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Vol1\_Introductory\_Material



**HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1**

**Standard for Trial Use Release 1.0**

May 2017

**Prototype of HL7 Standard for Trial Use**

**Sponsored by:**

**Public Health and Emergency Response Group**

**Structured Documents Work Group**

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| SNOMED CT | International Healthcare Terminology Standards Development Organization (IHTSDO)<http://www.ihtsdo.org/snomed-ct/get-snomed-ct> or info@ihtsdo.org |
| Logical Observation Identifiers Names & Codes (LOINC) | Regenstrief Institute |
| International Classification of Diseases (ICD) codes | World Health Organization (WHO) |
| NUCC Health Care Provider Taxonomy code set | American Medical Association. Please see 222.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services) |

**Structure of This Guide**

Two volumes comprise this *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Reportabillity Response, Release 1, Standard for Trial Use Release 1.0.* Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2. Volume 2 contains the normative HL7 Clinical Document Architecture, Release 2 (CDA R2) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version.

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# 1. Introduction

## 1.1 Purpose

The purpose of this *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, Standard for Trial Use Release 1.0* implementation guide (RR IG) is to specify a standard for the creation of a Reportability Response (RR) in Clinical Document Architecture, Release 2 (CDA R2) US Realm format. The submission of public health case reports for specific infectious and non-infectious conditions is required by law in all States and Territories in the United States. In addition to supporting critical public health functions in State, Local, and Territorial Public Health Agencies (PHAs), the data from these case reports will also indirectly support notifications between PHAs and to the Centers for Disease Control and Prevention (CDC) for the Nationally Notifiable Disease Surveillance System (NNDSS) and nationwide disease monitoring. After health providers have submitted public health case reports, the Reportability Response facilitates meaningful, real-time feedback from PHAs about the reportability status of those reports.

This interoperability standard will enable effective feedback to the reporting of events of public health interest from Electronic Health Record (EHR) technology and associated workflows. It offers the potential of enabling improved public health case reporting by facilitating information exchange between public health and clinical care with less burden for both. Doing so may also involve other new interoperability standards and potential functional changes in EHRs and public health surveillance systems. Case reporting from EHRs is important to public health surveillance for under-reported clinical cases, emergency management of new conditions and for conditions for which a laboratory result is not a definitive criterion. Case reporting from EHRs complements electronic laboratory reporting by providing critical clinical and demographic data that may not be included in laboratory reports. The Reportability Response addresses a request by healthcare providers in the United States for public health to improve communication frequency and quality with respect to submitted public health case reports.

The Reportability Response (RR) is so named because it is generated in response to a public health case report and contains information about the reportability status of that case report. Case reports sent by clinical care will be evaluated by a public health decision support system (such as the CSTE/CDC Reportable Conditions Knowledge Management System (RCKMS[[1]](#footnote-1))) based on predefined jurisdiction- and condition-specific rules. For each public health case report received by the public health decision support system, a corresponding Reportability Response file will be generated and sent back to the healthcare provider that sent the initial case report. In some cases, Public Health Agencies that receive the case report may also request to receive the corresponding Reportability Response. The Reportability Response is not expected to be the sole set of communication from a PHA to clinical care. Rather, it is expected to be provide meaningful, real-time feedback in an automated manner. Public Health Agencies that require further information or have additional guidance for healthcare providers will follow up through other means.

The RR file itself may be conveyed or referenced by a number of different transport methods. It will relay reportability evaluation, including that performed by public health decision support systems, such as the CSTE/CDC Reportable Conditions Knowledge Management System (RCKMS) and others. The ONC Structured Data Capture (SDC) initiative standard may be a good complement to the RR for the purpose of manually capturing supplemental disease-specific data that may not be available in the EHR into forms.

## 1.2 Audience

This IG is designed to provide public health surveillance systems developers the specifications for implementing functionality used by PHAs to generate RR files. This IG is also designed to provide EHR vendors with the specifications for developing the functionality of EHRs used in hospitals and by ambulatory care providers to receive electronic feedback about potential cases of reportable conditions from PHAs. The IG will be informative to health care providers, public health staff, analysts, and health information exchange organizations among others. Users of this IG must be familiar with the details of the HL7 CDA R2 document construction and the *Consolidated CDA Templates for Clinical Notes, DSTU 2.1* (C-CDA R2.1) templates. Additionally, users will benefit from knowledge of the *HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release* 2.

## 1.3 Organization of this Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing this Implementation Guide, whereas Volume 2 contains normative CDA R2 template definitions.

### 1.3.1 Volume 1: Introductory Material

This document, Volume 1, provides an overview of Clinical Document Architecture, Release 2 (CDA R2), summaries of recent changes to the standard, and information on how to understand and use the CDA R2 templates provided in Volume 2.

**Chapter 1**—Introduction

**Chapter 2**—Use Case for Electronic Case Reporting. This section describes the use case for the eCR along with the overall flow, assumptions, conditions, actors, roles and scenarios.

**Chapter 3**—CDA R2 Background. This section contains selected background material on the CDA R2 base standard, to aid the reader in conceptualizing the “templated CDA” approach to implementation guide development.

**Chapter 4**—Using This Implementation Guide. This section describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA R2 templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

**Chapter 5**— Reportability Response IG Specific Conformance Guidance. This section describes conformance guidance that is specific to this IG.

**Chapter 6**— Reportability Response Data Requirements. This section describes identified data requirements for the reportability response and how they map to the CDA R2 base standard.

**Appendices**— The Appendices include a list of acronyms and abbreviations, a high-level change log and a summary of extensions to CDA R2.

### 1.3.2 Volume 2: CDA R2 Templates and Supporting Material

Volume 2 includes CDA R2 templates and prescribes their use for a set of specific document types. The main chapters are:

**Chapter 1**—Document-Level Templates. This chapter defines the eICR document-type and its specific header constraints and references the required and optional section-level template containments.

**Chapter 2**—Section-Level Templates. This chapter defines the section-level templates referenced within the document and references the required and optional entry-level template containments.

**Chapter 3**—Entry-Level Templates. This chapter defines entry-level templates, called clinical statements. Machine processable data are sent in the entry templates. The entry templates are referenced by one or more section templates. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document.

**Chapter 4**—Participation and Other Templates. This chapter defines templates for CDA R2 participants (e.g., author, performer) and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.

**Chapter 5**—Template Ids in This Guide

**Chapter 6**—Value Sets in This Guide

**Chapter 7**—Code Systems in This Guide

## 1.4 Background

State, Local and Territorial laws and regulations require the reporting of cases and, at times, suspected cases of certain infectious and non-infectious conditions to public health agencies to support disease monitoring and surveillance. For the purpose of this implementation guide, related notifications from PHAs to the Centers for Disease Control and Prevention (CDC) and between PHAs are not in scope. Transmission of reportable laboratory results is helpful in identifying cases. Clinical laboratory result messages, however, frequently lack critical clinical and demographic data needed for surveillance.

