



Keeping your ADaM metadata in sync

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I will *drag* you through...

- Initial approach of creating ADaM



Learnings!

- Use learnings

Reflect & develop

- Disseminate learnings and ideas



Initial approach

- What are ADaM metadata?
- Automatic generation of ADaM datasets:
 - Driven by metadata.
 - Created SAS programs for ADaM datasets.

	A	B	C	D	E	F
	table	enabled	join_ord	join_type	predecessor	table_join_key
1						
21	ADAE	Y	1		sdtm.ae	
22	ADAE	Y	2	left join	adam.adsl	usubjid
23	ADAE	Y	3	left join	work.AE_TRTPEREVENT	usubjid, aeseq, aerefid
24	ADAE	Y	4	left join	work.suppa	usubjid, aespid
25	ADAE	N	5	left join	sdtm.dm	usubjid
26	ADAE	Y	6	left join	work.aedianum_list	usubjid, aerefid
27	ADAE	N	7	left join	sdtm.ta	ae.studyid, ae.epoch, adsl.arm

```

127      , adsl.BMIG1BL      as BMIG1BL      length=20 label='Body Mass Index Group
128      , adsl.BMIG1BLN    as BMIG1BLN    length=8 label='Body Mass Index Group
129      , adsl.HBA1CBL      as HBA1CBL      length=8      format=5.2 label='HbA1c at Ba
130      , adsl.HBA1CBLU    as HBA1CBLU    length=40 label='HbA1c at Baseline Un
131      , adsl.DIABDUR      as DIABDUR      length=8      format=5.1 label='Diabetes Du
132      , adsl.DIABDURU    as DIABDURU    length=40 label='Diabetes Duration Un
133      , adsl.STRAT01      as STRAT01      length=40 label='Stratification number
134      , "AE"             as SRCDOM      length=10 label='Source Data '
135      , "AESPID"          as SRCVAR      length=10 label='Source Variable '
136      , input(AESPID,best.) as SRCVAL      length=8 label='Source Sequence N
137      , ""               as ADELFL      length=1 label='Record Deletion Flag '
138      , ""               as ADELREAS    length=200 label='Reason for Deletion of the Rec
139      , "Y"              as ANL01FL     length=1 label='Analysis Record Flag 01 '
140      , ""               as ANL01REA    length=200 label='Analysis Record Flag 01 Reason
141      , ""               as NNMQ02FL    length=200 label='NN Medical Queries - Allergy '
142      , ""               as NNMQ08FL    length=200 label='NN Medical Queries - Injection
143      , ""               as NNMQ10FL    length=200 label='NN Medical Queries - Medicatio
144      , ""               as NNMQ99FL    length=200 label='NN Medical Queries - Lipodystro
145
146 from      sdtm.ae
147 left join  adam.adsl
148 on        ae.usubjid=adsl.usubjid
149 left join  work.AE_TRTPEREVENT
150 on        ae.usubjid=AE_TRTPEREVENT.usubjid
151 and       ae.aeseq=AE_TRTPEREVENT.aeseq
152 and       ae.aerefid=AE_TRTPEREVENT.aerefid
153 left join  work.suppa
154 on        ae.usubjid=suppa.usubjid
155 and       ae.aespid=suppa.idvarval

```

Learnings

- Approach is not striving for simplicity.
- *Traditional programmers are frustrated.*

Our ADaM model was too immature for full-blown automation.

