Creating PDF™ Documents including Links, Bookmarks and a Table of Contents with the SAS® Software.

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ABSTRACT

At the Pharmaceutical Company NV Organon clinical studies are performed and using the SAS system statistical appendices are created. These appendices usually contain huge amounts of listings, tables, analyses and graphs and are part of electronic submissions. Nowadays the Adobe© Portable Document Format (PDF) is the standard document format. This format can be read on different platforms and includes objects to easily navigate by using bookmarks and hyperlinks. In this way even large documents are very accessible.

This paper describes 2 SAS macros that combine various types of SAS output into PDF files, containing hyperlinks, bookmarks and a table of contents.

First, the SAS macro %_SAS2PS combines all SAS output into one big Postscript™ file. This postscript file contains all SAS output, including a table of contents and so-called PDFmark operators. Then the macro %_PS2PDF will send this postscript file through Acrobat Distiller™, resulting in a PDF file that contains a table of contents, bookmarks and hyperlinks.

INTRODUCTION

In clinical studies investigators at several study centers fill in Case Report Forms (CRFs). These CRFs are then entered in to a Clinical Data Management System. In our case this is Clintrial™, but we are heading towards Oracle Clinical™.

From the Clinical Data Management System data retrievals are being made in the form of SAS data sets. These are kept on the SAS Clinical Data Warehouse. Here the statistical analyses are performed. These statistical analyses result in several documents that will be part of electronic submissions.

The Documents are stored in a Document Management System. In our case this is Documentum™. Out of the Document Management System the electronic submission will be compiled.

When pharmaceutical companies submit electronic documents to the American Food and Drug Administration (FDA) it has to be in the Portable Document Format (PDF) [1]. PDF has been accepted as a standard for providing documents in electronic format by the International Conference on Harmonization (ICH).

In this presentation we will concentrate on how to get from SAS output to the PDF format. To get from SAS output to the PDF format we will go via Postscript. This is also a graphic format developed by Adobe and it is closely related with the PDF format.

The SAS that we use is quite simple. Only SAS/BASE is used and then only DATA STEPS, PROC SORT and PROC DATASETS.

ENVIRONMENT

The technical environment that we work in at the moment is as follows:

➢ Microsoft Windows NT 4, service pack 4
➢ SAS version 6.12, Technical Support level TS045. Only SAS/BASE is used. In fact only a few basic procedures are used, like PROC SORT and PROC DATASETS and DATA STEPS.
➢ Adobe Acrobat 4.05c

THE PDF FORMAT

The PDF format is developed by the Adobe Company and enables users to exchange and view electronic documents independent of the environment in which they were created. This document format is the basis of the Acrobat software. The PDF format is closely related to Postscript. Postscript is a page description language developed in the early 1980s by Adobe Systems as well. It describes the appearance of a printed page. PDF documents also include objects, such as annotations, hypertext links and bookmarks that are not part of the page itself but are very useful for interactive viewing and navigating. These objects make it easy to add cross-references to documents.

In their guidelines [1] the FDA writes:

"*Hypertext links and bookmarks are techniques used to improve navigation through PDF documents. Hypertext links can be designated by rectangles using thin lines or by blue text*"

and:

"*In general, for documents with a table of contents, provide bookmarks and hypertext links for each item listed in the table of contents including all tables, figures, publications, other references, and appendices. These bookmarks and hypertext links are essential for the efficient navigation through documents. In general, including a bookmark to the main table of contents for a submission or item is helpful. Make the bookmark hierarchy identical to the table of contents. Avoid using bookmark levels in addition to those present in the table of contents.*"

Being able to navigate very large documents in an easy and clear way is an important issue. PDF files are structured and optimized for fast and efficient access of random pages of the document.

A PDF file consists of four sections: a header, a body, a cross-reference table and a trailer.

Figure 1. *Structure of a PDF file*
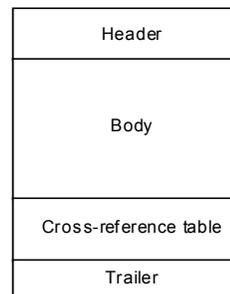
The header is a one-line entry that tags the file as being a PDF file. It contains the version number of the PDF file. The most current PDF files have the header line %PDF-1.3.

