

HL7 Tooling Work Group

HL7 EHR Work Group

User Guide for

**Electronic Health Record-System
Functional Model, Profile Designer Tool**

November 2014

Chapter One: Overview



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Preface

Notes to readers

This is an overview for the HL7 EHR-S FM Profile Designer Tool. The basis for this tool was The EHR-S FM, release 2. The development of the tool was approved by both the EHR workgroup and the Tooling workgroup, and hence became a full HL7 International tooling project.

This chapter aligns with phase 2 of the development process of the EHR-S FM tool. If and when HL7 International decides to carry out phase 3 of the development process, this chapter will change accordingly.

Acknowledgements

The project team is indebted to the EHR and Tooling Workgroup for their contributions towards the development of the EHR-S FM tool and the User Guide presented here. We are thankful to every person who was able to contribute, whether for a short period of time, or week-in/week-out work. We cannot thank you enough. Participants in the development of the tool, including workgroup contributors and other participants, can be found in the table 1.

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Table 1: Acknowledgements.



1. Introduction and Overview

The first version of the Electronic Health Record-System Functional Model (EHR-S FM) passed ballot as a Draft Standard for Trial Use (DSTU) in April 2004. From that moment onward, the EHR-S FM has undergone a process of improvement and completion as an international standard. This process is the work of the HL7 EHR Workgroup. In their experience with the EHR-S FM, workgroup members realized that the complexity of the EHR-S FM has increased during the years. Out of this experience the requirement for a tool to manage the EHR-S FM became obvious. This led to a project proposal for two phases: phase 1 the tool for the EHR-S FM, phase 2 for making Functional Profiles. Hence, the project proposal for tooling development was granted in 2012.

Documentation that goes with the EHR-S FM tool focuses on end-user tasks for using the Electronic EHR-S FM Profile Designer tool as it is developed as an extension in Enterprise Architect (EA). This documentation is to be seen as a user guide and tool description. This Overview Chapter describes the background of the HL7 EHR-S FM Profile Designer tool. Both the development of the tool and the content of the tool are explained. This chapter is part of the package with specific user guides that goes with the HL7 EHR-S FM Profile Designer tool. What is in the package is described below in paragraph 1.1.4.

1.1 Background

1.1.1 What is HL7?

Established in 1987, Health Level Seven (HL7) is an American National Standards Institute (ANSI) accredited, not-for-profit standards-development organization, whose mission is to provide standards for the exchange, integration, sharing, and retrieval of electronic health information; support clinical practice; and support the management, delivery and evaluation of health services. ANSI accreditation, coupled with HL7's own procedures, dictates that any standard published by HL7 and submitted to ANSI for approval, be developed and ratified by a process that adheres to ANSI's procedures for open consensus and meets a balance of interest requirement by attaining near equal participation in the voting process by the various constituencies that are materially affected by the standard (e.g., vendors, providers, government agencies, consultants, non-profit organizations). This balance of interests ensures that a particular constituency is neither refused participation nor is it allowed to dominate the development and ratification of a proposed standard. More information and background on ANSI is available on their website at: <http://www.ANSI.org>

1.1.2 What is the Electronic Health Record-System Functional Model?

The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings and realms, enables a standardized description and common understanding of functions sought or available in a given setting (e.g., intensive care, cardiology, office practice in one country or primary care in another country).

1.1.3 How is the tool for the Electronic Health Record-System functional Model developed?

The process of the development of the EHR-S FM Profile Designer tool is described below. The design is included in the file: EHR_S_FP_ToolDesignPhase2.eap



1. Phase 2 of the tool development was based on phase 1. Enterprise Architect was used because of its availability to the HL7 community, experience with tool development, and its import – export capabilities.
2. The input for the phase 2 tool development were: 1 The EHR-S FM R2 standard, in particular the conformance clause, 2 How-To Guide for Creating Functional Profiles, 3 Requirements determined by the HL7 EHR WG, 4 The use cases developed in collaboration with the HL7 EHR WG, 5 The type of Functional Profiles, and 6 The process of functional Profile development.
3. Another important input was the experience of several EHR WG members working on the development of a specific Functional Profile. Their input was of great value.
4. Based on chapter 6 Conformance clause of the EHR-S FM standard and the How-to Guide for Creating Functional Profiles a design was made in Enterprise Architect. This design was approved by the EHR WG.
5. The design was implemented in an extension on Enterprise Architect. In figure 1 the principle of the design and how the tool works is shown. Bases on the Base Model a Profile Definition is developed in which all the elements for the new Functional Profiles are defined. From the Profile Definition a Functional Profile is compiled based on compiler instructions. These instructions are based on the rules for developing Functional Profiles.

