

A man in a white shirt and tie is shown from the waist up, holding a glowing, translucent sphere with his right hand. The sphere contains a 3D bar chart. To the right of the sphere is a globe with a red line graph overlaid on it. Further right is a 3D bar chart with orange and yellow bars. The background is a soft-focus collage of various elements: binary code (0s and 1s), mathematical symbols like pi (π) and infinity (∞), letters like 'e', 'A', 'z', and '@', and other abstract shapes. The overall color palette is warm, with yellows, oranges, and soft blues.

SAS Drug Development (SDD) 2.1 – Changes and Enhancements

SAS Institute Japan株式会社
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平田 明弘

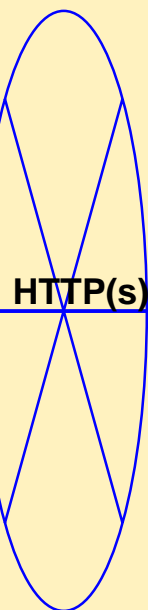
SDD2.1 Changes and Enhancements

- 1 . システム環境
- 2 . Data Explorer: 定義データ・Studyのブラウジング
- 3 . Process Editor: 解析・帳票SASプログラムの定義・実行
- 4 . **Data Definition Explorer** : 定義データの変数属性・変数値比較
- 5 . **Exporter** : 定義データのエクスポート
- 6 . **Study Definition Editor** : Studyデータ定義(Data Explorer)
- 7 . Results Bundle Viewer: プロセス実行出力ビューワー
- 8 . Versions: 各ファイルのバージョンニング
- 9 . Audit Trail: 監査証跡
- 10 . Documenter: 作成フォルダーのドキュメント化(PDF+ZIP)

SAS ® Drug Development 2.1 システム概略構成図

各クライアント

- Browsers: * 1
IE5.5 or Netscape 7.0
JRE 1.4.2以降




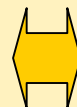
HTTP(s)

Secure Socket Layer

Fire Wall


Web・Applicationサーバ

- [Solaris8]
- BEA **WebLogic8.1** * 1 
- JDK **1.4.2以降**
- Drug Development CD (Web Server pieces)
(Xythos **4.0.48.10**)
- Drug Development CD (Application Server pieces)
- YASSP Security Hardening * 2






PC SASサーバ

- [Win2kServerSP3]
- Base SAS8.2
- Drug Development File Access
 - SAS/ACCESS to PC File Formats
 - SAS/CONNECT


 既存データ変換



SASサーバ

- [Solaris8]
- JDK **1.4.2以降**
- Base SAS8.2(**DBCS**)
 - SAS/CONNECT
 - SAS/GRAPH
 - SAS Integration Technologies
 - SAS/STAT
- Drug Development CD (Application Server pieces)
- YASSP Security Hardening * 2


 データアクセス
 データ加工
 データ解析


Dataサーバ

- [Solaris8]
- **Oracle9.2.0.1.0** * 1
- JDK **1.4.2以降**
- YASSP Security Hardening * 2


 データ管理

*1 別途ライセンスの購入

*2 YASSP: Yet Another Solaris Security Package (任意導入)

ログイン後画面

Study Definition Editorタブの追加

SAS Drug Development - Microsoft Internet Explorer

ファイル(E) 編集(E) 表示(V) お気に入り(A) ツール(T) ヘルプ(H)

戻る 検索 お気に入り メディア

アドレス(D) https://drugdevdemo.sas.com/p21/mainScreen.do 移動 リンク >>

SAS Drug Development You are logged in as: Akihiro Hirata

Settings Tools Admin Help Search+ Search Logout

Data Explorer Process Editor Data Definition Explorer Exporter Results Bundle Viewer Study Definition Editor

