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Standards-based Clinical Data Repository

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Abstract

During the treatment process of a patient the physician usually requests a Laboratory Report (e.g. a blood count) from the laboratory. The delivery of the Laboratory Report is usually performed via fax or letter to the treating physician. The structured laboratory data, which were initially generated by the laboratory, are not available for the physician. Furthermore, the physician has to import the Laboratory Report manually to the Electronic Medical Record (EMR) system. Thus, enabling the electronic data exchange between a laboratory and relevant healthcare providers improves the current treatment processes.

The aim was the connection between a laboratory and an existing distributed Health Information Exchange (HIE), where several healthcare providers are connected to exchange medical documents via the Cross-Enterprise Document Sharing (XDS) profile. A challenge was to perform the integration transparently with existing established exchange mechanisms and interfaces. While the Laboratory Information System (LIS) sends laboratory data via Health Level 7 (HL7) V2 messages over Transmission Control Protocol/Internet Protocol (TCP/IP), the HIE follows the document-based approach, and exchanges documents via XDS transactions over SOAP 1.2.

A Clinical Data Repository (CDR) has been established for the storage and management of the laboratory data as Fast Healthcare Interoperability Resources (FHIR) resources. Furthermore, a Health Service Bus (HSB) has been developed to support the communication between the LIS, the CDR, and the HIE participating systems and components. The Clinical Document Architecture (CDA) standard was used to create a structured laboratory document, which has been exchanged with the participating healthcare providers of the HIE. The HSB integrates translation engines, which are responsible for the mapping from HL7 V2 messages into FHIR resources and further from FHIR resources into CDA documents.

The integration of the laboratory with the HIE was successful. An adequate mapping between the HL7 V2, FHIR, and CDA standards has been specified. Gaps between the particular standards have been identified and if necessary, an extension of the data structure has been defined. FHIR has proven its suitability as a flexible and robust storage format and its ability to provide the appropriate data structure to map laboratory data from HL7 V2 and convert FHIR resources to a CDA document.

Kurzfassung

Während der Behandlung eines Patienten ist es nicht unüblich, dass der behandelnde Arzt eine Laboruntersuchung in Auftrag gibt (z.B. Erstellung eines Blutbildes). Die Übermittlung des Laborbefunds geschieht meist mittels Fax oder per Post. Die strukturierten Labordaten, die vom Labor initial erstellt werden, sind für den Arzt nicht verfügbar. Überdies muss der Arzt den Laborbefund manuell in sein Praxisverwaltungssystem importieren. Der elektronische Datenaustausch zwischen dem Labor und den Gesundheitsdienstleistern stellt somit eine Verbesserung des bisherigen Behandlungsprozesses dar.

Ziel war die Integration eines Labors an einen bestehenden verteilten Health Information Exchange (HIE), in welchem bereits angebundene klinische Systeme einen Dokumentenaustausch mittels Cross-Enterprise Document Sharing (XDS) durchführen. Eine Herausforderung war die Umsetzung einer transparenten Anbindung durch Nutzung der bereits etablierten Mechanismen zum Datenaustausch und der verfügbaren Schnittstellen. Während das Laborinformationssystem (LIS) seine Labordaten mittels Health Level 7 (HL7) V2 Nachrichten über TCP/IP verschickt, folgt der HIE dem dokumentenbasierten Ansatz zum Datenaustausch mittels XDS über SOAP 1.2. Für das Labor wurde ein Clinical Data Repository (CDR) entwickelt und installiert, welches Labordaten mittels Fast Healthcare Interoperability Resources (FHIR) Ressourcen speichert und verwaltet. Außerdem wurde ein Health Service Bus (HSB) entwickelt um die Kommunikation zwischen dem LIS, dem CDR und den am HIE angebundenen Systemen zu unterstützen. Strukturierte Laborbefunde, welche auf dem Clinical Document Architecture (CDA) Standard basieren, konnten erstellt und mit am HIE angebundenen Gesundheitsdienstleistern ausgetauscht werden. Der HSB integriert Übersetzungsservices, welche für die Umwandlung von HL7 V2 Nachrichten in FHIR Ressourcen und in weiterer Folge von FHIR Ressourcen in CDA Dokumente verantwortlich sind.

Die Integration des Labors an den HIE war erfolgreich. Eine adäquate Übersetzung zwischen den Standards HL7 V2, FHIR und CDA konnte spezifiziert werden. Unterschiede zwischen den jeweiligen Standards konnten identifiziert werden und wenn notwendig, wurden Erweiterungen der Datenstrukturen definiert. Der FHIR Standard konnte seine Eignung als flexibles und robustes Speicherformat unter Beweis stellen und hat gezeigt, dass nicht nur Labordaten aus HL7 V2 Nachrichten damit abgebildet werden können, sondern auch, dass aus zusammenhängenden FHIR Ressourcen CDA Dokumente erstellt werden können.

Contents

Index of abbreviations

ACK	General Acknowledgement Message
AD	Address
ADT	Admission, Discharge, Transfer Message
ANSI	American National Standards Institute
API	Application Programming Interface
B	Backwards
BIN	Binary
C	Conditional
CD	Concept Descriptor
CDA	Clinical Document Architecture
CDR	Clinical Data Repository
CDW	Clinical Data Warehouse
CE	Coded Element
CEM	Clinical Element Model
CIS	Clinical Information System
CNN	Composite ID Number And Name Simplified
CO	Coded Ordinal
CQ	Composite Quantity With Units
CS	Coded Simple
CV	Coded Value
CWE	Coded With Exceptions
CX	Extended Composite ID With Check Digit
D-MIM	Domain Message Information Model
DICOM	Digital Imaging and Communications in Medicine
DR	Date/Time Range
DRG	Diagnosis Related Group
DSTU	Draft Standard for Trial Use
DT	data type
ED	Encapsulated Data
EHR	Electronic Health Record
EI	Entity Identifier
EIP	Entity Identifier Pair
EMR	Electronic Medical Record
ERR	Error Segment

ESB Enterprise Service Bus
FHH Family Health History
FHIR Fast Healthcare Interoperability Resources
FN Family Name
FT Formatted Text
FTAM File Transfer, Access and Management
FTP File Transfer Protocol
HAPI HL7 application programming interface
HD Hierarchic Designator
HEGP Georges Pompidou European Hospital
HIE Health Information Exchange
HIS Health Information System
HITSP Health Information Technology Standards Panel
HL7 Health Level 7
HPD Health Provider Directory
HSB Health Service Bus
HTTP Hypertext Transfer Protocol
I2B2 Informatics for Integrating Biology and the Bedside
ID Coded Values For HL7 Defined Tables
IHE Integrating Healthcare in the Enterprise
II Instance Identifier
IS Coded Value For User-Defined Tables
ISO International Organization for Standardization
ITI IT Infrastructure
IVL Interval
JSON JavaScript Object Notation
LIS Laboratory Information System
LIST List
MDM Medical Document Management Message
MIME Multipurpose Internet Mail Extensions
MLLP Minimal Lower Layer Protocol
MSH Message Header
MSA Message Acknowledgment Segment
NDL Name With Location And Data
NM Numeric
NTE Notes and Comments
O Optional
OAuth Open Authorization
OBR Observation Request
OBX Observation
OID Object Identifier
OMI Imaging Order Message
ON Organization Name

ORC Order Common
ORI Imaging Order Acknowledgement Message
ORU Unsolicited Observation Message
OSI Open System Interconnection
PACS Picture Archiving and Communication System
PaLM Pathology and Laboratory Medicine
PID Patient Identification
PN Person Name
PV1 Patient Visit
PV2 Patient Visit - Additional Information
QA Quality Assurance
R Required
R-MIM Refined Message Information Model
RDF Resource Description Framework
REST Representational State Transfer
RIM Reference Information Model
RPC Remote Procedure Call
RT Repeatable
SAD Street Address
SDO Standards Developing Organization
Seq Sequence Number
SFT Software Segment
SOA Service Oriented Architecture
SOAP Simple Object Access Protocol
SPM Specimen
SPS Specimen Source
ST String
STU Standard for Trial Use
TCP/IP Transmission Control Protocol/Internet Protocol
TEL Telecommunications Address
TF Technical Framework
TS Time Stamp
TX Text
UHN University Health Network
UI User Interface
UID Unique Identifier
UML Unified Modeling Language
URI Uniform Resource Identifier
UTHSC University of Tennessee Health Science Center
V2 Version 2
V3 Version 3
XAD Extended Address
XCN Extended Composite ID Number And Name

XDS Cross-Enterprise Document Sharing
XML Extensible Markup Language
XON Extended Composite Name And Identification Number For Organizations
XPN Extended Person Name
XSLT eXtensible Stylesheet Language Transformations
XTN Extended Telecommunication Number

CHAPTER 1

Introduction

1.1 Problem statement

During the treatment process of a patient the physician usually requests a Laboratory Report (e.g. a blood count) from the laboratory. The physician takes a blood sample from the patient and this specimen is delivered to the laboratory. The laboratory analyses the specimen and stores the results in the database of the Laboratory Information System (LIS). The storage format of the structured data is usually a proprietary format. Furthermore, the used codes of the laboratory results are often internal codes, which means that a foreign laboratory is not able to interpret these codes. A Laboratory Report in the PDF format is created by performing the relevant database queries and rendering the laboratory data to a defined document template. The Laboratory Report as PDF is sent via fax or letter to the treating physician. The structured data are not available to the physician. If he/she wants to manage the information of the Laboratory Report, he/she has to import the document manual. The physician's assistant has to scan the Laboratory Report and imports the scanned PDF document to the Electronic Medical Record (EMR) system. If the physician wants to search for specific laboratory results or he/she wants to monitor a specific laboratory value over a defined time frame, this coded information has to be entered manually to the EMR system. The manual management of Laboratory Reports is an additional effort for the physician. For this reason the connection between the LIS and clinical systems would highly support the physicians treatment process.

A German health insurance has developed a Health Information Exchange (HIE), where several medical practices, hospitals and clinics are connected for the purpose of exchanging medical documents. This documents-based approach builds upon the Integrating Healthcare in the Enterprise (IHE) profile Cross-Enterprise Document Sharing (XDS), which facilitates the sharing of clinical documents between disparate clinical systems [1]. XDS provides a framework to store clinical documents indexed by their metadata.
Connecting a laboratory to the HIE would allow the physicians to retrieve the patient's Laboratory Reports directly from the LIS. Structured laboratory data do not get lost. Furthermore

there is no manual management of a Laboratory Report necessary, which reduces the amount of time expended. Moreover the exchange of a structured Laboratory Report document with the participating healthcare providers of the HIE would allow further processing and the analysis of the laboratory data.
For the HIE connection the LIS has to support the XDS interfaces for querying document metadata entries and retrieving documents, but it is only able to exchange laboratory data via Health Level 7 (HL7) V2 messages. Therefore, a solution has to be specified, which enables the connection between the laboratory and the HIE without performing adaptions to the LIS and the participating healthcare providers of the HIE.

1.2 Aim of the work

The central goal of the work is to provide a solution for the connection of a Laboratory Information System (LIS) to a document-based Health Information Exchange (HIE). One important requirement is that the laboratory shall be integrated in the distributed environment in a transparent way, which does not influence the already established document exchange mechanism and uses existing interfaces of the systems. As the HIE only supports the exchange of documents, the laboratory data have to be converted in a suitable document format without losing structured information. This is the reason why the Clinical Document Architecture (CDA) standard is used, which specifies the structure and semantics of clinical documents for the medical information exchange between healthcare providers [2]. Furthermore, a Clinical Data Repository (CDR) has to be developed, which has to store and index the laboratory data as smallest possible reasonable data unit, including the ability to assemble new tailored structured documents in an on-demand manner based on specific query requests. The interface specifications, the implementation and the storage format have to be based on established standards and best practices in healthcare to ensure consistency, reliability, interoperability and sustainability. Both, HL7 V2 and CDA are inefficient storage formats. Hence, the new Fast Healthcare Interoperability Resources (FHIR) standard is used for storing laboratory data in the CDR and querying the data from the CDR. Mapping tables have to be specified for the conversion from a HL7 V2 message into FHIR resources. Furthermore, the mapping from FHIR resources into a CDA document has to be defined. A Health Service Bus (HSB) has to be implemented, which shall support the communication between the CDR and the systems to be connected. It has to receive HL7 V2 messages from the LIS, convert them into FHIR resources based on the previous defined mappings and store them in the CDR. Moreover, the HSB has to process incoming queries or retrieve document requests from the clinical systems connected to the HIE. The requested laboratory data in the form of FHIR resources have to be queried from the CDR. Afterwards the HSB has to convert the FHIR resources into a CDA document and has to return this structured Laboratory Report to the requesting clinical system.
The aim of this architectural approach is to provide a solution, which allows the connection between HL7 V2 sending systems and systems acting as XDS Document Consumer. The specification of the mapping tables and the design of the implementation were driven by the following research questions:

- Is it possible to provide an adequate mapping from HL7 V2 messages into FHIR resources and further from FHIR resources into CDA documents?
- What are the gaps in the structure and semantics between the particular standards and how can the gaps be closed to define adequate mappings?
- What data are lost and how can it be assessed?
- Is it useful to build the whole laboratory use case on open standards?
- Is the intended architecture comprising a CDR and a HSB suitable for the laboratory integration?
- Can this approach be applied to other domains like radiology or pharmacy?

1.3 Methodological approach

Based on the defined research questions an examination of the standards and best practices as well as an identification of their strengths and weaknesses has to be performed. Subsequently an analysis of the HL7 messages has to be conducted, to get an understanding of the sent laboratory data. The analysis results are the base for the HL7 interface definition and the conversion definition from HL7 V2 to FHIR. When the needed FHIR resources and their used data elements are defined, the interface definition and the conversion from FHIR to CDA can be specified. After finalizing the specification, the implementation can be realized. After the software is deployed in the test environment of the distributed clinical environment, a testing phase together with the stakeholder of the laboratory and the clinical systems can start. Finally an evaluation of the developed software and its translation engine is performed.

1.4 Structure of the work

The remaining master thesis consists of the Chapters 2-6 and an appendix. Chapter 2 treats related work as state of the art in the context of clinical data integration in distributed systems and provides insight into the usage of established medical standards. Chapter 3 provides some details on the standards, which are relevant for the implementation of the laboratory connection to the HIE. In Chapter 4 the implementation of the laboratory use case is described and includes the mapping tables for the conversion from HL7 V2 into FHIR and from FHIR into CDA. The Chapter 5 analyses the results of the specified mappings and evaluates if the mappings lead to a big data loss. Furthermore, it exposes problems occurred. Finally the work completes with a conclusion. The appendix contains further details and examples.

CHAPTER 2

Related work

The following Chapter outlines selected papers, which discuss the integration of CDRs in distributed systems and focuses on necessary technical steps to ensure successful implementation of the particular project. Besides that another topic is the connection between different systems and how the technical hurdles are overcome.

2.1 Integration of a Clinical Data Warehouse (CDW) by using HL7 RIM

The University of Virginia had a large project, where the main goal was to exchange disparate biomedical data to support clinical and biologic research [3]. A local academic CDW was used to store clinical data. The clinical data consists of administrative patient information, information about the patient's visits and information created during a visit like diagnosis, laboratory results, procedures, etc. "Clinical data exchange in meaningful ways requires a common syntax, shared vocabularies for unambiguous concept representation and agreement on how concepts are interrelated" [3]. Thus, the HL7 Reference Information Model (RIM) was used for representing the stored data of the CDW [3]. "The Reference Information Model (RIM) is an information model for health care data developed by HL7 International" [4]. "Based on the Unified Modeling Language (UML), the RIM consists of a generic set of classes from which more specific health classes are derived" [4]. To facilitate the information exchange between the CDW and the disparate systems transformation tools had to be developed and utilized to transform between local data schemas and the standards-based conceptual data models. The extracted clinical data from the disparate systems were mapped into the HL7 RIM and afterwards sent to the CDW. "The transmitted Extensible Markup Language (XML) data were parsed and transformed into local terms and structures of the database" [3]. The paper is describing in detail the initial efforts at mapping clinical concepts from a CDW with an underlying relational database to the HL7 RIM as a standardized data model for exchanging clinical data.

2.2 Clinical data integration of distributed systems using HL7 RIM

The University of Tennessee Health Science Center (UTHSC) implemented a prototype for a Health Information Exchange (HIE) to support the meaningful information retrieval among disparate healthcare systems [5]. One of the challenges of health information integration is the lack of a common standard to support mapping across distributed data sources. "Hence, the prototype, which integrated distributed clinical data sources, used Refined Message Information Model (R-MIM) classes from HL7 V3-RIM as a global view along with a collaborative centralized web-based mapping tool to tackle the evolution of both global and local schemas" [5]. The implemented prototype was integrated as plug-in to the clinical data management system. The integrated clinical data consisted of patient administrative data, as well as drug administration information from three data sources, which were built on different underlying database technologies, i.e. Oracle, MySQL and MS Access [5]. R-MIMs were used to model specific case scenarios within the HL7 Version 3 (V3) standard. "Each R-MIM is a subset of the Domain Message Information Model (D-MIM), and D-MIM is a subset of the RIM" [6]. "The R-MIM contains only those classes, attributes, and associations required to compose the specific set of messages or documents" [6]. For each underlying data model of the distributed system a mapping configuration was defined by using the web-based mapping tool. The mapping information for each site has been configured. Afterwards the administrator was able to perform queries against the global data view by usage of a User Interface (UI). After the query has been received the mapping information was consulted and the query was decomposed into sub queries and processed against the global view (HL7 V3-RIM). The requested data consisted of partial retrieved data from the participating sites and were combined to a final result and provided to the user.

2.3 Integration of a Clinical Data Warehouse (CDW) with a clinical information system

At the Georges Pompidou European Hospital (HEGP) in southwest Paris a Clinical Information System (CIS) has been integrated with a CDW [7]. "The CDW facilitates functionality like clinical research, quality evaluations and outcome studies for clinicians" [7]. It is based on the Informatics for Integrating Biology and the Bedside (I2B2) framework and utilizes the five-axis star schema (PATIENT, PROVIDER, VISIT, CONCEPT and OBSERVATION). The integration of the PATIENT, PROVDIER and VISIT was straightforward. As the components of the HEGP CIS structure their data already according to the five axes, the data could be directly extracted and integrated into the I2B2 schema of the CDW. To integrate the CONCEPT and OBSERVATION information to the CDW as well, a mapping had to be implemented, which consisted of two integration steps: 1) a query that returns raw data from the data source, 2) a mapping of the queried data to the I2B2 format. The design and implementation of the integration also included security principles. Therefore, an anonymization of all the patient data, which can identify the patient, were applied [7]. Seven main different data sources were integrated into the CDW, which contained data like laboratory results, drug prescriptions, clinical observations from structured

forms, medical act codes, ICD-10 codes, consultation, and hospitalization text reports from the cardiovascular department and Diagnosis Related Group (DRG) codes.

2.4 Integration of electronic patient record information in a data warehouse solution

"The University Health Network (UHN) comprises three large academic teaching hospitals: Toronto General Hospital, Toronto Western Hospital and Princess Margaret Hospital" [8]. "The three hospitals share clinical information management systems that manage administrative data, process admissions, discharges and transfers, support departmental operations and allow clinicians to enter orders and review results for most diagnostic tests on-line" [8]. UHN carried out a clinical decision support project for retrieving data from the electronic patient record and creating an analytical Clinical Data Warehouse (CDW) [8]. "Transactional data from the electronic patient record were converted into HL7 messages and afterwards exported via an interface engine" [8]. The HL7 messages were combined to one file one a day. The file, which contains the HL7 messages, was transferred via FTP from the interface engine into the CDW. The data were now used for administrative and clinical decision support. Simple analyses could be performed directly with the CDW. Additionally external analytical programs such as SPSS and SAS or reporting tools as Crystal Reports were utilized in combination with the CDW [8, 9].

2.5 The Health Service Bus (HSB): An architecture and case study in achieving interoperability in healthcare

A prototype HSB was implemented to demonstrate a solution for the three hierarchic levels of interoperability in healthcare [10]. The HSB represents an interoperability framework and is based on the Enterprise Service Bus (ESB) middleware software architecture, which provides a loosely-coupled, highly distributed approach to enterprise integration [10].
The interoperability levels are the following [10]:

- **Technical interoperability:** "It addresses the communication of data between different applications of systems over a network" [10]. The HSB is built on a messaging core and provides one of the best solutions for this problem.
- **Semantic interoperability:** It deals with the problem that a sender transmits data to a receiver and both have the same understanding of the information in association with its context [10].
- **Process interoperability:** "It refers to social or workflow engineering aspects of interoperability" [10].

A prototype HSB implementation was set up using the Mule Open-Source ESB and comprised the following features and services connected to the bus [10]:

- **Translation service:** This service provides the ability to map between different health standards (HL7 Version 2 (V2), HL7 V3 and OpenEHR) by usage of eXtensible Stylesheet Language Transformations (XSLT) stylesheets.
- **SNOMED CT service:** This service integrates a terminology service, which loads its terminology from XML files. For this reason a subset of the SNOMED CT terminology was converted to XML.
- **Email drop service:** This service connects to a SMTP and is automatically sending emails to a designated mail address when errors occur. The other services on the HSB are using this service for error notification.
- **Content-based router:** A content-based router examines the contents of a message and routes the messages based on the specific information.
- **Patient records in the HSB:** The HSB includes an XML-based database in which patient records are stored in the OpenEHR format. The HSB receives the information in HL7 V3 format. The integrated translation service maps the HL7 V3 message into the OpenEHR format for storage in the database.

The small proof-of-concept demonstrated that the ESB is a powerful technology for standards-based integration and communication in healthcare [10]. It proved that the HSB using Mule ESB Open-Source software achieved all three levels of interoperability and has the potential to be adapted to a larger industry-based solution [10].

2.6 Profiling Fast Healthcare Interoperability Resources (FHIR) of family health history based on the clinical elements models

"Intermountain Healthcare is a not-for-profit, community-oriented organization based on Salt Lake City in Urah and operates 22 hospitals and more than 185 clinicls throughout the regions" [11]. Furthermore, it provides a web-based Family Health History (FHH) collection tool named OurFamilyHealth and shall allow patients to enter FHH data by building a graphical family pedigree and assign detailed demographic, disease histories and health behavior to specific members in their history [11]. FHH is an important input for diagnosis and risk assessment in clinical genetics. OurFamilyHealth only collects patient's FHH and does not integrate a decision support function. A connection between an external risk assessment service such as HughesRiskService was planned. Furthermore, OurFamilyHealth does not provide any interfaces to exchange data between other applications such as Cerner's CDR. For that reason a profile that consists of FHIR resources, which covers the essential FHH data, has been developed. A gap analysis between the FHH Clinical Element Model (CEM) elements, which are previously used to represent the FHH information, and the existing FHIR resources has been performed. The following categories have been identified from the gap analysis [11]:

- **Exact match:** concept of data elements are the same compared to data types and value sets

- **Mapping required:** race and ethnicity in the two domains have the same concepts, but different value sets, which makes a mapping necessary.
- **Reasoning required:** e.g. inferring a family member's adoption status in his/her family from a HL7 relationship code of the person and proband.
- **Type conversion:** age in years can be calculated from date of birth.
- **No match:** existing FHIR resources do not cover specific information, which require the definition of an extension or additional FHIR Observation resources.

"The specified FHIR profile has been implemented using the HL7 application programming interface (HAPI) framework, an open source based Java library for creating and validating FHIR messages" [11]. The FHH data is stored in XML in the database of the OurFamilyHealth. This empirical patient data are extracted and decomposed as Java objects. Afterwards the FHIR resources represented in the XML format are created out of these Java objects. The specified profile was successfully implemented and was the first step to connect OurFamilyHealth with the risk assessment service HughesRiskApp.

2.7 Patient-centered radiology with FHIR: an introduction to the use of FHIR to offer radiology a clinically integrated platform

"The typical radiology interpretation process often starts with viewing images without reading supporting clinical information to avoid framing bias" [12]. After the initial review the radiologist searches in the EMR for a patient's history of present illness, medical history, laboratory reports and other relevant medical information [12]. Therefor the radiologist usually has to open and authenticate with an additional software, where he/she has to search for the patient and his/her medical record. The reason is that there is often no integration between the Picture Archiving and Communication System (PACS) and the EMR. This missing integration is time-consuming and in the worst case important information may be missed or may be taken out of context. The fact is that if radiologists have access to relevant information of the patient, this can improve value of patient care.
The relevant EMR data can be integrated into the clinical workflow of a radiologist by using the new FHIR standard in combination with Representational State Transfer (REST) [12]. "It is an interoperability standard developed by HL7 and functions as an Application Programming Interface (API) for developers to access needed clinical information" [12]. Its service-oriented approach provides the ability to formulate queries with specific query arguments, which allow the access of definite data [12].
The FHIR DiagnosticOrder resource contains the orders placed by clinicians for imaging studies and can be used to generate worklists [12]. Furthermore, it is possible to use query arguments to get a filtered view of worklist entries. The FHIR DiagnosticOrder resource contains a reference to a FHIR Practitioner resource who ordered the study. This resource provides information about the clinician and his/her contact information. The FHIR Patient resource contains information about the patient like demographics, gender, date of birth, contact information, etc. Furthermore,

most resources contain an element called “subject” or “patient”, which references to the patient resource. Laboratory results are stored in the FHIR Observation resource. Details about allergies of the patient can be found in the FHIR AllergyIntolerance resource.
The following sample queries can provide relevant data from the EMR system [12]:

- <FHIR-Server-HTTP-URL>/DiagnosticOrder
  This query displays the results of all FHIR DignosticOrders.
- <FHIR-Server-HTTP-URL>/DiagnosticOrder?status=requested&code=24627-2
  The query provides all requested orders with the LOINC code “24627-2” for a CT chest.
- <FHIR-Server-HTTP-URL>/Observation?patient=123&code=2160-0
  This query returns the FHIR Observations with the LOINC code “creatinine” for the patient with the identifier “123”.
- <FHIR-Server-HTTP-URL>/Practitioner/5144
  The query provides the FHIR Practitioner with the identifier “5144”.

