Clinical Development

JNJ-7472179

EPO_INT3

Anonymisation Data Derivation Specification Document

<table>
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<tr>
<th>Document Type</th>
<th>Reference document</th>
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</thead>
<tbody>
<tr>
<td>Document Version</td>
<td>Final</td>
</tr>
<tr>
<td>Date</td>
<td>24 Feb 2017</td>
</tr>
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<td>Response to Chemotherapy - TERM</td>
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<td>Tranai3 - TRANAI3</td>
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<td>Transfusion Information - TRANS_SI</td>
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<td>1.4.68.</td>
<td>Urinalysis (Test Tape) - URIN_SI</td>
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<td>Status and Version</td>
<td>Release Date</td>
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1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

<table>
<thead>
<tr>
<th>Dataset</th>
<th>Name of dataset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating Program</td>
<td>The program that created the dataset</td>
</tr>
<tr>
<td>Description</td>
<td>Short description</td>
</tr>
<tr>
<td>Unique Identifier</td>
<td>Unique key</td>
</tr>
<tr>
<td>Sorted by</td>
<td>Sort key</td>
</tr>
<tr>
<td>Notes</td>
<td>Any useful notes</td>
</tr>
</tbody>
</table>

Part II: Variables within dataset

<table>
<thead>
<tr>
<th>Variable</th>
<th>SAS variable name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Character or Numeric</td>
</tr>
<tr>
<td>Label</td>
<td>SAS variable label</td>
</tr>
<tr>
<td>Codes</td>
<td>Codelist name</td>
</tr>
<tr>
<td>Comments</td>
<td>Variable source derivation explanation if variable derived.</td>
</tr>
</tbody>
</table>

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided due to sensitivity of the data.
- Investigator Information will not be provided.
- Date of birth will not be provided, only age in years will be provided.
- Age will be grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/center numbers will be assigned in a random manner so they are not matching the subject and site/center numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove “Other” free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial and Bottle number will not be provided.
- Central Lab Specimen Label Number will not be provided.
- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Completely missing variables those are not annotated in CRF will not be included in the De-Identified datasets.
- Partial date’s relative day cannot be calculated.
- Datasets with zero observations will not be submitted (ex.EPDEMO,NORMAL,SMEDBI3X)
- Comment datasets (CMNT,EPCMNT) will be submitted with zero observation.
- AGE is not present in DEMO dataset. So it will be added in DEMO from PROFILE dataset.
- PPROFILE dataset is meant for data reconciliation purpose. This datasets will be removed.
- Due to sensitive information INVN and JOURNAL datasets will be removed.
- REF.DATE (Visit Date) will be used as Reference Date to derive relative days (referred as REF. DATE in the document).

1.3. Data Files
The EPO_INT3 Clinical Study Report (CSR) data should be used for converting to de-identification.
1.4. Data Domains

1.4.1. Demographics - DEMO

<table>
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<tr>
<td>Creating program</td>
<td>demo.sas</td>
</tr>
<tr>
<td>Description</td>
<td>Demographics</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO</td>
</tr>
</tbody>
</table>
| Notes            | Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INIT, INO, VDATE, BIRTH, BIRTHF, VISITNO, EVENT_ID, SPECIFY
Below listed variable is not a part of raw dataset. It has been added to retain the age related information in the De-identified dataset:
AGE (Source: PROFILE Dataset)
AGEUNIT (Source: PROFILE Dataset) |

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>OBSNO</td>
<td>num</td>
<td>Obsno</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>STUDY</td>
<td>char</td>
<td>Study</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
<td>Randomly assigned Patient Number for De-Identity</td>
<td></td>
</tr>
<tr>
<td>Variable</td>
<td>Type</td>
<td>Label</td>
<td>Codes</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td>---------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>DCENTER</td>
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<td>Center Assigned for De-Identity</td>
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<tr>
<td>D_COUNTRY</td>
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<td>De-Identify Country</td>
<td>Group element to protect PII.</td>
<td></td>
</tr>
<tr>
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<td>num</td>
<td>Vdatef</td>
<td>Collected at CRF.</td>
<td></td>
</tr>
<tr>
<td>SEX</td>
<td>num</td>
<td>Sex</td>
<td>Collected at CRF.</td>
<td></td>
</tr>
<tr>
<td>RACE</td>
<td>num</td>
<td>Race</td>
<td>Collected at CRF.</td>
<td></td>
</tr>
<tr>
<td>AGE</td>
<td>char</td>
<td>Age in Years</td>
<td>If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.</td>
<td></td>
</tr>
<tr>
<td>AGEUNIT</td>
<td>char</td>
<td>Unit For Age</td>
<td>Collected at CRF.</td>
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1.4.2. Study Drug Administrator - ADMIN

