

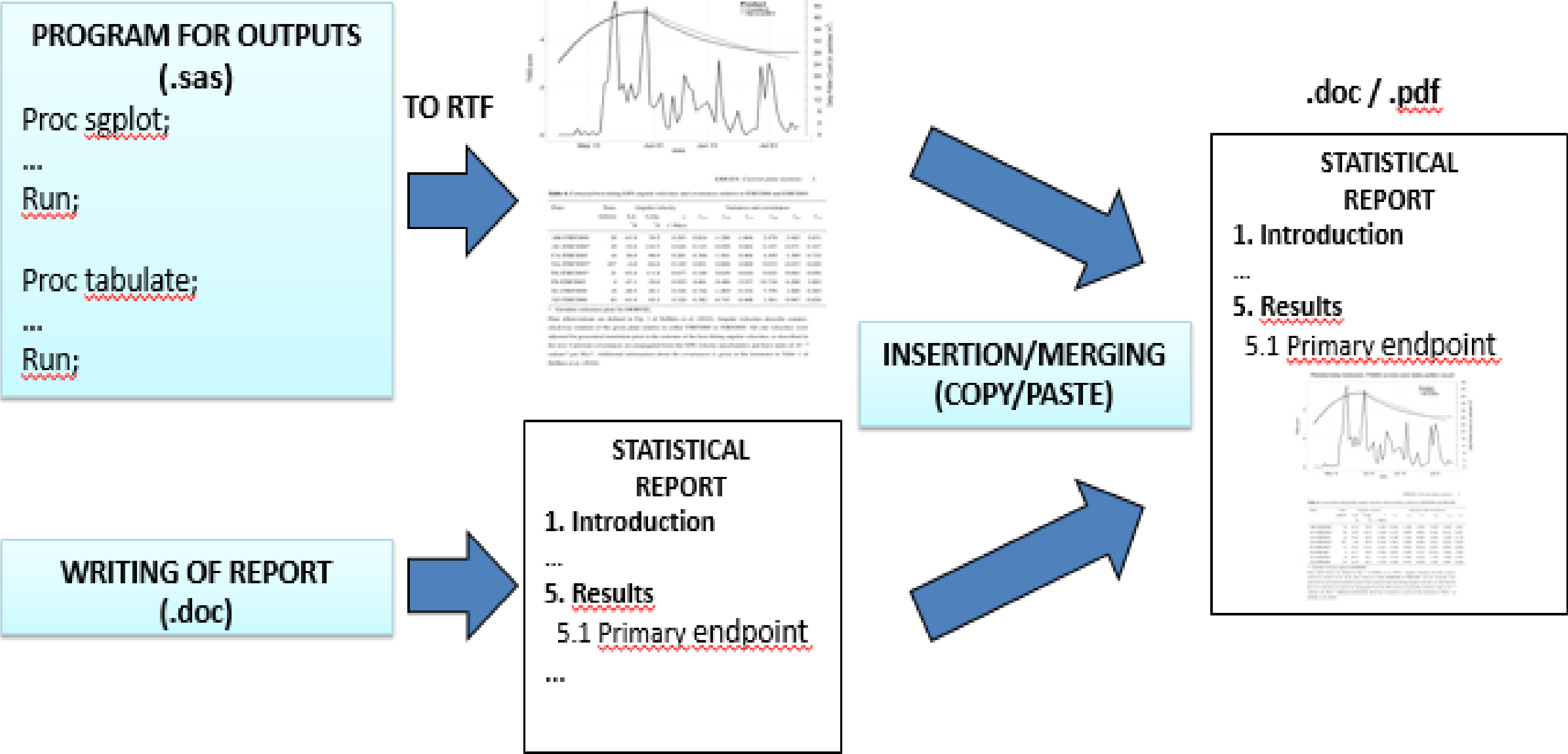
Automated Generation of Clinical Study Reports using SAS and RTF (literate programming)

Rajaram Venkatesan



Literate Programming

- “Methodology that combines a **programming language** with a **documentation language**, thereby making programs more robust, more portable, more easily maintained, and arguably more fun to write than programs that are written only in a high-level language” (Donald Knuth, Literate Programming -1984)
- Integrate text, code and results in one file
- **Reproducible** statistical analyses i.e., Possible to re-run if data change
- Source file is regular SAS file but with code and text added with special command

