REAL WORLD TESTING PLAN TEMPLATE

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. **While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide – Coming Soon
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
  - ↳ *Section VII.B.5 — "Real World Testing"*

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan. Each section provides a field for submitting responses and/or explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information

required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: Genius Solutions

Product Name(s): ehrTHOMAS

Version Number(s): 3.0

Certified Health IT: ehrTHOMAS

Product List (CHPL) ID(s): 15.05.05.2737.GENI.01.00.1.180802

Developer Real World Testing Page URL:
http://www.geniussolutions.com/ehrTHOMAS/ehrTHOMAS2015Ed_ONCTransparency.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing[1].

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

Genius Solutions chooses to test its only electronic medical record (EMR) product, ehrTHOMAS. We are selecting the settings of care that are representative of most Genius Solutions' clients. ehrTHOMAS was intended to work in ambulatory settings with most of the customers being eligible physicians of the quality payment program working as a solo practitioner up to working in a setting with 4-5 multiple providers. Additional staff in the office that uses ehrTHOMAS ranges from one to 20 individuals, excluding the provider. The majority of our customer base is comprised of offices that practice Podiatry, Chiropractic, Mental Health and Internal Medicine. Participants to this testing will be selected based on the following:

- History utilizing Genius Solutions' products
- Granted permission to access and extract patient health information for testing purposes
- Connections to third parties and state registries
- Care setting

[1] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

All testing would be done on the client's server or workstation. All testing participants must allow Genius Solutions to have full access to their system during the testing period. Each participant will know what type of information will be taken from their system for testing purposes.

Testing sessions with the testing participant and the moderator will be recorded to observe the actions of the user. All screen capturing recordings will be stored on an encrypted hard drive and deleted after the testing has been completed.

Our goal is to test the following measures and metrics outlined in this plan through three testing periods throughout the year. We believe that just testing with a participant once will not test on-going electronic health information exchange, interoperability with other applications and data registries, and conformance to the technical file standards and code sets. We believe that testing ehrTHOMAS in real world situations three times a year will allow us to collect a sufficient amount of data to provide evidence of interoperability.

We are selecting the measures based on what is required for certification for the real world testing. The designing of the procedures is based on what we believe is an adequate testing protocol that can be performed with limited human and capital resources. The testing procedures were created with minimal interruption to client services and client workflow. Most data points are collected by the moderator and do not require the testing user's participation. The measures that do require user participation will be scheduled with a moderator.

Any type of test data or files that are needed for the testing measures will be extracted from another EMR and patient information will be modified for security purposes and pushed through a DataMotion portal. We have included the use of test patients in our measures as many of our clients are smaller offices that may not want to include certain functionality into their workflow. We ask our testing participants, at a minimum, to record and transmit test patient data to test for interoperability. We recommend that all offices attempt to use and send real patient data to demonstrate ehrTHOMAS interoperability in a real world setting.

In any situation where the testing moderator cannot communicate with a third party that is receiving our files, we would like to run all files through a file validator. We believe that this would be a good indicator that our system's files conform to the technical standards and code sets and be readily utilized in other applications and products.

Considering that this is the first plan created for real-world testing, we are closely monitoring how our measures are performed, the data we are collecting, and the feedback from our customers. All of these items will be reviewed to see if we are adequately capturing data that provides evidence of on-going interoperability with ehrTHOMAS given the amount of resources allotted. Our future testing will change based on the outcomes of this initial test.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ *Identify standard versions*
- ✓ *Indicate what certification criteria in which product(s) has been updated*
- ✓ *If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products*
- ✓ *CHPL ID for each Health IT Module*
- ✓ *Method used for standard update (e.g., SVAP)*
- ✓ *Date notification sent to ONC-ACB*
- ✓ *If SVAP, date notification sent to customers*
- ✓ *Measure used to demonstrate conformance with updated standard(s)*
- ✓ *Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?*

Standard (and version)	ICD-10CM SNOMED CT RxNorm HL7 2.5.1 HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes C-CDA Release 1.1 and 2.1 HL7 QRDA Category I Release 3 Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A
Method used for standard update	N/A
Date of ONC-ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A
USCDI-updated certification criteria (and USCDI version)	N/A

MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach(es) chosen meet the intent and purpose of Real World Testing.

