

Making the leap from Excel to a Database used for Reporting

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 Shafi Consultancy Ltd.

Outline

- Current process
- Advantages and disadvantages of using Excel
- Step by step transition from Excel
- Benefits of using a database
- Summary

Current process

- Excel is widely used to manage expectations
 - To list what outputs we have to produce
 - Define names and locations of programs and output files
 - Manage status of programs and outputs
 - State who wrote and validated programs and when

Current process

I	J	K	L	M	N	O
tlfnum	Title	pgmloc	pgmname	outno	outloc	outname
1.1.1	Patient analysis sets and reasons for exclusion - RS	pgm/ctr/tpopu.sas	tpopu.sas	T1	lst/tpopu_t1.lst	tpopu_t1.lst
1.2.1.1	Demographic data - TS	pgm/ctr/ct/demo.sas	demo.sas	T1	lst/demo_t1.lst	demo_t1.lst
1.2.1.2	Demographic data - FAS	pgm/ctr/ct/demo.sas	demo.sas	T2	lst/demo_t2.lst	demo_t2.lst
1.2.1.3	Concomitant diagnoses by MedDRA SOC and preferred term - TS	pgm/ctr/condiag.sas	condiag.sas	T1	lst/condiag_t1.lst	condiag_t1.lst
1.2.1.4	Concomitant therapies during screening by WHO INN - TS	pgm/ctr/conmed.sas	conmed.sas	T1	lst/conmed_t1.lst	conmed_t1.lst
1.2.1.5	New concomitant therapies during study part A by WHO INN - TS	pgm/ctr/conmed.sas	conmed.sas	T2	lst/conmed_t2.lst	conmed_t2.lst
1.2.1.6	New concomitant therapies during study part B by WHO INN - TS2	pgm/ctr/conmed.sas	conmed.sas	T3	lst/conmed_t3.lst	conmed_t3.lst
1.2.1.7	Use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors during screening - TS	pgm/ctr2/cttass.sas	cttass.sas	T1	lst/cttass_t1.lst	cttass_t1.lst
1.2.1.8	New use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors	pgm/ctr2/cttass.sas	cttass.sas	T2	lst/cttass_t2.lst	cttass_t2.lst
1.2.1.9	New use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors	pgm/ctr2/cttass.sas	cttass.sas	T3	lst/cttass_t3.lst	cttass_t3.lst

Advantages & disadvantages of using Excel

- Advantages
 - Everyone knows how to use it
 - Easy to create and get started
 - Easy to manage and adapt
 - Easy to share

Advantages & disadvantages of using Excel

- Disadvantages
 - Lack of transparency
 - Lack of control and traceability
 - Manual intervention required
 - No added benefits beyond the data

Step by step transition from Excel

- Identify the key data to manage
 - Table numbers, titles
 - Program and output filenames and locations
- Define additional supporting data
 - Table shell names for each output
 - Macro parameter names and values

Step by step transition from Excel

Type	tlfnum	Title
Table	1.1.1	Patient analysis sets and reasons for exclusion - RS
Table	1.2.1.1	Demographic data - TS
Table	1.2.1.2	Demographic data - FAS
Table	1.2.1.3	Concomitant diagnoses by MedDRA SOC and preferred term - TS

pgmloc	pgmname	outno	outloc	outname	logname
pgm/ctr/tpopu.sas	tpopu.sas	T1	lst/tpopu_t1.lst	tpopu_t1.lst	tpopu.log
pgm/ctr/ct/demo.sas	demo.sas	T1	lst/demo_t1.lst	demo_t1.lst	demo.log
pgm/ctr/ct/demo.sas	demo.sas	T2	lst/demo_t2.lst	demo_t2.lst	demo.log
pgm/ctr/condiag.sas	condiag.sas	T1	lst/condiag_t1.lst	condiag_t1.lst	condiag.log

shell name	Parameter 1	Parameter 2
sh_popu1	pop=%STR(RANFL='Y')	
sh_dem1	pop=%STR(TRTFL='Y')	vars=AGE #SEX #RACE HT WT
sh_dem1	pop=%STR(FASFL='Y')	vars=AGE #SEX #RACE HT WT
sh_cd1	pop=%STR(TRTFL='Y')	

