SAS MELBOURNE USER GROUP

17 SEPTEMBER 2014



A journey into the world of SAS :: Statistics and the Pharmaceutical industry

VOTE FOR TODAY'S BEST PRESENTATION...

DON'T FORGET TO CHECK YOUR EMAIL – TO COMPLETE THE SMUG ONLINE SURVEY

By completing the online survey you could win...



2 x adult passes to Hoyts La Premiere



NOVOTECH The Asia Pacific CRO

Entry into the world of SAS

Statistics in the Pharmaceutical Industry

SMUG Q3 2014

Dr Elisa Young

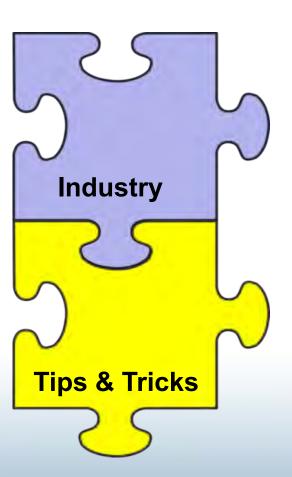
Overview



- Statistics in the Pharmaceutical Industry
 - Getting there...
 - The learning curve
 - Clinical trials
 - Statistical activities in clinical trials
- Case Studies

(Customising programs to meet client needs)

- Case study 1: PROC REPORT
- Case study 2: PROC SGPLOT
- Lessons Learnt
- > Help!
- Where to now?



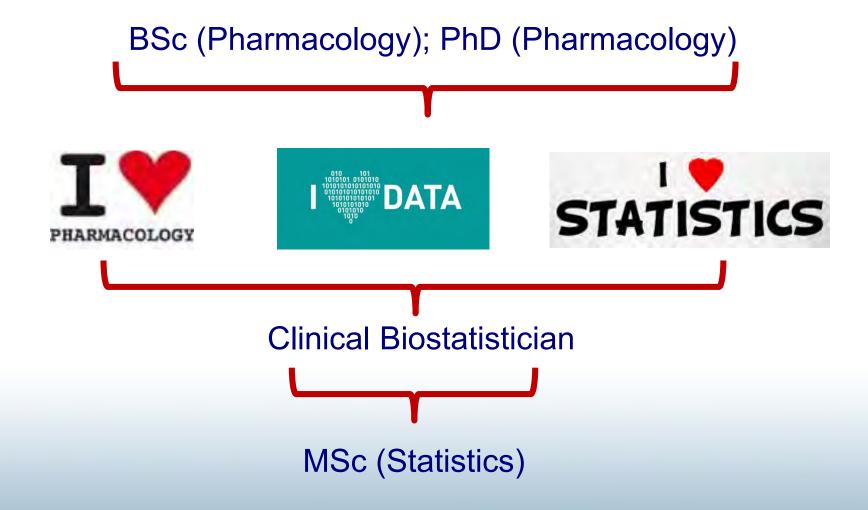


Statistics in the Pharmaceutical Industry

Getting there

How my journey began





Job seeking.....



Biostatistician/Statistical Programmer

We are looking for a Biostatisticiamia join of design, develop and evaluate HIREDs, systems to determine the outder the outd include:-

- Design, analysis, review and interpret
- Perform sample size estimations
- Ensure compliance with applicable regulator
- Participate in review and/or preparation of reports, presenting findings to internal/exter
- Review case report forms and data manage collection
- Prepare and write statistical analysis plans
- Validate and execute statistical programs u
- Interact with project managers, data m acting as client liaison for statistical matters

• Prepare randomisation specifications, generate schedules and verify randomisation components

etrics Department. In this role you will tatistical analysis services and develop Some of the tasks you will be involved in

data, Phase I-Phase IV

sections of study protocols and study s r**e**uired

sure efficient and accurate data

SAS tables, listings and figures during the data analysis phase,



Statistics in the Pharmaceutical Industry

Clinical Trials

What is a Clinical Trial?



'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

World Health Organisation (WHO)

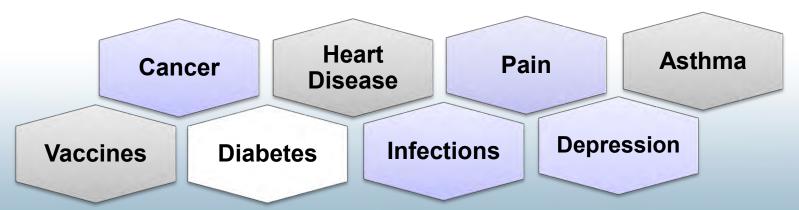
- Examples:
 - New interventions: Does it work, is it safe, is it better than existing.
 - Compare existing interventions
 - New ways to use or combine existing interventions

Why Conduct Clinical Trials?



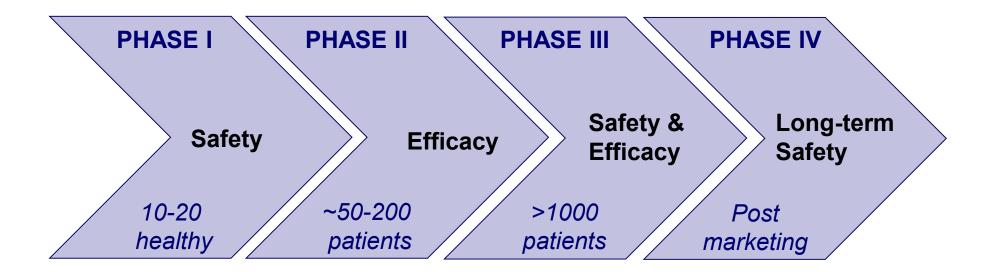
Most modern medical interventions are a direct result of clinical research.

- Only way to properly determine whether new medicines are effective and safe.
- Ensures that any improvement as a result of the intervention occurs for many people and is not just a random effect for a one person.
- They help people to live longer and healthier lives, and help reduce pain and disability.
- Improve health care services by raising standards of treatment.



Clinical Trials - Phases





Clinical Research Organisations (CROs)

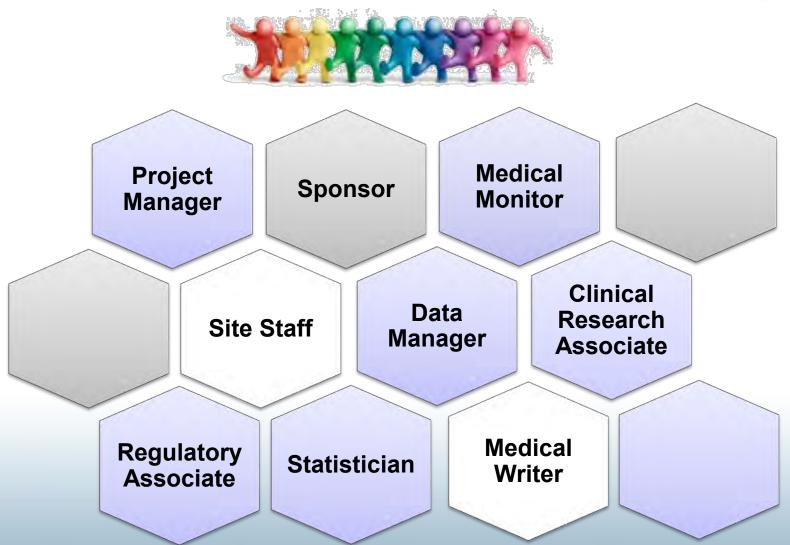


Service-based companies specialising in the high-quality conduct of clinical studies primarily on behalf of pharmaceutical, biotechnology and medical device companies.

- Independent (minimises bias)
- Quicker
- Cheaper
- > Flexible
- Highly experienced

Clinical Trials – Study Team







Statistics in the Pharmaceutical Industry

The Role of the Statistician/SAS Programmer in Clinical Trials

Key Statistical Activities



Standard

- Study Design
- Sample Size Estimate S
- Randomization Schedule <a>S
- Statistical Analysis Plan
- Mock Tables, Listings and Figures (Shells)
- Bring together datasets from various sources
- Derived datasets §
- Programming of Tables, Listings and Figures S
- Quality Control

Emerging

- Risk Based Monitoring s
- Data Cleaning §

Regulations and Guidelines



- Federal Laws
 - FDA: Title 21 of Code of Federal Regulations (CFR)
 - Part 11: Handling of electronic records
 - Part 50: Protection of Human Subjects
 - Part 820: Use of validated software
- Federal Guidelines
 - ICH E9: Statistical Principles for Clinical Trials
 - FDA Industry Guideline for E9: Statistical Principles for Clinical Trials
- Industry Statistical Standards
 - CDISC

SAS in the Pharmaceutical Industry



- SAS is globally recognized* as the de facto industry standard for clinical trial data analysis and reporting
- Validated, stable, FDA compliant, reproducible, scalable
- Powerful and flexible analytical and data management capabilities
- * By Pharmaceutical Companies, Regulatory Bodies and Contract Research Organisations

SAS at Novotech



Single desktop license:

SAS Base v9.4

SAS/STAT

SAS/GRAPH

Enterprise Guide



Case Studies

(Customising programs to meet client needs)

Tables, Listings and Figures

What do I mean by Tables, Listings & Figures?



Output that contains all the study data, to be submitted to regulatory bodies:

Listings: Raw data (per patient, per visit, etc.)

Tables: Summary data, i.e. descriptive statistics

Inferential statistics (ANCOVA, t-tests, etc.)

