Data Dictionary

January 4, 2024

Included Datasets

Dataset: DM

Table 1: Summary of 'DM'

Order	Variable	Type	Label	Summary
1	ID	character	subject id	
2	AGE	integer	Age	mean:34.22; sd:6.95; range:20-60
3	SEX	factor		M, F
4	RACE	factor		BLACK OR AFRICAN AMERICAN, ASIAN, WHITE
5	COUNTRY	factor		BRA, NGA, PAK, CHN, USA, RUS, JPN, GBR, CAN
6	ARM	factor		B: Placebo, C: Combination, A: Drug X
7	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.85; sd:3.2; range:0.68-25.12
8	STRATA1	factor		C, A, B

Dataset: ex_adae

Table 2: Summary of 'ex_adae'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.77; sd:7.66; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	WHITE, BLACK OR AFRICAN AMERICAN, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S2, S1
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.87; sd:3.52; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	LOW, HIGH, MEDIUM
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 2: 'ex_adae' has 1,934 rows and 48 columns

Table 2: Summary of 'ex_adae'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	N, Y
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-16
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-18 03:09:28.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-09 12:29:30.956201
25	EOSSTT	factor	End of Study Status	COMPLETED, DISCONTINUED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-09
27	EOSDY	integer	End of Study Relative Day	mean:596.94; sd:221.55; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-09
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-06
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Analysis Sequence Number	mean:3.95; sd:2.44; range:1-10
33	AESEQ	integer	Sponsor-Defined Identifier	mean:3.95; sd:2.44; range:1-10
34	AETERM	factor	Reported Term for the Adverse Event	trm B.2.1.2.1, trm D.1.1.4.2, trm A.1.1.1.2, trm D.2.1.5.3, trm A.1.1.1.1, trm D.1.1.1.1, trm B.1.1.1.1, trm C.2.1.2.1, trm C.1.1.1.3, trm B.2.2.3.1

Table 2: Summary of 'ex_adae'

Order	Variable	Type	Label	Summary
35	AELLT	factor	Lowest Level Term	llt B.2.1.2.1, llt D.1.1.4.2, llt A.1.1.1.2, llt D.2.1.5.3, llt A.1.1.1.1, llt D.1.1.1.1, llt B.1.1.1.1, llt C.2.1.2.1, llt C.1.1.1.3, llt B.2.2.3.1
36	AEDECOD	factor	Dictionary-Derived Term	dcd B.2.1.2.1, dcd D.1.1.4.2, dcd A.1.1.1.2, dcd D.2.1.5.3, dcd A.1.1.1.1, dcd D.1.1.1.1, dcd B.1.1.1.1, dcd C.2.1.2.1, dcd C.1.1.1.3, dcd B.2.2.3.1
37	AEHLT	factor	High Level Term	hlt B.2.1.2, hlt D.1.1.4, hlt A.1.1.1, hlt D.2.1.5, hlt D.1.1.1, hlt B.1.1.1, hlt C.2.1.2, hlt C.1.1.1, hlt B.2.2.3
38	AEHLGT	factor	High Level Group Term	hlgt B.2.1, hlgt D.1.1, hlgt A.1.1, hlgt D.2.1, hlgt B.1.1, hlgt C.2.1, hlgt C.1.1, hlgt B.2.2
39	AEBODSYS	factor	Body System or Organ Class	cl B.2, cl D.1, cl A.1, cl D.2, cl B.1, cl C.2, cl C.1
40	AESOC	factor	Primary System Organ Class	cl B, cl D, cl A, cl C
41	AESEV	factor	Severity/Intensity	MODERATE, MILD, SEVERE
42	AESER	factor	Serious Event	N, Y
43	AREL	factor	Analysis Causality	N, Y
44	ASTDTM	POSIXct, POSIXt	Analysis Start Datetime	2019-10-20 20:00:00 – 2023-08-26 20:00:00
45	AENDTM	POSIXct, POSIXt	Analysis End Datetime	2020-01-05 19:00:00 – 2023-09-01 20:00:00
46	ASTDY	integer	Analysis Start Relative Day	mean:307.4; sd:218.2; range:0-730
47	AENDY	integer	Analysis End Relative Day	mean:467.67; sd:214.38; range:1-732
48	AETOXGR	factor	Analysis Toxicity Grade	3, 2, 1, 5, 4