While case reporting from clinical care to Public Health Agencies is considered to be a core public health function, its electronic implementation has been slow to advance nationally because of a number of challenges. Laws requiring the reporting of infectious and non-infectious conditions are written individually by each public health jurisdiction. Geographic differences in condition prevalence and other jurisdictional variations have created a complex array of reporting expectations making it difficult for providers to know when, where, and what to report. Healthcare providers, for their part, have been historically inconsistent in reporting from clinical care by any process. For example, a recent CDC study indicated that of the cases of Lyme disease recorded as a clinical diagnosis in clinical care, only about one out of ten are reported to the appropriate PHA[[2]](#footnote-2).

Case reports are important for tracking disease trends at the Local, State and National levels, but also serve to feed surveillance and outbreak management systems that support the investigation and management of individual cases and outbreaks in routine and emergent public health situations. State, Local and Territorial PHAs are authorized by law to receive identifiable case data to enable these activities.

Previous efforts to develop standards for the exchange of case data between clinical care and public health have been challenged by inter-organizational exchange issues. These issues include efforts to develop numerous implementation guides to accommodate individual conditions and efforts to try to harmonize different jurisdictional reporting nuances and program specific data into one consolidated data specification.

Now, Stage 3 of the CMS EHR Incentive Program (Meaningful Use) program has identified electronic public health case reporting as an option for clinical reporters to meet Meaningful Use criteria. A goal of this implementation guide is to contribute to future certification criteria to ensure that consistent, comparable responses to those case reports are sent by Public Health Agencies and that the response can be parsed and integrated by EHR vendors and clinical care providers regardless of the jurisdictions in which they must report.

This Reportability Response IG builds on experience, specifications and lessons learned from the previous releases of the HL7 Implementation Guide for CDA Release 2: Public Health Case Reporting; The ONC S&I Framework Public Health Case Reporting Initiative (PHRI); the Council of State and Territorial Epidemiologists (CSTE) “Minimum EHR Data for an Electronic Initial Case Report (eICR)”; work done by CSTE and CDC on the Reportable Conditions Knowledge Management System (RCKMS); and the Association of State and Territorial Health Officials (ASTHO), Association of Public Health Laboratories (APHL), and the CDC work on trigger codes for reportable conditions as part of the Public Health Community Platform (PHCP).

## 1.5 Scope of the Implementation Guide

The following areas are In Scope for this IG:

* The data elements to be sent by a public health decision support system to produce the Reportability Response;
* The specification of a Reportability Response;
* The structure of the Reportability Response in HL7 CDA R2 format;
* A description of the stakeholders and actors for each public health reporting User Story;
* The definition of a standard exchange format including structure and content (i.e., vocabulary); and
* Identification of the full requirements to generate reports from public health decision support systems to healthcare providers (in all clinical settings where EHR data is used for reporting purposes, e.g., inpatient, outpatient, emergency room, urgent care)

The following areas are Out of Scope for this IG:

* The specific methods for public health decision support to transmit Reportability Response files to healthcare providers. Some of these are described in this IG for context purposes only;
* The methods for healthcare providers to receive and process Reportability Response files;
* The specification and methods for sending the Reportability Response from public health to healthcare providers;
* The specifications for PHAs to notify the Centers for Disease Control and Prevention of nationally notifiable diseases;
* The definition of specifications and guidelines on reportable event criteria (e.g., defining reportable conditions) – this implementation guide will enable healthcare providers to receive a Reportability Response, but will not define all the reporting criteria or all potential elements that a jurisdiction may want in a complete report;
* The description of the process for healthcare providers to add information into an EHR or auxiliary system;
* The description of the process for public health agencies to perform follow-up activities, including case monitoring;
* The definition of specifications and guidelines for reporting by means other than the transmission of an electronic message or document (e.g., telephone voice, manual web-entry and mailed or faxed information);
* The identification of security requirements, methodologies, procedures, and/or protocols; and
* The identification of information and data stewardship practices and policies.

## 1.6 Current Project

This *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, Standard for Trial Use Release 1.0* specification was developed and produced by the HL7 Public Health and Emergency Response Workgroup and co-sponsored by the HL7 Structured Documents Workgroup. It is intended to be used alongside the *HL7 Implementation Guide for CDA® Release 2: HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2*.

The current project allows for inclusion of the following information in a Reportability Response file:

* A reference to the public health case report that triggered the generation of the Reportability Response and when it was received by the public health decision support system
* A short, human-readable version of directed text by the PHA to the provider
* A human-readable synopsis of the coded information in the Reportability Response
* Contact information (originating from the public health case report) for the patient and provider in question
* Contact information for each public health jurisdiction in which the conditions in the public health case report were potentially reportable

Since public health case reports may contain information about multiple reportable conditions and those conditions are potentially reportable in multiple jurisdictions, the Reportability Response will contain a significant portion of information organized by the combination of condition and reportable jurisdiction:

* A coded representation of the public health jurisdiction and condition
* The determination of reportability provided by a public health decision support system
* Contact information for the public health jurisdiction
* The expected timeframe for reporting of the condition in the jurisdiction
* An indicator as to whether action is required on the part of the provider in response to the submission of the public health case report
* One or more links to public health resources that are relevant to clinical care, including:
  + Detailed guideline and treatment information
  + Jurisdictional reporting criteria
  + Specimen collection information
* A request for the provider to send supplemental data in order for public health to make a proper reportability determination, including:
  + The deadline by which supplemental data should be sent to public health
  + A link to the form where the healthcare provider can submit supplemental data

### 1.6.1 Errata or Enhancements

Comments regarding errata or enhancements may be noted on the HL7 STU Comments page:<http://www.hl7.org/dstucomments/>.

## 1.7 Stakeholders

|  |  |
| --- | --- |
| **Stakeholders** | **Description** |
| Electronic Health Record (EHR) /  Electronic Medical Record (EMR) | The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. Source: http://www.himss.org/ASP/topics\_ehr.asp. For purposes of this IG, EHR can also be interpreted to refer to applications that some vendors may call an Electronic Medical Record (EMR). |
| Healthcare Provider | Any supplier of a healthcare service, i.e., a person or organization that furnishes, bills, or is paid for healthcare in the normal course of business. Includes physicians and healthcare provider staff, as well as ancillary healthcare personnel (e.g., laboratory personnel). |
| Health IT Vendor | A vendor or supplier is a company/consortium that provides health information technology products and/or services, in this case, for supporting health or healthcare. |
| Intermediary System | System that sits between EHR systems and Public Health Information Systems to facilitate exchange and routing of messages.  Examples:  · Health Information Exchange (HIE) Organizations (HIEs) - Organizations, including state Designated Entities for Health Information Exchange, as well as other organizations, that manage health information exchange among different corporate entities. Includes Regional Health Information Organizations (RHIOs).  · Public Health Community Platform (PHCP) Integration Engine  · An application that receives messages from the EHR system and parses, and routes messages to a PHA or public health decision support. |
| Laboratory | The laboratory is a producer of laboratory test results (filler or, at times, placer of a laboratory order). |
| Laboratory Information System (LIS) | An application to streamline the management of laboratory processes including data collection, workflow management, and report generation. May provide an automatic interface to laboratory analytical instruments to transfer verified results to nurse stations, chart carts, and remote physician offices. Also referred to as a Laboratory Information Management System. |
| Public Health Agency (PHA) | For the purposes of this IG, a PHA is a governmental entity at the federal, state, territorial, local or tribal level that is legally entitled to establish public health case reporting requirements and receive case reports. |
| Public Health Decision Support (PHDS) | For the purposes of this IG, PHDS provides clinicians, staff and public health practitioners with knowledge about reporting cases to public health and information about the condition that has been identified. Examples include the Reportable Conditions Knowledge Management System (RCKMS), the Notifiable Condition Detector (NCD), and Electronic Support for Public Health (ESP). |
| Public Health System | Jurisdictional information systems that may, among other things, receive public health case reports. |
| Standards Development Organization | An organization that identifies the need for, locates interested parties, and writes specifications that all parties in a particular field of human endeavor can use to their mutual benefit. For the purpose of this document, the field is health or health interoperability and recognition by the American National Standards Institute (ANSI) or the International Standards Organization (ISO) is accepted as evidence that a particular organization is a SDO. |