The combination of using the FHIR standard and API tools like DICOMWeb enable the integration of relevant clinical information from EMR systems to clinical workflows [12].

CHAPTER 3

Fundamentals

Since the purpose of this work is the storage of laboratory data in a CDR and the connection of the CDR to a distributed document-driven Health Information Exchange (HIE), the following sections provide an overview of the used standards. First of all the Health Level 7 (HL7) V2 standard is examined as this is the most commonly used messaging standard by the laboratory to provide laboratory data to external systems. HL7 V2 builds on the EDIFACT standard and is a global standard and international-wide in use [13]. It was initially designed in the 1980s and is not suited to match the demands of state-of-the-art IT architectures.
For this reason HL7 started the design of a follow-up-standard for health data sharing and processing. The result was the FHIR standard, which was initially published in 2014 [14]. The new FHIR standard is used to store and manage the laboratory data in the smallest, reasonable data units for exchange, also called FHIR resource [15]. Moreover, it integrates modern web-based communication technologies like Representational State Transfer (REST), which provides easy and fast access to resources combined with extensive filtering possibilities by usage of query arguments [15].
Finally the CDR has to be connected to the HIE, which uses Cross-Enterprise Document Sharing (XDS) as document exchange mechanism. XDS specifies services and Simple Object Access Protocol (SOAP) interfaces for the purpose of document sharing. As the XDS does not specify any document content restriction, it would be possible to return the appropriate FHIR resources, when a clinical system as a Document Consumer requests for a specific Laboratory Report. This would not be useful for the intended purpose as the requesting clinical system has to display the received FHIR resources in a human-readable structure and form. This would require the clinical system to implement a displaying functionality for FHIR resources. Each new clinical system, which participates in the HIE, would have to implement such a functionality. However, the CDR has to be connected to the distributed environment in a transparent way, so that already connected systems do not have to implement new functionality or interfaces. For this reason the Clinical Document Architecture (CDA) standard is used to exchange the laboratory data over XDS transactions, as this data structure represents a structured clinical document and this format is well-known by clinical systems and usually can be displayed in a human-readable

structure and form. Furthermore, IHE developed an implementation guideline for the creation of a CDA-based Clinical Laboratory Report, which fits very well the requirements and needs of structuring laboratory data for healthcare providers and patients.
Figure 3.1 illustrates the interoperability problems of the connection between the laboratory and the HIE. The missing technical interoperability prevents the communication between the particular systems and services. The LIS is only able to send data over Transmission Control Protocol/Internet Protocol (TCP/IP). While the FHIR-based CDR is only able to process REST requests. Participating systems of the HIE exchange documents through XDS transactions over SOAP 1.2. Furthermore, the LIS transports the structured laboratory data as part of a HL7 V2 message. The CDR stores, manages and exchanges the data in the form of FHIR resources. The participating systems of the HIE expect to receive a structured document in the form of CDA. These different data formats lead to a semantic interoperability problem.

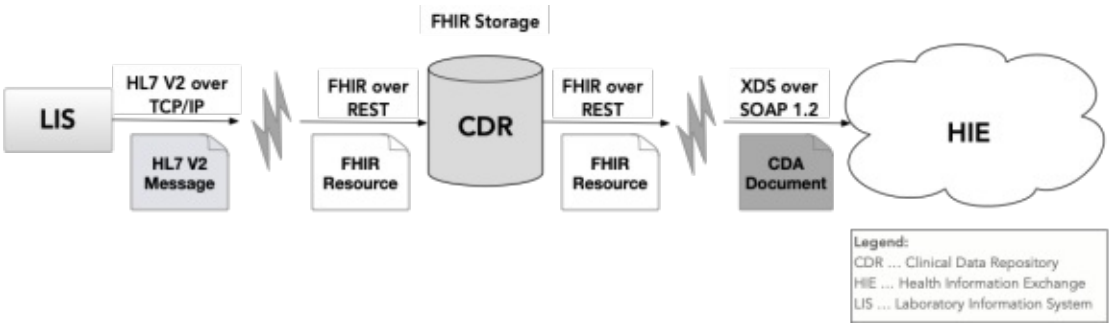

Figure 3.1: Interoperability problems of the connection between the laboratory and the HIE

The following subsections provide answers to the following questions:

1. **How is the basic framework of the particular standard structured?**
   The answer to this question provides a basic understanding of the standard and is necessary for the upcoming mapping from one data structure into the other one. Furthermore, it has to be examined, if the FHIR standard is flexible enough to reconstruct the information of a HL7 V2 message. Moreover, the standard has to facilitate the assembly of related FHIR resources to construct a whole CDA document.

2. **Is the data structure extensible?**
   Each HL7 V2 message, sent by the laboratory, represents a laboratory report. The laboratory defines, which information is relevant and has to be transmitted to the CDR, which stores this information. Afterwards the CDR has to return this information to requesting systems. If one of the used standards is not able to embed the relevant laboratory data, there must be a way to extend the data structure.

3. **Which transport mechanisms are defined for the particular standard?**
   For the interface specification it is necessary to know how the HL7 V2 message is transmitted. Furthermore, the defined transport mechanisms of the FHIR standard have an impact

on the CDR interfaces. Any restrictions and limitations on the transport mechanisms have to be considered in the interface specification. The goal is the definition of a solution for the recently described technical interoperability problems between the particular systems.

4. **What are the strengths and weaknesses of the particular standard?**
   The answer to the last question provides the strong and weak points of the particular standard and is an important indication, if the selected standards are suitable for the implementation of the laboratory use case.

Regarding these questions the following sections are divided into a framework description of the standard, an explanation of the extensibility, the possible transport mechanisms and a list of strengths and weaknesses of the particular standard.

3.1 Health Level 7 (HL7) V2

3.1.1 HL7 V2 Framework

"Health Level 7 (HL7) Version 2 (V2) is a messaging standard developed by Health Level 7 (HL7) International, which is a non-for-profit Standards Developing Organization (SDO)" [13]. It defines structured messages for the exchange of information between central as well as distributed healthcare systems and environments. [13]. It contains message standards covering the patient administration, patient accounting, patient care, document management, clinical laboratory automation, clinical observation data, such as laboratory result etc. [13]. "HL7 V2 is one of the worldwide most important and most frequently used messaging standards in healthcare and it is frequently adapted" [13].

Table 3.1 illustrates the HL7 V2 version history. HL7 V2.0 was published in 1988 [16]. Since 1996 HL7 V2.2 is an American National Standards Institute (ANSI) accredited standard [16]. HL7 V2.5 is the commonly used version of clinical systems(e.g. Health Information System (HIS) or LIS). In 2014 HL7 V2.8 was published [16]. HL7 V2+ is still under development [16].
"All HL7 V2 versions are backwards-compatible with earlier HL7 versions" [13]. "The HL7 standard allows HL7 processing applications to ignore message elements they do not expect" [13]. "This means that applications may receive HL7 messages with newer HL7 versions and the new information is not part of the older supported HL7 message" [13]. "This new information can be ignored without throwing an exception" [13].
The following subsections will describe the structure of an HL7 message and how it can be extended.

Table 3.1: HL7 V2 version history [16] [13]

Publication Date	HL7 Version	Details
1987	V1	
1988	V2.0	
1990	V2.1	
1994	V2.2	ANSI accredited standard since 1996

1998	V2.3	ANSI approval since May 1997
2000	V2.4	ANSI approval since October 2000
2003	V2.5	publication as an International Organization for Standardization (ISO) standard (ISO/HL7 27931:2009)
2007	V2.6	
2011	V2.7	
2014	V2.8	
2018	V2+	in development

3.1.1.1 Message structure

Figure 3.2 depicts the structure of an HL7 V2 message. “An HL7 V2 message is an atomic unit of data and consists of segments in a defined sequence” [13]. “An HL7 segment in turn is a logical grouping of data fields identified by three letter identification (e.g. Message Header (MSH), Patient Identification (PID), Observation (OBX) etc.) at the beginning” [13]. “It is also possible to group segments to a logical unit which is called a segment group” [13]. “An HL7 field is a string of characters and the contents is defined by one of the HL7 data types” [13]. “A data type is the basic building block used to construct or restrict the contents of a data field” [13]. Of course HL7 defines primitive data types like String (ST), Numeric (NM), Time Stamp (TS) etc. Furthermore, complex data types can be used to describe data sets like Composite ID Number And Name Simplified (CNN), Coded Element (CE), Extended Telecommunication Number (XTN) etc. A complex data type may split an HL7 field into one or many components. A component may be split into zero or many subcomponents based on the defined data type.

The purpose of an HL7 message is defined by the message type (e.g. Admission, Discharge, Transfer Message (ADT), Medical Document Management Message (MDM), Unsolicited Observation Message (ORU) etc.) [13]. Furthermore, an HL7 message has a trigger event, which describes the real world event that initiates the exchange of the HL7 message (e.g. ADTˆA04 Register a patient, ADTˆA23 Delete a patient record etc.) [13]. “There exists a one to many relationship between the message type and the trigger event” [13].

For each HL7 message, which is sent by an HL7 source, an HL7 acknowledgement message is defined. The HL7 receiver receives the HL7 message from the HL7 source and responds with an HL7 acknowledgement message (see also Figure 3.4). For example the response of the Imaging Order Message (OMI) is the Imaging Order Acknowledgement Message (ORI). Whereas the HL7 receiver responds with the General Acknowledgement Message (ACK), when receiving an Unsolicited Observation Message (ORU).

For the construction of an HL7 message certain characters are used [13]. The Table 3.2 lists the special characters, which are used to separate segments, fields, components and subcomponents [13].

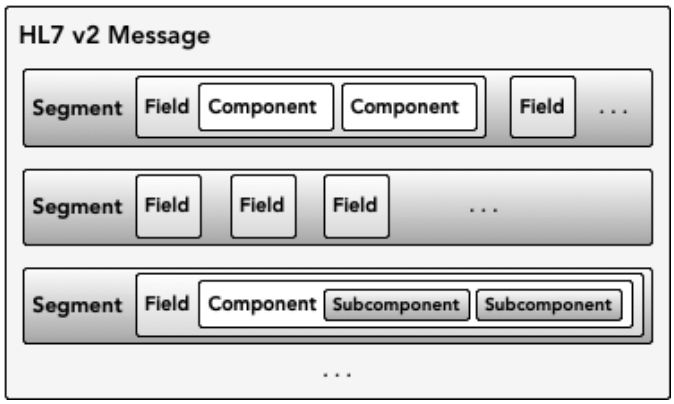

Figure 3.2: HL7 V2 message structure [13]

Table 3.2: HL7 delimiter values [13]

Delimiter	Value	Description
Segment terminator	<CR>	Terminates a segment record.
Field separator	|	Separates two adjacent data fields within a segment.
Component separator	^	Separates adjacent components of a data field.
Subcomponent separator	&	Separates adjacent subcomponents of data fields.
Repetition separator	~	Separates multiple occurrences of a field.
Escape character	\	Escape character for use with any field represented by an String (ST), Text (TX) or Formatted Text (FT) data type, or for use with the data (fourth) component of the Encapsulated Data (ED) data type.

Example - HL7 PID segment

Figure 3.3 is an example of a Patient Identification (PID) segment, which contains all the necessary HL7 delimiters to provide the patient information in this segment. The PID segment starts with the three letter identification of the segment. Each field is separated with the field separator. The list of patient identifiers can be found in PID-3. The component PID-3.1 contains the patient ID “1234123”. Furthermore, the component PID-3.4 provides some details about the assigning authority of the patient ID. The data type Hierarchic Designator (HD) is set to PID-3.4, which means that the assigning authority information is split into subcomponents using the subcomponent separator. PID-5 contains the name of the patient and the data type Extended Person Name (XPN) is set to this field. The surname can be taken from PID-5.1 and PID-5.2 embeds the firstname. The coded type of the name is defined in PID-5.7. PID-5 contains two types of patient names: the legal name (defined by “L”) and the birthname (defined by “B”) of the patient. Both names are split by the repetition separator. The birthdate of the patient is set in the field PID-7 with the Date Type Time Stamp (TS). The gender code “F” for female can be taken from PID-8 and is defined by the data type Coded Value For User-Defined Tables (IS). The address of the patient is set in the field PID-11. Address details are defined by the data type Extended Address (XAD). Street name, city, postal code etc. are set in the respective components of the field PID-11.

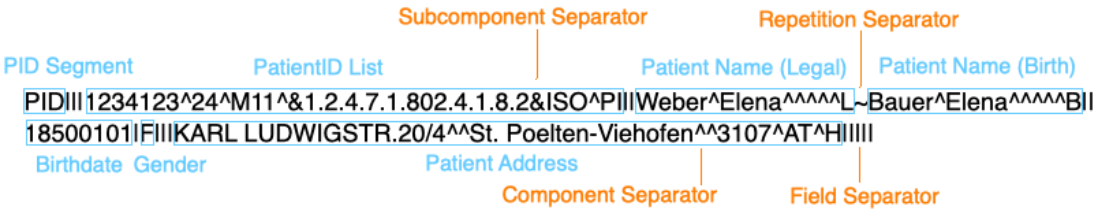

Figure 3.3: HL7 V2 Patient Identification (PID) segment [13]

Example - HL7 CNN data type
Table 3.3 illustrates the definition of the HL7 data type CNN. The CNN data type splits a field into 11 components, which contain details about a person identification and name. For each component a data type is defined.

Table 3.3: HL7 data type CNN [13]

SEQ	LEN	DT	OPT	TBL	Componentname
1	15	ST	O		ID Number
2	50	ST	O		Family Name
3	30	ST	O		Given Name
4	30	ST	O		Second and Further Given Names or Initials Thereof
5	20	ST	O		Suffix (e.g. JR)
6	20	ST	O		Prefix (e.g. Dr.)
7	5	IS	O	0360	Degree (e.g. MD)
8	4	IS	O	0297	Source Table
9	20	IS	C	0363	Assigning Authority - Namespace ID
10	199	ST	C		Assigning Authority - Universal ID
11	6	ID	C	0301	Assigning Authority - Universal ID Type

Another depiction of the CNN definition using the HL7 delimiters would be the following [13]: *<ID Number (ST)>&<Family Name (ST)>&<Given Name (ST)>&<Second and Further Given Names or Initials Thereof (ST)>&<Suffix (e.g., JR or III) (ST)>&<Prefix (e.g., DR) (ST)>&<Degree (e.g., MD (IS)>&<Source Table (IS)>&<Assigning Authority - Namespace ID (IS)>&<Assigning Authority - Universal ID (ST)>&<Assigning Authority - Universal ID Type (ID)>*

An example with values for the CNN could look like the following:
123456&Mayr&Susanne&Maria&&Dr.&&&&urn:oid:1.2.145.0.46.3.11&ISO

3.1.1.2 Extensions

There are several possibilities to extend HL7 messages with local extension(s) to fit local requirements for the information transport [13]. The following subsections provide some details of how

an HL7 message and embedded parts can be extended.

Extensions for HL7 messages
It is allowed to define custom HL7 messages. A custom HL7 message has to start with the letter Z (e.g. ZSM for "Sandra's customized message") and the structure of the custom message has to be specified. There are the following options to extend an HL7 message [13]:

- "The definition of a local Z message is necessary for covering information, which is not covered by an existing HL7 message" [13]. "Official HL7 segments should be used where possible" [13].
- "The first HL7 segment in the Z Message has to be the Message Header (MSH) segment" [13]. "The entirely rest of the Z message may consist of Z segments, but can contain HL7 segments too" [13].
- "A local Z acknowledgement message must begin with an MSH segment followed by an Message Acknowledgment Segment (MSA) segment, an optional Software Segment (SFT) segment and a conditional Error Segment (ERR) segment" [13].
- "Defined Z segments may be added to an official HL7 message" [13]. "The trigger event may remain the same if the intent of the message has remained unchanged" [13].
- "Adding additional HL7 segments (like Notes and Comments (NTE)) to an official HL7 message is not a good way to add additional information" [13]. "For future releases it may lead to an unparsable HL7 message" [13].

Extensions for HL7 trigger events
"The definition of custom trigger events is allowed and has to start with the letter Z" [13].

Extensions for HL7 segments
"All segment ID codes beginning with the letter Z are reserved for locally defined segments" [13]. "Therefore, it is possible to define custom segments and use them to extend HL7 messages" [13]. "Z segments can also be added to segment groups" [13].

Extensions for HL7 data types
"Custom data types can be defined" [13]. The following rules have to be considered [13]:

- "If possible, HL7 defined data types shall be used for Z segments. Otherwise custom data types can be used for Z segments" [13].
- "It is not allowed to redefine the data type of an existing component (e.g. from NM to ST)" [13].
- "Z data types also can be created by extending existing HL7 data types by adding new components" [13].

Extensions for HL7 Tables
HL7 specifies for specific data fields a set of coded values, which can be used [13]. If these values are not sufficient, a custom value set can be defined for the HL7 data field with the data type Coded With Exceptions (CWE). Furthermore for a Z field a custom value set in form of a local Table can be assigned.

3.1.2 Exchange mechanism

"The term "Level 7" refers to the highest level of the ISO Open System Interconnection (OSI) model hence HL7 defines messages for the application layer" [13]. HL7 compliant applications shall support the Minimal Lower Layer Protocol (MLLP) over TCP/IP.
"MLLP is a reliable message transport protocol and bases on a minimalistic OSI-session layer framing protocol" [17]. It provides an interface between HL7 applications. The HL7 message is framed in a block and sent to the destination HL7 application (also called HL7 receiver or HL7 destination). Afterwards the destination HL7 application sends a receipt confirmation in form of a commit acknowledgement message to the source HL7 application (also called HL7 source) (see Figure 3.4). "The MLLP acknowledgement protocol is synchronous" [17].
HL7 does not require other transport protocols, but does not specify any restrictions [13]. It is possible to use other transfer protocols like File Transfer, Access and Management (FTAM), File Transfer Protocol (FTP), Kermit, Hypertext Transfer Protocol (HTTP) etc.

Figure 3.4: HL7 communication over MLLP [17]

3.1.3 Strengths and weaknesses

There are the following strengths of the HL7 V2 standard:

- HL7 V2 is a global standard and is used internationally [13].
- An HL7 V2 message is highly extensible and the versions are backward-compatible [13].
- There is a strong industry and community support for HL7 V2 [18].
- HL7 V2 is very flexible in the usage of the exchange mechanisms. There are no special restrictions to use other transfer protocols than MLLP [13].
- For the HL7 V2 standard a detailed specification is existing and the learning overhead is an order of weeks [18].

There are the following weaknesses of the HL7 V2 standard:

- The technology of the HL7 V2 standard is old and not state-of-the-art, but it is still one of the common used standards in healthcare.
- HL7 V2 is only a messaging standard. It is not possible to persist this structure in a database. A proprietary database structure has to be defined for persisting HL7 V2 message content.
- The HL7 V2 specification leaves a great scope in the implementation of the HL7 V2 messages (e.g. flexibility of using terminologies, usage of specific fields etc.). The resulting consequences are interoperability problems.
- HL7 V2 messages are compiled from common HL7 data segments. Correct processing of a particular message however can be challenging since despite the common segments, interpretation depends on the semantic segment rules of the specific message type.

3.2 Clinical Document Architecture (CDA)

3.2.1 CDA Framework

"Clinical Document Architecture (CDA) is an ANSI-certified standard from HL7 and it is based upon the HL7 V3 RIM, data types and vocabulary standards" [19]. "CDA Release 1.0 was published in 2000 and CDA Release 2.0 was published in 2005" [20]. "The standard has also been adopted as ISO/HL7 27932:2009 standard" [21].
"CDA specifies the structure and semantic of clinical documents for electronic data exchange in the medical environment" [19]. "A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content" [2]. It is encoded in XML and is composed of Header and Body information (see Figure 3.5).

3.2.1.1 Header

The CDA header sets the context for the clinical document and contains information such as document creation time, author and custodian of the document, which patient it applies to and the visit or encounter for which it describes healthcare services [19].
Table 3.4 illustrates the three logical parts of the header, which are divided into attributes, participants and relationships of the header [2]. The header attributes comprises an document identifier, a document type, a creation time of the document, a document title etc. The header participants provide some details about the participating people of the document, such as the author, the enterer of the data, the patient etc. The Header relationships contain information about the order, the parent document(s), the encounter of a patient etc.

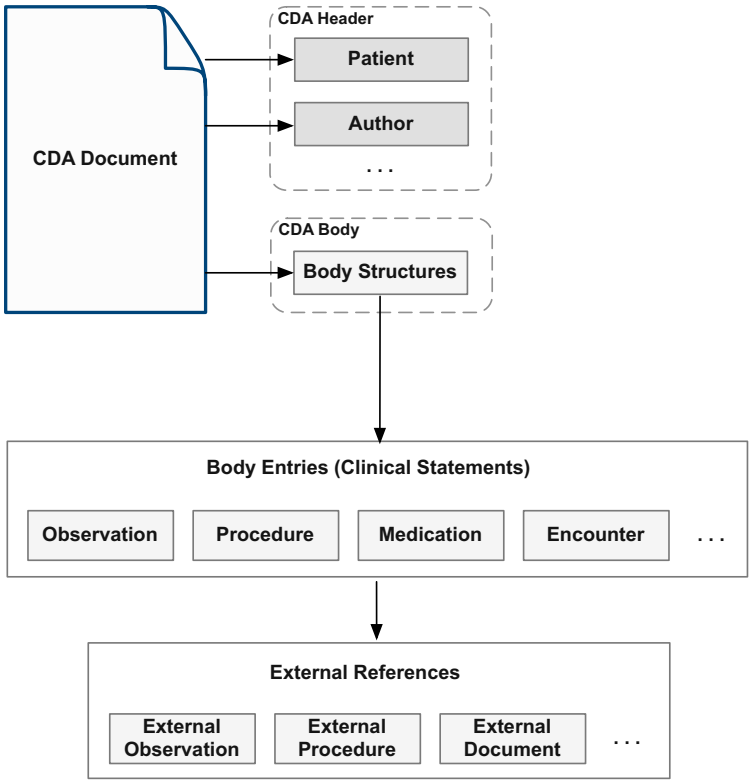

Figure 3.5: CDA structure [22]

Table 3.4: Logical parts of the CDA header [2]

Logical part	Header element	Card.	Description
Header attributes	realmCode	0..*	country code
	typeId	1..1	reference to the CDA R2 standard
	templateId	0..*	defines the compliance with specific specifications and guidelines
	id	1..1	unique instance identifier of the document
	code	1..1	specifies the particular kind of document (e.g. referral summary)
	title	0..1	title of the document
	effectiveTime	1..1	creation time of the document
	confidentialityCode	1..1	level of confidentiality of the document
	languageCode	0..1	human language in which the document is written

	setId	0..1	common identifier across all document revisions
	versionNumber	0..1	document version after replacement (integer)
	copyTime (deprecated)	0..1	time a document is released
Header participants	recordTarget	1..*	patient information
	author	1..*	author of the document (person or device)
	dataEnterer	0..1	person who entered the text of the document
	informant	0..*	person who has relevant information about the patient
	custodian	1..1	originator organization of the document, which has to maintain it
	informationRecipient	0..*	person who shall get a copy of the document
	legalAuthenticator	0..1	person who has legally authenticated the document
	authenticator	0..*	person who attested to the accuracy of the document
	participant	0..*	other participants (e.g. primary care physician, emergency contact, etc.)
Header relationships	inFulfillmentOf	0..*	order information (e.g. order id of a laboratory study)
	documentationOf	0..*	information about the healthcare service, which was performed (e.g. colonoscopy)
	relatedDocument	0..*	parent document (e.g. former version after a replacement)
	authorization	0..*	consent information associated with the document
	componentOf	0..1	encounter information

An example of a header information is illustrated in Listing 3.1. “The element typeId contains the unique identifier for the CDA Release 2 hierarchical description” [2]. The instance identifier is set in the element id. The element code describes the type of the document. Furthermore, document details like title, effectiveTime, and confidentialityCode can be set. The element recordTarget describes the patient, for whom the document is created. It contains patient identifiers, the name of the patient, gender, contact information, address information etc. The header also contains details about participating people. In the example an author is set, who has an identifier and a name. The originator organization of the document is set in the element custodian. Finally the body information can be embedded in the element component.

