Redaction Tool

Document Version 0.1, 01 May 2022
Author: Harald v. Aschen

Introduction

The "Full DAR-Redaction"[1] tool is for redacting the assessment reports templates and joining the parts to a single Word file.

Link to the tool: https://full-dar-redaction.apps.public.bfarm.de/

The tool is hosted at BfArM.

The tool can be used with any modern browser.

How to use

Generate the Draft Assessment Report templates

Please download the draft templates from the Clinical Trials information system. You should be able to generate them as RMS as soon as the RMS selection phase has finished, and the RMS is selected. For this, please open the trial, open the right application, click on "Evaluation", scroll down to "Assessment Part I", open the "Draft Assessment Report", unlock this section, ideally, click on "Select all" and click on "Generate template":
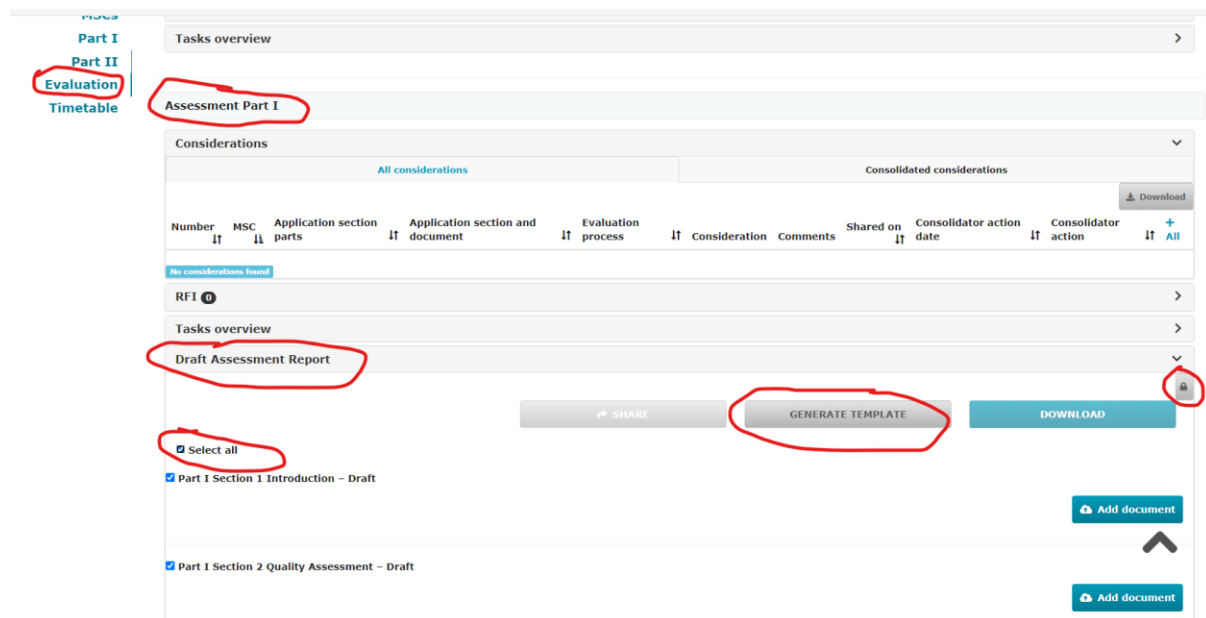
The seven templates will be generated and downloaded to your local computer.

---

[1] DAR: Draft Assessment Report

Fill out the templates. Everything that is written in the red "Workspace" will be removed (aka "redacted") by this tool, e.g., look at the part 7, Conclusion:

8 CONCLUSION OF THE RMS

Is the overall benefit/risk ratio acceptable for approval and considered as positive for the individual subject participating in the clinical trial (**from quality, non-clinical, clinical, statistical and regulatory perspectives)?**	Yes ☐ No ☐
Workspace: *Here is my personal text that will be redacted! You can insert anything in this cell. Please be aware: if you add additional cells, they will not be removed. Please be careful to copy and paste any cell into this "workspace" cell, as this might destroy this table and the tool cannot redact any more.*	
Assessor's comment on benefit/risk:	

All what is in the "Workspace" will be removed, e.g., for the above document:

8 CONCLUSION OF THE RMS

Is the overall benefit/risk ratio acceptable for approval and considered as positive for the individual subject participating in the clinical trial (**from quality, non-clinical, clinical, statistical and regulatory perspectives)?**	Yes ☐ No ☐
Assessor's comment on benefit/risk:	

The clinical trial is approvable
Yes ☐
No ☐ as requests for additional information exist that need to be resolved

Please be aware that you should close all documents that you would like to redact by the tool, otherwise you will get an error message during uploading.