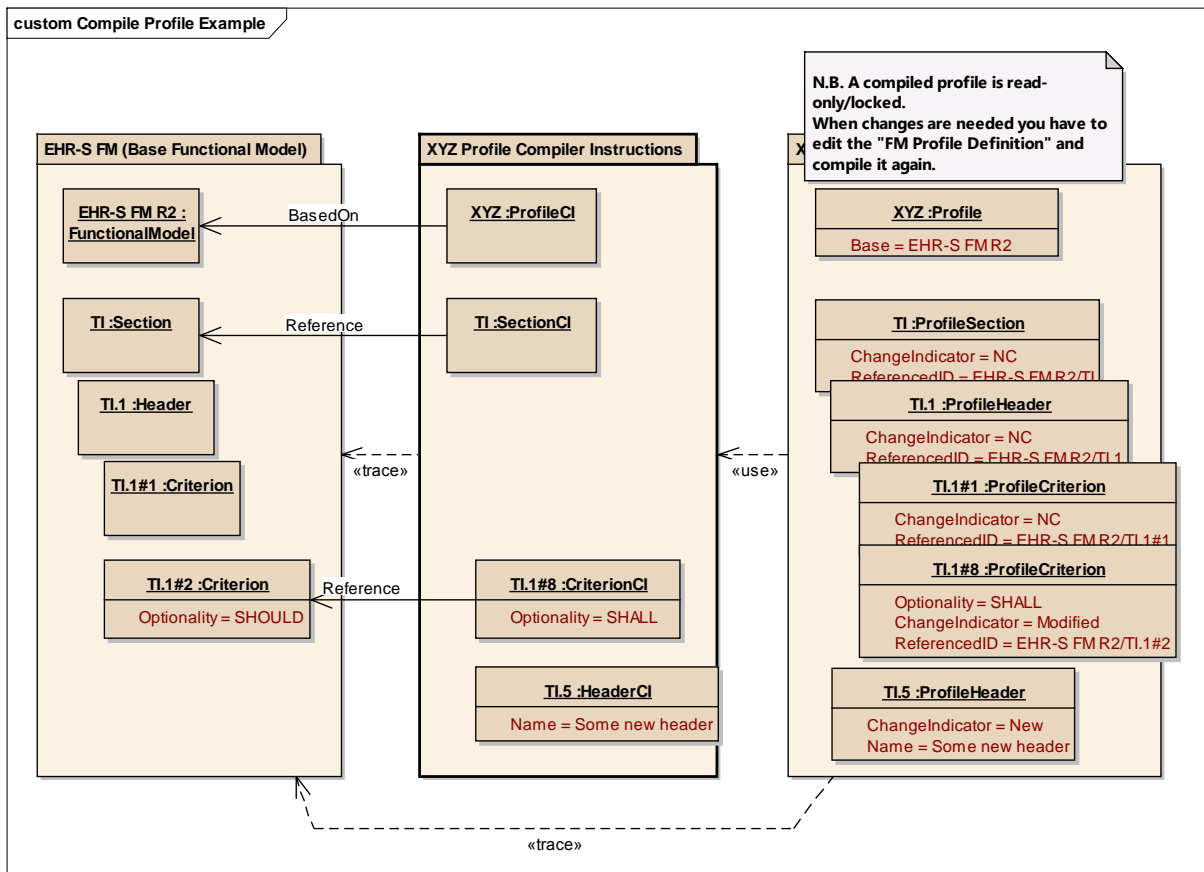


Figure 1. Principle of tool design.

6. Validation rules were described based on the rules for Functional Profile development. These rules were implemented using schematron. The user is able to generate as many validation reports as desired. The reports contain warnings or errors against the validation rules.



7. The development of two Functional Profiles was used to test the first draft of the tool. Based on experiences the tool was adjusted to meet the requirements of the user.
8. In a later phase HL7 Italy used the tool to develop a Realm Functional Profile based on the EHR-S FM R2. The Realm Functional Profile is stated in the Italian language. Several issues and questions came up when using the tool for the translation. If these were applicable for phase 2 they were handled. If the issues and questions are applicable to phase 3 of the tool development they were postponed to handle in phase 3.
9. The Compiled Profile, this is the new Functional Profile, is represented in XML, in particular the HL7 MAX format for publications. With the use of the Max file of the Compiled Functional Profile, artifacts for publications are developed. Using XSLT transformations, the MAX export can be represented as a HTML page, using a Cascading Style Sheet (CSS). From this, additional publication artifacts can be generated using HL7 publication tools.

1.1.4 What is the Tool EHR-S Functional Model Package?

The EHR-S Functional Model tool Package includes the following materials:

Document title	File name
The EHR-S FM Profile Designer tool extension for Enterprise Architect.	HL7_FM_EA_Extension vx.14.xxxx.msi (vx is for version of the EHR-S FM, 14.xxx stands for the date according ISO data time format).
Design of the EHR-S FM Profile Designer Tool	EHR_S_FP_ToolDesignPhase2.eap
Readers Guide:	EHR_S_FM_TOOL_C0_Readme
Chapter One. Overview	EHR_S_FM_TOOL_C1_Overview
Chapter One. Overview, updated version for phase 2	EHR_S_FM_TOOL_C1_OverviewPhase2
Chapter Two. Installing the extensions, HL7 EHR-S FM and HL7 Max.	<i>EHR_S_FM_FP_Designer_TOOL_Installing the extension.pdf</i>
User Guides 'Overview & Definitions' NOTE: this is based on the EHR-S FM Standard with references to how to use the tool and user guides.	1Preface.pdf 2IntroductionandOverview.pdf 3TheSectionsFunctionalModel.pdf 4FunctionalProfiles.pdf 5EHRFSMComponents.pdf 6ConformanceClauseIntroduction.pdf 7ConformanceClausConcepts.pdf 8ConformanceClauseConformanceCriteria.pdf 9FMStructure&Extensibility.pdf 10FPConformance.pdf 11RulesNewFunctions.pdf 12UseCases.pdf 13ConditionalSHALL.pdf 14Glossary.pdf
User Guides 'Browse'	ReadEHRFSM.pdf SearchEHRFSM.pdf TraceabilityElements.pdf
User Guides 'Creation'	0Introduction.pdf 1CreateNewProfile.pdf 2LoadBaseModel.pdf 3CreatePackageforFP.pdf 4ProvideGeneralInformation.pdf 5CreateUMLmodelNewFP.pdf 6CreateProfileDefinition.pdf 7CreateCompiledProfile.pdf 8Validation.pdf