Figures: Graphical representations of critical parameters

Typical Listings and Figures:

Subject Disposition Adverse Events

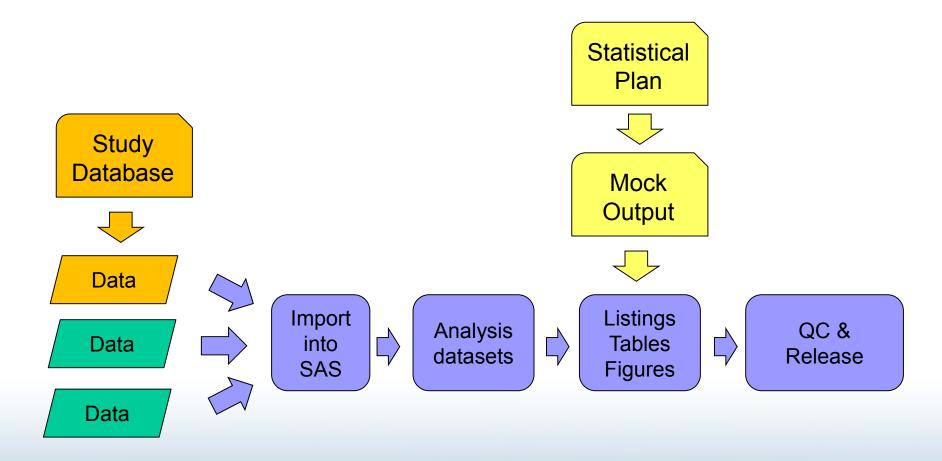
Demographics Concomitant Medications

Medical History Safety: Laboratory, ECG, vital signs

Efficacy (treatment & disease specific) Questionnaires

Programming of Tables, Listings & Figures







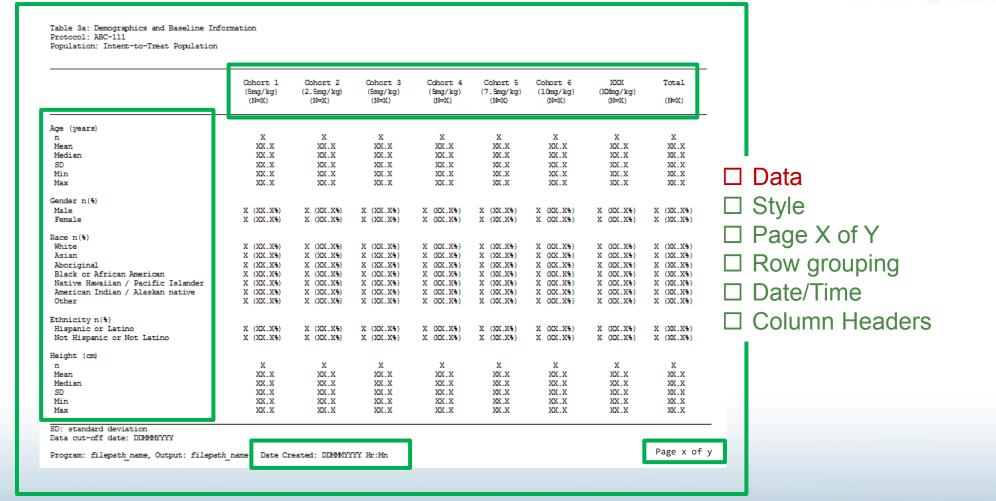
Case Studies

(Customising programs to meet client needs)

PROC REPORT

The mock.....





The data.....



	cohort	pod	pam	order	stat	result	_sortpage_	dummy
1	1		age		^^n	8	1	1
2	2		age		^^n	8	1	1
3	3		age	1		8	1	1
4	4		age	1		6	1	1
5	5		age	1		8	1	1
6	6		age	1	^^n	9	1	1
7	99		age	1	^^n	47	1	1
8	1		age	2	^ ^ Mean	65.1	1	1
9	2		age		^ ^ Mean	62.0	1	1
10	3		age		^ ^ Mean	67.5	1	1
11	4		age		^ ^ Mean	65.2	1	1
12	5		age		^ ^ Mean	57.4	1	1
13	6		age	2	^ ^ Mean	64.4	1	1
14	99		age	2	^ ^ Mean	63.6	1	1
15	1		age	3	^ ^ Median	63.5	1	1
16	2		age	3	^ ^ Median	63.5	1	1
17	3	1	age	3	^ ^ Median	69.0	1	1
18	4		age	3	^ ^ Median	70.5	1	1
19	5	1	age	3	^ ^ Median	59.0	1	1
20	6		age	3	^ ^ Median	65.0	1	1
21	99	1	age	3	^ ^ Median	65.0	1	1
22	1		age	4		7.9	1	1
23	2		age		^^SD	9.0	1	1
24	3	1	age		^^SD	10.9	1	1
25	4		age		^^SD	11.7	1	1
26	5	1	age	4	^^SD	12.8	1	1

The Default - Program



```
ods listing close;
 ods rtf file = "&out\Table 3 - Demographics (1).rtf";
 goptions reset=footnote reset=title;
 options nonumber nodate orientation=landscape papersize="ISO A4";
□ proc report data = abc.table final nocenter;
     column ( sortpage  pod parm order stat cohort, result dummy);
     define sortpage / group order=data noprint;
     define pod
                        / group order=data noprint;
     define parm
                      / group order=data " ";
     define order
                       / group noprint;
                  / group " " style(column header)=[cellwidth=4.5cm just=1];
     define stat
                       / across " " style(column header)=[cellwidth=2.5cm just=c];
     define cohort
                      / display " " style(column header)=[cellwidth=2.5cm just=c];
     define result
     define dummy
                        /analysis noprint;
     break after sortpage / page;
     compute after sortpage / style=[JUST=L];
         line "SD: Standard Deviation":
     endcomp;
     Title1 j=1 "Table 3: Demographics";
     Title2 j=1 "Protocol: ABC";
     Title3 j=1 "Study Population: Intent-to-Treat (ITT) Population";
     footnotel "Data cut-off date: &cutdaterpt.";
     footnote2 "Program: Table 3 - Demographics.sas (version &version); Output: Table 3 - Demographics (1).rtf";
 run:
 ods rtf close;
 ods listing;
```

The Default - Output



Table 3: Demographics

Protocol: ABC

Study Population: Intent-to-Treat (ITT) Population

		1	2	3	4	5	6	99
age	n	8	8	8	6	8	9	47
	Mean	65.1	62.0	67.5	65.2	57.4	64.4	63.6
	Median	63.5	63.5	69.0	70.5	59.0	65.0	65.0
	SD	7.9	9.0	10.9	11.7	12.8	5.9	9.8
	Min	54	48	47	49	40	54	40
	Max	82	74	80	77	75	71	82
sex	Male	4 (50.0%)	6 (75.0%)	3 (37.5%)	3 (50.0%)	3 (37.5%)	2 (22.2%)	21 (44.7%)
	Female	4 (50.0%)	2 (25.0%)	5 (62.5%)	3 (50.0%)	5 (62.5%)	7 (77.8%)	26 (55.3%)
race	White	6 (75.0%)	7 (87.5%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	8 (88.9%)	43 (91.5%)
	Asian	2 (25.0%)	0	0	0	0	1(11.1%)	3 (6.4%)
	Aboriginal	0	0	0	0	0	0	0
	Black or African American	0	0	0	0	0	0	0
	Native Hawaiian / Pacific Islander	0	0	0	0	0	0	0
	American Indian / Alaskan native	0	0	0	0	0	0	0
	Other	0	1 (12.5%)	0	0	0	0	1 (2.1%)
ethnicity	Hispanic or Latino	0	0	0	0	0	0	0
	Not Hispanic or Not Latino	0	0	0	0	0	0	0
	Missing	8 (100.0%)	8 (100.0%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	9 (100.0%)	47 (100.0%)

Data cut-off date: 11JUL2014

Program: Table 3 - Demographics.sas (version 1.4); Output: Table 3 - Demographics (1).rtf

☑ Data

☐ Style

☐ Page X of Y

☐ Row grouping

□ Date/Time

☐ Column Headers

Table and Page Style – Program (1)



```
□proc template;
     define style Styles.Custom;
     parent = Styles.RTF;
     STYLE SystemTitle /
         FONT FACE = "Arial, Times New Roman, Helvetica"
         FONT SIZE = 1.8;
     STYLE SystemFooter /
         FONT FACE = "Arial, Times New Roman, Helvetica"
         FONT SIZE = 1.8;
     STYLE Header /
         FONT FACE = "Arial, Times New Roman, Helvetica"
         FONT SIZE = 1.8;
     STYLE Data /
         FONT FACE = "Arial, Times New Roman, Helvetica"
         FONT SIZE = 1.8;
     STYLE Table /
         FONT FACE = "Arial, Times New Roman, Helvetica"
         FONT SIZE = 1.8
         FONT WEIGHT = medium
         FRAME = ABOVE
         RULES = GROUPS;
     replace Body from Document "Controls the Body file." /
          bottommargin = undef
          topmargin = undef
          rightmargin = undef
          leftmargin = undef;
     CLASS text /
          'continued' = " ";
 end;
 run;
```

Table and Page Style – Program (2)



```
ods listing close;
ods rtf style=custom file = "&out\Table 3 - Demographics (2).rtf";

goptions reset=footnote reset=title;
options nonumber nodate orientation=landscape papersize="ISO A4"
topmargin="0.5 in" bottommargin="0.5 in"
rightmargin="0.5 in" leftmargin="0.5 in";
```

Table and Page Style - Output



Table 3: Demographics Protocol: ABC

Study Population: Intent-to-Treat (ITT) Population

		1	2	3	4	5	6	99
age	n	8	8	8	6	8	9	47
-	Mean	65.1	62.0	67.5	65.2	57.4	64.4	63.6
	Median	63.5	63.5	69.0	70.5	59.0	65.0	65.0
	SD	7.9	9.0	10.9	11.7	12.8	5.9	9.8
	Min	54	48	47	49	40	54	40
	Max	82	74	80	77	75	71	82
sex	Male	4 (50.0%)	6 (75.0%)	3 (37.5%)	3 (50.0%)	3 (37.5%)	2 (22.2%)	21 (44.7%)
	Female	4 (50.0%)	2 (25.0%)	5 (62.5%)	3 (50.0%)	5 (62.5%)	7 (77.8%)	26 (55.3%)
race	White	6 (75.0%)	7 (87.5%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	8 (88.9%)	43 (91.5%)
	Asian	2 (25.0%)	` 0	` 0 ´	0	` 0	1 (11.1%)	3 (6.4%)
	Aboriginal	0	0	0	0	0	0	` 0 ´
	Black or African American	0	0	0	0	0	0	0
	Native Hawaiian / Pacific	0	0	0	0	0	0	0
	Islander							
	American Indian / Alaskan	0	0	0	0	0	0	0
	native							
	Other	0	1 (12.5%)	0	0	0	0	1 (2.1%)
ethnicity	Hispanic or Latino	0	0	0	0	0	0	0
	Not Hispanic or Not Latino	0	0	0	0	0	0	0
	Missing	8 (100.0%)	8 (100.0%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	9 (100.0%)	47 (100.0%)