Step by step transition from Excel

- Automate some parts:
 - Who creates/updates programs and when
 - Who validates programs and when
 - If a program is updated then change the status of validated outputs
 - Auto-generate programs using supporting data
 - Produce summary of the current status

Benefits of using a database

- Automatically document key transparency data, e.g. who did what and when, including changes
- Can be used by applications to use the data for further benefits
 - To auto generate programs
 - To submit programs
 - To manage outputs

Benefits of using a database

Auto-generated programs

```

/*=====
*
* STUDY          : Study                      CREATION DATE: 12JUL2016
*
* PROGRAM        : demo.sas
*
* PROGRAMMER     : John Smith
*
* DESCRIPTION    : Create following outputs:
*                  - T1 Demographic data - TS
*                  - T2 Demographic data - FAS
*
* USER REQUIREMENTS : SAP
*
* SAS VERSION    : SASV9.4
*
* COMMENTS      :
*
*-----
*|
* REVISION HISTORY
*
* DATE          :
* PROGRAMMER    :
* REASON FOR CHANGE :
*
*=====

```

```

*****
***
***
*** Output No. T1
*** Title: 1.2.1.1 Demographic data - TS
***
*****

%sh_dem1 ( outno = T1
            ,pop=%STR(TRTFL='Y')
            ,vars=AGE #SEX #RACE HT WT
            );

*****
***
*** Output No. T2
*** Title: 1.2.1.2 Demographic data - FAS
***
*****

%sh_dem1 ( outno = T2
            ,pop=%STR(FASFL='Y')
            ,vars=AGE #SEX #RACE HT WT
            );

*****
***
***
*** End of Program
***
*****

```

Benefits of using a database

Application with summary of current status

Study Name: study_002 Total Number of Outputs: 15

■ No Program 0 ■ In Development 11 ■ To Be validated 3 ■ Validated 1
● No Output 4 ● Old Output 4 ● Current Output 7

Expand All Expand Sections Auto Generate
Collapsed All Collapsed Sections Programs

+ 1 TRIAL STUDY002

- + 1.1 Definition of analysis sets
 - Table 1.1.1 - Patient analysis sets and reasons for exclusion - RS
- + 1.2 Demographic data and baseline characteristics
 - + 1.2.1 Demographic data, concomitant diagnoses and therapies
 - Table 1.2.1.1 - Demographic data - TS
 - Table 1.2.1.2 - Demographic data - FAS
 - Table 1.2.1.3 - Concomitant diagnoses by MedDRA SOC and preferred term - TS
 - Table 1.2.1.4 - Concomitant therapies during screening by WHO INN - TS
 - Table 1.2.1.5 - New concomitant therapies during study part A by WHO INN - TS
 - Table 1.2.1.6 - New concomitant therapies during study part B by WHO INN - TS2
 - Table 1.2.1.7 - Use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors during screening - TS
 - Table 1.2.1.8 - New use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors
 - Table 1.2.1.9 - New use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors2
 - + 1.2.2 Diabetic baseline characteristics, antidiabetic therapies and diabetic medical history
 - Table 1.2.2.1 - Baseline efficacy variables and duration of diabetes - FAS
 - Table 1.2.2.2 - Antidiabetic treatment at enrolment - FAS
 - Table 1.2.2.3 - Relevant medical history - TS
- + 1.3 Compliance data
 - Table 1.3.1 - Compliance data during study part A - FAS
 - Table 1.3.1 - Compliance data during study part B - TS2

Benefits of using a database

Example of Study Status Reports

Study Name: study_002

Current Status Of Outputs By Table Number

Show entries

Search:

TLF Number	Title	Program Location	Program Name	programmer Name	Date/Time of Last Program Update	Output Location	Output Name	Date/Time of Last Output Update	Validator Name	Current Status	Date/Time of Last Status Update
Table 1.1.1	Patient analysis sets and reasons for exclusion - RS	pgm/ctr/	tpopu.sas	dummy_user1	27 Sep 2016 19:24:46	lst/	tpopu_t1.lst	06 Oct 2016 16:36:54	dummy_user1	Validated	06 Oct 2016 16:14:28
Table 1.2.1.1	Demographic data - TS	pgm/ctr/	demo.sas	dummy_user1	28 Sep 2016 16:31:33	lst/	demo_t1.lst	06 Oct 2016 15:45:18		In Development	28 Sep 2016 16:31:33
Table 1.2.1.2	Demographic data - FAS	pgm/ctr/	demo.sas	dummy_user1	28 Sep 2016 16:31:33	lst/	demo_t2.lst	06 Oct 2016 15:45:18		In Development	28 Sep 2016 16:31:33
Table 1.2.1.3	Concomitant diagnoses by MedDRA SOC and preferred term - TS	pgm/ctr/	condiag.sas	dummy_user1	27 Sep 2016 19:24:46	lst/	condiag_t1.lst	28 Sep 2016 17:10:51		In Development	27 Sep 2016 19:24:46
Table 1.2.1.4	Concomitant therapies during screening by WHO INN - TS	pgm/ctr/	conmed.sas	dummy_user1	02 Oct 2016 15:02:33	lst/	conmed_t1.lst	28 Sep 2016 17:10:55		To Be validated	09 Oct 2016 15:32:02
Table 1.2.1.5	New concomitant therapies during study part A by WHO INN - TS	pgm/ctr/	conmed.sas	dummy_user1	02 Oct 2016 15:02:33	lst/	conmed_t2.lst	28 Sep 2016 17:10:55		To Be validated	09 Oct 2016 15:32:02
Table 1.2.1.6	New concomitant therapies during study part B by WHO INN - TS2	pgm/ctr/	conmed.sas	dummy_user1	02 Oct 2016 15:02:33	lst/	conmed_t3.lst	28 Sep 2016 17:10:55		To Be validated	09 Oct 2016 15:32:02
Table 1.2.1.7	Use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors during screening - TS	pgm/ctr/	cttass.sas	dummy_user2	28 Sep 2016 17:03:33	lst/	cttass_t1.lst	28 Sep 2016 17:10:59		In Development	28 Sep 2016 17:03:33
Table 1.2.1.8	New use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors	pgm/ctr/	cttass.sas	dummy_user2	28 Sep 2016 17:03:33	lst/	cttass_t2.lst	28 Sep 2016 17:10:59		In Development	28 Sep 2016 17:03:33
Table 1.2.1.9	New use of ASA, antihypertensives, lipid lowering drugs or P-gp and CYP 3A4 inhibitors2	pgm/ctr/	cttass.sas	dummy_user2	28 Sep 2016 17:03:33	lst/	cttass_t3.lst	28 Sep 2016 17:10:59		In Development	28 Sep 2016 17:03:33

Benefits of using a database

- Can store data about more than one trial and be efficient in their usage
 - Copy outputs required from study to study
 - Search historical studies for analysis performed and associated programs
 - Version control of programs and outputs
- Can define and implement standards

Benefits of using a database

Search historical tables and analyses

Advanced Search Across Studies

Select Category: +

Criteria - Phase: ☒ Phase 1 ☐ Phase 3 ☐ Phase 2 x

Criteria - Population Type: x

Search Result

5 studies found for: phase = 1 | population = TS |

Show entries

# Access	Study	Table Number And Output Name
1	study_001	Table 1.1.5 Number of treated patients in study part B by country and centre - TS2
2	study_001	Table 1.2.3 Number of patients with important protocol violations in study part A - TS
3	Study_004	Table 1.1.5 Number of treated patients in study part B by country and centre - TS2
4	Study_004	Table 1.2.3 Number of patients with important protocol violations in study part A - TS

