



**HL7's Initial Report to the Office of the National Coordinator
Standards Development Organization
Collaboration to Enhance Standards Alignment,
Testing, and Measurement**

Friday, April 1, 2016

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1 Introduction

In September of 2015, Health Leven Seven (HL7) was award a grant by the Office of the National Coordinator to develop a plan to enhance the conformance testing infrastructure across its portfolio of implementation guides. The following report describes:

- The project scope
- Current infrastructure
- The work accomplished to date, particularly the results of a gap analysis of existing tools for in-scope implementation guides
- Our current thinking on the high-level approach HL7 will take to ensure conformance testing is developed and available, including issues and challenges with the approach. This information will be developed more fully over the remaining months of the project.
- Our current thoughts regarding metrics to capture and reliably measure standards implementation and use
- Cost, as understood to date, to implement the approach

2 Scope of this Report

HL7 is an international organization with more 35 affiliates around the world. Many of our affiliates have realm-specific implementation guides that are not readily available to our staff and/or not written in English. Therefore, the project was scoped to include only those implementation guides that were developed for the US and/or Universal realms. This report specifically does not address implementation guides developed for non-US or non-Universal realms, although the assumption is that the recommended approach can be extended to include those implementation guides as a later time.

The implementation guides covered by this project are listed below

1. HL7 CDA (®) R2 Implementation Guide: Patient-friendly language for Consumer User Interfaces, Release 1
2. HL7 CDA® R2 Implementation Guide: Medication Therapy Management (MTM) Templates, Release 1 - US Realm
3. HL7 Fast Healthcare Interoperability Resources Specification (FHIR), Release 1 (DSTU)
4. HL7 Fast Healthcare Interoperability Resources Specification (FHIR), Release 2 (DSTU)
5. HL7 Implementation Guide for Arden Syntax, Release 1
6. HL7 Implementation Guide for CDA Release 2: Plan-to-plan Personal Health Record PHR Data Transfer, Release 1 - US Realm
7. HL7 Implementation Guide for CDA Release 2: Public Health Case Reporting, Release 1 - US Realm

8. HL7 Implementation Guide for CDA® R2: Patient Generated Document Header Template, Release 1
9. HL7 Implementation Guide for CDA® Release 2 – Level 3: Emergency Medical Services; Patient Care Report, Release 1 – US Realm
10. HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates - Clinical Documents for Payers – Set 1 , Release 1 (US Realm)
11. HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) DSTU Release 2
12. HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1
13. HL7 Implementation Guide for CDA® Release 2: Healthcare Associated Infection (HAI) Reports, Release 1
14. HL7 Implementation Guide for CDA® Release 2: Healthcare Associated Infection (HAI) Reports, Release 2
15. HL7 Implementation Guide for CDA® Release 2: HIV/AIDS Services Report, Release 1 - US Realm
16. HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1
17. HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 (US Realm)
18. HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DSTU Release 3 (QRDA)
19. HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 (US Realm)
20. HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
21. HL7 Implementation Guide: Decision Support Service, Release 1.1 (US Realm) Draft Standard for Trial Use
22. HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1
23. HL7 Implementation Guides for CDA Release 2: Consolidated CDA Templates for Clinical Notes, Release 1 - US Realm
24. HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 1 - US Realm
25. HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2 - US Realm
26. HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 2 (DSTU) - Release 1
27. HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 2 (DSTU) - Release 2
28. HL7 Version 2.5.1 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Cytogenetics Model (US Realm), Release 1
29. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1

30. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 2, DSTU Release 1.1
31. HL7 Version 2.5.1 Implementation Guide: Height and Weight Report, Release 1 - US Realm
32. HL7 Version 2.5.1 Implementation Guide: Orders and Observations; Interoperable Laboratory Result Reporting to EHR, Release 1
33. HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (DSTU) - Release 1
34. HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (DSTU) - Release 2
35. HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1(DSTU)
36. HL7 Version 2.6 Implementation Guide: Blood Bank Donation Services, Release 1 - US Realm
37. HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 4
38. HL7 Version 3 Implementation Guide: Annotated ECG, R1
39. HL7 Version 3 Implementation Guide: Canonical Pedigree (Family History) Interoperability, Release 1 - US Realm
40. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, Release 1
41. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval Application (Infobutton), Release 4
42. HL7 Version 3 Implementation Guide: Drug Stability Reporting (eStability) R2, Release 2
43. HL7 Version 3 Implementation Guide: Drug Stability Reporting (eStability) R2, Release 3
44. HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1
45. HL7 Version 3 Implementation Guide: Regulated Product Submission R2, Release 1
46. HL7 Version 3 Implementation Guide: Regulated Studies; Annotated ECG R1, Release 2 - US Realm
47. HL7 Version 3 Implementation Guide: Regulated Studies; CDISC Content to Message - Study Participation, Release 1
48. HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 1
49. HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 3
50. HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 4
51. HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 5
52. HL7 Virtual Medical Record for Clinical Decision Support (vMR-CDS) XML Implementation Guide, Release 1 - US Realm
53. HL7/ASTM Implementation Guide for CDA[®] R2 -Continuity of Care Document (CCD[®]) Release 1
54. Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm)
55. v2.5.1 Implementation Guide: Orders & Observations; Ambulatory Care Lab Result (ELINCS), Release 1

3 Current Infrastructure

Founded in 1987, HL7 has been developing Healthcare IT standards for nearly 30 years. During that time there have been limited and somewhat uncoordinated efforts both by HL7 and various external organizations to develop documents, conformance statements, tooling and services that enable limited validation and/or limited conformance testing. Currently, there is little, if any, consistency in these approaches across product lines, an issue that will be addressed as this project moves forward.

A non-exhaustive overview of the various validation/conformance-related activities that have been undertaken over the years are described by product line below.

3.1 Version 2

- [The Health Level Seven Version 2.x Message Profiling Specification Version 2.2](#) (published by HL7 in late 2000) - HL7 V2.x Message Profiling provides a guideline for documenting particular uses of HL7 messages. The intent was that a defined V2.x message profile would be uploaded to the [HL7 Version 2 Global Profile Registry](#), thereby moving the HL7 V2.x standard closer to “plug and play” interfaces. In reality, the profile specification and registry were used infrequently by the membership, likely due to the fact that vendors felt they would be exposing confidential/proprietary information. This Profiling Specification was eventually inserted directly into the Version 2 standard as Chapter 2B, which is described below.
- [Messaging Workbench](#) – The Messaging Workbench is a multipurpose productivity tool for HL7 V2.x implementers. It facilitates rapid development of specifications and reports. It also incorporates an online message validation service, and message generator for use in testing.
- [Australian Healthcare Messaging Laboratory](#) (University of Ballarat - Australia) – Developed by the University of Ballarat in Australia, this site provides message testing against HL7 Version 2.3.1.
- [Message Maker](#) – This tool was developed via a collaboration effort between the National Institute of Standards and Technology (NIST) and HL7. NIST is directing their efforts towards the development of a conformance-testing tool that automatically generates test messages for HL7 message profile specifications. The messages can be used to test systems for conformance. A prototype of Message Maker is available at this site. All NIST produced source code, documents, and associated products are in the public domain. Message Maker is a work-in-progress, as such, not all planned functionality is implemented; feedback on its design, feature set, and usefulness is welcomed.
- [Chapter 2B of the current V2.x specification](#) – This chapter outlines the methodology for producing a message profile, which is a precise and unambiguous specification of one or more standard HL7 messages that have been analyzed for a particular use case. The profile prescribes a set of precise constraints upon one or more standard HL7 messages and is expressed using XML Schema Language. Messages that adhere to the constraints of a message profile are said to be conformant to the profile.

While the methodology for constructing a profile has been documented here, not all HL7 Version 2 implementation guides provide conformance profiles for each message. Additionally, profiles found in Version 2 implementation guides are not consistently located nor are they currently complete enough to develop robust conformance tools.

- [Immunization Conformance Testing](#) – In 2014, HL7 partnered with Aegis to develop conformance testing for Immunization History messages (VXU, ACK) as provided in the HL7 Version 2.5.1 Implementation Guide Immunization Messaging Release 1.4. A profile was created to test conformance to three use cases. It was apparent that the implementation guide was not fully constrained and was under specified. HL7 therefore hired a contractor to work with Aegis to create useful conformance statements and profiles. Once developed, the Aegis conformance testing tool performed well and provided the type of robust conformance testing expected from a professional conformance testing company.