SD: Standard Deviation

☑ Data

☑ Style

☐ Page X of Y

☐ Row grouping

□ Date/Time

☐ Column Headers

Data cut-off date: 11JUL2014

Program: Table 3 - Demographics.sas (version 1.4); Output Table 3 - Demographics (2).rtf

Page X of Y

Page X of Y - Program



```
ods listing close;
 ods tagsets.rtf sample style=custom file = "&out\Table 3 - Demographics (3).rtf";
ods escapechar = '^';
 goptions reset=roothote reset=title;
 options nonumber nodate orientation=landscape papersize="ISO A4"
         topmargin="0.5 in" bottommargin="0.5 in"
        rightmargin="0.5 in" leftmargin="0.5 in";
∃proc report data = abc.table final nocenter;
    column ( sortpage pod parm order stat cohort, result dummy);
    define sortpage / group order=data noprint;
    define pod
                      / group order=data noprint;
                       / group order=data " ";
    define parm
    define order
                      / group noprint;
    define stat
                      / group " " style(column header)=[cellwidth=4.5cm just=1];
    define cohort
                      / across " " style(column header)=[cellwidth=2.5cm just=c];
    define result
                       / display " " style(column header)=[cellwidth=2.5cm just=c];
    define dummy
                       / analysis noprint;
    break after sortpage / page;
    compute after sortpage / style=[bordertopcolor=black bordertopwidth=2 just=1];
        line "SD: Standard Deviation";
    endcomp;
    Title1 j=1 "Table 3: Demographics";
    Title2 j=1 "Protocol: ABC";
    Title3 j=1 "Study Population: Intent-to-Treat (ITT) Population";
    footnote1 "Data cut-off date: &cutdaterpt." j=r "Page ^{pageof}";
    footnote2 "Program: Table 3 - Demographics.sas (version &version); Output: Table 3 - Demographics (3).rtf";
 run;
 ods tagsets.rtf sample close;
 ods listing;
```

Page X of Y - Output



Table 3: Demographics Protocol: ABC

Study Population: Intent-to-Treat (ITT) Population

		1	2
age	n	8	8
	Mean	65.1	62.0
	Median	63.5	63.5
	SD	7.9	9.0
	Min	54	48
	Max	82	74
sex	Male	4 (50.0%)	6 (75.0
	Female	4 (50.0%)	2 (25.0
race	White	6 (75.0%)	7 (87.
	Asian	2 (25.0%)	0
	Aboriginal	0	0
	Black or African American	0	0
	Native Hawaiian / Pacific	0	0
I.	slander		
	American Indian / Alaskan	0	0
r	native		
	Other	0	1 (12.
ethnicity	Hispanic or Latino	0	0
	Not Hispanic or Not Latino	0	0
	Missing	8 (100.0%)	8 (100.
SD: Stan	dard Deviation		
		,	

Age (years) Mean Median SD Min Max Gender n(%) Male Female Race n(%) White Asian Aboriginal Black or African American Native Hawaiian / Pacific Islander American Indian / Alaskan native Other Ethnicity n(%) Hispanic or Latino Not Hispanic or Not Latino Height (cm) Mean Median SDMin Max SD: standard deviation

☑ Data

☑ Style

☑ Page X of Y

☐ Row Grouping

□ Date/Time

☐ Column Headers

Data cut-off date: 11JUL2014

Program: Table 3 - Demographics.sas (version 1.4); Output Table 3 - Demographics (3).rtf

Page 1 of 1

Row Grouping - Program



dummy

order

```
∃proc format;
       value podlabel
                                                                                  VIEWTABLE: Abc.Table final
            1='Age (years)'
                                                                                                            pam
            2='Gender n(%)'
                                                                                                         1 age
            3='Race n(%)'
                                                                                                         1 age
            4='Ethnicity n(%)';
                                                                                                         1 age
 run;
                                                                                    4
                                                                                                         1 age
                                                                                    5
                                                                                                         1 age
 ods listing close;
                                                                                                         1 age
 ods tagsets.rtf sample style=custom file = "&out\Table 3 - Demographics (4).rtf"-
 ods escapechar = '^';
 goptions reset=footnote reset=title;
 options nonumber nodate orientation=landscape papersize="ISO A4"
         topmargin="0.5 in" bottommargin="0.5 in"
         rightmargin="0.5 in" leftmargin="0.5 in";
∃proc report data = abc.table final nocenter;
     column ( sortpage pod order stat cohort, result dummy);
     define sortpage / group order=data noprint;
     define pod
                        / group order=data noprint;
     define order
                         / group noprint;
                        / group " " style(column header)=[cellwidth=6.0cm just=1];
     define stat
                         / across " " style(column header)=[cellwidth=2.5cm just=c];
     define cohort
     define result
                        / display " " style(column header)=[cellwidth=2.5cm just=c];
     define dummy
                        / analysis noprint;
     break after _sortpage_ / page;
     compute after sortpage / style=[bordertopcolor=black bordertopwidth=2 just=1];
         line "SD: Standard Deviation";
     endcomp;
     compute before pod / style=[just=1];
         line " ";
         line @O pod podlabel.;
     endcomp;
     Title1 j=1 "Table 3: Demographics";
     Title2 j=1 "Protocol: ABC";
     Title3 j=1 "Study Population: Intent-to-Treat (ITT) Population";
     footnote1 "Data cut-off date: &cutdaterpt." j=r "Page ^{pageof}";
     footnote2 "Program: Table 3 - Demographics.sas (version &version); Output: Table 3 - Demographics (4).rtf";
 ods tagsets.rtf sample close;
 ods listing;
```

Row Grouping - Output



Table 3: Demographics Protocol: ABC

Study Population: Intent-to-Treat (ITT) Population

1	2	3	4	5	6	99
8	8	8	6	8	9	47
			_			63.6
						65.0
						9.8
						40
82	74	80	77	75	71	82
4 (50.0%)	6 (75.0%)	3 (37.5%)	3 (50.0%)	3 (37.5%)	2 (22.2%)	21 (44.7%
4 (50.0%)	2 (25.0%)	5 (62.5%)	3 (50.0%)	5 (62.5%)	7 (77.8%)	26 (55.3%
6 (75.0%)	7 (87.5%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	8 (88.9%)	43 (91.5%
2 (25.0%)	0	0	0	0	1 (11.1%)	3 (6.4%)
` 0 ′	0	0	0	0	` 0 ´	` 0
0	0	0	0	0	0	0
0	0	0	0	0	0	0
0	0	0	0	0	0	0
0	1 (12.5%)	0	0	0	0	1 (2.1%)
0	0	0	0	0	0	0
0	0	0	0	0	0	0
8 (100.0%)	8 (100.0%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	9 (100.0%)	47 (100.0%
	4 (50.0%) 4 (50.0%) 6 (75.0%) 2 (25.0%) 0 0 0	8 8 65.1 62.0 63.5 63.5 7.9 9.0 54 48 82 74 48 82 74 48 650.0%) 6 (75.0%) 4 (50.0%) 2 (25.0%) 6 (75.0%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	8 8 8 8 8 65.1 62.0 67.5 63.5 69.0 7.9 9.0 10.9 54 48 47 82 74 80 4 (50.0%) 6 (75.0%) 3 (37.5%) 4 (50.0%) 2 (25.0%) 5 (62.5%) 6 (75.0%) 7 (87.5%) 8 (100.0%) 2 (25.0%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	8 8 8 8 6 65.1 62.0 67.5 65.2 63.5 63.5 69.0 70.5 7.9 9.0 10.9 11.7 54 48 47 49 82 74 80 77 4 (50.0%) 6 (75.0%) 3 (37.5%) 3 (50.0%) 4 (50.0%) 2 (25.0%) 5 (62.5%) 3 (50.0%) 6 (75.0%) 7 (87.5%) 8 (100.0%) 6 (100.0%) 2 (25.0%) 0 0 0 0 0 0 0	8 8 8 8 6 8 6 8 65.1 62.0 67.5 65.2 57.4 63.5 63.5 69.0 70.5 59.0 7.9 9.0 10.9 11.7 12.8 54 48 47 49 40 82 74 80 77 75 75 75 75 75 75 75 75 75 75 75 75	8 8 8 6 8 9 65.1 62.0 67.5 65.2 57.4 64.4 63.5 63.5 69.0 70.5 59.0 65.0 7.9 9.0 10.9 11.7 12.8 5.9 54 48 47 49 40 54 82 74 80 77 75 71 4 (50.0%) 6 (75.0%) 3 (37.5%) 3 (50.0%) 3 (37.5%) 2 (22.2%) 4 (50.0%) 2 (25.0%) 5 (62.5%) 3 (50.0%) 5 (62.5%) 7 (77.8%) 6 (75.0%) 7 (87.5%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (100.0%) 8 (88.9%) 2 (25.0%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

☑ Data

☑ Style

☑ Page X of Y

☑ Row grouping

□ Date/Time

☐ Column Headers

Data cut-off date: 11JUL2014

Program: Table 3 - Demographics.sas (version 1.4); Output Table 3 - Demographics (4).rtf

