

A long Way down from an Output-Window to the Bottom of pdf – some Shortcuts

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**PhUSE 2012
TS07**

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Introduction of Tables, Listings and Figures generated as pdf-Files with the SAS® Output Delivery System (ods) in a CRO (Contract Research Organization) Environment.

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Introduction

Motivation:

- **CRS Clinical Research Services GmbH is a full Service CRO**
- **Approx. 50 Trials per Year in "Clinical Data Management" - most of them Phase I Studies**
- **Company exists for more then 30 Years:
Restrictions based on existing Standards and Customs**
- **Growing demands on Documentation, Traceability**
- **Electronic Common Technical Document (eCTD)**
- **Improvement of Programming**
- **Previous Standard:
Output-Window, Word-Processing-Macros, doc-File**

Introduction

Implementation:

- **Definition of Specifications**
- **Establish an appropriate Style-Template**
- **Find proper Solutions for all structural Elements (Bookmarks)**
- **Integrate the new Process (Manuals, SOPs, Training)**
- **Convince Clients (resp. Sponsors) to accept new Procedures**
- **Follow Up, Assessment, Correction**

Important Specifications

- **SAS/ods for pdf or rtf Output?**
- **Which Procedures (proc report, proc print, proc tabulate, graphic procedures) will be used?**
- **Which Degree of Standardization is applied?**
- **Do not under-estimate Familiarity!**
- **Appearance of Output identical with previous Standards!**

Important Specifications

- Which structural Elements ?
(Page x of y, Bookmarks, Table of Contents, etc.)
- One pdf-File for each Output Object (i.e. Table, Listing or Figure) or complete Subsections in one pdf-File?

	Page x of y	Customized Bookmarks	Table of Contents
One pdf-file for each Output Object	☺	☺	☹
Several Output Objects in one pdf-file	☹	☺	☺

Electronic Common Technical Document (eCTD)

Company's Interpretation of:

**Electronic Common Technical Document Specification –
Appendix 7 Specification for Submission Formats**

- **File Type and Size: pdf-Files < 100 MB**
- **Courier 9pt and/or Times New Roman 11pt**
- **No Colors in Text and Graphics**
- **Page Orientation Landscape for Tables, Listings and Figures**
- **Paper Size A4: Top 5cm, Bottom 3cm, Left 3cm, Right 3cm Margins**
- **Bookmark Hierarchy “with no additional Bookmark Levels beyond those present in the Table of Contents”**
- **“Only the internal Page Numbers of the Document are expected (1-n)”,
Page x of y in Addition**

Style-Template

- **Without Style Template, the pdf Output is formatted according to pre-specified Definitions (do not fit Needs of Clinical Trails)**
- **A carefully designed Style, created with the Template Procedure**
- **Fonts, Appearance of Tables, Alignments of Headers and Columns, Page Margins, Colors and many more Features**
- **No Need to define a complete Style from Scratch, predefined Styles e.g. "journal" used as a Parent Style**
- **A short Example Code of a Template Procedure is given, the whole Code covers approx. 300 Lines and is Property of CRS**

Style-Template

```
proc template;
  define style COMPANY_STYLE;
    parent = styles.journal;
    replace fonts /
      /*Titles from title statement*/
      'TitleFont' = ("Courier",9pt)
      /* Titles from proc statement*/
      'TitleFont2' = ("Courier",9pt)
      /*table row headings*/
      'HeadingFont' = ("Courier",9pt);
      /*set page margins*/
    replace Body from Document /
      topmargin = 5cm
      leftmargin = 3cm
      rightmargin = 3cm
      bottommargin = 3cm;
      /*appearance of data*/
    style data /
      font = ("Courier",9pt)
      background=white
      foreground=black
      just=left;
    end;
  run;
```

Regular Way to pdf-Bookmarks

Introduction to Examples:

- Examples are based on SASHELP.CLASS Data
- Examples run with some Options, given for Consistency Reasons, might be adapted
- Same for the "escapechar", which is a Control Character for SAS/ods
- The proc sort, by-Statements will be used
- Examples run with SAS for Windows, version 9.2 on XP_PRO Platform
- First Steps are very simple and yield pdf-Bookmarks at once