3.2 Version 3

- [Refinement, Constraint and Localization, Release 2](#) – This is a normative and ANSI-approved standard describing the rules for constraining the Version 3 Reference Information Model (RIM), vocabulary domains and data type specifications to develop conformance profiles (among other artifacts).
- [HL7's Model Interchange Format](#) (MIF) – This informative document was produced and balloted by HL7. It refers to a set of schemas used to define HL7's artifact meta-model and a format for persisting and exchanging HL7 artifacts and the various artifact instances published in MIF format. While the MIF's primary intended audience is internal HL7 constituents, it is used as the computational syntax for publishing HL7 artifacts and is therefore of interest to implementers of HL7 standards. Many implementers have chosen to construct applications that load information about HL7 standards from their MIF representation. Because the MIF is more complete than the schema representations, this allows software to take advantage of such information as whether elements are mandatory, vocabulary bindings, etc.
- [HL7 Eclipse Tooling](#) – This tool allows developers to build/edit message instances based on the V3 Reference Information Model (RIM) that are continuously validated against the MIF and schema.

3.3 Clinical Document Architecture (CDA)

- MIF and related schemas – Same as above as CDA is within the Version 3 family of standards
- [Trifolia](#) – Developed by Lantana and made available to HL7 members free of charge, Trifolia Workbench HL7 Web Edition is a read-only repository of all HL7 CDA templates and implementation guides that have been authored using Trifolia and balloted through HL7. This tool allows users to browse templates, view their constraints, and generate Microsoft Word and HTML documentation from those templates. Additionally, HL7 members can create implementation guides and templates,

and control edit access to its templates.

- [CDA Examples](#) – More recently, the HL7 Structured Documents work group has formed a task force to accept examples of various CDA document sections. The task force has established a set of rules for submission and acceptance of these artifacts. Essentially, the examples indicate how to represent data within a section of a clinical document for a very specific use case. Several section examples can be amalgamated to produce a document tailored for a specific use case. Use of these examples is strongly encouraged by HL7 but not required. Ultimately, the goal is that these examples will be adopted extensively in the community thereby becoming the industry defacto representations. Uptake of these examples will greatly reduce variation thereby increasing interoperability.

3.4 FHIR

- Built in [Conformance Rules](#) - The FHIR specification, more so than HL7's other standards, has built in conformance rules that assist with validation/conformance.

The FHIR specification describes a set of resources as well as several frameworks for exchanging those resources between different systems. Applications claiming conformance to this specification make the claim with respect to a specific framework and in regards to specific details about their use of those frameworks and resource contents. Specifically, applications claim conformance to one or more of the following frameworks:

- RESTful FHIR: The Restful API
- FHIR messaging: Message based exchange
- FHIR documents: Document based exchange.

To provide specific details about usage of the frameworks and resource contents, FHIR provides a conformance layer that implementers and national/regional programs can use to provide a computable statement about how the resources and their exchange paradigm are used to solve particular use cases. The conformance layer is implemented using the following key resources:

Value Set	Defines a set of coded values (see " Using Codes " for more details)
StructureDefinition	Makes rules about how a resource (or type) and its data elements are used in a particular context. A structure definition references value sets for the coded elements in a resource
Conformance	A statement of the kinds of resources and operations provided and/or consumed by an application. The conformance resource references profiles to describe specific use of resources by the application. Systems can only claim to be conformant to FHIR if they have a Conformance instance that describes their behavior and they can do all of things that Conformance instance declares.

Implementation Guide	A single coherent collection of conformance statements, profiles, value set, and documentation describing a set of interoperable applications
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- [Validating resources](#) – The FHIR specification supports validation of resources against the original specification, against an implementation guide and against a specific profile. Resources can be tested for conformance by:
 - [Using the XML Schema](#) - for XML instances only
 - [Using the FHIR Validator](#) - a java jar provided as part of the specification
 - [Asking a FHIR Server](#) - using the \$validate operation
 - [Via a web interface](#) - using a web form on a test server

Additional information about each of these is provided at the links above.

- Conformance resources – the FHIR project is developing a suite of conformance resources that allow a complete computable description of an implementation that can be processed by testing services such as [Aegis Touchstone](#) or [Mitre Crucible](#)--both of which are working with the FHIR project—or with other testing services as required.

3.5 [CIMI](#)

Unlike the products described above, CIMI is an HL7 work group that is creating a shared repository of detailed clinical information models using an approved formalism (either Archetype Definition Language (ADL) or Archetype Modeling Language (AML). These models are based on a common set of base data types, with formal bindings of the models to standard coded terminologies. The repository of models is open to everyone and the models are licensed free of charge.

The CIMI effort is akin to the CDA Examples library in that their models specify how to represent data. While the organization does not require the use of CIMI models, the hope is that they will be widely adopted across the community and therefore become the defacto representations. Like the use of CDA Examples, use of the CIMI models decrease variation in the representation of data thereby increasing interoperability.

4 [Conformance Tooling Gap Analysis](#)

HL7 hired a contractor to perform a gap analysis to determine the current conformance tooling available for the set of implementation guides included in the scope of this project.

For the purposes of the gap analysis, conformance tool was defined as any tool that validates conformance to one or more specific implementation guides. Tools that may be configured to validate particular implementation guides but which do not do so “out-of-the-box” were excluded from the

analysis. A number of these tools were listed in the analysis of the current infrastructure above. A list of these tools is provided later in this report under the heading of General Tools.

The primary objectives of the gap analysis were to:

- Identify and evaluate all extant conformance tooling for implementation guides within the scope of this project. The following information was collected for each identified tool:
 - Developer or owner
 - Users
 - Platform
 - Cost, licensing or intellectual property restrictions
 - URL
 - Certification program
 - Perceived strengths and weaknesses
- For guides without tools, identify the perceived need for tooling and estimate the effort required to develop tools.
- Provide recommendations regarding the creation of tooling to fill the identified gaps and prioritize the needs.

The agreed approach to the gap analysis combined extensive online research with community engagement to ensure the results were as comprehensive as possible and that the analysis of gaps in existing tooling reflects the real needs of the implementers who use implementation guides considered in-scope for this project. The overall approach was as follows:

1. **Project Initiation:** Kick off the project. Develop a template for the gap analysis and a set of metrics to assess the need for tooling where none exists; submit both to HL7 for approval.
2. **Information Collection:** Seek out and identify all extant implementation guide conformance tooling and collect the required information. Sources of information regarding tooling included HL7 mailing list and Skype chat archives, community blogs, vendor websites, government (e.g. ONC, NIST) websites and general Web searches using appropriate search terms.
3. **Community Engagement:** In many respects a subset of Information Collection. A survey was developed in collaboration with HL7 and distributed to a mailing list of over 18,000 that included HL7 members and non-members. Responses were collected and overall trends and specific tooling requests were extracted.
4. **Analysis:** The metrics developed and agreed to during project initiation were applied to implementation guides without conformance tooling. Strengths and weaknesses of identified tools were assessed according to a set of pre-determined strengths and weaknesses approved by HL7.
5. **Catalog Development:** A draft of the tooling catalog and recommendations were developed, incorporating the information collected from the community and various online sources.

6. **Project Closure:** Final review and approval of the gap analysis; delivery of the finished product to HL7. As of this writing, the gap analysis has been completed.

4.1 Vendor Selection

HL7 issued an RFP on December 14, 2015 to catalogue conformance tooling available for implementation guides within the scope of this project. Three responses were received by the January 6, 2016 deadline. HL7 Staff reviewed the proposals to ensure they met the stated requirements. Further evaluation gave preference to resources who:

- Are actively engaged in current HL7 activities
- Are familiar with methods and technology used by HL7
- Have relevant skills and experience

While all of the proposals were strong, only one was within the budget set forth by ONC’s grant for this project. We therefore signed a contract with this resource on January 28, 2016.

4.2 Methodology for Rating (Evaluating) Available Tools

The methodology for rating the available tools is based on seven key metrics that we feel are an indicator of quality:

- Cost – Cost is a consideration for everyone. While free isn’t always the best choice, particularly if quality is lacking, but a good free tool is ideal.
- Platform – Most tools are web-based although a few aren’t. While we assume that web is preferable, there may be some HIPAA related issues with using web-based tools.
- License- Open source is preferable and within the open source world, Apache-like licenses that have no restrictions on distribution are preferable to the copyleft license such as GPL.
- Documentation – Documentation that provides clear instructions for users is a critical component of any conformance tool. This metric is therefore more heavily weighted than the previous two.
- Viability – Viability refers to an active community of users that provide input and feedback to the tool. An active community is critical to keeping the tool up to date. Like Documentation, the component is more heavily weighted than others.
- Ease of use – While not always possible, a tool that is intuitive to use is always welcomed by the user.
- Robustness – Robustness in this context refers to rigorousness of the testing. Happy path is least desirable.

