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HL7 CDA® R2 Implementation Guide:

Quality Reporting Document Architecture Category I (QRDA I),

Release 1, STU Release 5.3 - US Realm

HL7 Standard for Trial Use

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**Volume 1 — Introductory Material**

Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 18 months from the date of publication. Suggestions for revision should be submitted at <http://www.hl7.org/dstucomments/index.cfm>.

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Structure of This Guide

Two volumes comprise this *HL7 Standard for CDA® Release 2: Quality Reporting Document Architecture Category I (QRDA I), Release 1, STU Release 5.3 - US Realm.*

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 Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version.

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This specification is a set of constraints on existing work, and the extent to which it can accommodate the expressive requirements of quality reporting over time is a function of the richness of the model on which it is built, the Health Level Seven (HL7) Reference Information Model (RIM) and the RIM document standard, and the Clinical Document Architecture Release 2 (CDA R2). We thank all those who have worked for over a decade to produce these fundamental specifications; we especially thank the HL7 Clinical Quality Information Work Group for their support of this project.

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Contents

[1 Introduction 11](#_Toc120387618)

[1.1 Purpose 11](#_Toc120387619)

[1.2 Audience 11](#_Toc120387620)

[1.3 Approach 11](#_Toc120387621)

[1.4 Organization of the Guide 11](#_Toc120387622)

[1.4.1 Volume 1 Introductory Material 12](#_Toc120387623)

[1.4.2 Volume 2 CDA Templates and Supporting Material 12](#_Toc120387624)

[1.5 Contents of the Package 13](#_Toc120387625)

[2 CDA AND QRDA 14](#_Toc120387626)

[2.1 CDA R2 Background 14](#_Toc120387627)

[2.2 Templated CDA 14](#_Toc120387628)

[2.3 QRDA Background 15](#_Toc120387629)

[2.3.1 QRDA Category I – Single Patient Report 15](#_Toc120387630)

[2.3.2 QRDA Category II – Patient List Report (retired) 16](#_Toc120387631)

[2.3.3 QRDA Category III – Calculated Report 16](#_Toc120387632)

[2.4 Relationship to Health Quality Measures Format: eMeasure 16](#_Toc120387633)

[2.5 Current Project 17](#_Toc120387634)

[2.6 Scope 19](#_Toc120387635)

[3 Design Considerations 20](#_Toc120387636)

[3.1 Determining a Clinical Statement’s Status 20](#_Toc120387637)

[3.2 Rendering Header Information for Human Presentation 20](#_Toc120387638)

[3.3 Unknown and No Known Information 21](#_Toc120387639)

[3.4 Asserting an Act Did Not Occur with a Reason 25](#_Toc120387640)

[3.5 Use of UTC Time Zone Offset in Datetimes 28](#_Toc120387641)

[4 Using This Implementation Guide 30](#_Toc120387642)

[4.1 Conformance Conventions Used in This Guide 30](#_Toc120387643)

[4.1.1 Errata or Enhancements 30](#_Toc120387644)

[4.1.2 Templates and Conformance Statements 30](#_Toc120387645)

[4.1.3 Template Versioning 32](#_Toc120387646)

[4.1.4 Open and Closed Templates 33](#_Toc120387647)

[4.1.5 Conformance Verbs (Keywords) 34](#_Toc120387648)

[4.1.6 Cardinality 35](#_Toc120387649)

[4.1.7 Optional and Required with Cardinality 35](#_Toc120387650)

[4.1.8 Vocabulary Conformance 36](#_Toc120387651)

[4.1.9 Containment Relationships 37](#_Toc120387652)

[4.1.10 Data Types 38](#_Toc120387653)

[4.1.11 Document-Level Templates "Properties" Heading 38](#_Toc120387654)

[4.2 XML Conventions Used in This Guide 38](#_Toc120387655)

[4.2.1 XPath Notation 38](#_Toc120387656)

[4.2.2 XML Examples and Sample Documents 39](#_Toc120387657)

[5 QRDA Category I Framework 40](#_Toc120387658)

[5.1 Measure Section 40](#_Toc120387659)

[5.2 Reporting Parameters Section 40](#_Toc120387660)

[5.3 Patient Data Section 40](#_Toc120387661)

[6 Quality Data Model-Based QRDA 41](#_Toc120387662)

[6.1 Introduction 41](#_Toc120387663)

[6.2 QDM-Based QRDA Category I Construction Rules 45](#_Toc120387664)

[6.2.1 How Many QRDA Documents Should be Created? 45](#_Toc120387665)

[6.2.2 Generate a QRDA for Which Patients? 45](#_Toc120387666)

[6.2.3 How Much Data Should be Sent? 45](#_Toc120387667)

[6.2.4 What if There are No Data in the EHR? 46](#_Toc120387668)

[6.3 Generating a QDM-Based QRDA Category I Instance from a QDM-Based eCQM 46](#_Toc120387669)

[6.4 QDM-Based QRDA Category I Instance Validation 49](#_Toc120387670)

[6.5 Processing Considerations 50](#_Toc120387671)

[6.5.1 Guidance for Ensuring Data Uniqueness 50](#_Toc120387672)

[6.5.2 Guidance for Reason Template Placement When Specifying “Not Done” with a Reason 52](#_Toc120387673)

[7 References 54](#_Toc120387674)

[Appendix A — Acronyms and Abbreviations 56](#_Toc120387675)

[Appendix B — High-Level Change Log 59](#_Toc120387676)

[Volume 1 Summary of Changes 59](#_Toc120387677)

[Volume 2 Summary of Changes 60](#_Toc120387678)

[General Changes (not specifically stated in tables below) 60](#_Toc120387679)

[Summary Tables 60](#_Toc120387680)

[Appendix C — Extensions to CDA R2 67](#_Toc120387681)

[Appendix D — Unique Device Identification (UDI) Issuing Agency Formats 69](#_Toc120387682)

[Appendix E — HQMF QDM Datatype to QRDA Mapping Tables 73](#_Toc120387683)

Figures

[Figure 1: Templated CDA 14](#_Toc120387684)

[Figure 2: Overview of Quality Framework 17](#_Toc120387685)

[Figure 3: nullFlavor Example 21](#_Toc120387686)

[Figure 4: Attribute Required (nullFlavor not allowed) 22](#_Toc120387687)

[Figure 5: Allowed nullFlavors When Element is Required (with xml examples) 22](#_Toc120387688)

[Figure 6: Unknown Medication Example 23](#_Toc120387689)

[Figure 7: Unknown Medication Use of Anticoagulant Drug Example 23](#_Toc120387690)

[Figure 8: No Known Medications Example 24](#_Toc120387691)

[Figure 9: Value Known, Code for Value Not Known 24](#_Toc120387692)

[Figure 10: Value Completely Unknown 24](#_Toc120387693)

[Figure 11: Value Known, Code in Required Code System Not Known But Code from Another Code System is Known 25](#_Toc120387694)

[Figure 12: Not Done Example for QDM Element Defined with a Direct Referenced Code 26](#_Toc120387695)

[Figure 13: Not Done Example for QDM Element Defined with Value Set 27](#_Toc120387696)

[Figure 14: Not Done Example – Device Order Not Done (with Value Set) 28](#_Toc120387697)

[Figure 15: Constraint Conformance Including "such that it" Syntax Example 32](#_Toc120387698)

[Figure 16: Versioned Template Change Log Example 33](#_Toc120387699)

[Figure 17: Constraints Format – only one allowed 35](#_Toc120387700)

[Figure 18: Constraints Format – only one like this allowed 35](#_Toc120387701)

[Figure 19: Binding to a Single Code 36](#_Toc120387702)

[Figure 20: XML Expression of a Single-Code Binding 36](#_Toc120387703)

[Figure 21: XML Document Example 39](#_Toc120387704)

[Figure 22: XPath Expression Example 39](#_Toc120387705)

[Figure 23: ClinicalDocument Example 39](#_Toc120387706)

[Figure 24: QDM Element Structure 41](#_Toc120387707)

[Figure 25: Relationship Between QDM, eCQM, and QRDA 42](#_Toc120387708)

[Figure 26: QDM Data Element Representation in a QRDA Category I Instance 44](#_Toc120387709)

[Figure 27: Fully Formed Template in a QRDA Category I Instance 49](#_Toc120387710)

Tables

[Table 1: Contents of the Package 13](#_Toc120387711)

[Table 2: Contexts Table Example—Care Goal (V6) 31](#_Toc120387712)

[Table 3: Constraints Overview Example— Care Goal (V6) 31](#_Toc120387713)

[Table 4: Example Value Set Table (Referral Types) 37](#_Toc120387714)

[Table 5: Example of Duplicate Entries (Same Code in Multiple Value Sets) 43](#_Toc120387715)

[Table 6: Union of Quality Datatypes from eCQM of Interest 47](#_Toc120387716)

[Table 7: QDM HQMF Pattern to QRDA Mapping Table 48](#_Toc120387717)

[Table 8: Key Elements for Determining Data Uniqueness 51](#_Toc120387718)

[Table 9: Placement of Reason (V3) Template for “Medication, Not Discharged” 53](#_Toc120387719)

[Table 10: High-Level Change Log 61](#_Toc120387720)

[Table 11: New Templates 66](#_Toc120387721)

[Table 12: Retired Templates 66](#_Toc120387722)

[Table 13: GS1 UDI Format 69](#_Toc120387723)

[Table 14: Health Industry Business Communications Council (HIBCC) UDI Format 70](#_Toc120387724)

[Table 15: International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) UDI Format 72](#_Toc120387725)

[Table 16: ICCBBA UDI Format for Blood Bags Only 72](#_Toc120387726)

[Table 17: HQMF QDM Template to QRDA Template Mapping Table 73](#_Toc120387727)

[Table 18: QDM Attribute Patterns to CDA Elements in Specific Templates Mapping Table 78](#_Toc120387728)

[Table 19: HQMF QDM Attribute Patterns to QRDA Elements Mapping Table 81](#_Toc120387729)

# Introduction

## Purpose

This two-volume implementation guide (IG) describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for Quality Reporting Document Architecture (QRDA) documents. The National Academy of Medicine, formerly called the Institute of Medicine (IOM), definition of quality is: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”[[1]](#footnote-1) For care quality to be evaluated, it must be standardized and communicated to the appropriate organizations.

QRDA is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data. Quality measurement in health care is complex. Accurate, interpretable data efficiently gathered and communicated is key in correctly assessing that quality care is delivered.

## Audience

The audience for this implementation guide includes software developers and implementers with reporting capabilities within their electronic health record (EHR) systems; developers and analysts in receiving institutions; and local, regional, and national health information exchange networks who wish to create and/or process CDA reporting documents created according to this specification.

## Approach

The approach taken here is consistent with balloted implementation guides for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the Health Level Seven (HL7) Reference Information Model (RIM) defined in the CDA R2 Refined Message Information Model (RMIM). Implementation guides such as this add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

This implementation guide is the QRDA I Release 1 Standard for Trial Use (STU) Release 5.3 (QRDA I R1 STU5.3). The [QRDA Background](#_Background) and [Current Project](#_Current_Project_2) sections describe the development of the STU.

## Organization of the Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing CDA and QRDA, whereas Volume 2 contains normative CDA template definitions for the QRDA Category I (individual patient) report framework and the QDM-Based QRDA in which the patient data entry-level templates are derived from the Quality Data Model (QDM).[[2]](#footnote-2)

### Volume 1 Introductory Material

This document, Volume 1, provides an overview of CDA, summaries of recent changes to the standard, and information on how to understand and use the CDA templates provided in Volume 2.

* **Chapter 1—Introduction**
* **Chapter 2—CDA and QRDA** contains background material on the CDA R2 base standard, a description of the "templated CDA” approach to implementation guide development, and background on QRDA.
* **Chapter 3—Design Considerations** includes descriptions of overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in Volume 2 of this guide.
* **Chapter 4**—**Using This Implementation Guide** describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA 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—QRDA Category I Framework** describes the QRDA Framework and recent changes.
* **Chapter 6—Quality Data Model-Based QRDA** describes the relationship between the QDM, Health Quality Measures Format (HQMF), and QRDA. It also describes the concept of dynamic generation of QDM QRDA documents.
* **Chapter 7—References** lists URLs to standards, documents, and information related to QRDA.
* **Appendices**. The Appendices include a high-level change log, a summary of extensions to CDA R2, a summary of Unique Device Identification (UDI) issuing agency formats, and the HQMF QDM Datatype to QRDA Mapping Tables.

### Volume 2 CDA Templates and Supporting Material

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

* **Chapter 1—Document-Level Templates** defines the US Realm Header (V3) template that applies to the QRDA Document Category I Framework and the QDM-Based QRDA. It defines each of the document types and header constraints specific to each as well as the section-level templates (required and optional) for each.
* **Chapter 2—Section-Level Templates** defines the section templates referenced within the document types. Sections are atomic units and can be reused by future specifications.
* **Chapter 3—Entry-Level Templates** 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. Entries are atomic units and can be reused by future specifications.
* **Chapter 4—Subentry Templates** defines templates for recording facility and transfer location information.
* **Chapter 5—Participation and Other Templates** defines templates for the CDA author participant and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.
* **Chapters 6—**Provide lists of template Ids, value sets, and code systems used in this guide as well as a list of retired templates and a detailed change log.

## Contents of the Package

The following files comprise this implementation guide package.

Table 1: Contents of the Package

|  |  |  |
| --- | --- | --- |
| Filename or folder | Description | Standards Applicability |
| CDAR2\_IG\_QRDA\_I\_R1\_STU5.3\_2021NOV\_Vol1\_2022DEC\_with\_errata.pdf | Implementation Guide Introductory Material | Normative |
| CDAR2\_IG\_QRDA\_I\_R1\_STU5.3\_2021NOV\_Vol2\_2022DEC\_with\_errata.pdf | Implementation Guide Template Library and Supporting Material | Normative |

# CDA AND QRDA

## 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, have the following characteristics:

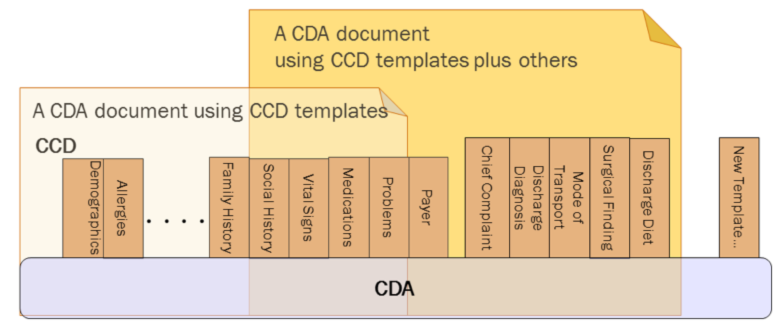
* Persistence
* Stewardship
* Potential for authentication
* Context
* Wholeness
* Human readability

CDA 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.

## Templated CDA

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 is referred to as “templated CDA.” In this approach, a library is created containing modular CDA templates such that the templates can be reused across any number of CDA document types, as shown in the following figure.

Figure 1: Templated CDA



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

* **Document-level templates:** These templates constrain fields in the CDA header and define containment relationships to CDA 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 section and define containment relationships to CDA 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 contain a Systolic Blood Pressure observation.
* **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.
* **Participation and other templates:** These templates group a common set of constraints for reuse in CDA documents. 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 throughout the implementation guide in place of repeating constraints.

A CDA implementation guide (such as this one) includes references to those templates that are applicable. On the implementation side, a CDA instance populates the template identifier (templateId) field where it wants to assert conformance to a given template. On the receiving side, the recipient can not only test the instance for conformance against the CDA Extensible Markup Language (XML) schema, but also test the instance for conformance against asserted templates.

