

SAS Views 2001

Is it harder for a pharmaceutical company to move from SAS V6.12 to V8.2 than it is for a country to qualify for the world cup?

Football is a Thinking Mans Game

Ronaldo on his son:

“He will be called Ronald, because we like going to McDonald’s”

David Beckham on his son:

“I would like to have Brooklyn christened but I’m not sure which religion yet”

Who, What, Why?

- Gary Kennedy
 - Team Leader Statistics
- Project Leader of migration to latest SAS version
 - Currently V6.12, moving to V8.2
- Why choose me?
 - Ten years SAS experience and regularly attend SEUGI/SUGI
 - Stupid enough to say yes

Outline of Presentation

- 1) Introduction - Done
- 2) Regulations in the pharmaceutical industry
- 3) What should we think about when moving versions?
- 4) Do we need to do perform a full validation?
- 5) The project team
- 6) Testing SAS in our environment
- 7) Informal Testing of SAS
- 8) Training the users
- 9) Conclusions

Regulations in the Pharmaceutical Industry

- Regulatory requirement 21 CFR Part 11 - Electronic Signatures
- It is a BI requirement that all software/hardware is validated if it is used to produce data for a regulatory submission
- This goes beyond the SAS to the validation of the hardware (i.e. UNIX box) the software will be stored on
- Also, how will SAS interact with the other software we use
 - Will we lose functionality?
 - Will we have a reduction in performance?

What Should we Think About When Moving Versions?

- Agree project team members
- Functional requirements and specifications
- Installation qualification (IQ)
- Risk assessment
- Qualification plan
- Test strategy
- Specify test cases
- Training plan
- S.O.P.s for validation
- Review of validation every two years

Moving Versions is no Longer a Simple Task

- With previous versions the migration was performed in < 1 month
- Now our aim is to move to SAS V8.2 by end of March 2002!
- Is this really all necessary?
 - BI requirement
 - Regulatory requirement for electronic signatures but may also expand to other regulations in the future
 - Good business practice

Do we Need to Perform a Full Validation?

- SAS has been a standard in the pharmaceutical industry for many years
- We have many years experience in using SAS at B.I.
- Qualification and not Validation
 - less emphasis on SAS
 - more emphasis on our hardware and environment
- Write Risk Assessment to explain why

Project Team

- Project leader
- Validation/qualification manager
- Validation/qualification consultant
- Information services representative
- Oracle Clinical representative
- CARE representative
- SAS expert

Testing SAS in Our Environment

- Standard SAS Test Streams
- Informal Testing
- Single Study Test (run programs for one study and compare output between versions)
- Performance Testing at each OPU?
- Compatibility of SAS 8.2 with O*C 4.0
- Compatibility with CARE

Managers Need to Always Remain Positive

Kevin Keegan:

“The good news for Nigeria is that they’re two-nil down very early in the game”

Managers Need to Keep Calm

Ron Atkinson:

“I never comment on referees and I’m not going to break the habit of a lifetime for that prat”

Managers Need to be Decisive

Jimmy Hill:

“Don’t sit on the fence Terry, what chance do you think Germany has got of getting through?”

Terry Venables:

“I think it’s fifty-fifty”

Informal Testing of SAS

- 16 users using V8 for 2 months
- Base procedures, Stats. Procedures, Environment & ODS
- “BI Guide” to V8
- Assess new functionality?
- What functionality is most useful to BI?
- What functionality is difficult to understand or implement?
- What tips can we give new users?
- What SAS bugs were found?
- Testing results very positive on new features

Informal Testing of SAS (Example1)

- We regularly save graphs into catalogues using the GOUT option

```
Proc Gplot data=c.test gout=c.mycat;
```

```
Plot X*Y;
```

```
Run;
```

- When you clear the results window the output for the graph within the permanent catalogue (c.mycat) is removed as well



Results

Results

- Gplot: The SAS System
 - Plot of $x * y$

Explorer

SAS Environment

Contents of 'C.Mycat'

SAS Environment

- Libraries
 - C
 - Mycat
 - Rage
 - Sashelp
 - Sasuser
 - Stdmac
 - Stndrds
 - Work
- File Shortcuts

Gplot

Log - (Untitled)

79 libname c 'c:\';

NOTE: Libref C was successfully assigned as follows:

Engine: V8

Physical Name: c:\

80

81 data c.test;

82 do x = 1 to 10;

83 y = x * 2;

84 end;

85 run;

NOTE: The data set C.TEST has 1 observations and 2 variables.

