# CDFM PROCESS GUIDANCE

# Guidance for Numbering of Variables in ADaM Datasets

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### 

### Version 1.0

## General Guidance:

* Follow the ordering of variables in the “-Standard Ordering-” column, in the order presented when available.
* TIER x: Tiers are provided to follow it sequentially.
* While adding new variables please use the “-Other section”, only if they do not fit into any previously defined category.
* All the variables related to the records start date should come first followed by variables related to the records end date.

## ADSL

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| **Variable Type** | **Numbering Convention** | **Standard Ordering** | **Guidance** |
| Identifiers | 1-99 | TIER 1:  1 = STUDYID  2 = USUBJID  3 = SUBJID  4 = SITEID | This section is fixed. No changes are allowed |
| TIER 2:  SITEGRy  SITEGRyN | All site grouping, or other pooling variables, (-with character variables first followed by their corresponding numeric variables.) |
| Treatment Description Variables | 100-199 | TIER 1:  100 = ARM | This section is fixed. No changes are allowed |
| TIER 2:  TRTxxP, TRTxxPN, TRTxxA, TRTxxAN | 1) Planned Treatment variables should precede Actual Treatment variables.  2) Character variables should precede numeric variables |
| TIER 3:  TRTSEQP, TRTSEQPN, TRTSEQA, TRTSEQAN |
| TIER 4:  TRxxPGy, TRxxPGyN, TRxxAGy and TRxxAGyN |  |
| Trial Dates/Times | 200-299 | TIER 1:  200 = RANDDT  201 = INCNDT | If these variables are available, they would stick to these numbers |
| TIER 2:  TRTSDT, TRTSTM, TRTSDTM,  TRTSDTF, TRTSTMF, TRTEDT, TRTETM, TRTEDTM, TRTEDTF, TRTETMF | Treatment Start Dates and End Dates, (with start dates/times preceding end dates/times) |
| TIER 3:  TRxxSDT, TRxxSTM, TRxxSDTM,  TRxxSDTF, TRxxSTMF,  TRxxEDT, TRxxETM, TRxxEDTM,  TRxxEDTF, TRxxETMF | Variables for “Date of First Exposure in Period xx” followed by variables for “ Date of Last Exposure in Period xx” (with start dates/times preceding end dates/times) |
| TIER 4:  APxxSDT, APxxSTM, APxxSDTM,  APxxSDTF, APxxSTMF, APxxEDT  APxxETM, APxxEDTM, APxxEDTF  APxxETMF | Analysis Period timing variables (with start dates/times preceding end dates/times). |
| TIER 5:  xxSDT, xxEDT | This section will include any Trial date/time variable(s), not included above (with start dates/times preceding end dates/times). |
| Population Indicators | 300-399 | INCNFL, ENRLFL, RANDFL, SAFFL, ITTFL, PPROTFL, COMPLFL | Population Flag variables as needed. |
| Demographic and Grouping Variables | 400-499 | AGE, AGEU, SEX, RACE, AGEGRy, AGEGRyN, RACEGRy, RACEGRyN, COUNTRY | All types of grouping variables, including Age Group, Race Group, etc., |
| Other (Study-Need) Variables | 800-899 | DTHCAUS, DTHDT, DTHFL | Death related variables, etc. |

