

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



**JULIE MADDOX
SAS INSTITUTE
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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

SAS Data Integration Studio 4.6 - CDI Admin

File Edit View Check Outs Actions Debug Tools Window Help

New [Icons]

Folders Inventory

My Folder
ClinicalDI Course
PainXD
ADaM
Documents
External Domains
Jobs
RaveDomains
Reports
SDTM
SrcData
Domains from Medidata Rave
External Domains (PainXD)
MEDIDATASTUDYLOG
MREXTRACTLOG
PainXD
PainXD ADaM
PainXD Reports
PainXD SDTM Domains
PainXD Source Data
PainXD Study Terminology
PainXD2
SubjectInfo1
SubjectInfo2
Products
Shared Data
System
User Folders

Transformations

Access
Analysis
Archived
Change Data Capture
Clinical
Control
Data
Data Quality
Hadoop
High-Performance Analytics

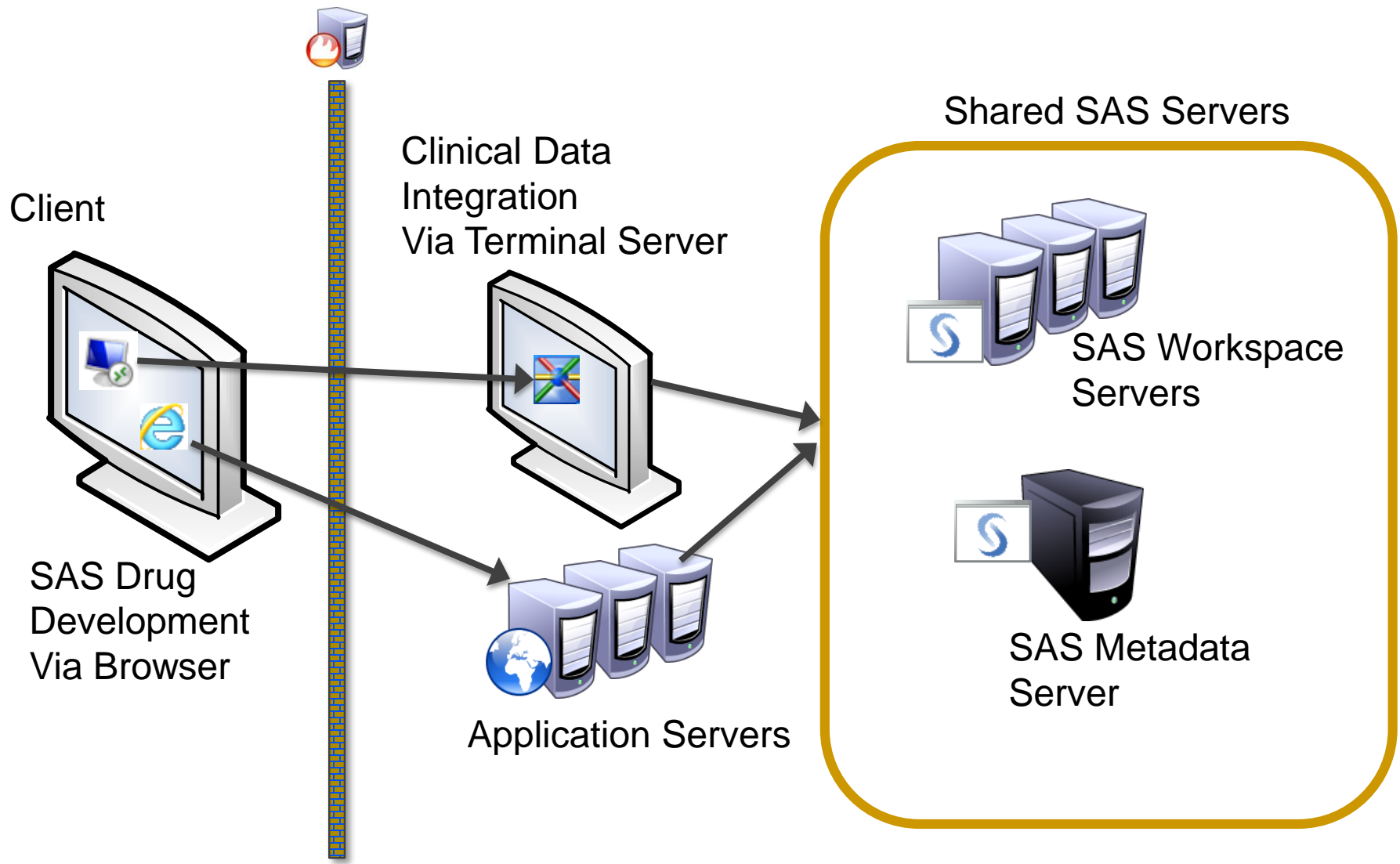
Clinical Administration

Defaults
Studies
Submissions
Data Standards
ADAM V2.1
SDTM V3.1.2
SDTM V3.1.3
Column Groups
Domain Templates
AE (Adverse Events)
CE (Clinical Events)
CM (Concomitant Medications)
CO (Comments)
DA (Drug Accountability)
DM (Demographics)
DS (Disposition)
DV (Protocol Deviations)