Dataset: ex_adaette

Table 3: Summary of 'ex_adaette'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.43; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	BLACK OR AFRICAN AMERICAN, WHITE, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S1, S2
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.44; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 3: 'ex_adaette' has 1,200 rows and 42 columns

Table 3: Summary of 'ex_adaette'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	DISCONTINUED, COMPLETED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.3; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Sequence Number	mean:2; sd:0.82; range:1-3
33	TTESEQ	integer	Sequence Number	mean:2; sd:0.82; range:1-3
34	PARAM	factor	Parameter	Time to first occurrence of any adverse event, Time to first occurrence of any serious adverse event, Time to first occurrence of a grade 3-5 adverse event

Table 3: Summary of 'ex_adaette'

Order	Variable	Type	Label	Summary
35	PARAMCD	factor	Parameter Code	AETTE1, AETTE2, AETTE3
36	AVAL	numeric	Analysis Value	mean:0.25; sd:0.28; range:0-2.64
37	AVALU	factor	Analysis Value Unit	YEARS
38	ADTM	POSIXct, POSIXt	Analysis Datetime	2019-11-01 20:00:00 – 2023-09-06 20:00:00
39	ADY	integer	Analysis Relative Day	mean:321.45; sd:210.45; range:0-730
40	CNSR	integer	Censor	mean:0.25; sd:0.43; range:0-1
41	EVNTDESC	character	Event or Censoring Description	
42	CNSDTDSC	character	Censor Date Description	

Dataset: ex_adcm

Table 4: Summary of 'ex_adcm'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.77; sd:7.66; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	WHITE, BLACK OR AFRICAN AMERICAN, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S2, S1
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.87; sd:3.52; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	LOW, HIGH, MEDIUM
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 4: Summary of 'ex_adcm'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	N, Y
22	RANDDT	Date	Date of Randomization	2019-09-28 − 2021-09-16
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 − 2021-09-18 03:09:28.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 − 2023-09-09 12:29:30.956201
25	EOSSTT	factor	End of Study Status	COMPLETED, DISCONTINUED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 − 2023-09-09
27	EOSDY	integer	End of Study Relative Day	mean:596.94; sd:221.55; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 − 2023-09-09
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 − 2023-10-06
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Analysis Sequence Number	mean:3.95; sd:2.44; range:1-10
33	CMSEQ	integer	Sponsor-Defined Identifier	mean:3.95; sd:2.44; range:1-10
34	CMDECOD	factor	Standardized Medication Name	medname B_1/4, medname C_1/2, medname A_2/3, medname A_3/3, medname C_2/2, medname A_1/3, medname B_4/4, medname B_2/4, medname B_3/4

Table 4: Summary of 'ex_adcm'

Order	Variable	Type	Label	Summary
35	CMCAT	factor	Category for Medication	medcl B, medcl C, medcl A
36	CMCLAS	factor	Medication Class	medcl B, medcl C, medcl A
37	ATIREL	factor	Time Relation of Medication	CONCOMITANT, PRIOR
38	ASTDTM	POSIXct, POSIXt	Analysis Start Datetime	2019-10-20 20:00:00 – 2023-08-26 20:00:00
39	AENDTM	POSIXct, POSIXt	Analysis End Datetime	2020-01-05 19:00:00 – 2023-09-01 20:00:00
40	ASTDY	integer	Analysis Start Relative Day	mean:307.4; sd:218.2; range:0-730
41	AENDY	integer	Analysis End Relative Day	mean:467.67; sd:214.38; range:1-732

Dataset: ex_adlb

Table 5: Summary of 'ex_adlb'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.43; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	BLACK OR AFRICAN AMERICAN, WHITE, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S1, S2
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.44; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 5: Summary of 'ex_adlb'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	DISCONTINUED, COMPLETED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.21; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Sequence Number	mean:11; sd:6.06; range:1-21
33	LBSEQ	integer	Sequence Number	mean:11; sd:6.06; range:1-21
34	LBTESTCD	factor	Lab Test or Examination Short Name	ALT, CRP, IGA

Table 5: Summary of 'ex_adlb'