Date Created: DDMMMYYYY Hr:Mn

Page 1 of 1

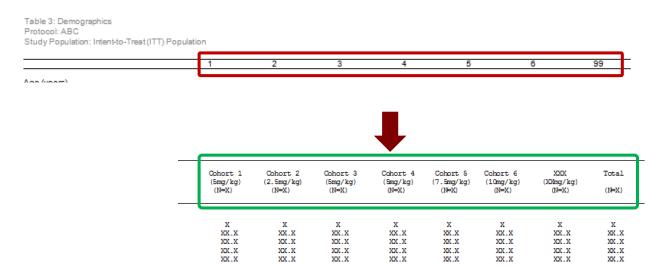
Date and time - Program



```
∃data null;
     call symput('exedate', put(today(),date9.));
     call symput('exetime', put(time(),time5.));
 run;
 ods listing close;
 ods tagsets.rtf sample style=custom file = "&out\Table 3 - Demographics (5).rtf";
 ods escapechar = '^';
 goptions reset=footnote reset=title;
 options nonumber nodate orientation=landscape papersize="ISO A4"
         topmargin="0.5 in" bottommargin="0.5 in"
         rightmargin="0.5 in" leftmargin="0.5 in";
Eproc report data = abc.table final nocenter;
     column ( sortpage  pod order stat cohort, result dummy);
     define sortpage / group order=data noprint;
     define pod
                         / group order=data noprint;
     define order
                         / group noprint;
     define stat
                        / group " " style(column header)=[cellwidth=6.0cm just=1];
     define cohort
                        / across " " style(column header)=[cellwidth=2.5cm just=c];
     define result
                        / display " " style(column header)=[cellwidth=2.5cm just=c];
     define dummy
                        / analysis noprint;
     break after sortpage / page;
     compute after sortpage / style=[bordertopcolor=black bordertopwidth=2 just=1];
         line "SD: Standard Deviation";
     endcomp;
     compute before pod / style=[just=1];
         line " ";
         line @O pod podlabel.;
     endcomp;
     Title1 j=1 "Table 3: Demographics";
     Title2 j=1 "Protocol: ABC";
     Title3 j=1 "Study Population: Intent-to-Treat (ITT) Population";
     footnote1 "Data cut-off date: &cutdaterpt." j=r "Page ^{pageof}";
                                                                                                                        Created on &exedate at &exetime.";
     footnote2 "Program: Table 3 - Demographics.sas (version &version);
                                                                            Output: Table 3 - Demographics (5).rtf;
 run:
 ods tagsets.rtf sample close;
  ods listing;
```

Date and time - Output





Data
Style
Page X of Y
Row grouping
Date/Time
Column Headers

Data cut-off date: 11JUL2014
Program: Table 3 - Demographics.sas (version 1.4); Output: Table 3 - Demographics (5).rtf; Created on 12SEP2014 at 23:10

Column Headings – Program (1)



dd_demo_all

	cohort	cohort_label	randno	sex	race	age	itt
1		Cohort 1I(1.0mg/kg)	002-006-001	Male	White	82	1
2		Cohort 1 (1.0mg/kg)	002-006-002	Male	Asian	62	1
3		Cohort 1I(1.0mg/kg)	002-007-001	Male	White	63	1
4		Cohort 1I(1.0mg/kg)	002-007-002	Female	White	67	1
5		Cohort 1I(1.0mg/kg)	002-007-003	Female	White	63	1
6		Cohort 2l(2.0mg/kg)	002-008-001	Male	White	66	1
7		Cohort 3I(3.0mg/kg)	002-008-002	Male	White	47	1
8		Cohort 3I(3.0mg/kg)	002-008-003	Female	White	66	1
9		Cohort 3I(3.0mg/kg)	002-008-004	Female	White	79	1
10		Cohort 4I(4.0mg/kg)	002-008-005	Male	White	49	1
11		Cohort 5I(5.0mg/kg)	002-008-006	Male	White	68	1
12		Cohort 6I(6.0mg/kg)	002-008-007	Female	White	63	1
13		Cohort 6I(6.0mg/kg)	002-008-008	Female	White	69	1
14		Cohort 3I(3.0mg/kg)	002-009-001	Female	White	59	1
15		Cohort 4I(4.0mg/kg)	002-009-002	Male	White	69	1
16	4	Cohort 4I(4.0mg/kg)	002-009-003	Female	White	72	1
17		Cohort 6I(6.0mg/kg)	002-009-004	Male	White	71	1
18		Cohort 6I(6.0mg/kg)	002-009-005	Male	White	68	1
19		Cohort 6I(6.0mg/kg)	002-009-006	Female	White	60	1
20		Cohort 61(6.0mg/kg)	002-009-007	Female	Asian	65	1
21		Cohort 1 (1.0mg/kg)	002-010-001	Female	White	66	1
22		Cohort 5I(5.0mg/kg)	002-010-002	Female	White	66	1
23		Cohort 1 (1.0mg/kg)	002-011-001	Female	Asian	64	1

Cohort 1	Cohort 2	Cohort 3	Cohort 4
(5mg/kg)	(2.5mg/kg)	(5mg/kg)	(Smg/kg)
(N=X)	(N=X)	(N=X)	(N=X)
X	X	X	X
XX.X	XX.X	XX.X	XX.X
XX.X	XX.X	XX.X	XX.X
XX.X	XX.X	XX.X	XX.X
XX.X	XX.X	XX.X	XX.X

Column Headings – Program (2)



	cohort	cohort_label	COUNT
1	1	Cohort 1 (1.0mg/kg)	8
2	2	Cohort 2l(2.0mg/kg)	8
3	3	Cohort 3I(3.0mg/kg)	8
4	4	Cohort 4 (4.0mg/kg)	6
5	5	Cohort 5I(5.0mg/kg)	8
6	6	Cohort 6l(6.0mg/kg)	9
7	99	Total	47



proc format cntlin=fmts;
run;

fmts

	fmtname	start	label
1	mdfmt	1	Cohort 1 (1.0mg/kg) (N=8)
2	mdfmt	2	Cohort 2 (2.0mg/kg) (N=8)
3	mdfmt	3	Cohort 3l(3.0mg/kg)l(N=8)
4	mdfmt	4	Cohort 4 (4.0mg/kg) (N=6)
5	mdfmt	5	Cohort 5l(5.0mg/kg)l(N=8)
6	mdfmt	6	Cohort 6 (6.0mg/kg) (N=9)
7	mdfmt	99	Totall(N=47)

Column Headings – Program (3)



```
∃data null ;
     call symput('exedate', put(today(),date9.));
     call symput('exetime', put(time(),time5.));
 run:
 ods listing close;
 ods tagsets.rtf sample style=custom file = "&out\Table 3 - Demographics (6).rtf";
 ods escapechar = '^';
 goptions reset=footnote reset=title;
 options nonumber nodate orientation=landscape papersize="ISO A4"
         topmargin="0.5 in" bottommargin="0.5 in"
        rightmargin="0.5 in" leftmargin="0.5 in";
∃proc report data = abc.table final nocenter split="|
     column ( sortpage pod order stat cohort, result dummy);
     define sortpage / group order=data noprint;
     define pod
                        / group order=data noprint;
     define order
                        / group noprint;
    define stat
                       / group " " style(column header)=[cellwidth=6.0cm just=1]
    define cohort
                        / across " " style(column header)=[cellwidth=2.5cm just=c] format=rndfmt.;
                        / display " " style(column header)=[cellwidth=2.5cm just=c]
    define result
    define dummy
                        / analysis noprint;
    break after sortpage / page;
     compute after _sortpage_ / style=[bordertopcolor=black bordertopwidth=2 just=1];
         line "SD: Standard Deviation";
     endcomp;
     compute before pod / style=[just=1];
        line " ";
        line @O pod podlabel.;
     endcomp;
    Title1 j=1 "Table 3: Demographics";
    Title2 j=1 "Protocol: ABC";
    Title3 j=1 "Study Population: Intent-to-Treat (ITT) Population";
    footnote1 "Data cut-off date: &cutdaterpt." j=r "Page ^{pageof}";
     footnote2 "Program: Table 3 - Demographics.sas (version &version);
                                                                          Output: Table 3 - Demographics (6).rtf; Created on &exedate at &exetime.";
 ods tagsets.rtf sample close;
 ods listing;
```

Column Headings – Output



Table 3: Demographics Protocol: ABC

Study Population: Intent-to-Treat (ITT) Population

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6	
	(1.0mg/kg)	(2.0mg/kg)	(3.0mg/kg)	(4.0mg/kg)	(5.0mg/kg)	(6.0mg/kg)	Total
	(N=8)	(N=8)	(N=8)	(N=6)	(N=8)	(N=9)	(N=47)
Age (years)							
	8	8	8	6	8	9	47
n Mean	65.1	62.0	67.5	65.2	57.4	64.4	63.6
Median	63.5	63.5	69.0	70.5	59.0	65.0	65.0
SD	7.9	9.0	10.9	11.7	12.8	5.9	9.8
Min	54	48	47	49	40	54	40
Max	82	74	80	77	75	71	82
MBX	02	/4	80	"	75	71	02
Gendern(%)							
Male	4 (50.0%)	6 (75.0%)	3 (37.5%)	3 (50.0%)	3 (37.5%)	2 (22.2%)	21 (44.7%)
Female	4 (50.0%)	2 (25.0%)	5 (62.5%)	3 (50.0%)	5 (62.5%)	7 (77.8%)	26 (55.3%)
Race n(%)							
White	6 (75.0%)	7 (87.5%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	8 (88.9%)	43 (91.5%)
Asian	2 (25.0%)	0	0	0	0	1 (11.1%)	3 (6.4%)
Aboriginal	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0
Native Hawaiian / Pacific Islander	0	0	0	0	0	0	0 _
American Indian / Alaskan native	ō	ō	ō	ō	ō	ō	0 1
Other	0	1 (12.5%)	0	0	0	0	1 (2.19
Ethnicity n(%)							<u> </u>
Hispanic or Latino	0	0	0	0	0	0	0
Not Hispanic or Not Latino	0	0	ō	0	0	0	_
Missing	8 (100.0%)	8 (100.0%)	8 (100.0%)	6 (100.0%)	8 (100.0%)	9 (100.0%)	0 47 (100.0
SD: Standard Deviation	2 (. 50.0 %)	2 (.20.070)	2 (.20.070)	2 (.20.070)	2 (.20.070)	2 (.20.070)	(