Regular Way to pdf-Bookmarks

```
options nodate nonumber nocenter orientation = landscape papersize = A4;
ods escapechar = "^";

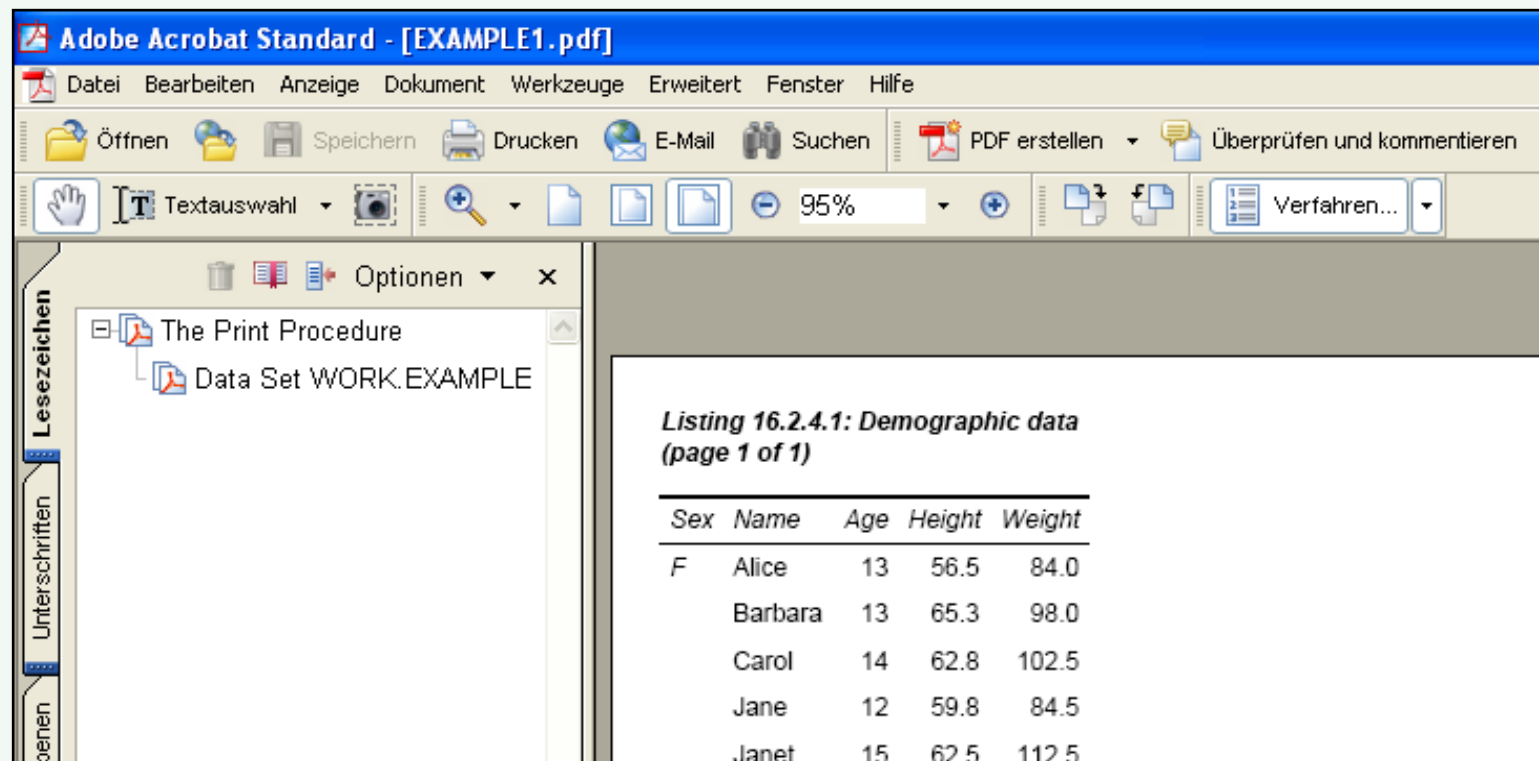
proc sort data=SASHELP.CLASS out = EXAMPLE;
by SEX;
run;

ods pdf file = "P:\TEMP\EXAMPLE1.pdf" style = journal;
title1 justify=left "Listing 16.2.4.1: Demographic data";
title2 justify=left "(page ^{thispage} of ^{lastpage})" justify =right "&SYSDATE9";

proc print data=EXAMPLE noobs;
var NAME AGE HEIGHT WEIGHT;
id SEX;
by SEX;
run;

ods pdf close;
```

Regular Way to pdf-Bookmarks



Customized Bookmarks for Listings

- Bookmarks are not in the Shape as intended
- The Content of the Bookmark has no meaningful Title
- Moreover the Default Bookmark has two Levels

Sample Code for Proc Print:

- Previous Example is repeated, several Statements are added
- Macro Variable "MY_TITLE" is defined, controls Title and Content of Bookmark
- contents = "" in the Procedure Statement, omits Second Level Entries
- ods proclabel inserted