Home

Home

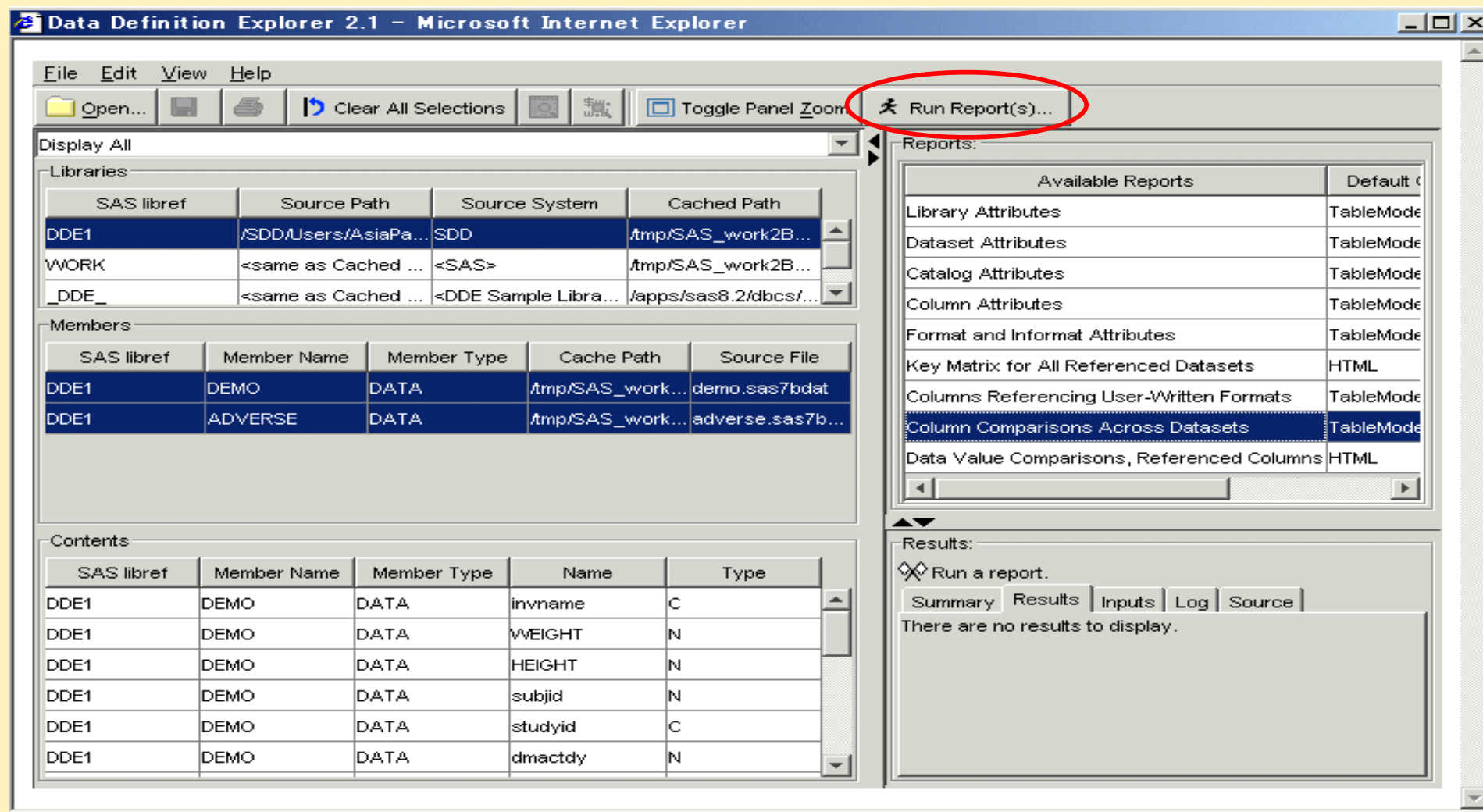
Platform home folder

Name /	Size	Type	Modified	Modified by	Signed	Locked
SDD	1389588 KB	folder	04/04/23 15時38分26秒 GMT	chdeck		

Some description for PharmaSUG

Data Definition Explorer

～ データセット間の変数属性比較



Data Definition Explorer 2.1 - Microsoft Internet Explorer

File Edit View Help

Open... Clear All Selections Toggle Panel Zoom Run Report(s)...

Display All

Libraries

SAS libref	Source Path	Source System	Cached Path
DDE1	/SDD/Users/AsiaPa...	SDD	/tmp/SAS_work2B...
WORK	<same as Cached ...	<SAS>	/tmp/SAS_work2B...
DDE	<same as Cached ...	<DDE Sample Libra...	/apps/sas8.2/dbcs/...

Members

SAS libref	Member Name	Member Type	Cache Path	Source File
DDE1	DEMO	DATA	/tmp/SAS_work...	demo.sas7bdat
DDE1	ADVERSE	DATA	/tmp/SAS_work...	adverse.sas7b...