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<tr>
<td>Description</td>
<td>Study Drug Administrator</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO, DY, EVENT_ID, VISITNO, WEEK, DOSENO</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO, DY, EVENT_ID, VISITNO, WEEK, DOSENO</td>
</tr>
<tr>
<td>Notes</td>
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</tr>
<tr>
<td>Variable</td>
<td>Type</td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
</tr>
<tr>
<td>OBSNO</td>
<td>num</td>
</tr>
<tr>
<td>STUDY</td>
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<td>DPATNO</td>
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<tr>
<td>VISITNO</td>
<td>num</td>
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<tr>
<td>WEEK</td>
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<td>DOSENO</td>
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<td>DATEF</td>
<td>num</td>
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<td>WEIGHT</td>
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<td>DOSE</td>
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<td>ML</td>
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<tr>
<td>DY</td>
<td>num</td>
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1.4.3. Adverse Events - ADVE

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<tr>
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<td>char</td>
<td>Study</td>
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<td>Collected at CRF.</td>
</tr>
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<td>Randomly assigned Patient Number for de-identity</td>
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<td>Visit Number</td>
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<tr>
<td>WEEK</td>
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<tr>
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<td>AE Occured</td>
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<td>BY_WHOCO</td>
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<td>Stopdf</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>OBS</td>
<td>num</td>
<td>Obs</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EVENT_ID</td>
<td>char</td>
<td>Event_Id</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>ONSETDY</td>
<td>num</td>
<td>Relative Onset Day of AE</td>
<td></td>
<td>If DONSET and REF.DATE not missing then perform below logic to calculate ONSETDY, If DONSET less than REF.DATE then (DONSET - REF.DATE). Else if DONSET is greater than equal to REF.DATE then (DONSET - REF.DATE) +1.</td>
</tr>
<tr>
<td>STOPDY</td>
<td>num</td>
<td>Relative Stop day</td>
<td></td>
<td>If STOPD and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPD less than REF.DATE then (STOPD - REF.DATE). Else if STOPD is greater than equal to REF.DATE then (STOPD - REF.DATE) +1.</td>
</tr>
<tr>
<td>Variable</td>
<td>Type</td>
<td>Label</td>
<td>Codes</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>------</td>
<td>----------------</td>
<td>-------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ADVE_TM</td>
<td>num</td>
<td>Time</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>ADVE_DY</td>
<td>num</td>
<td>Relative Day</td>
<td></td>
<td>If <em>DATE</em> and REF.DATE not missing then perform below logic to calculate ADVE_DY, If <em>DATE</em> less than REF.DATE then (<em>DATE</em> - REF.DATE). Else if <em>DATE</em> is greater than equal to REF.DATE then (<em>DATE</em> - REF.DATE) +1.</td>
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1.4.4. Bone marrow - BONEMARR

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<th>Dataset</th>
<th>BONEMARR</th>
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<tbody>
<tr>
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<td>bonemarr.sas</td>
</tr>
<tr>
<td>Description</td>
<td>Bonemarr</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO,MMETA</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO,MMETA</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-identity</td>
<td></td>
<td>Randomly assigned Patient Number for de-identity</td>
</tr>
<tr>
<td>MMETA</td>
<td>num</td>
<td>Mmeta</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>MMETAF</td>
<td>char</td>
<td>Mmetaf</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
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</table>
1.4.5. Chemotherapy - CHEMO

<table>
<thead>
<tr>
<th>Dataset</th>
<th>CHEMO</th>
</tr>
</thead>
<tbody>
<tr>
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<td>chemo.sas</td>
</tr>
<tr>
<td>Description</td>
<td>Chemotherapy</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO, VISITNO, CYCLES, DRUG, CSTARTDY, OBSNO</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO, VISITNO, CYCLES, DRUG, CSTARTDY, OBSNO</td>
</tr>
<tr>
<td>Notes</td>
<td>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: INIT, INO, CSTART, CSTOP, ORIG_TXT, <em>USER</em>, <em>DATE</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
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<td>Relative Cstart day</td>
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<td>If CSTART and REF.DATE not missing then perform below logic to calculate CSTARTDY, If CSTART less than REF.DATE then (CSTART - REF.DATE). Else if CSTART is greater than equal to REF.DATE then (CSTART - REF.DATE) +1.</td>
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<tr>
<td>CSTOPDY</td>
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<td>Relative Cstop Day</td>
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<td>If CSTOP and REF.DATE not missing then perform below logic to calculate CSTOPDY, If CSTOP less than REF.DATE then (CSTOP - REF.DATE). Else if CSTOP is greater than equal to REF.DATE then (CSTOP - REF.DATE) +1.</td>
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1.4.6. Serum Chemistry - CHEM_SI

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If VDATE and REF.DATE not missing then perform below logic to calculate VDY, if VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE - REF.DATE) +1.
1.4.9. Concomitant Therapy - CURM

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<td>Is Patient Evaluable For Efficacy Analys</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EFFF</td>
<td>char</td>
<td>Decode For Eff (1=No, 2=Yes)</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EFFCF</td>
<td>char</td>
<td>Decode For Eff (1=No, 2=Yes)</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>ITTF</td>
<td>char</td>
<td>Decode For Itt (1=No, 2=Yes)</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>SAFF</td>
<td>char</td>
<td>Decode For Saf (1=No, 2=Yes)</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>PNO</td>
<td>char</td>
<td>Protocol Number</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>PERIOD</td>
<td>num</td>
<td>Period For Initiation of Study Med</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>SEQUENCE</td>
<td>num</td>
<td>Treatment Sequence</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>XORDER</td>
<td>num</td>
<td>Cross-Over Order</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>THRPYDAY</td>
<td>num</td>
<td>Total Days On Therapy</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>STARTDY</td>
<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.</td>
</tr>
<tr>
<td>STOPDY</td>
<td>num</td>
<td>Relative Medication Stop Day</td>
<td></td>
<td>If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT - REF.DATE) +1.</td>
</tr>
</tbody>
</table>
1.4.11. Doseex - DOSEEX

