



Unlocking the Power
of Health Information

HEALTH LEVEL SEVEN, International

User Guide for
HL7 Profile Designer Tool

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A manual for the use of the HL7 EHR-S FM Profile Designer Tool, an extension on Sparx Enterprise Architect.



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Preface

Notes to readers

This is an manual for the HL7 Profile Designer tool. The basis for this tool was were two projects. One to get the EHR-S FM R2 into the tool and two to derive functional profiles from the EHR-S FM R2. The base for this manual is the inclusion of the PHR-S FM R2 into the Profile Designer Tool. The development of the tool was approved by HL7 International.

This manual aligns with the development process of the Profile Designer Tool in 2018 for the inclusion of the PHR-S FM R2 into the tool.

Acknowledgements

The project team is indebted to the EHR and Tooling Workgroup for their contributions towards the further development of the Profile Designer Tool and the manual 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. Direct and indirect participants in the development of the tool, including workgroup contributors and other participants, can be found in the in table 1.

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Table 1: Acknowledgements.



1. Introduction

The first version of the Electronic Health Record-System Functional Model (EHR-S FM R1) passed ballot as a Draft Standard for Trial Use (DSTU) in April 2004. From there the EHR-S FM has undergone a process of completion and improvement as an international standard. This process is the work of the EHR Workgroup. In their experience with the EHR-S FM, workgroup members realized that the complexity of the EHR-S FM has increased over 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 R2, phase 2 for making Functional Profiles derived from the EHR-S FM R2. The Profile Designer Tool was developed and used for several functional profiles based on the EHR-S FM R2. Based on this experience a new project started for the inclusion of the Personal Health Record-System Functional Model (PHR-S FM R2). The PHR-S FM was published as a normative standard in May 2014. The PHR-S FM was not only balloted within the HL7 community, but also in the ISO¹ community. The result of this was an ISO standard ISO/HL7 16527:2016 Health informatics -- HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)

This manual for the use of the HL7 Profile Designer Tool focuses on end-user tasks for using the HL7 Profile Designer tool as it is developed as an extension in Sparx Enterprise Architect (EA).

1.1 Background

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 interest goal 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>

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

¹ ISO: International Organization for Standardization



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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)².

What is the Personal Health Record-System Functional Model?

The Personal Health Record System Functional Model, Release 1 standard specifies features and functions necessary to create and effectively manage PHRs and that help an individual maintain a longitudinal view of his or her health history. Personal Health Record information is expected to be sent, received, or exchanged from multiple systems, including: Electronic Health Record systems, insurer systems, payer systems, health information exchanges, public health systems, Internet-based health education sites, clinical trials systems, and/or collaborative care systems³.

How is the HL7 EHR- S FM and PHR S FM Profile Designer tool developed?

The process of the development of the HL7 Profile Designer tool is described below.

In phase 1 of the tool development the goal was to import the EHR-S FM R2 into Enterprise architect as a UML model. A design, UML metamodel and several use cases were described and approved by the HL7 EHR WG. The result is an extension (Add-on) on Sparx Enterprise Architect with which the EHR-S FM could be imported and edited. In phase 2 the design and metamodel were expanded to get the tool ready for creating functional profiles from the EHR-S FM. The extension on Sparx Enterprise Architect was adjusted and expanded. This manual has been created in different phases of the project, using different versions of EA. Some of the figures will be from version 11, others from version 12 and again the latest changes use version 13. The older figures are left because not everybody will use the same version, and the illustration is still correct although the figure looks a bit different.

Sparx Enterprise Architect was used because of its free availability to the HL7 community, experience with tool development, and its import – export capabilities. The latest development was to get the tool ready for the import of the PHR-S FM or any other functional model e.g., the HL7 Consumer Mobile Health Application Functional Framework (cMHAFF) through spreadsheets.

The references that were used 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,
6. The process of functional Profile development,

² HL7 International, (2014). HL7 EHR-S FM electronic Health Record System Functional Model, Release 2 (EHR-S FM R2)

³ HL7 International, (2014). HL7 PHR-S FM Personal Health Record System Functional Model, Release 1 (PHR-S FM R1)

7. The experience of several EHR WG members with the development of a Functional Profile.

The basis of the HL7 Profile Designer Tool is shown in figure 1.

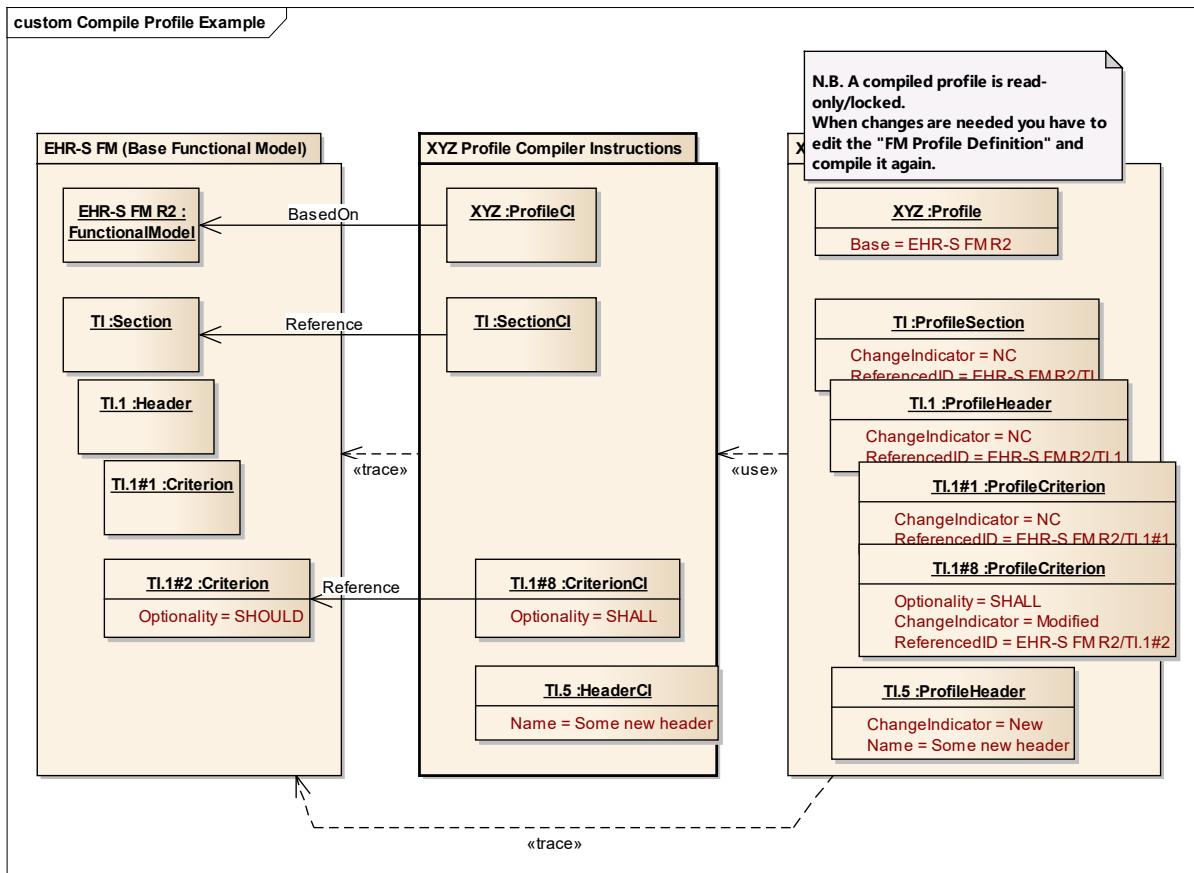


Figure 1. Basis of the tool design.

1.2 Purpose and Scope

The purpose of the latest project (end of 2018) is to adjust the tool to include the PHR-S FM into the tool so that Functional Profiles derived from the PHR-S FM can be created. The tool will enforce profiling rules, and exports as documents, support for XML interchange format for reuse across profile tool instances or for use in other tools. The difference with earlier phases in the tool development is the import of the PHR-S FM through an Excel spreadsheet into the tool. The result is an Excel spreadsheet template so that future functional models can be imported into the tool.

A second purpose of the recent project is to test if the functionality for creating functional profiles can be used when the PHR-S FM is the base model for that. An actual functional profile derived from the PHR-S FM was not created, just a test functional profile.

1.3 Use cases

Use cases, as shown in figure 2, were reviewed and approved by the HL7 EHR WG.

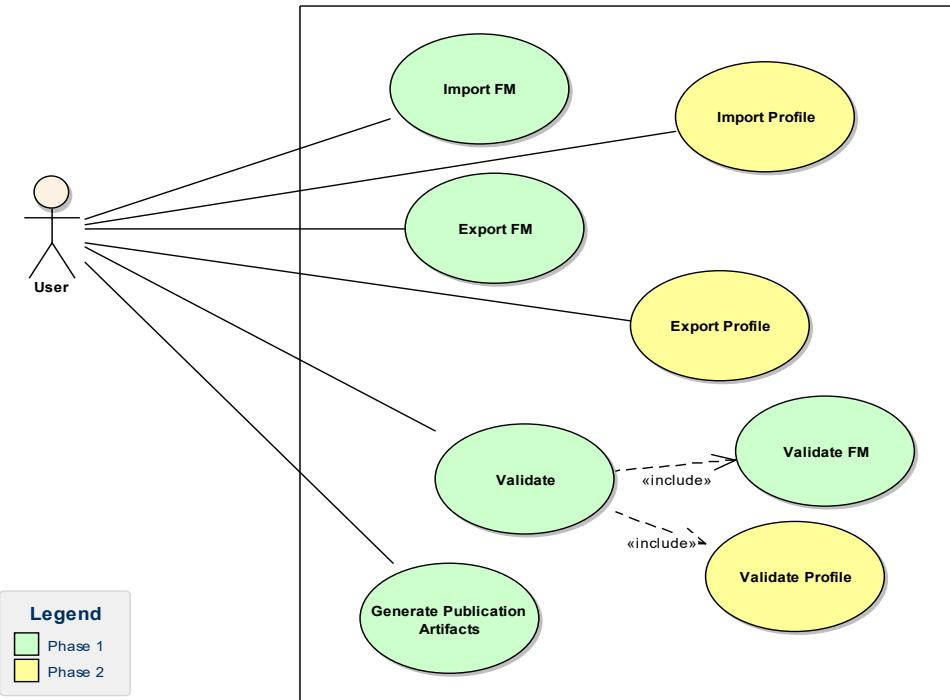


Figure 2. Use cases for tool development.⁴

1.4 UML Meta Model

For development of the Profile Designer tool a Meta Model was developed. This metamodel was recently confirmed by the HL7 EHR WG. 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 a FM in which sections, headers, functions and criteria are organized. In figure 3 the FM Meta Model is presented in Unified Model Language (UML).

⁴ The colors come from the two phases in the old project. However, they are applicable for the recent project also.

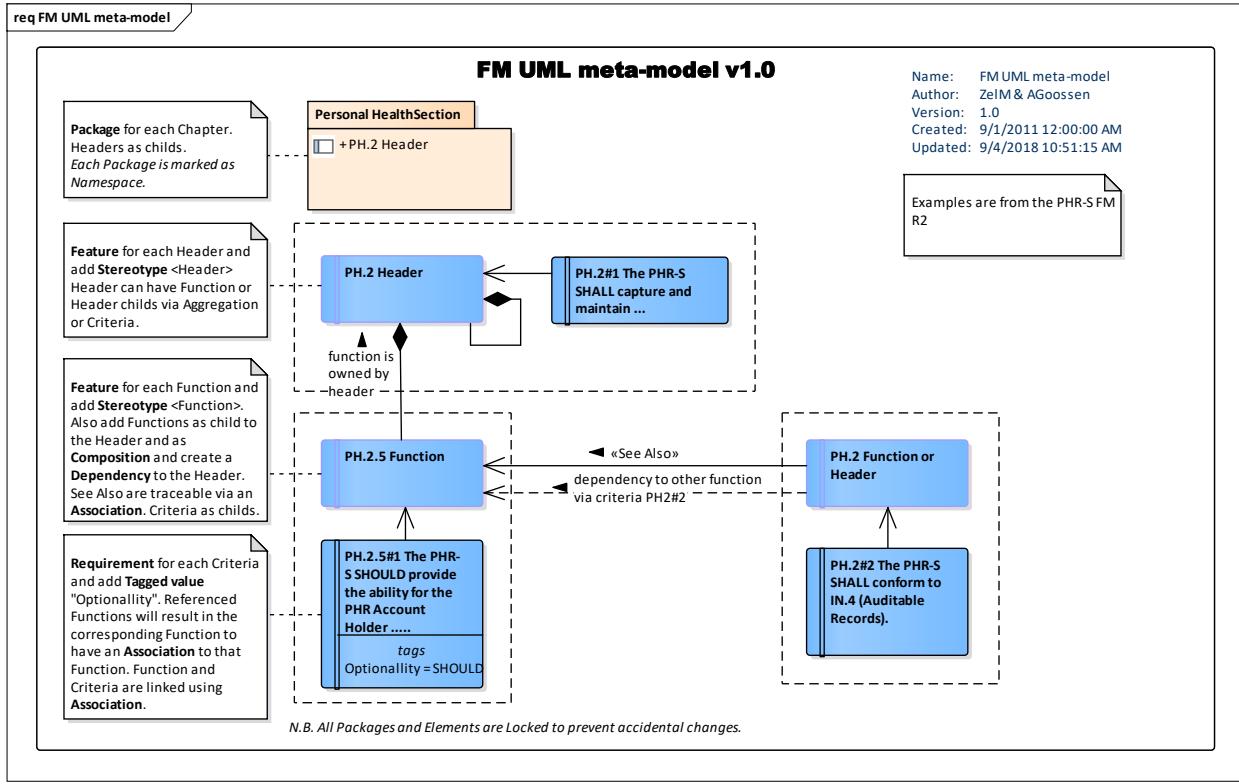


Figure 3. FM UML Meta model.

1.5 Excel Template for importing a FM

The initial tool development took the EHR-S FM in a custom FM XML schema as input.

However, given the work and experience in the last few years the inclusion of a functional profile was realized by the import of a FP in a Excel spreadsheet. A template for this was created. The demand for the same approach with functional models was growing, so a Excel template for the import of a functional model was created and the extension was adjusted.

For this recent development we move to standard Excel XML (this approach is also used for FHIR). We created a spreadsheet that is compatible with the FM meta-model and created a XML transformation script that takes the Excel XML and transforms it to MAX XML conforming to the FM meta-model and the tool structure.



2. Definitions of terms

With the FMs and FPs comes a Glossary where terms that are used in the FM or FP are defined. The terms in this chapter contains the terms used for the HL7 Profile Designer 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 FIM EHR System Function and Information Model

http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG#EHR_System_Function_and_Information_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>

MAX Model Automated eXchange Format simplified version of XMI to store object (UML) models

FP Functional Profile

FM Functional Model



4. Installing the EA extension for the HL7 Profile Designer Tool

4.1 Introduction

To work with the HL7 Profile Designer Tool there are a couple of things that needs to be done. In this chapter the steps to install the Profile Designer Tool extension and the HL7 MAX extension will be described.

In Appendix 2 is described how to get Enterprise Architect for HL7 International members. A license for HL7 members can be obtained at specific conditions. Contact HL7 Headquarters for these conditions. For installing Enterprise Architect there is an URL to the Sparx Systems website with support information.

In paragraph 4.2 the installation of the EHR-S FM extension is described. It is possible that the development of the extension will be continued in time. So, in the future an update of the extension can be expected. How to update the extension is described in paragraph 4.3.

The same applies to the MAX extension. How to install the extension is described in paragraph 4.4 and how to update in paragraph 4.5.

4.2. Installing the EHR-S FM extension

The Enterprise Architect extension for the HL7 Profile Designer Tool is a .msi file which can be obtained by contacting the EHR WG co-chairs. See http://wiki.hl7.org/index.php?title=EHR_Leadership for contact information.

The installer for the extension is a file called: "HL7_FM_EA_Extension vX.jj.mmdd.RENAME_TO_.msi" or "HL7_FM_EA_Extension vX.jj.mmdd.msi". This is depending on the characteristics of the download site. The reason for this name change to msi is that some websites or e-mail programs do not allow sending a code directly, hence a name change to the extension.

To add this extension to EA you have to execute the following steps:

- Copy or save the Extension.Setup.msi to/on your local hard drive.
- Rename as above if applicable.
- **Make sure EA is not running! Close EA if it is.**
- Open the Windows Explorer and look for the folder in where you copied or saved the Extension msi. See figure 4.
- Rename the extension to .msi by removing the part 'RENAME_TO_'. See figure 4.

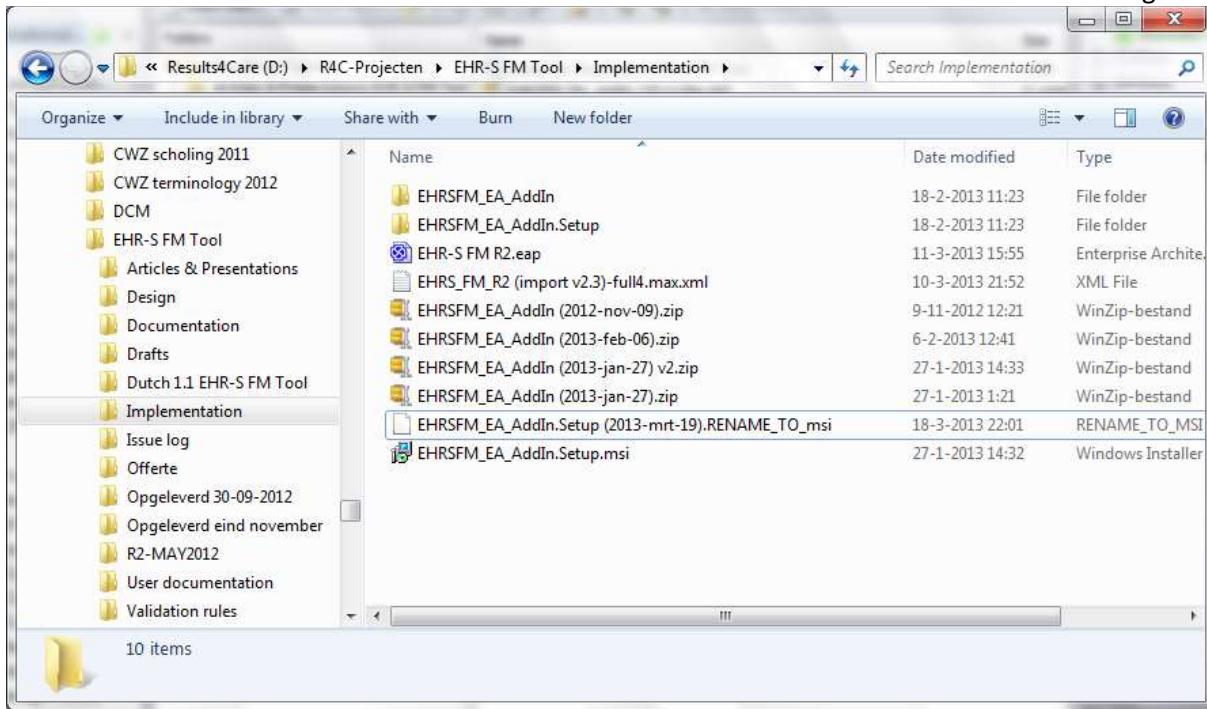


Figure 4. Windows explorer with an example location of the Profile Designer extension.

- Then select the file, right-click and choose "Install". See figure 5.



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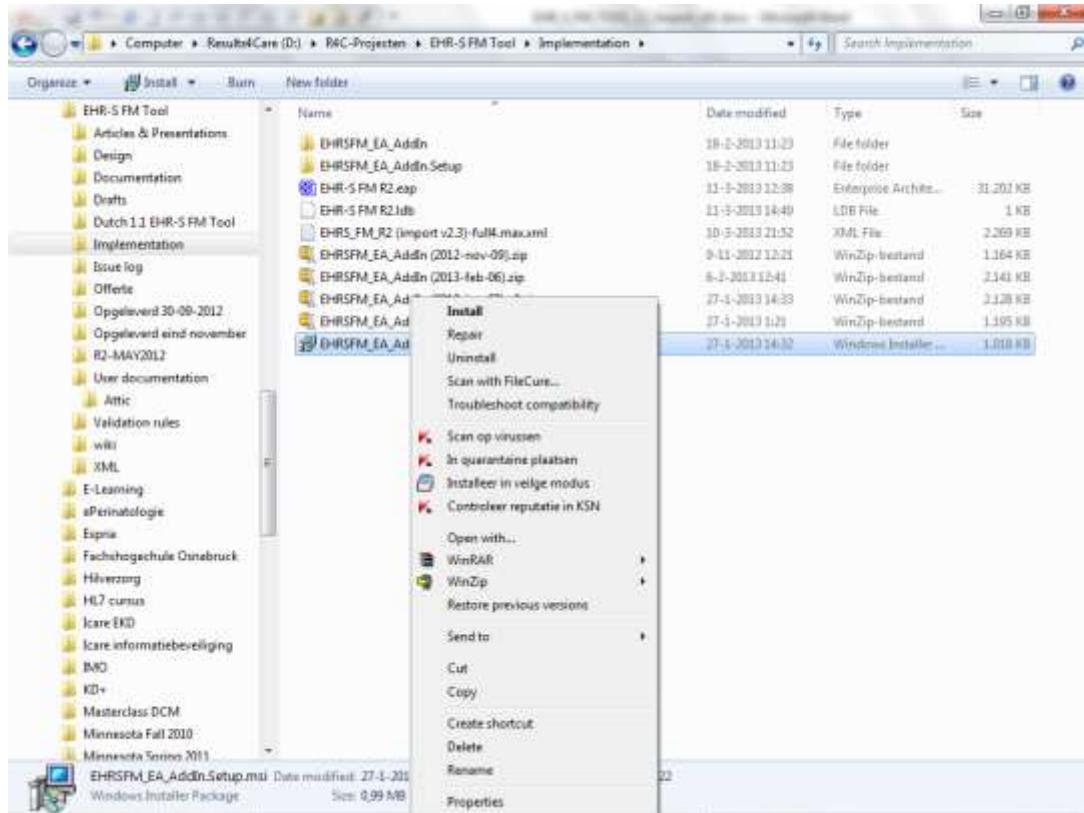


Figure 5. Install the EHR-S FM extension.

- The following screen will pop up. See figure 6. Click on the Next button.

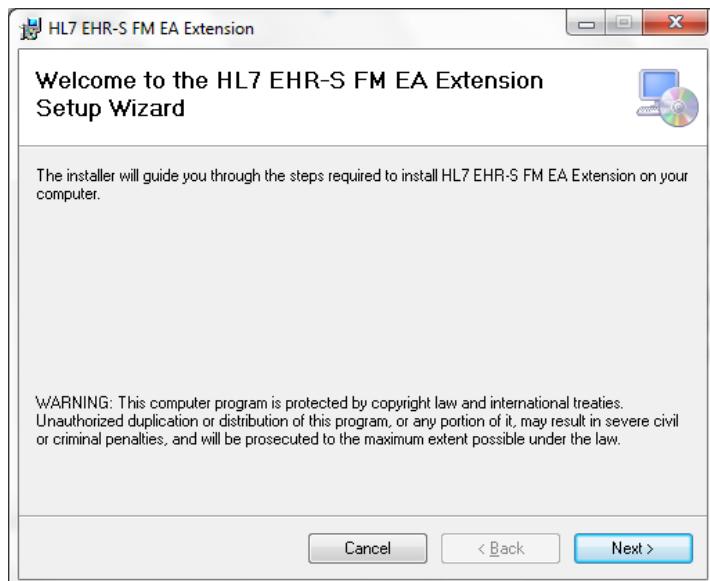


Figure 6. Setup Wizard of the EHR-S FM Extension.



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- The Wizard will ask you where you want to install the EHR-S FM extension on your computer. You can choose your folder of choice by clicking on Browse. See figure 7. After that click on the Next button.

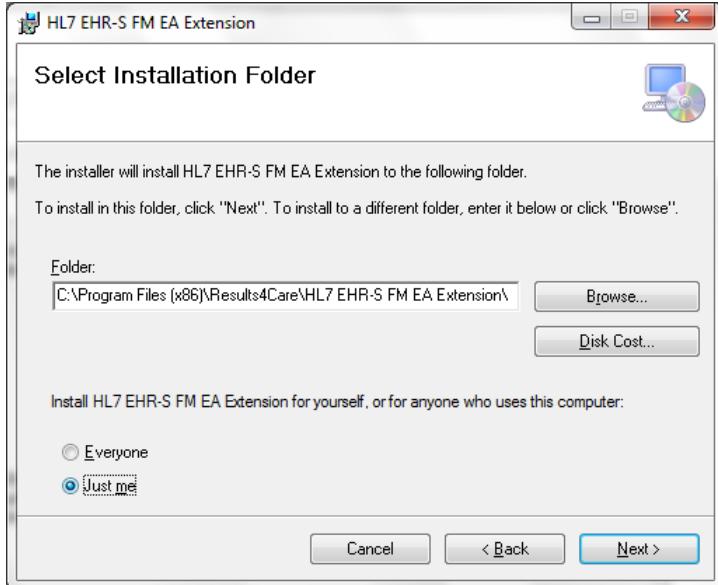


Figure 7. Select Installation folder.

- Confirm the installation in the next Wizard screen by clicking on Next. See figure 8.

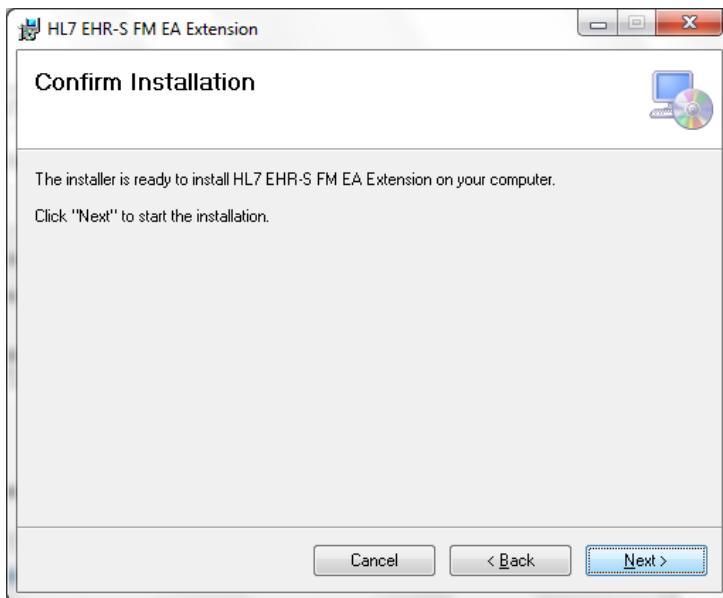


Figure 8. Confirm the installation of the EHR-S FM Extension.

The installation will run. See figure 9.



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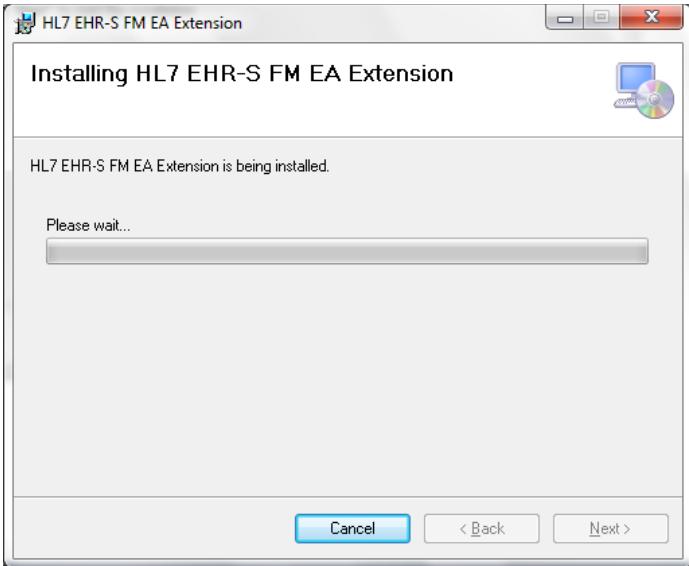


Figure 9. The installation of the EHR-S FM extension.

- When the installation is complete, you will get a next wizard screen saying that the installation is completed. See figure 10. Click on the Close button to exit the wizard.

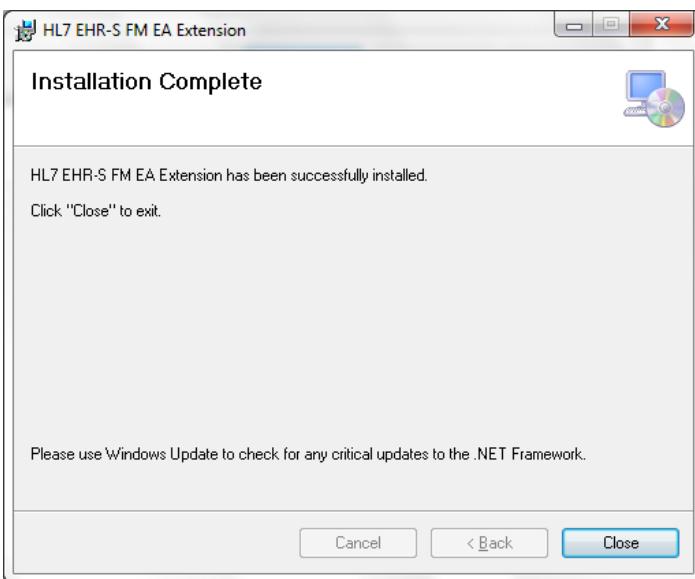


Figure 10. The installation of the extension is complete.

- Start EA. Now you can open any .eap file with a FM or FP.

To see more information on the extension after installation, follow the next steps:

- Right click on the model in the Project Browser in EA and select Extensions.
- Select HL7 FM and select About. See figure 11.



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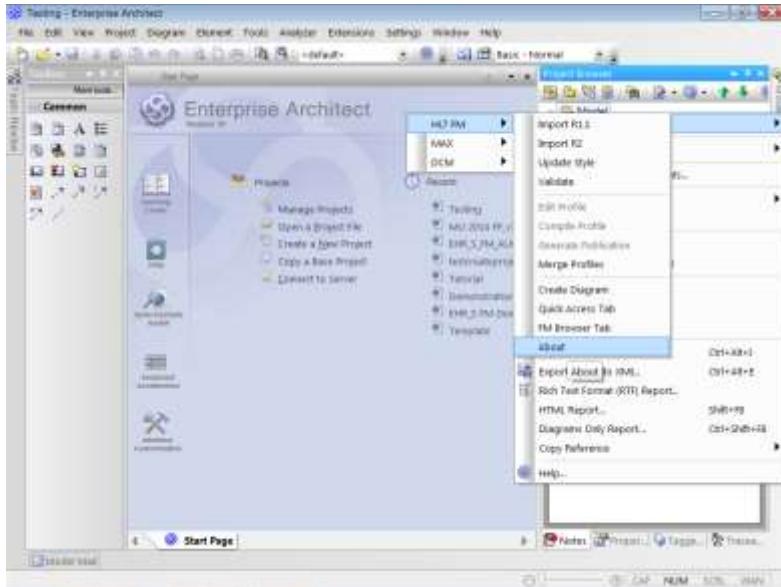


Figure 11. See more information about the HL7 Profile Designer Tool.

A window with information will open, see figure 12.



Figure 12. Information on the HL7 Profile Designer tool.

Or select 'Extend' in the top navigation, select 'HL7 FM' and select 'About'.



Manual HL7 Profile Designer Tool

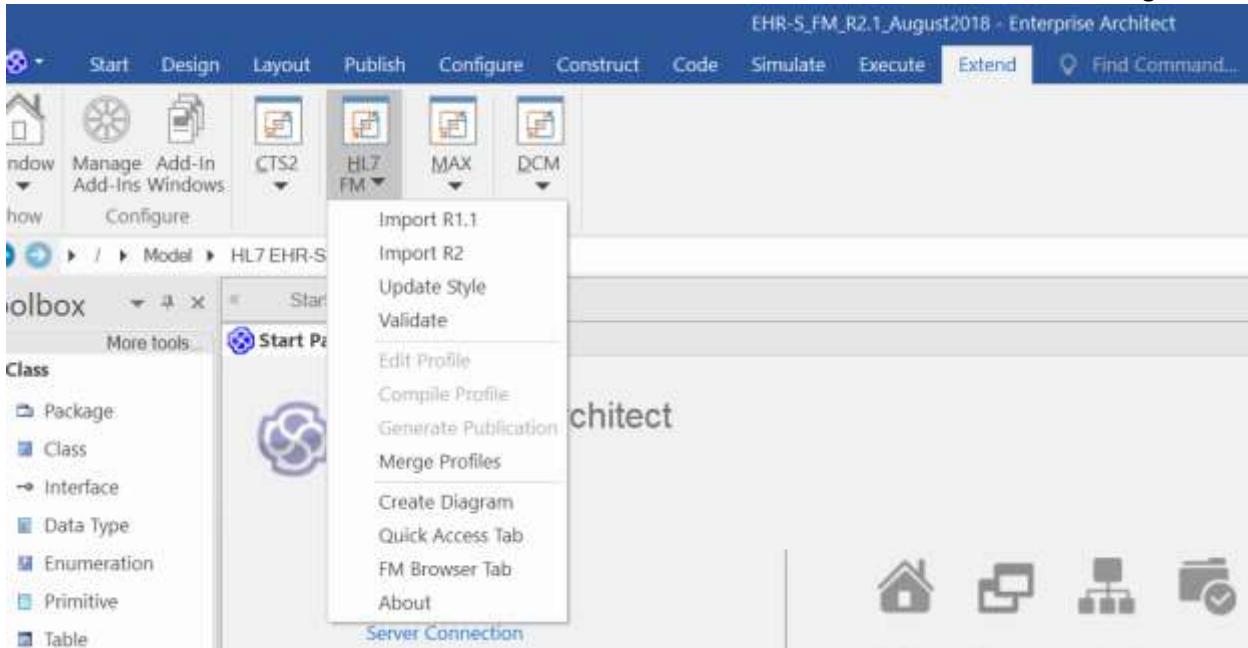


Figure 13. See more information about the HL7 Profile Designer Tool. (In EA version 13.5).

4.3. Update the EHR-S FM extension

If there is a new version of the HL7 Profile Designer Tool extension for Enterprise Architect, you need to install this new version to update the extension. A new version of the HL7 Profile Designer Tool extension contains new functionalities in the HL7 Profile Designer Tool. Because the tool is in development, a new release of the extension is foreseen.

The newer version of the extension can be installed as described in paragraph 1.3. First you have to uninstall the old version of the extension. To do so, go to the windows explorer and the folder in where you saved the extension. Select the file, right-click and select Uninstall. Uninstall will run automatically after confirmation.

4.4. Installing the HL7 MAX extension

The MAX import/export functionality is included in the HL7 Profile Designer Tool extension.

The full MAX functionalities are available in the separate HL7 MAX extension. This is not needed for the HL7 Profile Designer Tool extension to work. However, you want to use more MAX functionalities in your project, please install the MAX extension. This extension can be found at:
<https://app.box.com/s/ndhk4hhn2adzcho42sus>

The filename of the MAX extension is "MAX_EA_Extension-X.jj.mmdd.msi" (eg MAX_EA_Extension-1.17.1106.msi). Also 'How-to guides' can be found in the folder Documentation. The installation of the MAX extension is done in the same way as the EHR-S FM FP Extension.



4.5. Update the MAX extension

As said in 4.4 the MAX import/export functionality is included in the EHR-S FM FP extension. The full MAX functionalities are available in the separate MAX extension. A new version of the MAX extension can be downloaded from <https://app.box.com/s/ndhk4hnh2adzcho42sus>

Update the MAX extension is done in the same way as an update of the EHR-S FM FP extension.

4.6. Open the EHR-S FM .eap file

To browse or work on the FM or FP in Enterprise Architect you need the content of the FM or FP. This format can be the, so called .eap file, which EA can read or the MAX file of the FM or FP. Both files can be obtained by contacting the EHR WG co-chairs. See http://wiki.hl7.org/index.php?title=EHR_Leadership for contact information.

Or, if you are a HL7 member, you can download the computable artefacts from the EHR WG Products page: <http://www.hl7.org/Special/committees/ehr/products.cfm>

To open the .eap file in EA follows the next steps:

Copy the .eap file to your local hard drive. Then there are two ways to open that .eap file.

1. The easiest way: Open Windows Explorer and look for the folder where you copied the .eap file to. Double click on the file and Enterprise Architect will start. You will see the EHR-S FM under Recent on the Start page of EA. In the Project Browser you see the EHR-S FM. See figure 11.

Name	Date modified	Type
Clinical Model Services	10/3/2018 8:13 PM	File folder
Comments on the EHR_S FM R2.0.1.docx	9/29/2017 3:42 PM	Microsoft Office Wor...
Comments on the EHR_S FM R2.0.1_v02.docx	10/4/2017 9:39 AM	Microsoft Office Wor...
EHR_S FM R2.1.EAP	10/8/2018 9:27 AM	Enterprise Architect R...
ehrs-fm_R2.1 for REVIEW.pdf	10/22/2018 1:04 PM	Adobe Acrobat Docu...
HL7 EHR-S FM R 2.1 - PSS.docx	8/11/2017 4:09 PM	Microsoft Office Wor...
New Functions in FP_v01.docx	10/9/2017 4:54 PM	Microsoft Office Wor...
New Functions in FP_v02_mgj.docx	10/9/2017 5:02 PM	Microsoft Office Wor...
References_EHR-S_FM_v01.docx	10/9/2017 10:38 AM	Microsoft Office Wor...
TitlePage.docx	10/22/2018 2:19 PM	Microsoft Office Wor...
Validation Output v01.txt	10/8/2018 9:29 AM	Text Document

Figure 14. Open an .eap file from the Windows Explorer.

The result is shown in figure 15.



Manual HL7 Profile Designer Tool

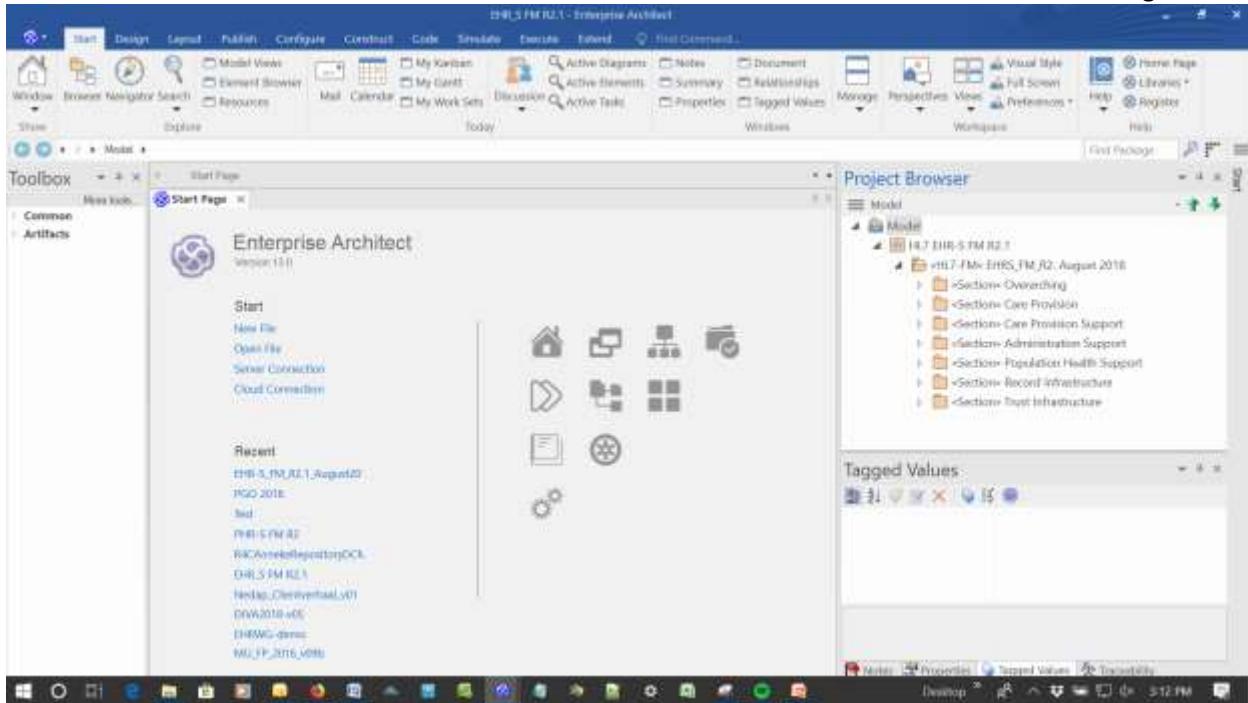


Figure 15. Open .eap file in Enterprise Architect, as seen in the Project Browser.

2. Open Enterprise Architect by going to All programs -> Enterprise Architect -> click on the icon of EA
 - You will get the Start Page of EA. See figure 16.

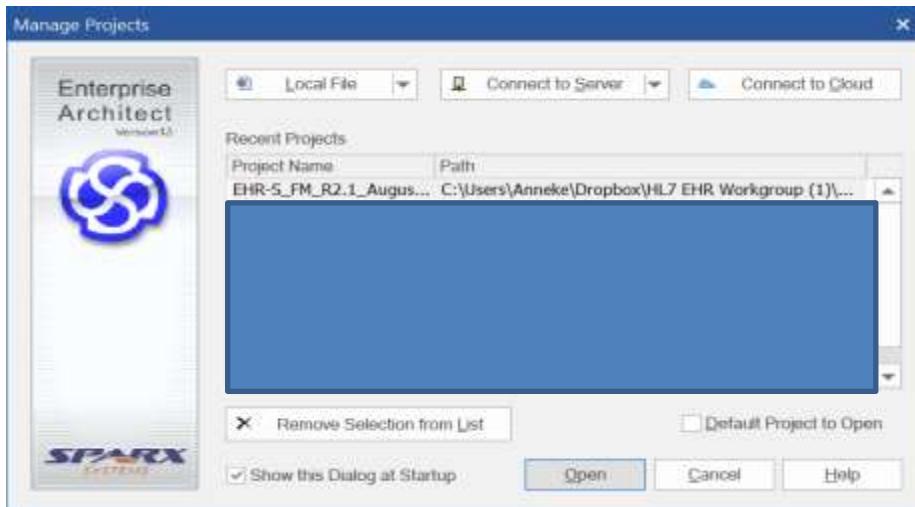


Figure 16. Open EA, list with projects. Note: Blue part is added to hide existing projects.

- To get more explanation on the Start Page of EA you can watch the video on YouTube, <http://www.youtube.com/watch?v=PK6rcXTb84Q>. Note: This is not a video from Sparx but gives a good explanation of the Start Page.

5 Read the EHR-S FM

To read or browse through a FM or FP in Enterprise Architect you have to open the content of the FM or FP, the function list, in a format, so called .eap file, which EA can read. Download this .eap file from <http://www.hl7.org/Special/committees/ehr/products.cfm> (computable artefacts) and save it to on your local drive. Then there are several ways to open the .eap file.

5.1 Open Enterprise Architect

You will get the Start Page of EA with a separate window to open a (recent) file you worked on. Go to Local File and choose Browse. Now you can search for the eap file in the windows explorer.