## QRDA Background

In early pilots of the QRDA initiative, participating organizations confirmed the feasibility of using the HL7 CDA as the foundation for the QRDA specification. The participants concluded that CDA provided the technical underpinnings for communicating pediatric and adult quality measures for both inpatient and ambulatory care settings.

In later pilots, the HL7 Child Health Work Group and the Structured Documents Work Group developed a QRDA DSTU, Release 1 (R1), first published in September 2008.

The QRDA DSTU R1 defined three categories of quality reporting: A [QRDA Category I – Single Patient Report](#_QRDA_Category_I), a [QRDA Category II – Patient List Report](#_QRDA_Category_II), and a [QRDA Category III – Calculated Report](#_QRDA_Category_III). The concepts of the report types are described below.

### QRDA Category I – Single Patient Report

A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on. A QRDA Category I report contains raw applicable patient data. When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics.

### QRDA Category II – Patient List Report (retired)

A QRDA Category II report is a multi-patient-level quality report. Each report contains quality data for a set of patients for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on.

Whereas a QRDA Category I report contains only raw applicable patient data, a QRDA Category II report includes flags for each patient indicating whether the patient qualifies for a measure’s numerator, denominator, exclusion, or other aggregate data element. These qualifications can be pooled and counted to create the QRDA Category III report.

QRDA Category II was only a ballot for comment and was never taken through a ballot cycle.

### QRDA Category III – Calculated Report

A QRDA Category III report is an aggregate quality report. Each report contains calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time.

Data needed to generate QRDA Category II and QRDA Category III reports need to be included in the collected QRDA Category I reports, as the processing entity will not have access to additional data sources.

## Relationship to Health Quality Measures Format: eMeasure

The HL7 Health Quality Measures Format (HQMF) is a standard for representing a health quality measure as an electronic document. A quality measure is a quantitative tool that provides an indication of the performance of an individual or organization in relation to a specified process or outcome via the measurement of an action, process, or outcome of clinical care. Quality measures are often derived from clinical guidelines and are designed to determine whether the appropriate care has been provided given a set of clinical criteria and an evidence base. Quality measures are also often referred to as performance measures or quality indicators. A quality measure expressed in HQMF format is referred to as an electronic clinical quality measure, or “eCQM”.

Measure developers, drawing upon available evidence, devise measurable parameters to gauge the quality of care in a particular area. These measurable parameters are assembled into quality measures, which are then expressible as eCQMs. The eCQMs define the information to be retrieved from the EHR data and other data, which are then assembled into QRDA quality reports and submitted to quality or other organizations. This relationship is summarized in the [Overview of Quality Framework](#F_Overview_of_quality_framework) figure.

While there is no prerequisite that a QRDA document must be generated based on an eCQM, the QRDA standard is written to tightly align with HQMF.

Figure 2: Overview of Quality Framework



## Current Project

Since the creation of QRDA Category I R1[[5]](#footnote-5), understanding of the end-to-end electronic quality reporting process has increased. HL7 created a standard for the Health Quality Measures Format (HQMF), also known as “eMeasure.”[[6]](#footnote-6) Using this standard, quality measures are redefined using HL7 RIM semantics, thus expressing the measures using a well-vetted model. The measure fully expressed in HQMF is known as an eCQM. The goal is to enable formally expressed criteria within an eCQM to be converted into queries expressed to retrieve EHR data.

QRDA Category I R2[[7]](#footnote-7) was published in 2012. It simplified the QRDA framework and correlated the QRDA with the HQMF standard.[[8]](#footnote-8) In addition to updating the QRDA Category I DSTU, the QRDA Category I R2 included a specific QRDA Category I DSTU designed to carry data based on Meaningful Use Stage 2 quality measures expressed in HQMF format. The QRDA Category I R2 recommended use of defined CDA templates based on the QDM, the same model used in the construction of Meaningful Use Stage 2 eCQMs. Since the publication of QRDA Category I R2 in 2012, the standard has experienced very rapid adoption. The Meaningful Use Stage 2 rulemaking specifies it as the standard for reporting patient level data for clinical quality measures.[[9]](#footnote-9)

In June 2015, QRDA Category I R1 DSTU 3[[10]](#footnote-10) was published. QRDA Category I R1 DSTU 3 incorporated errata changes approved June 2014 and took that work further. QRDA I R1 DSTU 3 re-used the US Realm Header (V2) from the *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2* (C-CDA R2).[[11]](#footnote-11) The updates of the QRDA Category I R1 DSTU 3 included: updates of templates to align with the Quality Data Model (QDM) version 4.1.2, incorporation of appropriate QRDA Category I Release 2 (R2) DSTU comments that were considered as New Feature Requests, and updates of the QRDA I R1 DSTU3 templates to align with the published C-CDA R2 templates, where applicable.

In April 2016, QRDA Category I R1 DSTU 3.1 was released. QRDA Category I R1 DSTU 3.1 incorporated errata and new feature requests approved since the publication of QRDA Category I R1 DSTU 3. The updates of the QRDA Category I R1 STU 3.1 include updates of templates to align with QDM version 4.2. QDM version 4.2 was published in August 2015. There are many changes between QDM version 4.2 and its predecessor 4.1.2. As a result of these changes QRDA templates were updated and new QRDA templates were created. Shortly after the publication of QRDA Category I DSTU 3, the *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1* (C-CDA R2.1)[[12]](#footnote-12) was published to support “on-the-wire” compatibility with C-CDA R1.1 systems and to include approved errata to C-CDA R2. QRDA I R1 DSTU 3.1 was also updated to reuse the US Realm Header (V3) and C-CDA R2.1 templates where applicable. QRDA Category I R1 STU 4[[13]](#footnote-13), incorporated errata approved since the publication of QRDA Category I R1 DSTU 3.1. The updates of the QRDA Category I R1 STU 4 also include updates of templates to align with QDM version 4.3.

QRDA Category I R1 STU 5 was released in December 2017 and incorporated errata approved since the publication of QRDA Category I R1 STU 4. The updates of the QRDA Category I R1 STU 5 also include template updates to align with QDM version 5.3. QDM 5.3 represents a significant change because the previous QDM logic and mathematical operators were replaced with a new HL7 standard for logic expression, Clinical Quality Language (CQL).[[14]](#footnote-14) QDM 5.3 contains only the conceptual data model used to express the individual data elements. The QDM data model is also modified to more explicitly define the information desired including cardinality and timing details.

QRDA Category 1 R1 STU 5.1 was published in December 2018 to support QDM 5.4 and address the errata approved since the publication of QRDA Category I R1 STU 5. Beginning from the QDM 5.4, QDM specification is used in conjunction with CQL which provides the ability to express logic that is human-readable yet structured enough to electronically processing a query.[[15]](#footnote-15) QDM 5.4 update details can be found in the Change Log of the QDM 5.4 specification. In October 2019, an Errata update to the QRDA Category I R1 STU 5.1 was published.

QRDA Category I R1 STU 5.2 was published in February 2020 to support QDM 5.5 and address the errata approved since the publication of QRDA Category I R1 STU 5.1 and its Errata update. QDM 5.5 update details can be found in the Change Log of the QDM 5.5 specification. An Errata update to STU 5.2 was published in June 2020.

This current update, QRDA Category I R1 STU 5.3 supports QDM 5.6 and address the trackers approved that require changes. QDM 5.6 change details can be found in the Change Log of the QDM 5.6 specification.

This implementation guide is considered as a “Quality Data Model-Based QRDA implementation guide”. Rather than a specific implementation guide for each measure or set of measures, reporting organizations will be able to dynamically generate QRDA instances based on the corresponding eCQM(s). This is described in detail in the [Quality Data Model-Based QRDA](#_Quality_Data_Model) chapter.

The QRDA framework provides guidance such that conformant measure-specific QRDA implementation guides can be developed through the HL7 process, by quality organizations, provider organization, and other quality stakeholder.

## Scope

This implementation guide is a conformance profile, as described in the “Refinement and Localization” section of the *HL7 Version 3 Interoperability Standards*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture, Release 2.0.* This implementation guide does not describe every aspect of CDA. Rather, it defines constraints on the base CDA used in a QRDA document in the US realm. Additional optional CDA elements, not included here, can be included and the result will be compliant with the specifications in this guide.

# Design Considerations

Design considerations describe overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in Volume 2 of this guide.

## Determining a Clinical Statement’s Status

A general recipient requirement is to be able to determine the status of an entry—whether it (a problem, a medication administration, etc.) is active, completed, or in some other state. Often complicating the determination is the interplay between an act’s various components (such as statusCode and effectiveTime), and inconsistent modeling between different objects.

This guide uses general rules for formalizing the representation of an object’s status.

This IG follows the following principles of C-CDA’s approach to status:

* Act.statusCode **specifies the state of the entry**: Per the RIM, the statusCode “reflects the state of the activity. In the case of an Observation, this is the status of the activity of observing, not the status of what is being observed”.
* Act.moodCode **and** Act.statusCode **are inter-related**: Generally, an Observation in EVN (event) mood is a discrete event (you look, listen, measure; you record what you see; you're done), so generally an Observation in EVN mood will have a statusCode of “completed”. An exception is a prolonged period of observation, where potentially you’d have an observation in EVN mood that is “active”. For an Observation in RQO (request) mood, the statusCode generally remains “active” until the request is complete, at which time the statusCode changes to “completed”. For an Observation in GOL (goal) mood, the statusCode generally remains “active” as long as the observation in question is still an active goal for the patient.
* Act.effectiveTime **and** Act.statusCode **are inter-related**: Per the RIM, the effectiveTime, also referred to as the “biologically relevant time”, is the time at which the observation holds for the patient. So, whereas the effectiveTime is the biologically relevant time, the statusCode is the state of the activity. For a provider seeing a patient in the clinic today, observing a history of heart attack that occurred five years ago, the status of the observation is completed, and the effectiveTime is five years ago.

## Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document. An example of this would be a doctor using an EHR that already contains the patient’s name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR’s user interface.

Good practice recommends that the following be present whenever the document is viewed:

* Document title and document dates
* Service and encounter types, and date ranges as appropriate
* Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
* Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
* Date of birth for recordTarget(s)
* Patient identifying information

## Unknown and No Known Information

Information technology solutions store and manage data, but sometimes data are not available. An item may be unknown, not relevant, or not computable or measureable, such as where a patient arrives at an emergency department unconscious and with no identification.

In many cases, the C-CDA standard will stipulate that a piece of information is required (e.g., via a SHALL conformance verb). However, in most of these cases, the standard provides an “out”, allowing the sender to indicate that the information isn’t known.

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types Release 1 specification that accompanies the CDA R2 normative standard. However, it should be noted that the focus of C-CDA R2 is on the unambiguous representation of known data, and that in general, the often subtle nuances of unknown information representation are less relevant to the recipient.

Many fields in C-CDA contain a “@nullFlavor” attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case in which information is unknown. Allowable values for populating the attribute give details about the reason the information is unknown, as shown in the following example.

Figure 3: nullFlavor Example

<birthTime nullFlavor=”UNK”/> <!--Sender does not know the birthTime, but a proper value is applicable -->

Use null flavors for unknown, required, or optional attributes:

NI No information. This is the most general and default null flavor.

NA Not applicable. Known to have no proper value (e.g., last menstrual period for a male).

UNK Unknown. A proper value is applicable, but is not known.

ASKU Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).

NAV Temporarily unavailable. The information is not available, but is expected to be available later.

NASK Not asked. The patient was not asked.

MSK There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.

OTH The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA R2 normative edition.

Any SHALL, SHOULD or MAYconformance statement may use nullFlavor, unless the nullFlavor is explicitly disallowed (e.g., through another conformance statement which includes a SHALL conformance for a vocabulary binding to the @code attribute, or through an explicit SHALL NOT allow use of nullFlavor conformance).

Figure 4: Attribute Required (nullFlavor not allowed)

1. SHALL contain exactly one [1..1] code (CONF:15407).

a. This code SHALL contain exactly one [1..1] @code="11450-4" Problem List   
 (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).

or

2**.** SHALL contain exactly one [1..1] **effectiveTime/@value** (CONF:5256).

Figure 5: Allowed nullFlavors When Element is Required (with xml examples)

1. SHALL contain at least one [1..\*] id

2. SHALL contain exactly one [1..1] code

3. SHALL contain exactly one [1..1] effectiveTime

<entry>

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

<id nullFlavor="**NI**"/>

<code nullFlavor="**OTH**">

<originalText>New Grading system</originalText>

</code>

<statusCode code="completed"/>

<effectiveTime nullFlavor="**UNK**"/>

<value xsi:type="CD" nullFlavor="OTH">

<originalText>Spiculated mass grade 5</originalText>

</value>

</observation>

</entry>

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn’t know an attribute of an act, that attribute can be null.

Figure 6: Unknown Medication Example

1. SHALL contain exactly one [1..1] code

<entry>

**<text>patient was given a medication but I do not know what it was</text>**

<substanceAdministration moodCode="EVN" classCode="SBADM">

<consumable>

<manufacturedProduct>

<manufacturedLabeledDrug>

<code **nullFlavor="NI"**/>

</manufacturedLabeledDrug>

</manufacturedProduct>

</consumable>

</substanceAdministration>

</entry>

2. If the sender doesn’t know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

Figure 7: Unknown Medication Use of Anticoagulant Drug Example

<entry>

<substanceAdministration moodCode="EVN" classCode="SBADM" **nullFlavor="NI">**

**<text>I do not know whether or not patient received an anticoagulant**

**drug</text>**

<consumable>

<manufacturedProduct>

<manufacturedLabeledDrug>

**<code code="81839001" displayName="anticoagulant drug"**

**codeSystem="2.16.840.1.113883.6.96"**

**codeSystemName="SNOMED CT"/>**

</manufacturedLabeledDrug>  
 </manufacturedProduct>  
 </consumable>  
 </substanceAdministration>  
</entry>

3. If the sender wants to state "no known", a negationInd can be used on the corresponding act (substanceAdministration, Procedure, etc.)

Previously, Continuity of Care Document (CCD[[16]](#footnote-16)), IHE, and Health Information Technology Standards Panel (HITSP[[17]](#footnote-17)) recommended using specific codes to assert no known content, for example 160244002 No known allergies or 160245001 No current problems or disability. Specific codes are still allowed; however, use of these codes is not recommended.

These next examples illustrate nuances of representing information in coded fields when information is a negative assertion, for example when it is not the case that the patient has an allergy or when it is not the case that a patient takes a medication. The phrases "no known allergies" or "no known medications" are typically associated with this type of negative assertion.

Figure 8: No Known Medications Example

<entry>

<substanceAdministration moodCode="EVN" classCode="SBADM" **negationInd="true">**

**<text>No known medications</text>**

<consumable>

<manufacturedProduct>

<manufacturedLabeledDrug>

**<code code="410942007" displayName="drug or medication"**

**codeSystem="2.16.840.1.113883.6.96"**

**codeSystemName="SNOMED CT"/>**

</manufacturedLabeledDrug>

</manufacturedProduct>

</consumable>

</substanceAdministration>

</entry>

Figure 9: Value Known, Code for Value Not Known

<entry>

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

…

<value xsi:type="CD" nullFlavor="OTH">

<originalText>Spiculated mass grade 5</originalText>

</value>

</observation>

</entry>

Figure 10: Value Completely Unknown

<entry>

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

…

<value xsi:type="CD" nullFlavor="UNK"/>

</observation>

</entry>

Figure 11: Value Known, Code in Required Code System Not Known But Code from Another Code System is Known

<entry>

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

…

<value xsi:type="CD" nullFlavor="OTH">

<originalText>Spiculated mass grade 5</originalText>

<translation code="129742005" displayName="spiculated lesion"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"/>/>

</value>

</observation>

</entry>

## Asserting an Act Did Not Occur with a Reason

The negationInd attribute, if true, specifies that the act indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). negationInd=**"**true**"** is an acceptable way to make a clinical assertion that something did not occur, for example, “no gestational diabetes”. The QDM attribute Negation Rationale is represented by setting negationInd=**"**true**"** and stating the reason (rationale). A nested reason for the act not being done can be represented through the use of an entryRelationship clinical statement with an actRelationship type of **"**RSON**"** to a Reason (V3) template.