	9CreatePublication.pdf
User Guides 'Edit Functional Profiles'	AddingEHR_S_FMFPcomponents.pdf MovingEHR_S_FMFPcomponents.pdf CollaborationFunctionalProfile.pdf ProjectManagement.pdf TrackingChanges.pdf
User Guides 'Export'	ExportSection.pdf Basic FM Export Table Template.rtf
User Guide Combine, Compare and Merge	CombineCompareMerge.pdf
Frequently asked questions, FAQ	FAQ.pdf
How-to Guide for Creating Functional Profiles NOTE: is not part of phase 2 of the tool development. However, in the guide references to how to use the tool and user guides are given. Finalization of the guide will take place after the HL7 WGM of January 2015.	InstructionsIntroduction.pdf InstructionsGettingStarted.pdf InstructionsGeneralFPInformation.pdf InstructionsCreatingConformanceClause.pdf InstructionsSelectingFunctions.pdf InstructionsCreatingCC.pdf Principles.pdf InstructionsRegistration&Ballot.pdf
Tutorial presentation	TutorialpresentationPhase2.pptx
Validation Rules	Phase2EHR S FM Tool ValidationRules.xlsx
XML Generator for EHR-S FM spreadsheet	EHR-S FM_R2_XML-Generator.zip
Validation testing of EHR-S FM via XML artifacts	fm-max-validation-test.xml FM-validation.sch fm-validation.xslt Validation output (2013-apr-18).txt
XSLT for MAX to HTML	max2html.xsl functional-model.css functional-model.scss ehr-s-fm-ballot.mif
Publication documentation generated from the EHR-S FM tooling output in html and pdf	EHR-S-FM_R2-from-max.html functional-model.css max2html.xsl EHR-S-FM_R2-from-max.pdf
Source code for the EHR-S FM Extension	HL7 SourceCodeEHR-S FM Tool (2013-may-27).zip

Table 2: Package EHR-S FM Profile Designer tool phase 2.

1.2 Purpose and Scope

The purpose of the project is to produce a desktop tool to create EHR-S FM Functional Profiles (starting with the EHR-S FM R2). The tool will support the Profiles creation process, enforce profiling rules, exports the profiles as documents, supports XML interchange format (MAX) for reuse across profile tool instances or for use in other tools. The project starts with Enterprise Architect, which is a windows based tool, which is available via Sparx. The EHR-S FM Extension tool will be available through Health Level 7.

The EHR systems must meet a large package of requirements, such as HL7 specified in the EHR-S FM R2 (Electronic Health Record System Functional Model Release 2) standard. Functional Profiles that were developed, most of them based on an older version of the EHR-S FM, were managed in Excel spreadsheets, leading to laborious work, missing linkages between the requirements, or worse: to errors in the Functional Profile and/or the traceability to the EHR-S FM. Hence, HL7 seeks tooling that allows better management of the EHR-S FM (phase 1 of the tooling project). In addition, based on the EHR-S FM R2, a multitude of Functional Profiles are and will be created, functioning as a domain specific specialization of the EHR-S FM R2. However, such profiles will inherit to a large extend EHR-S FM R2 capabilities and validation rules. Hence, HL7 wants to have a tool allowing to easily deriving



profiles from the EHR-S FM that can be managed independently, but keeps all the characteristics. This was phase 2 of the tooling project.

1.2.1 Tool EHR-S Functional Model Scope

The scope of the project is divided into two phases. Phase 1 is the development of the Functional Model tool, which ended in 2013 and phase 2 is the development of the EHR-S FM Profile Designer tool, which ended 2014. In figure 2 shows how phase 1 and 2 are divided with respect to functionalities.

Phase 1 consisted of the import of the EHR-S FM R2 into Enterprise Architect. This incorporates the Functional Model validation rules, the validation of the EHR-S FM R2 content to produce EHR-S FM ballots through the export of the Functional Model. Phase two will be focused on the development and validation of a Functional Profile.

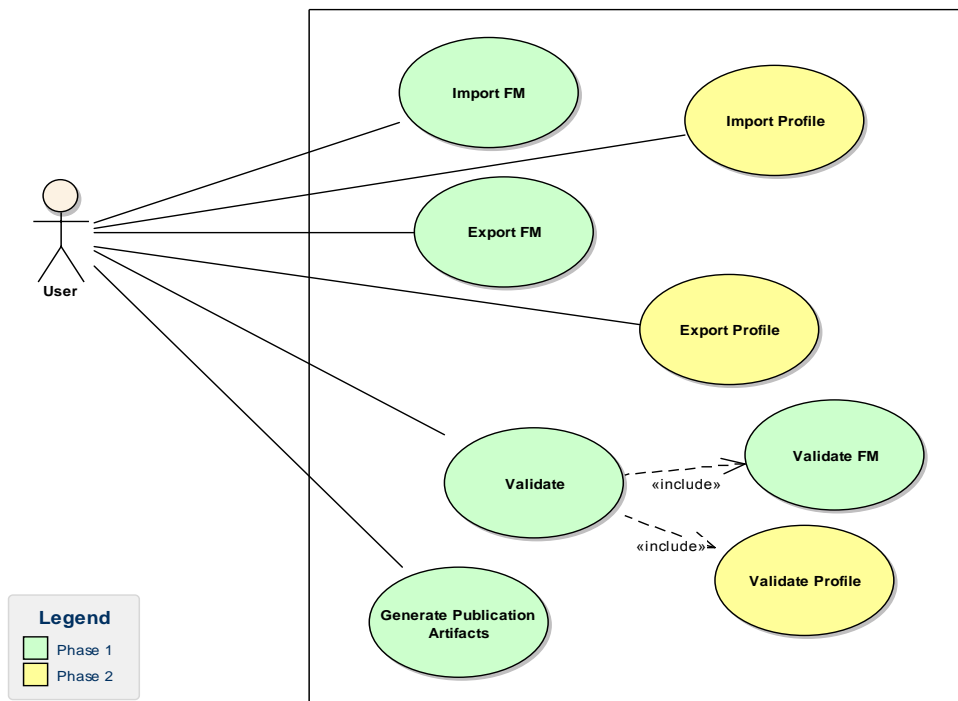


Figure 2. Phase 1 and 2 of the development of the EHR-S FM tool.

1.3 Overview and Definition of the Tool for the EHR-S Functional Model

The EHR-S Functional Model is composed of a list of functions, known as the Function List, which is divided into seven sections: Overarching, Care Provision, Care Provision Support, Population Health Support, Administrative Support, Record Infrastructure and Trust Infrastructure. In figure 3 the seven sections are shown as it is in the Functional Model tool in Enterprise Architect.