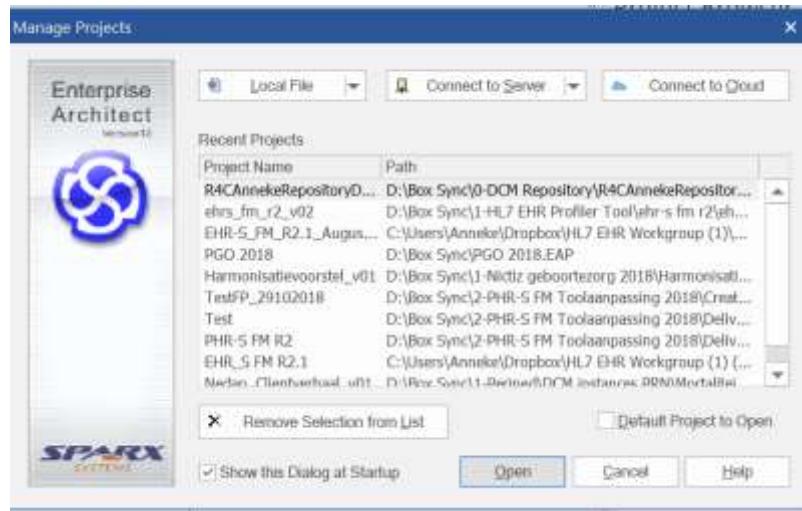


Figure 17. Start of Enterprise Architect.

- To get more explanation on the Start Page of EA you can watch the video on YouTube, <http://www.youtube.com/watch?v=PK6rcXTb84Q>. Note: This is not a video from Sparx but gives a good explanation of the Start Page.
- Another way to open the .eap file on your computer is to cancel the window as shown above, go to Open File and choose file in the Windows Explorer.

5.2. Start from Windows Explorer

You can also open Windows Explorer and look for the folder where you saved the file to. Double click on the file and Enterprise Architect will start. You will see the FM or FP under Recent on the Start page of EA. In the Project Browser you see the FM or FP. See figure 18.



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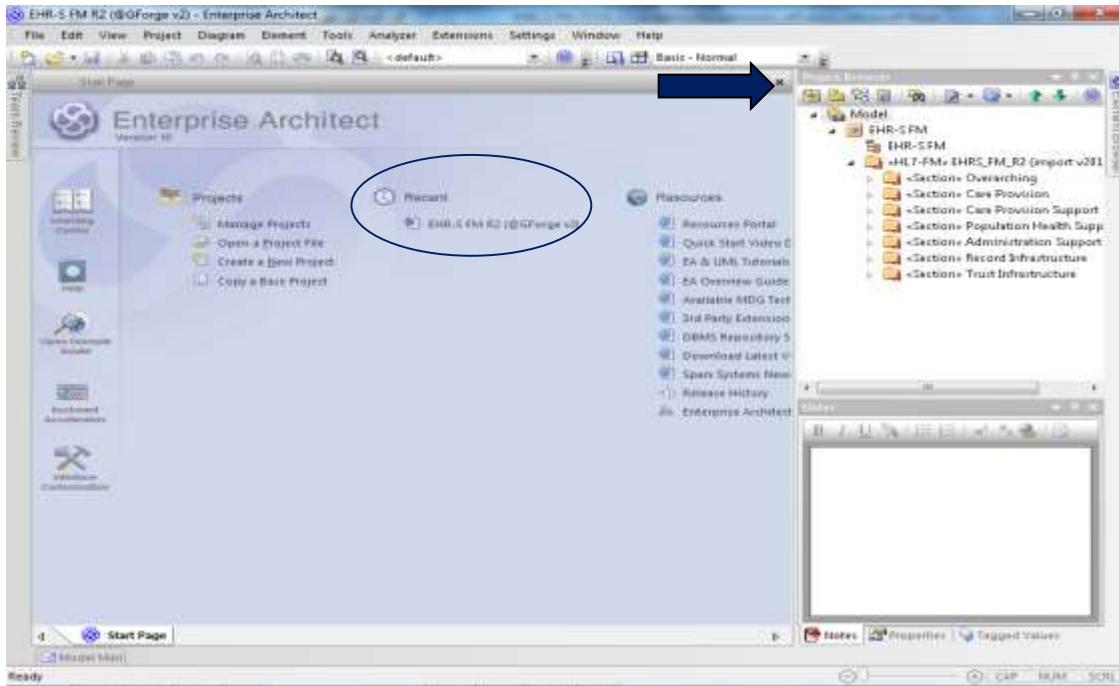


Figure 18. Recent projects on the Start Page of Enterprise Architect.

The project browser of Enterprise Architect will show the model. See figure 18.

- To see the content of EHR-S FM open the Model in the Project Browser. See figure 19.

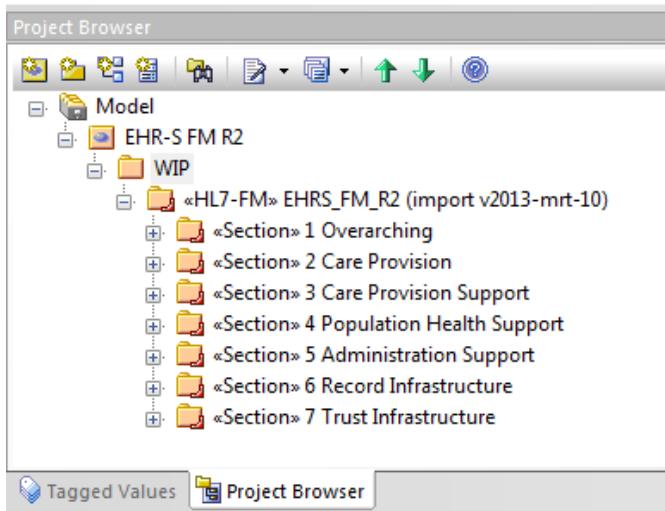


Figure 19. The content of EHR-S FM in EA.

- Now you can browse through the content of the EHR-S FM by clicking on a section, then a header, then a function. Then you will see the conformance criteria belonging to a function.

6 Search the EHR-S FM

Both the FM and FP can be a comprehensive standard, in particular the function list. If you are looking for certain functions of conformance criteria on a certain topic, it can be difficult to find them in the function list. EA can help you on this by using the search functionality.

6.1. Using the search function in EA

- In the top navigation of EA there is a Search optionality. Choose 'Search in Model'.
- Or press Ctrl+Alt+A or ctrl F.

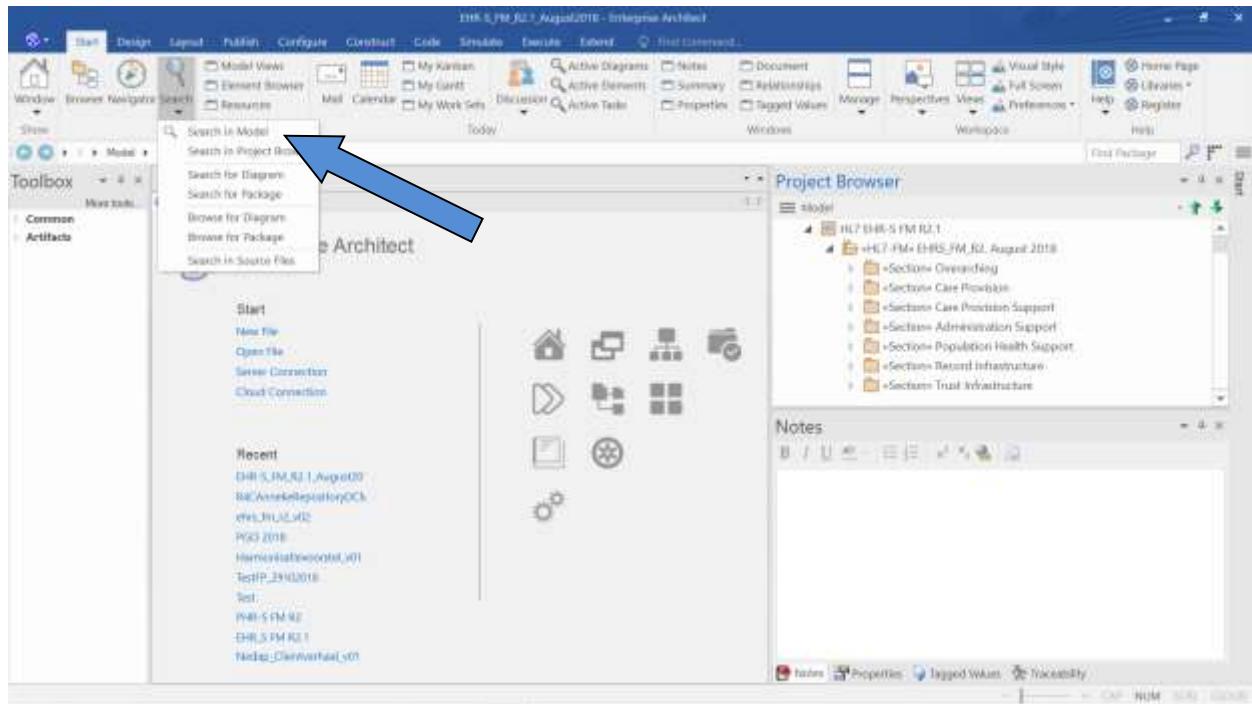


Figure 20. Search functionality of EA.

- You will get a screen as shown in figure 21. Know you can search the FM or FP by putting a keyword in the field 'Search Term'. For example, 'Allergy' as shown in figure 21.



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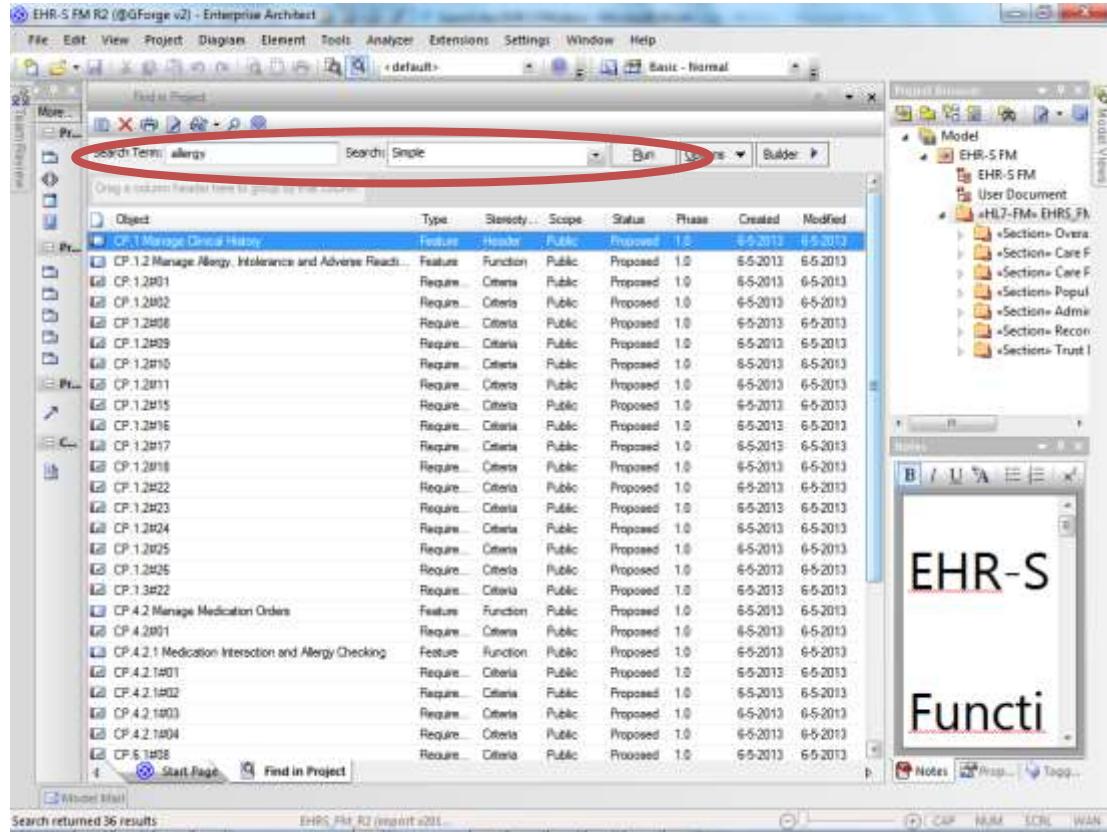


Figure 21. The use of the search functionality in EA.

- When you do a 'Simple 'search, as shown in the field 'Search', EA will give you an overview of all the FM or FP components wherein the term 'Allergy' is used.
- Figure 21. The results of a search example for 'Allergy'.
- Double click on one of the results, e.g. CP.1.2#01, and you will get the properties of that element. In this way you can easily review the properties of an element.
- You can export the search result, or a selected part of it, See next page.
- If you want to do a search for a group of elements, for example all the criteria in the section Record Infrastructure with a SHOULD and MAY, you need to follow the following steps:
- Click on the package of the section you want to search, in this case Record Infrastructure.Record. Then 'Find in Project'.
- Leave the field Search Term empty.
- In the Search window, figure 3, you can choose for a simple search.
- If you did a search on the high-level package, you can select the RI section to export.

For more explanation, see the Help in EA, Model Search.

6.2. Export search results

To export the search results, follow the next steps:



Manual HL7 Profile Designer Tool

- Select the results in the search window which you want to export.
- Right click, select Documentation, select Generate Documentation for selected items. See figure 22.

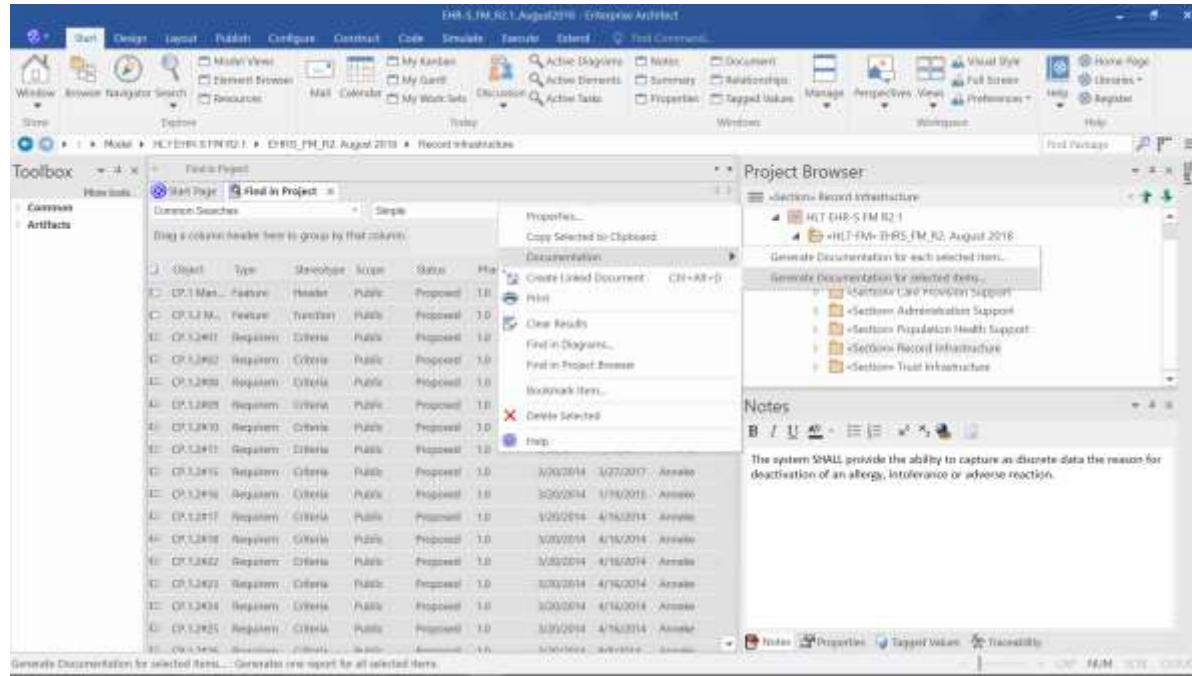


Figure 22. Export search results to a Document.

- You will get a dialogue where you can select the template for the export. See figure 23.

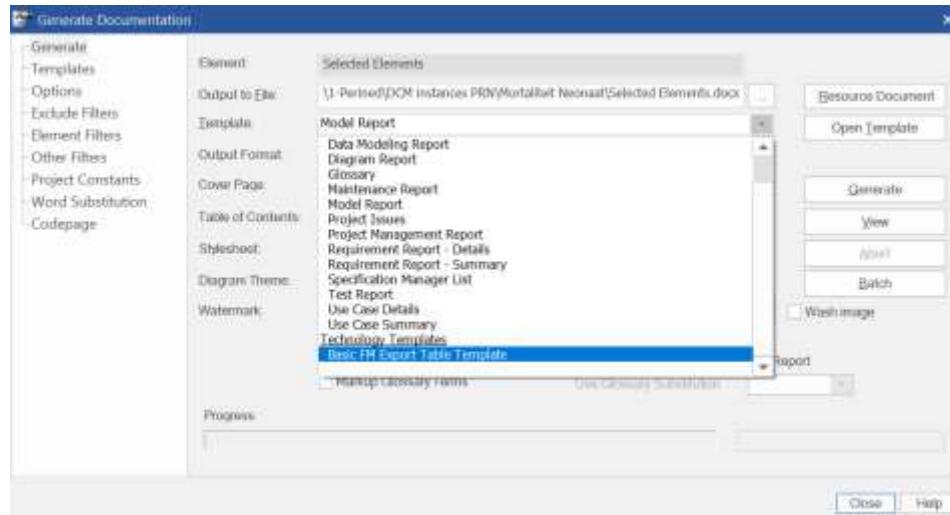


Figure 23. Template selection for the Documentation.

7 Traceability of the elements in EHR-S FM

7.1. General

In the FM or FP there are different relationships between the elements. The Traceability window in Enterprise Architect enables you to quickly see how elements, headers, functions and criteria in a functional model or profile, are connected and how they influence each other. How to use this functionality is explained below.

- When a header, function or criterion is selected in the Project Browser it immediately becomes the top point in the Traceability window.

To get the Traceability window select Window in the top navigation and select Traceability. See figure 24.

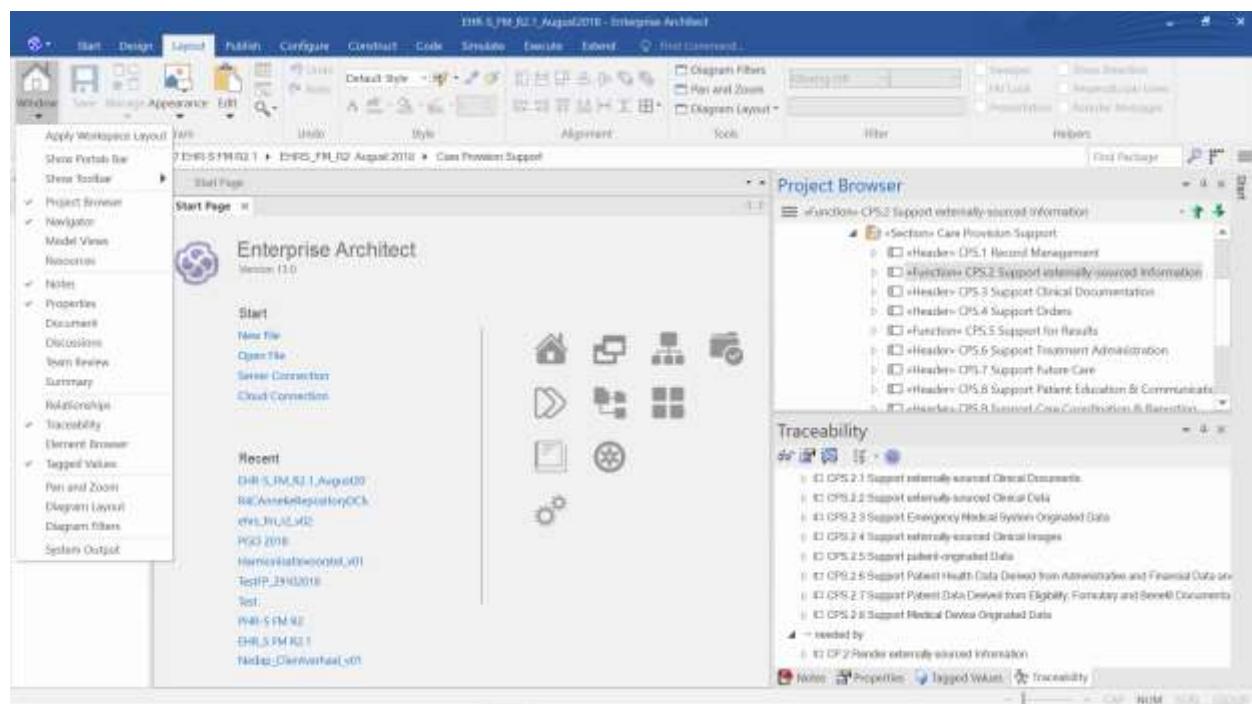


Figure 24. Open the Traceability window.

The window will open, and you will see the traceability for the selected header, function or criterion. See figure 24. Now you can drag the Traceability view to the navigation right beside the Notes, Properties and Tagged Values. This is visible under the Project Browser.

See figure 25. In this case the function CP.1.1 Manage Patient History is selected.

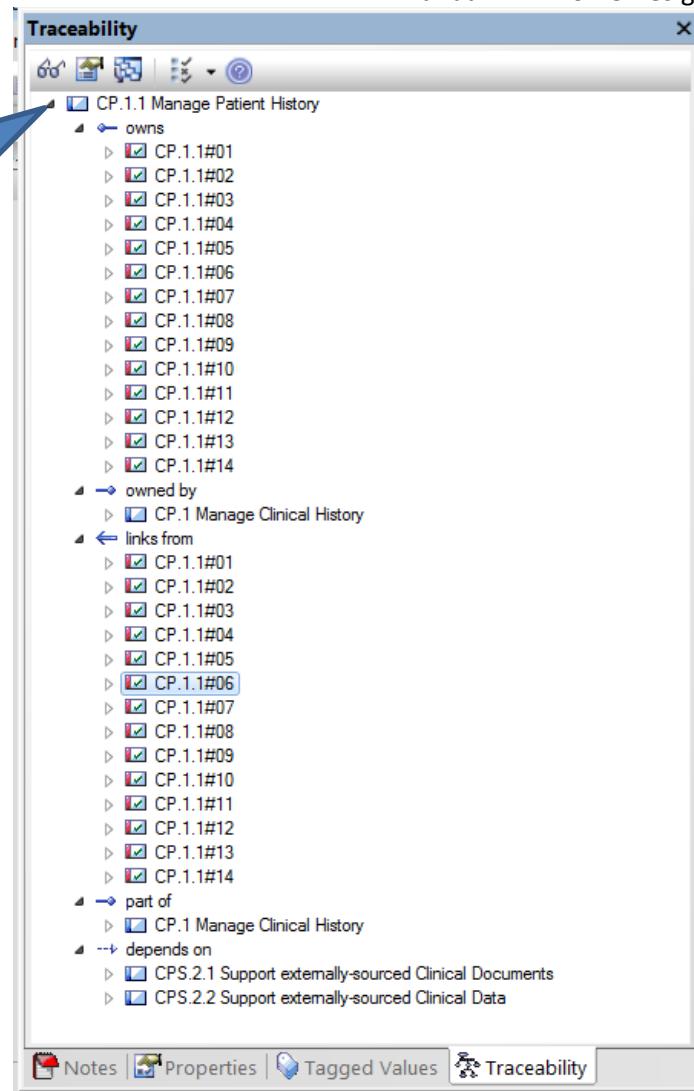
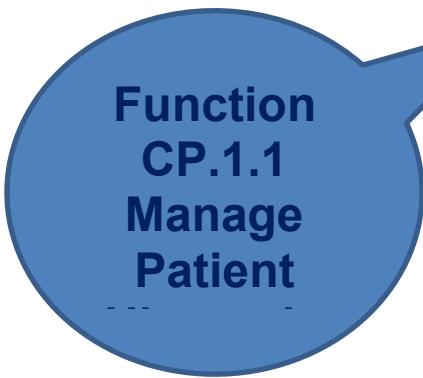


Figure 25. Traceability of CP.1.1 in the EHR-S FM.

In the Traceability window you see that the selected function is the top point in the window. You see the different relationships of function CP.1.1 Manage Patient History:

- **Owns** means that the chosen function, CP.1.1, *owns*, so has, the listed criteria. See figure 25.
- **Owned by**: the header (parent) where the function belongs to. In this case CP.1 Manage Clinical history.
- **Links from** means the other direction. The criteria mentioned here links from the function CP.1.1. If you open a criterion in the Traceability window, it is showed that the criterion is owned by the function CP.1.1 and links to the function CP.1.1.
- **Part of**: means that the selected function is part of another element, in this case header CP.1.

- **Depends on:** relationships with other functions, so called ConsequenceLink. In some criteria of function CP.1.1 there is the text 'conforms to function', in this case functions CPS.2.1 and CPS.2.2.

Headers, functions and criteria have their own kind of relationships. Just click on them and view the relationships in the traceability view.

In the traceability window you can also view the related element properties. To view this:

- Right click on the element you want to view (in the traceability window), for example CP.1.1#
- Select 'View Related Element Properties'.
- The view of the selected element will open. See figure 26.

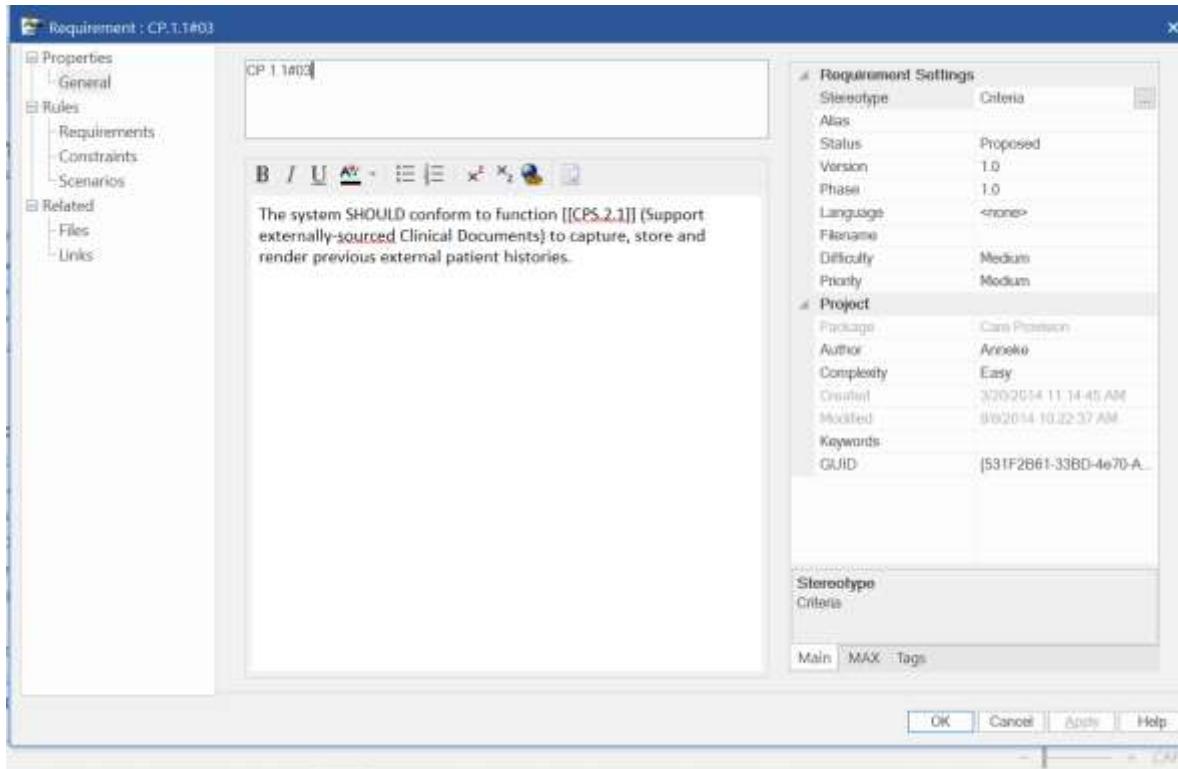


Figure 26. View Related Element Properties opened from the traceability view.

7.2. Traceability view in a diagram

Another way to look at the different relationships between the elements is by adding a diagram to the FM or FP package. To do this, follow the next steps.

- Right click on the package of the FM or FP, click on Add and next on add Diagram.
- Select Extended in the left box and Requirements in the right box. In the Name field you can give the diagram a name. Click OK.
- Now you see new diagram in the Project Browser. See figure 27.

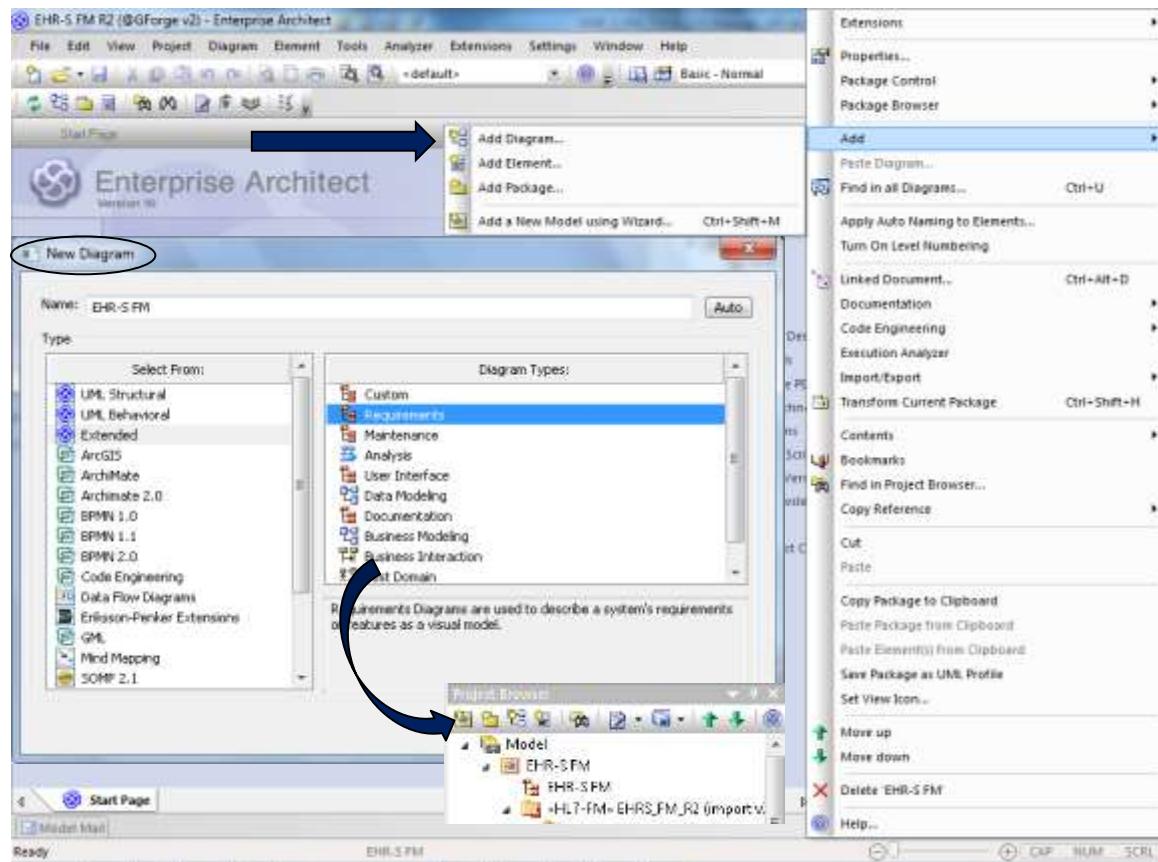


Figure 27. Add a Diagram to the EHR-S FM.

- Now you see a Grid in EA (empty window for the diagram). Select a function in the EHR-S FM model, click on that and drag this function to the Grid. In the box, Paste Element, select Link in the Paste as field and click on OK. See figure 28.



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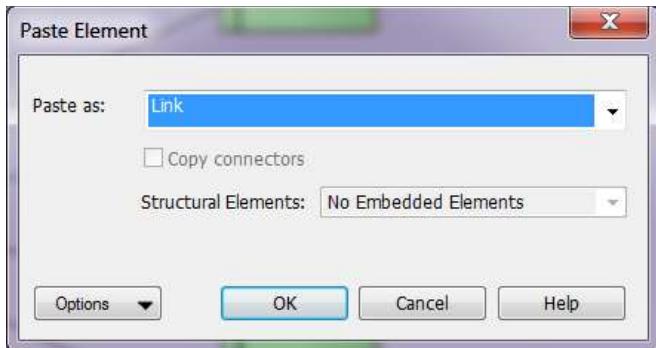


Figure 28. Making a diagram of a selected function.

- Now you see the selected function as a class in the diagram window.
- Right click on the class and select 'Insert Related Elements'. You will get the following (Figure 29):

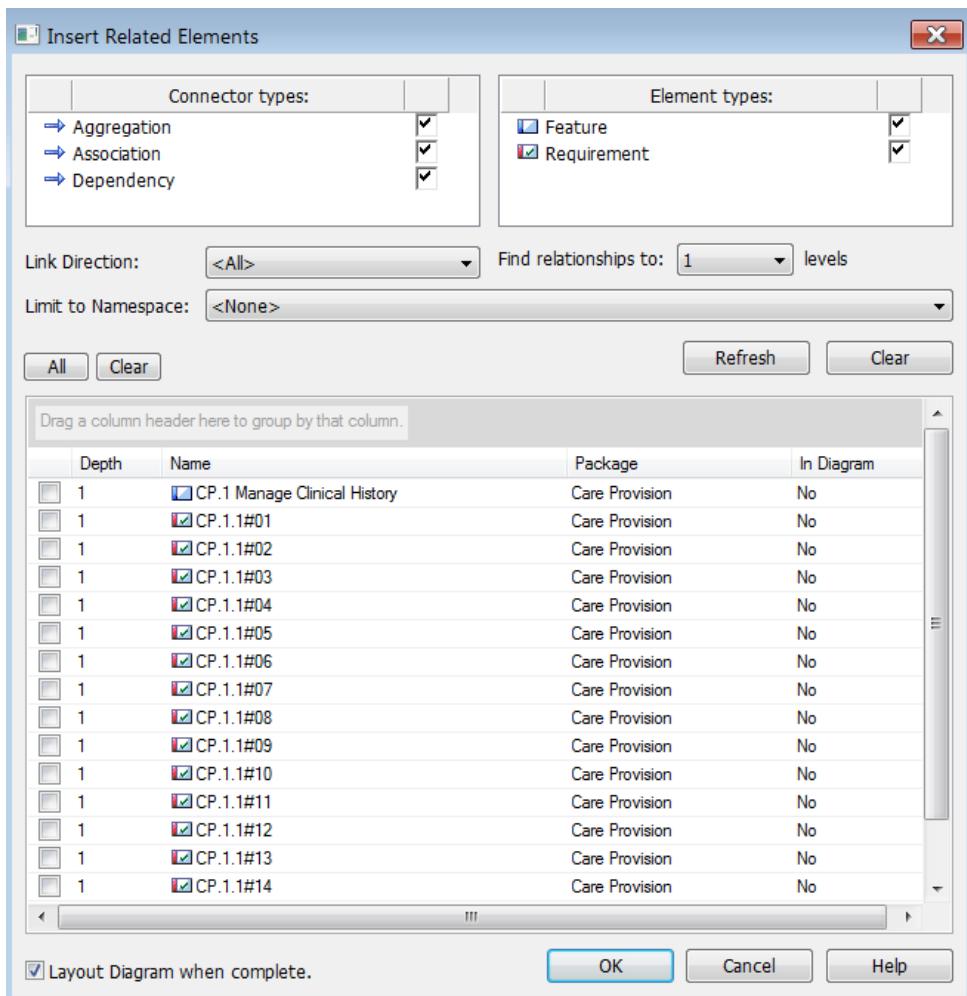


Figure 29. Insert Related Elements in Enterprise Architect in the context of the EHR-S FM.

- After this you can select the
 - 1) Connector types,
 - 2) Element types,
 - 3) Link direction,
 - 4) Find relationships to,
 - 5) Limit to Namespace,
 - 6) All elements (is linked to find relationships to)
 - Every single change must be followed by clicking on the Refresh button.
- After selecting OK you will get a diagram which shows the relationships of the selected function. See figure 30, a diagram of function CP.1.1 and its relationships. Here you see again the relationship with functions CPS.2.1 en CPS.2.2.

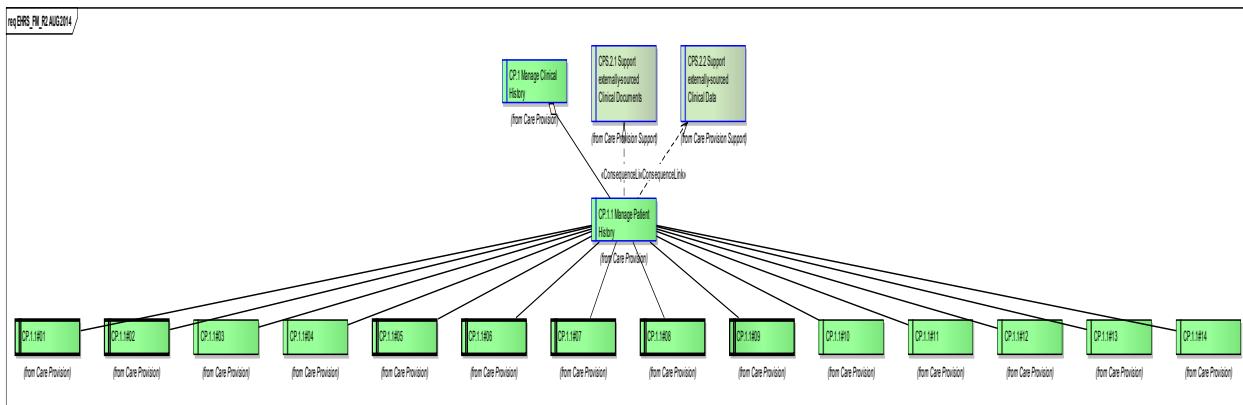


Figure 30. Relationship diagram of function CP.1.1.

- By a right click on the diagram field (so not on a class and not on a relationship) the properties of the diagram can be changed. See figure 31.

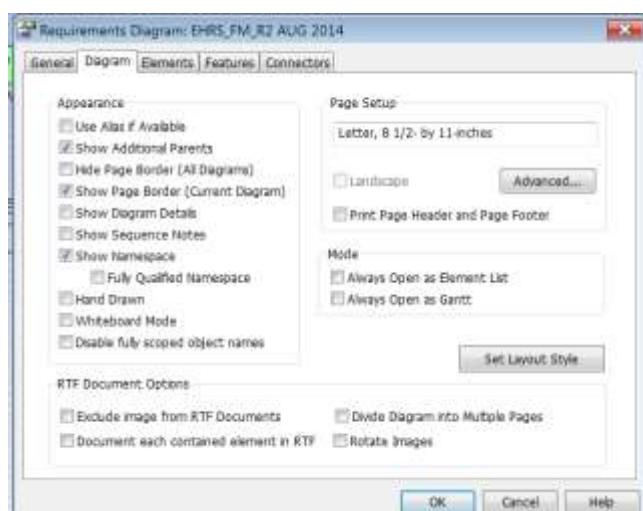


Figure 31. Properties of the diagram.

7.3. Diagram of a function without relationships

A different diagram can be made via the Profile Designer Tool Extension. This kind of a diagram shows all the criteria that belong to a selected function.

- Click right on a function and select Extension. Select EHR-S FM and select Create Diagram. See figure 32.

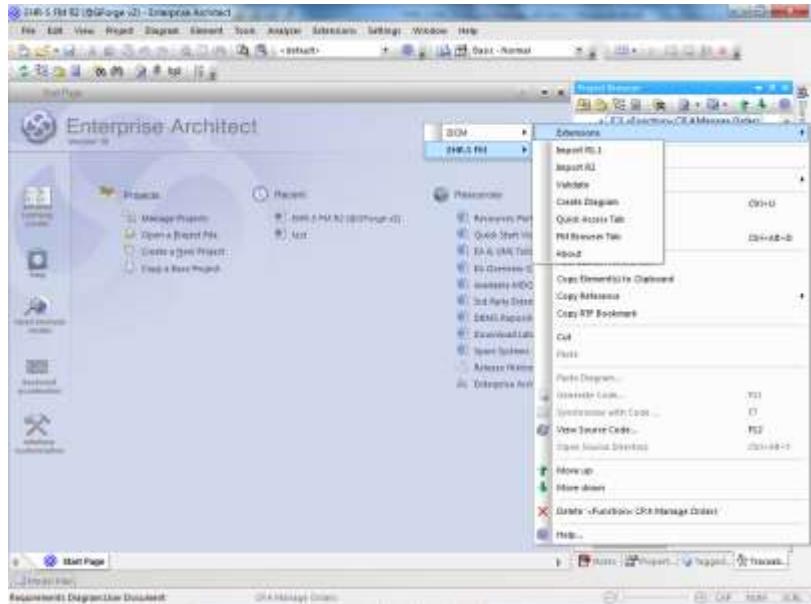


Figure 32. Create a diagram via the EHR-S FM Extension.

- An example in figure 33.

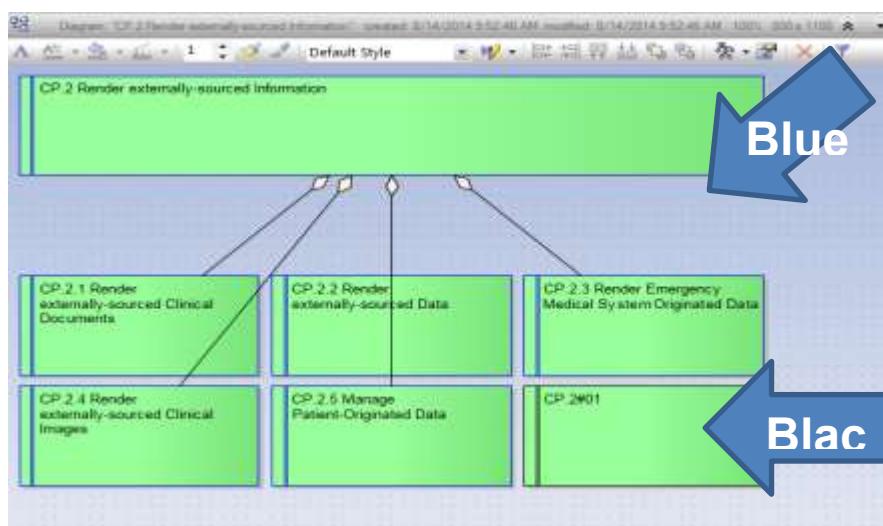


Figure 33. An example diagram of a function, without relationships, via the EHR-S FM Extension.



Manual HL7 Profile Designer Tool

Because the diagram is a diagram of a header, you see the functions and criteria belonging to that header. The functions and criteria are distinguished from each other with a bold blue line for the function and a bold black line for the criteria.

In figure 34 a diagram of a function is shown. All the criteria belonging to the function are listed. The criteria with a bold black line are SHALL criteria. The others are SHOULD or MAY criteria.

If you select a criterion the criterion text can be read in the notes.

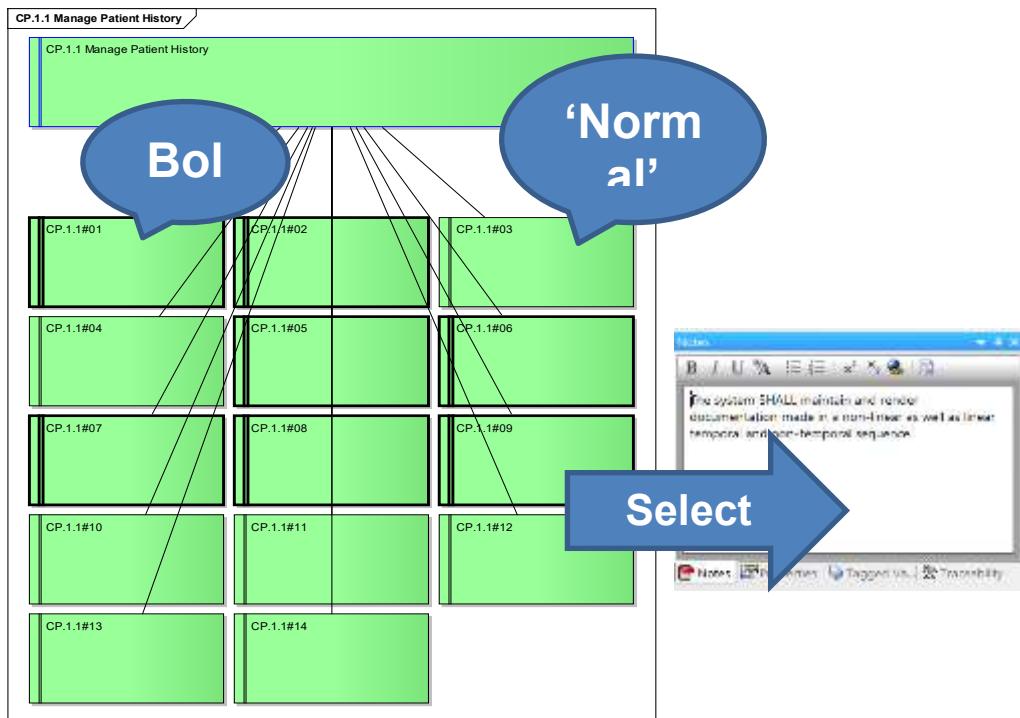


Figure 34. Diagram of a function.