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria

- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

DESCRIPTION OF MEASUREMENT/METRIC

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
Receive Patient Health Information via Direct Messaging	Genius Solutions utilizes DataMotion as its direct messaging vendor for our providers to send and receive direct messages from other providers. The user is to receive Clinical Care Documents (CCDs) via Direct Messaging. We hope to be able to utilize what the provider/user already has within their direct messaging inbox. If a CCD is not available, the Moderator of the testing will send a test patient directly to the provider through the DataMotion portal. The testing moderator should be able to easily identify the patient that the CCD refers to as well as all the sections within the CCD. The rate of successful viewing of the CCDs received, the rate of errors when receiving or viewing CCDs, and the number of complaints of CCDs not being received by the system will be recorded.
Incorporating Patient Health Information from Direct Messaging	The user is to take some of the CCDs that were retrieved from the measure, Receive Patient Health Information via Direct Messaging, and incorporate it directly into ehrTHOMAS. If the testing user did not receive a CCD during the testing period, the user will at least utilize a test patient and test patient data from direct messaging for testing purposes. The testing user will be strongly encouraged to incorporate the outside EHI into their EHR system. When incorporating the patient's health information, the system should be able to match the CCD and the patient automatically. If there is a discrepancy with the patient demographic data, the user should be able to match the patient manually. Users are to select the data in which they want to incorporate. At minimum, we would like to have the patient's medication/allergy information incorporated into the patient's chart. If the testing user would like to import the patient's conditions, that will be acceptable. The rate of successful patient matching automatically, the rate of manual patient matching, the rate of successful incorporation of patient data, and the rate of errors when incorporating patient health information will be recorded.
Prescribe a Medication	Genius Solution utilizes DrFirst as its primary eRX vendor for our providers to maintain their medication and allergy lists and send prescriptions electronically.

	The user is to create and send a new prescription to be sent to a pharmacy. Once completed, the moderator is to check within ehrTHOMAS to see the prescription's status and other information that may pertain to that medication order. The moderator is to verify that the SIG that is inputted into DrFirst matches the SIG that is loaded into ehrTHOMAS. The rate of successful prescription transmissions, the rate of errors encountered when submitting prescriptions, the SIG match rate, and complaints that prescriptions were not received will be recorded.
Export Clinical Data Summaries	The user is to create a list of clinical summaries for a specific date range within ehrTHOMAS. The moderator is to validate the number of clinical summaries that were created through a visual inspection. The moderator will upload all of the clinical summaries through a CCD validator to ensure data integrity and conformance. The rate of successful exports, the rate of errors encountered while exporting, and the rate of successfully validated CCDs will be recorded.
Record and Create a Care Plan	The user is to record a patient's care plan to include the patient's goals, health concerns, health status evaluation and outcomes, and interventions. The user is strongly encouraged to create care plans for real patients, however, the creation of a care plan for at least one fake patient during the testing period is required for testing if real patients are not utilized. A CCD will be generated for the moderator to submit for validation to ensure data integrity and conformance. The rate of successful CCD exports, errors encountered while exporting the CCD and the rate of successful CCD validations will be recorded.
Generate a Clinical Quality Measure (CQM) Report	The participants for this measure will also include any client that would like a courtesy Promoting Interoperability or CQM check from our EHR support representatives. The support staff will be directed to follow this measurement's description and obtain data for analysis. The user is to use the information inside their ehrTHOMAS database to generate a CQM report and export a QRDA file. The QRDA file will be validated with a QRDA validator to ensure data integrity and conformance. The rate of successful generation of CQM reports, errors encountered while generating the CQM report, any complaints from the testing participant regarding their CQM measures, the rate of successful exports of the QRDA file, the rate of errors encountered while exporting the QRDA file, and the rate of successful QRDA validations will be recorded.
Send CCDs to the Portal	The user is to send a CCD to a connected patient to the Genius Portal. The user is encouraged to send health information to real patients, but for testing purposes, they must send at least one CCD for a test patient. The moderator will confirm from the test patient that the CCD: ● is in readable format when viewing the CCD, ● includes the provider's name and office contact information, ● and can be downloaded and viewed in a readable format.

	Some of the CCDs that are exported to be sent to the portal will be validated with a CCD validator to ensure integrity and conformance by the moderator. The rate of successful CCD export for transmission, the rate of errors while sending CCDs to the portal, the rate of viewable and downloadable test patient CCDs, the rate of successfully validated CCDs, and the number of complaints of not receiving a CCD or issues reading or downloading will be recorded.
Submit and Receive Patient Immunization Information	The user is to record patient immunization records for real patients and create an HL7 immunization message to be sent to a state registry. The moderator will validate the immunization information message through an HL7 validator. A handful of HL7 files that were exported will be checked against the registry to ensure that the file was sent and the information presented is accurate. The information that we are checking for is: ● Patient's name, ● Date of birth, ● Type of immunization received, and ● Lot number. If the state sends acknowledgement files back to the EHR, the user is to obtain a response from their EHR system. At this time, Genius Solutions only has a handful of clients that are signed up for the QBP messages with their state's registry. How this data point will be collected will be based on the outcome of the recruitment of testing participants. Two approaches have been formulated: Approach (A): If the testing participant is actively participating in sending query messages to retrieve immunization history records, the participant will be required to only submit one query for a real life patient for testing purposes. Querying for other patients' immunization history will be encouraged. The rate of responses back from the state will be recorded. The HL7 query message will be validated by the moderator through an HL7 validator. Approach (B): If the testing participant is not actively participating in sending query messages, the participant will create a QBP message to be validated by the moderator through an HL7 validator. The rate of valid HL7 immunization messages, rate of successful HL7 immunization transmission, errors occurred while transmitting immunization messages, the rate of data matching in the immunization transmission, the rate of valid HL7 query messages, the rate of successful acknowledgement and patient immunization history received, and errors occurred while obtaining messages from the state will be recorded.