Each tool was then scored again the following rubric:

Metric	Weight	Scoring Rule	Points
		Criterion	
Cost (C)	1.00	Free	2
		<\$10,000 USD	1

		\$10,000 USD	0
		Unknown	0
Platform (P)	1.00	Web	1
		Other	0
		Unknown	0
License (L)	1.00	Open-source (MIT, Apache or similar)	2
		Open-source (GPL or similar)	1
		Proprietary	0
		Unknown	0
Documentation (D)	2.00	Excellent	3
		Good	2
		Fair	1
		Poor	0
		Unknown	0
Viability (V)	2.00	Maintained, many users	3
		Maintained, few users	2
		Maintained, users unknown	2
		Unmaintained, many users	1
		Unmaintained, few users	0
		Unknown	0
Ease of use (E)	1.00	Easy	2
		Moderate	1
		Difficult	0
		Unknown	0
Robustness (R)	2.00	Broad & robust test coverage	2
		Some edge or invalid cases	1
		Schema/schematron validation	1
		"Happy path" only	0
		Unknown	0
Total score = C = P + L + (Dx2) + (Vx2) + E + (Rx2)			

The score calculated according to the above rubric was then converted to a qualitative rating:

- **Excellent:** Score = 21
- **Good:** Score= 14 - 20
- **Fair:** Score=7 - 13
- **Poor** Score= <7

Refer to Appendix A for the list of available tools rating using the rubric above.

4.3 Methodology for Prioritizing the Implementation Guides for which Tooling is Needed

The methodology for prioritizing the implementation guides for which tooling is needed is based on four key metrics:

- Number of implementation guide downloads from the HL7 website – This was used as an indicator of popularity and implementation and, by extension, demand for associated conformation tooling.

- Implementation guide version or release number – We assumed that newer releases of implementation guides are given priority as new system implementations should be using the most recent implementation guide and new implements are like to have the greatest need for conformance tooling.
- Associated standards – Standards that are expected to have a longer lifespan going forward warrant great effort. This implies that less effort should be directed to ensure tooling to support legacy standards.
- Community feedback – The hired resource developed a survey to collect data from the community. A highly-engaged community that will make the effort to provide feedback indicates that tooling would likely see significant usage and that warrants investment. This metric was weighted more heavily than the other three.

Each of the implementation guides was then scored based on the following rubric:

Metric	Scoring Rule	
	Criterion	Points
Number of implementation guide downloads (D)	>=100 downloads	2
	>= 20 downloads	1
	< 20 downloads	0
Implementation guide version or release number (V)	Newest release of implementation guide	2
	Older release of implementation guide	0
Associated standard (S)	FHIR	2
	CDA	1
	V3	0
	V2	0
Community feedback (F)	Each request for tooling	4
Total score = D + V + S + F		

The score calculated according to the above rubric was then converted to a qualitative description of need according to the following rules:

- **High:** Score >= 6
- **Medium High:** Score=5
- **Medium:** Score=4
- **Medium Low:** Score=3
- **Low:** Score < 3

4.4 Results of Gap Analysis

The results of the gap analysis will be presented as follows:

- A list of the implementation guides included in the scope of this project and the available conformance tools, if any, that support them.
- Details of each of the conformance tools that support an implementation guide within the scope of this project
- A list of the implementation guides for which conformance tooling is needed ordered by need (high, medium-high, medium, medium-low and) is provided.

4.4.1 Implementation Guides and Available Conformance Testing Tools

The following table lists the conformance tooling identified for each implementation guide. For additional details on a particular tool, please refer to the entry in the *Details of Conformance Tools* table (below) indicated in the “Reference #” column.

Tool Name	Owner	URL	Reference #
<i>HL7 CDA (®) R2 Implementation Guide: Patient-friendly language for Consumer User Interfaces, Release 1</i>			
No tools found			
<i>HL7 CDA® R2 Implementation Guide: Medication Therapy Management (MTM) Templates, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Fast Healthcare Interoperability Resources Specification (FHIR), Release 1 (DSTU)</i>			
No tools found			
<i>HL7 Fast Healthcare Interoperability Resources Specification (FHIR), Release 2 (DSTU)</i>			
Sprinkler	Furore	http://fhir.furore.com/Products#sprinkler	17
Crucible	MITRE Corporation	https://projectcrucible.org/	18
Touchstone Project	AEGIS.net	https://touchstone.aegis.net/touchstone/	19
<i>HL7 Implementation Guide for Arden Syntax, Release 1</i>			
No tools found			
<i>HL7 Implementation Guide for CDA Release 2: Plan-to-plan Personal Health Record PHR Data Transfer, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Implementation Guide for CDA Release 2: Public Health Case Reporting, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® R2: Patient Generated Document Header Template, Release 1</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2 – Level 3: Emergency Medical Services; Patient Care</i>			

Tool Name	Owner	URL	Reference #
<i>Report, Release 1 – US Realm</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates - Clinical Documents for Payers – Set 1, Release 1 (US Realm)</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) DSTU Release 2</i>			
SITE C-CDA Validator	Office of the National Coordinator (ONC)	http://sitenv.org/c-cda-validator	12
SMART C-CDA Scorecard	SMART	http://ccda-scorecard.smartplatforms.org/static/ccdaScorecard/#/	16
<i>HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2: Healthcare Associated Infection (HAI) Reports, Release 1</i>			
NSHN CDA Validator (HAI_Validator_4_MU3)	Centres for Disease Control (CDC)	https://github.com/brhoAtCDC/HAI_Validator_4_MU3	11
<i>HL7 Implementation Guide for CDA® Release 2: Healthcare Associated Infection (HAI) Reports, Release 2</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2: HIV/AIDS Services Report, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1</i>			
No tools found			
<i>HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 (US Realm)</i>			
National Health Care Surveys Release 1.1, DSTU Validation	National Institute of Standards and Technology (NIST)	http://cda-validation.nist.gov/cda-validation/muNHCS.html	13
<i>HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DSTU Release 3 (QRDA)</i>			

Tool Name	Owner	URL	Reference #
Cypress Validation Utility	Project Cypress	https://validator.projectcypress.org	14
<i>HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 (US Realm)</i>			
Cancer Report Validator	National Institute of Standards and Technology (NIST)	http://cda-validation.nist.gov/cda-validation/muCRV.html	15
<i>HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1</i>			
Edge Testing Tool	National Institute of Standards and Technology (NIST)	https://edge.nist.gov/ett/#/home	7
<i>HL7 Implementation Guide: Decision Support Service, Release 1.1 (US Realm) Draft Standard for Trial Use</i>			
No tools found			
<i>HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1</i>			
Edge Testing Tool	National Institute of Standards and Technology (NIST)	https://edge.nist.gov/ett/#/home	7
Transport Testing Tool	National Institute of Standards and Technology (NIST)	http://transport-testing.nist.gov/ttt/	4
<i>HL7 Implementation Guides for CDA Release 2: Consolidated CDA Templates for Clinical Notes, Release 1 - US Realm</i>			
Edge Testing Tool	National Institute of Standards and Technology (NIST)	https://edge.nist.gov/ett/#/home	7

Tool Name	Owner	URL	Reference #
SITE C-CDA Validator	Office of the National Coordinator (ONC)	http://sitenv.org/c-cda-validator	12
SMART C-CDA Scorecard	SMART	http://ccda-scorecard.smartplatforms.org/static/ccdaScorecard/#/	16
<i>HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2 - US Realm</i>			
No tools found			
<i>HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 2 (DSTU) - Release 1</i>			
No tools found			
<i>HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 2 (DSTU) - Release 2</i>			
Electronic Directory of Service Test Suite	National Institute of Standards and Technology (NIST)	http://hl7v2-edos-r1-testing.nist.gov/edos-r2/#/home	8
<i>HL7 Version 2.5.1 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Cytogenetics Model (US Realm), Release 1</i>			
No tools found			
<i>HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1</i>			
Electronic Laboratory Reporting test Suite	National Institute of Standards and Technology (NIST)	http://hl7v2-elr-testing.nist.gov/mu-elr/	10
<i>HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 2, DSTU Release 1.1</i>			
Electronic Laboratory Reporting test Suite	National Institute of Standards and Technology	http://hl7v2-elr-r2-testing.nist.gov/mu3-elr/	10

