Meta-data Driven Automation of TLF Programs

Rafi Rahi

PhUSE SDE - Basel

16th May 2017

Outline

- Introduction
- Essential requirements for automation
- How automation can be implemented
- How automation can add benefit
- Summary

Introduction

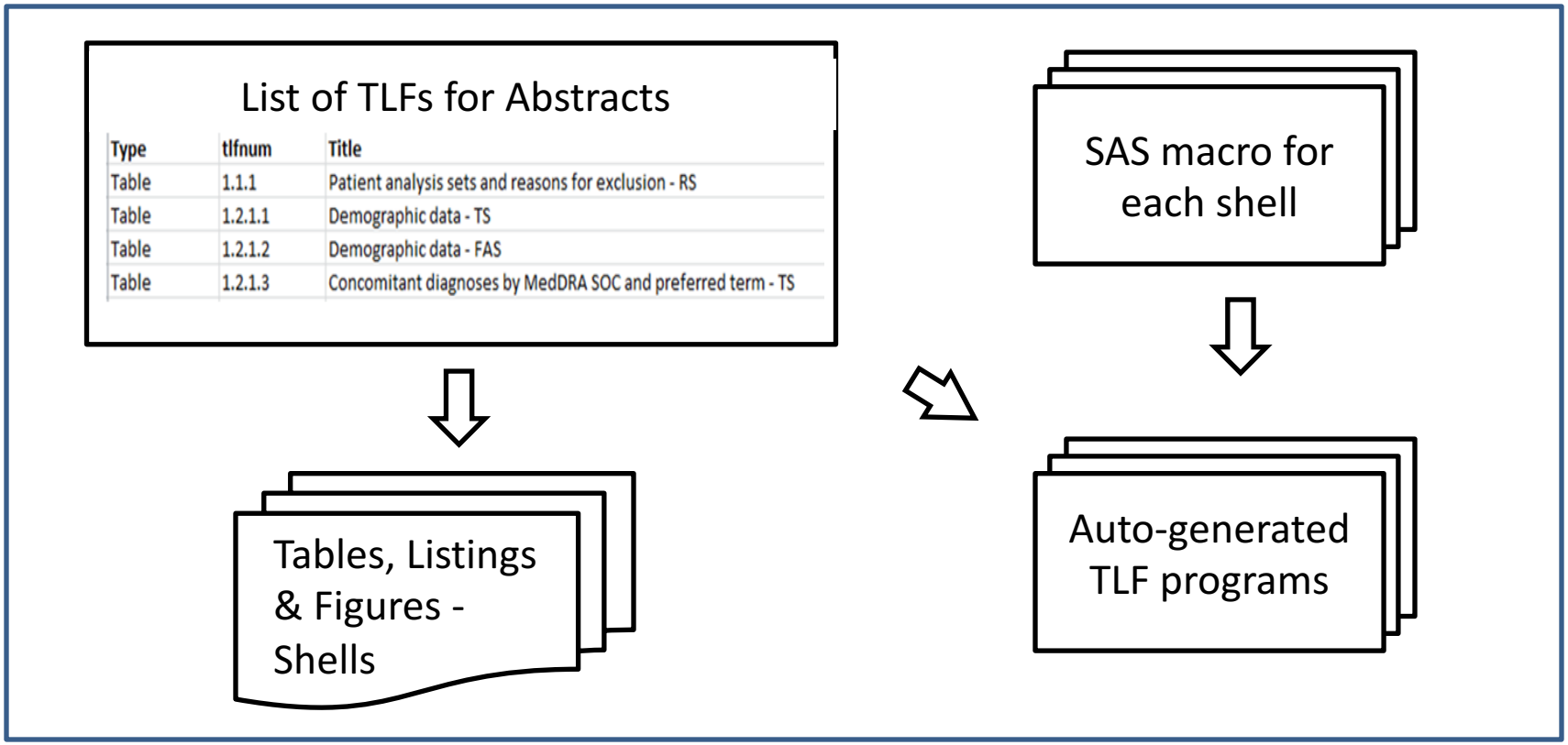
- As programmers we are all really busy
  - Number of TLFs are increasing
  - Timelines are reducing
- How can we reduce the burden on programming resource?
  - Reduce the number of outputs?
  - Increase resource?
- We need to work SMARTER!
  - Define standards
  - Automate

Essential requirements for automation

- Standards
  - Input: Data – SDTM/ADaM
  - Output: TLF – Standard table shells
  - Process: Standard macros for each TLF shell
- Meta-data
  - Structured data used to map the flow of data:

INPUT ⟹ PROCESS ⟹ OUTPUT

How automation can be implemented



Metadata

Shafi Consultancy Ltd.

