

**FOR FDA**

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# DATASETS TABLE OF CONTENTS

| **Dataset** | **Original Name** | **Description** | **Key Variables** | **Location** |
| --- | --- | --- | --- | --- |
| pkdata.xpt | ODONXXXXPOPPKXXXX31OCT20.csv | Optional ex: PK dataset | optional ex:USUBJID,TIME | [**#datasets#pkdata.xpt**](./pkdata.xpt) |
| patab.xpt | cpt2.tab | optional ex:Posthoc | optional ex:ID,TIME | [**#datasets#patab.xpt**](./patab.xpt) |

# VARIABLE DEFINITION TABLES

## pkdata

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Optional ex: PK dataset** | | | | | |
| Name of original version: ODONXXXXPOPPKXXXX31OCT20.csv | | | | | |
| Structure: optional ex:per subject per time point | | | | | |
| Dataset: [**pkdata.xpt**](./pkdata.xpt) | | | | | |
| Program: [**script or program name if applicable ex:phxsetting.txt**](../programs/script or program name if applicable ex:phxsetting.txt) | | | | | |
| **Variable** | **Label** | **Type** | **Code Range** | **Unit** | **Detailed Description** |
| IDCHANGE | X.ID | Num | 1 - 273 |  | X.ID |
| DV | Dependent variable | Num | 0 - 447 |  | Dependent variable |
| LNDV | LNDV | Num | -999 - 6.10256 |  | LNDV |
| AMT | Amount administer | Num | 2 - 90 |  | Amount administer |
| EVID | Even identifier | Num | 0 - 1 |  | Even identifier |
| MDV | Missing dependent variable | Num | 0 - 1 |  | Missing dependent variable |
| RTIME | RTIME | Num | 0 - 11592.3 |  | RTIME |
| FORM | Formulation | Num | 1 - 1 |  | Formulation |
| FAST | Fasted condition | Num | -999 - 1 |  | Fasted condition |
| AGE | Age | Num | 30 - 87 |  | Age |
| SEX | Sex | Num | 1 - 2 |  | Sex |
| RACE | Race | Num | -999 - 9 |  | Race |
| COUNTRY | Country | Num | 1 - 385 |  | Country |
| BHT | Baseline height | Num | 145 - 193.04 |  | Baseline height |
| BWT | Baseline weight | Num | 40.8 - 129.501 |  | Baseline weight |
| BBSA | Baseline body surface area | Num | 1.34 - 2.48 |  | Baseline body surface area |
| BBMI | Baseline body massindex | Num | 14.53 - 44.23 |  | Baseline body massindex |
| BALB | Baseline albumine | Num | -999 - 5.2 |  | Baseline albumine |
| ALB | Albumine | Num | -999 - 5.2 |  | Albumine |
| BALP | Baseline alkaline phosphatase | Num | 7.6 - 2167 |  | Baseline alkaline phosphatase |
| ALP | Alkaline phosphatase | Num | 0 - 2167 |  | Alkaline phosphatase |
| BALT | Baseline alanine aminotransferase | Num | 7 - 350 |  | Baseline alanine aminotransferase |
| ALT | Alanine aminotransferase | Num | 7 - 540 |  | Alanine aminotransferase |
| BAST | Baseline aspartate aminotransferase | Num | 5 - 551 |  | Baseline aspartate aminotransferase |
| AST | Aspartate aminotransferase | Num | 5 - 790 |  | Aspartate aminotransferase |
| BBILI | Baseline bilirubin | Num | 0.1 - 2.925 |  | Baseline bilirubin |
| BILI | Bilirubin | Num | 0.1 - 6.2 |  | bilirubin |
| BCREAT | Baseline creatinine | Num | 0.3 - 1.8419 |  | Baseline creatinine |
| CREAT | Creatinine | Num | 0.3 - 2.2035 |  | Creatinine |
| BCRCL | Baseline creatinine clearance | Num | 33.221 - 402.029 |  | Baseline creatinine clearance |
| CRCL | Creatinine clearance | Num | 29.3271 - 402.029 |  | Creatinine clearance |
| BEGFR | Baseline estimated glomerular filtration rate | Num | 30.15 - 300.165 |  | Baseline estimated glomerular filtration rate |
| EGFR | Estimated glomerular filtration rate | Num | 24.55 - 300.165 |  | Estimated glomerular filtration rate |
| TULOC | Tumor location | Num | 1 - 27 |  | Tumor location |
| TUTYPE | Tutype | Num | 1 - 27 |  | tutype |
| ECOG | Ecog | Num | -99 - 2 |  | ecog |
| PPI | Ppi | Num | 0 - 1 |  | ppi |
| CYPINH | Cypinh | Num | 0 - 1 |  | cypinh |
| CYPIND | Cypind | Num | 0 - 1 |  | cypind |
| BHEPIMP | Bhepimp | Num | 0 - 2 |  | bhepimp |
| HEPIMP | Hepimp | Num | 0 - 3 |  | hepimp |
| BRIMPC | Brimpc | Num | 0 - 2 |  | brimpc |
| RIMPC | Rimpc | Num | 0 - 3 |  | rimpc |
| BRIMPE | Brimpe | Num | 0 - 2 |  | brimpe |
| RIMPE | Rimpe | Num | 0 - 3 |  | rimpe |