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<td>Description</td>
<td>Doseex</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO,STARTDY,STOPDY</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO,STARTDY,STOPDY</td>
</tr>
<tr>
<td>Notes</td>
<td>Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: RTITLE2, EPO, DATE, STARTDT, STOPDT, MEDSTRTM, MEDSTPTM, RTITLE1, RTITLE3, REGIMEN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
<td></td>
<td>Randomly assigned Patient Number for de-identity</td>
</tr>
<tr>
<td>REGORDER</td>
<td>num</td>
<td>Order of Regimens</td>
<td></td>
<td>Collect at CRF.</td>
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<tr>
<td>PNO</td>
<td>char</td>
<td>Protocol Number</td>
<td></td>
<td>Collect at CRF.</td>
</tr>
<tr>
<td>PERIOD</td>
<td>num</td>
<td>Period For Initiation of Study Med</td>
<td></td>
<td>Collect at CRF.</td>
</tr>
<tr>
<td>SEQUENCE</td>
<td>num</td>
<td>Treatment Sequence</td>
<td></td>
<td>Collect at CRF.</td>
</tr>
<tr>
<td>XORDER</td>
<td>num</td>
<td>Cross-Over Order</td>
<td></td>
<td>Collect at CRF.</td>
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<tr>
<td>THRPLYDAY</td>
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<td>Total Days On Therapy</td>
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### Variable Details

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<th>Comments</th>
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</thead>
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<tr>
<td>STARTDY</td>
<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.</td>
</tr>
<tr>
<td>STOPDY</td>
<td>num</td>
<td>Relative Medication Stop Day</td>
<td></td>
<td>If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT - REF.DATE) +1.</td>
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1.4.12. Effpval - EFFPVAL

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<td>Unique identifier</td>
<td>PVAL</td>
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<tr>
<td>Sorted by</td>
<td>PVAL</td>
</tr>
<tr>
<td>Notes</td>
<td></td>
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<table>
<thead>
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<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
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<td>Pr&gt;Chi</td>
<td></td>
<td>Collected at CRF.</td>
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</table>
1.4.13.  **EPO Comment - EPCMNT**

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<td>Description</td>
<td>EPO Comment</td>
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<tr>
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<td>Not applicable</td>
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<tr>
<td>Sorted by</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Notes</td>
<td>Comments data is sensitive data, contains free text information. Will be submitted empty dataset.</td>
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<table>
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<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
</thead>
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<tr>
<td>OBSNO</td>
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<td>Obsno</td>
<td></td>
<td>Empty data will be submitted.</td>
</tr>
<tr>
<td>STUDY</td>
<td>char</td>
<td>Study</td>
<td></td>
<td>Empty data will be submitted.</td>
</tr>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
<td>Empty data will be submitted.</td>
<td></td>
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<tr>
<td>CMTCODE</td>
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<td>Relative Sample Day</td>
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<td>SAMDF</td>
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<td>Samdf</td>
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<td>Visit Number</td>
<td>Empty data will be submitted.</td>
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<td>EVENT_ID</td>
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<tr>
<td>Description</td>
<td>Epepo</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO,EPODY,EPOVAL,OBSNO</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO,EPODY,EPOVAL,OBSNO</td>
</tr>
<tr>
<td>Notes</td>
<td>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT,EPOD</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Label</th>
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</thead>
<tbody>
<tr>
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<td>Obsno</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>STUDY</td>
<td>char</td>
<td>Study</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
<td>Randomly assigned Patient Number for de-identity</td>
<td></td>
</tr>
<tr>
<td>FORCEN</td>
<td>num</td>
<td>Forcen</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EPODF</td>
<td>num</td>
<td>Epodf</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EPOVAL</td>
<td>num</td>
<td>Epoval</td>
<td></td>
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<td>num</td>
<td>Visit Number</td>
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<td>Collected at CRF.</td>
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### Variable Type Label Codes Comments

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<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
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<td>EVENT_ID</td>
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<td>Event_Id</td>
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<td>Collected at CRF.</td>
</tr>
<tr>
<td>EPODY</td>
<td>num</td>
<td>Relative Epod Day</td>
<td></td>
<td>If EPOD and REF.DATE not missing then perform below logic to calculate EPODY, If EPOD less than REF.DATE then (EPOD - REF.DATE). Else if EPOD is greater than equal to REF.DATE then (EPOD-REF.DATE) +1.</td>
</tr>
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#### 1.4.15. EPO Serum Levels - EPO