SD: Standard Deviation

☑ Data

☑ Style

☑ Page X of Y

☑ Row grouping

☑ Date/Time

☑ Column Headers

Data cut-off date: 11JUL2014

Program: Table 3 - Demographics.sas (version 1.4); Output: Table 3 - Demographics (6).rtf; Created on 12SEP2014 at 23:39

Page 1 of 1



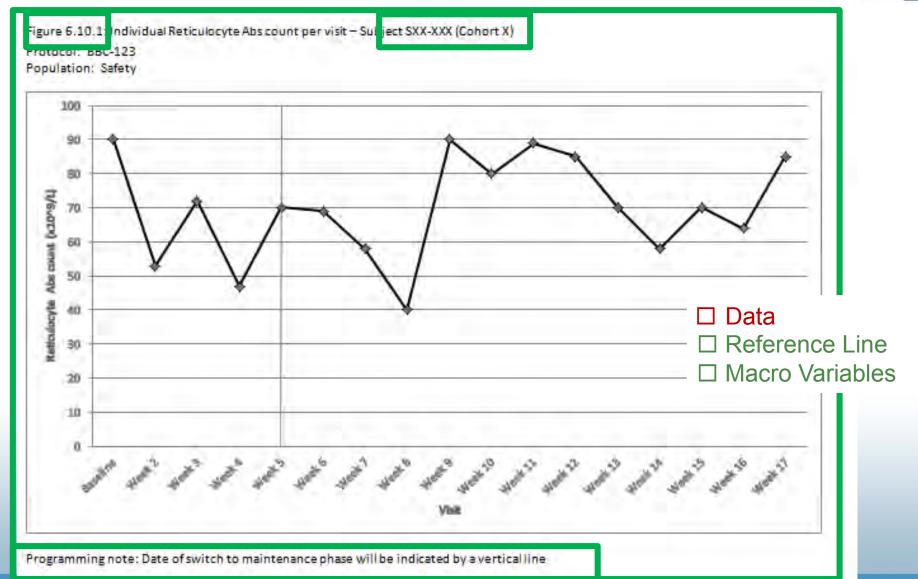
Case Studies

(Customising programs to meet client needs)

PROC SGPLOT

The mock.....





The data.....



Cohort 1	\$04-003 \$04-003 \$04-003 \$04-003 \$04-003	Baseline Week 2 Week 3 Week 4 Week 5	2013-10-25 2013-11-01 2013-11-08 2013-11-15	40
Cohort 1 Cohort 1 Cohort 1 Cohort 1 Cohort 1	S04-003 S04-003 S04-003 S04-003	Week 3 Week 4 Week 5	2013-11-01 2013-11-08	76 40 7
Cohort 1 Cohort 1 Cohort 1 Cohort 1	S04-003 S04-003 S04-003	Week 4 Week 5	2013-11-08	
Cohort 1 Cohort 1 Cohort 1	S04-003 S04-003	Week 5		7
Cohort 1 Cohort 1	S04-003		2013-11-15	
Cohort 1			2013-11-13	67
		Week 6	2013-11-22	56
	S04-003	Week 7	2013-11-29	43
Cohort 1	S04-003	Week 8	2013-12-06	229
Cohort 1	S04-003	Week 9	2013-12-12	142
Cohort 1	S04-003	Week 10	2013-12-20	111
Cohort 1	S04-003	Week 11	2013-12-27	
Cohort 1	S04-003	Week 12	2014-01-03	90
Cohort 1	S04-003	Week 13	2014-01-10	80
Cohort 1	S04-003	Week 14	2014-01-17	75
Cohort 1	S04-003	Week 15	2014-01-24	58
Cohort 1	S04-003	End of Study	2014-02-07	93
Cohort 1	S04-004	Baseline		18
Cohort 1	S04-004	Week 2	2013-11-04	22
Cohort 1	S04-004	Week 3	2013-11-11	1
Cohort 1	S04-004	Week 4	2013-11-18	2
Cohort 1	S04-004	Week 5	2013-11-25	17
Cohort 1	S04-004	Week 6	2013-12-02	1(
	Cohort 1	Cohort 1 S04-003 Cohort 1 S04-004	Cohort 1 S04-003 Week 9 Cohort 1 S04-003 Week 10 Cohort 1 S04-003 Week 11 Cohort 1 S04-003 Week 12 Cohort 1 S04-003 Week 13 Cohort 1 S04-003 Week 14 Cohort 1 S04-003 Week 15 Cohort 1 S04-003 End of Study Cohort 1 S04-004 Baseline Cohort 1 S04-004 Week 2 Cohort 1 S04-004 Week 3 Cohort 1 S04-004 Week 4 Cohort 1 S04-004 Week 5 Cohort 1 S04-004 Week 6	Cohort 1 S04-003 Week 9 2013-12-12 Cohort 1 S04-003 Week 10 2013-12-20 Cohort 1 S04-003 Week 11 2013-12-27 Cohort 1 S04-003 Week 12 2014-01-03 Cohort 1 S04-003 Week 13 2014-01-10 Cohort 1 S04-003 Week 14 2014-01-17 Cohort 1 S04-003 Week 15 2014-01-24 Cohort 1 S04-003 End of Study 2014-02-07 Cohort 1 S04-004 Baseline . Cohort 1 S04-004 Week 2 2013-11-04 Cohort 1 S04-004 Week 3 2013-11-11 Cohort 1 S04-004 Week 4 2013-11-18 Cohort 1 S04-004 Week 5 2013-11-25 Cohort 1 S04-004 Week 6 2013-12-02

Plotting the Data – Program (1)



```
ods escapechar = '~';
ods graphics / noborder width = 25cm height=12cm imagefmt=jpeg; /* Set graphics size and format */
```

```
Title1 j=1 font = "Arial" height = 10pt color = black
    "Figure 6.10.1: Individual Reticulocyte Abs Count per visit - Subject S04-003 (Cohort 1);";

Title2 j=1 font = "Arial" height = 10pt color = black "Protocol: BBC-123";

Title3 j=1 font = "Arial" height = 10pt color = black "Study Population: Safety Population";

footnote1 j=1 font = "Arial" h = 10pt color = black " ";

footnote2 j=1 font = "Arial" h = 10pt color = black "Clinical cut-off date: &cutdaterpt" j=r "Page 1 of 1";

footnote3 j=1 font = "Arial" h = 10pt color = black
    "Program: Figure6.10-Reticuloctyes.sas (version &version);

Output: Figure6.10.1-Reticuloctyes (S04-003).rtf;

Date Created: &exedate &exetime";
```

Plotting the Data – Program (2)



```
ods listing close;
ods tagsets.rtf_sample style = bbc
    file = "&out\Figure6.10.1-Reticuloctyes (S04-003).rtf"
    nogfootnote nogtitle;
```

```
options nonumber nodate orientation=landscape papersize="ISO A4" topmargin="0.5 in" bottommargin="0.5 in" rightmargin="0.5 in" leftmargin="0.5 in";
```

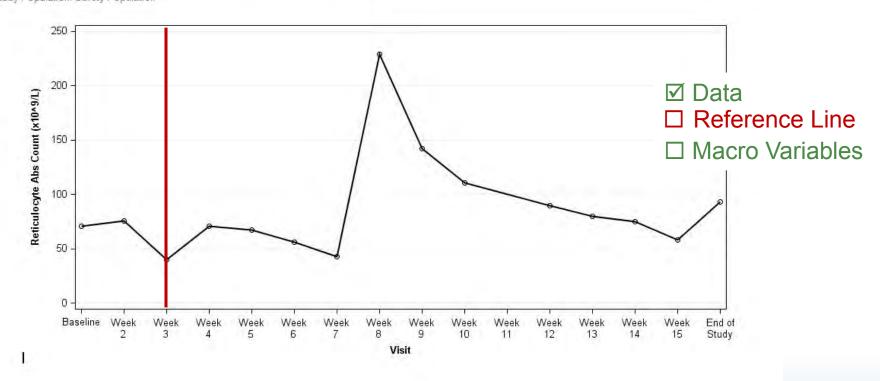
```
proc sqplot data=1bh7;
                                                        Note: Couldn't use \(^\) as the
    yaxis label = "Reticulocyte Abs Count (x10^9/L)"
                                                        escapechar due to the use
          grid values = (0 \text{ to } 250 \text{ by } 50);
                                                        of the symbol in the axis title.
    xaxis label = "Visit"
                                                        Hence set to "~"
          type=discrete
          fitpolicy=splitalways
          splitchar="|"
          discreteorder=data;
    vline visit2 / response = result
                   markers
                   markerattrs = (color=black symbol=circle)
                   lineattrs = (color=black thickness=2);
run;
```

```
ods tagsets.rtf_sample close;
ods listing;
```

Plotting the Data – Output



Figure 6.10.1: Individual Reticulocyte Abs Count per visit – Subject S04-003 (Cohort 1); Protocol: BBC-123 Study Population: Safety Population



Clinical cut-off date: 11JUL2014 Program: Figure 6.10-Reticuloctyes.sas (version 1.0);

Output: Figure 6.10.1-Reticuloctyes (S04-003).rtf;

Date Created: 14SEP2014 21:29

Page 1 of 1

Reference line – Program (1)



mp_visit = Name of visit
patient switched to
maintenance phase

mpyn = Did the patient switch to
maintenance phase (0 = no, 1 = yes)

	cohort	pid	visit2	visit_dt	result	mpyn	mp_visit
1	Cohort 1	S04-003	Baseline		70.5	1	Week 3
2	Cohort 1	S04-003	Week 2	2013-10-25	76	1	Week 3
3	Cohort 1	S04-003	Week 3	2013-11-01	4(1	Week 3
4	Cohort 1	S04-003	Week 4	2013-11-08	7	1	Week 3
5	Cohort 1	S04-003	Week 5	2013-11-15	67	1	Week 3
6	Cohort 1	S04-003	Week 6	2013-11-22	56	1	Week 3
7	Cohort 1	S04-003	Week 7	2013-11-29	43	1	Week 3
8	Cohort 1	S04-003	Week 8	2013-12-06	229	1	Week 3
9	Cohort 1	S04-003	Week 9	2013-12-12	142	1	Week 3
10	Cohort 1	S04-003	Week 10	2013-12-20	111	1	Week 3
11	Cohort 1	S04-003	Week 11	2013-12-27		1	Week 3
12	Cobort 1	CUN UUS	Woold12	2014 01 02	or	4	Weeld?