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns="urn:hl7-org:v3">
   <!-- unique identifier for the CDA Release 2 Hierarchical
      Description -->
   <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
   <!-- instance identifier -->
   <id root="1.2.40.0.13.1.1.10.242.7.195.20120109191846606.32768"/>
   <!-- document type represented by LOINC code -->
   <code code="11502-2" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Laboratory Report"/>
   <!-- title of the document -->
   <title>Laboratory Report</title>
   <effectiveTime value="20141102000000+0200"/>
   <!-- confidentiality level of the document -->
   <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"
      codeSystemName="Confidentiality" displayName="Normal"/>
   <!-- patient information -->
   <recordTarget typeCode="RCT">
      <patientRole classCode="PAT">
         <id extension="234715" root="1.3.6.1.4.1.21367.13.20.3000"/>
         <telecom nullFlavor="NI"/>
         <patient classCode="PSN">
            <name>
               <given>Max</given>
               <family>Mustermann</family>
            </name>
         </patient>
      </patientRole>
   </recordTarget>
   <!-- author of the document -->
   <author>
      <time value="20141102000000+0200"/>
      <assignedAuthor>
         <id extension="2.18.1.429.53.1"
            root="2.16.17.710.809.1000.903.1.1.3.3"/>
         <assignedPerson>
            <name>
               <given>Derek</given>
               <family>Shepard</family>
               <prefix>Dr.</prefix>
            </name>
         </assignedPerson>
      </assignedAuthor>
   </author>
   <!-- originator organization of the document -->
   <custodian>
      <assignedCustodian>
         <representedCustodianOrganization>
            <id root="2.16.17.710.809.1000.903.1.1.3.3"/>
```

```
            <name>Sacred Heart Hospital</name>
         </representedCustodianOrganization>
      </assignedCustodian>
   </custodian>
   <component>
      <!-- CDA Body area -->
   </component>
</ClinicalDocument>
```

Listing 3.1: Example - CDA header

3.2.1.2 Body

The CDA body contains the actual clinical information such as observations, diagnoses, medications and treatments in form of the human-readable, narrative text [19]. Additionally to this human-readable, narrative text, there may be a machine-readable information, which describes the human-readable, narrative text using coded values [19]. Listing 3.2 illustrates an example of the structure of a CDA body. The element structuredBody contains one or more sections defined by component/section. A section describes a type of clinical information like vital signs or current medication. It may contain the human-readable, narrative text and may contain entries, which include the machine-readable content.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns="urn:hl7-org:v3">
   <!-- CDA Header area -->
   <component>
      <structuredBody>
         <!-- section -->
         <component>
            <section>
               <text>
                  <!-- narrative text of the section -->
               </text>
               <entry>
                  <!-- entry of the section, which includes the
                     machine-readable content -->
               </entry>
            </section>
         </component>
      </structuredBody>
   </component>
</ClinicalDocument>
```

Listing 3.2: Example - CDA body

CDA Levels
The CDA standard differentiates between three levels of document definitions [2]:

- *CDA Level 1* - "There are no constraints defined for a CDA Level 1" [2]. The medical information in the body part can be narrative text, but also another format like PDF or JPEG. The CDA body does not contain any coded information (see Listing 3.3).
- *CDA Level 2* - "The CDA sections comply with section-level templates and contain already coded information in form of a section code (see Listing 3.4)" [2].
- *CDA Level 3* - "The CDA sections comply with entry-level templates and contain machine-readable CDA entries (see Listing 3.5)" [2].

```
<?xml version="1.0" encoding="UTF-8"?>
<component>
   <section>
      <title>History of present illness</title>
      <text>stabbing chest pain and desire to urinate</text>
   </section>
</component>
```

Listing 3.3: CDA Level 1

```
<?xml version="1.0" encoding="UTF-8"?>
<component>
   <section>
      <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"
         codeSystemName="LOINC" displayName="History of present
         illness"/>
      <title>History of present illness</title>
      <text>stabbing chest pain and desire to urinate</text>
   </section>
</component>
```

Listing 3.4: CDA Level 2

```
<?xml version="1.0" encoding="UTF-8"?>
<component xmlns:xsi= "http://www.w3.org/2001/XMLSchema-instance">
  <section>
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.25"/>
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2"/>
    <!-- section type defined by LOINC code -->
    <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
       codeSystemName="LOINC" displayName="Vital signs"/>
    <title>Coded Vital Signs</title>
    <!-- narrative text -->
    <text>Heart Beat: 60 /min (limit: 60-100)</text>
    <!-- coded entry -->
    <entry>
```

```
13        <organizer classCode="CLUSTER" moodCode="EVN">
14          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
15          <id extension="4711" root="1.2.3.4.5.6.7.8.9"/>
16          <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT" displayName="Vital signs"/>
17          <statusCode code="completed"/>
18          <effectiveTime value="2020010101+0200"/>
19          <component typeCode="COMP">
20            <observation classCode="OBS" moodCode="EVN">
21              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
22              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.2"/>
23              <id extension="4711" root="1.2.3.4.5.6.7.8.9"/>
24              <code code="8867-4" codeSystem="2.16.840.1.113883.6.1"
                    codeSystemName="LOINC" displayName="Heart Beat"/>
25              <statusCode code="completed"/>
26              <effectiveTime value="20100414095558+0200"/>
27              <value unit="/min" value="60" xsi:type="PQ"/>
28              <referenceRange typeCode="REFV">
29                <observationRange>
30                  <value xsi:type="IVL_PQ">
31                    <low unit="/min" value="60"/>
32                    <high unit="/min" value="130"/>
33                  </value>
34                </observationRange>
35              </referenceRange>
36            </observation>
37          </component>
38        </organizer>
39      </entry>
40    </section>
41</component>
```

Listing 3.5: CDA Level 3

3.2.1.3 Data types

CDA defines primitive data types like ANY and Boolean. Text and Multimedia information can be described with the data types String (ST), Encapsulated Data (ED) and Binary (BIN). Demographic data can be represented by using data types like Address (AD), Organization Name (ON), Person Name (PN) etc. Coded values can be set by using data types like Concept Descriptor (CD), Coded Value (CV), Coded Ordinal (CO), Coded With Equivalents (CE) etc. CDA includes data types for dates and times like Time Stamp (TS), Interval of Time (IVL_TS) etc. Furthermore, CDA defines data types for describing collections like Interval (IVL) or List (LIST).

Listing 3.6 illustrates the CDA data type “PersonName”. The surname, given name and prefix of a person are set.

```xml
<?xml version="1.0" encoding="UTF-8"?>
<name>
   <given>Elena</given>
   <family>Weber</family>
   <prefix>Dr.</prefix>
</name>
```

Listing 3.6: CDA data type “PersonName”

3.2.1.4 Templates

The CDA specification does not define the creation or management of documents [2]. It does not specify that a CDA document has to contain a specific clinical content. Any type of document (e.g. Referral Summary, Laboratory Report, Emergency Note, Discharge Summary etc.) can be created by the CDA standard.
Harmonization organizations such as HL7, Integrating Healthcare in the Enterprise (IHE), Health Information Technology Standards Panel (HITSP) etc. started to specify implementation guidelines for specific document types (e.g. Discharge Summary, Laboratory Report, Nursing Note) [19]. Implementation guidelines define restrictions and templates for a specific document type. Templates are collections of business rules. They are applied to a specific part of a document or message and are defined to meet the needs of a specific use case. Templates exist for a whole document, parts of a header section and for the body in form of section or entry templates.

3.2.1.5 Extensibility

“CDA allows to include additional XML elements and attributes that are not part of the CDA schema” [2]. The meaning of the standard data items must not be changed [2]. Thus, it is possible to add local information to the CDA. Clinical systems, which want to process the content of the CDA, have to be able to ignore these custom elements. Furthermore, they have to render such CDA documents successfully with a stylesheet, which ignores such extensions.

3.2.2 Exchange mechanism

“The standard does not specify how clinical documents shall be transported or stored” [2]. CDA documents can be exchanged by utilization of transport mechanisms such as Cross-Enterprise Document Sharing (XDS), Digital Imaging and Communications in Medicine (DICOM), Multipurpose Internet Mail Extensions (MIME) attachments to email, HTTP, FTP, HL7 V2 messages, or other protocols.

3.2.3 Strengths and weaknesses

There are the following strengths of the CDA standard:

- There is no specific transport mechanism necessary to exchange CDA documents. The standard is flexible enough to be compatible with a wide range of environments and transport mechanisms in the medical area [2].
- CDA was and is very successful to transport medical information in a coded way to allow further analyses and processing by clinical systems [2].

There are the following weaknesses of the CDA standard:

- The CDA specification and the implementation guidelines are very complex [19]. The huge number of already available templates creates a high effort for implementers.
- CDA is not modular enough, because it is designed as a document exchange architecture, which makes it very limited and inflexible for current requirements like analysis [18].
- CDA is a standard, which describes the structure of a document. It is not possible to persist this structure in a database. A proprietary database structure has to be defined for persisting CDA content.

3.3 Fast Healthcare Interoperability Resources (FHIR)

3.3.1 FHIR Framework

"Fast Healthcare Interoperability Resources (FHIR) as a draft standard has been created by the HL7 International and describes formats, elements, and an API for exchanging health information" [**?**]. HL7 International published FHIR Draft Standard for Trial Use (DSTU) Release 1 in 2014 [14]. The current version is FHIR Release 4 and FHIR Release 5 is already a work in progress [14]. Details about the version history of FHIR are illustrated in Table 3.5.
"FHIR is built around the concept of resources" [15]. The FHIR specification describes a set of resources and several different ways of exchanging the resources between systems. Details about the exchange mechanisms can be found in Subsection 3.3.2.

Table 3.5: FHIR version history [14]

Date	Version	Description
2020-08-20	4.5.0	FHIR Release 5 (work in progress)
2019-10-30	4.0.1	FHIR Release 4 (current version)
2019-10-24	3.0.2	FHIR Release 3 (Standard for Trial Use (STU))
2015-10-24	1.0.2	FHIR DSTU 2
2014-09-30	0.0.82	FHIR DSTU 1

3.3.1.1 Resources

A FHIR resource is a modular component or unit [15]. These resources can easily be assembled to a set of components to fulfill the requirements of a healthcare use case. There are different types of resources in order to solve different problems in healthcare.

The UML diagram in Figure 3.6 illustrates the FHIR Resource and the FHIR DomainResource. It also displays the FHIR Meta, which inherits the FHIR Element.

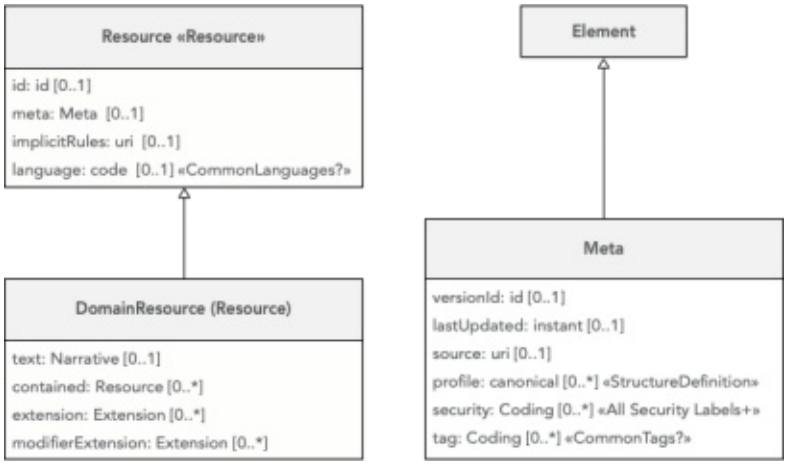

Figure 3.6: UML diagram - Relation between FHIR DomainResource and FHIR Resource [15]

"A resource is an entity that

- has a known identity (a URL) by which it can be addressed,
- identifies itself as one of the types of resource defined in the FHIR specification,
- contains a set of structured data items as described by the definition of the resource type and
- has an identified version that changes if the contents of the resource changes" [15].

Key parts of a FHIR resource
A FHIR resource is composed of four key parts. Figure 3.7 displays an example of the resource FHIR Patient with the four key parts, which are described in the following.

Resource identity and metadata
Each resource has an unique identity also called logical id [24]. This id is set once for a resource and does not change during the lifecycle of a resource. A resource consists of a number of metadata, which identify the resource and provides information about the lifecycle of the resource. Figure 3.6 illustrates the resource and Meta objects. A FHIR server has to maintain this

Figure 3.7: FHIR Patient in XML representation [23]

information for the stored resources.

Human-readable summary
Each resource that is a DomainResource may include a human-readable narrative block, which contains the summary of the resource to present its content to a human [25]. The narrative block may contain additional descriptive information, which is not part of the structured data. The narrative block is embedded as XHTML fragment to the Resource.

Standard data
The main content of the resource consists of the structured data defined by FHIR [23]. For each resource there is a definition of which structured elements are part of the resource and which data type can be used. FHIR provides an exhaustive specification for the FHIR resources

and Furthermore, it contains a lot of examples in XML, JavaScript Object Notation (JSON) or Resource Description Framework (RDF) representation.

Extensions
FHIR provides the possibility to add additional information to a FHIR Resource by adding so-called FHIR Extensions (see also section 3.3.1.4) [26].

Resource types
FHIR already defined a number of resource types, which are described in detail in the official FHIR specification [27]. FHIR categorized the resource types, which are illustrated in Table 3.6 [27].

Table 3.6: Resource types [27]

Category	Purpose	Examples
Foundation	The category "Foundation" contains resources to support conformance, terminology, security, documents and other use cases.	StructureDefinition, ValueSet, ImplementationGuide, CodeSystem, AuditEvent, Composition, DocumentReference, Bundle, Consent, MessageHeader
Base	The category "Base" consists of resources, which represent individuals, entities, workflow and management in healthcare.	Patient, Practitioner, Organization, HealthcareService, Device, Schedule, Task, Encounter, EpisodeOfCare
Clinical	The category "Clinical" includes resources that provide core clinical record keeping, care provision and support for diagnostic services, medication and immunization process and represent request and response pairs.	AllergyIntolerance, Observation, Procedure, DiagnosticReport, Medication, Immunization, CarePlan, RiskAssessment, Communication, CommunicationRequest
Financial	The category "Financial" is all about support, billing, payment and other general financial use cases.	Coverage, Invoice, PaymentNotice, Account, InsurancePlan
Specialized	The category "Specialized" contains resources to fulfill the very specific topics public health & research, definitional artifacts, evidence-based medicine, quality reporting & testing and medication definition.	ResearchStudy, Evidence, Measure, TestReport, ObservationDefinition, MedicinalProduct, MedicinalProductIngredient

3.3.1.2 Data types

FHIR defines the following categories of data types [28]:

- Primitive data types are single elements with a primitive value like uri, boolean, date, dateTime, string, code, integer etc.
- Complex data types are re-usable clusters of elements for general purposes. For example the data types Address and HumanName are part of this category. The data type Address contains elements for describing an address such as line, city, state, postalCode etc. The DataType HumanName represents a name of a person and contains elements such as family, given, prefix, suffix etc.
- Metadata data types are used for metadata resources such as Expression, ParameterDefinition, TriggerDefinition etc.
- Special purpose data types are defined to fulfill specific usages. It contains the data types Meta, Reference, Narrative, Extension etc.

The Listing 3.7 illustrates the FHIR data type "HumanName":

```
<?xml version="1.0" encoding="UTF-8"?>
<name>
   <use value="official" />
   <family value="Weber"/>
   <given value="Elena" />
</name>
<name>
   <use value="maiden" />
   <family value="Bauer" />
   <given value="Elena" />
</name>
```

Listing 3.7: Example - FHIR data type "HumanName"

3.3.1.3 Resource references

"FHIR provides the possibility to set resource references from one resource (source) to another one (target)" [29]. "Resource references make it possible to create a web of information in healthcare" [29]. Figure 3.8 illustrates the UML diagram for the FHIR Reference.

3.3.1.4 Extensions

"One of the major advantages of FHIR is that the core FHIR specification of the resources is simple and just includes information, which is used by the majority in healthcare" [26]. "If there is the need to add additional information to a resource, it is possible to define and use extensions for this need" [26]. Every element in a resource or data type includes an optional "Extension" child element that may be present any number of times. Figure 3.9 illustrates the UML diagram

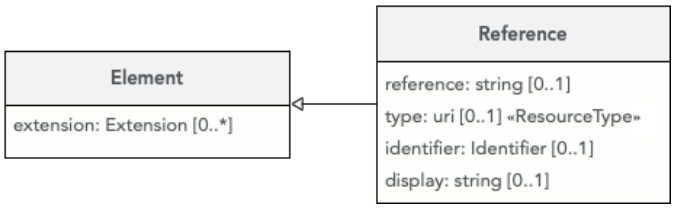

Figure 3.8: UML diagram - FHIR Reference [29]

for the FHIR Extension. "The url element of the Extension identifies the retrievable Extension Definition (StructureDefinition) that defines the content and the meaning of the Extension" [26]. "The value[x] of the Extension consists of the name "value" and the title-cased name of the defined data type (e.g. valueBoolean, valueInteger, valueString)" [26].

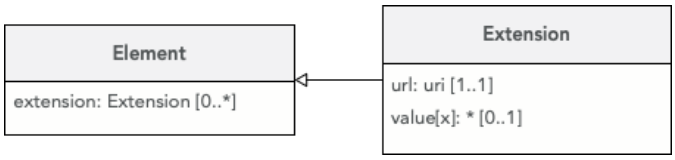

Figure 3.9: UML diagram - FHIR Extension [26]

3.3.2 Exchange mechanism

"FHIR as an interface specification defines five principles for exchanging data between healthcare systems" [30]. A RESTful API describes operations to create, update, delete, search and read FHIR resources (see also Subsection 3.3.2.1). Furthermore, a Messaging Framework has been defined, where a source application sends messages to a destination application (see Subsection 3.3.2.2). In addition FHIR specifies the construction of documents (see Subsection 3.3.2.3). It is also possible to use FHIR in combination with a Service Oriented Architecture (SOA) (see section 3.3.2.4). Finally FHIR provides some considerations on how the contents of FHIR resources can be stored depending on several design decisions (see Subsection 3.3.2.5).

3.3.2.1 RESTful API

"The RESTful API is a client/server Application Programming Interface (API) designed to follow the principles of RESTful design for create, read, update and delete operations, along with search and execute (operations) support" [31]. "Representational State Transfer (REST) relies on a stateless, client-server, cacheable communications protocol, where the HTTP protocol is used" [32]. "REST is a much more simpler mechanism than using Remote Procedure Call (RPC) and Web Services (SOAP, WSDL, etc.)" [32]. "The RESTful API describes the FHIR resources as a set of operations (also interactions) on resources where individual resource instances are managed in collections by their type" [31]. "FHIR servers provide a so-called Capability Statement,

which specifies which interaction is supported by the server" [31]. In the following the relevant interactions are described [31]:

- With the **read** interaction it is possible to retrieve a particular resource based on its URI. The interaction is performed by an HTTP GET command.
- The **vread** interaction allows to retrieve a particular version of a resource based on its URI. The interaction is performed by an HTTP GET command.
- With the **update** interaction it is possible to update an already existing resource with a new version.
- The client can create a new resource by using the **create** interaction and performs therefore an HTTP POST command. The request body has to contain the FHIR resource to create. The server will create the identifier and the meta information for the new resource. Furthermore, the server returns for the successful created resource a location header, which contains the new logical Id and the version Id (if versioning is supported by the server).
- The **search** interaction supports the usage of some filter criteria to search for a specific set of resources. The interaction can be performed with an HTTP GET as well as with an HTTP POST command.
- The delete interaction is used to remove an existing resource from the server by performing an HTTP DELETE command.

3.3.2.2 Messaging

FHIR defines a messaging framework where a source application sends a request message to a destination application and answers after further message processing with one or more response messages [33]. The message exchange is processed, because a specific action or event happened. This approach is very similar to the HL7 V2 standard. Both, the request and response message consists of a FHIR Bundle identified by the Bundle.type="message" with the first resource in the Bundle being the FHIR resource MessageHeader.
FHIR does not specify the transfer mechanism of the messages, but may include file transfer, HTTP-based transfer, MLLP etc. The FHIR messaging framework defines a synchronous as well as an asynchronous message exchange pattern [33]. For the asynchronous messaging the receiver sends an acknowledgement answer immediately after receiving the request message from the sender. After processing the request message the receiver responds to the sender with a response message separately [33]. As compared to the synchronous messaging the receiver first processes the received request message and answers afterwards to the sender with a response message.

3.3.2.3 Documents

With the FHIR resource Composition it is possible to build documents. "A FHIR Composition defines the structure and narrative content necessary for a document" [34]. "The sum of the information of a document has to be included as entries in a Bundle where Bundle.type="document"" [34].

"The FHIR Composition provides the basic framework for the document and references the relevant resources (e.g. Patient, Participant, Organization, Allergies, etc.), which are as well part of the Document-Bundle" [34].

3.3.2.4 Services

FHIR can be exchanged in the context of Services [35]. "SOA is an architecture pattern using Services to encapsulate and provide discrete pieces of application functionality" [35]. "SOA provides a framework for loose-coupling and addressing pre-conditions, exception handling, and other implementation considerations of complex distributed systems" [35]. "FHIR defines an easy-to-implement approach to access healthcare resources" [35]. The combination of FHIR and SOA can provide a lot of benefits and the advantages of both can be used [35].

3.3.2.5 Persistent storage

It is a principal design decision, how applications and FHIR servers store the FHIR information [36]. Usually all applications store the FHIR information in some persistent layer (e.g. database). There are several considerations, which are relevant for the design decision on how the data storage schema has to look like for an application [36].

Considerations

- If the data storage schema is designed to support storage efficiency, it would make sense to normalize the FHIR resource and store this information instead of the whole FHIR resource [36]. In this case it has to be considered that the FHIR resource has to be reconstructed [36].
- If the goal is to have a robust and stable data storage schema for FHIR resources, storing directly the resources would be a good approach [36].
- If the information, which an application receives, is not specified in detail and the application has to deal with any data, the mapping from FHIR resources to an internal data storage schema may be challenging. Especially the extensibility approach of FHIR has to be considered in the case of receiving no defined data [36].
- Systems, which have a well-defined data set will store the data in a designed data storage schema and map the received FHIR resources to their schema [36].
- Of course there is also the possibility to take a hybrid approach - storing FHIR resources natively and storing a well-controlled subset of information in the designed data storage schema [36].

Furthermore, the need of specific functional requirements will affect the design decision too like

- the integrity/audit reasons can make the need of the original form of the FHIR resource,

- the possibility to provide some unified view/analysis/process based on a coherent view of the information from resources with different FHIR Versions and
- the relevance of handling with FHIR versions [36].

3.3.3 Strengths and weaknesses

There are the following strengths of the FHIR standard:

- FHIR is based on a modern, flexible and state-of-the-art technology (e.g. REST) [23].
- The resource approach of FHIR enables the creation of modular data structures and is therefore an alternative to document-centric approaches (e.g. CDA) or message approaches (e.g. HL7 V2). It is possible to construct new sets of data.
- It exists a free accessible online FHIR specification with many examples, diagrams, and detailed description [23].
- The FHIR specification includes a lot of examples and there are also multiple implementation libraries (e.g. HAPI FHIR Library) available to guarantee a fast and easy development [23].
- FHIR uses modern web standards as XML, JSON, HTTP, Open Authorization (OAuth) and REST [23].
- FHIR provides the possibility of ontology-based analysis with formal mapping for correctness [23].
- FHIR resources can be easily extended for specific medical use cases to fulfill the requirements of specific healthcare processes in various countries [23].
- FHIR can be used for various current medical use cases as mobile phone applications, cloud communication, data sharing between healthcare provider systems (e.g. Electronic Health Record (EHR), Electronic Medical Record (EMR)) etc. [23].

There are the following weaknesses of the FHIR standard:

- FHIR resources are infinitely extensible, which makes it hard for EHR systems to integrate these resources and interpret that new Extensions [36].

CHAPTER 4

Implementation

The previous chapters provided an overview about established standards used in medical informatics. These standards represent the foundation for the development of the connection between the laboratory and the standards-based CDR.
This chapter provides details about the setup of the HIE and defines the workflow and interfaces of the laboratory environment. Furthermore, it includes the mapping definitions for the transformation from HL7 V2 into FHIR and from FHIR into CDA R2.

4.1 Setup of the laboratory environment

On behalf of a German health insurance company a digital health network was to be provided with an official start in production going back to 2018.
From October 2019 to March 2020 a new laboratory environment was implemented, deployed and connected to the HIE in the Quality Assurance (QA) system. Tests were performed together with the laboratory and the integration partners of the connected healthcare providers. A deployment of the laboratory environment in the production environment has never been performed as the pilot project ended in the middle of 2020.
My role in connecting the laboratory environment was the following:

- Conceptualize the specification for the laboratory workflows and data flows
- Definition of the mappings between HL7 V2.5, FHIR STU3, and CDA R2
- Technical coordination with the laboratory system developers
- Development of the Java-based HSB interfaces for the storage, query, and retrieval of Laboratory Reports in the CDR as an add-on of an already existing HSB component
- Deployment and configuration of the HSB and performing tests for the integration of the laboratory environment

The following tasks were out of my scope:

- Development and deployment of the FHIR server acting as a CDR
- Development and deployment of the Gateway
- Development of the basic framework of the HSB
- Installation and configuration of the servers, were the software was to be deployed
- Network and firewall configuration

The Figure 4.1 illustrates a high-level architecture of the laboratory environment, which has to be connected to the HIE. The distributed HIE connects several environments of medical practices, hospitals and clinics for the purpose of exchanging medical documents. The connection to the new laboratory environment will be part of the next sections. This Section provides an overview of the laboratory environment.

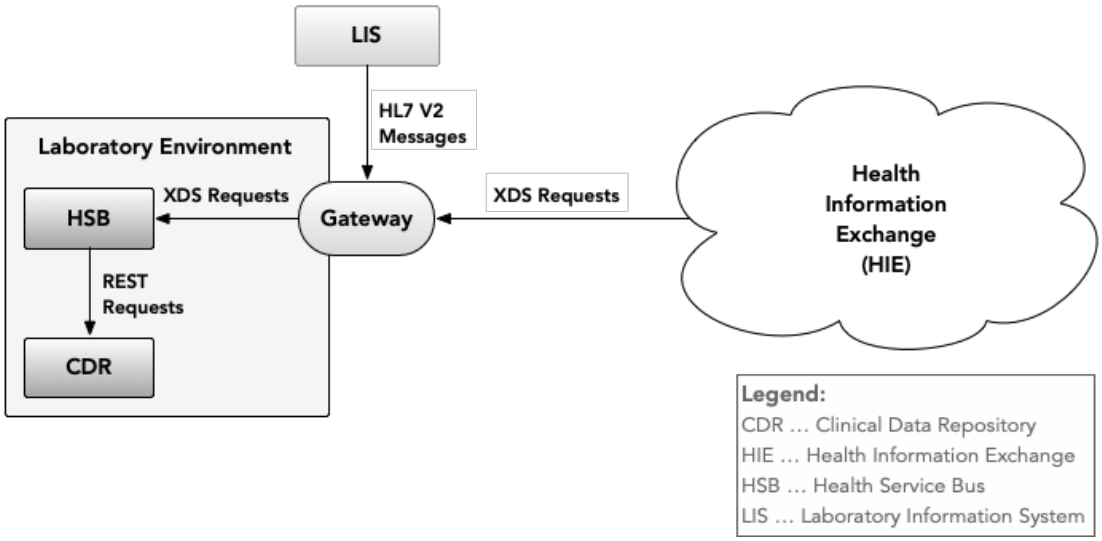

Figure 4.1: High-level architecture of the laboratory environment

A German laboratory wants to be connected to the HIE to share laboratory data with their patients and healthcare providers. As a prerequisite its own laboratory infrastructure has to be built. The connector between the laboratory environment and the HIE is a Gateway. The Gateway of the laboratory (Lab_Gateway) responds to the incoming requests from other environments and is responsible for the access control.