<table>
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</tr>
<tr>
<td>Description</td>
<td>EPO Serum Levels</td>
</tr>
<tr>
<td>Unique identifier</td>
<td>DPATNO, VISITNO, EPODY, OBSNO</td>
</tr>
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<td>Sorted by</td>
<td>DPATNO, VISITNO, EPODY, OBSNO</td>
</tr>
<tr>
<td>Notes</td>
<td>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information: INIT, INO, EPO</td>
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<table>
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<tr>
<th>Variable</th>
<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
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<tr>
<td>OBSNO</td>
<td>num</td>
<td>Obsno</td>
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<td></td>
</tr>
<tr>
<td>STUDY</td>
<td>char</td>
<td>Study</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>Variable</td>
<td>Type</td>
<td>Label</td>
<td>Codes</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>------</td>
<td>------------------------------</td>
<td>-------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
<td></td>
<td>Randomly assigned Patient Number for de-identity</td>
</tr>
<tr>
<td>VISITNO</td>
<td>num</td>
<td>Visit Number</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>WEEK</td>
<td>num</td>
<td>Study Week</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EPOF</td>
<td>num</td>
<td>Epof</td>
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<td>Collected at CRF.</td>
</tr>
<tr>
<td>EVENT_ID</td>
<td>char</td>
<td>Event_Id</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EPODY</td>
<td>num</td>
<td>Relative Epo Day</td>
<td></td>
<td>If EPO and REF.DATE not missing then perform below logic to calculate EPODY, If EPO less than REF.DATE then (EPO - REF.DATE). Else if EPO is greater than equal to REF.DATE then (EPO-REF.DATE) +1.</td>
</tr>
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1.4.16. Eposerum - EPOSERUM

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<tr>
<td>Notes</td>
<td>Below listed variables will be dropped from dataset due to repetition of the information: EPO, EPOD, STARTDT</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPATNO</td>
<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
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<td>Randomly assigned Patient Number for de-identity</td>
</tr>
<tr>
<td>VISITNO</td>
<td>num</td>
<td>Visit Number</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>WEEK</td>
<td>num</td>
<td>Study Week</td>
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<td>Collected at CRF.</td>
</tr>
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<td>EPOF</td>
<td>num</td>
<td>Date Flag</td>
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<td>Collected at CRF.</td>
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<td>EPODF</td>
<td>num</td>
<td>Date Flag</td>
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<td>Collected at CRF.</td>
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<td>EPOVAL</td>
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<td>Epo Serum Level Result</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>EPO_DY</td>
<td>num</td>
<td>Relative Day Recorded When Sample Taken</td>
<td></td>
<td>If EPO and REF.DATE not missing then perform below logic to calculate EPO_DY, If EPO less than REF.DATE then (EPO - REF.DATE). Else if EPO is greater than equal to REF.DATE then (EPO-REF.DATE) +1.</td>
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</table>

Variable EPO_DY is calculated based on the logic described in the Notes section.
<table>
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<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPODY</td>
<td>num</td>
<td>Relative Day Recorded With Sample Results</td>
<td></td>
<td>If EPOD and REF.DATE not missing then perform below logic to calculate EPODY, If EPOD less than REF.DATE then (EPOD - REF.DATE). Else if EPOD is greater than equal to REF.DATE then (EPOD-REF.DATE) +1.</td>
</tr>
<tr>
<td>STARTDY</td>
<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.</td>
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1.4.17. Evali3 - EVALI3

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<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
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<td>num</td>
<td>Patient Number Assigned for De-Identity</td>
<td></td>
<td>Randomly assigned Patient Number for de-identity</td>
</tr>
<tr>
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<td>Order of Regimens</td>
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<tr>
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<td>Treatment</td>
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<td>num</td>
<td>Is Patient Evaluable For Efficacy Analys</td>
<td></td>
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<tr>
<td>ITT</td>
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<td>Is Patient Evaluable For Itt Analysis</td>
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<tr>
<td>TUMORTYP</td>
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### Variable Types and Labels

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<th>Codes</th>
<th>Comments</th>
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<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
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<td>char</td>
<td>Decode For Eff (1=No, 2=Yes)</td>
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<td>Collected at CRF.</td>
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<td>Collected at CRF.</td>
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### 1.4.18. Hemai3 - HEMAI3

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<td>Hemai3</td>
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</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO, VISITNO, STARTDY, LABDY, CRFWEEK</td>
</tr>
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If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.
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<td>Relative Last Day of Double-Blind Phase</td>
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<td></td>
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<tr>
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<td>Relative Sample Day</td>
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1.4.19. Hembi3 - HEMBI3

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<td>FHGB</td>
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If CORRDT and REF.DATE not missing then perform below logic to calculate CORRDAY, If CORRDT less than REF.DATE then (CORRDT - REF.DATE). Else if CORRDT is greater than equal to REF.DATE then (CORRDT - REF.DATE) +1.
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1.4.20. Hematology - HEM_SI

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1.4.21. History and Extent of Malignancy - HISTORY

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<td>If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE - REF.DATE) +1.</td>
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1.4.22. Harmone Therapy, Immunotherapy - HORRA

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<td>Notes</td>
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1.4.26. Keyadve1 - KEYADVE1

