

Automated generation of appendix to the Clinical Study Report

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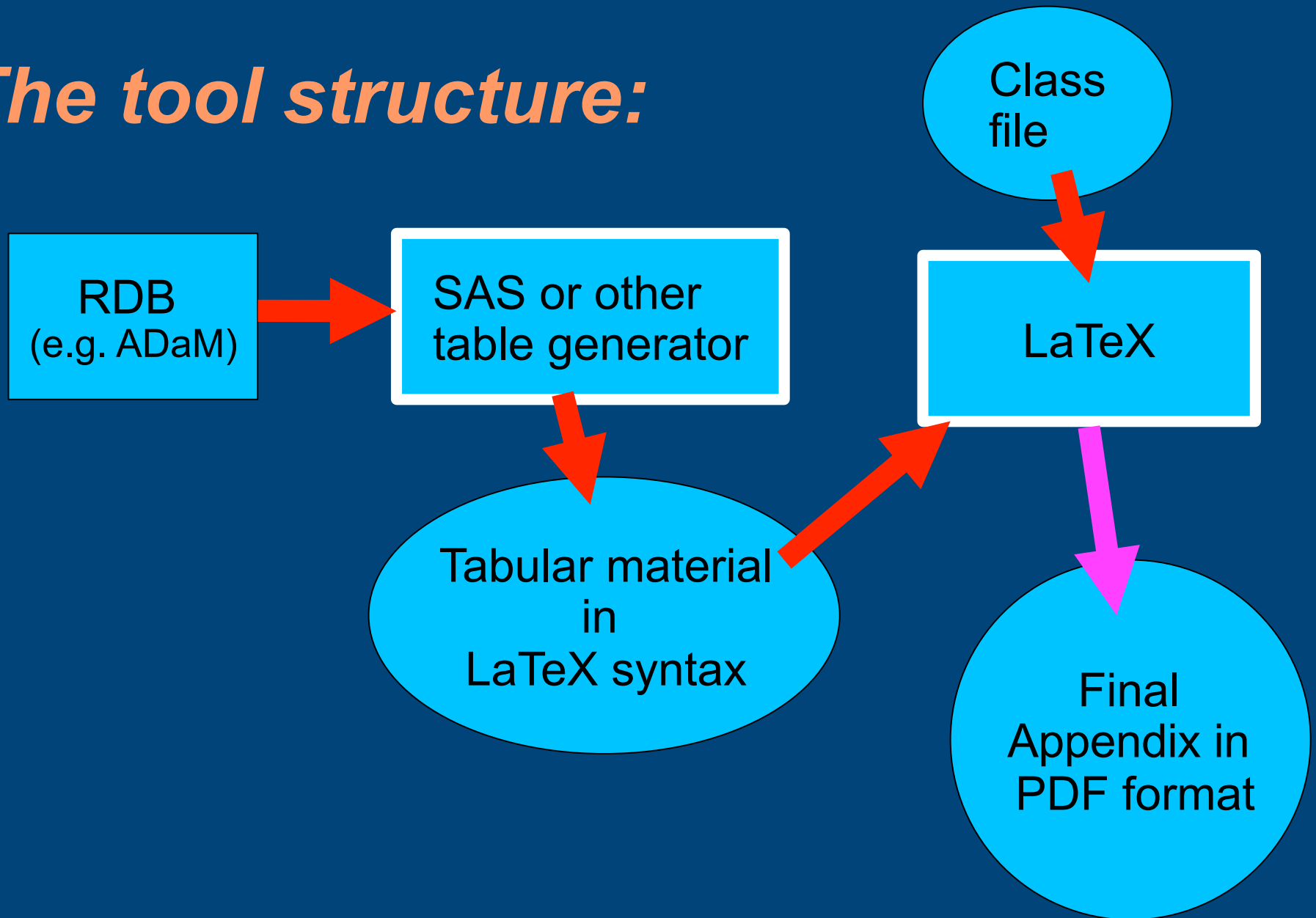
Why we do appendices:

- A good place for
 - listings of individual data,
 - graphics illustrating individual and
 - extensive summary statistics
 - Required by the ICH E3 (Appendix 16.2) – only listings
 - Fixed format with a standardized content
 - Can be generated very easily from a well designed data base with the appropriate tools
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The appendix generation process