NOTE: if the function has a lot of criteria the diagram is still a little bit crisscross. You can make the diagram more structured and viewable by dragging the criteria around until the diagram is readable.

7.4. Traceability to an older version of the Functional Model or Profile

The traceability of a header, function or criterion to the same header, function or criterion in an older version of the Functional Model or Profile can be found in the Tagged values. Both the version of the Functional Model or Profile is included, in the Reference.Alias, as the ID of the header, function or criterion in the older version, for example Reference.FunctionID. See figure 35.



Manual HL7 Profile Designer Tool

The screenshot shows the Manual HL7 Profile Designer Tool interface. The Project Browser pane on the left displays a hierarchical tree structure of functional models and their components. A large blue arrow points from the text "Reference to the older version &" towards the Tagged Values pane. The Tagged Values pane on the right shows a table for a specific function, with the "Tagged Va..." tab circled in blue at the bottom.

Feature (CP.1.1 Manage Patient History)	
MAX::ID	39
Reference.Alias	EHR-S_FM_R1.1
Reference.ChangeInfo	Modified
Reference.FunctionID	DC.1.2
Row	33

Figure 35. References for a function to an older version of the functional Model.

Another example is given in figure 36. In this figure the refence to the older version of the Function Model is given, Reference.Alias, the reference to the function, Reference.FunctionID, and the criterion, Reference.CriterialID in the older function, and if the criterion was modified, Reference.Changeinfo.

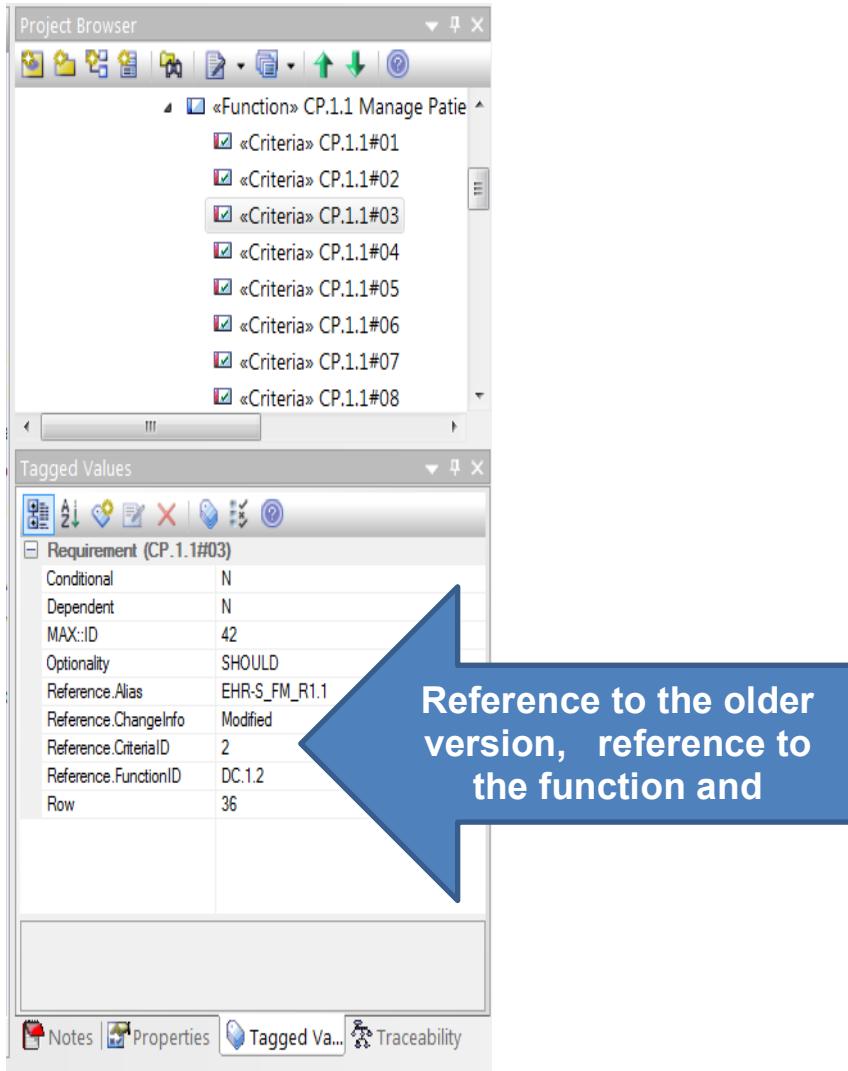


Figure 36. References for a function and criterion to an older version of the functional Model.

8 Create a Functional Profile

8.1. Introduction

Design

A new Functional Profile is based on a Base Model. This can be the EHR-S FM (starting with Release 2.0) or an existing Functional Profile (based on the EHR-S FM R 2.0). From the Base Model a Profile Definition is defined. This Profile Definition is based on the so-called Compiler instructions that were implemented in the tool based on the design of the tool (see figure 37). After defining the Profile Definition, the new Functional Profile can be compiled. The Profile Definition, the Base Model and the Compiled Profile are

modeled in a UML model. In other words, they are related, so the Profile Definition uses the Base Model and creates the Compiled Profile.

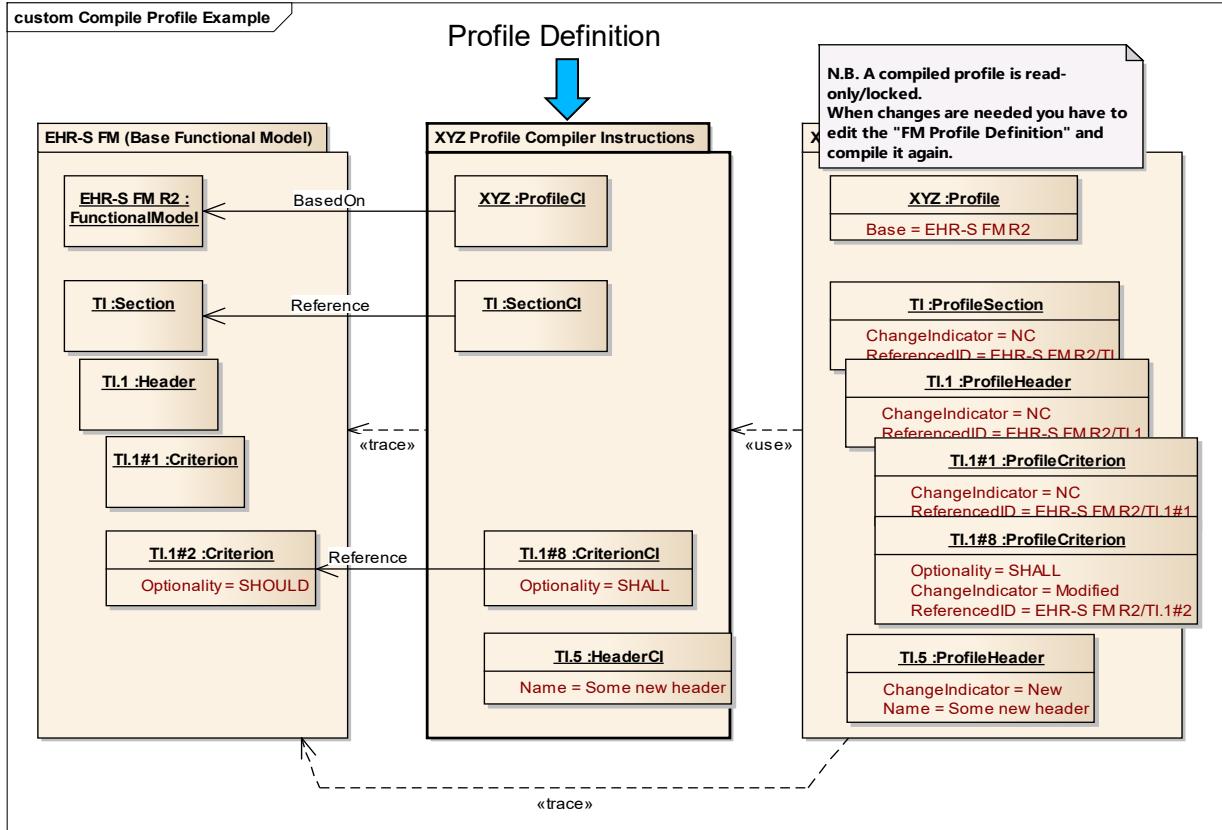


Figure 37. Compile Profile example.

The Profile Definition is based on the Base Model. In this you define what will be included or excluded for the new Functional Profile. The Compiled Profile is based on the Profile Definition. So everything that was included will show up in the Compiled Profile. If a parent was not explicitly included in the Profile Definition, it is included automatically in the Compiled Profile. Based on the compiler instructions you will find certain features in the Compiled Profile, for example the ChangeIndicator in the Tagged Values.

For the development of a new Functional Profile a new project in Enterprise Architect is created. See description in the EA Learning Center, section 'Create a Functional Profile'. In that new Model the following three packages needs to be created, 1) Profile Definition, 2) Base Model and 3) the new Compiled Functional Profile. See example in figure 38.



Manual HL7 Profile Designer Tool

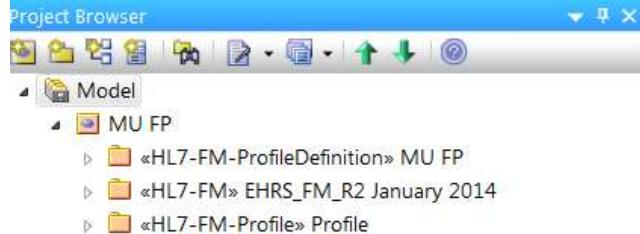


Figure 38. The three packages for the development of a new Functional Profile.

For the relationship between these three a UML diagram needs to be created in the package 'Profile Definition'. An example of such a diagram is shown in figure 3. The diagram reflects the parts as shown in the design of the tool, figure 37.

At this moment you need to create this diagram manually.

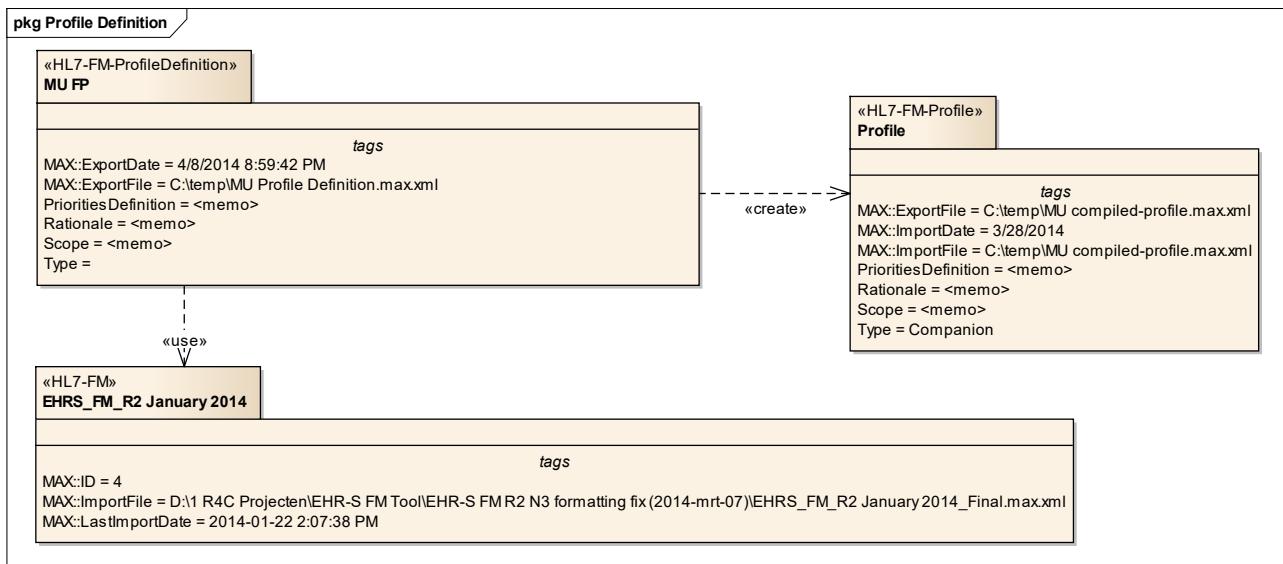


Figure 39. UML diagram for Profile Definition.

Now that you know what your goal is when you are going to create a new Functional Profile and how it looks like when you are going to use the tool, you can go and create a new Functional Profile.



8.2. The FM as a model

In the FM standard is mentioned that it includes a ‘function list’. However, with the development of the tool and the inclusion of the content of the FM in the tool, we are going towards a model instead of a list. Besides that functions are listed in the tool, they are also related to each other. So making changes in functions this will also affect the relationships.

An example that occur during phase 2 of the tool development:

Some criteria that comes with a function has the text ‘conforms to function X.x. This means that there is a dependency between the function to where the criterion belongs to and the reference function. Criteria are included by default if you included a function in the Profile Definition. So, the referenced function will appear in the Compiled Profile. In the cases during phase 2 the project teams didn’t want to have these reference functions in the new Functional Profile. The solution for this is to explicitly exclude the criterion in where there is a reference to another function.

An example when creating new functions:

When you decided to create a new function in your Functional Profile (according to the rules) you have to model this new function in the context of the FM. It is not enough to create a new function in the list with existing functions. The new function needs to be related to its parent. For example, if you want to create a new function CP.1.10, you have to model this in a diagram and relate this new function to the parent, «Header» CP.1 Manage Clinical History.

An example when creating new conformance criteria:

When you decide to create new criteria in a function (according to the rules) you have to model these new criteria in the context of the FM. It is not enough to create these new criteria in the list of existing criteria in a function. The new criteria need to be related to the function. For example, if you want to create two new criteria in function CP.1.9, you have to model this in a diagram and relate these new criteria to the function «Function» CP.1.9 Manage Adverse Events.

The fact that the FM is now in EA means that the FM is really becoming a model instead of a list of functions. Be aware of this when you are working on a new Functional Profile.

8.3. Create a new project for a new Functional Profile

The first step in the creation of a new Functional profile is the creation of a new project in Enterprise Architect, EA. This is done by using the Start Page of Enterprise Architect. The second step is the loading of the Base Model. The third step is the creation of a package for the new Functional Profile. The last step is the creation of the UML diagram for the Profile Definition.

NOTE: be sure that you have installed the latest version of the extension before you are going to develop a new functional profile! Contact the EHR WG co-chairs to get the latest version. Name of the extension is 'HL7_FM_EA_Extension jjjjmmdd'.

Check regularly if a new version is available!

Create a new project in EA:

Open EA using the shortcut on your computer or go to start and select EA. The result is shown in figure 40.

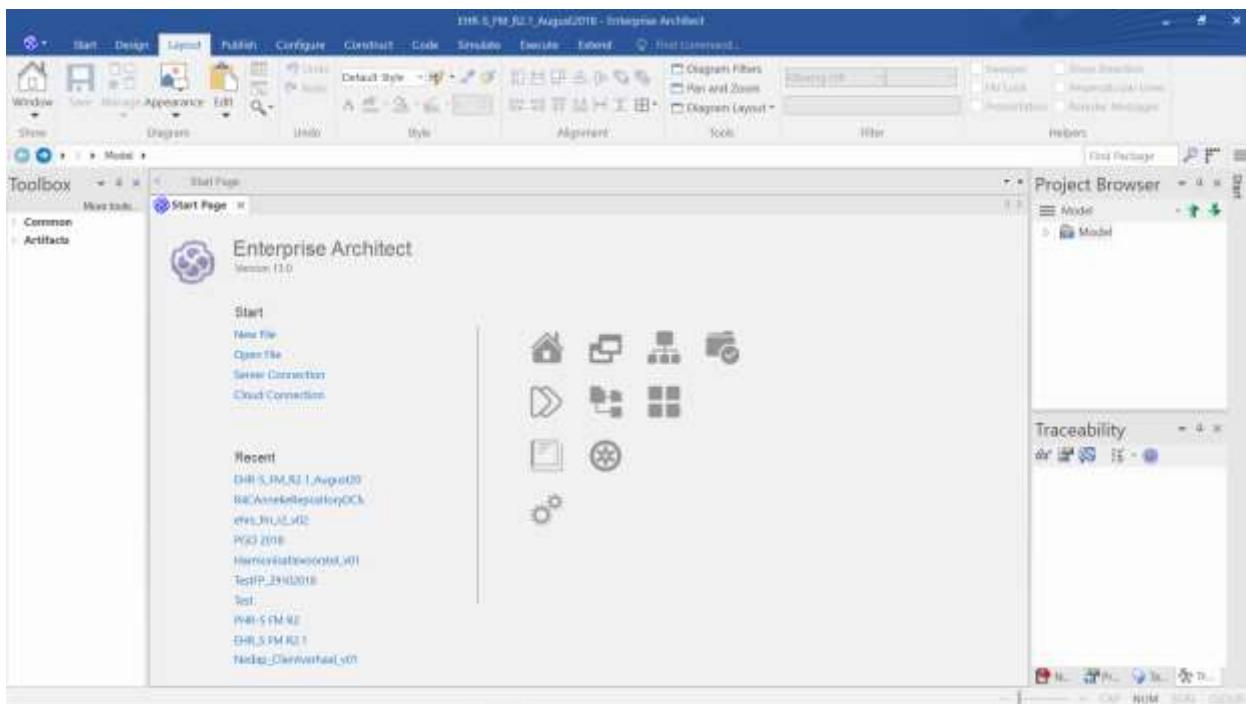


Figure 40. Start Page of EA.

- Select 'New File'.
- You will get the Windows Explorer.
- Select the folder in where you want to save the new project. Give the project a name, e.g Child Health Functional Profile, and click on Save.
- The Model Wizard of EA will be shown, but you can cancel that.
- In EA the new project is shown in the project browser. See also figure 40 in the Project Browser.



Manual HL7 Profile Designer Tool

- In the project you need to create a View. Right click on 'Model' in the Project Browser and select 'Add' and select 'Add View'. See figure 41.

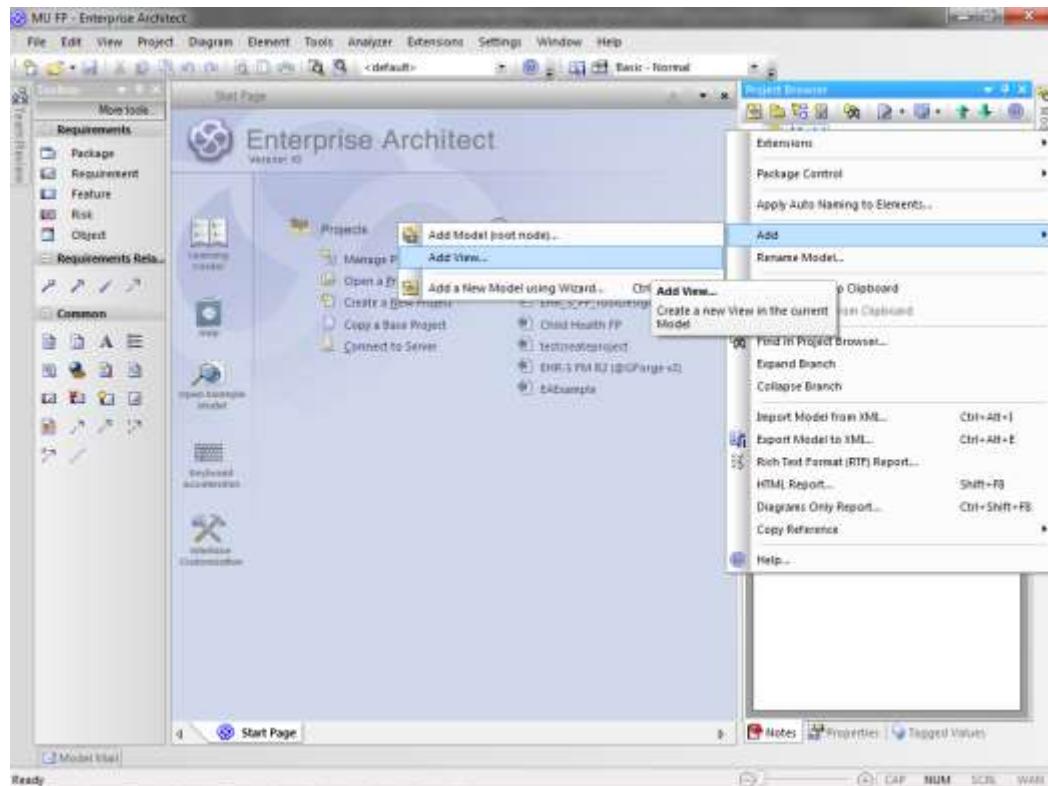


Figure 41. Adding a View in the new project.

- Select 'simple' from the list (figure 42) and give the view a name, e.g. Meaningful Use Functional Profile, MU FP. After that select 'OK'. The name of this view is the name of the Functional Profile you want to create. See figure 42.



Figure 42. Giving the view a name.



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- In that View you need to create one Package for the Profile Definition. The Profile Definition is based on the Base Model. In the Profile Definition you define the new Functional Profile.
- Right click on the package 'View' and select 'Add' and then 'Add package'. See figure 43.

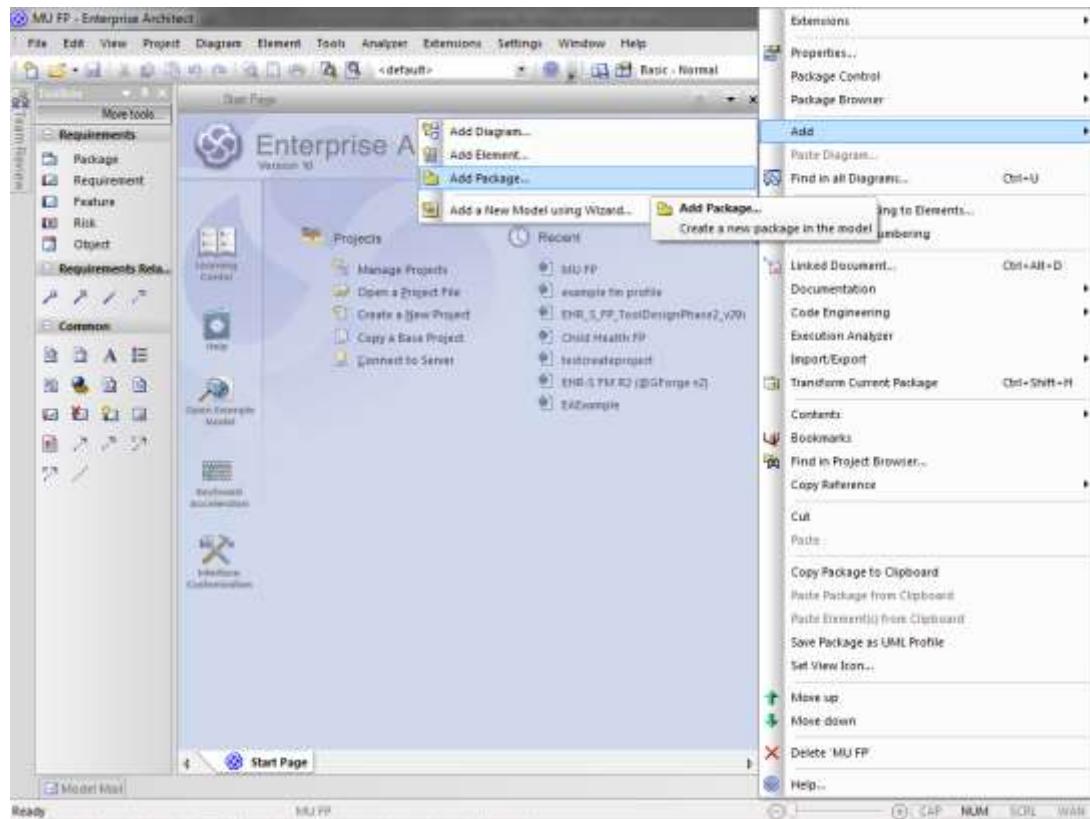


Figure 43. Adding a package to the 'View' of the new project.

- Give the package the name 'Profile Definition' in the Name field. See figure 44.
- Choose for 'Automatically add new diagram'.

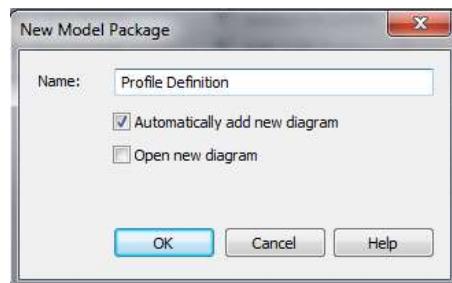


Figure 44. Giving the new package a name.

- Select 'UML Structural' and for Diagram Type 'Package'.



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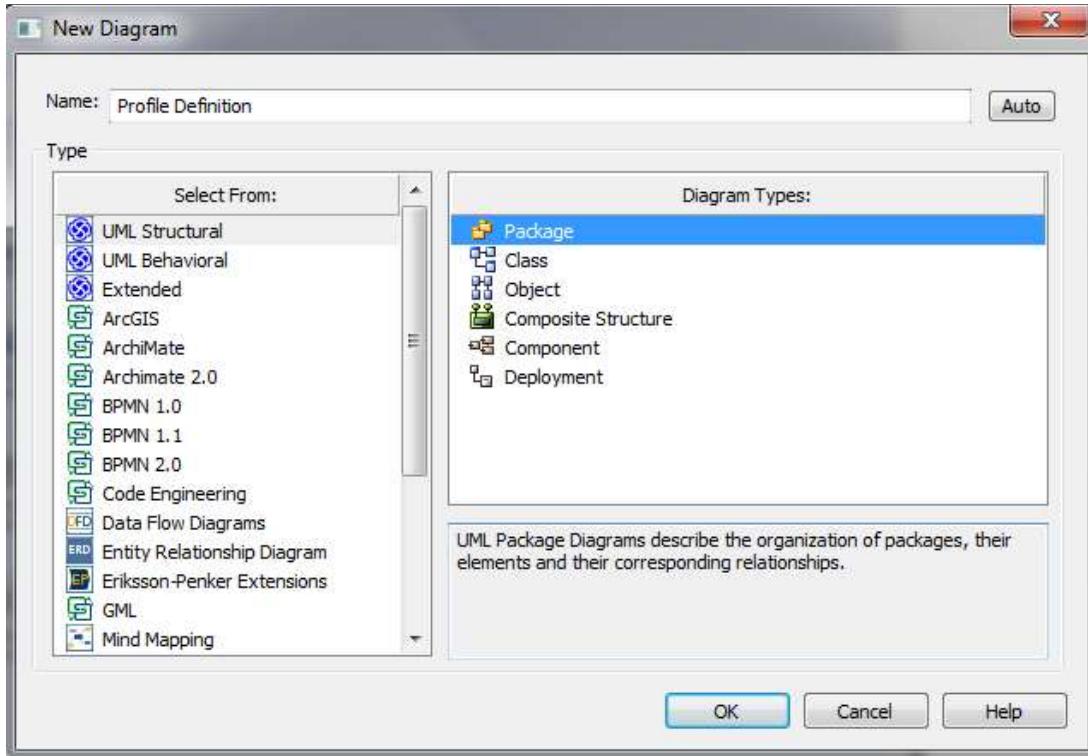


Figure 45. Selection type of diagram in the Profile Definition.

In the Project Browser now you see the new project with a view and the package 'Profile Definition'. See figure 46.

In 'Create UML model for the new Functional Profile' there is a description of how to create a UML diagram for the Profile Definition. This diagram can only be created after loading the Base Model and the creation of the package for the new Functional Profile. So load the Base Model and create a package for the new functional first.

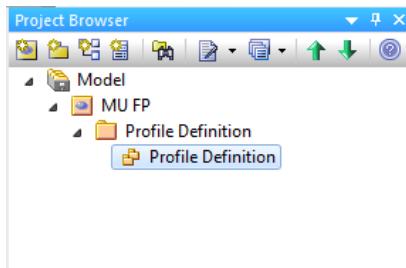


Figure 46. New project with view and package Profile Definition.

Now we will finish the package for the Profile Definition.

- Open the Properties for the package Profile Definition (double click on the package) and select the follow stereotype in the Stereotype field: HL7-FM-ProfileDefinition. Now you can click on the Properties window (on top of the window) and drag this next to the notes underneath the Project Browser.
- Or go directly to the Properties underneath the Project Browser. See figure 47.

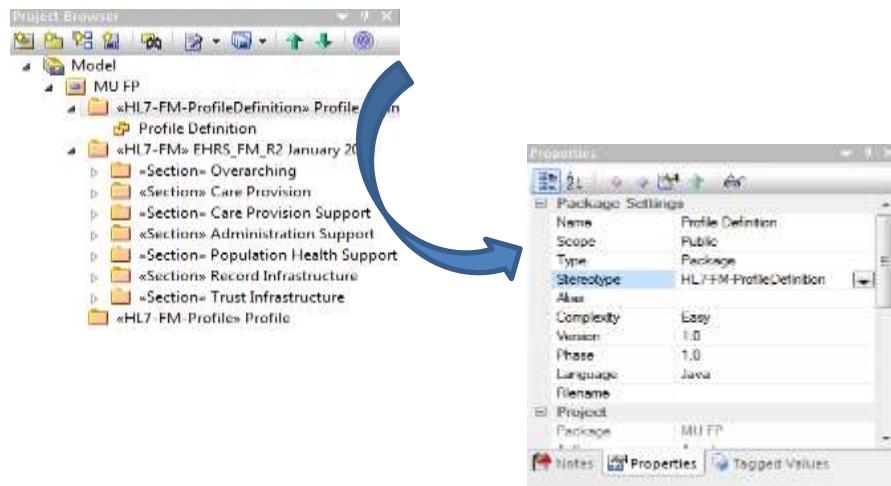


Figure 47. Properties of Profile Definition.

- Open the Tagged Values and create the File Path for the Profile Definition. See figure 48. Close after choosing the file path. This in the Tagged Value MAX::ExportFile.
- It is possible that you have to create this Tagged Value.



Manual HL7 Profile Designer Tool

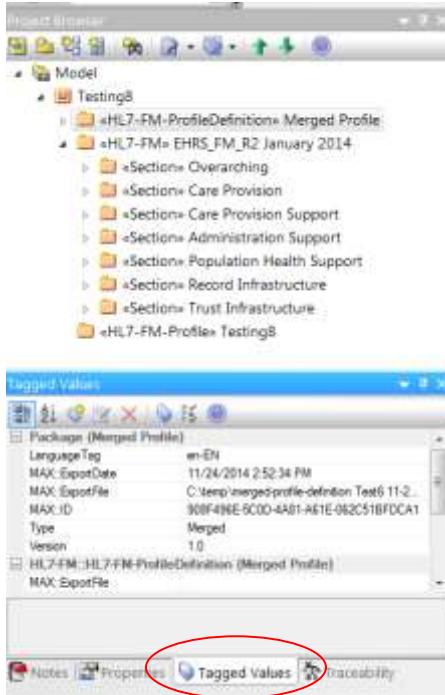


Figure 48. Creation of File Path Profile Definition.

- Click on the icon in the Tagged Values window, see figure 48, in the red circle.
- In the window enter the Tagged Value as shown in figure 48.
- Enter also the file path and click OK. The file path can be changed after you clicked OK.
- However, the Tagged value cannot be changed after clicked OK. If you made a mistake, delete the Tagged Value and start again.

Now you can load the Base Model.

8.4. Load a Base Model for creation of a new Functional profile

The first rule for Functional Profiles is the identification of the Functional Model or Functional Profile from which you want to derive the new Functional Profile. This is the so called 'Base Model'. To do so you have to select the FM or FP for that and load the FM or FP into Enterprise Architect⁵. To do so you will need the MAX file of that FM or FP. Be sure that you use the latest version of the MAX file! Ask the EHR WG co-chairs for the file.

To load the Base Model:

- Select the project in where you want to have the Base Model.
- Select the 'View' package. You created this before when you created a new project in EA for the creation of your functional profile.

⁵ This is only possible for Functional profiles based on the FM or FP Release 2.



Manual HL7 Profile Designer Tool

- Click right and select Extensions as shown in figure 49.
- Select HL7 FM.

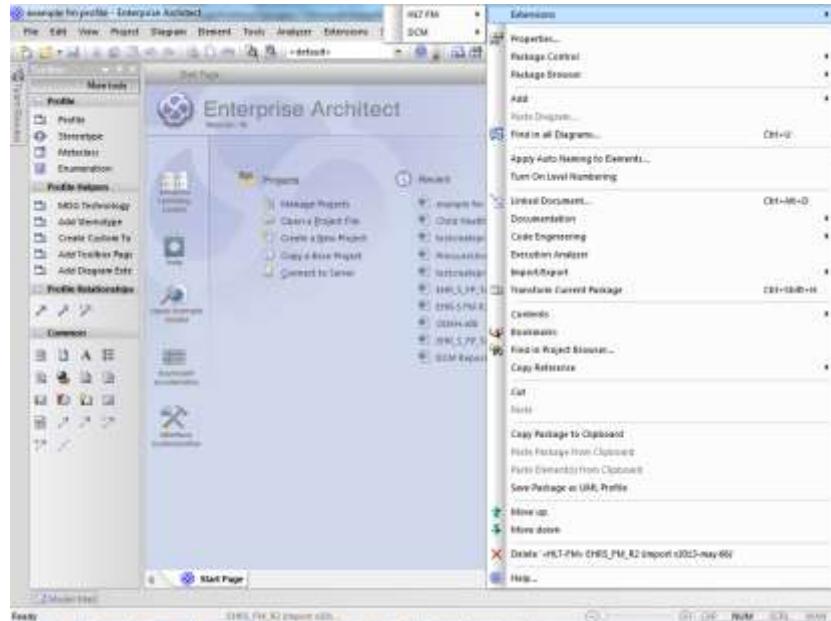


Figure 49. Load Base Model by using the Extension functionalities.

- Now select the Quick Access Tab. See figure 50.

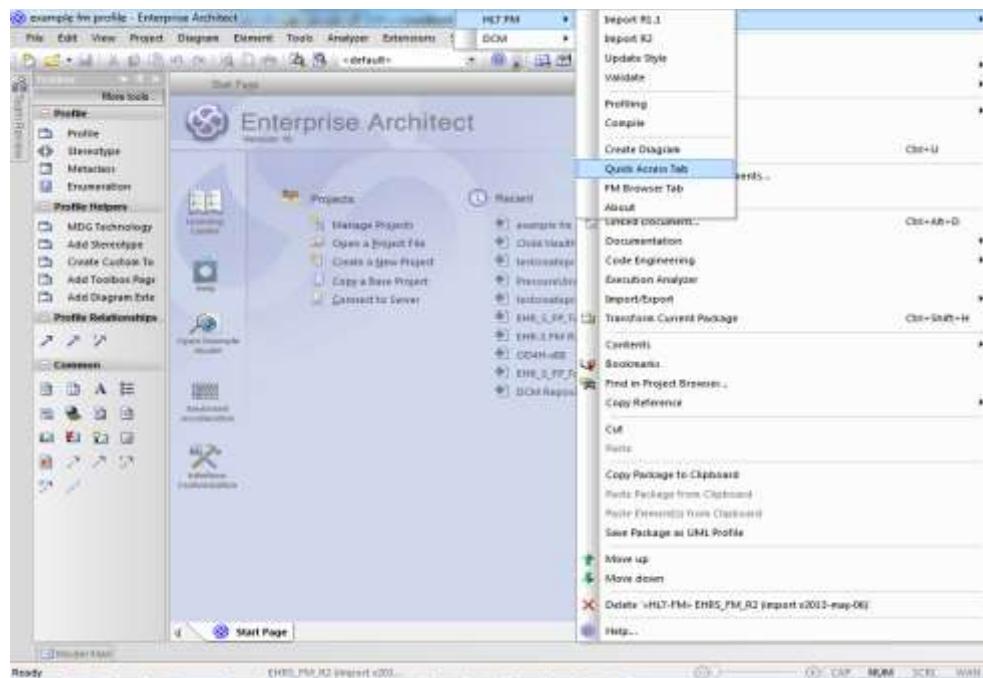


Figure 50. The Quick Access Tab in the HL7 FM Extension.



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The result is shown in figure 51.



Figure 51. Quick Access Tab in the HL7 FM Extension.

Now you can import the FM or an existing FP by selecting the option in the Quick Access Tab. We will import the EHR-S FM for our example. For this we use the MAX file of the EHR-S FM. Follow the next steps.

- Select 'Import MAX' in the Quick Access Tab.
- Look for the MAX file in the Windows Explorer. When you click OK, EA will load the FM as the Base Model. This will take a couple of minutes.
- In the 'View' package you will see a second package (beside the package with the Profile Definition) with the Base Model. See figure 52.

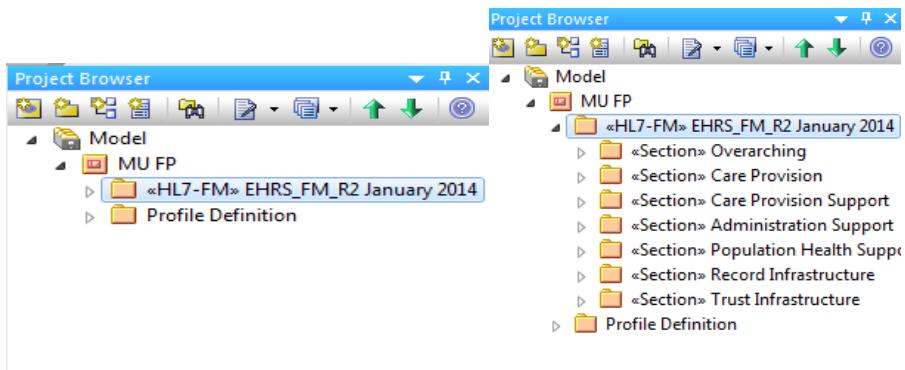


Figure 52. Project Browser with Profile Definition and the Base Model.

- Open the Tagged Values and select the file Path of the Base Model. See figure 53.
- To add a new Tagged Value see description in paragraph 'CreateNewProfile'.



Manual HL7 Profile Designer Tool

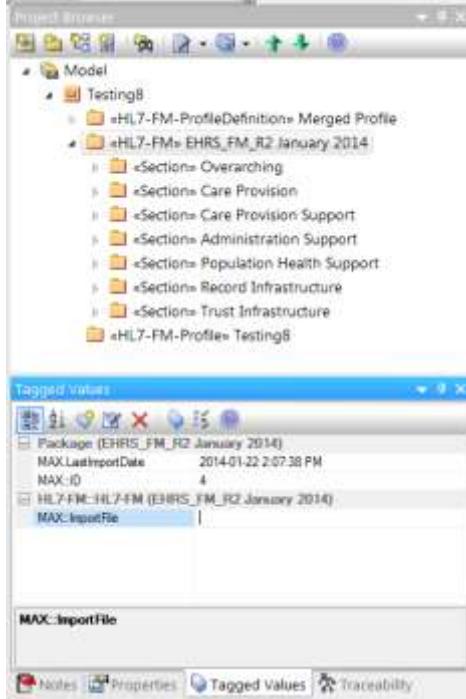


Figure 53. Including the File Path of the MAX Import File of the Base Model.

From this Base Model you define the new Functional Profile.

8.5. Create package for (compiled) Functional Profile

The third step is the creation of a package for the new Functional Profile.

Note: This step can be done **after** you:

- Created a new project in Enterprise Architect, EA, see in chapter ‘Creation’ the user guide ‘1CreateNewProfile.pdf’.
- Loaded the Base Model in the project, see in chapter ‘Creation’ the user guide

Note: And **before** you:

- Create the UML diagram for the Profile Definition

NOTE: be sure that you have installed the latest version of the extension before you are going to develop a new functional profile! Contact the EHR WG co-chairs to obtain the extension. Name of the extension is ‘HL7_FM_EA_Extension jjjjmmdd’. Check on a regularly base if a new version is available!

Creation of a package for the new Functional Profile:

- In the View you need to create a Package for the new (compiled) Functional Profile. The new (compiled) Functional Profile is based on the Profile Definition.
- Right click on the package ‘View’ and select ‘Add’ and then ‘Add package’. See figure 54.



Manual HL7 Profile Designer Tool

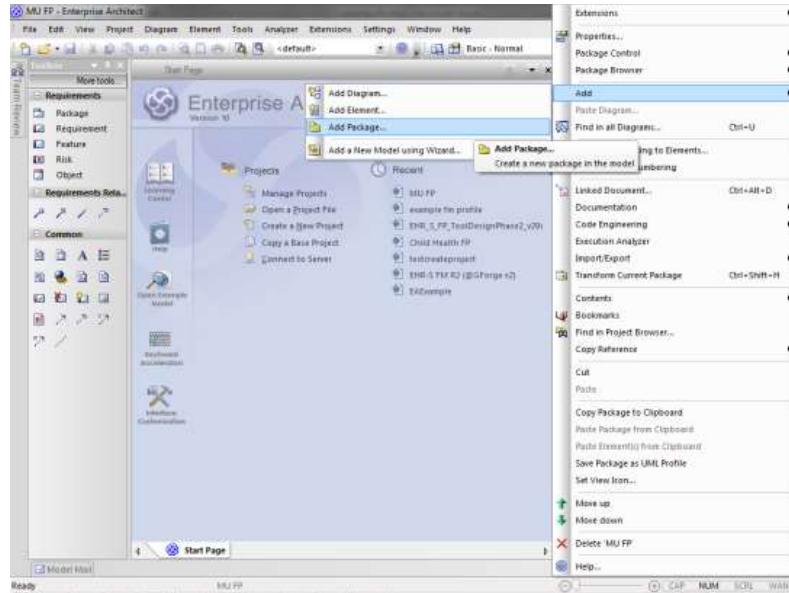


Figure 54. Adding a package to the 'View' of the new project.

- Give the package the name 'Profile' in the Name field. See figure 55.
- Don't select a diagram. So the boxes are empty. See figure 55.

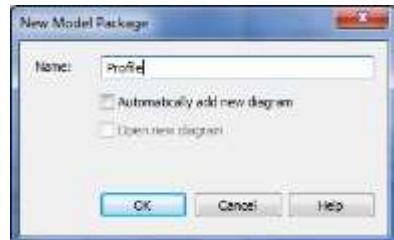


Figure 55. Giving the new package a name.

In the Project Browser now you see the package 'Profile'. See figure 56.

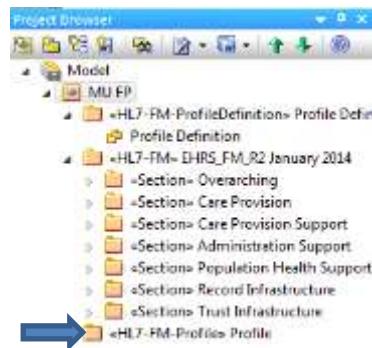


Figure 56. The third package 'Profile' in the new project.

- Open the Properties for the package ‘Profile’ and select the stereotype in the Stereotype field: HL7-FM-Profile. Or go to the Properties underneath the Project Browser. See figure 57.

