SUPER DEMO: THE INTEGRATION OF SAS DRUG DEVELOPMENT AND SAS CLINICAL DATA INTEGRATION

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PHARMASUG 2014
What Is SAS Drug Development?

Key Features:
- Secure centralized content repository
- Integrated SAS development and execution environment
- Auditing and traceability
- Work and task management
- Job management and scheduling
- Collaborative work environment
What Is SAS Clinical Data Integration?

- Provides support for CDISC standards, SEND, SDTM, ADaM, Define
- Centralized metadata management
- Visual transformation tools
Advantages of Hosting SAS Drug Development & SAS Clinical Data Integration

- Shared Environment: Metadata Server and SAS Workspace Server
- Shared workspace for programs and data
- Dynamic Library/File assignments using macro variable
- Code developed in CDI executes without changes inside SDD
Hosted SAS Drug Development & SAS Clinical Data Integration

Client

Clinical Data Integration Via Terminal Server

SAS Drug Development Via Browser

Application Servers

Shared SAS Servers

SAS Workspace Servers

SAS Metadata Server
Scenario - Creating the Define.xml File

SAS Clinical Data Integration, provides a CDISC-Define transformation to build the define.xml file from the study domain metadata.
CDI Job to create Define File

- Provide name and location of define file
- Provide list of Domain tables and location to include in the define file

CDI Document Object

SAS Library Object
Advantages of Hosting SAS Drug Development & SAS Clinical Data Integration

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- Shared workspace, for programs, data

```sas
%let _SASWS_ = /sddshared/SASWorkspaces/%SYSGET(USER);
```

- Macro variable identifies the location of the root-level folder for the SDD Workspace
- Allows for the same program to run in CDI, in the SDD Workspace as well as the SDD Repository without any modifications.
_sasws_ Macro Variable

This macro variables can be referenced in SAS programs.

- LIBNAME statements
- FILENAME statements
- Other SAS statements

libname sdtm "&_sasws_/QAGPharma/PainXD-Study101/Files/Data/sdtm";
filename define "&_sasws_/QAGPharma/PainXD-Study101/Files/define.xml";
%include "&_sasws_/QAGPharma/PainXD-Study101/Files/Macros/setup.sas";
%let StudyPath=&_sasws_/QAGPharma/PainXD-Study101;
Define.xml File Properties

```
/*============================================================================*
  * Step: CDISC-Define Creation  A5QYDZT9.BL000339  *
  * Transform: CDISC-Define Creation  *
  * Description:  *
  *  *
  * Target Tables: CRT-DDS Results - work.crtdds_results A5QYDZT9.BN0001JT  *
  *============================================================================*/

%let transformID = %quote(A5QYDZT9.BL000339);
%let trans_rc = 0;
%let etls_stepStartTime = %sysfunc(datetime(), datetime20.);

options nomprint;
options NOQUOTELENMAX;
options NOSYNTAXCHECK;
%let _cdiopath = %sysfunc(pathname(work));
libname _cdiopath "&_cdiopath";
%cst_setStandardProperties{ _cstStandard=CST-FRAMEWORK, _cstSubType=initialize};

%let workPath=%sysfunc(pathname(work));
%let define=&_sasws_/Study1/Files/SDTM/define.xml
%let definesrc=%sysfunc(kreverse(%sysfunc(kscan(%sysfunc(kreverse(&define)),1,"/"))));
%let definePath=%sysfunc(ksubstr(&define,1,(%sysfunc(klength("&define"))-%sysfunc(klength("&definesrc")))));
```

Metadata Name: Create Define.xml

Diagram  Code  Log  Output
SAS Library Properties for SDTM domains
Develop Code in CDI, Save directly into SDD
Saved CDI Code appears in SDD workspace
Execute CDI Code in SDD – no code changes required
Define file is created in the Specified folder

<table>
<thead>
<tr>
<th>Datasets for Study Julie</th>
<th>Description</th>
<th>Structure</th>
<th>Purpose</th>
<th>Keys</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM</td>
<td>Demographics</td>
<td>Special Purpose Domains - One record per subject</td>
<td>Tabulation</td>
<td>STUDYID, USUBJID</td>
<td>Demographics SAS transport file</td>
</tr>
</tbody>
</table>

Go to the top of the define.xml

Date of document generation (2014-05-28T19:55:53+00:00)

### Demographics Dataset (DM)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Label</th>
<th>Type</th>
<th>Controlled Terms or Format</th>
<th>Origin</th>
<th>Role</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>text</td>
<td></td>
<td></td>
<td>Identifier</td>
<td>Unique identifier for a study.</td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>text</td>
<td></td>
<td></td>
<td>Identifier</td>
<td>Two-character abbreviation for study domain.</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject</td>
<td>text</td>
<td></td>
<td></td>
<td>Identifier</td>
<td>Identifier used to uniquely identify subjects across all studies.</td>
</tr>
</tbody>
</table>
Check in Program into Repository

Mark program for addition and check it in to repository
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QUESTIONS ???