCDA file	Y	
		The receiving facility will be contacted to validate that they received the C-CDA file and were able to Download it and Open it without complications.	Y	The receiving user is able to open and view the file in human readable version (.html) of the C-CDA.	Y	
		• The record associated with the C-CDA generation event will be located within our system database, and the	Y	The inspected file shows no visual malformations.		
				The generated C-CDA file is stored in the system database		

170.315 (b)(1): Transition of Care						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		generated C-CDA will be validated using ONC's validation tool to test for standards compliance.		• The generated file passes compliance validation using ONC's CDA Validation tool		

170.315 (b)(2): Clinical Information Reconciliation and Incorporation						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Caguas **Test Execution Date:** 1/27/2023 **Facility Representative:** Janelys Ramirez Salas Ismael Guillen Ramirez **Sabiamed Representative:** Bryan Gonzalez Feliciano	1 CCDA File tested Visual Inspection Data inspection using SQL Compliance validation using ONC Test tool	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to import the received CCDA file to the patient record.	Y	The user is able to import a received C-CDA file and perform a full data econciliation, including medications, diagnoses and allergies into the patient record. Once the information is reconciled into the patient record, the user is able to access and see the reconciled data from within the patient record.
		A date/time will be coordinated with a system user at the selected facility that currently uses the C-CDA Reconciliation process for incoming referrals	Y	The user is able to perform a full data reconciliation, including medications, diagnoses, and allergies of the received C-CDA file into the patient record	Y	
		At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the user receiving a C-CDA file for a real patient that was transferred into their facility and observe how was the data reconciliation process performed.	Y	Both the C-CDA file and all reconciled data are correctly reconciled to the patient record	Y	
		The user will receive the C-CDA file and perform a full C-CDA reconciliation of the received clinical data, including all allergies, diagnoses, and medications.	Y	The reconciled C-CDA file is accessible and viewable from within the patient record	Y	
		After reconciliation, it will be validated that the reconciled file is accessible and viewable in the patient's record, and that all reconciled data was correctly stored into the system.	Y	All reconciled data is correctly and fully persisted to the database (this will be validated by executing SQL queries against transactional tables for allergies, medications, and problems).	Y	
		A new C-CDA file will be generated after data	Y	All newly reconciled data is accessible from within	Y	

170.315 (b)(2): Clinical Information Reconciliation and Incorporation						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		reconciliation is Performed.		the patient medical record		
		The new C-CDA file will be visually inspected to ensure that it contains all newly reconciled data and contains no cosmetic malformations.	Y	A C-CDA file generated after reconciliation is performed includes all reconciled data	Y	The user is able to generate a CCDA file after reconciliation is performed. Sabiamed's user is able to validate the file using ONC's validation Tool.
		The newly generated C-CDA file will be validated using ONC's CDA validation tool to test for compliance with the applicable standards.	Y	A C-CDA file generated after reconciliation was performed passes validation using ONC's CDA Validation tool.	Y	

170.315 (b)(3): Electronic Prescribing						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Relied Upon Software: DoseSpot **Test Executed At:** Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/30/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	1 Prescription used for testing Visual Inspection of received prescription at pharmacy Data inspection using SQL query	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The physician is able to launch the e-Prescribing module	Y	The physician was able to select a patient and a pharmacy based on the patient's preference (Selected Pharmacy was: Farmacia Ruiz Belvis). The physician was able to document and send process an electronic prescription for the selected patient. The pharmacy confirmed having received the prescription with no errors and was able to fill it. The information stored in the database matched the information entered by the user. The functionality of the criteria was successfully validated.
		A date/time will be coordinated with a system user that currently uses the e-Prescription functionality.	Y	The physician is able to document and transmit an electronic prescription for a real patient	Y	
		At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of a physician documenting and transmitting an electronic prescription for a real patient to their preferred pharmacy.	Y	The pharmacy validates that they received the prescription	Y	
		The selected pharmacy will be contacted to validate that they received the prescription and that it contains all required information to be able to fill it.	Y	The pharmacy validates that they were able to fill the prescription	Y	
		We will validate that all prescription data is completely and correctly persisted into the database by executing SQL queries against the corresponding transactional tables.	Y	We validate that all prescription data is completely and correctly committed to database	Y	