Based on the gained information from Chapter 3 the innovative FHIR standard provides the gadgets for storing, managing, and querying structured data. The FHIR resource concept makes

it possible to define a very flexible data structure for the laboratory data. In this case a standard FHIR server fulfills the requirements of storing, managing and querying structured laboratory data. Furthermore, FHIR queries support additional data processing and analysis possibilities of the laboratory data.
The usage of a FHIR server, which acts as CDR, provides clear benefits, but causes a massive integration problem. The CDR is not able to respond to Cross-Enterprise Document Sharing (XDS) requests for querying and retrieving of documents sent by the Gateway. For this reason an HSB shall fill the communication gap between the Gateway and the CDR. Furthermore, this component shall support the Laboratory Information System (LIS) in providing laboratory data to the CDR.

Thus, the laboratory environment consists of the following components:

- **Clinical Data Repository (CDR)**
  The Clinical Data Repository (CDR) stores and manages laboratory data, which were provided by the LIS. It offers extensive query possibilities for retrieving specific clinical data from a patient or a certain group of patients. A Java-based FHIR server acts as a CDR and is responsible for storing and managing FHIR resources. Basically any standard FHIR server can be deployed.

- **Health Service Bus (HSB)**
  "A Health Service Bus (HSB) implements a communication system between mutually interacting software applications in a SOA" [37]. In that specific case the Java-based HSB integrates an interface to receive HL7 V2.5 messages from the LIS. The HL7 message V2.5 is converted to FHIR resources and stored in the CDR. Furthermore, it also integrates an interface to receive XDS requests for querying and retrieving of documents from the Gateway of the laboratory (Lab_Gateway), translates the requests to FHIR query requests, and forwards the response in the correct format to the Lab_Gateway.

- **Gateway**
  In each connected environment a so-called Gateway is deployed. The Gateway forwards XDS requests to other environments and receives requests from internal services or other Gateways. Furthermore, the access control and enforcement are also important parts of the Gateway. The whole HIE builds on a Gateway-to-Gateway-Communication, which means that the services in an environment are not directly reachable by a service from another environment.

4.2 Interface specification

The previous Section provided an overview about the setup of the laboratory environment, which has to be connected to the Health Information Exchange (HIE). The current section describes the interfaces and technical workflows of the HSB and the CDR for storing, querying and retrieving the laboratory data from the laboratory environment. Figure 4.2 illustrates the endpoints of the HSB, which are the following:

- an incoming MLLP endpoint for receiving the HL7 V2.5 message type “Unsolicited Observation Message (ORU), Event R01”
- an incoming SOAP 1.2 endpoint for receiving document requests, which are compliant with the Cross-Enterprise Document Sharing (XDS) specification, i.e. [ITI-18] Registry Stored Query and [ITI-43] Retrieve DocumentSet
- an outgoing REST interface to send store (HTTP POST), delete (HTTP DELETE) and query (HTTP GET) requests to the CDR

Furthermore, the HSB integrates

- an HL7 V2 translation service to transform HL7 V2.5 ORUˆR01 messages to FHIR STU3 resources and uses the HAPI library, which is an open-source, object-oriented HL7 2.x parser for Java [38]. Further details about the HL7 into FHIR mapping are described in Section 4.3.
- a FHIR translation service to transform FHIR STU3 resources to a CDA R2 document. Further details about the FHIR into CDA mapping are described in Section 4.4.
- a terminology service, which persists value sets of several code systems in XML files. This service supports the translation of one code value from a code system to an appropriate code value of another code system. As an example this makes it possible to map HL7 code values into FHIR code values.
- a configuration for the HL7 adapter as well as a configuration for the XDS interface

4.2.1 HL7 adapter of the Health Service Bus (HSB)

The sequence diagram in Figure 4.3 illustrates the workflow of storing the laboratory data to the CDR. The LIS sends an HL7 message over MLLP to the integrated HL7 adapter of the HSB (1). When the HL7 adapter receives an HL7 message, the message is parsed into Java objects by the HAPI library. The HAPI validates the received HL7 message. If the HL7 message is not compliant with the HL7 V2.5 specification, the HL7 adapter responds with an HL7 ACK message, which contains details about the errors that occurred.
The HL7 message is converted into FHIR resources based on the specified mapping tables from Section 4.3 (2). The Message Control ID from MSH-10 contains the unique identifier for the FHIR Composition resource. The HL7 adapter performs a FHIR query to determine, if there is already a previous version of the Laboratory Report stored in the CDR (3). If a FHIR Composition with the requested id is already stored in the CDR, this preliminary Laboratory Report is replaced by deleting the existing FHIR Composition resource and all referenced FHIR resources (5), when storing the new version from the HL7 message (6).
Finally an HL7 ACK message is sent to the LIS (8). The HL7 ACK message contains details about the success of processing the message or details about any errors that occurred.

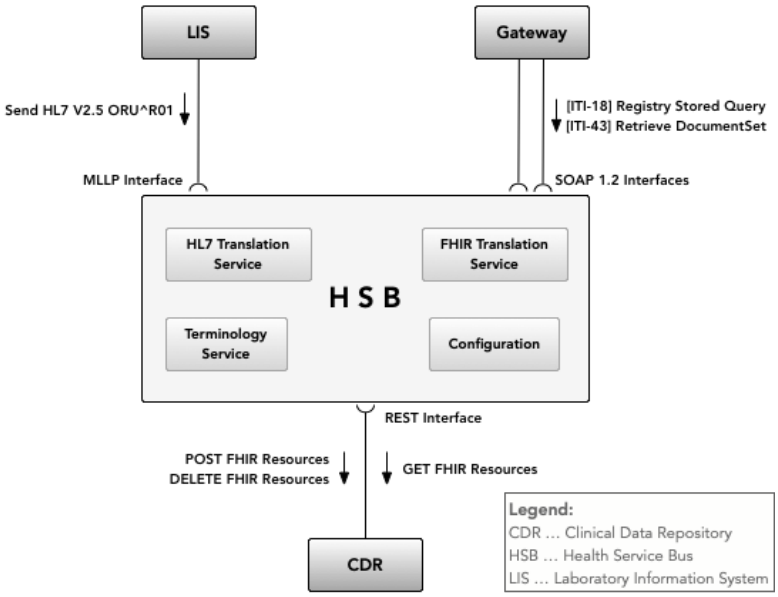

Figure 4.2: Interfaces of the HSB

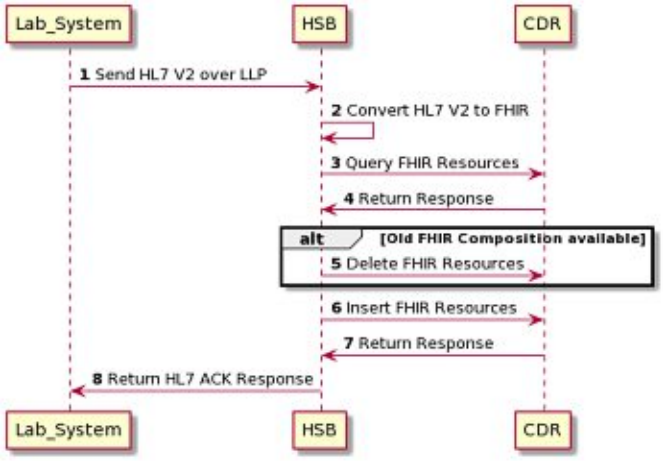

Figure 4.3: Storing laboratory data to the CDR

4.2.2 XDS interface of the HSB

The sequence diagram in Figure 4.4 illustrates the workflow of querying and retrieving Laboratory Reports.

4.2.2.1 Querying a Laboratory Report

If the healthcare provider wants to query XDS DocumentEntries of a patient, the clinical system performs an [IT Infrastructure (ITI)-18] Registry Stored Query request to the Clinic_Gateway (1). A DocumentEntry is a set of metadata, which describes a document (e.g. uniqueId, creation time, title, type of the document etc.) [39]. It does not contain the document contents itself. Once the Lab_Gateway received the [ITI-18] Registry Stored Query request (2), the Lab_Gateway forwards the request to the HSB (3). It queries the FHIR Composition resources of the requested patient from the CDR (4). Each returned FHIR Composition represents a potential Laboratory Report. For this reason the HSB creates for each FHIR Composition on-demand a DocumentEntry (6). The uniqueId of the DocumentEntry equals the identifier of the FHIR Composition. The metadata values for the DocumentEntries are extracted from the FHIR Composition resource, like identifier, date, title, type, confidentiality etc. Metadata values, which cannot be mapped from the FHIR Composition, are set by a configuration value. The HSB sends the [ITI-18] Registry Stored Query query response with the embedded DocumentEntries to the Lab_Gateway (7). Subsequently the Lab_Gateway returns the DocumentEntries embedded in a query response to the Clinic_Gateway (8). The Clinic_Gateway returns the response to the clinical system (9).

4.2.2.2 Retrieving a Laboratory Report

If the healthcare provider wants to retrieve a Laboratory Report from the previously returned list of DocumentEntries, the clinical system sends a [ITI-43] Retrieve DocumentSet request to the Clinic_Gateway (10). This request contains as input parameter the uniqueId of the DocumentEntry, for which the contents of the document shall be retrieved. The Clinic_Gateway sends the request to the Lab_Gateway. The Lab_Gateway forwards the request to the HSB. The HSB extracts the uniqueId of the requested DocumentEntry from the request. Subsequently the HSB queries the CDR for the FHIR Composition and related resources, where the identifier of the FHIR Composition is equal to the uniqueId of the DocumentEntry. Thereafter the HSB transforms the returned FHIR resources to an IHE clinical Laboratory Report document whose underlying standard is CDA. The HSB returns an [ITI-43] Retrieve DocumentSet response with the embedded CDA Laboratory Report to the Lab_Gateway. The Lab_Gateway returns the CDA Laboratory Report embedded in the response to the Clinic_Gateway. The Clinic_Gateway forwards the CDA Laboratory Report embedded in the response to the patient's portal.

4.3 Mapping of HL7 V2 to FHIR

The previous Section described the storage of laboratory data (see also section 4.2.1 for details). The integrated HL7 adapter of the HSB transforms the received the HL7 V2.5 message type Unsolicited Observation Message (ORU) Event R01 to FHIR STU3 resources and stores the resources in the CDR. This Section addresses the mapping of HL7 V2.5 ORUˆR01 to FHIR STU3 resouces.

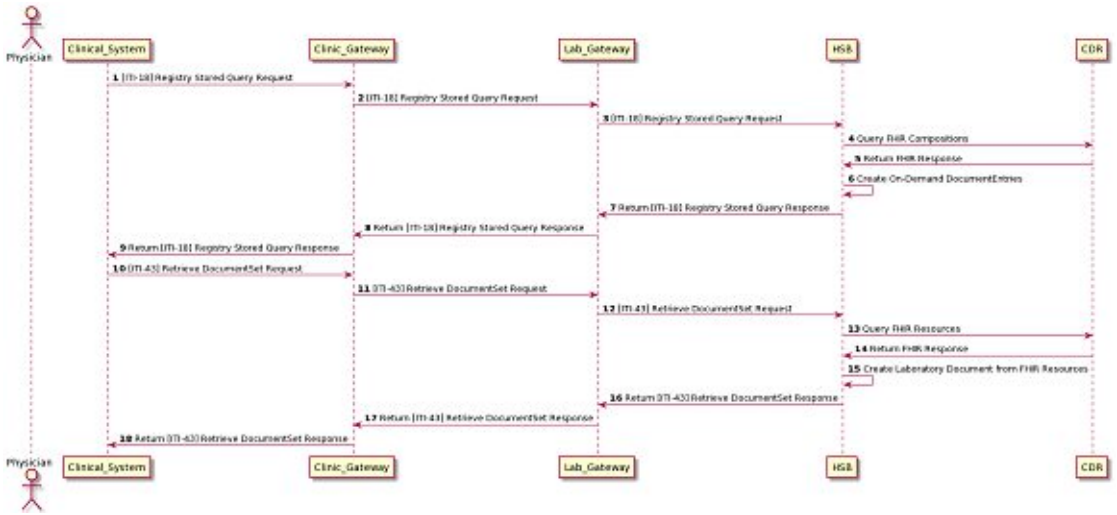

Figure 4.4: Query and retrieval of a Laboratory Report

4.3.1 HL7 ORUˆR01 Message Structure

Figure 4.5 illustrates the message structure of the HL7 V2.5 ORUˆR01 message. The HL7 ORU message is used to transmit laboratory results to other systems [13]. The message comprises several segments and logical segment groups. Specific segment groups and segments may be Optional (O) or Required (R). If a segment group is repeatable the whole group and its included segment groups and segments may be available more than once. A repeatable segment may be available more than once too. The ORUˆR01 message includes the PATIENT_RESULT segment group, which is composed of the following segment groups [13]:

- **PATIENT**
  This segment group contains details about the patient identification and demographics. It may contain information about the next of kin and associated parties.
- **VISIT**
  Information about the patient visit can be found in the VISIT group.
- **ORDER_OBSERVATION**
  The ORDER_OBSERVATION group contains information about the timing/quantity, the observations of the laboratory order and the specimen.
- **TIMING_QTY**
  Timing/Quantity information can be found in this segment group.
- **OBSERVATION**
  The OBSERVATION group includes details about the observation of the laboratory order.

- **SPECIMEN**
  This segment group describes the specimen (e.g. type of the specimen, collection date, collector etc.).

ORU^R01	Option
MSH (Message Header)	Required
SFT (Software Segment)	Optional, Repeatable
PATIENT_RESULT Group	Required, Repeatable
PATIENT Group	Optional
PID (Patient Identification)	Required
PD1 (Additional Demographics)	Optional
NTE (Notes and Comments)	Optional, Repeatable
NK1 (Next of Kin/Associated Parties)	Optional, Repeatable
VISIT Group	Optional
PV1 (Patient Visit)	Required
PV2 (Patient Visit - Additional Info)	Optional
ORDER_OBSERVATION Group	Required, Repeatable
ORC (Order Common)	Optional
OBR (Observation Request)	Required
NTE (Notes and comments)	Optional, Repeatable
TIMING_QTY Group	Optional, Repeatable
TQ1 (Timing/Quantity)	Required
TQ2 (Timing/Quantity Order Sequence)	Optional, Repeatable
CTD (Contact Data)	Optional
OBSERVATION Group	Optional, Repeatable
OBX (Observation related to OBR)	Required
NTE (Notes and comments)	Optional, Repeatable
FT1 (Financial Transaction)	Optional, Repeatable
CTI (Clinical Trial Identification)	Optional, Repeatable
SPECIMEN Group	Optional, Repeatable
SPM (Specimen)	Required
OBX (Observation related to Specimen)	Optional, Repeatable
DSC (Continuation Pointer)	Optional

Figure 4.5: HL7 ORUˆR01 message [13]

The HL7 V2.5 ACK Event R01 is illustrated in Figure 4.6. The HL7 adapter responds with the HL7 V2.5 ACKˆR01 message. This message contains acknowledgment information or details about any errors that occurred.

ACK^R01	Option
MSH (Message Header)	Required
SFT (Software Segment)	Optional, Repeatable
MSA (Message Acknowledgment)	Required
ERR (Error)	Optional, Repeatable

Figure 4.6: HL7 ACKˆR01 message [13]

4.3.2 FHIR resources representing a Laboratory Report

FHIR STU3 provides an extensive list of resource types. This resource list has been examined and the resources, which fit for the laboratory use case have been selected. Table 4.1 lists the used FHIR resources and the HL7 segments and fields from which the data will be extracted.

Table 4.1: HL7 mapping overview

FHIR Resource	Description	HL7 segment
Composition	"A set of healthcare-related information that is assembled together into a single logical document" [40].	MSH, Patient Visit (PV1), Patient Visit - Additional Information (PV2), Order Common (ORC), Observation Request (OBR), OBX
Patient	"The resource contains patient details like identification, demographics, and other administrative information" [41].	PID
Organization	"The resource provides contact and other information of various organizations" [42].	MSH-4, OBR-10, OBR-16, OBR-32, OBR-33, ORC-11, ORC-12 / ORC-21 + ORC-22 + ORC-23, OBX-15, OBX-16
Practitioner	"A person who is directly or indirectly involved in the provisioning of healthcare" [43].	OBR-10, OBR-16, OBR-32, OBR-33, ORC-11, ORC-12 + ORC-24, OBX-15, OBX-16
PractitionerRole	"A specific set of roles/locations/specialties/services that a practitioner may perform at an organization for a period of time" [44].	
Encounter	"An interaction between a patient and healthcare provider(s) for the purpose of providing healthcare service(s) or assessing the health status of a patient" [45].	ORC, OBR
DiagnosticReport	"The report contains findings and interpretation of diagnostic tests" [46].	OBR
Specimen	"A sample to be used for analysis" [47].	OBR, Specimen (SPM)
Observation	"Measurements and simple assertions made about a patient, device or other subject" [48].	OBX

The UML diagram in Figure 4.7 illustrates the relation between the FHIR resources. The FHIR Composition represents a laboratory report. The FHIR Composition contains information like an identifier, a creation time, a title, a type of document etc. and references to the related FHIR resources like FHIR Patient, FHIR Practitioner, FHIR DiagnosticReport, etc.
The subject of the FHIR Composition refers to the patient instance for whom the Laboratory

Report is created. The authors of the Laboratory Report may be stored in a FHIR Practitioner or FHIR Organization resource. The link between a FHIR Practitioner and the FHIR Organization he/she is employed at, can be set using the FHIR PractitionerRole resource. The section of the FHIR Composition refers to the FHIR DiagnosticReport resource, which describes the findings and interpretation of the laboratory analysis. The FHIR DiagnosticReport links to the FHIR Observation resources and the FHIR Specimen.

4.3.3 HL7 Mapping tables

This Subsection describes the mapping from HL7 V2.5 segments of the ORUˆR01 to proper FHIR STU3 resources. For each relevant HL7 segment a mapping table has been created. The table content is sorted by the Sequence Number (Seq) of the respective HL7 segment. Only the relevant HL7 fields, which are mapped to a FHIR attribute, are listed in the table. Relevant mappings of data types are referenced in the appropriate FHIR element. Furthermore, important FHIR and/or Required (R) attributes with no HL7 mapping are added to the table too. If a HL7 segment can be mapped into more than one FHIR resource, a further table header is added to the table for each additional FHIR resource. The cardinality (Card.) of the respective HL7 field is added to the subsequent column. The column "Option" describes, if the HL7 field is Required (R), Optional (O), Conditional (C), Backwards (B) or Repeatable (RT) (RT means that a specific content of a HL7 field can be added more than once). The cardinality (Card.) of the respective FHIR resource element is also added to the subsequent column. Moreover, several HL7 mapping tables of HL7 data type (DT) and HL7 code mappings can be found in the appendix.

Creation of the mappings
Initially the particular HL7 V2.5 segment has been studied. Relevant FHIR resources to cover a Laboratory Report have been determined by studying the available FHIR resources and its usage (see also the UML diagram in Figure 4.7). For each HL7 field an appropriate attribute of the proper FHIR STU3 resource has been searched by comparing the descriptions of the current HL7 field and the contemplable FHIR attributes. Once an appropriate attribute was found, the next step was to check if the HL7 data type (DT) and the FHIR data type (DT) correlate. Usually a mapping from one to the other data type was possible. In some special cases missing values were taken from a configuration. Moreover HL7 defines for specific HL7 DTs like Coded Value For User-Defined Tables (IS) and Coded Values For HL7 Defined Tables (ID) code lists. These HL7 codes have been mapped to the corresponding FHIR codes. The code mappings have been performed by the terminology service.

4.3.3.1 Mapping of the HL7 MSH segment

The HL7 Message Header (MSH) segment contains information necessary to construct the FHIR Composition (see Table 4.2). The unique identifier of the FHIR Composition is set from the field MSH-10 Message Control ID. The laboratory source system must ensure that this identifier is unique for a Laboratory Report. The custodian of the FHIR Composition is extracted from the value of MSH-4 Sending Facility. The HL7 adapter of the HSB loads an organization map from the configuration, which contains a list of organizations with organization identifier in the form

of an Object Identifier (OID), organization name, address and contact information. Based on the extracted OID of the Sending Facility the HL7 adapter gets the organization details for the custodian from the configuration. The attribute title is not available in the HL7 message. For this reason the HL7 adapter loads this value from a configuration.

4.3.3.2 Mapping of the HL7 PID segment

The HL7 Patient Identification (PID) segment contains identification, demographics, address and contact information of a patient and is mapped to the FHIR Patient resource (see Table 4.3). The HL7 data type XPN is mapped to the FHIR data type HumanName (see Table A.7). The attribute use of the FHIR HumanName defines the use of the name like official, maiden, nickname etc. PID-5 contains the official name of the patient, whereas PID-6 contains the maiden name of the patient.
The gender code is set in PID-8 and the code value is taken from the defined code table. As FHIR defined its own gender codes, a mapping from the HL7 codes to the FHIR codes have to be performed by the terminology service. As an example, the result of the code mapping can be viewed in Table A.14. Moreover, PID-16 provides the marital status of the patient. The code from the HL7 component PID-16.1 has to be mapped to the corresponding FHIR code by the terminology service (see also Table A.16). Finally the address and the contact information (phone number, email, fax, etc.) of the patient is mapped to the FHIR attributes.

4.3.3.3 Mapping of the HL7 PV1 segment

Basically the HL7 Patient Visit (PV1) segment provides information about the patient visit, which correlates with the FHIR Encounter resource (see Table 4.4). Usually a patient encounter is not recorded for laboratory services, thus the PV1 data is insignificant. Only the time period of the laboratory service provision is extracted from this segment.

4.3.3.4 Mapping of the HL7 PV2 segment

Just like for HL7 PV1 segment, the information of the HL7 Patient Visit - Additional Information (PV2) segment is not relevant for the laboratory use case. PV1 provides details about the type of the FHIR Composition, the service event and the code of the section of the Laboratory Report and is set to the FHIR Composition resource (see Table 4.5).

4.3.3.5 Mapping of the HL7 ORC segment

The HL7 Order Common (ORC) segment covers the relevant information about an laboratory order (see Table 4.6). The order numbers for a laboratory order can be extracted from ORC-2 Placer Order Number, ORC-3 Filler Order Number, ORC-4 Placer Group Number, and ORC-8 Parent. This information is stored in the inFulfillmentOf-section of the CDA Laboratory Report. The FHIR Composition does not provide any adequate attribute to store the order numbers of the laboratory order. For this reason the FHIR Composition is extended by the extension cda-inFulFillmentOf [50]. Listing 4.1 shows an example of the extension, which comprises the cda-inFulFillmentOf url and the value of the order number. For each order number such an

extension has to be created and added to the FHIR Composition. The definition of individual system Uniform Resource Identifier (URI)'s for different order numbers allows to identify the placer order number or the filler order number in a later step.
Furthermore, the ordering provider is an important information of the laboratory report. As an example, this may be the primary care physician, who arranges the creation of a blood panel for the patient by the laboratory. This information is stored in the field ORC-12 Ordering Provider or OBR-16 Ordering Provider. Unfortunately the FHIR Composition does not provide any attribute to store the ordering physician. Thus the FHIR Encounter is used to store information about participants of the Laboratory Report like the ordering provider. The HL7 DT Extended Composite ID Number And Name (XCN) is mapped to the FHIR Participant resource and linked to the FHIR Encounter resource. Listing 4.2 illustrates an example of an ordering provider in the FHIR Encounter. Moreover, the ORC segment may contain details about the ordering facility. This information is mapped to a FHIR Organization. The link between the FHIR Practitioner and the FHIR Organization is created using the FHIR PractitionerRole resource. This FHIR resource provides a reference for both FHIR resources, the FHIR Practitioner and the FHIR Organization.

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<Composition xmlns="http://hl7.org/fhir">
 <!-- In Fulfillment of Extension-->
   <extension url="http://hl7.org/fhir/StructureDefinition
   /ccda-in-fulfillment-of-order-extension">
      <valueIdentifier>
         <system value="1.2.3.45.63.2.123414.23"/>
         <value value="8348345"/>
      </valueIdentifier>
   </extension>
</Composition>
```

Listing 4.1: Extension "In Fulfillment of" [50]

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<Encounter xmlns="http://hl7.org/fhir">
   <id value="d7513599-796b-41cf-824d-0e87a05c8d1c"/>
   <status value="finished"/>
   <subject>
      <reference
         value="Patient/b1a9ada5-cc74-486e-a603-ec7dbdf788f5"/>
   </subject>
   <!-- Ordering Provider Start -->
   <participant>
     <!-- role of the participant -->
      <type>
         <coding>
            <system
               value="http://hl7.org/fhir/v3/ParticipationType"/>
            <code value="REF"/>
            <display value="referrer"/>
         </coding>
```

```
      </type>
      <period>
         <start value="2020-02-18T06:11:42+01:00"/>
      </period>
      <individual>
        <!-- reference to the FHIR Practitioner resource, which
            contains the information of the ordering provider -->
        <reference
           value="Practitioner/9213a2dd-7ac8-4ce4-af16-f075b0681"/>
      </individual>
   </participant>
   <!-- Ordering Provider End -->
</Encounter>
```

Listing 4.2: Ordering Provider [45]

4.3.3.6 Mapping of the HL7 OBR segment

The HL7 Observation Request (OBR) segment transports information of an order for a diagnostic study or observation, physical exam or assessment [13]. The OBR segment is applied for diagnostic services (e.g. laboratory, EKG) or clinical observations (e.g. vital signs, physical exam) [13].
The information covered in the HL7 OBR segment is mapped to the FHIR DiagnosticReport and FHIR Specimen resource (see Table 4.7). A describing code for the diagnostic report, a time period, when the laboratory order was performed and other interesting data can be used from the HL7 OBR segment. The OBR segment also contains details about the result interpreters. As the FHIR DiagnosticReport does not provide an attribute to define the result interpreters, this information is stored in the FHIR Composition. The result interpreters in the fields OBR-32 and OBR-33 are mapped to the FHIR Practitioner and a reference of these FHIR resources is added to the author element of the FHIR Composition (Table A.2 provides details of the Name With Location And Data (NDL) mapping).
Furthermore, the data from the field OBR-16 Ordering Provider are added to the FHIR Encounter resource (see Subsection 4.3.3.5 for more details).
The HL7 OBR segment may provide specimen information, which includes the specimen source name, information about the collection like collector, collection method, date and time of the event etc. The specimen data can be set to the FHIR Specimen resource.