To report a QDM data element that is not done (when negationInd="true") with a reason, such as "Medication Not Administered" with negation rationale attribute indicating it is due to patient reason, the following steps must be followed:

1. Must set the attribute negataionInd="true"
2. If QDM data element in eCQM specification is defined using a value set, for example, ["Medication, Not Ordered": "Warfarin"]:

* Must provide code/[@nullFlavor="NA"]
* Must provide the value set OID instead of a specific code from the value set.
  + Set the code attribute code/sdtc:valueset="[VSAC value set OID]"
  + Use code/originalText for the text description of the concept in the pattern "None of value set: [value set name]"

1. If QDM data element in eCQM specification is defined using direct referenced code[[18]](#footnote-18):
   * Must not provide code/[@nullFlavor="NA"]
   * Must provide the direct referenced code. Set the code attribute code ="[The Direct Referenced Code]"
2. Must provide the reason for negation, such as a medical reason or a patient reason

* Provide an entryRelationship to a Reason (V3) (templateId: 2.16.840.1.113883.10.20.24.3.88:2017-08-01") with an actRelationship type of "RSON" is required. See **Error! Reference source not found.** for more details.

Figure 12 shows a “not done” example for reporting a QDM element that is defined with a direct referenced code. The negationInd=**"**true**"** and the code is the direct referenced code. Figure 13 shows an example of “not done” for reporting a QDM element that is defined with a value set, where the measure intent is to indicate none of the codes from the value set Antibiotic Medications for Pharyngitis was administered.

Figure 12: Not Done Example for QDM Element Defined with a Direct Referenced Code

<!-- QDM Data Type: Intervention, Performed (Intervention not performed,

with Negation Rationale (negationInd="true" and Reason given) -->

<act classCode="ACT" moodCode="EVN" negationInd="true">

<!-- Conforms to C-CDA R2.1 Procedure Activity Act (V2) -->

<templateId root="2.16.840.1.113883.10.20.22.4.12"

extension="2014-06-09" />

<!-- Intervention Performed (V6) -->

<templateId root="2.16.840.1.113883.10.20.24.3.32"

extension="2021-08-01" />

<id root="db734647-fc99-424c-a864-7e3cda82e703" />

<!-- This is an example of negating a Direct Referenced Code -->

<code code="419553002"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="diet education"/>

<statusCode code="completed" />

<effectiveTime value="202108111235"/>

<author>

<templateId root="2.16.840.1.113883.10.20.24.3.155" extension="2019-12-01" />

<time value="201908111235"/>

<assignedAuthor>

<id nullFlavor="NA"/>

</assignedAuthor>

</author>

<!-- QDM Attribute: Reason (V3) -->

<entryRelationship typeCode="RSON">

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

<templateId root="2.16.840.1.113883.10.20.24.3.88"

extension="2017-08-01" />

<code code="77301-0"

codeSystem="2.16.840.1.113883.6.1"

displayName="Reason care action performed or not"

codeSystemName="LOINC" />

<value xsi:type="CD" code="105480006"

codeSystem="2.16.840.1.113883.6.96"

displayName="refusal of treatment by patient"

codeSystemName="SNOMED CT"/>

</observation>

</entryRelationship>

</act>

Figure 13: Not Done Example for QDM Element Defined with Value Set

<!--Medication administered not done,

patient refusal: Drug declined by patient - reason unknown.

No "Antibiotic Medications for Pharyngitis" were administered -->

<substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">

<templateId root="2.16.840.1.113883.10.20.22.4.16" extension="2014-06-09" />

<templateId root="2.16.840.1.113883.10.20.24.3.42" extension="2021-08-01" />

<id root="9a5f4d94-ccad-4d57-80ea-27737545c7ed" />

<statusCode code="completed" />

<effectiveTime value="202108111235"/>

<doseQuantity nullFlavor="NA" />

<consumable>

<manufacturedProduct classCode="MANU">

<!-- Conforms to C-CDA R2.1 Medication Information (V2) -->

<templateId root="2.16.840.1.113883.10.20.22.4.23"

extension="2014-06-09" />

<id root="37bfe02a-3e97-4bd6-9197-bbd0ed0de79e" />

<manufacturedMaterial>

<code nullFlavor="NA"

sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001">

<originalText>

None of value set: Antibiotic Medications for Pharyngitis

</originalText>

</code>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

<author>

<templateId root="2.16.840.1.113883.10.20.24.3.155" extension="2019-12-01" />

<time value="202108111235"/>

<assignedAuthor>

<id nullFlavor="NA"/>

</assignedAuthor>

</author>

</substanceAdministration>

Several QDM data types, including Device Order, Device Recommended, Encounter Order, and Encounter Recommended, are modeled using the Supply or Encounter act[[19]](#footnote-19). However, both the Supply and Encounter act classes in CDA R2 do not support negationInd attribute, hence not supporting the Negation Rationale QDM attribute for these QDM data types. New templates such as Device Order Act were introduced in QRDA R1 STU 3.1 to serve as act wrapper that wrap the templates for these QDM data types to allow the use of negationInd attribute. Figure 14 shows an example of Device Order not done.

Figure 14: Not Done Example – Device Order Not Done (with Value Set)

<act classCode="ACT" moodCode="RQO" negationInd="true">

<templateId root="2.16.840.1.113883.10.20.24.3.130" extension="2021-08-01"/>

<id root="ec8a6ff8-ed4b-4f7e-82c3-e98e58b45de7"/>

<code code="SPLY" codeSystem="2.16.840.1.113883.5.6" displayName="Supply" codeSystemName="ActClass"/>

<entryRelationship typeCode="SUBJ">

<supply classCode="SPLY" moodCode="RQO">

<templateId root="2.16.840.1.113883.10.20.22.4.43" extension="2014-06-09"/>

<!-- Device Order (V6) -->

<templateId root="2.16.840.1.113883.10.20.24.3.9" extension="2021-08-01"/>

<id root="6a8d037d-f144-4071-9d1f-8a92a11dedc6"/>

<statusCode code="active"/>

<author>

<templateId root="2.16.840.1.113883.10.20.24.3.155" extension="2019-12-01" />

<time value="202102101030"/>

<assignedAuthor>

<id nullFlavor="NA"/>

</assignedAuthor>

</author>

<participant typeCode="DEV">

<participantRole classCode="MANU">

<playingDevice classCode="DEV">

<code nullFlavor=”NA”

sdtc:valueSet="2.16.840.1.113883.3.117.1.7.1.230">

<originalText>

None of value set: Venous foot pumps (VFP) SNOMEDCT Value Set

</originalText>

</code>

</playingDevice>

</participantRole>

</participant>

</supply>

</entryRelationship>

<!-- QDM Attribute: Reason -->

<entryRelationship typeCode="RSON">

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

<templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-08-01"/>

<code code="77301-0" codeSystem="2.16.840.1.113883.6.1"

displayName="Reason care action performed or not" codeSystemName="LOINC"/>

<value xsi:type="CD" code="105480006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Refusal of treatment by patient (situation)" />

</observation>

</entryRelationship>

</act>

## Use of UTC Time Zone Offset in Datetimes

If no UTC offset is provided in a datetime, then the provided datetime will be utilized as it is given with no modification (for example, with regards to location). A UTC time zone offset should not be reported in a QRDA Category I document, even if the datetime value is more precise than day, unless one or more of the datetime fields are from different time zones or any datetimes overlap with Daylight Savings time adjustments. In such cases, a UTC offset must be specified everywhere a time component in a datetime field is provided, with the following two exceptions: the effectiveTime element of the Reporting Parameter Act template and birthTime/value.

This IG assumes that datetime fields are reported in accordance with the rules regulating Daylight Savings Time. Certain areas of the United States do not adjust their local time to Daylight Savings Time. Datetimes reported from these areas without a UTC time zone offset while Daylight Savings is in effect in other areas may be inconsistent with what is expected. If no UTC time zone offset is provided, then no offset or daylight saving will be assumed or applied and the given datetime is used.

For example, Daylight Savings took effect in 2019 on March 10 at 2 AM, when the time moved from 1:59 AM to 3 AM. A datetime of March 10, 2019, at 2:15 AM can be valid as a reported local time in locations that do not observe Daylight Savings.

In other instances, when the time is moved back an hour during the return to Standard time, the report could erroneously indicate that an event's starting time is after its ending time. Daylight Savings ceased in 2019 on November 3 at 2 AM, when the time moved from 1:59 AM back to 1 AM. An event could have begun at 1:50 AM in Daylight Savings Time and ended 40 minutes later at 1:30 AM in Standard Time.

In order to provide accurate data a QRDA report must contain the UTC offset for situations in which no UTC offset would lead to a datetime or sequence of events. Failure to include the offset could lead to inaccurate reports.

# Using This Implementation Guide

This chapter describes the rules and formalisms used to constrain the CDA R2.1 standard. It describes the formal representation of CDA 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. This guide further constrains templates in the C-CDA R2.1 standard.

## Conformance Conventions Used in This Guide

### Errata or Enhancements

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

### Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository.[[20]](#footnote-20) 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](#_Open_and_Closed_2). 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:2.16.840.1.113883.10.20.24.3.1:2017-08-01).

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 the template uses.

Table 2: Contexts Table Example—Care Goal (V6)

| Contained By: | Contains: |
| --- | --- |

| Contained By: | Contains: |
| --- | --- |
| [Patient Data Section QDM (V8)](#S_Patient_Data_Section_QDM_V8) (optional) | [Target Outcome (V2)](#E_Target_Outcome_V2) (optional)  [Related To](#SE_Related_To) (optional)  [Entity Care Partner](#SE_Entity_Care_Partner) (optional)  [Entity Patient](#SE_Entity_Patient) (optional)  [Entity Organization](#SE_Entity_Organization) (optional)  [Entity Practitioner](#SE_Entity_Practitioner) (optional)  [Status (V2)](#E_StatusV2) (optional)  [Entity Location](#SE_Entity_Location) (optional) |

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

Table 3: Constraints Overview Example— Care Goal (V6)

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2021-08-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [4509-11245](#C_4509-11245) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [4509-11246](#C_4509-11246) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = GOL |
| @negationInd | 0..0 | SHALL NOT |  | [4509-28040](#C_4509-28040) |  |
| templateId | 1..1 | SHALL |  | [4509-11247](#C_4509-11247) |  |
| @root | 1..1 | SHALL |  | [4509-11248](#C_4509-11248) | 2.16.840.1.113883.10.20.24.3.1 |
| @extension | 1..1 | SHALL |  | [4509-27067](#C_4509-27067) | 2021-08-01 |
| … |  |  |  |  |  |

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 (CONF:81-7899) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31" (CONF: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. The next chapters describe specific aspects of conformance statements—open vs. closed templates, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 15: Constraint Conformance Including "such that it" Syntax Example

***Age Observation***

[observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.31 (open)]

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:81-7613).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:81-7614).
3. SHALL contain exactly one [1..1] templateId (CONF:81-7899) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...

### Template Versioning

A new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published” to indicate the template is unchanged from the previous version 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.

A new version of a template is explicitly linked to the prior version, enabling the automatic generation of the detailed change log found in Volume 2, Chapter 9 “Changes From Previous Version”.

An example of the change log for a versioned template is shown in the following figure. In this example, Care Goal (V5) (2.16.840.1.113883.10.20.24.3.1:2019-12-01) has versioned to Care Goal (V6) (2.16.840.1.113883.10.20.24.3.1:2021-08-01).

Figure 16: Versioned Template Change Log Example

| Change | Old | New |
| --- | --- | --- |
| Name | Care Goal (V5) | Care Goal (V6) |
| Oid | urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2019-12-01 | urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2021-08-01 |
| ... |  |  |
| CONF #: 4509-27067 Modified | SHALL contain exactly one [1..1] @extension="2019-12-01" (CONF:4444-27067). | SHALL contain exactly one [1..1] @extension="2021-08-01" (CONF:4509-27067). |
| ... |  |  |

### Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

There are no closed templates in this guide.

Open templates allow HL7 implementers to develop additional structured content not constrained within this guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

### Conformance Verbs (Keywords)

The keywords shall, should, may, need not, should not, and shall not in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.[[21]](#footnote-21)

* shall: an absolute requirement
* shall not: an absolute prohibition against inclusion
* should/should not: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
* may/need not: truly optional; can be included or omitted as the author decides with no implications

The keyword "shall" allows the use of nullFlavor unless the requirement is on an attribute or the use of nullFlavor is explicitly precluded.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

* 1. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it
     1. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

* 1. It is recommended (**SHOULD**) that the structuredBody contains a component.
     1. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),
     2. **Else if** the component does not exist, the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

* 1. This structuredBody SHALL contain exactly one [1..1] component (CONF:1098-29086) such that it
     1. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

...means that the structuredBody is always required to have a component.

### Cardinality

The cardinality indicator (0..1, 1..1, 1..\*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

* 0..1 zero or one
* 1..1 exactly one
* 1..\* at least one
* 0..\* zero or more
* 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 17: Constraints Format – only one allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777).

a. This participantSHALL contain exactly one [1..1] **@typeCode**="LOC"   
 (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)   
 (CONF:2230).

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

Figure 18: Constraints Format – only one like this allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777) such that it

a. SHALL contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem:

2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

### Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

*Optional* means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..\*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with MAY or SHOULD are both considered "optional" conformances.

*Required* means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n], where m >=1 and n >=m (for example, [1..1] or [1..\*]). In these cases, the element must be present in the instance. Conformance statements formulated with SHALL are required conformances. If an element is required but it is not known, the @nullFlavor attribute must be used. See [Unknown and No Known Information](#_Unknown_and_No).

### Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) used in the binding definitions of template conformance statements do not appear in the XML instance of a CDA document. The definition of the template must be referenced to determine or validate the vocabulary conformance requirements of the template.

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and of coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 19: Binding to a Single Code

2. SHALL contain exactly one [1..1] code (CONF:15403).

a) This code SHALL contain exactly one [1..1] @code="11450-4" Problem List

(CONF:15408).

b) This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1"

(CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF: 31141).

The notation conveys the actual code (11450-4), the code’s displayName (Problem List), the OID of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is “Coded Simple” or “CS”, in which case it is prohibited. The displayName and the codeSystemName are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 20: XML Expression of a Single-Code Binding

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"

displayName="Problem List"

codeSystemName=”LOINC”/>

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 V3 Normative Edition 2010*[[22]](#footnote-22) sections on Abstract Data Types and XML Data Types R1.

When a template uses value set bindings, value set tables are presented below the template or are referenced if they occur elsewhere in the specification. The value set table provides the value set identifier, a description, and a link to the source of the value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a DYNAMIC stability, implementers creating a CDA document must go to the location in the URL to check for the most current version of the value set expansion.