170.315 (b)(6): Data Export						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/30/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	10 CCDA files generated 3 CCDA files randomly selected for validation Visual Inspection of selected files Compliance inspection using ONC CCDA Validator	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to perform the data export for a user-selected group of 10 patients	Y	The CCDA of 10 patients were successfully generated and stored in the repository. Out of the 10 generated CCDA's, 3 of then were randomly selected for visual inspection and the inspection was successful. The selected 3 CCDAs passed validation using ONC's CCDA Validator. The functionality of the criteria was successfully validated.
		A date/time will be coordinated with a system user that currently uses the functionality to be tested.	Y	Human readable version of the C-CDA files are correctly formatted, readable, and show no cosmetic malformations.	Y	
		At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user performing a data export for a set of patients, of no less than 10 patients.	Y	XML version of the generated C-CDA files pass a validation test using ONC's CDA Validation tool.	Y	
		The exported human readable version of 3 of the generated C-CDA files will be visually inspected to detect any cosmetic malformations	Y			
		3 of the exported C-CDA files in XML format will be tested using ONC CDA Validator to test compliance.	Y			

170.315 (c)(1): Clinical Quality Measures – Record and Export						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/26/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Bryan Gonzalez Feliciano	4 QRDA I files generated (2 measures for 2 patients) for validation Comparison of Cypress tool calculations with ClinNext 10 eCQM module used for validation of all measure populations Cypress tool used to measure QRDA Category I format compliance	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to execute an e-CQM report for the selected 2 measures	Y	The user is able to select 2 measures and identify 2 patients that are listed in the correct populations for each selected measure. Also, the user is able to generate and export a QRDA1 file for each of the identified patients.
		A date/time will be coordinated with a system user that currently uses ClinNext 10 e-CQM module	Y	The 2 patients identified for each of the 2 measures are listed in the correct measure populations	Y	
		The user will identify 2 patients that are contained within 2 e-CQM measures that the facility currently reports to CMS prior to the visit	Y	The user is able to perform an export containing QRDA I files for the 4 patients	Y	
		At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user generating the report for the selected 2 measures for the timeframe that contains those 4 visits.	Y	Sabiamed's resource is able to import the 4 QRDA I files into Cypress validation tool without errors	Y	The user provides the QRDA1 files generated to a Sabiamed's resource, so the files can be imported to Cypress validation tool in order to validate that the files have no structural errors. The calculations between Cypress and the system's eCQM module must math for both measures.
		Both the calculated values for those measures and the detailed patient list within the generated report will be inspected to ensure that all selected patients fall in the correct populations within the 2 tested measures, when compared against the documented clinical data.	Y	Cypress validation tool returns no conformance errors in any of the 4 files	Y	
		The generated QRDA I files will be imported into Cypress to validate standards compliance,	Y	Cypress calculations match the calculations performed by the system	Y	

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170.315 (c)(1): Clinical Quality Measures – Record and Export						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		calculate on what measures and populations those 4 patients reside, and compare that with the calculations performed by ClinNext 10 e-CQM module. The results must match.		eCQM module, for both measures.		

170.315 (c)(2): Clinical Quality Measures – Import and Calculate						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/26/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Bryan Gonzalez Feliciano	1 QRDA Category III file generated containing information for each of the 2 measures tested Comparison of Cypress tool calculations with ClinNext 10 eCQM module used for validation of QRDA Category III file calculations Cypress tool used to measure QRDA Category III format compliance	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The imported test data is deleted from the system to restore the system to the pre-test state.	Y	The user is able to import the Cypress generated data set for the 2 identified measures without errors and run a report for the date range that contains the imported data set. The user is able to observe where the patients fall within the measure populations of each of the 2 selected measures and is able to export QRDA Category III files for the selected measures.
		A date/time will be coordinated with a system user that currently uses ClinNext 10 e-CQM module	Y	The imported test data is deleted from the system to restore the system to the pre-test state.	Y	
		The user will identify 2 e-CQM measures that the facility reports to CMS prior to the visit.	Y	The imported test data is deleted from the system to restore the system to the pre-test state.	Y	
		Sabiamed resource will produce a Cypress data set for the 2 selected measures prior to the test.	Y	The imported test data is deleted from the system to restore the system to the pre-test state.	Y	The user provides the QRDA Category III files generated to a Sabiamed's resource, so the files can be imported to Cypress validation tool in order to validate that the files have no structural errors. The calculations between Cypress and the system's eCQM module must math for both measures, and a successful result must be shown within the Cypress validation tool for each measure.
		At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user importing the Cypress data set into the system.	Y	The imported test data is deleted from the system to restore the system to the pre-test state.	Y	
		The user will perform a QRDA Category III export for the time range that contains those patients.	Y	The imported test data is deleted from the system to restore the system to the pre-test state.	Y	