4.3.3.7 Mapping of the HL7 SPM segment

The HL7 Specimen (SPM) segment provides specimen information that include the specimen source name, information about the collection like collector, collection method, date and time of the event etc. The specimen data can be set to the FHIR Specimen resource (see Table 4.8 and Table 4.7). Listing 4.3 illustrates an example of a mapped FHIR Specimen.

```xml
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<Specimen xmlns="http://hl7.org/fhir">
   <id value="8691978f-a109-4de7-9a16-39b8bc825fe0"/>
   <identifier>
      <system value="1.2.279.0.76.3.1.138.1.16.2"/>
      <value value="7237234992"/>
   </identifier>
   <type>
      <coding>
         <system value="2.16.840.1.113883.5.129"/>
         <code value="BLD"/>
         <display value="Blood"/>
      </coding>
   </type>
   <subject>
      <reference
         value="Patient/38075267-3209-41ac-bc7a-13b6e01bed88"/>
   </subject>
   <receivedTime value="2020-02-25T10:44:15+01:00"/>
   <collection>
      <collector>
         <reference
            value="Practitioner/925eec32-1f39-465b-8606-594868be2c"/>
      </collector>
      <collectedDateTime value="2020-02-24T09:40:00+01:00"/>
      <bodySite>
         <coding>
            <system value="2.16.840.1.113883.5.1052"/>
            <code value="LAFC"/>
            <display value="left antecubital fossa"/>
         </coding>
      </bodySite>
   </collection>
   <note>
      <authorPractitioner>
         <reference
            value="Practitioner/925eec32-1f39-465b-8606-594868be2c"/>
      </authorPractitioner>
      <text value="some specimen comment"/>
   </note>
</Specimen>
```

Listing 4.3: FHIR Specimen example

4.3.3.8 Mapping of the HL7 OBX segment

An HL7 Observation (OBX) segment represents the smallest indivisible unit of a report [13]. In case of the HL7 ORUˆR01 message the OBX segment represents the single results of the laboratory study. The OBX segment can be mapped to the FHIR Observation resource (see Table

4.9). An OBX can contain textual data, numeric data, encapsulated data, binary data etc. The field OBX-2 Value Type defines the data type of the value in field OBX-5 Observation Value. Listing 4.4 shows in the example two OBX segments with two different value types. The first OBX defines a Numeric (NM) data type for the field OBX-5 Observation Value. The second OBX defines the data type String (ST) for the field OBX-5 Observation Value. Listing 4.5 displays the mapping of the second OBX segment to the FHIR Observation resource in XML format.
Finally the participants of the laboratory order from the fields OBX-15 Producer's ID and OBX-16 Responsible Observer are mapped to the FHIR Practitioner resource and referenced in the FHIR Composition resource.

```
OBX|0001|NM|THROMB^Thrombozyten^HGW||416|GPt/l|176 -
    391|H|||F|||||74757968^Grey^Victoria^^^Dr.
    med.^^^&urn:oid:1.2.229.0.71.4.15&ISO|||20200123154439|

OBX|0002|ST|BORMBL^Borrelia burgdorferi-IgM-Ak im
    Serum^HGW||NEGATIV||NEGATIV|N|||F|||||74757968^Grey^Victoria^^^Dr.
    med.^^^&urn:oid:1.2.229.0.71.4.15&ISO|||20200125103044|
NTE|0002|L|Borrelien-spezifische Antikoerper im Immunoblot (IB)
    nicht bestaetigt: Aerztliche Befundbewertung Serologisch kein
    sicherer Anhalt fuer Borrelien-Infektion. Bei klinischem Verdacht
    auf Borreliose empfehlen wir eine Kontrolluntersuchung in ca. 4
    Wochen.|
```

Listing 4.4: OBX example

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<Observation xmlns="http://hl7.org/fhir">
   <id value="c25410ed-3be3-466d-81bf-4993bd92b7f4"/>
   <status value="final"/>
   <category>
      <coding>
         <system value="http://hl7.org/fhir/observation-category"/>
         <code value="laboratory"/>
         <display value="Labor"/>
      </coding>
   </category>
   <code>
      <coding>
         <code value="BORMBL"/>
         <display value="Borrelia burgdorferi-IgM-Ak im Serum"/>
         <system value="2.74.123.1.113933.5.54"/>
      </coding>
   </code>
   <subject>
      <reference
         value="Patient/e4977900-1d2a-45e8-8855-617871661910"/>
   </subject>
   <effectiveDateTime value="2020-01-25T10:30:44+01:00"/>
   <performer>
```

```
24        <reference
              value="Practitioner/f389e081-09d1-47b6-a8b3-a4bdd77327db"/>
25     </performer>
26     <valueString value="NEGATIV"/>
27     <interpretation>
28        <coding>
29           <system value="2.16.840.1.113883.5.83"/>
30           <version value="20150101"/>
31           <code value="N"/>
32           <display value="Normal (applies to non-numeric results)"/>
33        </coding>
34     </interpretation>
35     <comment
36        value="Borrelien-spezifische Antikoerper im Immunoblot (IB)
              nicht bestaetigt: Aerztliche Befundbewertung Serologisch
              kein sicherer Anhalt fuer Borrelien-Infektion. Bei
              klinischem Verdacht auf Borreliose empfehlen wir eine
              Kontrolluntersuchung in ca. 4 Wochen."
37     />
38 </Observation>
```

Listing 4.5: FHIR Observation example

4.3.3.9 Mapping of the HL7 NTE segment

Additional comments for single observations, the order of the observations or the patient can be provided by using the HL7 NTE segment (see Table A.9 for details).

4.3.3.10 Mapping of the HL7 XCN and NDL data types

The HL7 data types Extended Composite ID Number And Name (XCN) and Name With Location And Data (NDL) contain information about relevant participating persons of the Laboratory Report (see Tables A.1 and A.2). The HL7 adapter of the HSB extracts the organization ID from the subcomponent XCN-9.2 Universal ID of the Assigning Authority or XCN-14.2 Universal ID of the Assigning Facility. In the case of the data type NDL the organization ID is extracted from the subcomponent NDL-1.10 Universal ID of the Assigning Authority or NDL-7.2 Universal ID of the Assigning Facility. Subsequent the HL7 adapter searches for organization details in the organization map from the configuration. The organization ID represents the key with which an organization instance can be loaded. If the organization instance is found in the map, a FHIR Organization resource is created and linked with the FHIR Practitioner created from the data type XCN or NDL. The link between the FHIR Practitioner and the FHIR Organization is created by usage of the FHIR PractitionerRole, which contains a reference of both resources, the FHIR Practitioner and the FHIR Organization. Furthermore, the address and contact information can be adopted from the related FHIR Organization, if the FHIR Practitioner does not contain this information.

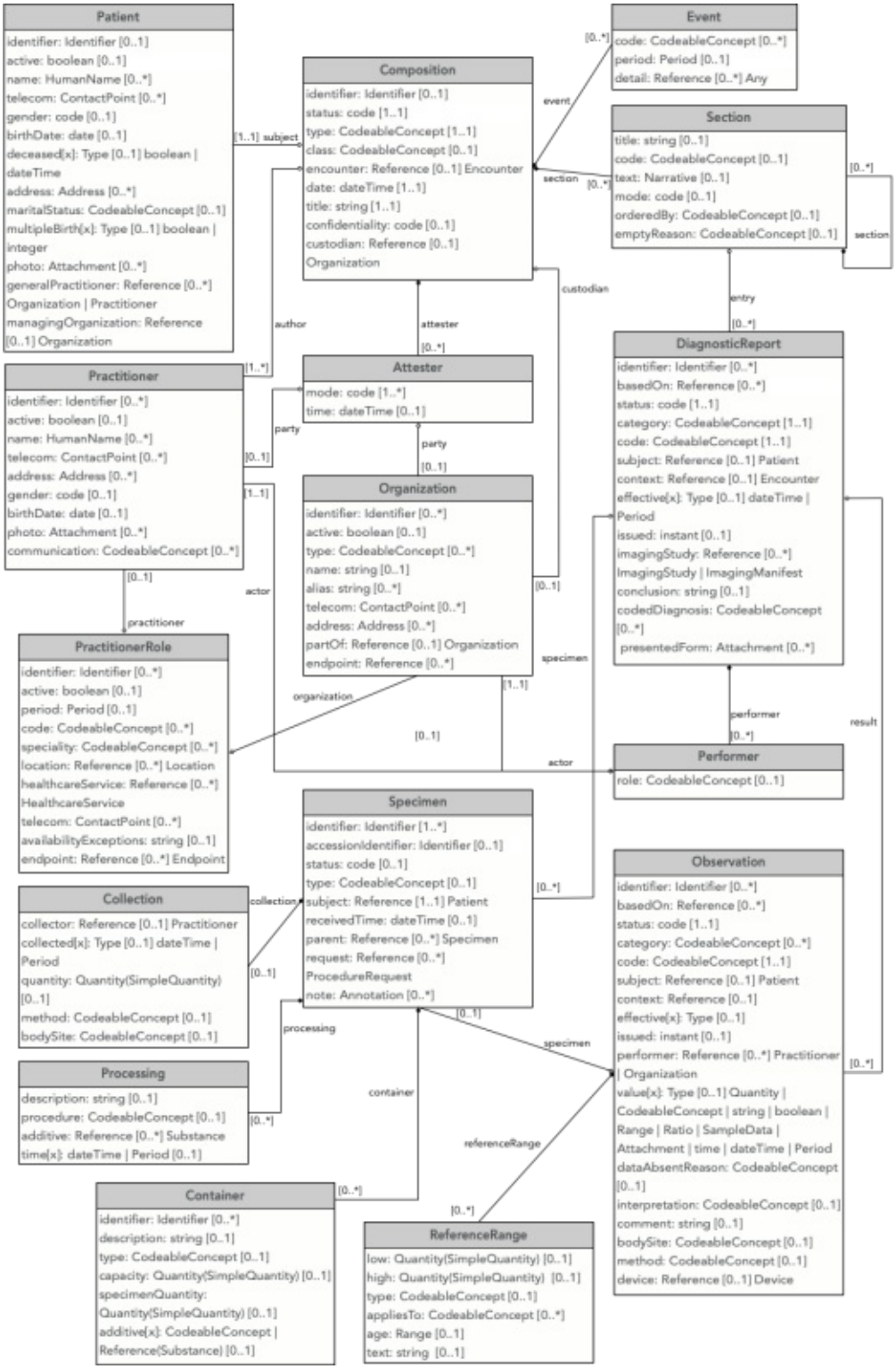

Figure 4.7: UML diagram - FHIR STU3 resources of a laboratory report [49]

Table 4.2: Mapping of the HL7 MSH segment [13] [40]

Seq	Name	HL7 DT	Option	FHIR Composition	FHIR DT	Card.
4	Sending Facility	HD	O			
4.2	Universal ID	ST	C	custodian (organization map from configuration)	Reference(Organization)	0..1
7	Date / Time of Message	TS	R	date	dateTime	1..1
10	Message Control ID	ST	R	identifier	Identifier	0..1
19	Principal Language of Message	CWE	O	language (inherited)	code	0..1
				type (configuration value)	CodeableConcept	1..1
				subject (see Tables 4.3)	Reference(Patient | Group | Device | Substance)	1..1
				encounter (see Table 4.6 and 4.7)	Reference(Encounter)	0..1
				title (configuration value)	string	1..1

Table 4.3: Mapping of the HL7 PID segment [13] [41]

Seq	Name	HL7 DT	Option	FHIR Patient	FHIR DT	Card.
3	Patient Identifier List	CX	R, RT	identifier	Identifier	0..*
3.1	ID Number	ST	R	identifier/value	string	0..1
3.4	Assigning Authority	HD	R			
3.4.2	Universal ID	ST	R	identifier/system	uri	0..1
5	Patient Name	XPN	R, RT	name (see Table A.7) name/use="official" (default)	HumanName code	0..* 0..1
5.7	Name Type Code	ID	O	name/use	code	0..1
5.1	Family Name	FN	R	name/family	string	0..1
5.2	Given Name (First Name)	ST	O	name/given	string	0..*
5.3	Second and Further Given Names	ST	O	name/given	string	0..*
5.4	Suffix	ST	O	name/suffix	string	0..*
5.5	Prefix	ST	O	name/prefix	string	0..*

6	Mother's Maiden Name	XPN	O, RT	name (see Table A.7) name/use="maiden"	HumanName code	0..* 0..1
6.1	Family Name	ST	R	name/family	string	0..1
6.2	Given Name (First Name)	ST	O	name/given	string	0..*
6.3	Second and Further Given Names	ST	O	name/given	string	0..*
6.4	Suffix	ST	O	name/suffix	string	0..*
6.5	Prefix	ST	O	name/prefix	string	0..*
7	Date/Time of Birth	TS	O	birthDate	date	0..1
8	Administrative Sex	IS	O	gender (see Table A.14)	code	0..1
11	Patient Address	XAD	O, RT	address (see Table A.6)	Address	0..*
11.1	Street Address	SAD	O	address/line	string	0..*
11.3	City	ST	O	address/city	string	0..1
11.4	State or Province	ST	O	state	string	0..1
11.5	Zip or Postal Code	ST	O	address/postalCode	string	0..1
11.6	Country	ST	O	address/country (ISO 3166 3 letter code)	string	0..1
11.7	Address Type	ID	C	address/use	code	0..1
13	Patient Number - Home	XTN	O, RT	telecom (see Table A.8) telecom/use="home"	ContactPoint code	0..* 0..1
13.1	Telephone Number		B	telecom/value (deprecated as of HL7 V2.3)	string	0..1
13.3	Telecommunication Equipment Type	ID	R	telecom/system	uri	0..1
13.4	Email Address	ST	O	telecom/value telecom/system="email"	string code	0..1 0..1
13.5	Country Code	NM	O			
13.6	Area/City Code	NM	O			
13.7	Local Number	NM	O	telecom/value	string	0..1
13.8	Extension	NM	O			

13.10	Extension Prefix	ST	O			
14	Phone Number - Business	XTN	O, RT	telecom (see Table A.8) telecom/use="work"	ContactPoint code	0..* 0..1
14.1	Telephone Number		B	telecom/value (deprecated as of HL7 V2.3)	string	0..1
14.3	Telecommunication Equipment Type	ID	R	telecom/system	uri	0..1
14.4	Email Address	ST	O	telecom/value telecom/system="email"	string code	0..1 0..1
14.5	Country Code	NM	O			
14.6	Area/City Code	NM	O			
14.7	Local Number	NM	O	telecom/value	string	0..1
14.8	Extension	NM	O			
14.10	Extension Prefix	ST	O			
16	Marital Status	CE	O	maritalStatus (see Table A.3)	CodeableConcept	0..1
16.1	Identifier	ST	O	maritalStatus/coding/code (see Table A.16)	code	0..1
				maritalStatus/coding/system= "http://hl7.org/fhir/v3 /MaritalStatus" [51]	uri	0..1

Table 4.4: Mapping of the HL7 PV1 segment [13] [40]

Seq	Name	HL7 DT	Option	FHIR Composition	FHIR DT	Card.
				event	BackboneElement	0..*
				event/period	Period	0..1
44	Admit Date/Time	TS	O	event/period/start	dateTime	0..1
45	Discharge Date/Time	TS	O	event/period/end	dateTime	0..1

Table 4.5: Mapping of the HL7 PV2 segment [13] [40]

Seq	Name	HL7 DT	Option	FHIR Composition	FHIR DT	Card.
3	Admit Reason	CE	O	type (see Table A.3)	CodeableConcept	1..1
				type/coding	Coding	0..*
3.1	Identifier	ST	O	type/coding/code	code	0..1
3.2	Text	ST	O	type/coding/display	string	0..1
3.3	Name of Coding System	ID	O	type/coding/system	uri	0..1
				section	BackboneElement	0..*
3	Admit Reason	CE	O	section/code	CodeableConcept	0..1
				section/code/coding	Coding	0..*
3.1	Identifier	ST	O	section/code/coding/code	code	0..1
3.2	Text	ST	O	section/code/coding/display	string	0..1
3.3	Name of Coding System	ID	O	section/code/coding/system	uri	0..1
				event	BackboneElement	0..*
3	Admit Reason	CE	O	event/code (see Table A.3)	CodeableConcept	0..*
				event/code/coding	Coding	0..*
3.1	Identifier	ST	O	event/code/coding/code	code	0..1
3.2	Text	ST	O	event/code/coding/display	string	0..1
3.3	Name of Coding System	ID	O	event/code/coding/system	uri	0..1

Table 4.6: Mapping of the HL7 ORC segment [13] [45] [42]

Seq	Name	HL7 DT	Option	FHIR Composition	FHIR DT	Card.
				extension	Extension	0..*
				extension/url="http://hl7.org/fhir/StructureDefinition/ccda-in-fulfillment-of-order-extension"	uri	1..1
				extension/valueIdentifier	Identifier	1..1
2	Placer Order Number	EI	C	extension/valueIdentifier/value	string	0..1
3	Filler Order Number	EI	C	extension/valueIdentifier/value	string	0..1
4	Placer Group Number	EI	O	extension/valueIdentifier/value	string	0..1
8	Parent	EIP	O	extension/valueIdentifier/value	string	1..1
5	Order Status	ID	O	status	code	1..1
				attester	BackboneElement	0..*
11	Verified By	XCN	O, RT	attester/party (see Table A.1)	Reference(Practitioner | Patient | Organization)	0..1
28	Confidentiality Code	CWE	O			
28.1	Identifier	ST	O	confidentiality/value	code	0..1
Seq	**Name**	**HL7 DT**	**Option**	**FHIR Encounter**	**FHIR DT**	**Card.**
				participant	BackboneElement	0..*
				participant/type	CodeableConcept	0..*
				participant/type/code="REF"	string	0..1
				participant/type/display="referrer"	string	0..1
				participant/type/system="http://hl7.org/fhir/v3/ParticipationType"	uri	0..1
12	Ordering Provider	XCN	O, RT	participant/individual (see Table A.1)	Reference(Practitioner | RelatedPerson)	0..1
				participant/period	Period	0..1
15	Order Effective Date/Time	TS	O	participant/period/start	dateTime	0..1

24	Ordering Provider Address	XAD	O, RT	participant/individual (see Table A.6) address of the FHIR Participant of the Ordering Provider)	Reference(Practitioner | RelatedPerson)	0..1
				subject (see Table 4.3)	Reference(Patient | Group)	0..1
Seq	**Name**	**HL7 DT**	**Option**	**FHIR Organization**	**FHIR Data Type**	**Card.**
21	Ordering Facility Name	XON	O, RT	identifier (see Table A.5)	Identifier	0..*
21.1	Organization Name	ST	O	name	string	0..1
				identifier	Identifier	0..*
21.10	Organization Identifier	ST	O	identifier/value	string	0..1
22	Ordering Facility Address	XAD	O, RT	address (see Table A.6)	Address	0..*
23	Ordering Facility Phone Number	XTN	O, RT	telecom (see Table A.8)	ContactPoint	0..*

Table 4.7: Mapping of the HL7 OBR segment [13] [40] [45] [47]

Seq	Name	HL7 DT	Option	FHIR DiagnosticReport	FHIR DT	Card.
4	Universal Service Identifier	CE	R	code	CodeableConcept	1..1
				code/coding	Coding	0..*
4.1	Identifier	ST	O	code/coding/code	code	0..1
4.2	Text	ST	O	code/coding/display	string	0..1
4.3	Name of Coding System	ID	O	code/coding/system	uri	0..1
				effective[x]	dateTime | Period	0..1
7	Observation Date/Time	TS	C	effectiveDateTime/value | effectivePeriod/start	dateTime	0..1
8	Observation End Date/Time	TS	O	effectivePeriod/end	dateTime	0..1
22	Results Rpt/Status Chng – Date/-Time	TS	C	issued	instant	0..1
24	Diagnostic Serv Sect ID	ID	O	category	CodeableConcept	0..1
25	Result Status	ID	C	status	code	1..1
				subject (see Table 4.3)	Reference(Patient | Group | Device | Substance)	1..1

				specimen	Reference(Specimen)	0..*
				result (see Table 4.9)	Reference(Observation)	0..*
Seq	**Name**	**HL7 DT**	**Option**	**FHIR Composition**	**FHIR DT**	**Card.**
2	Placer Order Number	EI	C	extension for inFulfillmentOf, see ORC-2 (see Table 4.6)		
3	Filler Order Number	EI	C	extension for inFulfillmentOf, see ORC-3 (see Table 4.6)		
32	Principal Result Interpreter	NDL	O	author (see Table A.2)	Reference(Practitioner | Patient | RelatedPerson | Device)	1..*
33	Assistant Result Interpreter	NDL	O, RT	author (see Table A.2)	Reference(Practitioner | Patient | RelatedPerson | Device)	1..*
Seq	**Name**	**HL7 DT**	**Option**	**FHIR Encounter**	**FHIR DT**	**Card.**
				participant	BackboneElement	0..*
				participant/type	CodeableConcept	0..*
				participant/type/code=“REF”	string	0..1
				participant/type/display= “referrer”	string	0..1
				participant/type/system= “http://hl7.org/ fhir/v3/ParticipationType”	uri	0..1
16	Ordering Provider	XCN	R, RT	participant/individual (see Table A.1)	Reference(Practitioner | RelatedPerson)	0..1
				participant.period	Period	0..1

Seq	Name	HL7 DT	Option	FHIR Specimen	FHIR DT	Card.
				collection	BackboneElement	0..1
7	Observation Date/Time	TS	C	collection/collectedDateTime	dateTime	0..1
9	Collection Volume	CQ	O	collection/quantity		
9.1	Quantity	NM	O	collection/quantity/value	decimal	0..1
9.2	Units	CE	O			
9.2.1	Identifier	ST	O	collection/quantity/code	code	0..1
9.2.2	Text	ST	O	collection/quantity/unit	string	0..1
9.2.3	Name of Coding System	ID	O	collection/quantity/system	uri	0..1
10	Collector Identifier	XCN	O, RT	collection/collector (see Table A.1)	Reference(Practitioner)	0..1
14	Specimen Received Date/ Time	TS	B	receivedTime	dateTime	0..1
15	Specimen Source	SPS	B			
15.1	Specimen Source Name or Code	CWE	O	type (see Table A.4)	CodeableConcept	0..1
				type/coding	Coding	0..*
15.1.1	Identifier	ST	O	type/coding/code	code	0..1
15.1.2	Text	ST	O	type/coding/display	string	0..1
15.1.3	Name of Coding System	ID	O	type/coding/system	uri	0..1
15.1.7	Coding System Version ID	ST	C	type/coding/version	string	0..1
15.3	Specimen Collection Method	TX	O	method/text	CodableConcept	0..1
15.4	Body Site	CWE	O	collection/bodySite (see Table A.4)	CodableConcept	0..1
				collection/bodySite/coding	Coding	0..*
15.4.1	Identifier	ST	O	collection/bodySite/coding/code	code	0..1
15.4.2	Text	ST	O	collection/bodySite/coding/display	string	0..1
15.4.3	Name of Coding System	ID	O	collection/bodySite/coding/system	uri	0..1
39	Collector's Comment	CE	O	note	Annotation	0..*
				subject (see Table 4.3)	Reference (Patient | Group | Device | Substance)	1..1

Table 4.8: Mapping of the HL7 SPM segment [13] [47]

Seq	Name	HL7 DT	Option	FHIR Specimen	FHIR DT	Card.
2	Specimen ID	EIP	O	identifier	Identifier	0..*
2.1	Placer Assigned Identifier	EI	O	identifier[x]	Identifier	
2.1.1	Entity Identifier	ST	O	identifier[x]/value	string	0..1
2.1.3	Universal ID	ST	C	identifier[x]/system	uri	0..1
2.2	Filler Assigned Identifier	EI	O	identifier[y]	Identifier	
2.2.1	Entity Identifier	ST	O	identifier[y]/value	string	0..1
2.2.3	Universal ID	ST	C	identifier[y]/system	uri	0..1
4	Specimen Type	CWE	R	type (see Table A.4)	CodeableConcept	0..1
				type/coding	Coding	0..*
4.1	Identifier	ST	O	type/coding/code	code	0..1
4.2	Text	ST	O	type/coding/display	string	0..1
4.3	Name of Coding System	ID	O	type/coding/system	uri	0..1
5	Specimen Type Modifier	CWE	O, RT	probably relevant to adapt the type code		
				processing	BackboneElement	0..*
6	Specimen Additives	CWE	O, RT	processing/additive	Reference(Substance)	0..*
				collection	BackboneElement	0..1
7	Specimen Collection Method	CWE	O	collection/method (see Table A.4)	CodeableConcept	0..1
				collection/method.coding	Coding	0..*
7.1	Identifier	ST	O	collection/method/coding/code	code	0..1
7.2	Text	ST	O	collection/method/coding/display	string	0..1
7.3	Name of Coding System	ID	O	collection/method/coding/system	uri	0..1
8	Specimen Source Site	CWE	O	collection/bodySite	CodeableConcept	0..1
				collection/bodySite/coding	Coding	0..*
8.1	Identifier	ST	O	collection/bodySite/coding/code	code	0..1
8.2	Text	ST	O	collection/bodySite/coding/display	string	0..1
8.3	Name of Coding System	ID	O	collection/bodySite/coding/system	uri	0..1

9	Specimen Source Site Modifier	CWE	O, RT	probably relevant to adapt the bodySite code		
12	Specimen Collection Amount	CQ	O	collection/quantity	SimpleQuantity	0..1
12.1	Quantity	NM	O	collection/quantity/value	decimal	0..1
12.2	Units	CE	O			
12.2.1	Identifier	ST	O	collection/quantity/code	code	0..1
12.2.2	Text	ST	O	collection/quantity/unit	string	0..1
12.2.3	Name of Coding System	ID	O	collection/quantity/system	uri	0..1
14	Specimen Description	ST	O, RT	note	Annotation	0..*
17	Specimen Collection Date/Time	DR	O	collected[x]	dateTime | Period	0..1
17.1	Range Start Date/Time	TS	O	collectedDateTime/value | collectedPeriod/start	dateTime | Period	0..1
17.2	Range End Date/Time	TS	O	collectedPeriod/end	Period	0..1
18	Specimen Received Date/Time	TS	O	receivedTime	dateTime	0..1
20	Specimen Availability	ID	O	status	code	0..1
				container	BackboneElement	0..*
27	Container Type	CWE	O	container/type	CodeableConcept	0..1
				code/coding	Coding	0..*
27.1	Identifier	ST	O	code/coding/code	code	0..1
27.2	Text	ST	O	code/coding/display	string	0..1
27.3	Name of Coding System	ID	O	code/coding/system	uri	0..1
				subject (see Table 4.3)	Reference(Patient | Group | Device | Substance)	1..1

Seq	Name	HL7 DT	Option	FHIR Substance	FHIR DT	Card.
6	Specimen Additives	CWE	O, RT	code (see Table A.4)	code	1..1
				code/coding	Coding	0..*
6.1	Identifier	ST	O	code/coding/code	code	0..1
6.2	Text	ST	O	code.coding/display	string	0..1
6.3	Name of Coding System	ID	O	code/coding/system	uri	0..1

Table 4.9: Mapping of the HL7 OBX segment [13] [48]

Seq	Name	HL7 DT	Option	FHIR Observation	FHIR DT	Card.
2	Value Type	ID	C	Data type for value[x]	varies	0..1
3	Observation Identifier	CE	R	code (see Table A.3)	CodeableConcept	1..1
				code/coding	Coding	0..*
3.1	Identifier	ST	O	code/coding/code	code	0..1
3.2	Text	ST	O	code/coding/display	string	0..1
3.3	Name of Coding System	ID	O	code/coding/system	uri	0..1
5	Observation Value	varies	C, RT	Value for value[x]	varies	0..1
6	Units	CE	O	value[x] (see Table A.3)		
7	References Range	ST	O	referenceRange	BackboneElement	0..*
8	Abnormal Flags	IS	O, RT	interpretation (value is mapped to CodeableConcept config entry)	CodeableConcept	0..1
10	Nature of Abnormal Test	ID	O, RT	referenceRange/type	CodeableConcept	0..1
11	Observation Result Status	ID	R	status	code	1..1
14	Date/Time of the Observation	TS	O	effectiveDateTime	dateTime	0..1
15	Producer's ID	CE	B	performer	Reference(Practitioner | Organization | Patient | RelatedPerson)	0..*

16	Responsible Observer	XCN	B, RT	performer (see Table A.1)	Reference(Practitioner | Organization | Patient | RelatedPerson)	0..*
17	Observation Method	CE	O, RT	method (see Table A.3)	CodeableConcept	0..1
				method.coding	Coding	0..*
17.1	Identifier	ST	O	method/coding/code	code	0..1
17.2	Text	ST	O	method/coding/display	string	0..1
17.3	Name of Coding System	ID	O	method/coding/system	uri	0..1
19	Date/Time of the Analysis	TS	O	effectiveDateTime (if OBX-14 is empty)	dateTime	0..1
				subject (see Table 4.3)	Reference(Patient)	0..1
				comment (from related NTE, see Table A.9)	string	0..1
Seq	**Name**	**HL7 DT**	**Option**	**FHIR Composition**	**FHIR DT**	**Card.**
16	Responsible Observer	XCN	B, RT	author (see Table A.1)	Reference(Practitioner | Patient | RelatedPerson | Device)	1..*

4.4 Mapping of FHIR to CDA

The FHIR STU3 resources are stored and managed in the CDR. Each FHIR STU3 Composition represents a Laboratory Report document and references the related FHIR resources. Subsection 4.3.2 depicts the particular FHIR resources and their relationship.
This Section describes the mapping from the FHIR STU3 resources to a CDA. The HSB creates the IHE Clinical Laboratory Report based on the content of the FHIR resources.

4.4.1 CDA Laboratory Report

The IHE Pathology and Laboratory Medicine (PaLM) Technical Framework (TF) provides an implementation guideline for the creation of an IHE Clinical Laboratory Report [52]. The IHE Laboratory Report is compliant to the CDA R2 standard, but implements additional guidelines and restrictions based on the specified content modules of the IHE PaLM TF.

4.4.1.1 CDA header content modules

In Table 4.10 the content modules of the CDA header of the Laboratory Report is explained in more detail.

Table 4.10: Laboratory Report - CDA header content modules [52]

CDA Element	Card.	Usage	Description
realmCode	0..*	R	Identifies the national extension of the document. The code “UV” (universal) defines the international context.
typeId	1..1	R	Contains the reference to the CDA R2 standard. @root=“2.16.840.1.113883.1.3” @extension=“POCD_HD000040“
templateId	0..*	R	Defines the compliance to the specification of the Clinical Laboratory Report. @root=“1.3.6.1.4.1.19376.1.3.3“
id	1..1	R	Contains the unique instance identifier of the laboratory report.
code	1..1	R	If the Laboratory Report is a multidisciplinary report and contains many specialities, the LOINC code “11502-2” has to be used. For a single discipline Laboratory Report the appropriate LOINC code of the specialities section has to be used.
effectiveTime	1..1	R	Contains the creation date and time of the Laboratory Report.
confidentialityCode	1..1	R	Defines the level of confidentiality of the report.
languageCode	0..1	R	Contains the human language in which the report is written.
setId	0..1	R	Provides the common identifier across all document revisions.

versionNumber	0..1	O	Contains the document version after replacement.
recordTarget	1..*	R	The Laboratory Report allows to add human as well as non-human patient information to the recordTarget. For this special use case the laboratory system only provides information of human patients. The recordTarget shall provide information about the identifier, name, gender, birth date, address and contact information of the patient.
author	1..*	R	At least one author has to be set, which can be a software system or a person.
custodian	1..1	R	Represents the organization that is in charge of maintaining the Laboratory Report.
informationRecipient	0..*	O	Contains the person who shall get a copy of the report. The section shall contain the templateId with root="1.3.6.1.4.1.19376.1.3.3.1.4"
legalAuthenticator	0..1	O	Represents the person who has legally authenticated the report.
authenticator	0..*	O	**Laboratory Results Validator:** Contains the clinical expert(s) who performed the clinical validation of the report or single results. The laboratory results validators are identified by the templateId@root="1.3.6.1.4.1.19376.1.3.3.1.5" and the @typeCode="AUTHEN".
participant	0..*	O	**Ordering Provider:** The ordering provider of the order is identified by the templateId@root="1.3.6.1.4.1.19376.1.3.3.1.6" and the typeCode="REF" (referrer).
inFulfillmentOf	0..*	O	Contains the placer order number or the placer group number.
documentationOf	0..*	O	Provides result event(s) produced by the laboratory. Furthermore, it contains the information, if the report is non-final (lab:statusCode@code="active").
documentationOf .serviceEvent.performer	0..*	O	**Laboratory Performer:** Person(s), who have performed the reported tests. For a single performer of the whole report this information has to be set to the CDA header, otherwise the performer shall be added directly to the organizer or observation. The templateId root="1.3.6.1.4.1.19376.1.3.3.1.7" identifies the laboratory performer.

relatedDocument	0..*	R	Provides the parent document information.
componentOf	0..1	O	Describes the encounter during which the reported laboratory observations were ordered.

4.4.1.2 CDA body content modules

The Laboratory Report must have at least one laboratory speciality section [52]. The report allows a multidisciplinary, but also a single disciplinary speciality.
Figure 4.8 illustrates the structure of a speciality section. The section contains a narrative text part (Level 2) as well as an entry element (Level 3). This Laboratory Report Data Processing Entry is identified by the templateId@root="1.3.6.1.4.1.19376.1.3.1". The entry may include information about the specimen collection. Furthermore, the entry may contain one or more Laboratory Battery Organizers with the corresponding observations. "A Laboratory Battery Organizer is used to group Laboratory Observations for a battery of tests" [52].
The FHIR DiagnosticReport represents the Laboratory Battery Organizer. The FHIR Observation corresponds to the CDA observation. Also the FHIR Specimen can be mapped to the CDA entry content modules Specimen Collection and Specimen Received.

4.4.2 FHIR Mapping tables

This Subsection describes the mapping from FHIR STU3 resources to the CDA Clinical Laboratory Report. For each relevant FHIR resource a mapping table has been created. The table content is sorted by the order of the resource attributes. Only the relevant FHIR attributes, which may contain a content from the recently mapped HL7 message, are listed in the table. Furthermore, important CDA and/or required elements with no FHIR mapping are added to the table too. Relevant mappings of data types are referenced in the appropriate CDA element. The cardinality (Card.) of the respective FHIR element as well as for the CDA element is added to the subsequent columns. Additionally several FHIR mapping tables and FHIR code mappings can be found in the appendix.

Creation of the mappings
Initially the particular FHIR STU3 resources and the relevant CDA sections and elements of the IHE Clinical Laboratory Report have been studied. For each FHIR attribute an appropriate section or element of the proper CDA Laboratory Report has been searched by comparing the descriptions of the current FHIR attributes and the contemplable CDA sections and elements. Once an appropriate section or element was found, the next step was to check if the FHIR data type (DT) and the CDA data type (DT) correlate. Usually a mapping from one to the other data type was possible. In some special cases missing values were taken from a configuration. Moreover FHIR defines for specific DTs like code or CodeableConcept code lists. These FHIR codes have been mapped to the corresponding CDA codes. The code mappings have been performed by the terminology service.

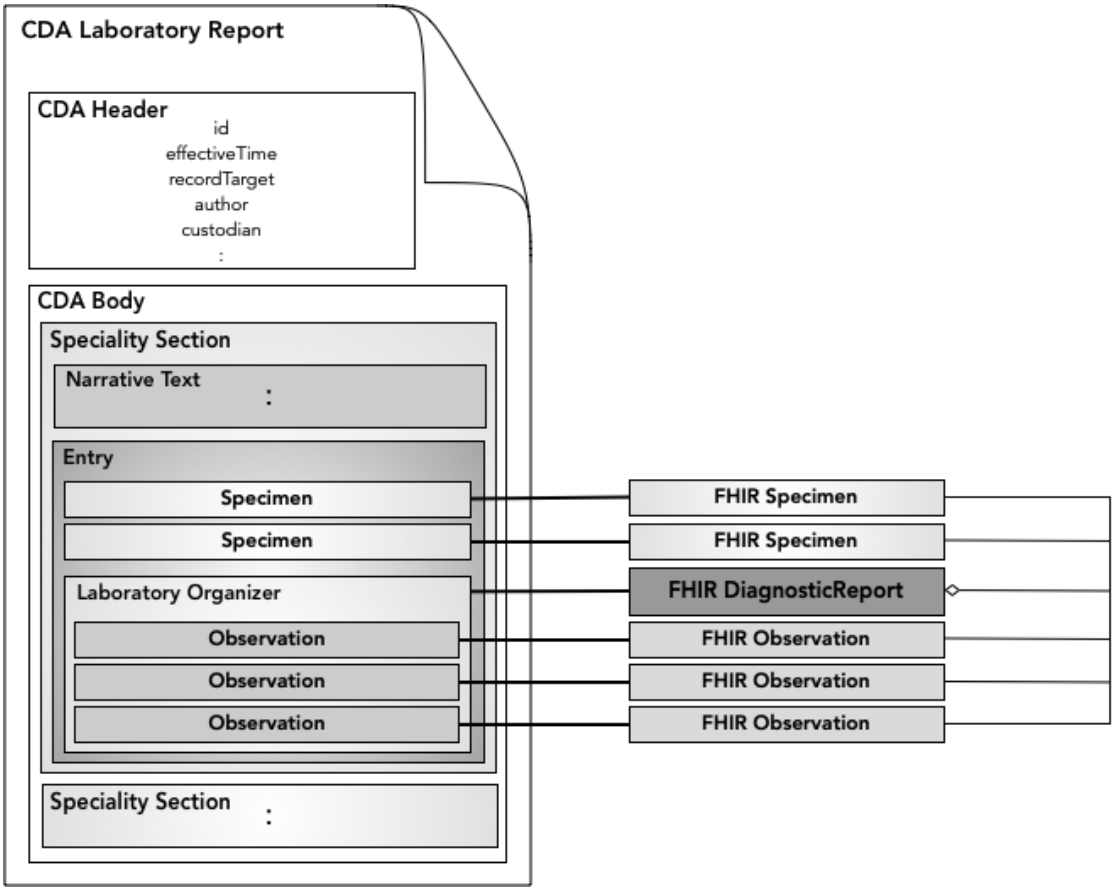

Figure 4.8: CDA body structure of the Laboratory Report [52]

4.4.2.1 Mapping of the FHIR Composition resource

The FHIR STU3 Composition covers the relevant information for the CDA header of the Laboratory Report (see Table 4.11). Furthermore, it contains the references to all FHIR resources building the Laboratory Report. The subject of the FHIR Composition refers to the FHIR Patient resource, which is described in the Subsection 4.4.2.2. The referenced FHIR Practitioners from the author attribute are converted to the author section of the CDA (see also Subsection 4.4.2.3). The attesters of the FHIR Composition provide the data to construct the authenticator sections for the laboratory results validator. The attribute event contains the information about the healthcare services and has to be set to the documentationOf section. This section indicates if the report is a final or a non-final Laboratory Report.
The FHIR Composition does not contain any countryCode information. For this reason the realmCode is set by configuration value. The values for the typeId and the templateId are defined by the CDA R2 standard and the IHE PaLM profile and are also set by configuration value. The FHIR Composition does not provide any information about the dataEnterer and informationRecipient

section of the CDA header. These sections cannot be mapped from the FHIR Composition, although the information may be available in the initial HL7 message.

4.4.2.2 Mapping of the FHIR Patient resource

For the available attributes of the FHIR STU3 Patient resource a comprehensive mapping to the CDA recordTarget section is possible (see Table 4.12). Of course it is necessary to pay attention to the FHIR codes of the attributes gender and maritalStatus. The code mapping tables the in Tables A.15 and A.17 illustrate that the code mappings between the recommended value sets for FHIR and CDA are almost similar and there is just a minor deviation. The code mapping are performed by the terminology service.

4.4.2.3 Mapping of the FHIR Practitioner, FHIR PractitionerRole and FHIR Organization resources

The FHIR STU3 Practitioner represents a person directly or indirectly involved in the laboratory order and the performed services. For the available attributes of the FHIR Practitioner resource a comprehensive mapping to the CDA assignedEntity or related CDA sections like assignedAuthor, relatedEntity, associatedEntity etc. is possible (see Table 4.15). The FHIR Practitioner does not hold any information about the organization he/she is employed at and the performed role. This information can be added using the FHIR PractitionerRole resource. The performed role or function of a laboratory participant can be set to the code attribute of the FHIR PractitionerRole. The reference to the FHIR Practitioner can be extracted from the practitioner attribute of the FHIR PractitionerRole and the reference to the FHIR Organization is stored in the organization attribute of the FHIR PractitionerRole. After that the FHIR Organization is mapped to the CDA representedOrganization or related CDA sections like receivedOrganization, representedCustodianOrganization etc. A comprehensive mapping from FHIR Organization to the proper CDA section is possible (see Table 4.14). Listing 4.6 illustrates a mapping result for the CDA Laboratory Results Validator. The section authenticator contains a user ID, the name of the validator, address information and contact details. Furthermore, the the element representedOrganization contain information about the laboratory he/she is employed at.