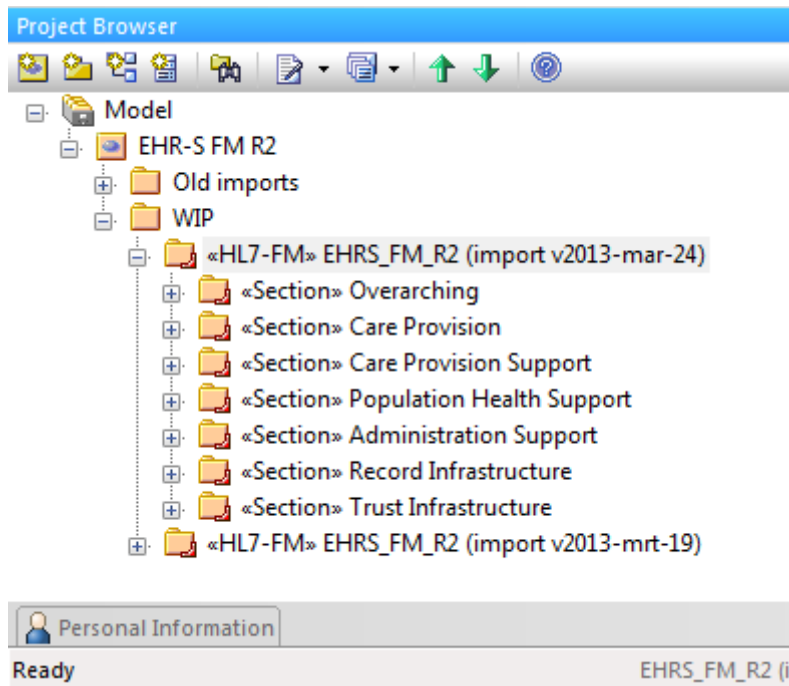


Figure 3. Function List in the various Sections.

1.3.1 EHR-S FM R2 UML Meta Model

With the analysis of the EHR-S FM there grew a deeper understanding of the underlying construction, structure, validation rules and theory of the EHR-S FM. For development of the Functional Model tool a Meta Model is developed based on this analysis. This Meta Model is required to keep an overview of the tool design and functionality. In this case it is important for the underlying structure of the EHR-S FM in which sections, headers, functions and criteria are organized. In figure 4 the Meta Model of the EHR-S FM tool is presented in Unified Model Language (UML).

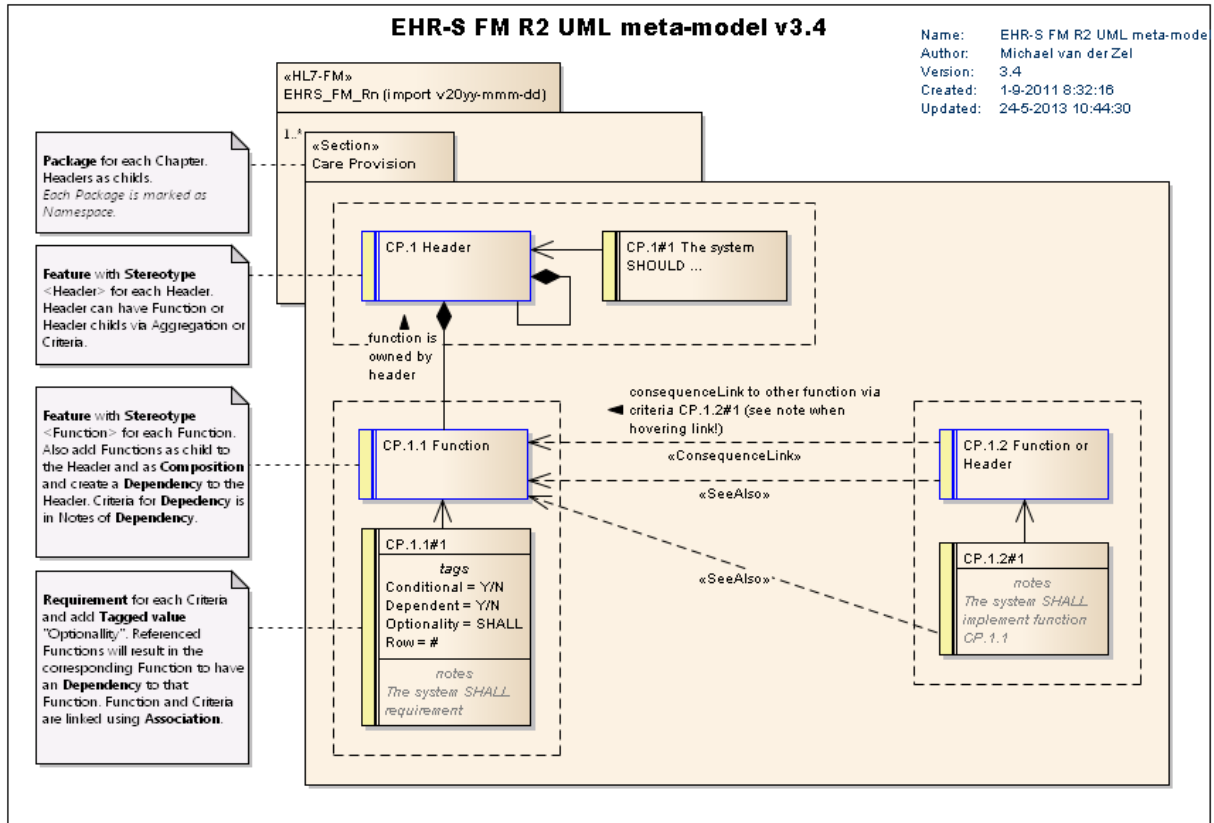


Figure 4: UML Meta Model EHR-S FM R2.