Generating ADaM datasets in the same way

List of ADaM datasets

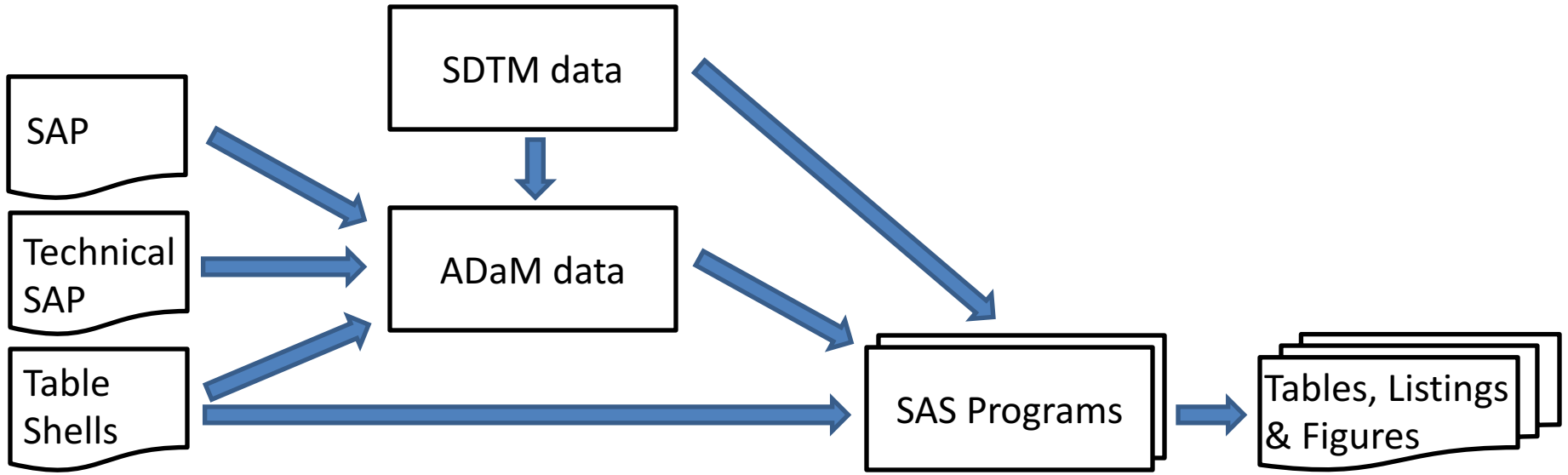
Type	tlfnum	Title
Dataset	1.1.1	ADSL
Dataset	1.1.2	ADAE
Dataset	1.1.3	ADCM
Dataset	1.1.4	ADLB

