



PhUSE EU Connect 2018

*How to easily
generate define.pdf
from Define.XML -
Submission
Request*

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Agenda

- // Authorities Request during submission process
- // How to solve it
- // Conclusion



Authorities Request during submission process

Requirement for submission:

// SDTM datasets and its define.xml (incl. SDRG)

// ADaM datasets and its define.xml (incl. ADRG)

During the submission process:

// Provide dataset and its define to each requests

// Example: Req 17. Please provide a dataset that contains a list of all subjects for xxxxxxxxxxxx. The dataset should contain four variables with an indicator for the item(s) submitted. The variables should be clearly described in the define files.

// Example: Req 19. xxxxxxxxxxxx

// Etc.



Authorities Request during submission process

After answering all requests:

Please provide **ONE text searchable, “Master” Define.PDF** file that describes all of the datasets with all the bookmarks and links to each dataset. For example, the AE define file will be contained in this one master Define.PDF. It should be **specifically bookmarked** in a way so that the reviewer can click on the bookmark (**bookmarks usually appear on the left hand side in adobe acrobat**) and go directly to the first page of the AE define file.

After a follow up call with FDA, we received the information, that the reviewer needs a **readable hard copy of the Define.PDF that is independent of the server**. The reviewer indicated that it will **not be acceptable to submit a pure “print” of your XML define**.



How to solve it

Steps:

- // Modification of XSL Style Sheets

- // Small modification of XSL Style Sheets by removing the bookmarks of define.xml

- // Converting using Adobe Acrobat

- // Converting of define.xml to define.pdf using Adobe Acrobat Toolbar in Internet Explorer

- // Modification of links to external files

- // All links to external files are transferred to full-paths and not relative-paths. So the links must be corrected.

- // Combine several PDFs to ONE master PDF

How to solve it

Modification of XSL Style Sheets

Remove the div id = menu (line 102 to 361)

```

102      <div id="menu">
103          <!-- Skip Navigation Link for Accessibility -->
104          <a name="top" class="invisible" href="#main">Skip Navigation Link</a>
105
106      <span class="standard">
110      </span>
111
112      <ul class="hmenu">
113
114          <!-- ***** -->
115          <!-- ***** Annotated CRF ***** -->
116          <!-- ***** -->
117      <xsl:if test="$g_xndMetaDataVersion/def:AnnotatedCRF">
131      </xsl:if>
132
352          </a>
353          </li>
354      </xsl:for-each>
355  </ul>
356  </li>
357  </xsl:if>
358  </xsl:if>
359
360  </ul>
361  </div>
362  <!-- end of menu -->

```



How to solve it

Modification of XSL Style Sheets

Optimize the main position by change left (22%) to left (5%)

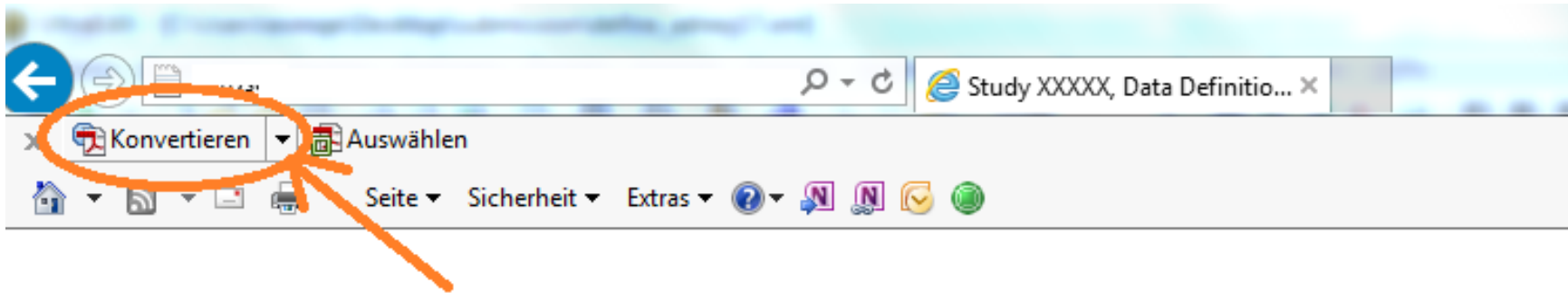
```
2123 #main{
2124 position:absolute;
2125 left:22%;
2126 top:0px;
2127 overflow:auto;
2128 color:#000000;
2129 background-color:#FFFFFF;
2130 }
```

To

```
2123 #main{
2124 position:absolute;
2125 left:5%;
2126 top:0px;
2127 overflow:auto;
2128 color:#000000;
2129 background-color:#FFFFFF;
2130 }
```

How to solve it

Converting Define.XML to Define.PDF



Analysis Datasets for Study XXXXX (xxxxxxxxxxxxx)

Dataset	Description	Class

How to solve it

Modification of links to external files

All links to external files are transferred to full-paths and not relative-paths. So the links must be corrected.