1.3.2 EHR-S FM R2 XML schema

Based on the Meta Model described in 1.3.1 an EHR-S FM spreadsheet XML schema was developed. The development of this schema is important for the proper representation of the EHR-S FM in UML. In figure 5 this EHR-S FM XML schema is represented.



EHR-S FM Spreadsheet XML Schema

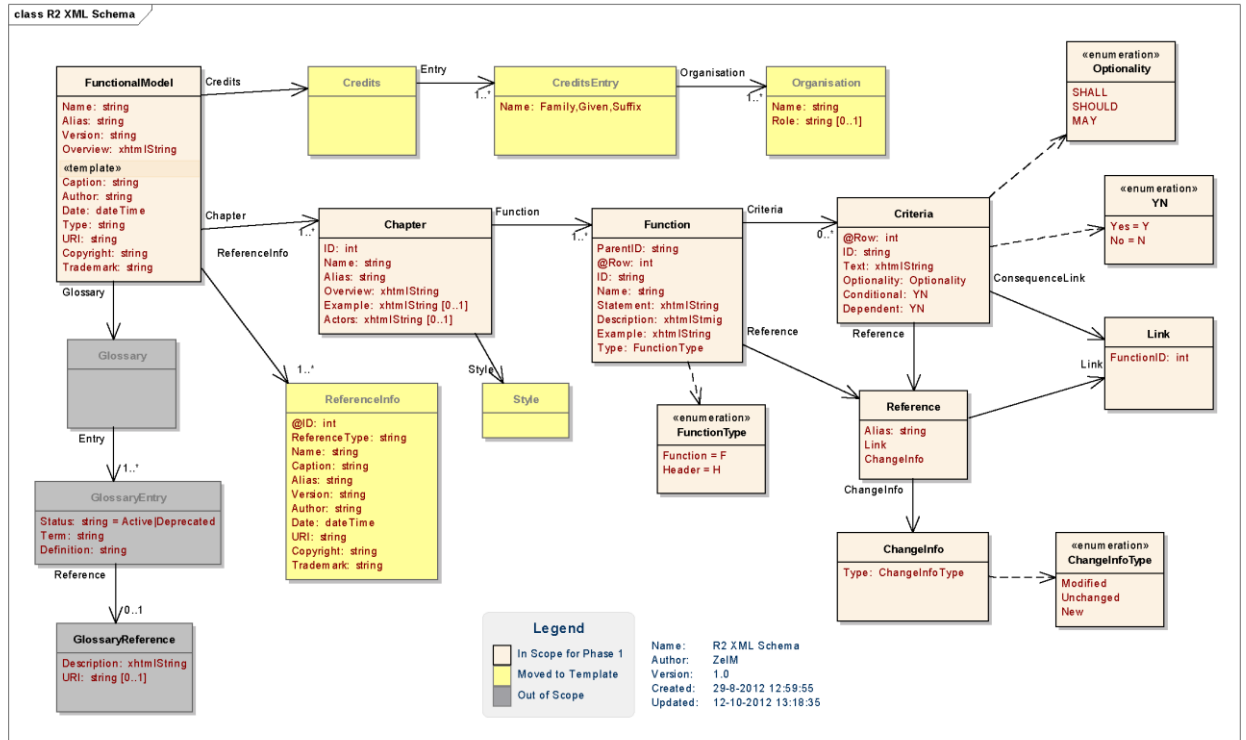


Figure 5: EHR-S FM R2 XML schema.

1.3.3 Mapping of the EHR-S FM R2 XML schema to the EHR-S FM UML Meta Model

From the XML schema representation (Figure 5) of the EHR-S FM an UML model equivalent has been designed. Figure 6 illustrates the mapping of the XML schema to the EHR-S FM UML Meta Model. This mapping is imported to ensure the consistency between the spreadsheet, the XML and the UML representations of the EHR-S FM.