```
1<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
2<ClinicalDocument xmlns="urn:hl7-org:v3"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
3  <!-- Laboratory Results Validator Snippet -->
4    <authenticator>
5       <templateId root="1.3.6.1.4.1.19376.1.3.3.1.5"/>
6       <time value="20200226011424+0100"/>
7       <signatureCode code="S"/>
8       <!-- values mapped from FHIR Practitioner -->
9       <assignedEntity>
10         <id extension="1.2.276.0.76.4.16"
               root="1.2.279.0.91.7.1.251"/>
11         <addr>
12            <country>DEU</country>
```

```
            <city>Anklam</city>
            <postalCode>17389</postalCode>
            <streetAddressLine>Breitfurt Str. 22</streetAddressLine>
         </addr>
         <telecom use="WP" value="tel:038341191-0"/>
         <telecom use="WP" value="mailto:kontakt@labor-anklam.de"/>
         <assignedPerson>
            <name>
               <given>Katharina</given>
               <family>Bauer</family>
               <prefix>Dr. med.</prefix>
            </name>
         </assignedPerson>
         <!-- values mapped from FHIR Organization -->
         <representedOrganization>
            <id extension="1.2.3.1.331.2"
               root="1.2.279.0.91.7.1.251"/>
            <name>MVZ Labor Anklam GmbH</name>
            <telecom use="WP" value="tel:038341191-0"/>
            <telecom use="WP"
               value="mailto:kontakt@labor-anklam.de"/>
            <addr>
               <country>DEU</country>
               <city>Anklam</city>
               <postalCode>17389</postalCode>
               <streetAddressLine>Breitfurt Str.
                  22</streetAddressLine>
            </addr>
         </representedOrganization>
      </assignedEntity>
   </authenticator>
</ClinicalDocument>
```

Listing 4.6: CDA example - Laboratory Results Validator [52]

4.4.2.4 Mapping of the FHIR Encounter resource

The Ordering Provider of the Laboratory Report is transmitted in the FHIR STU3 Encounter. The mapping of the FHIR Encounter is illustrated in Table 4.13. The code attribute of the FHIR PractitionerRole identifies the referrer and this code value is set to the practitioner[@typeCode] as well. An example of the Ordering Provider is illustrated in Listing 4.7. This section contains details about the referrer like an identifier, name, address details and contact information.

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<ClinicalDocument xmlns="urn:hl7-org:v3"
   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <!-- Ordering Provider Snippet -->
   <participant typeCode="REF">
      <time value="20200126000000+0100"/>
```

```
      <associatedEntity classCode="PROV">
         <id extension="603984501" root="1.2.271.0.73.4.16"/>
         <addr>
            <country>DEU</country>
            <city>Anklam</city>
            <postalCode>17389</postalCode>
            <streetAddressLine>Sonnenblumenweg 18</streetAddressLine>
         </addr>
         <telecom use="WP" value="tel:039311496-0"/>
         <associatedPerson>
            <name>
               <given>Hermann</given>
               <family>Mayer</family>
               <prefix>Dr. med.</prefix>
            </name>
         </associatedPerson>
         <scopingOrganization>
            <id extension="788905005" root="1.2.276.0.76.4.17"/>
            <name>Arztpraxis Dr. Mayer</name>
            <telecom use="WP" value="tel:039311496-0"/>
            <addr>
               <country>DEU</country>
               <city>Anklam</city>
               <postalCode>17389</postalCode>
               <streetAddressLine>Sonnenblumenweg
                  18</streetAddressLine>
            </addr>
         </scopingOrganization>
      </associatedEntity>
   </participant>
</ClinicalDocument>
```

Listing 4.7: CDA example - Ordering Provider [52]

4.4.2.5 Mapping of the FHIR DiagnosticReport resource

The CDA Laboratory Battery Organizer is created out of the data from the FHIR STU3 DiagnosticReport and groups the CDA Observations for a battery of tests. The identifier, code, the status and the time of the battery can be taken from the FHIR DiagnosticReport (see Table 4.16). Furthermore, the referenced FHIR Observations from the FHIR DiagnosticReport can be added to the Organizer (see also Subsection 4.4.2.7).

4.4.2.6 Mapping of the FHIR Specimen resource

The FHIR STU3 Specimen includes all relevant data to build the CDA Specimen Collection (see Table 4.17). The CDA mapping result of the FHIR Specimen resource is illustrated in Listing 4.3 and in Listing 4.8. Because there is no proper CDA element available for the FHIR Substance, this FHIR resource is not listed.

```xml
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<entryRelationship typeCode="COMP">
   <procedure classCode="PROC" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
      <code code="33882-2" codeSystem="2.16.840.1.113883.6.1"
         codeSystemName="LOINC" displayName="Specimen Collection"/>
      <effectiveTime value="20200224094000+0100"/>
      <targetSiteCode code="LACF"
         codeSystem="2.16.840.1.113883.5.1052" codeSystemName="HL7
         ActSite" displayName="left antecubital fossa"/>
      <participant typeCode="PRD">
         <participantRole classCode="SPEC">
            <id root="1.2.279.0.76.3.1.138.1.16.2"
               extension="7237234992"/>
            <playingEntity>
               <code code="BLD" displayName="Blood"
                  codeSystem="2.16.840.1.113883.5.129"
                  codeSystemName="HL7 SpecimenType">
                  <originalText>
                     <reference value="#lab17371111_cda.specimen1"/>
                  </originalText>
               </code>
            </playingEntity>
         </participantRole>
      </participant>
      <entryRelationship typeCode="COMP">
         <act classCode="ACT" moodCode="EVN">
            <templateId root="1.3.6.1.4.1.19376.1.3.1.3"/>
            <code code="SPRECEIVE"
               codeSystem="1.3.5.1.4.1.19376.1.5.3.2"
               codeSystemName="IHEActCode" displayName="Specimen
               Receive"/>
            <effectiveTime value="20200225104415+0100"/>
         </act>
      </entryRelationship>
   </procedure>
</entryRelationship>
```

Listing 4.8: CDA example - Specimen Collection [52]

4.4.2.7 Mapping of the FHIR Observation resource

The FHIR STU3 Observation includes all relevant data to build the CDA Laboratory Observation (see Table 4.18). The CDA mapping result of the FHIR Observation resource is illustrated in Listing 4.5 and in 4.9.
As the data type of the FHIR value varies depending on the transmitted data, the mapping procedure has to support the conversion of the FHIR data types Quantity, CodeableConcept,

String, Boolean, Range, Time, DateTime, Period etc. Furthermore, the referred performers have to be added to the CDA Laboratory Observation.