EG (ECG Test Results)
EX (Exposure)
FA (Findings About)
IE (Inclusion/Exclusion Criterion Not Met)
LB (Laboratory Test Results)
MB (Microbiology Specimen)
MH (Medical History)
MS (Microbiology Susceptibility)
PC (PK Concentrations)
PE (Physical Examination)
POOLDEF (Pool Definition)
PP (PK Parameters)
QS (Questionnaire)
RELREC (Related Records)
RS (Disease Response)
SC (Subject Characteristics)
SE (Subject Elements)
SU (Substance Use)
SUPPAE (Supplemental Qualifiers - AE)
SV (Subject Visits)
TA (Trial Arms)
TE (Trial Elements)
TI (Trial Inclusion/Exclusion Criteria)
TR (Tumor Results)
TS (Trial Summary)
TU (Tumor Identification)
TV (Trial Visits)
VS (Vital Signs)
Validation Datasets
Terminology Packages

Advantages of Hosting SAS Drug Development & SAS Clinical Data Integration

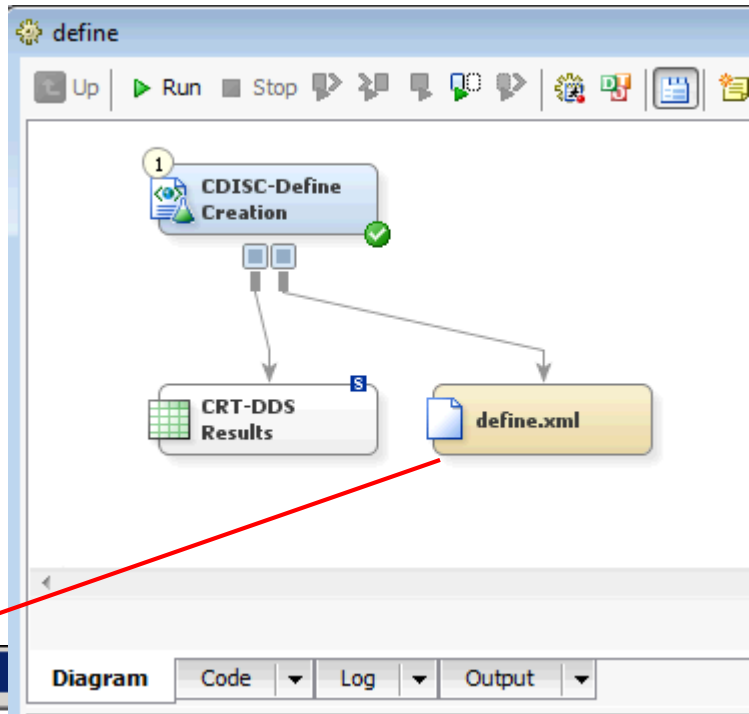
- Shared Environment: Metadata Server and SAS Workspace Server
- Shared workspace for programs and data
- Dynamic Library/File assignments using macro variable
- Code developed in CDI executes without changes inside SDD

Hosted SAS Drug Development & SAS Clinical Data Integration



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.



