Metadata description for ADEG, ADPC, ADSL, and ADDM data tables of the “CiPA Phase I ECG Biomarker Validation” publicly available in comma separated values (csv) format files at <https://physionet.org/physiobank/database/ecgcipa/>.

Study

# Analysis Variables Metadata for ADEG

| **Variable Name** | **Variable Label** | **Type** |
| --- | --- | --- |
| STUDYID | Study Identifier | Char |
| USUBJID | Unique Subject Identifier | Char |
| TRTSEQP | Planned Sequence of Treatments | Char |
| TRTP | Planned Treatment | Char |
| TRTSEQA | Actual Sequence of Treatments | Char |
| TRTA | Actual Treatment | Char |
| PARAM | Parameter | Char |
| PARAMCD | Parameter Code | Char |
| APERIOD | Period  | Num |
| APERIODC | Period (C) | Char |
| AVISIT | Analysis Visit | Char |
| AVISITN | Analysis Visit (N) | Num |
| ATPT | Analysis Time Point | Char |
| ATPTN | Analysis Time Point (N) | Num |
| ATPTREF | Analysis Reference Time Point | Char |
| ARDTM | Date/Time of Reference | Num |
| AARDTM | Actual Date/Time of Reference | Num |
| ARRLT | Actual Relative Time from Reference Time TimePoint | Num |
| NRRLT | Nominal Relative Time from Reference Time Point | Num |
| RRLTU | Relative Time from Reference Time Point Units | Char |
| ADTM | Analysis Date and Time | Num |
| ADT | Analysis Date | Num |
| ATM | Analysis Time | Num |
| ADY | Analysis Relative Day | Num |
| AVISDY | Analysis Visit Day | Num |
| APERDAY | Analysis Nominal Period Day | Num |
| EGREPNUM | ECG Replicate Number | Num |
| AVAL | Analysis Value | Num |
| AVALC | Analysis Value | Char |
| EGSTRESU | Units of Analysis Value | Char |
| DTYPE | Derivation Type | Char |
| ABLFL | Baseline Record Flag | Char |
| AEGBLFL | Baseline Flag for Records used to Derive the Baseline | Char |
| BASE | Baseline Value | Num |
| CHG | Change from Baseline | Num |
| BASETYPE | Baseline Type | Char |
| ACOMPFL | Comparator Record Flag | Char |
| COMP | Comparator Value | Num |
| COMPBASE | Baseline Value of the Comparator | Num |
| COMPCHG | Change from Baseline in the Comparator | Num |
| CCOMPCHG | Change from Baseline Corrected for the Comparator | Num |
| COMPTYPE | Comparator Type | Char |
| ECGPCFL | ECG Matching PK Flag | Char |
| EGSEQ | Sequence Number | Num |
| EGLEAD | Lead Location Used for Measurement | Char |
| EGREFID | ECG Reference ID | Char |
| CRITy | Analysis Criterion y | Char |
| CRITyFL | Criterion y Evaluation Result Flag | Char |
| IUTANLFL | Intersection Union Test Analysis Flag | Char |
| CATANLFL | Categorical Analysis Flag | Char |
| ASEANLFL | Assay Sensitivity Analysis Flag | Char |
| CQTANLFL | Concentration QT Analysis Flag | Char |

# Analysis Variables Metadata for ADPC

| **Variable Name** | **Variable Label** | **Type** |
| --- | --- | --- |
| STUDYID | Study Identifier | Char |
| USUBJID | Unique Subject Identifier | Char |
| TRTSEQP | Planned Sequence of Treatments | Char |
| TRTP | Planned Treatment | Char |
| TRTSEQA | Actual Sequence of Treatments | Char |
| TRTA | Actual Treatment | Char |
| APERIOD | Period | Char |
| APERIODC | Period (C) | Num |
| AVISIT | Analysis Visit | Char |
| AVISITN | Analysis Visit (N) | Num |
| ATPT | Analysis Time Point | Char |
| ATPTN | Analysis Time Point (N) | Num |
| ATPTREF | Analysis Reference Time Point | Char |
| ARDTM | Date/Time of Reference | Num |
| AARDTM | Actual Date/Time of Reference | Num |
| ARRLT | Actual Relative Time from Reference Time TimePoint | Num |
| NRRLT | Nominal Relative Time from Reference Time Point | Num |
| RRLTU | Relative Time from Reference Time Point Units | Char |
| ADTM | Analysis Date and Time | Num |
| ADT | Analysis Date | Num |
| ATM | Analysis Time | Num |
| ADY | Analysis Relative Day | Num |
| AVISDY | Analysis Visit Day | Num |
| APERDAY | Analysis Nominal Period Day | Num |
| PARAM | Analyte Name | Char |
| PARAMCD | Analyte Code | Char |
| AVAL | Analysis Value | Num |
| PCSTRESU | Units of Analysis Value | Char |
| LLOQFL | Lower Limit of Quantification Flag | Char |
| PCSEQ | Sequence Number | Num |

# Analysis Variables Metadata for ADSL

| **Variable Name** | **Variable Label** | **Type** |
| --- | --- | --- |
| STUDYID | Study Identifier | Char |
| USUBJID | Unique Subject Identifier | Char |
| SUBJID | Subject Identifier for the Study | Char |
| SITEID | Site Identifier | Char |
| AGE | Age | Num |
| AGEU | Age Units | Char |
| SEX | Sex | Char |
| RACE | Race | Char |
| ETHNIC | Ethnic | Char |
| ARM | Planned Arm | Char |
| ACTARM | Actual Arm | Char |
| TRT01P | Planned Treatment for Period 1 | Char |
| TRT02P | Planned Treatment for Period 2 | Char |
| TRT01PN | Planned Treatment for Period 1 (N) | Num |
| TRT02PN | Planned Treatment for Period 2 (N) | Num |
| TRT01A | Actual Treatment for Period 1 | Char |
| TRT02A | Actual Treatment for Period 2 | Char |
| TRT01AN | Actual Treatment for Period 1 (N) | Num |
| TRT02AN | Actual Treatment for Period 2 (N) | Num |
| TRTSEQP | Planned Sequence of Treatments | Char |
| TRTSEQPN | Planned Sequence of Treatments (N) | Num |
| TRTSEQA | Actual Sequence of Treatments | Char |
| TRTSEQAN | Actual Sequence of Treatments (N) | Num |

# Analysis Variables Metadata for ADDM

| **Variable Name** | **Variable Label** | **Type** |
| --- | --- | --- |
| STUDYID | Study Identifier | Char |
| USUBJID | Unique Subject Identifier | Char |
| PARAM | Parameter | Char |
| PARAMCD | Parameter Code | Char |
| AVAL | Analysis Value | Num |
| AVALU | Units of Analysis Value | Char |