Order	Variable	Type	Label	Summary
35	LBTEST	factor	Lab Test or Examination Name	Alanine Aminotransferase Measurement, C-Reactive Protein Measurement, Immunoglobulin A Measurement
36	LBCAT	factor	Category for Lab Test	CHEMISTRY, IMMUNOLOGY
37	LBSTRESC	character	Character Result/Finding	
38	ASPID	integer	Analysis Sponsor Identifier	mean:4200.5; sd:2425.02; range:1-8400
39	PARAM	factor	Parameter	Alanine Aminotransferase Measurement, C-Reactive Protein Measurement, Immunoglobulin A Measurement
40	PARAMCD	factor	Parameter Code	ALT, CRP, IGA
41	AVAL	numeric	Analysis Value	mean:49.94; sd:8.16; range:20.63-80.48
42	AVALU	factor	Analysis Value Unit	U/L, mg/L, g/L
43	BASE2	numeric	Screeening Value	mean:49.81; sd:8.24; range:24.29-80.48
44	BASE	numeric	Baseline Value	mean:50; sd:8.34; range:23.97-79.12
45	BASETYPE	factor	Baseline Type	LAST
46	ABLFL2	factor	Screening Record Flag	Y,
47	ABLFL	factor	Baseline Record Flag	, Y
48	CHG2	numeric	Absolute Change from Screening	mean:0.13; sd:10.7; range:-41.08-42.81
49	PCHG2	numeric	Percentage Change from Screening	mean:2.82; sd:23.44; range:-64.32-158.63
50	CHG	numeric	Absolute Change from Baseline	mean:-0.04; sd:10.72; range:-39.98-41.61
51	PCHG	numeric	Percentage Change from Baseline	mean:2.5; sd:23.4; range:-59.01-164.32
52	DTYPE	logical	Derivation Type	
53	ANRIND	factor	Analysis Reference Range Indicator	HIGH, NORMAL, LOW

Table 5: Summary of 'ex_adlb'

Order	Variable	Type	Label	Summary
54	ADTM	POSIXct, POSIXt	Analysis Datetime	2019-10-06 20:00:00 – 2023-09-02 20:00:00
55	ADY	integer	Analysis Relative Day	mean:310.51; sd:213.89; range:0-731
56	ATPTN	integer	Analysis Timepoint (N)	mean:1; sd:0; range:1-1
57	AVISIT	factor	Analysis Visit	SCREENING, BASELINE, WEEK 1 DAY 8, WEEK 2 DAY 15, WEEK 3 DAY 22, WEEK 4 DAY 29, WEEK 5 DAY 36
58	AVISITN	integer	Analysis Visit (N)	mean:2; sd:2; range:-1-5
59	LOQFL	factor	Limit of Quantification Flag	N, Y

Dataset: ex_admh

Table 6: Summary of 'ex_admh'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.77; sd:7.66; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	WHITE, BLACK OR AFRICAN AMERICAN, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S2, S1
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.87; sd:3.52; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	LOW, HIGH, MEDIUM
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 6: 'ex_admh' has 1,934 rows and 41 columns

Table 6: Summary of 'ex_admh'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	N, Y
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-16
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-18 03:09:28.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-09 12:29:30.956201
25	EOSSTT	factor	End of Study Status	COMPLETED, DISCONTINUED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-09
27	EOSDY	integer	End of Study Relative Day	mean:596.94; sd:221.55; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-09
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-06
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Analysis Sequence Number	mean:3.95; sd:2.44; range:1-10
33	MHSEQ	integer	Sponsor-Defined Identifier	mean:3.95; sd:2.44; range:1-10
34	MHTERM	factor	Reported Term for the Medical History	trm B_2/3, trm D_2/3, trm A_2/2, trm D_3/3, trm A_1/2, trm D_1/3, trm B_1/3, trm C_2/2, trm C_1/2, trm B_3/3

Table 6: 'ex_admh' has 1,934 rows and 41 columns

Table 6: Summary of 'ex_admh'

Order	Variable	Type	Label	Summary
35	MHDECOD	factor	Dictionary-Derived Term	trm B_2/3, trm D_2/3, trm A_2/2, trm D_3/3, trm A_1/2, trm D_1/3, trm B_1/3, trm C_2/2, trm C_1/2, trm B_3/3
36	MHBODSYS	factor	Body System or Organ Class	cl B, cl D, cl A, cl C
37	MHSOC	factor	Primary System Organ Class	cl B, cl D, cl A, cl C
38	ASTDTM	POSIXct, POSIXt	Analysis Start Datetime	2019-10-20 20:00:00 – 2023-08-26 20:00:00
39	AENDTM	POSIXct, POSIXt	Analysis End Datetime	2020-01-05 19:00:00 – 2023-09-01 20:00:00
40	ASTDY	integer	Analysis Start Relative Day	mean:307.4; sd:218.2; range:0-730
41	AENDY	integer	Analysis End Relative Day	mean:467.67; sd:214.38; range:1-732