## BDS Structure

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| **Variable Type** | **Numbering**  **Convention** | **Standard Ordering** | **Guidance** |
| Identifiers | 1-99 | TIER 1:  1 = STUDYID  2 = USUBJID | This section is fixed. No changes are allowed. |
| TIER 2:  3 = SUBJID  4 = SITEID | Numbered when applicable |
| TIER 3:  xxSEQ, xxCAT, xxDTC, VISIT, VISITNUM | SDTM source variables. |
| Timing Variables | 100-199 | TIER 1:  ADT, ATM, ADTM, ADY, ADTF, ATMF, ASTDT, ASTTM, ASTDTM, ASTDY,  ASTDTF, ASTTMF, AENDT, AENTM,  AENDTM, AENDY, AENDTF, AENTMF | All the Start Dates (collection dates) and End Dates (with start dates/times preceding end dates/times). |
| TIER 2:  AVISIT, AVISITN, ATPT, ATPTN, APERIOD, APERIODC, APHASE, ARELTM, ARELTMU, APERSDT, APERSTM, APERSDTM, APERSDTF,  APERSTMF, APEREDT, APERETM,  APEREDTM, APEREDTF, APERETMF | Additional timing variables (if included) such as: Analysis visit, period, phase, start relative days, end relative days (with start dates/times preceding end dates/times). |
| TIER 3:  \*DT, \*TM, \*DTM, \*ADY, \*DTF,  \*TMF, \*SDT, \*STM, \*SDTM, \*SDY,  \*SDTF, \*STMF, \*EDT, \*ETM, \*EDTM, \*EDY, \*EDTF, \*ETMF | Analysis date variables not directly characterizing AVAL and/or AVALC in numeric format (with start dates/times preceding end dates/times). |
| Parameter Related Variables | 200-299 | TIER 1:  200 = PARAM  201 = PARAMCD | This section is fixed. No changes are allowed |
| TIER 2:  PARAMN  PARAMTYP  PARCATy  PARCATyN | Variables numbered (as available). |
| Analysis Values | 300-399 | TIER 1:  AVAL, AVALC, AVALCATy, AVALCAyN  TIER 2:  BASE, BASEC, BASECATy, BASECAyN, BASETYPE, BNRIND, BNRINDN  TIER 3:  CHG, CHGCATy, PCHG, PCHGCATy  R2BASE, R2AyLO, R2AyHI, SHIFTy  SHIFTyN, DTYPE, AWRANGE, AWTARGET, AWTDIFF, AWLO, AWHI, AWU, STARTDT, CNSR, EVNTDESC, ANRIND, ANRINDN, ANRLO, ANRHI, AyLO, AyHI  TIER4:  BTOXGR, BTOXGRN, BTOXLO, BTOXHI, ATOXGR, ATOXGRN, TOXDIRLO, TOXDIRHI, CTCTERM, CTCAESOC, CTCTRMLO, CTCTRMHI | AVAL variables comes first, followed by BASE, Change and Percent Change, Ratio and other variables as listed |
| Flags | 400-499 | ANL01FL, ANL02FL, ANL03FL, PREFL, ONTRTFL, ABLFL, ABLFLN, ANLzzFL, ANLzzFN, ONTRTFL, ONTRTFN, LVOTFL, LVOTFN, ITTRFL, ITTRFN, ITTPFL, ITTPFN, SAFRFL, SAFRFN, SAFPFL, SAFPFN, FASRFL, FASRFN, FASPFL, FASPFN, PPROTRFL, PPROTRFN, PPROTPFL, PPROTPFN, COMPRFL, COMPRFN, COMPPFL, COMPPFN, ENRLFL, RANDFL, CRITy, CRITyFL, CRITyFN | Baseline related flag variables, followed by analysis flag variables. CRIT related variables are added to this section to keep CRITy and CRITyFL variables together |
| Treatment Variables | 500-599 | TRTP, TRTPN, TRTA, TRTAN |  |
| Other (Study-Need) Variables | 800-899 |  | Additional analysis or Data Point Traceability variables required for analysis may be included in this section. |