Contents

SAS libref	Member Name	Member Type	Name	Type
DDE1	DEMO	DATA	invname	C
DDE1	DEMO	DATA	WEIGHT	N
DDE1	DEMO	DATA	HEIGHT	N
DDE1	DEMO	DATA	subjid	N
DDE1	DEMO	DATA	studyid	C
DDE1	DEMO	DATA	dmactdy	N

Reports:

Available Reports	Default C
Library Attributes	TableMode
Dataset Attributes	TableMode
Catalog Attributes	TableMode
Column Attributes	TableMode
Format and Informat Attributes	TableMode
Key Matrix for All Referenced Datasets	HTML
Columns Referencing User-Written Formats	TableMode
Column Comparisons Across Datasets	TableMode
Data Value Comparisons, Referenced Columns	HTML

Results:

Run a report.

Summary Results Inputs Log Source

There are no results to display.

Data Definition Explorer

～ 比較結果レポートの保存

Data Definition Explorer 2.1 - Microsoft Internet Explorer

File Edit View Help

Open... Clear All Selections Toggle Panel Zoom Run Report(s)...

Display All

Libraries

SAS libref	Source Path	Source System	Cached Path
DDE1	/SDD/Users/AsiaPa...	SDD	/tmp/SAS_work2B...
WORK	<same as Cached ...	<SAS>	/tmp/SAS_work2B...
DDE	<same as Cached ...	<DDE Sample Libra...	/apps/sas8.2/dbcs/...

Members

SAS libref	Member Name	Member Type	Cache Path	Source File
DDE1	DEMO	DATA	/tmp/SAS_work...	demo.sas7bdat
DDE1	ADVERSE	DATA	/tmp/SAS_work...	adverse.sas7b...

Contents

SAS libref	Member Name	Member Type	Name	Type
DDE1	DEMO	DATA	invname	C
DDE1	DEMO	DATA	WEIGHT	N
DDE1	DEMO	DATA	HEIGHT	N
DDE1	DEMO	DATA	subjid	N
DDE1	DEMO	DATA	studyid	C
DDE1	DEMO	DATA	dmactdy	N

Reports:

Available Reports	Default
Library Attributes	TableMode
Dataset Attributes	TableMode
Catalog Attributes	TableMode
Column Attributes	TableMode
Format and Informat Attributes	TableMode
Key Matrix for All Referenced Datasets	HTML
Columns Referencing User-Written Formats	TableMode
Column Comparisons Across Datasets	TableMode
Data Value Comparisons, Referenced Columns	HTML

Results:

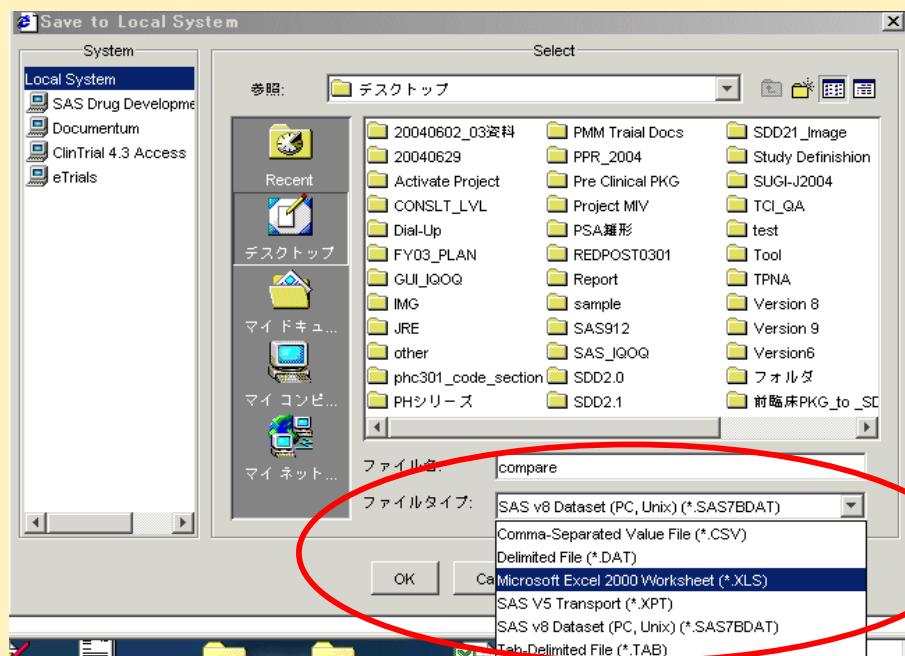
Column Comparisons (2004/07/20 2:06:18 GMT)