- A well-designed clinical data base is organized with reporting in mind
 - Not a reflection how data was collected!
 - The appendix should reflect the data base, but with explanatory information above variable labels
 - Reflect, not mirror (only meaningful data should be listed etc)
 - The formatting of an appendix, both template and individual tables, can easily be done by the appropriate (free) software (TeX)
 - What we need is a tool that can produce the appropriate text-files with tabular information to TeX
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The tool structure:



The "SAS" program

```
let string vars= {
    "AGE" "Age\t(yrs)" "0" "",
    "sex" "Sex\t" "-1" "1@2||Male@Female",
    "race" "Race\t" "-1" "1@2@3||Caucasian@Black@Oriental",
    "BMI" "BMI\l\t(kg/m$^2$)" "1" "",
    "FEV1" "@2 FEV$ 1$\t(L)" "2" "",
    "FEV1%PN" "\l\t(\% P.N.)" "0" "",
    "treat" "\tTreatment" "-1" "A@B||Treat A@Treat B"};

let string cvars = {"CENTRE" "\tCentre" "0",
                    "PATIENT" "\tPat.No." "0"};

head="Listing of baseline characteristics";

call ListOfData("RDB/demo",vars,cvars,head,"TeX/list1",0);
```

Which produces the file list.tex:

```
\begin{table}[htp]
\caption{First demograhic table}
\begin{center}
{\footnotesize\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}\hline
\multicolumn{1}{|c|}{Centre/}&\multicolumn{1}{c|}{Age}&\multicolumn{1}{c|}{Sex}&
\multicolumn{1}{c|}{Race}&\multicolumn{1}{c|}{BMI}&\multicolumn{2}{c|}{FEV$1}& \\\
\multicolumn{1}{|c|}{Pat.No.}&\multicolumn{1}{c|}{(yrs)}&\multicolumn{1}{c|}{\overline{}}&
&\multicolumn{1}{c|}{(kg/m$^2$)}&\multicolumn{1}{c|}{(L)}&
&\multicolumn{1}{c|}{(\% P.N.)}&\multicolumn{1}{c|}{Treatment}\\ \hline
101/28 & 53 & Female & Black & 34. & 1.39 & 71 & Treat A & \\\
102/1 & 44 & Male & Caucasian & 24.7 & 1.73 & 70 & Treat B & \\\
102/2 & 60 & Female & Caucasian & 30.0 & 2.04 & 99 & Treat A & \\\
102/3 & 53 & Male & Caucasian & 25.6 & 1.44 & 63 & Treat B & \\\
102/4 & 30 & Female & Caucasian & 32.0 & 1.78 & 62 & Treat A & \\\
102/5 & 35 & Female & Caucasian & 32.4 & 1.51 & 63 & Treat A & \\\
102/51 & 31 & Female & Caucasian & 23.7 & 2.77 & 81 & Treat B & \\\
\hline
\end{tabular}}
\end{center}
\end{table}
```

Which LaTeX transforms into...

Centre/ Pat.No.	Age (yrs)	Sex	Race	BMI (kg/m ²)	FEV ₁ (L)	FEV ₁ (% P.N.)	Treatment
101/28	53	Female	Black	34.2	1.39	71	Treat A
102/1	44	Male	Caucasian	24.7	1.73	70	Treat B
102/2	60	Female	Caucasian	30.0	2.04	99	Treat A
102/3	53	Male	Caucasian	25.6	1.44	63	Treat B
102/4	30	Female	Caucasian	32.0	1.78	62	Treat A
102/5	35	Female	Caucasian	32.4	1.51	63	Treat A
102/51	31	Female	Caucasian	23.7	2.77	81	Treat B

Or, rather, something better not distorted by Powerpoint

What else do we need?

- SAS to produce a text file with tabular material
 - Graphs can be included!
- A control file to run LaTeX on
- A document format file (appendix.cls)

The last two are developed once and for all when the tool is set up

```
\documentclass[11pt,listoftables,dvips]{appendix}
\appendixno{12.2.1}
\drug{Drugname}
\documentno{?}
\studycode{D9830C00021}
\version{01}
\title{Disposition of each patient (completion/
discontinuation)}
\author{Anders Käll\'en}
\date{\today }

\begin{document}
\maketitle
\setcounter{subsubsection}{1}
\footnotesize
\include{list}
\end{document}
```

*A quick demonstration of how it
might work in practice*



Summary:

- With a properly constructed report data base, to construct submission ready appendices with data listings and other displays of individual data can be automated
 - No need for adjustments by medical communication scientists
- The design of the document (house style of PDF) is done once and for all when constructing the tool
- With a standardized data base, the submission ready appendices are done "in a blink of time"