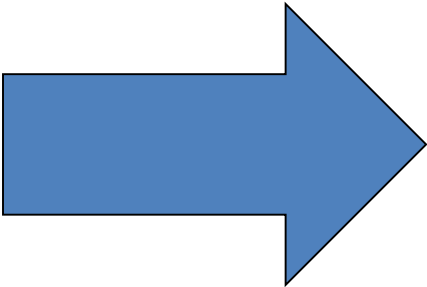


PROGRAM FOR OUTPUTS AND REPORT

```
%rrtfopen;  
  Proc sgplot; ...  
  Proc tabulate; ...  
  Run; ...  
  
%rtlfoutp(outfilnm=t14010301)  
...  
%rrtfclos;
```

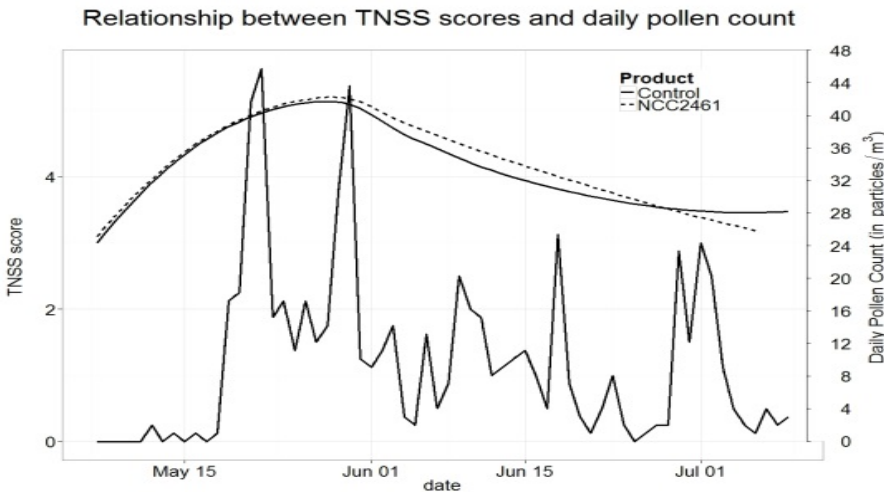
PROGRAM FOR REPORTING

```
%rrtfopen;  
...  
%rtlfoutp(outfilnm=f14010301);  
...  
%rtlfoutp(outfilnm=t14010301);  
...  
%rrtfclos;
```



STATISTICAL
REPORT

- 1. Introduction
- ...
- 5. Results
 - 5.1 Primary endpoint



ERRATA: Current plate motions 3

Table 4. Corrected best-fitting GPS angular velocities and covariances relative to ITRF2000 and ITRF2005

Plate	Num. stations	Angular velocity		Variances and covariances							
		Lat. °N	Long. °E	ω (°/Myr)	σ_{xx}	σ_{xy}	σ_{yz}	σ_{yy}	σ_{yz}	σ_{zz}	
AM-ITRF2000	20	-61.9	59.5	0.283	0.816	-1.286	-1.604	2.479	2.945	3.831	
AU-ITRF2000*	20	-32.6	-142.5	0.626	0.125	-0.090	0.082	0.107	-0.071	0.107	
CA-ITRF2005	16	36.9	-98.9	0.261	0.706	-1.561	0.484	4.459	-1.309	0.716	
NA-ITRF2005*	457	-6.8	-84.8	0.189	0.001	0.000	0.000	0.032	-0.023	0.020	
PA-ITRF2005*	21	-63.4	111.8	0.677	0.168	0.029	-0.010	0.035	-0.002	0.056	
PS-ITRF2005	4	-47.1	-29.6	0.925	8.601	-9.486	-5.537	10.718	6.200	3.892	
SU-ITRF2000	18	-48.5	86.1	0.326	0.746	-1.809	-0.434	7.799	1.800	0.565	
YZ-ITRF2000	83	-61.9	65.3	0.320	0.382	-0.747	-0.468	1.561	0.967	0.628	

* - Geodetic reference plate for MORVEL.
Plate abbreviations are defined in Fig. 1 of DeMets et al. (2010). Angular velocities describe counter-clockwise rotation of the given plate relative to either ITRF2000 or ITRF2005. All site velocities were adjusted for geocentral translation prior to the estimate of the best-fitting angular velocities, as described in the text. Cartesian covariances are propagated from the GPS velocity uncertainties and have units of 10^{-8} radians² per Myr². Additional information about the covariances is given in the footnotes to Table 1 of DeMets et al. (2010).