Table 4: Example Value Set Table (Referral Types)

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Referral Types 2.16.840.1.113883.11.20.9.56  A value set of SNOMED-CT codes descending from "3457005" patient referral (procedure).  Value Set Source: <http://vtsl.vetmed.vt.edu/TerminologyMgt/RF2Browser/ISA.cfm?SCT_ConceptID=3457005> | | | |
| Code | Code System | Code System OID | Print Name |
| 44383000 | SNOMED CT | 2.16.840.1.113883.6.96 | Patient referral for consultation |
| 391034007 | SNOMED CT | 2.16.840.1.113883.6.96 | Refer for falls assessment (procedure) |
| 86395003 | SNOMED CT | 2.16.840.1.113883.6.96 | Patient referral for family planning (procedure) |
| 306106002 | SNOMED CT | 2.16.840.1.113883.6.96 | Referral to intensive care service (procedure) |
| 306140002 | SNOMED CT | 2.16.840.1.113883.6.96 | Referral to clinical oncology service (procedure) |
| 396150002 | SNOMED CT | 2.16.840.1.113883.6.96 | Referral for substance abuse (procedure) |
| ... | | | |

### Containment Relationships

Containment constraints between a section and its entry are indirect in this guide, meaning that where a section asserts containment of an entry, that entry can either be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..\*] **entry** (CONF:8647) such that it
   1. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48) (CONF:8801).

the Advance Directive Observation can be a direct child of the section (i.e., section/entry/AdvanceDirectiveObservation) or a further descendent of that section (i.e., section/entry/…/AdvanceDirectiveObservation). Either of these are conformant.

All other containment relationships are direct, for example:

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21" (CONF:7928).

The templateId must be a direct child of the section (i.e., section/templateId).

### Data Types

All data types used in a CDA document are described in the CDA R2 normative edition. All attributes of a data type are allowed unless explicitly prohibited by this specification.

### Document-Level Templates "Properties" Heading

In Volume 2 of this implementation guide, each document-level template has a "Properties" heading for ease of navigation. The Properties heading is an organizational construct, underneath which relevant CDA act-relationships and roles are called out as headings in the document.

## XML Conventions Used in This Guide

### XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[[23]](#footnote-23) in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a monospace font.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a ‘@’) and catenated with a ‘/’ symbol.

Figure 21: XML Document Example

<author>

<assignedAuthor>

...

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

...

</assignedAuthor>

</author>

In the above example, the code attribute of the code could be selected with the XPath expression in the next figure.

Figure 22: XPath Expression Example

author/assignedAuthor/code/@code

### XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this monospace font. XML elements (code, assignedAuthor, etc.) and attribute names (SNOMED CT, 17561000, etc.) also appear in this monospace font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 23: ClinicalDocument Example

<ClinicalDocument xmls="urn:h17-org:v3">

...

</ClinicalDocument>

# QRDA Category I Framework

A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported. A QRDA Category I report contains raw applicable patient data. When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics.

## Measure Section

A Measure Section template contains explicit reference to the measure or measures being reported. The standard allows a QRDA Category I report instance to contain data for any number of measures.

## Reporting Parameters Section

The Reporting Parameters Section provides information about the reporting time interval and may contain other information that provides context for the patient data being reported. The receiving organization may tell the reporting organizations what information is needed in this section.

## Patient Data Section

The Patient Data Section conveys all the patient data elements expected in the measure(s) stated in the Measure Section. A patient data element is information about a particular person (as opposed to a population). Examples include: individual’s test results, individual’s encounter location, and an individual’s date of birth.

In the Quality Data Model-Based QRDA, corresponding template patterns exist for the majority of the QDM Quality Datatypes and Attributes. Where possible, data elements in a QRDA framework instance should be communicated with entry-level templates from the C-CDA R2.1. In many cases these templates will require further constraint to convey the exact data elements required by a measure or set of measures. Data elements should always be sent with a date/time stamp.

# Quality Data Model-Based QRDA

## Introduction

This section introduces the Quality Data Model (QDM), and describes how it is used to construct both QDM-based eCQMs and corresponding QDM-based QRDA documents as defined in this guide.

From HL7's perspective, the QDM is a domain analysis model that defines concepts recurring across quality measures. The figure below illustrates components of the QDM relevant to understanding how that model guides the construction of CDA templates in QRDA documents.

Figure 24: QDM Element Structure



The QDM breaks a concept down into a “QDM Datatype” based on the category (or class) of information and the context (or state) of expected used (Figure 24 shows the example of Medication, Administered), and “QDM Attributes.” The category defines which code system(s) should be used to express the data element (e.g., RxNorm for medications, LOINC for Laboratory Tests). A “QDM Data Element” is the combination of a QDM datatype, the associated value set or direct referenced code, and the desired attributes[[24]](#footnote-24). QDM Attributes represent various metadata associated with the QDM Datatype, such as timing, or category-specific characteristics, as shown above in the Medication, Administered example. Previous versions of QDM required a value set to define every data element. Some value sets contained only a single code. This practice provided an alternate identifier (the value set name) for the code system concept. Beginning with QDM version 5.3, QDM data elements can use either a value set or a single code. The term used for the single code is *direct referenced code*. eCQMs use such direct referenced codes when only one code system concept meets the definition of the QDM data element.

Figure 25 illustrates the relationship between QDM and QRDA (and eCQMs).

Figure 25: Relationship Between QDM, eCQM, and QRDA



QDM datatypes have been manually converted into HL7 Reference Information Model (RIM)-derived XML patterns that, when coupled with value sets or direct referenced codes, become QDM Data Elements that can be used as data criteria within a QDM-based eCQM.

Each QDM datatype pattern is assigned a unique ID, which is present in the eCQM, and which is mapped to a corresponding CDA template.

A QDM data element further constrains a QDM datatype pattern via vocabulary binding to either a value set or a direct referenced code. The linked CDA template can be further constrained through a corresponding value set or a direct referenced code.

The further constraint on a CDA template through value set or direct referenced code provides the ability to define new QDM-based eCQMs (e.g., assign new value sets or direct referenced codes to existing QDM datatypes thereby creating new QDM data elements) without the need to update this guide. In essence, this guide has predefined CDA templates corresponding to QDM datatypes, and it provides a mechanism for referencing arbitrary value sets or direct referenced codes, thereby allowing a QRDA instance to conform to a QDM data element.

Previous releases of the QRDA Category I IG (QRDA I STU R4 and prior) required the value set OID that the code is drawn from (as specified in an eCQM for QDM data elements or QDM attributes) must be reported. This was done by requiring the sdtc:valueSet attribute where the value set binding occurs when creating QRDA templates for QDM data elements. As a result, if the same code is contained by multiple value sets, the same Quality datatype may have to be reported multiple times, each associated with a different value set by assigning sdtc:valueSet attribute’s value a different OID.

For example, the eCQM specification (CMS104v6) for the Discharged on Antithrombotic Therapy measure (STK-10) defines “Encounter, Performed: Non-Elective Inpatient Encounter” using “Non-Elective Inpatient Encounter SNOMEDCT Value Set (2.16.840.1.113883.3.117.1.7.1.424)”, and the eCQM specification (CMS111v6) for the Median Admit Decision Time to ED Departure Time for Admitted Patient (ED-2) defines "Encounter, Performed: Encounter Inpatient" using "Encounter Inpatient SNOMEDCT Value Set (2.16.840.1.113883.3.666.5.307)". The SNOMED CT code 32485007 “Hospital admission (procedure)” is contained in both of these two value sets. As shown in Table 5, this same hospital admission encounter data (the same encounter code, data stamp) from EHR had to be reported twice, each with a different value set. In some cases, this could potentially lead to a large duplication of data in a QRDA Category I report and adds burden to the receiving system for downstream processing.

Table 5: Example of Duplicate Entries (Same Code in Multiple Value Sets)

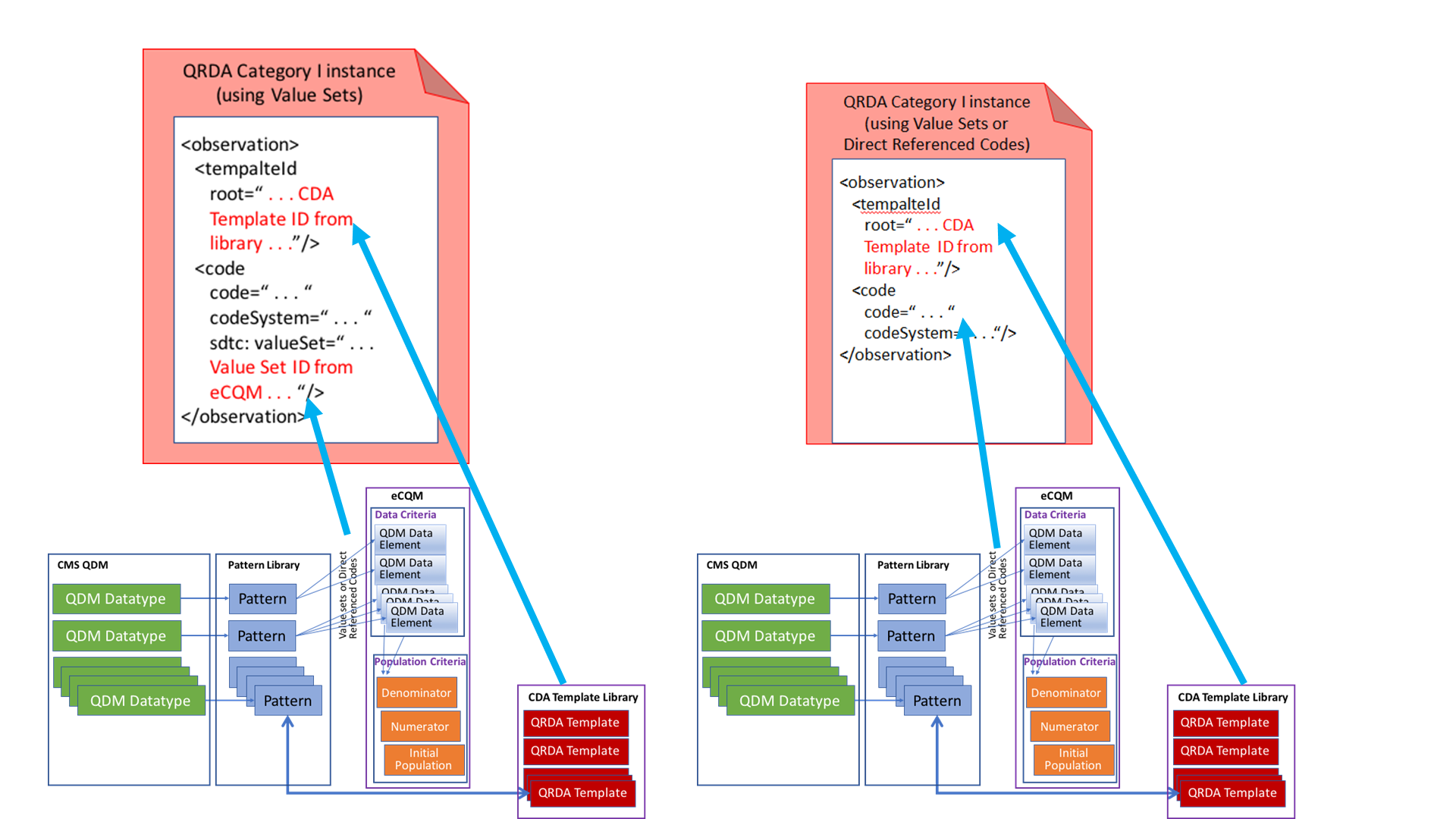
|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **QDM data type** | **Instance Identifier** | **Admission Time** | **Discharge Time** | **Encounter Code** | **Encounter Code Display Name** | **Value Set OID** |
| Encounter Performed | 49741bcc-496d-4b20-bcb6-619e0335342c | 2019-07-24  03:40 | 2019-07-31  12:40 | 32485007 | Hospital admission (procedure) | 2.16.840.1.113883.3.117.1.7.1.424 |
| Encounter Performed | 49741bcc-496d-4b20-bcb6-619e0335342c | 2019-07-24  03:40 | 2019-07-31  12:40 | 32485007 | Hospital admission (procedure) | 2.16.840.1.113883.3.666.5.307 |

Feedback received from the implementation communities is to submit patient data as it exists in the medical record and not duplicated due to eCQM value sets used in the same or different measures within a topic or across topics. Each QDM data element needs to contain all of the attributes required by each measure (e.g., principal diagnosis, discharge status, etc.) that are reported in the same QRDA Category I file. The receiving system will be able to use terminology look up to match which value sets the code belongs to.

Beginning with QDM 5.3, direct referenced codes can be used to describe QDM elements instead of having to create a value set that contains only a single code. For example, eCQM logics can directly reference the SNOMED CT code 4525004 “Emergency department patient visit (procedure)”, and it does not have to create a value set to contain the code 4525005 only. Requiring the sdtc:valueSet be submitted does not support the direct referenced codes use case.

As further described in 6.5.1 Guidance for Ensuring Data Uniqueness, the presence of duplicated data in a QRDA Category I file not only could potentially lead to increased data processing time, but most importantly, might cause incorrect processing and therefore produce unexpected measure results when calculated by other entities. Therefore, beginning from the QRDA Category I R1 STU 5, the constraints that specify SHALL requirement for sdtc:valueSet were removed from the affected templates specified in the Volume 2 of the IG. In addition, sdtc:valueSet must not be provided when report a positive QDM data element, both value sets or direct referenced codes are referenced the same way as depicted in Figure 26. sdtc:valueSet shall only be used in reporting negated QDM data elements to provide the value set OID.

Figure 26: QDM Data Element Representation in a QRDA Category I Instance



This guide describes how to construct a QDM-based QRDA document for any QDM-based eCQM rather than give prescriptive rules for QRDA construction on an eCQM-by-eCQM basis.

## QDM-Based QRDA Category I Construction Rules

This section provides guidelines on when to create QRDA documents and what data to include.

### How Many QRDA Documents Should be Created?

A QDM-based QRDA Category I instance contains data on a single patient for one or more QDM-based eCQMs. Each eCQM for which data is included shall be referenced in a QRDA Measure Section that adheres to the Measure Section QDM template.

As a result of this rule, a QRDA Category I instance may contain data elements for multiple measures, thus it is very important to include date/time stamps for the various objects (e.g., to know that a particular medication was administered during a particular encounter). This guide, therefore, further constrains those CDA templates used elsewhere, such as in C-CDA R2.1, e.g., to require date/time stamps.

### Generate a QRDA for Which Patients?

As noted above, a QDM-based QRDA Category I instance will reference one or more eCQMs in the QRDA Measure Section. Some quality programs may require that a QDM-based QRDA Category I instance reference only those eCQMs for which the corresponding Initial Population (IPOP) criteria have been met. Other quality programs may require that a QDM-based QRDA Category I instance reference a pre-negotiated set of measures.

A QRDA document should be created for each patient meeting the IPOP criteria of at least one of the referenced eCQM(s). No QRDA document should be created for patients that fail to meet any of the IPOP criteria.

Where a QRDA document references multiple measures, the patient should have met at least one of the referenced IPOP criteria. For instance, at a hospital reporting on three acute myocardial infarction measures (AMI-1, AMI-2, AMI-3), where the quality program requires that all three eCQMs be referenced in the QRDA Category I instance, if a patient meets the IPOP for AMI-1, AMI-2, or AMI-3, then a QRDA for that patient will be generated. As described below, that QRDA would contain data for all referenced eCQMs.

Often times, a quality program implementing QRDA will provide prescriptive guidelines that define the exact rules for which eCQMs to reference in a QDM-based QRDA Category I instance or the exact triggers for sending a QRDA document. Where such prescriptive guidelines exist, they take precedence over the more general guidance provided here.

### How Much Data Should be Sent?

QDM-based QRDA adheres to a "scoop and filter" philosophy, whereby data from an EHR are scooped up and filtered, and the remaining content is packaged into the instance.

When the recipient of the instance has access to no other EHR data, it is important that the instance include data elements relevant to computing eCQM criteria, as well as the other data elements defined in an eCQM —for stratification, for risk adjustment, etc. Every data element present in the EHR that is required by the referenced eCQM(s), not just those needed to compute criteria, shall be included in the QRDA document.

