

Generating Tables, Listings and Figures Without Any Programs

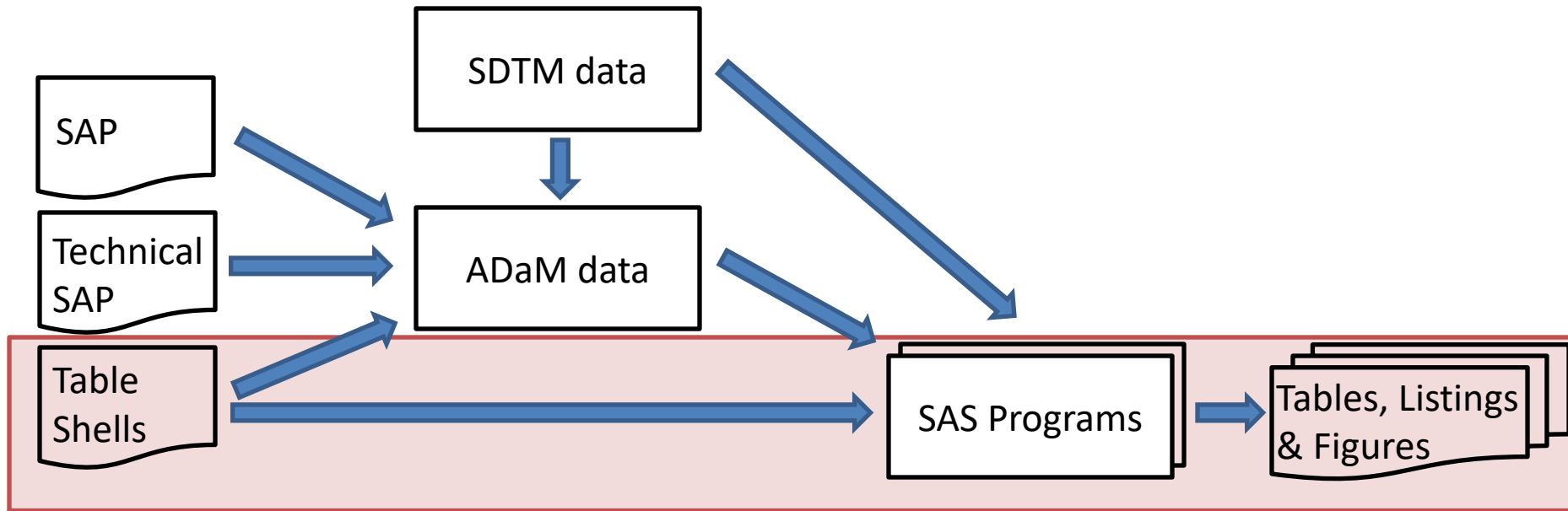


 Shafi Consultancy Ltd.

