

Organize and report your clinical data today!

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Organize and report your clinical data today!

- Here is the idea, in 3 bullets:

- Use existing business assets
- Define metadata structures for “data” and “reporting”
- Plan, implement in steps, and track progress



1 LIST OF STUDY DATA

2 SCHEDULE OF SNAPSHOTS

3 LIST OF STANDARD REPORTS

4 LIST OF REPORTING REQUESTS

- Types

- Clinical study databases (studies, multiple study pools)
- Other data (pharmacovigilance database, clinical trial management system)
- Standard formats (SDTM, ADaM)

- Retrieval

- Find data quickly when requested → rely on **◆1 List of Study Data** (not on your memory!)
- Do not fear to report on “ongoing” or “less-than-perfect” data

- Plan to automate the aggregation of data

- Support a data browsing service

- Realize that although tools can carry the load, a sound clinical data accrual process has to be designed, implemented, and maintained first

- A robust data lifecycle must be put in place to ensure smooth operations

◆1 List of Study Data*

Product	Study	Status	Study SDTM Path	Pool SDTM Path
<name1>	<study1>	FINAL_CSR	...\<name1>\<study1>\sdm	...\<name1>\pool\fin_sdm
<name1>	<study2>	FINAL_CSR	...\<name1>\<study2>\sdm	...\<name1>\pool\fin_sdm
<name1>	<study3>	FINAL_DATA	...\<name1>\<study3>\sdm	...\<name1>\pool\long_sdm
<name1>	<study4>	ONGOING	...\<name1>\<study4>\sdm	...\<name1>\pool\long_sdm
<name2>	<study11>	FINAL_DATA	...\<name2>\<study11>\sdm	...\<name2>\pool\long_sdm
<name2>	<study12>	ONGOING	...\<name2>\<study12>\sdm	...\<name2>\pool\long_sdm
<name2>	<study13>	ONGOING	...\<name2>\<study13>\sdm	...\<name2>\pool\long_sdm
<name2>	<study14>	NO_DATA		

* SDTM dataset paths are shown but also applies for ADaM datasets.

Automate the aggregation of data

```
%macro Win_LIBNAMES;
%* Import LIBNAMES worksheet to Win_LIBNAMES dataset
*****;
proc import datafile="C:\sddshared\SASWorkspaces\Files\Metadata\Win_LIBNAMES.csv"
DBMS=CSV OUT=Win_LIBNAMES;
run;

%* Create macro variable &NObs (number of observations)
%* Create macro variable &&study&i (libref for observation&i)
%* Create macro variable &&path&i (path for observation&i)
*****;
proc sql noprint;
  select count(*) into :NObs from Win_LIBNAMES;
  select study into :study1-:study%left(&NObs) from Win_LIBNAMES;
  select path into :path1-:path%left(&NObs) from Win_LIBNAMES;
quit;

%* Write LIBNAME statement for each observation
*****;
%do i=1 %to &NObs;
  LIBNAME &&study&i "&&path&i";
%end;
run;
%mend Win_LIBNAMES;

%Win_LIBNAMES
```

Sample SAS® macro code to read in
1 LIST OF STUDY DATA as a LIBNAME ...

Automate the aggregation of data (2)

```
MPRINT:  proc import datafile="C:\sddshared\SASWorkspaces\Files\Metadata\Win_LIBNAMES.csv" DBMS=CSV
OUT=Win_LIBNAMES;
MPRINT:  ADLM;
MPRINT:  run;
```

NOTE: 132 records were read from the infile 'C:\sddshared\SASWorkspaces\Files\Metadata\Win_LIBNAMES.csv'.
NOTE: The data set WORK.WIN_LIBNAMES has 132 observations and 5 variables.

```
MPRINT:  proc sql noprint;
MPRINT:  select count(*) into :NObs from Win_LIBNAMES;
MPRINT:  select study into :study1-:study132 from Win_LIBNAMES;
MPRINT:  select path into :path1-:path132 from Win_LIBNAMES;
MPRINT:  quit;
```

NOTE: PROCEDURE SQL used 0.01 seconds

```
MPRINT:  LIBNAME PDS79 "C:\sddshared\SASWorkspaces\Files\PDS79\SDTM";
```

NOTE: Libref PDS79 was successfully assigned as follows:
Physical Name: C:\sddshared\SASWorkspaces\Files\PDS79\SDTM

```
MPRINT:  LIBNAME PDS80 "C:\sddshared\SASWorkspaces\Files\PDS80\SDTM";
```

NOTE: Libref PDS80 was successfully assigned as follows:
Physical Name: C:\sddshared\SASWorkspaces\Files\PDS80\SDTM

```
MPRINT:  LIBNAME PDS81 "C:\sddshared\SASWorkspaces\Files\PDS81\SDTM";
```

NOTE: Libref PDS81 was successfully assigned as follows:
Physical Name: C:\sddshared\SASWorkspaces\Files\PDS81\SDTM

... resolves into
these statements.

Example: 1 List of Study Data*

Tumor_Type	Study	Status	Study_Path
Liver	PDS1	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS1
Liver	PDS2	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS2\final
Prostate	PDS79	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS79\SDTM
Prostate	PDS80	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS80\SDTM
Prostate	PDS81	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS81\SDTM
Prostate	PDS127	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS127\ADaM
Prostate	PDS132	FINAL_DE-ID	C:\sddshared\SASWorkspaces\Files\PDS132\ADaM

Metadata of each study and path is transparent and is easy to view.