List of Macros and Purpose

Sr. #	Macro	Purpose
1	URTFTAGS	Useful RTF tags can be used within data step or macro
2	RRTFOPEN	Initializes RTF document
3	RTITLEPG	Creates Title page of CSR template
4	RSGNTRPG	Creates Signature page of CSR template
5	RSUMRYPG	Creates Summary page of CSR template
6	RACKNWDG	Creates Acknowledgements page of CSR template
7	RTOCPAGE	Creates TOC page of CSR template
8	RHEADING	Inserts headings
9	RPARAGRP	Insert paragraphs
10	RLISTITM	Insert bullet and numbering
11	RTLFOUTP	Inserts Tables, Listings and Figures created by standard macros
12	RRTFCLOS	Closes RTF document which is initiated by RRTFOPEN

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%RHEADING

- **TEXT**= Heading Text
- **HEADLVL**= Heading levels up to 6. Default 1.

- 1 INTRODUCTION**
- 1.1 Objectives of the study**
- 2 MATERIAL AND METHODS LEVEL 1**
- 2.1 Trial design LEVEL 2**
- 2.1.1 Trial population LEVEL 3**
- 2.1.1.1 Inclusion criteria LEVEL 4**
- 2.1.1.1.1 Exclusion criteria LEVEL 5**
- 2.1.1.1.1.1 Product allocation, product groups and timing LEVEL 6**

- **SPACEB**= Spacing before heading text **SPACEA**= Spacing after heading text

[illegible]

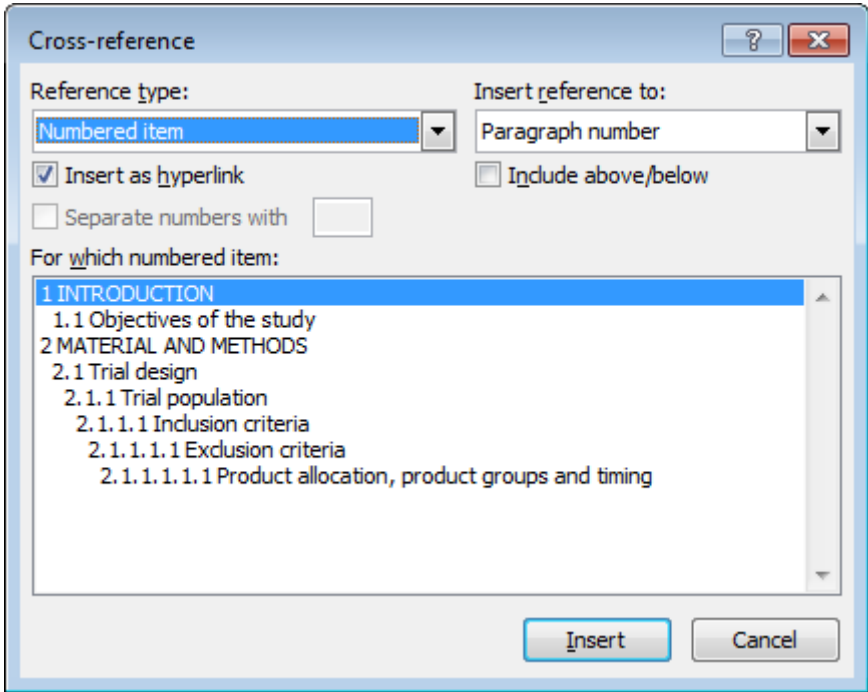
MATERIAL AND METHODS

%RHEADING

- **FONTSIZE=** Font size

Sample text
Sample text
Sample text
Sample text
Sample text
Sample text
Sample text
Sample text
Sample text
Sample text