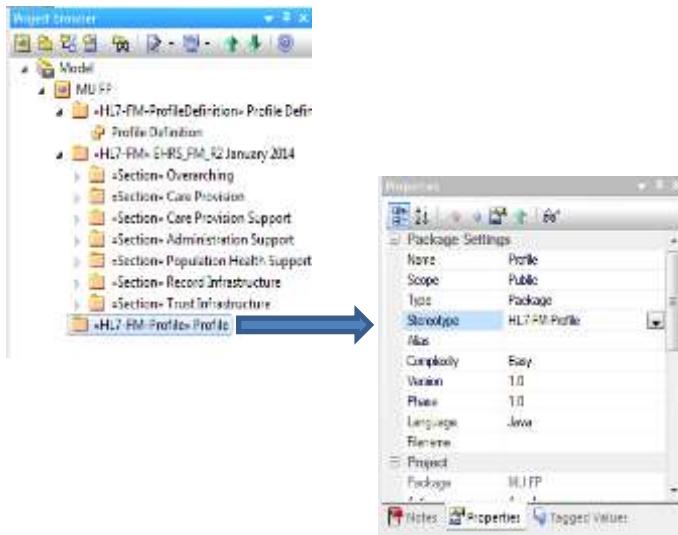


Figure 57. Properties of package ‘Profile’.

- Open the Tagged Values to include the File Path for both the MAX Import and Export File.
- This is done in the same way as including the file path for the other packages. See description in chapter ‘Creation’ the user guide ‘1CreateNewProfile.pdf’ .

Now you can create the UML diagram for the Profile Definition.

8.6. Create UML model for the new Functional Profile

For the Profile Definition you need to create a UML model in where is shown how the Profile Definition, the Base Model and the actual new Functional Profile relates to each other. This needs to be done so everything you define form the Base Model is included in the Profile Definition. And of course everything that is defined in the Profile Definition is included in the actual new Functional Profile.

The creation of the UML model can be done after you:

- Created a new project in Enterprise Architect, EA.
- Loaded the Base Model.
- Created a package for the new Functional Profile.

Follow the next steps:



Manual HL7 Profile Designer Tool

- Open the package with the Profile Definition. You will see the diagram you added to this package. See figure 58.
- Double click on the diagram ‘Profile Definition’. An empty diagram field will open.

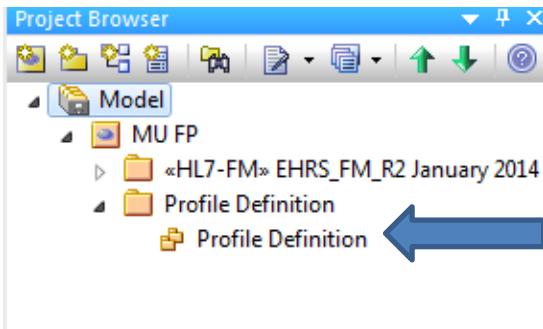


Figure 58. Diagram in Profile Definition.

- Drag the three packages to this diagram field. The three packages are: Profile Definition, the Base Model and the Profile. See figure 59.

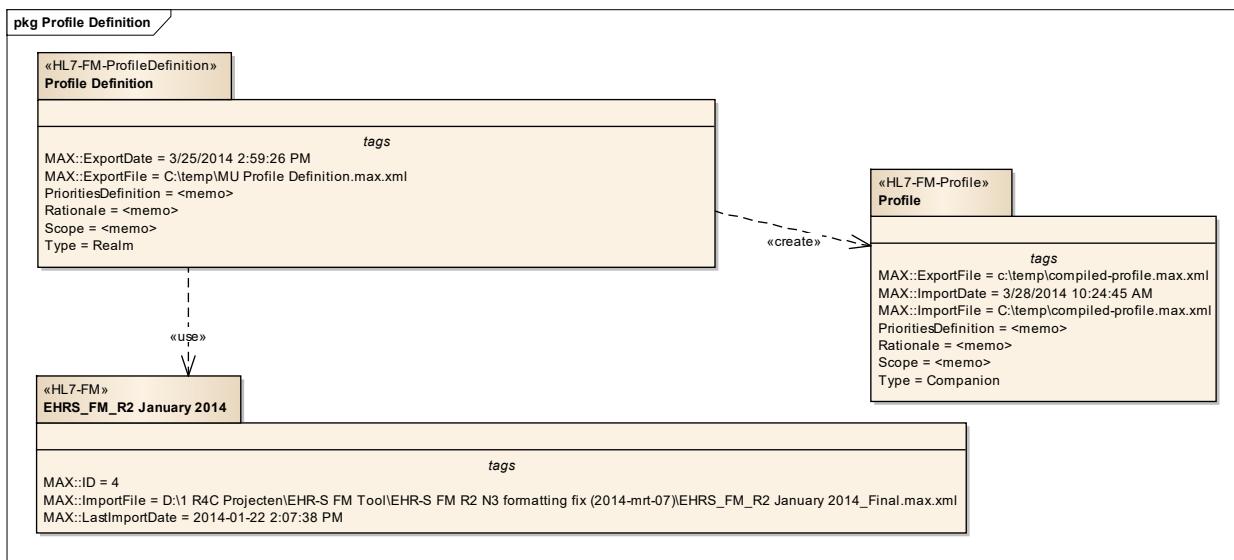


Figure 59. The UML Model for Profile Definition.

To connect the three packages and show their dependencies:

- Drag a connector from Profile Definition to Profile, select Dependency, and stereotype ‘create’.
- Drag a connector from Profile Definition to Base Model, select Dependency, and stereotype ‘use’.
- Enter stereotype: double click on the connector for the properties of the connector. The connector from Profile Definition to Profile shall get the stereotype ‘create’. See figure 60.
- The connector from the Profile Definition to the Base Model shall get the stereotype ‘use’.



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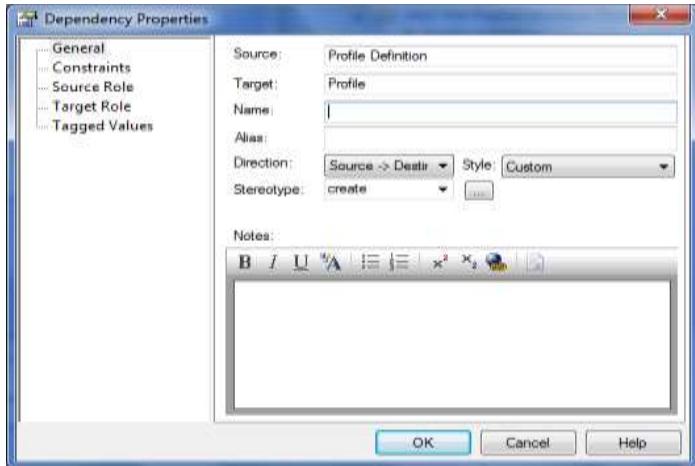


Figure 60. Dependency Properties.

To include the Tagged Values in the packages (if you did not do this already):

- Select a package in the diagram. Now you will see the Tagged Values for that package. You find the Tagged Values next to the properties underneath the Project Browser.

The figure consists of three side-by-side screenshots of the 'Tagged Values' browser window, each showing a different package's properties and their associated tagged values.

- Left Screenshot:** Shows the 'Profile Definition' package. It lists the following tagged values:
 - MAX::ExportDate
 - MAX::ExportFile
 - ProfileDefinition <memo>
 - Rationale <memo>
 - Scope <memo>
- Middle Screenshot:** Shows the 'EHRS_FM_R2 January 2014' package. It lists the following tagged values:
 - MAX::ID 4
 - MAX::ImportFile EHRS_FM_R2 January 2014_Fin...
 - MAX::LastImport... 2014-01-22 2:07:38 PM
- Right Screenshot:** Shows the 'Profile' package. It lists the following tagged values:
 - MAX::ExportFile c:\Temp\compiled-profile.max.xml
 - MAX::ImportDate <need to added>
 - MAX::ImportFile c:\Temp\compiled-profile.max.xml

Below each screenshot, a title identifies the package:

- Tagged Values of Profile Definition
- Tagged Values of Base Model
- Tagged Values of Profile

Figure 61. Tagged Values of a package.



The Tagged Values for the three packages shall be as follows:

1. Profile Definition:
 - a. MAX::ExportDate: the date the file was created. If you define the profile from the Base Model, this date will be included. Example: May/08/2014.
 - b. MAX::ExportFile: the name of the MAX file that is exported and the File Path where it is saved on your computer. Example: C:\temp\MU Profile Definition.max.xml
2. The Base Model:
 - a. MAX::ID: this will be added automatically.
 - b. MAX::ImportFile: the name of the MAX file that is used for the import of the Base Model and the File Path where it is saved on your computer. Example: D:\1 R4C Projecten\EHR-S FM Tool\EHR-S FM R2 N3 formatting fix (2014-mrt-07)\EHRS_FM_R2 January 2014_Final.max.xml
 - c. MAX::LastImportDate: the date the base model was imported in the tool.
3. Profile:
 - a. MAX::ExportFile: the name of the MAX export file and the File Path where this is saved on your computer. Example: C:\temp\MU compiled-profile.max.xml.
 - b. MAX::ImportDate: the date on which you imported the MAX import file.
 - c. MAX::ImportFile: the name of the MAX import file and the File Path where this is saved on your computer.

You can add new Tagged Values as described earlier.

Be sure that the notation of the Tagged Value is conform the description above.

Now you are ready to add general information on the new FP and to create the Profile Definition.

8.7. Provide General Information

A basic requirement of all profiles is to unique identify and to convey general information about the Functional Profile.

In the EHR-S FM FP Designer Tool this is done by filling in the Profile Metadata.

Provide Identify Information

- Double click on the package 'Profile Definition'. The result is a form in where you can provide the general information. See figure 62. Select OK when you are ready.



Manual HL7 Profile Designer Tool

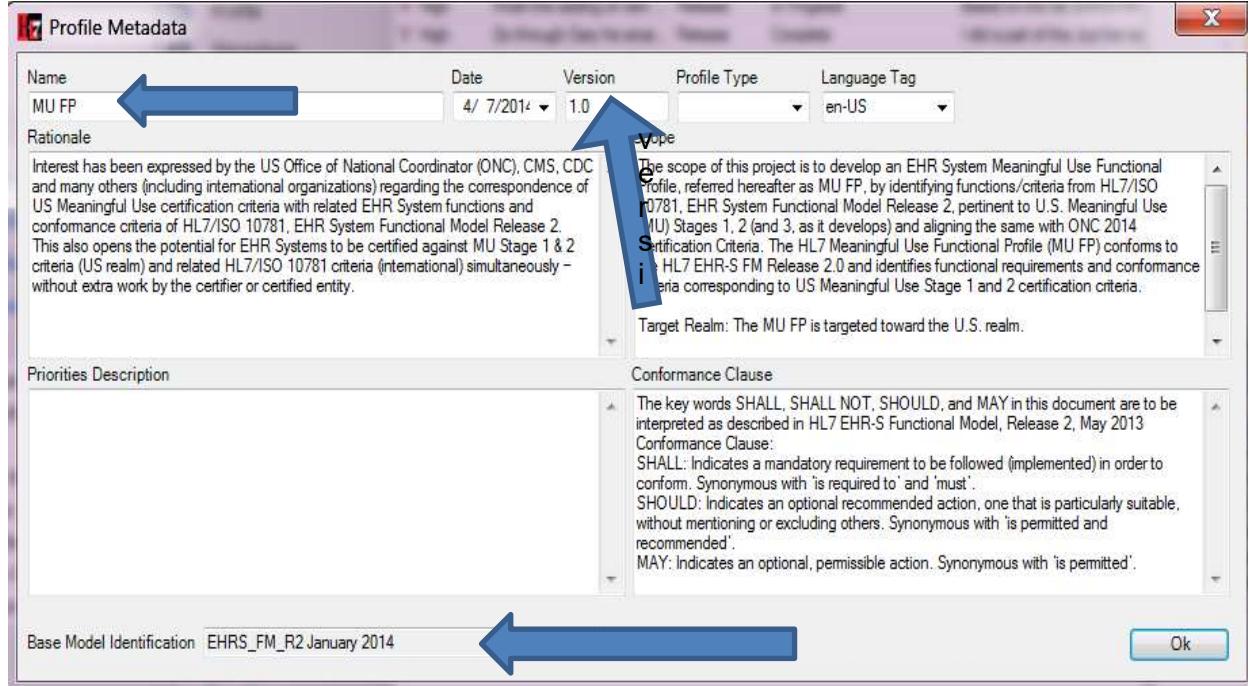


Figure 62. General information in the tool.

You can always go back to this Metadata during the development of the FP or finalize it at the end of the development.

NOTE: You cannot compile a Functional Profile in the tool when the metadata are not described! However, you can use dummy text and come back later to fill in the right text.

For further instructions on this, see the document on 'How-to Guide for creating functional profiles'.

8.8. Create the Functional Profile definition

The base for the new Functional Profile is the Base Model, FM or FP. The Profile Definition for the new Functional Profile is based on that Base Model.

Working on the Profile Definition it can happen that you make changes in the Base Model from which you derive the new Functional Model. To prevent that it is wise to lock the Base Model. For this you need to install the MAX extension as described in paragraph 4.4.

Lock/unlock the Base Model

- Click right on the package with the Base Model, select Extensions and then MAX.
- From this extension select 'Lock'.
- If you double click on an element in the Base Model, you see that the element is locked, right upper corner. See figure 63.



Manual HL7 Profile Designer Tool

EHR-S FM Function: CP.4 Manage Orders @11/10/2014 1:33:59 PM

CP.4 Manage Orders

ID CP.4

Name* CP.4 Manage Orders

Statement Provide the ability to manage clinical orders and results including medication, non-medication, diagnostic tests, blood products, other biologics and referrals, using order sets as appropriate.

Description
[Change Note](#)

The provision of clinical care includes the need to order from a variety of treatments using order sets as appropriate as well as reviewing the results of treatment. Orders for treatments may include medications, non-medication therapies (e.g., physical therapy, special diet, immunizations, non-allopathic regimens); diagnostic care (e.g., laboratory, radiology); blood products and other biologics (e.g., blood transfusions, human growth hormones). Patients are often referred to other health care providers for more specialized diagnostic workup, and/or treatment. An effective EHR-S must include support and management of these processes and associated documentation.

* = Profiled **Ok** **Cancel** **Apply** **Help**

Figure 63. Locked function in the Base Model.

- To unlock the Base Model, use the same path, but select ‘Unlock’.

Create Profile Definition

- In the Base Model select a section and click right.
- Select Extension and HL7 FM.
- Select Edit Profile in the menu. See figure 64.

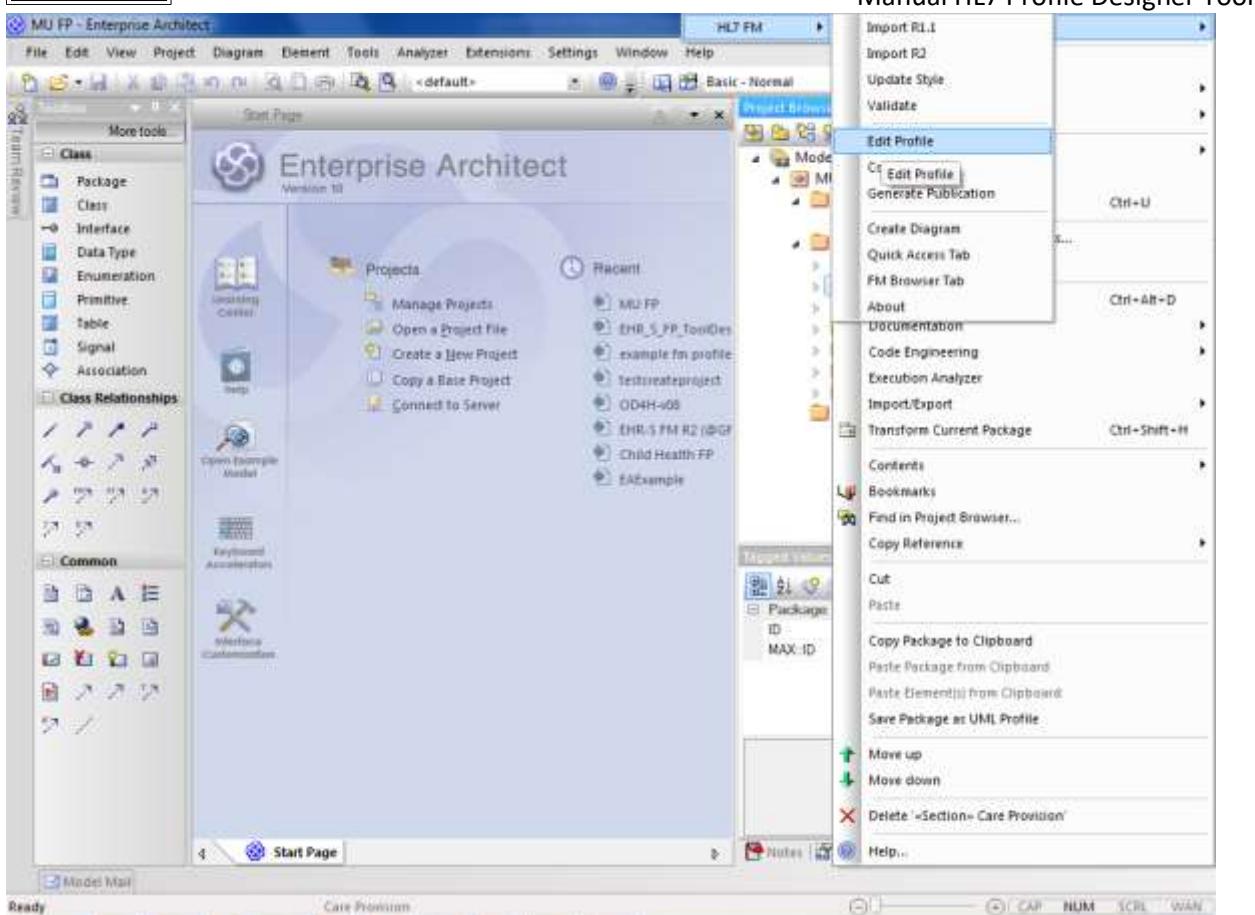


Figure 64. HL7 FM Extension menu.

The result of this is shown in figure 65.

The Edit Profile form

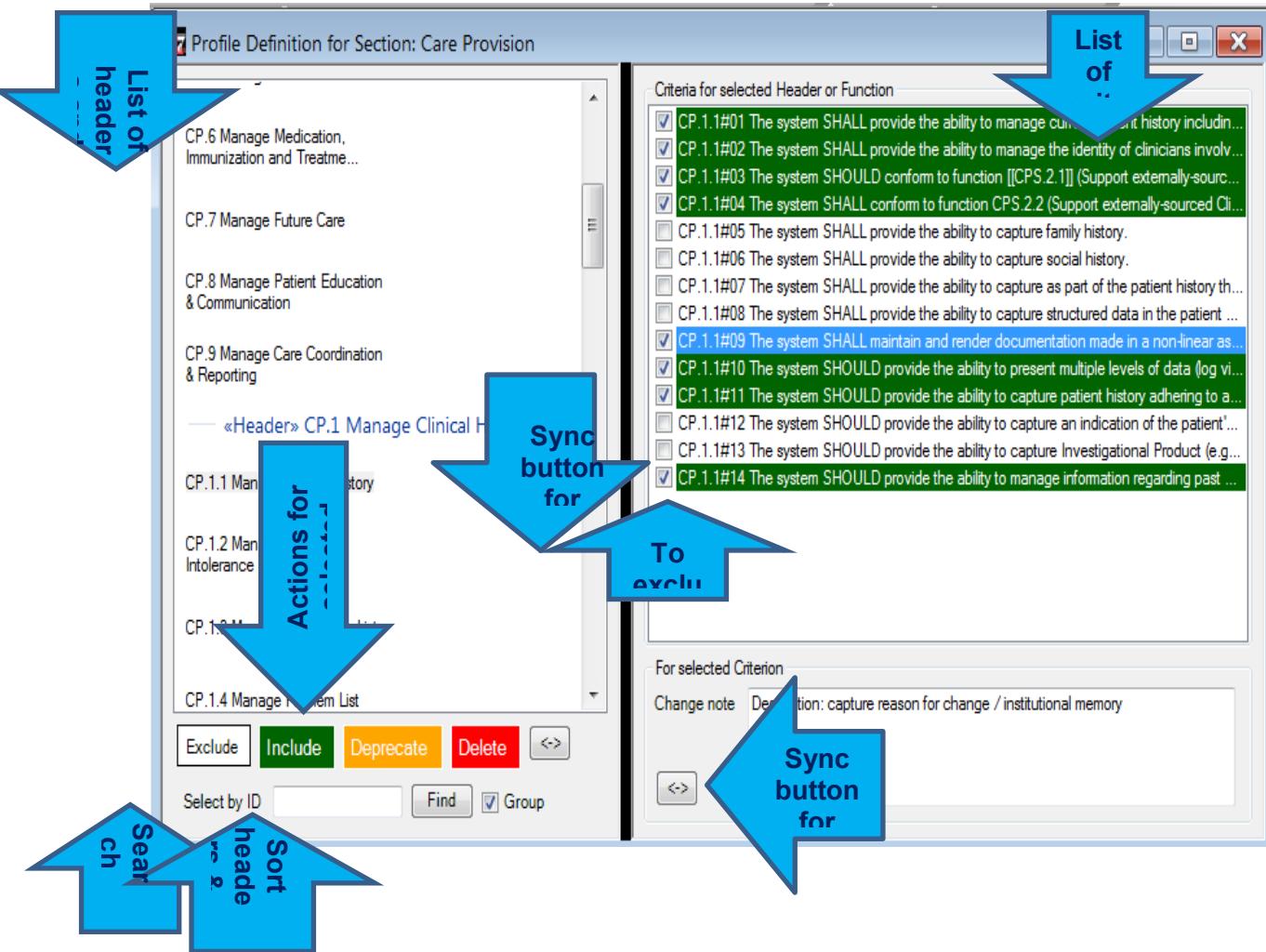


Figure 65. User interface (UI) for the Profile Definition.

- On the left you see the list with headers and functions that are in the specific section, in this case Care Provision.
- Also on the left, on the bottom, are the actions for the selected header and functions (the colored options). You can exclude, include, deprecate or delete them.
- Also on the left, on the bottom, is the possibility to search for a header or function, search is done by entering the ID.
- Also on the left, on the bottom, is the possibility to sort the headers and functions in another way. See figure 66.



Manual HL7 Profile Designer Tool

Profile Definition for Section: Care Provision

Care Provision	Criteria for selected Header or Function
CP.1 Manage Clinical History	<input checked="" type="checkbox"/> CP.1.1#01 The system SHALL provide the ability to manage current patient history includin...
CP.1.1 Manage Patient History	<input checked="" type="checkbox"/> CP.1.1#02 The system SHALL provide the ability to manage the identity of clinicians involv...
CP.1.2 Manage Allergy, Intolerance and Adverse Reaction List	<input checked="" type="checkbox"/> CP.1.1#03 The system SHOULD conform to function [[CPS.2.1]] (Support externally-sourc...
CP.1.3 Manage Medication List	<input checked="" type="checkbox"/> CP.1.1#04 The system SHALL conform to function CPS.2.2 (Support externally-sourced Cli...
CP.1.4 Manage Problem List	<input type="checkbox"/> CP.1.1#05 The system SHALL provide the ability to capture family history.
CP.1.5 Manage Health-Related Factors List	<input type="checkbox"/> CP.1.1#06 The system SHALL provide the ability to capture social history.
CP.1.6 Manage Immunization List	<input type="checkbox"/> CP.1.1#07 The system SHALL provide the ability to capture as part of the patient history th...
CP.1.7 Manage Medical Equipment, Prosthetic/Orthotic, Device List	<input type="checkbox"/> CP.1.1#08 The system SHALL provide the ability to capture structured data in the patient ...
CP.1.8 Manage Patient and Family Preferences	<input checked="" type="checkbox"/> CP.1.1#09 The system SHALL maintain and render documentation made in a non-linear as...
CP.1.9 Manage Adverse Events	<input checked="" type="checkbox"/> CP.1.1#10 The system SHOULD provide the ability to present multiple levels of data (log vi...
CP.2 Render externally-sourced Information	<input checked="" type="checkbox"/> CP.1.1#11 The system SHOULD provide the ability to capture patient history adhering to a...
CP.2.1 Render externally-sourced Clinical Documents	<input type="checkbox"/> CP.1.1#12 The system SHOULD provide the ability to capture an indication of the patient'...
CP.2.2 Render externally-sourced Data	<input type="checkbox"/> CP.1.1#13 The system SHOULD provide the ability to capture Investigational Product (e.g...
CP.2.3 Render Emergency Medical System Originated Data	<input checked="" type="checkbox"/> CP.1.1#14 The system SHOULD provide the ability to manage information regarding past ...
CP.2.4 Render externally-sourced Clinical Images	
CP.2.5 Manage Patient-Originated Data	
CP.3 Manage Clinical Documentation	
CP.3.1 Conduct Assessments	
CP.3.2 Manage Patient Clinical Measurements	
CP.3.3 Manage Clinical Documents and Notes	
CP.3.4 Manage Patient-Specific Care and Treatment Plans	
CP.3.5 Acknowledge/Amend Other Provider Documentation	
CP.4 Manage Orders	
CP.4.1 Use Order Sets	
CP.4.2 Manage Medication Orders	

Exclude Include Deprecate Delete <>

Select by ID Find Group

For selected Criterion

Change note Description: capture reason for change / institutional memory

<>

Figure 66. Edit Profile form with Headers and Functions sorted in another way.

- On the right the list with criteria for the selected header of function, in this case CP.1.1 Manage Patient History.
- If the function is included, all the criteria are included by default. By checking out the box twice, empty box, the criterion is excluded. The criterion is grey now.
- By clicking on this button the selected element is opened in the Project Browser. In the process of reviewing the element you can also review the relationships in the Traceability View.
- In the top navigation select View, and select Traceability View. Drag this window next to the Tagged Values. See figure 67. See User Guide 'TraceabilityElements.pdf' in chapter 'browse'.



The screenshot shows the 'Project Browser' and 'Traceability' views in the HL7 Profile Designer Tool.

Project Browser: Shows a tree structure of profile elements. At the top level is 'CP.1.1'. Under 'CP.1.1' is 'CP.1.1 Manage Patient History'. Below it are seven items labeled '«CI» CP.1.1#01' through '«CI» CP.1.1#07'.

Traceability: Shows relationships for the selected element 'CP.1.1 Manage Patient History'. It lists various associations:

- subtype of CP.1.1 Manage Patient History
- ← supertype of CP.1.1 Manage Patient History
- owns
- owned by
- links from
- part of
- composed of
- depends on CPS.2.1 Support externally-sourced Clinical Data
- depends on CPS.2.2 Support externally-sourced Clinical Data
- owned by

At the bottom of the Traceability view, there are tabs for Notes, Properties, Tagged..., and Traceability... (which is currently selected).

Figure 67. Traceability view of the selected element in the Edit Profile form.

Actions on headers and functions

Headers and Functions are excluded by default. If you want to have a function in your Functional Profile, you need to include that function. The parent of that function, this can be a header, will be auto-included in the Functional Profile. So a header will be included when you are including functions of that header. There is no need to include the header explicitly.

- When you include a Header or Function, this will be shown as **Green**. You will see in the Profile Definition, in the Tagged Value, the included function.
- When you deprecate a Header or Function, this will be shown as **Orange**. You will see in the Profile Definition, in the Tagged Value, that the function is deprecated, it is indicated as DEP.



Manual HL7 Profile Designer Tool

- When you delete a Header or Function, this will be shown as **Red**. You will see in the Profile Definition, in the Tagged Value, that the function is deleted, it is indicated as D.
- A function can be excluded after it was included. All explicit excluded functions are in the Profile Definition and indicated as Excluded in the Tagged Values.

The result of including a function for the Profile Definition is shown in figure 68.

If there is a reference in a criterion, for example 'CP.1.1#03 The system **SHOULD conform to function CPS.2.1** (Support externally-sourced Clinical Documents) to capture, store and render previous external patient histories', function CPS.2.1 will be auto-included in the functional profile, because of the ConsequenceLink in the model. Check the relevancy of that criterion and the reference in it. Use the Sync button for that. In EA the selected function is opened. Now you can review the relationships in the Traceability view.

If you don't want to have that reference function in your Functional Profile, you need to exclude the criterion in which the reference is included. In that case CP.1.1#3 needs to be excluded.

Check again, because a referenced function can still be included because of another relationship. More about relationships between function see the 'How-to Guide for creating functional profiles'.

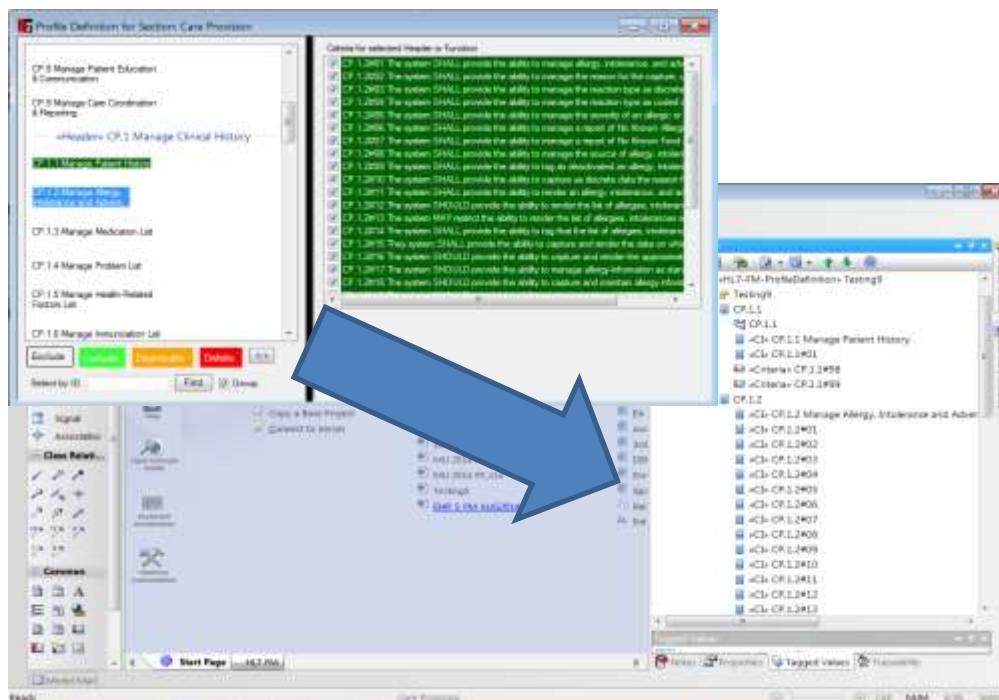


Figure 68. Example of a Profile Definition.

If you want to edit the header or function (name, statement or description):

- Select the header or function and select **Include**.



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- Double click on that header or function in the Edit Profile form on the left.
- The form of that header or function will open and changes can be made. See figure 69.
- This can also be done by including the header or function and double click on that header or function in de Project browser view. The form will also open.
- To compare the changes with the original text, click 'Switch to base element'.
- To save the changes you made, click on Apply if you still want to continue working. Click OK if you also want to close the form.

EHR-S FM Function: CP.1.1 Manage Patient History (Profile Definition) @11/24/2014 12:40:18 PM

CP.1 Manage Clinical History / CP.1.1 Manage Patient History

ID	CP.1.1	Priority*	EN
Name	CP.1.1 Manage Patient History		
Statement	Manage medical, procedural/surgical, mental health, substance use, social and family negative histories, patient-reported or externally available patient clinical history.		
Description*	The history of the current illness and patient historical data related to previous medical procedures performed on the patient, clinicians involved in procedures or in past consultations, and family members is captured through such methods as patient reporting (e.g., interview, medical alert band) or electronic or non-electronic historical data. This data may take the form of a pertinent positive such as "The patient/family member has had..." or a pertinent negative such as "The patient/family member has not had...". When first seen by a health care provider, patients typically bring with them clinical information from past encounters. This and similar information may supplement locally captured documentation and notes wherever appropriate. Information regarding the patient's living situations may be an important means for a provider to uniquely identify a patient or to identify illnesses that may occur within a given proximity. Information regarding past or present living situations or environmental factors related to the patient or the fetal death may include a description of the father's type of occupation and occupational demographic information (such as the name and location of the employment). For example, it may be important for the clinician to know that the patient works in an occupation where lead exposure is common. It may also be important for the clinician to know that the patient lives in a house where asbestos routinely appears on clothing.		
<u>Change Note</u>	Changed the text		

Compare the text with the original text in the base model.

Date on which you made the change.

Switch to base Element

filed Ok Cancel Apply Help

Figure 69. An in the Edit Profile form selected function.

In the function the description can be changed. If you 'Switch to base element', you will see that everything is locked to prevent you from making changes in the base model. See figure below.



EHR-S FM Function: CP.1.1 Manage Patient History @11/24/2014 11:36:49 AM X

CP.1 Manage Clinical History / CP.1.1 Manage Patient History

* ID: CP.1.1

Name: CP.1.1 Manage Patient History

Statement:
Manage medical, procedural/surgical, mental health, substance use, social and family history. This includes pertinent positive and negative histories, patient-reported or externally available patient clinical history.

Description:
[Change Note](#)
The history of the current illness and patient historical data related to previous medical diagnoses, surgeries and other procedures performed on the patient, clinicians involved in procedures or in past consultations, and relevant health conditions of family members is captured through such methods as patient reporting (e.g., interview, medical alert band) or electronic or non-electronic historical data. This data may take the form of a pertinent positive such as "The patient/family member has had..." or a pertinent negative such as "The patient/family member has not had...". When first seen by a health care provider, patients typically bring with them clinical information from past encounters. This and similar information may supplement locally captured documentation and notes wherever appropriate. Information regarding the patient's living situations may be an important means for a provider to uniquely identify a patient or to identify illnesses that may occur within a given proximity. Information regarding past or present living situations or environmental factors related to the patient or the fetal death may include a description of the father's type of occupation and occupational demographic information (such as the name and location of the employment). For example, it may be important for the clinician to know that the patient works in an occupation where lead exposure is common. It may also be important for the clinician to know that the patient lives in a household where asbestos routinely appears on clothing.

[Back to Profile Definition Element](#) * = Profiled Ok Cancel Apply Help

Figure 70. Form of a function opened in the Edit Profile form with locked view 'Switch to base element'.

NOTE: changes in headers and functions are bound by certain rules. These rules are described in the 'How-to Guide for creating functional profiles', file name 'How-to Guide_R2_final'.

The * next to a field indicates that the element is profiled (included or changes were made).

Principles:

- If you include a function, the parent of that function will be included in the compiled profile automatically!
- If you include a criterion in where there is a reference to another function, this function will be included automatically.

NOTE: All the actions you perform needs to be saved. This is done by closing the Edit Profile.

Actions on criteria

Criteria of a selected and included header or function **are included in the Profile Definition by default**.

- If you include a function, all criteria will be included automatically by the compiler.
- If you don't want to have a criterion in the functional profile, you have to explicitly exclude that criterion. See figure 71. Select that criterion in the Edit Profile form and click twice on the box. The checkbox is empty and the criterion is grey.



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Profile Definition for Section: Care Provision

Criteria for selected Header or Function

<input checked="" type="checkbox"/> CP.1.2#01 The system SHALL provide the ability to manage allergy, intolerance, and adverse reaction information.
<input checked="" type="checkbox"/> CP.1.2#02 The system SHALL provide the ability to manage the reason for the capture, and the source of the information.
<input type="checkbox"/> CP.1.2#03 The system SHALL provide the ability to manage the reaction type as discrete data.
<input type="checkbox"/> CP.1.2#04 The system SHALL provide the ability to manage the reaction type as coded data.
<input checked="" type="checkbox"/> CP.1.2#05 The system SHALL provide the ability to manage the severity of an allergic or adverse reaction.
<input checked="" type="checkbox"/> CP.1.2#06 The system SHALL provide the ability to manage a report of No Known Allergy or Intolerance.
<input checked="" type="checkbox"/> CP.1.2#07 The system SHALL provide the ability to manage a report of No Known Food Allergy or Intolerance.
<input checked="" type="checkbox"/> CP.1.2#08 The system SHALL provide the ability to manage the source of allergy, intolerance, and adverse reaction information.
<input checked="" type="checkbox"/> CP.1.2#09 The system SHALL provide the ability to tag as deactivated an allergy, intolerance, or adverse reaction.
<input checked="" type="checkbox"/> CP.1.2#10 The system SHALL provide the ability to capture as discrete data the reason for the capture, and the source of the information.
<input checked="" type="checkbox"/> CP.1.2#11 The system SHALL provide the ability to render an allergy, intolerance, and adverse reaction information.
<input checked="" type="checkbox"/> CP.1.2#12 The system SHOULD provide the ability to render the list of allergies, intolerances and adverse reactions.
<input checked="" type="checkbox"/> CP.1.2#13 The system MAY restrict the ability to render the list of allergies, intolerances and adverse reactions.
<input checked="" type="checkbox"/> CP.1.2#14 The system SHALL provide the ability to tag that the list of allergies, intolerances and adverse reactions is incomplete.
<input type="checkbox"/> CP.1.2#15 The system SHALL provide the ability to capture and render the date on which the allergy, intolerance, or adverse reaction occurred.
<input type="checkbox"/> CP.1.2#16 The system SHOULD provide the ability to capture and render the approximate date on which the allergy, intolerance, or adverse reaction occurred.
<input checked="" type="checkbox"/> CP.1.2#17 The system SHOULD provide the ability to manage allergy-information as standard HL7 message.
<input checked="" type="checkbox"/> CP.1.2#18 The system SHOULD provide the ability to capture and maintain allergy information.

CP.8 Manage Patient Education & Communication

CP.9 Manage Care Coordination & Reporting

«Header» CP.1 Manage Clinical History

CP.1.1 Manage Patient History

CP.1.2 Manage Allergy, Intolerance and Advers...

CP.1.3 Manage Medication List

CP.1.4 Manage Problem List

CP.1.5 Manage Health-Related Factors List

CP.1.6 Manage Immunization List

Exclude Include Deprecate Delete

Select by ID Find Group

Figure 71. Edit Profile form with excluded criteria.

- If the function is included automatically because of a reference in another function, all the criteria of that function will be included automatically. You need to review them.
- If you change a criterion in the function (text and/or optionality), the function will be also included automatically. In that case you don't need to explicitly include the function. However, if in the process of Profile creation, the function needs to be excluded, check the criterion.

NOTE: Remember, a criterion is included in the Profile Definition when you include a function. Only when you explicitly exclude the criterion it is excluded in the Profile Definition.

If you want to edit a criterion:

- Double click on that criterion in the Profile Definition in the Project browser. You will get the Criteria Form. See figure 72.

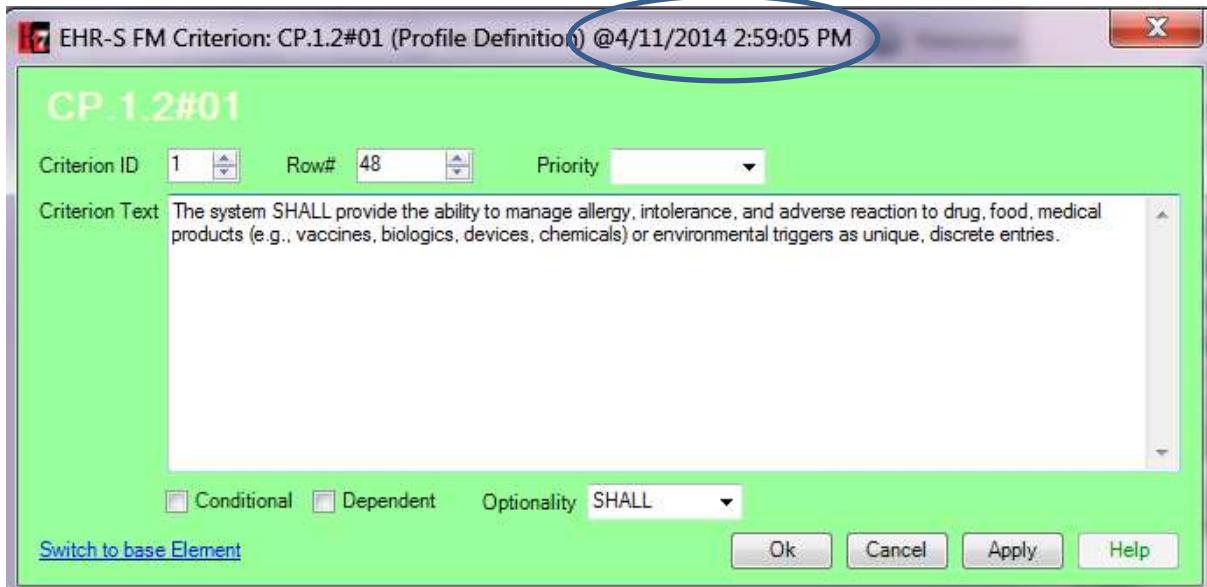


Figure 72. Criteria Form for editing the criterion.

- *Change the optionality:* select the Optionality field and choose the optionality you want.
- The changed optionality can be seen in the Tagged Values of that criterion in the Profile Definition. See figure 73.

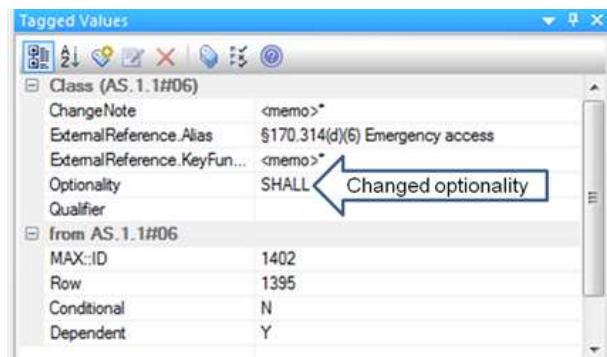


Figure 73. Tagged Values of a selected criterion with changed optionality.

NOTE: follow the rules for changing the optionality. See in the standard chapter 6 Conformance Clause.

Functional domain profiles claiming conformance to the Functional Model MAY

- *Change the text of the criterion:* this is done in the field Criterion Text. Click Apply to confirm the changes.
- See the original criterion text: click on ‘Switch to base Element’: you can read the original text of the criterion. See figure 74. Notice that the fields are grey. This is because you are viewing the text in the Base Model. You are prevented for making changes in the Base Model.

EHR-S FM Criterion: CP.1.2#01 @4/11/2014 11:33:47 AM

CP.1.2#01

Criterion ID	1	Row#	48
Criterion Text	The system SHALL provide the ability to manage allergy, intolerance, and adverse reaction to drug, food, medical products (e.g., vaccines, biologics, devices, chemicals) or environmental triggers as unique, discrete entries.		
<input type="checkbox"/> Conditional <input type="checkbox"/> Dependent Optionality: SHALL ▼			
Back to Profile Definition Element		Ok	Cancel
		Apply	Help

Figure 74. The Criteria Form with the original text of the criterion.

- To assign the Priority click on the dropdown menu in the box Priority and select the priority you want to assign, Essential Now, EN, Essential Future, EF or Optional, OPT.

Assigning a priority can be done on both function and criterion level. State in the Profile Metadata how you assigned the priorities and how to interpret them. This because:

- You can assign Essential Now on function level, but certain criteria of that function can be assigned Essential Future.
- You can assign a priority on function level and this is applicable for all the criteria of that function.
- You can only assign priority on criteria level.

The result of a validation of the Profile Definition is a warning that not all priorities were assigned or that there is an inconsistency in assigning the priorities.

Another functionality for ‘Priorities’ is assigning a new priority in General Information.

- Just enter the abbreviation of the new priority in the Priority field.
- Describe the new priority in the Profile Metadata in the Priorities Definition as follows: EFT – text (abbreviation space – space explanation).
- In the custom form the full text of the abbreviation is shown if you go to the priority field.
- Click OK when you are done editing the criterion.
- The changed text of the criterion is also changed in the Edit Profile form.
- In the Profile Definition the text of included criteria is not shown in the Notes. However, if the criterion text was changed, this text can be viewed in the Notes.