Summary Results Inputs Log Source

	Library Name	Member Name	Column Na
1	DDE1	ADVERSE	aeocom
2	DDE1	ADVERSE	aedecod
3	DDE1	ADVERSE	aeout

Data Definition Explorer

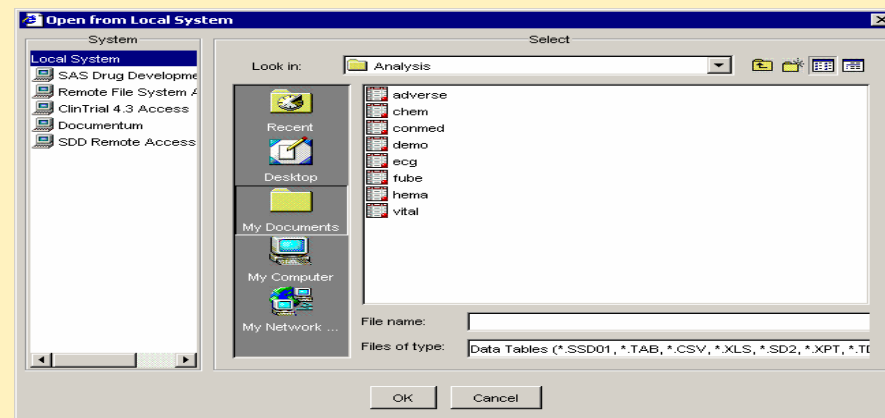
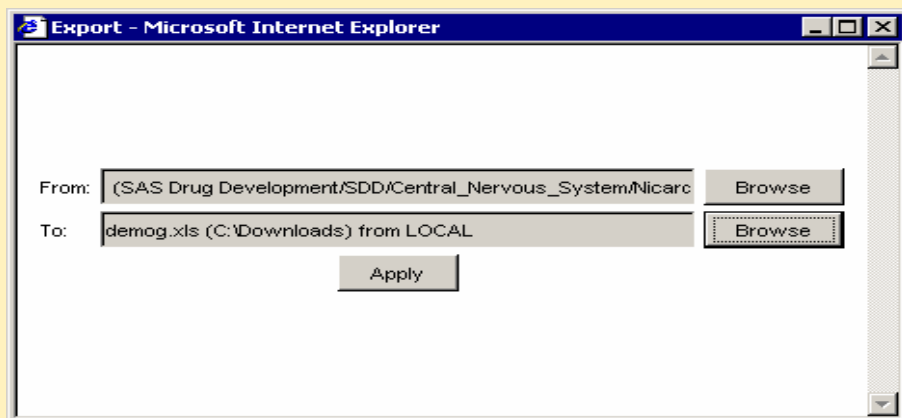
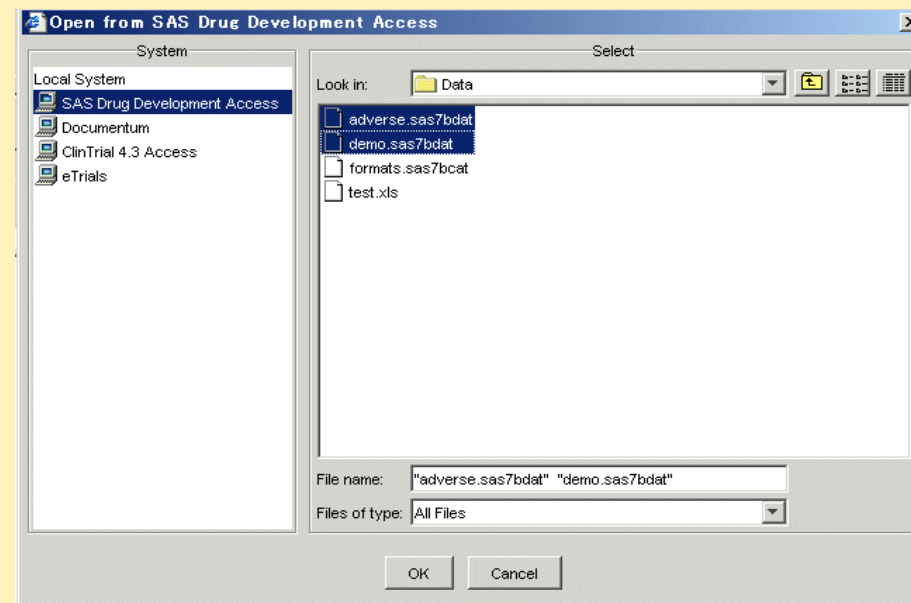
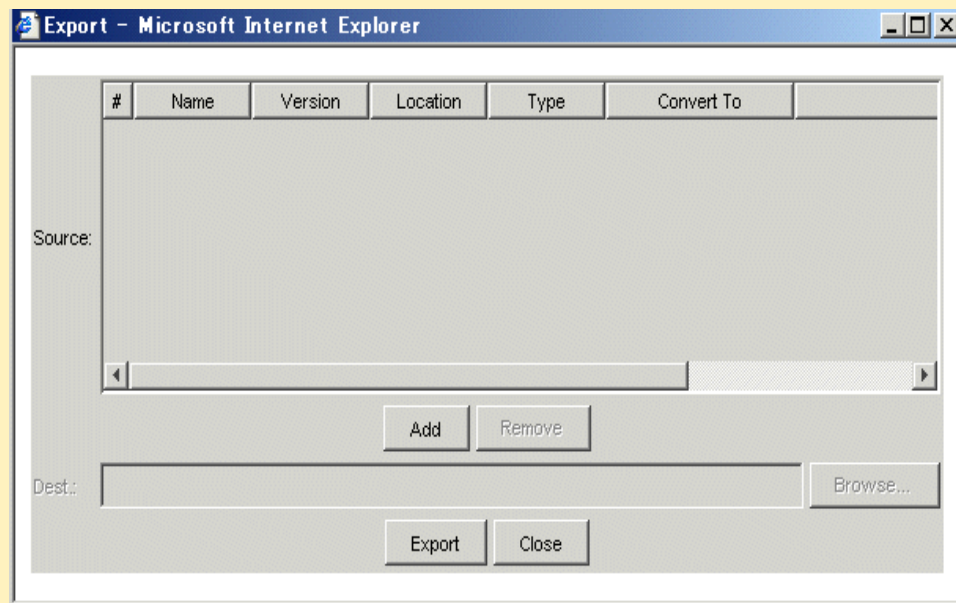
～ 保存先およびファイル名の指定