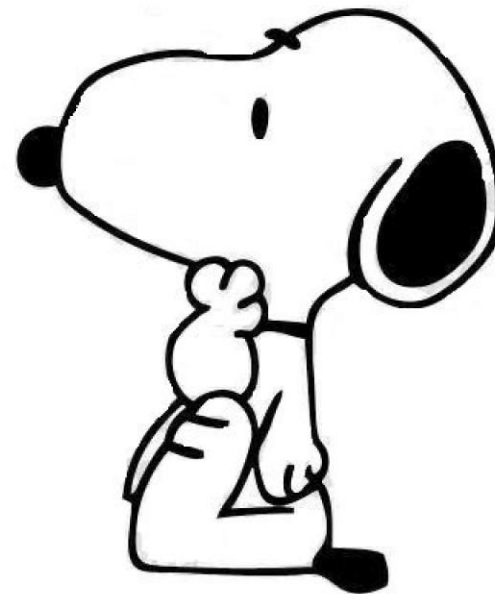


Time for reflection

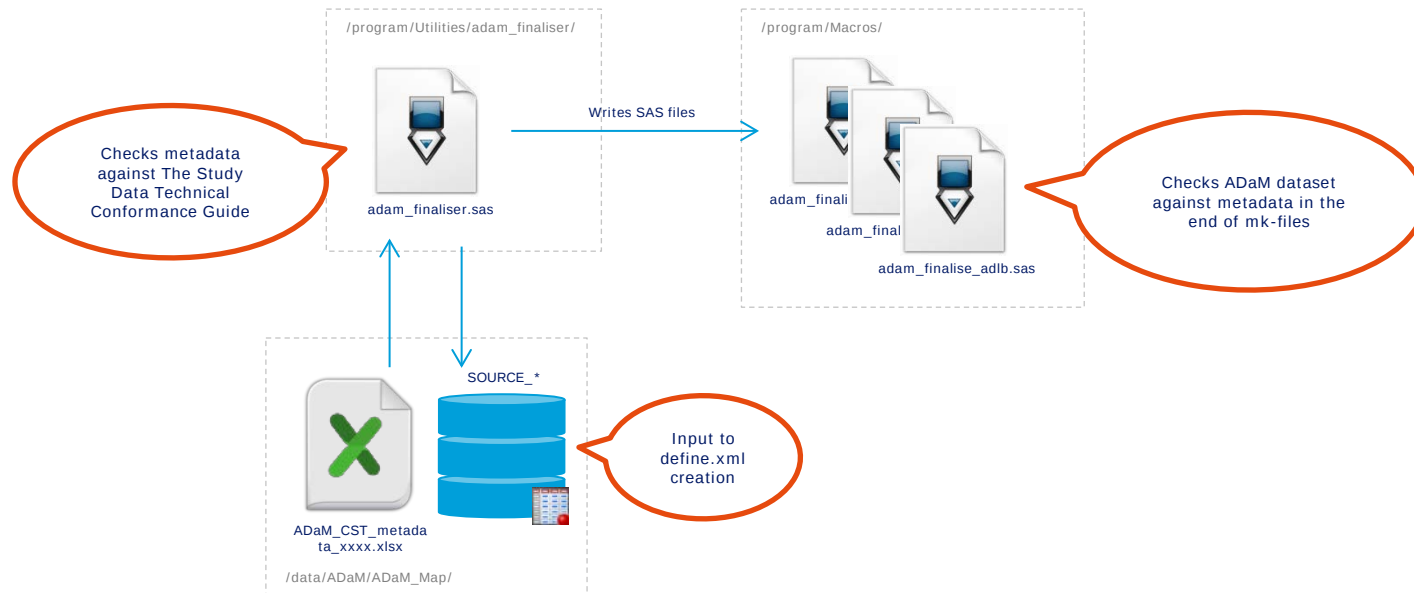
- Metadata were synchronised with ADaM datasets at all times;



- Generation of define.xml.
 - Ease movement of employees.
 - Management tool.
- Focus on typing in ADaM metadata, i.e. minimal back-end work.
- Going towards submission-ready metadata.
- ADaM Metadata are maintained only one place.



... and now to the development (1)



... and now to the development (2)

	A	B	C	D	E	F	G	H
1	include	build	id	table	label	class	structure	keys
4	Y	N	0030	ADSL	Subject Level Analysis	ADSL	One record per subject	USUBJID
5	Y	N	0040	ADLB	Lab Analysis	BDS	One record per subject per parameter per analysis visit	USUBJID TOPIC_CD PARAMCD
6	Y	N	0050	ADXL	Lab Analysis (CONV)	BDS	One record per subject per parameter per analysis visit	USUBJID TOPIC_CD PARAMCD
7	Y	N	0060	ADVS	Vital Signs Analysis	BDS	One record per subject per parameter per analysis	USUBJID PARAMCD AVISIT AS
8	Y	N	0070	ADXV	Vital Signs Analysis (CONV)	BDS	One record per subject per parameter per analysis	USUBJID PARAMCD AVISIT AS
9	Y	N	0080	ADAE	Adverse Events Analysis	OCCDS	One record per subject per adverse event	USUBJID AETERM ASEQ
10	Y	N	0090	ADHYPO	Hypoglycaemic Episode Analysis	OCCDS	One record per subject per Hypoglycemic Episode	USUBJID ASEQ

adam_finalise_adae.sas	18-05-2016 13:01	SAS File	11 KB
adam_finalise_adce.sas	23-05-2016 10:07	SAS File	9 KB
adam_finalise_adcm.sas	23-05-2016 10:07	SAS File	8 KB
adam_finalise_adec.sas	23-05-2016 10:16	SAS File	7 KB
adam_finalise_adeg.sas	23-05-2016 10:07	SAS File	7 KB
adam_finalise_adohd.sas	23-05-2016 10:07	SAS File	7 KB

```

      left join adam.adc1cey (where=(aerefid eq AE )) as b
        on a.USUBJID=b.USUBJID
       and a.ASTDT ge b.astdt and a.ASTDT le b.aendt
    order by a.USUBJID,
             a.AREFID;

quit;

```

```

*****
* Finalise dataset by checking against CST metadata sheet
*****
%adam_finalise_adae(dsin=pre_adae4);
|

```

... and now to the development (3)

- What happens with the input dataset:
 - Dataset is sorted by “keys”.
 - Exceptions are handled with easy comprehensible error messages;
 - Metadata variable is missing in dataset.
 - Type between metadata variable and dataset variable differs.
 - Dataset is reshaped with length, label, format attributes from metadata.
- Additional post processing: Business rules foot prints are collected.

 AVISITN	 ADT		BRDOC	 PARCAT1	 LBMEDIUM	 LBSEQ	
800	20APR2015		<ATM ADTMIPARTIAL TIME RULE 1><ANL01FL ANL01REAIRESCHEDULED RULE 2>	HORMONES	SERUM	2315	
800	04MAY2015		<ATM ADTMIPARTIAL TIME RULE 1>	HORMONES	SERUM	2316	

Take home messages

- Ensure that ADaM metadata are in sync with ADaM datasets!
- Force programmers to fill in metadata during trial!
- Automate the process.
- Catch likely errors and inform user to create usability.



Take home messages

~~Strive for~~
SIMPLICITY