Study PainXD2, Data Definitions - Windows Internet Explorer

C:\CDICourse\PainXD2\define.xml

Study PainXD2, Data Definitions

Datasets for Study PainXD2				
Dataset	Description	Structure	Purpose	
DM	Demographics	- Special Purpose Domains - One record per subject	Tabulation	STU
QS	Questionnaire	- Findings - One record per questionnaire per question	Tabulation	STU

CDI Job to create Define File

The screenshot shows a SAS window titled 'create define.xml *'. The main area displays a flow diagram with three nodes: 'CDISC-Define Creation' (top), 'CRT-DDS Results' (bottom left), and 'define.xml' (bottom right). Arrows indicate a flow from 'CDISC-Define Creation' to both 'CRT-DDS Results' and 'define.xml'. A callout box points to the 'define.xml' node.

Overlaid on the right is the 'CDISC-SOURCE to CRT-DDS Properties' dialog box. It has tabs for 'General', 'Tables', 'Generation', 'Reports', 'Options', and 'Code'. The 'General' tab is active, showing:

- Data Model Type: SDTM (dropdown menu)
- Study/Submission: PainXD (dropdown menu)
- Available Tables by Study/Submission: A table listing domain identifiers and names.

Identifier	Name
AE	Adverse Events
DM	Demographics
QS	Questionnaire
SUPPDM	DM Supplemental Qualifiers
XP	Pain Diary

Provide name and location of define file



CDI Document Object



SAS Library Object

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

Advantages of Hosting SAS Drug Development & SAS Clinical Data Integration

- Shared Environment: Metadata Server & SAS Workspace Server
- Shared workspace, for programs, data

```
%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.

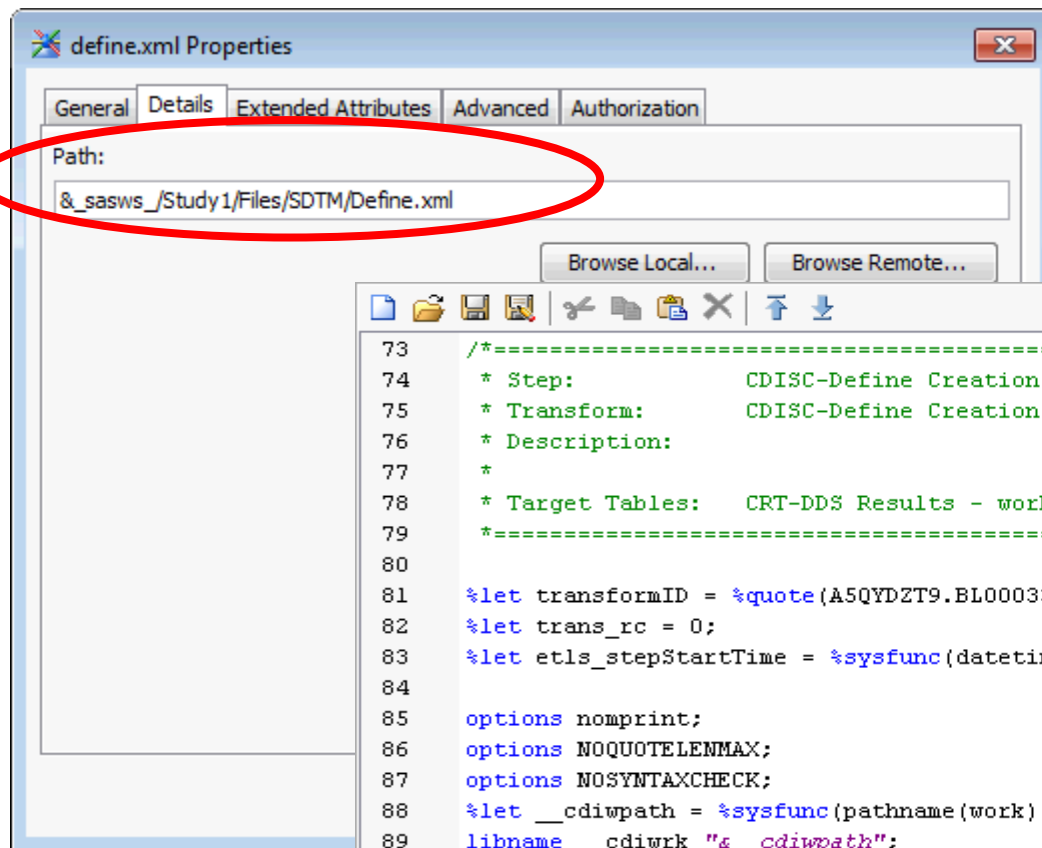
sasws Macro Variable

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