The tool
If you click on the link you see:

On the left side you see the button "Reset form". With this button you can clear your file selection and remove any error message.

You have two possibilities:

- Redact different parts at once and join them in the right order.
- Redact one part individually.

Redaction of more than one part of the draft assessment

Convert Draft Assessment Report Part I

Please select each part of the DAR files. Convert the quality part individually below!
For a substantial modification please upload also the introduction and the conclusion, too. These parts will be redacted and then joined together in a Word file. The Word file will have removed the fields "Author" and "Last modified by". Because of the difficulties about embedded graphics or individual fonts you have to save the redacted Word file as PDF on your own.

File Type	Select docx template
Part I Section 1 Introduction – Draft	Choose File No file chosen
Part I Section 3 Pre clinical Assessment – Draft	Choose File No file chosen
Part I Section 4 Clinical Assessment – Draft	Choose File No file chosen
Part I Section 5 Statistical Methodological Assessment – Draft	Choose File No file chosen
Part I Section 6 Regulatory Assessment – Draft	Choose File No file chosen
Part I Section 7 Conclusion – Draft	Choose File No file chosen

Redact DAR part I without Quality

Here you can redact more than one part at once and join these parts together in the right order.

Example to redact all parts at once for an initial application:

Convert Draft Assessment Report Part I

Please select each part of the DAR files. Convert the quality part individually below!

For a substantial modification please upload also the introduction and the conclusion, too. These parts will be redacted and then joined together in a Word file. The Word file will have removed the fields "Author" and "Last modified by". Because of the difficulties about embedded graphics or individual fonts you have to save the redacted Word file as PDF on your own.

File Type	Select docx template
Part I Section 1 Introduction – Draft	Choose File · Introduction...rt_part_I.docx
Part I Section 3 Pre clinical Assessment – Draft	Choose File · Pre_Clinical...t_part_I.docx
Part I Section 4 Clinical Assessment – Draft	Choose File · Clinical_Ass...t_part_I.docx
Part I Section 5 Statistical Methodological Assessment – Draft	Choose File · Statistical_M..._part_I.docx
Part I Section 6 Regulatory Assessment – Draft	Choose File · Regulatory_...t_part_I.docx
Part I Section 7 Conclusion – Draft	Choose File · Conclusion_...t_part_I.docx

Redact DAR part I without Quality

But: You don't have to upload all parts together. If you have a substantial modification and not all parts needed to be redacted and joined, you can only upload the needed parts. E.g.

- Section 1: Introduction
- Section 5: Statistical Methodological Assessment
- Section 7: Conclusion

Then you would upload only these parts, as shown here:

## Convert Draft Assessment Report Part I

Please select each part of the DAR files. Convert the quality part individually below!

For a substantial modification please upload also the introduction and the conclusion, too. These parts will be redacted and then joined together in a Word file. The Word file will have removed the fields "Author" and "Last modified by". Because of the difficulties about embedded graphics or individual fonts you have to save the redacted Word file as PDF on your own.

File Type	Select docx template
Part I Section 1 Introduction – Draft	Choose File · Introduction...rt_part_I.docx
Part I Section 3 Pre clinical Assessment – Draft	Choose File · No file chosen
Part I Section 4 Clinical Assessment – Draft	Choose File · No file chosen
Part I Section 5 Statistical Methodological Assessment – Draft	Choose File · Statistical_M..._part_I.docx
Part I Section 6 Regulatory Assessment – Draft	Choose File · No file chosen
Part I Section 7 Conclusion – Draft	Choose File · Conclusion_...t_part_I.docx

