

DATA MANAGEMENT • BIOSTATISTICS • PROGRAMMING • MEDICAL WRITING • PHARMACOVIGILANCE



Quanticate

A PASSION FOR EXCELLENCE

By Julie Oates



Global Solutions from the World's
Largest Data-Dedicated CRO

www.quanticate.com

Agenda



- Requirements
- The “thinking programmer”
- Breaking the task down
- UNIX/SAS code
- Audit file
- Documentation
- Benefits of the process
- Questions?

Requirements



"To build a system which reacts to display creation and runs the related QC programs automatically and compiles the information in one central place. This needs to work for at least 2 different studies with differing standards."

The thinking programmer!



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When
de

Do I need to
consider
switching
code on/off?

Will the
cross
ent
data?

What is the

How can I
maintain and
update the
QC
information?

Do
restri
can run it

When setting
up the
directory
what folders
are
required?

What are the
assumptions
?
convention?

Are there
any
limitations to
the system?



The thinking programmer!



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... and so the task begins



Breaking down the task



- Setting up the environment
- Directory structure
- QC programming naming convention
- The main components of the process
 1. Setting up the QC reporting environment
 2. Checking the displays vs QC programs available
 3. Copying QC programs from MASTER directory
 4. Running the QC programs
 5. Checking the QC logs
 6. Copying the information back to file

Breaking down the task



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Clients current set-up



- Display names
 - Fairly standard filename, not always a standard directory structure
- QC programs
 - Existing: Not standard (filename or directory structure)
 - New QC programs will be required
- Using SAS (version 9.13) on a Unix platform SunOS (version 5.10)

Setting up the environment



- GLOBPROT.SAS includes
 - Date of the reporting effort: e.g. 26SEP2011
 - Type of deliverable: e.g. SRT, CSR etc
 - Standard “Client” macro library path
 - Formats
 - Subsetting code
 - Macro vars including:
 - outdir_lib: Display directory
 - m_lib: QC Master directory
 - q_lib: QC Reporting effort directory

Breaking down the task



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Plan for directory structure

Directories

QC_MASTER

QC_26SEP2011

Sub-directories

programs

programs

output

output

archive

archive

...

...

Breaking down the task



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QC program naming convention



Display names

demo4_saf.html

Linking variable

demo4

QC program name

qc_demo4.sas

Breaking down the task



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The main components to the process – macro driven



- **P1_NEWDIRYN=Y:** Setting up the QC reporting environment
- **P2_QCVSOUTYN=Y:** Checking the displays vs QC programs available
 - 2a] Displays to be QCed
 - 2b] QC programs already in QC reporting effort
 - 2c] QC logs already in QC reporting effort
 - 2d] QC programs in the MASTER area
 - 2e] Incorporating the QC spreadsheet
 - 2f] Creating the match and defining the status
- **P3_COPYQCYN=Y:** Copying QC programs from QC_MASTER/programs
- **P4_RUNQCYN=Y:** Running the QC programs
- **P5_CHKLOGYN=Y** Checking the LOGs

Copy **and update** the QC spreadsheet information

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Copy **and update** the QC spreadsheet information

1] QC reporting environment - the code



%sysexec %str(

cd &m_lib;

QC_MASTER/programs

cd ../../;

mkdir QC_&snapdt2;

QC_26SEP2011

cd QC_&snapdt2;

mkdir programs;

QC_26SEP2011/programs

mkdir ...

cp -p &m_lib.globprot.sas &q_lib.globprot.sas;

);

1] QC reporting environment

- the code (continued)



```
%if %sysfunc(fileexist("&q_lib.qc_plan_&snapdt2d..csv")) eq 0
%then %do;
    %sysexec %ostr(
        cp -p    &m_lib.qc_plan.csv
                &q_lib.qc_plan_&snapdt2d..csv;
    );
%end;
```

2a] Displays to be QCed



```
%sysexec %str(
```

```
cd &outdir_lib;
```

Display directory

Internal date/time stamp

```
perl -nle 'print "$ARGV: $&" if /(0[1-9]|12[0-9]|3[01])  
(JAN|FEB|MAR|APR|MAY|JUN|JUL|AUG|SEP|OCT|NOV|DEC)  
(11|12)\ ([0-1][0-9]|2[0-3]):([0-5][0-9])/ ' *. * > &q_lib.dd.txt;  
);
```

Unix God

– Tomas Demcenko



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2b-d] Collating the QC information



%sysexec %str(

cd &q_lib ;

ls -l qc_*.sas > &q_lib.qcprog.txt;

ls -el qc_*.log > &q_lib.qclog.txt;

cd &m_lib;

ls -l qc_*.sas > &q_lib.qcmaster.txt;

