

TEST DATA SIMULATOR

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Agenda

- ❖ **Challenges**
- ❖ **What is TDS?**
- ❖ **How it Works?**
- ❖ **Scenarios**
- ❖ **TDS Homepage**
- ❖ **TDS Parameters**
- ❖ **Sample Outputs**
- ❖ **Benefits**
- ❖ **Defensive Coding Technique - Sample**



Challenges

Name for
Subject ID
is never the
same

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Is Sex Male or
Female,
M or F, 1 or 2?

Study #2 – dmng.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Name for
demography
dataset is
variable???

Study #4 – dmngph.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

Study #3 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Gender or
Sex, what will
today's
submission
use?

Adapted from slide courtesy of Armando Oliva, M.D. and Amy Malla, FDA



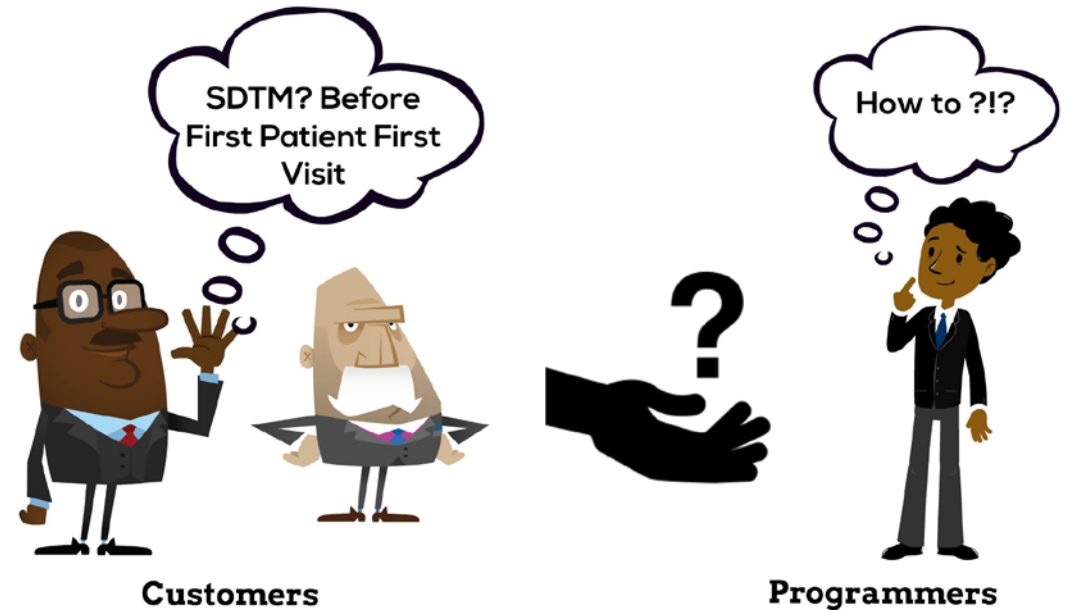
What is TDS?