Redact DAR part I without Quality

After you have uploaded the needed parts, please click on "Redact DAR part I without Quality". If all is working as expected you get the following result:
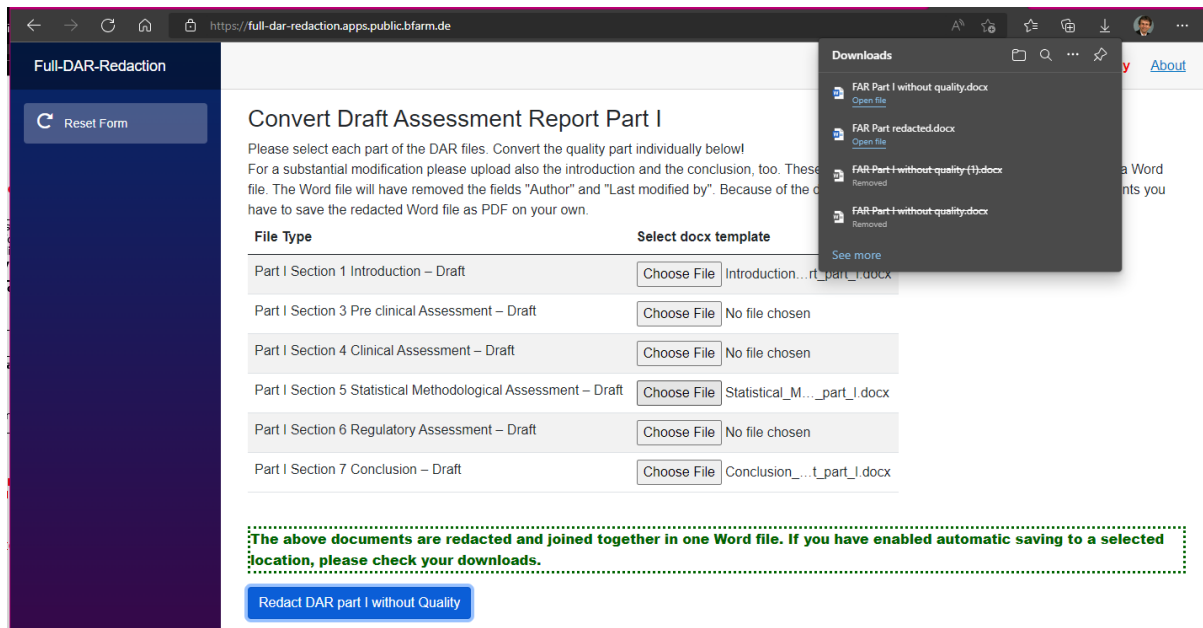
Or a popup might be opened to ask you where to save the file named

- FAR Part I without quality.docx

Please check your downloads to see where the file has been saved.

Redact individual parts
You can also redact any individual parts by using the second upload functionality:

Choose the right part, click on the redaction button and it will download the redacted word file, named: "FAR Part redacted.docx".

Other redactions

Also, the fields "author" and "last modified by" are removed. To check, click on the menu "File" → "Info:
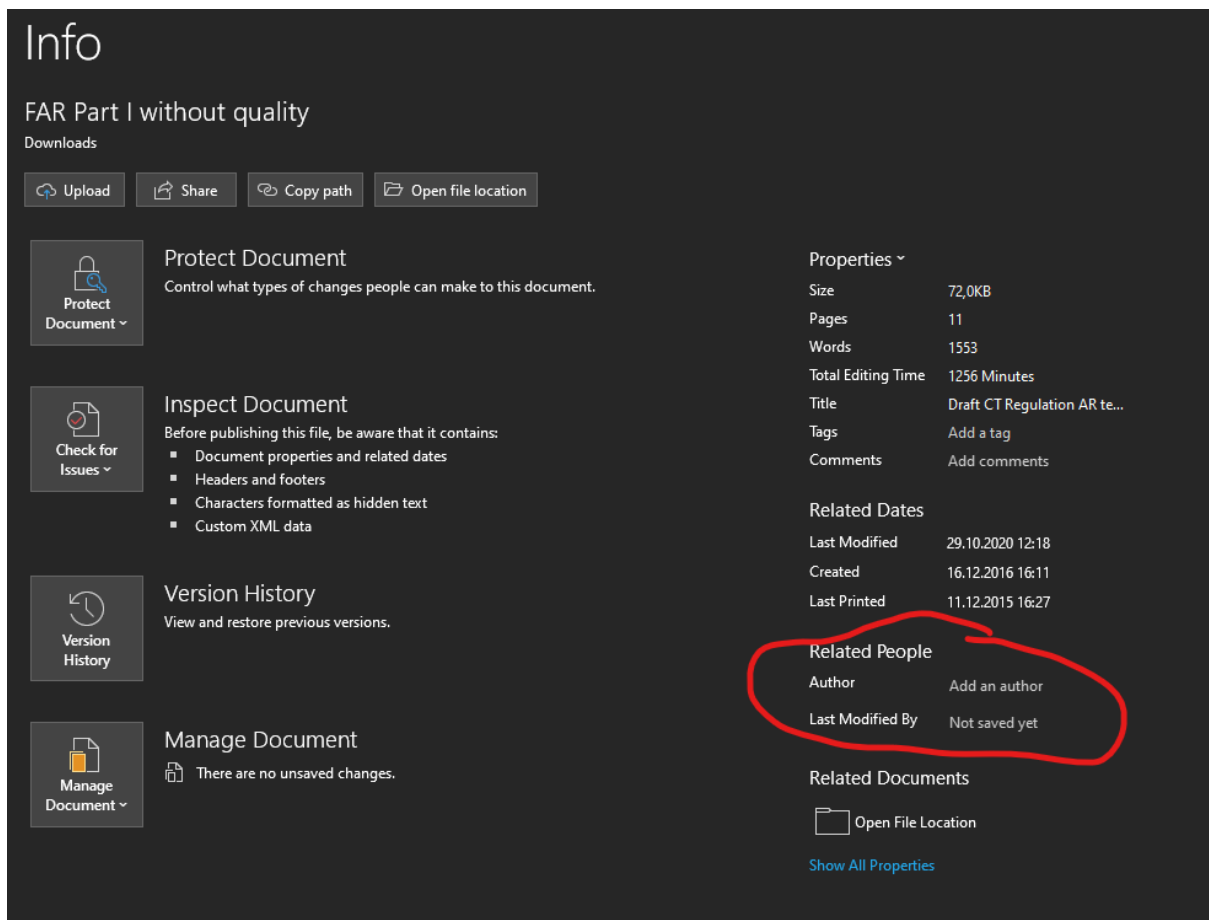
Please consider, if you add any other personal field (e.g., maybe by your content management system, like Microsoft SharePoint), these fields will not be removed by the tool.