Dataset: **ex_adqs**

Table 7: Summary of 'ex_adqs'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.43; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	BLACK OR AFRICAN AMERICAN, WHITE, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S1, S2
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.44; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 7: Summary of 'ex_adqs'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	DISCONTINUED, COMPLETED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.2; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Analysis Sequence Number	mean:18; sd:10.1; range:1-35
33	QSSEQ	integer	Sequence Number	mean:18; sd:10.1; range:1-35
34	PARAM	factor	Parameter	BFI All Questions, Fatigue Interference, Function/Well-Being (GF1,GF3,GF7), Treatment Side Effects (GP2,C5,GP5), FKSI-19 All Questions

Table 7: Summary of 'ex_adqs'

Order	Variable	Type	Label	Summary
35	PARAMCD	factor	Parameter Code	BFIALL, FATIGI, FKSI-FWB, FKSI-TSE, FKSIALL
36	AVAL	numeric	Analysis Value	mean:49.94; sd:8.03; range:15.58-80.48
37	BASE2	numeric	Screeening Value	mean:49.89; sd:8.3; range:23.97-80.48
38	BASE	numeric	Baseline Value	mean:50.13; sd:8.28; range:21.68-74.52
39	ABLFL2	factor	Screening Record Flag	Y,
40	ABLFL	factor	Baseline Record Flag	, Y
41	CHG2	numeric	Absolute Change from Screening	mean:0.05; sd:10.6; range:-42.59-43.9
42	PCHG2	numeric	Percentage Change from Screening	mean:2.67; sd:23.3; range:-63.97-158.19
43	CHG	numeric	Absolute Change from Baseline	mean:-0.18; sd:10.53; range:-43.82-40.85
44	PCHG	numeric	Percentage Change from Baseline	mean:2.17; sd:23.06; range:-67.92-167.51
45	ADTM	POSIXct, POSIXt	Analysis Datetime	2019-10-03 20:00:00 – 2023-09-16 20:00:00
46	ADY	integer	Analysis Relative Day	mean:310.02; sd:213.13; range:0-731
47	AVISIT	factor	Analysis Visit	SCREENING, BASELINE, WEEK 1 DAY 8, WEEK 2 DAY 15, WEEK 3 DAY 22, WEEK 4 DAY 29, WEEK 5 DAY 36
48	AVISITN	integer	Analysis Visit (N)	mean:2; sd:2; range:-1-5
49	LOQFL	factor	Limit of Quantification Flag	N, Y

Dataset: ex_adrs

Table 8: Summary of 'ex_adrs'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.43; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	BLACK OR AFRICAN AMERICAN, WHITE, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S1, S2
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.44; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 8: Summary of 'ex_adrs'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	DISCONTINUED, COMPLETED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.25; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Analysis Sequence Number	mean:3.5; sd:1.71; range:1-6
33	RSSEQ	integer	Sequence Number	mean:3.5; sd:1.71; range:1-6
34	PARAM	factor	Parameter	Best Confirmed Overall Response by Investigator, Investigator End Of Induction Response, Overall Response by Investigator - by visit

Table 8: Summary of 'ex_adrs'

Order	Variable	Type	Label	Summary
35	PARAMCD	factor	Parameter Code	BESRSPI, INVET, OVRINV
36	AVAL	integer	Analysis Value	mean:2.39; sd:1.08; range:1-5
37	AVALC	factor	Analysis Value (C)	PR, SD, CR, PD, NE
38	ADTM	POSIXct, POSIXt	Analysis Datetime	2019-10-10 20:00:00 – 2023-08-23 20:00:00
39	ADY	integer	Analysis Relative Day	mean:204.66; sd:187.87; range:0-731
40	AVISIT	factor	Analysis Visit	END OF INDUCTION, BASELINE, SCREENING, FOLLOW UP
41	AVISITN	integer	Analysis Visit (N)	mean:467.67; sd:498.79; range:-1-999