Tool Name	Owner	URL	Reference #
	Technology (NIST)		
<i>HL7 Version 2.5.1 Implementation Guide: Height and Weight Report, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Version 2.5.1 Implementation Guide: Orders and Observations; Interoperable Laboratory Result Reporting to EHR, Release 1</i>			
No tools found			
<i>HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (DSTU) - Release 1</i>			
Lab Results Interface Validation Suite	National Institute of Standards and Technology (NIST)	http://hl7v2-lab-testing.nist.gov/mu-lab/	9
<i>HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (DSTU) - Release 2</i>			
Lab Results Interface Validation Suite	National Institute of Standards and Technology (NIST)	http://hl7v2-lab-testing.nist.gov/mu-lab/	9
<i>HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1(DSTU)</i>			
Lab Results Interface Validation Suite	National Institute of Standards and Technology (NIST)	http://hl7v2-lab-testing.nist.gov/mu-lab/	9
<i>HL7 Version 2.6 Implementation Guide: Blood Bank Donation Services, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 4</i>			
MedlinePlus Connect	U.S. National Library of Medicine	https://www.nlm.nih.gov/medlineplus/connect/overview.html	1
<i>HL7 Version 3 Implementation Guide: Annotated ECG, R1</i>			
No tools found			

Tool Name	Owner	URL	Reference #
<i>HL7 Version 3 Implementation Guide: Canonical Pedigree (Family History) Interoperability, Release 1 - US Realm</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, Release 1</i>			
MedlinePlus Connect	U.S. National Library of Medicine	https://www.nlm.nih.gov/medlineplus/connect/overview.html	1
<i>HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval Application (Infobutton), Release 4</i>			
MedlinePlus Connect	U.S. National Library of Medicine	https://www.nlm.nih.gov/medlineplus/connect/overview.html	1
<i>HL7 Version 3 Implementation Guide: Drug Stability Reporting (eStability) R2, Release 2</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Drug Stability Reporting (eStability) R2, Release 3</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Regulated Product Submission R2, Release 1</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Regulated Studies; Annotated ECG R1, Release 2 - US Realm</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Regulated Studies; CDISC Content to Message - Study Participation, Release 1</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 1</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 3</i>			
No tools found			
<i>HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 4</i>			

Tool Name	Owner	URL	Reference #
Pragmatic Validator Lite™ SPL Validation Tool ¹	Pragmatic Data	http://pragmaticdata.com/content/view/33/39/	2
<i>HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 5</i>			
No tools found			
<i>HL7 Virtual Medical Record for Clinical Decision Support (vMR-CDS) XML Implementation Guide, Release 1 - US Realm</i>			
No tools found			
<i>HL7/ASTM Implementation Guide for CDA® R2 -Continuity of Care Document (CCD®) Release 1</i>			
CDA Validation Tool	National Institute of Standards and Technology (NIST)	http://cda-validation.nist.gov/cda-validation/validation.html	3
<i>Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm)</i>			
No tools found			
<i>v2.5.1 Implementation Guide: Orders & Observations; Ambulatory Care Lab Result (ELINCS), Release 1</i>			
ELINCS Data Generation and Evaluation (EDGE) Tool	California Health Care Foundation (CHCF)	https://elincs.chcf.org	6

4.4.2 Details of Available Conformance Tools

The following table provides additional details for each conformance tool that was identified in the table above:

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
1	MedlinePlus Connect (US National Library of Medicine)	Web	Proprietary, free to use	Many ²	None	A Web application and Web service interface that conform to the HL7 Context-Aware Knowledge Retrieval (Infobutton)

¹ The tool's website does not explicitly identify which release of the Guide is supported, but a (now broken) link appears to reference Release 4; it is therefore inferred that this is the supported release. The existence of such broken links on the tool's site, and the absence of any clear indication of when the tool was last updated or what release of the Guide is used suggest that this tool should be used with caution

² <https://www.nlm.nih.gov/medlineplus/connect/users.html>

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>Knowledge Request URL-Based Implementation IG. Could be used to test implementations of that Guide. Does not appear to provide detailed validation reports.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web-based • Free to use • Documentation is good <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed-source <p>Other Comments:</p> <ul style="list-style-type: none"> • Not specifically a conformance tool • Free service that conforms to Infobutton IGs • Would be useful for testing new implementations of these IGS
2	Pragmatic Validator Lite™ SPL Validation Tool (Pragmatic Data)	Web	Proprietary , free to use	Unknown	None	<p>Provides validation reports for structured product labels. Exact test coverage/level of detail is not clear.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web-based • Free to use <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed source • No documentation

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>to speak of</p> <ul style="list-style-type: none"> Does not appear to be maintained (broken links on website) <p>Other Comments:</p> <ul style="list-style-type: none"> States that it validates input against FDA conformance rules, which in turn reference the SPL R4 IG
3	CDA Validation Tool (NIST)	Web	Proprietary, free to use	<i>Medinformatix, mTuitive</i>	ONC Health IT Certification Program	<p>Uses schematron-based validation to test for conformance for a number of CDA IGs and other specifications.</p> <p>Strengths:</p> <ul style="list-style-type: none"> Web-based Free to use Supports multiple IGs Easy to use <p>Weaknesses:</p> <ul style="list-style-type: none"> Proprietary, closed source Little documentation
4	Transport Testing Tool (NIST)	Web; users may run their own local instance on a Java application server	Free, open source (public domain)	<i>Myca Health Inc., Lantana Consulting Group</i>	ONC Health IT Certification Program	<p>Provides a Web front-end for testing against ONC certification criteria. Notably, includes testing for CCDA conformance. Outputs for CCDA testing include identification on non-conforming XML snippets as well as</p>

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>warnings/errors and the conformance statement that is not being met.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web-based • Free to use • Open source • Supports multiple IGs <p>Weaknesses:</p> <ul style="list-style-type: none"> • Complex; documentation is weak • Unintuitive, difficult to navigate • Being discontinued; replaced by Edge Testing Tool (see #7, below)
5	CDA Validator (Lantana Consulting Group)	Web	Proprietary, free to use	<i>mTuitive, Lantana Consulting Group</i>	None	<p>Prototype for the NIST CDA Validation Tool. Appears to use schematron-based validation.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Supports many IGs • Easy to use <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed source • No documentation
6	ELINCS Data	Web	Proprietary	Unknown	None	May be

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
	Generation and Evaluation (EDGE) Tool (CHCF)		, free to use			offline/discontinued Other Comments <ul style="list-style-type: none"> While referred to by various online sources, the tool appears to be unavailable at the moment It is unclear if this is temporary, or if CHCF has discontinued it
7	Edge Testing Tool (NIST)	Web; users may run their own local instance if desired (Java based)	Proprietary , free to use	<i>Myca Health Inc.</i>	ONC Health IT Certification Program	Comprehensive validation & conformance testing suite for ONC certification. Supports a number of IGs, including C-CDA. C-CDA conformance testing includes both IG and vocabulary conformance tests. Strengths: <ul style="list-style-type: none"> Web-based Free to use Supports multiple IGs Documentation available Weaknesses: <ul style="list-style-type: none"> Somewhat complex Proprietary, closed-source
8	Electronic Directory of Service Test Suite (NIST)	Web	Proprietary , free to use	Unknown	None	Provides two comprehensive test plans for validating conformance to the HL7 Version 2.5.1 Implementation Guide: S&I

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>Framework Laboratory Test Compendium Framework R2. Appears to generate detailed testing reports.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web-based • Free to use • Broad test coverage <p>Weaknesses:</p> <ul style="list-style-type: none"> • Somewhat complex, documentation is incomplete • Does not appear to test deliberately incorrect inputs • Proprietary, closed-source
9	Lab Results Interface Validation Suite (NIST)	Web	Proprietary, free to use	Unknown	ONC Health IT Certification Program	<p>Provides comprehensive test plans for validating conformance to HL7 v2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1. Appears to generate detailed testing reports.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web-based • Free to use • Documentation available • Broad test