Submit and Receive Syndromic Surveillance Information	The user is to export syndromic surveillance information to their state's registry. At this time, Genius Solutions does not have any clients that are utilizing this function of the program. How this data point will be collected will be based on our customer's participation in the syndromic surveillance registry and their cooperation participating in the real world testing. Two approaches have been formulated: Approach (A): If the testing participant is actively sending HL7 files to a syndromic surveillance registry, the user is to create a batch of HL7 syndromic surveillance files. The HL7 files will be validated within a HL7 validator to ensure its compliance with the standard and contain all the necessary message segments. If the registry is capable of sending ACK messages, the user is to obtain that message within ehrTHOMAS. If ACK messages are not being sent, the moderator will reach out to the registry to confirm submission of the data. The rate of successful file creations and transmission, the rate of validated HL7 files, and errors occurred while transmitting will be recorded. Approach (B): If the testing participant is not actively sending HL7 syndromic surveillance registry, the testing office will create a batch of HL7 syndromic surveillance files from ehrTHOMAS for the moderator to be validated within a HL7 validator. The rate of successful file creations, the rate of valid HL7 files, and the errors occurred while creating a file will be recorded.
Test API Connection: Patient Selection	At this time, Genius Solutions does not have any clients or third parties that are utilizing ehrAPI. How this data point will be collected will be based on our customer or third party's participation. Two approaches have been formulated: Approach (A): If the testing user has a third party software that utilizes ehrAPI, the moderator will work directly with the third party software vendor to request at least one real patient from ehrTHOMAS and ehrTHOMAS should return a patient token. The moderator will verify the accuracy of the patient identification information being exchanged. The rate of accurate patient identification exchange, the rate of errors during the testing exchange, and complaints or issues from the third party vendor during the testing period will be recorded. Approach (B): If the testing user does not have a third party software that utilizes ehrAPI, then the moderator will apply an API tester application

	created by Genius Solutions on the server. This API tester application will utilize the API connections to request and receive at least one real patient's identification token from ehrTHOMAS. The moderator will record the successful token exchange between the API tester and ehrTHOMAS. The rate of accurate patient identification exchange, and the rate of errors during the exchange will be recorded.
Test API Connection: Data Category Request	At this time, Genius Solutions does not have any clients or third parties that are utilizing the ehrAPI. How this data point will be collected will be based on our customer or third party's participation. Two approaches have been formulated: Approach (A): If the testing user has a third party software that utilizes ehrTHOMAS API, the moderator will work directly with the third party software vendor to test this measure. After requesting the patient token in the measure, Test API Connection: Patient Selection, Approach (A), the third party application is to initiate at least one patient data category request from ehrTHOMAS. The moderator will validate the returned patient health information with the third party vendor. If CCDs are extracted from ehrTHOMAS, the moderator will obtain the CCD from the third party vendor and validate the CCD through a CCD validator. The rate of the accurate and successful data category exchange, the rate of validated CCDs, the rate of errors during transmission, and the number of issues or complaints throughout the testing period will be recorded. Approach (B): If the testing user does not have a third party software that utilizes the ehrTHOMAS API, then the moderator will apply an API tester created by Genius Solutions on the server. This measure will follow the Test API Connection: Patient Selection, Approach (B), and use the same real patient. The API tester will utilize the API connections to request data from ehrTHOMAS for a specific category. A CCD will be extracted from the API tester to be validated and checked for accuracy by the moderator. The rate of accurate and successful data category extraction, the rate of validated CCDs, and the rate of errors will be recorded.
Test API Connection: All Data Request	At this time, Genius Solutions does not have any clients or third parties that are utilizing the ehrTHOMAS API. How this data point will be collected will be based on our customer or third party's participation. Two approaches have been formulated: Approach (A): If the testing user has a third party software that utilizes ehrTHOMAS API, the moderator will work directly with the third party software

	vendor to validate that all the data for at least one real patient is being pulled from ehrTHOMAS. The moderator will verify with the third party vendor the accuracy of the returned patient health information. If a CCD has been created out of the data returned, the moderator will obtain the CCD from the third party vendor and validate the file through a CCD validator. The rate of accurate and successful returns of patient data, and the rate of validated CCDs, the rate of errors during transmission, and complaints from the third party vendor during the testing period will be recorded. Approach (B): If the testing user does not have a third party software that utilizes the ehrTHOMAS API, then the moderator will apply an API tester created by Genius Solutions on the server. This API validator will utilize the API connections and extract all the data for the same patient in Test API Connection: Patient Selection, Approach (B). The moderator is to confirm that the patient data returned is accurate. A CCD will be exported out of the API tester to be validated by a CCD validator. The rate of accurate and successful returns of patient data, and the rate of validated CCDs, and the rate of errors during transmission will be recorded.