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Principle: everything that was changed can be viewed in the Profile Definition. Even if a criterion was excluded, deprecated or deleted this is included in the Profile Definition. Elements that were included in the Profile Definition, but not changed, are included in the Profile Definition, but text and optionality are not shown. The ChangeIndicator that indicates that something was changed compared to the base model will be added in the Compiled Profile.

Add functions and/or criteria

To add functions or criteria to the Functional Profile Definition, see the chapter on Editing the FP.

Compile the Functional Profile

If you want to compile the Functional Profile you are creating, you can do that by selecting the package Profile Definition, right click, go to Extension and HL7 FM and select Compile Profile. See figure 75.

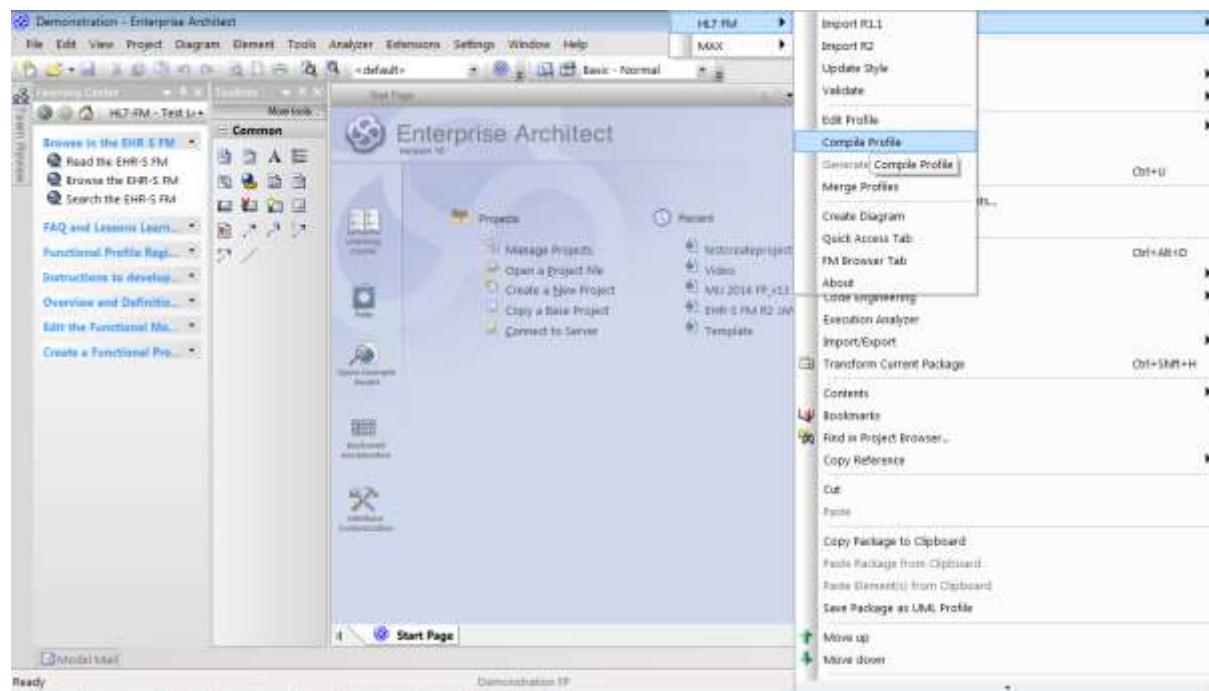


Figure 75. Compile the new functional profile.

How to manage the new Compiled Functional Profile is described in paragraph 'Create Compiled Profile'. Before that you can validate your work on the FP.



8.9. Validation of Profile Definition and Compiled Profile

All the rules for Functional Profile creation were included in the Profile Designer Tool as validation rules. Running a validation will give you a report on errors and warnings on the work you have done on the Profile Definition or the Compiled Profile. To run a validation of your work, you use the extension.

Validation of the Profile Definition

Before you are going to compile the Compiled Profile, it is useful to run a validation on the Profile Definition. This validation will give you a report on errors and warnings.

Example of an error is:

In a Functional Domain Profile, a 'shall' criterion shall not be changed to a 'should' or 'may' criterion. The error message is 'The change of the optionality is not allowed in the Functional Domain Profile'.

Example of a warning is:

The tool supports the qualification of the timeframe for the functions with 'Essential Future' are required to be implemented.

The warning is 'You did not include a timeframe for when the function is required to be implemented'.

Validation of the Compiled Profile

For a last check you can run a validation on the Compiled Profile before you are going to publish it.

Run a validation:

- Select the package of the Profile Definition or the package of the Compiled Profile. If you select the last one be sure that you have the Compiled Profile imported in EA.
- Right click and select Extensions.
- Select HL7 FM and select Validate. See figure 76.



Manual HL7 Profile Designer Tool

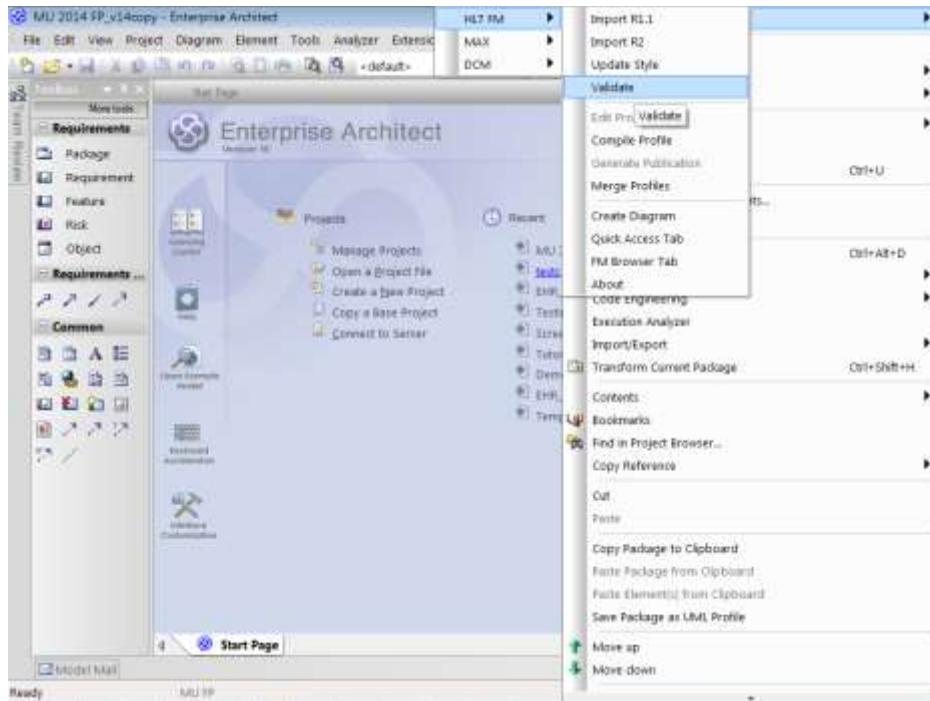


Figure 76. Run a validation.

EA will execute a validation on the Profile Definition or Compiled Profile. This will take a moment. A report as a System output is shown.

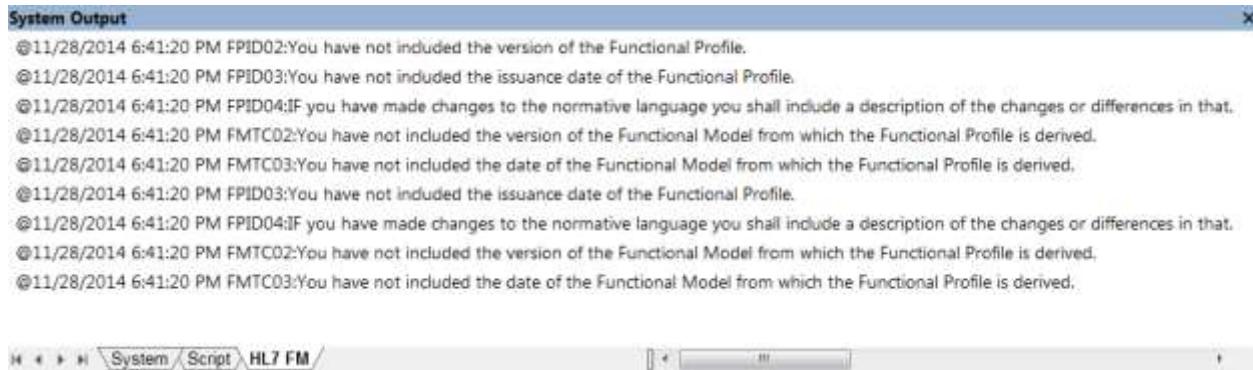


Figure 77. A report of the validation of the Compiled Profile.

Based on the errors in the report you can adjust the Profile Definition and based on the warnings you can review the Profile Definition. You can adjust the Profile Definition after review.

Now you can compile the Compiled Profile again based on the adjusted Profile Definition.



8.10. Create the Compiled Profile

The base for the new Functional Profile is the Profile Definition. If you don't have done that, go and create the Profile Definition first.

To create the compiled profile:

- Right click on the package 'Profile Definition'.
- Select Extension, select HL7 FM.
- Select 'Compile Profile' from the list. See figure 78.

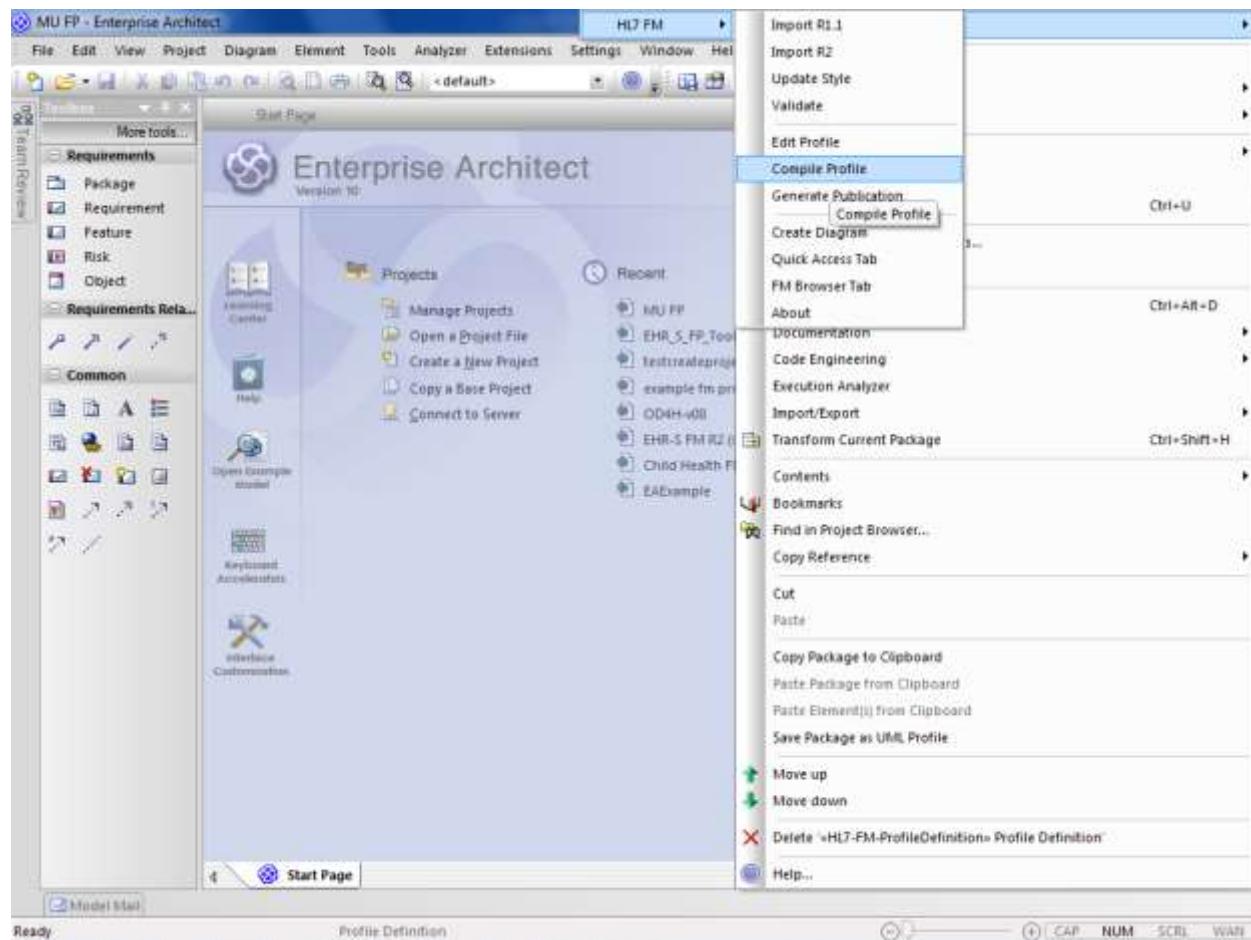


Figure 78. Compile Profile.

The result is a MAX file in the folder in where you wanted to save the compiled profile. You defined this in the Tagged Values of the package of the Profile Definition, as MAX::ExportFile.



Manual HL7 Profile Designer Tool

- Copy the file and change the file name by adding the date on which you compiled the profile. This is important because in the process of developing a new Functional Profile and the ballot of that Profile, you need to update the Profile Definition and compile the Profile again. In this way you keep track of the history.
- You can now import this file into EA.
- Select the package «HL7-FM-Profile» for the compiled profile.
- Right click, select Extensions, Select Quick Access tab. See figure 79.

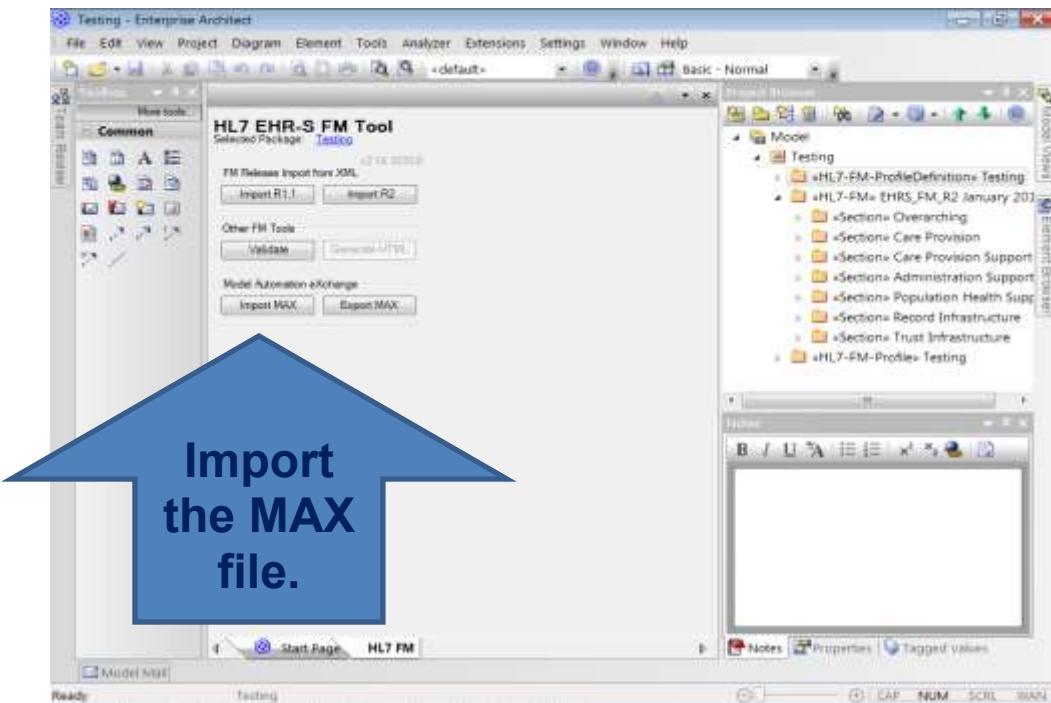


Figure 79. The Quick Access tab of the tool.

- Select 'Import MAX'.
- Select the max file from the Windows Explorer and click OK.

EA will now import the Compiled Profile in the package «HL7-FM-Profile». This will take a couple of minutes. The result is shown in figure 80.



Manual HL7 Profile Designer Tool

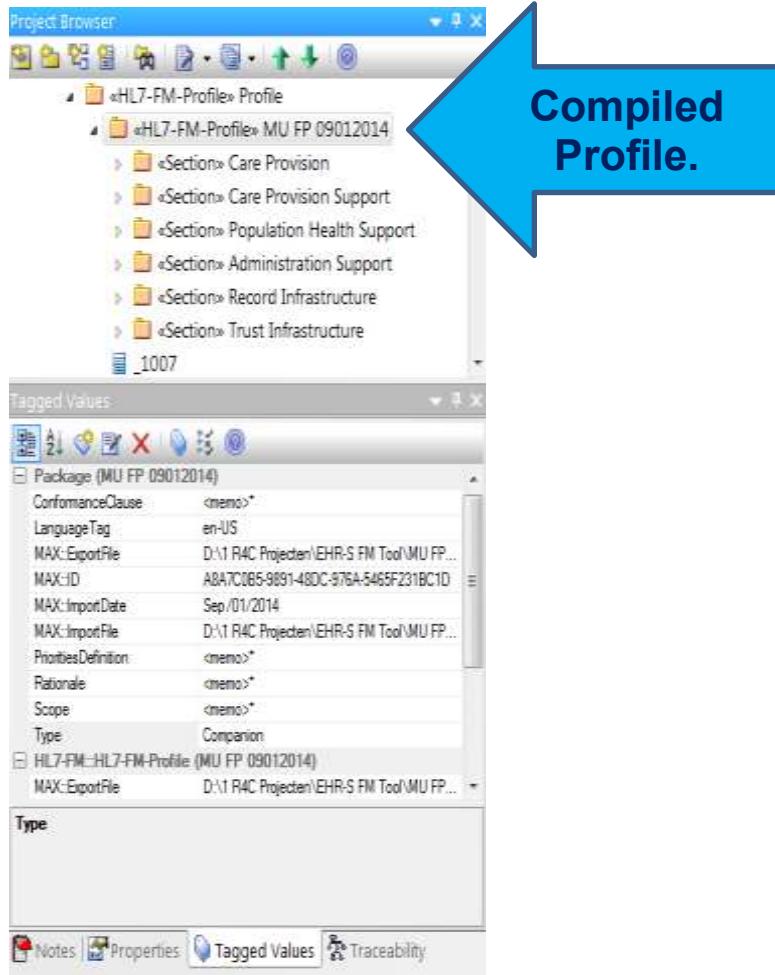


Figure 80. The new Functional Profile.

- When you select the (wrong) package 'Profile', if you want to compile the Functional Profile, you will get the message as shown in figure 81.

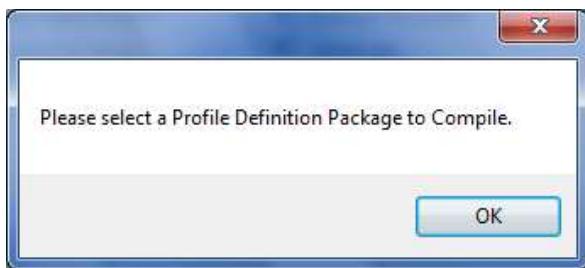


Figure 81. Message when selecting a wrong package.

NOTE: If you import the MAX file of the Compiled Profile multiple times in the process of profile creation, delete the older Compiled Profile in EA by right click on the Compiled Profile and Delete.



Manual HL7 Profile Designer Tool

Include also the individual classes with the numbers. See figure 82. If you don't do that the .eap file of your project gets to large!

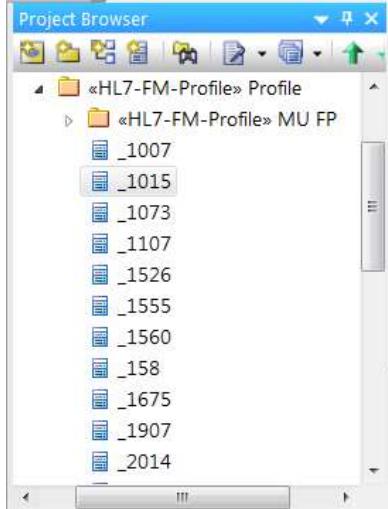


Figure 82. The Compiled Profile with individual classes.

Important:

- When you created the Compiled Profile add the date of creation to the filename. In this way you can save this file over time when compiling the Functional Profile again later in the process of creating a Functional Profile.
- Before you import a new Compiled Profile in EA, remove the older version of the Compiled Profile. Otherwise the .eap file will become very large and will be damaged.
- If this occurs, you can repair the .eap file.
- Select 'Project' in the top navigation, select 'Data Management' and select Manage .eap file. See figure 83.
- Now select 'Repair .eap file. EA will repair the .eap file for you.

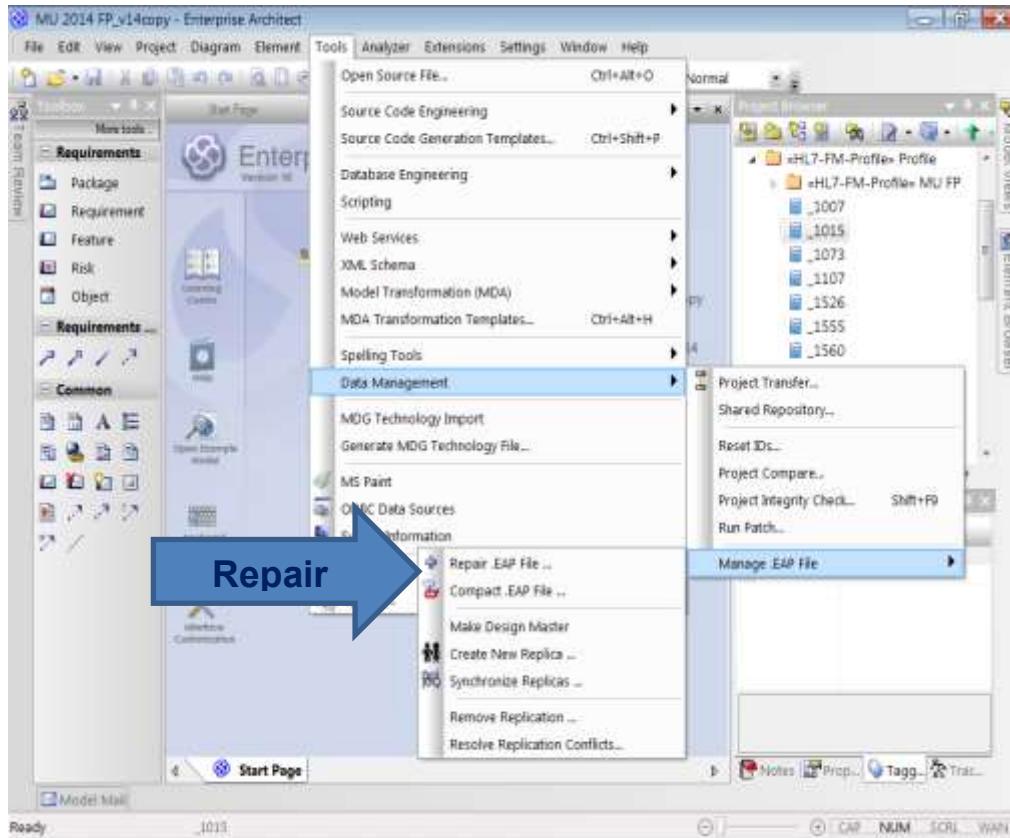


Figure 83. Repair the .eap file (in version 12 of EA this is done by going to 'Project' in the top navigation).

The MAX file is the new Functional Profile which you can make available for others within the HL7 community. So it is part of the package of the new Functional Profile.

The MAX file is also used to create other publication formats. How to create for example a pdf publication, see chapter 9.

8.11. Edit the Functional Model or Profile

This document describes the way new components, sections, headers, functions and/ or conformance criteria of the EHR-S FM can be added with support of the EHR-S FM Profiling Tool.

Add a Section

Adding a section in the Functional Profile is not allowed. If a Realm wants to add a section and stay conformant with the EHR-S FM, then the Realm shall discuss this with the HL7 International EHR WG.

In case of a new release of the FM a new section can be added.

To add a new section follows the next steps:

- Click right on the EHR-S FM Package and add a package. See figure 84.



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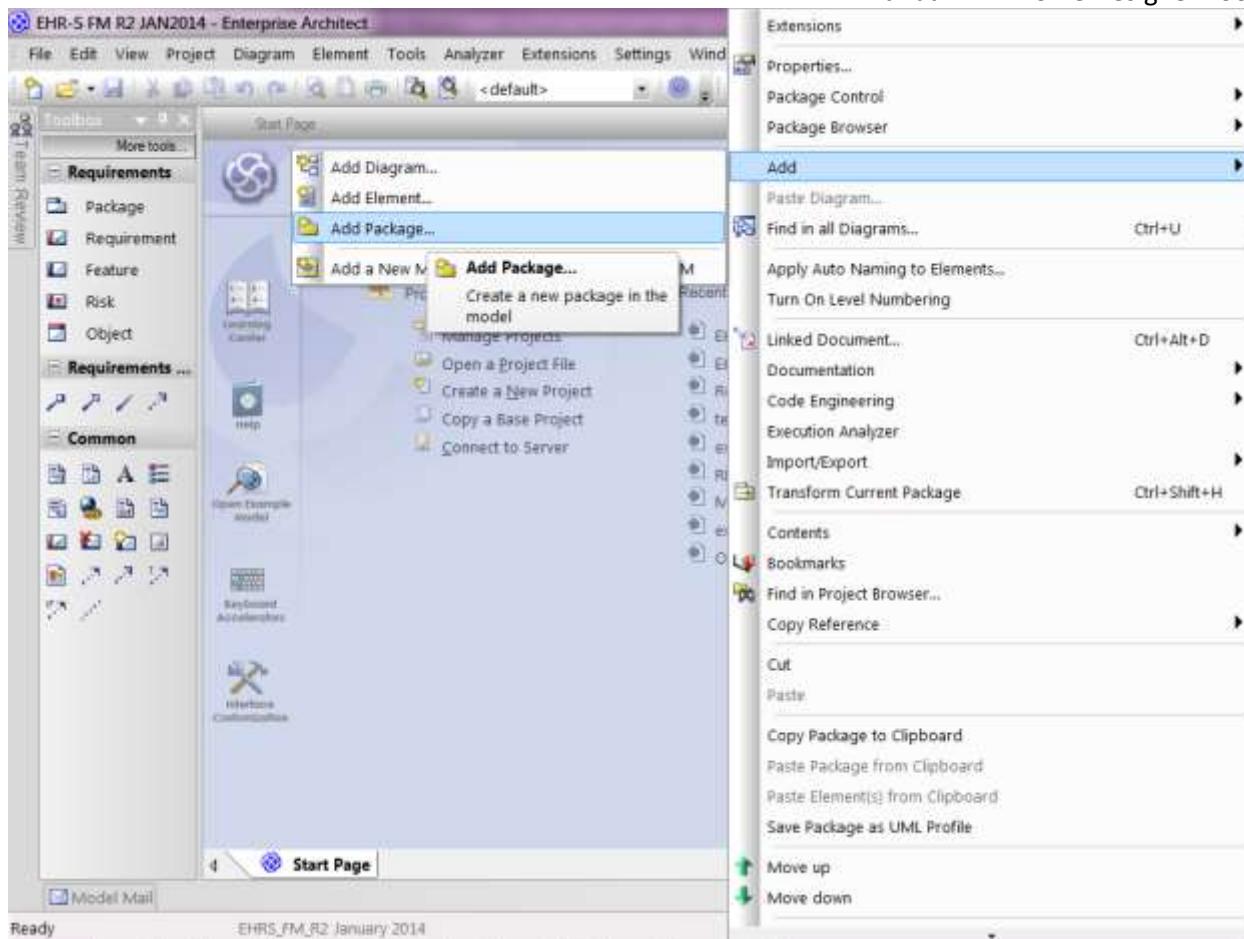


Figure 84. Add a package to create a new section.

- Give the section a name in the Name field. See figure 85. You don't need to add automatically a new diagram.

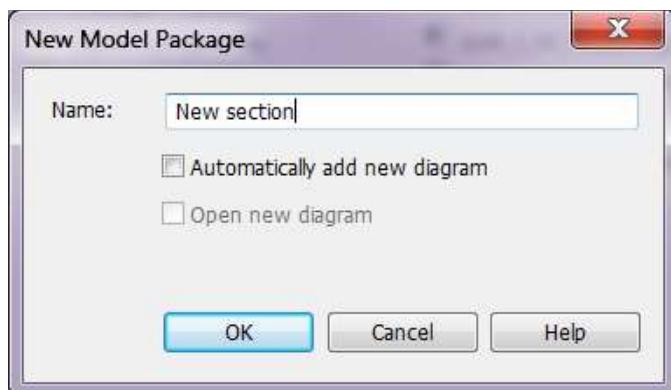


Figure 85. New package for a new section.

- The new section is shown in the project Browser. See figure 86.
- The stereotype of a section is Section. Assign this stereotype manually.

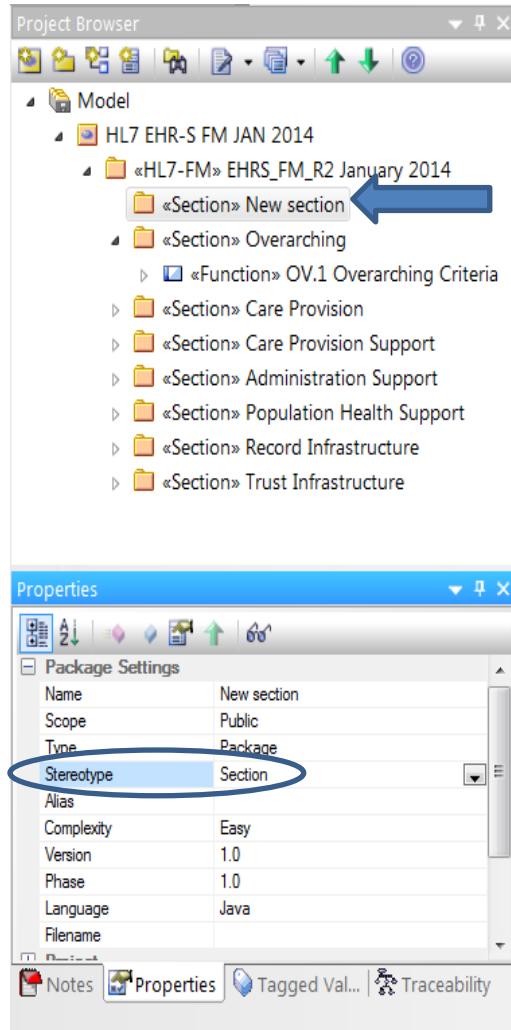


Figure 86. New section in Project Browser, including stereotype.

Add a function

Add a function in the Functional Model

The addition of a new function is done in the package of the FM. Follow the next steps:

- Create a diagram of the parent for which you want to create a new child function. See chapter on Traceability of elements.
- Select in the toolbox the option 'More tools' and select the HL7 toolbox. See figure 87.



Manual HL7 Profile Designer Tool

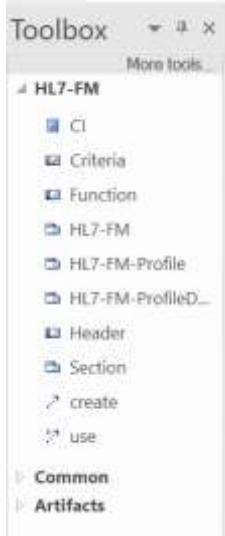


Figure 87. The HL7 FM Toolbox.

- Drag a new function from the HL7 Toolbox to the diagram. See figure 88.
- The Type of the new function is Feature.
- The Stereotype of the new function is Function.
- Both are included, because the HL7 FM Toolbox was used.
- Connect the new function to the parent with an aggregation type connector. See figure 88.

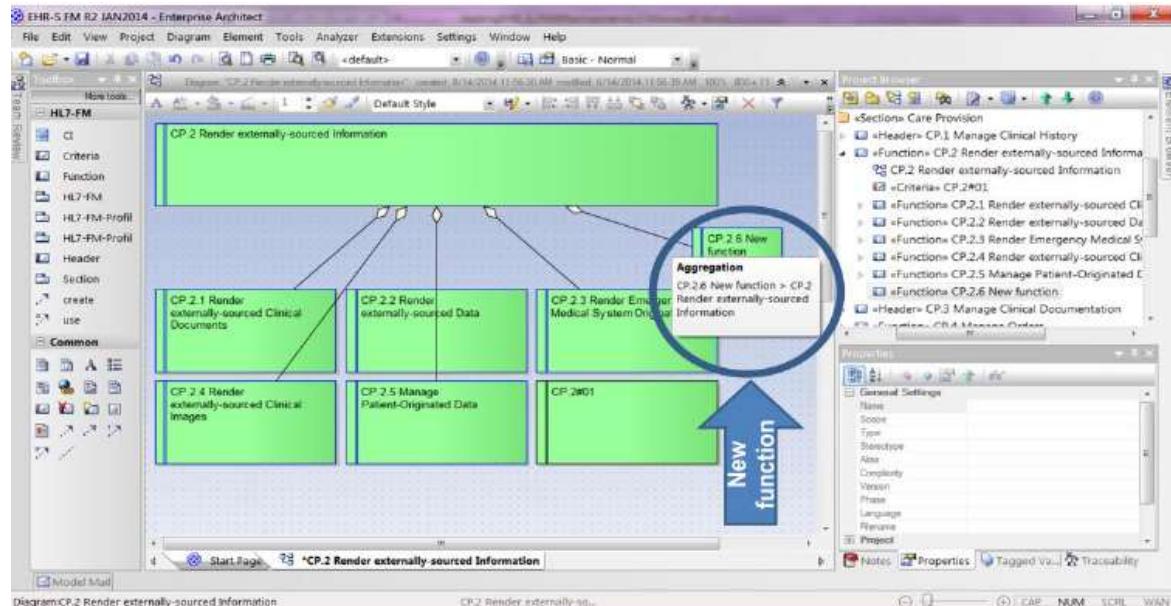


Figure 88. New child function created in a diagram.

Add a function in the Functional Profile

The addition of a new function in the Functional Profile is done in the Profile Definition adhering to the rules in the standard. To link the new function to a Header or section a UML model needs to be created. Follow the next steps:

- Add a new diagram to the package Profile Definition. However now you choose to add a diagram.
- Give the diagram a name. See figure 89 as an example.

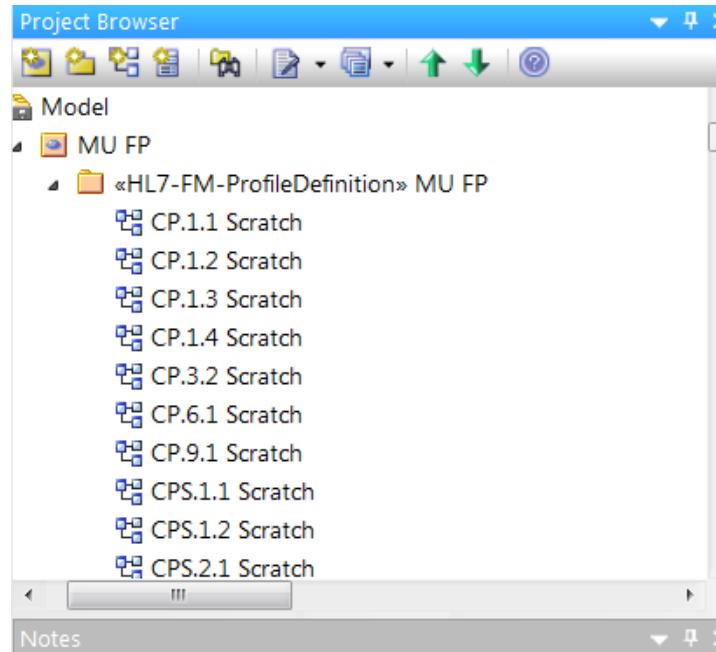


Figure 89. A scratch for adding new functions.

- Drag the parent Header or Section from the base model to the diagram.
- Drag a new function from the HL7 FM Toolbox to the diagram.
- The Type of the new function is Feature.
- The stereotype of the new function is Function.
- Both are included, because the HL7 FM Toolbox was used.
- Connect the new function with a Compose connector from the toolbox. See figure 90.

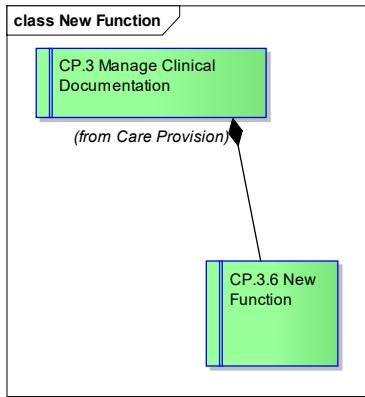


Figure 90. Model for new function.

Add a criterion

Add a criterion in the Functional Model

To add a new criterion follow the next steps:

- Create a diagram of the function in where you want to create a new criterion. See chapter on Traceability of elements.
- Select in the toolbox the option 'More tools' and select the HL7 FM Toolbox.
- Drag a new criterion from the toolbox to the diagram.
- The type of the new criterion is Requirement.
- The Stereotype of the new criterion is Criteria.
- Both are included, because the HL7 Toolbox was used.
- Connect the new criterion to the function. The connector that is used is coming from the toolbox of a class diagram. See figure 91.

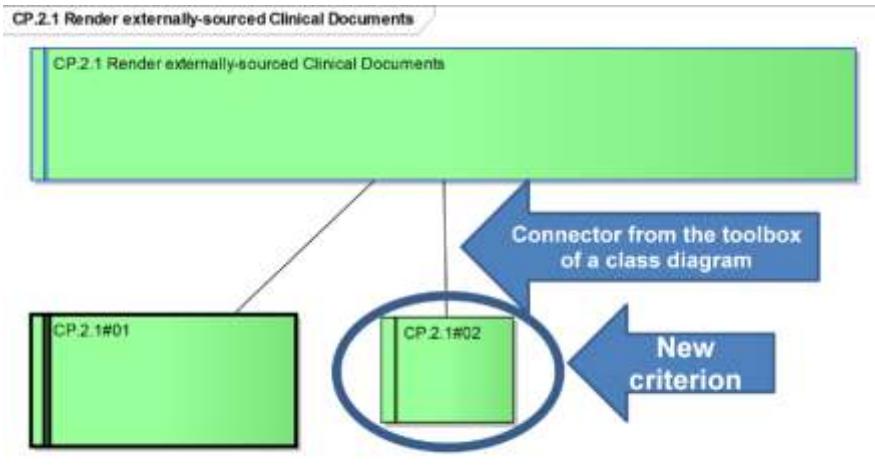


Figure 91. The addition of a new criterion to a function.

Add a criterion in the Functional Profile

The addition of a new criterion in the Functional Profile is done in the Profile Definition. To link the new criterion to a function a UML model needs to be created. Follow the next steps:

- Add a new diagram to the package Profile Definition. However now you choose to add a diagram.
- Give the diagram a name. The Id of the function can be used for the name.
- Drag the function, in which you want to add a new criterion, from the base model to the diagram.
- Drag a new criterion from the HL7 FM Toolbox to the diagram.
- The Type of the new function is Requirement.
- The Stereotype of the new function is Criteria.
- Both are included, because the HL7 FM Toolbox was used.
- Connect the new function with a Compose connector from the UML Class toolbox. See figure 92 as an example.
- Notice that the new function or criterion has the right colors belonging to the section in where they were created. This is because of the use of the Id. If you change the Id, for example TI to CP, the color will change automatically to the color belonging to TI or CP section.

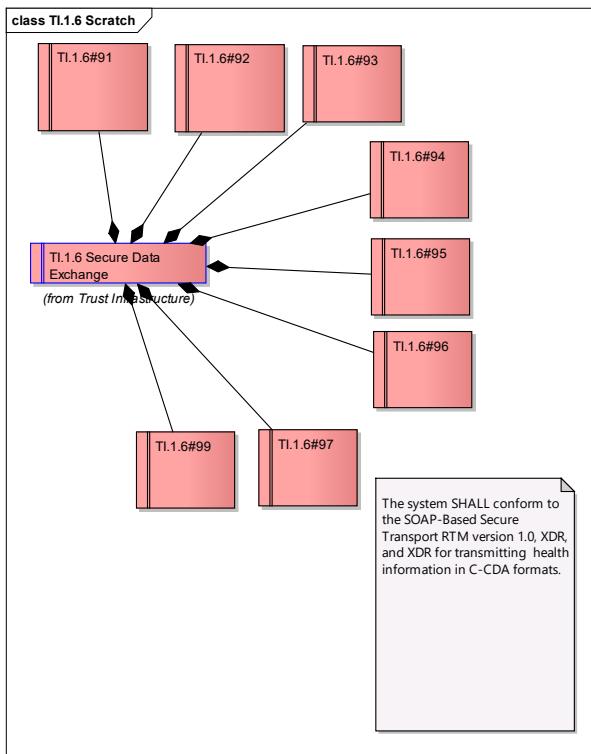


Figure 92. Model for new criteria.

NOTE: After the models are created and saved, the diagram can be deleted. However, in the process of a FP development it is possible that it is necessary to add more new functions and/or criteria to the same parent. You can use the diagram you already created.

8.12. Moving EHR-S FM Components

This document describes the way components, sections, headers, functions and/ or conformance criteria, of the FM or FP can be moved.

In a Functional Profile it is likely that you move criteria to another function, so we will start to describe this first.

Move a criterion from one Header/Function to another

The issues when moving a criterion are:

- The Id of the criterion
- The associations that comes with the criterion
- The corresponding color of the section if you move the criterion from one section to another section.

To move a criterion from one Header/ Function to another you need to perform the following steps:

1. Make a diagram of the function to which you want to move the criterion.
 - Click right on that function and choose Extension, choose HL7 FM and then Create Diagram. See figure 93.

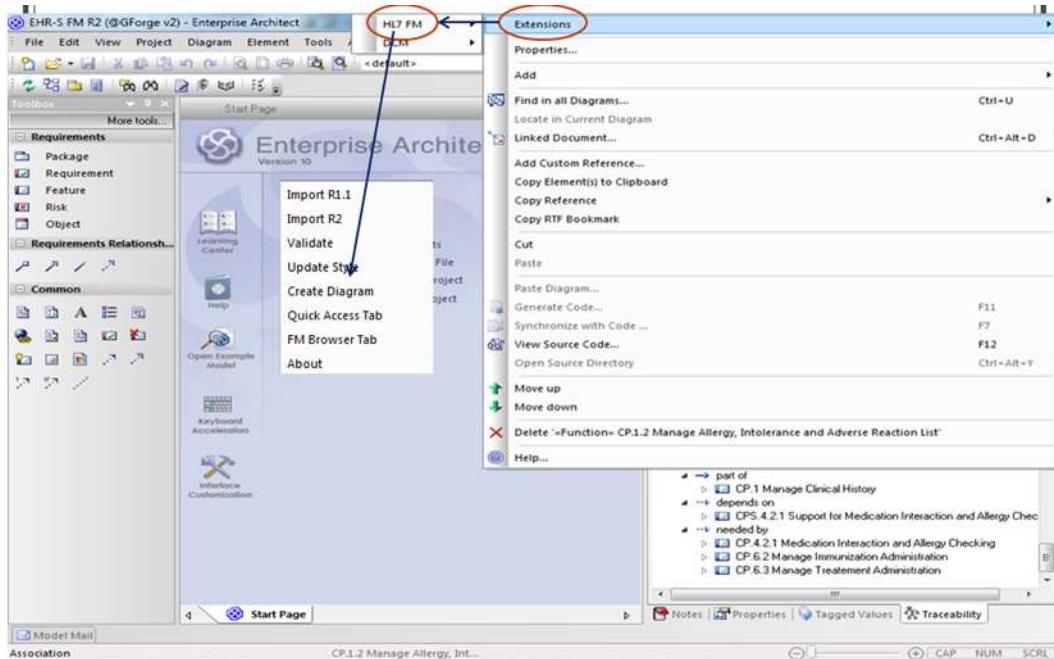


Figure 93. Creation of a diagram with the use of the extension.

