



Product Highlights of Life Sciences (Proc CDISC & SAS ODM Viewer)

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CDISC Standards

- Operational Data Model (ODM)
- Study Data Tabulation Model (SDTM)
- Case Report Tabulation Data Definition Specification (CRTDDS - aka define.xml)
- Laboratory Data Model (Lab)
- Analysis Data Model (ADaM)
- Standard Exchange of Non-clinical Data (SEND)

SAS Involvement

- Ed Helton
 - Chief Strategist, Regulatory and Biomedical Affairs
- David Handelsman
 - Solutions Strategist, Clinical R&D
- Eric Brinsfield
 - Director Consulting Services
- Anthony Friebeul
 - XML Strategist, Platform R&D

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- Ed Helton
 - CDISC Board of Directors
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- Eric Brinsfield
 - [ADaM Team](#)
- Anthony Friebe
 - XML Strategist, Platform R&D

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 - CDISC Board of Directors
- David Handelsman
 - CDISC Industry Advisory Board
- Eric Brinsfield
 - ADaM Team
- Anthony Friebe
 - ODM Team
 - define.xml Team (principal contributor)
 - ODM/HL7 Harmonization Team

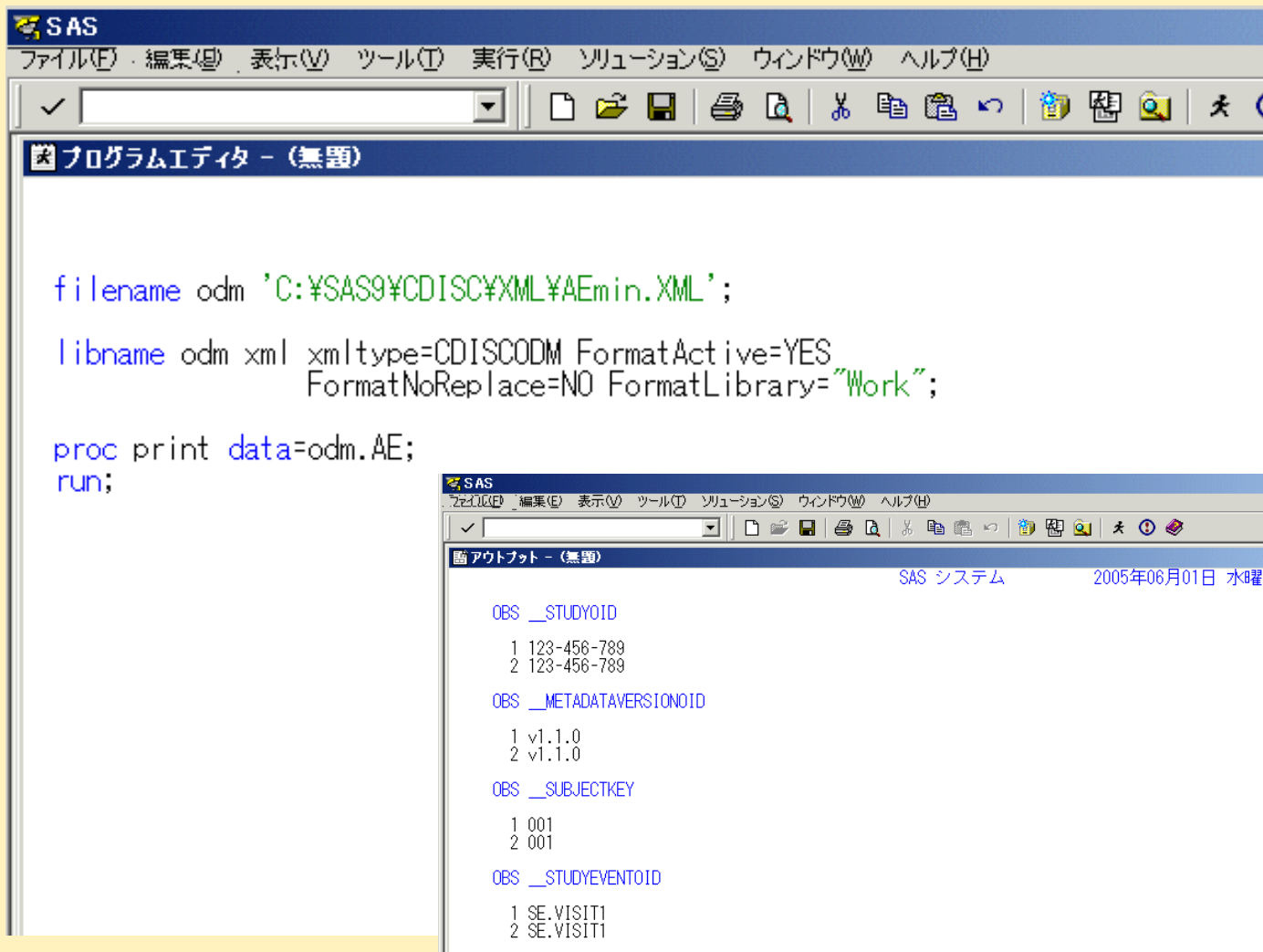
SAS Position

- Project customer investment in legacy systems
- Provide path for new technology migration
- Activity support and participate in standards processes and organization (like CDISC)
- Continue to evolve built-in product support

SAS CDISC Support

- XML Engine **ODM** native mode (SAS 9)
- XML Engine and XMLMap Extensions
- PROC CDISC(**ODM,SDTM**)
- New base SAS formats/informats for **ISO-8601**
(**ex.2005-12-15T13:14:17**)
- SAS CDISC ODM Viewer (Now **only in English**)
Module is available(free download).
This Viewer is a **beta** copy, for evaluation process.

SAS XML Libname Engine ODM Syntax



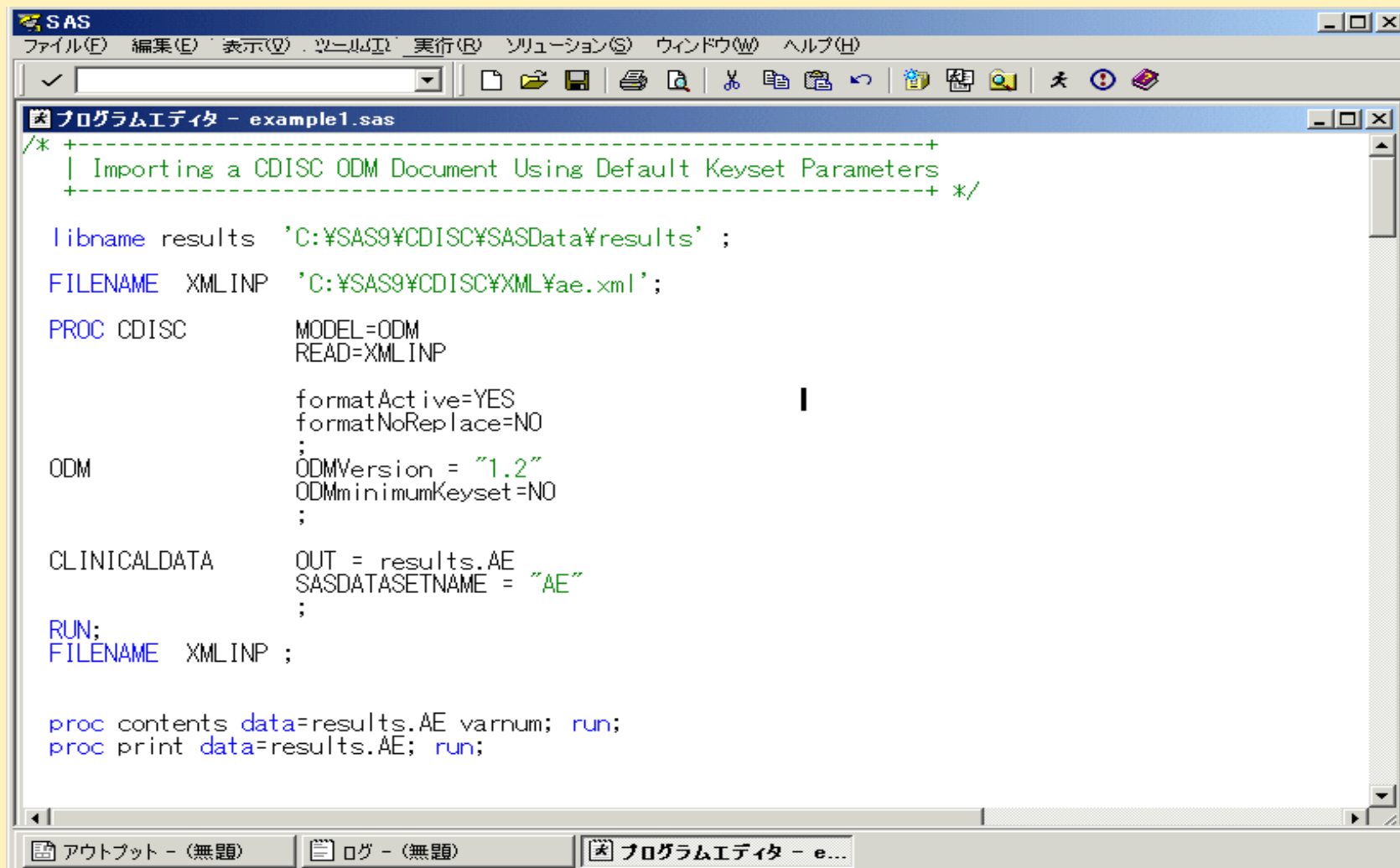
The image shows two windows from the SAS software interface. The top window is the 'プログラムエディタ - (無題)' (Program Editor - (Untitled)) window, which contains the following SAS code:

```
filename odm 'C:¥SAS9¥CDISC¥XML¥AEmin.XML';  
libname odm xml xmltype=CDISCODM FormatActive=YES  
                FormatNoReplace=NO FormatLibrary="Work";  
proc print data=odm.AE;  
run;
```