ASSOCIATED CERTIFICATION CRITERIA

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
Receive Patient Health Information via Direct Messaging	*170.315 (b)(1): Transitions of Care*
Incorporating Patient Health Information from Direct Messaging	*170.315 (b)(2): Clinical Information Reconciliation and Incorporation*
Prescribe a Medication through DrFirst	*170.315 (b)(3): Electronic Prescribing*
Export Data Summary	*170.315 (b)(6): Data Export*
Record and Create a Care Plan	*170.315 (b)(9): Care Plan*
Generate a Clinical Quality Measure (CQM) Report	*170.315 (c)(1): Clinical Quality Measures - Record and Export* *170.315 (c)(3): Clinical Quality Measures - Report*
Send CCDAs to the Portal	*170.315(e)(1) View, download, and transmit to 3rd party*
Export Immunization Records and Requesting Immunization History	*170.315 (f)(1): Transmission to Immunization Registries*

Export Syndromic Surveillance Records	*170.315 (f)(2): Transmission to Public Health Agencies - Syndromic Surveillance*
Test API Connection: Patient Selection and Data Category Request	*170.315(g)(7) Application access - patient selection* *170.315(g)(8) Application access - data category request*
Test API Connection: All Data Request	*170.315(g)(9) Application access - all data request*

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification
Receive Patient Health Information via Direct Messaging	This measure showcases an integral part of real world interoperability where patient information is exchanged from one office to another. We believe that many of our ambulatory practices, especially specialty offices will get patient referrals or follow ups from other offices. It is important that the appropriate information is being received from other offices for the practice to understand the health of their patients to provide excellent care. We specifically focused on the patient health information that is received through our Direct Messaging to test the functionality of our direct messaging partner, DataMotion Direct, within ehrTHOMAS. This is the main channel of patient data exchange and is the relied upon software for this functionality. DataMotion Direct is certified for 170.315 (h)(2): Direct Project, Edge Protocol, and XDR/XDM. ehrTHOMAS users must utilize DataMotion Direct to meet the base criteria for a 2015 Edition Certification. At minimum we ask our users to receive at least one CCD for a test patient during each testing period as a safety net to ensure appropriate data exchange. We do believe that many of the selected participants are recipients of patient health information from outside providers, however, it is possible that no real life patient data is received during the testing period. We included the number of complaints the user might have when receiving a CCD from another provider since it would be unknown to the user and the moderator that a CCD was transmitted to their system. This data point will illuminate any problems with the data exchange.
Incorporating Patient Health Information from Direct Messaging	This measure is another integral part of real world interoperability where patient information is integrated directly into the EMR program. We understand the importance for providers to maintain up to date information about their patient's health information to provide the best possible care. We are using this measure in conjunction with the Receive Patient Health Information via Direct Messaging measure as these two measures are interrelated to one another; the information derived for this measure cannot occur without information from the previous measure.

	Similar to the Receive Patient Health Information via Direct Messaging measure, we ask our users to incorporate at least one CCD into a test patient account during the test period as a safety net in case the testing provider or office does not receive any outside CCDs during the testing period. Patient matching is an important aspect for our providers. We have observed that offices do not want to spend time searching for a patient to match data to. There can be a lot of user errors when matching a patient which can cause significant problems with patient care. We want to ensure that our capability to automatically match patients accurately and the testing users' ability to manually match the patient from an outside CCD to their patient's chart is working as intended. We chose to only update the medication and the allergies as a mandatory requirement for this measure since some offices may only want to include conditions that are applicable to their specialty within their charts.
Prescribe a Medication through DrFirst.	Prescribing medications is a common treatment for most conditions and can be detrimental to a patient's care if their medication is inaccurate or the delivery is delayed. We recognize the importance of accurate and timely delivery of prescriptions to the pharmacy for positive patient outcomes. ehrTHOMAS' certification for 170.315(b)(3): Electronic prescribing heavily relies on Rcopia, developed by our electronic prescribing partner, DrFirst. We want to ensure the functionalities of e-prescribing in Rcopia sends and incorporates electronic prescriptions appropriately within ehrTHOMAS and works as intended. We included the number of complaints received from the office as a data point for our testing since it may be possible that the signals received may indicate a confirmed transmission of a prescription but the data exchange may have halted somewhere down the connection pipeline.
Export Clinical Data Summaries	Genius Solutions does not see a lot of users utilizing this feature often, however, we recognize that some users may want to send all the information for their patient to another settling of care to ensure a high level of care or sending their patient's clinical data to a registry. While this measure is a required measure for the Real World testing criteria and for the information blocking, we believe that it is important that our customers have access to their own patient information. Testing this measurement will ensure that our capability to export data is intact. The participants selected for this measure are established clients of Genius Solutions with plentiful patient data. At the time of planning, we do not believe that we will have to create fake patient data to test the export functionality. We are including a CCD validation data point in our testing to ensure that the CCDs being outputted by ehrTHOMAS conforms to the C-CDA specification standard. Conforming to the technical standards would be a high indicator that the CCDs exported from ehrTHOMAS will be utilized in other EMRs or clinical registries.