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<component typeCode="COMP"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
   <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.3.1.6"/>
      <id nullFlavor="NI"/>
      <code code="BORRG" codeSystem="1.2.276.0.76.3.1.335.1.15.3"
         codeSystemName="Analysetyp des MVZ Labor Anklam GmbH"
         codeSystemVersion="20200101"
         displayName="Borrelia burgdorferi-IgG-Ak im Serum">
         <originalText>
            <reference value="#lab493811111211_cda.observation1"/>
         </originalText>
      </code>
      <statusCode code="completed"/>
      <effectiveTime value="20200123055125+0100"/>
      <value unit="AU/ml" value="74" xsi:type="PQ"/>
      <interpretationCode code="H"
         codeSystem="2.16.840.1.113883.5.83" codeSystemName="HL7
         ObservationInterpretation" codeSystemVersion="20150101"
         displayName="Above high normal"/>
      <performer typeCode="PRF">
         <templateId root="1.3.6.1.4.1.19376.1.3.3.1.7"/>
         <assignedEntity>
            <!-- identification, name, address and contact
               information of the performer -->
            <representedOrganization>
               <!-- identification, name, address and contact
                  information of the performer's organization -->
            </representedOrganization>
         </assignedEntity>
      </performer>
      <referenceRange typeCode="REFV">
         <observationRange classCode="OBS" moodCode="EVN.CRT">
            <interpretationCode code="N"/>
         </observationRange>
      </referenceRange>
   </observation>
</component>
```

Listing 4.9: CDA example - Laboratory Observation [52]

Table 4.11: Mapping of the FHIR STU3 Composition resource [40] [52]

Name	FHIR DT	Card.	ClinicalDocument	CDA DT	Card.
identifier	Identifier	0..1	id (see Table A.11) setId (see TableA.11)	II II	1..1 1..1
identifier/value	string	0..1	id[@extension] setId[@extension]	UID UID	0..1 0..1
identifier/system	uri	0..1	id[@root] setId[@root]	ST ST	0..1 0..1
status	code	1..1	documentationOf/serviceEvent /lab:statusCode[@code]		0..1
type	CodeableConcept	1..1	code (see TableA.12)	CE	1..1
class	CodeableConcept	0..1	-		
subject	Reference(Any)	1..1	recordTarget (see Table4.12)		1..*
encounter	Reference(Encounter)	0..1	componentOf /encompassingEncounter		0..1 1..1
date	dateTime	1..1	effectiveTime	TS	1..1
author	Reference(Practitioner | Device | Patient | RelatedPerson)	1..*	author (see Table 4.15)		1..*
title	string	1..1	title	ST	0..1
confidentiality	code	0..1	confidentiality	CE	1..1
attester	BackboneElement	0..*	authenticator		0..*
attester/mode	code	1..*	authenticator/signatureCode	CS	1..1
attester/time	dateTime	0..1	authenticator/time	TS	1..1
attester/party	Reference(Practitioner | Patient | Organization)	0..1	authenticator/assignedEntity (see Table 4.15)		1..1
custodian	Reference(Organization)	0..1	custodian (see Table 4.14)		1..1
event	BackboneElement	0..*	documentationOf /serviceEvent		0..* 1..1

event/code	CodeableConcept	0..*	documentationOf/serviceEvent/code (see Table A.12)	CE	0..1
event/period	Period	0..1	documentationOf/serviceEvent /effectiveTime	IVL_TS	0..1
event/period/start	dateTime	0..1	documentationOf/serviceEvent /effectiveTime/low	TS	0..1
event/period/end	dateTime	0..1	documentationOf/serviceEvent /effectiveTime/high	TS	0..1
section	BackboneElement	0..*	component /structuredBody /component /section		1..1 1..1 1..* 1..1
section/title	string	0..1	component/structuredBody/component /section/title	ST	0..1
section/code	CodeableConcept	0..1	component/structuredBody/component /section/code (see Table A.12)	CE	0..1
section/text	Narrative	0..1	component/structuredBody/component /section/text		0..1
section/entry	Reference(Any)	0..*	component/structuredBody/component /section/entry		0..*
extension	Extension	0..*	inFulfillmentOf		0..*
extension/valueIdentifier	Identifier	0..1	inFulfillmentOf/order/id (see Table A.11)	II	1..*
			realmCode (configuration value)	CS	0..*
			typeId (configuration value)	II	1..1
			templateId (configuration value)	II	0..*
language (inherited)	code	0..1	languageCode[@code]	CS	0..1
			dataEnterer		0..1
			informationRecipient		0..*

Table 4.12: Mapping of the FHIR STU3 Patient resource [41] [52]

Name	FHIR DT	Card.	recordTarget/patientRole	CDA DT	Card.
identifier	Identifier	0..*	id (see Table A.11)	II	1..*
identifier/value	string	0..1	id[@extension]	UID	0..1
identifier/system	uri	0..1	id[@root]	ST	0..1
active	boolean	0..1	-		
name	HumanName	0..*	patient/name (see Table A.10)	PN	0..*
name/use	code	0..1	patient/name[@use]		
name/family	string	0..1	patient/name/family	ST	0..*
name/given	string	0..*	patient/name/given	ST	0..*
name/prefix	string	0..*	patient/name/prefix	ST	0..*
name/suffix	string	0..*	patient/name/suffix	ST	0..*
name/period	Period	0..1	patient/name/validTime	IVL_TS	0..1
telecom	ContactPoint	0..*	telecom	TEL	0..*
gender	code	0..1	administrativeGenderCode (see Table A.15)	CE	0..1
birthDate	date	0..1	patient/birthTime	TS	0..1
address	Address	0..*	addr (see Table A.13)	AD	0..*
address/use	code	0..1	addr[@use]		0..1
address/line	string	0..*	addr/streetAddressLine	ST	0..*
address/city	string	0..1	addr/city	ST	0..*
address/state	string	0..1	addr/state	ST	0..*
address/postalCode	string	0..1	addr/postalCode	ST	0..*
address/country	string	0..1	addr/country	ST	0..*
maritalStatus	CodeableConcept	0..1	maritalStatusCode (see Tables A.12 and A.17)	CE	0..1
maritalStatus/coding	Coding	0..*			
maritalStatus/coding/system	uri	0..1	maritalStatusCode[@codeSystem] maritalStatusCode[@codeSystemName]	UID ST	0..1 0..1

maritalStatus/coding /version	string	0..1	maritalStatusCode[@codeSystemVersion]	ST	0..1
maritalStatus/coding/code	code	0..*	maritalStatusCode[@code]	CS	0..1
maritalStatus/coding /display	string	0..*	maritalStatusCode[@displayName]	ST	0..1
maritalStatus/text	string	0..*	maritalStatusCode/originalText	ED	0..1

Table 4.13: Mapping of the FHIR STU3 Encounter resource [45] [52]

Name	FHIR DT	Card.	participant	CDA DT	Card.
identifier	Identifier	0..*	-		
status	code	1..1	-		
class	Coding	0..1	-		
participant	BackboneElement	0..*	participant		0..*
participant/type	CodeableConcept	0..*			
participant/type/coding.code	CodeableConcept	0..*	[@typeCode] | associatedEntity[@classCode]		
participant/period	Period	0..1			
participant/period/start	dateTime	0..1	time | time/low	IVL_TS | TS	0..1
participant.period.end	dateTime	0..1	time/high	TS	0..1
participant/individual	Reference(Practitioner | RelatedPerson)	0..1	associatedEntity (see Table 4.15)		
period	Period	0..1	-		

Table 4.14: Mapping of the FHIR STU3 Organization resource [42] [52]

Name	FHIR DT	Card.	representedOrganization	CDA DT	Card.
identifier	Identifier	0..*	id (see Table A.11)	II	0..*
identifier/value	string	0..1	id[@extension]	UID	0..1
identifier/system	uri	0..1	id[@root]	ST	0..1
name	string	0..1	name	ON	0..*
telecom	ContactPoint	0..*	telecom	TEL	0..*
address	Address	0..*	addr (see Table A.13)	AD	0..*
address/use	code	0..1	addr[@use]		0..1
address/line	string	0..*	addr/streetAddressLine	ST	0..*
address/city	string	0..1	addr/city	ST	0..*
address/state	string	0..1	addr/state	ST	0..*
address/postalCode	string	0..1	addr/postalCode	ST	0..*
address/country	string	0..1	addr/country	ST	0..*

Table 4.15: Mapping of the FHIR STU3 Practitioner resource [43] [52]

Name	FHIR DT	Card.	assignedEntity	CDA DT	Card.
identifier	Identifier	0..*	id (see Table A.11)	II	1..*
identifier/value	string	0..1	id[@extension]	UID	0..1
identifier/system	uri	0..1	id[@root]	ST	0..1
			assignedPerson		0..1
name	HumanName	0..*	assignedPerson/name (see Table A.10)	ST	0..*
name/use	code	0..1	assignedPerson/name[@use]		
name/family	string	0..1	assignedPerson/name/family	ST	0..*
name/given	string	0..*	assignedPerson/name/given	ST	0..*
name/prefix	string	0..*	assignedPerson/name/prefix	ST	0..*
name/suffix	string	0..*	assignedPerson/name/suffix	ST	0..*
name/period	Period	0..1	assignedPerson/name/validTime	IVL_TS	0..1
telecom	ContactPoint	0..*	telecom	TEL	0..*
address	Address	0..*	addr (see Table A.13)	AD	0..*
address/use	code	0..1	addr[@use]		0..1
address/line	string	0..*	addr/streetAddressLine	ST	0..*
address/city	string	0..1	addr/city	ST	0..*
address/state	string	0..1	addr/state	ST	0..*
address/postalCode	string	0..1	addr/postalCode	ST	0..*
address/country	string	0..1	addr/country	ST	0..*

Table 4.16: Mapping of the FHIR STU3 DiagnosticReport resource [46] [52]

Name	FHIR DT	Card.	entry/act/entryRelationship/organizer	CDA DT	Card.
identifier	Identifier	0..*	id (see Table A.11)	II	0..*
identifier/value	string	0..1	id[@extension]	UID	0..1
identifier/system	uri	0..1	id[@root]	ST	0..1
status	code	1..1	status	CS	1..1
category	CodeableConcept	1..1	-		
code	CodeableConcept	1..1	code (see Table A.12)	CD	0..1
code/coding	Coding	0..*			
code/coding/system	uri	0..1	code[@codeSystem] code[@codeSystemName]	UID ST	0..1 0..1
code/coding/version	string	0..1	code[@codeSystemVersion]	ST	0..1
code/coding/code	code	0..*	code[@code]	CS	0..1
code/coding/display	string	0..*	code[@displayName]	ST	0..1
subject	Reference(Patient)	0..1	see Table 4.12		
context	Reference(Encounter)	0..1	see Table 4.13		
effective[x]	dateTime | Period	0..*	effectiveTime	IVL_TS	0..1
specimen	Reference(Specimen)	0..*	see Table 4.17		
result	Reference(Observation)	0..*	component/observation (see Table 4.18)		
conclusion	string	0..1	Annotation Comment with templateId="1.3.6.1.4.1.19376.1.5.3.1.4.2"		

Table 4.17: Mapping of the FHIR STU3 Specimen resource [47] [52]

Name	FHIR DT	Card.	entry/act/entryRelationship /procedure	CDA DT	Card.
identifier	Identifier	1..*	participant/participantRole/id (see Table A.11)	II	0..*
identifier/value	string	0..1	participant/participantRole/id[@extension]	UID	0..1
identifier/system	uri	0..1	participant/participantRole/id[@root]	ST	0..1
status	code	0..1	-		
type	CodeableConcept	0..1	participant/participantRole /playingEntity/code (see Table A.12)	CE	0..1
type/coding	Coding	0..*			
type/coding/system	uri	0..1	participant/participantRole /code[@codeSystem] participant/participantRole/playingEntity /code[@codeSystemName]	UID ST	0..1 0..1
type/coding/version	string	0..1	participant/participantRole/playingEntity /code [@codeSystemVersion]	ST	0..1
type/coding/code	code	0..*	participant/participantRole/playingEntity /code[@code]	CS	0..1
type/coding/display	string	0..*	participant/participantRole/playingEntity /code[@displayName]	ST	0..1
subject	Reference(Patient)	0..*	see Table 4.12		
receivedTime	dateTime	0..1	entryRelationship/act/effectiveTime	IVL_TS	0..1
collection	BackboneElement	0..1			
collection/collector	Reference(Practitioner)	0..1	performer (see Table 4.15)		0..*
collection/collected[x]	dateTime | Period	0..1	effectiveTime	IVL_TS	0..1
collection/quantity	SimpleQuantity	0..1	-		
collection/method	CodeableConcept	0..1	-		
collection/bodySite	CodeableConcept	0..1	targetSiteCode (see Table A.12)	CD	0..*

collection/bodySite.coding	Coding	0..*			
collection/bodySite/coding /system	uri	0..1	targetSiteCode[@codeSystem] targetSiteCode[@codeSystemName]	UID ST	0..1 0..1
collection/bodySite/coding /version	string	0..1	targetSiteCode[@codeSystemVersion]	ST	0..1
collection/bodySite/coding /code	code	0..*	targetSiteCode[@code]	CS	0..1
collection/bodySite/coding /display	string	0..*	targetSiteCode[@displayName]	ST	0..1
processing	BackboneElement	0..1			
processing/additive	Reference(Substance)	0.1			
container	BackboneElement	0..*			
container/type	CodeableConcept	0..1			
note	Annotation	0..*			

Table 4.18: Mapping of the FHIR STU3 Observation resource [48] [52]

Name	FHIR DT	Card.	observation	CDA DT	Card.
identifier	Identifier	0..*	id (see Table A.11)	II	0..*
identifier/value	string	0..1	id[@extension]	UID	0..1
identifier/system	uri	0..1	id[@root]	ST	0..1
status	code	1..1	statusCode	CE	0..1
category	CodeableConcept	0..*	-		
code	CodeableConcept	1..1	code (see Table A.12)	CD	1..1
code/coding	Coding	0..*			
code/coding/system	uri	0..1	code[@codeSystem] code[@codeSystemName]	UID ST	0..1 0..1
code/coding/version	string	0..1	code[@codeSystemVersion]	ST	0..1
code/coding/code	code	0..*	code[@code]	CS	0..1
code/coding/display	string	0..*	code[@displayName]	ST	0..1
subject	Reference(Patient)	0..1	-		
context	Reference(Encounter | EpisodeOfCare)	0..1	-		
effective[x]	dateTime | Period	0..1	effectiveTime		
issued	instant	0..1			
performer	Reference(Practitioner | Organization)	0..*	performer (see Table 4.15)		0..*
value[x]	varies	0..1	value	ANY	0..*
interpretation	CodeableConcept	0..1	interpretationCode (see Table A.12)	CE	0..*
interpretation/coding	Coding	0..*			
interpretation/coding/system	uri	0..1	interpretationCode [@codeSystem] interpretationCode [@codeSystemName]	UID ST	0..1 0..1
interpretation/coding/version	string	0..1	interpretationCode [@codeSystemVersion]	ST	0..1
interpretation/coding/code	code	0..*	interpretationCode[@code]	CS	0..1
interpretation/coding/display	string	0..*	interpretationCode[@displayName]	ST	0..1

comment	string	0..1	entryRelationship/act/text/reference		
method	CodeableConcept	0..1	methodCode (see Table A.12)	CE	0..*
method/coding	Coding	0..*			
method/coding/system	uri	0..1	methodCode[@codeSystem]	UID	0..1
			methodCode[@codeSystemName]	ST	0..1
method/coding/version	string	0..1	methodCode[@codeSystemVersion]	ST	0..1
method/coding/code	code	0..*	methodCode[@code]	CS	0..1
method/coding/display	string	0..*	methodCode[@displayName]	ST	0..1
specimen	Reference(Specimen)	0..1			
referenceRange	BackboneElement	0..*	referenceRange		0..*
referenceRange/low	SimpleQuantity	0..1	referenceRange/observationRange/value /low		0..1
referenceRange/high	SimpleQuantity	0..1	referenceRange/observationRange/value /high		0..1
referenceRange/type	CodeableConcept	0..1	referenceRange/observationRange/value /interpretationCode (see Table A.12)	CE	0..1
referenceRange/type/coding	Coding	0..*			
referenceRange/type/coding /system	uri	0..1	referenceRange/observationRange/value /interpretationCode[@codeSystem]	UID	0..1
			referenceRange/observationRange/value /interpretationCode[@codeSystemName]	ST	0..1
referenceRange/type/coding /version	string	0..1	referenceRange/observationRange/value /interpretationCode[@codeSystemVersion]	ST	0..1
referenceRange/type/coding /code	code	0..*	referenceRange/observationRange/value /interpretationCode[@code]	CS	0..1
referenceRange/type/coding /display	string	0..*	referenceRange/observationRange/value /interpretationCode[@displayName]	ST	0..1

CHAPTER 5

Evaluation

The previous Chapter 4 described the implementation and integration of a laboratory environment to a distributed, document-based Health Information Exchange. It specified the FHIR data model for the storage of the laboratory data in the CDR. Furthermore, it defined the performed mappings of the translation engines of the HSB. The HSB provided the necessary interfaces to close the communication gaps between the single systems and services and facilitated the transparent connection between the LIS and the HIE. This Chapter is going to reflect on the major mapping results and elaborates on the challenges and limitations of performing mappings from one data structure to the other one.

5.1 Comparison of the document information

Table 5.1 provides a comparison of the document information of the standards HL7 V2, FHIR STU3 and CDA R2. For the CDA sections and elements realmCode, dataEnterer, informationRecipient and performer of the service event are no appropriate FHIR resources and elements available. This information is lost between the mapping from HL7 to FHIR. Especially the order numbers are relevant for the Laboratory Report and are part of the inFulfillmentOf section in the CDA. FHIR does not provide any standard element to set this information. For this reason the extension “CDA In Fulfillment of” [50] was added to the FHIR Composition.
The optional value for the title of the document and the section is not available in the HL7 message, but this is a insignificant value as the code of the document and the section shall contain a representative display name. Furthermore, the time and the signature code of the authenticator are not available in the HL7 message. The time is an optional value and for the signature code the fixed value “S” for the CDA has to be used.
Two major issues have been identified in the mapping from HL7 to FHIR, which caused the need of a workaround. In the HL7 V2.5 MSH segment there is no information about the custodian available. The custodian can be deduced from the MSH-4 Sending Facility, but the data type HD only provides the possibility to send an organization ID. An organization map from the

configuration has to provide the details of an organization (name, address, contact information), where the key is the organization ID from MSH-4. Furthermore, the organization map can be used to set missing organization information for healthcare practitioners. The big disadvantage of this workaround is the administration and maintenance of the organization map. For this reason HL7 V2.6 and higher versions provide the new field MSH-22 Sending Responsible Organization (Extended Composite Name And Identification Number For Organizations (XON)) to send more details for the custodian.

Table 5.1: Comparison of the document information [13] [52] [40]

CDA ClinicalDocument	FHIR Composition	HL7 Segment / Field
realmCode	-	MSH-17 Country Code
id	identifier	MSH-10 Message Control ID
code	type	PV2-3 Admit Reason
title	title	-
effectiveTime	date	MSH-7 Date/Time of Message
confidentialityCode	confidentiality	ORC-28 Confidentiality Code
languageCode	language (inherited)	MSH-19 Principal Language of Message
setId	identifier	MSH-10 Message Control ID
versionNumber	set by the FHIR versioning	-
recordTarget	subject	PID
author	author	OBR-16 Responsible Observer, OBR-32 Principal Result Interpreter, OBX-33 Assistant Result Interpreter
dataEnterer	-	ORC-10 Entered By
custodian	custodian	MSH-4 Sending Facility
informationRecipient	-	OBR-28 Result Copies To
authenticator	attester/party	ORC-11 Verified By
authenticator/signatureCode	attester/mode	-
authenticator/time	attester/time	-
inFulfillmentOf	extension	ORC-2 Placer Order Number, ORC-3 Filler Order Number, ORC-4 Placer Group Number
documentationOf/serviceEvent	event/code	PV2-3 Admit Reason
documentationOf/serviceEvent	event/period/start	PV1-44 Admit Date/Time
documentationOf/serviceEvent	event/period/end	PV1-45 Discharge Date/Time
documentationOf/serviceEvent /lab:statusCode	status	ORC-5 Order Status
documentationOf/serviceEvent /performer	-	OBX.15 Producer's ID

component/structuredBody /section/title	section/title	-
component/structuredBody /section/code	section/code	PV2-3 Admit Reason
CDA ClinicalDocument	**FHIR Encounter**	**HL7 Segment / Field**
participant[@typeCode="REF"]	encounter/participant	ORC-12 Ordering Provider, ORC-24 Ordering Provider Address
participant[@typeCode="REF"] /time	encounter/participant/time	ORC-15 Order Effective Date/Time
participant[@typeCode="REF"] /associatedEntity /scopingOrganization	FHIR Organization 5.4	ORC-21 Ordering Facility Name, ORC-22 Ordering Facility Address, ORC-23-Ordering Facility Phone Number

5.2 Comparison of the patient information

There were no conspicuous findings on the comparison of the patient structures (see Table 5.2 for details). All relevant information can be set to all three structures. HL7 and CDA provide more values for the definition of the patient (e.g. race, religion etc.), but the FHIR patient structure is sufficient to capture the relevant information.

Table 5.2: Comparison of the patient information [13] [52] [41]

CDA recordTarget/patientRole	**FHIR Patient**	**HL7 PID**
id	identifier	PID-3 Patient Identifier List
-	active	-
addr	address	PID-11 Patient Address
addr[@use]	address/use	
addr/streetAddressLine	address/line	PID-11.1 Street Address
addr/postalCode	address/postalCode	PID-11.5 Zip or Postal Code
addr/city	address/city	PID-11.3 City
addr/country	address/country	PID-11.6 Country
addr/state	address/state	PID-11.4 State or Province
telecom[@value]	telecom/value	
telecom[@use]	telecom/use	
patient/name	name	PID-5 Patient Name
patient/name[@use]	name/use	PID-5.7 Name Type Code
patient/name/given	name/given	PID-5.2 Given Name, PID-5.23 Second and Further Given Names
patient/name/family	name/family	PID-5.1 Family Name

patient/name/prefix	name/prefix	PID-5.4 Suffix
patient/name/suffix	name/suffix	PID-5.5 Prefix
patient/administrativeGenderCode	gender	PID-8 Administrive Sex
patient/birthTime	birthDate	PID-7 Date/Time of Birth
patient/maritalStatusCode	martitalStatus	PID-16 Marital Status

5.3 Comparison of the healthcare practitioner information

The CDA and the FHIR structure for constructing healthcare practitioner information are very similar (see also Table 5.3). One of the main differences are that the FHIR Practitioner provides elements to set the gender, birthDate, qualification and spoken languages in the communication element. There is no possibility to add a role, function or the organization he/she is employed. For this reason the FHIR Practitioner has to be extended by using the FHIR PractitionerRole resource. This resource allows to set the role and a reference to the organization he/she is employed.
The data types XCN and NDL do not contain any information about the address and the contact information of the practitioner. For this reason the organization map from the configuration is used as a workaround. XCN-9.2 Universal ID of Assigning Authority or XCN-14.2 Universal ID of Assigning Facility as well as NDL-1.10 Universal ID of Assigning Authority or NDL-7 Universal ID of Assigning Facility contain the organization ID to get address and contact details from the organization.

Table 5.3: Comparison of the healthcare practitioner information [13] [52] [43]

CDA assigningEntity	FHIR Practitioner	HL7 XCN / NDL
id	identifier	XCN-1 ID Number, NDL-1.1 ID Number
assignedPerson/name	name	
assignedPerson/name[@use]	name/use	XCN-10 Name Type Code
assignedPerson/name/family	name/family	XCN-2 Family Name, NDL-1.2 Family Name
assignedPerson/name/given	name/given	XCN-3 Given Name, XCN-4 Second and Further Given Names or Initials Thereof, NDL-1.3 Given Name, NDL-1.4 Second and Further Given Names or Initials Thereof
assignedPerson/name/prefix	name/prefix	XCN-6 Prefix, NDL-1.6 Prefix
assignedPerson/name/suffix	name/suffix	XCN-5 Suffix, NDL-1.5 Suffix
assignedPerson/name/validTime	name/validTime	XCN-19 Effective Date, XCN-20 Expiration Date
addr	address	-

telecom	telecom	-

5.4 Comparison of the healthcare organization

As the HL7 data type XON only provides details about the name and the identifier of the organization, additional data types like XAD and XTN would be needed to set the missing FHIR Organization elements (see also Table 5.4). As a workaround the organization map from the configuration may provide the address and contact information for an organization.

Table 5.4: Comparison of the healthcare organization information [13] [52] [42]

CDA representedOrganization	FHIR Organization	HL7 XON
id	identifier	XON-10 Organization Identifier
name	name	XON-1 Organization Name
telecom	telecom	-
addr	address	-

5.5 Comparison of the laboratory battery organizer information

In principal the relevant information for creating the battery organizer is available (see Table 5.5). Unfortunately the FHIR STU3 DiagnosticReport does not contain any element to set the interpreter of the laboratory results. Thus, this information is added to the author of the FHIR Composition. The FHIR STU4 DiagnosticReport resource already provides the new element resultsInterpreter and could make the workaround of setting this information to the author of the FHIR acSTU3 Composition obsolete.

Table 5.5: Comparison of laboratory the battery organizer information [13] [52] [46]

CDA entry/act /entryRelationship/organizer	FHIR DiagnosticReport	HL7 OBR
id	identifier	-
code	code	OBR-4 Universal Service Identifier
status	status	OBR-25 Result Status
effectiveTime	effective[x]	OBR-7 Observation Date/-Time, OBR-8 Observation End Date/Time
performer	performer	-

author	-	OBR-32 Principal Result Interpreter, OBR-33 Assistant Result Interpreter

5.6 Comparison of the specimen information

Table 5.6 compares the data structures to construct a specimen. In this case HL7 V2 and FHIR cover a lot of details regarding the specimen of a Laboratory Report. The CDA structure does not support details like the collection method or quantity, the container type etc.

Table 5.6: Comparison of the specimen information [13] [52] [47]

CDA entry/act /entryRelationship/procedure	FHIR Specimen	HL7 OBR / SPM
participant/participantRole/id	identifier	SPM-2 Specimen ID
participant/participantRole /playingEntity/code	type	OBR-15.1 Specimen Source Name or Code, SPM-4 Specimen Type
entryRelationship/act /effectiveTime	receivedTime	OBR-14 Specimen Received Date/Time, SPM-18 Specimen Received Date/Time
performer	collection/collector	OBR-10 Collector Identifier
effectiveTime	collection/collected[x]	OBR-7 Observation Date/-Time, SPM-17 Specimen Collection Date/Time
targetSiteCode	collection/bodySite	OBR-15.4 Body Site, SPM-8 Specimen Source Site
-	collection/method	OBR-15.3 Specimen Collection Method, SPM-7 Specimen Collection Method
-	collection/quantity	OBR-9 Collection Volume, SPM-12 Specimen Collection Amount
-	processing/additive	SPM-6 Specimen Additives
-	container/type	SPM-27 Container Type
-	note	OBR-39 Collector's Comment, SPM-14 Specimen Description
-	status	SPM-20 Specimen Availability

5.7 Comparison of the observation information

Table 5.7 shows that each observation data structure covers the relevant information. The mapping from HL7 V2 to FHIR and CDA does not lose any important information.

Table 5.7: Comparison of the observation information [13] [52] [48]

CDA observation	FHIR Observation	HL7 OBX
id	identifier	-
code	code	OBX-3 Observation Identifier
statusCode	status	OBX-11 Observation Result Status
effectiveTime	effective[x]	OBX-14 Date/ Time of the Observation, OBX-19 Date/-Time of the Analysis
value	value[x]	OBX-2 Value Type, OBX-5 Observation Value, OBX-6 Units