```

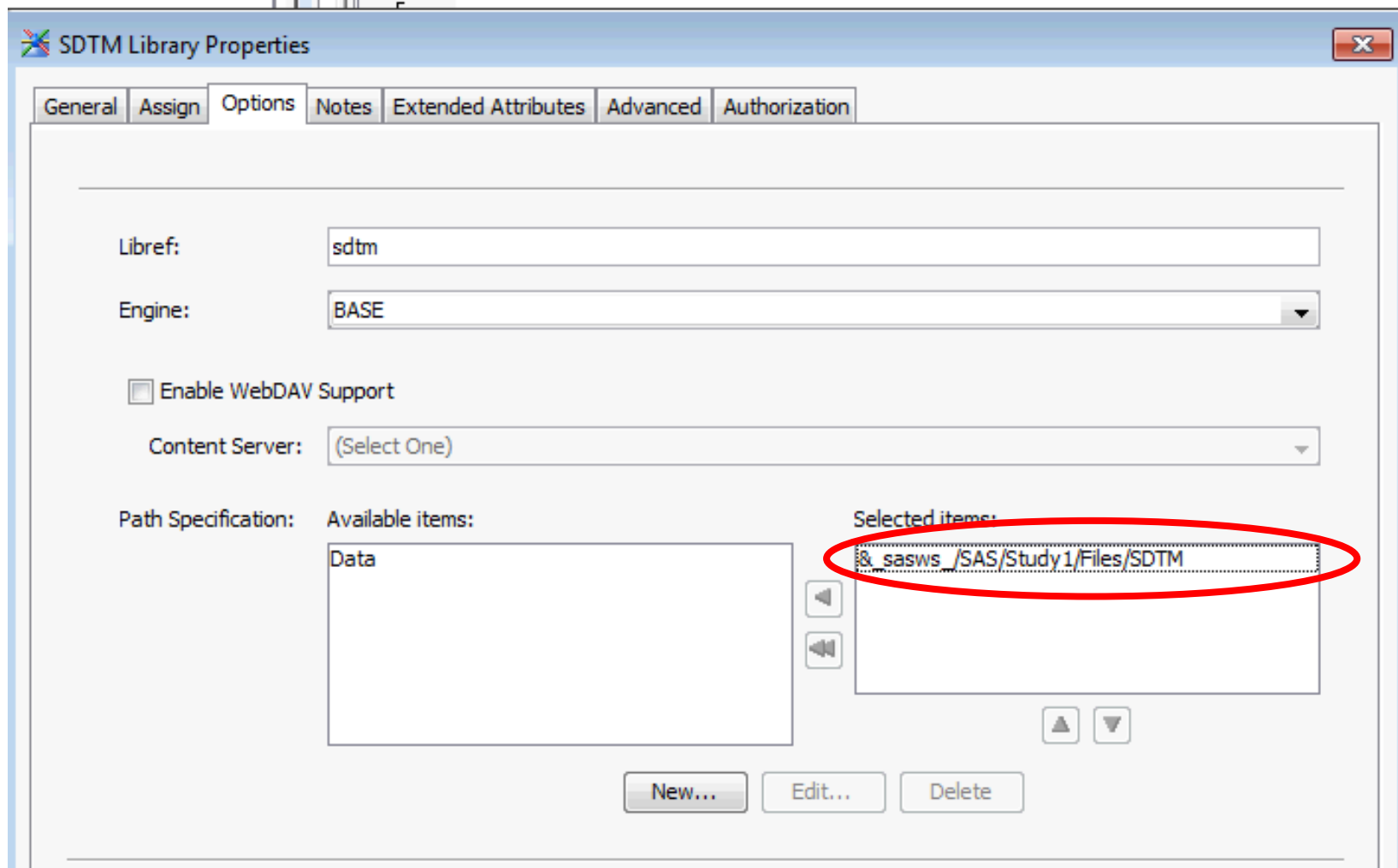
73  /*=====*/
74  * Step:           CDISC-Define Creation           A5QYDZT9.BL000339 *
75  * Transform:      CDISC-Define Creation           *
76  * Description:    *
77  *                *
78  * Target Tables:  CRT-DDS Results - work.crtdds_results A5QYDZT9.BN0001JT *
79  *=====*/
80
81  %let transformID = %quote(A5QYDZT9.BL000339);
82  %let trans_rc = 0;
83  %let etls_stepStartTime = %sysfunc(datetime(), datetime20.);
84
85  options nomprint;
86  options NOQUOTELENMAX;
87  options NOSYNTAXCHECK;
88  %let __cdiwwpath = %sysfunc(pathname(work));
89  libname __cdiwrk "&__cdiwwpath";
90  %cst_setStandardProperties(_cstStandard=CST-FRAMEWORK, _cstSubType=initialize);
91
92
93  %let workPath=%sysfunc(pathname(work));
94  %let define=&_sasws_/Study1/Files/SDTM/define.xml
95  %let delimiter=%sysfunc(kreverse(%sysfunc(kscan(%sysfunc(kreverse(&define)),1,'/'))));
96  %let definePath=%sysfunc(ksubstr(&define,1, (%sysfunc(klength("&define"))-%sysfunc(klength("&
97

```

Metadata Name: Create Define.xml

Diagram Code Log Output

SAS Library Properties for SDTM domains