- **CROSSREF=** Cross reference to Heading sections



Sample call

```
%rheading(text=INTRODUCTION);  
%rheading(headlvl=2,text=Objectives of the study);  
%rheading(text=MATERIAL AND METHODS);  
%rheading(headlvl=2,text=Trial design);  
%rheading(headlvl=3,text=Trial population);  
%rheading(headlvl=4,text=Inclusion criteria);  
%rheading(headlvl=5,text=Exclusion criteria);  
%rheading(headlvl=6,text=Product allocation$comma product groups and  
timing);
```

Result

1 INTRODUCTION

1.1 Objectives of the study

2 MATERIAL AND METHODS LEVEL 1

2.1 Trial design LEVEL 2

2.1.1 Trial population LEVEL 3

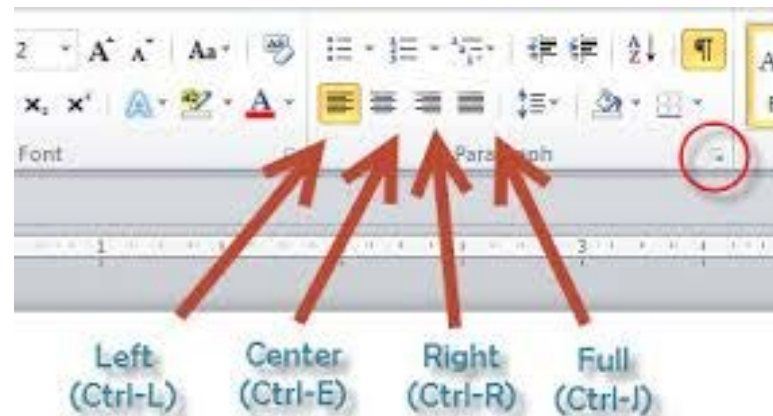
2.1.1.1 Inclusion criteria LEVEL 4

2.1.1.1.1 Exclusion criteria LEVEL 5

2.1.1.1.1.1 *Product allocation, product groups and timing* LEVEL 6

%RPARAGRPH

- **TEXT**= Paragraph Text
- **SPACEB**= Spacing before paragraph text
- **SPACEA**= Spacing after paragraph text
- **FONTSIZE**= Font size
- **STYLE** = Style of paragraph text
 - **Bold**
 - *Italic*
 - ***Bold Italic***
- **JUST** = Alignment of paragraph text



Left alignment is also called flush-left, left-justified, or ragged right.

Right alignment, is also called flush-right, right-justified, or ragged left.

Centered text is, well, centered!

Justified text is sometimes called fully-justified or full alignment and lines up evenly on both the left and the right sides except for the last line of a paragraph.

Sample call

```
%rparagrp(text = %str(The primary outcome of interest was change in weight  
from baseline at month 12.));  
%rparagrp(text = %str($CROSSREF(tvs) provides the inferential statistics  
results using Analysis of Covariance (ANCOVA) model analysis on change in  
weight from baseline at month 12 for full analysis set.));  
%rparagrp(text = %bquote($ITALIC(Change in weight from baseline = Baseline  
weight + Stratification factor (Gender and Site) + Treatment)$NEWPARA  
Analysis was performed using 2-sided test at $SALPHA.=0.05.$NEWPARA  
The change from baseline in weight at month 12 was statistically  
%sysfunc(ifc(&pvalue lt 0.05, significant,non-significant)) (LS Mean (SE) =  
&estimate; 95% CI = &clm; p=&pvalue).));
```

Result

The primary outcome of interest was change in weight from baseline at month 12.

[Table 3](#) provides the inferential statistics results using Analysis of Covariance (ANCOVA) model analysis on change in weight from baseline at month 12 for full analysis set.

