

# Clinical Study Data Report

Study Attributes :

Description :

File Type : Snapshot

Granularity :

File OID : 987-654-321

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**Study : 123-456-789**

**Study Name : CDISC Test Study II**

**Study Description :** This file contains test data for the CDISC Connect-A-Thon event scheduled for the DIA 11th Annual European Workshop on Clinical Data Management.

**Protocol Name : CDISC-123-456-789**

**Basic Definitions : Units of Measure**

There are no Units of Measure defined

**Study : 123-456-789**

**Metadata Version : Version 1.01**

**Include Prior MetaData Version :** There are no prior metadata versions defined

**Protocol Study Events :**

| Study Event ID | Order Number | Mandatory ? |
|----------------|--------------|-------------|
| SE.VISIT0      |              | Yes         |
| SE.VISIT1      |              | Yes         |

**Study Event Definitions :**

| Name           | ID        | Repeating ? | Type      | Category |
|----------------|-----------|-------------|-----------|----------|
| Pre-treatment  | SE.VISIT0 | No          | Scheduled |          |
| Post-treatment | SE.VISIT1 | No          | Scheduled |          |

**Form Definitions :**

| Name                 | ID            | Repeating ? |
|----------------------|---------------|-------------|
| Adverse Events       | FORM.AE       | No          |
| Concom Meds          | FORM.CONMED   | No          |
| Demography           | FORM.DEMOG    | No          |
| Treatment Assignment | FORM.DRUGPHRM | No          |
| Pharmacokinetics     | FORM.PHARMVIT | No          |
| Physical Exam        | FORM.VITPHYEX | No          |

**Item Group References for Form : Adverse Events**

| Item Group Name | Item Group ID | Order Number | Mandatory ? |
|-----------------|---------------|--------------|-------------|
| Adverse Events  | IG.AE         |              | No          |

## Item Group References for Form : Concom Meds

| Item Group Name | Item Group ID | Order Number | Mandatory ? |
|-----------------|---------------|--------------|-------------|
| Concom Meds     | IG.CONMED     |              | No          |

## Item Group References for Form : Demography

| Item Group Name | Item Group ID | Order Number | Mandatory ? |
|-----------------|---------------|--------------|-------------|
| Demography      | IG.DEMOG      |              | No          |

## Item Group References for Form : Treatment Assignment

| Item Group Name      | Item Group ID | Order Number | Mandatory ? |
|----------------------|---------------|--------------|-------------|
| Treatment Assignment | IG.DRUG_TRT   |              | No          |

## Item Group References for Form : Pharmacokinetics

| Item Group Name  | Item Group ID | Order Number | Mandatory ? |
|------------------|---------------|--------------|-------------|
| Pharmacokinetics | IG.PHARMO1    |              | No          |

## Item Group References for Form : Physical Exam

| Item Group Name | Item Group ID | Order Number | Mandatory ? |
|-----------------|---------------|--------------|-------------|
| Physical Exam   | IG.PHYEX      |              | No          |

## Item Groups :

## Part 1 :

| Name                 | ID          | Rep.? | Is Ref. Data ? |
|----------------------|-------------|-------|----------------|
| Adverse Events       | IG.AE       | Yes   | No             |
| Concom Meds          | IG.CONMED   | Yes   | No             |
| Demography           | IG.DEMOG    | Yes   | No             |
| Treatment Assignment | IG.DRUG_TRT | Yes   | No             |
| Pharmacokinetics     | IG.PHARMO1  | Yes   | No             |
| Physical Exam        | IG.PHYEX    | Yes   | No             |

## Part 2 :

| Name           | SAS Dataset | Domain | Origin | Role | Comment |
|----------------|-------------|--------|--------|------|---------|
| Adverse Events | AE          |        |        |      |         |

| Name                 | SAS Dataset | Domain | Origin | Role | Comment |
|----------------------|-------------|--------|--------|------|---------|
| Concom Meds          | CONMED      |        |        |      |         |
| Demography           | DEMOG       |        |        |      |         |
| Treatment Assignment | DRUG_TRT    |        |        |      |         |
| Pharmacokinetics     | PHARMO1     |        |        |      |         |
| Physical Exam        | PHYEX       |        |        |      |         |

#### Items for Item Group : Adverse Events

| Item Name                             | Item ID     | Order Number | Mandatory ? |
|---------------------------------------|-------------|--------------|-------------|
| Internal unique identifier for record | IT.REC_ID   |              | No          |
| Therapeutic Area                      | IT.TAREA    |              | No          |
| Protocol Number                       | IT.PNO      |              | No          |
| Country                               | IT.SCTRY    |              | No          |
| Record status, 5 levels, internal use | IT.F_STATUS |              | No          |
| Line Number                           | IT.LINE_NO  |              | No          |
| Conmed Indication                     | IT.AETERM   |              | No          |
| Start Month - Enter Two Digits 01-12  | IT.AESTMON  |              | No          |
| Start Day - Enter Two Digits 01-31    | IT.AESTDAY  |              | No          |
| Start Year - Enter Four Digit Year    | IT.AESTYR   |              | No          |
| Derived Start Date                    | IT.AESTDT   |              | No          |
| Stop Month - Enter Two Digits 01-12   | IT.AEENMON  |              | No          |
| Stop Day - Enter Two Digits 01-31     | IT.AEENDAY  |              | No          |
| Stop Year - Enter Four Digit Year     | IT.AEENYR   |              | No          |
| Derived Stop Date                     | IT.AEENDT   |              | No          |
| Severity                              | IT.AESEV    |              | No          |
| Relationship to study drug            | IT.AEREL    |              | No          |
| Outcome                               | IT.AEOUT    |              | No          |
| Actions taken re study drug           | IT.AEACTTRT |              | No          |
| Actions taken, other                  | IT.AECONTRT |              | No          |
| Investigational Site                  | IT.SITE     |              | No          |