170.315 (c)(2): Clinical Quality Measures – Import and Calculate						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		The QRDA I files corresponding to the patients in the imported data will be isolated (this is necessary since this is a live system and real patients will be included in the exported data set).	Y			
		The QRDA Category III files for the patients matching the Cypress data set will be imported back into Cypress for calculations validation.	Y			
		Cypress results will be analyzed and documented. The result should be a 100% success rate for all measures tested within Cypress.	Y			
		The imported test data is deleted from the system to restore the system to the pre-test state.	Y			

170.315 (c)(3): Clinical Quality Measures – Report						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/26/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Bryan Gonzalez Feliciano	1 QRDA Category I file generated containing information for each patient within each measure populated tested Comparison of Cypress tool calculations with ClinNext 10 eCQM module used for validation of QRDA Category I file calculations Cypress tool used to measure QRDA Category I format compliance	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to import the Cypress generated data set for the 2 identified measures without errors and without developer assistance.	Y	The user is able to import the Cypress generated data set for the 2 identified measures without errors and run a report for the date range that contains the imported data set. The user is able to observe where the patients fall within the measure populations of each of the 2 selected measures and is able to export QRDA Category I files for the selected measures.
		A date/time will be coordinated with a system user that currently uses ClinNext 10 e-CQM module	Y	User is able to run a report for the date range that contains the imported data set and observe where the imported patients fall within the populations of each of the 2 selected measures.	Y	
		The user will identify 2 e-CQM measures that the facility reports to CMS prior to the visit.	Y	The user is able to perform an export containing the QRDA Category I files for the imported patients within the 2 selected measures.	Y	
		Sabiamed resource will produce a Cypress data set for the 2 selected measures prior to the test.	Y	Sabiamed's resource is able to import the exported data set into Cypress without errors.	Y	The user provides the QRDA Category I files generated to a Sabiamed's resource, so the files can be imported to Cypress validation tool in order to validate that the files have no structural errors. The calculations between Cypress and the system's eCQM module must math for both measures, and a successful result must be shown within the
		In the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user importing the Cypress data set into the system.	Y	Cypress validation tool returns no standards compliance errors in any of the imported QRDA Category I files.	Y	
		The user will perform a data export for the time range that contains those patients.	Y	Cypress compares the calculations with the imported data set with the calculations on the Cypress generated data set and reports no	Y	

170.315 (c)(3): Clinical Quality Measures – Report						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
				mismatches in any of the 2 tested measures.		Cypress validation tool for each measure.
		The QRDA Category I files corresponding to the patients in the imported data will be isolated (this is necessary since this is a live system and real patients will be included in the exported data set).	Y			
		The QRDA Category I files for the patients matching the Cypress data set will be imported into Cypress for calculations validation.	Y			
		Cypress results will be analyzed and documented. The result should be a 100% success rate for all measures tested within Cypress.	Y			
		The imported test data is deleted from the system.	Y			