XML to EA UML Mapping

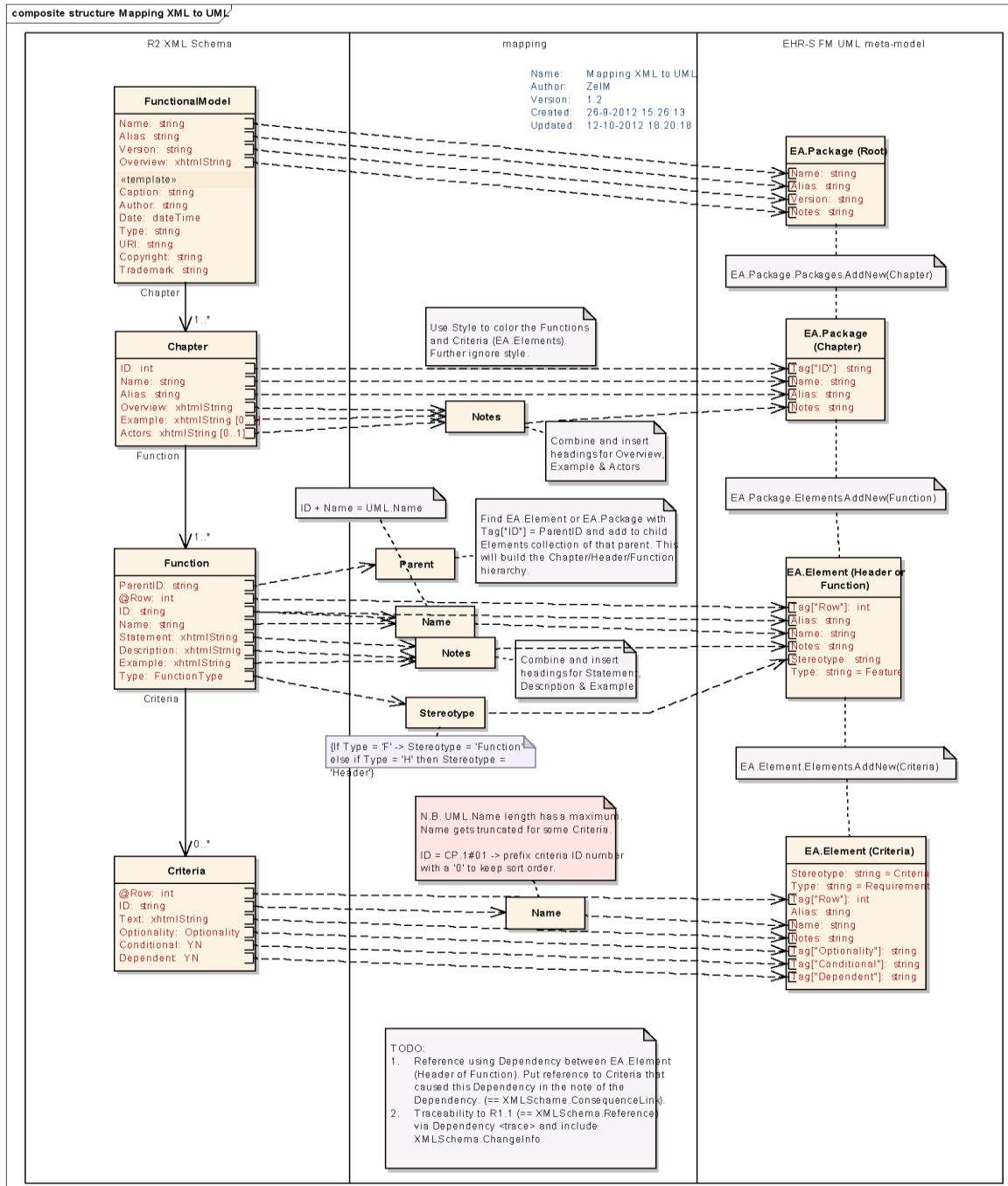


Figure 6: Mapping of EHR-S FM R2 XML schema to UML Meta Model.



1.3.4 EHR-S Function List Components

The EHR-S Function List is a list (superset) of functions organized into discrete sections and subsections. Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR-S. Each function in the HL7 EHR-S Functional Model is identified and described using a set of elements or components as seen in figure 7.

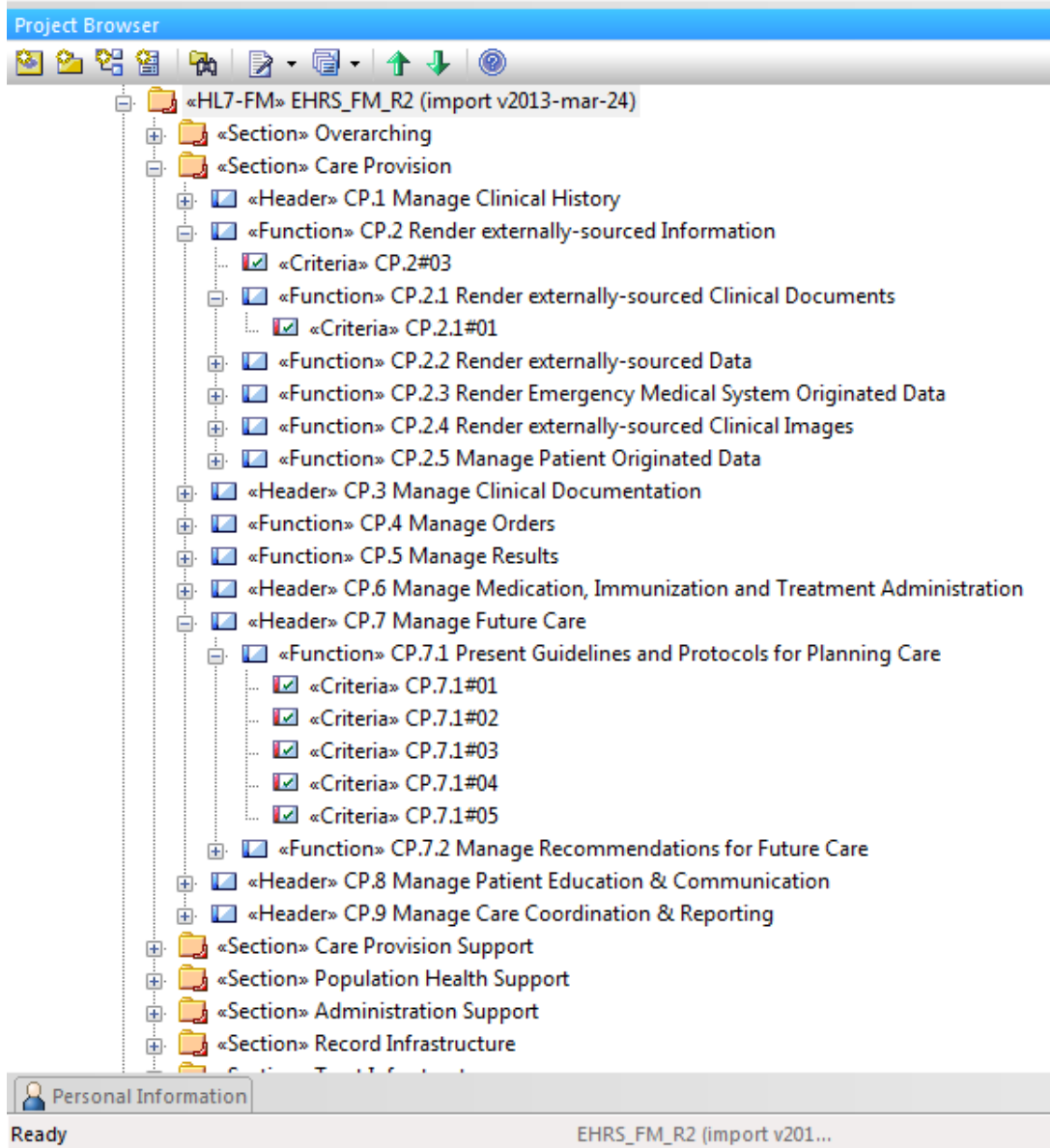


Figure 7. Function List Example.