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>coverage</p> <p>Weaknesses:</p> <ul style="list-style-type: none"> Does not appear to test deliberately incorrect inputs Proprietary, closed-source
10	<p>Electronic Laboratory Reporting test Suite (NIST)</p> <p>(IG Release 1)</p> <p>(IG Release 2)</p>	Web	Proprietary, free to use	Unknown	ONC Health IT Certification Program	<p>Provides comprehensive test plans for validating conformance several lab IGs. Appears to generate detailed testing reports.</p> <p>Strengths:</p> <ul style="list-style-type: none"> Web-based Free to use Documentation available Broad test coverage <p>Weaknesses:</p> <ul style="list-style-type: none"> Does not appear to test deliberately incorrect inputs Proprietary, closed-source
11	<p>NSHN CDA Validator (HAI_Validator_4_MU3) (CDC)</p>	Windows	Free/open source (Apache license)	Unknown	ONC Health IT Certification Program	<p>Uses schema/schematron validation to test conformance to HL7 Implementation Guide for CDA Release 2 — Level 3: Healthcare Associated Infection Reports, Release 1. Output does not appear particularly “user-friendly” – command-</p>

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>line only, not much detail.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Free • Open-source • Documentation provided <p>Weaknesses:</p> <ul style="list-style-type: none"> • Requires download/installation
1 2	SITE C-CDA Validator (ONC)	Web	Proprietary, free to use	Unknown	ONC Health IT Certification Program	<p>Easy to use online tool that checks conformance to C-CDA1 R1.1 and R2.1, as well as a number of ONC certification criteria.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Easy to understand and use • Supports multiple IGs <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed-source • No documentation
1 3	National Health Care Surveys Release 1.1, DSTU Validation (NIST)	Web; users may run their own local instance if desired (Java based)	Proprietary, free to use	Unknown	ONC Health IT Certification Program	<p>Web-based tool that generates a user-friendly report by way of schema and schematron validation. Output includes references to specific sections of the document that</p>

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>are non-conformant, and the associated conformance statement.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Documentation provided <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed-source
1 4	Cypress Validation Utility (Project Cypress)	Web	Proprietary, free to use	<i>Medinformatix, Myca Health Inc.</i>	None	<p>Not clear exactly how validation is performed (likely schema/schematron); output format is unclear, but likely to be reasonably good as the tool is associated with SITE and ONC.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed-source • No documentation available
1 5	Cancer Report Validator (NIST)	Web	Free, open source (Apache license)	Unknown	None	<p>Validates CDA documents against the HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU</p>

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<p>Release 1.1 - US Realm. Exact mechanism of validation is not specified. Supports multiple test cases.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Open source • Multiple test cases <p>Weaknesses:</p> <ul style="list-style-type: none"> • Very little documentation
16	SMART C-CDA Scorecard (SMART)	Web	Free, open source (license unclear)	<i>mTuitive</i>	None	<p>Very easy to use tool to support C-CDA use. Good documentation, helpful examples. Includes support for terminology validation. Produces a detailed, helpful and easy to read output report.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Open source • Easy to use, good documentation & examples <p>Other Comments:</p> <ul style="list-style-type: none"> • Not a <i>conformance</i> tool per se – complements conformance tools and helps encourage best practices

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
17	Sprinkler (Furore)	Web or Windows command line	Free, open source (MIT license)	Unknown	None	<p>Automated testing tool for FHIR servers using a REST interface. Uses the server's conformance statement (if available) to determine what resources, operations, etc. to test. No example output.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Open source • Easy to use <p>Weaknesses:</p> <ul style="list-style-type: none"> • Only works against FHIR servers • Minimal documentation • May not test edge cases or deliberately incorrect interactions/resources fully
18	Crucible (Mitre)	Web	Free, open source (Apache license)	Unknown	None	<p>Automated testing tool for FHIR servers using a REST interface. Produces convenient graphical output.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Open source • Easy to use <p>Weaknesses:</p>

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
						<ul style="list-style-type: none"> • Only works against FHIR servers • Minimal documentation • May not test edge cases or deliberately incorrect interactions/resources fully
19	Touchstone Project (AEGIS)	Web	Free, proprietary	118 users; 48 organizations. Identities not disclosed.	None	<p>Configurable, scriptable testing platform. Many existing tests/test scripts (often driven by IHE connectathon tracks), and users can define their own tests. Test output is detailed, and presented in a very useful and readable way.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Web based • Free to use • Well documented <p>Weaknesses:</p> <ul style="list-style-type: none"> • Requires registration • More complex than alternatives (Sprinkler, Crucible) • Proprietary, closed-source
20	FHIR Validator (HL7)	Java, command-line	Free, open source	All FHIR developers (part of FHIR build process); others	None	A simple command-line tool for validating FHIR resources. Output is detailed but can be cryptic.

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
				unknown		<p>Strengths:</p> <ul style="list-style-type: none"> • Free to use • Open source • Documentation available <p>Weaknesses:</p> <ul style="list-style-type: none"> • Requires download • Significant manual configuration
2 1	Gazelle External Validation Service (IHE)	Web	Free, closed-source	Unknown	None	<p>Applies both schematron and model-based validation. No example output available to assess.</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Supports multiple standards/IGs • Web based • Free to use • Simple, easy to use • Reasonably good documentation (though documentation is not linked directly from the tool) <p>Weaknesses:</p> <ul style="list-style-type: none"> • FHIR conformance only supports XML-encoded resources • Proprietary, closed-source

#	Tool Name & Owner	Platform	Licensing & Cost	Users	Certification Program	Description & Evaluation
2 2	Developers Integration Lab (Aegis)	Web	Free, closed-source	Unknown	None	<p>Applies a wide variety of tests against many kinds of systems. Provides detailed reporting of results. Which standards/IGs are supported does not appear to be clearly documented; logging in is presumably necessary</p> <p>Strengths:</p> <ul style="list-style-type: none"> • Supports multiple standards/IGs • Web based • Free to use • Fairly good documentation <p>Weaknesses:</p> <ul style="list-style-type: none"> • Proprietary, closed-source • Difficult to determine without signing up what IGs are supported
2 3	Pre-Submission Validation Application (CMS)	Windows (Java), requires download	Free for users of QualityNet Secure Portal	Unknown	None	Open only to eligible hospitals with QualityNet access; unable to assess fully.
2 4	Submission Engine Validation Tool (CMS)	Web	Free for users of QualityNet Secure Portal	Unknown	None	Open only to those with QualityNet access; unable to assess fully.

4.4.3 List of Implementation Guides Needing Tooling Prioritized by Need

The following table identifies Implementation Guides that lack associated conformance tooling and, for each guide, provides an assessment of the need to develop tooling and the estimated effort required for development.

It is notable that community feedback included relatively few requests for more tooling; many respondents felt that existing tools were generally good, and critical comments focused more on the fragmented nature of the existing tooling ecosystem. There may be a greater need for increased consistency and best practices guidance with regard to existing tooling than for the development of entirely new tools.

The estimates below are very high-level; the specific level of effort required to develop tooling will be highly variable depending on the specific requirements of the tool. A simple command-line validator for a CDA implementation guide would be relatively simple; providing a Web-based user interface for the same tool might significantly increase the effort involved. Furthermore, developing more precise estimates would require a high degree of familiarity with the specifics of each guide and the use cases it support.

#	Implementation Guide	Need for Tooling		Estimated Time to Develop Tooling	
		Need	Rationale	Hours	Rationale
1	HL7 Implementation Guide for CDA® R2: Patient Generated Document Header Template, Release 1	Med-High (5)	<ul style="list-style-type: none"> Popular (many downloads) Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
2	HL7 Implementation Guide for CDA® Release 2 – Level 3: Emergency Medical Services; Patient Care Report, Release 1 – US Realm	Med-High (5)	<ul style="list-style-type: none"> Popular (many downloads) Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is

#	Implementation Guide	Need for Tooling		Estimated Time to Develop Tooling	
		Need	Rationale	Hours	Rationale
					adequate
3	HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1	Med-High (5)	<ul style="list-style-type: none"> Popular (many downloads) Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
4	HL7 Implementation Guide for CDA Release 2: Plan-to-plan Personal Health Record PHR Data Transfer, Release 1 - US Realm	Medium (4)	<ul style="list-style-type: none"> Somewhat popular (moderate # of downloads) Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
5	HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates - Clinical Documents for Payers – Set 1 , Release 1 (US Realm)	Medium (4)	<ul style="list-style-type: none"> Somewhat popular (moderate # of downloads) Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
6	HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1	Medium (4)	<ul style="list-style-type: none"> Somewhat popular (moderate # of downloads) 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or