Develop Code in CDI, Save directly into SDD

The screenshot displays the SAS Data Integration Studio 4.8 interface. The main window shows a 'define' project with a code editor containing SAS code for a step named 'CDISC-Define Creation'. The code includes macro variables for transformID, trans_rc, and etls stepStartTime.

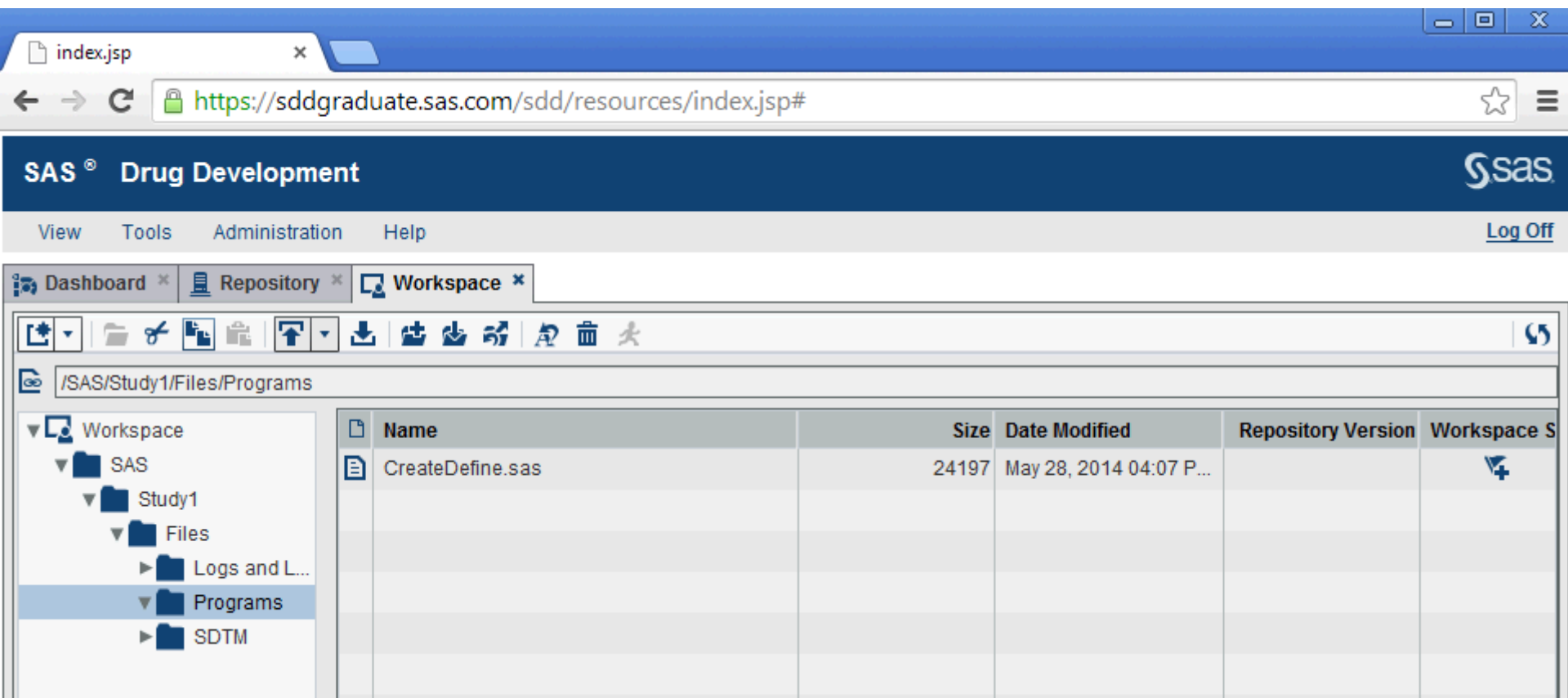
The 'Code' tab is selected in the 'Diagram' view, and the 'Save Text to File' option is highlighted in the 'File' menu. The 'Remote...' sub-menu is also highlighted, indicating the selection of a remote location for saving the file.

The 'Save text to remote file' dialog box is open, showing the 'Look in' field set to 'cdilax01.unx.sas.com'. The file list shows various directories, and the 'Name' field is populated with the path: '/sddshared/SASWorkspaces/sasjqm/SAS/Study1/Files/Programs/CreateDefine.sas'. The 'Type' is set to 'SAS Files (*.sas)'.

The 'Details' panel at the bottom shows a table of steps in the workflow:

Order	Name	Status
1	Precode	✓ Co
2	CDISC-Define Creation	✓ Co
3	Postcode	✓ Co
	define	✓ Co

Saved CDI Code appears in SDD workspace




The screenshot shows a web browser window with the URL <https://sddgraduate.sas.com/sdd/resources/index.jsp#>. The page title is "SAS® Drug Development". The navigation menu includes "View", "Tools", "Administration", and "Help". The main content area shows a workspace view with a tree on the left and a table on the right.

The tree view shows the following structure:

- Workspace
 - SAS
 - Study1
 - Files
 - Logs and L...
 - Programs
 - SDTM

The table below shows the contents of the "Programs" folder:

Name	Size	Date Modified	Repository Version	Workspace S
CreateDefine.sas	24197	May 28, 2014 04:07 P...		

Execute CDI Code in SDD – no code changes required

The screenshot displays the SAS Drug Development interface. At the top, the title bar reads "SAS® Drug Development". Below it are menu options: "View", "Tools", "Administration", and "Help". The main window has several tabs: "Dashboard", "Repository", "Workspace", and "SAS Session 1: CreateDefine.sas". A toolbar with various icons is visible below the tabs. On the left side, there is a sidebar with "Editors" and "Libraries" sections. The main editor area shows the code for "CreateDefine.sas":