## 1.8 Future Work / Relationships to Other Projects / Standards

Establishing an HL7 CDA R2 standard implementation guide for an eICR that can be used by all jurisdictions and all conditions is a critical step in advancing the electronic implementation of case reporting between EHRs and Public Health Agencies. There are also other parts of the clinical care – public health workflow that need consideration when this has been accomplished.

1. Specifications need to be developed for PHAs to create and communicate computable and interoperable alerts for consumption by EHRs to render to their clinical users. PHA alerting today is typically generalized and may relate to multiple suspicious cases, environmental events, or other important public health information important for clinical care providers. Providing an interoperability standard for communicating these alerts could enable PH alerts viewable by clinical staff from within an EHR, as well as be computable and queryable. This alerting area may be in scope for other public health projects.
2. With the advent of HL7 FHIR, there will be needs to also map data elements to FHIR, to possibly develop new FHIR resources, and/or FHIR profiles for the Reportability Response. This work will proceed as part of this project by working from relevant data elements in the Reportability Response IG.
3. For the complete public health reporting continuum, two additional reporting mechanisms are important for consideration in future related work; reporting between public health jurisdictions or Public Health to Public Health reporting, and Public Health Case Notification.

In some instances, investigations may be started in one jurisdiction and then transferred to another jurisdiction. This is often due to a report being made based on a provider location or hospital location because the patient's residence was unknown at the time of report or because of the reporting rules within a specific jurisdiction. This is regular process that jurisdictions routinely complete; often as a manual process. Being able to transfer cases and associated investigation information to the appropriate jurisdiction electronically would help make the reporting process more efficient and may provide the necessary information for more timely and accurate public health intervention.

Additionally, some reportable conditions identified by the State and other Public Health Agencies are also notifiable. The CSTE and CDC determine the notifiable conditions, for which there is the need to send notifications to the CDC. Characteristically, there have been times where individual disease and other public health programs have used different data elements for seemingly similar content. There are instances where different Public Health Agencies use different data elements names and definitions, typically because of conditions that were made reportable in one or more PHAs before the CSTE and CDC made them notifiable. Having standardized an eICR, and with appropriate support, it would be valuable for HL7 to convene all of the involved parties in a neutral setting to establish common standards for the FHIR resources and profiles for condition-specific data as well.

## 1.9 Contents of the Package

|  |  |  |
| --- | --- | --- |
| Filename | Description | Standards Applicability |
| %HL7 Ballot Code%\_2017MAY\_  Vol1\_Introductory\_Material.docx | Implementation Guide Introductory Material | Normative |
| %HL7 Ballot Code%\_2017MAY\_  Vol2\_Templates\_and\_Supporting\_Material.docx | Implementation Guide Template Library and Supporting Material | Normative |
| %HL7 Ballot Code%\_2017MAY\_ Sample.xml | Sample file | Informative |
| GForge link: [CDA Schema](http://gforge.hl7.org/gf/project/strucdoc/frs/?action=FrsReleaseBrowse&frs_package_id=302) | CDA Schema | Informative |
| GForge link: [PHCASERPT eIC GForge](http://gforge.hl7.org/gf/project/pher/scmsvn/?action=browse&path=%2Ftrunk%2FPHCASERPT_eICR%2F)  GForge SVN url: http://gforge.hl7.org/svn/pher/trunk/PHCASERPT\_eICR/ | Schematron files.  GForge account required. See: [GForge SVN Access Info](http://gforge.hl7.org/gf/project/pher/scmsvn/?action=AccessInfo) for details. | Informative |

# 2. Use Case for the Reportability Response

The scope of this implementation guide is limited to the generation of an eICR from clinical care. However, eICR generation is only one part of the overall electronic case reporting flow. The broader electronic case reporting flow is depicted in the Context Use Case Flow Diagram below, and is also referenced in the Use Case Assumptions, Pre-Conditions. and Post-Conditions sections of this chapter. The broader electronic case reporting (eCR) picture is included both to show where eICR fits (the focus for this IG), and to highlight integral components that should be addressed in subsequent IGs or companion guidance to provide adequate support for full eCR implementation.

## 2.1 Context Use Case Flow Diagram

The diagram below is intended to set the context for the overall flow of eCR, while showing where initiation and creation of the Reportability Response fits within the flow. The context use case flow diagram is intentionally general as it recognizes that:

* the eICR could be manually initiated by a clinician or automatically initiated based on a match of patient data to a code in a set of codes provided by public health;
* could be created and sent from an EHR system; or be
* created in an EHR and sent through a designee of clinical care, such as an HIE,