#### Items for Item Group : Concom Meds

| Item Name                             | Item ID     | Order Number | Mandatory ? |
|---------------------------------------|-------------|--------------|-------------|
| Internal unique identifier for record | IT.REC_ID   |              | No          |
| Compound                              | IT.R_DRUG   |              | No          |
| Therapeutic Area                      | IT.TAREA    |              | No          |
| Protocol Number                       | IT.PNO      |              | No          |
| Country                               | IT.SCTRY    |              | No          |
| Record status, 5 levels, internal use | IT.F_STATUS |              | No          |
| Line Number                           | IT.LINE_NO  |              | No          |
| Medication For Conmed                 | IT.MEDIC    |              | No          |
| Start Month - Enter Two Digits 01-12  | IT.STRTMON  |              | No          |
| Start Day - Enter Two Digits 01-31    | IT.STRTDAY  |              | No          |
| Start Year - Enter Four Digit Year    | IT.STRTYR   |              | No          |
| Derived Start Date                    | IT.STRT_DT  |              | No          |
| Check if Ongoing                      | IT.ONGOING  |              | No          |
| Stop Month - Enter Two Digits 01-12   | IT.STOPMON  |              | No          |
| Stop Day - Enter Two Digits 01-31     | IT.STOPDAY  |              | No          |
| Stop Year - Enter Four Digit Year     | IT.STOPYR   |              | No          |
| Derived Stop Date                     | IT.STOP_DT  |              | No          |
| Dose and Unit                         | IT.DOSEUNIT |              | No          |
| Conmed Route                          | IT.ROUTE    |              | No          |
| Conmed Regimen                        | IT.REGIMEN  |              | No          |
| Conmed Indication                     | IT.INDIC    |              | No          |
| Check If Taken for AE                 | IT.AE_RELAT |              | No          |
| Investigational Site                  | IT.SITE     |              | No          |

#### Items for Item Group : Demography

| Item Name                             | Item ID     | Order Number | Mandatory ? |
|---------------------------------------|-------------|--------------|-------------|
| Internal unique identifier for record | IT.REC_ID   |              | No          |
| Compound                              | IT.R_DRUG   |              | No          |
| Therapeutic Area                      | IT.TAREA    |              | No          |
| Protocol Number                       | IT.PNO      |              | No          |
| Country                               | IT.SCTRY    |              | No          |
| Record status, 5 levels,              | IT.F_STATUS |              | No          |

| Item Name            | Item ID    | Order Number | Mandatory ? |
|----------------------|------------|--------------|-------------|
| internal use         |            |              |             |
| Height               | IT.HT      |              | No          |
| Weight               | IT.WT      |              | No          |
| Gender               | IT.SEX     |              | No          |
| Date of Birth        | IT.DOB     |              | No          |
| Ethnic Group         | IT.RACE    |              | No          |
| Height Units         | IT.HTUNITS |              | No          |
| Weight Units         | IT.WTUNITS |              | No          |
| Investigational Site | IT.SITE    |              | No          |

#### Items for Item Group : Treatment Assignment

| Item Name                             | Item ID     | Order Number | Mandatory ? |
|---------------------------------------|-------------|--------------|-------------|
| Internal unique identifier for record | IT.REC_ID   |              | No          |
| Compound                              | IT.R_DRUG   |              | No          |
| Therapeutic Area                      | IT.TAREA    |              | No          |
| Protocol Number                       | IT.PNO      |              | No          |
| Country                               | IT.SCTRY    |              | No          |
| Record status, 5 levels, internal use | IT.F_STATUS |              | No          |
| Assigned Study Drug Treatment         | IT.DRUG_TRT |              | No          |
| Investigational Site                  | IT.SITE     |              | No          |

#### Items for Item Group : Pharmacokinetics

| Item Name                             | Item ID     | Order Number | Mandatory ? |
|---------------------------------------|-------------|--------------|-------------|
| Internal unique identifier for record | IT.REC_ID   |              | No          |
| Compound                              | IT.R_DRUG   |              | No          |
| Therapeutic Area                      | IT.TAREA    |              | No          |
| Protocol Number                       | IT.PNO      |              | No          |
| Country                               | IT.SCTRY    |              | No          |
| Record status, 5 levels, internal use | IT.F_STATUS |              | No          |
| Pretreatment yr                       | IT.PKYR0    |              | No          |
| 1-h year                              | IT.PKYR1    |              | No          |
| 2-h year                              | IT.PKYR2    |              | No          |
| 3-h year                              | IT.PKYR3    |              | No          |
| 4-h year                              | IT.PKYR4    |              | No          |

| Item Name            | Item ID     | Order Number | Mandatory ? |
|----------------------|-------------|--------------|-------------|
| 8-h year             | IT.PKYR8    |              | No          |
| 16-h year            | IT.PKYR16   |              | No          |
| 24-h year            | IT.PKYR24   |              | No          |
| Meal year            | IT.MEALYR   |              | No          |
| Pretreatment mon     | IT.PKMON0   |              | No          |
| 1-h mon              | IT.PKMON1   |              | No          |
| 2-h mon              | IT.PKMON2   |              | No          |
| 3-h mon              | IT.PKMON3   |              | No          |
| 4-h mon              | IT.PKMON4   |              | No          |
| 8-h mon              | IT.PKMON8   |              | No          |
| 16-h mon             | IT.PKMON16  |              | No          |
| 24-h mon             | IT.PKMON24  |              | No          |
| Meal mon             | IT.MEALMON  |              | No          |
| Pretreatment day     | IT.PKDAY0   |              | No          |
| 1-h day              | IT.PKDAY1   |              | No          |
| 2-h day              | IT.PKDAY2   |              | No          |
| 3-h day              | IT.PKDAY3   |              | No          |
| 4-h day              | IT.PKDAY4   |              | No          |
| 8-h day              | IT.PKDAY8   |              | No          |
| 16-h day             | IT.PKDAY16  |              | No          |
| 24-h day             | IT.PKDAY24  |              | No          |
| Meal day             | IT.MEALDAY  |              | No          |
| Not done             | IT.NOTDONE  |              | No          |
| Pretreatment date    | IT.PK_DT0   |              | No          |
| 1-h date             | IT.PK_DT1   |              | No          |
| 2-h date             | IT.PK_DT2   |              | No          |
| 3-h date             | IT.PK_DT3   |              | No          |
| 4-h date             | IT.PK_DT4   |              | No          |
| 8-h date             | IT.PK_DT8   |              | No          |
| 16-h date            | IT.PK_DT16  |              | No          |
| 24-h date            | IT.PK_DT24  |              | No          |
| Date of last meal    | IT.MEAL_DT  |              | No          |
| Pretreatment time    | IT.PK_TIM0  |              | No          |
| 1-h time             | IT.PK_TIM1  |              | No          |
| 2-h time             | IT.PK_TIM2  |              | No          |
| 3-h time             | IT.PK_TIM3  |              | No          |
| 4-h time             | IT.PK_TIM4  |              | No          |
| 8-h time             | IT.PK_TIM8  |              | No          |
| 16-h time            | IT.PK_TIM16 |              | No          |
| 24-h time            | IT.PK_TIM24 |              | No          |
| Time of last meal    | IT.MEALTIM  |              | No          |
| Investigational Site | IT.SITE     |              | No          |