- **2016**

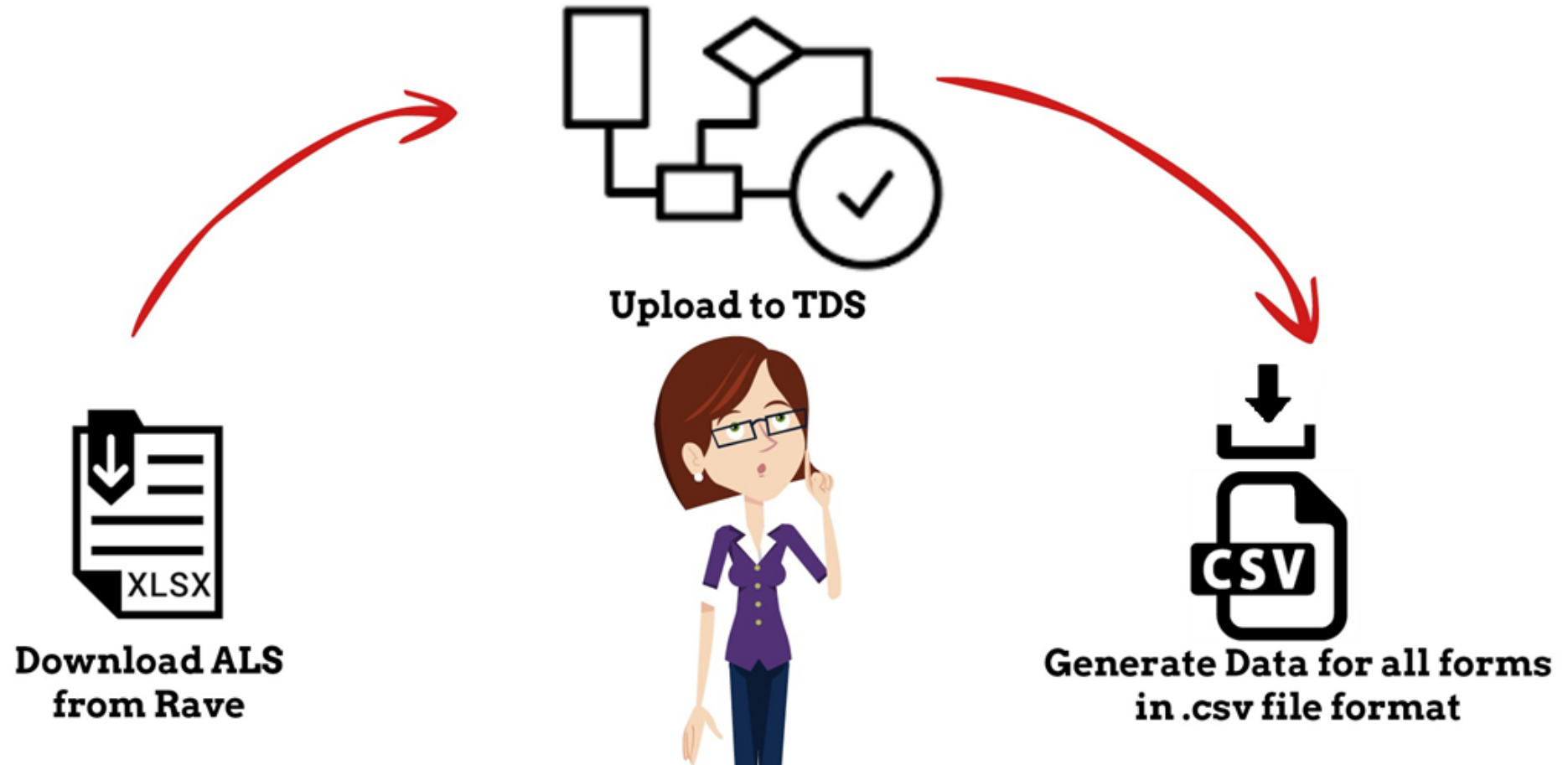
- Client request for a SDTM and related Deliverables @ “First Patient First Visit”

- **Thought process to address the end goal:**

- Through sufficient Data
- Additional Bonus –
 - Reduce Programming Time of SDTM
 - Defensive Programming
 - Downstream activities -



How it works?



Scenarios!!

Screen Failures

Subject screened
but not randomized

Subject randomized,
but did not receive
study treatment

Subject randomized,
received study treatment,
but discontinued

Subjects being
randomized,
treated, completed

Subject died



Blinded studies,
have define dummy
information for DM,
EX, SE & DS



TDS Homepage

Browser address bar: <http://ciifdev2013:34826/sites/TDG/SitePages/Home.aspx> Test Data Simulator - Home

File Edit View Favorites Tools Help

Home - Risk Portal - India... FranklinCovey LinkedIn Google WFH-Portal IPL - Home SuccessFactors Log in Test Data Simulator - Home

SharePoint Bhaskar Subramanian

BROWSE PAGE SHARE FOLLOW

 CHILTERN Test Data Simulator

Search this site

TDS Home

Upload Rave Draft Browse... Upload



TDS Parameters

Note :-All fields are Mandatory.