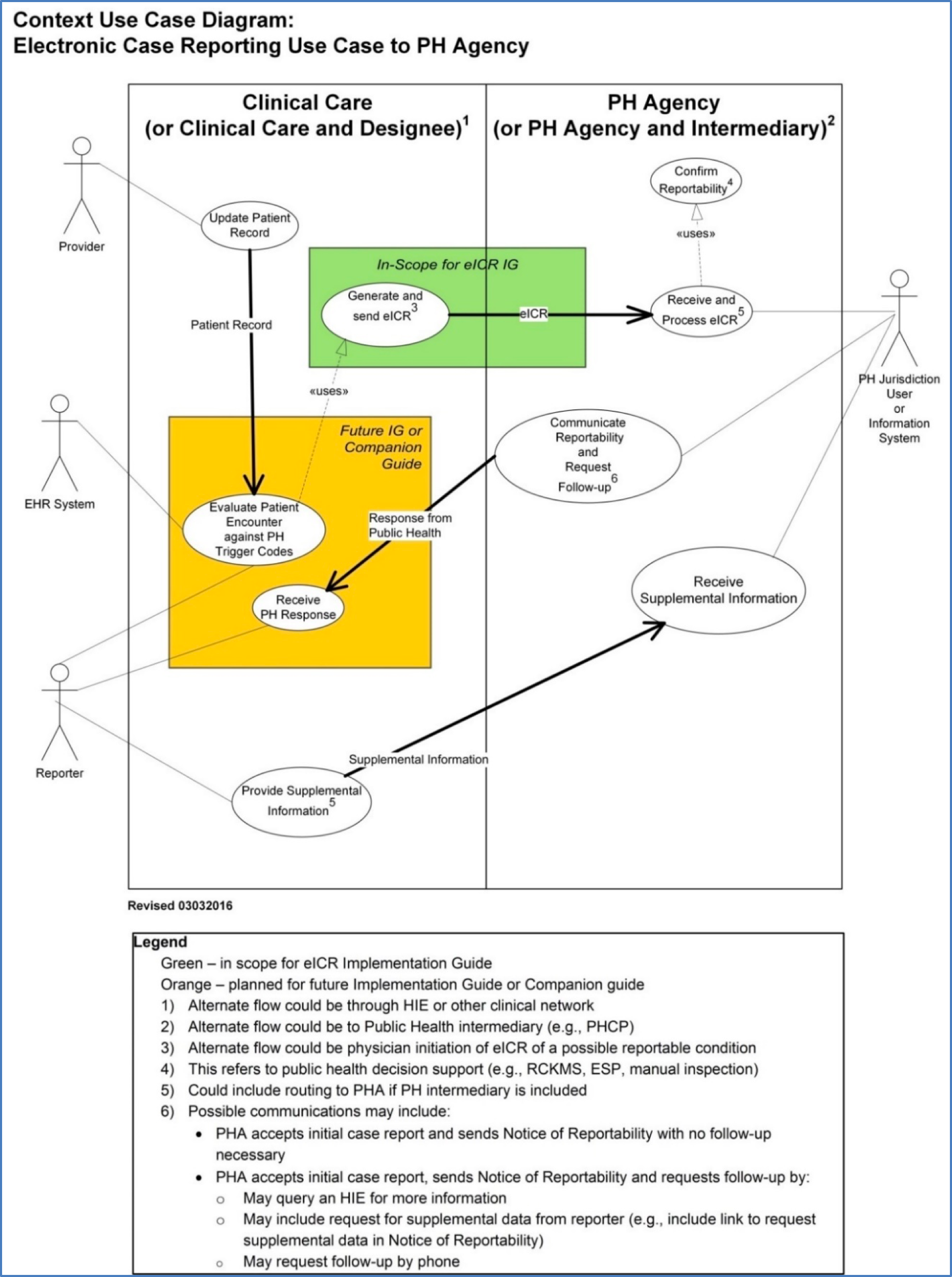
as shown in swim lane [1] of the context use case flow diagram.

Likewise, the eICR could be:

* received directly by the PHA; or by an
* intermediary for the PHA, such as the Public Health Community Platform (PHCP) or an HIE,
* as shown in swim lane [2] of the context use case flow diagram.

Confirm Reportability (context use case flow diagram [4]) is a function that operates against the eICR once received by the PHA (or its intermediary). Its role is to determine if the report meets jurisdictional reporting requirements and to which jurisdiction(s) the report should be sent. Again, in keeping with the general depiction of the eCR flow, the confirmation of reportability could be met by:

* a centralized but jurisdiction specific decision support service such as RCKMS;
* a localized decision support service such as ESP; or
* using manual inspection at a jurisdiction in the absence of an automated approach.



## 2.2 Use Case Assumptions

* Patient-level clinical information is entered, imported, or accessed by a healthcare provider using an EHR system.
* Broadly-acceptable security and transport protocols, patient identification methodology, privacy and security procedures, coding, vocabulary, and normalization standards exist and are in use by the EHR system and PHA system.
* The EHR system contains or has access to all relevant information and data (e.g., demographic, clinical, laboratory, pharmacy) to generate a complete and accurate eICR in accordance with requirements described in this implementation guide.
* Appropriate data and information stewardship practices are adopted by exchange partners.
* Network and policy infrastructure exist to enable consistent, appropriate, and accurate information exchange across exchange partners.
* The PHA system may be a single stand-alone system or based upon a component-based architecture. The PHA may interface with other systems that are used to help create, populate or transmit the report to healthcare providers.
* The PHA system is in place, is capable of generating a Reportability Response, and sends the report in a standardized structured format.
* These information systems may be a single stand-alone system or be component based systems used to receive, process, store or archive, as appropriate, the report for review and/or analysis.
* There is a standard structure and set of data elements for the Reportability Response, that is accepted by all jurisdictions, for all conditions.
* The PHA system is capable of sending the Reportability Response to an EHR system or its intermediary system.
* The intermediary system HIE, if used, is responsible for passing the acknowledgement from the EHR system to the Public Health Agency Information system ; the intermediary system may send separate acknowledgements, but these are not considered the authoritative acknowledgement.

## 2.3 Pre-Conditions

The following have occurred:

* An authoritative set of reportable condition trigger codes, as provided and defined by PH (available at [PHIN VADS](https://phinvads.cdc.gov/vads/SearchVocab.action) RCTC), is maintained and used within the EHR system.
* The creation of an eICR is initiated by one of two methods:
  + An automated match of information in a patient record for an encounter to a set of trigger codes within the EHR; or
  + Manual initiation of the creation of an electronic report to public health by a provider.
* The EHR system populates/generates a report using all appropriate information (e.g., data elements and terminology) for the eICR.
* The receiving system receives and processes the eICR electronically (transmission by fax does not qualify).
* The receiving system electronically groups multiple eICRs sent from one encounter when multiple trigger code events are matched (e.g. a laboratory result of a reportable condition saved in EHR and clinical diagnosis of reportable condition saved in an EHR problem list).
* The PHA system and/or its intermediary system has received the eICR.
* eICRs are grouped and de-duplicated by receiving system(s).
* A record of an eICR sent from the EHR to the public health agency is stored in a log within the authoring system at the EHR.
* A record of receipt of the eICR is recorded in a log, in the PHA system and/or its intermediary system.

## 2.4 Post-Conditions

* The EHR system and/or its intermediary system has received the Reportability Response.
* Reportability Responses are grouped and de-duplicated by receiving system(s).
* A record of a Reportability Response sent from public health to the healthcare provider is stored in a log within the authoring system at the PHA system and/or its intermediary system.
* A record of receipt of the Reportability Response is recorded in a log, in the EHR system.