170.315 (e)(1): View, Download and Transmit to 3rd Party						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Caguas **Test Execution Date:** 1/30/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	1 patient selected for validation Visual Inspection of CCDA file Data inspection using SQL Query Compliance validation of CCDA using ONC Test tool Verification of Audit Log for assessing event logging accuracy	At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user performing these actions:	Y	The user is able to successfully grant a patient access to the Patient Portal	Y	The user was able to grant a patient access to the Patient Portal during the registration process. The patient then received instructions through the email and was able to access the login page. Using the two factor authentication in the form of a text message code, the patient was able to access the Patient Portal account. The patient was able to view all the information of his clinical encounter. The patient was able to generate a CCDA for his visit, view the generated CCDA, download a Zip file containing files. All the information displayed in the portal was the same entered when registering the patient. All the
		Registering a test patient	Y	The patient receives a patient portal registration welcome e-mail	Y	
		Granting portal access to the test patient	Y	The patient is able to complete the registration process by clicking on the registration link contained in the welcome e-mail	Y	
		Reading the system generated "Welcome to the Patient Portal" email and completing the registration and 2-step authentication process.	Y	Once registration is completed, the patient is able to perform the 2-step authentication process and login into the Patient Portal account	Y	
		Documenting the following information into the patient's medical record: Allergies, Medications, Diagnoses, Family History, and Vital Signs	Y	The patient is able to view all clinical information that was captured	Y	
		Generating a Discharge Summary C-CDA for the patient	Y	The patient is able to view audit events for all sections visited as well as for C-CDA generation requests performed by the facility against his clinical profile	Y	
		Login into the Patient Portal account as the test patient	Y	The patient is able to View C-CDA files generated against his clinical profile	Y	

170.315 (e)(1): View, Download and Transmit to 3rd Party						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		Validating that all patient demographic information is accurate	Y	All inspected files are fully readable and contain no malformations.	Y	information contained in the CCDA matched the clinical information associated with the encounter. The audit trail of the patient registered both the Login and View events. The audit trail of the patient registered the CCDA generation and download of the .Zip events. The functionality of the criteria was successfully validated.
		Validating that all clinical information is accurate	Y			
		Validating that an audit log entry was captured for the login event	Y			
		Validating that an audit log entry was captured for each clinical section viewed by the user	Y			
		Validating that an audit log entry was captured for the C-CDA generation event	Y			
		Validating that that the generated C-CDA file is viewable from within the patient portal	Y			

170.315 (f)(1): Transmission to Immunization Registries						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/30/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	2 patients selected for validation and transmission Confirmation of receiving system used as acknowledge of successful vaccination record transfer Comparison of imported vaccination record (from receiving PREIS exchange system) vs. documented vaccination information used to access accuracy of data received and stored in receiving system	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to successfully generate an export the patient Immunization record for the 2 selected patients to the IIS/PREIS	Y	The system allowed the user to completely document vaccination information for the selected patients, including expiration date, funding source, Lot number, CVX, VCX and all the required additional fields. The information was then exported to the PREIS health information exchange system and a receipt confirmation screen was displayed to the user. The audit of the transaction was registered and confirmed in the history of export and import screen. The information imported from the PREIS was used to confirm the information received and stored in their system was identical to the information sent during the Export process.
		A date/time will be coordinated with a system user that currently uses ClinNext 10 Immunization module	Y	The user is able to Import the immunization record for those 2 patients in order to view the immunization information that was stored in the PREIS (IIS) for each of the patients	Y	
		The user will identify 2 patients for which Immunization information was documented not more than 2 weeks prior to the test.	Y	The imported immunization information matches the immunization record that was transmitted	Y	
		In the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the documented immunizations for the 2 selected patients	Y			
		The user will transmit the immunization records to the PREIS, and the PREIS returns no errors when processing the files	Y			
		The user will perform an Import for those 2 patients in order to validate that the immunization information persisted in PREIS matches the immunization information	y			

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170.315 (f)(1): Transmission to Immunization Registries						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		that was documented for the patients in ClinNext 10.				The functionality of the criteria was successfully validated.