Dataset: ex_adsl

Table 9: Summary of 'ex_adsl'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.44; range:20-69
6	SEX	factor	Sex	M, F, U, UNDIFFERENTIATED
7	RACE	factor	Race	ASIAN, BLACK OR AFRICAN AMERICAN, AMERICAN INDIAN OR ALASKA NATIVE, WHITE, MULTIPLE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
8	COUNTRY	factor	Country	CHN, RUS, USA, NGA, PAK, BRA, CAN, GBR, JPN
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	C, A, B
15	STRATA2	factor	Stratification Factor 2	S2, S1
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.45; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 9: Summary of 'ex_adsl'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	COMPLETED, DISCONTINUED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.52; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904

Table 9: 'ex_adsl' has 400 rows and 31 columns

Dataset: ex_adtte

Table 10: Summary of 'ex_adtte'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.43; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	BLACK OR AFRICAN AMERICAN, WHITE, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S1, S2
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.44; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 10: Summary of 'ex_adtte'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	DISCONTINUED, COMPLETED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.3; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Sequence Number	mean:2; sd:0.82; range:1-3
33	TTESEQ	integer	Sequence Number	mean:2; sd:0.82; range:1-3
34	PARAM	factor	Parameter	Event Free Survival, Overall Survival, Progression Free Survival
35	PARAMCD	factor	Parameter Code	EFS, OS, PFS

Table 10: Summary of 'ex_adtte'

Order	Variable	Type	Label	Summary
36	AVAL	numeric	Analysis Value	mean:90.12; sd:98.3; range:0.08-978.41
37	AVALU	factor	Analysis Value Unit	DAYS
38	ADTM	POSIXct, POSIXt	Analysis Datetime	2019-12-01 19:00:00 – 2023-08-17 20:00:00
39	ADY	integer	Analysis Relative Day	mean:321.16; sd:213.69; range:0-729
40	CNSR	integer	Censor	mean:0.26; sd:0.44; range:0-1
41	EVNTDESC	character	Event or Censoring Description	
42	CNSDTDSC	character	Censor Date Description	

Dataset: **ex_advs**

Table 11: Summary of 'ex_advs'

Order	Variable	Type	Label	Summary
1	STUDYID	character	Study Identifier	
2	USUBJID	character	Unique Subject Identifier	
3	SUBJID	character	Subject Identifier for the Study	
4	SITEID	character	Study Site Identifier	
5	AGE	integer	Age	mean:34.88; sd:7.43; range:20-69
6	SEX	factor	Sex	M, F, UNDIFFERENTIATED, U
7	RACE	factor	Race	BLACK OR AFRICAN AMERICAN, WHITE, ASIAN, AMERICAN INDIAN OR ALASKA NATIVE, NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, MULTIPLE
8	COUNTRY	factor	Country	BRA, CAN, CHN, GBR, JPN, NGA, PAK, RUS, USA
9	INVID	character	Investigator Identifier	
10	ARM	factor	Description of Planned Arm	A: Drug X, C: Combination, B: Placebo
11	ARMCD	factor	Planned Arm Code	ARM A, ARM C, ARM B
12	ACTARM	factor	Description of Actual Arm	A: Drug X, C: Combination, B: Placebo
13	ACTARMCD	factor	Actual Arm Code	ARM A, ARM C, ARM B
14	STRATA1	factor	Stratification Factor 1	B, A, C
15	STRATA2	factor	Stratification Factor 2	S1, S2
16	BMRKR1	numeric	Continous Level Biomarker 1	mean:5.76; sd:3.44; range:0.17-21.39
17	BMRKR2	factor	Categorical Level Biomarker 2	MEDIUM, LOW, HIGH
18	ITTFL	factor	Intent-To-Treat Population Flag	Y

Table 11: Summary of 'ex_advs'