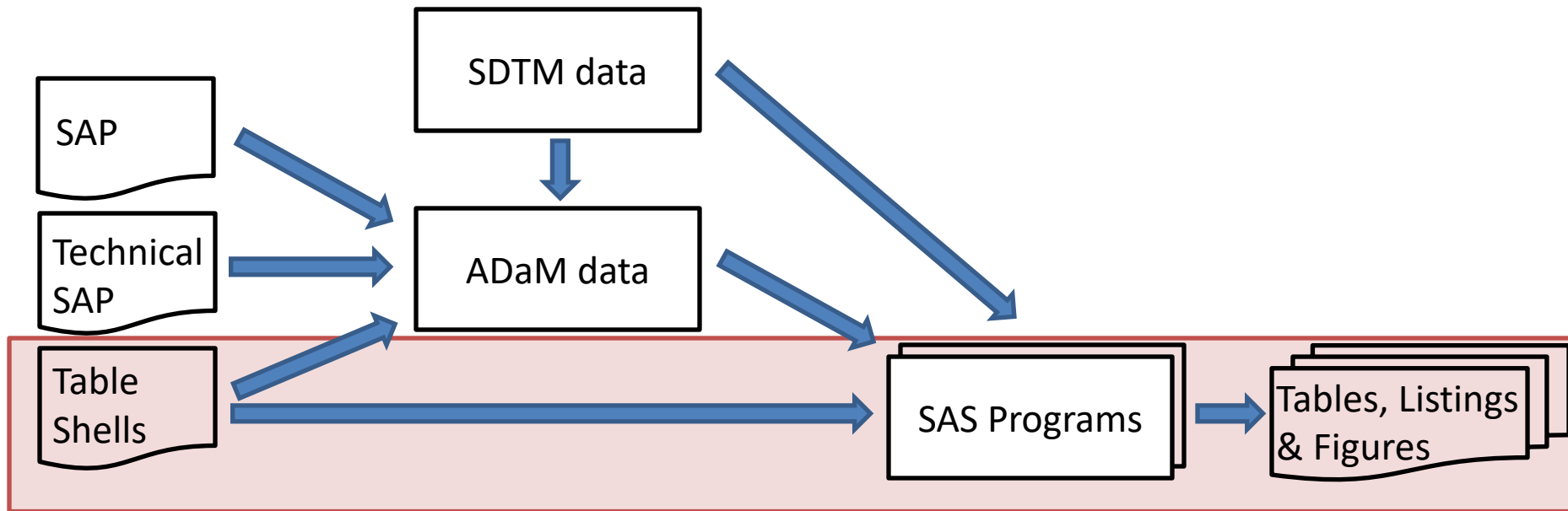
Overview

- Current process to produce tables, listings and figures
- Problems with the current process
- New process
- New process in practise
- Summary