#	Implementation Guide	Need for Tooling		Estimated Time to Develop Tooling	
		Need	Rationale	Hours	Rationale
			<ul style="list-style-type: none"> Newest IG version CDA 		schematrons <ul style="list-style-type: none"> Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
7	HL7 Version 2.5.1 Implementation Guide: Orders and Observations; Interoperable Laboratory Result Reporting to EHR, Release 1	Medium (4)	<ul style="list-style-type: none"> Popular (many downloads) Newest IG version 	High	<ul style="list-style-type: none"> Leverage existing libraries to assist in validation (e.g. HAPI) Multiple tests & test scripts probably needed May need to expose interface endpoint
8	HL7 Version 3 Implementation Guide: Canonical Pedigree (Family History) Interoperability, Release 1 - US Realm	Medium (4)	<ul style="list-style-type: none"> Popular (many downloads) Newest IG version 	High	<ul style="list-style-type: none"> V3 is represented as XML; can be validated with schemas or schematrons Multiple tests & test scripts probably needed May need to expose interface endpoint
9	HL7 CDA (®) R2 Implementation Guide: Patient-friendly language for Consumer User Interfaces, Release 1	Med-Low (3)	<ul style="list-style-type: none"> Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate

#	Implementation Guide	Need for Tooling		Estimated Time to Develop Tooling	
		Need	Rationale	Hours	Rationale
10	HL7 CDA® R2 Implementation Guide: Medication Therapy Management (MTM) Templates, Release 1 - US Realm	Med-Low (3)	<ul style="list-style-type: none"> Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
11	HL7 Implementation Guide for CDA® Release 2: Healthcare Associated Infection (HAI) Reports, Release 2	Med-Low (3)	<ul style="list-style-type: none"> Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
12	HL7 Implementation Guide for CDA® Release 2: HIV/AIDS Services Report, Release 1 - US Realm	Med-Low (3)	<ul style="list-style-type: none"> Newest IG version CDA 	Medium	<ul style="list-style-type: none"> CDA is represented as XML; can be validated with schemas or schematrons Multiple test cases not needed No need to expose interface endpoint; upload or copy/paste is adequate
13	HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2 - US Realm	Med-Low (3)	<ul style="list-style-type: none"> Somewhat popular (moderate # of downloads) Newest IG 	High	<ul style="list-style-type: none"> Leverage existing libraries to assist in validation (e.g. HAPI) Multiple tests &

#	Implementation Guide	Need for Tooling		Estimated Time to Develop Tooling	
		Need	Rationale	Hours	Rationale
			version		test scripts probably needed <ul style="list-style-type: none"> • May need to expose interface endpoint
14	HL7 Version 2.5.1 Implementation Guide: Height and Weight Report, Release 1 - US Realm	Med-Low (3)	<ul style="list-style-type: none"> • Somewhat popular (moderate # of downloads) • Newest IG version 	High	<ul style="list-style-type: none"> • Leverage existing libraries to assist in validation (e.g. HAPI) • Multiple tests & test scripts probably needed • May need to expose interface endpoint
15	HL7 Version 2.6 Implementation Guide: Blood Bank Donation Services, Release 1 - US Realm	Med-Low (3)	<ul style="list-style-type: none"> • Somewhat popular (moderate # of downloads) • Newest IG version 	High	<ul style="list-style-type: none"> • Leverage existing libraries to assist in validation (e.g. HAPI) • Multiple tests & test scripts probably needed • May need to expose interface endpoint
16	HL7 Version 3 Implementation Guide: Regulated Product Submission R2, Release 1	Med-Low (3)	<ul style="list-style-type: none"> • Somewhat popular (moderate # of downloads) • Newest IG version 	High	<ul style="list-style-type: none"> • V3 is represented as XML; can be validated with schemas or schematrons • Multiple tests & test scripts probably needed • May need to expose interface endpoint

#	Implementation Guide	Need for Tooling		Estimated Time to Develop Tooling	
		Need	Rationale	Hours	Rationale
17	HL7 Version 3 Implementation Guide: Regulated Studies; Annotated ECG R1, Release 2 - US Realm	Med-Low (3)	<ul style="list-style-type: none"> Somewhat popular (moderate # of downloads) Newest IG version 	High	<ul style="list-style-type: none"> V3 is represented as XML; can be validated with schemas or schematrons Multiple tests & test scripts probably needed May need to expose interface endpoint
18	HL7 Version 3 Implementation Guide: Structured Product Labeling, Release 5	Med-Low (3)	<ul style="list-style-type: none"> Somewhat popular (moderate # of downloads) Newest IG version 	High	<ul style="list-style-type: none"> V3 is represented as XML; can be validated with schemas or schematrons Multiple tests & test scripts probably needed May need to expose interface endpoint
19	All other guides	Low (< 3)	<ul style="list-style-type: none"> Few to no downloads No community requests Old versions of IGs, or standards with a short expected lifespan 	n/a	<ul style="list-style-type: none"> Tooling development is not advised

4.4.4 Other Tools

As noted earlier in this report, there are a number of tools that do not test for conformance to a particular implementation guide but may be configured to act as conformance tools, typically by obtaining or creating an appropriate profile. These tools were not fully analyzed in the gap analysis but are listed in the table below.

Tool Name	Owner	Licensing & Cost	URL
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Tool Name	Owner	Licensing & Cost	URL
Messaging Workbench	HL7	Free	http://gforge.hl7.org/gf/project/mwb/
7Edit	Real Seven	Proprietary; \$249	http://www.7edit.com/
Trifolia	Lantana Consulting Group	Proprietary; unknown	http://www.lantanagroup.com/resources/trifolia/
Forge	Furore	Free	http://fhir.furore.com/Forge
ART-DÉCOR	ART-DÉCOR Expert Group	Free	https://art-decor.org/mediawiki/index.php/Main_Page
Gazelle ObjectsChecker	IHE	Unknown	https://gazelle.ihe.net/content/gazelle-objectschecker
Model-Driven Health Tools	Unknown	Free	http://cdatools.org/
Inspector of Quality Healthcare Data (iQHD)	Stella Technology	Proprietary, Unknown	http://stellatechnology.com/wp/products/iqhd/

4.4.5 Other Recommendations From the Gap Analysis

The contractor hired to perform the gap analysis suggested that HL7 organize the existing tooling ecosystem before it develops or commissions the development of additional tooling. Broadly, they made three recommendations related to the ecosystem and two related to additional tooling that should be considered in the near term:

- Develop a public tooling catalog
- Develop a tooling endorsement or certification program
- Develop and provide guidance for format and content of conformance tool output
- Ensure tooling is available for public health-related implementation guides
- Ensure tooling is available to support FHIR Structured Data Capture

Each of these recommendations is discussed briefly below.

4.4.5.1 Develop a Public Tooling Catalog

Contractor recommended that HL7 create a public tooling catalog – a central, authoritative index of conformance tools similar to the information provided in section 4.4.1 of this report. Such a catalog could include:

- A mechanism for members of the community to submit new tools for inclusion

- Community members could also flag tools that are out of date, superseded or unmaintained, helping others to find the best and most reliable tools
- A mechanism by which members of the community could indicate their need for a tool that does not exist
 - This would provide information to the vendor and open-source software communities, helping them to identify unmet needs

The catalog should be publicly accessible (i.e. not only HL7 members) to maximize its value. Effectively, such a catalog would continue the work of the gap analysis.

Implementing a public catalog would provide a “quick win”, potentially at relatively little cost to HL7, and would help the community more effectively leverage existing tools

4.4.5.2 Develop Tooling Endorsement or Certification

The community expressed interest in some form of endorsement or approval of conformance tools by HL7. An approval or endorsement scheme could be combined with the public tooling catalog described previously. Such a system might offer approval to conformance tools that met a basic set of requirements, for example:

- Clearly states which implementation guide or guides are supported
- Provides adequate documentation
- Actively maintained, with contact information for the maintainer(s) provided
- Implements best practices for tool outputs (see next recommendation)

This type of certification program would be of great assistance to implementers in quickly finding the most up-to-date and reliable conformance tools, and would give community members confidence that the tools they are using are trustworthy.

4.4.5.3 Develop Best Practice Guidance for Conformance Tool Outputs

A number of comments received from community members noted the inconsistency between tools. While individual tools may be useful, their outputs can vary widely both in form and content, which can be challenging for organizations that use multiple implementation guides and conformance tools.

HL7 should consider providing guidelines for the format and content of conformance tool outputs; these could be aligned to the ONC Health IT Certification Program test methods.