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<tr>
<td>PHASE</td>
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<td>If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT - REF.DATE) +1.</td>
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1.4.27. Keyadve2 - KEYADVE2

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<td>If DONSET and REF.DATE not missing then perform below logic to calculate ONSETDY, If DONSET less than REF.DATE then (DONSET - REF.DATE). Else if DONSET is greater than equal to REF.DATE then (DONSET- REF.DATE) +1.</td>
</tr>
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<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT- REF.DATE) +1.</td>
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<tr>
<td>DBENDDY</td>
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<td>Relative Last Day of Double-Blind Phase</td>
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<td>If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT- REF.DATE) +1.</td>
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1.4.28. Keyaeex - KEYAEEX

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<td>Notes</td>
<td>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements or due to missing values: VERBATIM, DONSET, STOPD, STOPDT, ONSETDT, ADVDESC, INO, DATE, STARTDT, DBNDT, INVNAME, SURN, FORE, REGDAY, STOPTIME, TONSET</td>
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<table>
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<tr>
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<th>Comments</th>
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<td>Randomly assigned Patient Number for de-identity</td>
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<td>If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT - REF.DATE) +1.</td>
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1.4.29. Keycomp - KEYCOMP

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<th>Codes</th>
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<td>Randomly assigned Patient Number for de-identity</td>
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<td>Collected at CRF.</td>
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<td>Collected at CRF.</td>
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<td>Study Day</td>
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If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY. If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than or equal to REF.DATE then (STATUSDT - REF.DATE) + 1.
### Variable

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<th>Codes</th>
<th>Comments</th>
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#### 1.4.30. Keycomp1 - KEYCOMP1

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1.4.32. Keycurm - KEYCURM

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   KEYCURM

Creating program
   keycurm.sas

Description
   Keycurm

Unique identifier
   DPATNO, VISITNO, CSTARTDY, CSTOPDY, DRUGCODE, TOTDOSE

Sorted by
   DPATNO, VISITNO, CSTARTDY, CSTOPDY, DRUGCODE, TOTDOSE

Notes
   Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements:
   VERBATIM, CSTART, CSTOP, INDICAT, ORIG_TXT, _USER_, _DATE_, INDICT, CSTARTDT, CSTOPDT, GENDESC, ATC_CD, ATC_TEXT, INO, DATE, INVNAME, SURN, FORE, MEDSTRDT

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### 1.4.33. Keydose - KEYDOSE

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#### Notes
Below listed variables will be dropped from dataset due to non significant elements or due to repetition of the information or due to missing values: EPO, DATE, STARTDT, STOPDT, MEDSTRTM, MEDSTPTM, RTITLE1, RTITLE2, RTITLE3, REGIMEN

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<td>If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT- REF.DATE) +1.</td>
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1.4.34. Keylab1 - KEYLAB1

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Notes: Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: LABDATE, LABDT, SAMPDT, COLLECT, COLLECTF, FLAGF, LABLOC, ENDPT, DATE, STARTDT, REC_ID, COLORDF, ORIGFLAG, BIRTHDT, SEX, AGE, SASDATE, STOPDT, START, STOP

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1.4.35. Keysae - KEYSAE

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</tr>
<tr>
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</tr>
<tr>
<td>DURDAY</td>
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<td>Duration of AE</td>
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</tr>
<tr>
<td>STUDYDAY</td>
<td>num</td>
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</tr>
<tr>
<td>PHASE</td>
<td>num</td>
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</tr>
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<tr>
<td>STOPDY</td>
<td>num</td>
<td>Relative Stop Day of AE</td>
<td></td>
<td>If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT - REF.DATE) +1.</td>
</tr>
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<td>Relative Onset Day of AE</td>
<td></td>
<td>If ONSETDT and REF.DATE not missing then perform below logic to calculate ONSETDY, If ONSETDT less than REF.DATE then (ONSETDT - REF.DATE). Else if ONSETDT is greater than equal to REF.DATE then (ONSETDT - REF.DATE) +1.</td>
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1.4.37. Keysae2 - KAYSAE2

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<th>Comments</th>
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<td>Randomly assigned Patient Number for de-identity</td>
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<tr>
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<tr>
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<td>ACTION</td>
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<td>CONCOM</td>
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<td>ADVEXPF</td>
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<td>If STOPDT and REF.DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REF.DATE then (STOPDT - REF.DATE). Else if STOPDT is greater than equal to REF.DATE then (STOPDT - REF.DATE) +1.</td>
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1.4.38. Keyvit1 - KEYVIT1

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<td>Codes</td>
<td>Comments</td>
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</tr>
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<td></td>
<td>Collected at CRF.</td>
</tr>
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<td>Percent Change</td>
<td></td>
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</tr>
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<tr>
<td>REGDAY</td>
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</tr>
<tr>
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<td></td>
<td>If EVDATE and REF.DATE not missing then perform below logic to calculate EVDY, If EVDATE less than REF.DATE then (EVDATE - REF.DATE). Else if EVDATE is greater than equal to REF.DATE then (EVDATE - REF.DATE) + 1.</td>
</tr>
<tr>
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1.4.39. Keyfile_2 - KFILE_2