## 2.5 Actors and Roles

|  |  |
| --- | --- |
| **Actor** | **Role** |
| Provider | * A person in clinical care organization that updates information in the EHR System |
| EHR System (healthcare provider system) | * Collect, receive, and/or store data on a patient record * Consume and maintain trigger codes * Match trigger code and generate eICR * Create report and transport to intermediary system or appropriate PHA |
| Reporter | * A person in clinical care organization that is responsible for reporting to public health |
| Public Health Agency System | * Receive eICR from EHR system or intermediary * Determine reportability status using predefined jurisdiction- and condition-specific rules * Generate the Reportability Response * Send the Reportability Response to the EHR system or its intermediary |
| PH Jurisdiction User | * The person in a public health agency that uses the information contained in the PHA system |
| Clinical Care (or Clinical Care and Designee) | * Implementer and user or EHR System; or * As designee of clinical care (e.g., HIEs): * Receive eICR from EHR system and send to Intermediary or PHA system |
| Public Health Agency (or PHA and Intermediary) | * Recipient of eICR from EHR system or clinical care designee * Confirmer of reportability * And if at PH intermediary, sender of eICR to PHA system |

## 2.6 Reportability Response Scenarios

The Reportability Response is used to inform healthcare providers of the actions that public health may take in response to case reports. It is expected that the Reportability Response may contain different sets of data based on the content of the eICRs that are received by PHA systems (or their intermediaries). The scenarios outlined in this section are expected to occur commonly and should be accommodated by the Reportability Response file.

### 2.6.1 One or More Reportable Condition in One or More Jurisdiction

In the most common scenario, the Reportability Response is expected to communicate back to healthcare providers that one or more condition has been determined to be reportable in one or more public health jurisdiction. In this case, a healthcare provider has entered one of the RCTC trigger codes on a patient’s record, the EHR system has generated an eICR, the eICR has been sent to a PHA system (or its intermediary), and a decision support system has used a set of rules to determine reportability. The Reportability Response should contain some of the information received in the eICR and a series of information about the

### 2.6.2 Unknown Reportability: Data was Missing in the eICR

There are many data elements in the eICR that are not required for a file to be generated and sent to public health. In part, this is because public health has a indicated a desire to receive any and all data that may be helpful to establish a case. For example, if a patient is admitted to the emergency room and it is believed that they are suffering from an infectious condition but parts of the patient’s travel history are completely unknown, public health is still interested in starting an investigation into that case. An automated public health decision support system can make a determination of reportability if that information is available in the eICR. If sufficient data is not included in the eICR (but it is possible to include that data within an eICR file), a Reportability Response file should be generated by the PHA system and sent back to the healthcare provider informing them that the reportability of the condition is unknown due to missing data.

### 2.6.3 Unknown Reportability: Supplemental Data is Needed

In order to determine reportability, public health requires a distinct set of information for each potentially reportable condition. Some of this information is not expected to be present in the EHR system (and, by extension the eICR), or it may be present in the EHR system but exist in a format that a PHA system is unable to use. For example, some conditions require specific information about where a patient has traveled and for how long. This information may be available in free text within the EHR system, but an automated public health decision support system may require coded data to make a positive determination of reportability. In these circumstances, it is expected that the Reportability Response file will be used to inform the healthcare provider that supplemental data (i.e., data that is never expected to be included in an eICR) is needed to determine reportability.

### 2.6.4 No Reportable Conditions

The RCTC trigger codes list contains a superset of codes used to determine whether a public health case report should be passed on to the public health agency. As such, it is expected that an eICR generated in response to an RCTC trigger code may not contain any reportable conditions (in any public health jurisdictions). In the event that a PHA system receives an eICR and determines that no reportable conditions exist (for any of the jurisdictions deemed relevant for the eICR file), the Reportability Response should indicate to the healthcare provider that no reportable conditions were found in the eICR and no further action should be taken. Over time, these Reportability Response files can be used to gauge the effectiveness of certain RCTC trigger codes in notifying public health of possible reportable conditions.

### 2.6.5 Unable to Parse eICR

Based on the existence of a trigger code, an EHR system generates an eICR file and sends it to one or more appropriate PHAs (or their respective intermediaries). Before the eICR file is parsed and the data within the file is used to determine whether a reportable condition is present, the file is processed through a file validation utility. The file is deemed by the validation utility to be invalid (due to the absence of certain data elements that are required according to the eICR specification, unclosed xml nodes, etc.). Because the file is deemed to be invalid, reportability cannot be determined and it is possible that the document ID of the eICR may not be accessible. To assist the healthcare provider in troubleshooting and resolving these file integrity issues, the Reportability Response file should be sent back to the healthcare provider explaining that the receiving system was unable to parse the eICR and reporting:

* the date and time that the PHA system (or its intermediary) received the eICR file, and
* the filename of the eICR that was received

Technical staff at the healthcare provider can use this information from the Reportability Response to begin a root-cause analysis into the problem with the eICR file that was sent.

### 2.6.6 Manually Reported eICR

In the event that a healthcare provider feels that a patient has a condition that should be reported to public health, they may choose to manually initiate an eICR. Based on this belief, the provider clicks a button, selects an option, or otherwise starts a workflow to send a manually reported eICR. The provider enters their reason for suspecting a reportable condition into the EHR and it sends an eICR to the PHA system (or its intermediary). Because the eICR is manually generated and does not contain one of the RCTC trigger codes, the PHA system may not be able to make an automatic determination of reportability and should then send the eICR file directly through to the appropriate public health agency (or agencies) that can be determined from the eICR file. After sending the eICR file, the PHA system should generate a Reportability Response file containing the jurisdictions to which the eICR file was sent. The EHR system should receive this Reportability Response file and notify the provider that their manually initiated eICR was sent to the relevant public health agencies.

## 2.7 Reportability Response Short Description

The Reportability Response Short Description is a human-readable version of directed text by the PHA to the provider. For every Reportability Response file, this data element should be populated with a brief message that can be included in an EHR system work queue. This short description should contain:

* an indicator as to whether or not the eICR contains one or more reportable conditions in one or more jurisdiction, or
* if a condition was deemed reportable in a given jurisdiction:
  + the human-readable name of the condition, and
  + the human-readable name of the jurisdiction in which the condition was deemed reportable by the PHA system (or its intermediary)
* if no conditions were deemed reportable in a given jurisdiction, an indicator as to whether this is the case because:
  + all information necessary to make a determination was included in the eICR, but none of the conditions reported in the eICR are reportable in any of the jurisdictions relevant to the patient, provider, and/or laboratory included in the eICR, or
  + reportability could not be determined because the eICR was missing information that is required to make a positive or negative determination of reportability, or
  + reportability could not be determined because the PHA system (or its intermediary) requires supplemental information that is not expected to be included in any eICR file, or
  + reportability could not be determined because the PHA system (or its intermediary) could not parse the eICR file.
* if the eICR was manually generated, an indicator that the eICR has been sent to one or more relevant public health agencies, including the human-readable name of those public health agencies.