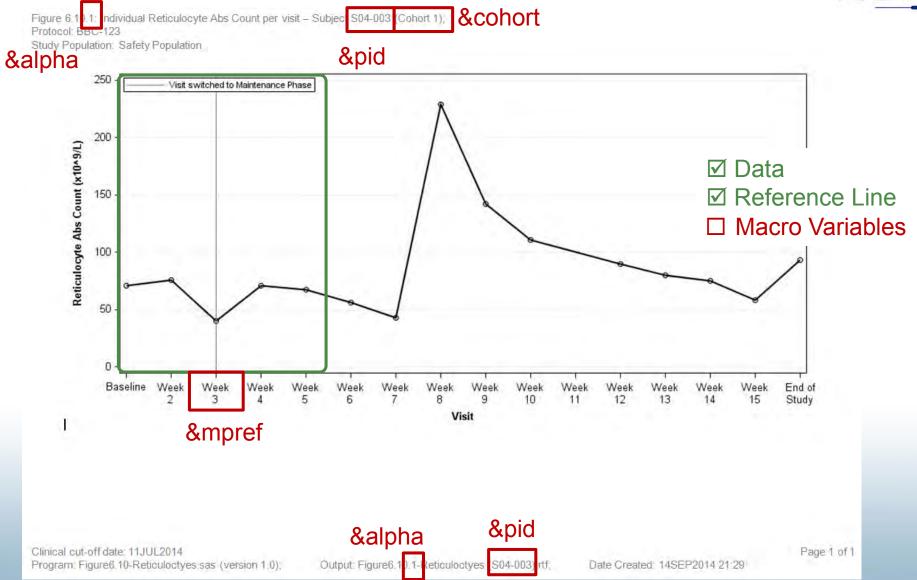
Reference line – Program (2)



```
∃proc sgplot data=lbh7;
     yaxis label = "Reticulocyte Abs Count (x10^9/L)"
           grid values = (0 to 250 by 50);
     xaxis label = "Visit"
           type=discrete
           fitpolicy=splitalways
           splitchar="|"
           discreteorder=data;
     vline visit2 / response = result
                    markerattrs = (color=black symbol=circle)
                    lineattrs = (color=black thickness=2);
     refline mp_visit / axis = X
                         lineattrs = (pattern=solid color=grey)
                         name='refline'
                         legendlabel = 'Visit switched to Maintenance Phase';
     keylegend 'refline' / title=''
                           valueattrs=(size=9)
                           location=inside
                           position=topleft
                           across=1
                           opaque;
 run;
 ods tagsets.rtf sample close;
 ods listing;
```

Reference line - Output





Macro Variables – Program (1)



options symbolgen mprint mlogic;

```
%macro fig610;
   proc sql noprint; /* Get distinct data */
       create table pid as
       select distinct cohort, pid, mpyn, mp_visit
       from bbc.lbh6;
   data pid;
                     /* Put count into a macro variable */
       set pid;
       n + 1;
       call symput('N', compress(put(n, best12.)));
    run;
    %DO I=1 %TO &N; /* Use the count macro in a DO statement *
       data null; /* Create remaining macro variables */
           set pid (where=(n=&I));
           call symput('pid', compress(pid));
           call symput('num', strip(put(&I, best.)));
           call symput ('cohort', strip(put(cohort, F8F8.)));
           call symput ('mpref', mp visit);
       run;
       data lbh7; /* Select data for one subject only */
           set bbc.1bh6;
           if pid="&pid";
        run;
```

Macro Variables – Program (2)



```
ods escapechar = '~';
ods graphics / noborder width = 25cm height=12cm imagefmt=jpeg;
Title1 i=1 font = "Arial" height = 10nt color = black
       "Figure 6.10. &num: Individual Reticulocyte Abs Count per visit - Subject &pid (&cohort);"
Title2 j=1 font = "Arial" height = 10pt color = black "Protocol: BBC-123";
Title3 j=1 font = "Arial" height = 10pt color = black "Study Population: Safety Population";
footnote1 j=1 font = "Arial" h = 10pt color = black " ";
footnote2 j=1 font = "Arial" h = 10pt color = black "Clinical cut-off date: &cutdaterpt" j=r "Page 1 of 1";
footnote3 j=1 font = "Arial" h = 10pt color = black
    "Program: Figure 6.10-Reticuloctyes.sas (version &version);
   Output: Figure 6.10. & num-Reticuloctyes (S04-003).rtf;
    Date Created: &exedate &exetime":
ods listing close;
ods tagsets.rtf sample style = bbc file = "&out\Figure6.10.&num-Reticuloctyes (&pid).rtf" nogfootnote nogtitle;
options nonumber nodate orientation=landscape papersize="ISO A4"
        topmargin="0.5 in" bottommargin="0.5 in" rightmargin="0.5 in" leftmargin="0.5 in";
```

Macro Variables – Program (3)



```
proc sgplot data=lbh7;
            yaxis label = "Reticulocyte Abs Count (x10^9/L)"
                  grid values = (0 \text{ to } 250 \text{ by } 50);
            xaxis label = "Visit"
                  type=discrete
                  fitpolicy=splitalways
                  splitchar="|"
                  discreteorder=data;
            vline visit2 / response = result
                           markerattrs = (color=black symbol=circle)
                           lineattrs = (color=black thickness=2);
            refline mp visit / axis = X
                                 lineattrs = (pattern=solid color=grey)
                                 name='refline'
                                 legendlabel = 'Visit switched to Maintenance Phase';
            keylegend 'refline' / title=''
                                   valueattrs=(size=9)
                                   location=inside
                                   position=topleft
                                   across=1
                                   opaque;
        run:
        ods tagsets.rtf sample close;
        ods listing;
    %END;
%mend fig610;
%fig610;
options nosymbolgen nomprint nomlogic;
```

Macro Variables – Output (1)



```
Results

☐ Sapplot: Figure 6.10.1: Individual Reticulocyte Abs Count per visit – Subject S04-003 (Cohort 1);

 🖮 🤖 Saplot: Figure 6.10.2: Individual Reticulocyte Abs Count per visit – Subject S04-004 (Cohort 1);
 🖮 🤖 Saplot: Figure 6.10.3: Individual Reticulocyte Abs Count per visit – Subject S04-007 (Cohort 1);

    Egyplot: Figure 6.10.4: Individual Reticulocyte Abs Count per visit – Subject S05-001 (Cohort 1);

   Sgplot: Figure 6.10.5: Individual Reticulocyte Abs Count per visit – Subject S05-003 (Cohort 1);
   Saplot: Figure 6.10.6: Individual Reticulocyte Abs Count per visit – Subject S05-004 (Cohort 1);
 Sapplot: Figure 6.10.7: Individual Reticulocyte Abs Count per visit – Subject S08-001 (Cohort 1);

    Egplot: Figure 6.10.8: Individual Reticulocyte Abs Count per visit – Subject S08-002 (Cohort 1);

 崫 📻 Saplot: Figure 6.10.9: Individual Reticulocyte Abs Count per visit – Subject S08-003 (Cohort 1);
 🔖 📻 Sgplot: Figure 6.10.10: Individual Reticulocyte Abs Count per visit – Subject S09-001 (Cohort 1);

    Egplot: Figure 6.10.11: Individual Reticulocyte Abs Count per visit – Subject S10-001 (Cohort 1);

   📻 Saplot: Figure 6.10.12: Individual Reticulocyte Abs Count per visit – Subject S10-002 (Cohort 1);

    Sqplot: Figure 6.10.13: Individual Reticulocyte Abs Count per visit – Subject S04-006 (Cohort 2);

    Egplot: Figure 6.10.14: Individual Reticulocyte Abs Count per visit – Subject S04-009 (Cohort 2);

 🚊 🣻 Saplot: Figure 6.10.15: Individual Reticulocyte Abs Count per visit – Subject S04-010 (Cohort 2);

    Egyplot: Figure 6.10.16: Individual Reticulocyte Abs Count per visit – Subject S04-011 (Cohort 2);

    Egplot: Figure 6.10.17: Individual Reticulocyte Abs Count per visit – Subject S04-012 (Cohort 2);

   📻 Saplot: Figure 6.10.18: Individual Reticulocyte Abs Count per visit – Subject S06-002 (Cohort 2);
   📻 Sgplot: Figure 6.10.19: Individual Reticulocyte Abs Count per visit – Subject S06-004 (Cohort 2);

    Egplot: Figure 6.10.20: Individual Reticulocyte Abs Count per visit – Subject S08-005 (Cohort 2);

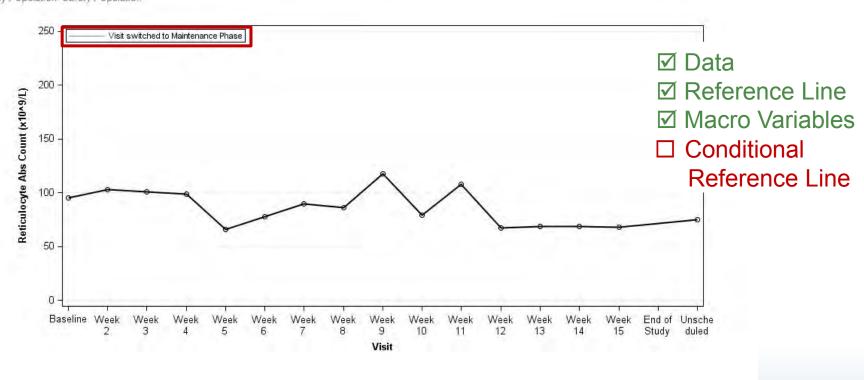
 🖮 📻 Sgplot: Figure 6.10.21: Individual Reticulocyte Abs Count per visit – Subject S08-007 (Cohort 2);

    Egplot: Figure 6.10.22: Individual Reticulocyte Abs Count per visit – Subject S10-003 (Cohort 2);
```

Macro Variables – Output (2)



Figure 6.10.4: Individual Reticulocyte Abs Count per visit – Subject S05-001 (Cohort 1): Protocol: BBC-123 Study Population: Safety Population



Clinical cut-off date; 11JUL2014 Program: Figure 6.10-Reticuloctyes.sas (version 1.0);

Output: Figure 6 10 4-Reticuloctyes (S04-003).rtf.