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<th>Comments</th>
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<td>Randomly assigned Patient Number for de-identity</td>
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1.4.40. Labnorm - LABNORM

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<td>If LABDT and REF.DATE not missing then perform below logic to calculate LABDY, If LABDT less than REF.DATE then (LABDT - REF.DATE). Else if LABDT is greater than equal to REF.DATE then (LABDT-REF.DATE) +1.</td>
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1.4.42. Labs1 - LABS1

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1.4.43.  Medical History - MEDHIS

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1.4.44. Normalsi - NORMALSI

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### 1.4.45. Otherlab - OTHERLAB

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1.4.47. Initial Physical Examination - PHYSEX

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### 1.4.48. Initial Blood Pressure, Ht., Wt. - PPVI

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### 1.4.50. Profeval - PROFEVAL

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<td>If LEPODT and REF.DATE not missing then perform below logic to calculate LEPODY, If LEPODT less than REF.DATE then (LEPODT - REF.DATE). Else if LEPODT is greater than equal to REF.DATE then (LEPODT-REF.DATE) +1.</td>
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<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.</td>
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### 1.4.51. Profex - PROFEX

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<td>Diagnosis of Malignancy</td>
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<tr>
<td>PERFPRE</td>
<td>num</td>
<td>Performance Score At Prestudy</td>
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<td>Collected at CRF.</td>
</tr>
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<td>Performance Score At Termination</td>
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<td>PHYSOLF</td>
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<td>Decode For Physol</td>
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<td></td>
<td>Collected at CRF.</td>
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<td>Decode For Mdiagnos</td>
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<td>Collected at CRF.</td>
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<td>Number of Days To Study Completion</td>
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<td>num</td>
<td>Relative Visit Day In Demo Dataset</td>
<td></td>
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</tr>
<tr>
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<td>num</td>
<td>Relative Completion Status Day</td>
<td></td>
<td>If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT - REF.DATE) +1.</td>
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<th>Codes</th>
<th>Comments</th>
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<td></td>
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</tr>
<tr>
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<td>If LEPODT and REF.DATE not missing then perform below logic to calculate LEPODY, If LEPODT less than REF.DATE then (LEPODT - REF.DATE). Else if LEPODT is greater than equal to REF.DATE then (LEPODT - REF.DATE) + 1.</td>
</tr>
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<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) + 1.</td>
</tr>
<tr>
<td>DBENDDY</td>
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<td>Relative Last Day of Double-Blind Phase</td>
<td></td>
<td>If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT - REF.DATE) + 1.</td>
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### 1.4.52. Profile - PROFILE

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<td>Description</td>
<td>Profile</td>
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<td>DPATNO</td>
</tr>
<tr>
<td>Sorted by</td>
<td>DPATNO</td>
</tr>
<tr>
<td>Notes</td>
<td>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to missing values: INO, COUNTRY, VDATE, BIRTHDT, SEX, RACE, RACESPEC, EPO, DTERM, STATUSDT, DEATHDT, LEPD, DATE, STARTDT, DBE-ENDDT, DIAGDT, LCHEMDT, SEXF, COUNTRF, INVNAME, SURN, FORE, OTHRSPEC</td>
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<table>
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<td>Protocol Number</td>
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<td>Randomly assigned Patient Number for de-identity</td>
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<td>CRESP</td>
<td>num</td>
<td>Patient's Response To Chemotherapy</td>
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<td>STATUS</td>
<td>num</td>
<td>Completion Status</td>
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</tr>
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<td>Diagnosis of Malignancy</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>PERFPRE</td>
<td>num</td>
<td>Performance Score At Prestudy</td>
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<td>Collected at CRF.</td>
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<td>PERFTERM</td>
<td>num</td>
<td>Performance Score At Termination</td>
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</tr>
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<td>Flag For Missing Parts of Dates</td>
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<td>Collected at CRF.</td>
</tr>
<tr>
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<td>Number of Days To Study Completion</td>
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<td>Collected at CRF.</td>
</tr>
<tr>
<td>AGE</td>
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<td>Age in Years</td>
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<td>If age is greater than 89 then group to '90+' otherwise AGE=AGE. Grouping will be performed based on HIPAA privacy rules.</td>
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<td>Time To Diagnosis In Months</td>
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</tr>
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<td>Treatment Code</td>
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<td>Collected at CRF.</td>
</tr>
<tr>
<td>VDY</td>
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<td>Relative Visit Day In Demo Dataset</td>
<td></td>
<td>If VDATE and REF.DATE not missing then perform below logic to calculate VDY, IF VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE-REF.DATE) +1.</td>
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<td>Relative Completion Status Day</td>
<td></td>
<td>If STATUSDT and REF.DATE not missing then perform below logic to calculate STATUSDY, If STATUSDT less than REF.DATE then (STATUSDT - REF.DATE). Else if STATUSDT is greater than equal to REF.DATE then (STATUSDT - REF.DATE) + 1.</td>
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<td>Relative Day of Death</td>
<td></td>
<td>If DEATHDT and REF.DATE not missing then perform below logic to calculate DEATHDY, If DEATHDT less than REF.DATE then (DEATHDT - REF.DATE). Else if DEATHDT is greater than equal to REF.DATE then (DEATHDT - REF.DATE) + 1.</td>
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<tr>
<td>LEPODY</td>
<td>num</td>
<td>Relative Day of Last Study Dose</td>
<td></td>
<td>If LEPODT and REF.DATE not missing then perform below logic to calculate LEPODY, If LEPODT less than REF.DATE then (LEPODT - REF.DATE). Else if LEPODT is greater than equal to REF.DATE then (LEPODT - REF.DATE) + 1.</td>
</tr>
<tr>
<td>STARTDY</td>
<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) + 1.</td>
</tr>
<tr>
<td>DBENDDY</td>
<td>num</td>
<td>Relative Last Day of Double-Blind Phase</td>
<td></td>
<td>If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT - REF.DATE) + 1.</td>
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### 1.4.53. Protocol - PROTOCOL