## 2.8 Reportability Response Synopsis

# 3. CDA R2 Background

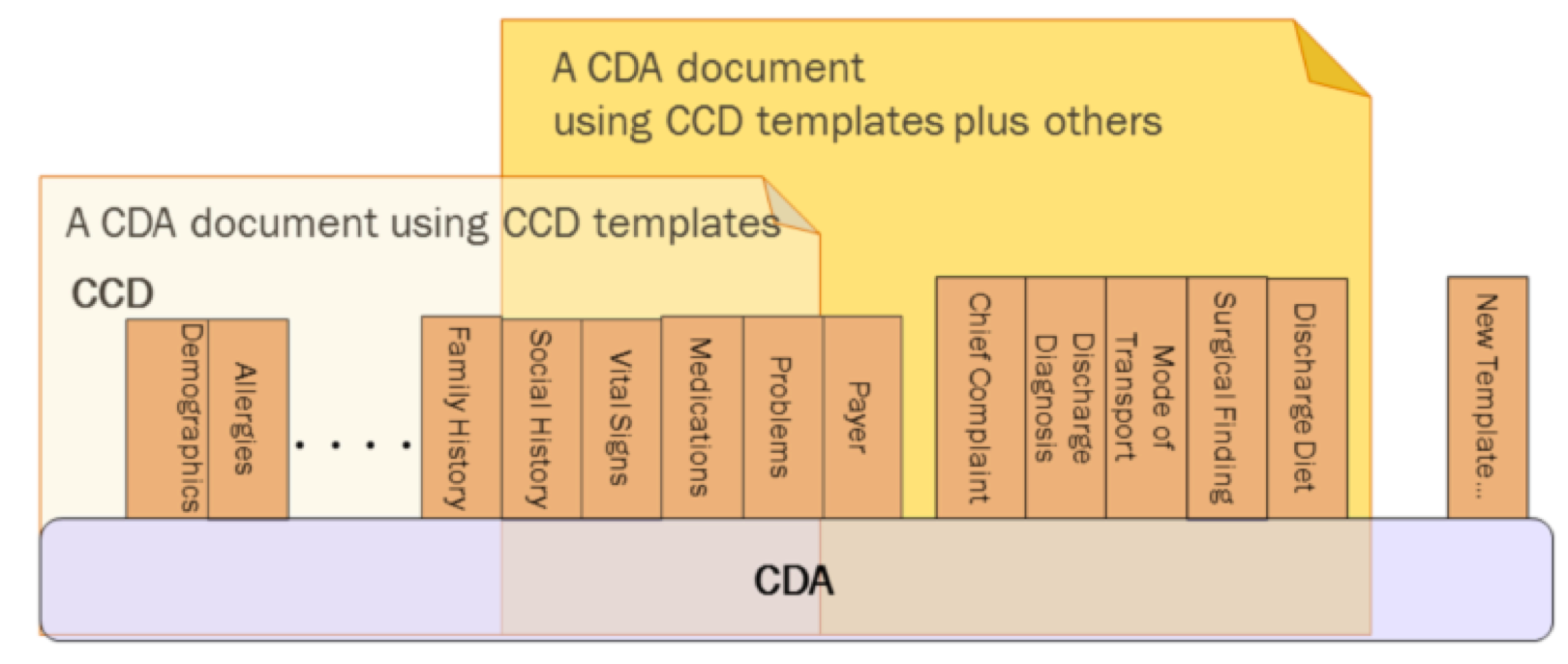
CDA R2 is “… a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1][[3]](#footnote-3). Clinical documents, according to CDA R2, have the following characteristics:

* Persistence
* Stewardship
* Potential for authentication
* Context
* Wholeness
* Human readability

CDA R2 defines a header for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

## 3.1 Templated CDA R2

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”[[4]](#footnote-4) section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA R2 is referred to as a “CDA template.” The “templated CDA” approach uses a library of modular CDA R2 template definitions. Templates can be reused across any number of CDA R2 document types, as shown in the following figure. Each template meets a defined purpose. Templates are managed over time through versioning. A template version is a specific set of conformance constraints designed to meet the template’s purpose.



There are many kinds of templates that might be created. Among them, the most common are:

**Document-level templates:** These templates constrain fields in the CDA R2 header, and define containment relationships to CDA R2 sections. For example, a History and Physical document-level template might require that the patient’s name be present, and that the document contain a Physical Exam section.

**Section-level templates:** These templates constrain fields in the CDA R2 section, and define containment relationships to CDA R2 entries. For example, a Physical Exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contains a Systolic Blood Pressure observation.

**Entry-level templates:** These templates constrain the CDA R2 clinical statement model in accordance with real-world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA R2 Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.

**Other templates:** Templates that exist to establish a set of constraints that are reused in the CDA R2 document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the implementation guide. They reduce the need to repeat constraints in templates that use the common set.

A CDA R2 implementation guide (such as this one) includes references to those template versions that are applicable.

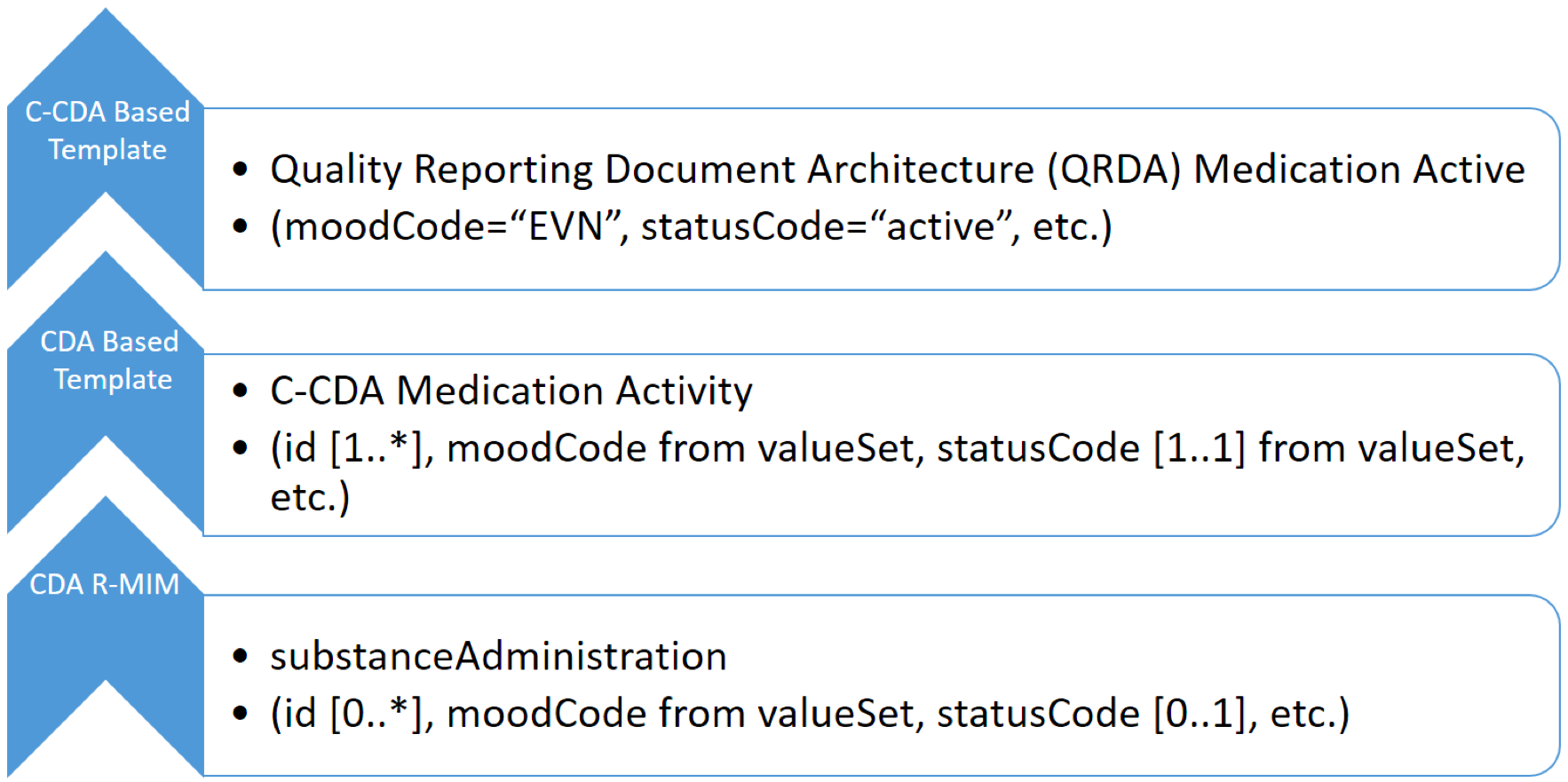
Regarding implementation, a CDA R2 instance populates the template identifier (templateId) field where it wants to assert conformance to a given template version. On the receiving side, the recipient can then not only test the instance for conformance against the CDA R2 Extensible Markup Language (XML) schema, but also test the instance for conformance against asserted templates.