Number of Subjects	5	
Study Start Date	01/01/2017	
Study End Date	12/31/2017	
	FormOID	FieldOID
Informed Consent Date	CONSENT	DSSTDATC
Date of Birth	DEMOG	BRTHDAT
Subject ID	PRIMARY	SUBJID
File Type	CSV	
Age	Min 6	Max 60

Note:-Select a Date field, If not select Birth Year





Sample Outputs

Name	Date modified	Type	Size
 AE.csv	3/30/2017 11:47 AM	Microsoft Excel C...	21 KB
 CM.csv	3/30/2017 11:47 AM	Microsoft Excel C...	18 KB
 DM.csv	3/30/2017 11:47 AM	Microsoft Excel C...	11 KB
 DS.csv	3/30/2017 11:47 AM	Microsoft Excel C...	10 KB
 DS_IC.csv	3/30/2017 11:47 AM	Microsoft Excel C...	10 KB
 DS_ICAM.csv	3/30/2017 11:47 AM	Microsoft Excel C...	13 KB
 DS_R.csv	3/30/2017 11:47 AM	Microsoft Excel C...	10 KB
 EX.csv	3/30/2017 11:47 AM	Microsoft Excel C...	141 KB
 FA.csv	3/30/2017 11:47 AM	Microsoft Excel C...	10 KB
 GM.csv	3/30/2017 11:47 AM	Microsoft Excel C...	14 KB
 IE.csv	3/30/2017 11:47 AM	Microsoft Excel C...	12 KB
 LB_1.csv	3/30/2017 11:47 AM	Microsoft Excel C...	33 KB
 LB_2.csv	3/30/2017 11:47 AM	Microsoft Excel C...	34 KB
 LB_3.csv	3/30/2017 11:47 AM	Microsoft Excel C...	19 KB
 LB_4.csv	3/30/2017 11:47 AM	Microsoft Excel C...	14 KB
 LB_P.csv	3/30/2017 11:47 AM	Microsoft Excel C...	14 KB
 LB_PK1.csv	3/30/2017 11:47 AM	Microsoft Excel C...	155 KB
 LB_PK2.csv	3/30/2017 11:47 AM	Microsoft Excel C...	181 KB
 LB_PK3.csv	3/30/2017 11:47 AM	Microsoft Excel C...	78 KB
 LB_PK4.csv	3/30/2017 11:47 AM	Microsoft Excel C...	15 KB
 LB_PK5.csv	3/30/2017 11:47 AM	Microsoft Excel C...	15 KB
 LB_PK6.csv	3/30/2017 11:47 AM	Microsoft Excel C...	15 KB
 MH.csv	3/30/2017 11:47 AM	Microsoft Excel C...	14 KB