The EHR may have more data than are relevant to the referenced eCQM(s) and more data than are needed to compute the criteria. For instance, a patient who has been in the Intensive Care Unit undergoing continuous blood pressure monitoring will have reams of blood pressure observations. QDM-based QRDA adheres to a "smoking gun" philosophy where, at a minimum, the conclusive evidence needed to confirm that a criterion was met shall be included in the instance.

At the very least, the QRDA document should include:

* For each data element in each referenced eCQM, smoking gun data that offer confirmatory proof, where a patient has met the criterion—For disjunctive criteria (i.e., where a criterion can be satisfied by one of multiple data elements) include minimal smoking gun data for at least one data element.
* Stratification variables, supplemental data elements, risk adjustment variables, and any other data element specified in the referenced eCQM(s)

A quality program implementing QRDA will often provide prescriptive guidelines that define additional data, outside the smoking gun, that may or must be sent (such as the complete problem or medication list). Where such prescriptive guidelines exist, those take precedence over the more general guidance provided here. In other words, the “smoking gun” heuristic ensures that the minimum is present in the QRDA, and does not preclude inclusion of additional data.

### What if There are No Data in the EHR?

Not all data elements defined within the referenced eCQM will be present in the EHR for each patient for which a QDM-based QRDA Category I instance is to be sent. Following from the scoop and filter philosophy, a QDM-based QRDA document will not contain data elements that aren't present in the source system. For instance, if an eCQM has a criterion “patient is in the Numerator if they have blue eyes” and the patient doesn't have eye color captured in the source system, then the corresponding QRDA document will not contain an eye color observation for that patient.

Whereas a QDM-based QRDA defines this consistent approach to missing data, the QDM-based eCQM defines the logical processing of missing data (e.g., how to classify a patient into various populations in the absence of an eye color observation). In other words, the eCQM addresses how it factors in missing data when calculating criteria, and it is the job of the QDM-based QRDA to include relevant data that was present in the EHR, and to not include data that was missing from the EHR.

## Generating a QDM-Based QRDA Category I Instance from a QDM-Based eCQM

This guide does not give prescriptive rules for QRDA construction on an eCQM-by-eCQM basis, but rather, describes how to construct a QDM-based QRDA instance for any QDM-based eCQM (eCQMs that are specified using QDM as data models). This section walks through an illustrative QRDA generation process, to illustrate how to construct a QDM-based QRDA for one or more QDM-based eCQMs. Detailed mapping tables, that allow an implementer to figure out which templates to include in a QDM-based QRDA Category I instance based on the criteria and other data elements in a QDM-based eCQM are included in the appendix "[HQMF QDM Datatype to CDA Mapping Tables](#T_HQMF_QDM_Pattern_to_CDA_Template_Mappi)".

Illustrative steps to construct a QDM-based QRDA for a given patient in this scenario:

1. Identify those eCQMs to be included in the QRDA document. List each of these eCQMs in the “Measure Section QDM” section template (identifier urn:oid:2.16.840.1.113883.10.20.24.2.3).
2. For all eCQMs in the “Measure Section QDM” section template, take the union of QDM data elements. Include all data elements, including those needed to calculate population criteria, those needed for stratification, those needed for risk adjustment, etc. You'll wind up with a table, looking something like this:

Table 6: Union of Quality Datatypes from eCQM of Interest

| QDM Element | QDM Datatype HQMF Template ID | Value Set Name / Direct Referenced Code Description | Value Set ID | **Direct Referenced Code – Code System** | Direct Referenced Code |
| --- | --- | --- | --- | --- | --- |
| Diagnosis: Pregnancy | 2.16.840.1.113883.10.20.28.3.110:2021-02-01 | Pregnancy Grouping Value Set | 2.16.840.1.113883.3.526.3.378 | NA | NA |
| Medication, Administered: Aspirin | 2.16.840.1.113883.10.20.28.3.45:2021-02-01 | Aspirin RxNorm Value Set | 2.16.840.1.113883.3.666.5.626 | NA | NA |
| Medication, Administered: Beta Blocker | 2.16.840.1.113883.10.20.28.4.45:2021-02-01 | Beta Blocker Therapy RxNorm Value Set | 2.16.840.1.113883.3.526.3.1174 | NA | NA |
| Assessment, Performed: Patient Health Questionnaire 9 | urn:hl7ii:2.16.840.1.113883.10.20.28.4.117:2021-02-01 | PHQ-9 Direct Referenced Code | NA | LOINC | 70271-2 |

1. For each QDM datatype identified, identify the corresponding QRDA template from this guide. The [HQMF QDM Pattern to QRDA Template Mapping Table](#T_HQMF_QDM_Pattern_to_CDA_Template_Mappi) in the appendix maps from HQMF QDM datatype Template ID to the corresponding QRDA template ID. You'll wind up with a table, looking something like this:

Table 7: QDM HQMF Pattern to QRDA Mapping Table

| QDM Element | QDM Datatype  HQMF Template ID | Value Set Name | Value Set ID | QRDA Template Name | QRDA Template ID |
| --- | --- | --- | --- | --- | --- |
| Diagnosis: Pregnancy | 2.16.840.1.113883.10.20.28.3.110:2021-02-01 | Pregnancy Grouping Value Set | 2.16.840.1.113883.3.526.3.378 | Diagnosis | urn:hl7ii:2.16.840.1.113883.10.20.24.3.137:2021-08-01  2.16.840.1.113883.10.20.24.3.135:2021-08-01 |
| Medication, Administered: Aspirin | 2.16.840.1.113883.10.20.28.3.45:2021-02-01 | Aspirin RxNorm Value Set | 2.16.840.1.113883.3.666.5.626 | Medication Administered | 2.16.840.1.113883.10.20.24.3.42:2021-08-01 |
| Medication, Administered: Beta Blocker | 2.16.840.1.113883.10.20.28.3.45: 2021-02-01 | Beta Blocker Therapy RxNorm Value Set | 2.16.840.1.113883.3.526.3.1174 | Medication Administered | 2.16.840.1.113883.10.20.24.3.42:2021-08-01 |
| … |  |  |  |  |  |
| **QDM Data Element** | QDM datatype  Pattern ID | **Direct Referenced Code Description** | Direct Referenced Code | **CDA Template Name** | **CDA Template Library ID** |
| Assessment, Performed: Patient Health Questionnaire 9 | urn:hl7ii:2.16.840.1.113883.10.20.28.4.117:2021-02-01 | PHQ-9 Depression Scale | 70271-2 | Assessment, Performed | urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2021-08-01 |
| … |  |  |  |  |  |

Given this, an implementer can figure out which QRDA templates to include in a QDM-based QRDA Category I instance, given one or more QDM-based eCQMs.

1. Not all QDM HQMF patterns correspond to QRDA templates. QDM Attributes for instance, map to fields within CDA templates, as shown in the [HQMF QDM Attribute Patterns to QRDA Elements in Specific Templates Mapping Table](#T_Attribute_Patterns_to_CDA_in_Specifict) and the [HQMF QDM Attribute Patterns to QRDA Elements Mapping Table](#T_Attribute_Patterns_to_CDA_Elements). For example, eCQM “Antithrombotic Therapy By End of Hospital Day 2” has a criterion “Diagnosis: Intravenous or Intra arterial Thrombolytic (tPA) Therapy Prior to Arrival,” where the “Diagnosis” QDM datatype maps to the QRDA “Diagnosis” template, diagnosis code is drawn from the value set “Intravenous or Intra arterial Thrombolytic (tPA) Therapy Prior to Arrival”. The resulting instance is illustrated in the following figure.

Figure 27: Fully Formed Template in a QRDA Category I Instance

<!-- Diagnosis: Intravenous or Intra arterial Thrombolytic Therapy Prior to Arrival -->

<act classCode="ACT" moodCode="EVN">

<!-- Problem Concern Act (V3) -->

<templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2015-08-01"/>

<!—Diagnosis Concern Act (V5) -->

<templateId root="2.16.840.1.113883.10.20.24.3.137” extension="2021-08-01"/>

...

<entryRelationship typeCode="SUBJ">

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

<!-- Problem observation (V3) template -->

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

<!—Diagnosis (V4) template -->

**<templateId root="2.16.840.1.113883.10.20.24.3.135" extension=**"**2021-08-01**"**/>**

<id root="2a620155-9d11-439e-92b3-5d9815ff4de8"/>

<code code="29308" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="diagnosis">

<translation code="282291009" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="diagnosis/>

</code>

<statusCode code="completed"/>

<effectiveTime>

<!-- Onset Datetime -->

<low value="20210329090000"/>

</effectiveTime>

<value xsi:type="CD" code="Z92.82"

codeSystem="2.16.840.1.113883.6.90"

codeSystemName="ICD10CM"

displayName="Status post administration of tPA (rtPA)in a different facility within the last 24 hours prior to admission to current facility"/>

</observation>

</entryRelationship>

</act>

## QDM-Based QRDA Category I Instance Validation

The dynamic approach to QDM-based QRDA Category I instance generation, coupled with the construction rules, has implications for instance validation. While the typical Schematron-based validation used in many CDA implementation guides will be applicable here (e.g., if an entry asserts a templateId, then validate that the instance conforms to that template), other types of validation are also made possible by the fact that the QRDA references relevant eCQMs.

Types of validation that can be performed on a QDM-based QRDA Category I instance include:

* Test that where a templateId is asserted, the instance conforms to that template.
* Test that where a code is referenced, the supplied code is a member of the value sets or a direct referenced code specified by the eCQMs.
* Data elements for referenced eCQMs may or may not be present. Absence of data elements from referenced eCQMs does not constitute an error. It would be possible for a validation report to issue warnings, showing which of the data elements from referenced eCQMs are not present in the QRDA.
* Test whether the QRDA contains more data than is required by the referenced eCQMs. This type of test might be necessary, for instance, by federal agencies precluded from receiving data above and beyond that which is absolutely required by an eCQM. It would be possible for a validation report to issue warnings, showing that there are templates (or extensions to open templates) present that aren’t specifically called for by the referenced eCQMs.

A quality program implementing QRDA may provide prescriptive guidelines that define validation criteria. Where such prescriptive guidelines exist, they take precedence over the more general guidance provided here.

## Processing Considerations

### 6.5.1 Guidance for Ensuring Data Uniqueness

The presence of duplicated data in a QRDA Category I file not only could potentially lead to increased data processing time, but most importantly, might cause incorrect processing and therefore produce unexpected measure results when calculated by other entities.

What makes data unique in a QRDA Category I file to ensure data is not treated as duplicate? The id element in a CDA template contains two elemental parts: a root (which must be a Globally Unique Identifier (GUID) or an OID[[25]](#footnote-25)) and an optional extension (which can be any string of characters). If the extension is present, the combination of root plus extension must be globally unique.[[26]](#footnote-26) Identical id for an element refers to the same instance of an event. For example, two HbA1c lab tests for the same patient performed on different occurrences, each test is considered an instance of [“Laboratory Test, Performed”: “HbA1c Laboratory Test”] and each must have a unique id, perhaps with slightly different extensions between the two ids (instances) if their roots are the same. Two entries in a QRDA Category I file from the same QDM data type with the identical ids are considered as duplicates.[[27]](#footnote-27)

Table 8 lists the key elements for determining data uniqueness in a QRDA Category I file. Special consideration should be given to ensure data uniqueness for **inpatient encounters** since it drives the measure processing and outcomes. As shown in Table 8, in addition to the use of the id element, three additional key elements are also used when determining the uniqueness of data for inpatient encounters.

Table 8: Key Elements for Determining Data Uniqueness

| QDM Data Type | Key Elements |
| --- | --- |
| Data types except Encounter | Precondition: same QRDA template   * Id element—combination of @root and @extension (if @extension is present)   + act/id   + observation/id   + procedure/id   + substanceAdministration/id   + supply/id |
| Encounter  containing inpatient code (each episode of care) | Precondition: same QRDA template   * Encounter id element (encounter/id)— combination of @root and @extension (if @extension is present) * Encounter code (encounter/code) * Admission date time (encounter/effectiveTime/low) * Discharge date time (encounter/effectiveTime/high)   Each episode of care (EOC) shall have one unique inpatient encounter id and if there are other types of encounters present (e.g., ED) during the same episode of care, they shall have their own unique encounter ids. If there is data for multiple episodes of care within the same QRDA Category I file, then each episode of care shall have its own unique inpatient encounter id. Should there be another reference to an encounter/EOC in a QRDA Category I file, then users should reference the previously reported encounter id of that inpatient encounter instance or EOC. |
| Other Encounter (Encounter containing codes other than inpatient code) | Precondition: same QRDA template   * Encounter id element (encounter/id)—combination of @root and @extension (if @extension is present) * Encounter code (encounter/code) |

For example, a hospital inadvertently submits a QRDA Category I file to a quality reporting program with two “Encounter, Performed” instances. Both instances have the same encounter id, inpatient encounter code, admission and discharge date times; one instance contains data for principal diagnosis and the other instance contains data for facility location. Because the value of key elements of the two inpatient encounter instances match, the receiving system might consider them duplicate data. Therefore, it is possible that it may choose one of the two encounter instances for measure calculation or discrepancies may occur when merging the two instances, which could lead to unexpected measure results. Therefore, it is important for implementers to ensure that:

* Each reported QDM data element contains all of the attributes (e.g., discharge status, facility location, etc.) required by all measures, which are reported in the file, in the same QRDA template for the same instance.
* Not to duplicate QDM data element by including sdtc:valueset. (Note that sdtc:valueset is still required for Not Done events where attribute negationInd=**"**true**"** and shall only be used when submitting a Not-Done event.)[[28]](#footnote-28)

### 6.5.2 Guidance for Reason Template Placement When Specifying “Not Done” with a Reason

As specified in Section *3.4 Asserting an Act Did Not Occur with a Reason*, for a QDM data element that is not done (indicated by negationInd=**"**true**"**) with a reason, an entryRelationship for a Reason (V3) (templateId: 2.16.840.1.113883.10.20.24.3.88:2017-08-01) is required to specify the reason for the not-done event. Although Reason (V3) is not explicitly contained in every template, it is available for use in any template. The following guidance is provided to clarify the location of the Reason (V3) template when reported for a particular negated QDM data element in a QRDA Category I file to help avoid any potential ambiguities that may lead to unexpected measure results:

The Reason (V3) template (2.16.840.1.113883.10.20.24.3.88:2017-08-01) must be nested directly within the element containing the negationInd attribute.

When a parent template and a child template both allow negation, then the parent template must be negated and contain the Reason (V3) template.

For example, for “Medication, Not Discharged”, the parent Discharge Medication (V6) template (2.16.840.1.113883.10.20.24.3.105:2021-08-01) must have negationInd=**"**true**"** and directly contain the Reason (V3) template indicating reason for medication not discharged as shown in Table 9.

