Full PAM report

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Data Store V4 Oracle View CPP.....58
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Process Tree

¸Publish [1]
¸¸SAS Processing [1.1]
¸¸¸Create SAS Views of 2nd Level Oracle Views [1.1.1]
¸¸¸Build SAS Schema [1.1.2]
¸¸¸¸Create End of Trial SAS Table [1.1.2.1]
¸¸¸¸Demographics SAS Table [1.1.2.2]
¸¸¸¸Subset Patients [1.1.2.3]
¸¸¸¸Adverse Events [1.1.2.4]
¸¸¸¸Key Drug dates [1.1.2.5]
¸¸¸¸Create SAS Reports [1.1.2.6]
¸¸RESPONSES VIEW [1.2]
¸¸2nd Level Oracle Views [1.3]
¸¸RDCMS VIEW [1.4]

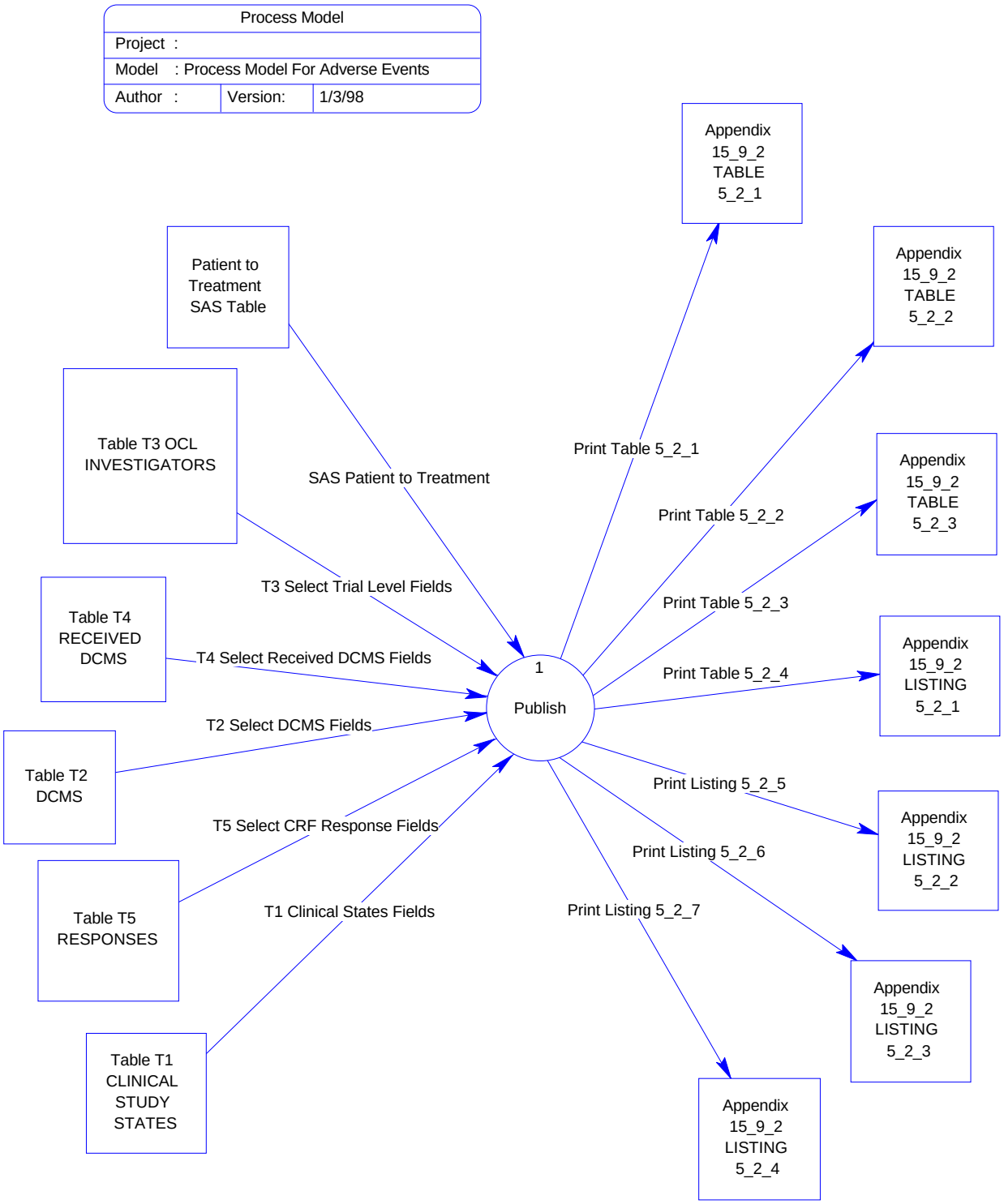
Specifications

Include specifications here...

PAM Graphs

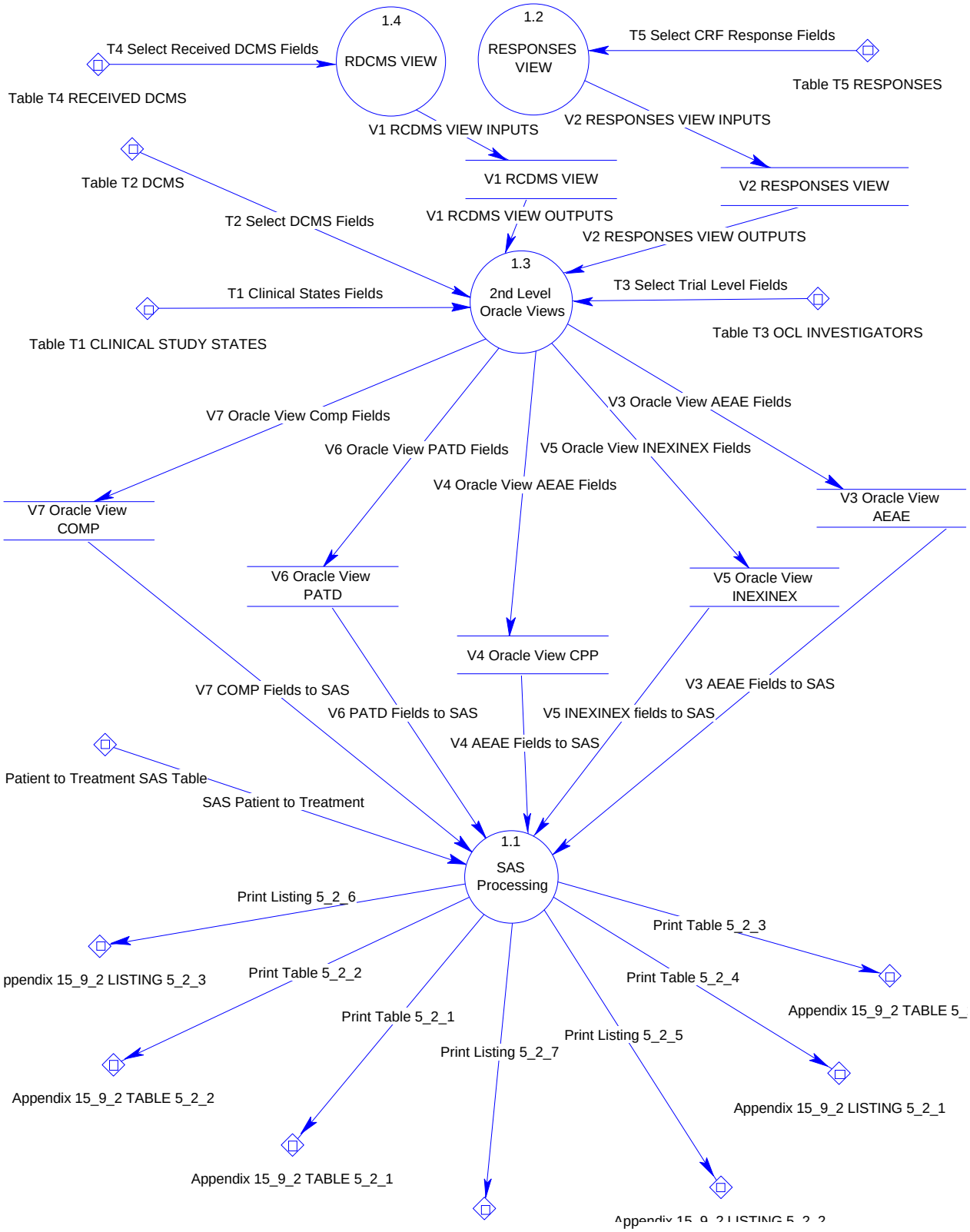
Root process graph

Graph



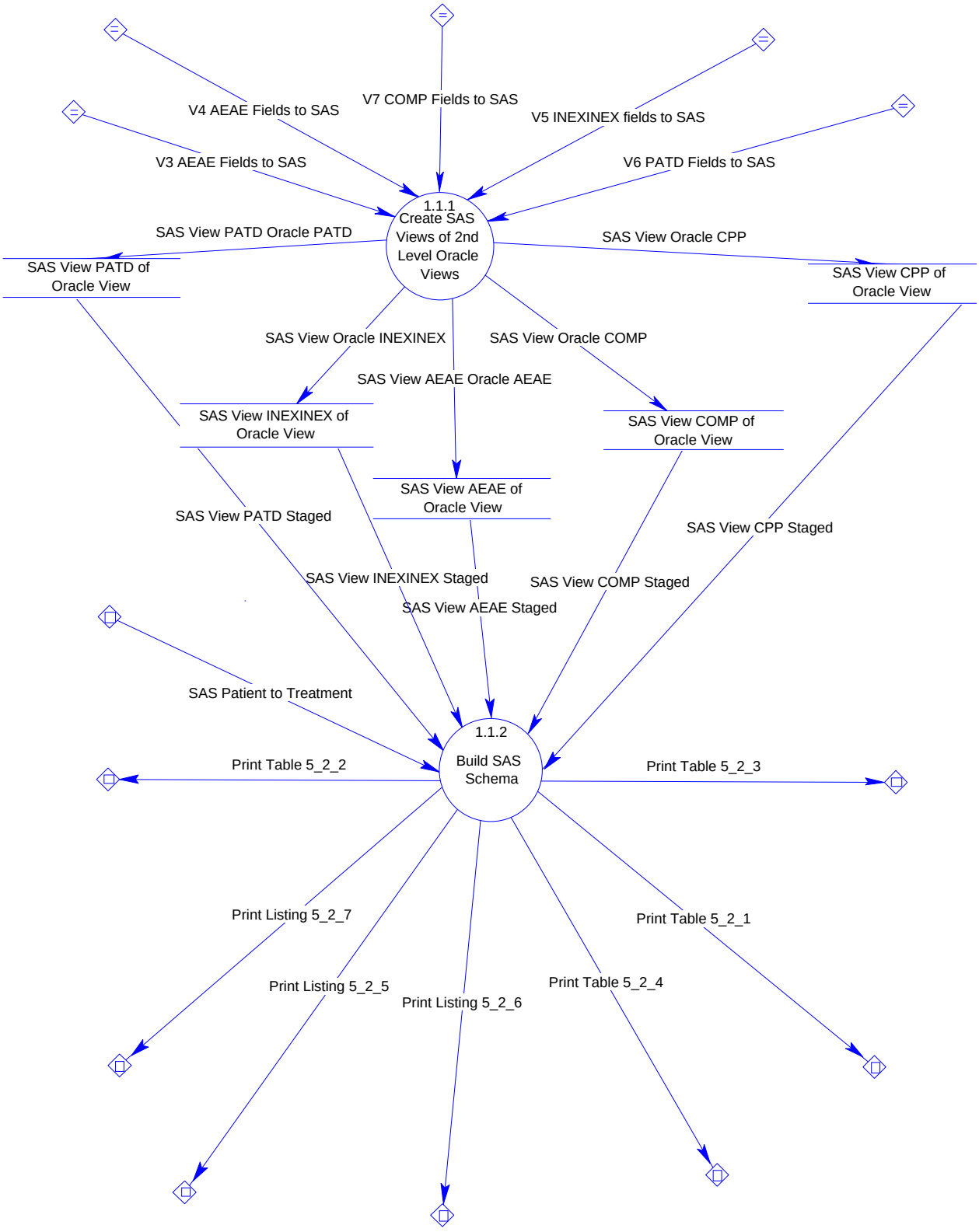
Subprocess Graph of Publish

Graph



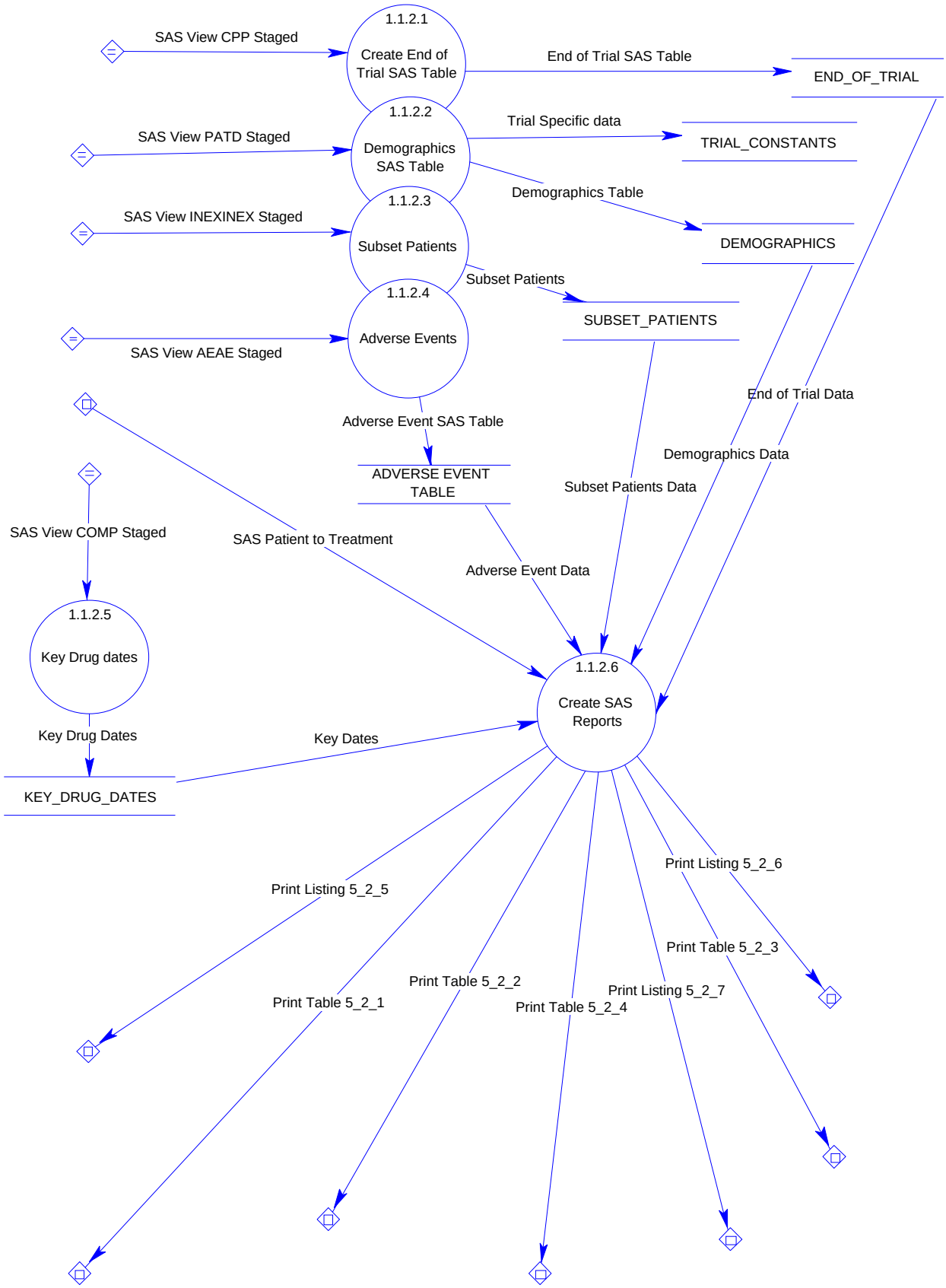
Subprocess Graph of SAS Processing

Graph



Subprocess Graph of Build SAS Schema

Graph


1.1.2.1
Create End of Trial SAS Table
SAS View CPP Staged
End of Trial SAS Table
END_OF_TRIAL
1.1.2.2
Demographics SAS Table
SAS View PATD Staged
Trial Specific data
TRIAL_CONSTANTS
Demographics Table
DEMOGRAPHICS
1.1.2.3
Subset Patients
SAS View INEXINEX Staged
Subset Patients
SUBSET_PATIENTS
1.1.2.4
Adverse Events
SAS View AEAE Staged
Adverse Event SAS Table
ADVERSE EVENT TABLE
End of Trial Data
Demographics Data
Subset Patients Data
SAS View COMP Staged
SAS Patient to Treatment
Adverse Event Data
1.1.2.5
Key Drug dates
1.1.2.6
Create SAS Reports
Key Drug Dates
Key Dates
KEY_DRUG_DATES
Print Listing 5_2_5
Print Listing 5_2_6
Print Table 5_2_3
Print Table 5_2_2
Print Table 5_2_1
Print Listing 5_2_7
Print Table 5_2_4

Domains

Domain List

Name	Code	Type
Oracle Tables	ORACLE_TABLES	A40
Oracle Views	ORACLE_VIEWS	A40
Oracle Views of Oracle Views	ORACLE_VIEWS_OF_ORACLE_VIEWS	A40
SAS Adverse Event Reports	SAS_ADVERSE_EVENT_REPORTS	A40
SAS Objects	SAS_OBJECTS	A40
SAS Views of Oracle Views	SAS_VIEWS_OF_ORACLE_VIEWS	A40

Domain Oracle Tables

Name: Oracle Tables
Code: ORACLE_TABLES
Label: Oracle Source data these are tables not views
Type: A
Length: 40 **Precision:** 0

Check

Low value:
High value:
Default value:
Unit:
Picture:
Uppercase: No **Lowercase:** No **Can't modify:** No
List of values:

Additional Client Validation Rule

Additional Server Validation Rule

This table is valdated using predefined rules, nightly.

Description

Only five tables are needed to produce all the adverse event reports. The Response table contains all the data for all CRFs. The value text field contains both numeric and character data. This column is charater and length 200 bytes.