SAS macros for transformations

ADaM definitions

SAS programs to generate ADaM datasets

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

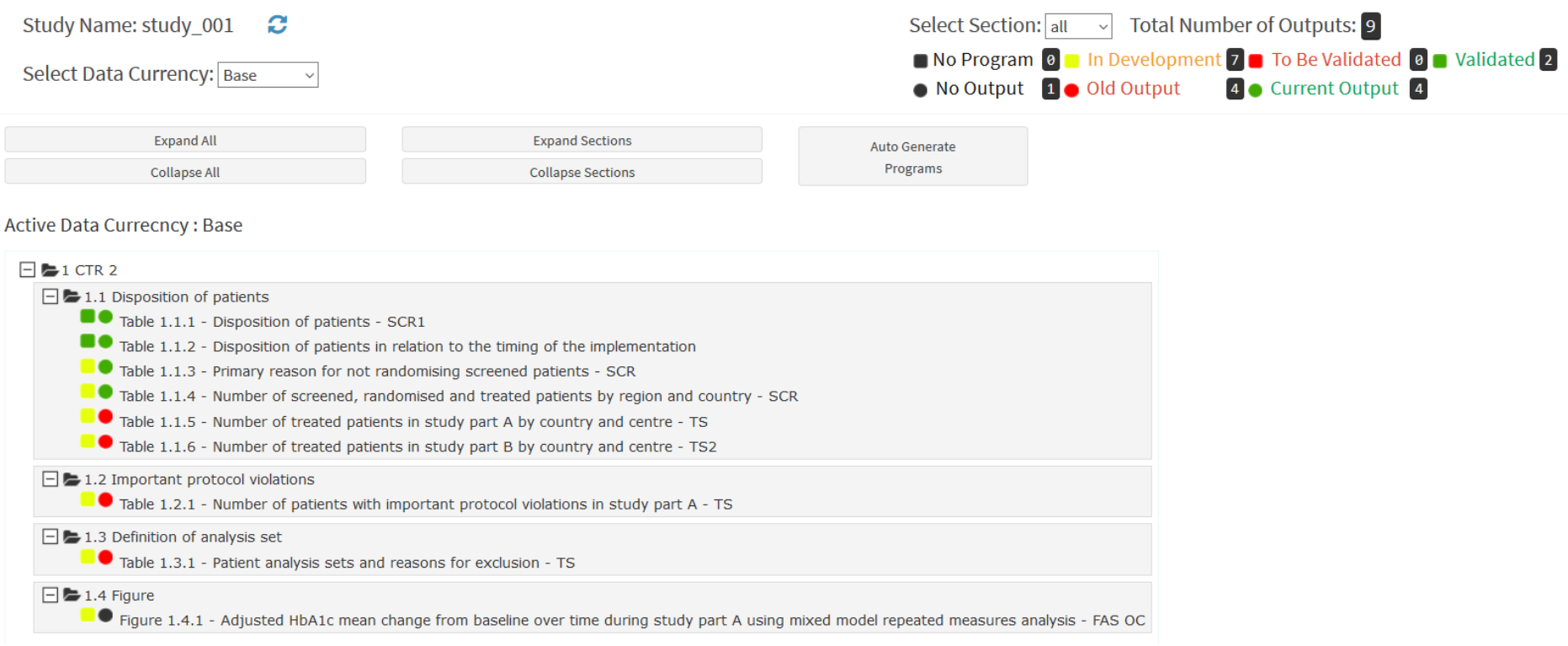
Excel is often used to capture TLF meta-data

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')	

Store all the meta-data into a system



Shafi Consultancy Ltd.