Record and Create a Care Plan	Creating a detailed post-visit patient care plan is critical for patients to improve or maintain their current health status. It is important for members of the patient's care team to acknowledge and support the efforts of other providers and to encourage the patient to follow their doctor's recommendations. Incorporating this information to a CCD eases the transmission of this data to patients and providers. Since writing this Real World Testing plan, we have many offices that are not utilizing this functionality to its fullest capability as it might interfere with their patient flow in the office. We have incorporated how we expect this functionality to work in real world scenarios into our testing plans with the full understanding that this initial plan may not be how it is actually used, if used at all. We have included the testing for at least one patient in the plan to meet the completion for the testing in case our participants are not utilizing this feature on real patients. We hope that we can learn more about our users' interactions to develop a more robust and integrated feature. We have included a data point for the validation of the CCD to ensure conformity with the certification criteria and with the technical standards for the CCD. We believe that conforming to the technical standards would be a high indicator that the CCDs exported from ehrTHOMAS will be utilized in other EMRs or for any patient portals.
Generate a Clinical Quality Measure (CQM) Report	Many Genius Solutions' clients are participating in a quality payment program for both Medicare and Medicaid. Each program requires physicians to submit clinical quality measures and upload those numbers to the appropriate channels. Normally, our support staff will call and assist clients who are participating in those programs to run their CQM reports throughout the year and export QRDA files at the end of the year for attestation submission. We have modified the participants to include any client that calls our support technicians for Promoting Interoperability and CQM checks to ease the moderator's workload and to obtain as much data from all of our customers as possible. The generation of CQM reports is extremely important for our clients in the quality payment program. Meeting a certain threshold for each measure ensures that the provider is delivering effective patient-centered care. We are measuring both the successful generation of the CQM report and QRDA file to ensure that our program meets the certification criteria. The inclusion of the validation of the QRDA as a data point is to ensure conformity with the certification standards. We have included a data point for complaints from the testing participant to illuminate any issues that might spawn from collecting the CQM data within the EMR.

Send CCDs to the Portal	Patients' expectations of receiving information about their health has increased as they become more tech savvy. We understand the importance of timely and accurate health information being sent to the patient so they can make education decisions regarding their wellbeing. Most of our client's workflows include the creation of the CCD that can be quickly uploaded to their office's portal where patients can view and download their health information. The participants for this measure are clients that have a portal connection to their EMR. We ask that one test patient is used to confirm that the transmission of the CCD has been completed successfully. Genius Solutions will have access to the test patient's portal to record a successful transmission to ensure that the data exchange between the provider and patient is stable during the testing period and that the files can be viewable and downloaded successfully from the portal. We are spot checking the CCDs that are being transported to the portal to ensure conformity with the technical standards by running the CCDs through a C-CDA validator. In the real world, it is likely that patients would be unwilling to let the office work with them to verify whether a CCD has transmitted successfully to their portal. The addition of the complaint data point is used to determine if there are issues with the transmission of the CCD or patients viewings or downloading their patient health information outside the testing protocol.
Submit and Receive Immunization Records	Some of our clients are required to send immunization records to their state. We also understand the importance for providers to send and receive their patient's immunization schedules from an Immunization Information System to educate them appropriately. To ensure interoperability between the state and the providers, we are testing our capability of exporting patient immunization records to the different immunization registries we work with. At the time of writing this real world testing plan, we are currently sending production files to the state of Michigan (MCIR) and Florida (FLShots). We would like to limit the testing participants to those that already have an established connection. If Genius Solutions has a client that would like to send immunization records to another state registry, we would like to test that during the next real world testing period. This will minimize the workload burden for the development and moderating team during the real world testing period. Additionally, this will allow the moderating and testing team to focus on the active data exchange connections. Not all participants will be utilized for this measurement since they may not perform immunizations within their office and it is outside the scope of their specialty. Only practices that have an active connection to an immunization registry will be utilized for this measure. We are including a data matching data point in our testing plans to verify that the information that we are entering into ehrTHOMAS matches with what appears in the immunization registry. We will be asking the office to log into