## patab

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **optional ex:Posthoc** | | | | | |
| Name of original version: cpt2.tab | | | | | |
| Structure: optional ex:per subject per time point | | | | | |
| Dataset: [**patab.xpt**](./patab.xpt) | | | | | |
| Program: [**script or program name if applicable ex:phxsetting.txt**](../programs/script or program name if applicable ex:phxsetting.txt) | | | | | |
| **Variable** | **Label** | **Type** | **Code Range** | **Unit** | **Detailed Description** |
| ID | Subject identifier | Num | 1 - 273 |  | Subject identifier |
| TIME | Time | Num | 0 - 11592 |  | Time |
| EVID | Even identifier | Num | 0 - 1 |  | Even identifier |
| AMT | Amount administer | Num | 0 - 90 |  | Amount administer |
| MDV | Missing dependent variable | Num | 0 - 1 |  | Missing dependent variable |
| DV | Dependent variable | Num | 0 - 447 |  | Dependent variable |
| PRED | Population prected response | Num | 0 - 104.88 |  | Population prected response |
| RES | Residual error | Num | -96.493 - 442.16 |  | Residual error |
| WRES | Weighted residual error | Num | -20.387 - 151.89 |  | Weighted residual error |
| IPRED | Individual prected response | Num | 0 - 147.86 |  | Individual prected response |
| CWRES | Conditional weighted residual error | Num | -3.537 - 7.5856 |  | Conditional weighted residual error |
| IRES | Individual residual error | Num | -143.13 - 312.68 |  | Individual residual error |
| FORM | Formulation | Num | 1 - 1 |  | Formulation |
| FAST | Fasted condition | Num | -999 - 1 |  | Fasted condition |
| AGE | Age | Num | 30 - 87 |  | Age |
| SEX | Sex | Num | 1 - 2 |  | Sex |
| RACE | Race | Num | -999 - 9 |  | Race |
| COUNTRY | Country | Num | 1 - 385 |  | Country |
| BHT | Baseline height | Num | 145 - 193.04 |  | Baseline height |
| BWT | Baseline weight | Num | 40.8 - 129.5 |  | Baseline weight |
| BBSA | Baseline body surface area | Num | 1.34 - 2.48 |  | Baseline body surface area |
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| ALB | Albumine | Num | -999 - 5.2 |  | Albumine |
| BALP | Baseline alkaline phosphatase | Num | 0 - 2167 |  | Baseline alkaline phosphatase |
| ALP | Alkaline phosphatase | Num | 0 - 2167 |  | Alkaline phosphatase |
| BALT | Baseline alanine aminotransferase | Num | 0 - 350 |  | Baseline alanine aminotransferase |
| ALT | Alanine aminotransferase | Num | 0 - 540 |  | Alanine aminotransferase |
| BAST | Baseline aspartate aminotransferase | Num | 0 - 551 |  | Baseline aspartate aminotransferase |
| AST | Aspartate aminotransferase | Num | 0 - 790 |  | Aspartate aminotransferase |
| BBILI | Baseline bilirubin | Num | 0 - 2.925 |  | Baseline bilirubin |
| BILI | Bilirubin | Num | 0 - 6.2 |  | bilirubin |
| BCREAT | Baseline creatinine | Num | 0 - 1.8419 |  | Baseline creatinine |
| CREAT | Creatinine | Num | 0 - 2.2035 |  | Creatinine |
| BCRCL | Baseline creatinine clearance | Num | 0 - 402.03 |  | Baseline creatinine clearance |
| CRCL | Creatinine clearance | Num | 0 - 402.03 |  | Creatinine clearance |
| BEGFR | Baseline estimated glomerular filtration rate | Num | 0 - 300.17 |  | Baseline estimated glomerular filtration rate |
| EGFR | Estimated glomerular filtration rate | Num | 0 - 300.17 |  | Estimated glomerular filtration rate |
| TULOC | Tumor location | Num | 0 - 27 |  | Tumor location |
| TUTYPE | Tutype | Num | 0 - 27 |  | tutype |
| ECOG | Ecog | Num | -99 - 2 |  | ecog |
| PPI | Ppi | Num | 0 - 1 |  | ppi |
| CYPINH | Cypinh | Num | 0 - 1 |  | cypinh |
| CYPIND | Cypind | Num | 0 - 1 |  | cypind |
| BHEPIMP | Bhepimp | Num | 0 - 2 |  | bhepimp |
| HEPIMP | Hepimp | Num | 0 - 3 |  | hepimp |
| BRIMPC | Brimpc | Num | 0 - 2 |  | brimpc |
| RIMPC | Rimpc | Num | 0 - 3 |  | rimpc |
| BRIMPE | Brimpe | Num | 0 - 2 |  | brimpe |
| RIMPE | Rimpe | Num | 0 - 3 |  | rimpe |
| ETA1 | Eta1 | Num | -2.2429 - 1.4264 |  | eta1 |
| ETA2 | Eta2 | Num | -1.944 - 3.0459 |  | eta2 |
| ETA3 | Eta3 | Num | -4.7383 - 1.3242 |  | eta3 |
| ETA4 | Eta4 | Num | -1.7448 - 1.5899 |  | eta4 |

# PROGRAMS TABLE OF CONTENTS

| **Program\_Original\_names** | **Description** | **Input\_Output\_log\_file\_original\_names** |
| --- | --- | --- |
| modcpt2.txt (original:cpt2.mod) | **Software used:** for PMDA filing ex:NONMEM VERSION 7.4.3  **Purpose:** for PMDA filing ex:NONMEM control stream of population PK base model | **[Input]**  pkdata.xpt  (original:ODON\_POPPK\_31OCT20.csv)    **[Output]**  patab.xpt  (original:cpt2.tab)    **[Dependency]** |