## Items for Item Group : Physical Exam

| Item Name                             | Item ID     | Order Number | Mandatory ? |
|---------------------------------------|-------------|--------------|-------------|
| Internal unique identifier for record | IT.REC_ID   |              | No          |
| Compound                              | IT.R_DRUG   |              | No          |
| Therapeutic Area                      | IT.TAREA    |              | No          |
| Protocol Number                       | IT.PNO      |              | No          |
| Country                               | IT.SCTRY    |              | No          |
| Record status, 5 levels, internal use | IT.F_STATUS |              | No          |
| Physical Exam Body System             | IT.BODY_SYS |              | No          |
| Normal/Abnormal/Not Done              | IT.ABNORM   |              | No          |
| Comment                               | IT.COMMT1   |              | No          |
| Investigational Site                  | IT.SITE     |              | No          |

## Items :

Items for which additional information is available are in red (and linked)

## Part 1 :

| Name                                | ID          | Data Type | Length | Signif. Digits |
|-------------------------------------|-------------|-----------|--------|----------------|
| Normal/Abnormal/Not Done            | IT.ABNORM   | integer   |        |                |
| Actions taken re study drug         | IT.AEACTTRT | text      | 1      |                |
| Actions taken, other                | IT.AECONTRT | text      | 1      |                |
| Stop Day - Enter Two Digits 01-31   | IT.AEENDAY  | text      | 2      |                |
| Derived Stop Date                   | IT.AEENDT   | text      | 8      |                |
| Stop Month - Enter Two Digits 01-12 | IT.AEENMON  | text      | 2      |                |
| Stop Year - Enter Four Digit Year   | IT.AEENYR   | text      | 4      |                |
| Outcome                             | IT.AEOUT    | text      | 1      |                |
| Relationship to study drug          | IT.AEREL    | text      | 1      |                |
| Severity                            | IT.AESEV    | text      | 1      |                |
| Start Day - Enter Two Digits 01-31  | IT.AESTDAY  | text      | 2      |                |
| Derived Start Date                  | IT.AESTDT   | text      | 8      |                |

| Name                                  | ID          | Data Type | Length | Signif. Digits |
|---------------------------------------|-------------|-----------|--------|----------------|
| Start Month - Enter Two Digits 01-12  | IT.AESTMON  | text      | 2      |                |
| Start Year - Enter Four Digit Year    | IT.AESTYR   | text      | 4      |                |
| Conmed Indication                     | IT.AETERM   | text      | 100    |                |
| Check If Taken for AE                 | IT.AE_RELAT | text      | 1      |                |
| Physical Exam Body System             | IT.BODY_SYS | integer   |        |                |
| Comment                               | IT.COMMT1   | text      | 200    |                |
| Date of Birth                         | IT.DOB      | text      | 8      |                |
| Dose and Unit                         | IT.DOSEUNIT | text      | 20     |                |
| Assigned Study Drug Treatment         | IT.DRUG_TRT | integer   |        |                |
| Record status, 5 levels, internal use | IT.F_STATUS | text      | 1      |                |
| Height                                | IT.HT       | float     |        |                |
| Height Units                          | IT.HTUNITS  | text      | 2      |                |
| Conmed Indication                     | IT.INDIC    | text      | 100    |                |
| Line Number                           | IT.LINE_NO  | float     |        |                |
| Meal day                              | IT.MEALDAY  | text      | 2      |                |
| Meal mon                              | IT.MEALMON  | text      | 2      |                |
| Time of last meal                     | IT.MEALTIM  | text      | 4      |                |
| Meal year                             | IT.MEALYR   | text      | 4      |                |
| Date of last meal                     | IT.MEAL_DT  | text      | 8      |                |
| Medication For Conmed                 | IT.MEDIC    | text      | 200    |                |
| Not done                              | IT.NOTDONE  | text      | 1      |                |
| Check if Ongoing                      | IT.ONGOING  | text      | 1      |                |
| Pretreatment day                      | IT.PKDAY0   | text      | 2      |                |
| 1-h day                               | IT.PKDAY1   | text      | 2      |                |
| 16-h day                              | IT.PKDAY16  | text      | 2      |                |
| 2-h day                               | IT.PKDAY2   | text      | 2      |                |
| 24-h day                              | IT.PKDAY24  | text      | 2      |                |
| 3-h day                               | IT.PKDAY3   | text      | 2      |                |
| 4-h day                               | IT.PKDAY4   | text      | 2      |                |
| 8-h day                               | IT.PKDAY8   | text      | 2      |                |
| Pretreatment mon                      | IT.PKMON0   | text      | 2      |                |
| 1-h mon                               | IT.PKMON1   | text      | 2      |                |
| 16-h mon                              | IT.PKMON16  | text      | 2      |                |
| 2-h mon                               | IT.PKMON2   | text      | 2      |                |
| 24-h mon                              | IT.PKMON24  | text      | 2      |                |
| 3-h mon                               | IT.PKMON3   | text      | 2      |                |