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**Notes**
Below listed variables will be dropped from dataset due to non significant elements:
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<th>Codes</th>
<th>Comments</th>
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</thead>
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</tr>
<tr>
<td>Variable</td>
<td>Type</td>
<td>Label</td>
<td>Codes</td>
<td>Comments</td>
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</tr>
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1.4.54. Pvalue - PVALUE

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1.4.55. EORTC QLQ-C30 - QLQC30

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1.4.56. Regi - REGI

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<td>Notes</td>
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<th>Type</th>
<th>Label</th>
<th>Codes</th>
<th>Comments</th>
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</thead>
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<td>DPATNO</td>
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<td>Patient Number Assigned for De-Identity</td>
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<td>Randomly assigned Patient Number for de-identity</td>
</tr>
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<td>REGORDER</td>
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<td>Regorder</td>
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<tr>
<td>TRTMENTF</td>
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1.4.57. Smedai3 - SMEDAI3

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<td>Smedai3</td>
</tr>
<tr>
<td>Unique identifier</td>
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<td>DPATNO, VISITNO, WEEK, DBENDDY, SMEDDY, DOSENO</td>
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<td>Notes</td>
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<td>num</td>
<td>Visit Number</td>
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<td>Collected at CRF.</td>
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<tr>
<td>WEEK</td>
<td>num</td>
<td>Study Week</td>
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<td>Collected at CRF.</td>
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<td>DOSENO</td>
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<td>Dose Number Within Week (1,2,3)</td>
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<td>Weight (Kg)</td>
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<tr>
<td>DOSE</td>
<td>num</td>
<td>Dose Given (U/Kg)</td>
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<td>Unit Measure</td>
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### Variable Data Derivation Specification

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<td>DBENDDY</td>
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<td>Relative Last Day of Double-Blind Phase</td>
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<td>If DBENDDT and REF.DATE not missing then perform below logic to calculate DBENDDY, If DBENDDT less than REF.DATE then (DBENDDT - REF.DATE). Else if DBENDDT is greater than equal to REF.DATE then (DBENDDT - REF.DATE) +1.</td>
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<tr>
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<td>num</td>
<td>Relative Day of Med Administration</td>
<td></td>
<td>If SMEDDT and REF.DATE not missing then perform below logic to calculate SMEDDY, If SMEDDT less than REF.DATE then (SMEDDT - REF.DATE). Else if SMEDDT is greater than equal to REF.DATE then (SMEDDT - REF.DATE) +1.</td>
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1.4.58. Smedbi3 - SMEDBI3

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<tr>
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<td>Was There A Change In Dosing</td>
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<td>Collected at CRF.</td>
</tr>
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### Variable Table

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#### 1.4.59. Smedci3 - SMEDCI3

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<td>Randomly assigned Patient Number for de-identity</td>
</tr>
<tr>
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<td>num</td>
<td>Study Week</td>
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<td>Collected at CRF.</td>
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<tr>
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<td>Order of Regimens</td>
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<tr>
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</tr>
<tr>
<td>STARTDY</td>
<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then ((STARTDT - REF.DATE)), Else if STARTDT is greater than equal to REF.DATE then ((STARTDT - REF.DATE) + 1).</td>
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### 1.4.60. Smedci3b - SMEDCI3B

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<th>Comments</th>
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<td>Randomly assigned Patient Number for de-identity</td>
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<td>Treatment</td>
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<td>Weekdoub</td>
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<td>Weekheld</td>
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<tr>
<td>DOUBLE</td>
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<td>Label</td>
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<td>Comments</td>
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<tr>
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<td>Was Patient's Dose Withheld</td>
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<tr>
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<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.</td>
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If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT - REF.DATE) +1.
1.4.61. Surgery - SURGERY

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<td>Notes</td>
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<th>Codes</th>
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<tr>
<td>STUDY</td>
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<td>Datef</td>
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<td>PROCE</td>
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**Variable** | **Type** | **Label** | **Codes** | **Comments**
---|---|---|---|---
DISEASE | char | Disease | | Collected at CRF.
DY | num | Relative Medication Start Day | | If DATE and REF.DATE not missing then perform below logic to calculate DY, If DATE less than REF.DATE then (DATE - REF.DATE). Else if DATE is greater than equal to REF.DATE then (DATE-REF.DATE) + 1.

