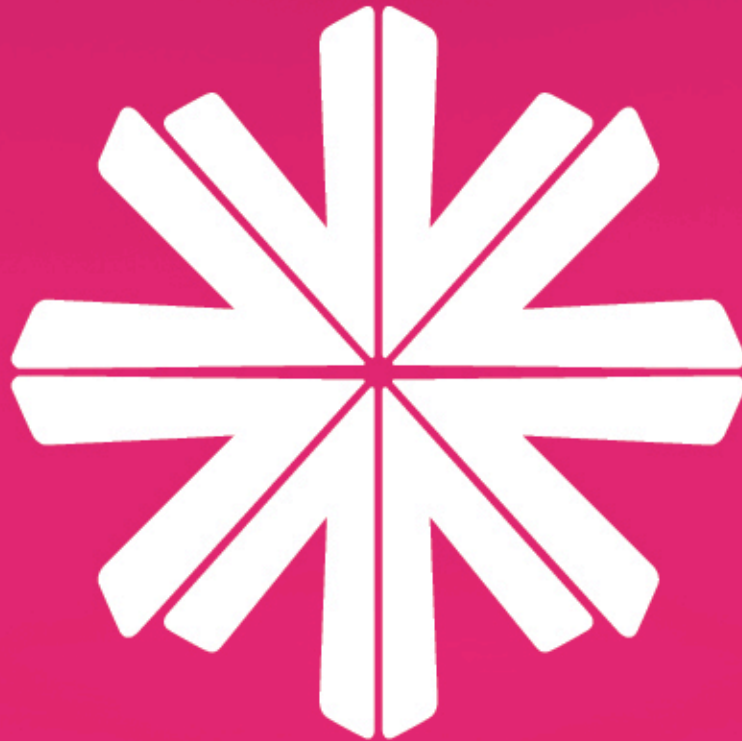


THE FUTURE OF
CLINICAL DEVELOPMENT



PRAHEALTHSCIENCES



Annual Conference

Barcelona 2016

Fast Track to Approval: Speed and Efficiency

9th-12th October Princessa Sofia Gran Hotel, Barcelona

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Fast Track to Approval: Speed and Efficiency



On the Fast Lane to Successful Submission

A Lead Programmer's Guide to Efficient, High Quality Submission Programming Deliverables