Current process to produce Tables, Listings and Figures

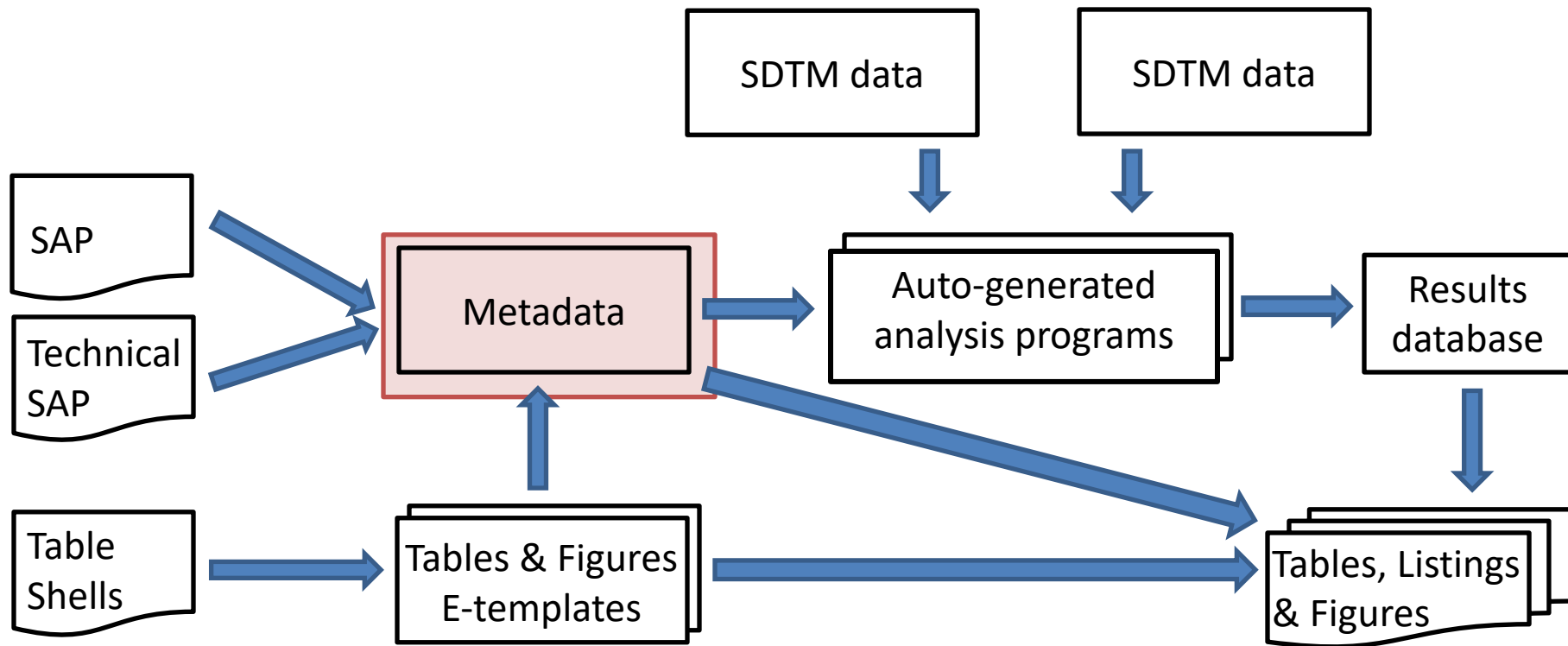


Problems with the current process



- Table shells change
- Additional requests from Medical Writing
- Time and resource intensive
- Repeated in every study

New process



New process in practise – analyse data

Tables/Figures required

- 3 TRIAL ANALYSIS
 - 3.1 Disposition
 - 3.1.1 - Analysis of Enrolled Patient
 - 3.1.2 - Analysis of Not Randomised Patient
 - 3.1.3 - Analysis of Randomised Patient
 - 3.1.4 - Analysis of Randomised and Not Treated by Treatment
 - 3.1.5 - Analysis of Not Discontinued by Treatment
 - 3.1.6 - Analysis of Discontinued by Treatment
 - 3.1.7 - Analysis of Terms of Discontinued by Treatment - TS
 - 3.2 Demography
 - 3.2.1 - Patient Treated by treatment - TS
 - 3.2.2 - Patient Treated by treatment - FAS
 - 3.2.3 - Analysis of Sex by treatment - TS
 - 3.2.4 - Analysis of Sex by treatment - FAS
 - 3.2.5 - Analysis of Race by treatment - TS
 - 3.2.6 - Analysis of Race by treatment - FAS
 - 3.2.7 - Analysis of Ethnicity by treatment - TS
 - 3.2.8 - Analysis of Ethnicity by treatment - FAS
 - 3.2.9 - Analysis of Age by treatment - TS
 - 3.2.10 - Analysis of Age by treatment - FAS
 - 3.2.11 - Analysis of Age (Categorical) by treatment - TS
 - 3.2.12 - Analysis of Age (Categorical) by treatment - FAS
 - 3.2.13 - Analysis of Baseline Weight by treatment - TS
 - 3.2.14 - Analysis of Baseline Weight by treatment - FAS

Metadata for a table

3.2.1 - Patient Treated by treatment - TS

Analysis Number :

3.2.1

Analysis Title :

Patient Treated by treatment - TS

Program Name :

anal_treated_pt_ts.sas

Program Location :

pgm/ctr/

Log Name :

anal_treated_pt_ts.log

Output Name :

anal_treated_pt_ts.lst

Output Location :

lst/

Macro Name :

T_MCOUNT

Primary
End points:

☐

Secondary
End points:

☐

parameter_1_name:

INDATA

parameter_1_value:

adam.adsl

parameter_2_name:

OUTDATA

parameter_2_value:

pt_trt_ts

parameter_3_name:

ANAL_VAR

parameter_3_value:

studyid

New process in practise – analyse data

Auto-generated program

```
*****  
***  
*** Output No.  
*** Title: 3.2.1 Patient Treated by treatment - TS  
***  
*****  
  
FILENAME O '!baseloc\lst\anal_treated_ts.lst '  
  
PROC PRINTTO PRINT=O NEW;  
RUN;  
  
%T_MCOUNT ( INDATA      = adam.ads1  
              , POPU       = TS  
              , ANAL_TITLE = Patient Treated by treatment - TS  
              , ANAL_NO    = 3.2.1  
              , MISSLINE   = 1  
              , TOTAL      = Y  
              , COLVARVAL  = trt  
              , COLVAR     = trtn  
              , PCTBY      = P  
              , PERCENT    = 2  
              , ANAL_VAR   = studyid  
              , OUTDATA    = pt_trt_ts  
              );  
  
PROC PRINTTO PRINT=PRINT;  
RUN;  
  
PROC PRINTTO LOG=LOG;  
RUN;
```

Result database

STAT_CODE	STAT_DECODE	RESULT	RESULT_DECODE
1	N	105.00	105
2	%	100.00	100.00
1	N	254.00	254
2	%	100.00	100.00
1	N	406.00	406
2	%	100.00	100.00
1	N	765.00	765
2	%	100.00	100.00

New process in practise – produce table

List of TLFs to produce

- 1 TRIAL STUDY_001
 - 1.1 Disposition of patients
 - Table 1.1.1 - Disposition of patients - TS
 - Table 1.1.2 - Primary reason for not randomising screened patients - TS
 - Table 1.1.3 - Number of screened, randomised and treated patients by region and country - TS
 - Figure 1.1.4 - Time to Discontinuation - Safety Population
 - 1.2 Demographic Information
 - Table 1.2.1 - Summary of demographic data - TS
 - Table 1.2.2 - Summary of Relevant medical history - TS
 - Listing 1.2.3 - Demographic data by country, centre and patients - TS
 - 1.3 Efficacy Analysis
 - Table 1.3.1 - Proportion of Subjects Achieving PASI90 Response During the 12-Week Double-Blind Treatment (FAS, Observed Case)

Select shell

Column Label (e.g Demographic Parameter)	Colvar1	Colvar2	Colvar3	...	
Select Analysis Item ▼					
Cat 1	XX.X	XX.X	XX.X	...	XX.X
Cat 2	XX.X	XX.X	XX.X	...	XX.X

New process in practise – produce table

Select analysis

Column Label (e.g Demographic Parameter)	DummyBlue	DummyGreen	DummyRed	Total
TS - studyid - Treated ☒ Show Only Title TSTD-SC-01	105 (100 . 0)	254 (100 . 0)	406 (100 . 0)	765 (100 . 0)
TS - age - Age [years] N MEAN MIN MAX	101 43 . 10 25 . 00 60 . 00	241 42 . 20 23 . 00 60 . 00	392 42 . 60 24 . 00 60 . 00	734 42 . 60 23 . 00 60 . 00

New process in practise – produce table

Table done

Output Preview

Table 1.2.1 Summary of demographic data - TS

	DummyBlue	DummyGreen	DummyRed	Total
Treated	105 (100 . 00)	254 (100 . 00)	406 (100 . 00)	765 (100 . 00)
Age [years]				
N	101	241	392	734
MEAN	43 . 10	42 . 20	42 . 60	42 . 60
MIN	25 . 00	23 . 00	24 . 00	23 . 00
MAX	60 . 00	60 . 00	60 . 00	60 . 00

Percentages are calculated using total number of treated patients per treatment group as the denominator.

Summary

- There are only a small number of analyses
 - Only a small number of macros to prepare
 - Limited resource required for new analyses
 - Analysis required is known from the start
- Metadata driving auto-generation of all analyses
- Limited e-templates required
- A core group can generate macros and e-templates

Summary

- TLFs can be prepared by Statistician or Medical Writer
 - Results used are all based on validated results
- As its all metadata driven its easy to compare different studies
 - See which analyses were performed
- Programmers have more time
 - To spend more time on data
 - To work on new analyses

Questions or Comments?



Shafi Chowdhury

shafi@shaficonsultancy.com

www.shaficonsultancy.com

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Innovative Solutions using Emerging Technology**

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