Reference List

Reference	Name	Code
Data Item	T1_ACCESS_ONLY_IN_BROWSE_IND	T1_ACCESS_ONLY_IN_BROWSE_IND
Data Item	T1_COMMENT_TEXT	T1_COMMENT_TEXT
Data Item	T1_CREATED_BY	T1_CREATED_BY
Data Item	T1_CREATION_TS	T1_CREATION_TS
Data Item	T1_CURRENT_FLAG	T1_CURRENT_FLAG
Data Item	T1_DATA_ENTRY_ENABLED_FLAG	T1_DATA_ENTRY_ENABLED_FLAG
Data Item	T1_DCI_BOOK_DFLT_IN_DE_IND	T1_DCI_BOOK_DFLT_IN_DE_IND

Reference	Name	Code
Data Item	T1_DEFAULT_DE_PAGE_HEIGHT	T1_DEFAULT_DE_PAGE_HEIGHT
Data Item	T1_DEFAULT_DE_PAGE_WIDTH	T1_DEFAULT_DE_PAGE_WIDTH
Data Item	T1_DISC_RESOLVE_IN_DE_IND	T1_DISC_RESOLVE_IN_DE_IND
Data Item	T1_FIRST_PASS_FROM_LOGIN_FLAG	T1_FIRST_PASS_FROM_LOGIN_FLAG
Data Item	T1_FROZEN_FLAG	T1_FROZEN_FLAG
Data Item	T1_IMAGING_ENABLED_FLAG	T1_IMAGING_ENABLED_FLAG
Data Item	T1_LAST_BATCH_TS	T1_LAST_BATCH_TS
Data Item	T1_LAST_DATA_REVISION_SN	T1_LAST_DATA_REVISION_SN
Data Item	T1_LAST_VIEW_UPDATE_TS	T1_LAST_VIEW_UPDATE_TS
Data Item	T1_MANUAL_DISC_IN_BROWSE_IND	T1_MANUAL_DISC_IN_BROWSE_IND
Data Item	T1_OCL_THES_DISC_AT_DE_IND	T1_OCL_THES_DISC_AT_DE_IND
Data Item	T1_OCL_THES_LOV_IND	T1_OCL_THES_LOV_IND
Data Item	T1_PASS2_NOT_BY_PASS1_IND	T1_PASS2_NOT_BY_PASS1_IND
Data Item	T1_PRIVILEGED_UPDATE_IND	T1_PRIVILEGED_UPDATE_IND
Data Item	T1_SECOND_PASS_ALERT_IND	T1_SECOND_PASS_ALERT_IND
Data Item	T1_SECOND_PASS_REQUIRED_FLAG	T1_SECOND_PASS_REQUIRED_FLAG
Data Item	T1_THESAURUS_LOV_IND	T1_THESAURUS_LOV_IND
Data Item	T1_UNENROLLED_ALERT_IND	T1_UNENROLLED_ALERT_IND
Data Item	T1_UNIVARIATE_ALERT_IND	T1_UNIVARIATE_ALERT_IND
Data Item	T2_CLINICAL_STUDY_ID	T2_CLINICAL_STUDY_ID
Data Item	T2_COLLECTS_LAB_TESTS_FLAG	T2_COLLECTS_LAB_TESTS_FLAG
Data Item	T2_CREATED_BY	T2_CREATED_BY
Data Item	T2_CREATION_TS	T2_CREATION_TS
Data Item	T2_DATE_ORDER_CODE	T2_DATE_ORDER_CODE
Data Item	T2_DCM_DCI_QG_TYPE_CODE	T2_DCM_DCI_QG_TYPE_CODE
Data Item	T2_DCM_ID	T2_DCM_ID
Data Item	T2_DCM_LAYOUT_SN	T2_DCM_LAYOUT_SN
Data Item	T2_DCM_QUAL_VALUE_TEXT	T2_DCM_QUAL_VALUE_TEXT
Data Item	T2_DCM_STATUS_CODE	T2_DCM_STATUS_CODE
Data Item	T2_DCM_SUBSET_SN	T2_DCM_SUBSET_SN
Data Item	T2_DEFAULT_PAGE_HEIGHT	T2_DEFAULT_PAGE_HEIGHT
Data Item	T2_DEFAULT_PAGE_WIDTH	T2_DEFAULT_PAGE_WIDTH
Data Item	T2_DESCRIPTION	T2_DESCRIPTION
Data Item	T2_DISPLAY_SN	T2_DISPLAY_SN
Data Item	T2_DOMAIN	T2_DOMAIN
Data Item	T2_HELP_TEXT	T2_HELP_TEXT
Data Item	T2_LAST_STATUS_CHANGE_TS	T2_LAST_STATUS_CHANGE_TS
Data Item	T2_LAYOUT_EDITED_FLAG	T2_LAYOUT_EDITED_FLAG
Data Item	T2_LAYOUT_GENERATION_TS	T2_LAYOUT_GENERATION_TS
Data Item	T2_LAYOUT_REGENERATION_REQ_FLAG	T2_LAYOUT_REGENERATION_REQ_FLAG
Data Item	T2_LAYOUT_VER_NUM	T2_LAYOUT_VER_NUM
Data Item	T2_MODIFICATION_TS	T2_MODIFICATION_TS
Data Item	T2_MODIFIED_BY	T2_MODIFIED_BY
Data Item	T2_NAME	T2_NAME
Data Item	T2_ORIGINAL_DCM_ID	T2_ORIGINAL_DCM_ID
Data Item	T2_ORIGINAL_DCM_LAYOUT_SN	T2_ORIGINAL_DCM_LAYOUT_SN
Data Item	T2_ORIGINAL_DCM_SUBSET_SN	T2_ORIGINAL_DCM_SUBSET_SN
Data Item	T2_PROD_GENERATION_TS	T2_PROD_GENERATION_TS
Data Item	T2_QUAL_QUESTION_DVG_ID	T2_QUAL_QUESTION_DVG_ID
Data Item	T2_QUAL_QUESTION_DVG_SUBSET_NUM	T2_QUAL_QUESTION_DVG_SUBSET_NUM
Data Item	T2_QUAL_QUESTION_ID	T2_QUAL_QUESTION_ID
Data Item	T2_QUAL_QUESTION_PROMPT	T2_QUAL_QUESTION_PROMPT
Data Item	T2_REPLICATION_IND	T2_REPLICATION_IND

Reference	Name	Code
Data Item	T2_RETIREMENT_REASON_TYPE_CODE	T2_RETIREMENT_REASON_TYPE_CODE
Data Item	T2_SHORT_NAME	T2_SHORT_NAME
Data Item	T2_STATUS_COMMENT_TEXT	T2_STATUS_COMMENT_TEXT
Data Item	T2_SUBSET_NAME	T2_SUBSET_NAME
Data Item	T2_WINDOW_HEIGHT	T2_WINDOW_HEIGHT
Data Item	T2_WINDOW_WIDTH	T2_WINDOW_WIDTH
Data Item	T3_ACTIVE_FLAG	T3_ACTIVE_FLAG
Data Item	T3_ADDRESS_LINE_1	T3_ADDRESS_LINE_1
Data Item	T3_ADDRESS_LINE_2	T3_ADDRESS_LINE_2
Data Item	T3_ADDRESS_LINE_3	T3_ADDRESS_LINE_3
Data Item	T3_ADDRESS_NAME	T3_ADDRESS_NAME
Data Item	T3_CITY	T3_CITY
Data Item	T3_COUNTRY	T3_COUNTRY
Data Item	T3_CREATED_BY	T3_CREATED_BY
Data Item	T3_CREATION_TS	T3_CREATION_TS
Data Item	T3_FIRST_NAME	T3_FIRST_NAME
Data Item	T3_INITIALS	T3_INITIALS
Data Item	T3_INVESTIGATOR	T3_INVESTIGATOR
Data Item	T3_INVESTIGATOR_ID	T3_INVESTIGATOR_ID
Data Item	T3_LAST_NAME	T3_LAST_NAME
Data Item	T3_MODIFICATION_TS	T3_MODIFICATION_TS
Data Item	T3_MODIFIED_BY	T3_MODIFIED_BY
Data Item	T3_OWNING_LOCATION	T3_OWNING_LOCATION
Data Item	T3_PHONE_NUMBER	T3_PHONE_NUMBER
Data Item	T3_POSTAL_CODE	T3_POSTAL_CODE
Data Item	T3_STATE	T3_STATE
Data Item	T3_TITLE	T3_TITLE
Data Item	T4_ACCESSIBLE_TS	T4_ACCESSIBLE_TS
Data Item	T4_ACTUAL_EVENT_ID	T4_ACTUAL_EVENT_ID
Data Item	T4_BLANK_FLAG	T4_BLANK_FLAG
Data Item	T4_CLIN_PLAN_EVE_ID	T4_CLIN_PLAN_EVE_ID
Data Item	T4_CLIN_PLAN_EVE_NAME	T4_CLIN_PLAN_EVE_NAME
Data Item	T4_CLINICAL_STUDY_ID	T4_CLINICAL_STUDY_ID
Data Item	T4_COMMENT_TEXT	T4_COMMENT_TEXT
Data Item	T4_DATA_COMMENT_TEXT	T4_DATA_COMMENT_TEXT
Data Item	T4_DATA_LOCK_FLAG	T4_DATA_LOCK_FLAG
Data Item	T4_DATA_LOCK_TS	T4_DATA_LOCK_TS
Data Item	T4_DCM_DATE	T4_DCM_DATE
Data Item	T4_DCM_ID	T4_DCM_ID
Data Item	T4_DCM_LAYOUT_SN	T4_DCM_LAYOUT_SN
Data Item	T4_DCM_SUBSET_SN	T4_DCM_SUBSET_SN
Data Item	T4_DCM_TIME	T4_DCM_TIME
Data Item	T4_DOCUMENT_NUMBER	T4_DOCUMENT_NUMBER
Data Item	T4_END_TS	T4_END_TS
Data Item	T4_ENTERED_BY	T4_ENTERED_BY
Data Item	T4_INVESTIGATOR	T4_INVESTIGATOR
Data Item	T4_INVESTIGATOR_ID	T4_INVESTIGATOR_ID
Data Item	T4_LAB	T4_LAB
Data Item	T4_LAB_ASSIGNMENT_TYPE_CODE	T4_LAB_ASSIGNMENT_TYPE_CODE
Data Item	T4_LAB_ID	T4_LAB_ID
Data Item	T4_LAB_MODIFICATION_TS	T4_LAB_MODIFICATION_TS
Data Item	T4_LAST_DATA_CHANGE_TS	T4_LAST_DATA_CHANGE_TS
Data Item	T4_LAST_STATUS_CHANGE_TS	T4_LAST_STATUS_CHANGE_TS
Data Item	T4_LOG_IN_TS	T4_LOG_IN_TS

Reference	Name	Code
Data Item	T4_MODIFICATION_TS	T4_MODIFICATION_TS
Data Item	T4_MODIFIED_BY	T4_MODIFIED_BY
Data Item	T4_PASS_ONE_BY	T4_PASS_ONE_BY
Data Item	T4_PASS_ONE_TS	T4_PASS_ONE_TS
Data Item	T4_PASS_TWO_BY	T4_PASS_TWO_BY
Data Item	T4_PASS_TWO_TS	T4_PASS_TWO_TS
Data Item	T4_PATIENT	T4_PATIENT
Data Item	T4_PATIENT_POSITION_ID	T4_PATIENT_POSITION_ID
Data Item	T4_QUALIFYING_VALUE	T4_QUALIFYING_VALUE
Data Item	T4_RECEIVED_DCI_ID	T4_RECEIVED_DCI_ID
Data Item	T4_RECEIVED_DCM_ENTRY_TS	T4_RECEIVED_DCM_ENTRY_TS
Data Item	T4_RECEIVED_DCM_ID	T4_RECEIVED_DCM_ID
Data Item	T4_RECEIVED_DCM_STATUS_CODE	T4_RECEIVED_DCM_STATUS_CODE
Data Item	T4_SITE	T4_SITE
Data Item	T4_SITE_ID	T4_SITE_ID
Data Item	T4_SN	T4_SN
Data Item	T4_SUBEVENT_NUMBER	T4_SUBEVENT_NUMBER
Data Item	T4_VISIT_NUMBER	T4_VISIT_NUMBER
Data Item	T5_AUDIT_COMMENT_TEXT	T5_AUDIT_COMMENT_TEXT
Data Item	T5_CLINICAL_STUDY_ID	T5_CLINICAL_STUDY_ID
Data Item	T5_DATA_CHANGE_REASON_TYPE_CODE	T5_DATA_CHANGE_REASON_TYPE_CODE
Data Item	T5_DATA_COMMENT_TEXT	T5_DATA_COMMENT_TEXT
Data Item	T5_DCM_QUESTION_GROUP_ID	T5_DCM_QUESTION_GROUP_ID
Data Item	T5_DCM_QUESTION_ID	T5_DCM_QUESTION_ID
Data Item	T5_DISCREPANCY_INDICATOR	T5_DISCREPANCY_INDICATOR
Data Item	T5_END_TS	T5_END_TS
Data Item	T5_ENTERED_BY	T5_ENTERED_BY
Data Item	T5_EXCEPTION_VALUE_TEXT	T5_EXCEPTION_VALUE_TEXT
Data Item	T5_RECEIVED_DCM_ID	T5_RECEIVED_DCM_ID
Data Item	T5_REPEAT_SN	T5_REPEAT_SN
Data Item	T5_RESPONSE_ENTRY_TS	T5_RESPONSE_ENTRY_TS
Data Item	T5_RESPONSE_ID	T5_RESPONSE_ID
Data Item	T5_SECOND_PASS_INDICATOR	T5_SECOND_PASS_INDICATOR
Data Item	T5_VALIDATION_STATUS	T5_VALIDATION_STATUS
Data Item	T5_VALUE_TEXT	T5_VALUE_TEXT

Domain Oracle Views

Name: Oracle Views
Code: ORACLE_VIEWS
Label:
Type: A
Length: 40 **Precision:** 0

Check

Low value:
High value:
Default value:
Unit:

Uppercase: No **Lowercase:** No **Can't modify:** No
List of values:

Additional Client Validation Rule

Additional Server Validation Rule

the RESPONSE and RCDMS views have been tested throughly.

Description

First level views consist of RCDMS_VIEW and RESPONSES_VIEW. These views along with Table T1-T5 are used to create the second level Oracle views.

Reference List

Reference	Name	Code
Data Item	V1_CLINICAL_STUDY_ID	V1_CLINICAL_STUDY_ID
Data Item	V1_DCM_QUESTION_GROUP_ID	V1_DCM_QUESTION_GROUP_ID
Data Item	V1_DCM_QUESTION_ID	V1_DCM_QUESTION_ID
Data Item	V1_END_TS	V1_END_TS
Data Item	V1_ENTERED_BY	V1_ENTERED_BY
Data Item	V1_EXCEPTION_VALUE_TEXT	V1_EXCEPTION_VALUE_TEXT
Data Item	V1_RECEIVED_DCM_ID	V1_RECEIVED_DCM_ID
Data Item	V1_REPEAT_SN	V1_REPEAT_SN
Data Item	V1_RESPONSE_ENTRY_TS	V1_RESPONSE_ENTRY_TS
Data Item	V1_RESPONSE_ID	V1_RESPONSE_ID
Data Item	V1_VALIDATION_STATUS	V1_VALIDATION_STATUS
Data Item	V1_VALUE_TEXT	V1_VALUE_TEXT
Data Item	V2_ACCESSIBLE_TS	V2_ACCESSIBLE_TS
Data Item	V2_ACTUAL_EVENT_ID	V2_ACTUAL_EVENT_ID
Data Item	V2_AS_OF_TS	V2_AS_OF_TS
Data Item	V2_CLIN_PLAN_EVE_ID	V2_CLIN_PLAN_EVE_ID
Data Item	V2_CLIN_PLAN_EVE_NAME	V2_CLIN_PLAN_EVE_NAME
Data Item	V2_CLINICAL_STUDY_ID	V2_CLINICAL_STUDY_ID
Data Item	V2_DATA_LOCK_FLAG	V2_DATA_LOCK_FLAG
Data Item	V2_DCM_DATE	V2_DCM_DATE
Data Item	V2_DCM_ID	V2_DCM_ID
Data Item	V2_DCM_LAYOUT_SN	V2_DCM_LAYOUT_SN
Data Item	V2_DCM_SUBSET_SN	V2_DCM_SUBSET_SN
Data Item	V2_DCM_TIME	V2_DCM_TIME
Data Item	V2_DOCUMENT_NUMBER	V2_DOCUMENT_NUMBER
Data Item	V2_END_TS	V2_END_TS
Data Item	V2_ENTERED_BY	V2_ENTERED_BY
Data Item	V2_INVESTIGATOR	V2_INVESTIGATOR
Data Item	V2_INVESTIGATOR_ID	V2_INVESTIGATOR_ID
Data Item	V2_LAB	V2_LAB
Data Item	V2_LAB_ID	V2_LAB_ID
Data Item	V2_LAST_DATA_CHANGE_TS	V2_LAST_DATA_CHANGE_TS
Data Item	V2_LOG_IN_TS	V2_LOG_IN_TS
Data Item	V2_MODIFICATION_TS	V2_MODIFICATION_TS
Data Item	V2_MODIFIED_BY	V2_MODIFIED_BY
Data Item	V2_PATIENT	V2_PATIENT
Data Item	V2_PATIENT_POSITION_ID	V2_PATIENT_POSITION_ID

Reference	Name	Code
Data Item	V2_QUALIFYING_VALUE	V2_QUALIFYING_VALUE
Data Item	V2_RECEIVED_DCM_ENTRY_TS	V2_RECEIVED_DCM_ENTRY_TS
Data Item	V2_RECEIVED_DCM_ID	V2_RECEIVED_DCM_ID
Data Item	V2_RECEIVED_DCM_STATUS_CODE	V2_RECEIVED_DCM_STATUS_CODE
Data Item	V2_SITE	V2_SITE
Data Item	V2_SITE_ID	V2_SITE_ID
Data Item	V2_SN	V2_SN
Data Item	V2_SUBEVENT_NUMBER	V2_SUBEVENT_NUMBER
Data Item	V2_VISIT_NUMBER	V2_VISIT_NUMBER
Data Item	V3_ACTEVENT	V3_ACTEVENT
Data Item	V3_AEOX	V3_AEOX
Data Item	V3_DCMTIME	V3_DCMTIME
Data Item	V3_INV	V3_INV
Data Item	V3_INVLNAME	V3_INVLNAME
Data Item	V3_INVSITE	V3_INVSITE
Data Item	V3_PT	V3_PT
Data Item	V3_REPEATSN	V3_REPEATSN
Data Item	V4_DCMDATE	V4_DCMDATE
Data Item	V4_DCMNAME	V4_DCMNAME
Data Item	V4_LOCKFLAG	V4_LOCKFLAG
Data Item	V4_PT	V4_PT
Data Item	V4_PTNO	V4_PTNO
Data Item	V4_REPEATSN	V4_REPEATSN
Data Item	V5_BTHYMD	V5_BTHYMD
Data Item	V5_HTU	V5_HTU
Data Item	V5_INV	V5_INV
Data Item	V5_INVSITE	V5_INVSITE
Data Item	V5_PATINIT	V5_PATINIT
Data Item	V5_PTNO	V5_PTNO
Data Item	V5_SEX	V5_SEX
Data Item	V5_SMPKY	V5_SMPKY
Data Item	V5_TDEPCYMD	V5_TDEPCYMD
Data Item	V6_MEDBDT	V6_MEDBDT
Data Item	V7_COMPCD	V7_COMPCD
Data Item	V7_MDCHK	V7_MDCHK
Data Item	V7_PTNO	V7_PTNO

Domain Oracle Views of Oracle Views

Name: Oracle Views of Oracle Views
Code: ORACLE_VIEWS_OF_ORACLE_VIEWS
Label:
Type: A
Length: 40 **Precision:** 0

Check

Low value:
High value:
Default value:
Unit:

Uppercase: No **Lowercase:** No **Can't modify:** No
List of values:

Additional Client Validation Rule

Additional Server Validation Rule

There appear to be some problems with the 2nd level Oracle views. SAS users cannot extract critical data dictionary data from Oracle views without hanging the server. Not only does the SAS user have to reboot the client, the user creates a ghost connection that only the DBA can clean up.

Description

Second level Oracle views form the input for the SAS views of the second level Oracle views. These views could easily be eliminated.
Eliminating these views would simplify the design and greatly speed up access to Oracle data. The SAS views of the second level Oracle views would be replaced by SAS views of first level Oracle views.
Even better would be SAS views of Oracle tables.

Reference List

Reference	Name	Code
Data Item	V3_ACCESSTS	V3_ACCESSTS
Data Item	V3_AEACT	V3_AEACT
Data Item	V3_AECASE	V3_AECASE
Data Item	V3_AEDUR	V3_AEDUR
Data Item	V3_AEDURU	V3_AEDURU
Data Item	V3_AEENDC	V3_AEENDC
Data Item	V3_AEENDDT	V3_AEENDDT
Data Item	V3_AEENDTM	V3_AEENDTM
Data Item	V3_AEENDYMD	V3_AEENDYMD
Data Item	V3_AEFUP	V3_AEFUP
Data Item	V3_AEI	V3_AEI
Data Item	V3_AEINT	V3_AEINT
Data Item	V3_AENM	V3_AENM
Data Item	V3_AENMD	V3_AENMD
Data Item	V3_AENML	V3_AENML
Data Item	V3_AENMO	V3_AENMO
Data Item	V3_AEONDT	V3_AEONDT
Data Item	V3_AEONSET	V3_AEONSET
Data Item	V3_AEONSETU	V3_AEONSETU
Data Item	V3_AEONTM	V3_AEONTM
Data Item	V3_AEONYMD	V3_AEONYMD
Data Item	V3_AEOUT	V3_AEOUT
Data Item	V3_AEPTIT	V3_AEPTIT
Data Item	V3_AEPTITCD	V3_AEPTITCD
Data Item	V3_AEQ	V3_AEQ
Data Item	V3_AEREL	V3_AEREL
Data Item	V3_AESER	V3_AESER
Data Item	V3_AESOC	V3_AESOC
Data Item	V3_AESOCCD	V3_AESOCCD
Data Item	V3_AEST1	V3_AEST1
Data Item	V3_AEST2	V3_AEST2

Reference	Name	Code
Data Item	V3_AEST3	V3_AEST3
Data Item	V3_AEST4	V3_AEST4
Data Item	V3_AETHP	V3_AETHP
Data Item	V3_AETRT	V3_AETRT
Data Item	V3_AEX	V3_AEX
Data Item	V3_CPEVENT	V3_CPEVENT
Data Item	V3_DCMDATE	V3_DCMDATE
Data Item	V3_DCMNAME	V3_DCMNAME
Data Item	V3_DCMSUBNM	V3_DCMSUBNM
Data Item	V3_DOCNUM	V3_DOCNUM
Data Item	V3_LOCKFLAG	V3_LOCKFLAG
Data Item	V3_LOGINTS	V3_LOGINTS
Data Item	V3_LSTCHGTS	V3_LSTCHGTS
Data Item	V3_PTNO	V3_PTNO
Data Item	V3_STUDY	V3_STUDY
Data Item	V3_SUBSETSN	V3_SUBSETSN
Data Item	V3_TPATT	V3_TPATT
Data Item	V3_TRCD	V3_TRCD
Data Item	V4_ACCESSTS	V4_ACCESSTS
Data Item	V4_ACTEVENT	V4_ACTEVENT
Data Item	V4_CPEVENT	V4_CPEVENT
Data Item	V4_DCMSUBNM	V4_DCMSUBNM
Data Item	V4_DCMTIME	V4_DCMTIME
Data Item	V4_DOCNUM	V4_DOCNUM
Data Item	V4_INEXI	V4_INEXI
Data Item	V4_INEXQ	V4_INEXQ
Data Item	V4_INEXX	V4_INEXX
Data Item	V4_INV	V4_INV
Data Item	V4_INVLNAME	V4_INVLNAME
Data Item	V4_INVSITE	V4_INVSITE
Data Item	V4_LOGINTS	V4_LOGINTS
Data Item	V4_LSTCHGTS	V4_LSTCHGTS
Data Item	V4_STUDY	V4_STUDY
Data Item	V4_SUBSETSN	V4_SUBSETSN
Data Item	V4_TPATT	V4_TPATT
Data Item	V4_TRCD	V4_TRCD
Data Item	V5_ACCESSTS	V5_ACCESSTS
Data Item	V5_ACTEVENT	V5_ACTEVENT
Data Item	V5_AGE	V5_AGE
Data Item	V5_AGEQ	V5_AGEQ
Data Item	V5_AGEU	V5_AGEU
Data Item	V5_ALCAB	V5_ALCAB
Data Item	V5_ALCCD	V5_ALCCD
Data Item	V5_ALHCD	V5_ALHCD
Data Item	V5_BTHDT	V5_BTHDT
Data Item	V5_CONDT	V5_CONDT
Data Item	V5_CPEVENT	V5_CPEVENT
Data Item	V5_DCMDATE	V5_DCMDATE
Data Item	V5_DCMNAME	V5_DCMNAME
Data Item	V5_DCMSUBNM	V5_DCMSUBNM
Data Item	V5_DCMTIME	V5_DCMTIME
Data Item	V5_DOCNUM	V5_DOCNUM
Data Item	V5_HT	V5_HT
Data Item	V5_ILDR	V5_ILDR
Data Item	V5_INVLNAME	V5_INVLNAME