The body contains all the pages of the document, hypertext links, bookmarks and any other item that is part of the document. The elements comprising a page are contained in the file as separate objects and may be used again on different pages (for example a watermark).

A table at the end of the document (the cross-reference table) describes each object's position in the file. A special object (called the catalog) defines the document's contents, i.e. its pages, links and bookmarks. If a program like Acrobat Reader wants to process the file, it only has to load the cross-reference table into memory and use it to access arbitrary pages and their graphical and hypertext content. In this way the time required to open the file is not related to the size of the file.

The trailer contains "pointers" to a few important objects in the document, namely the root object of the document, the root object of the bookmarks, and the information who created the file and when it was created.
Another advantage of the PDF format is that the free available Adobe Acrobat Reader makes it possible to read PDF files by many users on various platforms.

CREATING PDF FILES

There are different ways to create PDF files out of SAS output.

➢ With the installation of the Adobe Acrobat package one can install a virtual printer driver (PDFwriter). If one prints to this driver from any Windows application that is capable of printing, the result is a PDF file. However, one will not get any bookmarks or hyperlinks. And also, because PDFwriter creates PDF files using TrueType fonts, these PDF files might not be searchable or indexable.

➢ It is also possible to read in the SAS output and directly create PDF files according to the PDF format as it is described in the Portable Document Format Reference Manual [2]. This could be programmed in SAS or another language like Perl. This is a very complex job that requires a lot of expertise of the PDF specification.

➢ SAS version 8.2 has the PDF output driver in the Output Delivery System (ODS) in production. This driver is very promising. This version will be released by the time this paper is being finished. In version 8.1 it's only experimental. Something like the following code will create a PDF file with bookmarks and a hyperlink:

```
ODS printer pdf file="example.pdf";
proc report data=test;
  compute before _page_
/style={url="file:b.pdf"};
        line 'Link to that other file?';
    endcomp;
  run;
  quit;
ODS printer close;
```

However, there will be no table of contents. It has to be seen how flexible the creation of bookmarks is. And how will it deal with portrait/landscape mixed and text/graphs mixed? At this moment there is not much information on creating PDF files with ODS, but it is clearly something to keep an eye on.

➢ Another possibility is to read in the SAS output and create a Postscript file that has embedded PDFmark operators. These PDFmark operators can be used to create bookmarks and hyperlinks. The PDFmark operator is a PostScript operator that allows for the inclusion of PDF features when the PostScript file is converted to PDF by Acrobat Distiller. It is only implemented in Acrobat Distiller. This is the way that is described in this paper.

By searching the Internet one can find several tools that are able to convert SAS output to the PDF format. The added value of what is presented in this paper is how to add bookmarks, hyperlinks and a table of contents to PDF files with the SAS System.
Also, text and graphics, landscape and portrait can be mixed together in one document.

THE PROCESS

The process how to get from SAS output to PDF is the following: We have a lot of SAS text output (tables, analyses, listings) and graphic output in a large number of files. We call a SAS macro (%_SAS2PS), which combines all of these files into one big Postscript file. This Postscript file includes a table of contents and also information that will be used to create bookmarks and hyperlinks in the PDF file. Once the Postscript file has been created it will be converted to PDF by using Acrobat Distiller. This

can either be done manually or - completely automated - by calling a SAS macro called %_PS2PDF. This SAS macro %_PS2PDF will send the Postscript file to Acrobat Distiller and return the resulting PDF file.

Acrobat Distiller is set up in the following way:
It works with a so-called 'watched folder' named PS2PDF. This folder has 2 subfolders: IN and OUT.
Acrobat Distiller watches every 15 seconds to the IN subfolder. Whenever a Postscript file is detected in this folder Acrobat Distiller will convert it to a PDF file in the the OUT subfolder. And then, of course, it will delete the Postscript file. Otherwise it would be distilled again.
The folder PS2PDF is a network folder that can be accessed by everyone in the company. This ensures that everyone will be using Acrobat Distiller in a consistent way; everyone is using the same Distiller parameters for pagesize, compression, font embedding, etc.

TYPES OF OUTPUT

Within our department we basically create 3 different kinds of documents with SAS. In fact they are appendices to a much bigger report.