- Methods and tools

- Common in industry: SQL joins, Office, Adobe, SAS
- In own function: data acquisition, analysis, review
- Other intra-company ways of working

- Batch reporting mindset

- Align reporting snapshots where possible, coordinate between with providers and recipients
- Build and maintain **◆2 Schedule of Snapshots** for
 - Annual reporting to authorities, Periodic safety review, Interim analyses, planned CSRs and submissions, Publications

- Facilitate reporting for customers

- Demo existing reports → rely on **◆3 Lists of Standard Reports** & on **◆4 Reporting Requests** (not on your memory!)
- Offer published reports, refreshed reports, support for self-reporting

◆2 Schedule of Snapshots*

Year	Product	Report Type	SDTM snap	SDTM delivery	Safety reporting	Annual reporting
2015	<name1>	Safety	2-Jan-15	9-Jan-15	12-Jan-15 to 23-Jan-15	
2015	<name1>	Safety	2-Apr-15	9-Apr-15	13-Apr-15 to 24-Apr-15	
2015	<name1>	Safety & Annual	2-Jul-15	9-Jul-15	13-Jul-15 to 24-Jul-15	13-Jul-15 to 17-Jul-15
2015	<name1>	Safety	2-Oct-15	9-Oct-15	12-Oct-15 to 23-Oct-15	

* Can also schedule for ADaM dataset delivery.

◆3 List of Standard Reports

Report Type	Report Name	Products; Studies	Data	Methods
Patient Profile	Graphical Patient Profile	<name2>; All	Study SDTMs	<tool3>
Patient Profile	Formatted Patient Profile (By-Patient Listing)	<name1>, <name2>; All	Study SDTMs	<tool3>
Patient Profile	Formatted Patient Profile (By-Patient Listing)	<name1>; <study1>, <study2>	Study ADaMs	<tool1>
Cleaning/ Review	SAE Reconciliation Differences	All; All	Study OC, Safety DB	<tool2>
Annual	Cumulative Exposure (3 reports)	All; All	Study SDTMs	<tool1>, <tool3>
Safety	Disposition and Discontinuation Reasons	All; All	Study SDTMs	<tool1>, <tool3>
Safety	Demographics	All; All	Study SDTMs	<tool1>, <tool3>
Safety	Study Medication Exposure	All; All	Study SDTMs	<tool1>, <tool3>
Safety	Incidence of AEs	All; All	Study SDTMs	<tool1>, <tool3>

◆4 List of Reporting Requests

Status	Due Date	Type	Report Name	Data	Method
Completed	2015-10-09	New	<name1> <study4> Missing Pages Report	Study SDTMs	<tool1>
Ongoing	2015-10-16	Change	<name1> Subject narrative list for 120DSU - ongoing LTFU studies - <study3>	Study ADaMs	<tool1>
Ongoing	2015-10-23	New	<name1> Subject narrative list for 120DSU - ongoing LTFU studies - <study4>	Study ADaMs	<tool1>
Ongoing	2015-10-28	Change	Standard Side-by-Side-Reconciliation-Listing-OC-Pt-vs-SafetyDB-Pt: CR6 Update	Study OC, Safety DB	<tool2>
Not_started	2015-11-06	Refresh	<name2> 2015 Annual Report	Study SDTMs	<tool1>
Not_started	2015-11-13	Refresh	<name2> 2015 Q4 Safety Report	Study SDTMs	<tool1>

- Clarify responsibility/timing for each step

Extracting/ receiving	Checking compliance	Registering/ loading	Refreshing pools	Running reports
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- Centrally determine and agree on default timing for process steps and inform partner teams (not the other way around!)

- Commit to implementation

- One compound has to go first. Subsequent ones must follow same specs.
- Determine and circulate **◆2 Schedule of Snapshots**
- One tool has to go first. Alternate tools should be identified as complementary or replacing.
- Don't adopt a new tool just because it is shiny.

Implement in steps: Get up and running in Year 0-1!

- Start in the present: current programming (SAS) on current data (SDTM)
 - Start with newest, then ongoing studies, then all interventional studies, then all
- Start with most standard domains
 - Start with demog and disposition, study med administration, AEs, conmeds, labs, vitals and ECGs
 - Stick to industry and company standards and map between these standards
- Inventory your own clinical data
 - Organize SDTMs and ADaMs: for studies, then pools, then customized sets
 - Create and maintain metadata of available clinical data (**◆1 List of Study Data**)
 - Create metric reports on your data: cumulative counts, accruing delta counts
- Inventory your deliverables
 - Track ongoing and completed requests (**◆4 List of Reporting Requests**)
 - Create reports on your deliverables: yearly counts on type, customers

Implement in steps: Maintain and improve in Year 1-2

- Maintain operations! Incrementally improve!
 - More data: studies, then pools, then customized sets
- Upgrade CDISC compliance check programming
 - Move from a semi-manual process to a fully automated one
- Upgrade pooling programming
 - Enact proactive, defensive programming to avoid data errors
 - Pool data from metadata (**◆1 List of Study Data**)
 - Move from periodically pooling to creating *on demand*
 - Optimize for browsing and reporting in the tools under consideration
- Create and upgrade standard reports (**◆3 List of Standard Requests**)
 - Deliver static reports (PDF), then filtered reports (XLS or SAS datasets)
 - Build delta reporting (if not already built), then improve delta reporting

- Advertise own data sources and services
 - Take time to post stories about “data accrual and reporting”
 - Commit to providing updates, at least every 6 months: in department meetings, blogs, et cetera
- Put in annual objectives
 - Say what you will do and then do what you said
 - Commit to semi-automation, then full automation
- Measure productivity before, during, and after

- Clarify metadata for “Data” and “Reporting”
 - ◆ 1 List of Study Data
 - ◆ 2 Schedule of Snapshots
 - ◆ 3 List of Standard Reports
 - ◆ 4 List of Reporting Requests
- Implement in steps using existing standards, tools, and resources
- Then add improvements and measure progress

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