The bottom window is the 'アウトプット - (無題)' (Output - (Untitled)) window, which displays the output of the PROC PRINT statement. The output is as follows:

```
SAS システム 2005年06月01日 水曜日 午前09時54分07.  
  
OBS __STUDYOID  
1 123-456-789  
2 123-456-789  
  
OBS __METADATAVERSIONOID  
1 v1.1.0  
2 v1.1.0  
  
OBS __SUBJECTKEY  
1 001  
2 001  
  
OBS __STUDYEVENTOID  
1 SE.VISIT1  
2 SE.VISIT1
```

PROC CDISC Input Syntax



```

SAS
ファイル(F) 編集(E) 表示(V) ツール(T) 実行(R) ソリューション(S) ウィンドウ(W) ヘルプ(H)
プログラムエディタ - example1.sas
/* -----
| Importing a CDISC ODM Document Using Default Keyset Parameters
|----- */

libname results 'C:\SAS9\CDISC\SASData\results' ;
FILENAME XMLINP 'C:\SAS9\CDISC\XML\ae.xml' ;

PROC CDISC      MODEL=ODM
                READ=XMLINP

                formatActive=YES
                formatNoReplace=NO
                ;
ODM             ODMVersion = "1.2"
                ODMminimumKeyset=NO
                ;

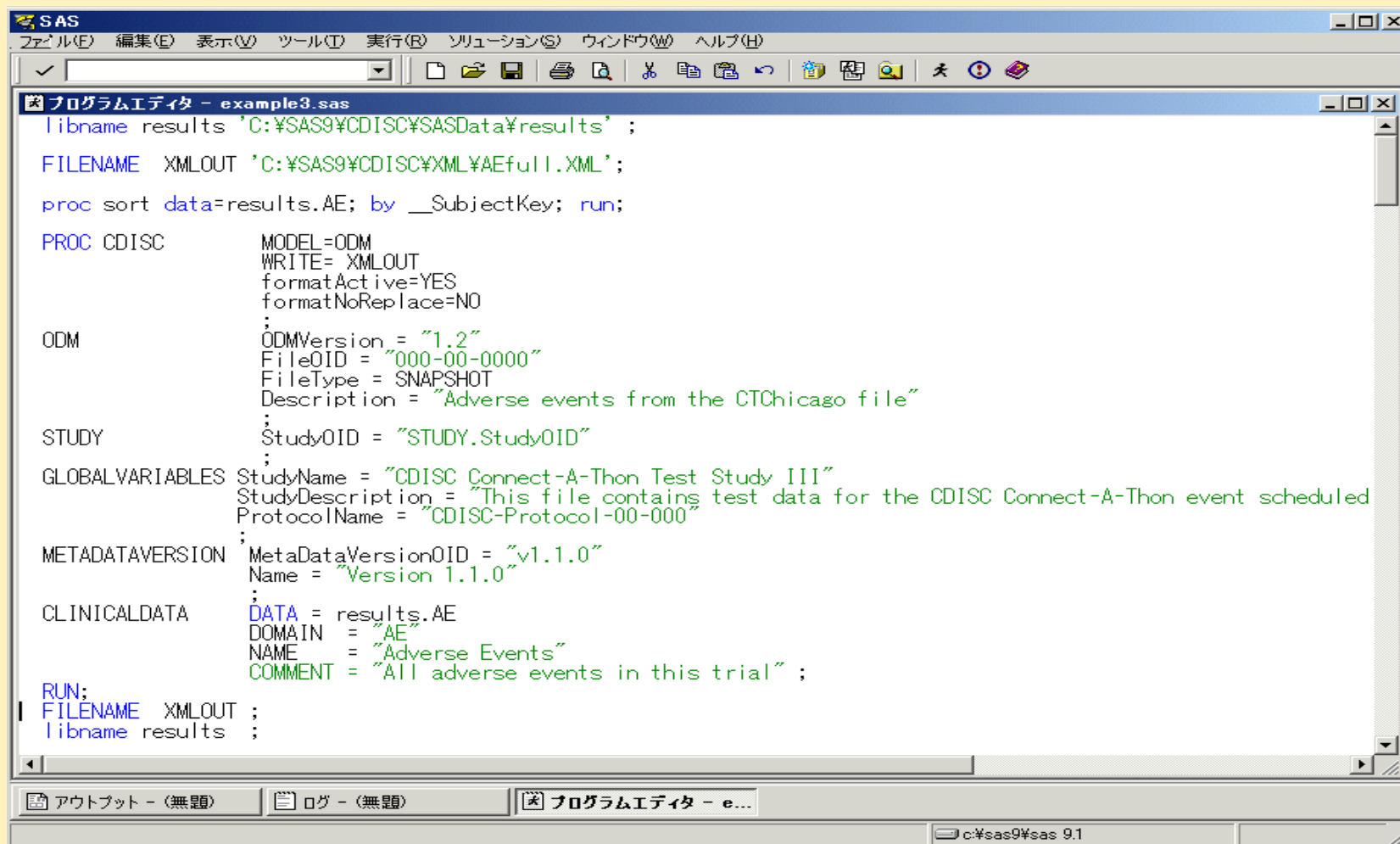
CLINICALDATA   OUT = results.AE
                SASDATASETNAME = "AE"
                ;

RUN;
FILENAME XMLINP ;

proc contents data=results.AE varnum; run;
proc print data=results.AE; run;