170.315 (f)(3): Transmission to Public Health Agencies – Reportable Laboratory Test and Values/Results						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/30/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	2 patients selected for validation Visual inspection of the received HL7 files at the receiving system Validation of received HL7 files using ONC Validation tool	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The user is able to fully document the lab. test results for the 2 selected patients	Y	The user was able to document laboratory results for the selected patients and generate HL7 test result files. The generated HL7 files were successfully transmitted to the receiving system. Visual inspection of the received HL7 files confirmed the data inserted into the generated files matched the documented information. Generated HL7 files were successfully validated using ONC context free Validation tool. The criteria functionality was successfully validated.
		A date/time will be coordinated with a laboratory at the selected facility	Y	The user is able to transmit the HL7 files to PRDoH Health Gorilla	Y	
		In the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the laboratory user documenting lab. results for 2 real patients and transmitting the Information to PRDoH Health Gorilla	Y	PRDoH Health Gorilla is able to receive and process the files	Y	
		PRDoH Health Gorilla will review the received files for content and structure	Y	The information in both files match the documented lab. test results	Y	
		The information in both HL7 files will be compared with the Lab results that were documented for each patient to validate there are no data inconsistencies	Y	HL7 files are successfully validated using the ONC's context free ELR Validation tool.	Y	
		Both HL7 files will be validated using ONC's context free ELR Validation tool.	y			

170.315 (f)(5): Transmission to Public Health Agencies – Electronic Case Reporting						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 1/25/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Joanne Brenes Catinchi	1 rule based on patients with a COVID-19 diagnosis on a specific day was used for testing Comparison of a SQL query for the selected diagnosis vs. the patient list returned by rule was used for validation	Create a trigger for the selected diagnosis	Y	The user is able to create a trigger for the selected diagnosis	Y	The system allowed for the creation of rule for patients with encounter on a single day with a COVID-19 ICD-10 diagnosis. The rule was executed and results were displayed in the screen, displaying the correct set of patients. The system allowed to generate a CCDA for the returned patient. The report matched the same as the results on the ClinNext 10 screen, which were also validated using a SQL query. The criteria functionality was successfully validated.
		Execute a report for the selected trigger	Y	The user is able to execute a report for the selected trigger	Y	
		Generate C-CDA files for all patients included in the generated report	Y	The user is able to generate C-CDA files for all patients included in the generated report	Y	
		The list of patients generated by the trigger matches the patients returned by a SQL query for the same trigger criteria (diagnosis).	Y	The list of patients generated by the trigger matches the patients returned by a SQL query for the same trigger criteria (diagnosis).	Y	

170.315 (g)(7): Application Access – Patient Selection						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 2/01/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Bryan Gonzalez Feliciano Raul Burgos Delgado	1 patient selected for validation SQL queries used to validate API result set against data stored in DB Postman used to validate format and contents of the record set returned by the API	A test date/time will be coordinated with the selected facility	Y	The tester is able to provision a test application within the facility's database (emulating a real third-party application).	Y	The tester is able to provide a tool (Postman) to simulate a real third party application and to successfully place restful calls for each set of parameters using a valid security token.
		At the scheduled date/time, we will perform 3 queries against the facility database: one for patient last name, another for patient first name and last name, and another one for patient first name, last name and date of birth. The results of each query will be saved as a reference data set.	Y	Using Postman, the tester is able to place Restful calls coming from the 3rd party app, for each set of selected set of parameters using a valid security token.	Y	
		We will provision a test application that will emulate a third-party application placing Restful calls to the API	Y	Using Postman, the tester is unable to place restful calls to the API with an expired security token.	Y	The tester is unable to place restful calls to the API with an expired or invalid security token.
		Service calls will be setup in postman, one for each of set of parameters for which each SQL query was executed: patient last name, patient first name and last name, and patient first name, last name and date of birth	Y	Using Postman, the tester is unable to place restful calls to the API with an invalid security token.	Y	
		The data returned for each service call will be compared with the reference result set of the corresponding SQL query. There should be a	Y			

170.315 (g)(7): Application Access – Patient Selection						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		matching data set for each service call.				