➢ The Statistical appendix (**STAT**). This contains SAS output in the form of tables, analyses, graphics and listings. It is divided in different sections. (see appendix, figure 6)

➢ The Individual Data Listings (**IDL**) contain different listings. No sections are used here. (see appendix, figure 7)

➢ The Case Report Form tabulations (**CRF**) contain patient profiles. In these kind of appendices we can add tags to use customized bookmarks and bold or underlining. (see appendix, figure 8)

SAS OUTPUT CONVENTIONS

In order to produce SAS output that fits in our system for generating PDF output we need to have some conventions. For portrait we use:

```
OPTIONS linesize=94 and pagesize=87;
```

and for landscape:

```
OPTIONS linesize=145 and pagesize=56;
```

We also use the following options:

```
OPTIONS NOCENTER NODATE NONUMBER;
```

Dates and page numbering are taking care of by the %_SAS2PS macro and the programs that generate the output.

We also have some conventions for specifying titles. They start with one of the following keywords:

Table	Analysis
Listing	Figure

Then we have a number like <section>-<number> (STAT appendix) or just <number> (IDL appendix).

A typical title in SAS output might look like:

```
Table 1.1-A     Disposition of Subjects.
                All-Subjects-Randomized Group.
```

To recognize landscape output, we add a '#' to the title:

```
#Table 1.1-A     Disposition of Subjects.
                 All-Subjects-Randomized Group.
```

There can be up to 10 titles, but they can be no longer than 86 columns, which has to do with the table of contents.

Here we see some titles in the table of contents of an appendix with Statistical Analyses:

Figure 2.   *An example of a table of contents*

GRAPHIC FILES

Graphics are generated with the SAS Postscript device PSL.

Since we need the title of a graphic in the table of contents, every graphic file has a corresponding text-file with the title in it.

Furthermore, every graphic file contains only one graphic.

So, when we have 3 graphics, we might have the following files:

Graphic file	Title file
F61A.FIG	F61A.FIT
F61B.FIG	F61B.FIT
F61C.FIG	F61C.FIT

The content of a FIT file of a landscape figure might look like:

```
#Figure 6.1.E  Normal Q-Q plot of residuals.
              Outcome variable: Prothrombin
              Outliers excluded
              Per Protocol group
```

THE POSTSCRIPT FORMAT

Postscript is a programming language that describes the contents of a page. A 'page' is a graphic that can contain all kinds of objects:

- Basic shapes like lines, circles, curves, rectangles
- Text in various typefaces, sizes and orientation
- Pictures that are described by pixels (bitmaps)

These objects can be scaled, rotated, translated or colored.

Postscript was developed in the early 1980s by Adobe Systems and is closely related to PDF.

A big advantage of postscript is the independence from different devices (screen, printer,...) and the operating system.

Postscript files are just ASCII files, so they can be generated on every operating system.

Postscript can be viewed with on many platforms with Ghostscript, an interpreter that displays Postscript and PDF.

It also has the ability to convert PostScript language files to many raster formats and print them on printers that don't have PostScript language capability built in.

The World Wide Web home page for Ghostscript, Ghostview and GSview is at http://www.cs.wisc.edu/~ghost/index.htm [3]

The unit of measurement in PostScript is the point. There are 72 points per inch. Thus, an A4-size sheet of paper measures 595 by 842 points, that is 8,3 inch by 11,7 inch.

Or, in the USA, a Letter-size sheet of paper measures 612 by 792 inch, which is 8,5 by 11 inch.

The PostScript coordinate system resembles the Cartesian coordinate system, with the origin (0,0) in the lower left corner of the page. PostScript operators allow you to manipulate the coordinate system if you want (translate, scale, rotate, and so on).

A nice introduction to Postscript can be found on the Internet in the first guide to Postscript (see [4]).