Reference	Name	Code
Data Item	V5_LOCKFLAG	V5_LOCKFLAG
Data Item	V5_LOGINTS	V5_LOGINTS
Data Item	V5_LSTCHGTS	V5_LSTCHGTS
Data Item	V5_PT	V5_PT
Data Item	V5_RACE	V5_RACE
Data Item	V5_RACEA	V5_RACEA
Data Item	V5_REPEATSN	V5_REPEATSN
Data Item	V5_SMM	V5_SMM
Data Item	V5_SMOKCD	V5_SMOKCD
Data Item	V5_SMY	V5_SMY
Data Item	V5_STUDY	V5_STUDY
Data Item	V5_SUBSETSN	V5_SUBSETSN
Data Item	V5_TDDT	V5_TDDT
Data Item	V5_TDDURM	V5_TDDURM
Data Item	V5_TDDURY	V5_TDDURY
Data Item	V5_TDEPCDT	V5_TDEPCDT
Data Item	V5_TDHIST	V5_TDHIST
Data Item	V5_TDICD	V5_TDICD
Data Item	V5_TDPT	V5_TDPT
Data Item	V5_TDSPIN	V5_TDSPIN
Data Item	V5_TDYMD	V5_TDYMD
Data Item	V5_TPATT	V5_TPATT
Data Item	V5_TRCD	V5_TRCD
Data Item	V5_WT	V5_WT
Data Item	V5_WTU	V5_WTU
Data Item	V6_ACCESSTS	V6_ACCESSTS
Data Item	V6_ACTEVENT	V6_ACTEVENT
Data Item	V6_ATRCD	V6_ATRCD
Data Item	V6_ATRSTDT	V6_ATRSTDT
Data Item	V6_ATRSTTM	V6_ATRSTTM
Data Item	V6_CPEVENT	V6_CPEVENT
Data Item	V6_DCMDATE	V6_DCMDATE
Data Item	V6_DCMNAME	V6_DCMNAME
Data Item	V6_DCMSUBNM	V6_DCMSUBNM
Data Item	V6_DCMTIME	V6_DCMTIME
Data Item	V6_DOCNUM	V6_DOCNUM
Data Item	V6_DRGSTPDT	V6_DRGSTPDT
Data Item	V6_DRGYMD	V6_DRGYMD
Data Item	V6_FOLLOW	V6_FOLLOW
Data Item	V6_INV	V6_INV
Data Item	V6_INVLNAME	V6_INVLNAME
Data Item	V6_INVSITE	V6_INVSITE
Data Item	V6_LOCKFLAG	V6_LOCKFLAG
Data Item	V6_LOGINTS	V6_LOGINTS
Data Item	V6_LSTCHGTS	V6_LSTCHGTS
Data Item	V6_MEDB	V6_MEDB
Data Item	V6_MEDBOX	V6_MEDBOX
Data Item	V6_MEDBX	V6_MEDBX
Data Item	V6_PT	V6_PT
Data Item	V6_PTNO	V6_PTNO
Data Item	V6_REPEATSN	V6_REPEATSN
Data Item	V6_STUDY	V6_STUDY
Data Item	V6_SUBSETSN	V6_SUBSETSN
Data Item	V6_TERMCD	V6_TERMCD
Data Item	V6_TERMCDC	V6_TERMCDC

Reference	Name	Code
Data Item	V6_TERMOX	V6_TERMOX
Data Item	V6_TERMPOP	V6_TERMPOP
Data Item	V6_TERMX	V6_TERMX
Data Item	V6_TPATT	V6_TPATT
Data Item	V6_TRCD	V6_TRCD
Data Item	V7_ACCESSTS	V7_ACCESSTS
Data Item	V7_ACTEVENT	V7_ACTEVENT
Data Item	V7_ADMOX	V7_ADMOX
Data Item	V7_ADMTKN	V7_ADMTKN
Data Item	V7_ADMX	V7_ADMX
Data Item	V7_BFSTTM	V7_BFSTTM
Data Item	V7_COMP	V7_COMP
Data Item	V7_COMP1HML	V7_COMP1HML
Data Item	V7_COMP2LDT	V7_COMP2LDT
Data Item	V7_COMP2LTM	V7_COMP2LTM
Data Item	V7_COMPACC	V7_COMPACC
Data Item	V7_COMPCH	V7_COMPCH
Data Item	V7_COMPCHDT	V7_COMPCHDT
Data Item	V7_COMPDDT	V7_COMPDDT
Data Item	V7_COMPDIFF	V7_COMPDIFF
Data Item	V7_COMPDISP	V7_COMPDISP
Data Item	V7_COMPEXC	V7_COMPEXC
Data Item	V7_COMPEXP	V7_COMPEXP
Data Item	V7_COMPMISS	V7_COMPMISS
Data Item	V7_COMPRDT	V7_COMPRDT
Data Item	V7_COMPREA	V7_COMPREA
Data Item	V7_COMPRED	V7_COMPRED
Data Item	V7_COMPREL	V7_COMPREL
Data Item	V7_COMPRESC	V7_COMPRESC
Data Item	V7_COMPRET	V7_COMPRET
Data Item	V7_COMPRET2	V7_COMPRET2
Data Item	V7_COMPUSU	V7_COMPUSU
Data Item	V7_COMPXTRA	V7_COMPXTRA
Data Item	V7_CPEVENT	V7_CPEVENT
Data Item	V7_DCMDATE	V7_DCMDATE
Data Item	V7_DCMNAME	V7_DCMNAME
Data Item	V7_DCMSUBNM	V7_DCMSUBNM
Data Item	V7_DCMTIME	V7_DCMTIME
Data Item	V7_DOCNUM	V7_DOCNUM
Data Item	V7_DRGSTPDT	V7_DRGSTPDT
Data Item	V7_DRGSTPTM	V7_DRGSTPTM
Data Item	V7_DRGYMD	V7_DRGYMD
Data Item	V7_INV	V7_INV
Data Item	V7_INVLNAME	V7_INVLNAME
Data Item	V7_INVSITE	V7_INVSITE
Data Item	V7_LOCKFLAG	V7_LOCKFLAG
Data Item	V7_LOGINTS	V7_LOGINTS
Data Item	V7_LSTCHGTS	V7_LSTCHGTS
Data Item	V7_MDCHKDT	V7_MDCHKDT
Data Item	V7_MRIDT	V7_MRIDT
Data Item	V7_MRITM	V7_MRITM
Data Item	V7_PT	V7_PT
Data Item	V7_REPEATSN	V7_REPEATSN
Data Item	V7_STUDY	V7_STUDY
Data Item	V7_SUBSETSN	V7_SUBSETSN

Reference	Name	Code
Data Item	V7_TPATT	V7_TPATT
Data Item	V7_TRCD	V7_TRCD

Domain SAS Adverse Event Reports

Name: SAS Adverse Event Reports
Code: SAS_ADVERSE_EVENT_REPORTS
Label:
Type: A
Length: 40 **Precision:** 0

Check

Low value:
High value:
Default value:
Unit:
Picture:
Uppercase: No **Lowercase:** No **Can't modify:** No
List of values:

Additional Client Validation Rule

Additional Server Validation Rule

All Adverse event reports are coded in Proc Report. A dataset is produced by proc report and that dataset is used for QC.

Description

These reports are encapsulated postscript ready for Adobe publishing software. These reports are not suitable for MS-Word, however QUARK-Express, Ventura Publisher 7, Adobe PageMaker and Adobe FrameMaker can produce Adobe Portable Format without any lose of detail. Note that Postscript printers and PDF writer are not used to produce PDF. Only Adobe Distiller is used. This assures maximum detail. All decimal points and minus signs are cleary represented
.

Domain SAS Objects

Name: SAS Objects
Code: SAS_OBJECTS
Label:
Type: A
Length: 40 **Precision:** 0

Check

Low value:

High value:
Default value:
Unit:
Picture:
Uppercase: No **Lowercase:** No **Can't modify:** No
List of values:

Additional Client Validation Rule

Additional Server Validation Rule

SAS object validation is done nightly.

Description

SAS Objects consist of many format types, ie grseg (postscript) catalogs, SAS datasets, SAS formats, Catams (flat files), etc.

Reference List

Reference	Name	Code
Data Item	ACTEVENT_VISIT_NUMBER	ET_VSN
Data Item	ACTEVENT_Visit_Number	KD_VSN
Data Item	ACTEVENT_VISIT_NUMBER	AE_VSN
Data Item	ACTEVENT_VISIT_NUMBER	PT_VSN
Data Item	ACTEVENT_VISIT_NUMBER	ST_VSN
Data Item	AE_AEK_PKEY_PATIENT_OCCURENCE	AE_AEK
Data Item	AE_AEP_COMPUCRAFT_PRIMARY_KEY	AE_AEP
Data Item	AE_TR_F_STUDY_TRIAL_NUMBER	AE_TR_F
Data Item	AEACT_ACTION_TAKEN	AE_ACT
Data Item	AEAE_AEOUT	AEAE_AEOUT
Data Item	AEAE_AEPTITCD	AEAE_AEPTITCD
Data Item	AEAE_AEREL	AEAE_AEREL
Data Item	AEAE_AESER	AEAE_AESER
Data Item	AEAE_AEST4	AEAE_AEST4
Data Item	AEAE_AETRT	AEAE_AETRT
Data Item	AEAE_TRCD	AEAE_TRCD
Data Item	AEDUR_DURATION	AE_DUR
Data Item	AEENDC_END_DATE_CONTINUED	AE_ENC
Data Item	AEENDDT_END_DATE	AE_EDD
Data Item	AEENDTM_END_TIME	AE_EDT
Data Item	AEENDYMD_REPORTED_END_DATE	AE_RED
Data Item	AEFUP2_FOLLOWUP_TO_OUTCOME	AE_FUP
Data Item	AEI_INDICATOR	AE_IND
Data Item	AEINT_INTENSITY	AE_INT
Data Item	AENM_NAME	AE_NAM
Data Item	AENMO_DERIVED_NAME	AE_DNM
Data Item	AEONDT_ONSET_DATE	AE_OND
Data Item	AEONSETU_TIME_SINCE_LAST_DOSE	AE_TSL
Data Item	AEONTM_ONSET_TIME	AE_ONT
Data Item	AEONYMD_REPORTED_ONSET_DATE	AE_RON

Reference	Name	Code
Data Item	AEOUT_OUTCOME	AE_OUT
Data Item	AEPTIT_PREFERRED_TERM	AE_PRF
Data Item	AEPTITCD_PREFERRED_TERM_CODE	AE_PRT
Data Item	AEQ_QUALIFIER	AE_QUA
Data Item	AEREL_DRUG_RELATIONSHIP	AE_DRE
Data Item	AESER_SERIOUS	AE_SER
Data Item	AESOC_SYSTEM_ORGAN	AE_SOR
Data Item	AESOCCD_SYSTEM_ORGAN_CLASS_CODE	AE_SOC
Data Item	AEST1_SERIOUS_TYPE	AE_ASE
Data Item	AEST2_SERIOUS_TYPE	AE_BSE
Data Item	AEST3_SERIOUS_TYPE	AE_CSE
Data Item	AEST4_SERIOUS_TYPE	AE_DSE
Data Item	AETHP_THERAPY_REQUIRED	AE_THP
Data Item	AETRT_TREATMENT	AE_TRT
Data Item	AEX_COMMENT	AE_CMN
Data Item	ALCAB_HISTORY_OF_ALCOHOL_ABUSE	PT_HAL
Data Item	ALHCD_ALCOHOL_HISTORY	PT_ALH
Data Item	BTHDT_BIRTH_DATE	PT_BDT
Data Item	BTHYMD_REPORTED_BIRTH_DATE	PT_RBD
Data Item	COMP_REPEATSN	COMP_REPEATSN
Data Item	COMP_VISDT	COMP_VISDT
Data Item	COMPDDT_DATE_DISPENSED	KD_DDS
Data Item	COMPDISP_Number_of_Capsules_Dispensed	KD_NCD
Data Item	COMPRDT_Date_Returned	KD_DRT
Data Item	COMPREL_Medication_Taken_Reliably	KD_MTR
Data Item	COMPRET_Number_of_Capsules_Returned	KD_NCR
Data Item	CONDT_INFORMED_CONSENT_DATE	PT_NFR
Data Item	CPP_PT	CPP_PT
Data Item	CPP_TRCD	CPP_TRCD
Data Item	DRGSTPDT_Drug_Discon_Date	KD_DDD
Data Item	DRGSTPDT_DRUG_DISCONTINUATION_DATE	ET_DCD
Data Item	DRGSTPTM_Drug_Discontinuation_Time	KD_DDT
Data Item	DRGYMD_Drug_Discon_Reported_Date	KD_DYD
Data Item	DRGYMD_DRUG_DISCONTINUATION_REPORTED_	ET_DCR
Data Item	ET_ETK_COMPUCRAFT_PRIMARY_KEY	ET_ETP
Data Item	ET_TR_F_STUDY_FK_TO_TRIAL_TABLE	ET_TR_F
Data Item	ILDR_ILLICIT_DRUG_HISTORY	PT_ILD
Data Item	INEXI_INCLUSIONEXCLUSION_INDICATOR	ST_INA
Data Item	INEXINEX_TPATT	INEXINEX_TPATT
Data Item	INEXQ_INCLUSIONEXCLUSION_CRITERIA_N	ST_INN
Data Item	KD_KDK_COMPUCRAFT_PRIMARY_KEY	KD_KDP
Data Item	KD_KDK_PKEY_PATIENT_AND_OCCURENCE	KD_KDK

Reference	Name	Code
Data Item	PT_AGE_AGE_AGE	PT_AGE
Data Item	PT_PATIENT	ET_ETK
Data Item	PT_PATIENT	ST_PTN
Data Item	PT_PATIENT	AE_PTN
Data Item	PT_PATIENT	KD_PTN
Data Item	PT_PATIENT	PT_PTK
Data Item	PT_PTP_PT_PTK_COMPUCRAFT_PRIMARY_KEY	PT_PTP
Data Item	PT_TR_F_STUDY_FK_TO_TRIAL_TABLE	PT_TR_F
Data Item	RACE_RACE	PT_RCE
Data Item	REPEATSN_Occurrence_Number	KD_OCR
Data Item	REPEATSN_OCCURRENCE_NUMBER	ST_OCR
Data Item	REPEATSN_OCCURRENCE_NUMBER	ET_OCR
Data Item	REPEATSN_OCCURRENCE_NUMBER	PT_OCR
Data Item	REPEATSN_OCCURRENCE_NUMBER	AE_OCR
Data Item	SEX_SEX	PT_SEX
Data Item	ST_STK_COMPUCRAFT_PRIMARY_KEY	ST_STP
Data Item	ST_STK_PKEY_PATIENT__OCCURENCE	ST_STK
Data Item	TE_ATB_ATRSTDT_ACTUAL_TREATMENT_BEGIN_DATE	TE_ATB
Data Item	TE_ATE_ATRSPDT_ACTUAL_TREATMENT_STOP_DATE	TE_ATE
Data Item	TE_ATR_ATRCD_ACTUAL_TREATMENT_CODE	TE_ATR
Data Item	TE_OCR_ATRFREQ_ATTUAL_TREATMENT_FREQUENCY	TE_OCR
Data Item	TE_PTN_PT_PATIENT_NUMBER	TE_PTN
Data Item	TE_TEK_PKEY_PATIENT__OCCURENCE	TE_TEK
Data Item	TE_TEP_TE_TEK_COMPUCRAFT_PRIMARY_KEY	TE_TEP
Data Item	TERMCD_TERMINATION	ET_TER
Data Item	TERMPOP_ANALYSIS_POPULATION_FLAG	ET_APO
Data Item	TERMX_TERMINATION_COMMENT	ET_TCM
Data Item	TPATT_PATTERN_CODE	ET_PTN
Data Item	TPATT_PATTERN_CODE	ST_TPN
Data Item	TPATT_PATTERN_CODE	AE_PTC
Data Item	TPATT_Pattern_Code	KD_PTC
Data Item	TR_TRP_TR_TRK_COMPUCRAFT_PRIMARY_KEY	TR_TRP
Data Item	TRCD_Labeling_Abbreviation	KD_LAB
Data Item	TRCD_LABELING_ABBREVIATION	ET_LAB
Data Item	TRCD_LABELING_ABBREVIATION	ST_TRC
Data Item	TRCD_LABELING_ABBREVIATION	AE_LAB
Data Item	VISDT_Visit_Date	KD_VSD
Data Item	VISDT_VISIT_DATE	AE_VSD
Data Item	VISDT_VISIT_DATE	ET_VSD
Data Item	VISDT_VISIT_DATE	ST_VSD
Data Item	VISDT_VISIT_DATE	PT_VSD
Data Item	VISTM_VISIT_TIME	ET_VST
Data Item	VISTM_VISIT_TIME	PT_VST

Reference	Name	Code
Data Item	VISTM_VISIT_TIME	ST_VST
Data Item	VISTM_VISIT_TIME	AE_VST
Data Item	VISTM_Visit_Time	KD_VST

Domain SAS Views of Oracle Views

Name: SAS Views of Oracle Views
Code: SAS_VIEWS_OF_ORACLE_VIEWS
Label: SAS Objects are not Views
Type: A
Length: 40 **Precision:** 0

Check

Low value:
High value:
Default value:
Unit:
Picture:
Uppercase: No **Lowercase:** No **Can't modify:** No
List of values:

Additional Client Validation Rule

Additional Server Validation Rule

Description

SAS views of second level Oracle views further complicate SAS report generation. Most report generators requite a data model (Schema) designed for simple generation of reports. The process model and SAS schema both require a SAS data model to be created from the SAS views of the second level Oracle views.

If the Phamaceutical company does not want to create the SAS schema, then CompCraft suggests all report generation be done with a product like Crystal Reports (Seagate Inc). Sinse Crystal Reports can take avantage of th relational data model, where SAS cannot (because of the many layes of views).