```

PROC CDISC Output Syntax



```
libname results 'C:\$SAS9\CDISC\SASData\results' ;
FILENAME XMLOUT 'C:\$SAS9\CDISC\XML\AEfull.XML';
proc sort data=results.AE; by __SubjectKey; run;
PROC CDISC
    MODEL=ODM
    WRITE=XMLOUT
    formatActive=YES
    formatNoReplace=NO
    ;
ODM
    ODMVersion = "1.2"
    FileOID = "000-00-0000"
    FileType = SNAPSHOT
    Description = "Adverse events from the CTChicago file"
    ;
STUDY
    StudyOID = "STUDY.StudyOID"
    ;
GLOBALVARIABLES
    StudyName = "CDISC Connect-A-Thon Test Study III"
    StudyDescription = "This file contains test data for the CDISC Connect-A-Thon event scheduled
    ProtocolName = "CDISC-Protocol-00-000"
    ;
METADATAVERSION
    MetaDataVersionOID = "v1.1.0"
    Name = "Version 1.1.0"
    ;
CLINICALDATA
    DATA = results.AE
    DOMAIN = "AE"
    NAME = "Adverse Events"
    COMMENT = "All adverse events in this trial" ;
RUN;
FILENAME XMLOUT ;
libname results ;
```

PROC CDISC

- ODM read/write capability (Production)
- SDTM content validation (Production)
- CRT-DDS - aka define.xml (Coming soon)
- Lab, SEND, ADaM (Planning stage)

PROC CDISC – SDTM Syntax

```
PROC CDISC          MODEL=SDTM ;  
    SDTM            SDTMVersion="3.1" ;  
    DOMAINDATA DATA=results.AE  
                DOMAIN=AE  
                CATEGORY=EVENTS ;  
  
RUN ;
```