Each function in the EHR-S FM is identified and described using the following set of elements or components; ID, Type, Name, Statement, Description and Conformance Criteria. In the tool these sets



User Guide for Electronic Health Record-System Functional Model Tool Chapter One: Overview of elements or components are included. In figure 8 an example is represented as it is included in the tool. The ID, Statement and Description are visible after opening a function in the tool¹. The element ‘

Type’ is visible at the top of the dialogue. The conformance criteria are visible as shown in figure 7. For further explanation of the elements or components see chapter 1 Overview, 1.3.2 EHR-S Function List Components, of the EHR-S FM ballot Package.

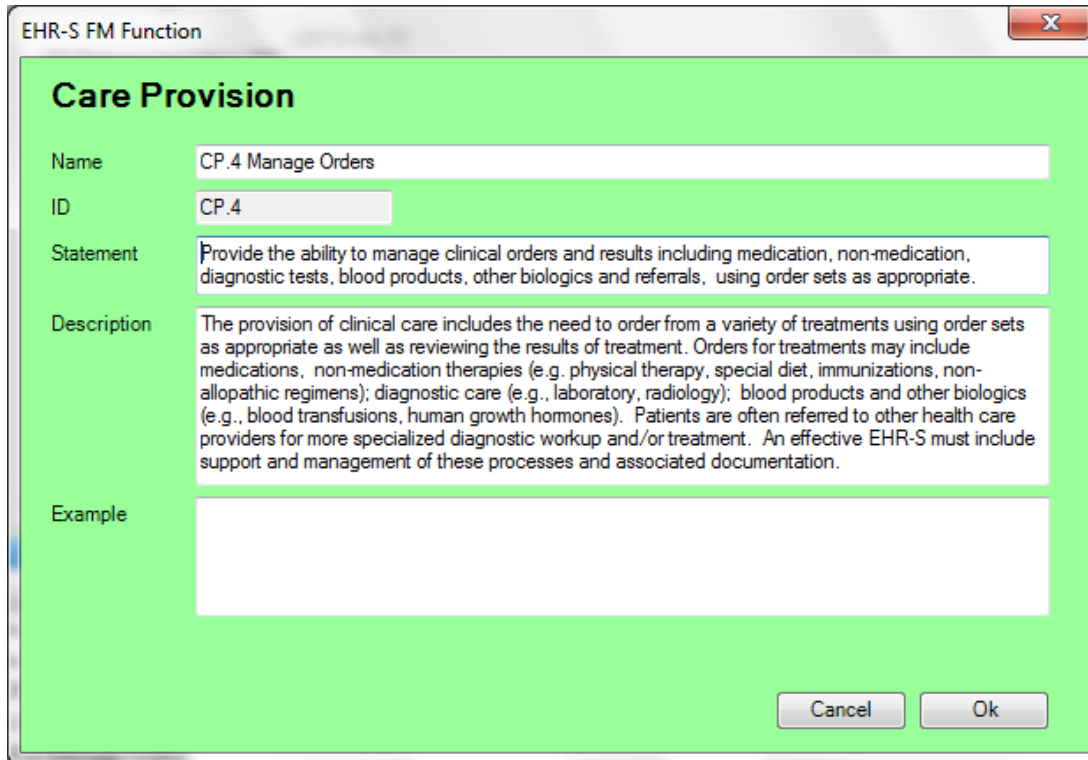


Figure 8. Example of component (function) in the EHR-S FM R2.

When you look at the Tagged values of this component it will show you some features of this component. Included is the traceability to Release 1.1 of the EHR-S FM. (Figure 9).

¹ How to open a function in the tool is explained in EHR_S_FM_TOOL_C4_Manage
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Property Name	Value
Conditional	N
Dependent	N
Optionality	SHALL
Reference.Alias	EHR-S_FM_R1.1
Reference.ChangeInfo	Modified
Reference.CriteriaID	3
Reference.FunctionID	DC.1.1.3.3
Row	754

Figure 9. Tagged values in EA describing some features of the selected EHR-S FM Component.

1.3.5 Import and export functionalities

In the EHR-S FM tool there are import and export functionalities. Figure 10 shows the possibilities at this moment.

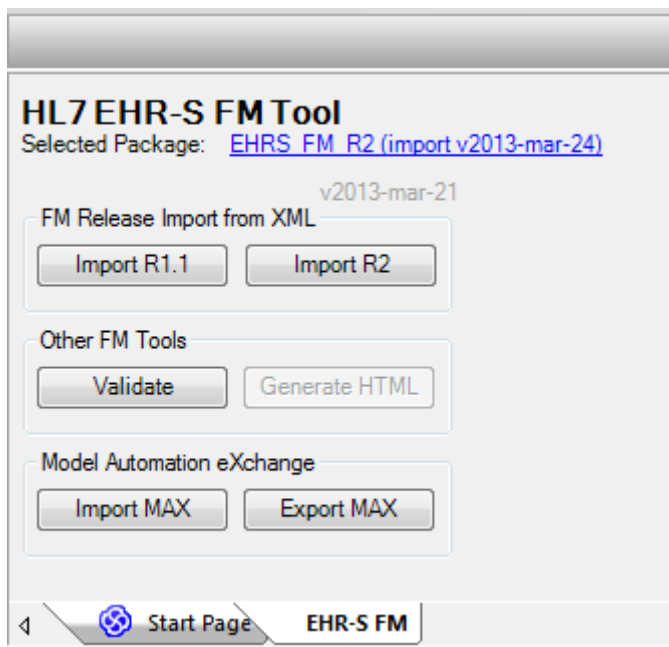


Figure10. Import and export functionalities of the EHR-S FM Tool as extension to EA.