Here is an example how we add text on a Postscript page:

We choose a font:
```
/Helvetica-Bold findfont 8 scalefont setfont
```

Move to a coordinate and place some underlined text:
```
108 730 moveto (Listing 4) ushow
```

Move to a coordinate and place some text:
```
205 730 moveto (Dosing Compliance.) show
```

Set another font:
```
/Helvetica findfont 8 scalefont setfont
```

Move to a coordinate and place some text:
```
205 723 moveto (Descriptives per Subject and
per Cycle.) show
```

Move to a coordinate and place some text:
```
205 716 moveto (Intent-to-Treat Group.) show
```

This results in the following:

Listing 4	Dosing Compliance.
	Descriptives per Subject and per Cycle.
	Intent-to-Treat Group.

In general:
>   *Choose font*
>   *X-coordinate Y-coordinate* **moveto** (*text to show*) **show**

A Postscript file that is well structured conforms to the Document Structuring Conventions (DSC). These conventions can be found

in [5].

The advantage of these conventions is that Postscript files conforming to DSC can be easily manipulated by other programs. For example: selected pages can be extracted or printed. Postscript documents that follow DSC are divided in different sections.

First there is a **prolog**. The prolog starts with the line **%!PS-Adobe-3.0**

Then there is a **header** section describing general document information ending with the **%%EndComments** comment. Between the **%%BeginProlog** and the **%%EndProlog** comment various procedures are defined.

After the **prolog** we have the **script**, which can be divided in:

The **document setup**, which is optional. It starts with **%%BeginSetup** and ends with **%%EndSetup**. This section can for example contain procedure calls for setting pagesize.

The **pages section** consist of 1 to *n* pages which should be functionally independent of the other pages. A page starts with **%%Page:** *comment*

The **document trailer** starts with the **%%Trailer** comment. It can describe the total number of pages or fonts used or can have termination - or cleanup routines.

The document ends with the **%%EOF** comment.

Figure 3.   *Document Structuring Conventions in Postscript*

```
%!PS-Adobe-3.0
%%Title: Protocol 068004 Appendix F
%%CreationDate: 29JUL99 18:31
%%Pages: (atend)
%%DocumentFonts: (atend)
%%Generated by: _SAS2PS 1.0a April 2000 (c) NV Organon
...
%%EndComments
%%BeginProlog
...
%%EndProlog
%%BeginSetup
...
%%EndSetup
%%Page: 1
...
%%Page: 2
...
%%Trailer
%%DocumentFonts: Courier Helvetica-Bold Helvetica
%%Pages: 474
%%EOF
```

THE PDFMARK OPERATOR

The PDFmark operator is a PostScript operator that allows for the inclusion of PDF features when the PostScript file is converted to PDF by Acrobat Distiller. It is only implemented in Acrobat Distiller.

PDFmark instructions are not processed when using the PDFwriter printer driver. A complete overview of the PDFmark operator can be found in Adobe's PDFmark Reference Manual [6] and in the book by Thomas Merz [7].

With the PDFmark operator a lot of specific PDF features can be implemented that otherwise would have to be done manually in Acrobat Exchange.

In this way bookmarks, hyperlinks, annotations and document information can be automatically generated when distilling the Postscript file.

The general syntax of the PDFmark operator is:

```
[       ...Various key-value pairs
        KIND pdfmark
```

KIND is a name specifying the kind of PDFmark.

A **bookmark**, known as an outline entry in PDF, is specified by using the PDFmark operator in conjunction with the name OUT.

The syntax for a bookmark marker is:

```
[/Title string
    /Count int
    ...Action-specifying key-value pairs...
    /OUT pdfmark
```

The **count** is required if the bookmark has subordinate bookmarks and then it specifies the number of subordinate bookmarks. If the value is positive, the bookmark will be open; if negative, the parent bookmark will be closed.
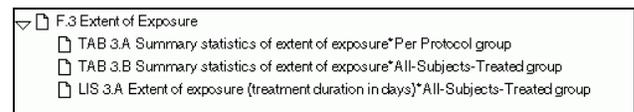
There are a few rules:
1. Bookmark markers appear in sequential order in the Postscript language file.
2. A bookmark with no subordinate bookmarks has no count key.

The bookmark must contain key-value pairs that specify an action (what happens if one clicks on the bookmark). Let's look at an example. We want to create the bookmarks in figure 4.