	their state's registry website to determine the accuracy of our system's EHI exchange functionality. We have a small number of customers that are participating in sending production QBP query messages to receive patient immunization history. We are concerned that these customers may not want to participate in our testing as it can be time consuming for their busy office. Therefore, we formulated two approaches for testing the query message. Approach (A) is testing the current production transmission of the QBP messages, while Approach (B) is testing the system's capability to prepare QBP messages effectively for real-time transmission. Genius Solutions would prefer to use Approach (A) for its testing, however, it will be dependent on the recruitment of the participants by the testing deadline. The HL7 immunization message and HL7 QBP query message file will be processed through an HL7 validator to ensure that the file meets the technical specifications. Additionally, it will also check to ensure that the file conforms to the appropriate code sets.
Submit and Receive Syndromic Surveillance Information	Genius Solutions understands the need to have real time data transmitted to public health agencies to detect outbreaks of viruses, bacteria, and other biological agents. At the time of writing this real world testing plan, there are no ehrTHOMAS customers that are sending production syndromic surveillance files to a state registry. Not all of our customers are suitable to submit syndromic surveillance. Additionally, ehrTHOMAS is not marketed to specialties that would send syndromic information. We have formulated two approaches based on customer participation with the real world testing on how we should collect data for this measure. Approach (A) is testing an active production connection between ehrTHOMAS and a state Syndromic Surveillance registry, while Approach (B) tests the program's capability to prepare syndromic HL7 files effectively for future real-time transmission. Approach (A) is Genius Solutions' preferred method for testing. Approach (B) is to be used if there is not an active syndromic surveillance connection after our participation deadline. Our testing plan includes how we expect this functionality to work in a real world scenario. With this being our first real world testing plan, we understand that our initial composition of the measure may not test enough aspects of the electronic health information exchange between our program and a registry. We hope that we can modify our future test plans based on the learning experiences and outcomes of this testing. The exported syndromic HL7 message will be passed through a HL7 validator to ensure that the file conforms to the technical specifications.
Test API Connection: Patient Selection and Data Category Request, and Test API Connection: All Data Request	Genius Solutions understands the industry's need for flexibility when it comes to patients accessing their health information. An intrinsic property of an API is its functionality of exchanging electronic information to another application, therefore, It is important that the ehrAPI has the capability to

	allow third parties to extract precise patient health information from ehrTHOMAS. At the time of writing this real world testing plan, there are no ehrTHOMAS customers utilizing a third party service that requires the ehrAPI. We have formulated two approaches based on our customers' and vendors' participation and utilization of the ehrAPI. Approach (A) is testing an active API connection between ehrTHOMAS and the third party application requesting patient information. Approach (B) is testing the ehrAPI functionality to be used in future third party application connections. Approach (A) is Genius Solutions' preferred approach, but its usage will be determined by the utilization of the ehrAPI before the approach deadline. We have included a data point for complaints from the third party vendors during the testing period since it may be unknown to the user and the moderator that issues might arise from patient health information returns that have not been observed or tested during the testing period. The data collected in Test API Connection, Approach (B) will be done through an API testing application that will be developed in-house. This API testing application will contain the functionality to appropriately gather data for testing the Patient Selection and Data Category Request, and All Data Request measurements. Approach (B) will validate our expectations of how our API will work in the real world, but we understand that changes may be needed as testing may illuminate improvements to develop a stronger and robust API. Any CCDs created utilizing the ehrAPI will be validated to ensure that the files meet the technical standards and therefore the interoperability between ehrTHOMAS and other applications.

CARE SETTING(S)

The expectation is that a developer's Real World Testing plan will address each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Ambulatory Care Centers	ehrTHOMAS was developed to be used with ambulatory practices which is primarily Genius Solutions' EHR customer base. Most practitioners in this space are eligible to participate in quality payment programs that require a

	certified EHR. We would like to continue to develop a program that will aid our customers in exchanging patient health information more efficiently. By testing with some of our customers, it will provide us with useful data to streamline the workflow while testing the technical capabilities of our software. We understand that not every specialty will be used for every measure within this testing plan as the measure may not be within their scope of practice. We foresee the following specialties to have adjusted measurements: ● Podiatry and Mental Health ○ Excluded from Submit and Receive Patient Immunization Information and Submit and Receive Syndromic Surveillance Information measures. ● Chiropractic ○ Excluded from Prescribe a Medication, Submit and Receive Patient Immunization Information and Submit, Receive Syndromic Surveillance Information measures.

EXPECTED OUTCOMES

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

(1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;

(2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,

(3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should <u>not</u> result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes

Receive Patient Health Information via Direct Messaging	*Since we are trying to not use synthetic data with this measure, we expect that all providers will be receiving a CCD from other providers on a regular basis. The moderator will inspect the provider's direct messaging inbox and observe the number of CCDs received from other providers. Errors experienced while accessing or viewing the CCD will be recorded. We expect that the CCD will be easily viewable and to be completed without errors.* *The moderator should be able to identify at least transitioning provider and contact information, the patient's name, DOB, the sections within the CCD, and the encounter diagnosis. This will determine that ehrTHOMAS is able to view CCDs in a human readable format.* *We also expect that ehrTHOMAS will be able to identify the errors within any invalid C-CDA documents received from an outside party.* *The testing provider or office will report all complaints of not receiving a CCD to the moderator during the testing period. We do not expect to receive any complaints from the testing provider or office.* *These data points will demonstrate on-going Maintenance of Certification for Transitions of Care as well as on-going EHI exchange functionality.*
Incorporating Patient Health Information from Direct Messaging	*The moderator should be observing the actions of the user throughout the testing period.* *The testing user should have a patient that matches the CCD that is received in the Receive Patient Health Information via Direct Messaging measure. We expect ehrTHOMAS to match the CCD to the patient's chart automatically most of the time with limited user interaction. The moderator will record the number of successful automatic patient matching.* *If the patient in the CCD does not match with a patient in ehrTHOMAS, we can expect that this is due to the patient being a new patient to the practice and has not been entered into the system yet or that there is user error entering the patient's information on either the other provider's or the testing provider's end. We believe that this can happen sometimes and the moderator will record the number of times the testing user must manually match a patient.* *The moderator will also record the number of errors that occur while matching the patient's CCD to the patient's chart. We do not expect to have any errors in patient matching.* *It is expected that the information within the CCD appropriately parses within ehrTHOMAS. We expect that the user can see the patient's active data within their medication list, allergy list and problem list as well as the new data from the CCD. We expect the user to know how to reconcile CCDs within ehrTHOMAS and update the medications/allergies in DrFirst and the patient's diagnoses directly into ehrTHOMAS based on what is revealed in the CCD. The moderator will record any errors incorporating patient health information.*

	The collected data points are used to demonstrate on-going functionality of incorporating patient data from other health providers and to test the system's conformity to the Clinical Information Reconciliation and Incorporation certification.
Prescribe a Medication	*The moderator should be observing the actions of the user throughout the testing period.* *We expect the user to know how to prescribe a medication within DrFirst. We expect that all prescribed medication should be created and transmitted to the pharmacy through Rcopia with no errors. If there are issues with the transmission of a prescription, we expect the cause to be due to an outage in the Rcopia health information network.* *The moderator should be able to verify that the prescription information is pulled down from Rcopia with the appropriate medication, SIG, frequency, and RxStatus and record the SIG match. We expect a 100% SIG match rate.* *The testing provider or office will report all complaints of the pharmacy not receiving prescriptions or the patient reporting missing prescriptions at the pharmacy to the moderator during the testing period. We expect that the complaints of missing prescriptions are due to user error.* *These data points will demonstrate on-going Maintenance of Certification for Electronic Prescribing as well as on-going EHI exchange functionality.*
Export Clinical Data Summaries	*The moderator should be observing the actions of the user throughout the testing period. We do not expect this measure to be performed in the users' everyday workflow.* *Genius Solutions does not expect the average user to know how to export clinical data out of ehrTHOMAS. While this functionality is explained through training, it is not a feature that users would perform on a regular basis. We expect to train the user on how to perform this measure prior to testing.* *We expect the number of records that are pulled from the EHR matches the number of CCDs that are being exported out of the system. The moderator will verify the number of records and report the verification as a successful export. The moderator will also record any errors that occurred while exporting. Little to no errors are expected to occur when exporting CCDs. The CCDs being generated are expected to contain all the patient information that has been entered into ehrTHOMAS.* *When verifying the exported CCDs through the C-CDA validator we expect all files to meet the standards specification. The moderator will report successful validations.* *The data points included in this measure will provide evidence of on-going Maintenance of Certification for Data Export while conforming to the technical standards for the C-CDA.*

Record and Create a Care Plan	*The moderator should be observing the actions of the user throughout the testing period. We do not expect this measure to be performed in the users' everyday workflow.* *As stated in our Justification section, we expect many of our customers not utilizing this functionality to its fullest capability. We expect to train our offices on how to perform this measure prior to testing.* *After the user exports a CCD, we expect the CCD to contain the "Goals" and "Health Concerns" sections. These sections will be verified by the moderator and be reported as a successful export. The moderator will also report any errors that occur while exporting the CCD.* *We expect that the CCDs being exported out of ehrTHOMAS will meet all the standards of specifications when being checked through the C-CDA validator. The moderator will report successful validations.* *The collected data points will provide evidence of on-going Maintenance of Certification for Care Plans and conformance to the technical standards of the C-CDA.*
Generate a Clinical Quality Measure (CQM) Report	*Genius Solutions expects that the users participating in the research are quality payment program providers, meaning that they are actively participating in either the Merit-based Incentive Payment System or the Medicaid EHR Incentive Program.* *We expect that the CQM report will be generated successfully without any errors. We expect little to no complaints from the testing participants regarding the CQM measures. If there are complaints regarding patients not showing up in the CQM report, it is likely that they are user error rather than system error.* *We also expect the QRDA file to export successfully and with no errors. All the measures within the QRDA file are expected to conform with the technical standards and produce no errors while validating the file.* *The data points associated with this measure will provide evidence of on-going Maintenance of Certification for Clinical Quality Measures: Report and Clinical Quality Measures: record and export.*
Send CCDAs to the Portal	*Genius Solutions does not expect that all patients of the testing participant will opt into creating a portal. Therefore, not all CCDs will be transmitted to the patient's portal. Of the patients who do have a portal account with the testing participant, we expect that all CCDs will be transmitted successfully with all the contents of the CCD.* *The moderator should be observing the actions of the user during the sending of a CCD to the portal. The moderator will verify that the CCD for the test patient has been transferred successfully to the test portal through a visual inspection. We expect to read the CCDs in a human readable form. We expect that the CCDs can be downloaded and read in a human readable form.*