interpretationCode	interpretation	OBX-8 Abnormal Flags
methodCode	method	OBX-17 Observation Method
targetSiteCode	bodySite	-
performer	performer	OBX-15 Producer's ID, OBX-16 Responsible Observer
Annotation Comment with templateId= "1.3.6.1.4.1.19376.1.5.3.1.4.2"	comment	NTE
referenceRange	referenceRange	OBX-7 References Range
referenceRange/observationRange /value/interpretationCode	referenceRange/type	OBX-10 Nature of Abnormal Test

5.8 Possible improvements

The previous Sections described the mapping gaps between the HL7 V2, FHIR and CDA standard. Nevertheless, the translation engines of the HSB were able to map the relevant laboratory data from HL7 V2 to FHIR and further from FHIR into CDA. This Section provides various suggestions to improve the developed solution.

The CDR is based on the FHIR version STU3. Table 3.5 illustrates that FHIR Release 4 is the current version. An upgrade from FHIR STU3 to FHIR Release 4 would provide new data elements and other improvements.

The current solution includes an organization map, which is part of the configuration of the HL7 adapter. An XML file contains a list of organizations with organization identifier in the

form of an OID, organization name, address and contact information. The organization ID represents the key with which an organization instance can be accessed. Experience in practice has shown that the administration and maintenance of the XML file are one of the more complex operations for a system administrator. The integration of a Health Provider Directory (HPD) would support the system administrator in maintaining of the list of organizations. Alternatively a list of organizations could be established directly in the CDR. A user interface could be developed to provide an administrative tool for the storage and management of the organizations in the CDR for the system administrator.

Finally the CDR provides comprehensive query options. Specific queries can be defined and the retrieved FHIR resources of these queries are assembled into a CDA Clinical Laboratory Report, that provides a distinct view to the laboratory data. The possibilities to analyse data using the developed solution has yet to be exhausted and will be an added value for treatment decisions in medicine, but also for future research.

CHAPTER 6

Conclusion

From October 2019 to March 2020 the described laboratory environment was implemented, deployed and connected to the HIE of a German health insurance company in the QA system. Tests were performed together with the laboratory and the integration partners of the connected healthcare providers. A deployment of the laboratory environment in the production environment has never been performed as the pilot project ended in the middle of 2020. Nevertheless, FHIR has proven its suitability as a flexible and robust storage format and its ability to provide the appropriate data structure to map laboratory data from HL7 V2 and convert FHIR resources to a CDA document. Furthermore, the evaluation of the results and the software tests together with the laboratory and the integration partners provided answers to the following research questions.

Is it possible to provide an adequate mapping from HL7 V2 messages into FHIR resources and further from FHIR resources into CDA documents?
The integration of the laboratory with the HIE was successful. The developed translation services of the HSB were able to map the received laboratory data from HL7 V2 into FHIR and further from FHIR into CDA. The resulting CDA Laboratory Reports included similar information compared to the original Laboratory Reports in the PDF format, which were created by rendering laboratory data to a defined document template. In the case of the CDA Laboratory Report the physician is now able to import structured data to his/her EMR.

What data are lost and how can it be assessed?
Chapter 5 described the mapping gaps between the HL7 V2, FHIR and CDA standard. The conversion between HL7 V2, FHIR and CDA for the creation of a Laboratory Report is possible and only causes an acceptable data loss. A requirement was that the resulting CDA Laboratory Report has to include at least similar information compared to the original Laboratory Report in the PDF format initially created by the laboratory. To fulfill this requirement only a FHIR extension for the laboratory order number had been defined. Of course the FHIR resources couldn't cover all the information, which could be set in a HL7 V2 message. A HL7 segment provides a very comprehensive set of data fields compared to a FHIR resource. As an example

the Patient Identification (PID) segment includes 39 data fields for the transmission of patient information covering the patient identification, demographics, address and contact data etc. The FHIR Patient resource only provides 16 main elements and references to describe a patient. Therefore, it was unexpected that these elements and references were sufficient to cover the central patient data from the HL7 message. This finding confirmed the robustness of the data structure and demonstrated that the FHIR resources focus on persisting central information.

Was it useful to build the whole use case on open standards?
The usage of existing standards saved a lot of time. Of course the mapping specification between the data structures had to be created, but the benefit of these open standards were that already stable data structures were available, because a lot of experts work on continuous improvements of these open standards.
Furthermore, another advantage is the availability of open libraries and programming guidelines how to integrate such open standards. This leads again to saving time. In addition an approved library is much less prone to errors as it is already proven and tested in practice.
A disadvantage of using an open standard could be that the implementation is less flexible than a proprietary software, which perfectly fits the requirements of the use case. And that is the reason why FHIR is brought into play. FHIR provides a slim data structure compared to HL7 V2. The Chapter 5 pointed out that for several data elements there were no mapping attribute available in FHIR. But FHIR is extensible by using the FHIR extensions. FHIR combines the advantages of using open standards and implementing a proprietary solution as the FHIR resources can be tailored to fit exactly the requirements. Of course this is one of the strength of using FHIR.

Is the intended architecture comprising a CDR and a HSB suitable for the laboratory integration?
The architecture comprising a CDR and a HSB is suitable for the transparent integration of a laboratory. The CDR in combination with the HSB provide a technology with the capability to store and index clinical information as smallest possible and reasonable data unit including the ability to assemble new tailored laboratory documents in an on-demand manner to support the physicians treatment process. This new approach of storing and exchanging defined data structures allows to support existing medical processes and can be a new, additional way of exchanging medical data in a structured way.

Can this approach be applied for other domains like radiology or pharmacy?
The developed approach could be adapted to bridge connection gaps for other domains like radiology or pharmacy. In the radiology domain information is transported via HL7 V2 messages too. The translation service of the HSB as well as the FHIR data structure of the CDR could be extended to fulfill the requirements of a radiology report. FHIR already provides resource types to cover imaging investigations (x-ray, CT, MRI etc.). Furthermore, a mapping of the DICOM Structured Report would be conceivable.
The pharmacy domain as well transmits pharmaceutical information via HL7 V2 messages. An integration of a pharmacy could be possible by extending the current solution.

APPENDIX A

Appendix

Table A.1: HL7 Extended Composite ID Number And Name (XCN) [13] [53]

Seq	Name	HL7 DT	Option	FHIR Practitioner	FHIR DT	Card.
1	ID Number	ST	O	identifier/value	string	0..1
2	Family Name	FN	O	name/family	string	0..1
3	Given Name	ST	O	name/given	string	0..*
4	Second and Further Given Names or Initials Thereof	ST	O	name/given	string	0..*
5	Suffix (e.g., JR or III)	ST	O	name/suffix	string	0..*
6	Prefix (e.g., DR)	ST	O	name/prefix	string	0..*
9	Assigning Authority	HD	O			
9.2	Universal ID	ST	C	identifier/system (default), organization ID	uri	0..1
10	Name Type Code	ID	O	name/use	code	0..1
14	Assigning Facility	HD	O			
14.2	Universal ID	ST	C	identifier/system (alternate), organization ID	uri	0..1
				name/period	Period	0..1
19	Effective Date	TS	O	name/period/start	dateTime	0..1
20	Expiration Date	TS	O	name/period/end	dateTime	0..1

Table A.2: HL7 Name With Location And Data (NDL) [13] [53]

Seq	Name	HL7 DT	Option	FHIR Practitioner	FHIR DT	Card.
1	Name	CNN	R			
1.1	ID Number	ST	O	identifier/value	string	0..1
1.2	Family Name	ST	O	name/family	string	0..1
1.3	Given Name	ST	O	name/given	string	0..*
1.4	Second and Further Given Names or Initials Thereof	ST	O	name/given	string	0..*
1.5	Suffix (e.g., JR or III)	ST	O	name/suffix	string	0..*
1.6	Prefix (e.g., DR)	ST	O	name/prefix	string	0..*
1.10	Assigning Authority - Universal ID	HD	C	identifier/system (default), organization ID	uri	0..1
7	Assigning Facility	HD	O	identifier/system (alternate), organization ID	uri	0..1

Table A.3: HL7 Coded Element (CE) [13] [53]

Seq	Name	HL7 DT	Option	FHIR CodeableConcept (DT)	FHIR DT	Card.
				default:		
				coding	Coding	0..*
1	Identifier	ST	O	coding/code	code	0..1
2	Text	ST	O	coding/display	string	0..1
3	Name of Coding System	ID	O	coding/system	uri	0..1
				alternate:		
4	Alternate Identifier	ST	O	coding/code	code	0..1
5	Alternate Text	ST	O	coding/display	string	0..1
6	Name of Alternate Coding System	ID	O	coding/system	uri	0..1

Table A.4: HL7 Coded With Exceptions (CWE) [13] [53]

Seq	Name	HL7 DT	Option	FHIR CodeableConcept (DT)	FHIR DT	Card.
				default:		
				coding	Coding	0..*
1	Identifier	ST	O	coding/code	code	0..1
2	Text	ST	O	coding/display	string	0..1
3	Name of Coding System	ID	O	coding/system	uri	0..1
7	Coding System Version ID	ST	C	coding/version	string	0..1
9	Original Text	ST	O	text	string	0..1
				alternate:		
4	Alternate Identifier	ST	O	coding/code	code	0..1
5	Alternate Text	ST	O	coding/display	string	0..1
6	Name of Alternate Coding System	ID	O	coding/system	uri	0..1
8	Alternate Coding System Version ID	ST	O	coding/version	string	0..1

Table A.5: HL7 Extended Composite Name And Identification Number For Organizations (XON) [13] [53]

Seq	Name	HL7 DT	Option	FHIR Organization	FHIR DT	Card.
1	Organization Name	ST	O	IF(XON.2 == A) THEN alias ELSE name	 string string	 0..* 0..1
6	Assigning Authority	HD	O	identifier/system (default)	uri	0..1
8	Assigning Facility	HD	O	identifier/system (alternate)	uri	0..1
				identifier	Identifier	0..*
10	Organization Identifier	ST	O	identifier/value	string	0..1

Table A.6: HL7 Extended Address (XAD) [13] [53]

Seq	Name	HL7 DT	Option	FHIR Address (DT)	FHIR DT	Card.
1	Street Address	SAD	O			
1.1	Street or Mailing Address	ST	O	line	string	0..*
1.2	Street Name	ST	O	line	string	0..*
1.3	Dwelling Number	ST	O	(XAD-1.2 + XAD-1.3)		
2	Other Designation	ST	O	line (additional information for the street address like 4. Floor)	string	0..*
3	City	ST	O	city	string	0..1
4	State or Province	ST	O	state	string	0..1
5	Zip or Postal Code	ST	O	postalCode	string	0..1
6	Country	ID	O	country	string	0..1
7	Address Type	ID	O	use	code	0..1
				period	Period	0..1
13	Effective Date	TS	O	period/start	dateTime	0..1
14	Expiration Date	TS	O	period/end	dateTime	0..1

Table A.7: HL7 Extended Person Name (XPN) [13] [53]

Seq	Name	HL7 DT	Option	FHIR HumanName (DT)	FHIR DT	Card.
1	Family Name	FN	R			
1.1	Surname	ST	R	family	string	0..1
1.2	Own Surname Prefix	ST	O	prefix can be added to family (e.g. “van” - such as van Beethoven)		
1.3	Own Surname	ST	O	set to a new family. use=“maiden”		
2	Given Name	ST	O	given	string	0..1
3	Second and Further Given Names or Initials Thereof	ST	O	given	string	0..*
4	Suffix (e.g., JR or III)	ST	O	suffix	string	0..*
5	Prefix (e.g., DR)	ST	O	prefix	string	0..*
7	Name Type Code	ID	O	use	code	0..1
				period	Period	0..1
12	Effective Date	TS	O	period/start	dateTime	0..1
13	Expiration Date	TS	O	period/end	dateTime	0..1

Table A.8: HL7 Extended Telecommunication Number (XTN) [13] [53]

Seq	Name	HL7 DT	Option	FHIR Address (DT)	FHIR DT	Card.
1	Telephone Number	ST	B	telecom/value (deprecated as of HL7 V2.3)	string	0..1
2	Telecommunication Use Code	ID	O	telecom/use	code	0..1
3	Telecommunication Equipment Type	ID	R	telecom/system	uri	0..1
4	Email Address	ST	O	telecom/value telecom/system="email"	string code	0..1 0..1
6	Country Code	NM	O			
6	Area/City Code	NM	O			
7	Local Number	NM	O	telecom/value	string	0..1
8	Extension	NM	O			
10	Extension Prefix	ST	O			

Table A.9: HL7 Notes and Comments (NTE) [13]

Seq	Name	HL7 DT	Option	FHIR	FHIR DT	Card.
3	Comment	FT	R	comments and additional information		

Table A.10: FHIR HumanName [53] [52]

Name	FHIR DT	Card.	Person Name (PN)	CDA DT	Card.
name	HumanName	0..*	name	PN	0..*
name.use	code	0..1	name[@use]		
name.family	string	0..1	name/family	ST	0..*
name.given	string	0..*	name/given	ST	0..*
name.prefix	string	0..*	name/prefix	ST	0..*
name.suffix	string	0..*	name/suffix	ST	0..*
name.period	Period	0..1	name/validTime	IVL_TS	0..1

Table A.11: FHIR Identifier [53] [52]

Name	FHIR DT	Card.	Instance Identifier (II)	CDA DT	Card.
identifier	Identifier		id	II	
identifier/value	string	0..1	id[@extension]	UID	0..1
identifier/system	uri	0..1	id[@root]	ST	0..1

Table A.12: FHIR CodeableConcept [53] [52]

Name	FHIR DT	Card.	Coded Element (CE)	CDA DT	Card.
code.coding	Coding	0..*	code	CE	
code.coding.system	uri	0..1	code[@codeSystem]	UID	0..1
			code[@codeSystemName]	ST	0..1
code/coding/version	string	0..1	code [@codeSystemVersion]	ST	0..1
code/coding/code	code	0..*	code[@code]	CS	0..1
code/coding/display	string	0..*	code[@displayName]	ST	0..1
code/text	string	0..*	name/originalText	ED	0..1

Table A.13: FHIR Address [53] [52]

Name	FHIR DT	Card.	Address (AD)	CDA DT	Card.
address	Address		addr	AD	
address/use	code	0..1	addr[@use]		0..1
address/line	string	0..*	addr/streetAddressLine	ST	0..*
address/city	string	0..1	addr/city	ST	0..*
address/district	string	0..1	addr/county	ST	0..*
address/state	string	0..1	addr/state	ST	0..*
address/postalCode	string	0..1	addr/postalCode	ST	0..*
address/country	string	0..1	addr/country	ST	0..*

Table A.14: HL7 Code Table 0001 - Administrative Sex Mapping [13] [54]

HL7 Value	HL7 Description	FHIR Value	FHIR Display
F	Female	female	female
M	Male	male	male
O	Other	other	other
U	Unknown	unknown	unknown
A	Ambiguous		
N	Not applicable		

Table A.15: FHIR Gender Mapping [54]

FHIR Value	CDA Value	CDA Display	CDA CodeSystem
female	F	Female	2.16.840.1.113883.5.1
male	M	Male	2.16.840.1.113883.5.1
other			
unknown	UN	Undifferentiated	2.16.840.1.113883.5.1

Table A.16: HL7 Code Table 0002 - Marital Status Mapping [13] [51]

HL7 Value	HL7 Description	FHIR Value	FHIR Display	FHIR Description
A	Separated	L	Legally Separated	
D	Divorced	D	Divorced	Marriage contract has been declared dissolved and inactive
M	Married	M	Married	A current marriage contract is active
S	Single	S	Never Married	No marriage contract has ever been entered
W	Widowed	W	Widowed	The spouse has died
C	Common law			
G	Living together			
P	Domestic partner	T	Domestic partner	Person declares that a domestic partner relationship exists.
R	Registered domestic partner			
E	Legally Separated	L	Legally Separated	
N	Annulled	A	Annulled	Marriage contract has been declared null and to not have existed
I	Interlocutory	I	Interlocutory	Subject to an Interlocutory Decree.
B	Unmarried	U	unmarried	Currently not in a marriage contract.
U	Unknown			
O	Other			
T	Unreported			
		P	Polygamous	More than 1 current spouse

Table A.17: FHIR Marital Status Mapping [51]

FHIR Value	FHIR Display	FHIR Description	CDA Value	CDA Display	CDA CodeSystem
A	Annulled	Marriage contract has been declared null and to not have existed	A	Annulled	2.16.840.1.113883.5.2
D	Divorced	Marriage contract has been declared dissolved and inactive	D	Divorced	2.16.840.1.113883.5.2
I	Interlocutory	Subject to an Interlocutory Decree.	I	Interlocutory	2.16.840.1.113883.5.2
L	Legally Separated	Legally Separated	L	Legally Separated	2.16.840.1.113883.5.2
M	Married	A current marriage contract is active	M	Married	2.16.840.1.113883.5.2
P	Polygamous	More than 1 current spouse	P	Polygamous	2.16.840.1.113883.5.2
S	Never Married	No marriage contract has ever been entered	S	Never Married	2.16.840.1.113883.5.2
T	Domestic partner	Person declares that a domestic partner relationship exists.	T	Domestic partner	2.16.840.1.113883.5.2
U	unmarried	Currently not in a marriage contract.			
W	Widowed	The spouse has died	W	Widowed	2.16.840.1.113883.5.2
UNK	unknown	A proper value is applicable, but not known.			

Bibliography

[1] "IHE IT Infrastructure Technical Framework Volume 2a - Transactions Part A - Sections 3.29 - 3.64," pp. 151–192, 2019, Accessed on: 2020-03-12. [Online]. Available: http://www.ihe.net/

[2] "CDA Release 2.0 Unofficial," Accessed on: 2019-11-14. [Online]. Available: http://xml.coverpages.org/CDA-Release2-Unofficial.html

[3] J. Lyman, S. Pelletier, K. Scully, J. Boyd, J. Dalton, S. Tropello, and C. Egyhazy, "Applying the HL7 reference information model to a clinical data warehouse." in *SMC*. IEEE, 2003, pp. 4249–4255. [Online]. Available: http://dblp.uni-trier.de/db/conf/smc/smc2003.html#LymanPSBDTE03

[4] "SearchHealthIT - Reference Information Model," Accessed on: 2020-02-20. [Online]. Available: https://searchhealthit.techtarget.com/definition/Reference-Information-Model-RIM

[5] T. Viangteeravat, M. N. Anyanwu, V. R. Nagisetty, E. Kuscu, M. E. Sakauye, and D. Wu, "Clinical data integration of distributed data sources using Health Level Seven (HL7) v3-RIM mapping." *J. Clinical Bioinformatics*, vol. 1, p. 32, 2011. [Online]. Available: http://dblp.uni-trier.de/db/journals/jclinbioinf/jclinbioinf1.html#ViangteeravatANKSW11

[6] "Refined Message Information Models (R-MIM)," Accessed on: 2020-02-20. [Online]. Available: http://www.corepointhealth.com/resource-center/hl7-resources/r-mim-refined-message-information-model

[7] E. Zapletal, N. Rodon, N. Grabar, and P. Degoulet, "Methodology of integration of a clinical data warehouse with a clinical information system: the HEGP case," *Stud Health Technol Inform.*, pp. 193–7, 2010. [Online]. Available: http://www.ncbi.nlm.nih.gov/pubmed/20841676

[8] C. S. Ledbetter and M. W. Morgan, "Toward Best Practice: Leveraging the Electronic Patient Record as a Clinical Data Warehouse," *Journal of healthcare information management*, vol. 15, pp. 119–132, 2001. [Online]. Available: http://www.ncbi.nlm.nih.gov/pubmed/11452574

[9] A. Ebidia, C. Mulder, B. Tripp, and M. W. Morgan, "Getting data out of the electronic patient record: critical steps in building a data warehouse for decision support." *Proc AMIA Symp*, pp. 745–9, 1999. [Online]. Available: http://www.biomedsearch.com/nih/Getting-data-out-electronic-patient/10566459.html

[10] A. Ryan and P. W. Eklund, "The Health Service Bus: An Architecture and Case Study in Achieving Interoperability in Healthcare," in *MEDINFO 2010 - Proceedings of the 13th World Congress on Medical Informatics, Cape Town, South Africa, September 12-15, 2010*, ser. Studies in Health Technology and Informatics, C. Safran, S. R. Reti, and H. F. Marin, Eds., vol. 160. IOS Press, 2010, pp. 922–926. [Online]. Available: https://doi.org/10.3233/978-1-60750-588-4-922

[11] J. Lee, N. C. Hulse, G. M. Wood, T. A. Oniki, and S. M. Huff, "Profiling Fast Healthcare Interoperability Resources (FHIR) of Family Health History based on the Clinical Element Models," in *AMIA 2016, American Medical Informatics Association Annual Symposium, Chicago, IL, USA, November 12-16, 2016*. AMIA, 2016. [Online]. Available: http://knowledge.amia.org/amia-63300-1.3360278/t004-1.3364525/f004-1.3364526/2500267-1.3364797/2500298-1.3364792

[12] P. I. Kamel and P. G. Nagy, "Patient-Centered Radiology with FHIR: an Introduction to the Use of FHIR to Offer Radiology a Clinically Integrated Platform," *Journal of Digital Imaging*, vol. 31, no. 3, pp. 327–333, 2018. [Online]. Available: https://doi.org/10.1007/s10278-018-0087-6

[13] HL7 International, "HL7 Messaging Standard Version 2.5 - An Application Protocol for Electronic Data Exchange in Healthcare Environments," 2003.

[14] ——, "FHIR - Publication (Version) History," Accessed on: 2021-02-27. [Online]. Available: http://www.hl7.org/fhir/directory.cfml

[15] ——, "HL7 FHIR," Accessed on: 2019-08-16. [Online]. Available: http://www.hl7.org/fhir

[16] HL7 Austria, "Kurzbeschreibung des HL7 Standards, Version 2.X," Accessed on: 2020-03-30. [Online]. Available: https://hl7.at/standard/hl7-version-2-x

[17] Work Group HL7, "Transport Specification: MLLP, Release 2," Accessed on: 2020-03-30. [Online]. Available: http://hl7.ihelse.net/hl7v3/infrastructure/transport/transport_mllp.html

[18] D. Bender and K. Sartipi, "HL7 FHIR: An Agile and RESTful approach to healthcare information exchange." in *CBMS*, P. P. Rodrigues, M. Pechenizkiy, J. Gama, R. Cruz-Correia, J. Liu, A. J. M. Traina, P. J. F. Lucas, and P. Soda, Eds. IEEE, 2013, pp. 326–331. [Online]. Available: http://dblp.uni-trier.de/db/conf/cbms/cbms2013.html#BenderS13

[19] K. W. Boone, *The CDA TM Book*. Springer, 2011.

[20] HL7 International, "HL7 – Health Level Seven International," Accessed on: 2019-10-01. [Online]. Available: http://www.hl7.org/

[21] "ISO/HL7 27932:2009 - Data Exchange Standards - HL7 Clinical Document Architecture, Release 2," Accessed on: 2019-11-14. [Online]. Available: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=44429

[22] HL7 Deutschland, "HL7 – Health Level Seven Germany," Accessed on: 2019-11-14. [Online]. Available: http://wiki.hl7.de

[23] HL7 International, "Introduction HL7 FHIR," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/summary.html

[24] ——, "Base Resource Definition," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/resource.html

[25] ——, "Narrative," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/narrative.html

[26] ——, "FHIR Extension," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/extensibility.html

[27] ——, "FHIR Resourcelist," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/resourcelist.html

[28] ——, "FHIR Data Types," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/datatypes.html

[29] ——, "FHIR Resource References," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/references.html

[30] ——, "FHIR Exchange Module," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/exchange-module.html

[31] ——, "RESTful API," Accessed on: 2019-08-16. [Online]. Available: https://www.hl7.org/fhir/http.html

[32] Dr. M. Elkstein, "Learn REST: A Tutorial," Accessed on: 2019-08-16. [Online]. Available: http://rest.elkstein.org/

[33] HL7 International, "Messaging using FHIR Resources," Accessed on: 2020-03-10. [Online]. Available: https://www.hl7.org/fhir/messaging.html

[34] ——, "FHIR Composition," Accessed on: 2020-03-10. [Online]. Available: https://hl7.org/FHIR/composition.html

[35] ——, "Using Resources with Services and Service-oriented Architecture," Accessed on: 2020-03-10. [Online]. Available: https://www.hl7.org/fhir/services.html

[36] ——, "Using FHIR in persistent stores," Accessed on: 2020-03-10. [Online]. Available: https://hl7.org/FHIR/storage.html

[37] “Enterprise Service Bus,” Accessed on: 2020-12-17. [Online]. Available: https://en.wikipedia.org/wiki/Enterprise_service_bus

[38] University Health Network, “HAPI - The Open Source HL7 API for Java,” Accessed on: 2020-03-30. [Online]. Available: https://hapifhir.github.io/hapi-hl7v2/

[39] “IHE IT Infrastructure Technical Framework Volume 3 - Cross-Transaction Specifications and Content Specifications: Cross-Enterprise Document Sharing (XDS) – Metadata Specifications,” p. 174, 2019, Accessed on: 2020-03-12. [Online]. Available: http://www.ihe.net/

[40] HL7 International, “FHIR STU3 Composition,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/composition.html

[41] ——, “FHIR STU3 Patient,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/patient.html

[42] ——, “FHIR STU3 Organization,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/stu3/organization.html

[43] ——, “FHIR STU3 Practitioner,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/practitioner.html

[44] ——, “FHIR STU3 PractitionerRole,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/practitionerrole.html

[45] ——, “FHIR STU3 Encounter,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/encounter.html

[46] ——, “FHIR STU3 DiagnosticReport,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/stu3/diagnosticreport.html

[47] ——, “FHIR STU3 Specimen,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/specimen.html

[48] ——, “FHIR STU3 Observation,” Accessed on: 2020-12-28. [Online]. Available: http://hl7.org/fhir/STU3/observation.html

[49] ——, “FHIR STU3 Resourcelist,” Accessed on: 2020-12-27. [Online]. Available: http://hl7.org/fhir/stu3/resourcelist.html

[50] ——, “Extension CDA In Fulfillment of,” Accessed on: 2020-12-30. [Online]. Available: https://www.hl7.org/fhir/2015may/extension-cda-infulfillmentof.html

[51] ——, “Value Set Marital Status,” Accessed on: 2020-12-29. [Online]. Available: http://hl7.org/fhir/STU3/valueset-marital-status.html

[52] “IHE Pathology and Laboratory Medicine Technical Framework Volume 3 - Content Modules,” p. 73, 2020, Accessed on: 2020-12-30. [Online]. Available: http://www.ihe.net/

[53] HL7 International, “FHIR Data Types,” Accessed on: 2020-12-29. [Online]. Available: http://hl7.org/fhir/STU3/datatypes.html

[54] ——, “Value Set Administrative Gender,” Accessed on: 2020-12-29. [Online]. Available: http://hl7.org/fhir/STU3/valueset-administrative-gender.html

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