

Project Number: MRG123

Sponsor: demo

#### **CONFIDENTIAL**

# Analysis data specification

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## 1 spec

**Description**: an example data set

| Column  | Туре      | Field      | Value  |
|---------|-----------|------------|--|
| С       | character | short-name | commented row indicator                          |
|         |           | values     | ., C   |
|         |           | long-name  | commented rows                                   |
| USUBJID | character | short-name | USUBJID  |
|         |           | long-name  | universal subject identifier                     |
| ID      | numeric   | short-name | ID   |
|         |           | long-name  | NONMEM ID number                                 |
| EVID    | numeric   | short-name | event ID   |
|         |           | long-name  | event ID indicator                               |
|         |           | comment    | per NONMEM specifications                        |
| MDV     | numeric   | short-name | MDV  |
|         |           | long-name  | missing DV indicator                             |
|         |           | comment    | per NONMEM specifications                        |
| SEQ     | numeric   | short-name | SEQ  |
|         |           | values     | 1 = concentration, $2 = $ response, $3 = $ other |
|         |           | long-name  | record type indicators                           |
| AMT     | numeric   | short-name | amount   |
|         |           | unit       | mg   |
|         |           | range      | 0 to 1000  |
|         |           | long-name  | dose amount                                      |
| II      | numeric   | short-name | II   |
|         |           | unit       | hours  |
|         |           | long-name  | interdose interval                               |
| CMT     | numeric   | short-name | Compartment                                      |
|         |           | values     | 1, 2, 3, 4                                       |
|         |           | long-name  | compartment number                               |
|         |           | comment    | per NONMEM specifications                        |
| TAFD    | numeric   | short-name | TAFD   |
|         |           | unit       | hours  |
|         |           | long-name  | time after first dose                            |
| WT      | numeric   | short-name | Weight   |
|         |           | unit       | kg   |
|         |           | range      | 40 to 100  |
|         |           | long-name  | baseline weight                                  |
| EGFR    | numeric   | short-name | eGFR   |
|         |           | unit       | ml/min/1.73m2                                    |
|         |           | range      | 10 to 300  |

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| Column | Type      | Field      | Value                                       |
|--------|-----------|------------|---|
|        |           | long-name  | estimated glomerular filtration rate        |
| STUDY  | character | short-name | Study                                       |
|        |           | values     | 100 = The first phase 1 study, $202 = $ The |
|        |           |            | first phase 2 study conducted only at sites |
|        |           |            | 1, 2, 3 when the formulation was still oral |
|        |           |            | liquid only, $303 =$ The renal impairment   |
|        |           |            | study, $203 = $ The second phase 2 study    |
|        |           | long-name  | study identifier                            |
| SEX    | numeric   | short-name | SEX   |
|        |           | values     | 0 = male, 1 = female                        |
| BQL    | numeric   | short-name | below limit of quantification               |
|        |           | values     | 0 = FALSE, 1 = TRUE                         |
|        |           | long-name  | DV value is below the quantitation limit    |
| DV     | numeric   | short-name | DV  |
|        |           | unit       | ng/mL                                       |
|        |           | long-name  | dependent variable                          |
|        |           | comment    | see SEQ                                     |
| DV2    | numeric   | short-name | DV2   |
|        |           | long-name  | second dependent variable                   |
| HAIR   | character | short-name | HAIR  |
|        |           | values     | 0 = brown, 1 = blonde, 2 = black            |
|        |           | long-name  | patient hair color                          |
| CLCR   | numeric   | short-name | creatinine clearance                        |
|        |           | unit       | ml/min                                      |
|        |           | range      | 40 to 180                                   |
| ALB    | numeric   | short-name | adjusted albumin                            |
|        |           | unit       | g/dL  |
|        |           | range      | 1 to 5                                      |
|        |           | comment    | in the lookup document as ALB2              |

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## 2 DEM104101F\_PKPD

**Description**: Population PKPD analysis data set

| Column | Туре      | Field      | Value  |
|--------|-----------|------------|--|
| С      | character | short-name | С  |
|        |           | values     | ., C   |
|        |           | long-name  | commented rows                                   |
| MDV    | numeric   | short-name | MDV  |
|        |           | long-name  | missing DV indicator                             |
|        |           | comment    | per NONMEM specifications                        |
| SEQ    | numeric   | short-name | SEQ  |
|        |           | values     | 1 = concentration, $2 = $ response, $3 = $ other |
|        |           | long-name  | record type indicators                           |
| AMT    | numeric   | short-name | AMT  |
|        |           | unit       | mg   |
|        |           | range      | 0 to 1000  |
|        |           | long-name  | dose amount                                      |

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|                        |  |  |  |

| Column | Туре    | Field      | Value                                |
|--------|---------|------------|--------------------------------------|
| II     | numeric | short-name | II                                   |
|        |         | unit       | hours                                |
|        |         | long-name  | interdose interval                   |
| CMT    | numeric | short-name | Compartment                          |
|        |         | values     | 1, 2, 3, 4                           |
|        |         | long-name  | compartment number                   |
|        |         | comment    | per NONMEM specifications            |
| TAFD   | numeric | short-name | TAFD                                 |
|        |         | unit       | hours                                |
|        |         | long-name  | time after first dose                |
| WT     | numeric | short-name | Weight                               |
|        |         | unit       | kg                                   |
|        |         | range      | 40 to 100                            |
|        |         | long-name  | baseline weight                      |
| EGFR   | numeric | short-name | eGFR                                 |
|        |         | unit       | ml/min/1.73 m2                       |
|        |         | range      | 10 to 300                            |
|        |         | long-name  | estimated glomerular filtration rate |
| SEX    | numeric | short-name | SEX                                  |
|        |         | values     | 0 = male, 1 = female                 |