| Name                                  | ID          | Data Type | Length | Signif. Digits |
|---------------------------------------|-------------|-----------|--------|----------------|
| 4-h mon                               | IT.PKMON4   | text      | 2      |                |
| 8-h mon                               | IT.PKMON8   | text      | 2      |                |
| Pretreatment yr                       | IT.PKYR0    | text      | 4      |                |
| 1-h year                              | IT.PKYR1    | text      | 4      |                |
| 16-h year                             | IT.PKYR16   | text      | 4      |                |
| 2-h year                              | IT.PKYR2    | text      | 4      |                |
| 24-h year                             | IT.PKYR24   | text      | 4      |                |
| 3-h year                              | IT.PKYR3    | text      | 4      |                |
| 4-h year                              | IT.PKYR4    | text      | 4      |                |
| 8-h year                              | IT.PKYR8    | text      | 4      |                |
| Pretreatment date                     | IT.PK_DT0   | text      | 8      |                |
| 1-h date                              | IT.PK_DT1   | text      | 8      |                |
| 16-h date                             | IT.PK_DT16  | text      | 8      |                |
| 2-h date                              | IT.PK_DT2   | text      | 8      |                |
| 24-h date                             | IT.PK_DT24  | text      | 8      |                |
| 3-h date                              | IT.PK_DT3   | text      | 8      |                |
| 4-h date                              | IT.PK_DT4   | text      | 8      |                |
| 8-h date                              | IT.PK_DT8   | text      | 8      |                |
| Pretreatment time                     | IT.PK_TIM0  | text      | 4      |                |
| 1-h time                              | IT.PK_TIM1  | text      | 4      |                |
| 16-h time                             | IT.PK_TIM16 | text      | 4      |                |
| 2-h time                              | IT.PK_TIM2  | text      | 4      |                |
| 24-h time                             | IT.PK_TIM24 | text      | 4      |                |
| 3-h time                              | IT.PK_TIM3  | text      | 4      |                |
| 4-h time                              | IT.PK_TIM4  | text      | 4      |                |
| 8-h time                              | IT.PK_TIM8  | text      | 4      |                |
| Protocol Number                       | IT.PNO      | text      | 15     |                |
| Ethnic Group                          | IT.RACE     | text      | 10     |                |
| Internal unique identifier for record | IT.REC_ID   | text      | 40     |                |
| Conmed Regimen                        | IT.REGIMEN  | integer   |        |                |
| Conmed Route                          | IT.ROUTE    | integer   |        |                |
| Compound                              | IT.R_DRUG   | text      | 8      |                |
| Country                               | IT.SCTRY    | text      | 4      |                |
| Gender                                | IT.SEX      | text      | 6      |                |
| Investigational Site                  | IT.SITE     | text      | 15     |                |
| Stop Day - Enter Two Digits 01-31     | IT.STOPDAY  | text      | 2      |                |
| Stop Month - Enter Two Digits 01-12   | IT.STOPMON  | text      | 2      |                |
| Stop Year - Enter Four                | IT.STOPYR   | text      | 4      |                |

| Name                                 | ID         | Data Type | Length | Signif. Digits |
|--------------------------------------|------------|-----------|--------|----------------|
| Digit Year                           |            |           |        |                |
| Derived Stop Date                    | IT.STOP_DT | text      | 8      |                |
| Start Day - Enter Two Digits 01-31   | IT.STRTDAY | text      | 2      |                |
| Start Month - Enter Two Digits 01-12 | IT.STRTMON | text      | 2      |                |
| Start Year - Enter Four Digit Year   | IT.STRTYR  | text      | 4      |                |
| Derived Start Date                   | IT.STRT_DT | text      | 8      |                |
| Therapeutic Area                     | IT.TAREA   | text      | 4      |                |
| Weight                               | IT.WT      | float     |        |                |
| Weight Units                         | IT.WTUNITS | text      | 2      |                |

## Part 2 :

| Name                                 | Code List Ref. | SAS Field Name | SDS Var Name |
|--------------------------------------|----------------|----------------|--------------|
| Normal/Abnormal/Not Done             | CL.N_A_ND      | ABNORM         |              |
| Actions taken re study drug          | CL.AEACTTR     | AEACTTRT       |              |
| Actions taken, other                 | CL.AECONTR     | AECONTRT       |              |
| Stop Day - Enter Two Digits 01-31    |                | AEENDAY        |              |
| Derived Stop Date                    |                | AEENDT         |              |
| Stop Month - Enter Two Digits 01-12  |                | AEENMON        |              |
| Stop Year - Enter Four Digit Year    |                | AEENYR         |              |
| Outcome                              | CL.AEOUT       | AEOUT          |              |
| Relationship to study drug           | CL.AEREL       | AEREL          |              |
| Severity                             | CL.AESEV       | AESEV          |              |
| Start Day - Enter Two Digits 01-31   |                | AESTDAY        |              |
| Derived Start Date                   |                | AESTDT         |              |
| Start Month - Enter Two Digits 01-12 |                | AESTMON        |              |
| Start Year - Enter Four Digit Year   |                | AESTYR         |              |
| Conmed Indication                    |                | AETERM         |              |
| Check If Taken for AE                | CL.AEREL       | AE_RELAT       |              |
| Physical Exam Body System            | CL.PE_TEST     | BODY_SYS       |              |

| Name                                  | Code List Ref. | SAS Field Name | SDS Var Name |
|---------------------------------------|----------------|----------------|--------------|
| Comment                               |                | COMMT1         |              |
| Date of Birth                         |                | DOB            |              |
| Dose and Unit                         |                | DOSEUNIT       |              |
| Assigned Study Drug Treatment         | CL.DRUGTRTF    | DRUG_TRT       |              |
| Record status, 5 levels, internal use | CL.F_STATU     | F_STATUS       |              |
| Height                                |                | HT             |              |
| Height Units                          |                | HTUNITS        |              |
| Conmed Indication                     |                | INDIC          |              |
| Line Number                           |                | LINE_NO        |              |
| Meal day                              |                | MEALDAY        |              |
| Meal mon                              |                | MEALMON        |              |
| Time of last meal                     |                | MEALTIM        |              |
| Meal year                             |                | MEALYR         |              |
| Date of last meal                     |                | MEAL_DT        |              |
| Medication For Conmed                 |                | MEDIC          |              |
| Not done                              |                | NOTDONE        |              |
| Check if Ongoing                      |                | ONGOING        |              |
| Pretreatment day                      |                | PKDAY0         |              |
| 1-h day                               |                | PKDAY1         |              |
| 16-h day                              |                | PKDAY16        |              |
| 2-h day                               |                | PKDAY2         |              |
| 24-h day                              |                | PKDAY24        |              |
| 3-h day                               |                | PKDAY3         |              |
| 4-h day                               |                | PKDAY4         |              |
| 8-h day                               |                | PKDAY8         |              |
| Pretreatment mon                      |                | PKMON0         |              |
| 1-h mon                               |                | PKMON1         |              |
| 16-h mon                              |                | PKMON16        |              |
| 2-h mon                               |                | PKMON2         |              |
| 24-h mon                              |                | PKMON24        |              |
| 3-h mon                               |                | PKMON3         |              |
| 4-h mon                               |                | PKMON4         |              |
| 8-h mon                               |                | PKMON8         |              |
| Pretreatment yr                       |                | PKYR0          |              |
| 1-h year                              |                | PKYR1          |              |
| 16-h year                             |                | PKYR16         |              |
| 2-h year                              |                | PKYR2          |              |
| 24-h year                             |                | PKYR24         |              |
| 3-h year                              |                | PKYR3          |              |
| 4-h year                              |                | PKYR4          |              |