### 3.1.1 Further Constraining Existing Templates

A CDA template is a set of conformance constraints on either the base CDA model (CDA Refined Reference Information Model or R-MIM) or another CDA template (such as an existing C-CDA R2.1 templates). A new template is created that contains all the constraints of the base template and which further constrains that template. Constraints can only be tightened, not loosened. These further constraints can, for example, tighten a SHOULD to a SHALL or change [0..\*] to [1..1]. Constraints can also be applied to vocabulary, for example, binding to a specific code system or value set or only allowing the use of a single specific code (single value binding).

The following figure illustrates this "layering" of constraints starting from the most general (CDA R-MIM) at the bottom to the most specific (C-CDA Based Template) at the top. Each level conforms to the constraints of the level below it and adds a further set of conformance

constraints to satisfy a particular use case:



The new template is fully conformant to the template it is based on, and contains the templateId of that template, as well as its own templateId. The following figure is an example of the presence of two templateIds to indicate that this template is asserting conformance to both templates:

<observation classCode="OBS" moodCode="EVN">

<!-- [C-CDA R2.1] Problem Observation (V3) -->

<templateId extension="2015-08-01" root="2.16.840.1.113883.10.20.22.4.4" />

<!-- [eICR R2 STU1.1 Problem Observation (RCTC) -->

<templateId extension="2017-01-01" root="2.16.840.1.113883.10.20.15.2.3.3" />

…

</observation>

### 3.1.2 Status of a Template Version

Each version of a template has a status. For example, a template version can be draft, active, or deprecated, etc. The HL7 Templates DSTU describes the various status states that may apply to a template version over the course of its lifecycle. Each version of a template has an associated status. Thus, one version of a template may be deprecated, while a newer version of that template may be draft or active.

# 4. Using This Implementation Guide

This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA R2 templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

## 4.1 Conformance Conventions Used in This Guide

## 4.2 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository[[5]](#footnote-5). An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the object identifier (OID) or uniform resource name (URN), and whether the template is open or closed. The identifier OID is the templateId/@root value; all templateIds have an @root value. Versioned templates also have an @extension value, which is a date identifying the version of this template; such templates are identified by URN and the HL7 version (urn:hl7ii). The URN identifier includes both the @root and @extension value for the templateId (for example, identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that this template uses.

Reportability Response Template Contexts

Each entry template also includes a constraints overview table to summarize the constraints in the template.

Reportability Response Template Constraints Overview

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a subordinate clause (like a "where" clause), which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus...

1. SHALL contain exactly one [1..1] templateId 81-7899) such that it

a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31" 81-10487).

...is understood as:

This template SHALL contain exactly one [1..1] templateId where it contains exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31".

This means that you must have a template id with @root="2.16.840.1.113883.10.20.22.4.31", but you can also have other template ids with different valued attributes.

The following figure shows a typical template’s set of constraints presented in this guide.

Constraints Format Example

The next chapters describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors (see also Reportabillity Response IG Specific Conformance Guidance).

### 4.2.1 Template Versioning

Under the "templated CDA" approach a new implementation guide can use existing CDA R2 templates from previously published implementation guides. A new version of an existing implementation guide reuses templates from either the previous version or another published IG. During the ballot and update phases, templates carry the designation "Published" to indicate the template is unchanged from the previous version or other IG or "Draft" to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same templateId/@root (identifier oid) and templateId/@extension as in the previous implementation guide. (In the case of older templates, the @extension attribute will not be present.) During a new ballot or update phase, "Published" is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The "Published" designation is removed in the final publication versions.

A revised version of a previously published template keeps the same templateId/@root as the previous version but is assigned a new templateId/@extension. The notation "(Vn)" (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, "Draft" is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the "Draft" designation is removed in the final publication versions.

### 4.2.2 Open and Closed Templates

### 4.2.3 Conformance Verbs (Keywords)

### 4.2.4 Cardinality

### 4.2.5 Optional and Required with Cardinality

### 4.2.6 Unknown and No Known Information

### 4.2.7 Vocabulary Conformance

### 4.2.8 Containment Relationships

### 4.2.9 Data Types

### 4.2.10 Document-Level Templates "Properties" Heading

## 4.3 XML Conventions Used in This Guide

### 4.3.1 XPath Notation

### 4.3.2 XML Examples and Sample Documents

# 5 Reportability Response IG Specific Conformance Guidance

## 5.1 Template Types

## 5.2 Narrative Creation

## 5.3 CDA Narrative Rendering: Receiver Responsibilities

The receiver of a Reportability Response CDA XML document, at a minimum, **SHALL** be able to display the following elements contained in the Section.text field (the CDA Narrative Block):

* All elements that receivers are required to interpret by the base CDA specification. These include, but are not restricted to the following:
  + <content>
  + <sub> and <sup>
  + <br>
* Elements that are defined in the base CDA specification but are not explicitly stated as receiver required elements:
  + <linkHtml>
  + <paragraph>
  + <table>
  + styleCode font style values:
    - Bold, Underline, Italics
    - Ordered
  + styleCode order list styles:
    - Arabic
    - LittleRoman
    - BigRoman
    - LittleAlpha
    - BigAlpha
  + styleCode unordered list styles:
    - Disc
    - Circle
    - Square