	The moderator will run a handful of real patient CCDs through a CCD validator and record the rate of valid CCDs. During the validation, we expect that the CCDs will conform to the technical standards. *The testing provider or office will report all complaints from the patient regarding missing patient health records or issues viewing or downloading their health information to the moderator. We expect little to no complaints from patients not receiving their patient health information. Similarly, we expect little to no complaints from patients not being able to view or download their health information.* *All the data points collected for this measure will provide evidence of on-going Maintenance of Certification for View, download, and transmit to 3rd party and on-going EHI exchange. It will also verify that the CCDs transmitted to the portal conforms to the technical standards.*
Submit and Receive Patient Immunization Information	*The moderator should be observing the actions of the user throughout the testing period. The moderator will also pull the appropriate HL7 files that are required for validation from the testing participant's system.* *We expect that the HL7 immunization messages will export successfully with no errors. We expect the files to be transmitted to MCIR and/or FLShots successfully with no issues. If there is an issue with the transmission of the message, we expect that to be on the registry's end. The transmitted immunization information is expected to match what was exported from ehrTHOMAS and what is being displayed by the registry.* *Any registry that sends ACK messages are expected to be imported into ehrTHOMAS successfully with no errors. We expect ehrTHOMAS to output a QBP message with no errors. If applicable, the QBP message will be transmitted and ehrTHOMAS will retrieve the immunization information successfully and without error.* *The immunization HL7 messages and the QBP messages are expected to conform to the current technical specifications and will be verified through the HL7 validator. We also expect files to have appropriate standard code sets for the CVX and the NDC. The moderator will record successful validations.* *The collected data points will provide evidence of on-going Maintenance of Certification for Transmission to Immunization Registries, on-going EHI exchange, and conformance to the technical standards of the HL7 and the code sets for the CVX and NDC.*
Export Syndromic Surveillance Records	*The moderator will be collecting the syndromic HL7 messages from the testing participant's system.* *We are expecting that we will be following Approach (B) for our testing since our product is not marketed to specialties that would be utilizing this functionality. We believe that ehrTHOMAS can demonstrate its capability to send real-time HL7 messages to future live production sites if the HL7 files being exported conforms to the technical standards.*

	The HL7 messages are expected to be exported and transmitted successfully and without errors. If there are any issues with transmission, we expect that to come from the registry's end. The moderator will confirm the transmission to the registry and record the data. *We expect the HL7 messages to conform to the technical standards and produce no errors. The moderator will record the successful validations.* *The collected data points are used to demonstrate on-going functionality of the system's electronic health information exchange and to test the system's conformity to the Transmission to Public Health Agencies - Syndromic Surveillance certification and the HL7 technical standards.*
Test API Connection: Patient Selection	*The moderator will work directly with the third party vendor or the API tester to collect the data for this measure.* *We expect that the ehrAPI will return a patient token that appropriately matches a patient within ehrTHOMAS. We do not expect any errors when receiving or sending the patient token through the API. If working with a third party vendor, we do not expect complaints regarding receiving a patient token.*
Test API Connection: Data Category Request	*The moderator will work directly with the third party vendor or the API tester to collect the data for this measure.* *We expect the ehrAPI will return the appropriate data category for the specific patient requested. We do not expect any issues or errors when returning the data. If a CCD is created, we expect the CCD to be valid and conform to the technical specifications for the file.*
Test API Connection: All Data Request	*The moderator will work directly with the third party vendor or the API tester to collect the data for this measure.* *We expect the ehrAPI will return all the patient data for the specific patient requested. We do not expect any issues or errors when returning the data. If a CCD is created, we expect the CCD to be valid and conform to the technical specifications for the file.*

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Generate CQM reports and Exporting a QRDA Files	All Care Settings	January 1st, 2022 to December 31st, 2022.

Develop and test software used for the Test API Connection measure.		Compete by February 25th, 2022.
Completion of recruiting test participants for Real World Testing	All Care Settings	February 25th, 2022
First testing period. Data will be collected and recorded.	All Care Settings	March 1st to April 1st, 2022
Second testing period. Data will be collected and recorded.	All Care Settings	July 1st to August 1st, 2022
Third testing period. Data will be collected and recorded.	All Care Settings	November 1st to December 1st, 2022
Analyzing the results and creation of final report		December 1st, 2022 to February 1st, 2023

ATTESTATION

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.[2]

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 the health IT developer's Real World Testing requirements.

Authorized Representative Name: Melissa Thanyakarn

Authorized Representative Email: melissa1@geniussolutions.com

Authorized Representative Phone: 586-751-9080

Authorized Representative Signature:

Date: 10/14/2021

[2] https://www.federalregister.gov/d/2020-07419/p-3582