| Name                                  | Code List Ref. | SAS Field Name | SDS Var Name |
|---------------------------------------|----------------|----------------|--------------|
| 8-h year                              |                | PKYR8          |              |
| Pretreatment date                     |                | PK_DT0         |              |
| 1-h date                              |                | PK_DT1         |              |
| 16-h date                             |                | PK_DT16        |              |
| 2-h date                              |                | PK_DT2         |              |
| 24-h date                             |                | PK_DT24        |              |
| 3-h date                              |                | PK_DT3         |              |
| 4-h date                              |                | PK_DT4         |              |
| 8-h date                              |                | PK_DT8         |              |
| Pretreatment time                     |                | PK_TIM0        |              |
| 1-h time                              |                | PK_TIM1        |              |
| 16-h time                             |                | PK_TIM16       |              |
| 2-h time                              |                | PK_TIM2        |              |
| 24-h time                             |                | PK_TIM24       |              |
| 3-h time                              |                | PK_TIM3        |              |
| 4-h time                              |                | PK_TIM4        |              |
| 8-h time                              |                | PK_TIM8        |              |
| Protocol Number                       |                | PNO            |              |
| Ethnic Group                          |                | RACE           |              |
| Internal unique identifier for record |                | REC_ID         |              |
| Conmed Regimen                        | CL.REGF        | REGIMEN        |              |
| Conmed Route                          | CL.ROUTEF      | ROUTE          |              |
| Compound                              |                | R_DRUG         |              |
| Country                               | CL.SCTRYF      | SCTRY          |              |
| Gender                                | CL.SEXF        | SEX            |              |
| Investigational Site                  | CL.SITEF       | SITE           |              |
| Stop Day - Enter Two Digits 01-31     |                | STOPDAY        |              |
| Stop Month - Enter Two Digits 01-12   |                | STOPMON        |              |
| Stop Year - Enter Four Digit Year     |                | STOPYR         |              |
| Derived Stop Date                     |                | STOP_DT        |              |
| Start Day - Enter Two Digits 01-31    |                | STRTDAY        |              |
| Start Month - Enter Two Digits 01-12  |                | STRTMON        |              |
| Start Year - Enter Four Digit Year    |                | STRTYR         |              |
| Derived Start Date                    |                | STRT_DT        |              |
| Therapeutic Area                      | CL.TAREAF      | TAREA          |              |

| Name         | Code List Ref. | SAS Field Name | SDS Var Name |
|--------------|----------------|----------------|--------------|
| Weight       |                | WT             |              |
| Weight Units |                | WTUNITS        |              |

## Part 3 :

| Name                                  | Origin | Role | Comment |
|---------------------------------------|--------|------|---------|
| Normal/Abnormal/Not Done              |        |      |         |
| Actions taken re study drug           |        |      |         |
| Actions taken, other                  |        |      |         |
| Stop Day - Enter Two Digits 01-31     |        |      |         |
| Derived Stop Date                     |        |      |         |
| Stop Month - Enter Two Digits 01-12   |        |      |         |
| Stop Year - Enter Four Digit Year     |        |      |         |
| Outcome                               |        |      |         |
| Relationship to study drug            |        |      |         |
| Severity                              |        |      |         |
| Start Day - Enter Two Digits 01-31    |        |      |         |
| Derived Start Date                    |        |      |         |
| Start Month - Enter Two Digits 01-12  |        |      |         |
| Start Year - Enter Four Digit Year    |        |      |         |
| Conmed Indication                     |        |      |         |
| Check If Taken for AE                 |        |      |         |
| Physical Exam Body System             |        |      |         |
| Comment                               |        |      |         |
| Date of Birth                         |        |      |         |
| Dose and Unit                         |        |      |         |
| Assigned Study Drug Treatment         |        |      |         |
| Record status, 5 levels, internal use |        |      |         |
| Height                                |        |      |         |
| Height Units                          |        |      |         |
| Conmed Indication                     |        |      |         |
| Line Number                           |        |      |         |

| Name                  | Origin | Role | Comment |
|-----------------------|--------|------|---------|
| Meal day              |        |      |         |
| Meal mon              |        |      |         |
| Time of last meal     |        |      |         |
| Meal year             |        |      |         |
| Date of last meal     |        |      |         |
| Medication For Conmed |        |      |         |
| Not done              |        |      |         |
| Check if Ongoing      |        |      |         |
| Pretreatment day      |        |      |         |
| 1-h day               |        |      |         |
| 16-h day              |        |      |         |
| 2-h day               |        |      |         |
| 24-h day              |        |      |         |
| 3-h day               |        |      |         |
| 4-h day               |        |      |         |
| 8-h day               |        |      |         |
| Pretreatment mon      |        |      |         |
| 1-h mon               |        |      |         |
| 16-h mon              |        |      |         |
| 2-h mon               |        |      |         |
| 24-h mon              |        |      |         |
| 3-h mon               |        |      |         |
| 4-h mon               |        |      |         |
| 8-h mon               |        |      |         |
| Pretreatment yr       |        |      |         |
| 1-h year              |        |      |         |
| 16-h year             |        |      |         |
| 2-h year              |        |      |         |
| 24-h year             |        |      |         |
| 3-h year              |        |      |         |
| 4-h year              |        |      |         |
| 8-h year              |        |      |         |
| Pretreatment date     |        |      |         |
| 1-h date              |        |      |         |
| 16-h date             |        |      |         |
| 2-h date              |        |      |         |
| 24-h date             |        |      |         |
| 3-h date              |        |      |         |
| 4-h date              |        |      |         |
| 8-h date              |        |      |         |
| Pretreatment time     |        |      |         |
| 1-h time              |        |      |         |

| Name                                     | Origin | Role | Comment |
|--|--------|------|---------|
| 16-h time                                |        |      |         |
| 2-h time                                 |        |      |         |
| 24-h time                                |        |      |         |
| 3-h time                                 |        |      |         |
| 4-h time                                 |        |      |         |
| 8-h time                                 |        |      |         |
| Protocol Number                          |        |      |         |
| Ethnic Group                             |        |      |         |
| Internal unique identifier<br>for record |        |      |         |
| Conmed Regimen                           |        |      |         |
| Conmed Route                             |        |      |         |
| Compound                                 |        |      |         |
| Country                                  |        |      |         |
| Gender                                   |        |      |         |
| Investigational Site                     |        |      |         |
| Stop Day - Enter Two<br>Digits 01-31     |        |      |         |
| Stop Month - Enter Two<br>Digits 01-12   |        |      |         |
| Stop Year - Enter Four<br>Digit Year     |        |      |         |
| Derived Stop Date                        |        |      |         |
| Start Day - Enter Two<br>Digits 01-31    |        |      |         |
| Start Month - Enter Two<br>Digits 01-12  |        |      |         |
| Start Year - Enter Four<br>Digit Year    |        |      |         |
| Derived Start Date                       |        |      |         |
| Therapeutic Area                         |        |      |         |
| Weight                                   |        |      |         |
| Weight Units                             |        |      |         |