Sample Dataset - DM

DM.csv - Excel

FILE HOME INSERT CoSign PAGE LAYOUT FORMULAS DATA REVIEW VIEW DEVELOPER ADD-INS

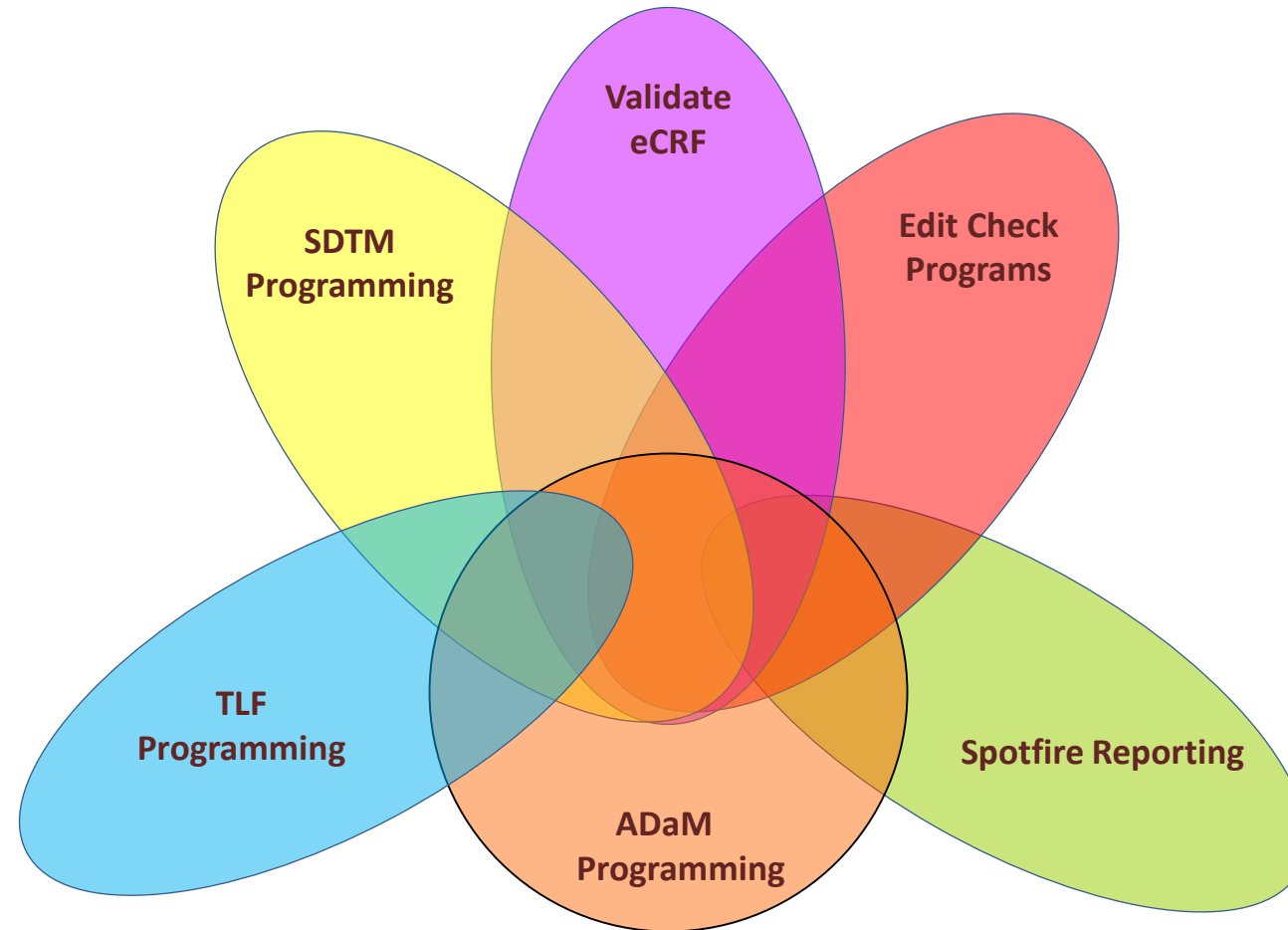
Senthilanand Sithan

AD21																					
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	
1	project	studyid	Subject	Site	SiteNumb	SiteGroup	InstanceN	InstanceR	Folder	FolderNar	DataPageI	DataPageI	PageRepe	RecordPo	MaxUpdat	SaveTS	BRTHDY	BRTHDY_S	BRTHMO	BRTHMO_BR	
2	AA-HPP-208	1839	1000	SITE1	2799	World	Screening	0	0	Screening	10214	Demograp	0	0	29Aug201	29Aug201	1	1	Jan	1	
3	AA-HPP-208	1839	1001	SITE1	2799	World	Screening	0	0	Screening	10230	Demograp	0	0	29Aug201	29Aug201	2	2	Feb	2	
4	AA-HPP-208	1839	1002	SITE1	2799	World	Screening	0	0	Screening	10944	Demograp	0	0	29Aug201	29Aug201	3	3	Mar	3	
5	AA-HPP-208	1839	1003	SITE1	2799	World	Screening	0	0	Screening	10063	Demograp	0	0	29Aug201	29Aug201	4	4	Apr	4	
6	AA-HPP-208	1839	1004	SITE1	2799	World	Screening	0	0	Screening	10244	Demograp	0	0	29Aug201	29Aug201	5	5	May	5	
7	AA-HPP-208	1839	1005	SITE2	9972	World	Screening	0	0	Screening	10005	Demograp	0	0	29Aug201	29Aug201	6	6	Jun	6	
8	AA-HPP-208	1839	1006	SITE2	9972	World	Screening	0	0	Screening	10096	Demograp	0	0	29Aug201	29Aug201	7	7	Jul	7	
9	AA-HPP-208	1839	1007	SITE2	9972	World	Screening	0	0	Screening	10273	Demograp	0	0	29Aug201	29Aug201	8	8	Aug	8	
10	AA-HPP-208	1839	1008	SITE2	9972	World	Screening	0	0	Screening	10844	Demograp	0	0	29Aug201	29Aug201	9	9	Sep	9	
11	AA-HPP-208	1839	1009	SITE2	9972	World	Screening	0	0	Screening	10421	Demograp	0	0	29Aug201	29Aug201	10	10	Oct	10	
	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ	AR	AS	AT	AU			
1	AGE	AGE_RAW	AGEU	AGEU_STD	SEX	SEX_STD	RAIAN	RAIAN_RAW	RASIAN	RASIAN_RAW	RBLACK	RBLACK_RAW	RWHITE	RWHITE_RAW	ROTHER	ROTHER_RAW	JAPANDSC	JAPANDSC_STD			
2	47	47	Days	DAYS	Male	M	0	0	0	0	0	0	0	0	0	0	0	Yes	Y		