Table 9: Placement of Reason (V3) Template for “Medication, Not Discharged”

| Negated QDM Data Element | QRDA Template | Guidance |
| --- | --- | --- |
| Medication, Not Discharged | Discharge Medication (V6)  (2.16.840.1.113883.10.20.24.3.105:2021-08-01)  Note: Reason (V3) for not done is contained directly within the Discharge Medication (V6) template | XPath for “Medication, Not Discharged” Reason Code:  ../act[templateId/@root="2.16.840.1.113883.10.20.24.3.105"][templateId/@extension="2021-08-01"][@negationInd="true"]/entryRelationship[@typeCode="RSON"]/observation[templateId/@root="2.16.840.1.113883.10.20.24.3.88"][templateId/@extension="2017-08-01"]/value[@xsi:type="CD"]/  **<!-- Discharge Medication(V6)-->**  <act classCode="ACT" moodCode="RQO" negationInd="true">  <templateId root="2.16.840.1.113883.10.20.24.3.105" extension="2021-08-01"/>  <id root="7fb6a7c9-a075-42da-8455-c114273895c0"/>  <code code="75311-1" codeSystem="2.16.840.1.1.113883.6.1" displayName="Discharge medications"/>  **<!-- Medication Activity(V2) -->**  <entryRelationship typeCode="SUBJ">  <substanceAdministration classCode="SBADM" moodCode="EVN">  <templateId root="2.16.840.1.113883.10.20.22.4.16" extension="2014-06-09"/>  ...  </substanceAdministration >  </entryRelationship>  **<!-- Reason(V3) for medication not discharged -->**  <entryRelationship typeCode="RSON">  <observation classCode="OBS" moodCode="EVN">  <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-08-01"/>  <code code="77301-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Reason care action performed or not"/>  <value xsi:type="CD" code="397745006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Medical contraindication (finding)"/>  </observation>  </entryRelationship>  </act> |

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1. Acronyms and Abbreviations

AHIMA American Health Information Management Association

AMA American Medical Association

BCG Bacillus Calmette–Guérin

CCD Continuity of Care Document

C-CDA R1, R1.1, R2, R2.1 Consolidated CDA (Release 1, 1.1, 2, and 2.1)

CCN CMS Certification Number

CCR Continuity of Care Record

CDA, CDA R2 Clinical Document Architecture (Release 2)

CDC Centers for Disease Control and Prevention

CDS clinical decision support

CFR Code of Federal Regulations

CHCA The Child Health Corporation of America

CMS Centers for Medicare and Medicaid Services

CPT Current Procedural Terminology

CQL Clinical Quality Language

CQM clinical quality measure

CVX Codes for Vaccine Administered

DI device identifier

DICOM Digital Imaging and Communications in Medicine

DRIV is derived from

DSTU Draft Standard for Trial Use

ECOG Eastern Cooperative Oncology Group

eCQM electronic clinical quality measure

EEG electroencephalogram

EHR electronic health record

EMR electronic medical record

EVN event

FDA Food and Drug Administration

FIPS Federal Information Processing Standards

GOL goal

HCO health care organization

HCT/P Human Cell & Tissue Products

HIBCC Health Industry Business Communications Council

HIE health information exchange

HIPAA Health Insurance Portability and Accountability Act of 1996

HIT healthcare information technology

HITSP Health Information Technology Standards Panel

HL7 Health Level Seven

HQMF Health Quality Measures Format

HTML Hypertext Markup Language

ICCBBA International Council for Commonality in Blood Banking Automation, Inc.

ICD International Classification of Diseases

IG implementation guide

IHE Integrating the Healthcare Enterprise

IHTSDO International Health Terminology Standard Development Organization

IOM Institute of Medicine

IPOP Initial Population

LOINC Logical Observation Identifiers Names and Codes

MAR Medication Administration Record

MPHO Medical Products of Human Origin

NA not applicable

NCQA National Committee for Quality Assurance

NDC National Drug Code

NDFRT National Drug File Reference Terminology

NHIN Nationwide Health Information Network

NHSN National Healthcare Safety Network

NI no information

NLM National Library of Medicine

NPI National Provider Identifier

NQF National Quality Forum

NUBC National Uniform Billing Committee

NUCC National Uniform Claim Committee

OID object identifier

ONC Office of National Coordinator

OTH not an element in the value domain

PDF Portable Document Format

PGP Pretty Good Privacy

PHIN VADS Public Health Information Network Vocabulary Access and Distribution System

PHR personal health record

PI production identifier

PKCS#7 public-key cryptography standard seven (Cryptographic Message Syntax Standard

PQ physical quantity

QDM Quality Data Model

QRDA Quality Reporting Document Architecture

RFC Request for Comments

RIM Reference Information Model

RMIM Refined Message Information Model

RQO request

RSNA Radiological Society of North America

S&I Standards and Interoperability

sdtc Structured Documents Technical Committee

SDWG Structured Documents Working Group

SNOMED CT Systematized Nomenclature of Medicine, Clinical Terms

SPL Structured Product Labeling

STU Standard for Trial Use

UCUM Unified Code for Units of Measure

UDI Unique Device Identification

UNII Unique Ingredient identifier

UNK unknown

URL uniform resource locator

URN uniform resource name

UUID universally unique identifier

VIS Vaccine Information Statement

vMR Virtual Medical Record

VSAC Value Set Authority Center

XML Extensible Markup language

XML-DSIG XML digital signature

XPath XML Path Language

1. High-Level Change Log

This implementation guide builds on the *HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture Category I (QRDA I); Release 1, STU Release 5.2 - US Realm*, Standard for Trial Use, February 2020, and its June 2020 Errata Update.

Volume 1 Summary of Changes

* Updated languages throughout to reflect that the IG is updated to support the QDM Version 5.6.
* Updated Figures 12 – 14, 16, and 27 to reflect templates updates
* Updated Tables 2, 3, 6, 7, 9 to reflect the templates updates
* Updated Appendix B. Volume 1 Summary of Changes
* Updated Appendix B. Volume 2 Summary of Changes
* Appendix E HQMF QDM Datatype to QRDA Mapping Tables
  + Updated to reflect the HQMF template ids from the HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL) – based Health Quality Measure Format (HQMF) Release 1 – US Realm, STU 4.1, March 2021, Volume 3 – QDM Templates for CQL-based HQMF,*[[29]](#footnote-29)* and the QRDA template ids in this guide (both guides are based on the QDM Version 5.6).

Volume 2 Summary of Changes

General Changes (not specifically stated in tables below)

1. Aligned with QDM Version 5.6 Guidance Update. Summary of the changes made in QDM Version 5.6 can be found in the Section 7.1 QDM 5.6 Changes of the QDM Version 5.6 specification[[30]](#footnote-30).
   1. Removed (retired) QRDA templates where corresponding QDM datatypes or QDM attributes have been removed.
   2. Added QRDA templates where new QDM data types and attributes have been introduced.
   3. Versioned templates and make required modifications to existing QRDA templates.
2. Reasons for templates are versioned include:
   1. Where a modification has been made to the template
   2. Where the implied template has been versioned
   3. Where contained templates have been versioned (Versioning a template at the bottom of a hierarchy causes a bubble-up effect and all the way up the tree, each containing template will need to be versioned.)
3. Where a template has been versioned for this specific STU, a new version number has been suffixed to the name of that template (e.g., Medication Order (V6)), and the extension "2021-08-01" has been added to the template identifier.

To reflect the change to the template identifier, a constraint for templateId/extension="2021-08-01" has been added.

1. Where contained templates have been versioned, references to those templates have been updated.

Summary Tables

For detailed template changes, please reference the Chapter 10. Changes from Previous Version in the Volume 2 of this IG. The tables below describe the high-level changes to the templates.

Table 10: High-Level Change Log

| Type of Template | Template | Summary of New Content or Update to Template |
| --- | --- | --- |
| Document | QDM-Based QRDA (V8) (urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2021-08-01) | * Template has been versioned. * Updated the contained Patient Data Section QDM (V7) to new version (V8). |
|  |  |  |
| Section | Patient Data Section QDM (V8)  (urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2021-08-01) | * Template has been versioned. * Removed references to the Device Applied template (the QDM data type was retired in QDM 5.6) * Changed from referencing the Encounter Performed Act to Encounter Performed (the negationRationale attribute was removed from the Encounter Performed QDM data type in QDM 5.6). |
|  |  |  |
| Entry | Adverse Event (V3)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.146: 2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Allergy Intolerance (V3)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.147:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Assessment Performed (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location * Added interpretationCode for interpretation. |
| Entry | Assessment Order (V3)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.158:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Assessment Recommended (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.145:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Care Goal (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Communication Performed (V3)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.156:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location as sender and recipient respectively. * Corrected the issue with CONF:4444-29163 that is identified in QRDA I STU5.2. The corrected conformance statement is CONF:4509-29163. |
| Entry | Device Order Act (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.130:2021-08-01) | * Template has been versioned (the contained Device Order has a new version). |
| Entry | Device Recommended Act (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.131:2021-08-01) | * Template has been versioned (the contained Device Recommended has a new version). |
| Entry | Diagnosis (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.135:2021-08-01) | * Template has been versioned (template was modified). * Added CONF:4509-28516 to state SHALL contain exactly one value and added a note “QDM Attribute: Code”. This is a clarification. * Updated CONF:4509-28885 to state this template SHALL be contained by Diagnosis Concern Act (V5). |
| Entry | Diagnosis Concern Act (V5)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.137:2021-08-01) | * Template has been versioned (the contained Diagnosis has a new version,) |
| Entry | Diagnostic Study Performed (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.18:2021-08-01) | * Template has been versioned (template was modified). * Updated to support two new QDM attributes of Diagnostic Study Performed   + Added interpretationCode for interpretation   + Added Related To for relatedTo * Added Entity Location. |
| Entry | Diagnostic Study Order (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.17:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Diagnostic Study Recommended (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.19:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Discharge Medication (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location as prescriber and recorder respectively. * Changed to use Author (V2) template for author dateTime |
| Entry | Encounter Performed (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.23:2021-08-01) | * Template has been versioned (template was modified). * Updated to support two new QDM attributes of Encounter Performed   + Added entryRelationship to Encounter Class for class.   + Added Related To for relatedTo * The contained Encounter Diagnosis QDM has a new version. * Added CONF:4509-32546 to state SHALL contain at most one Encounter Diagnosis QDM of rank 1. * Added Entity Location. |
| Entry | Encounter Order Act (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.132:2021-08-01) | * Template has been versioned (the contained Encounter Order has a new version). |
| Entry | Encounter Order (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.22:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Encounter Recommended Act (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.134:2021-08-01) | * Template has been versioned (the contained Encounter Recommended has a new version). |
| Entry | Encounter Recommended (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.24:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Family History Organizer QDM (V5)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.12:2021-08-01) | * Template has been versioned (the contained Family History Observation QDM has a new version). |
| Entry | Family History Observation QDM (V5)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.112:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Immunization Administered (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.140:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Immunization Order (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.143:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Intervention Order (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.31:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Intervention Performed (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.32:2021-08-01) | * Template has been versioned (template was modified). * Added Related To for the new relatedTo QDM attribute. * Added Entity Location. |
| Entry | Intervention Recommended (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.33:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Laboratory Test Performed (V5)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2021-08-01) | * Template has been versioned (template was modified). * Updated to support two new QDM attributes of Laboratory Test Performed   + Added interpretationCode for interpretation.   + Added Related To for relatedTo. * Added Entity Location. |
| Entry | Laboratory Test Order (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.37:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Laboratory Test Recommended (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.39:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Medication Active (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.41:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Medication Administered (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.42:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Medication Dispensed Act (V5)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.139:2021-08-01) | * Template has been versioned (the contained Medication Dispensed has a new version). |
| Entry | Medication Dispensed (V7)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.45:2021-08-01) | * Template has been versioned (template was modified). * Added Related To for the new relatedTo QDM attribute. * Added Entity Location as prescriber and dispenser respectively. |
| Entry | Medication Order (V7)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2021-08-01) | * Template has been versioned (template was modified). * Added Related To for the new relatedTo QDM attribute. * Added Entity Location. |
| Entry | Physical Exam Performed (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.59:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Physical Exam Order (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.58:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Physical Exam Recommended (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.60:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Procedure Performed (V7)  (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.64:2021-08-01) | * Template has been versioned (template was modified). * Added Related To to support the new relatedTo QDM attribute * Added Entity Location. |
| Entry | Procedure Order (V7)  (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.63:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Procedure Recommended (V7)  (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.65:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Provider Care Experience (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.67:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Patient Care Experience (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.67:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Program Participation (V3)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.154:2021-08-01) | * Template has been versioned (template was modified). * Removed Entities. |
| Entry | Substance Recommended (V6)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.75:2021-08-01) | * Template has been versioned (template was modified). * Added Entity Location. |
| Entry | Symptom Concern Act (V5)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.138:2021-08-01) | * Template has been versioned (the contained Symptom has a new version). |
| Entry | Symptom (V4)  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.136:2019-12-01) | * Template has been versioned (template was modified). * Added Entity Location. |

Table 11: New Templates

| Type of Template | Template | Reason for new template |
| --- | --- | --- |
| Entry | Encounter Class  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.171:2021-08-01) | New QDM attribute in QDM Version 5.6. |
| Subentry | Entity Location  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.170:2019-12-01) | New QDM item in QDM Version 5.6. |

Table 12: Retired Templates

| Type of Template | Template | Reason for retirement |
| --- | --- | --- |
| Entry | Device Applied (urn:hl7ii:2.16.840.1.113883.10.20.24.3.7:2021-08-01) | The QDM data type Device Applied was retired in QDM Version 5.6 |
| Entry | Encounter Performed Act  (urn:hl7ii:2.16.840.1.113883.10.20.24.3.133:2021-08-01) | The QDM attribute negationRationale was removed from the Encounter Performed QDM data type in QDM Version 5.6 |

1. Extensions to CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

Extensions created for this guide include:

* sdtc:raceCode - The raceCode extension allows for multiple races to be reported for a patient.
* sdtc:id - The id extension in the family history organizer on the related subject allows for unique identification of the family member(s).
* sdtc:deceasedInd - The deceasedIndextension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
* sdtc:deceasedTime - The deceasedTime extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
* sdtc:birthTime - The sdtc:birthTimeelement allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.
* sdtc:dischargeDispositionCode - The sdtc:dischargeDispositionCode element allows the provider to record a discharge disposition in an encounter activity.
* sdtc:signatureText - The sdtc:signatureText element provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. Details of what goes in the field are described in the *HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1*.[[31]](#footnote-31)

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

* An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
* All extensions are optional. An extension may be used, but need not be under this guide.
* A single namespace for all extension elements or attributes that may be used by this guide will be defined.
* The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdtc.
* This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
* Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
* Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
* An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

1. Unique Device Identification (UDI) Issuing Agency Formats

Each issuing agency has its own specified format for representing the two main components of a UDI – the Device Identifier (DI) and Production Identifiers (PI). The device identifier is a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. The production identifier is the conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device and include: lot or batch within which a device was manufactured; serial number of a specific device; expiration date of a specific device; date a specific device was manufactured; and for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c). The format of each issuing agency’s UDI is outlined in the tables below. These issuing agencies maintain responsibility for the uniqueness of their device identifiers.