Compare.xls

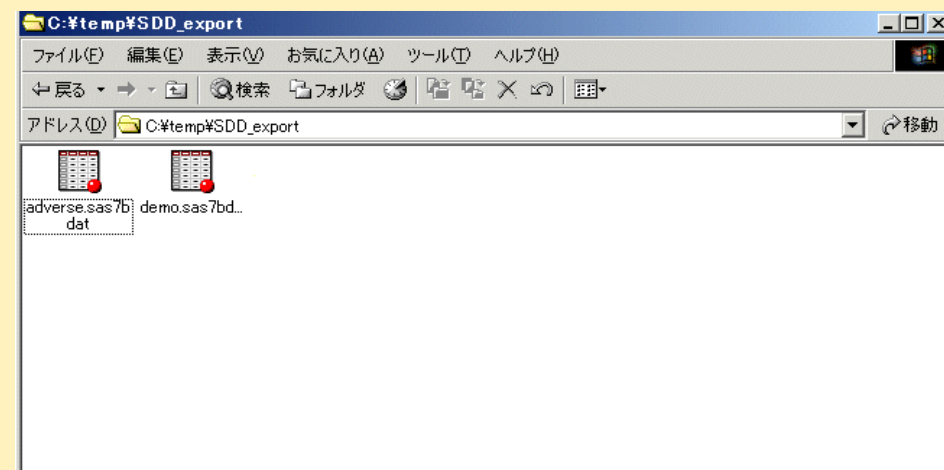
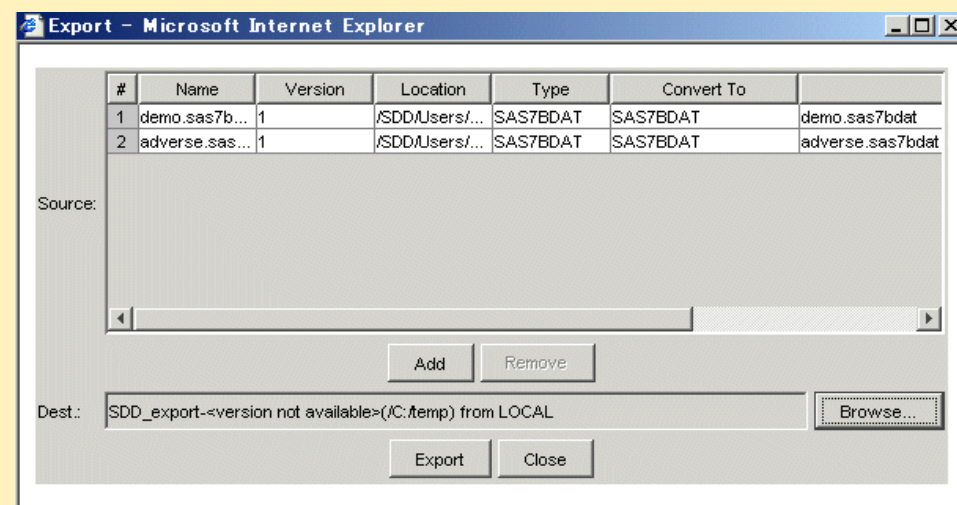
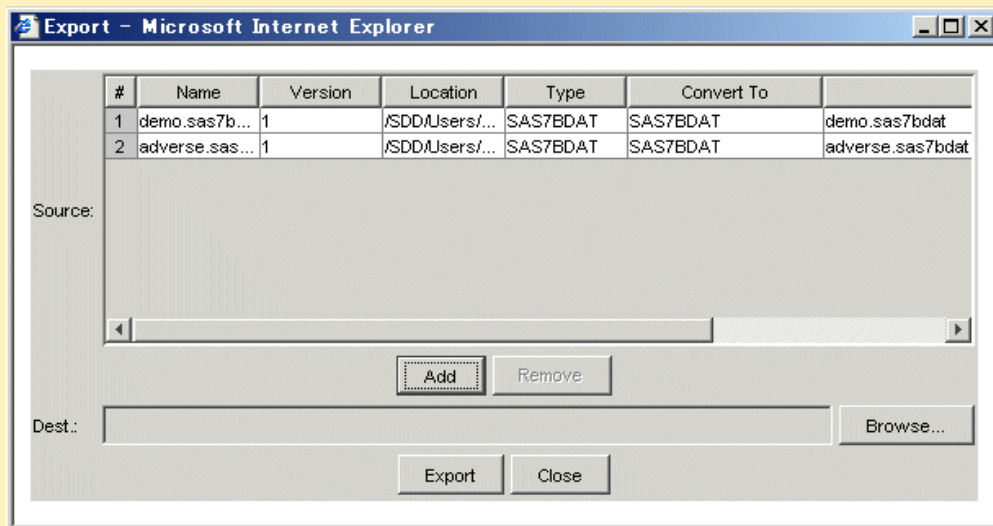
	A	B	C	D	E	F	G	H
1	Library_Name	Member_Name	Column_Name	Column_Sta	Column_Notes	Column_Label	Column_Type	Column_
2	DDE1	ADVERSE	aecom	OK	Unique	Comment	num	
3	DDE1	ADVERSE	aedecod	OK	Unique	AE Decode from C	char	
4	DDE1	ADVERSE	aeout	OK	Unique	Outcome of Event	num	
5	DDE1	ADVERSE	aesev	OK	Unique	Severity/Intensity	c num	
6	DDE1	DEMO	age	OK	Unique	Age in Years at Be	num	
7	DDE1	ADVERSE	bodsys	OK	Unique	Body System	char	
8	DDE1	DEMO	dmactdy	OK	Unique	Actual Day of Visit	num	
9	DDE1	DEMO	HEIGHT	OK	Unique	Height in Centimet	num	
10	DDE1	DEMO	invname	OK	Unique	Investigator Name	char	
11	DDE1	DEMO	race	OK	Unique	Race	char	
12	DDE1	DEMO	sex	OK	Unique	Sex	char	
13	DDE1	ADVERSE	studyid	OK		Study ID	char	
14	DDE1	DEMO	studyid	OK		Study ID	char	
15	DDE1	ADVERSE	subjid	OK		Subject ID	num	
16	DDE1	DEMO	subjid	OK		Subject ID	num	
17	DDE1	DEMO	TRTCD	OK	Unique	Treatment Code	num	
18	DDE1	ADVERSE	TRTGRP	Problem		Treatment Group	char	
19	DDE1	DEMO	TRTGRP	Problem	Differences: format	Treatment Group	char	
20	DDE1	DEMO	WEIGHT	OK	Unique	Weight in Kilogramm	num	
21								
22								