```
1 /*****  
2 * Job:          define                      A5QYDZT9.BE00033B *  
3 * Description:  
4 *  
5 * Metadata Server: cim605a                *  
6 * Port:        8561                       *  
7 * Location:    /User Folders/sasjgm/My Folder/julie/SDTM_Data *  
8 *  
9 * Server:      SASApp                     A5QYDZT9.AS000002 *  
10 *  
11 *  
12 * Generated on: Wednesday, May 28, 2014 2:45:35 PM EDT *  
13 * Generated by: sasjgm@carynt            *  
14 * Version:    SAS Data Integration Studio 4.8 *  
15 *****/  
16
```

Below the code editor is a "Log" window showing the execution output:

```
7349 4591  
7350 4592  
7351 4593  
7352 4594      /** Step end CDISC-Define Creation **/  
7353 4595  
7354 4596      %let etls_endTime = %sysfunc(datetime(),datetime.);  
7355 4597
```

At the bottom of the interface, a status bar shows "Errors: 0" and "Warnings: 0", which is highlighted with a red box.

Define file is created in the Specified folder

The screenshot shows the SAS Drug Development interface. The breadcrumb path is `/SAS/Study1/Files/SDTM`, which is highlighted with a red box. The file explorer on the left shows the folder structure: `Workspace > SAS > Study1 > Files > SDTM`. The file list on the right shows two files: `define.xml` and `define 1-0-0.xml`, both highlighted with red boxes. The browser window shows the URL `https://sddgraduate.sas.com/sdd/filehandler/work:///SAS/Study1/Files/SDTM/defin`. The main content area displays a table of datasets for 'Study julie'.

Datasets for Study julie					
Dataset	Description	Structure	Purpose	Keys	Location
DM	Demographics	Special Purpose Domains - One record per subject	Tabulation	STUDYID, USUBJID	Demographics SAS transport file

Go to the top of the [define.xml](#)

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

Demographics Dataset (DM)						
Variable	Label	Type	Controlled Terms or Format	Origin	Role	Comment
STUDYID	Study Identifier	text			Identifier	Unique identifier for a study.
DOMAIN	Domain Abbreviation	text			Identifier	Two-character abbreviation fo
USUBJID	Unique Subject	text			Identifier	Identifier used to uniquely iden across all studies for all applica

Check in Program into Repository

Mark program for addition and check it in to repository

The screenshot displays the SAS Drug Development application interface. The top navigation bar includes 'View', 'Tools', 'Administration', and 'Help', along with a 'Log Off' link. The main workspace shows a file explorer on the left with a tree view containing 'Workspace', 'SAS', 'Study1', 'Files', 'Logs an...', 'Programs', and 'SDTM'. The main area shows a table of files with columns for 'Name', 'Size', 'Date Modified', 'Repository Version', and 'Workspace Sta'. A context menu is open over the file 'CreateDefine.sas', listing various actions. The 'Check In' option is highlighted with a red circle.

Name	Size	Date Modified	Repository Version	Workspace Sta
CreateDefine.sas		28, 2014 04:07 P...		

- New...
- Open
- Cut
- Copy
- Paste
- Upload
- Download
- Mark for Addition
- Check In**
- Undo Checkout
- Rename
- Delete
- Run

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- Shared Environment: Metadata Server and SAS Workspace Server
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QUESTIONS ???



**THE
POWER
TO KNOW.**

SAS LIFE SCIENCE ANALYTICS FRAMEWORK



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