CDISC SDTM – Supported Domains

Supported SDTM 3.1 Domains	DOMAIN=	CATEGORY=
Demography	DM	Special
Comments	CO	Special
Concomitant Medications	CM	Interventions
Exposure	EX	Interventions
Substance Use	SU	Interventions
Adverse Events	AE	Events
Disposition	DS	Events
Medical History	MH	Events
ECG Test Results	EG	Findings
Inclusion/Exclusion Exception	IE	Findings
Laboratory Test Results	LB	Findings
Physical Examinations	PE	Findings
Questionnaires	QS	Findings
Subject Characteristics	SC	Findings
Vital Signs	VS	Findings

CDISC SDTM Validation – Metadata Level

- Verifies that all required variables are present in the data set
- Reports as an error any variables in the data set that are *not* defined in the domain
- Reports a warning for any expected domain variables that are *not* in the data set

CDISC SDTM Validation – Metadata Level

- Notes any *permitted* domain variables that are *not* in the data set
- Verifies that all domain variables are of the expected data type and proper length
- Detects any domain variables that are assigned a controlled terminology specification by the domain and do not have a format assigned to them Reports as an error any variables in the data set that are *not* defined in the domain

CDISC SDTM Validation – Data Level

- Verifies that all *required* variable fields do not contain missing values
- Detects occurrences of *expected* variable fields that contain missing values
- Detects the conformance of all ISO-8601 specification assigned values; including date, time, datetime, duration, and interval types
- Notes correctness of yes/no and yes/no/null responses,

PROC CDISC

- Does NOT convert existing SDS 2.x content to SDTM 3.x representations.
- Does NOT automatically generate the SAS V5 XPORT file from the data source.

SAS CDISC ODM Viewer



SAS CDISC Viewer

File | Tools | Help

Locations | Signatures | Properties

Tables | External Tables | Code lists | Users

Name	Description
IG.AE	AE Comment
IG.CONMED	Conmed Comment
IG.DEMOG	Demog Comment
IG.DRUG_TRT	Treatment Comment
IG.PHARMO1	PK Comment
IG.PHYEX	PE Comment
IG.REFSAMP	

Name	SASName	Length	Data Type	CodeList	Comment
Study Key	_StudyOID	100	string		Study Key
Metadata Version Key	_MetaDataVersionOI	100	string		Metadata Vers
Subject Key	_SubjectKey	100	string		Subject Key
Study Event Key	_StudyEventOID	100	string		Study Event K
Study Event Repeat K	_StudyEventRepeatK	100	string		Study Event F
Form Key	_FormOID	100	string		Form Key
Form Repeat Key	_FormRepeatKey	100	string		Form Repeat I
Item Group Key	_ItemGroupOID	100	string		Item Group Ke
Item Group Repeat K	_ItemGroupRepeatKe	100	string		Item Group Re
Compound	R_DRUG	8	string		
Therapeutic Area	TAREA	4	string	CLTAREAF	
Protocol Number	PNO	15	string		
Country	SCTRY	4	string	CLSCTRYF	
Record status, 5 level	F_STATUS	1	string	CLE_STATU	

Data | External Data | Text | Audit Trail

Table: IG.DEMOG

	_SubjectKey	R_DRUG	TAREA	PNO	SCTRY	F_STATUS	HT
▶	001	SDP	Oncology	143-02	United States	Source verified, queried	75
	002	SDP	Oncology	143-02	United States	Source verified, not queried	64
	003	SDP	Oncology	143-02	United States	Source verified, not queried	65
	004	SDP	Oncology	143-02	United States	Source verified, not queried	69
	005	SDP	Oncology	143-02	United States	Source verified, not queried	71
	006	SDP	Oncology	143-02	United States	Source verified, not queried	71
	007	SDP	Oncology	143-02	United States	Source verified, not queried	72
	008	SDP	Oncology	143-02	United States	Source verified, not queried	62
	009	SDP	Oncology	143-02	United States	Source verified, not queried	66
	010	SDP	Oncology	143-02	United States	Source verified, not queried	69
	011	SDP	Oncology	143-02	United States	Source verified, queried	61
	012	SDP	Oncology	143-02	United States	Source verified, not queried	66

More information...

- Mailing List

XMLEngine@SAS.com

- Development Web Pages

[Base SAS XML \(Extensible Markup Language\).htm](#)

(<http://support.sas.com/rnd/base/index-xml-resources.html>)

[SAS 9 1 3 XML LIBNAME Engine User's Guide.htm](#)

(<http://support.sas.com/rnd/base/topics/sxle913/usersguide913.htm>)

- [CDISC Documentation](#)



Thank You !