Scientific Technologies Corporation
ImmsLink® Real World Testing Plan
2024

Prepared by STChealth
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STChealth
411 South 1st Street
Phoenix, AZ 85004
480.745.8500 phone
602.598.7712 fax
www.STChealth.com

GENERAL INFORMATION

Plan Report ID Number: _20231120stc_____
Developer Name: _Scientific Technologies Corporation_____
Product Name(s): _ImmsLink®_____
Version Number(s): _5.0_____
Certified Health IT Product List (CHPL) ID(s): _15.02.05.2309.STCO.01.01.0.220110___
Developer Real World Testing Page URL: _https://immslink.com/certificationtesting/__

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

ImmsLink® provides a single nationwide gateway that allows a provider EHR to only a) submit new or corrected or historical immunization records for a single patient to the immunization registry where that provider is registered; and b) retrieve a single patient's immunization history (optionally with a CDSi-compliant immunization forecast for that patient) from that immunization registry. ImmsLink® translates the provider message sent to it into a conformant HL7 message which is then sent to the appropriate state/regional immunization registry system using that system's preferred messaging and application protocol (HL7 within SOAP over HTTP, raw HL7 over HTTP, raw HL7 over FTP, etc.).
ImmsLink® supports both doctors and pharmacists as immunization providers, and public and private schools as immunization history queriers (as part of enrollment requirements); therefore, the care settings specified in this plan will be doctors' offices, pharmacies, and school offices.
As a messaging gateway, the ImmsLink® system has no end-user interface for providers, but only a log of messages received and sent. This log, then, will be the source of the data used to demonstrate conformance.
The targeted certification criterion for this test plan is the "Transmission to Immunization Registries" criterion, 170.315(f)(1). To demonstrate conformance with this criterion, this test plan encompasses three efforts.
First, registry responses will be tabulated and the count of data-related error responses from the registries compared against a threshold goal.
Second, random samples of messages will be analyzed for compliance with the requirement to use NDC codes instead of CVX codes for newly administered vaccines (when the actual product is known).
Third, random samples of messages will be analyzed for compliance with the requirement to return an evaluated immunization history and forecast from the registry.

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

The only applicable standard is the HL7 2.5.1 IG for Immunization Messaging, Release 1.5, and July 2015 Addendum. These have not been updated since last certification.

Standard (and version)	(no updated standards)
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

The three measures chosen for the test plan demonstrate the correct transmission of requests and processing of responses to/from the immunization registries. These measures will be taken quarterly. Note that ImmsLink®

only provides two functions, regardless of care setting: immunization reporting and immunization history querying. The selected metrics measure the accuracy of these two functions.

Description of Measurements/Metrics

The first measure is a count of all error responses from a registry that are due to data-related errors (as opposed to, for example, those due to a network failure attempting to contact the registry, which are outside the scope of certification). As ImmsLink® maintains a log of all messages sent and error responses received, all messages will be sampled in this measure.
The second measure is a count of administered vaccine messages from provider EHRs known to use NDC codes to registries known to accept NDC codes where the NDC code was not included in the message to the registry. A random sample of 100 logged messages will be de-identified and manually reviewed.
The third measure is a count of messages where the provider requested an evaluated history and forecast, and the registry successfully matched the requested patient, but an evaluated history was not returned to the provider, a forecast was not returned to the provider, or neither was returned. A random sample of 100 logged messages will be de-identified and manually reviewed. The threshold of acceptance is a count of 0.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software
Count of data-related error responses from registries	§ 170.315(f)(1) Transmission to Immunization Registries (i) "…according to the IG IM Release 1.5, and the July 2015 Addendum" (ii) "in accordance with the HL7 2.5.1 standard, then HL7 2.5.1 IG for Immunization Messaging, Release 1.5, and July 2015 Addendum"	None
Count of newly administered vaccine messages without NDC codes	§ 170.315(f)(1) Transmission to Immunization Registries (i) "…using CVX codes for historical vaccines and NDC codes for newly administered vaccines."	None
Count of history/forecast requests that matched patient but didn't return history/forecast	§ 170.315(f)(1) Transmission to Immunization Registries (ii) "…enables a user to request, access and display the evaluated immunization history and forecast from an immunization registry for a patient"	None

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Count of data-related error responses from registries	Registry error responses will indicate any HL7 syntactic errors with the messages ImmsLink® generates, thus showing a non-conformity with the IG IM or the addendum.
Count of newly administered vaccine messages without NDC codes	This is a direct measure of conformity with the requirement to use NDC codes for newly administered vaccines.
Count of history/forecast requests that matched patient but didn't return history/forecast	This is a direct measure of conformity with the requirement to provide both evaluated history and forecast to the provider.

Care Setting(s)

Care Setting	Justification
Doctor's office/clinic/hospital	Doctors, clinicians, and hospital staff use ImmsLink® to report administered vaccinations and its querying capability to verify a patient's history.
Pharmacy	Pharmacists use ImmsLink®'s reporting capability to report administered vaccinations and its querying capability to verify a patient's history and possibly upsell an overdue vaccination.
School/school district	Schools and school districts use ImmsLink®'s querying capability to verify a student's vaccine history, ensuring enrollment requirements are met.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Count of data-related error responses from registries	Error rate < 0.5% of all sent messages.
Count of newly administered vaccine messages without NDC codes	Count of 0 or 1 out of the sample of 100 messages.
Count of history/forecast requests that matched patient but didn't return histo-ry/forecast	Count of 0 out of the sample of 100 messages.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Begin collection of information as laid out by the plan.	All	January 1, 2024
Data collection and review	All	Quarterly, 2024
End of Real World Testing period/final collection of all data for analysis	All	January 1-10, 2025
Analysis and report creation	All	January 10, 2025
Submit Real World Testing report to ACB (per their instructions)	All	January 15, 2025

ATTESTATION

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

Authorized Representative Name: _Matt Guthrie_____
Authorized Representative Email: _matt_guthrie@stchome.com_____
Authorized Representative Phone: _480.745.8500_____
Authorized Representative Signature: _Matt Guthrie_____
Date: _11/17/2023_____