Figure 4.   *Bookmarks*

Then we have to use the following code:

```
[/Title (F.3 Extent of Exposure)
    /Count 3
    /Page 121
    /View   [/XYZ 103 775 null]
/OUT pdfmark

[/Title (TAB 3.A Summary statistics of extent
of exposure*Per Protocol group)
    /Page 122
    /View [/XYZ 144.6 116.68 null]
/OUT pdfmark

[/Title (TAB 3.B Summary statistics of extent
of exposure*All-Subjects-Treated group)
    /Page 125
    /View [/XYZ 144.6 116.68 null]
/OUT pdfmark

[/Title (LIS 3.A Extent of exposure
\(treatment duration in days\)*All-Subjects-
Treated     group)
    /Page 128
    /View [/XYZ 144.6 116.68 null]
/OUT pdfmark
```

The key-value pair /**View** [/XYZ left top zoom] means: left and top specify the distance in points from the origin of the page to the top-left corner of the window. Zoom specifies the zoom factor, a null value means that the current value of the zoomfactor is retained.

Using the PDFmark operator in conjunction with the name ANN specifies a **hyperlink.**

The syntax for a hyperlink marker is:

```
[   /Rect  [llx lly urx ury]
    /Border [bx by c [d]]
    /SrcPg  pagenum
    /Color   array
```

```
      /Subtype /Link
      ...action-specific key-value pairs...
   /ANN pdfmark
```

Rect (required) defines an array of four numbers specifying the lower-left x, lower-left y, upper-right x, and upper-right y coordinates of the rectangle defining the link button.
Border (optional) defines the link's border properties, like corner radius and width of the link's border.
SrcPg (optional) defines the sequence number of the page on which the link has to appear. If this key is absent, the link marker must be defined on the same page as the link's source page.
Color (optional) defines the link's border color. It is an array with 3 integers, each between 0 and 1 specifying a color in the DeviceRGB space ((1 0 0) = red, (0 1 0) = green, (0 0 1) = blue)
Subtype (required) must be /Link.
The link must contain key-value pairs that specify the action.

Let's look at an example.
We want to create the link in figure 5.

Figure 5. *A hyperlink*

| Table 7.3.B | Summary statistics of Anticoagulatory variables | |
| | All–Subjects–Treated group. . . . . | F–333 |

First some Postscript:

```
108 291 moveto (Table 7.3.B) show
205 291 moveto (Summary statistics of
Anticoagulatory variables) show
205 283 moveto (All-Subjects-Treated group)
show
(F-333) Calc Dots
```

And then the PDFmark code for the hyperlink:

```
[   /Rect [ 106 281 528 301 ]
    /Color [0 0 1]
    /Page 25
    /View [/XYZ 144 117 null]
    /Subtype /Link
/ANN pdfmark
```

There are many more possibilities with these PDFmark operators as can be found in the excellent book by Thomas Merz [7].

THE SAS MACRO %_SAS2PDF
To convert all SAS output to a PDF document a SAS macro is being used called %_**SAS2PDF.**
Basically the %_**SAS2PS** macro does the following:
- read in all text files (SAS output) that are conforming to a FileMask (example F*.*).
- sort by section, type (table, analyses, ..) and number
- generate table of contents
- with a data step generate Postscript including:
  - rotation of landscape pages
  - bookmark and hyperlink information
  - graphics

The call and parameter syntax of this macro can be found in the appendix of this document.

THE SAS MACRO %_PS2PDF
To make the conversion of Postscript files to PDF very easy for the users, the SAS macro %_**PS2PDF** has been developed.
This macro use the KIXTART script language [8] to copy a

Postscript file to a folder on the network that is constantly watched by Acrobat Distiller. In this way the conversion from Postscript to PDF can be fully automated.
The only thing the user has to do, is calling a SAS macro:

```
%_ps2pdf(inlib=release, psfile=p12345.ps,
         distlib=distill,
         poltime=1, timeout=60);
```

Using this call a KIXTART script is created that converts the Postscript file in the *release* library to a PDF file, by copying it to a watched folder specified by the *distlib* library. The script will look every minute (*poltime*) for a maximum of 60 minutes (*timeout*) to see if the Postscript file has been converted to PDF.

CONCLUSION
With SAS/Base and Acrobat Distiller it is possible to create PDF documents from SAS output that include a table of contents, bookmarks and huperlinks. Text and graphics can combined and also portrait and landscape. This process can be completely automated.