Exporter ~ 複数ファイルの選択 (下段枠内はSDD2.0)



Exporter

～ 複数ファイルを選択して、任意のフォルダへ保存



Study Definition Editor

～ Data Explorer利用時のStudy定義
(SDD2.0では、手作業であった)

Study Definition Editor 2.1 - Microsoft Internet Explorer

File Tools Help

Study Label:

Patient/Subject keys:

Patient Label:

Visit:

Baseline:

☐ Multi-Phase

Treatment:

Period:

Domains

#	Name	Label	Unique?	Repeated Measur...	Status
---	------	-------	---------	--------------------	--------

Columns

#	Name	Alias	Label	Use	Type	Format
---	------	-------	-------	-----	------	--------

Study Definition Editor

~ Study名称、Patient主一変数選択

Study Definition Editor 2.1 - Microsoft Internet Explorer

File Tools Help

Study Label:

Patient/Subject keys:

Patient Label:

Visit:
Baseline:
☐ Multi-Phase
Treatment:
Period:

Domains

#	Name	Label	Unique?	Repeated Measur...	Status
1	adverse.sas7b...	adverse.sas7bdat	N	N	
2	demo.sas7bdat	demo.sas7bdat	Y	N	

Columns

#	Name	Alias	Label	Use	Type	Format
1	studyid		Study ID	<Patient identifier>	Character	\$F8.
2	subjid		Subject ID	<Patient identifier>	Numeric	BEST12.
3	aeout		Outcome of Event	Continuous response	Numeric	BEST12.
4	aedecod		AE Decode from Dictionary	Nominal response	Character	\$F21.
5	aeom		Comment	Continuous response	Numeric	BEST12.

Study Definition Editor

～ 作成したStudy情報のテスト

study_test.sdfxml-1 (SDD/Users/AsiaPacific/AkihiroHirata/study Information) from SAS Drug Devel - Micro...

File Tools Help

Set Format Search Path...
Test...

Stu... [Text Box]

Visit: [Dropdown]

Baseline: [Dropdown]

Patient/Subject keys: studyid
subjid [Browse...]

Multi-Phase ☐

Treatment: [Dropdown]

Period: [Dropdown]

Patient Label: Patient ID

Domains

#	Name	Label	Unique?	Repeated Measur...	Status
1	adverse.sas7b...	adverse.sas7bdat	N	N	
2	demo.sas7bdat	demo.sas7bdat	Y	N	

Up Down

Add... Custom... Remove View Data... Details...

Columns

#	Name	Alias	Label	Use	Type	Format
---	------	-------	-------	-----	------	--------

Up Down

Custom... Details...



study_test.sdfxml-1 (SDD/Users/AsiaPacific/AkihiroHirata/study Information) from SAS Drug Devel - Micro...

File Data Tools Help

adverse.sas7bdat

- Outcome of Event
 - AE Decode from Dict
 - N
 - First
 - Last
- Comment
 - N
 - Minimum
 - Maximum
 - Median
 - Mean
- Body System
 - N
 - First
 - Last
- Severity/Intensity of I...
- Treatment Group
 - N
 - First
 - Last

demo.sas7bdat

- Weight in Kilograms
- Age in Years at Bas...
- Sex
- Investigator Name
- Treatment Code