3	36	36	Hours	HOURS	Female	F	1	1	1	1	1	1	1	1	1	1	1	No	N		
4	29	29	Months	MONTHS	Undifferentiate	UN	0	0	0	0	0	0	0	0	0	0	0	Yes	Y		
5	29	29	Weeks	WEEKS	Unknown	U	1	1	1	1	1	1	1	1	1	1	1	No	N		
6	13	13	Years	YEARS	Male	M	0	0	0	0	0	0	0	0	0	0	0	Yes	Y		
7	43	43	Days	DAYS	Female	F	1	1	1	1	1	1	1	1	1	1	1	No	N		
8	10	10	Hours	HOURS	Undifferentiate	UN	0	0	0	0	0	0	0	0	0	0	0	Yes	Y		
9	38	38	Months	MONTHS	Unknown	U	1	1	1	1	1	1	1	1	1	1	1	No	N		
10	29	29	Weeks	WEEKS	Male	M	0	0	0	0	0	0	0	0	0	0	0	Yes	Y		
11	28	28	Years	YEARS	Female	F	1	1	1	1	1	1	1	1	1	1	1	No	N		





Generate Once !!!





Benefits



**SDTM Ready
Before FPFV**



**Enables
Standard Macro**



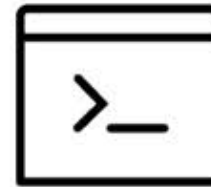
Reduce TAT/Development Time



**Increase Data
Quality**



Fast DB Lock



**Facilitates
Programming**



**Helps in Defensive
Programming**





Sample - Defensive Programming

	 Studyid	 Subjectid	 Birthdt	 Gender
1	A12345	IN001	12JAN2008	M
2	A12345	IN002	2009	F
3	A12345	IN003		f
4	A12345	IN004	17Sep1977	
5	A12345	IN005		n
6	A12345	IN006	Aug2004	F
7	A12345	IN007	13Nov1978	m

```
data dm;
  set raw.demog;
  if strip(gender) eq ' ' then put 'DM issue : Gender is missing for Subject : ' subjectid;
  else if upcase(strip(gender))='M' then sex='M';
  else if upcase(strip(gender))='F' then sex='F';
  else put 'DM issue : Please note for subject : ' subjectid ' then Gender is : ' gender;
run;
```

DM issue : Gender is missing for Subject : IN004

DM issue : Please note for subject : IN005 the Gender is : n

NOTE: There were 7 observations read from the data set WORK.DM.

NOTE: The data set WORK.DM1 has 7 observations and 5 variables.

NOTE: DATA statement used (Total process time):

real time	0.00 seconds
cpu time	0.00 seconds

Questions?





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