Additional information for Items :

Code Lists :



CodeLists for which additional information is available are in red (and linked)

| Name  | ID          | Data Type | SAS Format Name |
|---|-------------|-----------|-----------------|
| <a href="#">AE Action Taken, Study Drug</a>   | CL.AEACTTR  | text      | AEACTTR         |
| <a href="#">AE Action Taken, Other</a>        | CL.AECONTR  | text      | AECONTR         |
| <a href="#">AE Outcome</a>                    | CL.AEOUT    | text      | AEOUT           |
| <a href="#">AE Relationship to Study Drug</a> | CL.AEREL    | text      | AEREL           |
| <a href="#">AE Severity</a>                   | CL.AESEV    | text      | AESEV           |
| <a href="#">Assigned Study Drug</a>           | CL.DRUGTRTF | integer   | DRUGTRTF        |
| <a href="#">Record Status, Internal</a>       | CL.F_STATU  | text      | F_STATU         |
| <a href="#">Normal/Abnormal/Not Done</a>      | CL.N_A_ND   | integer   | N_A_ND          |
| <a href="#">PE Body System</a>                | CL.PE_TEST  | integer   | PE_TEST         |
| <a href="#">Conmed Regimen</a>                | CL.REGF     | integer   | REGF            |
| <a href="#">Conmed Route</a>                  | CL.ROUTEF   | integer   | ROUTEF          |
| <a href="#">Country</a>                       | CL.SCTRYF   | text      | SCTRYF          |
| <a href="#">Gender</a>                        | CL.SEXF     | text      | SEXF            |
| <a href="#">Investigational Site</a>          | CL.SITEF    | text      | SITEF           |
| <a href="#">Therapeutic Area</a>              | CL.TAREAF   | text      | TAREAF          |

Additional information for CodeList : [AE Action Taken, Study Drug](#)

| Coded Value | Decoded Value            | Language |
|-------------|--------------------------|----------|
| 0           | None                     | en       |
| 1           | Discontinued permanently | en       |
| 2           | Reduced                  | en       |
| 3           | Interrupted              | en       |

Additional information for CodeList : [AE Action Taken, Other](#)

| Coded Value | Decoded Value                         | Language |
|-------------|---------------------------------------|----------|
| 0           | None                                  | en       |
| 1           | Medication required                   | en       |
| 2           | Hospitalization required or prolonged | en       |
| 3           | Other                                 | en       |

Additional information for CodeList : [AE Outcome](#)

| Coded Value | Decoded Value                 | Language |
|-------------|-------------------------------|----------|
| 1           | Resolved, no residual effects | en       |
| 2           | Continuing                    | en       |
| 3           | Resolved, residual effects    | en       |
| 4           | Death                         | en       |

Additional information for CodeList : [AE Relationship to Study Drug](#)

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| 0           | None          | en       |
| 1           | Unlikely      | en       |
| 2           | Possible      | en       |
| 3           | Probable      | en       |

Additional information for CodeList : AE Severity

| Coded Value | Decoded Value    | Language |
|-------------|------------------|----------|
| 1           | Mild             | en       |
| 2           | Moderate         | en       |
| 3           | Severe           | en       |
| 4           | Life Threatening | en       |

Additional information for CodeList : Assigned Study Drug

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| 1           | Treatment A   | en       |
| 2           | Treatment B   | en       |
| 3           | Treatment C   | en       |

Additional information for CodeList : Record Status, Internal

| Coded Value | Decoded Value                | Language |
|-------------|------------------------------|----------|
| S           | Source verified, not queried | en       |
| V           | Source verified, queried     | en       |

Additional information for CodeList : Normal/Abnormal/Not Done

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| 1           | Normal        | en       |
| 2           | Abnormal      | en       |
| 3           | Not Done      | en       |

Additional information for CodeList : PE Body System

| Coded Value | Decoded Value               | Language |
|-------------|-----------------------------|----------|
| 1           | Head, Neck and Thyroid      | en       |
| 2           | Eyes, Ears, Nose and Throat | en       |
| 3           | Chest                       | en       |
| 4           | Lungs                       | en       |
| 5           | Heart                       | en       |
| 6           | Lymph Nodes                 | en       |
| 7           | Abdomen                     | en       |

| Coded Value | Decoded Value   | Language |
|-------------|-----------------|----------|
| 8           | Anorectal       | en       |
| 9           | Genitalia       | en       |
| 10          | Skin            | en       |
| 11          | Musculoskeletal | en       |
| 12          | Neurological    | en       |
| 13          | Other           | en       |

#### Additional information for CodeList : Conmed Regimen

| Coded Value | Decoded Value                   | Language |
|-------------|---------------------------------|----------|
| 1           | q.d.                            | en       |
| 2           | b.i.d.                          | en       |
| 3           | t.i.d.                          | en       |
| 4           | q.i.d.                          | en       |
| 5           | q.o.d.                          | en       |
| 6           | q.h.s.                          | en       |
| 7           | cont. IV                        | en       |
| 8           | prn                             | en       |
| 9           | If not in list, record as Other | en       |

#### Additional information for CodeList : Conmed Route

| Coded Value | Decoded Value  | Language |
|-------------|----------------|----------|
| 1           | IV             | en       |
| 2           | IM             | en       |
| 3           | PO             | en       |
| 4           | SC             | en       |
| 5           | PV             | en       |
| 6           | PR             | en       |
| 7           | Sublingual     | en       |
| 8           | Inhaled        | en       |
| 9           | Topical        | en       |
| 10          | If not in list | en       |

#### Additional information for CodeList : Country

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| USA         | United States | en       |

#### Additional information for CodeList : Gender

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| F           | Female        | en       |

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| M           | Male          | en       |

Additional information for CodeList : Investigational Site

| Coded Value | Decoded Value   | Language |
|-------------|-----------------|----------|
| FH          | Fred Hutchinson | en       |
| RP          | Roswell Park    | en       |

Additional information for CodeList : Therapeutic Area

| Coded Value | Decoded Value | Language |
|-------------|---------------|----------|
| ONC         | Oncology      | en       |

Presentations : There are no Presentations defined

## Administration Data :

User : ID = USR.cdisc001

Full Name : Shirley Williams

First Name : Shirley

Last Name : Williams

Organization: CDISC

Location : ID = LOC.CDISCHome

Location Name : CDISC Headquarters

Location Type : Other

Metadata Version Reference :