Error messages

The system will check if you upload Microsoft Word docx files. If you try to convert anything else, you will get an error message, e.g., if you have selected erroneous a

PDF file:

Convert Draft Assessment Report Part I

Please select each part of the DAR files. Convert the quality part individually below!
For a substantial modification please upload also the introduction and the conclusion, too. These parts will be redacted and then joined together in a Word file. The Word file will have removed the fields "Author" and "Last modified by". Because of the difficulties about embedded graphics or individual fonts you have to save the redacted Word file as PDF on your own.

File Type	Select docx template
Part I Section 1 Introduction – Draft	Choose File Introduction...rt_part_I.docx
Part I Section 3 Pre clinical Assessment – Draft	Choose File No file chosen
Part I Section 4 Clinical Assessment – Draft	Choose File declaration_...4_50937.pdf
Part I Section 5 Statistical Methodological Assessment – Draft	Choose File Statistical_M..._part_I.docx
Part I Section 6 Regulatory Assessment – Draft	Choose File No file chosen
Part I Section 7 Conclusion – Draft	Choose File Conclusion_...t_part_I.docx

Please upload only Microsoft Word files in format docx.

Redact DAR part I without Quality

You do not need to reset the form, simply click on "Choose File" again and upload the right document.

If you don't upload anything or if you try to upload other Office files (e.g., if you try to upload an Excel file), you will get:

Convert Draft Assessment Report Part I

Please select each part of the DAR files. Convert the quality part individually below!
For a substantial modification please upload also the introduction and the conclusion, too. These parts will be redacted and then joined together in a Word file. The Word file will have removed the fields "Author" and "Last modified by". Because of the difficulties about embedded graphics or individual fonts you have to save the redacted Word file as PDF on your own.

File Type	Select docx template
Part I Section 1 Introduction – Draft	Choose File No file chosen
Part I Section 3 Pre clinical Assessment – Draft	Choose File No file chosen
Part I Section 4 Clinical Assessment – Draft	Choose File No file chosen
Part I Section 5 Statistical Methodological Assessment – Draft	Choose File No file chosen
Part I Section 6 Regulatory Assessment – Draft	Choose File No file chosen
Part I Section 7 Conclusion – Draft	Choose File No file chosen

No parts uploaded for redaction. Please upload at least one DAR part.

Redact DAR part I without Quality

Important

Please consider that the tool is only joining the parts, as you would do by hand. As these parts have headings that would be wrong numbered after putting these parts together, the tool cannot do better. We are in internal discussions how to improve that.

Testing phase

The tool should be "production ready", but here you have the possibility to test the tool and provide feedback to me via email. What I would like to get as feedback:

- Do you have troubles getting the tool up and running? (E.g., you are trying to upload, and nothing is happening.)
- Do you get other error messages in your browser?
- Would you like to provide feedback on the filenames? Are you satisfied with the naming?
- Any other feedback or wishes?