Customized Bookmarks for Listings

```
ods pdf file = "P:\TEMP\EXAMPLE2.pdf" style = journal;

%let MY_TITLE = %str("Listing 16.2.4.1: Demographic data");

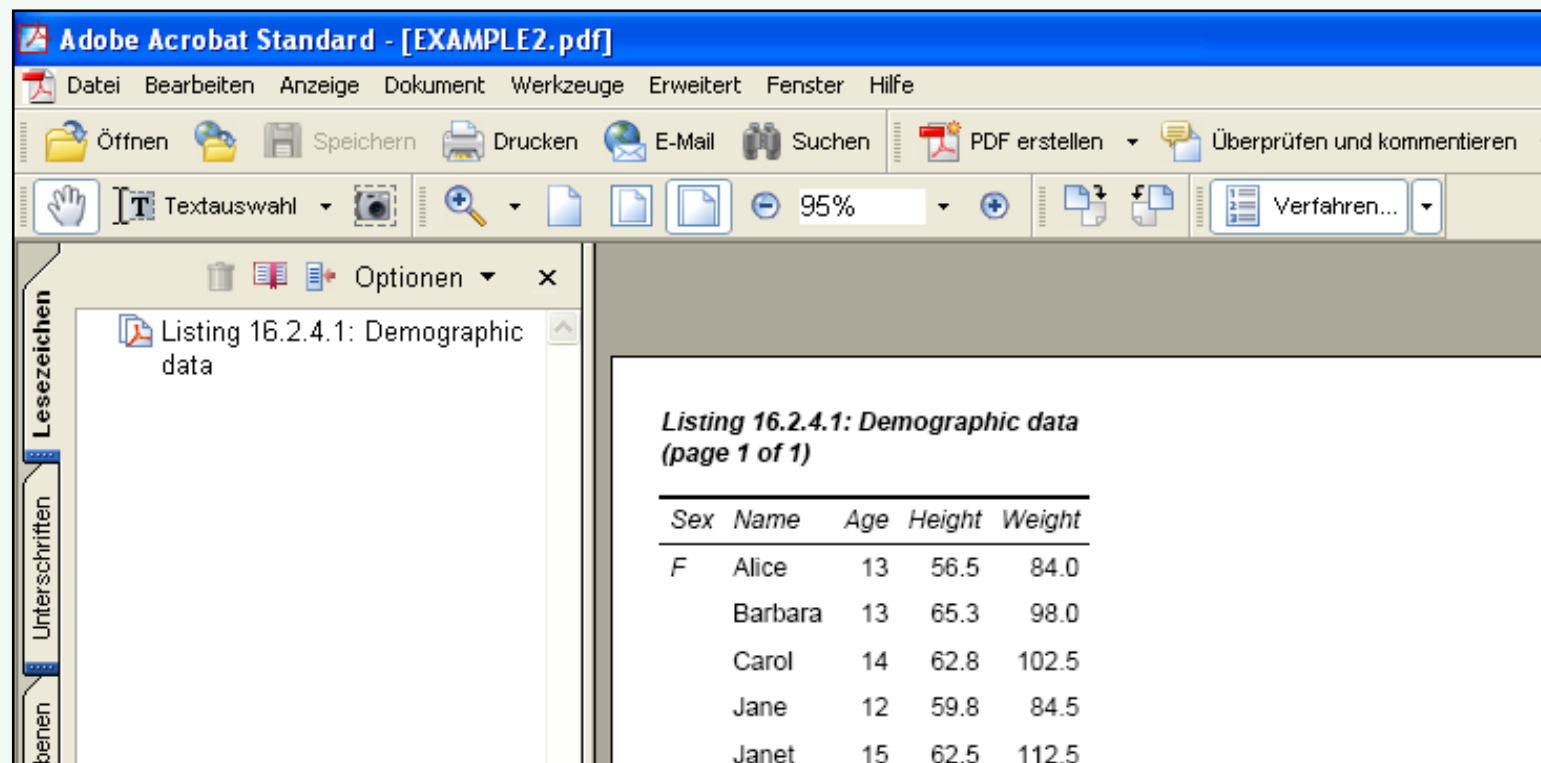
ods proclabel &MY_TITLE;

title1 justify=left &MY_TITLE;
title2 justify=left "(page ^{thispage} of ^{lastpage})" justify =right "&SYSDATE9";

proc print data=EXAMPLE noobs contents = "";
var NAME AGE HEIGHT WEIGHT;
id SEX;
by SEX;
run;

ods pdf close;
```

Customized Bookmarks for Listings



Customized Bookmarks for Tables

Sample Code for proc report

Assume two proc reports are necessary (not mandatory, enhances the Sample)