Date Created: 14SEP2014 21:29

Page 1 of 1

Conditional Reference Line - Program

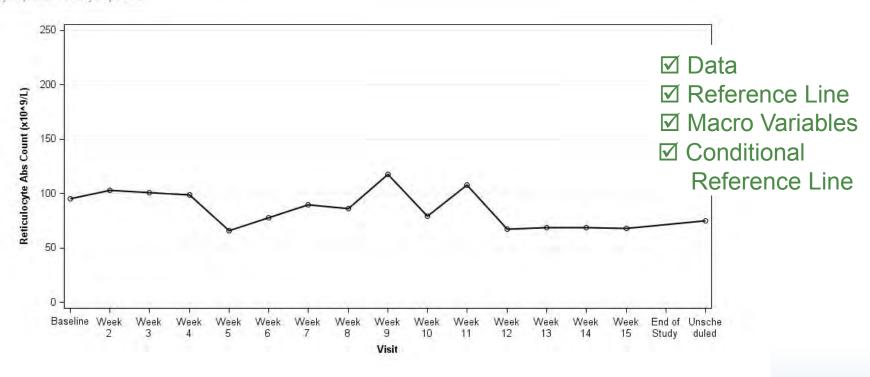


```
%DO I=1 %TO &N;
                 /* Use the count macro in a DO statement */
    data _null_; /* Create remaining macro variables */
       set pid (where=(n=&I));
       call symput('pid', compress(pid));
       call symput('num', strip(put(&I, best.)));
                                                     proc sgplot data=bbc.lbh6 (where=(pid="&pid"));
       call symput ('cohort', strip(put(cohort, F8F8.
       call symput ('mpref', mp visit);
                                                         yaxis label = "Reticulocyte Abs Count (x10^9/L)"
       call symput ('mpynref',strip(mpyn));
                                                                grid values = (0 to 250 by 50);
    run;
                                                         xaxis label = "Visit"
                                                               type=discrete
                                                                fitpolicy=splitalways
                                                               splitchar="|"
                                                               discreteorder=data;
                                                         vline visit2 / response = result
                                                                        markers
                                                                        markerattrs = (color=black symbol=circle)
                                                                        lineattrs = (color=black thickness=2);
                                                         %if "&mpynref"="1" %then %do;
                                                             refline mp visit / axis = X
                                                                                  lineattrs = (pattern=solid color=grey)
                                                                                  name='refline'
                                                                                  legendlabel = 'Visit switched to Maintenance Phase';
                                                             keylegend 'refline' / title=''
                                                                                    valueattrs=(size=9)
                                                                                    location=inside
                                                                                    position=topleft
                                                                                    across=1
                                                                                    opaque;
```

Conditional Reference Line - Output



Figure 6.10.4: Individual Reticulocyte Abs Count per visit – Subject S05-001 (Cohort 1)) Protocol: BBC-123 Study Population: Safety Population



Clinical cut-off date: 11JUL2014

Program: Figure 6.10-Reticuloctyes.sas (version 1.0); Output: Figure 6.10.4-Reticuloctyes (S05-001).rtf; Date Created. 14SEP2014 21:29

Page 1 of 1



Lessons Learnt

Certification & Experience



Certification

- ✓ SAS Certified Base Programmer for SAS 9
- ✓ SAS Certified Advanced Programmer for SAS 9
- ✓ SAS Certified Clinical Trials Programmer Using SAS 9

Experience

- ✓ Working on over 20 studies:
 - ✓ TLF packages
 - ✓ Sample size estimates
 - ✓ Randomisation schedules
 - ✓ Statistical Analysis Plans
 - ✓ Protocols
 - ✓ Statistical Reports
- ✓ Process improvement

Key points for new SAS (bio)statisticians



- Know the study (design, objectives, treatment, disease)
- Know the data
- Know the regulations
- Get the specifications right <u>before</u> programming
- > SAS
 - Think "HOW" not "IF"
 - Try different programming approaches
 - Program using your logic (but don't assume others have the same logic)
 - Keep it readable indentations, annotations
 - Use macros judiciously
 - Maintain a clean log*
 - Version control
 - Leave plenty of time for validation and QC
 - Be willing to admit "I don't know"
 - Ask for help



HELP!!

HELP!! General Online Searching





- SAS Online Support: https://support.sas.com/
- SAS User Group Whitepapers
 - http://www.pharmasug.org/
 - http://www.lexjansen.com/ (various SAS proceedings)
- SAS Sample Programs and Data from SAS published books
 - http://ftp.sas.com/samples/index
- Specific to Statistical Analyses in SAS
 - http://www.ats.ucla.edu/stat/sas/

HELP!! Communities & User Groups



- SAS Community Forums
 - General https://communities.sas.com/community/support-communities
 - Health Care, including pharmaceutical https://communities.sas.com/community/supportcommunities/sas_in_health_care_related_fields
 - Australia and New Zealand https://communities.sas.com/groups/sanzoc
 - Melbourne
 https://communities.sas.com/groups/sanzoc/content?filterID=content
 ~category[smug]
- http://www.sascommunity.org/wiki/Main_Page
- SAS-L RSS Feed (https://listserv.uga.edu/cgi-bin/wa?A0=sas-l)

HELP!! Offline



- SAS help
- > SAS Books / eBooks

My SAS Library



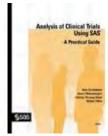






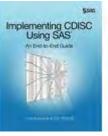




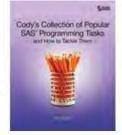














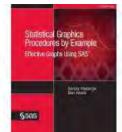




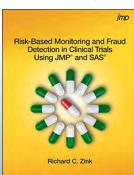






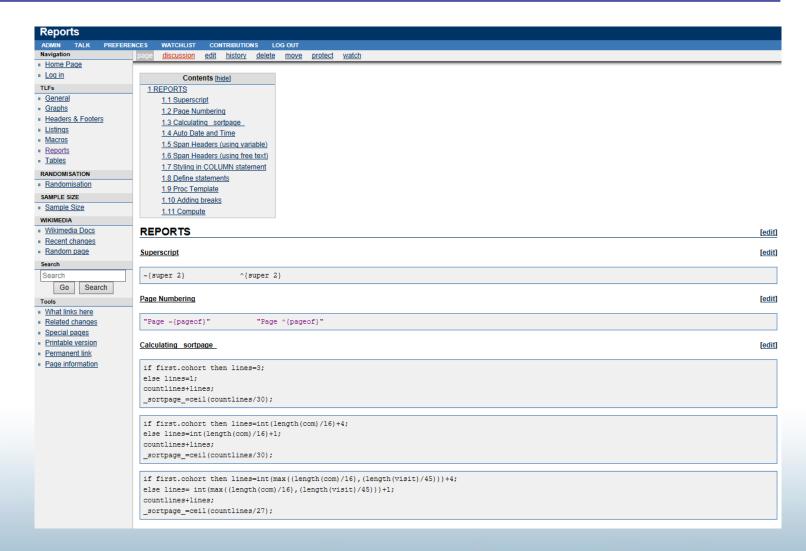






Wiki – Central repository for code snippets







Where to now?

Where to from here?



SAS

- Cleverer programming (work smarter, not harder)
- > RRR (Reuse, Refine, Recycle) (SAS Clinical Data Integration)
- ➤ CDISC / XML (SAS Clinical Standards Toolkit, PROC CDISC)
- Risk-based monitoring (JMP Clinical)

Statistics

- Mixed modelling
- Multiple comparisons
- Time-to-event analyses
- Pharmacometrics





What should new SAS programmers focus on to become top SAS programmers?