4.4.5.4 Ensure Tooling is Available for Public Health-Related Guides

One of the two specific requests for tooling received from the community was for conformance tooling to support public health-related implementation guides. The commenter noted the relevance of such guides to meaningful use. Currently, the only public health-related guide lacking tooling is HL7

Implementation Guide for CDA Release 2: Public Health Case Reporting, Release 1 - US Realm. HL7 may wish to explore the creation of tooling for this guide.

4.4.5.5 Ensure Tooling is Available to Support FHIR Structured Data Capture

One community commenter noted that they would likely have a need for conformance tooling to support FHIR Structured Data Capture once the standard becomes normative. This is notable, as it was one of only two specific requests for tooling received.

5 Proposed Approach

HL7's proposed approach at this point in time is to require that its implementation guides provide relevant conformance statements that are machine computable and robust enough to enable conformance tooling vendors to develop conformance tooling concurrent with the development of the implementation guide. HL7 feels very strongly that it should not develop conformance testing tools internally but should provide robust conformance statements that allow tooling experts to do so.

ONC has also requested that HL7 identify a means to collect and report implementation/usage data at the message level on an annual basis.

To achieve the desired future state HL7 will need to:

- Develop a policy that requires conformance statements in all implementation guides
- Develop a guidance document that defines how to develop robust conformance statement
- Train work groups to develop the conformance statements
- Recruit conformance facilitators
- Develop a plan for creating conformance statements for all or some subset of extant implementation guides for which there is not conformance tooling.
- Develop a certification program to certify conformance tools and/or tooling vendors
- Develop and maintain a tooling catalog
- Continue efforts to create examples (CDA) and models (CIMI) for representing data
- Identify method to collect and report implementation/usage metrics annually

Each of these activities is described briefly below.

5.1 Develop a Policy that Requires Conformance Statements in all Implementation Guides

HL7 must develop, implement and enforce a policy requiring that all implementation guides balloted through the organization include relevant machine-processable conformance statements that conform to a pre-developed set of criteria. These conformance statements will likely be balloted as part of the underlying implementation guides.

Issues:

- Since the HL7 community at large is not well versed in writing conformance statements, the organizations will need to decide who ballots these statements. We may need to introduce a new class of voting members (conformance tooling vendors) who vote separately but simultaneously on the statements for some period of time until the HL7 community at large develops some expertise in this area. This would ensure that the conformance statements receive sufficient review from a community of voters who are knowledgeable and have appropriate skills. It would also ensure a feedback loop from the tooling vendors to the standards developers.
- Should balloting of the conformance statements be rolled into the implementation guide ballot at some point in the future? If so, what is the appropriate time for doing this?
- Requiring that all implementation guides contain appropriate conformance statements will likely impact the speed at which implementation guides are developed and ready for ballot.
- These open issues will be presented to the HL7 Technical Steering Committee for continued discussion and resolution.

5.2 Develop a Guidance Document that Defines How to Develop Robust Conformance Statement

HL7 will need to undertake development of a guidance document, probably authored by an external consultant with input from HL7's Technical Steering Committee, our Conformance & Guidance for Implementation/Testing work group and the HL7 Standards Governance Board, that defines how to develop these conformance statements and the required content/format, etc. The HL7 Technical Steering Committee recommends that this guide be written by a hired consultant who will be tasked with researching best practices, other industry literature and work with the HL7 groups noted above to ensure that the guidance reflects that knowledge and is suitable for HL7 standards.

Issues:

- Which internal bodies will have input on this document and oversee its development.
- Which internal body (e.g. the Technical Steering Committee, the entire HL7 Community, etc) will approve this document and how that will be achieved.
- HL7 will need to secure funding (whether from the HL7 budget or an external funder) and develop

5.3 Train Work Groups to Develop the Conformance Statements

Obviously, HL7 will need to develop and provide free training targeted to the HL7 work groups on the process and criteria involved in developing conformance statements. While we have a few conformance tooling vendors that participate in HL7, we do not perceive wide-spread expertise in this area among the current HL7 community. Training will need to be ongoing for some period of time, probably at least two years. Training can be offered via webinar (both live and recorded) and at the HL7 Working Group

Meetings. While we envision introducing a conformance facilitator role to the organization that can lead conformance statement development within the work groups, the general membership does need some education on the purpose and importance of conformance statements and a cursory understanding of how to develop them.

Issues:

- Do we need multiple levels of training (e.g., one level for general membership and a more rigorous program for conformance facilitators).
- HL7 will need to secure funding (either from the HL7 budget or an external funder) to develop the training.

5.4 Recruit Conformance Facilitators

Requiring a conformance facilitator for each implementation guide, much like the current requirement for vocabulary, modeling and publishing facilitators for other projects, will ensure development of cadre of volunteers well versed in the development of conformance statements and that this skill becomes ingrained in all work groups. It is noteworthy that the HL7 project scope statement already provides a conformance facilitator field for implementation guide projects; obviously at some time the organization was clearly thinking about developing conformance statement skills more broadly across the organization. This role is currently defined as follows: “The Conformance Facilitator, recommended for Implementation Guide projects, is a member of the integration team with in-depth knowledge of interoperability standards and conformance/constraint rules. This individual advises the project team on the use of HL7 standards and the constraint(s) requested to support the stakeholder requirements”. This above statement would need to change “recommendation” to a “requirement”.

Issues:

- Do we have enough volunteers to develop the role fully
- Who would be in charge of the conformance facilitator development program
- Will development of this program require financial resources beyond those needed for the training discussed above

These issues will be taken to the Technical Steering Committee for discussion and resolution.

5.5 Update Extant Implementation Guides for Which no Tooling is Available

One of the most critical steps will be the development and rollout of a plan for creating conformance statements for all or some set of the implementation guides that currently have no conformance tooling

support. The Technical Steering Committee will be tasked with making a recommendation to be approved by the HL7 Board regarding how this will be implemented. There are several choices:

- Require that all implementation guides without conformance tooling be updated within some period of time to produce the needed conformance statements and related tooling. This may be an unpopular decision within the work groups and may require that the work be done for hire. Given that 34 implementation guides fall into this category, it is unlikely this would be the decision.
- Require that only some implementation guides be updated within some period of time to produce the needed conformance statement and related tooling. This may be an unpopular decision within the work groups and may require that the work be done for hire.
- Require that no implementation guides without conformance tooling be updated to produce the needed conformance statements and related tooling but do require that all implementation guides going forward produce the required conformance statements.

Issues:

- Requiring work groups to update extant implementation guides may be unpopular as work within HL7 is typically generated bottom up vs. top down.
- Given the bullet above, updating extant implementation guides may need to be hired out. Should that be the case, HL7 will need to secure funding, either internally or from an external source, to complete this work.

5.6 Develop Certification Program to Certify Conformance Tools and/or Tooling Vendors

Much like programs that certify MU tools, HL7 needs a program whereby we certify various tools that adhere to criteria that we establish. Work needed to create this program would include development of a practical guide for conformance tooling vendors on expected format and output for tools. We could develop these to be aligned to the ONC Health IT Certification Program test methods. Much more additional work needs to be undertaken by HL7 in this area to fully understand the work involved.

Issues:

- Very little thinking has been done to date on how to implement this program. We sense this will involve a fair amount of effort and financial resources

- HL7 will need to secure funding, either internally or from an external source, to complete this work
- Although likely appreciated by implementers, certifying tools or tooling vendors may not be a popular decision among the tooling vendors

5.7 Develop and Maintain a Tooling Catalog

As recommended by the contractor hired to complete the gap analysis, HL7 implementers would greatly appreciate a tooling catalog that would serve as an authoritative, central index of conformance tools. This would provide a mechanism for tool developers to be advised of the need for new tools, to allow implementers to flag issues with tools (out of date, errors, etc) and even rate them to steer implementers to the best tools for any given implementation guide.

Issues:

- While much of the analysis for the catalog has been completed by the contractor hired to undertake the tools gap analysis, there is still a significant amount of work to be completed to get the catalog online.
- HL7 has a webmaster and other technical resources that could undertake the needed work but given other responsibilities, the timeframe for completing this work is currently unknown.
- There are a number of issues around maintaining the catalog and keeping it current. It is unclear whether this work would be done by internal HL7 resources or outsourced.
- If the catalog is to be developed and maintained by an outside resource, HL7 will need to find funding, either internally or externally, to complete the work.