Change in weight from baseline = Baseline weight + Stratification factor (Gender and Site) + Treatment

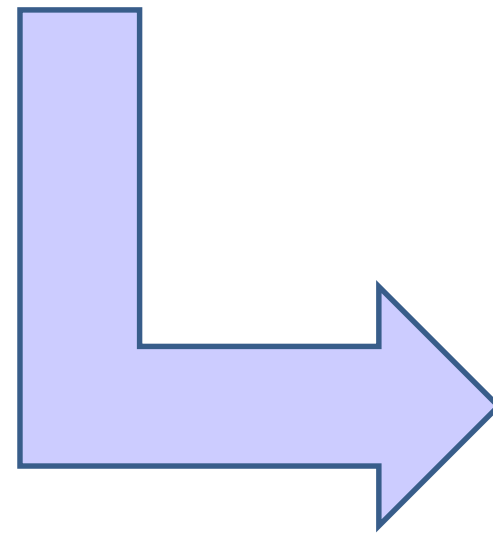
Analysis was performed using 2-sided test at $\alpha=0.05$.

The change from baseline in weight at month 12 was statistically non-significant (LS Mean (SE) = 4.15 (3.37); 95% CI = -2.47, 10.76; $p=0.2186$).

%RTLFOUTP

- Inserts Tables, Listings and Figures created by standard macros
- It accepts PNG and JPEG graphs (may be from R, SAS, S-Plus etc.)
 - **DIRPATH**= Tables, Listings and Figure location. Default will be standard folder structure ...\\Output\\TLF
 - **OUTFILNM**= Output filename of Table, Listing and Figure
 - **GHEIGHT**= Adjust Figure Height
 - **GWIDTH**= Adjust Figure Width
 - **GARATIO**= Adjust Figure Aspect Ratio

```
%rheading(headlvl=5, text=%str(Via Area Under the Curve));  
%rparagrp(text=%str(Similar to what was presented in the  
previous section, this AUC analysis represents  
the difference between the gender rather than  
the differences between term and pre-term infants));  
proc sgplot; /*code producing f2_fatAUCsex image*/ run;  
%rtlfoutp(OUTFILNM=f2_fatAUCsex);
```



2.2.1.1.4 Via Area Under the Curve

Similar to what was presented in the previous section, this AUC analysis represents the difference between the gender rather than the differences between term and pre-term infants

