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)

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SAS Involvement

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

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

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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

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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.

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SAS XML Libname Engine ODM 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 - (無題)

```
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;
```

SAS

ファイル(F) 編集(E) 表示(V) ツール(T) ソリューション(S) ウィンドウ(W) ヘルプ(H)

アウトプット - (無題)

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
```

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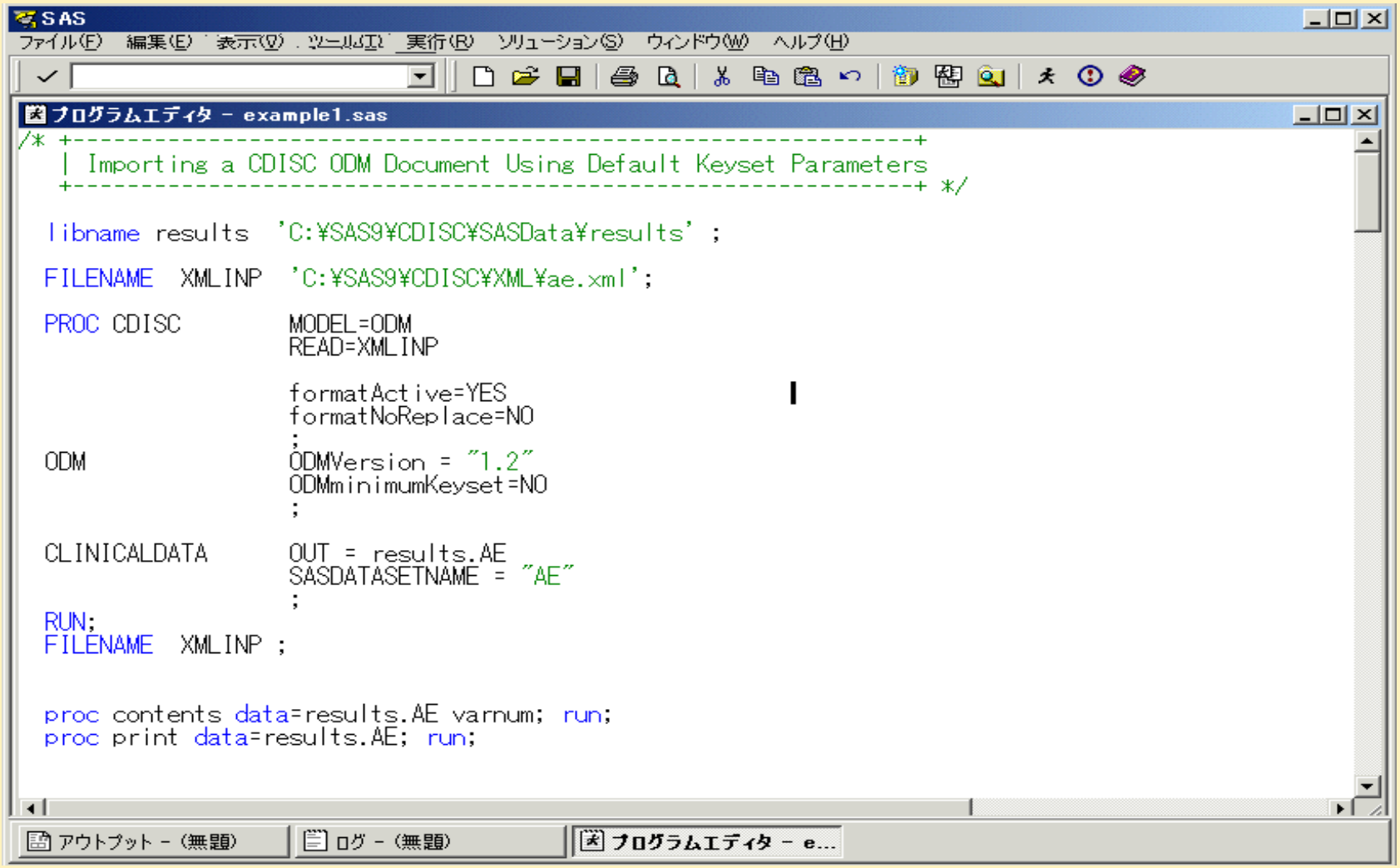
PROC CDISC Input Syntax



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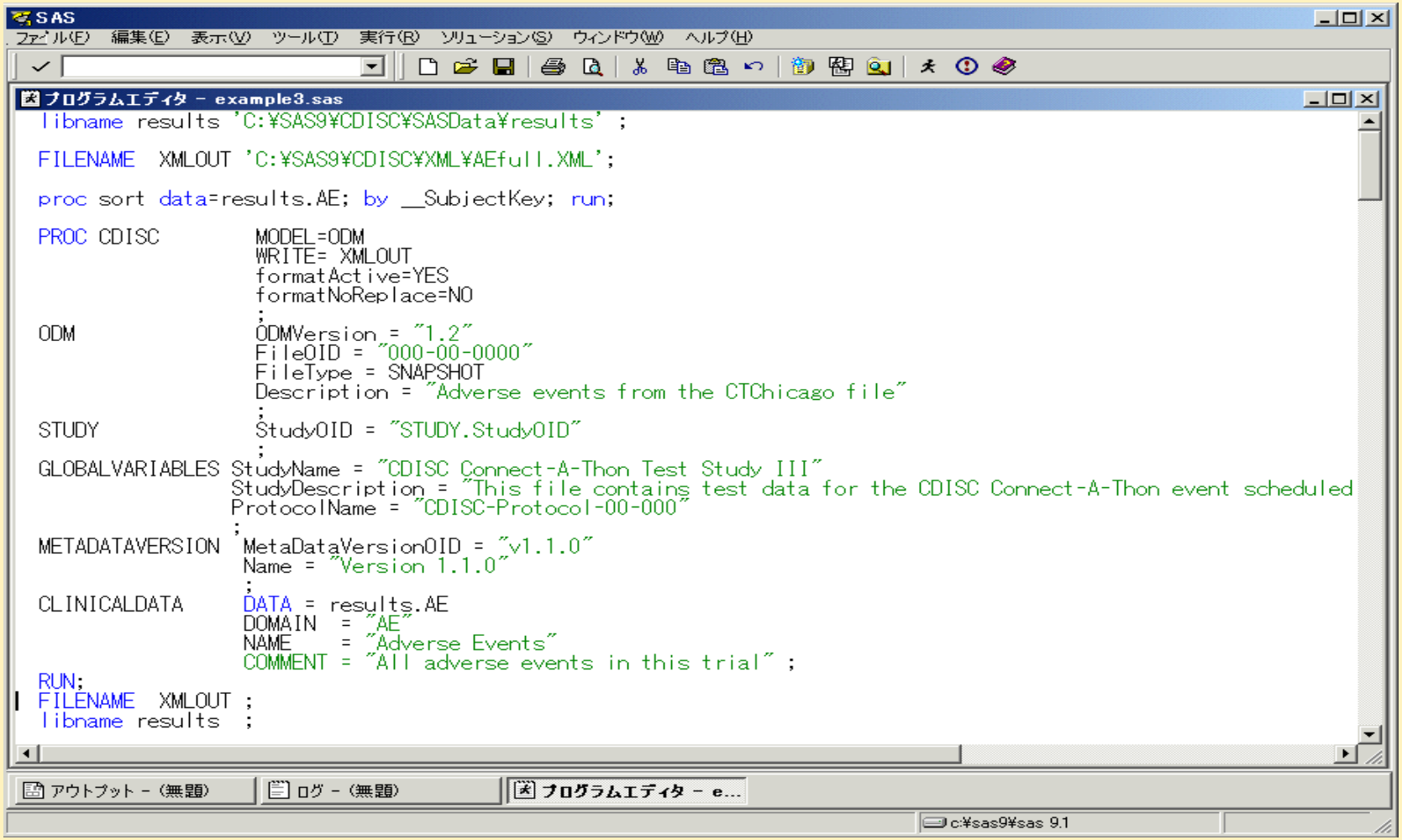
PROC CDISC Output Syntax



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PROC CDISC

- ODM read/write capability (Production)
- SDTM content validation (Production)
- CRT-DDS - aka define.xml (Coming soon)

- Lab,SEND,ADaM (Planning stage)

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PROC CDISC – SDTM Syntax

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

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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