REFERENCES
[1] FDA (January 1999, IT 2). Guidance for Industry: Providing Regulatory Submissions in Electronic Format - General Considerations. U.S. Food and Drug Administration, Rockville, MD. (http://www.fda.gov/cder/guidance/index.htm) (Electronic Submissions)
[2] PDF Reference Version 1.3, 2nd Ed. Addison-Wesley, 7/3/00 (http://partners.adobe.com/asn/developer/technotes/acrobatpdf.html)
[3] Ghostscript, Ghostview and GSView. (http://www.Cs.Wisc.Edu/~ghost/index.Htm)
[4] First guide to Postscript. (http://www.Cs.Indiana.EDU/docproject/programming/postscript/postscript.Html)
[5] Adobe Developer Support, PostScript Language Document Structuring Conventions Specification, Adobe Technical note #5001, version 3.0 (Document 5001.DSC_Spec.pdf on Adobe's server)
[6] Adobe Developer Support, PDFmark Reference Manual, Adobe Technical note #5150, (Document pdfmark.pdf on Adobe's server)
[7] Thomas Merz, Web Publishing with Acrobat/PDF, Springer-Verlag Berlin Heidelberg 1998, ISBN: 3-540-63762-1
See also: http://www.Pdflib.Com/pdfmark/index.Html
[8] Kixtart can be found at http://www.kixtart.org/

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APPENDIX

Figure 6. *Statistical appendix F*

Draft

CONFIDENTIAL F–51 P36205

Table 2–E.1.1 **Carbohydrate Parameters at Baseline.**
Per Treatment Group
All–Subjects–Treated group.

Variable	Statistic	1 mg E2 Org 30659 7.5 µg	15 µg	30 µg	60 µg	2 mg E2 Org 30659 7.5 µg	15 µg	30 µg	60 µg	Overall
Glucose AUC (mmol*h/L)	Mean	31.4	34.0	36.0	37.2	39.6	39.9	35.9	32.2	35.9
	Median	30.1	34.5	35.0	37.1	37.2	38.6	36.6	31.1	35.8
	SD	6.9	5.7	3.8	8.6	12.6	4.8	5.4	4.5	7.2
	n	4	14	10	7	8	5	5	4	57
Glucose after 120 min 1)										
missing	n			1	1					2
below ref. range	n	4	15	10	6	7	5	5	4	56
above ref. range	n				1	1	1			3
missing	%			9.1	12.5					3.3
below ref. range	%	100.0	100.0	90.9	75.0	87.5	83.3	100.0	100.0	91.8
above ref. range	%				12.5	12.5	16.7			4.9
Insulin AUC (mIU*h/L)	Mean	160.0	153.6	177.6	117.3	204.6	139.8	177.6	163.2	163.1
	Median	138.9	132.6	185.0	120.7	201.2	123.1	179.6	111.3	146.0
	SD	108.7	83.3	64.5	32.7	72.2	32.3	48.9	123.3	71.9
	n	3	12	9	6	8	6	5	4	53

Page 50 of 185   123%   8,26 x 11,68 in

Figure 7. *Appendix G (Individual Data Listing)*

CONFIDENTIAL   G-143

Listing 7.B   Pre-trial and concomitant medication plus coded and related
                               derived data.
                               Drugs coded according to WHO DD version .
                               Indication coded according to WHO ICD revision 10.