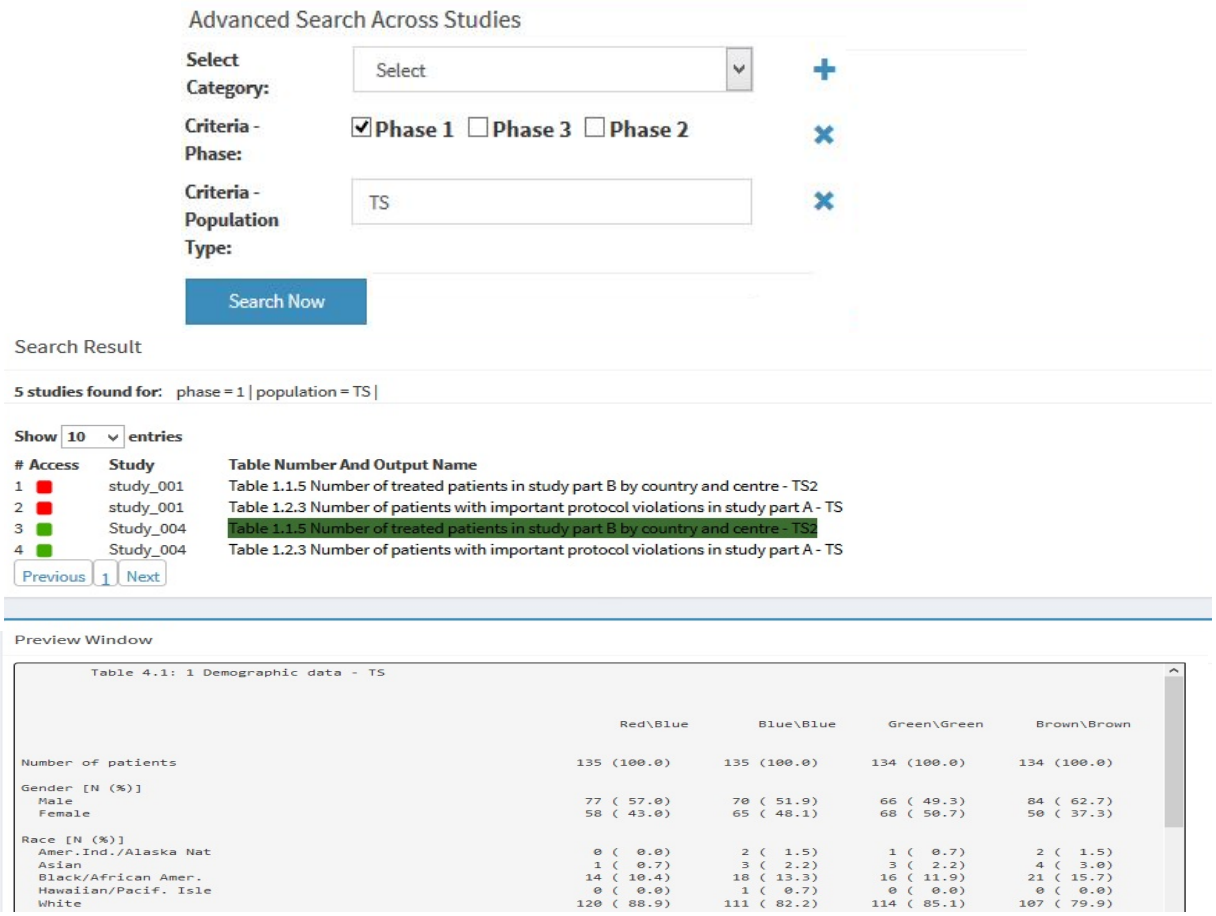
Auto-generated programs – follow GPP

```
/*=============================================================
*
* 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                          ***;
***                                                           ***;
*****************************************************************;
```

Shafi Consultancy Ltd.

Search meta-data for historical tables



Shafi Consultancy Ltd.

How automation can add benefit

- The system is designed to enforce standards:
  - Standard TLF shells
  - Standard macros
  - SAS programs follow Good Programming Practices
  - SAS programs are easy to read for FDA reviewers
- Automation will give programmers time to do more interesting programming and check to raise quality
- Automation is NOT there to reduce the role of programmers or to reduce the size of programming groups

Summary

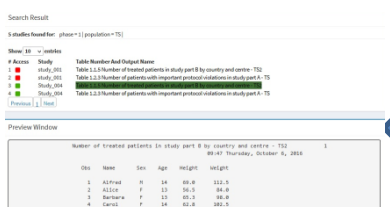
Excel Metadata for TLFs and shells

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



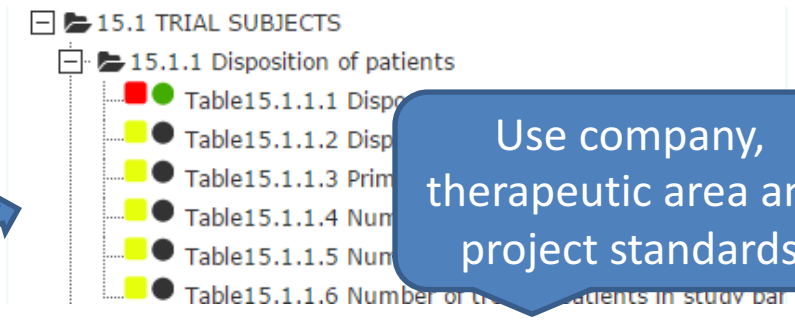
Database

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



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?

Rafi Rahi

rafi@shaficonsultancy.com

www.shaficonsultancy.com

Using the advancement of science and technology to provide innovative solutions that continue to provide benefit beyond the current problem

Shafi Consultancy Ltd.