## Occurrence structure

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| **Variable Type** | **Numbering**  **Convention** | **Standard Ordering** | **Guidance** |
| Identifiers. | 1 - 99 | TIER 1:  1 = STUDYID  2 = USUBJID  TIER 2:  SUBJID, SITID, xxSEQ, SRCDOM | This section is fixed. No changes are allowed. |
|  |  |
| Dictionary Coding Variables | 100 - 199 | TIER 1:  --TERM  TIER 2:  --DECOD, --BODSYS, --BDYSYCD, --BASENM  TIER 3:  --LLT, --LLTCD, --PTCD  TIER 4:  --HLT, --HLTCD, --HLGTCD  TIER 5:  --SOC, --SOCCD | xxTERM variables, followed by xxDECOD, xxBODSYS, etc., in the order presented |
| Timing variables | 200 - 299 | TIER 1:  --STDTC,  TIER 2:  ASTDT, ASTDTM, ASTDTF, ASTTMF  TIER 3:  --ENDTC  TIER 4:  AENDT, AENDTM, AENDTF, AENTMF  TIER 5:  ASTDY, --STDY, AENDY, --ENDY, ADURN, ADURU, --DUR, APERIOD, APERIODC, APHASE | All the Start Dates (collection dates) and End dates. Always add the start date variables first, followed by end date variables. |
| Indicator variables | 300 - 399 | TIER 1:  TRTEMFL, --TRTEM  TIER 2:  ANLzzFL  TIER 3:  PREFL, FUPFL | Include –TRTEM (e.g. AETRTEM from SUPPAE), if collected. ANLzzFL, PREFL, FUPFL may not be needed for all studies, so they should be included only if needed for analysis. |
| Occurrence Flag variables | 400 - 499 | TIER 1:  AOCCFL, AOCCSFL, AOCCPFL  TIER 2:  AOCCIFL, AOCCSIFL, AOCCPIFL  TIER 3:  AOCCzzFL, CMATC1FL, CMATC2FL, CMATC3FL, CMATC4FL | The other occurrence flags should be defined only following the first occurrence and 1st maximum severity flags. |
| Treatment variables | 500 – 599 | DOSE--ON, DOSE--ONU  DOSECUM, DOSECUMU | These variables should be used only if required for analysis purposes. |
| Descriptive variables | 600 – 699 | TIER 1:  --SER,  TIER 2:  --SEV, --SEVN, ASEV, SEVGRy, SEVGRy  TIER 3:  --REL, --RELN, AREL, ARELN, RELGRy, RELGRyN,  TIER 4:  --TOXGR, --TOXGRN, ATOXGR, ATOXGRN, TOXGGRy, TOXGGRyN,  TIER 5:  --ACN | The sequence of variables defined in the ADaM dataset should be as follows:   * Seriousness * Severity * Relationship * Toxicity * Action taken   Any other flags required for analysis should be defined either as ANLzzFL or AOCCzzFL |
| MedDRA Query variables | 700 – 799 | TIER 1:  SMQzzNAM  TIER 2:  SMQzzCD  TIER 3:  SMQzzSC, SMQzzSCN  TIER 4:  CQzzNAM | Standard MedDRA Query and Sub-Query variables should precede any Customized Query (CQ) variables |
| Original or Prior Coding Variables | 800 – 899 | DECDORGy, BDSYORGy, HLGTORGy, HLTORGy, LLTORGy, LLTNORGy |  |
| Other (Study-Need) Variables | 900 – 999 | Other | Data Point Traceability variables required for analysis may be included in this section. |

## Other (AX----) structure

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| **Variable Type** | **Numbering**  **Convention** | **Standard Ordering** | **Guidance** |
| Identifiers | 1-99 | TIER 1:  1 = STUDYID  2 = USUBJID | This section is fixed. No changes are allowed. |
| TIER 2:  SUBJID, SITEID, xxSEQ, xxCAT, | If the source dataset is an SDTM Events class domain, then also put SDTM source variables here. |
| Timing Variables | 100-199 | TIER 1:  ASTDT, AENDT, etc., | All the Start Dates (collection dates) and End dates (with start dates/times preceding end dates/times). |
| TIER 2:  APERIOD, APERIODC, APHASE, etc., | Additional timing variables if included such as start date, end date, start relative days, end relative days (with start dates/times preceding end dates/times). |
| Treatment Variables | 200-299 | TRTP, TRTPN, TRTA, TRTAN |  |
| Flags | 300-399 | ABLFL, BASETYPE, DTYPE, ANL01FL, ANL02FL, ANL03FL, PREFL, ONTRTFL | Baseline related flag variables followed by analysis variable flag variables. |
| Other (Study-Need) Variables | 800-899 |  | e.g., Analysis variables, Data Point Traceability variables, etc. |