Assessment Report Proposal

Harald von Aschen

09.01.2019

Version 1.0

Background

CTFG would like to have the possibility for an automated generation from a draft assessment report to the final one. After some discussions in CTFG it was agreed to use the proposal from Hartmut Krafft to have a "Workspace" part in the assessment report that should be removed automatically.

Boundary conditions

Following boundary conditions should be met by the proposal:

- The proposal should use the standard "Office Open XML". For this the standard for the actual usable Microsoft Word versions should be used such that all Word versions starting with Word 2010 should be supported.
- Word Macros or Word plugins are not acceptable.
- The solution should be implemented only on the member state IT side. Nothing has to be changed on EMA side. Only the template assessment reports have to be done in a way that they are pre-generated based on the Office Open XML standard fulfilling the requirements mentioned below.
- An external software solution should be able to run on servers without any additional Office license or could run locally on a client PC with a Word installation.
- If other software is used, e.g. OpenOffice/LibreOffice or anything else this should in no way harm the usage of the assessment report templates. This might avoid using the software for redaction but should not hinder any work.
- If an NCA (e.g. Spain) has another local solution the proposed solution should not interfere with this systems.
- **The software is an "addition". It might be used for whom it is useful.**

Specification

The following standard is used

- ECMA-376 in the 3rd edition (June, 2011). All standards can be found here: http://www.ecma-international.org/publications/standards/Ecma-376.htm
- From this standard the "table caption" parameter is used as described here: http://officeopenxml.com/WPtableCaption.php

In detail, the workflow is as follows:

1. User is downloading the generated assessment report templates from the EUPD/CTIS prefilled with the data as today.
2. The user can edit anything in the document. If the user is editing the text in the red workspace table part, this table part can be removed. If the user accidentally removes this part and recreates it without the "table caption" the only consequence is that the redaction software will not remove anything else.
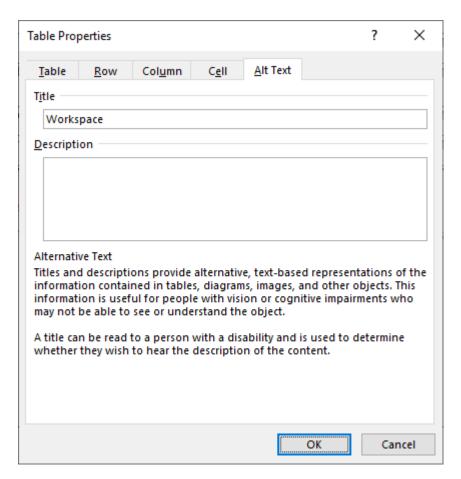
3. The user has to upload the word document to a local server or has to start the desktop application that will remove the table with the caption "Workspace".

Detail

Look at the document "Final Non-clinical AR June 2016 with hidden text Harald.docx":

4.2 Pharmacology

4.2.1 Primary pharmacodynamics

Summary

These pharmacology studies provide support for the pharmacological basis for the proposed trial	Yes ☐ No ☐ NA ☐
Were relevant in vitro and/or in vivo models studied?	Yes ☐ No ☐ NA ☐
Is the intended pharmacological effect expected/ possible at clinical exposure?	Yes ☐ No ☐ NA ☐
Were pharmacologically active major metabolites identified?	Yes ☐ No ☐ NA ☐
Is the IMP a first-in-class compound?	Yes ☐ No ☐ NA ☐

Workspace:

This is an example text that should be removed for the final AR!

Other Text! You can use any format and copy & paste from other documents, even graphics.

Sadfdasf

beschreibung

Right click on the table with paragraph "Workspace" and select properties:

The table caption (named here "table properties" and "title") is set to "Workspace".

For having this table separated from the previous one there is a paragraph with the smallest possible height between these two tables.

In the XML file this looks as follows, the paragraph has also assigned a format style named "MyTable":

```
</w:tbl>
<w:p w14:paraId="7DB4E331" w14:textId="7FEAE1E2" w:rsidR="00925744" w:rsidRPr="00486B9B" w:rsidRDefault="00925744" w:rsidP="0071584E">
    <w:pPr>
        <w:pStyle w:val="MyTable"/>
    </w:pPr>
</w:p>
<w:tbl>
    <w:tblPr>
        <w:tblW w:w="0" w:type="auto"/>
        <w:tblBorders>
            <w:top w:val="single" w:sz="4" w:space="0" w:color="auto"/>
            <w:left w:val="single" w:sz="4" w:space="0" w:color="auto"/>
            <w:bottom w:val="single" w:sz="4" w:space="0" w:color="auto"/>
            <w:right w:val="single" w:sz="4" w:space="0" w:color="auto"/>
            <w:insideH w:val="single" w:sz="4" w:space="0" w:color="auto"/>
            <w:insideV w:val="single" w:sz="4" w:space="0" w:color="auto"/>
        </w:tblBorders>
        <w:tblLook w:val="04A0" w:firstRow="1" w:lastRow="0" w:firstColumn="1" w:lastColumn="0" w:noHBand="0" w:noVBand="1"/>
            <w:tblCaption w:val="Workspace"/>
    </w:tblPr>
```

The software is looking for a table with the table caption set to "Workspace" and will remove the first row.