Study ID : 123-456-789

Metadata Version ID : v1.01

Effective Date : 20011019T10:45:57-05:00

Signature Definition : ID = SD.cdisc001-es

Methodology : Electronic

Signature Meaning : Signature Meaning

Legal Reason : Legal Reason

Clinical Data: Study = 123-456-789

MetaDataVersion ID = v1.01

## Subject Data:

Subject Key = 001

## Study Event Data:

Study Event = Pre-treatment

## Form Data:

ID = Demography

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46902604 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels,              | V        |          |            |

| Item                 | Value     | is Null? | Trans.Type |
|----------------------|-----------|----------|------------|
| internal use         |           |          |            |
| Height               | 73        |          |            |
| Weight               | 204       |          |            |
| Gender               | M         |          |            |
| Date of Birth        | 19600403  |          |            |
| Ethnic Group         | Caucasian |          |            |
| Height Units         | in        |          |            |
| Weight Units         | lb        |          |            |
| Investigational Site | RP        |          |            |

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46878904 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Assigned Study Drug Treatment         | 1        |          |            |

| Item                 | Value | is Null? | Trans.Type |
|----------------------|-------|----------|------------|
| Investigational Site | RP    |          |            |

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46881304 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Pretreatment yr                       | 1999     |          |            |
| 1-h year                              | 1999     |          |            |
| 2-h year                              | 1999     |          |            |
| 3-h year                              | 1999     |          |            |
| 4-h year                              | 1999     |          |            |
| 8-h year                              | 1999     |          |            |
| 16-h year                             | 1999     |          |            |
| 24-h year                             | 1999     |          |            |
| Meal year                             | 1999     |          |            |
| Pretreatment mon                      | 06       |          |            |

| Item                 | Value    | is Null? | Trans.Type |
|----------------------|----------|----------|------------|
| 1-h mon              | 06       |          |            |
| 2-h mon              | 06       |          |            |
| 3-h mon              | 06       |          |            |
| 4-h mon              | 06       |          |            |
| 8-h mon              | 06       |          |            |
| 16-h mon             | 06       |          |            |
| 24-h mon             | 06       |          |            |
| Meal mon             | 06       |          |            |
| Pretreatment day     | 20       |          |            |
| 1-h day              | 20       |          |            |
| 2-h day              | 20       |          |            |
| 3-h day              | 20       |          |            |
| 4-h day              | 20       |          |            |
| 8-h day              | 20       |          |            |
| 16-h day             | 20       |          |            |
| 24-h day             | 21       |          |            |
| Meal day             | 20       |          |            |
| Pretreatment date    | 19990620 |          |            |
| 1-h date             | 19990620 |          |            |
| 2-h date             | 19990620 |          |            |
| 3-h date             | 19990620 |          |            |
| 4-h date             | 19990620 |          |            |
| 8-h date             | 19990620 |          |            |
| 16-h date            | 19990620 |          |            |
| 24-h date            | 19990621 |          |            |
| Date of last meal    | 19990620 |          |            |
| Pretreatment time    | 0600     |          |            |
| 1-h time             | 0700     |          |            |
| 2-h time             | 0800     |          |            |
| 3-h time             | 0900     |          |            |
| 4-h time             | 1000     |          |            |
| 8-h time             | 1400     |          |            |
| 16-h time            | 1800     |          |            |
| 24-h time            | 0600     |          |            |
| Time of last meal    | 0500     |          |            |
| Investigational Site | RP       |          |            |

## Form Data:

ID = Physical Exam



Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46869304 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 1        |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Item Group : Physical Exam

Repeat key: 2

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46869504 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |

| Item                                  | Value | is Null? | Trans.Type |
|---------------------------------------|-------|----------|------------|
| Country                               | USA   |          |            |
| Record status, 5 levels, internal use | V     |          |            |
| Physical Exam Body System             | 2     |          |            |
| Normal/Abnormal/Not Done              | 1     |          |            |
| Investigational Site                  | RP    |          |            |

Item Group : Physical Exam

Repeat key: 3

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46869604 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 3        |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Item Group : Physical Exam

Repeat key: 4

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46869804 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |

| Item                                  | Value         | is Null? | Trans.Type |
|---------------------------------------|---------------|----------|------------|
| Country                               | USA           |          |            |
| Record status, 5 levels, internal use | V             |          |            |
| Physical Exam Body System             | 4             |          |            |
| Normal/Abnormal/Not Done              | 2             |          |            |
| Comment                               | MILD WHEEZING |          |            |
| Investigational Site                  | RP            |          |            |

Item Group : Physical Exam

Repeat key: 5

| Item                                  | Value       | is Null? | Trans.Type |
|---------------------------------------|-------------|----------|------------|
| Internal unique identifier for record | 46869904    |          |            |
| Compound                              | SDP         |          |            |
| Therapeutic Area                      | ONC         |          |            |
| Protocol Number                       | 143-02      |          |            |
| Country                               | USA         |          |            |
| Record status, 5 levels, internal use | V           |          |            |
| Physical Exam Body System             | 5           |          |            |
| Normal/Abnormal/Not Done              | 2           |          |            |
| Comment                               | TACHYCARDIA |          |            |
| Investigational Site                  | RP          |          |            |

Item Group : Physical Exam

Repeat key: 6

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46870604 |          |            |
| Compound                              | SDP      |          |            |

| Item                                  | Value                 | is Null? | Trans.Type |
|---------------------------------------|-----------------------|----------|------------|
| Therapeutic Area                      | ONC                   |          |            |
| Protocol Number                       | 143-02                |          |            |
| Country                               | USA                   |          |            |
| Record status, 5 levels, internal use | V                     |          |            |
| Physical Exam Body System             | 6                     |          |            |
| Normal/Abnormal/Not Done              | 2                     |          |            |
| Comment                               | SLIGHTLY ENLARGED-NCS |          |            |
| Investigational Site                  | RP                    |          |            |

Item Group : Physical Exam

Repeat key: 7

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46870904 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 7        |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Item Group : Physical Exam

Repeat key: 8

| Item                       | Value    | is Null? | Trans.Type |
|----------------------------|----------|----------|------------|
| Internal unique identifier | 46871004 |          |            |

| Item                                  | Value  | is Null? | Trans.Type |
|---------------------------------------|--------|----------|------------|
| for record                            |        |          |            |
| Compound                              | SDP    |          |            |
| Therapeutic Area                      | ONC    |          |            |
| Protocol Number                       | 143-02 |          |            |
| Country                               | USA    |          |            |
| Record status, 5 levels, internal use | V      |          |            |
| Physical Exam Body System             | 8      |          |            |
| Normal/Abnormal/Not Done              | 3      |          |            |
| Investigational Site                  | RP     |          |            |