Tuesday, 11 October 2016

Hannes Engberg Raeder, Jim Witt

Michael Reich, Doris Kolb

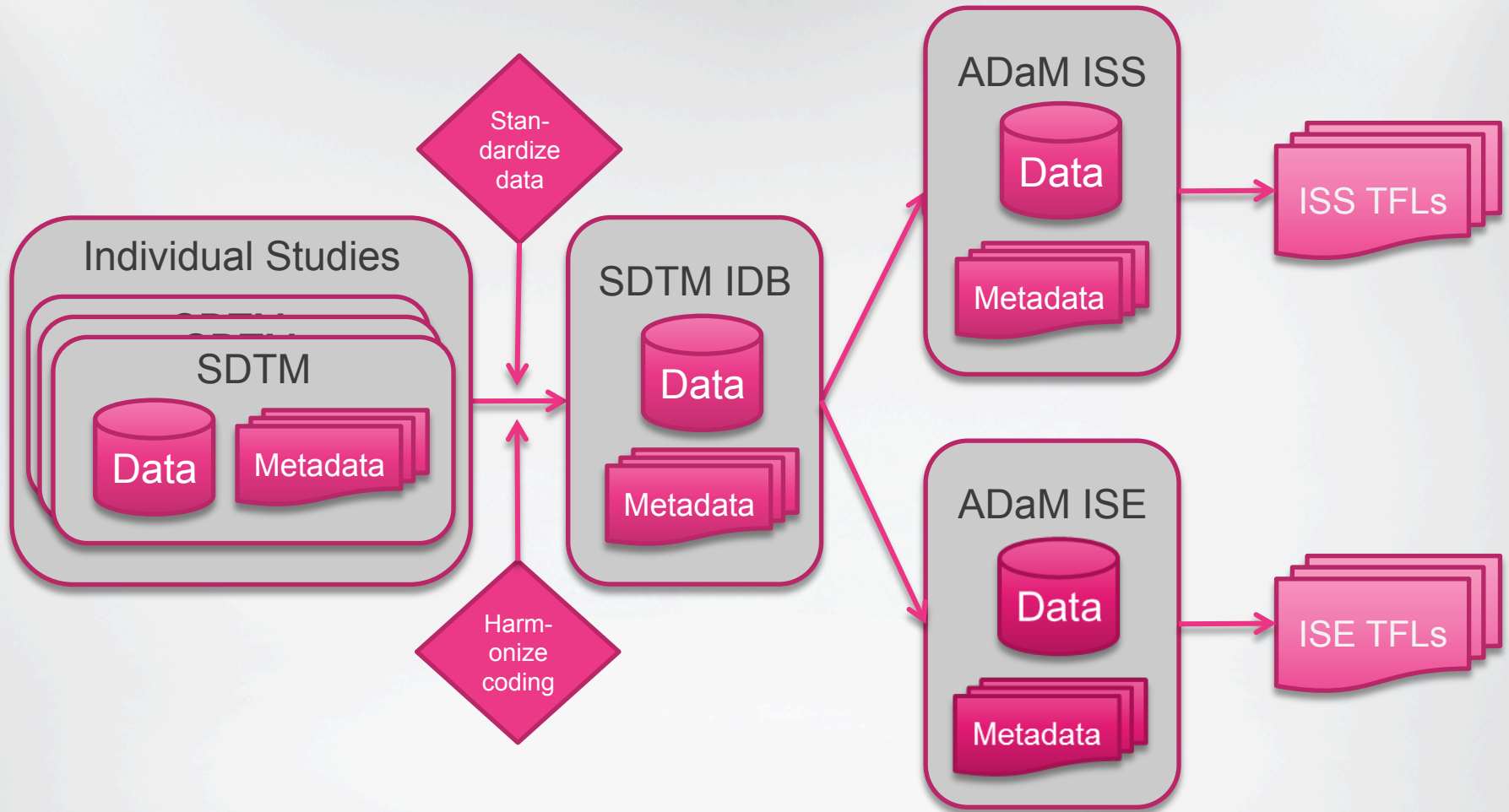


Overview

- Known knowns, known unknowns, unknown knowns, unknown unknowns
- Automation and efficiency
- Team management and communication



Overview





Receive material





Take inventory





What you think you're getting...

	Tabulation data?	aCRF?	Analysis data?	Analysis specs?	SAP?	CSR?	SAS programs?	...
Study 1	✓	✓	✓	✓	✓	✓	✓	✓
Study 2	✓	✓	✓	✓	✓	✓	✓	✓
Study 3	✓	✓	✓	✓	✓	✓	✓	✓
Study 4	✓	✓	✓	✓	✓	✓	✓	✓
Study 5	✓	✓	✓	✓	✓	✓	✓	✓
Study 6	✓	✓	✓	✓	✓	✓	✓	✓
Study 7	✓	✓	✓	✓	✓	✓	✓	✓
Study 8	✓	✓	✓	✓	✓	✓	✓	✓
Study 9	✓	✓	✓	✓	✓	✓	✓	✓
Study 10	✓	✓	✓	✓	✓	✓	✓	✓
Study 11	✓	✓	✓	✓	✓	✓	✓	✓
Study 12	✓	✓	✓	✓	✓	✓	✓	✓
Study 13	✓	✓	✓	✓	✓	✓	✓	✓
Study...	✓	✓	✓	✓	✓	✓	✓	✓



What you get

	Tabulation data?	aCRF?	Analysis data?	Analysis specs?	SAP?	CSR?	SAS programs?	...
Study 1			✓	✓				
Study 2			✓					
Study 3	✓		✓					
Study 4	✓							
Study 5	✓							
Study 6	✓		✓					
Study 7			✓					
Study 8								
Study 9		✓						
Study 10		✓						
Study 11		✓						
Study 12	✓				✓			
Study 13	✓		✓		✓			
Study...	✓	✓	✓	✓	✓	✓		



Find the gaps and fill them in

	Tabulation data?	aCRF?	Analysis data?	Analysis specs?	SAP?	CSR?	SAS programs?	...
Study 1		✓	✓	✓		✓		
Study 2			✓			✓		
Study 3	✓		✓			✓		✓
Study 4	✓	✓						
Study 5	✓	✓						
Study 6	✓		✓	✓	✓			
Study 7			✓		✓			
Study 8	✓				✓		✓	
Study 9	✓	✓					✓	
Study 10		✓						
Study 11		✓						
Study 12	✓				✓			✓
Study 13	✓		✓		✓			
Study...	✓	✓	✓	✓	✓	✓		



Some gaps may remain

	Tabulation data?	aCRF?	Analysis data?	Analysis specs?	SAP?	CSR?	SAS programs?	...
Study 1	✓	✓	✓	✓	✓	✓	✗	✓
Study 2	✓	✓	✓	✗	✓	✓	✗	✓
Study 3	✓	✗	✓	✗	✓	✓	✗	✓
Study 4	✓	✓	✓	✗	✗	✗	✗	✓
Study 5	✓	✓	✗	✗	✗	✓	✗	✓
Study 6	✓	✗	✓	✓	✓	✓	✗	✓
Study 7	✓	✗	✓	✗	✓	✓	✗	✓
Study 8	✓	✓	✓	✗	✓	✓	✓	✗
Study 9	✓	✓	✓	✗	✗	✗	✓	✗
Study 10	✓	✓	✓	✗	✗	✗	✗	✓
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Study 13	✓	✗	✓	✓	✓	✓	✓	✓
Study...	✓	✓	✓	✓	✓	✓	✓	✓



Known knowns, known unknowns, unknown knowns, unknown unknowns





Efficiency?