Table 13: GS1 UDI Format[[32]](#footnote-32)

| Issuing Agency | Data Delimiters | Identifier | Data type | Human Readable Field Size | Database Field Size |
| --- | --- | --- | --- | --- | --- |
| GS1 | (01) | DI | numeric | 16 | 14 |
| GS1 | (11) | Manufacturing/ Production Date | numeric [YYMMDD] | 8 | 6 |
| GS1 | (17) | Expiration Date | numeric [YYMMDD] | 8 | 6 |
| GS1 | (10) | Batch/Lot Number | alphanumeric | 22 | 20 |
| GS1 | (21) | Serial Number | alphanumeric | 22 | 20 |
| GS1 |  | Maximum Base UDI | alphanumeric | 76 | 66 |
| ex: (01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234 | | | | | |

Table 14: Health Industry Business Communications Council (HIBCC) UDI Format[[33]](#footnote-33)

| Issuing Agency | Data Delimiters | Identifier | Data Type | Human Readable Field Size | Database Field Size |
| --- | --- | --- | --- | --- | --- |
| HIBCC | + | DI | alphanumeric | 7 to 24 | 6 to 23 |
| HIBCC | $ | Lot Number Only | alphanumeric | 19 | 18 |
| HIBCC | $$7 | Lot Number Only (alternative option) | alphanumeric | 21 | 18 |
| HIBCC | $$ | Expiration Date followed by Lot Number | Expiration Date: numeric [MMYY] | 6 | 4 |
| Lot Number: alphanumeric | 18 | 18 |
| HIBCC | $$2 | Expiration Date followed by Lot Number | Expiration Date: numeric [MMDDYY] | 9 | 6 |
| Lot Number: alphanumeric | 18 | 18 |
| HIBCC | $$3 | Expiration Date followed by Lot Number | Expiration Date: numeric [YYMMDD] | 9 | 6 |
| Lot Number: alphanumeric | 18 | 18 |
| HIBCC | $$4 | Expiration Date followed by Lot Number | Expiration Date: numeric [YYMMDDHH] | 11 | 8 |
| Lot Number: alphanumeric | 18 | 18 |
| HIBCC | $$5 | Expiration Date followed by Lot Number | Expiration Date: numeric [YYJJJ] – Julian Date format | 8 | 5 |
| Lot Number: alphanumeric | 18 | 18 |
| HIBCC | $$6 | Expiration Date followed by Lot Number | Expiration Date: numeric [YYJJJHH] – Julian Date format with Hour option | 10 | 7 |
| Lot Number: alphanumeric | 18 | 18 |
| HIBCC | $+ | Serial Number only | alphanumeric | 20 | 18 |
| HIBCC | $$+7 | Serial Number only (alternative option) | alphanumeric | 22 | 18 |
| HIBCC | $$+ | Expiration Date followed by Serial Number | Expiration Date: numeric [MMYY] | 7 | 4 |
| Serial Number: alphanumeric | 18 | 18 |
| HIBCC | $$+2 | Expiration Date followed by Serial Number | Expiration Date: numeric [MMDDYY] | 10 | 6 |
| Serial Number: alphanumeric | 18 | 18 |
| HIBCC | $$+3 | Expiration Date followed by Serial Number | Expiration Date: numeric [YYMMDD] | 10 | 6 |
| Serial Number: alphanumeric | 18 | 18 |
| HIBCC | $$+4 | Expiration Date followed by Serial Number | Expiration Date: numeric [YYMMDDHH] | 12 | 8 |
| Serial Number: alphanumeric | 18 | 18 |
| HIBCC | $$+5 | Expiration Date followed by Serial Number | Expiration Date: numeric [YYJJJ] | 9 | 5 |
| Serial Number: alphanumeric | 18 | 18 |
| HIBCC | $$+6 | Expiration Date followed by Serial Number | Expiration Date: numeric [YYJJJHH] | 11 | 7 |
| Serial Number: alphanumeric | 18 | 18 |
| HIBCC | /S | Supplemental Serial Number, where lot number also required and included in main secondary data string | alphanumeric | 20 | 18 |
| HIBCC | /16D | Manufacturing Date (supplemental to secondary barcode) | numeric [YYYYMMDD] | 12 | 8 |
| HIBCC |  | Maximum Base UDI | alphanumeric | 70 to 87 | 58 to 75 |
| Ex of Human Readable Barcode: +H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ4567890123 45678/16D20130202C | | | | | |

Table 15: International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) UDI Format[[34]](#footnote-34)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Issuing Agency | Data Delimiters | Identifier | Data type | Human Readable Barcode  Field Size | Database Field Size |
| ICCBBA | =/ | DI | alphanumeric | 18 | 16 |
| ICCBBA | =, | Serial Number | alphanumeric | 8 | 6 |
| ICCBBA | = | Donation Identification Number | alphanumeric | 16 | 15 |
| ICCBBA | => | Expiration Date | numeric [YYYJJJ] | 8 | 6 |
| ICCBBA | =} | Manufacturing Date | numeric [YYYJJJ] | 8 | 6 |
| ICCBBA | &,1 | MPHO Lot Number | alphanumeric | 21 | 18 |
| ICCBBA |  | Maximum Base UDI for HCT/Ps | alphanumeric | 79 | 67 |
| Ex of Human Readable Barcode:=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123 | | | | | |

Table 16: ICCBBA UDI Format for Blood Bags Only

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Issuing Agency | Identifying Symbol | Identifier | Data type | Eye Readable Barcode Field Size | Database Field Size |
| ICCBBA | =) | DI for blood containers (bags) | alphanumeric | 12 | 10 |
| ICCBBA | &) | Lot Number for blood containers (bags) | alphanumeric | 12 | 10 |
| ICCBBA |  | Maximum Base UDI for Blood Bags | alphanumeric | 24 | 20 |
| Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678 | | | | | |

1. HQMF QDM Datatype to QRDA Mapping Tables

The [HQMF QDM Pattern to QRDA Template Mapping Table](#T_HQMF_QDM_Pattern_to_CDA_Template_Mappi) provides the name of the QDM quality datatype and its HQMF template ID and maps it to its corresponding QRDA template name and its template ID.

The [HQMF QDM Attribute Patterns to CDA Elements in Specific Templates Mapping Table](#Table16) provides the name of the QDM quality datatype and its HQMF template ID and maps it to the corresponding CDA element within particular templates using XPath notation.

The [HQMF QDM Attribute Patterns to CDA Elements Mapping Table](#T_Attribute_Patterns_to_CDA_Elements) provides the name of the QDM quality datatype and its HQMF pattern ID and maps it to the corresponding CDA element wherever it may be needed using XPath notation.

The QDM allows for an attribute “Negation Rationale” to be used with Quality Datatype Patterns to assert that the act did not occur or was not observed. Please refer to [Asserting an Act Did Not Occur with a Reason](#Asserting_an_Act) for information on how to represent this concept in CDA.

Table 17: HQMF QDM Template to QRDA Template Mapping Table

| QDM Datatype or Attribute Name | HQMF Template ID | QRDA Template Name | QRDA Template ID |
| --- | --- | --- | --- |
| Admission Source (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.123:2017-05-01 | Admission Source | urn:hl7ii:2.16.840.1.113883.10.20.24.3.151:2017-08-01 |
| Adverse Event | urn:hl7ii:2.16.840.1.113883.10.20.28.4.120:2021-02-01 | Adverse Event (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.146:2021-08-01 |
| Allergy / Intolerance | urn:hl7ii:2.16.840.1.113883.10.20.28.4.119: 2021-02-01 | Allergy Intolerance (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.147:2021-08-01 |
| Assessment Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.1312021-02-01 | Assessment Order (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.158:2021-08-01 |
| Assessment, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.117: 2021-02-01 | Assessment Performed (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2021-08-01 |
| Assessment, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.118: 2021-02-01 | Assessment Recommended (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.145:2021-08-01 |
| Care Goal | urn:hl7ii:2.16.840.1.113883.10.20.28.4.7: 2021-02-01 | Care Goal (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2021-08-01 |
| Communication Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.132: 2021-02-01 | Communication Performed (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.156:2021-08-01 |
| Component (attribute) | Component  urn:hl7ii:2.16.840.1.113883.10.20.28.4.121:2017-05-01  Laboratory Test Component  urn:hl7ii:2.16.840.1.113883.10.20.28.4.126:2017-05-01 | Component | urn:hl7ii:2.16.840.1.113883.10.20.24.3.149:2017-08-01 |
| Days Supplied  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.133:2018-05-01 | Days Supplied | urn:hl7ii:2.16.840.1.113883.10.20.24.3.157:2018-10-01 |
| Device, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.15:2021-02-01 | Device Order Act (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.130:2021-08-01 |
| Device, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.16:2021-02-01 | Device Recommended Act (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.131:2021-08-01 |
| Diagnosis | urn:hl7ii:2.16.840.1.113883.10.20.28.4.110:2021-02-01 | [Diagnosis](#E_Diagnosis_Active) Concern Act (V5) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.137:2021-08-01 |
| Diagnostic Study, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.22:2021-02-01 | Diagnostic Study, Order (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.17:2021-08-01 |
| Diagnostic Study, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.23: 2021-02-01 | [Diagnostic Study Performed](#E_Diagnostic_Study_Performed) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.18:2021-08-01 |
| Diagnostic Study, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.24:2021-02-01 | [Diagnostic Study Recommended](#E_Diagnostic_Study_Recommended) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.19:2021-08-01 |
| Encounter, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.27:2021-02-01 | [Encounter Order](#E_Encounter_Order) Act (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.132:2021-08-01 |
| Encounter, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.5:2021-02-01 | [Encounter Performed](#E_Encounter_Performed) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.133:2021-08-01 |
| Encounter, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.28:2021-02-01 | [Encounter Recommended](#E_Encounter_Recommended) Act (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.134:2021-08-01 |
| Entity – Care Partner  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.134:2019-05-01 | Entity Care Partner | urn:hl7ii:2.16.840.1.113883.10.20.24.3.160:2019-12-01 |
| Entity – Organization  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.135:2019-05-01 | Entity Organization | urn:hl7ii:2.16.840.1.113883.10.20.24.3.163:2019-12-01 |
| Entity – Patient  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.136:2019-05-01 | Entity Patient | urn:hl7ii:2.16.840.1.113883.10.20.24.3.161:2019-12-01 |
| Entity – Practitioner  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.137:2019-05-01 | Entity Practitioner | urn:hl7ii:2.16.840.1.113883.10.20.24.3.162:2019-12-01 |
| Entity – Location  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.142:2021-02-01 | Entity Location | urn:hl7ii:2.16.840.1.113883.10.20.24.3.172:2021-08-01 |
| Facility Location (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.92:2017-05-01 | [Facility Location](#Facility_Location) (V2) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.100:2017-08-01 |
| Family History | urn:hl7ii:2.16.840.1.113883. 0.20.28.4.111: 2021-02-01 | Family History Organizer QDM (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.12:2021-08-01 |
| Immunization, Administered | urn:hl7ii:2.16.840.1.113883.10.20.28.4.112: 2021-02-01 | [Immunization Administered](#E_Medication_Administered) (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.140:2021-08-01 |
| Immunization, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.113: 2021-02-01 | Immunization, Order (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.143:2021-08-01 |
| Incision dateTime (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.89:2017-05-01 | [Incision Datetime](#E_Incision_Datetime) | urn:oid:2.16.840.1.113883.10.20.24.3.89 |
| Intervention, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.35:2021-02-01 | [Intervention Order](#E_Intervention_Order) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.31:2021-08-01 |
| Intervention, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.36: 2021-02-01 | [Intervention Performed](#E_Intervention_Performed) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.32:2021-08-01 |
| Intervention, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.37:2021-02-01 | [Intervention Recommended](#E_Intervention_Recommended) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.33:2021-08-01 |
| Laboratory Test, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.41:2021-02-01 | [Laboratory Test Order](#E_Laboratory_Test_Order) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.37:2021-08-01 |
| Laboratory Test, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.42:2021-02-01 | [Laboratory Test Performed](#E_Laboratory_Test_Performed) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2021-08-01 |
| Laboratory Test, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.43: | [Laboratory Test Recommended](#E_Laboratory_Test_Recommended) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.39:2021-08-01 |
| Medication, Active | urn:hl7ii:2.16.840.1.113883.10.20.28.4.44:2021-02-01 | [Medication Active](#E_Medication_Active) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.41:2021-08-01 |
| Medication, Administered | urn:hl7ii:2.16.840.1.113883.10.20.28.4.45:2021-02-01 | [Medication Administered](#E_Medication_Administered) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.42:2021-08-01 |
| Medication, Discharge | urn:hl7ii:2.16.840.1.113883.10.20.28.4.48:2021-02-01 | Discharge Medication (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.105:2021-08-01 |
| Medication, Dispensed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.49:2021-02-01 | [Medication Dispensed](#E_Medication_Dispensed) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.45:2021-08-01 |
| Medication, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.51:2021-02-01 | [Medication Order](#E_Medication_Order) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2021-08-01 |
| Participation | urn:hl7ii:2.16.840.1.113883.10.20.28.4.130:2021-02-01 | Program Participation (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.154:2021-08-01 |
| Patient Care Experience | urn:hl7ii:2.16.840.1.113883.10.20.28.4.52: | [Patient Care Experience](#E_Patient_Care_Experience) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.48:2021-08-01 |
| Patient Characteristic | Patient Characteristic (V2)  urn: hl7ii:2.16.840.1.113883.10.20.28.4.53:2017-08-01 | Patient Characteristic Observation Assertion (V5) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.103:2019-12-01 |
| Patient Characteristic Clinical Trial Participant | urn:hl7ii:2.16.840.1.113883.10.20.28.4.6:2017-05-01 | [Patient Characteristic Clinical Trial Participant](#E_Patient_Characteristic_Clinical_Trial_) (V4) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.51:2017-08-01 |
| Patient Characteristic Expired | urn:hl7ii:2.16.840.1.113883.10.20.28.4.57:2017-05-01 | Patient Characteristic Expired (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.54:2016-02-01 |
| Patient Characteristic Payer | urn:hl7ii:2.16.840.1.113883.10.20.28.4.58:2017-05-01 | [Patient Characteristic Payer](#E_Patient_Characteristic_Payer) | urn:oid:2.16.840.1.113883.10.20.24.3.55 |
| Physical Exam, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.61:2021-02-01 | [Physical Exam Order](#E_Physical_Exam_Order) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.58:2021-08-01 |
| Physical Exam, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.62:2021-02-01 | [Physical Exam Performed](#E_Physical_Exam_Performed) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.59:2021-08-01 |
| Physical Exam, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.63:2021-02-01 | [Physical Exam Recommended](#E_Physical_Exam_Recommended) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.60:2021-08-01 |
| Present On Admission Indicator (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.140: | Present On Admission Indicator | urn:hl7ii:2.16.840.1.113883.10.20.24.3.169:2019-12-01 |
| Procedure, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.66:2021-02-01 | [Procedure Order](#E_Procedure_Order) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.63:2021-08-01 |
| Procedure, Performed | urn:hl7ii:2.16.840.1.113883.10.20.28.4.67:2021-02-01 | [Procedure Performed](#E_Procedure_Performed) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.64:2021-08-01 |
| Procedure, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.68: 2021-02-01 | [Procedure Recommended](#E_Procedure_Recommended) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.65:2021-08-01 |
| Provider Care Experience | urn:hl7ii:2.16.840.1.113883.10.20.28.4.70: 2021-02-01 | [Provider Care Experience](#E_Provider_Care_Experience) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.67:2021-08-01 |
| Rank  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.139:2019-05-01 | Rank | urn:hl7ii:2.16.840.1.113883.10.20.24.3.166:2019-12-01 |
| Reason (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.88:2017-05-01 | [Reason](#E_Reason) (V3) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.88:2017-08-01 |
| Related Person | urn:hl7ii:2.16.840.1.113883.10.20.28.4.141:2019-05-01 | Related Person QDM | urn:hl7ii:2.16.840.1.113883.10.20.24.3.170:2019-12-01 |
| Related To  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.127:2017-08-01 | Related To | urn:hl7ii:2.16.840.1.113883.10.20.24.3.150:2017-08-01 |
| Severity (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.93:2017-08-01 | [Severity Observation](#E_Severity_Observation) (V2) | urn:hl7ii:2.16.840.1.113883.10.20.22.4.8:2014-06-09 |
| Status (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.94:2017-08-01 | [Status](#E_Status) | urn:oid:2.16.840.1.113883.10.20.24.3.93 |
| Substance, Administered | urn:hl7ii:2.16.840.1.113883.10.20.28.4.73: 2021-02-01 | [Medication Administered](#E_Medication_Administered) (V6) | urn: hl7ii:2.16.840.1.113883.10.20.24.3.42:2021-08-01 |
| Substance, Order | urn:hl7ii:2.16.840.1.113883.10.20.28.4.77: 2021-02-01 | [Medication Order](#E_Medication_Order) (V7) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2021-08-01 |
| Substance, Recommended | urn:hl7ii:2.16.840.1.113883.10.20.28.4.78:2021-02-01 | [Substance Recommended](#E_Substance_Recommended) (V6) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.75:2021-08-01 |
| Symptom | urn:hl7ii:2.16.840.1.113883.10.20.28.4.116:2021-02-01 | [Symptom](#E_Symptom_Active) Concern Act (V5) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.138:2021-08-01 |
| Target Outcome  (attribute) | urn:hl7ii:2.16.840.1.113883.10.20.28.4.128:2017-08-01 | Target Outcome (V2) | urn:hl7ii:2.16.840.1.113883.10.20.24.3.119:2017-08-01 |