Item Group : Physical Exam

Repeat key: 9

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46871204 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 9        |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Item Group : Physical Exam

Repeat key: 10

| Item                       | Value    | is Null? | Trans.Type |
|----------------------------|----------|----------|------------|
| Internal unique identifier | 46871504 |          |            |

| Item                                  | Value  | is Null? | Trans.Type |
|---------------------------------------|--------|----------|------------|
| for record                            |        |          |            |
| Compound                              | SDP    |          |            |
| Therapeutic Area                      | ONC    |          |            |
| Protocol Number                       | 143-02 |          |            |
| Country                               | USA    |          |            |
| Record status, 5 levels, internal use | V      |          |            |
| Physical Exam Body System             | 10     |          |            |
| Normal/Abnormal/Not Done              | 2      |          |            |
| Comment                               | PET    |          |            |
| Investigational Site                  | RP     |          |            |

Item Group : Physical Exam

Repeat key: 11

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46871704 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 11       |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Item Group : Physical Exam

Repeat key: 12

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46872504 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 12       |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Item Group : Physical Exam

Repeat key: 13

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46873104 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Physical Exam Body System             | 13       |          |            |
| Normal/Abnormal/Not Done              | 1        |          |            |
| Investigational Site                  | RP       |          |            |

Study Event Data:

Study Event = Post-treatment

**Form Data:**

ID = Adverse Events

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Adverse Events

Repeat key: 1

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46898304 |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Line Number                           | 1        |          |            |
| Conmed Indication                     | HEADACHE |          |            |
| Start Month - Enter Two Digits 01-12  | 06       |          |            |
| Start Day - Enter Two Digits 01-31    | 10       |          |            |
| Start Year - Enter Four Digit Year    | 1999     |          |            |
| Derived Start Date                    | 19990610 |          |            |
| Stop Month - Enter Two Digits 01-12   | 06       |          |            |
| Stop Day - Enter Two Digits 01-31     | 14       |          |            |
| Stop Year - Enter Four Digit Year     | 1999     |          |            |

| Item                        | Value    | is Null? | Trans.Type |
|-----------------------------|----------|----------|------------|
| Derived Stop Date           | 19990614 |          |            |
| Severity                    | 1        |          |            |
| Relationship to study drug  | 0        |          |            |
| Outcome                     | 1        |          |            |
| Actions taken re study drug | 0        |          |            |
| Actions taken, other        | 1        |          |            |
| Investigational Site        | RP       |          |            |

Item Group : Adverse Events

Repeat key: 2

| Item                                  | Value      | is Null? | Trans.Type |
|---------------------------------------|------------|----------|------------|
| Internal unique identifier for record | 46903404   |          |            |
| Therapeutic Area                      | ONC        |          |            |
| Protocol Number                       | 143-02     |          |            |
| Country                               | USA        |          |            |
| Record status, 5 levels, internal use | V          |          |            |
| Line Number                           | 2          |          |            |
| Conmed Indication                     | CONGESTION |          |            |
| Start Month - Enter Two Digits 01-12  | 06         |          |            |
| Start Day - Enter Two Digits 01-31    | 11         |          |            |
| Start Year - Enter Four Digit Year    | 1999       |          |            |
| Derived Start Date                    | 19990611   |          |            |
| Severity                              | 1          |          |            |
| Relationship to study drug            | 0          |          |            |
| Outcome                               | 2          |          |            |
| Actions taken re study drug           | 0          |          |            |
| Actions taken, other                  | 1          |          |            |
| Investigational Site                  | RP         |          |            |

**Form Data:**

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

| Item                                  | Value    | is Null? | Trans.Type |
|---------------------------------------|----------|----------|------------|
| Internal unique identifier for record | 46896304 |          |            |
| Compound                              | SDP      |          |            |
| Therapeutic Area                      | ONC      |          |            |
| Protocol Number                       | 143-02   |          |            |
| Country                               | USA      |          |            |
| Record status, 5 levels, internal use | V        |          |            |
| Line Number                           | 1        |          |            |
| Medication For Conmed                 | TYLENOL  |          |            |
| Start Month - Enter Two Digits 01-12  | 06       |          |            |
| Start Day - Enter Two Digits 01-31    | 10       |          |            |
| Start Year - Enter Four Digit Year    | 1999     |          |            |
| Derived Start Date                    | 19990610 |          |            |
| Stop Month - Enter Two Digits 01-12   | 06       |          |            |
| Stop Day - Enter Two Digits 01-31     | 14       |          |            |
| Stop Year - Enter Four                | 1999     |          |            |

| Item                  | Value    | is Null? | Trans.Type |
|-----------------------|----------|----------|------------|
| Digit Year            |          |          |            |
| Derived Stop Date     | 19990614 |          |            |
| Dose and Unit         | 325/MG   |          |            |
| Conmed Route          | 3        |          |            |
| Conmed Regimen        | 8        |          |            |
| Conmed Indication     | HEADACHE |          |            |
| Check If Taken for AE | 0        |          |            |
| Investigational Site  | RP       |          |            |

Item Group : Concom Meds

Repeat key: 2

| Item                                  | Value      | is Null? | Trans.Type |
|---------------------------------------|------------|----------|------------|
| Internal unique identifier for record | 46901404   |          |            |
| Compound                              | SDP        |          |            |
| Therapeutic Area                      | ONC        |          |            |
| Protocol Number                       | 143-02     |          |            |
| Country                               | USA        |          |            |
| Record status, 5 levels, internal use | V          |          |            |
| Line Number                           | 2          |          |            |
| Medication For Conmed                 | SUDAFED    |          |            |
| Start Month - Enter Two Digits 01-12  | 06         |          |            |
| Start Day - Enter Two Digits 01-31    | 11         |          |            |
| Start Year - Enter Four Digit Year    | 1999       |          |            |
| Derived Start Date                    | 19990611   |          |            |
| Check if Ongoing                      | X          |          |            |
| Dose and Unit                         | 30/MG      |          |            |
| Conmed Route                          | 3          |          |            |
| Conmed Regimen                        | 8          |          |            |
| Conmed Indication                     | CONGESTION |          |            |
| Check If Taken for AE                 | 0          |          |            |
| Investigational Site                  | RP         |          |            |

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(automatically generated, layout still needs some improvement)

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