## 5.4 Lineage to Domain Analysis Model (DAM)

## 5.5 Null Values and the Reportability Response IG

# 6 Reportability Response Data Requirements

## 6.1 Identified Data Requirements

The table below contains a set of data element requirements proposed by the CDC and used to map data for this standard. The following sections contain reference tables and graphics of the data model used in this document.

|  |  |  |
| --- | --- | --- |
| **Data Element** | **Data Type** | **Description** |
| Reportability Response Unique Identifier | String | Each Reportability Response file should include a unique ID to allow for identification by PHA systems, EHR systems, or other interested parties |
| Reference to eICR CDA Document | String | At a minimum, each Reportability Response should contain the unique document ID associated with the eICR file that initiated its generation |
| Date and time of eICR Receipt | Date | To assist with troubleshooting and establish the elapsed time between the EHR sending the eICR and the PHA system (or its intermediary) receiving the eICR, the date and time of receipt should be included in the Reportability Response |
| Provider ID | String | If available, the provider ID received in the eICR should be passed back in the Reportability Response |
| Provider Name | String | If available, the provider name received in the eICR should be passed back in the Reportability Response |
| Provider Phone | String | If available, the provider phone number received in the eICR should be passed back in the Reportability Response |
| Provider Fax | String | If available, the provider fax received in the eICR should be passed back in the Reportability Response |
| Provider Email | String | If available, the provider email received in the eICR should be passed back in the Reportability Response |
| Provider Facility/Office Name | String | If available, the provider facility received in the eICR should be passed back in the Reportability Response |
| Provider Address | String | If available, the provider address received in the eICR should be passed back in the Reportability Response |
| Facility ID Number | String | If available, the facility ID number received in the eICR should be passed back in the Reportability Response |
| Facility Name | String | If available, the facility name received in the eICR should be passed back in the Reportability Response |
| Facility Type | String | If available, the facility type received in the eICR should be passed back in the Reportability Response |
| Facility Phone | String | If available, the facility phone received in the eICR should be passed back in the Reportability Response |
| Facility Fax | String | If available, the facility fax received in the eICR should be passed back in the Reportability Response |
| Facility Address | String | If available, the facility address received in the eICR should be passed back in the Reportability Response |
| Patient ID Number | String | If available, the patient ID number received in the eICR should be passed back in the Reportability Response |
| Patient Name | String | If available, the patient name received in the eICR should be passed back in the Reportability Response |
| Patient Phone | String | If available, the patient phone number received in the eICR should be passed back in the Reportability Response |
| Patient Email | String | If available, the patient email received in the eICR should be passed back in the Reportability Response |
| Parent/ Guardian Name | String | If available, the parent or guardian name received in the eICR should be passed back in the Reportability Response |
| Parent/ Guardian Phone | String | If available, the parent or guardian name received in the eICR should be passed back in the Reportability Response |
| Parent/ Guardian Email | String | If available, the parent or guardian email received in the eICR should be passed back in the Reportability Response |
| Patient Street Address | String | If available, the patient address received in the eICR should be passed back in the Reportability Response |
| Patient Birth Date | String | If available, the patient birth date received in the eICR should be passed back in the Reportability Response |
| Patient Birth Sex | String | If available, the patient birth sex received in the eICR should be passed back in the Reportability Response |
| Patient Race | String | If available, the patient race received in the eICR should be passed back in the Reportability Response |
| Patient Ethnicity | String | If available, the patient ethnicity received in the eICR should be passed back in the Reportability Response |
| Patient Preferred Language | String | If available, the patient’s preferred language received in the eICR should be passed back in the Reportability Response |
| Occupation | String | If available, the patient occupation received in the eICR should be passed back in the Reportability Response |
| Reportability Response Short Description | String | A human-readable version of directed text by the PHA to the provider. See %RR Short Description Section% for more information about how this data element is expected to be populated by the PHA system (or its intermediary) |
| Reportability Response Summary/Synopsis | String | A human-readable version of directed text by the PHA to the provider that contains significantly more information than the short description, including patient information, eICR routing information, and links to relevant public health information. See %RR Summary/Synopsis Section% for more information about how this data element is expected to be populated by the PHA system (or its intermediary) |
| Reportability Status | Value set? | A status code indicating whether the eICR file contained one or more reportable condition |
| eICR Encompassing Encounter ID | String | If available, the encompassing encounter ID from the eICR that generated the Reportability Response |
| Jurisdiction Code | Value Set | A code indicating the jurisdictions to which an eICR was sent by the PHA system (or its intermediary) |
| Jurisdiction Relevance Code | Value Set | A code indicating whether the jurisdiction is relevant because of:   * the patient’s home address, * the provider facility address, or * the laboratory address |
| Reportable Condition | Value Set | A code indicating a condition associated with an RCTC trigger code in the eICR |
| Reporting Location Address Info | String | The physical address to which the eICR has been sent (if a condition within the eICR is deemed reportable) |
| Reporting Location Description | String | A description of the organization or physical address to which the eICR has been sent (if a condition within the eICR is deemed reportable) |
| Determination of Reportability | Value Set | The determination of reportability generated by the PHA system (or its intermediary). Generally, this is expected to be Yes, No, or Maybe |
| Description of Reportability Determination | String | Further guidance on the reportability determination |
| Reporting Timeframe | Value Set | For a given condition within a jurisdiction, the mandated timeframe in which the condition should be reported to public health. |
| Reporting Action Required | Value Set | An indicator as to whether provider action is required, and if so, what type of action is required. |
| Deadline for supplemental data submission | Date | The deadline for submission of any supplemental data that public health requires (in addition to the data submitted via the eICR) to determine reportability of a given condition in a jurisdiction |
| Link to Supplemental Question Form | String | A link to a questionnaire that can be used to collect any supplemental data that public health requires (in addition to the data submitted via the eICR) to determine reportability of a given condition in a jurisdiction |
| Link to Supplemental Question Form Identifier | String | The ID to a link to a questionnaire that can be used to collect any supplemental data that public health requires (in addition to the data submitted via the eICR) to determine reportability of a given condition in a jurisdiction. This is included for healthcare providers that wish to compose the link to the supplemental question form themselves. |
| Link to public health references | String | A link (or series of links) which may assist clinicians in understanding or investigating conditions deemed reportable by the PHA system (or its intermediary) |

## 6.2 Reportability Response Data Model

### 6.2.1 Reportability Response Header

### 6.2.2 Reportability Response Summary Section

### 6.2.3 eICR Section

### 6.2.4 Reportability Response Coded Section

## 6.3 Mapping of Data Elements to Data Model

## 6.4 Reportability Response Template Hierarchy

## 6.5 Mapping of Elements to CDA R2 Templates

1. [www.cste.org/group/RCKMS](http://www.cste.org/group/RCKMS) [↑](#footnote-ref-1)
2. <http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html> [↑](#footnote-ref-2)
3. *HL7 CDA Release 2.*<http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7> [↑](#footnote-ref-3)
4. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-4)
5. Trifolia Workbench, <https://trifolia.lantanagroup.com/> [↑](#footnote-ref-5)