Order	Variable	Type	Label	Summary
19	SAFFL	factor	Safety Population Flag	Y
20	BMEASIFL	factor	Response Evaluable Population Flag	Y, N
21	BEP01FL	factor	Biomarker Evaluable Population Flag	Y, N
22	RANDDT	Date	Date of Randomization	2019-09-28 – 2021-09-21
23	TRTSDTM	POSIXct, POSIXt	Datetime of First Exposure to Treatment	2019-09-30 16:45:38.956201 – 2021-09-23 20:18:47.956201
24	TRTEDTM	POSIXct, POSIXt	Datetime of Last Exposure to Treatment	2021-09-18 04:40:43.956201 – 2023-09-24 07:57:11.956201
25	EOSSTT	factor	End of Study Status	DISCONTINUED, COMPLETED, ONGOING
26	EOSDT	Date	End of Study Date	2021-09-18 – 2023-09-24
27	EOSDY	integer	End of Study Relative Day	mean:596.73; sd:216.2; range:6-731
28	DCSREAS	factor	Reason for Discontinuation from Study	
29	DTHDT	Date	Date of Death	2021-09-18 – 2023-09-24
30	LSTALVDT	Date	Date Last Known Alive	2021-09-29 – 2023-10-16
31	study_duration_secs	numeric	NOT A STANDARD BUT NEEDED FOR RCD	mean:63113904; sd:0; range:63113904-63113904
32	ASEQ	integer	Analysis Sequence Number	mean:21.5; sd:12.12; range:1-42
33	VSSEQ	integer	Sequence Number	mean:21.5; sd:12.12; range:1-42
34	VSTESTCD	factor	Lab Test or Examination Short Name	DIABP, PULSE, RESP, SYSBP, TEMP, WEIGHT

Table 11: Summary of 'ex_advs'

Order	Variable	Type	Label	Summary
35	VSTEST	factor	Lab Test or Examination Name	Diastolic Blood Pressure, Pulse Rate, Respiratory Rate, Systolic Blood Pressure, Temperature, Weight
36	VSCAT	factor	Category for Lab Test	VITAL SIGNS
37	VSSTRESC	numeric	Character Result/Finding	mean:49.93; sd:8.02; range:15.58-80.48
38	ASPID	integer	Analysis Sponsor Identifier	mean:8400.5; sd:4849.89; range:1-16800
39	PARAM	factor	Parameter	Diastolic Blood Pressure, Pulse Rate, Respiratory Rate, Systolic Blood Pressure, Temperature, Weight
40	PARAMCD	factor	Parameter Code	DIABP, PULSE, RESP, SYSBP, TEMP, WEIGHT
41	AVAL	numeric	Analysis Value	mean:49.93; sd:8.02; range:15.58-80.48
42	AVALU	factor	Analysis Value Unit	Pa, beats/min, breaths/min, C, Kg
43	BASE2	numeric	Screeening Value	mean:49.9; sd:8.29; range:23.97-80.48
44	BASE	numeric	Baseline Value	mean:50.09; sd:8.17; range:20.63-74.52
45	BASETYPE	factor	Baseline Type	LAST
46	ABLFL2	factor	Screening Record Flag	Y,
47	ABLFL	factor	Baseline Record Flag	, Y
48	CHG2	numeric	Absolute Change from Screening	mean:0.02; sd:10.61; range:-41.08-43.9
49	PCHG2	numeric	Percentage Change from Screening	mean:2.61; sd:23.23; range:-62.08-149.34
50	CHG	numeric	Absolute Change from Baseline	mean:-0.16; sd:10.38; range:-43.84-40.32
51	PCHG	numeric	Percentage Change from Baseline	mean:2.14; sd:22.94; range:-69.54-189.72
52	DTYPE	factor	Derivation Type	
53	ANRIND	factor	Analysis Reference Range Indicator	HIGH, NORMAL, LOW

Table 11: Summary of 'ex_advs'

Order	Variable	Type	Label	Summary
54	ADTM	POSIXct, POSIXt	Analysis Datetime	2019-09-29 20:00:00 – 2023-09-08 20:00:00
55	ADY	integer	Analysis Relative Day	mean:310.68; sd:215.46; range:0-731
56	ATPTN	integer	Analysis Timepoint (N)	mean:1; sd:0; range:1-1
57	AVISIT	factor	Analysis Visit	SCREENING, BASELINE, WEEK 1 DAY 8, WEEK 2 DAY 15, WEEK 3 DAY 22, WEEK 4 DAY 29, WEEK 5 DAY 36
58	AVISITN	integer	Analysis Visit (N)	mean:2; sd:2; range:-1-5
59	LOQFL	factor	Limit of Quantification Flag	N, Y