5.8 Continue Efforts to Create Examples and Models for Representing Data

Efforts by the Structured Documents Examples task force and the CIMI work group should be continued. The organization should consider merging and expanding these efforts.

5.9 Identify Method to Collect and Report Implementation/Usage Metrics Annually

ONC has also requested as part of this grant that HL7 identify a method to accurately collect and report implementation/usage metrics annually. Our understanding of the request is that ONC would like the data collected and reported on a transaction (message) basis.

This is one of the most difficult aspects of this grant as there is no obvious source for which to collect and report the requested data. HL7 tracks the number of times an implementation guide is downloaded

from its website. While this data was used as part of the gap analysis (to determine popularity of a particular IG) it is not scientific (e.g., anyone can download the same implementation guide multiple times and our count mechanism doesn't account for that; all facilities that implement/use an implementation guide may not secure the implementation guide directly from the HL7 website, etc). For some transactions, vendors may be able to supply part or all of the data. For other transactions, the end user may be able to supply part or all of the data. Both sources would have some of the data. Thus, getting the data and structuring a methodology to interpret it (as some of the data might be reported by both the vendor and the end user) is difficult.

HL7 has done some work with the Pew Charitable Fund over the last several months and we approached them to determine if their polling arm would be interested in participating in a project to undertake this work. Unfortunately, Pew is not able to participate in projects that are funded by the US government. They did, however, suggest a few polling agencies that they have worked with in the past that might be interested, including:

- Hart Research
- Public Opinion Strategies

There are a number of other organizations that could assist in the development of a poll and the affiliated methodology for collecting data and interpreting the results, including organizations such as Westat, which maintains an organizational membership within HL7.

The HL7 Technical Steering Committee has had some discussion around this issue but has not made any progress in identifying a means or methodology for getting the desired data. HL7's Orders and Observations work group and the FHIR work groups (at least to some extent) are working on a standards maturity model that attempts to get a sense of how widely the specifications are implemented/used. While interesting, the standards maturity model will not provide the needed information.

Even if we could find a reliable source to provide the data, reporting that would likely require a significant amount of time and effort on the part of the organization responsible for reporting the data.

HL7 will need to do additional research to determine possible methods for collecting the desired data. As of the writing of this report, HL7 will commit to contacting Hart Research, Public Opinion Strategies and Westat to determine if they believe this is something they could and would be willing to undertake and what the timeline/cost might be.

Optionally, the government could enact a policy requiring vendors and/or providers to report this data annually and report that data on a public website.

Regardless of which method is selected, HL7 is of the opinion that it does not have the expertise to collect the data and would therefore recommend that the government either outsource the project or fund HL7 to oversee a project that it outsourced to a qualified entity.

6 Project Costs

As of the writing of this report, we do not have pricing costs for any of the activities that would be related to implementation of the recommended plan. Since HL7 does not plan to develop the needed conformance tools, we will not address those costs in this report.

At a minimum the following activities would likely require some funding, whether from HL7 or from an external source:

- Development of a guidance document that defines how to develop robust conformance statements
- Development of educational materials to train work groups to develop the conformance statements
- Development of materials and a program to train and recruit conformance facilitators
- Updates to some subset of the existing implementation guides to include conformance statements so that needed tools can be developed
- Development of a certification program to certify conformance tools and/or tooling vendors
- Development of an online tooling catalog

7 Conclusion/Next Steps

HL7 appreciates the opportunity to develop this plan for the ONC.

Next steps:

- Work with the HL7's Technical Steering Committee to determine which bodies within HL7 would provide input on the development of a guidance document that defines how to develop robust conformance statements, and ask those groups to undertake the necessary work to enable us to estimate the time/cost to produce the document.
- Work with HL7's Education Committee to estimate time/cost of developing an education program on conformance statement development targeted to the general HL7 membership and standards developers.
- Work with HL7's Education Committee to estimate time/cost to develop training for conformance facilitators

- Secure recommendation from the Technical Steering Committee that is then approved by the HL7 Board of Directors in terms of whether all, some subset or none of the existing implementation guides will be updated to include conformance statements so that needed tools can be developed. This decision will inform the budget and plan to accomplish that work.
- Undertake additional research to better understand the elements of a tooling certification program so that we can develop a plan and budget to undertake the needed work.
- Determine whether the online tooling catalog would be developed by HL7 staff or outsources and develop a timeline and budget for this project.
- While the HL7 Technical Steering Committee has discussed and agreed to the high-level plan outlined in this report, the next step is to secure a formal recommendation from that body endorsing the plan, that can be taken to the HL7 Board of Directors for approval.

8 Appendix A

Rating of available tools using the rubric in section 4.2.

Ref #	Tool Name	Attributes							Score	Quality
		Cost	License	Source	Supportability	Usability	Life of Use	Support		
1	MedRxFlow Connect (US National Library of Medicine)	Free	Web	Proprietary	Excellent	Maintained, none	Moderate	Unknown	15	Fair
2	Progenio Validator (Veri™ SP) Validation Tool (Progenio Data)	Free	Web	Proprietary	Poor	Unknown	Easy	Schemas/cheats/2	7	Poor
3	CDA Validator Tool (NIST)	Free	Web	Proprietary	Fair	Maintained, none	Easy	Schemas/cheats/13	14	Good
4	Varagon Testing Tool (NIST)	Free	Web	Open-source (MIT)	Poor	Maintained, none	Moderate	Schemas/cheats/14	14	Good
5	CDA Validator (Lumena Consulting Group)	Free	Web	Proprietary	Poor	Maintained, none	Easy	Schemas/cheats/15	14	Fair
6	SDMS Data Generation and Evaluation (SDGA) Tool (CINIS)	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	0	Poor
7	Edge Testing Tool (NIST)	Free	Web	Proprietary	Good	Maintained, none	Moderate	Some edge cases (PMS)	19	Good
8	Business Directors of Service Test Suite (NIST)	Free	Web	Proprietary	Fair	Maintained, users	Moderate	Some edge cases (PMS)	19	Good
9	Lab Results Interface Validation Suite (NIST)	Free	Web	Proprietary	Good	Maintained, users	Moderate	Some edge cases (PMS)	19	Good
10	Electronic Laboratory Reporting Test Suite (NIST)	Free	Web	Proprietary	Good	Maintained, users	Moderate	Some edge cases (PMS)	19	Good
11	MDM CDA Validator (MVA, Validator, & MDM) (CSC)	Free	Other	Open-source (MIT)	Good	Maintained, users	Moderate	Schemas/cheats/12	15	Good
12	SDT C-CDA Validator (NIST)	Free	Web	Proprietary	Poor	Maintained, users	Easy	Schemas/cheats/11	14	Fair
13	National Health Care Survey Release 1.1.0/1.0 Validation (NIST)	Free	Web	Proprietary	Good	Maintained, users	Easy	Schemas/cheats/13	15	Good
14	Cypress Validation Library (Project Cypress)	Free	Web	Proprietary	Poor	Maintained, none	Easy	Schemas/cheats/14	14	Fair
15	Cancer Report Validator (NIST)	Free	Web	Open-source (MIT)	Poor	Maintained, users	Moderate	Unknown	19	Fair
16	SMART C-CDA Source (SMART)	Free	Web	Open-source (MIT)	Excellent	Maintained, none	Easy	Broad & robust test	24	Excellent
17	Smarter (Furze)	Free	Web	Open-source (MIT)	Poor	Maintained, users	Easy	"happy path" only	11	Fair
18	Crucible (Mira)	Free	Web	Open-source (MIT)	Poor	Maintained, users	Easy	"happy path" only	11	Fair
19	Touchstone Project (MGS)	Free	Web	Proprietary	Excellent	Maintained, none	Moderate	Broad & robust test	20	Good
20	HR Validator (6.7)	Free	Other	Open-source (MIT)	Poor	Maintained, none	Moderate	Schemas/cheats/11	14	Fair
21	SMART External Validation Service (NIST)	Free	Web	Proprietary	Good	Maintained, users	Easy	Schemas/cheats/13	15	Good
22	Developer's Elevation Lab (Age)	Free	Web	Proprietary	Good	Maintained, none	Unknown	Unknown	14	Fair
23	Pre-Submission Validation Application (CMB)	Free	Other	Unknown	Unknown	Unknown	Unknown	Unknown	0	Poor
24	Submission Engine Validation Tool (CMB)	Free	Web	Unknown	Unknown	Unknown	Unknown	Unknown	0	Poor