XXX (xxxxxxxxxxxx)

Structure	Purpose	Keys	Location	Documentation
One record per subject	Analysis	USUBJID	adreq17.xpt	

file:///C:/Users/evmqe/Desktop/submission/adreq17.xpt

Below how to edit the link using adobe acrobat:

(see <https://helpx.adobe.com/acrobat/using/links-attachments-pdfs.html>)

Edit a link action

- 1 Select the Add or Edit link tool  (Tools > Edit PDF > Link > Add or Edit).
- 2 Double-click the link rectangle.
- 3 In the Actions tab of the Link Properties dialog box, select the listed action you want to change, and click Edit.



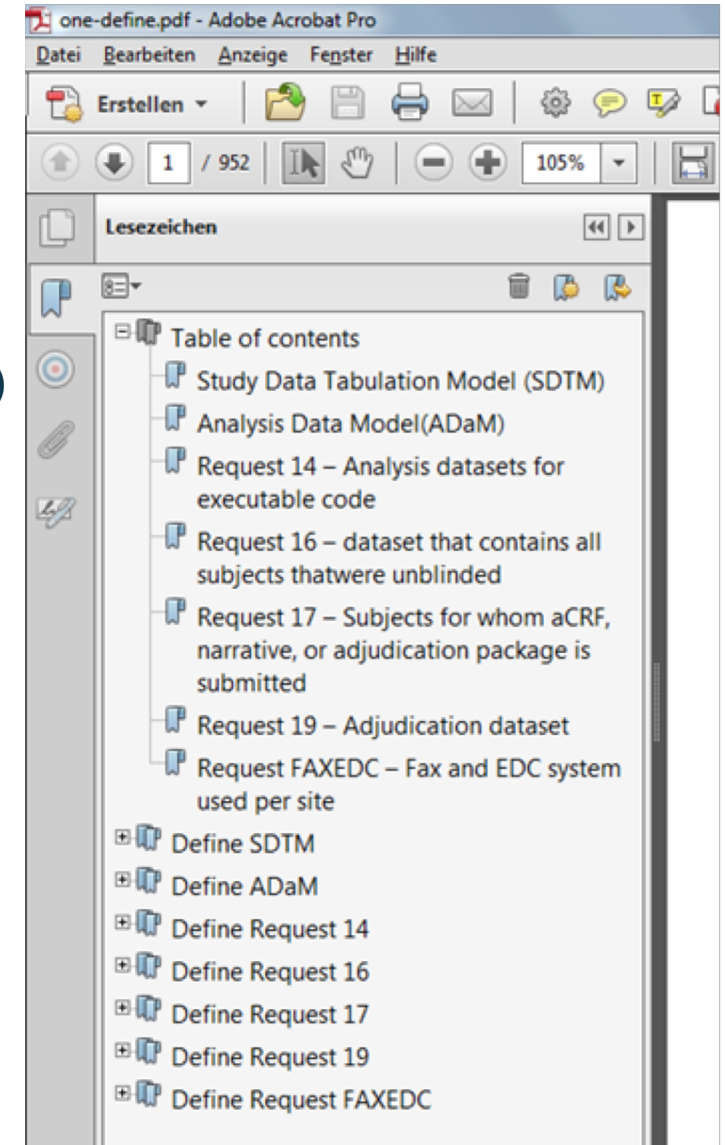
How to solve it

Combine several PDFs to ONE master PDF

Combining the several PDFs into ONE master PDF can be done using Adobe Acrobat.

(see: <https://helpx.adobe.com/acrobat/using/merging-files-single-pdf.html>)

All existing bookmarks and links to external files will be automatically merged.





Conclusion

Generating define.pdf directly using metadata should be basically not difficult, but the problem is that the define.xml might be created by external vendors.

By simple modification of XSL-stylesheet, we could solve the request within very short time and we just need a text editor and adobe acrobat.



Thank you!



Bye-Bye