You will get a diagram like the one in figure 94 below.

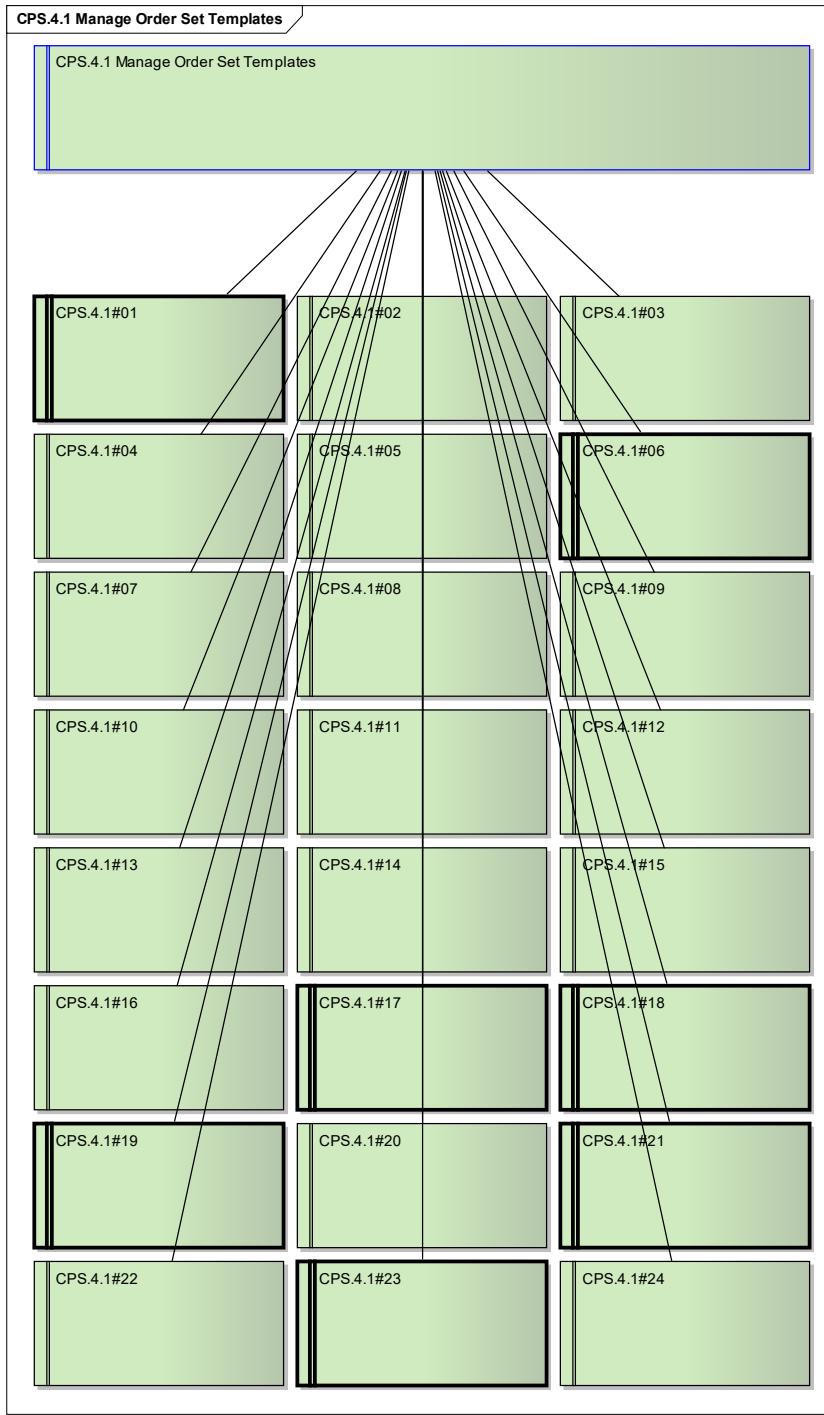


Figure 94. A diagram of a function.

- Open the Traceability View, Ctrl-Shift-4.
- Then right click on the criterion in the Traceability View you want to move. You will get several options. Choose 'Place Related Element in Diagram' as shown in figure 95.



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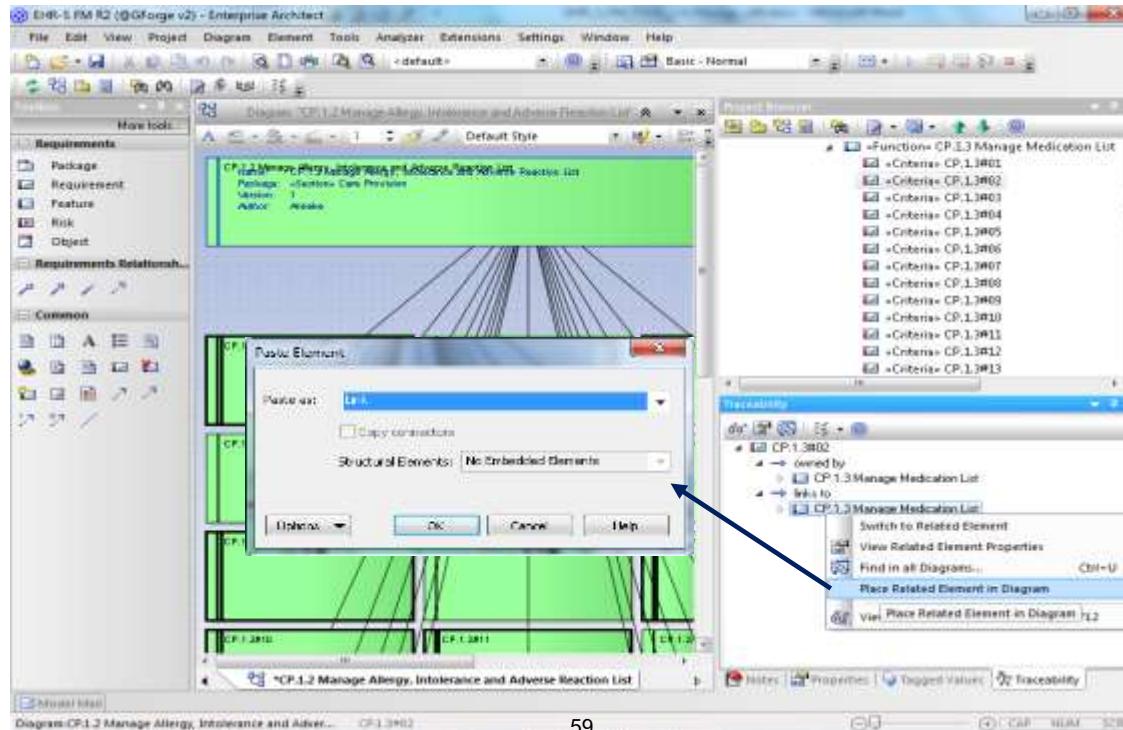


Figure 95. Place the Related Element in diagram.

- You will get a dialogue as shown in figure 95. Just click OK.
- The criterion is added to the diagram as a class. Add the Association from the Criteria to its Function in the Diagram (figure 96). You can also do this by choosing the Toolbox for Class and select the Associate connector from the Class Relationship. Save the diagram.

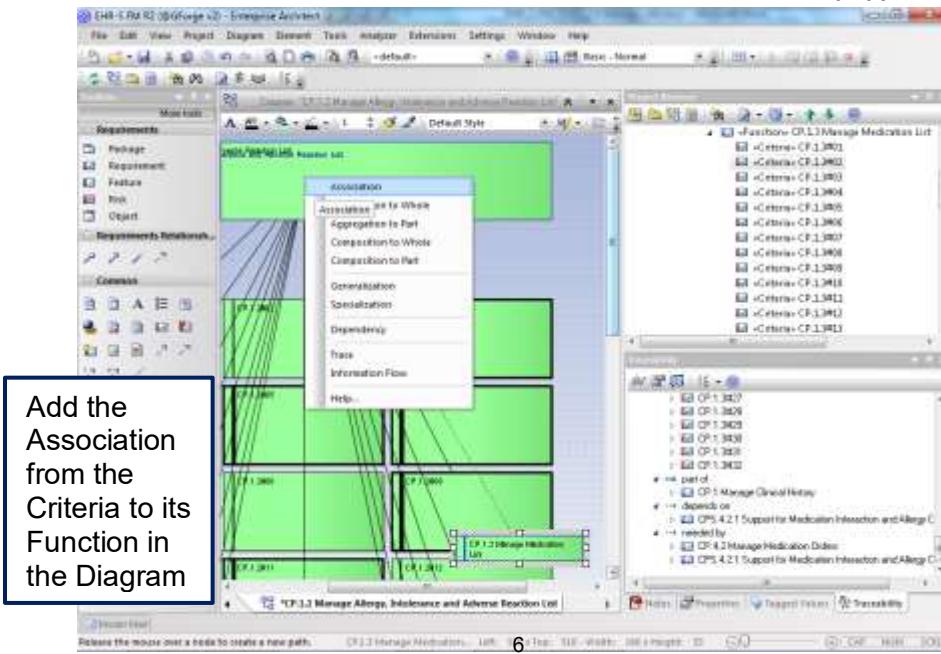


Figure 96. Add the Association from the Criterion to its Function in the Diagram.

Now you have moved the criterion to another function, you need to adjust the ID of the criterion. To do this:

- Select the class of the criterion in the diagram.
- Right click on the class and select Properties.
- The result is the Properties window as shown in figure 97.
- In the short description is the criterion ID. See figure 97.
- Now you can change the criterion ID (in this case) CPS.4.1#25.
- You can also do this in the Properties window underneath the Project Browser.



Manual HL7 Profile Designer Tool

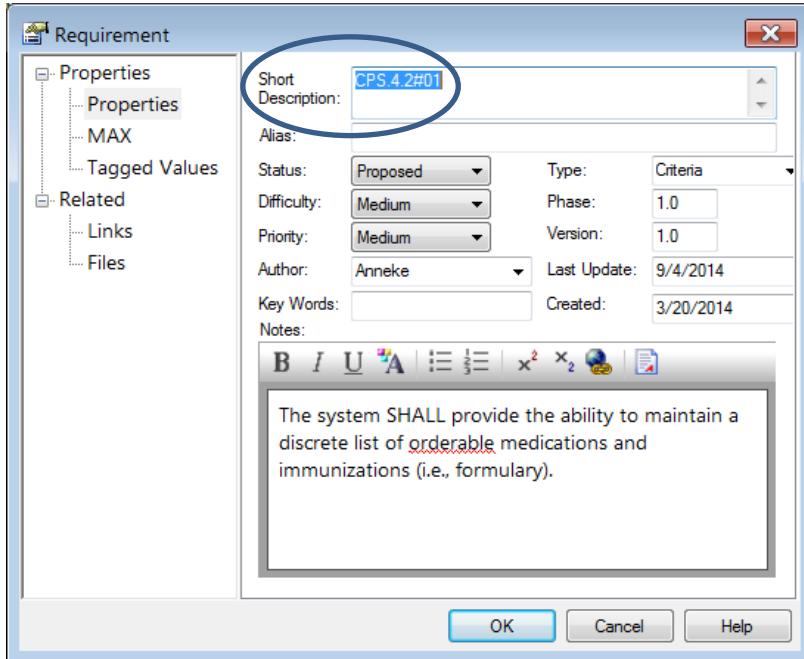


Figure 97. Properties window of the moved criterion.

If the criterion is moved to another section, then you can apply the correct Section to the criterion. Perform the following steps:

- Open the Properties window as described before.
- Now you can change the ID of the section. The criterion will get the ID of the new section.
- The corresponding color of that section is changed now.

If we use the example as described before and change the section ID, the criterion will get the color of that new section. If you double click on the criterion in the diagram, the criterion form will be in the right color of the new section. See figure 98. Of course, in our example above the criterion is linked to a function in CPS. Here the example is CP.4.1#99.

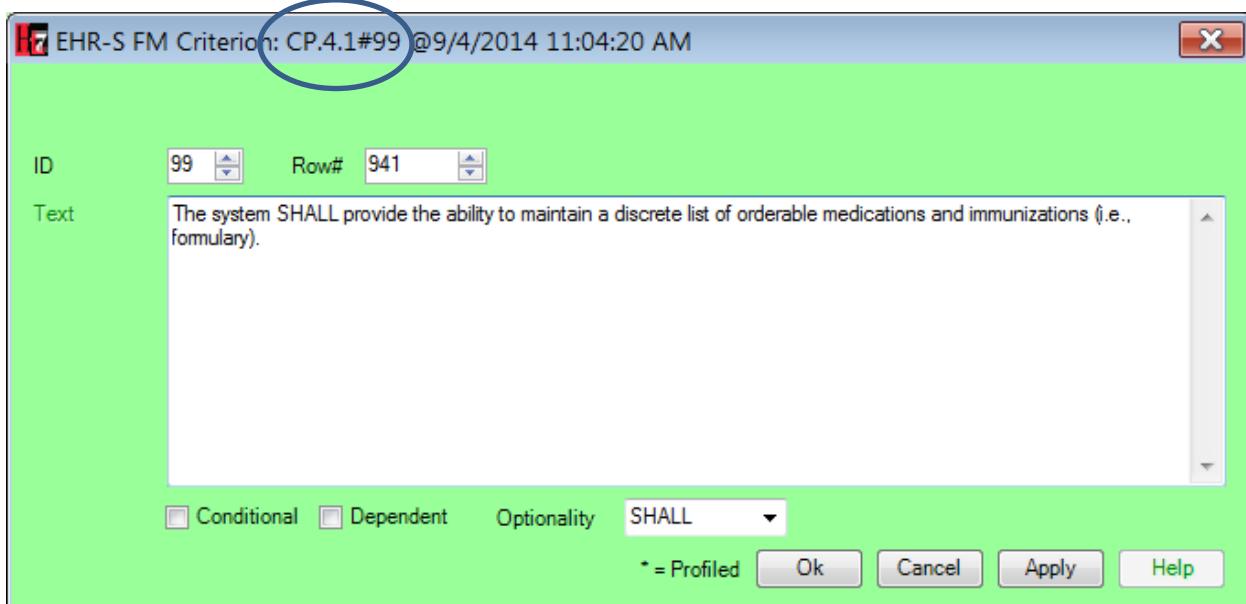


Figure 98. The criterion moved to another section.

In the Project Browser you can now move the criterion to the new function by selecting the criterion and drag it to the right place in the model. First you model the movement of the criterion to the new function. Second you move the criterion in the list of functions and criteria in the Project Browser.

The movement of a function is done in the same way. However, the parent to where the function is moved is the target. The description of how to move a function to a new parent is described below.

Move a Function from one parent to another

To move a function from one header to another header you need to be aware for some issues:

- The ID of the function
- The associations that goes with the function
- The corresponding color of the section if you move the function from one section to another section.

It is not likely that a function is being moved from its original place in the Functional Profile. This is because of its alignment with the Base Model from which the Functional Model is derived. So the use case that is used for the movement of a function is the one when the user is working on a new release of the Functional Model. A result of the ballot reconciliation can be that the function has to move to another parent and/or section. The principle of the movement is the same as the movement of a criterion. However, now you need to select the new parent for the function that you want to remove.

For example:

You want to move function CP.7.1 Present Guidelines and Protocols for Planning Care from Header CP.7 Manage Future Care to the new parent Header CP.6 Manage Medication, Immunization and Treatment Administration. *Remember, it is just an example!*

- Create a diagram for CP.6.
- Select the function CP.7.1 in the traceability view of the function and act the same as described for the movement of a criterion.
- Use the connector Aggregation to connect the function to the parent.
- The result is shown in figure 99.

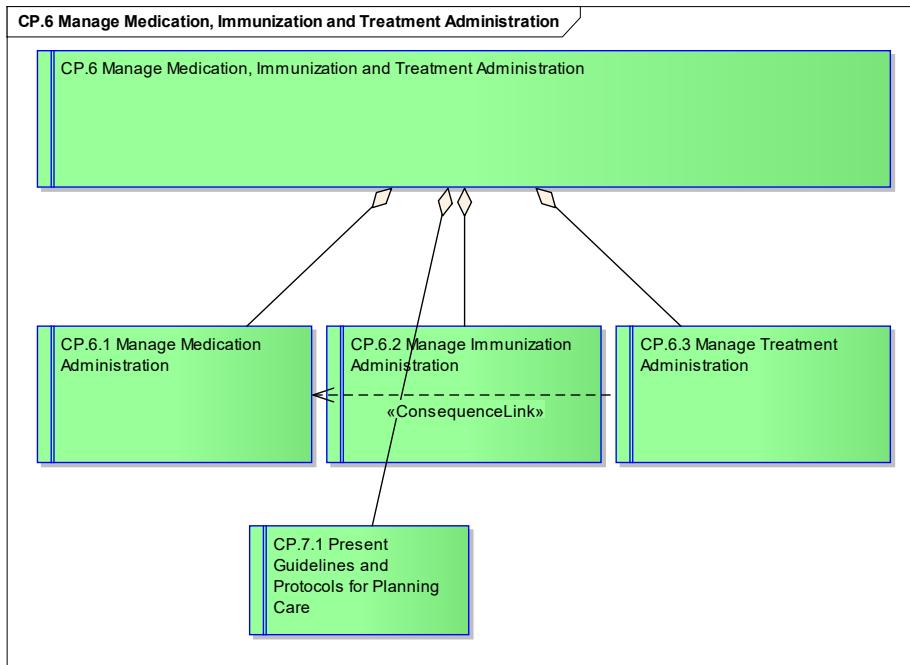


Figure 99. Movement of a function, diagram view.

Now you can change the ID of the function in the same way as for the criterion. See description above. If the function was moved to a parent in another section, the color of the function form will change automatically as you change the ID of the function.

Also, you can move the function to the right place in the Project Browser in the same way as described for the criterion.

Move a section

If you want to change the order of the sections in the Functional Model or Functional Profile you can use EA to do that. Open the eap of the model/ profile and go to Project Browser. In the Project Browser you

find arrows to move an element up and down in the model. This arrows you used for moving the criterion or function into the right place in the model. See figure 100.

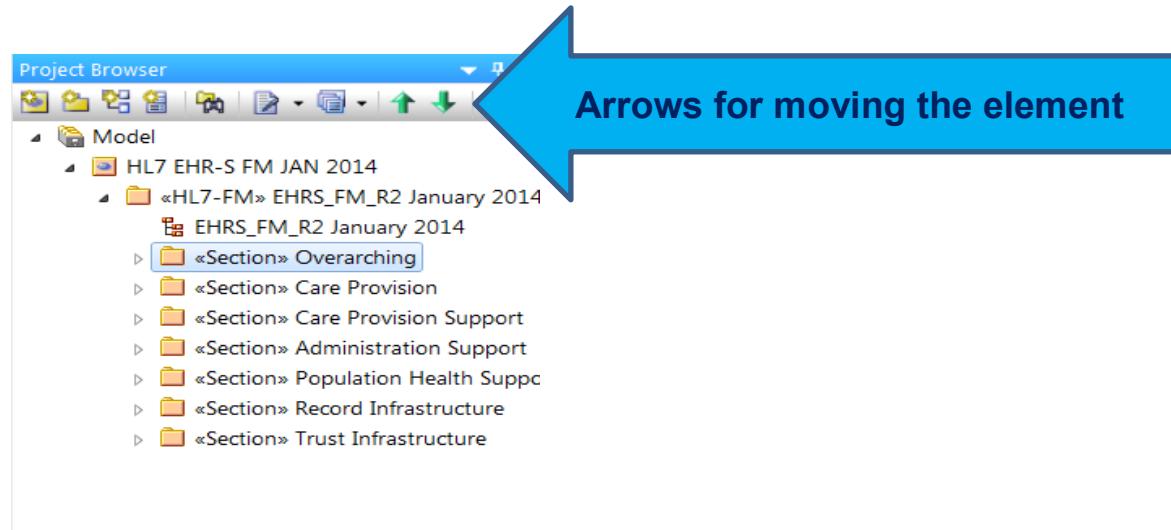


Figure 100. Move an element using the Project Browser in EA.

8.13. Export a section of the EHR-S FM using RTF

For the development of a Functional Profile several stakeholders are involved to review the EHR-S FM or an existing Functional Profile. The goal of the review is to determine if and how a function and its criteria shall be included in the Functional Profile. The review can take place in several ways.

1. Review with the EHR-S FM Tool

The most ideal way is to use the EHR-S FM tool and include or exclude functions and criteria right away when reviewing them. If adjustments are needed, this can be done right away or in a later stage. In the ChangeNote a remark can be made for this. You can also use the EA functionality Project Status for keeping track of tasks still to do. However, the project facilitator, the person who can work with the tool, needs to be present to do so. Is the project facilitator not able to attend such a meeting, for review purposes an export in a table can be made.

2. Review using an export in RTF (Rich Text Format document)

An export in EA of a part of the EHR-S FM R2 can be made. The assumption is that you want to create a new Functional Profile derived from a Base Model. The Base Model is reviewed by the project team. If you want to use an export for that review you need a template for the RTF export. To import this template and then export a RTF document, follow the next steps:

- Select the project of which you want to have an export.
- Select Document in the top navigation of EA. See figure 101.



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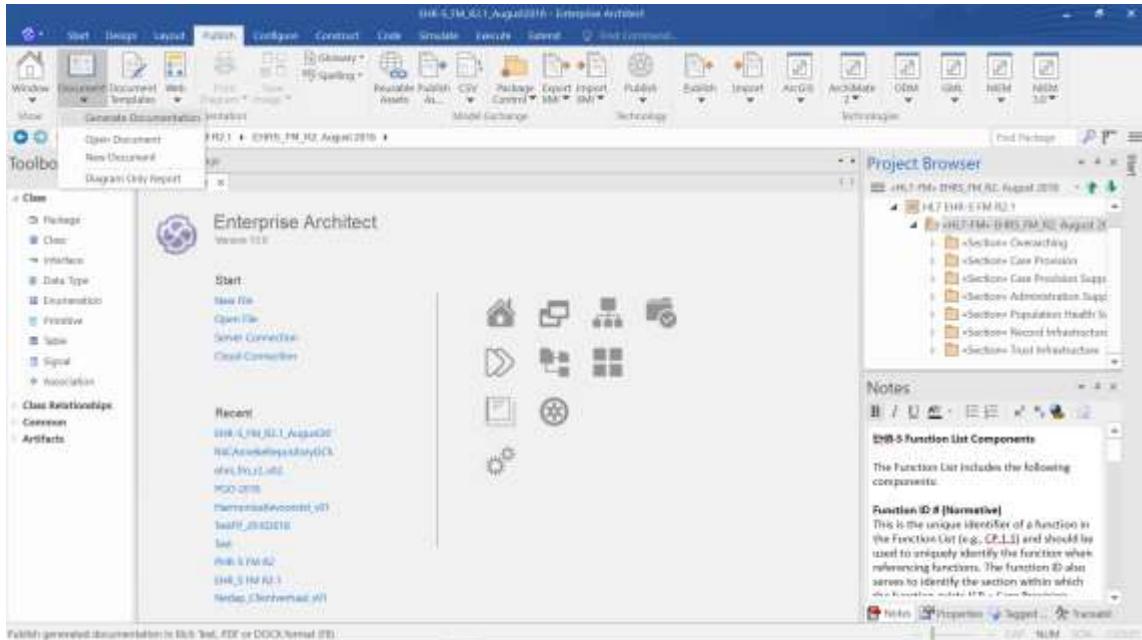


Figure 101. Generate documentation in EA.

- A window pops up (see figure 102) in where you can import the template you want to use for the export in a document.
- Select 'New Template', see figure 102.

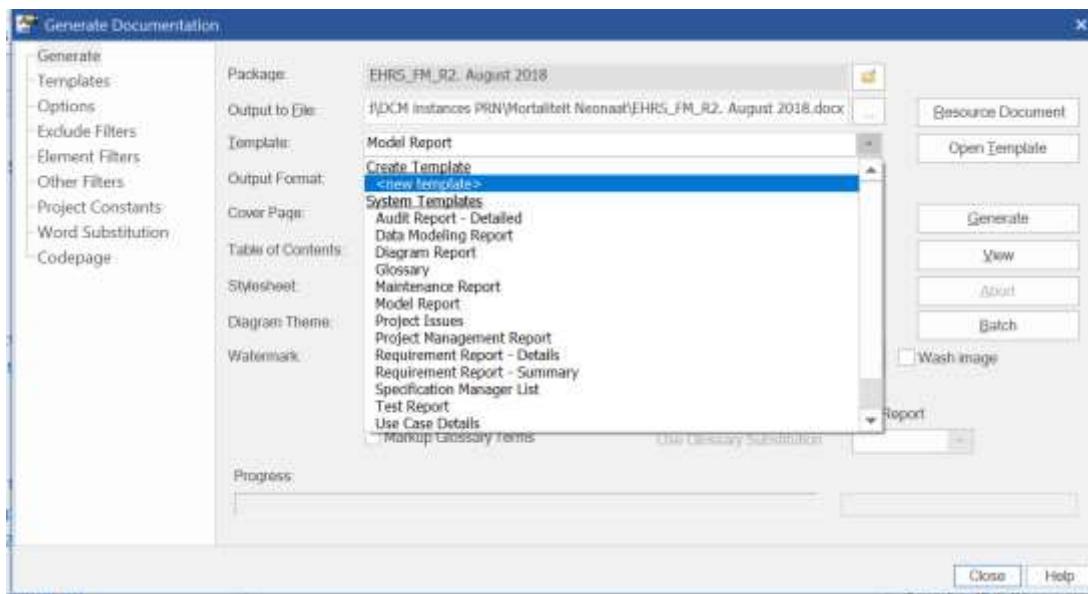


Figure 102. Selection of a template.



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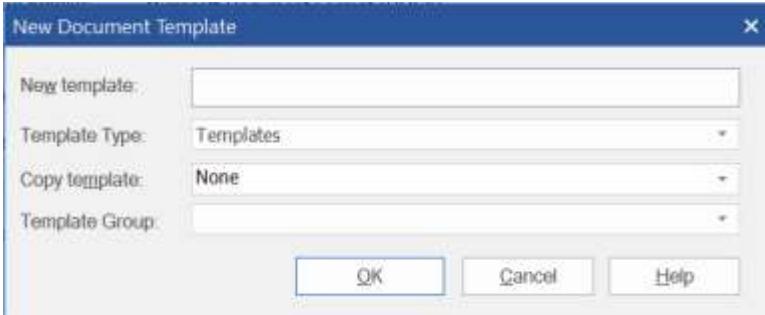


Figure 103. Window Generate Documentation.

- Type name of new template and click OK.
- In EA the window for creating a template or import a template for a document opens. See figure 104.

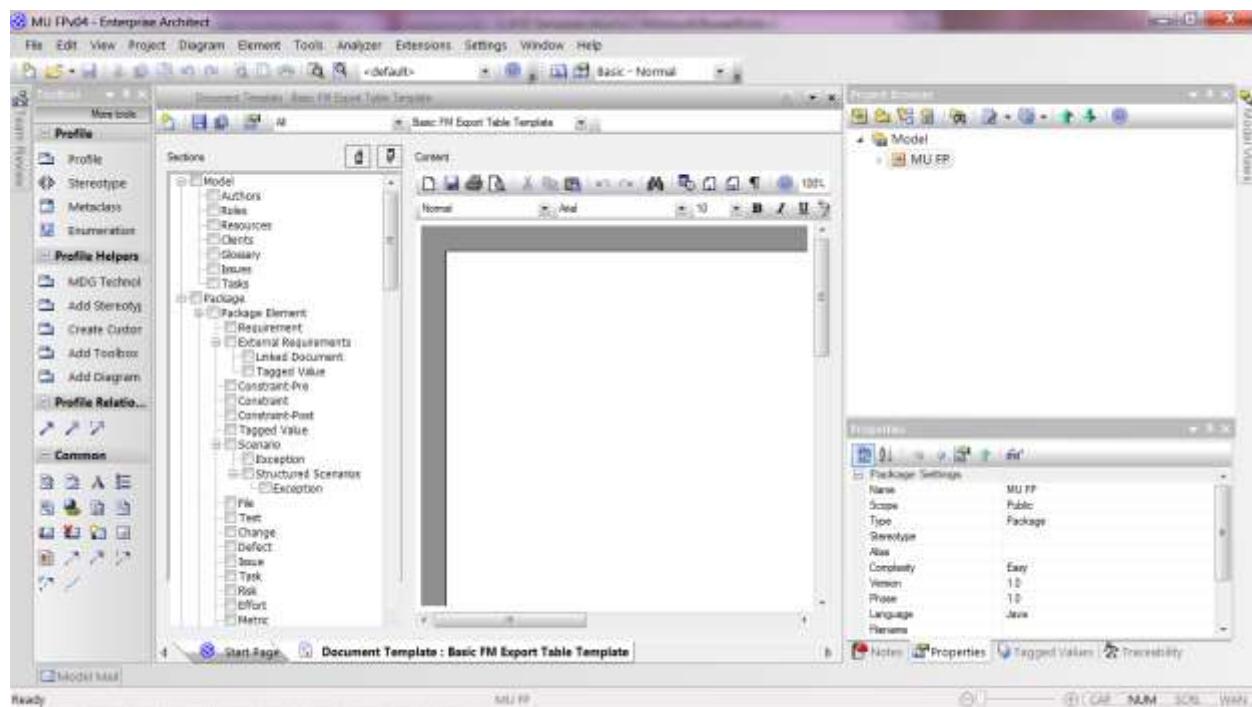


Figure 104. Document, template definition.

- Right click on the blank document field.
- Select File and then Import. See figure 105.
- The Window Explorer opens. Select the folder in where you saved the template (in this case the template with the name 'Basic FM Export Table Template') and click OK. You will see that the blank document field is now filled with the definition of the template. See figure 106.
- **NOTE:** the template needs to be imported in every eap file in where you want to have the template. So if you want to have the template in your eap in where you want to create a new Functional Profile, select that eap either in Windows Explorer or in EA (Start page, Projects).



Manual HL7 Profile Designer Tool

In other words, if you are creating multiple new Functional Profiles and you want to use the template, you need to import this template in every project you created for every new Functional Profile.

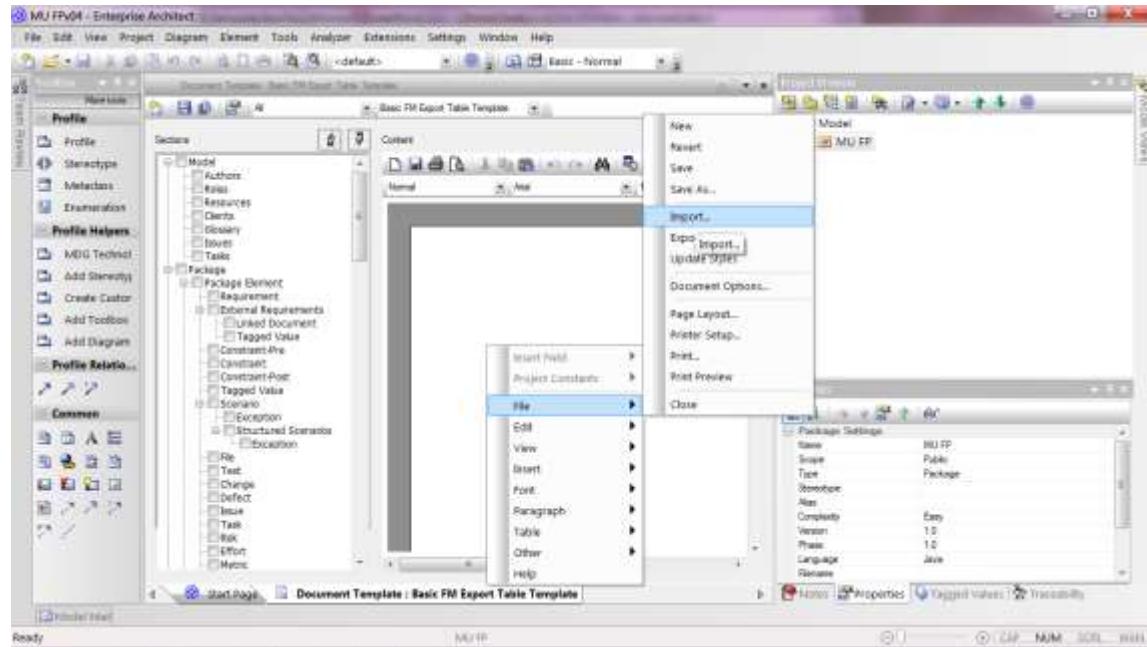


Figure 105. The import of an existing template.

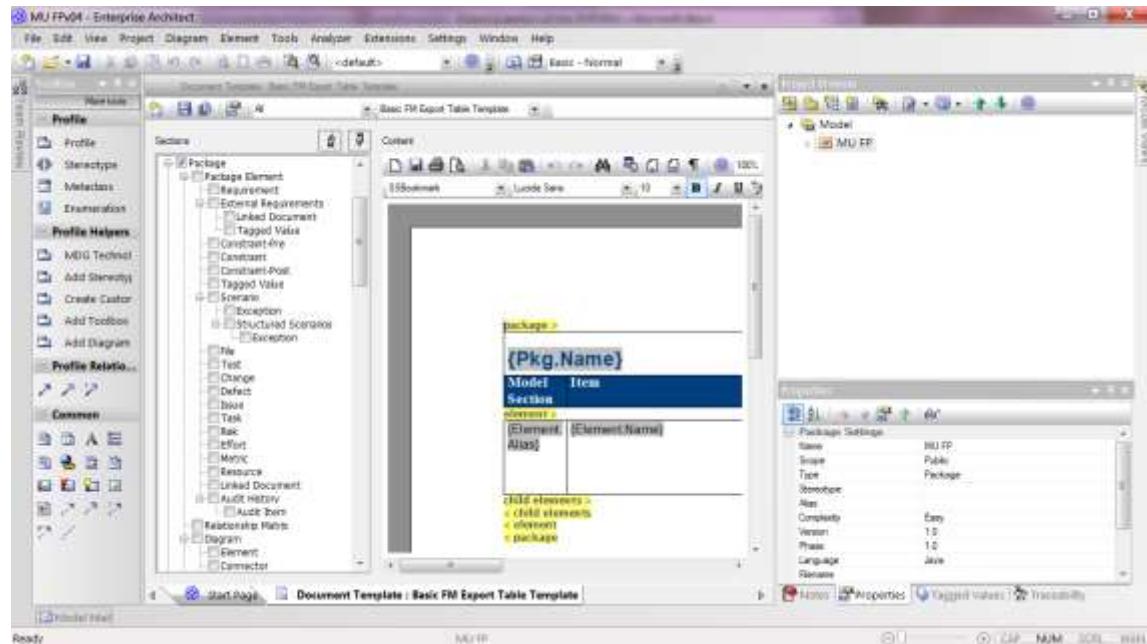


Figure 106. Document Template.

- Don't forget to save the template. See figure 107.



Manual HL7 Profile Designer Tool

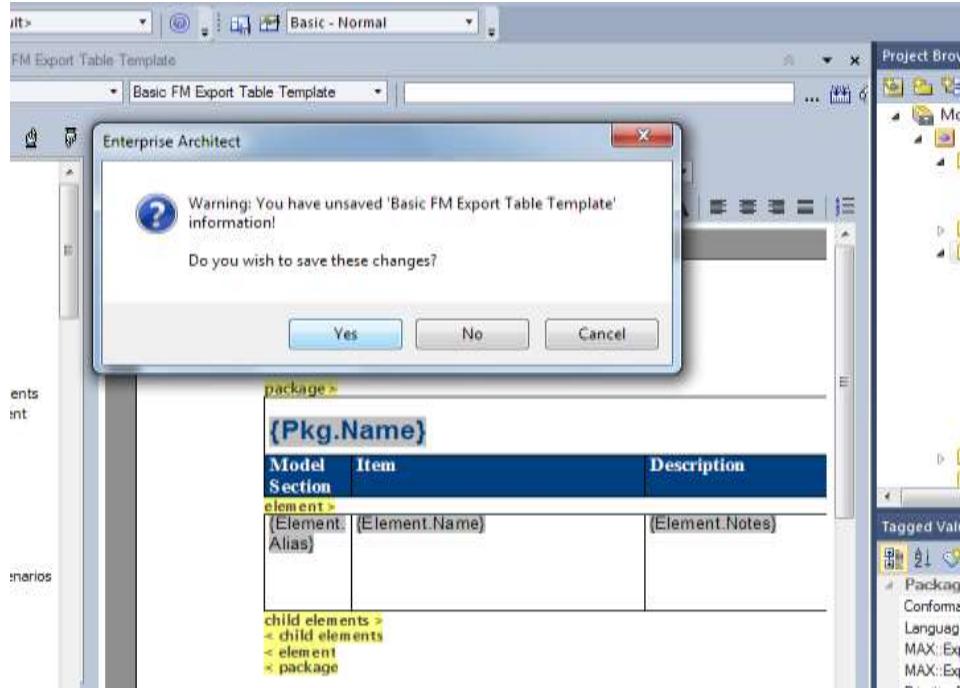


Figure 107. Save the imported template.

- Now you can go and export a part of the Base Model into a RTF with the use of the template.
- Select the section (package level) in the Base Model you want to export.
- Right click. See figure 97.
- Select the template you want to use for the export. See figure 108.
- EA will give you a message saying that the document is successfully exported.
- The export is a table in a document.

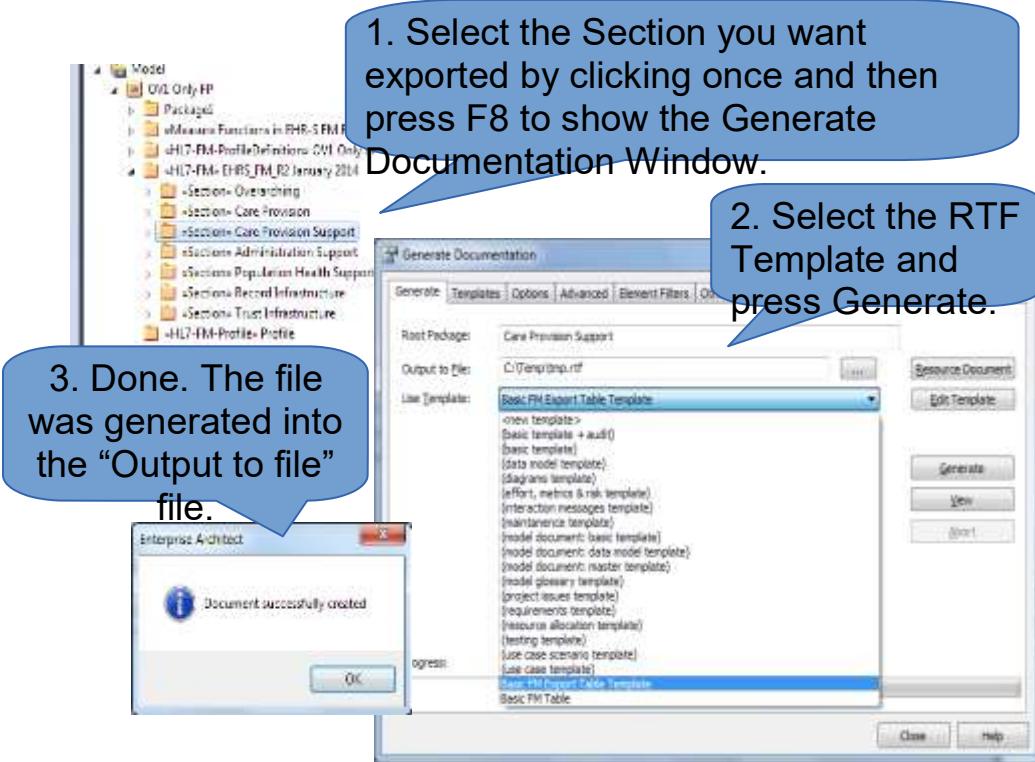
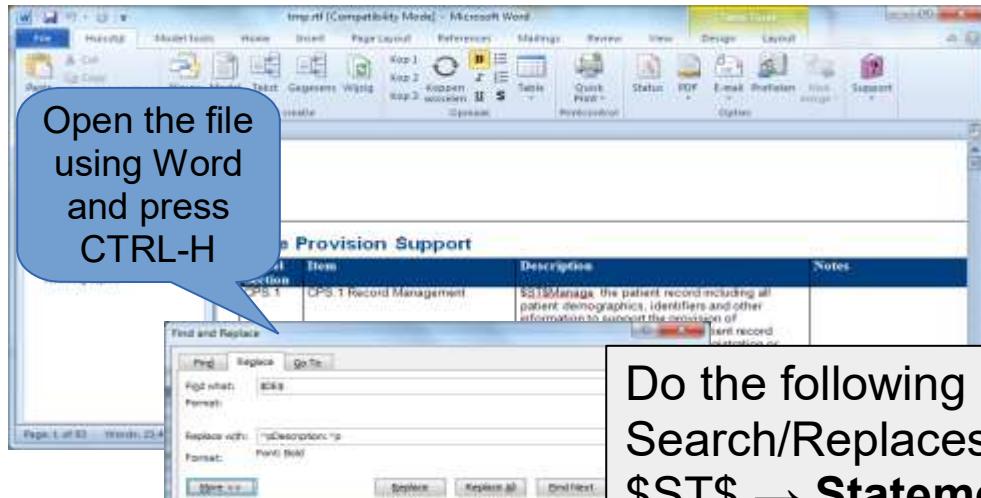


Figure 108. Export of a document.

In the word document there are several non-readable codes. You can cleanup these with the use of Word search/replace functionality.

- Open the export document using Word.
- Use CTRL H to open the search and replace window.
- Do the search and replace actions, figure 109.



Do the following Search/Replaces:

\$ST\$ → Statement:^p
\$DE\$ → ^pDescription:^p
\$EX\$ → <empty string>
\$AC\$ → <empty string>

Figure 109. Use Word Search/Replace to Cleanup

Now you have a word document that you can use in your project team for the review of a part of the Base Model. Decisions and changes that were made in this document you can execute with the Tool to create the Profile Definition.

3. Review on an export of search results

In the Tool it is possible to search for the non-shall criteria in a section. In most Functional Profile types, the criteria with optionality 'shall' will be inherited from the Base Model. The non-shall criteria need review on optionality and text.

- Select a section in where you want to do a search.
- Select Edit in the top navigation and select Search, search in model. See figure 110.