Reference List

Reference	Name	Code
Data Item	AEAE_ACTEVENT	AEAE_ACTEVENT
Data Item	AEAE_AEACT	AEAE_AEACT
Data Item	AEAE_AECASE	AEAE_AECASE
Data Item	AEAE_AEDUR	AEAE_AEDUR
Data Item	AEAE_AEDURU	AEAE_AEDURU
Data Item	AEAE_AEENDC	AEAE_AEENDC
Data Item	AEAE_AEENDDT	AEAE_AEENDDT
Data Item	AEAE_AEENDYMD	AEAE_AEENDYMD
Data Item	AEAE_AEFUP	AEAE_AEFUP
Data Item	AEAE_AEI	AEAE_AEI
Data Item	AEAE_AEINT	AEAE_AEINT

Reference	Name	Code
Data Item	AEAE_AENM	AEAE_AENM
Data Item	AEAE_AENMD	AEAE_AENMD
Data Item	AEAE_AENML	AEAE_AENML
Data Item	AEAE_AENMO	AEAE_AENMO
Data Item	AEAE_AEONDT	AEAE_AEONDT
Data Item	AEAE_AEONSET	AEAE_AEONSET
Data Item	AEAE_AEONSETU	AEAE_AEONSETU
Data Item	AEAE_AEONYMD	AEAE_AEONYMD
Data Item	AEAE_AEOX	AEAE_AEOX
Data Item	AEAE_AEPTIT	AEAE_AEPTIT
Data Item	AEAE_AEQ	AEAE_AEQ
Data Item	AEAE_AESOC	AEAE_AESOC
Data Item	AEAE_AESOCCD	AEAE_AESOCCD
Data Item	AEAE_AEST1	AEAE_AEST1
Data Item	AEAE_AEST2	AEAE_AEST2
Data Item	AEAE_AEST3	AEAE_AEST3
Data Item	AEAE_AETHP	AEAE_AETHP
Data Item	AEAE_AEX	AEAE_AEX
Data Item	AEAE_DCMSUBNM	AEAE_DCMSUBNM
Data Item	AEAE_DOCNUM	AEAE_DOCNUM
Data Item	AEAE_INVNAME	AEAE_INVNAME
Data Item	AEAE_INVSITE	AEAE_INVSITE
Data Item	AEAE_PT	AEAE_PT
Data Item	AEAE_PTNO	AEAE_PTNO
Data Item	AEAE_REPEATSN	AEAE_REPEATSN
Data Item	AEAE_STUDY	AEAE_STUDY
Data Item	AEAE_TPATT	AEAE_TPATT
Data Item	AEAE_VISDT	AEAE_VISDT
Data Item	AEAE_VISTM	AEAE_VISTM
Data Item	COMP_ACTEVENT	COMP_ACTEVENT
Data Item	COMP_COMPDDT	COMP_COMPDDT
Data Item	COMP_COMPDISP	COMP_COMPDISP
Data Item	COMP_COMPRDT	COMP_COMPRDT
Data Item	COMP_COMPREL	COMP_COMPREL
Data Item	COMP_COMPRET	COMP_COMPRET
Data Item	COMP_DCMSUBNM	COMP_DCMSUBNM
Data Item	COMP_DOCNUM	COMP_DOCNUM
Data Item	COMP_DRGSTPDT	COMP_DRGSTPDT
Data Item	COMP_DRGSTPTM	COMP_DRGSTPTM
Data Item	COMP_DRGYMD	COMP_DRGYMD
Data Item	COMP_INVNAME	COMP_INVNAME
Data Item	COMP_INVSITE	COMP_INVSITE
Data Item	COMP_PKEY	COMP_PKEY
Data Item	COMP_PT	COMP_PT
Data Item	COMP_PTNO	COMP_PTNO
Data Item	COMP_STUDY	COMP_STUDY
Data Item	COMP_TPATT	COMP_TPATT
Data Item	COMP_TRCD	COMP_TRCD
Data Item	COMP_VISTM	COMP_VISTM
Data Item	CPP_ACTEVENT	CPP_ACTEVENT
Data Item	CPP_DCMSUBNM	CPP_DCMSUBNM
Data Item	CPP_DOCNUM	CPP_DOCNUM
Data Item	CPP_DRGSTPDT	CPP_DRGSTPDT
Data Item	CPP_DRGYMD	CPP_DRGYMD
Data Item	CPP_INVNAME	CPP_INVNAME

Reference	Name	Code
Data Item	CPP_INVSITE	CPP_INVSITE
Data Item	CPP_PTNO	CPP_PTNO
Data Item	CPP_REPEATSN	CPP_REPEATSN
Data Item	CPP_STUDY	CPP_STUDY
Data Item	CPP_TERMCD	CPP_TERMCD
Data Item	CPP_TERMOX	CPP_TERMOX
Data Item	CPP_TERMPOP	CPP_TERMPOP
Data Item	CPP_TERMX	CPP_TERMX
Data Item	CPP_TPATT	CPP_TPATT
Data Item	CPP_VISDT	CPP_VISDT
Data Item	CPP_VISTM	CPP_VISTM
Data Item	INEXINEX_ACTEVENT	INEXINEX_ACTEVENT
Data Item	INEXINEX_DCMSUBNM	INEXINEX_DCMSUBNM
Data Item	INEXINEX_INEXI	INEXINEX_INEXI
Data Item	INEXINEX_INEXQ	INEXINEX_INEXQ
Data Item	INEXINEX_INVNAME	INEXINEX_INVNAME
Data Item	INEXINEX_INVSITE	INEXINEX_INVSITE
Data Item	INEXINEX_PT	INEXINEX_PT
Data Item	INEXINEX_PTNO	INEXINEX_PTNO
Data Item	INEXINEX_REPEATSN	INEXINEX_REPEATSN
Data Item	INEXINEX_STUDY	INEXINEX_STUDY
Data Item	INEXINEX_TRCD	INEXINEX_TRCD
Data Item	INEXINEX_VISDT	INEXINEX_VISDT
Data Item	INEXINEX_VISTM	INEXINEX_VISTM
Data Item	PATD_ACTEVENT	PATD_ACTEVENT
Data Item	PATD_AGE	PATD_AGE
Data Item	PATD_AGEQ	PATD_AGEQ
Data Item	PATD_AGEU	PATD_AGEU
Data Item	PATD_ALCAB	PATD_ALCAB
Data Item	PATD_ALHCD	PATD_ALHCD
Data Item	PATD_BTHDT	PATD_BTHDT
Data Item	PATD_BTHYMD	PATD_BTHYMD
Data Item	PATD_CONDT	PATD_CONDT
Data Item	PATD_DCMSUBNM	PATD_DCMSUBNM
Data Item	PATD_DOCNUM	PATD_DOCNUM
Data Item	PATD_ILDR	PATD_ILDR
Data Item	PATD_INVNAME	PATD_INVNAME
Data Item	PATD_INVSITE	PATD_INVSITE
Data Item	PATD_PATINIT	PATD_PATINIT
Data Item	PATD_PT	PATD_PT
Data Item	PATD_PTNO	PATD_PTNO
Data Item	PATD_RACE	PATD_RACE
Data Item	PATD_REPEATSN	PATD_REPEATSN
Data Item	PATD_SEX	PATD_SEX
Data Item	PATD_SMM	PATD_SMM
Data Item	PATD_SMOKCD	PATD_SMOKCD
Data Item	PATD_SMPKY	PATD_SMPKY
Data Item	PATD_SMY	PATD_SMY
Data Item	PATD_STUDY	PATD_STUDY
Data Item	PATD_TPATT	PATD_TPATT
Data Item	PATD_TRCD	PATD_TRCD
Data Item	PATD_VISDT	PATD_VISDT
Data Item	PATD_VISTM	PATD_VISTM

Data Flows

Data Flow List

Name	Code
Print Listing 5_2_5	PRINT_LISTING_5_2_5
Print Listing 5_2_6	PRINT_LISTING_5_2_6
Print Listing 5_2_7	PRINT_LISTING_5_2_7
Print Table 5_2_1	PRINT_TABLE_5_2_1
Print Table 5_2_2	PRINT_TABLE_5_2_2
Print Table 5_2_3	PRINT_TABLE_5_2_3
Print Table 5_2_4	PRINT_TABLE_5_2_4
SAS Patient to Treatment	SAS_PATIENT_TO_TREATMENT
T1 Clinical States Fields	T1_CLINICAL__STATES_FIELDS
T2 Select DCMS Fields	T2_SELECT_DCMS_FIELDS
T3 Select Trial Level Fields	T3_SELECT_TRIAL_LEVEL_FIELDS
T4 Select Received DCMS Fields	T4_SELECT_RECEIVED_DCMS_FIELDS
T5 Select CRF Response Fields	T5_SELECT__CRF_RESPONSE_FIELDS

Data Flow Print Listing 5_2_5

Name: Print Listing 5_2_5
Code: PRINT_LISTING_5_2_5
Label:

Description

Listing E
(Appendix 15.9.2 LISTING 5.2.X)

Adverse Events Leading to Treatment Discontinuation, by Treatment at Onset, WHO System Organ Class, Preferred Term, and Investigator's Reported Term
[A summary table (I) for this listing is optional - see below]

Data Flow Print Listing 5_2_6

Name: Print Listing 5_2_6
Code: PRINT_LISTING_5_2_6
Label:

Description

isting F
(Appendix 15.9.2 LISTING 5.2.X)
¸Adverse Event Data by Treatment at Onset, WHO System Organ Class and Preferred Term
(Source data Listing G and optional Listing J)

Data Flow Print Listing 5_2_7

Name: Print Listing 5_2_7

Code: PRINT_LISTING_5_2_7
Label:

Description

Listing G
(Appendix 15.12
LISTING 5.2.1)¸Adverse Event Data and Comments, by Treatment Group (or Treatment Sequence) and Patient
(Source data CRFs)

Data Flow Print Table 5_2_1

Name: Print Table 5_2_1
Code: PRINT_TABLE_5_2_1
Label:

Description

Table A
(Appendix 15.9.2. TABLE 5.2.1)

Number of Patients with Adverse Events by Treatment at Onset, WHO System Organ Class and Preferred Term
(Source data Listing F)

Data Flow Print Table 5_2_2

Name: Print Table 5_2_2
Code: PRINT_TABLE_5_2_2
Label:

Description

able B
(Appendix 15.9.2. TABLE 5.2.2)

Number of Patients with Adverse Events by Treatment at Onset, WHO System Organ Class, Preferred Term and Worst Intensity
(Source data Listing F)

Data Flow Print Table 5_2_3

Name: Print Table 5_2_3
Code: PRINT_TABLE_5_2_3
Label:

Description

Table C
(Appendix 15_9_2 TABLE 5_2_3)

Number of Patients with Adverse Events by Treatment at Onset, WHO System Organ Class, Preferred Term and Investigator's Final Relationship
(Source data Listing F)

Data Flow Print Table 5_2_4

Name: Print Table 5_2_4
Code: PRINT_TABLE_5_2_4
Label:

Data Flow SAS Patient to Treatment

Name: SAS Patient to Treatment
Code: SAS_PATIENT_TO_TREATMENT
Label: Function to Assign Treatment codes to Patients

Data Item List

Name	Code
TE_ATB_ATRSTDT_ACTUAL_TREATMENT_BEGIN_DATE	TE_ATB
TE_ATE_ATRSPDT_ACTUAL_TREATMENT_STOP_DATE	TE_ATE
TE_ATR_ATRCD_ACTUAL_TREATMENT_CODE	TE_ATR
TE_OCR_ATRFREQ_ATTUAL_TREATMENT_FREQUENCY	TE_OCR
TE_PTN_PT_PATIENT_NUMBER	TE_PTN
TE_TEK_PKEY_PATIENT__OCCURENCE	TE_TEK
TE_TEP_TE_TEK_COMPUCRAFT_PRIMARY_KEY	TE_TEP

Data Flow T1 Clinical States Fields

Name: T1 Clinical States Fields
Code: T1_CLINICAL__STATES_FIELDS
Label:

Data Item List

Name	Code
T1_ACCESS_ONLY_IN_BROWSE_IND	T1_ACCESS_ONLY_IN_BROWSE_IND
T1_COMMENT_TEXT	T1_COMMENT_TEXT
T1_CREATED_BY	T1_CREATED_BY
T1_CREATION_TS	T1_CREATION_TS
T1_CURRENT_FLAG	T1_CURRENT_FLAG
T1_DATA_ENTRY_ENABLED_FLAG	T1_DATA_ENTRY_ENABLED_FLAG
T1_DCI_BOOK_DFLT_IN_DE_IND	T1_DCI_BOOK_DFLT_IN_DE_IND
T1_DEFAULT_DE_PAGE_HEIGHT	T1_DEFAULT_DE_PAGE_HEIGHT
T1_DEFAULT_DE_PAGE_WIDTH	T1_DEFAULT_DE_PAGE_WIDTH

Name	Code
T1_DISC_RESOLVE_IN_DE_IND	T1_DISC_RESOLVE_IN_DE_IND
T1_FIRST_PASS_FROM_LOGIN_FLAG	T1_FIRST_PASS_FROM_LOGIN_FLAG
T1_FROZEN_FLAG	T1_FROZEN_FLAG
T1_IMAGING_ENABLED_FLAG	T1_IMAGING_ENABLED_FLAG
T1_LAST_BATCH_TS	T1_LAST_BATCH_TS
T1_LAST_DATA_REVISION_SN	T1_LAST_DATA_REVISION_SN
T1_LAST_VIEW_UPDATE_TS	T1_LAST_VIEW_UPDATE_TS
T1_MANUAL_DISC_IN_BROWSE_IND	T1_MANUAL_DISC_IN_BROWSE_IND
T1_OCL_THES_DISC_AT_DE_IND	T1_OCL_THES_DISC_AT_DE_IND
T1_OCL_THES_LOV_IND	T1_OCL_THES_LOV_IND
T1_PASS2_NOT_BY_PASS1_IND	T1_PASS2_NOT_BY_PASS1_IND
T1_PRIVILEGED_UPDATE_IND	T1_PRIVILEGED_UPDATE_IND
T1_SECOND_PASS_ALERT_IND	T1_SECOND_PASS_ALERT_IND
T1_SECOND_PASS_REQUIRED_FLAG	T1_SECOND_PASS_REQUIRED_FLAG
T1_THESAURUS_LOV_IND	T1_THESAURUS_LOV_IND
T1_UNENROLLED_ALERT_IND	T1_UNENROLLED_ALERT_IND
T1_UNIVARIATE_ALERT_IND	T1_UNIVARIATE_ALERT_IND

Data Flow T2 Select DCMS Fields

Name: T2 Select DCMS Fields
Code: T2_SELECT_DCMS_FIELDS
Label:

Data Item List

Name	Code
T2_CLINICAL_STUDY_ID	T2_CLINICAL_STUDY_ID
T2_COLLECTS_LAB_TESTS_FLAG	T2_COLLECTS_LAB_TESTS_FLAG
T2_CREATED_BY	T2_CREATED_BY
T2_CREATION_TS	T2_CREATION_TS
T2_DATE_ORDER_CODE	T2_DATE_ORDER_CODE
T2_DCM_DCI_QG_TYPE_CODE	T2_DCM_DCI_QG_TYPE_CODE
T2_DCM_ID	T2_DCM_ID
T2_DCM_LAYOUT_SN	T2_DCM_LAYOUT_SN
T2_DCM_QUAL_VALUE_TEXT	T2_DCM_QUAL_VALUE_TEXT
T2_DCM_STATUS_CODE	T2_DCM_STATUS_CODE
T2_DCM_SUBSET_SN	T2_DCM_SUBSET_SN
T2_DEFAULT_PAGE_HEIGHT	T2_DEFAULT_PAGE_HEIGHT
T2_DEFAULT_PAGE_WIDTH	T2_DEFAULT_PAGE_WIDTH
T2_DESCRIPTION	T2_DESCRIPTION
T2_DISPLAY_SN	T2_DISPLAY_SN
T2_DOMAIN	T2_DOMAIN
T2_HELP_TEXT	T2_HELP_TEXT
T2_LAST_STATUS_CHANGE_TS	T2_LAST_STATUS_CHANGE_TS
T2_LAYOUT_EDITED_FLAG	T2_LAYOUT_EDITED_FLAG
T2_LAYOUT_GENERATION_TS	T2_LAYOUT_GENERATION_TS
T2_LAYOUT_REGENERATION_REQ_FLAG	T2_LAYOUT_REGENERATION_REQ_FLAG
T2_LAYOUT_VER_NUM	T2_LAYOUT_VER_NUM
T2_MODIFICATION_TS	T2_MODIFICATION_TS
T2_MODIFIED_BY	T2_MODIFIED_BY
T2_NAME	T2_NAME

Name	Code
T2_ORIGINAL_DCM_ID	T2_ORIGINAL_DCM_ID
T2_ORIGINAL_DCM_LAYOUT_SN	T2_ORIGINAL_DCM_LAYOUT_SN
T2_ORIGINAL_DCM_SUBSET_SN	T2_ORIGINAL_DCM_SUBSET_SN
T2_PROD_GENERATION_TS	T2_PROD_GENERATION_TS
T2_QUAL_QUESTION_DVG_ID	T2_QUAL_QUESTION_DVG_ID
T2_QUAL_QUESTION_DVG_SUBSET_NUM	T2_QUAL_QUESTION_DVG_SUBSET_NUM
T2_QUAL_QUESTION_ID	T2_QUAL_QUESTION_ID
T2_QUAL_QUESTION_PROMPT	T2_QUAL_QUESTION_PROMPT
T2_REPLICATION_IND	T2_REPLICATION_IND
T2_RETIREMENT_REASON_TYPE_CODE	T2_RETIREMENT_REASON_TYPE_CODE
T2_SHORT_NAME	T2_SHORT_NAME
T2_STATUS_COMMENT_TEXT	T2_STATUS_COMMENT_TEXT
T2_SUBSET_NAME	T2_SUBSET_NAME
T2_WINDOW_HEIGHT	T2_WINDOW_HEIGHT
T2_WINDOW_WIDTH	T2_WINDOW_WIDTH

Data Flow T3 Select Trial Level Fields

Name: T3 Select Trial Level Fields
Code: T3_SELECT_TRIAL_LEVEL_FIELDS
Label: OCL Investigators

Data Item List

Name	Code
T3_ACTIVE_FLAG	T3_ACTIVE_FLAG
T3_ADDRESS_LINE_1	T3_ADDRESS_LINE_1
T3_ADDRESS_LINE_2	T3_ADDRESS_LINE_2
T3_ADDRESS_LINE_3	T3_ADDRESS_LINE_3
T3_ADDRESS_NAME	T3_ADDRESS_NAME
T3_CITY	T3_CITY
T3_COUNTRY	T3_COUNTRY
T3_CREATED_BY	T3_CREATED_BY
T3_CREATION_TS	T3_CREATION_TS
T3_FIRST_NAME	T3_FIRST_NAME
T3_INITIALS	T3_INITIALS
T3_INVESTIGATOR	T3_INVESTIGATOR
T3_INVESTIGATOR_ID	T3_INVESTIGATOR_ID
T3_LAST_NAME	T3_LAST_NAME
T3_MODIFICATION_TS	T3_MODIFICATION_TS
T3_MODIFIED_BY	T3_MODIFIED_BY
T3_OWNING_LOCATION	T3_OWNING_LOCATION
T3_PHONE_NUMBER	T3_PHONE_NUMBER
T3_POSTAL_CODE	T3_POSTAL_CODE
T3_STATE	T3_STATE
T3_TITLE	T3_TITLE

Data Flow T4 Select Received DCMS Fields

Name: T4 Select Received DCMS Fields
Code: T4_SELECT_RECEIVED_DCMS_FIELDS

Label:

Data Item List

Name	Code
T4_ACCESSIBLE_TS	T4_ACCESSIBLE_TS
T4_ACTUAL_EVENT_ID	T4_ACTUAL_EVENT_ID
T4_BLANK_FLAG	T4_BLANK_FLAG
T4_CLIN_PLAN_EVE_ID	T4_CLIN_PLAN_EVE_ID
T4_CLIN_PLAN_EVE_NAME	T4_CLIN_PLAN_EVE_NAME
T4_CLINICAL_STUDY_ID	T4_CLINICAL_STUDY_ID
T4_COMMENT_TEXT	T4_COMMENT_TEXT
T4_DATA_COMMENT_TEXT	T4_DATA_COMMENT_TEXT
T4_DATA_LOCK_FLAG	T4_DATA_LOCK_FLAG
T4_DATA_LOCK_TS	T4_DATA_LOCK_TS
T4_DCM_DATE	T4_DCM_DATE
T4_DCM_ID	T4_DCM_ID
T4_DCM_LAYOUT_SN	T4_DCM_LAYOUT_SN
T4_DCM_SUBSET_SN	T4_DCM_SUBSET_SN
T4_DCM_TIME	T4_DCM_TIME
T4_DOCUMENT_NUMBER	T4_DOCUMENT_NUMBER
T4_END_TS	T4_END_TS
T4_ENTERED_BY	T4_ENTERED_BY
T4_INVESTIGATOR	T4_INVESTIGATOR
T4_INVESTIGATOR_ID	T4_INVESTIGATOR_ID
T4_LAB	T4_LAB
T4_LAB_ASSIGNMENT_TYPE_CODE	T4_LAB_ASSIGNMENT_TYPE_CODE
T4_LAB_ID	T4_LAB_ID
T4_LAB_MODIFICATION_TS	T4_LAB_MODIFICATION_TS
T4_LAST_DATA_CHANGE_TS	T4_LAST_DATA_CHANGE_TS
T4_LAST_STATUS_CHANGE_TS	T4_LAST_STATUS_CHANGE_TS
T4_LOG_IN_TS	T4_LOG_IN_TS
T4_MODIFICATION_TS	T4_MODIFICATION_TS
T4_MODIFIED_BY	T4_MODIFIED_BY
T4_PASS_ONE_BY	T4_PASS_ONE_BY
T4_PASS_ONE_TS	T4_PASS_ONE_TS
T4_PASS_TWO_BY	T4_PASS_TWO_BY
T4_PASS_TWO_TS	T4_PASS_TWO_TS
T4_PATIENT	T4_PATIENT
T4_PATIENT_POSITION_ID	T4_PATIENT_POSITION_ID
T4_QUALIFYING_VALUE	T4_QUALIFYING_VALUE
T4_RECEIVED_DCI_ID	T4_RECEIVED_DCI_ID
T4_RECEIVED_DCM_ENTRY_TS	T4_RECEIVED_DCM_ENTRY_TS
T4_RECEIVED_DCM_ID	T4_RECEIVED_DCM_ID
T4_RECEIVED_DCM_STATUS_CODE	T4_RECEIVED_DCM_STATUS_CODE
T4_SITE	T4_SITE
T4_SITE_ID	T4_SITE_ID
T4_SN	T4_SN
T4_SUBEVENT_NUMBER	T4_SUBEVENT_NUMBER
T4_VISIT_NUMBER	T4_VISIT_NUMBER

Data Flow T5 Select CRF Response Fields

T5 Select CRF Response Fields

Code: T5_SELECT__CRF_RESPONSE_FIELDS
Label: Response data

Description

Response data is made available. However the tables with the Questions and possible responses are not known. These iformation will come from other external tables.