Preview Window

Table 4.1: 1 Demographic data - TS

	Red\Blue	Blue\Blue	Green\Green	Brown\Brown
Number of patients	135 (100.0)	135 (100.0)	134 (100.0)	134 (100.0)
Gender [N (%)]				
Male	77 (57.0)	70 (51.9)	66 (49.3)	84 (62.7)
Female	58 (43.0)	65 (48.1)	68 (50.7)	50 (37.3)
Race [N (%)]				
Amer.Ind./Alaska Nat	0 (0.0)	2 (1.5)	1 (0.7)	2 (1.5)
Asian	1 (0.7)	3 (2.2)	3 (2.2)	4 (3.0)
Black/African Amer.	14 (10.4)	18 (13.3)	16 (11.9)	21 (15.7)
Hawaiian/Pacif. Isle	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
White	120 (88.9)	111 (82.2)	114 (85.1)	107 (79.9)

Summary

- Excel is a quick and easy application to use and yes, it can be used to manage the TLFs
- Database allows automatic documentation of who performed what task and when
- Data from all trials can be stored in one database
- Databases allow standards to be defined and implemented consistently through applications

Summary

- Applications built for a database can add many functions, including:
 - Auto-generating programs
 - Implementing standards consistently
 - Provide summary status information
 - Look up historical data, easy to see programs & outputs used in other trials

Summary

Excel Metadata for TLFs and shells

Type	tlfnum	Title
Table	1.1.1	Patient analysis sets and reasons for exclusion - RS
Table	1.2.1.1	Demographic data - TS
Table	1.2.1.2	Demographic data - FAS
Table	1.2.1.3	Concomitant diagnoses by MedDRA SOC and preferred term - TS

pgmloc	pgmname	outno	outloc	outname	logname
pgm/ctr/tpopu.sas	tpopu.sas	T1	lst/tpopu_t1.lst	tpopu_t1.lst	tpopu.log
pgm/ctr/ct/demo.sas	demo.sas	T1	lst/demo_t1.lst	demo_t1.lst	demo.log
pgm/ctr/ct/demo.sas	demo.sas	T2	lst/demo_t2.lst	demo_t2.lst	demo.log
pgm/ctr/condiag.sas	condiag.sas	T1	lst/condiag_t1.lst	condiag_t1.lst	condiag.log

shell name	Parameter 1	Parameter 2
sh_popu1	pop=%STR(RANDFL=Y)	
sh_dem1	pop=%STR(TRTFL=Y)	vars=AGE #SEX #RACE HT WT
sh_dem1	pop=%STR(FASFL=Y)	vars=AGE #SEX #RACE HT WT
sh_cd1	pop=%STR(TRTFL=Y)	

Search historical programs & output

Database

Display current summary status

Total Number of Outputs: 15

■ No Program 15
 ■ In Development 0
 ■ To Be validated 0
 ■ Validated 0
 ● No Output 15
 ● Old Output 0
 ● Current Output 0

Display titles in an informative format

15.1 TRIAL SUBJECTS

15.1.1 Disposition of patients

- ■ Table15.1.1.1 Dispo
- ● Table15.1.1.2 Dispo
- ● Table15.1.1.3 Prim
- ● Table15.1.1.4 Num
- ● Table15.1.1.5 Num
- ● Table15.1.1.6 Number of the patients in study bar

Use company, therapeutic area and project standards

Auto-generate and submit programs

Develop programs interactively in SAS

Set program status to validated that change automatically if code changes



Shafi Consultancy Ltd.

Questions or Comments?



Shafi Chowdhury

shafi@shaficonsultancy.com

www.shaficonsultancy.com



Shafi Consultancy Ltd.