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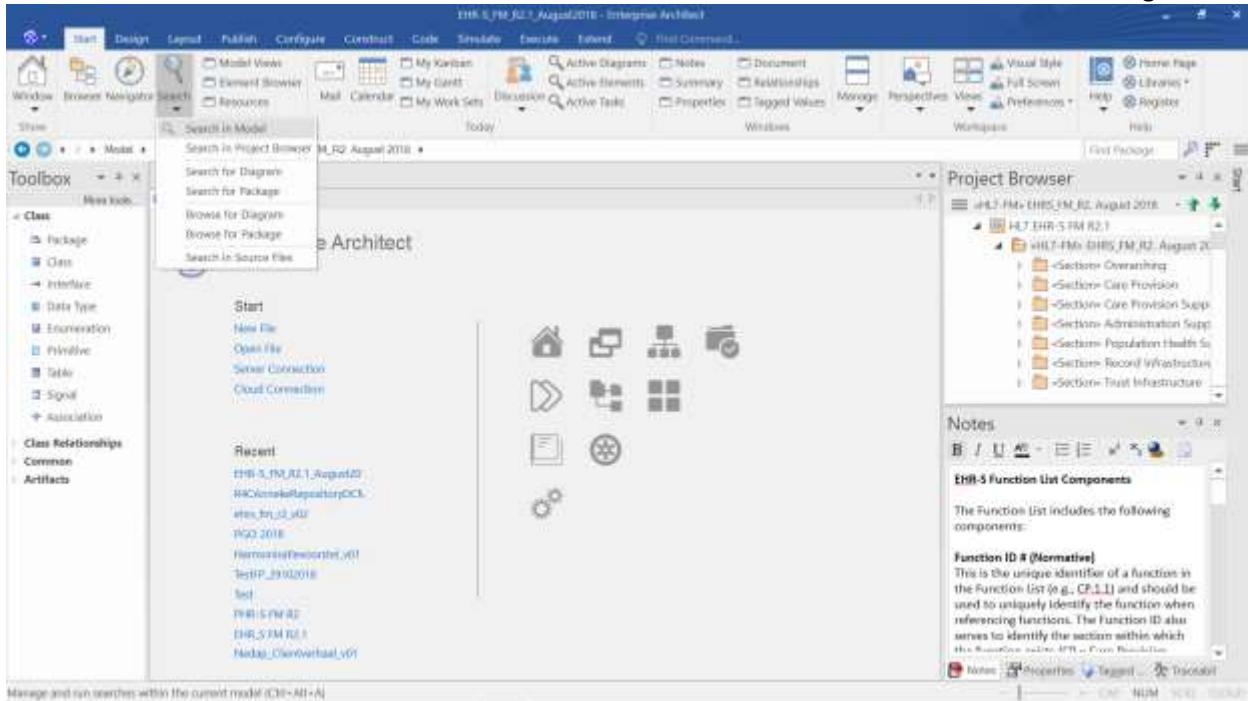


Figure 110. Search in section of Base Model.

- The search window will open.
- Select Find non-shall in the Search Field. See figure 111.
- Select Run next to the Search field.



Figure 111. Search on non-shall criteria.

The search results are shown in EA.

- Select all results.
- Right click and select Documentation and then RTF report on selected items. See figure 112.
- The window Generate documentation will open. See figure 112.
- Follow the same steps as mentioned for figure 112.



Manual HL7 Profile Designer Tool

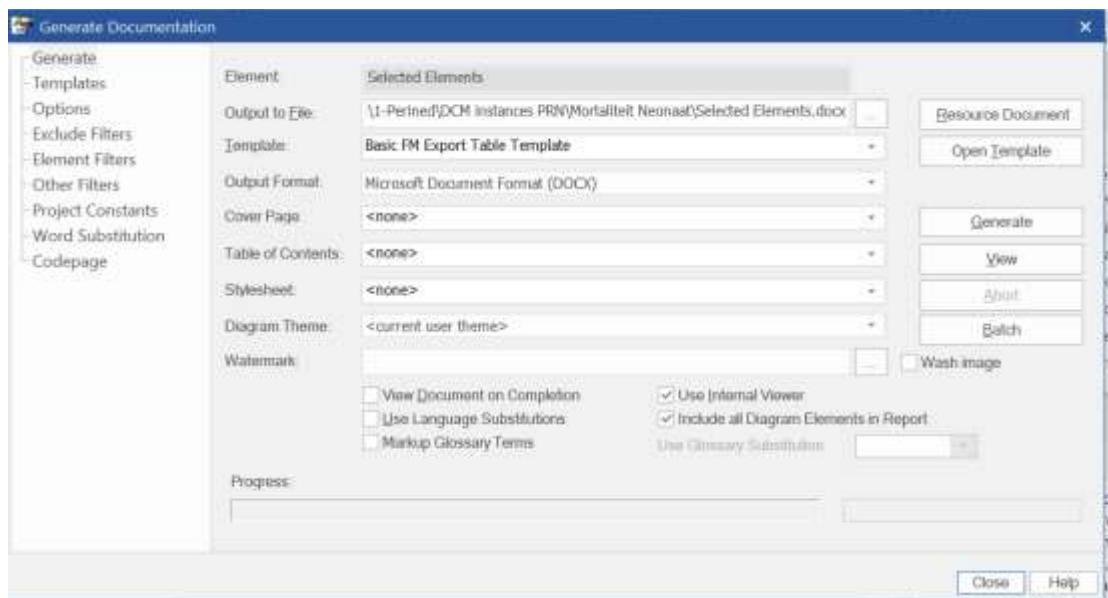
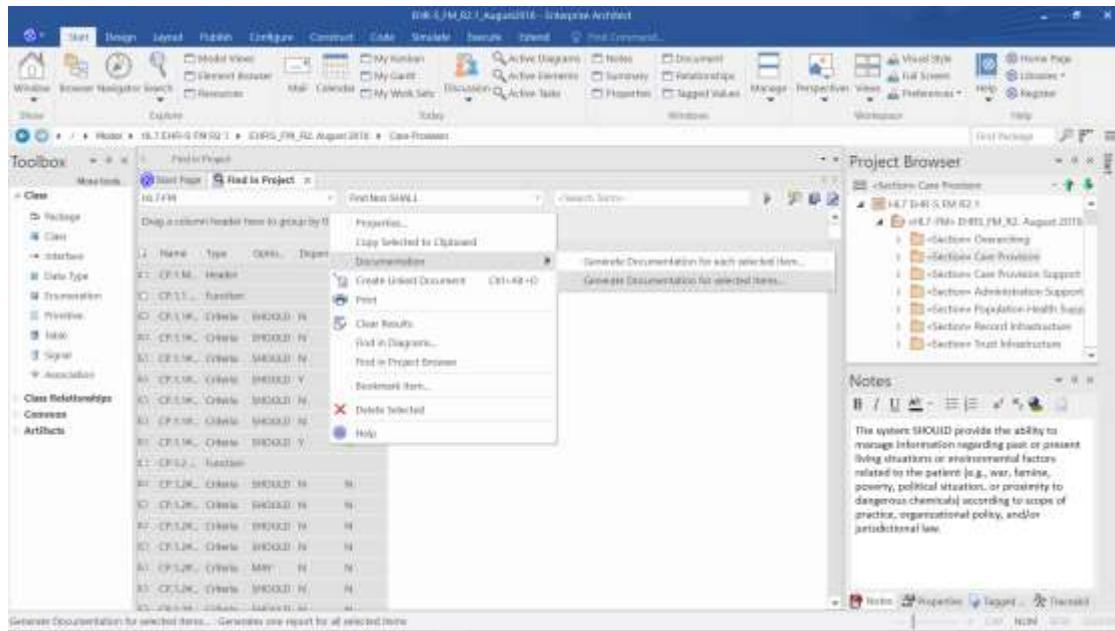


Figure 112. Export on search results with Template.



9 Importing a Functional Model from an Excel spreadsheet: conversion steps

This chapter is about the transformation of an Functional Model that is created in an Excel spreadsheet into a MAX file that can be imported in EA. To support the work with Functional Models, e.g. for balloting or for new releases, an Excel spreadsheet was created in the format of a Template which can be used to import any Functional Model into the EHR Profile Designer Tool, now and in the future. The template is a separate file, available at the file location of the EHR workgroup. The Excel spreadsheet is converted to a MAX file and then included into the tool.

This process requires some technical knowledge in working with the command prompt in Windows. In the explanations the notation <R> will be used. This stands for press the enter button. The Enter button is called Return as well, hence the R.

9.1. The following steps will prepare the Functional Model for import in EA (and for publication)

The result of these steps is a Functional Model in MAX format. This MAX file can be imported into EA. It is also possible to directly use it to create a publication, however, it will miss some validation steps that the HL7 EHR-S FM Profile Designer Tool offers to keep the materials consistent.

1. Use the Excel template for the EHR-S FM from HL7. This Functional Model Import Spreadsheet template is provided so that all required columns are available that facilitate a proper import into EA.
2. Create the Functional Model Content
3. If the FM is already prepared in a free form Excel spreadsheet, convert the free form Functional Model Content into the Functional Model Import Spreadsheet according to the Import Template.
 1. Make sure there is no column or row merging, start by copy - pasting values per cell only
 2. Extra columns are ignored
 3. Check if CC with '??' in de CC# column are present in the resulting file.
 4. Add the comment in the template: CC# SHALL be a number!
 5. Row# should start with '3' and is to refer back from the eap (and publication) to the import sheet.
4. Save the spreadsheet as "XML Spreadsheet Excel 2003" with extension ".excel.xml"
5. Prepare EA
Pre- requisites:
 1. EA v13.x installed
 2. MAX installed : <https://app.box.com/s/ndhk4hn2adzcho42sus>
 3. SaxonHE9-7-0-4N-setup installed per MAX instruction
6. Create a new Project in EA:

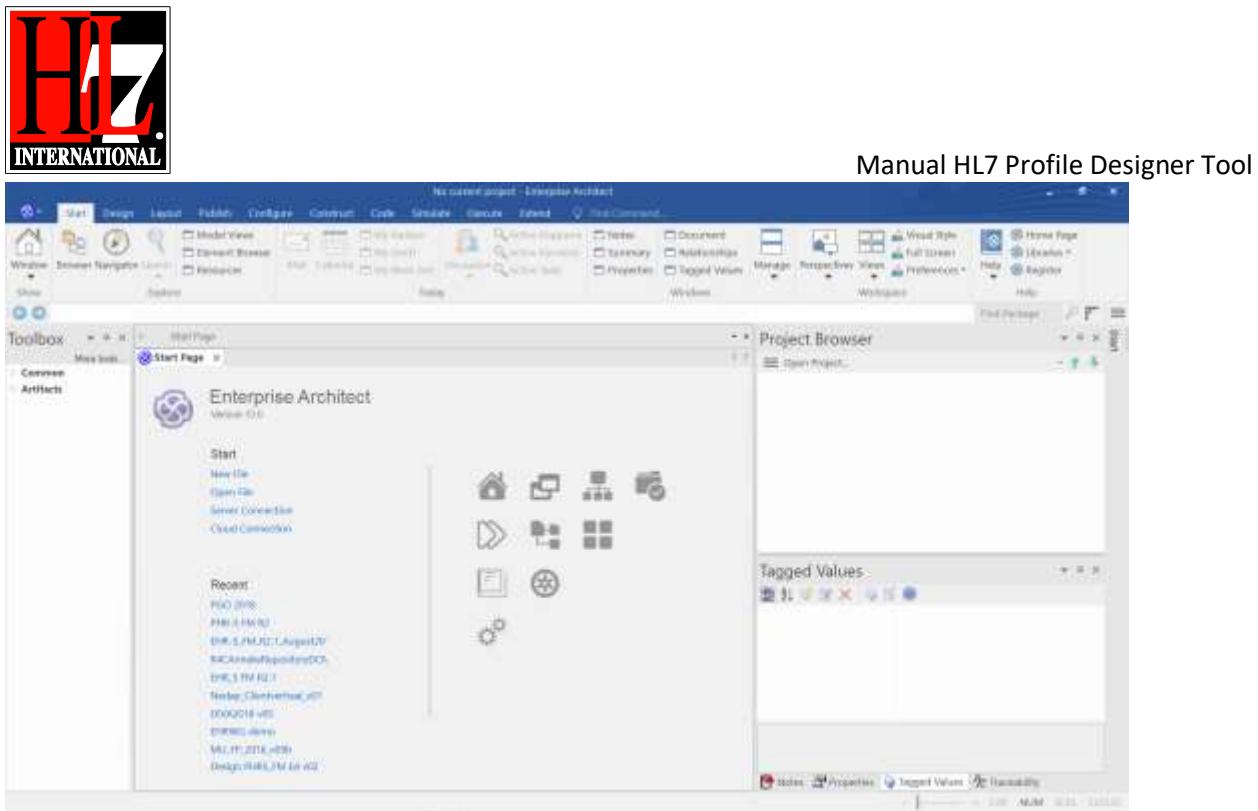


Figure 113. Starting a new file in EA for a new profiling project.

The Windows Explorer opens, choose the directory you want to save the project in, give the project a name. A Model Wizard will be opened by EA. Just click on Cancel. See figure 114 below.

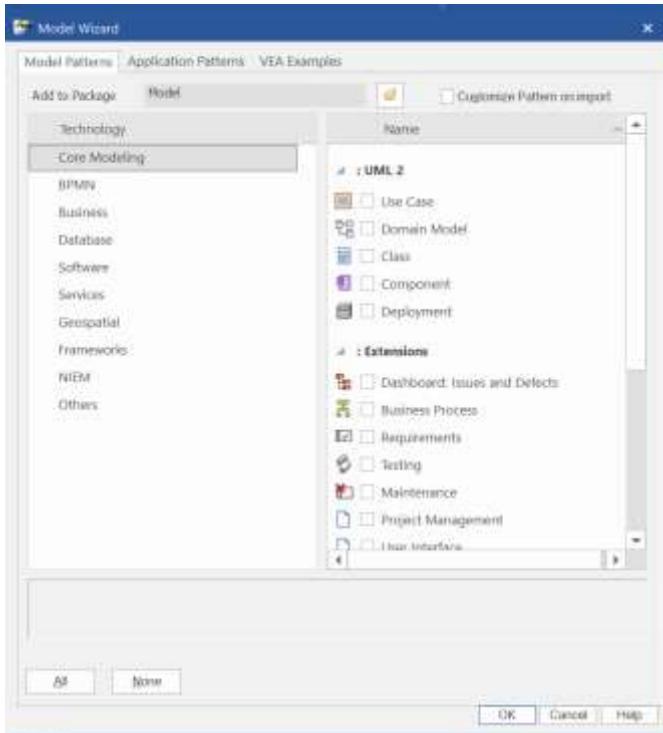


Figure 114. The model wizard in EA.



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In the project browser of EA a Model was created. See figure 115.

Add a View by right click, Add and choose View. See details in figure 115.

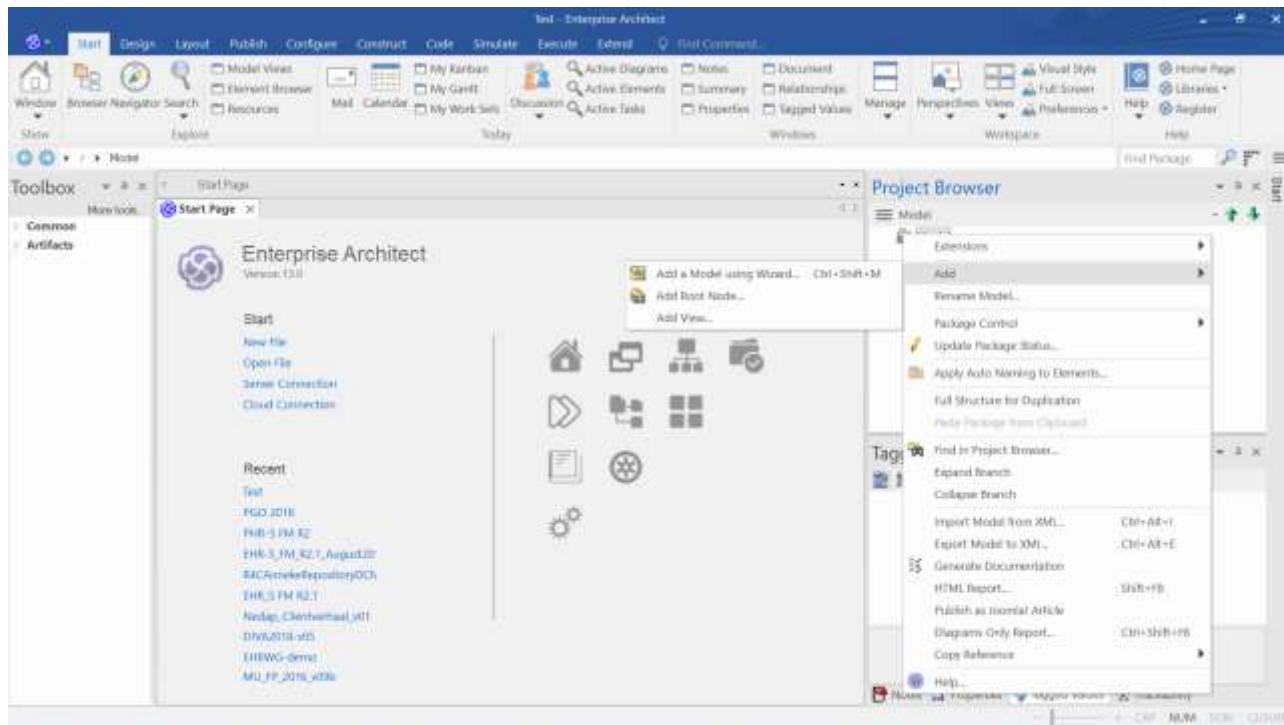


Figure 115. The EA project browser where a new model can be added and a view can be created.

Create the new View, Name it and choose Simple. Click OK. See figure 116.



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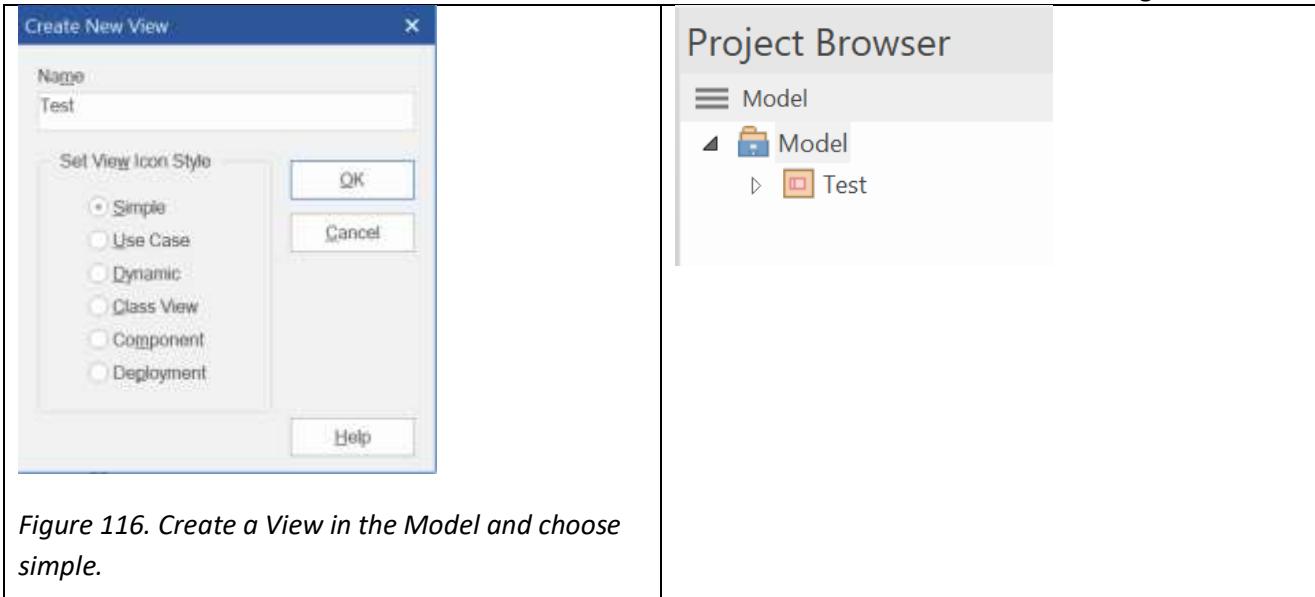


Figure 116. Create a View in the Model and choose simple.

9.2. Use the Command Prompt

The next step requires you to work at the windows command prompt. This will be explained step by step below.

Go to the Windows logo left under on your screen. (Figure 112)



Figure 117. The Windows logo.

Type cmd. The Command Prompt will appear. See figure 118 below.

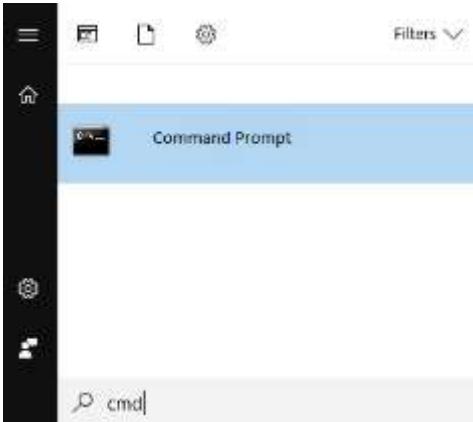


Figure 118. The Command Prompt C:



Choose Command Prompt as indicated in figure 118.

A black screen with C: as shown in figure 119 will appear.

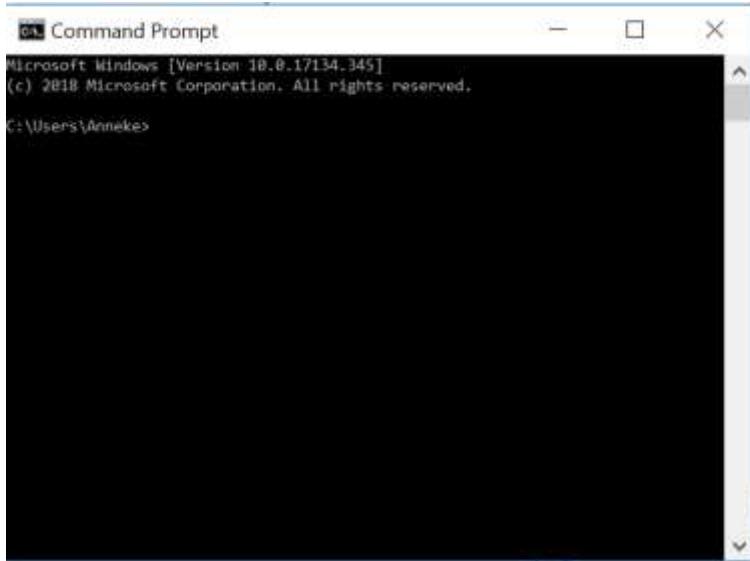


Figure 119. The Command Prompt C: with additional directories.

Move to C: if that is not the directory where you start. E.g. via giving the command cd.. and press <R>. Repeat this until you are in C:

To check if the right version of Saxon is installed use the file path where Saxon is installed. In this example it is in C:\ProgramFiles\Saxonica\SaxonHE9.7N\bin However, you might need to search to find the right directory Saxon is installed (which is much easier done via the Explorer program under windows). Use the cd command in the Command Line to move to the right directory.

In the example we have to go to drive D: because the files that are needed for the transformation are on D:

9.3 Work in Command Prompt

The next three steps explain what to do at the Command Prompt. The results will be a file in MAX format containing the Functional Profile.

At the Command line call XSLT and type the following:

```
transform -s:"PHR_S_FM 20180819.xlsx" -xsl:fm-excelxml2max.xslt -o:"PHR_S_FM  
20180819.max"
```

The max file of the FM is created in the same folder

```

C:\Program Files\Saxonica\SaxonHE9.7N\bin>transform -s:"PHR_S_FM 20180819.fods" -xsl:fm-fods2max.xslt -o:"PHR_S_FM 20180819.max"
Error at id on line 161 column 14 of fm-fods2max.xslt:
java.io.FileNotFoundException: Access to the path 'C:\Program
Files\Saxonica\SaxonHE9.7N\bin\PHR_S_FM 20180819.max' is denied.
java.io.FileNotFoundException: Access to the path 'C:\Program Files\Saxonica\SaxonHE9.7N\bin\PHR_S_FM 20180819.max' is denied.

C:\Program Files\Saxonica\SaxonHE9.7N\bin>:

D:\Box Sync\2-PHR-S FM Toolaanpassing 2018\Deliverable 4>transform -s:"PHR_S_FM 20180819.fods" -xsl:fm-fods2max.xslt -o:"PHR_S_FM 20180819.max"

D:\Box Sync\2-PHR-S FM Toolaanpassing 2018\Deliverable 4>
    
```

*Figure 120. The command prompt illustrating the use of Saxon to convert the *.fods file into a max file using the fods to max XSLT.*

The resulting file is a MAX formatted Functional Profile, which normally gets the date of the transform in the filename. The example shows a PHR S Functional Model transformed on the 19th of August 2018. The next step is to import this into EA. You can close the Command Prompt (type exit <R>)

Import the MAX XML file “PHR_S_FM 20180819.max”. Importing the above max file into EA and this will show the Functional Model see figure 116. Now this is done the transformation is completed and the Functional Model is available in EA. When done properly, the resulting file would be similar to PHR_S_FM 20180819.xlsx

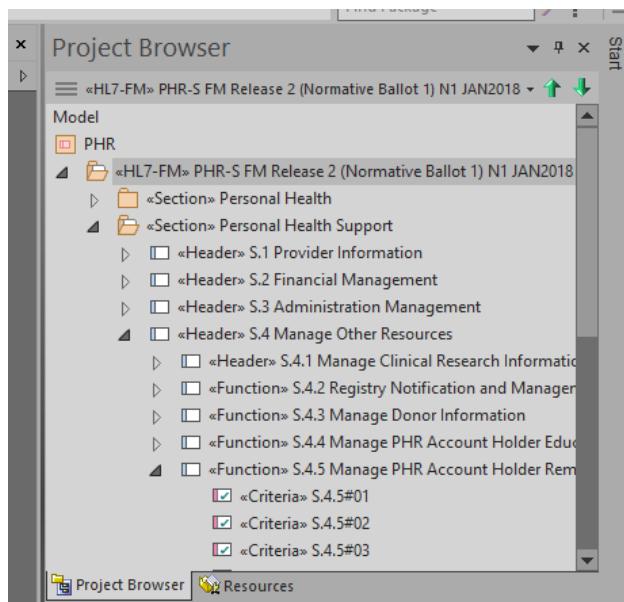


Figure 121. Import the above max file into EA and this will show the Functional Model.



10 Running Functional Model and Functional Profile Publication

10.1 Introduction

Now you created a new Functional Profile, you want to make a publication, so others can use the Functional Profile. For the creation of the publication you need the Model Automated eXchange (MAX) or MAX file of the Compiled Profile. -This MAX file is output of the Enterprise Architect (EA) EHR-S FM Profile Design Tool. That tool is an extension to EA and allows to specify the Functional Model and Functional Profiles in Unified Modeling Language (UML).

So first, in EA, from the Profile Definition you need to compile the Functional Profile. See in EA Learning Center section 'Create a Functional Profile', chapter 8.8. If all the steps in the EA extension are done, you can save that in a MAX format file. Once that step is done, you can move to create a publication. To do that, another set of software packages is necessary.

In this guide we give guidance on how to create the publication from the MAX file. In the process of creating the publication several software is used. Which software and where to find it is described below.

10.2 Use of Model Automated eXchange (MAX)

The source artifacts of the Functional Profile(s) are XML files in the specific publication format for HL7, this is called MAX. The goal of the HL7 MAX toolkit project is to enable the import, export, and round-tripping of a user defined subset of model elements specified in a UML modeling tool. XMI is the default definitive means by which models and model packages are imported and exported by UML modeling tools. MAX is intended to support capabilities not easily supported by XMI alone. Specifically, MAX addresses the desire to limit a model import/export to a subset of model elements and element features that possibly span model package boundaries and the ability to import/export using a user defined data structure. In phase one of MAX the only UML modeling tool being addressed is Enterprise Architect from Sparx Systems and the only import/export dataset definition is MS Excel. Because the EHR-S FM Profile Design tool uses EA and UML it was obvious to use MAX as the format for import and export of the Functional Model and Profile and collaborate with the MAX toolkit project.



10.3 Installation

The publication process is built on top of Java to provide cross-platform execution. Your system will need a base Java installation (either Java 6 or Java 7 should be acceptable; the author has only tested using Java 7).

For Mac users:

http://www.java.com/en/download/help/mac_install.xml

For Windows:

http://www.java.com/en/download/help/windows_manual_download.xml

If you are running a Linux/Unix based platform, it is assumed that you will be able to locate the appropriate Java packages and install using the designated package management system for your chosen Unix/Linux variant.

The standard Java processing chain for XML is utilized to produce the publication HTML and PDF files. The components are the standard pieces used by Java installations and have simple and straightforward installation instructions. The components have also been kept to a minimum to simplify installation.

The publication process is controlled and executed using ANT, the core build tool for Java development (<http://ant.apache.org>). The core of the publication process is the conversion from the MAX XML export from the Enterprise Architect Functional Model/Profiling tool into XHTML and XSL:FO (both are also XML formats). For this second step FOP is used.

This conversion from MAX is done using XSLT. ANT provides for execution of XSLT using XALAN (an XSLT 1.0 processor). Next, the resulting transformed XSL:FO file is converted into PDF using Apache FOP (<http://xmlgraphics.apache.org/fop/>).

ANT and FOP are installed from:

For Windows:

ANT: <http://ant.apache.org/bindownload.cgi>

FOP: <http://xmlgraphics.apache.org/fop/download.html>



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For Mac OS X:

Install Homebrew: <http://brew.sh>

Then in a Terminal window:

```
>brew install ant
```

```
>brew install fop
```

Once installed, verify that all of the tools are ready to operate with the following command:

```
>ant -version  
Apache Ant(TM) version 1.9.4 compiled on April 29 2014  
  
>fop -version  
  
FOP Version 1.1
```

The results (and version numbers) do not need to be identical to the above example but ANT 1.8 and FOP 1.1 should be the minimum.

Note: The build scripts also provide the formats for the creation of the CSS file that defines the formatting characteristics of the HTML document for the Functional Profile. The CSS file is produced using SASS (<http://sass-lang.com>), this tool is only needed when making changes to the CSS. To make changes to the CSS, the person must be familiar with Web Layout techniques, CSS3 (<http://www.w3.org/TR/2001/WD-css3-roadmap-20010523/>) and the SASS (specifically the scss) implementation of CSS.

Once the basis is installed get the publication tooling zip file via the EHR WG co-chairs. Extract them to work directory. The result will be a directory structure like this:

```
build.xml  
ehr-s-fm-ballot.mif  
fo/  
fop.xconf  
functional-model.css  
gen-refs.thor  
html/  
pdf/  
publication-base.properties  
source/  
transforms/  
  
.source:  
ehrs-fm-ballot.mif  
ehrs-fm.max  
ehrs-fm.max.backup
```



```
functional-model.scss
```

```
./transforms:  
max-fm2csv.xsl  
max-fm2fo.xsl  
max-fm2html.xsl  
max-fp2fo.xsl  
max-fp2html.xsl
```

Make sure that after extraction you edit the publication-base.properties file to reflect the directory where you installed fop. The directory is in the “fop.home” line. P.S. ignore the “sass.home” line.

10.4 Producing Publication Artifacts

The ANT script has been created to target a specific artifact such as the EHR-System Functional Model or the Meaningful Use Functional Profile. These targets are formalized within the script as EHR-S-FM and EHR-MU-FP and are executed with:

```
>ant EHR-S-FM
```

```
<the amount of output depends on which targets need to be generated>
```

10.5 Adding a new Publication Target

There are three things required to publish a new functional model or profile: the MAX file with content, an HL7 v3 ballot Model Interchange Format (MIF) file and a new target in the ANT script (build.xml). The description of each component follows:

1. The MAX source. All source files are placed in the source directory. This file must have a file extension of .max
2. The ballot info file. This file is also located in the source directory and must have the same base name as the MAX file (from #1) with –ballot appended. This file must have a file extension of .mif. This file uses the HL7 Model Interchange Format (another XML format) to describe ballot characteristics such as authors, additional preamble text, and formal title.
3. The new build target. The build.xml file will need to be updated to include the Functional Model or Profile being produced. The easiest method is to copy either the EHR-S-FM target or the EHR-MU-FP target, change the target name, and change the file.base-name.

**For a Functional Model:**

```
<!-- =====
target: EHR-S-FM
===== -->
<target name="EHR-S-FM" description="Build the output artifacts for the EHR-S Functional Model (PDF, HTML, EXCEL data)">

<property name="file.base-name" value="ehrs-fm"/>
<antcall target="artefacts">
    <param name="is-fm" value='true'/>
</antcall>

<antcall target="pdf">
    <param name="file.fo-transform" value="${dir.xsl}/max-fm2fo.xsl"/>
    <param name="file.max-file" value="${dir.source}/${file.base-name}.max"/>
    <param name="file.ballot-file" value="../${dir.source}/${file.base-name}-ballot.mif"/>
    <param name="file.additional-text" value="" />
    <param name="file.fo-file" value="${dir.fo}/${file.base-name}-iso.fo"/>
    <param name="file.out-file" value="${dir.pdf}/${file.base-name}-iso.pdf"/>
    <param name="format.generate-iso" value="true"/>
</antcall>
</target>
```

For the above FM the following files are expected:

source/**ehrs-fm.max**
source/**ehrs-fm-ballot.mif**

And the resulting files are:

fo/**ehrs-fm.fo**
fo/**ehrs-fm-iso.fo**
html/**ehrs-fm.html**
pdf/**ehrs-fm.pdf**
pdf/**ehrs-fm-iso.pdf**



For a Functional Profile:

```
<!-- ======  
 target: EHR-MU-FP  
 =====-->  
<target name="EHR-MU-FP" description="Build the output artifacts for the EHR System  
Functional Profile for Meaningful Use (PDF, HTML)">  
    <antcall target="artefacts">  
        <param name="file.base-name" value="ehr-mu-compiled-fp"/>  
        <param name="is-fm" value='false'/>  
    </antcall>  
</target>
```

For the above FP the following files are expected:

source/**ehr-mu-compiled-fp.max**
source/**ehr-mu-compiled-fp-ballot.mif**

And the resulting files are:

fo/**ehr-mu-compiled-fp.fo**
html/**ehr-mu-compiled-fp.html**
pdf/**ehr-mu-compiled-fp.pdf**

4. The build process expects a directory structure identical to the current structure, the build.xml in the root directory, a sub-directory called source with the MAX and the ballot files, an fo sub-directory, an html sub-directory, and a pdf-sub-directory.

**Note! All the file names are
only for illustration purposes.**



Appendix 1. Anticipated Uses

This appendix describes the different uses of the HL7 Profile Designer Tool. Each use is explained using a use case description.

Anticipated Use: read/ browse and search the FM

Although a user can read the FM in any given publication format of the FM, such as html or pdf, he can also read the 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 FM by using the search functionality of Enterprise Architect.

How the user can read and search the FM in Enterprise Architect is described in this manual.

Anticipated Development Approach: maintenance of the FM

Given the complexity of the FM the tool will be used for the maintenance of the FM. In particular it will be used producing ballot materials and carrying out the activities as decided during the ballot reconciliations.

➤ ***Use case 1. Minor adjustments to the text of the FM.***

In the Profile Designer Tool the EHR-S FM R2, R2.0.1 and R2.1 are included. Also several functional profiles were created with the tool. The experiences shows that typo's, inconsistencies and the use of wrong verbs are part of FM and FP development. The tool can be used to make corrections in the FM and/or FP and to generate the publication artifacts in a consistent manner.

➤ ***Use case 2. Development of a new release***

Anticipated Development Approach: development of a new release of the FM

When the workgroup decides to create a complete new release of the FM, the tool can be used to support this. It is envisioned that new sections, headers, functions and conformance criteria will be changed, removed and/or added to the EHR-S FM. If this is required, the tool should facilitate this development. It is anticipated that the validation rules check against the design principles of the FM. If there are fundamental changes in the design of the 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.

How the user can develop a new release of the 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 manual.

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 Profile Designer Tool is going to be used for the development of these Functional Profiles. Functional Profiles designate a subset of functions from the FM for use in specific care settings (e.g. Behavioral



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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.

Anticipated Development Approach: maintenance of a functional profiles

In future projects this could be added.

Anticipated Development Approach: translations and their maintenance

In future projects this could be added.



Appendix 2. Enterprise Architect as prerequisite

1. Getting Enterprise Architect

Sparx has offered to supply Enterprise Architect licenses to HL7 International members working on HL7 projects. Please go to the HL7 website for further instructions.

Individuals wishing to use Enterprise Architect for HL7 projects can download the software at <http://www.sparxsystems.com.au/products/ea/>

Most functions are available in the Enterprise Architect Professional edition. However, some functions will only work with Enterprise Architect Corporate edition. The HL7 license is the EA Corporate edition.

NOTE: September 18 2018, the extension for the Profile Designer tool does not work 100% with release 14 of EA! In particular, the double click on items does not open the custom FM UI elements. It is a known issue and we are working with Sparx to figure out how to solve this.

2. Installing Enterprise Architect

The user can consult the Sparx website for downloading and installing Enterprise Architect. Please go to: http://www.sparxsystems.com.au/support/faq/download_install.html.

For how to install EA please see:

<http://www.sparxsystems.com/resources/show-video.html?video=gettingstarted-installingea>

3. Introduction in using Enterprise Architect

Getting started with Enterprise Architect can be viewed on:

<http://www.sparxsystems.com/resources/demos/gettingstarted/getting-started-with-enterprise-architect.html>

Have a look at the basic functions in a nutshell watch:

<http://www.sparxsystems.com.au/resources/demos/eaoverview/index.html>

If you want to know more about Enterprise Architect, Sparx has more videos available to learn about Enterprise Architect. Below is a list of these videos.

Note: the videos are about Enterprise Architect, **NOT** about the EHR-S FM FP Designer Tool. However, getting familiar with EA, helps to work with the EHR-S FM Tool.

- After 'Getting started', take a break, play with the tool, then look at

<http://www.sparxsystems.com/resources/webinar/getting-started-with-ea13/webinar-getting-started-with-ea13.html>

- A couple other short videos that might be interesting



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http://www.youtube.com/watch?v=3FSVKjwm6S4&feature=c4-overview&list=UU1btSvXDURkqZQf_EpyvgQ

<http://www.youtube.com/watch?v=DGZay5eyeM4>

- When you are ready to interact with other EA users consider joining the Sparx Community site (it's free)

<https://community.sparxsystems.com/>

- If you want to read about it, take a look at

http://www.sparxsystems.com/enterprise_architect_user_guide/10/modeling_basics/uml.html



Appendix 3. Tracking Changes

During the development of the tool people with the experience of creating a new Functional Profile asked for the requirement of the possibility to track changes in the Profile Definition. See for detailed description of how to create a Profile Definition chapter '6CreateProfileDefinition'.

Enterprise Architect provides two separate but complementary facilities for tracking changes to data across the project. These are 1) Auditing and 2) Baselining and differencing to capture and roll back changes. These features are described below. First there is a use case description that gives the project facilitator a reason to use the feature.

1. *Auditing*⁶

Use Case

A project facilitator in a project of creating a new functional profile is creating the profile definition with a group of experts. Changes are made in descriptions of functions, optionality in conformance criteria, in the text of criteria, new functions are added and new criteria are added. During this process the expert team wants to look back at the changed that were made and the reason why they changed it.

Feature

Auditing on project-level enables the project facilitator to record model changes, so changes in the project developing a new Functional Profile, in EA. Auditing is not part of the EHR-S FM Tool, so it is not described in detail in this user guide.

By enabling Auditing, you can view information on changes such as:

- Who changed an element, e.g. changes in text or optionality in a function or criterion.
- How many elements they changed.
- When they changed the data, e.g. date and time when the changes were made.
- What the previous values were, e.g. the optionality was MAY and this is changed in a SHOULD.
- What type of elements they changed.

Auditing does **not** record changes to:

- RTF Templates
- Model Documents
- Baselines
- Profiles

⁶ Auditing in EA Help.



Features are:

Quickstart: You can quickly enable auditing and see it in action. See Help in EA chapter 'Auditing Quickstart'.

Settings: Once auditing is enabled within a project, you have a variety of options available for customizing what is recorded by the audit. See Help in EA chapter 'Audit Settings'.

The Audit View: To view what has been recorded by the audit, use the Audit View, which provides an interface to everything recorded by auditing. If security is enabled, you must have Audit View permission to display data in the Audit View. See Help in EA chapters 'Audit View' and 'List of Available Permissions'.

Model Views: You can also obtain a snapshot of selected items in the model, using the *Model View* facility. In the Corporate, Business and Software Engineering, Systems Engineering or Ultimate editions of EA, this facility enables you to automatically generate a snapshot at intervals and, if there are changes in the items collected by the defined search, to trigger a notification to you of such changes. This enables you to monitor work flow and other events of concern to you. See Help in EA chapters 'Model View' and 'Monitor Events'.

RTF Report: You can generate an RTF report that includes the audit history information for the selected element or package, by choosing the *basic + audit* RTF template. See Help in EA chapter 'Generate Documentation'.

Audit History: Using Auditing, you can track changes to an element or connector over time. However, enabling Auditing also enables an Audit History tab in the System Output window, which summarizes all changes made to the selected element or connector. See Help in EA chapter 'Audit History Tab'.

Performance Issues: By enabling auditing on a project, you increase the time taken for most actions. For most modeling tasks, this increase is insignificant; however, there are some instances where the difference is more substantial. See Help in EA chapter 'Performance Issues'.

Notes

- The Auditing facility is available in the Corporate, Business and Software Engineering, System Engineering and Ultimate editions
- **Warning** - If your site runs separate editions of Enterprise Architect, when Auditing is turned on in a project any Desktop or Professional edition users are locked out of the project; to restore access, turn Auditing off in the project from the Corporate, Business and Software Engineering, Systems Engineering or Ultimate edition instance of Enterprise Architect.

Auditing was not used in the process of the EHR-S FM FP Designer tool development.



2. *Baselining and differencing to capture and roll back changes*⁷

Use Case

After a ballot the suggested changes are made in the Profile Definition and the new version of the Functional Profile. Before balloting the new Functional Profile max file of this profile was saved and kept for historical and safety reasons.

After compiling the new version of the Functional Profile, the project team wants to see the changes they made in the new version of the Functional Profile in comparison with the version that went to ballot. They want to see the changes in a diff report and in a diagram.

Feature

The Enterprise Architect Corporate, that you need for working with the EHR-S FM Tool, provide a facility to '*baseline*' or snapshot a model branch in XMI format at a point in time, and store it within the model in compressed format.

More than one baseline can be stored against a single Enterprise Architect package; using baselines, you can compare packages at the current and earlier stages of development, using the *Compare (Diff)* utility.

The Compare utility enables you to compare the current model with:

- A Baseline
- An exported Enterprise Architect XMI file on disk
- A version-controlled Enterprise Architect XMI file on disk

Package Baselines

Enterprise Architect includes tools to help you manage and review changes to your models (functional profile) over time. These tools apply the concepts of *Baselines*, *Differencing* and *Merges*.

You use Baselines, Differencing and Merges essentially to compare two snapshots of a specific part of your project, to capture the differences between them and either roll back or incorporate selected changes or all changes.

Baselines

EA provides a facility to create a Baseline or 'snapshot' of the contents of a selected package and its child packages at a particular point in time; this enables you to later compare that branch of the model at that time with the current state of the branch.

Baselines are stored in the same XML format as is used for version control but are stored within the project in compressed format.

You can also have parallel copies of parts of your model for team development and create Baselines within each copy to merge changes into the project master. See for more detailed description the Help of EA chapter 'Baselines'.

⁷ Package Baselines in EA Help.



Differencing

Differencing (*Diff*, or *Compare*) enables you to explore the differences between:

- The current state of a specific part of your project, and
- Previous or parallel versions captured in a Baseline or an XMI 1.1 file on disk

The section includes an example of such a comparison. See for more detailed description the Help of EA chapters 'The Compare Utility (Diff)' and 'Example Comparison'.

Merges

Once Differencing is complete, you can merge information from the Baseline into the current project; it is not possible to go the other way.

You can:

- Merge information manually, change by change
- Merge information automatically by electing to merge in all changes in one batch procedure
- Revert completely to the original Baseline by importing the stored XMI directly
- Merge information and elements from a Baseline in a different project, making it possible to keep multiple versions of a single model in synch

The merge options are available through the toolbar, context menus and the keyboard on the Compare Utility tab, which shows the results of a comparison. See for more detailed description the Help of EA chapter 'Compare Utility Tab Options'.

Visual Differences in Diagrams

Changes to a model might include:

- Adding or removing elements and connectors on a diagram, or
- Changing the position of elements or the overall layout of a diagram

You might believe that a diagram has changed, and select to compare it with a baseline using a context menu option from the Project Browser. Alternatively, you might perform a baseline comparison on a package or a model and select from the comparison output any diagrams that are flagged as changed. See for more detailed description the Help of EA chapter 'Check Visual Changes to Diagrams'.