Data Item List

Name	Code
T5_AUDIT_COMMENT_TEXT	T5_AUDIT_COMMENT_TEXT
T5_CLINICAL_STUDY_ID	T5_CLINICAL_STUDY_ID
T5_DATA_CHANGE_REASON_TYPE_CODE	T5_DATA_CHANGE_REASON_TYPE_CODE
T5_DATA_COMMENT_TEXT	T5_DATA_COMMENT_TEXT
T5_DCM_QUESTION_GROUP_ID	T5_DCM_QUESTION_GROUP_ID
T5_DCM_QUESTION_ID	T5_DCM_QUESTION_ID
T5_DISCREPANCY_INDICATOR	T5_DISCREPANCY_INDICATOR
T5_END_TS	T5_END_TS
T5_ENTERED_BY	T5_ENTERED_BY
T5_EXCEPTION_VALUE_TEXT	T5_EXCEPTION_VALUE_TEXT
T5_RECEIVED_DCM_ID	T5_RECEIVED_DCM_ID
T5_REPEAT_SN	T5_REPEAT_SN
T5_RESPONSE_ENTRY_TS	T5_RESPONSE_ENTRY_TS
T5_RESPONSE_ID	T5_RESPONSE_ID
T5_SECOND_PASS_INDICATOR	T5_SECOND_PASS_INDICATOR
T5_VALIDATION_STATUS	T5_VALIDATION_STATUS
T5_VALUE_TEXT	T5_VALUE_TEXT

External Entities

External Entity List

Name	Code
Appendix 15_9_2 LISTING 5_2_1	APPENDIX_15_9_2_LISTING_5_2_1
Appendix 15_9_2 LISTING 5_2_2	APPENDIX_15_9_2_LISTING_5_2_2
Appendix 15_9_2 LISTING 5_2_3	APPENDIX_15_9_2_LISTING_5_2_3
Appendix 15_9_2 LISTING 5_2_4	APPENDIX_15_9_2_LISTING_5_2_4
Appendix 15_9_2 TABLE 5_2_1	APPENDIX_15_9_2__TABLE_5_2_1
Appendix 15_9_2 TABLE 5_2_2	APPENDIX_15_9_2_TABLE_5_2_2
Appendix 15_9_2 TABLE 5_2_3	APPENDIX_15_9_2_TABLE_5_2_3
Patient to Treatment SAS Table	PATIENT_TO_TREATMENT_SAS_TABLE
Table T1 CLINICAL STUDY STATES	TABLE_T1_CLINICAL_STUDY_STATES
Table T2 DCMS	TABLE_T2_DCMS
Table T3 OCL INVESTIGATORS	TABLE_T3_OCL_INVESTIGATORS
Table T4 RECEIVED DCMS	TABLE_T4_RECEIVED_DCMS
Table T5 RESPONSES	TABLE_T5_RESPONSES

External Entity Appendix 15_9_2 LISTING 5_2_1

Name: Appendix 15_9_2 LISTING 5_2_1

Code: APPENDIX_15_9_2_LISTING_5_2_1
Label:

Description

Listing D
(Appendix 15.9.2 LISTING 5.2.X)

Patients with Serious Adverse Events by Treatment at Onset, WHO System Organ Class and Preferred Term
[A summary table (H) for this listing is optional - see below]

Flow List

Connected via	Connected to	Src	Dst
Print Table 5_2_4	Publish (Process)		X

External Entity Appendix 15_9_2 LISTING 5_2_2

Name: Appendix 15_9_2 LISTING 5_2_2
Code: APPENDIX_15_9_2_LISTING_5_2_2
Label:

Description

Listing E
(Appendix 15.9.2 LISTING 5.2.X)

Adverse Events Leading to Treatment Discontinuation, by Treatment at Onset, WHO System Organ Class, Preferred Term, and Investigator's Reported Term
[A summary table (I) for this listing is optional - see below]

Flow List

Connected via	Connected to	Src	Dst
Print Listing 5_2_5	Publish (Process)		X

External Entity Appendix 15_9_2 LISTING 5_2_3

Name: Appendix 15_9_2 LISTING 5_2_3
Code: APPENDIX_15_9_2_LISTING_5_2_3
Label:

Description

Listing F
(Appendix 15.9.2 LISTING 5.2.X)
¸Adverse Event Data by Treatment at Onset, WHO System Organ Class and Preferred Term
(Source data Listing G and optional Listing J)

Flow List

Connected via	Connected to	Src	Dst
Print Listing 5_2_6	Publish (Process)		X

External Entity Appendix 15_9_2 LISTING 5_2_4

Name: Appendix 15_9_2 LISTING 5_2_4
Code: APPENDIX_15_9_2_LISTING_5_2_4
Label:

Description

Listing G
(Appendix 15.12
LISTING 5.2.1)¸Adverse Event Data and Comments, by Treatment Group (or Treatment Sequence) and Patient (Source data CRFs)

Flow List

Connected via	Connected to	Src	Dst
Print Listing 5_2_7	Publish (Process)		X

External Entity Appendix 15_9_2 TABLE 5_2_1

Name: Appendix 15_9_2 TABLE 5_2_1
Code: APPENDIX_15_9_2__TABLE_5_2_1
Label:

Description

Table A
(Appendix 15.9.2. TABLE 5.2.1)

Number of Patients with Adverse Events by Treatment at Onset, WHO System Organ Class and Preferred Term (Source data Listing F)

Flow List

Connected via	Connected to	Src	Dst
Print Table 5_2_1	Publish (Process)		X

External Entity Appendix 15_9_2 TABLE 5_2_2

Name: Appendix 15_9_2 TABLE 5_2_2
Code: APPENDIX_15_9_2_TABLE_5_2_2

Label:

Description

Table B
(Appendix 15.9.2. TABLE 5.2.2)

Number of Patients with Adverse Events by Treatment at Onset, WHO System Organ Class, Preferred Term and Worst Intensity
(Source data Listing F)

Flow List

Connected via	Connected to	Src	Dst
Print Table 5_2_2	Publish (Process)		X

External Entity Appendix 15_9_2 TABLE 5_2_3

Name: Appendix 15_9_2 TABLE 5_2_3
Code: APPENDIX_15_9_2_TABLE_5_2_3
Label:

Description

Table C
(Appendix 15_9_2 TABLE 5_2_3)

Number of Patients with Adverse Events by Treatment at Onset, WHO System Organ Class, Preferred Term and Investigator's Final Relationship
(Source data Listing F)

Flow List

Connected via	Connected to	Src	Dst
Print Table 5_2_3	Publish (Process)		X

External Entity Patient to Treatment SAS Table

Name: Patient to Treatment SAS Table
Code: PATIENT_TO_TREATMENT_SAS_TABLE
Label:

Flow List

Connected via	Connected to	Src	Dst
SAS Patient to Treatment	Publish (Process)	X	

External Entity Table T1 CLINICAL STUDY STATES

Name: Table T1 CLINICAL STUDY STATES
Code: TABLE_T1_CLINICAL_STUDY_STATES
Label:

Flow List

Connected via	Connected to	Src	Dst
T1 Clinical States Fields	Publish (Process)	X	

External Entity Table T2 DCMS

Name: Table T2 DCMS
Code: TABLE_T2_DCMS
Label:

Flow List

Connected via	Connected to	Src	Dst
T2 Select DCMS Fields	Publish (Process)	X	

External Entity Table T3 OCL INVESTIGATORS

Name: Table T3 OCL INVESTIGATORS
Code: TABLE_T3_OCL_INVESTIGATORS
Label:

Flow List

Connected via	Connected to	Src	Dst
T3 Select Trial Level Fields	Publish (Process)	X	

External Entity Table T4 RECEIVED DCMS

Name: Table T4 RECEIVED DCMS
Code: TABLE_T4_RECEIVED_DCMS
Label:

Flow List

Connected via	Connected to	Src	Dst
T4 Select Received DCMS Fields	Publish (Process)	X	

External Entity Table T5 RESPONSES

Name: Table T5 RESPONSES
Code: TABLE_T5_RESPONSES
Label: Main Fact Table for Oracle Clinical

Description

The Reponses table contains all the data recorded on all the CRF forms for a given trial. The table is skinny but very long. The table contains 17 columns. Key columns appear to be

DCM_QUESTION_ID -- Foreign Key to Question Text
RESPONSE_ID -- Foreign Key to Possible Responses
VALUE_TEXT -- Response Text from CRF

Note the many administative columns.

Flow List

Connected via	Connected to	Src	Dst
T5 Select CRF Response Fields	Publish (Process)	X	

Data stores

Data Store List

Name	Code
ADVERSE EVENT TABLE	ADVERSE_EVENT_TABLE
DEMOGRAPHICS	DEMOGRAPHICS
END_OF_TRIAL	END_OF_TRIAL
KEY_DRUG_DATES	KEY_DRUG_DATES
SAS View AEAE of Oracle View	SAS_VIEW_AEAE_OF_ORACLE_VIEWS
SAS View COMP of Oracle View	SAS_VIEW_COMP_OF_ORACLE_VIEW
SAS View CPP of Oracle View	SAS_VIEW_CPP_OF_ORACLE_VIEW
SAS View INEXINEX of Oracle View	SAS_VIEW_INEXINEX_OF_ORACLE_VIEW
SAS View PATD of Oracle View	SAS_VIEW_PATD_OF_ORACLE_VIEW
SUBSET_PATIENTS	SUBSET_PATIENTS
TRIAL_CONSTANTS	TRIAL_CONSTANTS
V1 RCDMS VIEW	V1_RCDMS_VIEW
V2 RESPONSES VIEW	V2_RESPONSES_VIEW
V3 Oracle View AEAE	V3_ORACLE_VIEW_AEAE
V4 Oracle View CPP	V4_ORACLE_VIEW_CPP
V5 Oracle View INEXINEX	V5_ORACLE_VIEW_INEXINEX
V6 Oracle View PATD	V6ORACLE_VIEW_PATD
V7 Oracle View COMP	V7_ORACLE_VIEW_COMP

Data Store ADVERSE EVENT TABLE

Name: ADVERSE EVENT TABLE

ADVERSE_EVENT_TABLE

Label:

Number: 10

Description

This table is a indexed SAS dataset and has been optimized for Adverse Event Reporting. This table is part of the SAS schema, described in the Adverse Event data Model.

Data Item List

Name	Code
AEACT_ACTION_TAKEN	AE_ACT
AE_AEK_PKEY_PATIENT_OCCURENCE	AE_AEK
AE_AEP_COMPUCRAFT_PRIMARY_KEY	AE_AEP
AEST1_SERIOUS_TYPE	AE_ASE
AEST2_SERIOUS_TYPE	AE_BSE
AEX_COMMENT	AE_CMN
AEST3_SERIOUS_TYPE	AE_CSE
AENMO_DERIVED_NAME	AE_DNM
AEREL_DRUG_RELATIONSHIP	AE_DRE
AEST4_SERIOUS_TYPE	AE_DSE
AEDUR_DURATION	AE_DUR
AEENDDT_END_DATE	AE_EDD
AEENDTM_END_TIME	AE_EDT
AEENDC_END_DATE_CONTINUED	AE_ENC
AEFUP2_FOLLOWUP_TO_OUTCOME	AE_FUP
AEI_INDICATOR	AE_IND
AEINT_INTENSITY	AE_INT
TRCD_LABELING_ABBREVIATION	AE_LAB
AENM_NAME	AE_NAM
REPEATSN_OCCURRENCE_NUMBER	AE_OCR
AEONDT_ONSET_DATE	AE_OND
AEONTM_ONSET_TIME	AE_ONT
AEOUT_OUTCOME	AE_OUT
AEPTIT_PREFERRED_TERM	AE_PRF
AEPTITCD_PREFERRED_TERM_CODE	AE_PRT
TPATT_PATTERN_CODE	AE_PTC
PT_PATIENT	AE_PTN
AEQ_QUALIFIER	AE_QUA
AEENDYMD_REPORTED_END_DATE	AE_RED
AEONYMD_REPORTED_ONSET_DATE	AE_RON
AESER_SERIOUS	AE_SER
AESOCCD_SYSTEM_ORGAN_CLASS_CODE	AE_SOC
AESOC_SYSTEM_ORGAN	AE_SOR
AETHP_THERAPY_REQUIRED	AE_THP
AE_TR_F_STUDY_TRIAL_NUMBER	AE_TR_F
AETRT_TREATMENT	AE_TRT
AEONSETU_TIME_SINCE_LAST_DOSE	AE_TSL
VISDT_VISIT_DATE	AE_VSD
ACTEVENT_VISIT_NUMBER	AE_VSN
VISTM_VISIT_TIME	AE_VST
AE_AEP_PRIMARY_KEY_ADVERSE_EVENTS	AEP_PRIMARY_KEY_ADVERSE_EVENTS

Flow List

Connected via	Connected to	Src	Dst
Adverse Event Data	Create SAS Reports (Process)	X	
Adverse Event SAS Table	Adverse Events (Process)		X

Data Store DEMOGRAPHICS

Name: DEMOGRAPHICS
Code: DEMOGRAPHICS
Label:
Number: 7

Description

This is the Demographics table in the SAS schema.

Data Item List

Name	Code
PT_AGE_AGE_AGE	PT_AGE
ALHCD_ALCOHOL_HISTORY	PT_ALH
BTHDT_BIRTH_DATE	PT_BDT
ALCAB_HISTORY_OF_ALCOHOL_ABUSE	PT_HAL
ILDR_ILLICIT_DRUG_HISTORY	PT_ILD
CONDT_INFORMED_CONSENT_DATE	PT_NFR
REPEATSN_OCCURRENCE_NUMBER	PT_OCR
PT_PATIENT	PT_PTK
PT_PTP_PT_PTK_COMPUCRAFT_PRIMARY_KEY	PT_PTP
BTHYMD_REPORTED_BIRTH_DATE	PT_RBD
RACE_RACE	PT_RCE
SEX_SEX	PT_SEX
SMPKY_SMOKING_HISTORY__PACK_YEARS	PT_SMP
SMY_SMOKING_HISTORY__YEAR_STOPPED	PT_SMY
PT_TR_F_STUDY_FK_TO_TRIAL_TABLE	PT_TR_F
VISDT_VISIT_DATE	PT_VSD
ACTEVENT_VISIT_NUMBER	PT_VSN
VISTM_VISIT_TIME	PT_VST

Flow List

Connected via	Connected to	Src	Dst
Demographics Data	Create SAS Reports (Process)	X	
Demographics Table	Demographics SAS Table (Process)		X

Data Store END_OF_TRIAL

Name: END_OF_TRIAL
Code: END_OF_TRIAL
Label:
Number: 5

Description

This is the completion of trail table in the SAS schema.

Data Item List

Name	Code
TERMPOP_ANALYSIS_POPULATION_FLAG	ET_APO
DRGSTPDT_DRUG_DISCONTINUATION_DATE	ET_DCD
DRGYMD_DRUG_DISCONTINUATION_REPORTED_	ET_DCR
PT_PATIENT	ET_ETK
ET_ETK_COMPUCRAFT_PRIMARY_KEY	ET_ETP
TRCD_LABELING_ABBREVIATION	ET_LAB
REPEATSN_OCCURRENCE_NUMBER	ET_OCR
TPATT_PATTERN_CODE	ET_PTN
TERMX_TERMINATION_COMMENT	ET_TCM
TERMCD_TERMINATION	ET_TER
ET_TR_F_STUDY_FK_TO_TRIAL_TABLE	ET_TR_F
VISDT_VISIT_DATE	ET_VSD
ACTEVENT_VISIT_NUMBER	ET_VSN
VISTM_VISIT_TIME	ET_VST

Flow List

Connected via	Connected to	Src	Dst
End of Trial Data	Create SAS Reports (Process)	X	
End of Trial SAS Table	Create End of Trial SAS Table (Process)		X

Data Store KEY_DRUG_DATES

Name: KEY_DRUG_DATES
Code: KEY_DRUG_DATES
Label:
Number: 9

Description

This table contains key dates for drug administration. This table is part of the SAS schema.

Data Item List

Name	Code
DRGSTPDT_Drug_Discon_Date	KD_DDD
COMPDDT_DATE_DISPENSED	KD_DDS

Name	Code
DRGSTPTM_Drug_Discontinuation_Time	KD_DDT
COMPRDT_Date_Returned	KD_DRT
DRGYMD_Drug_Discon_Reported_Date	KD_DYD
KD_KDK_PKEY_PATIENT_AND_OCCURENCE	KD_KDK
KD_KDK_COMPUCRAFT_PRIMARY_KEY	KD_KDP
TRCD_Labeling_Abbreviation	KD_LAB
COMPREL_Medication_Taken_Reliably	KD_MTR
COMPDISP_Number_of_Capsules_Dispensed	KD_NCD
COMPRET_Number_of_Capsules_Returned	KD_NCR
REPEATSN_Occurrence_Number	KD_OCR
TPATT_Pattern_Code	KD_PTC
PT_PATIENT	KD_PTN
VISDT_Visit_Date	KD_VSD
ACTEVENT_Visit_Number	KD_VSN
VISTM_Visit_Time	KD_VST

Flow List

Connected via	Connected to	Src	Dst
Key Dates	Create SAS Reports (Process)	X	
Key Drug Dates	Key Drug dates (Process)		X

Data Store SAS View AEAE of Oracle View

Name: SAS View AEAE of Oracle View
Code: SAS_VIEW_AEAE_OF_ORACLE_VIEWS
Label:
Number: 1

Description

AEAE

```
 select
        STUDY         as STUDY    label='Trial Number' format $15.
 ,      PT            as PT       label='Patient'       format $10.
 ,      PTNO          as PTNO     label='Patient Number' format 10.
 ,      TPATT         as TPATT    label='Pattern Code' format $8.
 ,      TRCD          as TRCD     label='Labeling Abbreviation' format $8.
 ,      DCMSUBNM      as DCMSUBNM label='DCM Subset Name' format $8.
 ,      DOCNUM        as DOCNUM   label='Document Number' format $20.
 ,      INVSITE       as INVSITE  label='Centre Number' format $10.
 ,      INVLNAME      as INVNAME  label='Name of Investigator' format $10.
 ,      ACTEVENT      as ACTEVENT label='Visit Number'   format 8.2
 ,      input(substr(DCMDATE,7,2)||substr(DCMDATE,5,2)||substr(DCMDATE,1,4),ddmmyy8.)   as VISDT
label='Visit Date' format date8.
,        input(substr(DCMTIME,1,2)||':'||substr(DCMTIME,3,2)||':'||substr(DCMTIME,5,2),time8.)   as VISTM
label='Visit Time' format time8.
```

```
  ,       REPEATSN       as REPEATSN label='Occurrence Number' format 3.
  ,       LOGINTS  as  LOGINTS  label='Login Timestamp'
 ,INPUT(AEI,3.) as AEI label="Adverse Event Indicator"   format YN1F.
 ,AENM as AENM label="Adverse Event Name"   format $50.
 ,AEONYMD as AEONYMD label="Adverse Event Reported Onset Date"   format $8.
 ,AEENDC as AEENDC label="Adverse Event End Date Continued"   format $CONT1F.
 ,AEENDYMD as AEENDYMD label="Adverse Event Reported End Date"   format $8.
 ,INPUT(AEINT,3.) as AEINT label="Adverse Event Intensity"   format AEINT1F.
 ,INPUT(AETHP,3.) as AETHP label="Adverse Event Therapy Required"   format AETHP1F.
 ,INPUT(AEACT,3.) as AEACT label="Adverse Event Action Taken"   format AEACT1F.
 ,INPUT(AEOUT,3.) as AEOUT label="Adverse Event Outcome"   format AEOUT1F.
 ,INPUT(AESER,3.) as AESER label="Adverse Event Serious"   format YN1F.
 ,INPUT(AEST1,3.) as AEST1 label="Adverse Event Serious Type"   format AESER1F.
 ,INPUT(AEST2,3.) as AEST2 label="Adverse Event Serious Type"   format AESER1F.
 ,INPUT(AEST3,3.) as AEST3 label="Adverse Event Serious Type"   format AESER1F.
 ,INPUT(AEST4,3.) as AEST4 label="Adverse Event Serious Type"   format AESER1F.
 ,INPUT(AEREL,3.) as AEREL label="Adverse Event Drug Relationship"   format YN1F.
 ,AEX as AEX label="Adverse Event Comment"   format $200.
 ,AECASE as AECASE label="Adverse Event Case ID Number"   format $11.
 ,AEPTIT as AEPTIT label="Preferred/Included Term"   format $200.
 ,AEPTITCD as AEPTITCD label="Preferred/Included term Code"   format $10.
 ,INPUT(SUBSTR(AEONDT,7,2)||SUBSTR(AEONDT,5,2)||SUBSTR(AEONDT,1,4),DDMMYY8.) as AEONDT
label="Adverse Event Onset Date"   format DATE9.
 ,INPUT(SUBSTR(AEENDDT,7,2)||SUBSTR(AEENDDT,5,2)||SUBSTR(AEENDDT,1,4),DDMMYY8.) as
AEENDDT label="Adverse Event End Date"   format DATE9.
 ,AEDUR as AEDUR label="Adverse Event Duration"   format 8.0
 ,INPUT(AEDURU,3.) as AEDURU label="Adverse Event Duration Unit"   format UNIT2F.
 ,AEONSET as AEONSET label="Adverse Event Time Since Last Dose"   format 4.0
 ,INPUT(AEONSETU,3.) as AEONSETU label="Adverse Event Unit of Onset Time"   format UNIT2F.
 ,AETRT as AETRT label="Adverse Event Treatment"   format $4.
 ,INPUT(AEQ,3.) as AEQ label="Adverse Event Qualifier"   format PGQ1F.
 ,AESOC as AESOC label="Adverse Event System Organ"   format $200.
 ,AESOCCD as AESOCCD label="Adverse Event System Organ Class Code"   format $10.
 ,AENMD as AENMD label="Adverse Event Derived Name"   format $50.
 ,INPUT(AEFUP,3.) as AEFUP label="Adverse Event Follow-Up to Outcome"   format AEFUP1F.
 ,AENML as AENML label="Adverse Event Language"   format $1.
 ,AENMO as AENMO label="Adverse Event Name Or. Lang."   format $50.
 ,AEOX as AEOX label="Adverse Event Comment Or. Lang."   format $200.
 from connection to oracle (select * from S0511_0018$STABLE.AEAE)
 where datepart(logints) <= '19SEP97'd;
  disconnect from oracle;
 quit;
```