);

QC snap directory

2b] QC programs

2c] QC log

MASTER directory

2d] QC programs

2e] QC_PLAN_26SEP11_SRT.CSV



Automated variables

DISPLAY	DISPLAYLOC	LINKVAR	DISPDT	QCPRG	QCLOG	QCDT
demo4_saf.htm	/project/study/output/26sep11_srt/	demo4	28SEP11:16:20:00	qc_demo4.sas	qc_demo4.log	30SEP11:04:09:00

STATUS	STATUSD	ORDER	AUTO_COMMENTS
0	Qced	28	1 MESSAGES - CHECK LOG (0 ERROR 1 WARNING 0 UNINIT 0 REPEATS)

Manual variables

MANUAL_COMMENTS	QCPASSED_YN	QCAPPROVER	QCAPP_DATE
All values matched with the actual output	Y	JO	30SEP11

Compiling the information



- List of:
 - dd.txt: Displays to QC (a):
 - qcmaster.txt: QC programs in Master area
 - qcprog.txt: QC programs in reporting effort area
 - qclog.txt: QC log (a) in reporting effort area
 - qc_plan*.csv: Existing QC_PLAN (a) contents

(a) Date information utilised

2f] Creating the match and defining the status



Displays to QC	QC program areas		Status
19APR12 (SRT)	QC_MASTER/ programs	QC_19APR12/ programs	
demo4_saf.html			4 = QC program required
demo4_saf.html	qc_demo4.sas		3 = Copy from QC_MASTER
demo4_saf.html	qc_demo4.sas	qc_demo4.sas (no log file)	2 = Run QC program
demo4_saf.html (20APR12)	qc_demo4.sas	qc_demo4.sas (log file date 21APR12)	1= QC run, Log/output need checking
demo4_saf.html (20APR12)	qc_demo4.sas	qc_demo4.sas (log file date 21APR12)	0 = QCed (based on manual cols)

Audit file



BDATE	BPTIME	BPNAME	BPTASK	BPADD
Date: 30NOV11	Time: 04:36	Name: Julie Oates	P1_NEWDIRYN=Y: Created directory QC_22NOV11 and subdir programs, output, archive and diff. Copied: QCSETUP.SAS, GLOBPROT.SAS and QC_PLAN.CSV from QC_MASTER/programs	
Date: 30NOV11	Time: 05:03	Name: Julie Oates	P2_QCVSOUTYN=Y: Identify which displays have QC programs in place, which need copying over from QC_MASTER/programs and which need writing	
Date: 30NOV11	Time: 05:03	Name: Julie Oates	P3_COPYQCYN=Y: Copy over QC programs from QC/MASTER/programs	qc_demo4.sas qc_ae4_disc.sas
Date: 30NOV11	Time: 05:03	Name: Julie Oates	P4_RUNQCYN=Y: Run QC programs	qc_demo4.sas qc_ae4_disc.sas
Date: 30NOV11	Time: 05:03	Name: Julie Oates	P5_CHKLOGYN=Y: Checks logs	
Date: 30NOV11	Time: 09:14	Name: Julie Oates	P2_QCVSOUTYN=Y: Identify which displays have QC programs in place, which need copying over from QC_MASTER/programs and which need writing	
Date: 30NOV11	Time: 09:14	Name: Julie Oates	P5_CHKLOGYN=Y: Checks logs	
Date: 01DEC11	Time: 06:27	Name: Julie Oates	P2_QCVSOUTYN=Y: Identify which displays have QC programs in place, which need copying over from QC_MASTER/programs and which need writing	
Date: 01DEC11	Time: 06:27	Name: Julie Oates	P5_CHKLOGYN=Y: Checks logs	
Date: 01DEC11	Time: 10:10	Name: Julie Oates	P2_QCVSOUTYN=Y: Identify which displays have QC programs in place, which need copying over from QC_MASTER/programs and which need writing	
Date: 01DEC11	Time: 10:10	Name: Julie Oates	P5_CHKLOGYN=Y: Checks logs	

The importance of...



- ... Documentation:
 - Assumptions
 - Limitations
 - Process and how it is linked
 - Explain how the macro variables drive it
 - Provide examples

Benefits of a process



- Consistency
 - QC directory structure
 - QC programming convention
 - Display naming convention (client)
- Ease of running in separate reporting effort
 - Same programs different globprot.sas
 - Contained area
- One central area (MASTER) with all QC programs
- Mainly automated but manual override
 - NOT the qc_plan.csv
- Time saving (example)
- Extra automated benefits in addition to the initial requirements

Questions?



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