- For Simplicity the two proc reports differ in the where-Line
- Code as before with Procedure Label and contents = ""
- Break to erase Second Level Entries with another contents = ""
- The second Proc Report is preceded by the ods pdf nobookmarkgen statement
- Page x of y Feature works

Customized Bookmarks for Tables

```
ods pdf file = "P:\TEMP\EXAMPLE4.pdf" style = journal;
%let MY_TITLE = %str("Table 14.1.1: Descriptive statistics of demographic data");

ods proclabel &MY_TITLE;

title1 justify=left &MY_TITLE;
title2 justify=left "(page ^{thispage} of ^{lastpage})" justify =right "&SYSDATE9";

proc report data=EXAMPLE nowd spanrows contents = "";
column SEX NAME AGE HEIGHT WEIGHT;
define SEX / group;
break before SEX / page contents = "";
where SEX = "M";
run;

ods pdf nobookmarkgen;

proc report data=EXAMPLE nowd spanrows contents = "";
column SEX NAME AGE HEIGHT WEIGHT;
define SEX / group;
break before SEX / page contents = "";
where SEX = "F";
run;

ods pdf close;
```

Customized Bookmarks for Tables

The screenshot shows the Adobe Acrobat Standard interface. The main window displays a PDF document titled "EXAMPLE4.pdf". The left sidebar contains a "Lesezeichen" (Bookmarks) panel with a single bookmark labeled "Table 14.1.1: Descriptive statistics of demographic data". The main content area shows the corresponding table from the PDF.

Table 14.1.1: Descriptive statistics of demographic data (page 1 of 2)

Sex	Name	Age	Height	Weight
M	Alfred	14	69	112.5
	Henry	14	63.5	102.5
	James	12	57.3	83
	Jeffrey	13	62.5	84
	John	12	59	99.5

Customized Bookmarks for Graphics

Sample Code for proc gplot

- Use of proclabel and Title Statements as described before
- `des = ""` disables Second Level Entries
- Step 1: Necessary to file the Graphic Output in an Output File
- Step 2: Filed Graphic is displayed with the proc greplay
- Page x of y Feature does not work in this Example

Customized Bookmarks for Graphics

```
ods pdf file = "P:\TEMP\EXAMPLE5.pdf" style = journal;
%let MY_TITLE = %str("Figure 14.1.1: Scatter plot of height by weight");

goptions nodisplay;

title1 justify=left h=9pt &MY_TITLE justify =right h=9pt "&SYSDATE9";

proc gplot data=EXAMPLE gout=EXAMPLE5;
plot WEIGHT * HEIGHT / des = "";
by SEX;
run;
quit;

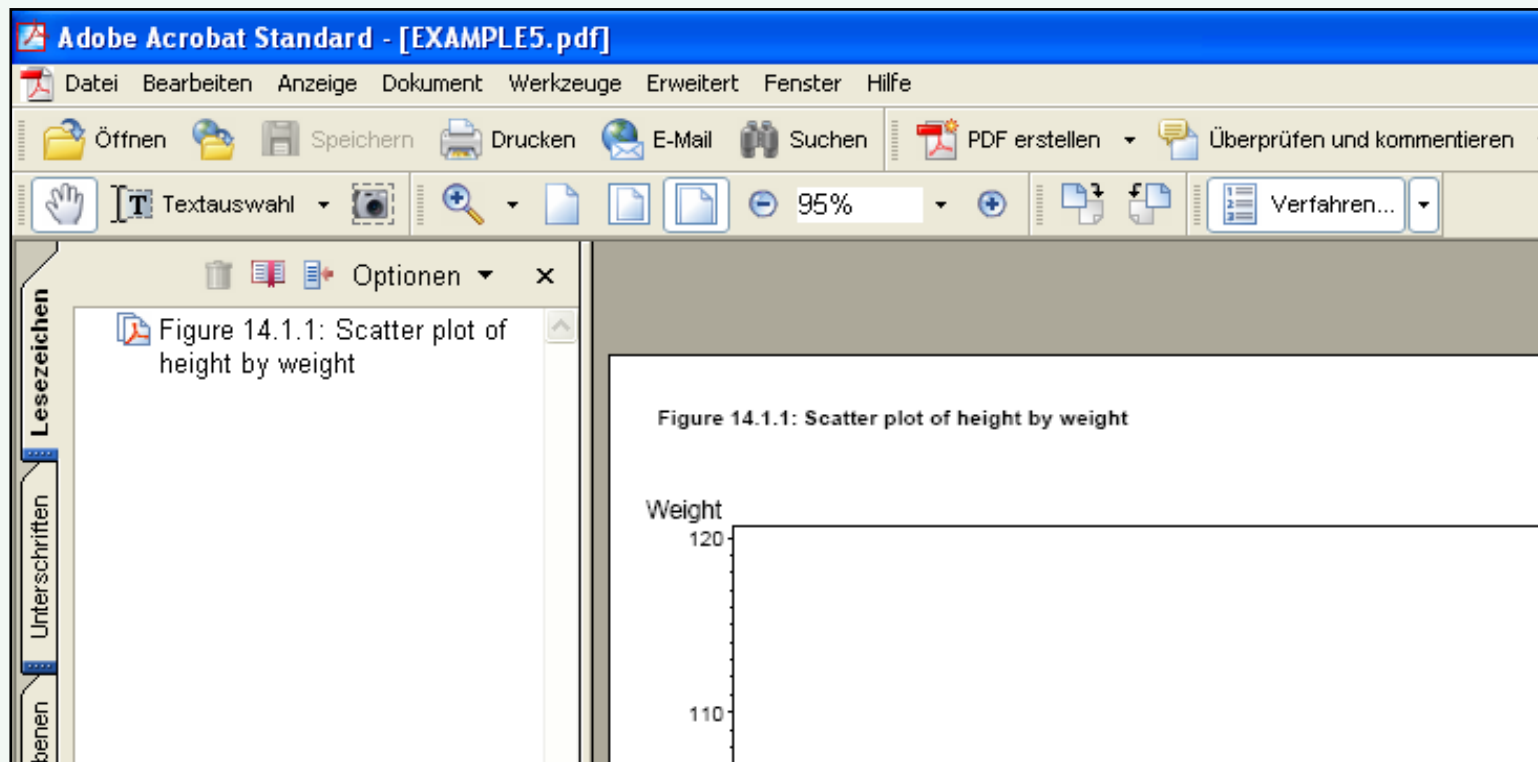
goptions display;

ods proclabel &MY_TITLE;

proc greplay igout = EXAMPLE5 nofs;
replay _all_;
delete _all_;
run;
quit;

ods pdf close;
```