Data Item List

Name	Code
AEAE_ACTEVENT	AEAE_ACTEVENT
AEAE_AEACT	AEAE_AEACT
AEAE_AECASE	AEAE_AECASE
AEAE_AEDUR	AEAE_AEDUR
AEAE_AEDURU	AEAE_AEDURU
AEAE_AEENDC	AEAE_AEENDC
AEAE_AEENDDT	AEAE_AEENDDT
AEAE_AEENDYMD	AEAE_AEENDYMD

Name	Code
AEAE_AEFUP	AEAE_AEFUP
AEAE_AEI	AEAE_AEI
AEAE_AEINT	AEAE_AEINT
AEAE_AENM	AEAE_AENM
AEAE_AENMD	AEAE_AENMD
AEAE_AENML	AEAE_AENML
AEAE_AENMO	AEAE_AENMO
AEAE_AEONDT	AEAE_AEONDT
AEAE_AEONSET	AEAE_AEONSET
AEAE_AEONSETU	AEAE_AEONSETU
AEAE_AEONYMD	AEAE_AEONYMD
AEAE_AEOUT	AEAE_AEOUT
AEAE_AEOX	AEAE_AEOX
AEAE_AEPTIT	AEAE_AEPTIT
AEAE_AEPTITCD	AEAE_AEPTITCD
AEAE_AEQ	AEAE_AEQ
AEAE_AEREL	AEAE_AEREL
AEAE_AESER	AEAE_AESER
AEAE_AESOC	AEAE_AESOC
AEAE_AESOCCD	AEAE_AESOCCD
AEAE_AEST1	AEAE_AEST1
AEAE_AEST2	AEAE_AEST2
AEAE_AEST3	AEAE_AEST3
AEAE_AEST4	AEAE_AEST4
AEAE_AETHP	AEAE_AETHP
AEAE_AETRT	AEAE_AETRT
AEAE_AEX	AEAE_AEX
AEAE_DCMSUBNM	AEAE_DCMSUBNM
AEAE_DOCNUM	AEAE_DOCNUM
AEAE_INVNAME	AEAE_INVNAME
AEAE_INVSITE	AEAE_INVSITE
AEAE_PT	AEAE_PT
AEAE_PTNO	AEAE_PTNO
AEAE_REPEATSN	AEAE_REPEATSN
AEAE_STUDY	AEAE_STUDY
AEAE_TPATT	AEAE_TPATT
AEAE_TRCD	AEAE_TRCD
AEAE_VISDT	AEAE_VISDT
AEAE_VISTM	AEAE_VISTM

Flow List

Connected via	Connected to	Src	Dst
SAS View AEAE Oracle AEAE	Create SAS Views of 2nd Level Oracle Views (Process)		X
SAS View AEAE Staged	Build SAS Schema (Process)	X	

Data Store SAS View COMP of Oracle View

Name: SAS View COMP of Oracle View

Code: SAS_VIEW_COMP_OF_ORACLE_VIEW

Number: 8

Description

COMP
select
STUDY as STUDY label='Trial Number' format $15.
, PT as PT label='Patient' format $10.
, PTNO as PTNO label='Patient Number' format 10.
, TPATT as TPATT label='Pattern Code' format $8.
, TRCD as TRCD label='Labeling Abbreviation' format $8.
, DCMSUBNM as DCMSUBNM label='DCM Subset Name' format $8.
, DOCNUM as DOCNUM label='Document Number' format $20.
, INVSITE as INVSITE label='Centre Number' format $10.
, INVLNAME as INVNAME label='Name of Investigator' format $10.
, ACTEVENT as ACTEVENT label='Visit Number' format 8.2
, input(substr(DCMDATE,7,2)||substr(DCMDATE,5,2)||substr(DCMDATE,1,4),ddmmyy8.) as VISDT label='Visit Date' format date8.
, input(substr(DCMTIME,1,2)||':'||substr(DCMTIME,3,2)||':'||substr(DCMTIME,5,2),time8.) as VISTM label='Visit Time' format time8.

, REPEATSN as REPEATSN label='Occurrence Number' format 3.

,DRGYMD as DRGYMD label="Drug Discontinuation Reported Date" format $8.
,INPUT(SUBSTR(DRGSTPDT,7,2)||SUBSTR(DRGSTPDT,5,2)||SUBSTR(DRGSTPDT,1,4),DDMMYY8.) as DRGSTPDT label="Drug Discontinuation Date" format DATE9.
,INPUT(DRGSTPTM,TIME8.) as DRGSTPTM label="Drug Discontinuation Time" format TIME8.
,INPUT(SUBSTR(COMPRDT,7,2)||SUBSTR(COMPRDT,5,2)||SUBSTR(COMPRDT,1,4),DDMMYY8.) as COMPRDT label="Date Returned" format DATE9.
,COMPRET as COMPRET label="Number of Capsules Returned" format 3.0
,INPUT(SUBSTR(COMPDDT,7,2)||SUBSTR(COMPDDT,5,2)||SUBSTR(COMPDDT,1,4),DDMMYY8.) as COMPDDT label="Date Dispensed" format DATE9.
,COMPDISP as COMPDISP label="Number of Capsules Dispensed" format 3.0
,INPUT(COMPREL,3.) as COMPREL label="Medication Taken Reliably" format YN1F.
from connection to oracle (select * from S0511_0018$STABLE.COMP);
disconnect from oracle;
quit;

Data Item List

Name	Code
COMP_ACTEVENT	COMP_ACTEVENT
COMP_COMPDDT	COMP_COMPDDT
COMP_COMPDISP	COMP_COMPDISP
COMP_COMPRDT	COMP_COMPRDT
COMP_COMPREL	COMP_COMPREL
COMP_COMPRET	COMP_COMPRET
COMP_DCMSUBNM	COMP_DCMSUBNM
COMP_DOCNUM	COMP_DOCNUM
COMP_DRGSTPDT	COMP_DRGSTPDT
COMP_DRGSTPTM	COMP_DRGSTPTM
COMP_DRGYMD	COMP_DRGYMD
COMP_INVNAME	COMP_INVNAME

Name	Code
COMP_INVSITE	COMP_INVSITE
COMP_PKEY	COMP_PKEY
COMP_PT	COMP_PT
COMP_PTNO	COMP_PTNO
COMP_REPEATSN	COMP_REPEATSN
COMP_STUDY	COMP_STUDY
COMP_TPATT	COMP_TPATT
COMP_TRCD	COMP_TRCD
COMP_VISDT	COMP_VISDT
COMP_VISTM	COMP_VISTM

Flow List

Connected via	Connected to	Src	Dst
SAS View COMP Staged	Build SAS Schema (Process)	X	
SAS View Oracle COMP	Create SAS Views of 2nd Level Oracle Views (Process)		X

Data Store SAS View CPP of Oracle View

Name: SAS View CPP of Oracle View
Code: SAS_VIEW_CPP_OF_ORACLE_VIEW
Label:
Number: 2

Description

CPP

```
select
        STUDY         as STUDY    label='Trial Number' format $15.
  ,     PT            as PT       label='Patient'       format $10.
  ,     PTNO          as PTNO     label='Patient Number' format 10.
  ,     TPATT         as TPATT    label='Pattern Code' format $8.
  ,     TRCD          as TRCD     label='Labeling Abbreviation' format $8.
  ,     DCMSUBNM      as DCMSUBNM label='DCM Subset Name' format $8.
  ,     DOCNUM        as DOCNUM   label='Document Number' format $20.
  ,     INVSITE       as INVSITE  label='Centre Number' format $10.
  ,     INVLNAME      as INVNAME  label='Name of Investigator' format $10.
  ,     ACTEVENT      as ACTEVENT label='Visit Number'   format 8.2
  ,     input(substr(DCMDATE,7,2)||substr(DCMDATE,5,2)||substr(DCMDATE,1,4),ddmmyy8.)   as VISDT
label='Visit Date' format date8.
,        input(substr(DCMTIME,1,2)||':'||substr(DCMTIME,3,2)||':'||substr(DCMTIME,5,2),time8.)   as VISTM
label='Visit Time' format time8.

  ,     REPEATSN      as REPEATSN label='Occurrence Number' format 3.

  ,DRGYMD as DRGYMD label="Drug Discontinuation Reported Date"   format $8.
  ,INPUT(SUBSTR(DRGSTPDT,7,2)||SUBSTR(DRGSTPDT,5,2)||SUBSTR(DRGSTPDT,1,4),DDMMYY8.) as
DRGSTPDT label="Drug Discontinuation Date"   format DATE9.
```

```
 ,INPUT(TERMCD,3.) as TERMCD label="Termination"    format TERMCD1F.
 ,TERMX as TERMX label="Termination Comment"    format $200.
 ,TERMPOP as TERMPOP label="Analysis Population Flag"    format $20.
 ,TERMOX as TERMOX label="Termination Comment Or. Lang"    format $200.
from connection to oracle (select * from S0511_0018$STABLE.CPP);
disconnect from oracle;
quit;
```

Data Item List

Name	Code
CPP_ACTEVENT	CPP_ACTEVENT
CPP_DCMSUBNM	CPP_DCMSUBNM
CPP_DOCNUM	CPP_DOCNUM
CPP_DRGSTPDT	CPP_DRGSTPDT
CPP_DRGYMD	CPP_DRGYMD
CPP_INVNAME	CPP_INVNAME
CPP_INVSITE	CPP_INVSITE
CPP_PT	CPP_PT
CPP_PTNO	CPP_PTNO
CPP_REPEATSN	CPP_REPEATSN
CPP_STUDY	CPP_STUDY
CPP_TERMCD	CPP_TERMCD
CPP_TERMOX	CPP_TERMOX
CPP_TERMPOP	CPP_TERMPOP
CPP_TERMX	CPP_TERMX
CPP_TPATT	CPP_TPATT
CPP_TRCD	CPP_TRCD
CPP_VISDT	CPP_VISDT
CPP_VISTM	CPP_VISTM

Flow List

Connected via	Connected to	Src	Dst
SAS View CPP Staged	Build SAS Schema (Process)	X	
SAS View Oracle CPP	Create SAS Views of 2nd Level Oracle Views (Process)		X

Data Store SAS View INEXINEX of Oracle View

Name: SAS View INEXINEX of Oracle View
Code: SAS_VIEW_INEXINEX_OF_ORACLE_VIEW
Label:
Number: 3

Description

INEXINEX

```
select
        STUDY        as STUDY    label='Trial Number' format $15.
 ,      PT           as PT       label='Patient'      format $10.
```

```
 ,       PTNO          as PTNO     label='Patient Number' format 10.
 ,       TPATT         as TPATT    label='Pattern Code' format $8.
 ,       TRCD          as TRCD     label='Labeling Abbreviation' format $8.
 ,       DCMSUBNM      as DCMSUBNM label='DCM Subset Name' format $8.
 ,       DOCNUM        as DOCNUM   label='Document Number' format $20.
 ,       INVSITE       as INVSITE  label='Centre Number' format $10.
 ,       INVLNAME      as INVNAME  label='Name of Investigator' format $10.
 ,       ACTEVENT      as ACTEVENT label='Visit Number'   format 8.2
 ,       input(substr(DCMDATE,7,2)||substr(DCMDATE,5,2)||substr(DCMDATE,1,4),ddmmyy8.)   as VISDT
label='Visit Date' format date8.
,         input(substr(DCMTIME,1,2)||':'||substr(DCMTIME,3,2)||':'||substr(DCMTIME,5,2),time8.)   as VISTM
label='Visit Time' format time8.

 ,       REPEATSN      as REPEATSN label='Occurrence Number' format 3.

 ,INPUT(INEXI,3.) as INEXI label="Inclusion/Exclusion Indicator"   format YN1F.
 ,INEXQ as INEXQ label="Inclusion/Exclusion Criteria Not Met"   format $4.
from connection to oracle (select * from S0511_0018$STABLE.INEXINEX);
disconnect from oracle;
quit;
```

Data Item List

Name	Code
INEXINEX_ACTEVENT	INEXINEX_ACTEVENT
INEXINEX_DCMSUBNM	INEXINEX_DCMSUBNM
INEXINEX_DOCNUM	INEXINEX_DOCNUM
INEXINEX_INEXI	INEXINEX_INEXI
INEXINEX_INEXQ	INEXINEX_INEXQ
INEXINEX_INVNAME	INEXINEX_INVNAME
INEXINEX_INVSITE	INEXINEX_INVSITE
INEXINEX_PT	INEXINEX_PT
INEXINEX_PTNO	INEXINEX_PTNO
INEXINEX_REPEATSN	INEXINEX_REPEATSN
INEXINEX_STUDY	INEXINEX_STUDY
INEXINEX_TPATT	INEXINEX_TPATT
INEXINEX_TRCD	INEXINEX_TRCD
INEXINEX_VISDT	INEXINEX_VISDT
INEXINEX_VISTM	INEXINEX_VISTM

Flow List

Connected via	Connected to	Src	Dst
SAS View INEXINEX Staged	Build SAS Schema (Process)	X	
SAS View Oracle INEXINEX	Create SAS Views of 2nd Level Oracle Views (Process)		X

Data Store SAS View PATD of Oracle View

Name: SAS View PATD of Oracle View
Code: SAS_VIEW_PATD_OF_ORACLE_VIEW
Label:

Number: 4

Description

PATD

```
select
        STUDY         as STUDY    label='Trial Number' format $15.
  ,     PT            as PT       label='Patient'       format $10.
  ,     PTNO          as PTNO     label='Patient Number' format 10.
  ,     TPATT         as TPATT    label='Pattern Code' format $8.
  ,     TRCD          as TRCD     label='Labeling Abbreviation' format $8.
  ,     DCMSUBNM      as DCMSUBNM label='DCM Subset Name' format $8.
  ,     DOCNUM        as DOCNUM   label='Document Number' format $20.
  ,     INVSITE       as INVSITE  label='Centre Number' format $10.
  ,     INVLNAME      as INVNAME  label='Name of Investigator' format $10.
  ,     ACTEVENT      as ACTEVENT label='Visit Number'   format 8.2
  ,     input(substr(DCMDATE,7,2)||substr(DCMDATE,5,2)||substr(DCMDATE,1,4),ddmmyy8.)   as VISDT
label='Visit Date' format date8.
,        input(substr(DCMTIME,1,2)||':'||substr(DCMTIME,3,2)||':'||substr(DCMTIME,5,2),time8.)   as VISTM
label='Visit Time' format time8.

  ,     REPEATSN      as REPEATSN label='Occurrence Number' format 3.

  ,INPUT(SUBSTR(CONDT,7,2)||SUBSTR(CONDT,5,2)||SUBSTR(CONDT,1,4),DDMMYY8.) as CONDT
label="Informed Consent Date"   format DATE9.
  ,PATINIT as PATINIT label="Patient Initials"   format $3.
  ,BTHYMD as BTHYMD label="Reported Birth Date"   format $8.
  ,INPUT(SUBSTR(BTHDT,7,2)||SUBSTR(BTHDT,5,2)||SUBSTR(BTHDT,1,4),DDMMYY8.) as BTHDT
label="Birth Date"   format DATE9.
  ,AGE as AGE label="Age"   format 3.0
  ,INPUT(AGEQ,3.) as AGEQ label="Age Qualifier"   format AGEQ1F.
  ,INPUT(AGEU,3.) as AGEU label="Age Unit"   format UNIT2F.
  ,INPUT(SEX,3.) as SEX label="Sex"   format SEX1F.
  ,INPUT(RACE,3.) as RACE label="Race"   format RACE1F.
  ,INPUT(SMOKCD,3.) as SMOKCD label="Smoking History"   format SMOKCD1F.
  ,SMM as SMM label="Smoking History - Month Stopped"   format 2.0
  ,SMY as SMY label="Smoking History - Year Stopped"   format 4.0
  ,SMPKY as SMPKY label="Smoking History - Pack Years"   format 3.1
  ,INPUT(ALCAB,3.) as ALCAB label="History of Alcohol Abuse"   format YN1F.
  ,INPUT(ALHCD,3.) as ALHCD label="Alcohol History"   format ALHCD1F.
  ,INPUT(ILDR,3.) as ILDR label="Illicit Drug History"   format ILDR1F.
 from connection to oracle (select * from S0511_0018$STABLE.PATD);
 disconnect from oracle;
 quit;
```

Data Item List

Name	Code
PATD_ACTEVENT	PATD_ACTEVENT
PATD_AGE	PATD_AGE
PATD_AGEQ	PATD_AGEQ

Name	Code
PATD_AGEU	PATD_AGEU
PATD_ALCAB	PATD_ALCAB
PATD_ALHCD	PATD_ALHCD
PATD_BTHDT	PATD_BTHDT
PATD_BTHYMD	PATD_BTHYMD
PATD_CONDT	PATD_CONDT
PATD_DCMSUBNM	PATD_DCMSUBNM
PATD_DOCNUM	PATD_DOCNUM
PATD_ILDR	PATD_ILDR
PATD_INVNAME	PATD_INVNAME
PATD_INVSITE	PATD_INVSITE
PATD_PATINIT	PATD_PATINIT
PATD_PT	PATD_PT
PATD_PTNO	PATD_PTNO
PATD_RACE	PATD_RACE
PATD_REPEATSN	PATD_REPEATSN
PATD_SEX	PATD_SEX
PATD_SMM	PATD_SMM
PATD_SMOKCD	PATD_SMOKCD
PATD_SMPKY	PATD_SMPKY
PATD_SMY	PATD_SMY
PATD_STUDY	PATD_STUDY
PATD_TPATT	PATD_TPATT
PATD_TRCD	PATD_TRCD
PATD_VISDT	PATD_VISDT
PATD_VISTM	PATD_VISTM

Flow List

Connected via	Connected to	Src	Dst
SAS View PATD Oracle PATD	Create SAS Views of 2nd Level Oracle Views (Process)		X
SAS View PATD Staged	Build SAS Schema (Process)	X	

Data Store SUBSET_PATIENTS

Name: SUBSET_PATIENTS
Code: SUBSET_PATIENTS
Label:
Number: 6

Description

This is table that contains data on subsetting patients for Adverse Events. It is also part of the SAS schema.

Data Item List

Name	Code
INEXI_INCLUSIONEXCLUSION_INDICATOR	ST_INA
INEXQ_INCLUSIONEXCLUSION_CRITERIA_N	ST_INN
REPEATSN_OCCURRENCE_NUMBER	ST_OCR

Name	Code
PT_PATIENT	ST_PTN
ST_STK_PKEY_PATIENT__OCCURENCE	ST_STK
ST_STK_COMPUCRAFT_PRIMARY_KEY	ST_STP
TPATT_PATTERN_CODE	ST_TPN
TRCD_LABELING_ABBREVIATION	ST_TRC
VISDT_VISIT_DATE	ST_VSD
ACTEVENT_VISIT_NUMBER	ST_VSN
VISTM_VISIT_TIME	ST_VST

Flow List

Connected via	Connected to	Src	Dst
Subset Patients	Subset Patients (Process)		X
Subset Patients Data	Create SAS Reports (Process)	X	

Data Store TRIAL_CONSTANTS

Name: TRIAL_CONSTANTS
Code: TRIAL_CONSTANTS
Label:
Number: 11

Description

This dimension table contains trial constants, such as trial description, trial principal investigator and trail codes. This table is also part of the SAS schema.