Table 18: QDM Attribute Patterns to CDA Elements in Specific Templates Mapping Table

| QDM Attribute Name | HQMF Template ID | QRDA Template Name and CDA Element XPath | QRDA Template ID |
| --- | --- | --- | --- |
| Active dateTime (attribute) | N/A | Immunization Order  /../substanceAdministration/effectiveTime/@value | Immunization Order (V4)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.143:2021-08-01 |
| Author dateTime (attribute) | N/A | Author  /…/author/time/@value | Author (V2)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.155:2019-12-01 |
| Class | Encounter Class  urn:hl7ii:2.16.840.1.113883.10.20.28.4.143:2021-02-01 | Encounter Performed  /…/encounter[@templateId="2.16.840.1.113883.10.20.24.3.23"][@extension="2021-08-01"]/entryRelationship/ act[@templateId="2.16.840.1.113883.10.20.24.3.171"][@extension="2021-08-01"]/code | Encounter Class  urn:hl7ii:2.16.840.1.113883.10.20.24.3.171:2021-08-01 |
| Prevalence Period (attribute) | N/A | Allergy Intolerance|  Diagnosis|Symptom  /../observation/effectiveTime/low  /../observation/effectiveTime/high | Allergy Intolerance (V3)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.147:2021-08-01  Diagnosis (V4)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.135:2021-08-01  Symptom (V4)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.136:2021-08-01 |
| Diagnosis  (attribute) | Encounter Diagnosis  urn:hl7ii:2.16.840.1.113883.10.20.28.4.138:2019-05-01 | Encounter Performed  /…/encounter[@templateId="2.16.840.1.113883.10.20.24.3.23"][@extension="2021-08-01"]/entryRelationship/ observation[@templateId="2.16.840.1.113883.10.20.24.3.168"][@extension="2021-08-01"]/value | Encounter Performed (V6)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.23:2021-08-01  Encounter Diagnosis QDM (V2)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.168:2021-08-01 |
| Discharge Disposition (attribute) | N/A | [Encounter Activit](#E_Encounter_Activities)y  /.../encounter[@templateId="2.16.840.1.113883.10.20.24.3.23"][@extension="2021-08-01"]/sdtc:dischargeDispositionCode | Encounter Performed (V6)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.23:2021-08-01 |
| Expiration dateTime  (attribute) | N/A | Patient Characteristic Expired  /.../observation[@templateId="2.16.840.1.113883.10.20.24.3.54"][@extension="2016-02-01"]/effectiveTime/low | Patient Characteristic Expired (V3)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.54:2016-02-01 |
| Location Period (attribute) | N/A | [Facility Location](#Facility_Location) /.../participant/time/low  /.../participant/time/high | Facility Location (V2)  urn: hl7ii:2.16.840.1.113883.10.20.24.3.100:2017-08-01 |
| Reference Range High  (attribute) | Laboratory Test Reference Range  urn:hl7ii:2.16.840.1.113883.10.20.28.4.124:2017-05-01 | Laboratory Test Performed  /../observation[@templateId="2.16.840.1.113883.10.20.24.3.38"][@extension="2021-08-01"]/entryRelationship/ observation[@templateId="2.16.840.1.113883.10.20.24.3.87"][@extension="2019-12-01"]/referenceRange/value | Laboratory Test Performed (V6)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2021-08-01  Result (V4)  urn:hl7ii: 2.16.840.1.113883.10.20.24.3.87:2019-12-01 |
| Reference Range Low  (attribute) | Laboratory Test Reference Range  urn:hl7ii:2.16.840.1.113883.10.20.28.4.124:2017-05-01 | Laboratory Test Performed  /../observation[@templateId="2.16.840.1.113883.10.20.24.3.38"][@extension="2021-08-01"]/entryRelationship/ observation[@templateId="2.16.840.1.113883.10.20.24.3.87"][@extension="2019-12-01"]/referenceRange/value | Laboratory Test Performed (V6)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2021-08-01  Result (V4)  urn:hl7ii: 2.16.840.1.113883.10.20.24.3.87:2019-12-01 |
| Relationships  (attribute) | N/A | Family History  /…/organizer[@templateId="2.16.840.1.113883.10.20.24.3.12"][@extension="2021-08-01"]/subject/relatedSubject/code | Family History Organizer QDM (V6)  urn:hl7ii: 2.16.840.1.113883.10.20.24.3.12:2021-08-01 |
| Related To  (attribute) | Related To  urn:hl7ii:2.16.840.1.113883.10.20.28.4.127:2017-08-01 | Assessment Performed|Care Goal|Communication Performed|Diagnostic Study Performed|Encounter Performed|Laboratory Test Performed|Medication Order|Physical Exam Performed|Procedure Performed  /../sdtc:inFulfillmentOf1/ [sdtc:templateId="2.16.840.1.113883.10.20.24.3.150"][@extension="2017-08-01"]/sdtc:id | Related To  urn:hl7ii:2.16.840.1.113883.10.20.24.3.150:2017-08-01 |
| Result  (attribute) | N/A | Assessment Performed  /../observation[@templateId="2.16.840.1.113883.10.20.24.3.144"][@extension="2021-08-01"]/value  Physical Exam Performed  /../observation [@templateId="2.16.840.1.113883.10.20.24.3.59"][@extension="2021-08-01"]/value | Assessment Performed (V4)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2021-08-01  Physical Exam Performed (V6)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.59:2021-08-01 |
| Result  (attribute) | Result (V2)  urn:hl7ii:2.16.840.1.113883.10.20.28.4.101:2017-08-01 | Intervention Performed|Procedure Performed|  /../observation[@templateId="2.16.840.1.113883.10.20.24.3.87"][@extension="2021-08-01"][@templateId="2.16.840.1.113883.10.20.22.4.2"][@extension="2015-08-01"]/value | Result (V4)  urn:hl7ii: 2.16.840.1.113883.10.20.24.3.87:2019-12-01 |
| Result  (attribute)  Result dateTime  (attribute) | Result (V2)  urn:hl7ii:2.16.840.1.113883.10.20.28.4.101:2017-08-01 | Laboratory Test Performed|Diagnostic Study Performed  /../observation[@templateId="2.16.840.1.113883.10.20.24.3.87"][@extension="2019-12-01"][@templateId="2.16.840.1.113883.10.20.22.4.2"][@extension="2015-08-01"]/value  /../observation[@templateId="2.16.840.1.113883.10.20.24.3.87"][@extension="2019-12-01"][@templateId="2.16.840.1.113883.10.20.22.4.2"][@extension="2015-08-01"]/effectiveTime/@value | Result (V4)  urn:hl7ii: 2.16.840.1.113883.10.20.24.3.87:2019-12-01 |
| Setting  (attribute) | N/A | Medication Order  /../substanceAdministration[@templateId="2.16.840.1.113883.10.20.24.3.47"][@extension="2021-08-01"][/participant[@typeCode="LOC"]/particpantRole/code | Medication Order (V7)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2021-08-01 |
| Supply  (attribute) |  | Medication Order|Substance Order  /../substanceAdministration[@templateId="2.16.840.1.113883.10.20.24.3.47"][@extension="2021-08-01"][/entryRelationship/ supply[@templateId="2.16.840.1.113883.10.20.24.3.99"][@extension="2021-08-01"]/quantity/@value  Immunization Order  /../substanceAdministration[@templateId="2.16.840.1.113883.10.20.24.3.143"][@extension="2021-08-01"][/entryRelationship/ supply[@templateId="2.16.840.1.113883.10.20.24.3.167"][@extension="2021-08-01"]/quantity/@value | Medication Order (V7)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2021-08-01  Immunization Order (V4)  urn:hl7ii:2.16.840.1.113883.10.20.24.3.143:2021-08-01 |

Table 19: HQMF QDM Attribute Patterns to QRDA Elements Mapping Table

| Quality Attribute Name | HQMF Template ID | QRDA Element XPath |
| --- | --- | --- |
| Relevant Period  (attribute) | N/A | /…/**effectiveTime** |
| Anatomical Location Site (attribute) | N/A | targetSiteCode. /.../[observation|procedure]/**targetSiteCode** |
| Dosage  (attribute) | N/A  Or  Dosage  urn:hl7ii:2.16.840.1.113883.10.20.28.4.125:2017-05-01  when used for Medication Dispensed | substanceAdministration/doseQuantity. /.../substanceAdministration/**doseQuantity** |
| Interpretation  (attribute) | N/A | /../interpretationCode |
| Frequency (attribute) | N/A | substanceAdministration/effectiveTime. /.../substanceAdministration/**effectiveTime/period** |
| Method (attribute) | N/A | methodCode. /.../[observation|procedure]/**methodCode** |
| Patient Characteristic Birthdate | urn:hl7ii:2.16.840.1.113883.10.20.28.4.54:2017-05-01  Direct reference code:  LOINC 21112-8 “Birth date” | /ClinicalDocument/recordTarget/patientRole/patient/**birthTime** |
| Patient Characteristic Ethnicity | urn: hl7ii:2.16.840.1.113883.10.20.28.4.56:2017-05-01 | /ClinicalDocument/recordTarget/patientRole/patient/**ethnicGroupCode** |
| Patient Characteristic Race | urn: hl7ii:2.16.840.1.113883.10.20.28.4.59:2017-05-01 | /ClinicalDocument/recordTarget/patientRole/patient/**raceCode** |
| Patient Characteristic Sex | urn:hl7ii:2.16.840.1.113883.10.20.28.4.55:2017-05-01 | /ClinicalDocument/recordTarget/patientRole/patient/**administrativeGenderCode** |
| Refills (attribute) | N/A | repeatNumber. /.../[substanceAdministration|supply]/**repeatNumber** |
| Route  (attribute) | N/A | routeCode. /.../substanceAdministration/**routeCode** |
| Negation Rationale | N/A | /.../@negationInd |

1. "Crossing the Quality Chasm”. <http://www.nationalacademies.org/hmd/Global/News%20Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx> [↑](#footnote-ref-1)
2. Quality Data Model. <https://ecqi.healthit.gov/qdm> [↑](#footnote-ref-2)
3. *HL7 CDA Release 2.* <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7> [↑](#footnote-ref-3)
4. *HL7 V3: Refinement, Constraint and Localization.* <https://www.hl7.org/implement/standards/product_brief.cfm?product_id=76> [↑](#footnote-ref-4)
5. HL7's naming conventions have been changed since these early releases - under today's naming conventions this would have been QRDA Category I Release 1, STU 1 [↑](#footnote-ref-5)
6. *HL7 HQMF R1,* <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97> [↑](#footnote-ref-6)
7. Similar to footnote 5, this would have today been called QRDA Category I Release 1, DSTU 2 [↑](#footnote-ref-7)
8. *HL7 HQMF R2.1,* <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97> [↑](#footnote-ref-8)
9. *HIT: Standards, Implementation Specifications, and Certification Criteria for EHR Technology, 2014 Edition.* <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf> [↑](#footnote-ref-9)
10. Due to the changes to the HL7’s naming conventions, this release is named QRDA Category R1 DSTU 3 instead of QRDA Category I R3. [↑](#footnote-ref-10)
11. HL7 C-CDA R2. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492> [↑](#footnote-ref-11)
12. HL7 C-CDA R2.1 and subsequent Errata. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492> [↑](#footnote-ref-12)
13. Note – The term “Standard for Trial Use” (STU) has replaced Draft Standard for Trial Use (DSTU) at the time of publication of QRDA Category I R1 STU 4. [↑](#footnote-ref-13)
14. Clinical Quality Language, Release 1 STU4. <https://cql.hl7.org/STU4/index.html> [↑](#footnote-ref-14)
15. Quality Data Model, Version 5.6. https://ecqi.healthit.gov/sites/default/files/QDM-v5.6-508.pdf [↑](#footnote-ref-15)
16. *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), Release 1.* http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=6 [↑](#footnote-ref-16)
17. *HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component (HITSP/C32)* .http://www.hitsp.org/ConstructSet\_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32 [↑](#footnote-ref-17)
18. Since QDM Version 5.3, QDM elements can be specified by either binding to value sets or direct referenced codes. [↑](#footnote-ref-18)
19. Note that the negationRationale attribute was removed from the Encounter Performed data type in QDM 5.6, therefore, the Encounter Performed Act template is retired in this guide as the act wrapper is no longer necessary. [↑](#footnote-ref-19)
20. Trifolia Workbench. <https://trifolia.lantanagroup.com/> [↑](#footnote-ref-20)
21. HL7, *Version 3 Publishing Facilitator's Guide.* <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> [↑](#footnote-ref-21)
22. *HL7 Version 3 Interoperability Standards.* <http://www.hl7.org/memonly/downloads/v3edition.cfm> [↑](#footnote-ref-22)
23. W3C, XML Path Language. <http://www.w3.org/TR/xpath/> [↑](#footnote-ref-23)
24. For the purposes of this document, we make reference to QDM Datatypes, and make no further reference to clinical categories or states. [↑](#footnote-ref-24)
25. The root element may also be any string containing only letters and numbers without spaces or other punctuation, but it is more difficult to ensure uniqueness when this option is used than when a GUID or OID is used. [↑](#footnote-ref-25)
26. See the HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1 for guidance on generating unique identifiers. [↑](#footnote-ref-26)
27. Quality Data Model, Version 5.6. <https://ecqi.healthit.gov/sites/default/files/QDM-v5.6-508.pdf>

    Table 29 QDM Attribute Definitions: The identifier of a specific instance of any QDM data element. CQL logic uses the .id reference to specify that a query expects a specific instance of an element to be retrieved. [↑](#footnote-ref-27)
28. As stated in section 6.1, the QRDA Category I IG STU R4 and prior releases required the value set OID which the code is drawn from, by requiring the sdtc:valueSet attribute when creating QRDA templates for QDM data elements. As a result, if the same code is contained by multiple value sets in one or more eCQMs, the same QDM data element may have to be reported multiple times in a QRDA Category I file, and each instance is associated with a different value set by assigning sdtc:valueSet attribute’s value to a different OID. To prevent data duplication, caused by requiring the value set OID to be provided, the SHALL requirement of using sdtc:valueSet has since been removed from the QRDA Category I IG STU 5. [↑](#footnote-ref-28)
29. HL7 CQL-based HQMF IG, STU R4.1 Volume 3 – QDM Templates for CQL-based HQMF, March 2021. [*http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=405*](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=405) [↑](#footnote-ref-29)
30. Quality Data Model, Version 5.6. https://ecqi.healthit.gov/sites/default/files/QDM-v5.6-508.pdf [↑](#footnote-ref-30)
31. *HL7 Digital Signatures.* <http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=131> [↑](#footnote-ref-31)
32. GS1 website. <http://www.gs1.org/> [↑](#footnote-ref-32)
33. HIBCC website. <http://www.hibcc.org/> [↑](#footnote-ref-33)
34. ICCBBA website <http://iccbba.org/> [↑](#footnote-ref-34)