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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

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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

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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,

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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.

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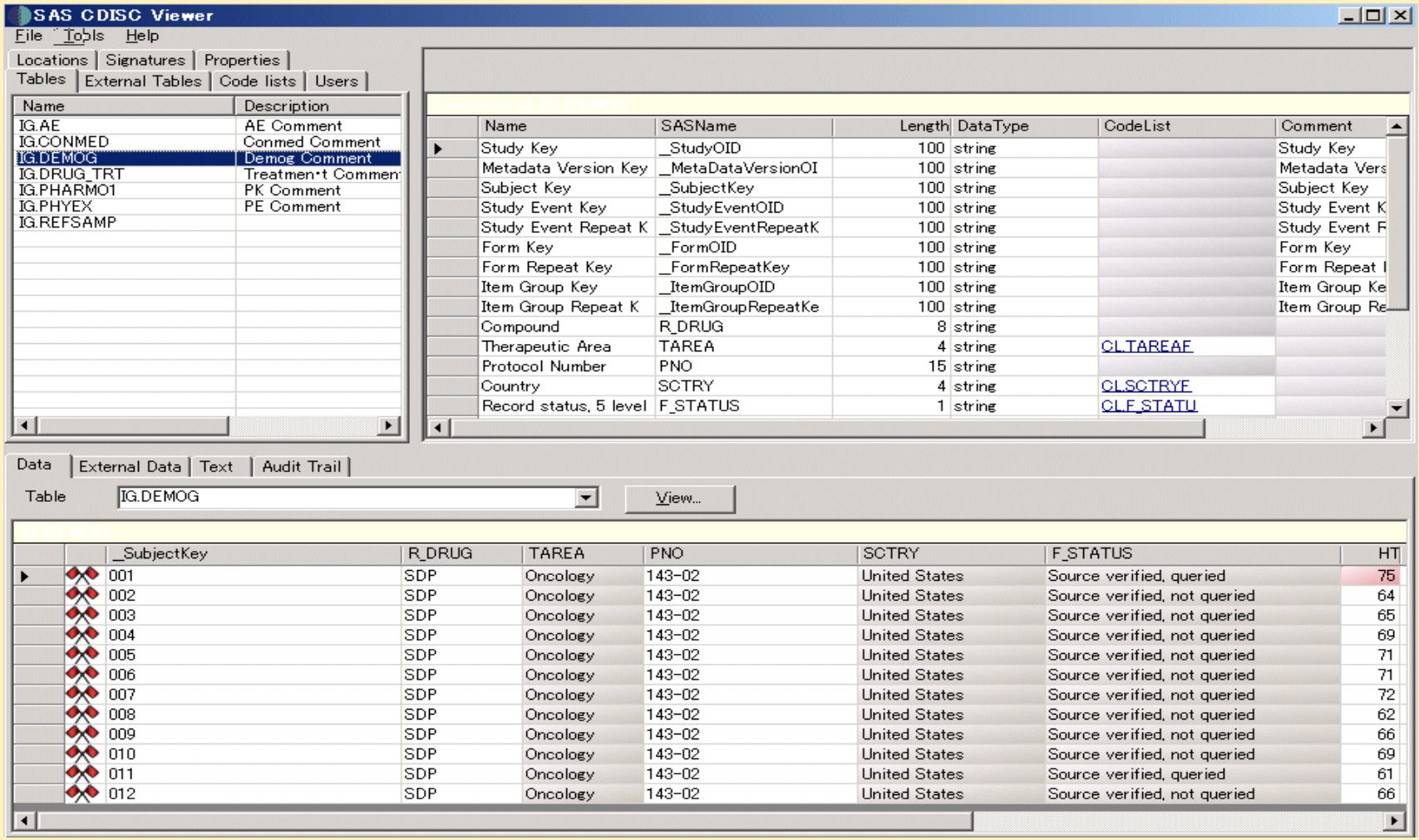
SAS CDISC ODM Viewer

SASODMVW



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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

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