Data Item List

Name	Code
TR_CTR_INVSITE_CENTRE_NUMBER	TR_CTR
TR_NIV_INVNAME_NAME_OF_INVESTIGATOR	TR_NIV
TR_TRK_STUDY_TRIAL_NUMBER	TR_TRK
TR_TRP_TR_TRK_COMPUCRAFT_PRIMARY_KEY	TR_TRP

Flow List

Connected via	Connected to	Src	Dst
Trial Specific data	Demographics SAS Table (Process)		X

Data Store V1 RCDMS VIEW

Name: V1 RCDMS VIEW
Code: V1_RCDMS_VIEW
Label:

Description

RDCMS_VIEW
select
rdcm.received_dcm_id,
rdcm.dcm_id,
rdcm.dcm_subset_sn,
rdcm.dcm_layout_sn,
rdcm.actual_event_id,
rdcm.received_dcm_entry_ts,
rdcm.end_ts,
rdcm.entered_by,
rdcm.dcm_date,
rdcm.dcm_time,
rdcm.received_dcm_status_code,
rdcm.qualifying_value,
rdcm.accessible_ts,
rdcm.log_in_ts,
rdcm.last_data_change_ts,
rdcm.data_lock_flag,
rdcm.sn,
rdcm.document_number,
rdcm.modification_ts,
rdcm.modified_by,
rdcm.subevent_number,
rdcm.investigator_id,
rdcm.investigator,
rdcm.clin_plan_eve_id,
rdcm.clin_plan_eve_name,
rdcm.visit_number,
rdcm.site_id,
rdcm.site,
rdcm.lab_id,
rdcm.lab,
rdcm.patient_position_id,
rdcm.patient,
rdcm.clinical_study_id
,to_date(2999999, 'J') as_of_ts

from
received_dcms rdcm

where
end_ts = to_date(3000000, 'J')
and rdcm.clinical_study_id = 10002202

Data Item List

Name	Code
V1_CLINICAL_STUDY_ID	V1_CLINICAL_STUDY_ID
V1_DCM_QUESTION_GROUP_ID	V1_DCM_QUESTION_GROUP_ID

Name	Code
V1_DCM_QUESTION_ID	V1_DCM_QUESTION_ID
V1_END_TS	V1_END_TS
V1_ENTERED_BY	V1_ENTERED_BY
V1_EXCEPTION_VALUE_TEXT	V1_EXCEPTION_VALUE_TEXT
V1_RECEIVED_DCM_ID	V1_RECEIVED_DCM_ID
V1_REPEAT_SN	V1_REPEAT_SN
V1_RESPONSE_ENTRY_TS	V1_RESPONSE_ENTRY_TS
V1_RESPONSE_ID	V1_RESPONSE_ID
V1_VALIDATION_STATUS	V1_VALIDATION_STATUS
V1_VALUE_TEXT	V1_VALUE_TEXT

Flow List

Connected via	Connected to	Src	Dst
V1 RCDMS VIEW INPUTS	RDCMS VIEW (Process)		X
V1 RCDMS VIEW OUTPUTS	2nd Level Oracle Views (Process)	X	

Data Store V2 RESPONSES VIEW

Name: V2 RESPONSES VIEW
Code: V2_RESPONSES_VIEW
Label:
Number: 17

Description

RESPONSES_VIEW

```
select
        r.clinical_study_id,
        received_dcm_id,
       dcm_question_id,
       response_id,
       value_text,
       validation_status,
       repeat_sn,
       response_entry_ts,
       end_ts,
       entered_by,
       dcm_question_group_id,
       exception_value_text

from
       responses r

 where
        end_ts = to_date(3000000, 'J')
;
```

Data Item List

Name	Code
V2_ACCESSIBLE_TS	V2_ACCESSIBLE_TS
V2_ACTUAL_EVENT_ID	V2_ACTUAL_EVENT_ID
V2_AS_OF_TS	V2_AS_OF_TS
V2_CLIN_PLAN_EVE_ID	V2_CLIN_PLAN_EVE_ID
V2_CLIN_PLAN_EVE_NAME	V2_CLIN_PLAN_EVE_NAME
V2_CLINICAL_STUDY_ID	V2_CLINICAL_STUDY_ID
V2_DATA_LOCK_FLAG	V2_DATA_LOCK_FLAG
V2_DCM_DATE	V2_DCM_DATE
V2_DCM_ID	V2_DCM_ID
V2_DCM_LAYOUT_SN	V2_DCM_LAYOUT_SN
V2_DCM_SUBSET_SN	V2_DCM_SUBSET_SN
V2_DCM_TIME	V2_DCM_TIME
V2_DOCUMENT_NUMBER	V2_DOCUMENT_NUMBER
V2_END_TS	V2_END_TS
V2_ENTERED_BY	V2_ENTERED_BY
V2_INVESTIGATOR	V2_INVESTIGATOR
V2_INVESTIGATOR_ID	V2_INVESTIGATOR_ID
V2_LAB	V2_LAB
V2_LAB_ID	V2_LAB_ID
V2_LAST_DATA_CHANGE_TS	V2_LAST_DATA_CHANGE_TS
V2_LOG_IN_TS	V2_LOG_IN_TS
V2_MODIFICATION_TS	V2_MODIFICATION_TS
V2_MODIFIED_BY	V2_MODIFIED_BY
V2_PATIENT	V2_PATIENT
V2_PATIENT_POSITION_ID	V2_PATIENT_POSITION_ID
V2_QUALIFYING_VALUE	V2_QUALIFYING_VALUE
V2_RECEIVED_DCM_ENTRY_TS	V2_RECEIVED_DCM_ENTRY_TS
V2_RECEIVED_DCM_ID	V2_RECEIVED_DCM_ID
V2_RECEIVED_DCM_STATUS_CODE	V2_RECEIVED_DCM_STATUS_CODE
V2_SITE	V2_SITE
V2_SITE_ID	V2_SITE_ID
V2_SN	V2_SN
V2_SUBEVENT_NUMBER	V2_SUBEVENT_NUMBER
V2_VISIT_NUMBER	V2_VISIT_NUMBER

Flow List

Connected via	Connected to	Src	Dst
V2 RESPONSES VIEW INPUTS	RESPONSES VIEW (Process)		X
V2 RESPONSES VIEW OUTPUTS	2nd Level Oracle Views (Process)	X	

Data Store V3 Oracle View AEAE

Name: V3 Oracle View AEAE
Code: V3_ORACLE_VIEW_AEAE
Label:
Number: 12

Description

```
AEAEA
select /*+
ORDERED USE_CONCAT
INDEX(dcm DCM_PK_IDX)
INDEX(i OCL_INVESTIGATOR_PK_IDX)
INDEX(r RESPONSE_DCMQG_NFK_IDX ) */
'0205_0201'                          STUDY,
dcm.name                          DCMNAME,
dcm.subset_name                      DCMSUBNM,
dcm.dcm_subset_sn                    SUBSETSN,
rdcm.document_number                 DOCNUM,
rdcm.site                         INVSITE,
rdcm.investigator                    INV,
nvl(i.last_name,'<Inv Name>')        INVLNAME,

rdcm.patient                         PT,
rdcm.accessible_ts                   ACCESSTS,
decode(substr(rdcm.patient,1,1)
,'0',to_number(rdcm.patient)
,'1',to_number(rdcm.patient)
,'2',to_number(rdcm.patient)
,'3',to_number(rdcm.patient)
,'4',to_number(rdcm.patient)
,'5',to_number(rdcm.patient)
,'6',to_number(rdcm.patient)
,'7',to_number(rdcm.patient)
,'8',to_number(rdcm.patient)
,'9',to_number(rdcm.patient)
,to_Number('')         )   PTNO,
substr(treat.treat_code(rdcm.clinical_study_id ,rdcm.patient_position_id)
,1,8)
TPATT,
substr(treat.treat_abbrev(rdcm.clinical_study_id
,rdcm.patient_position_id

,rdcm.clin_plan_eve_id)
,1,8)
TRCD,
rdcm.log_in_ts                    LOGINTS,
rdcm.last_data_change_ts             LSTCHGTS,
rdcm.data_lock_flag                  LOCKFLAG,
rdcm.clin_plan_eve_name              CPEVENT,
to_number(rdcm.visit_number||'.'||ltrim(to_char(rdcm.subevent_number,
'09'))) ACTEVENT,
rdcm.dcm_date                     DCMDATE,
rdcm.dcm_time                     DCMTIME,

r.repeat_sn                       REPEATSN

, max(decode(r.dcm_question_id, 10742602,substr(r.value_text, 1, 1), NULL)) AEI
, max(decode(r.dcm_question_id, 10741002,substr(r.value_text, 1, 50), NULL)) AEN
```

```
MO
, max(decode(r.dcm_question_id, 10740902,substr(r.value_text, 1, 50), NULL)) AEN
M

, max(decode(r.dcm_question_id, 10742502,substr(r.value_text, 1, 8), NULL)) AEON
YMD
, max(decode(r.dcm_question_id, 10741202,DECODE(substr(r.value_text,1,6),NULL,''
,SUBSTR(substr(r.value_text,1,6),1,2)||':')||DECODE(substr(r.value_text,1,6),NUL
L,'',SUBSTR(substr(r.value_text,1,6),3,2))||DECODE(LENGTH(substr(r.value_text,1,
6)),4,'',NULL,'',':'||SUBSTR(substr(r.value_text,1,6),5,2)), NULL)) AEONTM
, max(decode(r.dcm_question_id, 10742302,substr(r.value_text, 1, 1), NULL)) AEEN
DC
, max(decode(r.dcm_question_id, 10742402,substr(r.value_text, 1, 8), NULL)) AEEN
DYMD
, max(decode(r.dcm_question_id, 10740702,DECODE(substr(r.value_text,1,6),NULL,''
,SUBSTR(substr(r.value_text,1,6),1,2)||':')||DECODE(substr(r.value_text,1,6),NUL
L,'',SUBSTR(substr(r.value_text,1,6),3,2))||DECODE(LENGTH(substr(r.value_text,1,
6)),4,'',NULL,'',':'||SUBSTR(substr(r.value_text,1,6),5,2)), NULL)) AEENDTM
, max(decode(r.dcm_question_id, 10740802,substr(r.value_text, 1, 1), NULL)) AEIN
T
, max(decode(r.dcm_question_id, 10743302,substr(r.value_text, 1, 1), NULL)) AETH
PA
, max(decode(r.dcm_question_id, 10743402,substr(r.value_text, 1, 1), NULL)) AEAC

TA
, max(decode(r.dcm_question_id, 10741302,substr(r.value_text, 1, 1), NULL)) AEOU
T
, max(decode(r.dcm_question_id, 10743502,substr(r.value_text, 1, 1), NULL)) AESE
RA
, max(decode(r.dcm_question_id, 10743602,substr(r.value_text, 1, 1), NULL)) AEST
A1
, max(decode(r.dcm_question_id, 10743702,substr(r.value_text, 1, 1), NULL)) AEST
A2
, max(decode(r.dcm_question_id, 10743802,substr(r.value_text, 1, 1), NULL)) AEST
A3
, max(decode(r.dcm_question_id, 10743902,substr(r.value_text, 1, 1), NULL)) AEST
A4
, max(decode(r.dcm_question_id, 10741502,substr(r.value_text, 1, 1), NULL)) AERE
L
, max(decode(r.dcm_question_id, 10740402,substr(r.value_text, 1, 200), NULL)) AE
OX
, max(decode(r.dcm_question_id, 10740502,substr(r.value_text, 1, 200), NULL)) AE
X

, max(decode(r.dcm_question_id, 10742202,substr(r.value_text, 1, 1), NULL)) AEFU
P
, max(decode(r.dcm_question_id, 10741702,substr(r.value_text, 1, 11), NULL)) AEC
ASE
, max(decode(r.dcm_question_id, 10741402,substr(r.value_text, 1, 3), NULL)) AEQ
, max(decode(r.dcm_question_id, 10742702,substr(r.value_text, 1, 200), NULL)) AE
PTIT
, max(decode(r.dcm_question_id, 10742802,substr(r.value_text, 1, 10), NULL)) AEP
TITCD
, max(decode(r.dcm_question_id, 10742902,substr(r.value_text, 1, 200), NULL)) AE
```

```
SOC
, max(decode(r.dcm_question_id, 10743002,substr(r.value_text, 1, 10), NULL)) AES
OCCD
, max(decode(r.dcm_question_id, 10741102,substr(r.value_text, 1, 8), NULL)) AEON
DT
, max(decode(r.dcm_question_id, 10740602,substr(r.value_text, 1, 8), NULL)) AEEN
DDT
, max(decode(r.dcm_question_id, 10741802,to_number(r.value_text), NULL)) AEDUR
, max(decode(r.dcm_question_id, 10741902,substr(r.value_text, 1, 3), NULL)) AEDU

RU
, max(decode(r.dcm_question_id, 10742002,to_number(r.value_text), NULL)) AEONSET

, max(decode(r.dcm_question_id, 10742102,substr(r.value_text, 1, 3), NULL)) AEON
SETU
, max(decode(r.dcm_question_id, 10741602,substr(r.value_text, 1, 8), NULL)) AETR
T  from
rdcms_view                    rdcm,
dcms                          dcm,
responses_view                r
, ocl_investigators           i

where rdcm.clinical_study_id          = 10002202
and rdcm.dcm_id                       = 10055302
and dcm.dcm_id                        = 10055302
and dcm.dcm_subset_sn                 = rdcm.dcm_subset_sn
and dcm.dcm_layout_sn                 = 1
and i.investigator_id (+)             = rdcm.investigator_id
and r.received_dcm_id                 = rdcm.received_dcm_id

and r.dcm_question_group_id           =10091602

group by '0205_0201', dcm.name, dcm.subset_name, dcm.dcm_subset_sn,
rdcm.document_number, rdcm.site, rdcm.investigator,
rdcm.patient,
rdcm.accessible_ts, rdcm.log_in_ts, rdcm.last_data_change_ts,
rdcm.data_lock_flag,
rdcm.clin_plan_eve_name,
to_number(rdcm.visit_number||'.'||trim(to_char(rdcm.subevent_number,
'09'))),
rdcm.dcm_date, rdcm.dcm_time,
r.repeat_sn
, i.last_name
, rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id
```

Data Item List

Name	Code
V3_ACCESSTS	V3_ACCESSTS
V3_ACTEVENT	V3_ACTEVENT
V3_AEACT	V3_AEACT
V3_AECASE	V3_AECASE

Name	Code
V3_AEDUR	V3_AEDUR
V3_AEDURU	V3_AEDURU
V3_AEENDC	V3_AEENDC
V3_AEENDDT	V3_AEENDDT
V3_AEENDTM	V3_AEENDTM
V3_AEENDYMD	V3_AEENDYMD
V3_AEFUP	V3_AEFUP
V3_AEI	V3_AEI
V3_AEINT	V3_AEINT
V3_AENM	V3_AENM
V3_AENMD	V3_AENMD
V3_AENML	V3_AENML
V3_AENMO	V3_AENMO
V3_AEONDT	V3_AEONDT
V3_AEONSET	V3_AEONSET
V3_AEONSETU	V3_AEONSETU
V3_AEONTM	V3_AEONTM
V3_AEONYMD	V3_AEONYMD
V3_AEOUT	V3_AEOUT
V3_AEOX	V3_AEOX
V3_AEPTIT	V3_AEPTIT
V3_AEPTITCD	V3_AEPTITCD
V3_AEQ	V3_AEQ
V3_AEREL	V3_AEREL
V3_AESER	V3_AESER
V3_AESOC	V3_AESOC
V3_AESOCCD	V3_AESOCCD
V3_AEST1	V3_AEST1
V3_AEST2	V3_AEST2
V3_AEST3	V3_AEST3
V3_AEST4	V3_AEST4
V3_AETHP	V3_AETHP
V3_AETRT	V3_AETRT
V3_AEX	V3_AEX
V3_CPEVENT	V3_CPEVENT
V3_DCMDATE	V3_DCMDATE
V3_DCMNAME	V3_DCMNAME
V3_DCMSUBNM	V3_DCMSUBNM
V3_DCMTIME	V3_DCMTIME
V3_DOCNUM	V3_DOCNUM
V3_INV	V3_INV
V3_INVLNAME	V3_INVLNAME
V3_INVSITE	V3_INVSITE
V3_LOCKFLAG	V3_LOCKFLAG
V3_LOGINTS	V3_LOGINTS
V3_LSTCHGTS	V3_LSTCHGTS
V3_PT	V3_PT
V3_PTNO	V3_PTNO
V3_REPEATSN	V3_REPEATSN
V3_STUDY	V3_STUDY
V3_SUBSETSN	V3_SUBSETSN
V3_TPATT	V3_TPATT
V3_TRCD	V3_TRCD

Flow List

Connected via	Connected to	Src	Dst
V3 AEAE Fields to SAS	SAS Processing (Process)	X	
V3 Oracle View AEAE Fields	2nd Level Oracle Views (Process)		X

Data Store V4 Oracle View CPP

Name: V4 Oracle View CPP
Code: V4_ORACLE_VIEW_CPP
Label:
Number: 13

Description

CPP

```
select /*+
ORDERED USE_CONCAT
INDEX(dcm DCM_PK_IDX)

INDEX(i OCL_INVESTIGATOR_PK_IDX)
INDEX(r RESPONSE_DCMQG_NFK_IDX ) */
'0205_0117'                         STUDY,
dcm.name                        DCMNAME,
dcm.subset_name                 DCMSUBNM,
dcm.dcm_subset_sn               SUBSETSN,
rdcm.document_number            DOCNUM,
rdcm.site                       INVSITE,
rdcm.investigator               INV,
nvl(i.last_name,'<Inv Name>')   INVLNAME,
rdcm.patient                    PT,
rdcm.accessible_ts              ACCESSTS,
decode(substr(rdcm.patient,1,1)
,'0',to_number(rdcm.patient)
,'1',to_number(rdcm.patient)
,'2',to_number(rdcm.patient)
,'3',to_number(rdcm.patient)
,'4',to_number(rdcm.patient)
,'5',to_number(rdcm.patient)

,'6',to_number(rdcm.patient)
,'7',to_number(rdcm.patient)
,'8',to_number(rdcm.patient)
,'9',to_number(rdcm.patient)
,to_Number('')      )   PTNO,
substr(treat.treat_code(rdcm.clinical_study_id ,rdcm.patient_position_id)
,1,8)
TPATT,
substr(treat.treat_abbrev(rdcm.clinical_study_id
,rdcm.patient_position_id
```

```
,rdcm.clin_plan_eve_id)
,1,8)
TRCD,
rdcm.log_in_ts                    LOGINTS,
rdcm.last_data_change_ts          LSTCHGTS,
rdcm.data_lock_flag               LOCKFLAG,
rdcm.clin_plan_eve_name           CPEVENT,
to_number(rdcm.visit_number||'.'||ltrim(to_char(rdcm.subevent_number,
'09'))) ACTEVENT,

rdcm.dcm_date                     DCMDATE,
rdcm.dcm_time                     DCMTIME,

r.repeat_sn                       REPEATSN

, max(decode(r.dcm_question_id, 10439602,substr(r.value_text, 1, 8), NULL)) DRGY
MD
, max(decode(r.dcm_question_id, 10439502,substr(r.value_text, 1, 8), NULL)) DRGS
TPDT
, max(decode(r.dcm_question_id, 10439702,substr(r.value_text, 1, 1), NULL)) TERM
CD
, max(decode(r.dcm_question_id, 10439802,substr(r.value_text, 1, 200), NULL)) TE
RMOX
, max(decode(r.dcm_question_id, 10439902,substr(r.value_text, 1, 200), NULL)) TE
RMX
, max(decode(r.dcm_question_id, 10440002,substr(r.value_text, 1, 20), NULL)) TER
MPOP

 from
rdcms_view                    rdcm,
dcms                          dcm,
responses_view                    r
, ocl_investigators               i

where rdcm.clinical_study_id        = 10001802
and rdcm.dcm_id                   = 10033302
and dcm.dcm_id                    = 10033302
and dcm.dcm_subset_sn               = rdcm.dcm_subset_sn
and dcm.dcm_layout_sn               = 1
and i.investigator_id (+)         = rdcm.investigator_id
and r.received_dcm_id               = rdcm.received_dcm_id
and r.dcm_question_group_id         in (    10054402, 10054502 )

group by '0205_0117', dcm.name, dcm.subset_name, dcm.dcm_subset_sn,
rdcm.document_number, rdcm.site, rdcm.investigator,
rdcm.patient,
rdcm.accessible_ts, rdcm.log_in_ts, rdcm.last_data_change_ts,
rdcm.data_lock_flag,
rdcm.clin_plan_eve_name,
to_number(rdcm.visit_number||'.'||ltrim(to_char(rdcm.subevent_number,

'09'))),
rdcm.dcm_date, rdcm.dcm_time,
r.repeat_sn
```

, i.last_name
, rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id

Data Item List

Name	Code
V4_ACCESSTS	V4_ACCESSTS
V4_ACTEVENT	V4_ACTEVENT
V4_CPEVENT	V4_CPEVENT
V4_DCMDATE	V4_DCMDATE
V4_DCMNAME	V4_DCMNAME
V4_DCMSUBNM	V4_DCMSUBNM
V4_DCMTIME	V4_DCMTIME
V4_DOCNUM	V4_DOCNUM
V4_INEXI	V4_INEXI
V4_INEXQ	V4_INEXQ
V4_INEXX	V4_INEXX
V4_INV	V4_INV
V4_INVLNAME	V4_INVLNAME
V4_INVSITE	V4_INVSITE
V4_LOCKFLAG	V4_LOCKFLAG
V4_LOGINTS	V4_LOGINTS
V4_LSTCHGTS	V4_LSTCHGTS
V4_PT	V4_PT
V4_PTNO	V4_PTNO
V4_REPEATSN	V4_REPEATSN
V4_STUDY	V4_STUDY
V4_SUBSETSN	V4_SUBSETSN
V4_TPATT	V4_TPATT
V4_TRCD	V4_TRCD

Flow List

Connected via	Connected to	Src	Dst
V4 AEAE Fields to SAS	SAS Processing (Process)	X	
V4 Oracle View AEAE Fields	2nd Level Oracle Views (Process)		X