NOTE: DATA statement used:

real time 0.05 seconds

86

87 proc gplot data=c.test gout=c.mycat;

88 plot x*y;

89 run;

90 quit;

NOTE: There were 1 observations read from the data set C.TEST.

NOTE: PROCEDURE GLOT used:

real time 2.85 seconds



Results

Results

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90  quit;

NOTE: There were 1 observations read from the data set C.TEST.
NOTE: PROCEDURE GLOT used:
      real time          2.85 seconds
```

Informal Testing of SAS (Example2)

- The Proc Means statistics output now keep the attributes of the analysis variable used
- In version 6.12 they did not
- This option can be removed by adding the NOINHERIT option to the OUTPUT statement
- In general an improvement but V6.12 programs may produce different output unless amended

Patient	Country	Name of Investigator	Treatment	Planned Time	Level of Pain Relief
7078	IT	Bandettini	Meloxicam 7.5mg	0:15	Some
				0:30	A Little
				1:00	A Little
				1:30	A Little
				2:00	A Little
				3:00	None
				4:00	None
				5:00	None
				6:00	None
7079	IT	Bandettini	Ibuprofen 400mg	0:15	Some
				0:30	A Little
				1:00	A Little
				1:30	A Little
				2:00	A Little
				3:00	A Little
				4:00	A Little
				5:00	.
				6:00	.
7080	IT	Bandettini	Meloxicam 3.75mg	0:15	None
				0:30	None
				1:00	.
				1:30	.
				2:00	.
				3:00	.
				4:00	.
				5:00	.
				6:00	.

Patient	Country	Name of Investigator	Treatment	Number of Readings	Average Pain Score
7071	IT	Bandettini	Ibuprofen 400mg	3	Some
7073	IT	Bandettini	Meloxicam 15mg	5	Some
7074	IT	Bandettini	Meloxicam 1.875mg	3	Some
7076	IT	Bandettini	Meloxicam 3.75mg	9	2.22222222
7077	IT	Bandettini	Placebo	9	A Little
7078	IT	Bandettini	Meloxicam 7.5mg	9	0.66666667
7079	IT	Bandettini	Ibuprofen 400mg	7	1.14285714
7080	IT	Bandettini	Meloxicam 3.75mg	2	None

Football Commentators Help the Fans to Understand Football!



Trevor Brooking:

“That’s football, Mike, Northern Ireland have had several chances and haven’t scored but England have had no chances and scored twice”

Ron Atkinson:

“He dribbles a lot and the opposition don’t like it - you can see it all over their faces”

Training the SAS Users

- More than 400 SAS users at BI worldwide
- Different levels of SAS experience
 - Statisticians
 - Programmers
 - Data Managers
- Different levels of interest in SAS
 - just the output or how does it calculate the output?
- Language differences

What training is most important?

- How has the SAS environment changed (a lot!)?
- The ODS System
- What changes will need to be made to old programs so they produce identical output in V8?
- What features can we use in V8 to speed up our SAS programming?

How Should the Training be Given

- Demonstration with P.C.
 - difficult with so many to train
 - need large number of supervisors
- Presentation with screenshots + interactive sessions
 - Easier to manage
 - Possibly less effective
 - Important to break up presentation with tasks (20mins attention span)

Conclusions

- Validation/Qualification is now a regulatory requirement in the pharmaceutical industry
- Informal testing before a new version of SAS is valuable
 - tests SAS without constraints
 - tests SAS in your own environment
- How we train users in a new version of SAS is important if we want users to:
 - support the change fully
 - understand how the new version can benefit them

Conclusions

- Co-ordinating the Migration to SAS V8.2 has so far been a much more complex task than I initially predicted
- The Majority of the documentation in qualifying SAS in our environment will already have been done when we upgrade to the next version
- England's chances of qualifying for the World Cup will depend heavily on the players and the manager. Although the right kind of supporters is also a key factor.....