1.4.62. **Respose to Chemotherapy - TERM**

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<td>Study</td>
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<td>Collected at CRF.</td>
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<td>Label</td>
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<td>Randomly assigned Patient Number for de-identity</td>
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<td>Reason</td>
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</tr>
<tr>
<td>DIED</td>
<td>num</td>
<td>Died</td>
<td></td>
<td>Collected at CRF.</td>
</tr>
<tr>
<td>DDATEF</td>
<td>num</td>
<td>Ddatef</td>
<td></td>
<td>Collected at CRF.</td>
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<tr>
<td>AUTOPSY</td>
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</tr>
<tr>
<td>CHEMODY</td>
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<td>Relative Chemo Day</td>
<td></td>
<td>If CHEMO and REF.DATE not missing then perform below logic to calculate CHEMODY, If CHEMO less than REF.DATE then (CHEMO - REF.DATE). Else if CHEMO is greater than equal to REF.DATE then (CHEMO - REF.DATE) +1.</td>
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<tr>
<td>VDY</td>
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<td>Visit Day</td>
<td></td>
<td>If VDATE and REF.DATE not missing then perform below logic to calculate VDY, If VDATE less than REF.DATE then (VDATE - REF.DATE). Else if VDATE is greater than equal to REF.DATE then (VDATE - REF.DATE) +1.</td>
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<td>Type</td>
<td>Label</td>
<td>Codes</td>
<td>Comments</td>
</tr>
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<tr>
<td>EPODY</td>
<td>num</td>
<td>Epo Day</td>
<td></td>
<td>If EPO and REF.DATE not missing then perform below logic to calculate EPODY, If EPO less than REF.DATE then (EPO - REF.DATE). Else if EPO is greater than equal to REF.DATE then (EPO - REF.DATE) +1.</td>
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<td>If DTERM and REF.DATE not missing then perform below logic to calculate TERMDY, If DTERM less than REF.DATE then (DTERM - REF.DATE). Else if DTERM is greater than equal to REF.DATE then (DTERM - REF.DATE) +1.</td>
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<tr>
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<td>D Date</td>
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<td>If DDATE and REF.DATE not missing then perform below logic to calculate DDY, If DDATE less than REF.DATE then (DDATE - REF.DATE). Else if DDATE is greater than equal to REF.DATE then (DDATE - REF.DATE) +1.</td>
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### 1.4.63. Tranai3 - TRANAI3

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<th>Comments</th>
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<td>Randomly assigned Patient Number for de-identity</td>
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<tr>
<td>TRANREL</td>
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<td>Are Hgbs Related To Trans. Within 14 Day</td>
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<td>Hgb Recorded Immed. Prior Transfusion</td>
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<td>Treatment</td>
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<td>Relative Blood Transfusion Day</td>
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<tr>
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<td>num</td>
<td>Relative Medication Start Day</td>
<td></td>
<td>If STARTDT and REF.DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REF.DATE then (STARTDT - REF.DATE). Else if STARTDT is greater than equal to REF.DATE then (STARTDT-REF.DATE) +1.</td>
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## 1.4.64. Tranbi3 - TRANBI3

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<th>Codes</th>
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<tr>
<td>REGDESC</td>
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<tr>
<td>COMPDAYS</td>
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<td>Number of Days To Study Completion</td>
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<td>TRANSOL</td>
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<td>Was Pat Trans During Month 1</td>
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<tr>
<td>UNITSM1</td>
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<td>Sum of Units Trans During Month 1</td>
<td>Collected at CRF.</td>
<td></td>
</tr>
<tr>
<td>Variable</td>
<td>Type</td>
<td>Label</td>
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<td>Comments</td>
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</tr>
<tr>
<td>TRANSDBF</td>
<td>char</td>
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<tr>
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<td>Collected at CRF.</td>
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</tr>
<tr>
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<td>UNITSM0</td>
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<td>Sum of Units Transfused Prestudy</td>
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<td>Transm2=Yes Or Study Days &lt;=28</td>
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<td>If DATE56 and REF.DATE not missing then perform below logic to calculate _56DY, If DATE56 less than REF.DATE then (DATE56 - REF.DATE). Else if DATE56 is greater than equal to REF.DATE then (DATE56 - REF.DATE) +1.</td>
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<tr>
<td>_28DY</td>
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<td>Relative Day of 1 Month After Study Day</td>
<td></td>
<td>If DATE28 and REF.DATE not missing then perform below logic to calculate _28DY, If DATE28 less than REF.DATE then (DATE28 - REF.DATE). Else if DATE28 is greater than equal to REF.DATE then (DATE28 - REF.DATE) +1.</td>
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1.4.66. Transfusion Information - TRANS_SI

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<td>Transfusion Information</td>
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<td>DY</td>
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<td>Relative Medication Start Day</td>
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1.4.67.  Tve - TVE

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<td>Description</td>
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</tr>
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### 1.4.68. Urinalysis (Test Tape) - URIN_SI

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