Sub-ject	Drug name (preferred WHO name) [*]	Best ATC code	Total Daily dose [*]	Unit [*]	Route a) [*]	Start Day [*]	Stop Day [*]	Indication (WHO ICD des
Center: USA 006	Group: CCVR							
0101 ! Albuterol		R03CC	prn		ih	PC	-86*	CONT	J45.9	Asthm
! Alesse		G03FA	1	tab	po	Po	115	UNK	Z30.9	Contr
! Flagyl		G01AF	1000	mg	po	C	58	64	N76.0	Acute
! Flovent		R03BX	prn		ih	C	6	36	J45.9	Asthm
0102 ! Calcium		A12AA	1	tabs	po	PC	-92	CONT	E61	Defic
! Desogen		G03FA	1	tab	po	C	358	CONT	Z30.9	Contr
! Nutrilite		A11AB	3	tabs	po	PC	-92	CONT	E61	Defic
0103 ! Otc antihitamines		R06AX	prn		po	PC	-3397*		J30.1	Aller
									J30.1	Aller
0104 ! Ortho novum 7/7/7		G03AA	1	tab	po	P	-1577*	-2	Z30.9	Contr
0105 ! Antibiotic		J02AA	unk	unk	iv	P	-15	-12	A40.9	Strep
! Augmentin		J01CR	250	mg	po	P	-11	-2	A40.9	Strep
! Penicillin		J01C	unk	mg	po	P	-18	-15	A40.9	Strep
! Rocephin		J01DA	250	mg	im	C	56	56	N76.0	Acute
! Zithromax		J01FA	1	gm	po	C	56	56	N76.0	Acute
0107 ! Advil		M01AE	prn		po	PC	-365*		M25.5	Pain
									R52.9	Pain,
! Chromoslim		V06A	unk	tab	po	PC	-181*		N94.3	Preme
! Otc decongestant		R06AA	prn		po	PC	-89*		T78.4	Aller
! Permathene		C03AB	1	tab	po	PC	-21		R63.4	Abnor
! Pseudophedrine		R01BA	unk	tab	po	PC	-89*		J30.3	Other
! Tylenol		N02BE	prn		po	PC	-365*		M25.5	Pain

Figure 8. *Appendix H: Case Report Form Tabulation*

Acrobat Reader - [38607_h.pdf]

File   Edit   View   Tools   Window   Help

5101
5103
5104
5105
   DEMOGRAPHIC DATA
   SCREENING
   MEDICAL HISTORY
   HISTORY OF ALLERGIC (
   FERTILITY CHARACTERI:
   GENERAL MEDICAL EXA
   PELVIC EXAMINATION
   CERVICAL SMEAR
   INITIAL ULTRASOUND IN\
   LAST MENSES
   HORMONES AT SCREEN
   INCLUSION/EXCLUSION (
   TREATMENT PHASE
   PREGNANCY TEST (FIR:
   LAST MENSES (PRIOR T
   DRUG ADMINISTRATION
   CYST PUNCTURE
   ULTRASOUND INVESTIG.
   HCG EVALUATION
   HORMONES AT CENTRA
   LOCAL TOLERANCE
   LUTEAL PHASE
   SPERM ANALYSIS
   OOCYTE PICK-UP

```
CONFIDENTIAL                                    H-1029

CASE REPORT FORM TABULATION
SUBJECT: 5105              CENTRE/INVESTIGATOR: Oslo  N 010/ABYHOLM          TREATMENT
DEMOGRAPHIC DATA
----------------
Initials of subject: AN                     Date of birth: 20-AUG-66               Gender
Race: Caucasian                             Age at screening (years): 31           Body h
Body weight at screening (kg):  55.0

SCREENING
=========

MEDICAL HISTORY
---------------
Date of examination: 21-NOV-97              Does the subject have any clinically significant pre-e

Body system                                 Yes or No   Condition

Sensory organs
Nervous system
Cardiovascular system
Respiratory system
Gastro-intestinal tract
Liver
Endocrine system
Urogenital system
Musculoskeletal system
Haematologic conditions
Skin
Other

HISTORY OF ALLERGIC CONDITIONS
------------------------------
Date of examination: 21-NOV-97              Is there a history of allergic conditions?: No

FERTILITY CHARACTERISTICS
-------------------------
Date of examination: 21-NOV-97                  Cause of infertility:                  tubal
Early abortions in the past (no. of early abortions - < 16 weeks of gestation):         2
Late abortions in the past (no. of late abortions - >= 16 weeks, <28 weeks of gestation): 0
Ectopic pregnancies in the past (no. of ectopic pregnancies):                           1
Parity (no. of deliveries >= 28 weeks of gestation):                                    1
Duration of infertility:                                                                1  (years)
Is subject ever sterilized?:                                                            No
```