Add Remove

#	Patient ID	AE Decod... N	AE Decod... First	AE Decod... Last	Treatment... N	Treatment... First	Tre
1	NICSAH2:11201	5	ANEMIA	LIVER FUN...	5	NIC.15	NIC
2	NICSAH2:11202	5	BRADYCA...	VASOSPASM	5	NIC.15	NIC
3	NICSAH2:11203	9	ANEMIA	MASS EFF...	9	NIC.075	NIC
4	NICSAH2:11204	25	ANEMIA	VASOSPASM	25	NIC.075	NIC
5	NICSAH2:11205	11	ANEMIA	VASOSPASM	11	NIC.075	NIC
6	NICSAH2:11206	15	ANEMIA	VASOSPASM	15	NIC.075	NIC
7	NICSAH2:11207	22	ANEMIA	VASOSPASM	22	NIC.15	NIC
8	NICSAH2:11208	20	ANEMIA	VASOSPASM	20	NIC.15	NIC
9	NICSAH2:11209	15	ANEMIA	VASOSPASM	15	NIC.15	NIC
10	NICSAH2:11210	14	ANEMIA	THROMBO...	14	NIC.075	NIC
11	NICSAH2:11211	24	ANEMIA	VASOSPASM	24	NIC.075	NIC
12	NICSAH2:11212	21	ANEMIA	THROMBO...	21	NIC.15	NIC
13	NICSAH2:11213	24	ANEMIA	VASOSPASM	24	NIC.15	NIC
14	NICSAH2:11214	17	AGITATION	THROMBO...	17	NIC.075	NIC
15	NICSAH2:11215	19	ANEMIA	VASOSPASM	19	NIC.075	NIC
16	NICSAH2:11216	15	ATELECTA...	TACHYCA...	15	NIC.15	NIC
17	NICSAH2:11217	7	ANEMIA	VASOSPASM	7	NIC.075	NIC
18	NICSAH2:11218	16	ATELECTA...	VASOSPASM	16	NIC.15	NIC
19	NICSAH2:11219	5	EDEMA BR...	NAUSEA V...	5	NIC.075	NIC
20	NICSAH2:11220	15	AGITATION	VASOSPASM	15	NIC.15	NIC
21	NICSAH2:11221	18	ANEMIA	VASOSPASM	18	NIC.15	NIC
22	NICSAH2:11222	17	ANEMIA	VASOSPASM	17	NIC.15	NIC
23	NICSAH2:11223	13	ATELECTA...	VASOSPASM	13	NIC.075	NIC
24	NICSAH2:11224	17	ANEMIA	VASOSPASM	17	NIC.075	NIC
25	NICSAH2:11225	12	ANEMIA	VASOSPASM	12	NIC.15	NIC
26	NICSAH2:11226	6	ANEMIA	NAUSEA V...	6	NIC.075	NIC
27	NICSAH2:11227	9	ATELECTA...	VASOSPASM	9	NIC.075	NIC
28	NICSAH2:11228	5	ANEMIA	HYPOTENS	5	NIC.15	NIC

Total Rows: 365 | Filtered Rows: 365 | Variables: 11 | Excluded Rows: 0 | Excluded Cells: 0

Study Definition Editor

~ Study情報の保存

Study Information

Study Name: Study_test

Visit: [Dropdown]

Baseline: [Dropdown]

☐ Multi-Phase

Treatment: [Dropdown]

Period: [Dropdown]

Patient Label: Patient ID

Browse...

Domains

#	Name	Label	Unique?	Repeated Measur...	Status
1	adverse.sas7b...	adverse.sas7bdat	N	N	
2	demo.sas7bdat	demo.sas7bdat	Y	N	

Up

Down

Add... Custom... Remove View Data... Details...

Columns

#	Name	Alias	Label	Use	Type	Format
---	------	-------	-------	-----	------	--------

Up

Down

Custom... Details...

Save to SAS Drug Development Access

System

Local System

- SAS Drug Development Access
- Documentum
- ClinTrial 4.3 Access
- eTrials

Look in: study Information

study_test.sdfxml

File name: study_test.sdfxml

Files of type: SDD Study Metadata Definition (*.SDFXML)

OK Cancel

study Information

Actions					New Import	
Name /	Size	Type	Modified	Modified by	Signed	Locked
Drug compliance.tdfxml	73 KB	tableDef	03/07/02 7時27分26秒 GMT	akihirohira		
study_test.sdfxml	2 KB	studyDef	04/07/19 4時39分09秒 GMT	akihirohira		

Study test.sdfxml



The Power to Know[®]