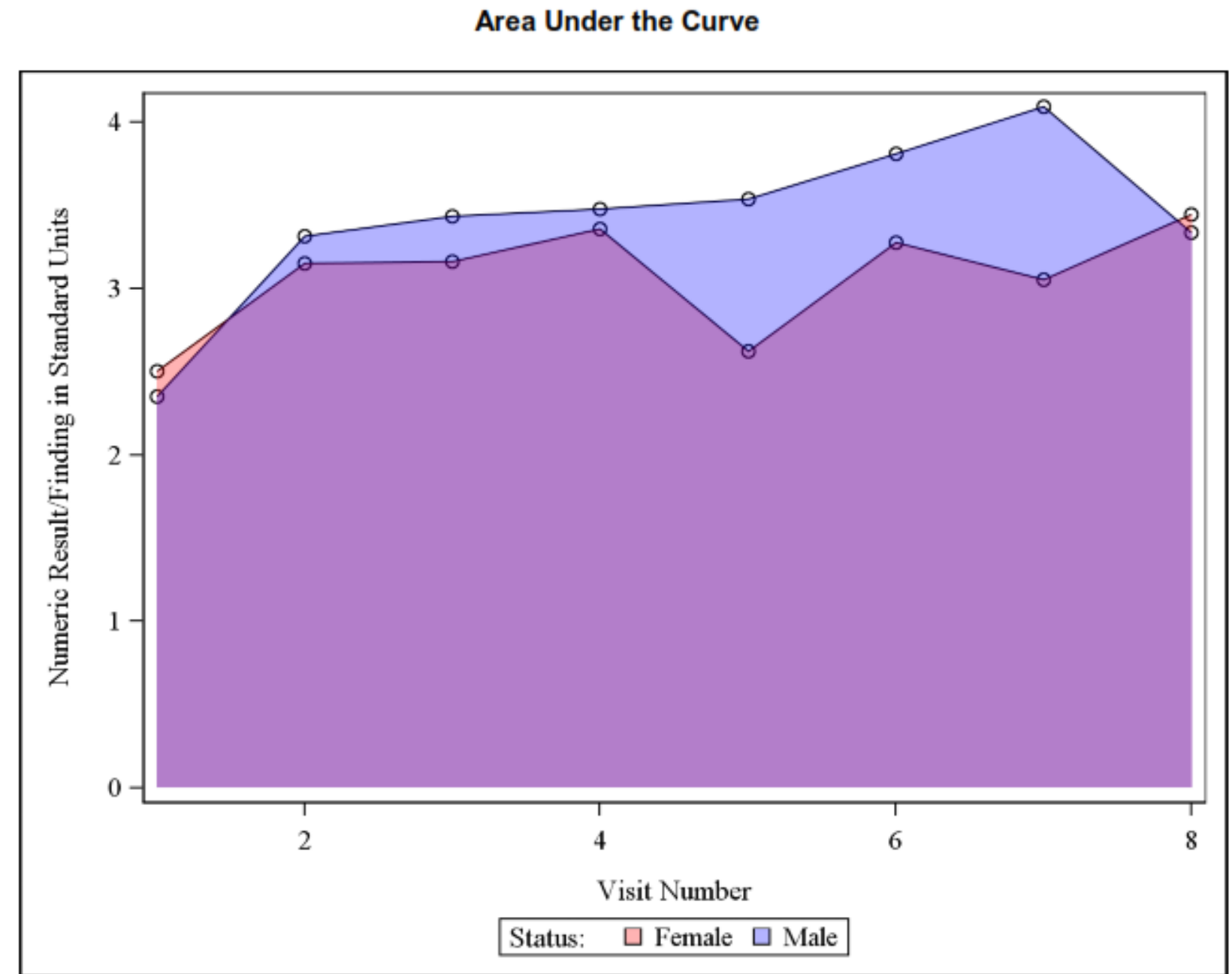


Figure 7: Area Under the curve for Fat (split by sex)

Sample call

```
%rlistitm(text=INTRODUCTION,style=arabic);  
%rlistitm(text=Objectives of the study|  
    Trial design|  
    Trial population|  
    Inclusion criteria,  
    style=lroman, nestlvl=1);  
%rlistitm(text=MATERIAL AND METHODS|RESULTS,style=arabic);  
%rlistitm(text=Description of the product groups,  
    style=lroman, nestlvl=1, restart=y);  
%rlistitm(text=Disposition of subjects,  
    style=lroman, nestlvl=1);  
%rlistitm(text=Primary outcome, restart=y, style=arabic);  
%rlistitm(text=Secondary outcomes);
```

Result

1. INTRODUCTION
 - i. Objectives of the study
 - ii. Trial design
 - iii. Trial population
 - iv. Inclusion criteria
2. MATERIAL AND METHODS
3. RESULTS
 - i. Description of the product groups
 - ii. Disposition of subjects
 1. Primary outcome
 - 1.1 Secondary outcomes

Available RTF tags

Tag	Purpose
NBSPACE	Non-breaking space
NEWLINE	New line
SUPER()	Superscript text
SUB()	Subscript text
BOLD()	Bold text
ITALIC()	<i>Italic text</i>
UNDERLINE()	<u>Underlined text</u>
CROSSREF()	Cross reference text
LE	Less than equal to sign ≤
GE	Greater than equal to sign ≥
BULLET	Bullet (•) before text
BULLETEM	Bullet (Em dash —) before text
BULLETEN	Bullet (En dash –) before text
LIST1	Uppercase roman numbering I, II, III
LIST2	Uppercase alphabetic numbering A, B, C
LIST3	Decimal numbering 1, 2, 3
LIST4	Lowercase alphabetic numbering a), b), c)
LIST5	Decimal numbering (1), (2), (3)
LIST6	Lowercase alphabetic numbering (a), (b),(c)
LIST7	Lowercase roman numbering. (i), (ii), (iii)

Tag	Purpose
TAB	Tab space
EMDASH	Em dash —
ENDASH	En dash –
LQUOTE	Left single quotation mark ‘
RQUOTE	Right single quotation mark ’
LDQUOTE	Left double quotation mark “
RDQUOTE	Right double quotation mark ”
BBORDER	Bottom solid borderline
TBORDER	Top solid borderline
SDEGREE	°

Thank You

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Sample Full Code



Sample.sas