Page 31 of 113   121%   11,68 x 8,26 in

THE MACRO %_SAS2PS

```
%MACRO _SAS2PS(Author=DCTO/Biometrics, Protocol=,
               Appendix=, AppType=,
               PageText=&Appendix, FileMask=&PageText.*.*,
               MakeTOC=Y,
               T1=Trial Population,
               T2=Demographics and other Subject Characteristics,
               T3=Extent of Exposure,
               T4=Dosing Compliance,
               T5=Concomitant Medication,
               T6=Efficacy,
               T7=Other Parameters,
               T8=Safety,
               T9=Post-Treatment Evaluations,
               T10=, T11=, T12=, T13=, T14=, T15=, T16=,
               T17=, T18=, T19=, T20=, T21=, T22=, T23=, T24=,
               WaterMrk=Y, WMtext=Draft,
               BookMark=Y, FirstPag=2,
               Inlib=release, Outlib=release,
               Outfile=&Protocol._&PageText..ps)
       / des='SAS output to Postscript converter';

%********************************************************************************
%*                     N.V. Organon/DCTO/Biometrics
%********************************************************************************
%*                        STANDARD MACRO
%* Macro         : _SAS2PS.SAS
%*
%* Author        : Lex Jansen
%*
%* Date          : June 1998
%*
%* Purpose       : Convert SAS output to one Postscript file
%*
%* Parameter(s) : (O=optional, M=mandatory)
%*
%*     Author   : (M) Department that created the postscript file.
%*                    default: DCTO/Biometrics
%*                    This default value should only be changed by departments
%*                    outside of DCTO/Biometrics.
%*
%*     Protocol : (M) Protocol number, used in the header of the pages
%*
%*
%*     Appendix : (O) Appendix (F, G, H),
%*                    if Apptype, Pagetext and Filemask are not specified,
%*                    the parameter 'Apptype' is used to set these parameters.
%*                    Appendix=F --> Apptype=STAT, Pagetext=F, Filemask=F*.*
%*                    Appendix=G --> Apptype=IDL,  Pagetext=G, Filemask=G*.*
%*                    Appendix=H --> Apptype=CRF,  Pagetext=H, Filemask=H*.*
%*
%*     AppType  :  (M) Type of appendix (STAT, IDL or CRF)
%*                    AppType=STAT, sections will be generated.
%*                                  at least T1 has to be defined.
%*                    AppType=IDL,  no sections will be generated.
%*                                  T1, ..., T24 will be ignored.
%*                    AppType=CRF,  no sections will be generated.
%*                                  no table of contents will be generated.
%*                                  Special formatting can be applied with tags:
%*                                  <1> and <2> for bookmarks,
%*                                  <U>=underline, <B>=Bold and <H>=Helvetica
%*
%*     PageText : (M) Text in Pagenumber
%*                    No Blanks allowed and text will be converted to uppercase.
%*                    First character has to be a letter.
%*                    Other characters can be letters, numbers or an underscore.
%*                    Deafault: &Appendix
%*
%*     FileMask : (M) Selection of files to include
%*                    default: &PageText.*.*
```

```
%*
%*    MakeTOC  : (M) Generate table of contents (Y/N) ?
%*               default: Y
%*
%*    T1, ..., T24
%*            : (O) Character strings with section titles.
%*               Enclose string in double quotes if neccesary.
%*               Do not use double quotes inside string.
%*               All section titles should be consecutive. If, for example,
%*               T1 and T3 are not empty, then T2 has to be non-empty,
%*               eventhough the contents of section 3 may be empty.
%*
%*    WaterMrk : (M) Generate watermark (Y/N) ?
%*               default: Y
%*
%*    WMtext   : (M) Watermark text in case WaterMrk=Y
%*               default: Draft
%*
%*    BookMark : (O) Generate bookmarks (Y/N) ?
%*               default: Y
%*
%*    FirstPag : (M) Starting pagenumber in output file.
%*               Default: 2
%*
%*    Inlib    : (M) Libname of library with input SAS files
%*               default: release
%*
%*    Outlib   : (M) Libname of library where postscript file will
%*               be written.
%*               default: release
%*
%*    Outfile  : (O) file of postscript file.
%*               If empty, the postscript file will be:
%*                   <protocol>_<pagetext>.ps
%*
%* SAS version : SAS 6.09 (VAX/VMS) / SAS 6.12 (WinNT)
%*
%***************************************************************************;
```