170.315 (g)(8): Application Access – Data Category Request						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 2/01/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Bryan Gonzalez Feliciano Raul Burgos Delgado	1 patient selected for validation SQL queries used to validate API result set against data stored in DB Postman used to validate format and contents of the record set returned by the API	A test date/time will be coordinated with the selected facility	Y	The tester is able to provision a test application within the database (simulating a real third-party application).	Y	The tester is able to provide a tool (Postman) to simulate a real third party application and to successfully place restful calls for each one of the data categories using a valid security token.
		At the scheduled date/time, we will perform queries against the facility database for the selected Patient ID and the transactional tables for each one of the 5 selected data categories: Problems, Allergies, Medications, Procedures, and Vitals. The result of each query will be saved as a reference data set.	Y	Using Postman, the tester is able to successfully place restful calls for each one of the 6 calls tested, using a valid security token.	Y	
		We will provision a test application that will simulate a third-party app. placing Restful calls to the facility API	Y	Using Postman, the tester is unable to place restful calls to the API with an expired security token.	Y	The tester is unable to place restful calls to the API with an expired or invalid security token.
		Six (6) calls will be setup in postman, one for the selected Patient ID and each of one the selected data categories, and another for the selected Patient ID and all the data categories within the same request.	Y	Using Postman, the tester is unable to place restful calls to the API with an invalid security token.	Y	
		The data returned for each one of the 6 service calls will be compared with the result of each corresponding SQL query. There should be a	Y			

170.315 (g)(8): Application Access – Data Category Request						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
		matching data set for each set of parameters tested.				

170.315 (g)(9): Application Access – All Data Request						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón **Test Execution Date:** 2/01/2023 **Facility Representative:** Janelys Ramirez Salas **Sabiamed Representative:** Bryan Gonzalez Feliciano Raul Burgos Delgado	1 patient selected for validation SQL queries used to validate API result set against data stored in DB Postman used validate format and contents of API result set	A test date/time will be coordinated with the selected facility	Y	The tester is able to provision a test application within the database (simulating a real third-party application connected to the API).	Y	The tester is able to provide a tool (Postman) to simulate a real third party application and to successfully place a restful call for the selected patient and the full CCDS (All Data Categories) using a valid security token.
		At the scheduled date/time, we will perform queries against the facility database for the selected Patient ID and the transactional tables for all data categories that comprise the Common Clinical Data Set (CCDS). The result of each query will be saved as a reference data set.	Y	Using Postman, the tester is able to successfully place a restful call for the selected patient and the full CCDS (All Data Categories)	Y	
		We will provision a test application that will simulate a third-party app. placing Restful calls to the facility API.	Y	Using Postman, the tester is unable to place Restful calls to the API with an expired security token.	Y	The tester is unable to place restful calls to the API with an expired or invalid security token.
		A call will be setup in postman for the selected Patient ID and all the data elements within the CCDS (All Data Categories).	Y	Using Postman, the tester is unable to place Restful calls to the API with an invalid security token.	Y	
		The data returned by the service will be compared with the result of the SQL queries. Both data sets should match.	Y			

170.315 (h)(1): Direct Project						
Facility / Participants	**Measurements and Testing Methods**	**Test Step**		**Expected Outcomes**		**Key Milestones Met**
		Test Step	Step Successfully Executed (Y/N)	Outcome	Outcome Met (Y/N)	
Test Executed At: Grupo HIMA San Pablo Bayamón (sender) Grupo HIMA San Pablo Caguas (receiver) **Test Execution Date:** 1/27/2023 **Facility Representative:** Janelys Ramirez Salas Armando Pacheco Maldonado (Sender) Ismael Guillen Ramirez (Receiver) **Sabiamed Representative:** Bryan Gonzalez Feliciano	1 patient CCDA file was used for validation of both CCDA transmission and reception test cases Visual inspection of the generated CCDA file at the receiving facility Visual inspection of a CCDA file received from another facility	A facility will be selected that currently use ClinNext 10 v.1.0	Y	The receiving facility receives the C-CDA file into the system user's Updox Direct inbox and is able to access and view it.	Y	A system user is able to receive a C-CDA file into his/her Updox Direct Inbox and is able to access and view the human readable format of the file with no cosmetic malformations
		A date will be coordinated with a system user at the selected facility that currently uses the "Updox direct inbox" a third-party web application that is integrated into ClinNext 10 and allow system users to send/receive C-CDA documents using the Direct standard.	Y	The receiving user is able to open and view the file C-CDA in Human Readable format and it shows no cosmetic malformations.	Y	
		At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the user sending and receiving a C-CDA file for a patient that was transferred into and out of their facility, over Direct protocol.	Y	The user is able to send a C-CDA file over Direct to a receiving facility.	Y	A system user is able to send a C-CDA file over direct to another healthcare facility