Extra: Log Review



Search Terms*

Error

Warning

INFO: Character

INFO: The variable

NOTE: At least

NOTE: Character

NOTE: Division

NOTE: Mathematical

NOTE: Merge

NOTE: Missing

NOTE: NOSPOOL

NOTE: Numeric

NOTE: Variable

NOTE: A CASE

Tip: Use Notepad++ software to find all occurrences of a search term in 1 (or more) logs

```
(S04-007).rtf
210
211 NOTE: PROCEDURE SGPLOT used (Total process time):
           real time
                             0.92 seconds
                             0.39 seconds
          cpu time
215 NOTE: There were 16 observations read from the data set WORK.LBH7
     NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column)
    NOTE: There were 1 observations read from the data set WORK._PID.
222 NOTE: DATA statement used (Total process time):
          real time
                             0.01 seconds
                             0.01 seconds
           cou time
226
     NOTE: There were 296 observations read from the data set WORK.LBH6
 Search "NOTE: Numeric" (44 hits in 1 file)
   new 2 (44 hits)
     Line 137: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column)
     Line 164: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column)
     Line 191: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column)
     Line 218: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column)
     Line 245: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column).
     Line 272: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column).
     Line 299: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column).
     Line 326: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column).
     Line 353: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column)
     Line 380: NOTE: Numeric values have been converted to character values at the places given by: (Line): (Column).
Normal text file
                               length: 53201 lines: 1463
                                                          Ln:218 Col:14 Sel:13|0
                                                                                            Dos\Windows
                                                                                                          ANSI as UTF-8
```

^{* &}quot;Validating Clinical Trial Data Reporting with SAS" by Carol Matthews & Brian Shiling



TIPS & TRICKS

Tips & tricks for the new and not so new to SAS

Brian Watts



TIPS AND TRICKS :: ABSTRACT

- Migrating old source code to EGuide
- Using code analyser to convert code to process flows
- Managing log capture interactively or in batch
- SAS Logs:
 - Post processing SAS logs and capturing more than just obvious errors
- ADsync:
 - Better practices to consider for synchronising Host Security (AD, LDAP etc) with SAS
 Metadata
- SAS VA:
 - A short drive through history on the way to Visual Analytics



TIPS & TRICKS

- EG note nodes, setting sasapp workspace default for file navigation
- EG Project Maintenance to change from sasapp to localhost
- Multiple flows in a project, moving code nodes from flow to flow
- Embedding code or leave it on disk and link it to EG flow?
- Using EG Analyse Program to convert code to a flow
- Filename to access many different non-SAS data types
- Filename to send basic email, set email system options
- Filename to allocate temporary log file in work library location
- Proc printto to redirect log to disk
- Use of data step to echo log back into EGuide
- Use of LogCheck macro to scan log
- Customising LogCheck macro to handle "known errors"



TIPS & TRICKS

- ADsync:What is a better practice for synchronising Host Security (AD, LDAP etc) with SAS Metadata
 - Decouple the riskier dependencies that break
 - Shift ownership to IT AD security team to push the data
 - maintaining people and process for AD extract is difficult to sustain
 - better if IT AD security are responsible to push the data
 - Once you have user and groups names landed pick them up with usual supplied user synchronisation
 - Optionally don't actually auto-delete groups/users from metadata
 - instead you could rename the users to indicate inactivation
 - easier to add in should they return to use
 - avoids 'deleterious' consequence of accidental auto-deletion!
 - Consider building the process as a custom DI transformation
 - another way to put more interactive control in your hands





- Narrative:
 - a quick journey through history to VA

ANALYTICS U & SANZOC UPDATE



Andrew Howell



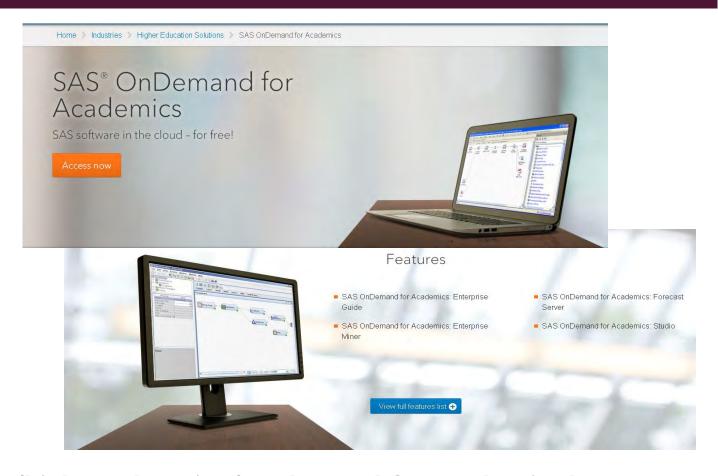
USER COMMUNITY UPDATES

- SAS University Edition
 - Online solutions for Academics
 - Your own free copy of SAS
- SAS Global Forum 2015 (Dallas, TX)
 - Call for papers open
 - Win a trip to SAS Global Forum
- SANZOC Update



SAS ON-DEMAND FOR ACADEMICS

- Online solutions for Academics
 - Enterprise Guide
 - Enterprise Miner
 - Forecast Server
 - SAS Studio



http://www.sas.com/en_us/industry/higher-education/on-demand-for-academics.html





- Your own free copy of SAS
 - Base/SAS
 - SAS/STAT
 - SAS/IML
 - SAS/Access
- Requirements
 - Windows 7+ (64-bit) / OS X 10.8+ / Linux
 - VMWare / VirtualBox
 - Web browser

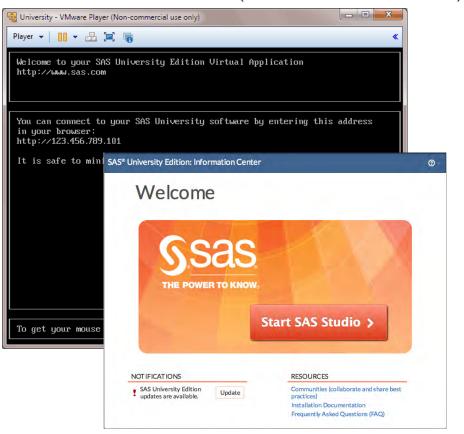


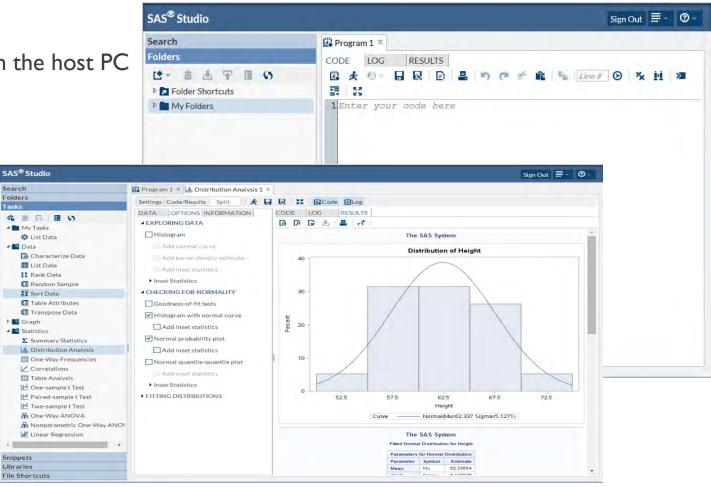
http://www.sas.com/en_us/software/university-edition.html



SAS UNIVERSITY EDITION

- Runs as a virtual SAS server
- Run via SAS Studio (HTML5 web interface) on the host PC





SAS GLOBAL FORUM 2015 26 – 29 APRIL, DALLAS TEXAS



- Call for papers now open
- Wide array of subject matter
 - Visual Analytics, Administration, Programming, Statistics
 - And many more...
- Benefits
 - International recognition, Peer review, Networking
 - Looks great on a CV!
- Speak to locals who have presented overseas:
 - Andrew Howell (SMUG & SANZOC) SGF 2013, SGF 2014
 - Brian Watts (SMUG speaker) SEUGI 2001, SEUGI 2002
 - Michelle Holmes (QUEST & SANZOC) SGF 2014



http://www.sas.com/en_us/events/2014Q1/sas-global-forum-2015/home.html

WIN A TRIP TO SAS GLOBAL FORUM 2015

- All presentations are judged by users
 - Last SMUG winner: David Cross, BUPA Health Dialog
- The Winner of each user group meeting, entered into the draw
 - From SMUG, SNUG, QUEST, SAUSAG, WASUP, etc





One winner wins a free trip to SAS Global Forum 2015

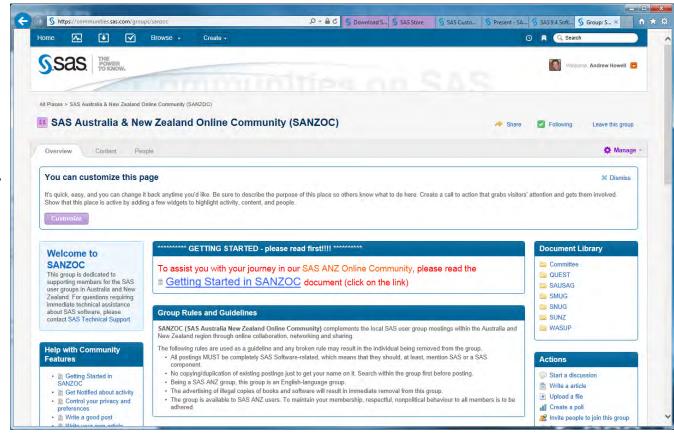
- Flights
- Accommodation
 - Registration
- Last year's winner was Bob Whitehead from Perth

Speak to a SMUG Committee member about presenting at SMUG

SAS AUSTRALIA & NEW ZEALAND ONLINE COMMUNITY (SANZOC)



- SANZOC now an open group
 - Available to anyone, allows overseas experts to participate in local discussions
 - No waiting for approval
 - Still moderated, discussions may be relocated.
- Encourage you all to join
 - Discover online communities
 - Continue user discussions
 - Remember to follow the SMUG avatar & committee members



http://communities.sas.com/groups/sanzoc

SAS EDUCATIONING YOU WHERE YOU WANT TO GO



the skills to fully realise the power of the SAS software in your hands





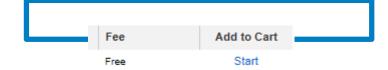
Validate your SAS software skills and earn the globally-recognised credential endorsed by SAS

1. Free Analytics U



2. Free e-Courses

- SAS Programming 1: Essentials
- SAS Statistics 1: Introduction to ANOVA, Regression, and Logistic Regression



3. Certification

- Set Yourself Apart
- Become More
- Hire Qualified Employees
- Demand More



Contact danny.cohen@sas.com for more information



QUESTIONS FOR THE PRESENTERS?

Q & A



THANK YOU FOR YOUR ATTENDANCE

DON'T FORGET TO COMPLETE THE EVALUATION SURVEY EMAIL

Please join us outside for Refreshments & Networking