Notes

- Package Baseline facilities are available in the Corporate⁸, Business and Software Engineering, Systems Engineering and Ultimate editions of Enterprise Architect.
- If a package under version control forms part of a Baseline, and that package is checked in to the model, you cannot merge the original data from the Baseline into that package.

⁸ This edition of EA is required to work with the Ehr-S FM Tool.



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- You can also obtain a snapshot of selected items in the model, using the Model Views facility; this facility enables you to automatically generate the snapshot at intervals and, if there are changes in the items collected by the defined search, to trigger a notification to you of such changes, which enables you to monitor work flow and other events of concern to you.
- If security is enabled you must have **Baselines - Manage** permission to create, import and delete Baselines, and **Baselines - Restore** permission to merge data from a Baseline; security permissions are not required to select an existing Baseline and perform a comparison with the model

In phase 2 of the EHR-S FM FP Designer tool development this functionality was not used. The max version of the Functional Profile can be used to compare the max files, compare two xml files.



Appendix 4. Working in a project on a new functional profile⁹

1. Introduction

The development of a new Functional Profile is usually done in a multidisciplinary project team. Depending on the part of the Base Model, domain expert, IT experts, security experts etc, are part of the project team. Collaboration of the project team can be done with or without using Enterprise Architect HL7 EHR-S FM Extension. The possibilities are:

1. **Without** using Enterprise Architect and the EHR-S FM Tooling extension. A **Project Facilitator** is using the EHR-S FM Tool to develop the new Functional Profile. The facilitator is making the Profile Definition when reviewing the Base Model with the project team. A possible way on this **is described** in this user guide.
2. **With** the use of Enterprise Architect and the EHR-S FM Tooling extension and the use of the EA functionality '**Project sharing**' and '**Network deployment**'. Several members of the project team are working on different parts of the profile definition at the same time and can contribute their particular knowledge. This possibility is **not described** in this user guide.
3. **With** the use of Enterprise Architect and the EHR-S FM Tooling extension and the use of the EA functionality '**Replication**'. Replication enables different users to work independently of one another, and to merge their changes at a later time. This possibility **is described** in this user guide.
4. **With** the use of Enterprise Architect and the EHR-S FM Tooling extension and the use of the EA functionality '**Security**'. In managing the project of development of a new functional profile, you might want to limit the access of members in the project team to update certain parts of the profile definition. This to prevent concurrent editing and limit the possibility of inadvertent changes in the profile definition by members not designated as model authors. This possibility **is described** in this user guide.

2. Development of a new Functional Profile without the use of Enterprise Architect and the EHR-S FM Profiling Tool extension

A project manager can assign a project facilitator to assist in the development of a new Functional Profile. This project facilitator is responsible for creating the Profile Definition in collaboration with the project team and finally creates the actual new Functional Profile with support of the HL7 EHR-S FM FP Designer Tool.

A project facilitator can have meetings with the rest of the project team and review the functions and criteria in the base model on their applicability for the new functional profile. The project facilitator can create the Profile Definition with support of the tool while reviewing the Base Model. When the project facilitator is not available for review of the Base Model an export of a section of the Base Model in a RTF document, with the functions and criteria in a table, can be made so team members can review the section of the Base Model. They can put in their review notes in the table and the project facilitator can review the table and the notes to create or adjust the Profile Definition for that section.

How to export a section or the non-shall criteria of a section in a rtf document is described in chapter 'Export a section of the EHR-S FM' in part Export.

⁹ This part will be replaced by a manual about working together with the webbased version of EA.



3. Development of a new functional profile with the use of Enterprise Architect and the EHR-S FM FP Designer Tool and the use of the EA functionality 'Replication'.

In the EA functionality 'Replication':

- The EA project of the development of a new functional profile is converted to a design master, and then replicas are made of the master.
- Members of the project team take the replicas, modify a part of the project, and then bring their replicas back to be synchronized with the master file.

In a project team a project facilitator can be the design master and other members of the project team use the replicas. The project facilitator synchronizes the replicas with the master file.

To use the functionality Replication:

1. Convert the base project to a design master.
2. Create replicas from the design master.
3. Take the replica away and work on it as required, then bring it back for synchronization with the design master.
4. Synchronize the replicas, with all changes, to both the master and the replica. Synchronizations are propagated in both directions, so they both finally contain the same information.
5. Resolve Conflicts.

These steps are described below with examples in the context of new functional profile creation.

4. Convert the base project to a design master.

When a new Functional Profile is developed, a new project in EA is created for that. See part Creation and follow the instructions. The result is a project in EA in where you have one package with the Profile Definition, one package with the Base Model and one package for the Compiled Profile.

This project is the so called master project from which you create replicas that can be modified independently of the master project and re-merged later.

For example: different groups of the project team can work independently on parts of the Profile Definition. Domain experts can work on the section Care Provision and Security experts can work on the section Trust Infrastructure. The project facilitator can synchronize the replicas with the design master.

To convert the project in to a design master follow the next steps:

Step 1: take a back-up of the required EA project. So you will always have a copy of the original project. The project is the eap file you created as a result of the part Creation.

Step 2: Select the project in the project browser.

Step 3: Select the Make Design Master menu option and follow the on-screen instructions. See figure 122. Select Tools in the navigation, select Data Management, Select Manage EAP. File and then select Make Design Master.



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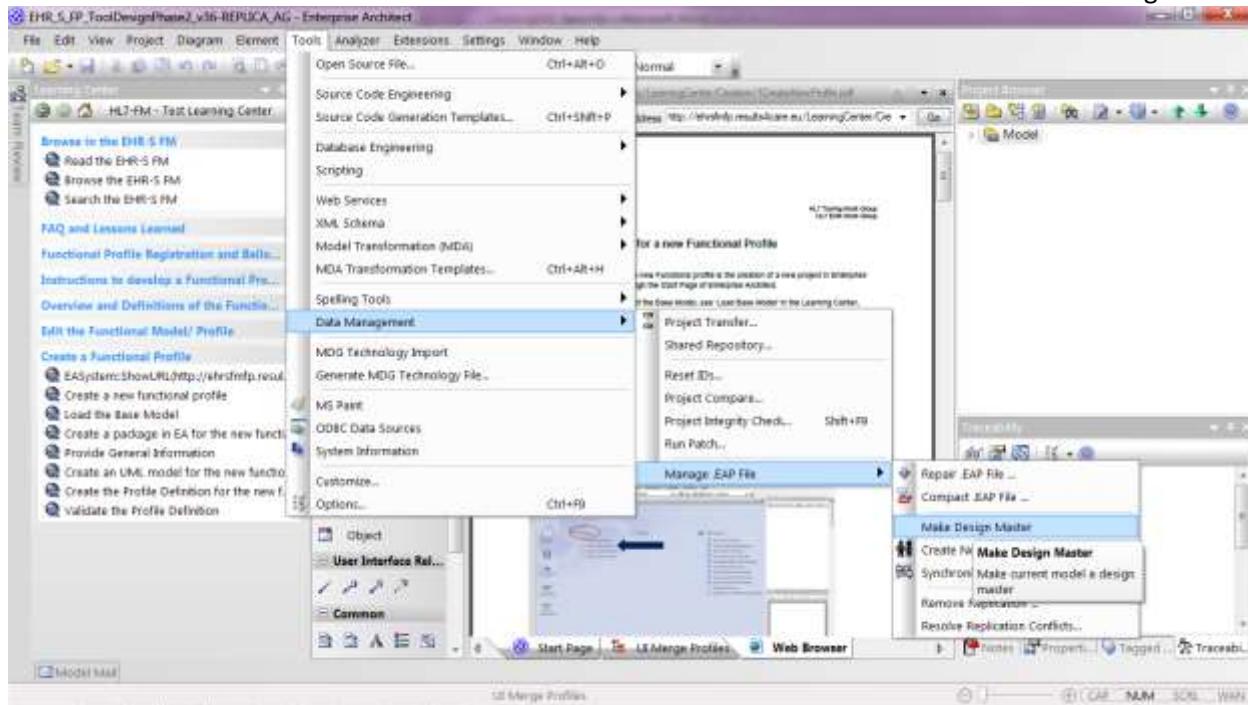
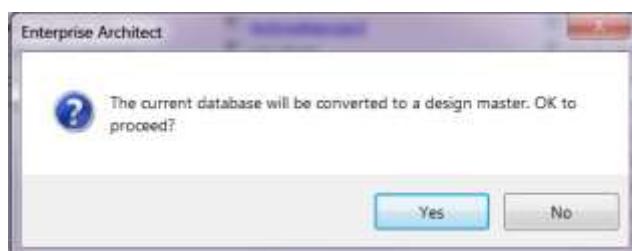


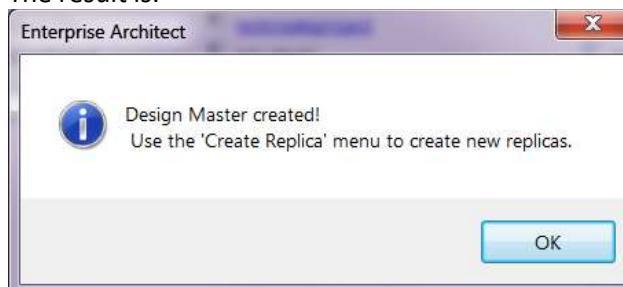
Figure 122. Make Design Master menu option.

You will get the following question:



Click Yes.

The result is:



5. Create replicas from the design master.

For example: different groups of the project team can work independently on parts of the Profile Definition by using a replica of the Design Master. In this way domain experts can work on the section Care Provision and security experts can work on the section Trust Infrastructure.

To create replicas follow the next steps:

Step 1: create a design master. This is done by following the previous part ‘Convert the base project to a design master’.

Step 2: select the Create New Replica menu option and follow the on-screen instructions. See figure 123. Select Tools in the navigation, select Data Management, Select Manage EAP. File and then select Create New Replica.

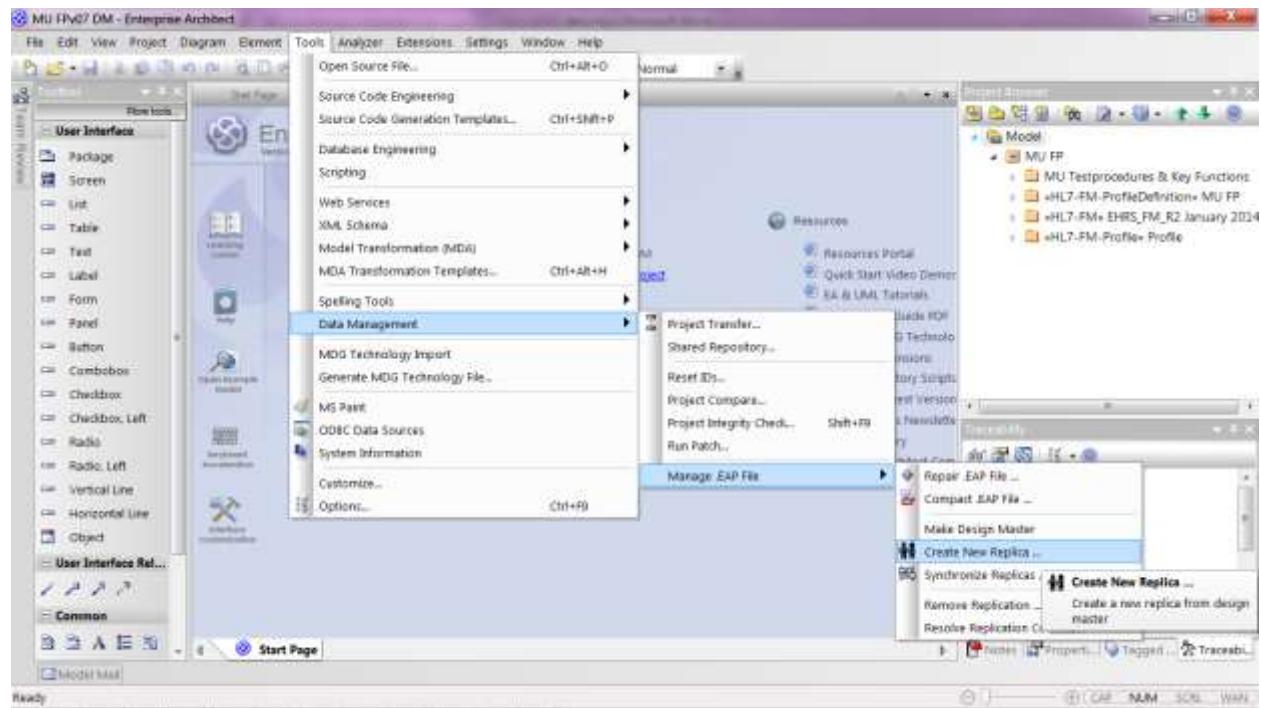


Figure 123. Create Replica menu option.

After selecting the Create Replica option you will get the Windows explorer. See figure 124.



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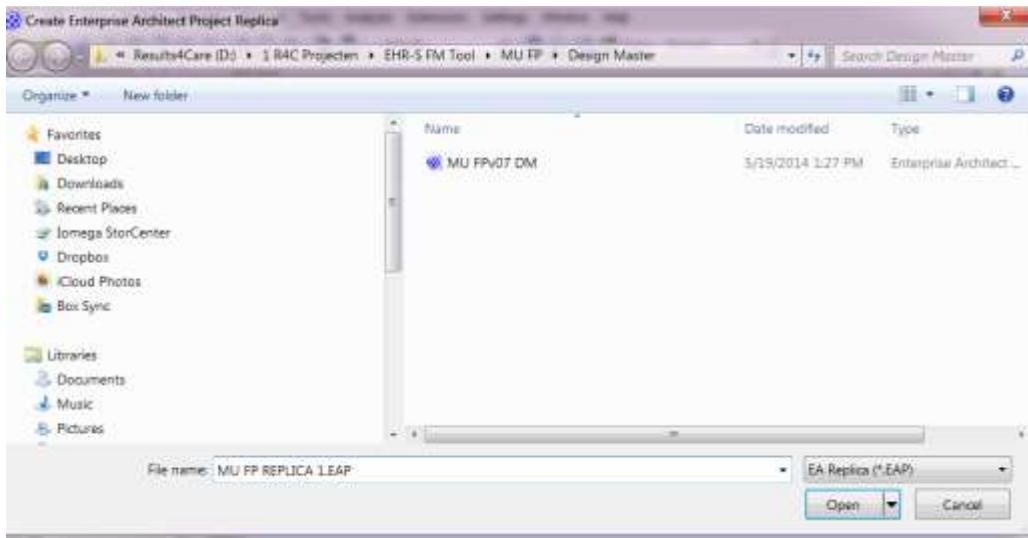
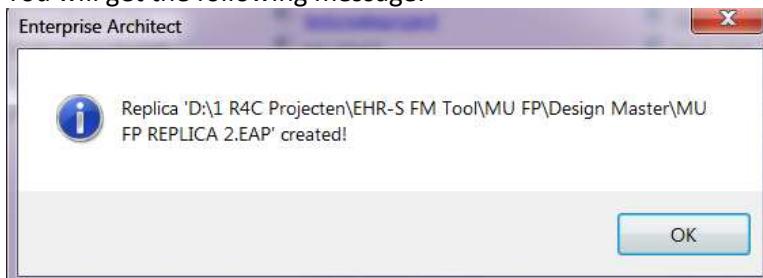


Figure 124. Creating a replica from the design master.

- Select the Design Master file (indicated with DM) and click on Open.

You will get the following message:



NOTE: If the functionality Security is enabled (in the Corporate¹⁰, Business and Software Engineering, Software Engineering and Ultimate editions of EA) you must have Manage Replicas permissions to create replica.

6. Take the replica away and work on it as required, then bring it back for synchronization with the design master.

You can create multiple replicas for the different expert groups you have in your project team. Each group can work with its own replica. After a period they bring back their replicas to be synchronized with the master file.

For example: different groups of the project team have worked independently on parts of the Profile Definition by using a replica of the Design Master. The domain experts worked on the section Care Provision and the security experts worked on parts of the section Trust Infrastructure. When they have

¹⁰ To use the tool with all the custom functionalities you need to work with EA corporate edition.



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finished their work they bring back the replica to the project facilitator. He/She will synchronize the replicas with the design master.

The synchronization of the replicas with the design master is used to:

- Merge the changes made in each replica with the design master, so that a new set of replicas with all changes can be generated and distributed.
- Combine the changes made to two replicas, should it be necessary for two team members to combine their work.

7. Synchronize the replicas

To synchronize the replicas with the design master follow the next steps:

Step 1. Open the design master project file. Or a replica project.

Step 2. Select the Synchronize Replicas menu option. See figure 125.

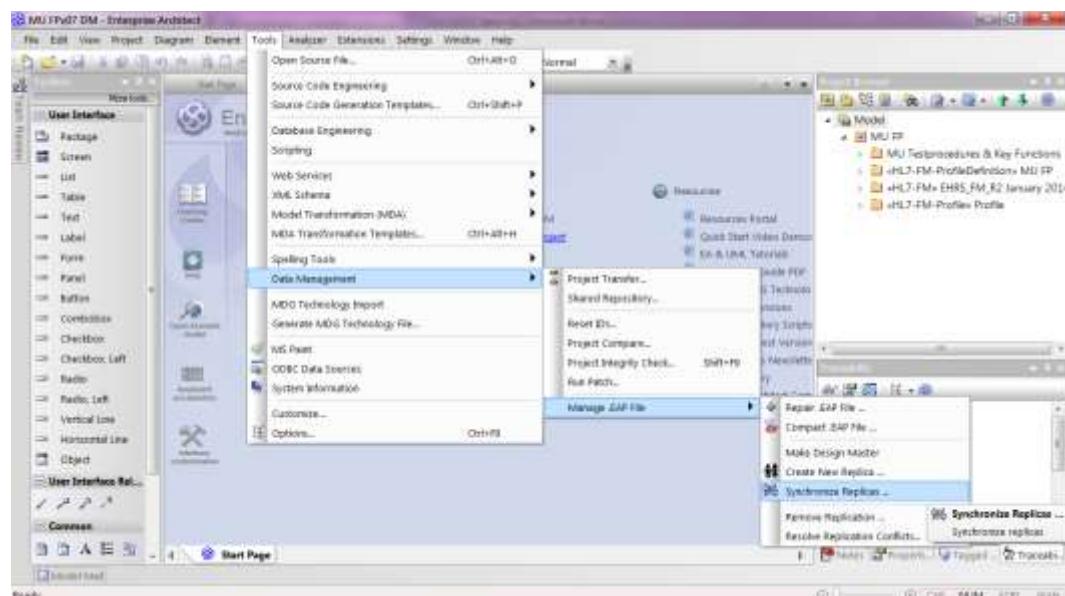


Figure 125. Synchronise Réplicas menu option.

Step 3. Locate and select the (second) required replica to merge the open project and the replica. See figure 126.



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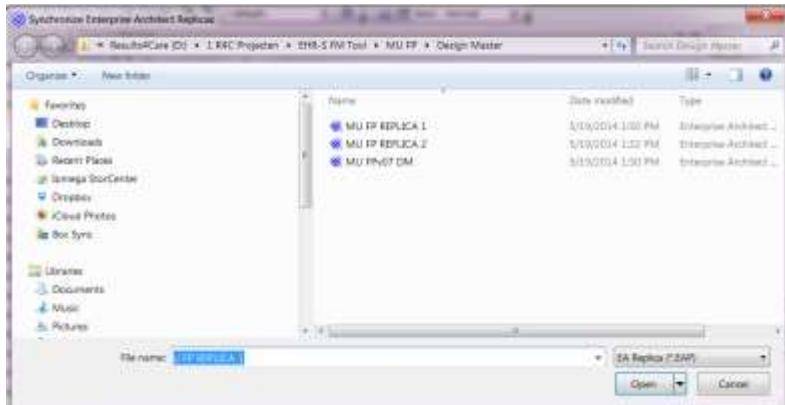


Figure 126. Select a replica for synchronization.

If you select 'Open', EA will synchronize the replica and the design master. When the synchronization is complete you will get the following message:



Notes:

- Information is copied both ways, including deletes, updates and new criteria or functions. Both Projects, design master and replica, end up containing identical information.
- If the synchronization process generates 'conflicting changes' errors, you should review and, if necessary resolve these conflicts.
- In the Corporate, Business and software engineering, system engineering and Ultimate editions of EA, if security is enabled you must have Manage Replicas permission to create replica.

8. Resolve conflicts

EA follows certain rules in merging. These rules are:

- Additions are cumulative. Example: if two replicas each created three new criteria in a function, this result in six new criteria after merging.
- Deletions prevail over modifications. Example: if one replica changes the optionality of a criterion and the other replica excluded the criterion, merging replicas results in both files losing the criterion.
- Conflicting modifications appear in the Resolve Replication Conflicts dialog.



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If two or more people are working on the same part of the profile definition from the base model, for example one or more domain experts, in their respective replicas between synchronizations, the replication engine has problems in resolving which changes is the master.

It is unlikely that more domain experts work with their own replica, but if IT experts have their own replica and work independently on the RI section it can happen that there is a conflict when synchronize the replicas. Conflicts can appear also when people make changes in other sections then the section it was agreed to work on. Later in the user guide we describe the 'Security' functionality of EA to prevent this.

How to deal with conflicts:

- Avoid the problem: ensure that each team member always work in a separate area (section or part of a section of the base model) of the profile definition within their replica.
- Check for conflicts: after synchronizing replicas, open the Resolve Conflicts dialog and check if there were any conflicts. See figure 127.

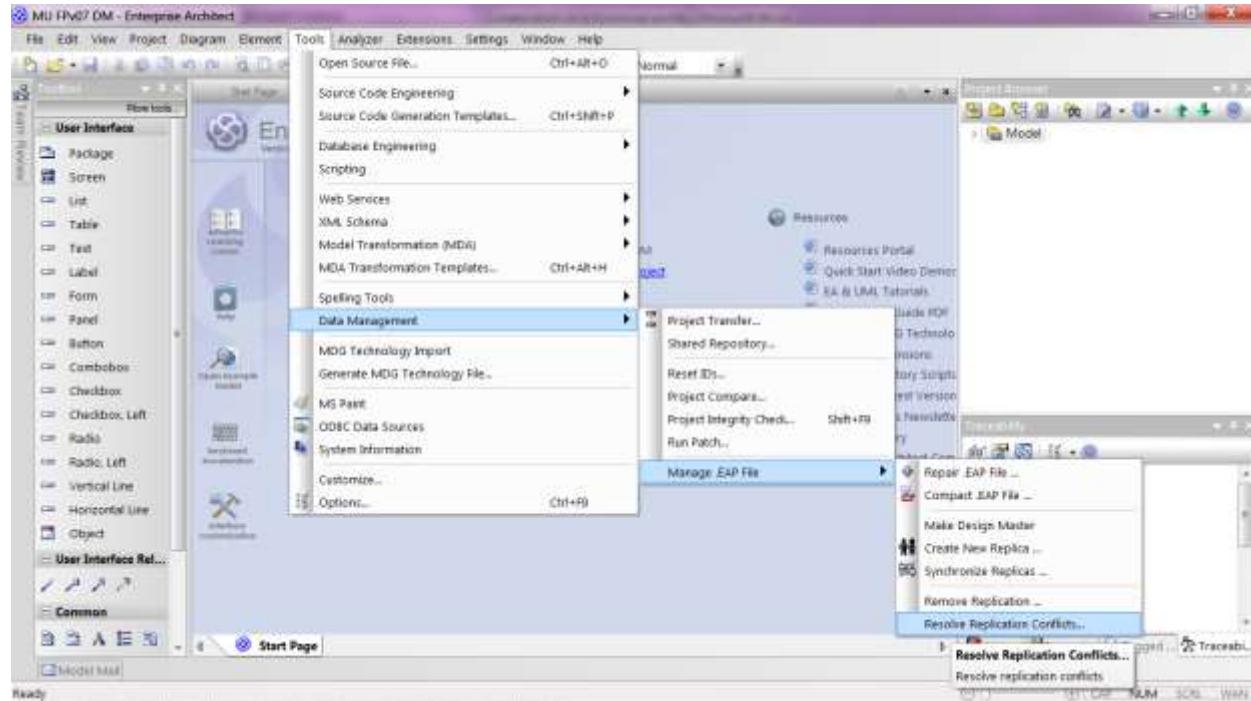


Figure 127. Resolve Replication Conflicts menu option.

The result is the following window in EA:



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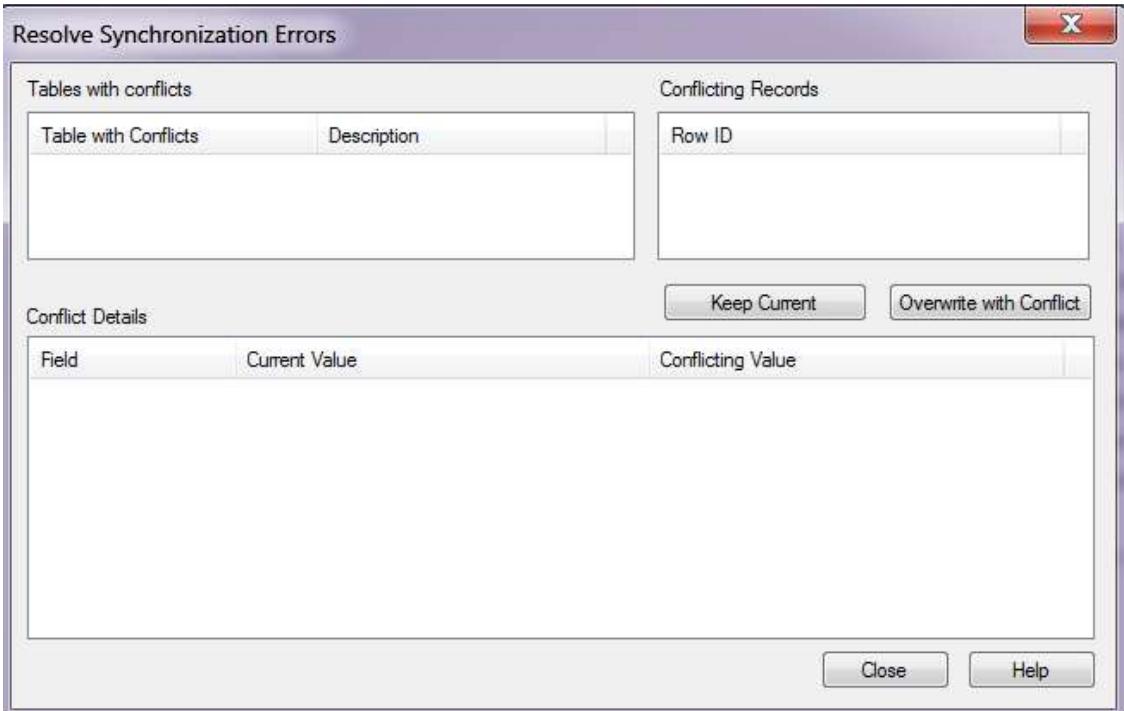


Figure 128. Resolve Synchronization Errors.

- Click on each entry in the Conflicting Records list.
- When the lost information appears in the Conflict Details list, click on the Overwrite with Conflict button.
- In the Conflict Records list, you can also copy each Row ID to the clipboard by right-clicking on the row and select the Copy to Clipboard menu option.
- You can locate the conflict in the Project Browser, by right-clicking on it and select the Find in Project Browser menu option. See figure 129.
- If you want to find the conflict in a diagram select the Find in all diagrams option. Can also be seen in figure 129.



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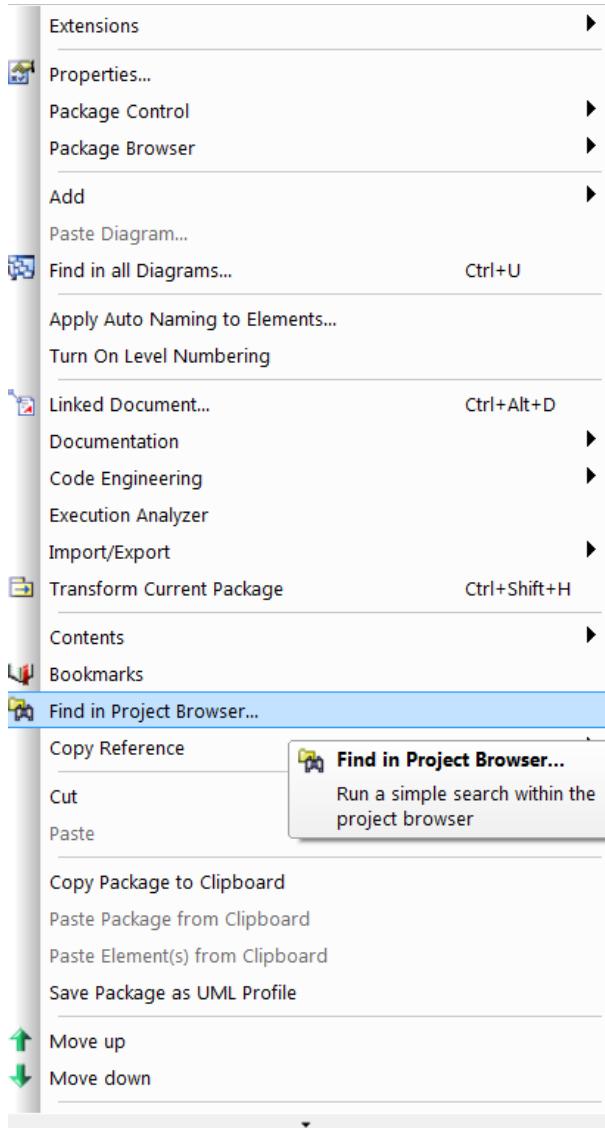


Figure 129. Locate the conflict in the Project Browser.

- Response to conflicts.

When a project record has been modified in different ways by different users, the replication engine selects one of the conflicting values based on rules within the replication manager. However, the replication engine stores the discarded changes and flags the conflict on the Resolve Conflicts dialog (figure 7) so that you can choose to roll in the discarded change instead.

Normally it is not necessary or desirable to examine conflicts, since they represent relatively inconsequential pieces of information that can very easily be modified through the normal Enterprise Architect interface; for example, by moving a diagram element.

The only case in which the Resolve Conflicts dialog should be used is where a substantial piece of information has been overridden by a user, and you want to retrieve it.

Example: if one group of IT experts is working on the RI section and made also changes in the TI sections (and this was not agreed on) you can restore this part by using the Resolve Conflicts dialog.

9. Development of a new functional profile with the use of Enterprise Architect and the EHR-S FM Tooling extension and the use of the EA functionality 'Security'.

As described in chapter 2 of this document team members can work independently in their own replica. However, that doesn't prevent them from working in another area of the model (profile definition) then agreed on.

Role-based (user) security in EA helps the project facilitator to control access to various editing functions by requiring that authors log in to the functional profile project with certain privileges. It also allows the project facilitator to lock elements per-user or per-group. This can help to improve collaborative work by preventing different users unintentionally editing the same information at the same time. It also limits the possibility of inadvertent model changes by users not designated as model authors.

For example: different groups of the project team can work independently on parts of the Profile Definition by using a replica of the Design Master. In this way domain experts can work on the section Care Provision and security experts can work on the section Trust Infrastructure. The section Trust Infrastructure can be 'locked' for the domain experts and the section Care provision can be 'locked' for the security experts by using role based user security.

The first step in using the functionality 'Security' is to enable Security in EA. How to do this is well described in the Help content of EA. Search for Enable Security in the help content. You need to go to the Sparx website, <http://www.sparxsystems.com/>, and then to the Registered users option.



Figure 130. Sparx website with option Registered users.



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Together with your license for EA you received your user ID and password that gives you access to the registered user section of our website. This area contains important information about latest releases, product updates and support.

To use the EA functionality 'Security' you need to enable security in EA. This because the user security is not enabled by default in EA, the project facilitator must enable it using an Authorization key obtained from the Sparx Systems website as described above. When you received the Authorization key follow the next steps¹¹:

- Select Project in the top level navigation, select Security and then Enable. The Enter authorization dialog displays.



Figure 131. The Enter authorization dialog.

- In the **Enter authorization key** field, type the authorization key from the Sparx Systems website. If required, select the **Automatically apply Exclusive Edit Locks to diagrams** checkbox. This option is ignored in *Require User Lock* security mode. In standard (*User/Group Locking*) mode, this option blocks multiple users from simultaneously attempting to modify the same diagram (see *Notes* below). For more details see the Help of EA, chapter 'Security Policy'.
- Click on the **OK** button. Security is enabled, and an **Admin** user and user group are created with all access rights and a password of **password**. For more details see the Help of EA, chapter 'List of Available Permissions'.
- Select the Project | Security | Login as Another User menu option, and log in as **Admin** with the initial password of **password**. If required, you can change the Admin password. For more details see the Help of EA, chapter 'Change Password'.

¹¹ Not all the described steps are explained in detail, because this is well described in the Help of EA. Another reason is that when you are going to use the Security functionality the assumption is that you know how EA works.



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- Set up users and permissions as required. For more details see the Help of EA, chapters 'Maintain Users', 'Assign User To Groups', 'Set Up Single Permissions', 'Maintain Groups' and 'Set Group Permissions'.



Appendix 5. Project Management

The development of a new Functional Profile is usually done in a project in where several parties are involved. Support for the project management can be done with several tools. As a project facilitator you can contribute to project management by using Enterprise Architect, EA. In this context it is important to determine what of the project management is done by the project leader, in another tool then EA, and what by the project facilitator, done in EA. To do this we will summarize the possibilities of EA that are relevant for the development of a new Functional Profile. Summarize and not describe, because the functionality is out of scope of the tooling project. We just want to point to the possibility of using EA for Project Management. How to handle these possibilities in EA is described in the Help of EA.

Project management with EA relevant for the development of a new Functional Profile

The relevant possibilities in EA are: Resource Management, Project Maintenance, and Project tasks and issues.

Resource Management: Resources are the people who work on the project of developing a new Functional Profile. You can assign roles to project team members and allocate tasks on specific parts of the Functional Profile, which enables tracking of effort and estimation of time to complete. See Help in EA, chapter 'Project Resources'. Example:

Some project team members, domain experts, are involved in the project to review the Care Provision and Care Provision Support functions on their applicability for the Functional Domain Profile.

Some project team members, security officers, are involved in the project to review the Trust Infrastructure functions for the new Functional Profile.

Project Maintenance: During a project you monitor and manage the development and progress of the development of a new Functional Profile, in particular the different parts project team members are working on. You can record problems, changes, issues and tasks that affect these different parts as they arise, and document the solution and associated details. Similarly, EA helps you to manage changes and issues that apply to the whole Functional Profile. See Help in EA, chapter 'Maintenance' and 'Changes and Defects'.

Project Tasks and Issues: In the course of a project, there are various tasks that are vital to the successful management and completion of the project, such as meetings. EA can help you record and monitor these, and manage project issues as they arise. See Help in EA, chapter 'Project Tasks' and 'Project Issues'.

- Project Tasks:
 - Review the tasks across the project over a period of time.
 - Review of the progress of these tasks.
 - Create new tasks if necessary.
 - Display and edit the details of the task.
 - Allocate a team member to a task.



- o Delete a task.
- o Create and send an email to the team member assigned to a task.
- o Create and send an email to the owner of the task.
- Project issues:
 - o Add, edit and delete issues.
 - o Generate and view a rich text format report of your issue list

More functionality in EA that can help you to manage the project:

- The Project Management Window
- Personal Tasks
- Internal Mail
- The Project Status View
- Project Calendar
- Project Glossary
- Update Package Status
- Monitor Change Events

These functionalities are described in the Help of EA.

During the development of the tool the project team worked on the Meaningful Use Functional Profile as a use case for the development. Working on that profile was done in timeslots that were out of sync of each other. So status and tasks need to be written down somewhere, to manage a proper development. The **Project Status View** in EA was used for that. The Project Status View documents tasks and issues that relate directly to the current project. The Project Status View allows entering a task, a description for it, priority assignment, type and status. See figure 132 below.



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The screenshot shows the Enterprise Architect interface with the title bar "MU 2014 FP_v10 - Enterprise Architect". The menu bar includes File, Edit, View, Project, Diagram, Element, Tools, Analyzer, Extensions, Settings, Window, Help. The toolbar has various icons for file operations. The left sidebar contains a tree view with categories like Profile, Profile Helpers, and Common. The main area displays a "Project Status" table with columns: Priority, Task, Type, Status, Owner, Description. The table lists several tasks with details such as priority (High or Medium), task description, type (Release), status (Complete, In Progress, New), owner (various names), and a detailed description. A right-hand panel titled "Project Browser" shows a tree structure with "Model" selected. Below the main window is a status bar with tabs for Tasks, Issues, and Project Statistics, and buttons for Start Page and Project Status.

Priority	Task	Type	Status	Owner	Description
V High	Debriefing up in the Tagged Values -> remove duplication in there	Release	Complete	wh...	
V High	Finish the adding of new criteria to MU FP	Release	Complete	Sor...	
V High	Go through Gary his emails with all the answers to my questions	Release	Complete	I di...	
V High	Key Function 777 in Package MU Keyfunctions	Release	In Progress	the...	
V High	Make a matrix or models for the MU test procedures and key fun...	Release	In Progress	The...	
V High	Worksheet of project team compare without version I worked in	Release	In Progress	EH...	
V Medium	Add priorities to functions and criteria	Release	In Progress	All...	
V Medium	In row 10/7 is the text (See applicable Test Procedures).	Release	In Progress	In...	
V Medium	In row 8/1 is the text (See #17 and 18 above). Is this the text in...	Release	In Progress	OK...	
V Medium	In the new criteria I included by mistake an A as the Reference	Release	New	The...	
V Medium	Overarching section add to MU FP	Release	New	Wa...	
V Medium	Relationshipmatrix in version 0.3	Release	New	Re...	
V Medium	Tagged Values bij sommige nieuwe criteria (zie ogen)	Release	Complete	Cri...	
V Medium	Test actions Following the actions that are described in the fol...	Release	In Progress	In...	

Figure 132. Project Status View of MU FP project.

Other functionalities of Project management were not used, but we consider them useful during a project to develop a new Functional Profile. However, other software for project management can also support you.



Appendix 6. Frequently asked questions, FAQ

During the development of the tool questions were asked about how the tool supports certain functionalities or how to deal with certain issues where users ran into. From these questions we created this document with FAQ. In the answer we will point to the chapter in the Learning Center in where a more detail description is given.

➤ How to create new criteria?

Q: I'm currently working on a new Functional Profile and want to add new criteria to the profile definition.

A: New criteria can be added to the Profile Definition by using the toolbox that is created for the HL7 FM extension. In the UI of enterprise Architect this toolbox can be shown by selecting 'More Tools' and then select 'HL7-FM'. The tools necessary for adding new criteria to the functional profile are in this toolbox. How to use this is described in chapter 8.11 Adding EHR_S FM/FP components in part Edit FP case the HL7 FM toolbox is not working is also described in the same chapter.

➤ Where can I find the HL7_FM_EA_Extension which I installed on my computer?

Q: There is a new version of the extension. I need to uninstall the older version before I can install the new version. However, where can I find the old version of the extension so I can uninstall this?

A: The old version of the extension can be found by either 1) go to the Windows Explorer and then to the folder in where you installed the extension. Then right-click and uninstall. Then it will run to uninstall the extension, or 2) go to the control panel and select Programs and Features. All the installed programs are listed. Select the extension and select uninstall in the top navigation.

How to uninstall and install the HL7_FM_EA_Extension is described in chapter 4 EHR_S_FM_FP Designer TOOL Installing the extension. The required file can be obtained by contacting the EHR WG co-chairs, contact details on: http://wiki.hl7.org/index.php?title=EHR_Leadership

➤ Is my work lost when I install a new version of the extension?

Q: I'm currently working on the Profile Definition in creating a new Functional Profile. Now there is a new version of the extension. Will the work I have done be safe when I install this new version?

A: You can safely uninstall the old version of the extension and install the new version. The work that you have done so far is safe!

➤ Do I need to follow the rules for Functional Profiles on priorities?

Q: I'm currently working on a new Functional Profile and assign priorities to functions/criteria. In the process of development, I want to assign the priority 'TE, temporarily essential', but this value is not in the valueset of priorities.



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A: In principle you need to follow the rules on priorities. When you have the need to create a new priority, you need to contact the HL7 International EHR WG to discuss the question. You can find the information of the co-chairs of the EHR WG on http://wiki.hl7.org/index.php?title=EHR_Leadership

➤ **I want to export a section in the Base Model, e.g the EHR-S FM. How do I do that?**

Q: I'm facilitating the project team by working with the tool to develop a new Functional Profile. I create the Profile Definition on the fly while sitting with the project team. However, sometimes it is not possible to join the project team (other appointment, holiday) and no one else can work with the tool. So I want to have an export of a section in the EHR-S FM. How do I do that?

A: An export of a section in the base model can be done by using the functionality of EA, Project -> Documentation. By the use of a specific template (**Basic FM Export Table Template.rtf**) the export can be a table in a word document. How to do this: see chapter 'Export Section' in part Export. The template with the filename 'Basic FM Export Table' can be obtained by contacting the EHR WG co-chairs http://wiki.hl7.org/index.php?title=EHR_Leadership

➤ **How to search for non-shall criteria in the Base Model?**

Q: We want to review the non-shall criteria and not all the criteria in a specific section of the Base Model. Is it possible to search for these criteria?

A: Select the section in the Base Model in which you want to search for non-shall criteria. Then go to 'Edit' (EA navigation) and select 'Find in project' or press Ctrl+Alt+A. The window which you can use for the search will pop up. Select in the Search field the option 'Find non-shall' and press run. Select all the search results, Ctrl A, and right click and select Documentation -> RTF report on selected items. See chapter 'Export Section' in part Export for a more detailed description.

➤ **On the forms of the function and criteria the buttons "apply" and "OK" are used. It is not clear what the actual final effect is of these buttons.**

Q: On the forms mentioned in the topic the buttons 'apply' and 'OK' are used. It is not clear what the final effects of these buttons are.

A: These buttons are used in Enterprise Architect and are applied in the same way in the tool. When you click OK the change you made will be effectuated and the form will close. If you click the 'Apply' button the change will also be effectuated, but the form stays open so you can continue working in the form.

➤ **How can I get the colors that comes with the sections in the EHR-S FM?**

Q: I imported the max file of the EHR-S FM and don't see the colors that come with the different sections in the EHR-S FM. What do I have to do to get this right?



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A: The definitions of the colors that come with the sections in the EHR-S FM are not in the max file. You can update the style by: select the EHR-S FM package in the Project Browser, right click, select Extensions, select HL7 FM, Update style. Now you can see the colors again.

➤ How can I include or exclude functions and/or criteria while developing a new functional profile?

Q: I'm creating a Profile Definition at this moment. When I have selected a section in the Base Model and go to Extensions and Edit profile I can include and exclude functions and criteria. However, it is not clear how to do this.

A: For a detailed description of how to include and exclude functions and criteria please see chapter 'Create Profile Definition' in part Creation.

➤ Priorities vs. criteria – what's the difference?

Q: What is the difference between priority and criteria?

A: Priorities pertain to the timing of when the function gets implemented by the system. Criteria (those statements with 'shall', 'should' or 'may') define what it means to actually implement or support the function within a system.

➤ I don't see the HL FM Toolbox

Q: I'm creating a Profile Definition for a new Functional Profile. I want to add functions and criteria. However, I cannot find the HL7 FM Toolbox. How can I add functions and criteria without this toolbox?

A: When there is a new version of EA it can happen that the HL7 FM Toolbox is not integrated in EA. How to add functions and criteria in the Profile Definition is described in chapter 8.11 'Adding EHR_S_FM / FP components' in part Edit FP.

➤ I cannot open the view on the metadata linked to the Profile Definition

Q: In the phase of setting up a new project in Enterprise Architect I added a view to the model in the Project browser. I also added a package for the Profile Definition. Now I wanted to add the metadata of the profile Definition, but when I double click on that package not the metadata view is opened but the property window.

A: the new project must be set up in total, the packages, the stereotype and the UML diagram. When this is done, the metadata view can be opened.