1.4 Anticipated Uses

This paragraph describes the different uses of the EHR-S FM Tool. Each use is explained using a use case description. This has been updated from phase 1 with results from phase 2 of the project.

1.4.1 *Anticipated Use: read/ browse and search the EHR-S FM*

Although a user can read the EHR-S FM in any given publication format of the EHR-S FM, such as html or pdf, he can also read the EHR-S FM in Enterprise Architect. The user can browse through the Functional Model looking at sections, headers, functions and conformance criteria. Besides that, the user can also look at the traceability of these elements. The user can also search in the EHR-S FM by using the search functionality of Enterprise Architect.

How the user can read, browse, and search the EHR-S FM in enterprise Architect is described in the detailed instructions in chapter 4 Manage.

1.4.2 *Anticipated Use: EHR System Function and Information Model*

In this project The EHR-S FM is used to develop a prototype, EHR-S FIM Release 2.1. The prototype has the purpose to:

1. Add conceptual information and data models for each EHR-S function
 - a. Make the EHR-S FM easier to use for analysts and engineers
 - b. Verify and validate EHR-S FM Release 2.0
2. Demonstrate Service Aware Interoperability Framework (SAIF) use
3. Support specific profiles (e.g., DAMs, DIMs, DCMs).

The EHR workgroup members responsible for these new developments have already experienced that this EHR-S FM tool makes it easier to use the EHR-S FM and to develop conceptual information and data models for each EHR-S function.

1.4.3 *Anticipated Development Approach: maintenance of the EHR-S FM*

Given the complexity of the EHR-S FM the tool first use is the maintenance of the current release of the EHR-S FM. In particular it is used producing ballot materials and carrying out the activities as decided during the ballot reconciliations.

➤ *Use case example. Minor adjustments to the text of the EHR-S FM.*

In the EHR-S FM tool release 2 of the EHR-S FM is included. Working with this release someone discovers that some verbs used in 'CP.1.2 Manage Allergy, Intolerance and Adverse Reaction List' are not included the verb hierarchy of the EHR-S FM. The EHR Workgroup decided that this must be corrected in the EHR-S FM. The tool assists in carrying out the change and to generate the publication artifacts in a consistent manner.

1.4.4 *Anticipated Development Approach: development of a new release of the EHR-S FM*

When the workgroup decides to create a complete new release of the EHR-S FM, the tool can be used to support this. It is envisioned that new sections, headers, functions and conformance criteria can be added, changed, or removed from the EHR-S FM. If this is required, the tool facilitates this development. The validation rules check against the design principles of the EHR-S FM. If there are fundamental changes in the design of the EHR-S FM, there might be changes required in the validation rules. In that case both the tool parts for the validation rules and the validation report need to be updated with the new rules.

How the user can develop a new release of the EHR-S FM in EA, e.g changes, traceability to EHR-S FM R2, remove and/or add components of the EHR-S FM, is described in the instructions in chapter 4 Manage.



1.4.5 Anticipated Development Approach: development of functional profiles

HL7 is an international community and supports the development of Functional Profiles, which are country specific (HL7 realm), or domain specific specifications within a standard. It is anticipated that the EHR-S FM tool is going to be used for the development of these Functional Profiles. Functional Profiles designate a subset of functions from the EHR-S FM for use in specific care settings (e.g. Behavioral Health) or functional areas (e.g. Clinical Research). In the document How-to Guide for Creating Functional Profiles is described how a functional profile can be made using the rules to go with that development.

A "functional profile" is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etcetera. Functional profiles help to manage the master list of functions. It is not anticipated that the full Functional Model will apply to any single EHR-S implementation.

1.4.6 Anticipated Development Approach: maintenance of a functional profiles

The EA tool is designed to maintain both the FM and the FP's. Specific functions are adding, moving, changing and deleting sections, headers, functions, and criteria. The validation rules can check if this is done correctly with respect to the profiling rules. In phase 2 an important feature is added: the combine, compare and merge function. This is in particular important for the long term maintenance for profiles. It is possible to compare any profile against one or two other profiles, and against the base profile. The user can select from the different profiles what is required and get the best result for future use. A merged profile can be made and saved as the results of maintenance work as well. However, Release, Versioning, and Date management does apply.

1.4.7 Anticipated Development Approach: translations and their maintenance

This anticipated development is out of scope in phase 1 & 2. Phase 3 has been accepted by the EHR workgroup and would develop additional functionalities for both FM and Profile translations.



2. Definitions of terms

With the EHR-S FM comes a Glossary where terms that are used in the EHR-S FM are defined. The terms in this chapter contains the terms used for the Functional Model tool.

Term	Definition
Ballot reconciliations	Is part of the ballot process within HL7. The ballot process involves participation from the healthcare community as well as formal Standards Development Organizations (SDO), such as ISO. Ballot reconciliation is the formal process for addressing the comments submitted by the HL7 participants.
UML Metamodel	In the UML metamodel in the context of the EHR-S FM, the concepts related to the EHR-S FM are brought together in a UML model. In the UML metamodel the properties of the EHR-S FM are highlighted. In the model the relationships of the concepts are also shown.

3. Abbreviations

Abbreviations	Explanation
ANSI	American National Standards Institute http://www.ansi.org/
EA	Enterprise Architect http://www.sparxsystems.com
EHR-S FM	Electronic Health Record System Functional Model
EHR-S FM	Electronic Health Record System Functional Profile
EHR-S FIM	EHR System Function and Information Model http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG#EHR_System_Function_and_Information_Model_28EHR-S_FIM.29.2C_R2.1
UML	Unified Model Language http://en.wikipedia.org/wiki/Unified_Modeling_Language
XMI	XML Metadata Interchange http://en.wikipedia.org/wiki/XML_Metadata_Interchange
XML	Extensible Markup Language http://en.wikipedia.org/wiki/XML