Customized Bookmarks for Graphics



What is missing, what is difficult?

Expect unexpected Hassles

Examples below turned out to be Time Killers

- **After generating one pdf-file for each Table, Listing or Figure, the Files are to be assembled with e.g. Adobe Acrobat® Standard Software**
- **Empty Lines in Tables:**
In the report Procedure the "break after VARNAM / skip" does not work
- **Page x of y does not work with the Graphic Procedures as described above**
- **Unexpected Results:**
In some rare Cases, Appearance of Tables or Listings is corrupted on Single Pages

What is missing, what is difficult?

Listing 16.2.7.1: Adverse Events				
(page 7 of 8)				
Subject No.	PID	Adverse event (Modified Term)	Adverse Event (Reported term)	Onset Date/Time
12-123 [AB]	112233	DROWSINESS	DROWSINESS	2012-06-02
		PRURITUS	PRURITUS	2012-06-03
12-456 [AB]	445566	TIREDNESS	TIREDNESS	2012-06-04
12-789 [AB]	778899	DROWSINESS	DROWSINESS	2012-06-05

Experience and Outlook

Clients (resp. Sponsors):

- **Acceptance of ca. 15 Companies is very high**
- **Some asked for the same Process with rtf files (In-Text Tables are already made with ods/rtf)**
- **Acceptance of Bookmarks in pdf-files is low**
Table of Contents is frequently requested

Clinical Staff / Internal Reviewers:

- **Do not appreciate the new Process,**
- **Some Revisions were done in Tables, Listings, Figures**
pdf was blamed for all spurious or unfamiliar
- **Importance of Comments in the familiar Word-Processing Software**

Experience and Outlook

SAS-Programmers:

- Work is more efficient
- Hard to get used to ods-Statements within SAS Procedures
- No other Software for formatting SAS Output is a large Gain and improves Traceability
- With growing Experience of SAS Programmers, much more is possible
- compared to an Output Window

Outlook:

- Customizing Bookmarks and Tables of Contents in order to come closer to the Needs of Users (explore proc document Possibilities)
- Display Company Logos and Trial Numbers with no outside SAS Efforts ("ods layout" and "ods region" Functionalities)

References

- Haworth, L.E., Zender, C.L., Burlew, M.M. (2009) Output Delivery System: The Basics and Beyond. SAS Institute Inc., Cary, NC.
- ICH M2 EWG (2008) Electronic Common Technical Document Specification, ICH eCTD Specification V 3.2.2
http://estri.ich.org/eCTD/eCTD_Specification_v3_2_2.pdf

Thank you for your Attention!