Data Store V5 Oracle View INEXINEX

Name: V5 Oracle View INEXINEX
Code: V5_ORACLE_VIEW_INEXINEX
Label:
Number: 14

Description

INEXINEX
select /*+

```
ORDERED USE_CONCAT
INDEX(dcm DCM_PK_IDX)
INDEX(i OCL_INVESTIGATOR_PK_IDX)
INDEX(r RESPONSE_DCMQG_NFK_IDX ) */
'S0511_0010'                    STUDY,
dcm.name                        DCMNAME,
dcm.subset_name                 DCMSUBNM,
dcm.dcm_subset_sn               SUBSETSN,
rdcm.document_number            DOCNUM,
rdcm.site                       INVSITE,
rdcm.investigator               INV,
nvl(i.last_name,'<Inv Name>')   INVLNAME,
rdcm.patient                    PT,
rdcm.accessible_ts              ACCESSTS,
decode(substr(rdcm.patient,1,1)
,'0',to_number(rdcm.patient)

,'1',to_number(rdcm.patient)
,'2',to_number(rdcm.patient)
,'3',to_number(rdcm.patient)
,'4',to_number(rdcm.patient)
,'5',to_number(rdcm.patient)
,'6',to_number(rdcm.patient)
,'7',to_number(rdcm.patient)
,'8',to_number(rdcm.patient)
,'9',to_number(rdcm.patient)
,to_Number('')    ) PTNO,
substr(treat.treat_code(rdcm.clinical_study_id ,rdcm.patient_position_id)
,1,8)
TPATT,
substr(treat.treat_abbrev(rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id)
,1,8)
TRCD,
rdcm.log_in_ts                  LOGINTS,

rdcm.last_data_change_ts        LSTCHGTS,
rdcm.data_lock_flag             LOCKFLAG,
rdcm.clin_plan_eve_name         CPEVENT,
to_number(rdcm.visit_number||'.'||ltrim(to_char(rdcm.subevent_number,
'09'))) ACTEVENT,
rdcm.dcm_date                   DCMDATE,
rdcm.dcm_time                   DCMTIME,

r.repeat_sn                     REPEATSN

, max(decode(r.dcm_question_id, 10056102,substr(r.value_text, 1, 1), NULL)) INEX
I
, max(decode(r.dcm_question_id, 10056202,substr(r.value_text, 1, 4), NULL)) INEX
Q  from
rdcms_view                  rdcm,
dcms                    dcm,
responses_view              r
```

```
, ocl_investigators              i


where rdcm.clinical_study_id          = 10000702
and rdcm.dcm_id                    = 10003502
and dcm.dcm_id                     = 10003502
and dcm.dcm_subset_sn                = rdcm.dcm_subset_sn
and dcm.dcm_layout_sn                = 1
and i.investigator_id (+)           = rdcm.investigator_id
and r.received_dcm_id                = rdcm.received_dcm_id
and r.dcm_question_group_id         =10008102

group by 'S0511_0010', dcm.name, dcm.subset_name, dcm.dcm_subset_sn,
rdcm.document_number, rdcm.site, rdcm.investigator,
rdcm.patient,
rdcm.accessible_ts, rdcm.log_in_ts, rdcm.last_data_change_ts,
rdcm.data_lock_flag,
rdcm.clin_plan_eve_name,
to_number(rdcm.visit_number||'.'||ltrim(to_char(rdcm.subevent_number,
'09'))),
rdcm.dcm_date, rdcm.dcm_time,
r.repeat_sn

, i.last_name
, rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id
```

Data Item List

Name	Code
V5_ACCESSTS	V5_ACCESSTS
V5_ACTEVENT	V5_ACTEVENT
V5_AGE	V5_AGE
V5_AGEQ	V5_AGEQ
V5_AGEU	V5_AGEU
V5_ALCAB	V5_ALCAB
V5_ALCCD	V5_ALCCD
V5_ALHCD	V5_ALHCD
V5_BTHDT	V5_BTHDT
V5_BTHYMD	V5_BTHYMD
V5_CONDT	V5_CONDT
V5_CPEVENT	V5_CPEVENT
V5_DCMDATE	V5_DCMDATE
V5_DCMNAME	V5_DCMNAME
V5_DCMSUBNM	V5_DCMSUBNM
V5_DCMTIME	V5_DCMTIME
V5_DOCNUM	V5_DOCNUM
V5_HT	V5_HT
V5_HTU	V5_HTU
V5_ILDR	V5_ILDR
V5_INV	V5_INV
V5_INVLNAME	V5_INVLNAME
V5_INVSITE	V5_INVSITE
V5_LOCKFLAG	V5_LOCKFLAG

Name	Code
V5_LOGINTS	V5_LOGINTS
V5_LSTCHGTS	V5_LSTCHGTS
V5_PATINIT	V5_PATINIT
V5_PT	V5_PT
V5_PTNO	V5_PTNO
V5_RACE	V5_RACE
V5_RACEA	V5_RACEA
V5_REPEATSN	V5_REPEATSN
V5_SEX	V5_SEX
V5_SMM	V5_SMM
V5_SMOKCD	V5_SMOKCD
V5_SMPKY	V5_SMPKY
V5_SMY	V5_SMY
V5_STUDY	V5_STUDY
V5_SUBSETSN	V5_SUBSETSN
V5_TDDT	V5_TDDT
V5_TDDURM	V5_TDDURM
V5_TDDURY	V5_TDDURY
V5_TDEPCDT	V5_TDEPCDT
V5_TDEPCYMD	V5_TDEPCYMD
V5_TDHIST	V5_TDHIST
V5_TDICD	V5_TDICD
V5_TDPT	V5_TDPT
V5_TDSPIN	V5_TDSPIN
V5_TDYMD	V5_TDYMD
V5_TPATT	V5_TPATT
V5_TRCD	V5_TRCD
V5_WT	V5_WT
V5_WTU	V5_WTU

Flow List

Connected via	Connected to	Src	Dst
V5 INEXINEX fields to SAS	SAS Processing (Process)	X	
V5 Oracle View INEXINEX Fields	2nd Level Oracle Views (Process)		X

Data Store V6 Oracle View PATD

Name: V6 Oracle View PATD
Code: V6ORACLE_VIEW_PATD
Label:
Number: 15

Description

PATD

select /*+
ORDERED USE_CONCAT

```
INDEX(dcm DCM_PK_IDX)
INDEX(i OCL_INVESTIGATOR_PK_IDX)
INDEX(r RESPONSE_DCMQG_NFK_IDX ) */
'S0511_0010'                    STUDY,
dcm.name                        DCMNAME,
dcm.subset_name                 DCMSUBNM,
dcm.dcm_subset_sn               SUBSETSN,
rdcm.document_number            DOCNUM,
rdcm.site                       INVSITE,
rdcm.investigator               INV,
nvl(i.last_name,'<Inv Name>')   INVLNAME,
rdcm.patient                    PT,
rdcm.accessible_ts              ACCESSTS,
decode(substr(rdcm.patient,1,1)
,'0',to_number(rdcm.patient)
,'1',to_number(rdcm.patient)
,'2',to_number(rdcm.patient)

,'3',to_number(rdcm.patient)
,'4',to_number(rdcm.patient)
,'5',to_number(rdcm.patient)
,'6',to_number(rdcm.patient)
,'7',to_number(rdcm.patient)
,'8',to_number(rdcm.patient)
,'9',to_number(rdcm.patient)
,to_Number('')     )   PTNO,
substr(treat.treat_code(rdcm.clinical_study_id ,rdcm.patient_position_id)
,1,8)
TPATT,
substr(treat.treat_abbrev(rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id)
,1,8)
TRCD,
rdcm.log_in_ts                  LOGINTS,
rdcm.last_data_change_ts        LSTCHGTS,
rdcm.data_lock_flag             LOCKFLAG,

rdcm.clin_plan_eve_name         CPEVENT,
to_number(rdcm.visit_number||'.'||trim(to_char(rdcm.subevent_number,
'09'))) ACTEVENT,
rdcm.dcm_date                   DCMDATE,
rdcm.dcm_time                   DCMTIME,

r.repeat_sn                     REPEATSN

, max(decode(r.dcm_question_id, 10108202,substr(r.value_text, 1, 8), NULL)) COND
T
, max(decode(r.dcm_question_id, 10108302,substr(r.value_text, 1, 3), NULL)) PATI
NIT
, max(decode(r.dcm_question_id, 10108102,substr(r.value_text, 1, 8), NULL)) BTHY
MD
, max(decode(r.dcm_question_id, 10107802,substr(r.value_text, 1, 8), NULL)) BTHD
T
```

```
, max(decode(r.dcm_question_id, 10107902,to_number(r.value_text), NULL)) AGE
, max(decode(r.dcm_question_id, 10107702,substr(r.value_text, 1, 3), NULL)) AGEQ


, max(decode(r.dcm_question_id, 10108002,substr(r.value_text, 1, 3), NULL)) AGEU

, max(decode(r.dcm_question_id, 10108502,substr(r.value_text, 1, 1), NULL)) SEX
, max(decode(r.dcm_question_id, 10108402,substr(r.value_text, 1, 1), NULL)) RACE

, max(decode(r.dcm_question_id, 10108602,substr(r.value_text, 1, 1), NULL)) SMOK
CD
, max(decode(r.dcm_question_id, 10108902,to_number(r.value_text), NULL)) SMM
, max(decode(r.dcm_question_id, 10109002,to_number(r.value_text), NULL)) SMY
, max(decode(r.dcm_question_id, 10108702,to_number(r.value_text), NULL)) SMPKY
, max(decode(r.dcm_question_id, 10109702,substr(r.value_text, 1, 1), NULL)) ALCA
B
, max(decode(r.dcm_question_id, 10109602,substr(r.value_text, 1, 1), NULL)) ALHC
D
, max(decode(r.dcm_question_id, 10109802,substr(r.value_text, 1, 1), NULL)) ILDR
from
rdcms_view                    rdcm,
dcms                          dcm,
responses_view                r

, ocl_investigators           i

where rdcm.clinical_study_id        = 10000702
and rdcm.dcm_id                     = 10007702
and dcm.dcm_id                      = 10007702
and dcm.dcm_subset_sn               = rdcm.dcm_subset_sn
and dcm.dcm_layout_sn               = 1
and i.investigator_id (+)           = rdcm.investigator_id
and r.received_dcm_id               = rdcm.received_dcm_id
and r.dcm_question_group_id         in (   10014602, 10014702, 10014502, 10
014902, 10014802, 10015002, 10015202, 10015302 )

group by 'S0511_0010', dcm.name, dcm.subset_name, dcm.dcm_subset_sn,
rdcm.document_number, rdcm.site, rdcm.investigator,
rdcm.patient,
rdcm.accessible_ts, rdcm.log_in_ts, rdcm.last_data_change_ts,
rdcm.data_lock_flag,
rdcm.clin_plan_eve_name,
to_number(rdcm.visit_number||'.'||trim(to_char(rdcm.subevent_number,

'09'))),
rdcm.dcm_date, rdcm.dcm_time,
r.repeat_sn
, i.last_name
, rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id
```

Data Item List

Name	Code
V6_ACCESSTS	V6_ACCESSTS
V6_ACTEVENT	V6_ACTEVENT
V6_ATRCD	V6_ATRCD
V6_ATRSTDT	V6_ATRSTDT
V6_ATRSTTM	V6_ATRSTTM
V6_CPEVENT	V6_CPEVENT
V6_DCMDATE	V6_DCMDATE
V6_DCMNAME	V6_DCMNAME
V6_DCMSUBNM	V6_DCMSUBNM
V6_DCMTIME	V6_DCMTIME
V6_DOCNUM	V6_DOCNUM
V6_DRGSTPDT	V6_DRGSTPDT
V6_DRGYMD	V6_DRGYMD
V6_FOLLOW	V6_FOLLOW
V6_INV	V6_INV
V6_INVLNAME	V6_INVLNAME
V6_INVSITE	V6_INVSITE
V6_LOCKFLAG	V6_LOCKFLAG
V6_LOGINTS	V6_LOGINTS
V6_LSTCHGTS	V6_LSTCHGTS
V6_MEDB	V6_MEDB
V6_MEDBDT	V6_MEDBDT
V6_MEDBOX	V6_MEDBOX
V6_MEDBX	V6_MEDBX
V6_PT	V6_PT
V6_PTNO	V6_PTNO
V6_REPEATSN	V6_REPEATSN
V6_STUDY	V6_STUDY
V6_SUBSETSN	V6_SUBSETSN
V6_TERMCD	V6_TERMCD
V6_TERMCDC	V6_TERMCDC
V6_TERMOX	V6_TERMOX
V6_TERMPOP	V6_TERMPOP
V6_TERMX	V6_TERMX
V6_TPATT	V6_TPATT
V6_TRCD	V6_TRCD

Flow List

Connected via	Connected to	Src	Dst
V6 Oracle View PATD Fields	2nd Level Oracle Views (Process)		X
V6 PATD Fields to SAS	SAS Processing (Process)	X	

Data Store V7 Oracle View COMP

Name: V7 Oracle View COMP
Code: V7_ORACLE_VIEW_COMP
Label:
Number: 16

Description

```
COMP
select /*+
ORDERED USE_CONCAT
INDEX(dcm DCM_PK_IDX)
INDEX(i OCL_INVESTIGATOR_PK_IDX)
INDEX(r RESPONSE_DCMQG_NFK_IDX ) */

'0205_0117'                          STUDY,
dcm.name                          DCMNAME,
dcm.subset_name                   DCMSUBNM,
dcm.dcm_subset_sn                 SUBSETSN,
rdcm.document_number              DOCNUM,
rdcm.site                         INVSITE,
rdcm.investigator                 INV,
nvl(i.last_name,'<Inv Name>')     INVLNAME,
rdcm.patient                      PT,
rdcm.accessible_ts                ACCESSTS,
decode(substr(rdcm.patient,1,1)
,'0',to_number(rdcm.patient)
,'1',to_number(rdcm.patient)
,'2',to_number(rdcm.patient)
,'3',to_number(rdcm.patient)
,'4',to_number(rdcm.patient)
,'5',to_number(rdcm.patient)
,'6',to_number(rdcm.patient)
,'7',to_number(rdcm.patient)

,'8',to_number(rdcm.patient)
,'9',to_number(rdcm.patient)
,to_Number('')       )   PTNO,
substr(treat.treat_code(rdcm.clinical_study_id ,rdcm.patient_position_id)
,1,8)
TPATT,
substr(treat.treat_abbrev(rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id)
,1,8)
TRCD,
rdcm.log_in_ts                    LOGINTS,
rdcm.last_data_change_ts          LSTCHGTS,
rdcm.data_lock_flag               LOCKFLAG,
rdcm.clin_plan_eve_name           CPEVENT,
to_number(rdcm.visit_number||'.'||ltrim(to_char(rdcm.subevent_number,
'09'))) ACTEVENT,
rdcm.dcm_date                     DCMDATE,
rdcm.dcm_time                     DCMTIME,


r.repeat_sn                       REPEATSN

, max(decode(r.dcm_question_id, 10435602,substr(r.value_text, 1, 1), NULL)) MDCH
```

```
K
, max(decode(r.dcm_question_id, 10435502,substr(r.value_text, 1, 8), NULL)) MDCH
KDT  from
rdcms_view                  rdcm,
dcms                        dcm,
responses_view              r
, ocl_investigators         i

where rdcm.clinical_study_id        = 10001802
and rdcm.dcm_id                     = 10032802
and dcm.dcm_id                      = 10032802
and dcm.dcm_subset_sn               = rdcm.dcm_subset_sn
and dcm.dcm_layout_sn               = 1
and i.investigator_id (+)           = rdcm.investigator_id
and r.received_dcm_id               = rdcm.received_dcm_id

and r.dcm_question_group_id         in (   10053802 )

group by '0205_0117', dcm.name, dcm.subset_name, dcm.dcm_subset_sn,
rdcm.document_number, rdcm.site, rdcm.investigator,
rdcm.patient,
rdcm.accessible_ts, rdcm.log_in_ts, rdcm.last_data_change_ts,
rdcm.data_lock_flag,
rdcm.clin_plan_eve_name,
to_number(rdcm.visit_number||'.'||trim(to_char(rdcm.subevent_number,
'09'))),
rdcm.dcm_date, rdcm.dcm_time,
r.repeat_sn
, i.last_name
, rdcm.clinical_study_id
,rdcm.patient_position_id
,rdcm.clin_plan_eve_id
```

Data Item List

Name	Code
V7_ACCESSTS	V7_ACCESSTS
V7_ACTEVENT	V7_ACTEVENT
V7_ADMOX	V7_ADMOX
V7_ADMTKN	V7_ADMTKN
V7_ADMX	V7_ADMX
V7_BFSTTM	V7_BFSTTM
V7_COMP	V7_COMP
V7_COMP1HML	V7_COMP1HML
V7_COMP2LDT	V7_COMP2LDT
V7_COMP2LTM	V7_COMP2LTM
V7_COMPACC	V7_COMPACC
V7_COMPCD	V7_COMPCD
V7_COMPCH	V7_COMPCH
V7_COMPCHDT	V7_COMPCHDT
V7_COMPDDT	V7_COMPDDT
V7_COMPDIFF	V7_COMPDIFF
V7_COMPDISP	V7_COMPDISP
V7_COMPEXC	V7_COMPEXC
V7_COMPEXP	V7_COMPEXP

Name	Code
V7_COMPMISS	V7_COMPMISS
V7_COMPRDT	V7_COMPRDT
V7_COMPREA	V7_COMPREA
V7_COMPRED	V7_COMPRED
V7_COMPREL	V7_COMPREL
V7_COMPRESC	V7_COMPRESC
V7_COMPRET	V7_COMPRET
V7_COMPRET2	V7_COMPRET2
V7_COMPUSU	V7_COMPUSU
V7_COMPXTRA	V7_COMPXTRA
V7_CPEVENT	V7_CPEVENT
V7_DCMDATE	V7_DCMDATE
V7_DCMNAME	V7_DCMNAME
V7_DCMSUBNM	V7_DCMSUBNM
V7_DCMTIME	V7_DCMTIME
V7_DOCNUM	V7_DOCNUM
V7_DRGSTPDT	V7_DRGSTPDT
V7_DRGSTPTM	V7_DRGSTPTM
V7_DRGYMD	V7_DRGYMD
V7_INV	V7_INV
V7_INVLNAME	V7_INVLNAME
V7_INVSITE	V7_INVSITE
V7_LOCKFLAG	V7_LOCKFLAG
V7_LOGINTS	V7_LOGINTS
V7_LSTCHGTS	V7_LSTCHGTS
V7_MDCHK	V7_MDCHK
V7_MDCHKDT	V7_MDCHKDT
V7_MRIDT	V7_MRIDT
V7_MRITM	V7_MRITM
V7_PT	V7_PT
V7_PTNO	V7_PTNO
V7_REPEATSN	V7_REPEATSN
V7_STUDY	V7_STUDY
V7_SUBSETSN	V7_SUBSETSN
V7_TPATT	V7_TPATT
V7_TRCD	V7_TRCD

Flow List

Connected via	Connected to	Src	Dst
V7 COMP Fields to SAS	SAS Processing (Process)	X	
V7 Oracle View Comp Fields	2nd Level Oracle Views (Process)		X

Processes

Process List

Name	Code
Publish	PUBLISH

Process Publish

Name: Publish
Code: PUBLISH
Label: Context Diagram
Number: 1
Lowest level: No

Description

This Process Model defines all processing needed to produce Adverse Event relatated information for FDA submission.

Input is Oracle Tables (not Views).

Output is Adobe Postscript reports ready for Adobe Pagemaker publishing software.

This Root process defines all the processing needed to:

1. Transform Oracle tables to 1st level Oracle Views.

2. Combine first level Oracle Views and Oracle Tables into 2nd Level Oracle Views

3. Recode 2nd Level Oracle views using SAS Views of 2nd Level Oracle Views.

4. Use these SAS Views to create a SAS schema consisting of SAS Objects.

5. Use this SAS schema to create and SAS code to produce postscript documentation for Adobe publishing software.

Flow List

Connected via	Connected to	Src	Dst
Print Listing 5_2_5	Appendix 15_9_2 LISTING 5_2_2 (External Entity)	X	
Print Listing 5_2_6	Appendix 15_9_2 LISTING 5_2_3 (External Entity)	X	
Print Listing 5_2_7	Appendix 15_9_2 LISTING 5_2_4 (External Entity)	X	
Print Table 5_2_1	Appendix 15_9_2 TABLE 5_2_1 (External Entity)	X	
Print Table 5_2_2	Appendix 15_9_2 TABLE 5_2_2 (External Entity)	X	
Print Table 5_2_3	Appendix 15_9_2 TABLE 5_2_3 (External Entity)	X	
Print Table 5_2_4	Appendix 15_9_2 LISTING 5_2_1 (External Entity)	X	
SAS Patient to Treatment	Patient to Treatment SAS Table (External Entity)		X
T1 Clinical States Fields	Table T1 CLINICAL STUDY STATES (External Entity)		X
T2 Select DCMS Fields	Table T2 DCMS (External Entity)		X

Connected via	Connected to	Src	Dst
T3 Select Trial Level Fields	Table T3 OCL INVESTIGATORS (External Entity)		X
T4 Select Received DCMS Fields	Table T4 RECEIVED DCMS (External Entity)		X
T5 Select CRF Response Fields	Table T5 RESPONSES (External Entity)		X