	Include in IDB?	Study status?	Tabulation data format	Data submission-compliant?	All metadata available?	Analysis data format	MedDRA version	WHODRUG version
Study 1	YES	LOCKED	LEGACY	NO	NO	LEGACY	...	...
Study 2	YES	LOCKED	LEGACY	YES	NO	LEGACY	...	...
Study 3	YES	PLANNED	SDTM	NO	NO	ADAM	...	...
Study 4	YES	PLANNED	SDTM	NO	NO	ADAM	...	...
Study 5	YES	ONGOING	SDTM	YES	YES	ADAM	...	...
Study 6	YES	LOCKED	LEGACY	NO	NO	LEGACY	...	...
Study 7	YES	LOCKED	LEGACY	YES	YES	LEGACY	...	...
Study 8	YES	LOCKED	SDTM	YES	YES	ADAM	...	...
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Study 13	YES	ONGOING	SDTM	YES	YES	ADAM	...	...
Study...	YES	ONGOING	SDTM	YES	YES	ADAM	...	...



Process





Process

```
data __IN<XX>;
  set <BASEDATA>;
  * Derive USUBJID;
  length STUDYID $16 DOMAIN $2 USUBJID $27;
  STUDYID = "<STUDYID>";
  DOMAIN = "<XX>";
  * TODO: Replace placeholder variables;
  USUBJID = kcompress("<STUDYID>" || "-" || kstrip(put(<SITEID>, z5.)) || "-" || kstrip(put(<SUBJID>, z7.)));
run;

* Create work dataset template and set together with base dataset;
* TODO: Add variables to setvar that are named the same as SDTM variables of the current domain;
*       but can just be set onto the template without issues (i.e. will not be cut-off and we;
*       want to retain their values [e.g. VISIT/VISITNUM, or similar]);
%g_DPAC_SDTM_createDSTemplate(domain=<XX>,
                              inds=__IN<XX>, outds=__<XX>1,
                              setvar=STUDYID#DOMAIN#USUBJID);

**** Pre-Processing;
* TODO: If this program is for EX, DS, or DM, the "Merging on RFSTDTC" steps need to ;
*       be removed. Instead you will need to derive this variable on your own;
*       the same way it is done for the DM domain;
* Merging RFSTDTC on domain;
proc sort data=__<XX>1; by USUBJID; run;
proc sort data=DM; by USUBJID; run;
data __<XX>2;
  merge __<XX>1 (in=a) DM (in=b keep=USUBJID RFSTDTC);
  by USUBJID;
  if a;
run;
```



Process

EXCAT	Category for Treatment	Assigned	Always 'STUDY DRUG'.
EXDOSE	Dose per Administration	CRF Page 34	use input(xe_g1,best.) if last in by group (subject, xe_cat2).
EXDOSU	Dose Units	CRF Page 34	Always 'mg'.



Process

Issue Summary					
Source	OpenCDISC ID	Publisher ID	Message	Severity	Found
AE					
	SD0080	FDAC208	AE start date is after the latest Disposition date	Error	4
	SD1097	FDAC022	No Treatment Emergent info for Adverse Event	Warning	155
CE					
	SD0013	FDAC107	CESTDTC is after CEENDTC	Error	5
	CT2002	FDAC341	CELOC value not found in 'Anatomical Location' extensible codelist	Warning	38
	CT2002	FDAC341	EPOCH value not found in 'Epoch' extensible codelist	Warning	57
	SD0021	FDAC117	Missing End Time-Point value	Warning	1
	SD1040	FDAC162	Redundancy in paired variables values	Warning	49
	SD1076	FDAC031	Model permissible variable added into standard domain	Warning	5
	SD1201	FDAC213	Duplicate USUBJID/--DECOD/--STDTC record	Warning	1
	SD0063A	FDAC033	SDTM/dataset variable label mismatch	Notice	2



Automation





Automation

Variable	Label	Type	Length / Display Format	Controlled Terms or Format	Source/Derivation/Comment
PARAM	Parameter	text	70	ADEXP Parameter	Assigned: Character decode of PARAMCD.
PARAMCD	Parameter Code	text	8	ADEXP Parameter Code	Assigned: See Value Level Metadata section.
PARAMN	Parameter (N)	integer	8	ADEXP Parameter (N)	Assigned: Numeric code of PARAM.
AVISIT	Analysis Visit	text	20	["Complete phase", "Initiation phase", "Maintenance phase"] < Analysis Visit >	Assigned: Character decode of AVISITN.



Automation



Variable	Where	Type	Length / Display Format
XNORRES	XNTESTCD = "STAGE" (Narcotrend Stage)	text	2
XNORRES	XNTESTCD = "THETREL" (Relative Theta Activity)	float	8.2
XNORRES	XNTESTCD = "TOTPWR" (Total Power)	float	8.2



Automation



Dataset	Description	Class	Structure	Keys
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	STUDYID, ARMCD, TAETORD
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	STUDYID, ETC
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	STUDYID, IECAT, IETESTCD
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	TSPARMCD, TSSEQ
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	STUDYID, ARMCD, VISITNUM
DM	Demographics	SPECIAL PURPOSE	One record per subject	STUDYID, USUBJID
CO	Comments	SPECIAL PURPOSE	One record per comment, per subject	STUDYID, USUBJID, RDOMAIN, IDVAR, IDVARVAL, COREF



Where is your team headed?





All pulling in the same direction?





Delegation and development





• Questions?