```
                          The COMPARE Procedure
                    Comparison of COMP.ADAE with COMPC.ADAE
                              (Method=EXACT)

                            Data Set Summary

      Dataset            Created         Modified  NVar   NObs

      COMP.ADAE    03MAR23:13:36:13  03MAR23:13:36:13   108     12
      COMPC.ADAE   03MAR23:13:36:12  03MAR23:13:36:12   103     12


                            Variables Summary

      Number of Variables in Common: 97.
      Number of Variables in COMP.ADAE but not in COMPC.ADAE: 11.
      Number of Variables in COMPC.ADAE but not in COMP.ADAE: 6.
      Number of Variables with Differing Attributes: 20.
```

```
         Listing of Variables in COMP.ADAE but not in COMPC.ADAE


             Variable  Type  Length  Label


             CQO3NAM   Char      35  Customized Query O3 Name
             AGEGR3    Char      25  Pooled Age Group 3
             AGEGR3N   Num        8  Pooled Age Group 3 (N)
             AGEGR4    Char       7  Pooled Age Group 4
             AGEGR4N   Num        8  Pooled Age Group 4 (N)
             AGEGR5    Char       4  Pooled Age Group 5
             AGEGR5N   Num        8  Pooled Age Group 5 (N)
             AGEGR6    Char       4  Pooled Age Group 6
             AGEGR6N   Num        8  Pooled Age Group 6 (N)
             AGEGR7    Char       7  Pooled Age Group 7
             AGEGR7N   Num        8  Pooled Age Group 7 (N)



         Listing of Variables in COMPC.ADAE but not in COMP.ADAE


             Variable  Type  Length  Label


             old_subj  Char      13  Unique Subject Identifier
             TRTP      Char      26  Planned Treatment
             TRTPN     Num        8  Planned Treatment (N)
             TRTA      Char      26  Actual Treatment
             TRTAN     Num        8  Actual Treatment (N)
             CQO1NAM   Char       1  Customized Query O1 Name



             Listing of Common Variables with Differing Attributes


Variable  Dataset      Type  Length  Label


usubjid   COMP.ADAE    Char      19
          COMPC.ADAE   Char      19  Unique Subject Identifier
AETERM    COMP.ADAE    Char      62  Reported Term for the Adverse Event
          COMPC.ADAE   Char     130  Reported Term for the Adverse Event
AEDECOD   COMP.ADAE    Char      47  Dictionary-Derived Term
          COMPC.ADAE   Char      61  Dictionary-Derived Term
AELLT     COMP.ADAE    Char      47  Lowest Level Term
          COMPC.ADAE   Char      61  Lowest Level Term
ADURC     COMP.ADAE    Char      11  Analysis Duration (C)
          COMPC.ADAE   Char      12  Analysis Duration (C)
ACOUNTRY  COMP.ADAE    Char      13  Analysis Country
          COMPC.ADAE   Char      18  Analysis Country
REGION1   COMP.ADAE    Char      13  Geographic Region 1
          COMPC.ADAE   Char      17  Geographic Region 1
AGEGR1    COMP.ADAE    Char       4  Pooled Age Group 1
          COMPC.ADAE   Char       7  Pooled Age Group 1
trt01p    COMP.ADAE    Char      26
          COMPC.ADAE   Char      26  Planned Treatment for Period 01
trt01a    COMP.ADAE    Char      26
          COMPC.ADAE   Char      26  Actual Treatment for Period 01
tr01pg1   COMP.ADAE    Char      10
          COMPC.ADAE   Char      10  Planned Pooled Treatment 1 for Period 01
tr01ag1   COMP.ADAE    Char      10
          COMPC.ADAE   Char      10  Actual Pooled Treatment 1 for Period 01
tr01pg2   COMP.ADAE    Char      21
          COMPC.ADAE   Char      21  Planned Pooled Treatment 2 for Period 01
```

```
tr01ag2   COMP.ADAE    Char    21
          COMPC.ADAE   Char    21   Actual Pooled Treatment 2 for Period 01
trt01pn   COMP.ADAE    Num      8
          COMPC.ADAE   Num      8   Planned Treatment for Period 01 (N)
trt01an   COMP.ADAE    Num      8
          COMPC.ADAE   Num      8   Actual Treatment for Period 01 (N)
tr01pg1n  COMP.ADAE    Num      8
          COMPC.ADAE   Num      8   Planned Pooled Trt 1 for Period 01 (N)
tr01pg2n  COMP.ADAE    Num      8
          COMPC.ADAE   Num      8   Planned Pooled Trt 2 for Period 01 (N)
tr01ag1n  COMP.ADAE    Num      8
          COMPC.ADAE   Num      8   Actual Pooled Trt 1 for Period 01 (N)
tr01ag2n  COMP.ADAE    Num      8
          COMPC.ADAE   Num      8   Actual Pooled Trt 2 for Period 01 (N)
```

```
                              Observation Summary

                    Observation      Base  Compare

                    First Obs           1        1
                    First Unequal       1        1
                    Last  Unequal      12       12
                    Last  Obs          12       12


         Number of Observations in Common: 12.
         Total Number of Observations Read from COMP.ADAE: 12.
         Total Number of Observations Read from COMPC.ADAE: 12.


         Number of Observations with Some Compared Variables Unequal: 12.
         Number of Observations with All Compared Variables Equal: 0.


                            Values Comparison Summary

         Number of Variables Compared with All Observations Equal: 42.
         Number of Variables Compared with Some Observations Unequal: 55.
         Number of Variables with Missing Value Differences: 13.
         Total Number of Values which Compare Unequal: 455.
         Maximum Difference: 1144800.


                          Variables with Unequal Values
```

Variable	Type	Len1	Len2	Label	Ndif	MaxDif	MissDif
usubjid	CHAR	19	19		8		0
AESEQ	NUM	8	8	Sequence Number	8	3.000	0
AETERM	CHAR	62	130	Reported Term for the Adverse Event	9		0
AEDECOD	CHAR	47	61	Dictionary-Derived Term	9		0
AEBODSYS	CHAR	67	67	Body System or Organ Class	7		0
AEBDSYCD	NUM	8	8	Body System or Organ Class Code	7	20791	0
AELLT	CHAR	47	61	Lowest Level Term	9		0
AELLTCD	NUM	8	8	Lowest Level Term Code	9	44683	0
AEPTCD	NUM	8	8	Preferred Term Code	9	36476	0
AEHLT	CHAR	79	79	High Level Term	9		0
AEHLTCD	NUM	8	8	High Level Term Code	9	57526	0
AEHLGT	CHAR	86	86	High Level Group Term	9		0
AEHLGTCD	NUM	8	8	High Level Group Term Code	9	51876	0
AESOC	CHAR	67	67	Primary System Organ Class	7		0
AESOCCD	NUM	8	8	Primary System Organ Class Code	7	20791	0
ASTDT	NUM	8	8	Analysis Start Date	9	13.000	0
ASTTM	NUM	8	8	Analysis Start Time	9	23820	6
ASTDTM	NUM	8	8	Analysis Start Date/Time	9	1144800	6
ASTDY	NUM	8	8	Analysis Start Relative Day	9	12.000	0
AENDT	NUM	8	8	Analysis End Date	9	12.000	0
AENTM	NUM	8	8	Analysis End Time	5	25980	4
AENDTM	NUM	8	8	Analysis End Date/Time	6	198780	4
AENDY	NUM	8	8	Analysis End Relative Day	9	13.000	0
ADURN	NUM	8	8	Analysis Duration (N)	7	101	0
ADURC	CHAR	11	12	Analysis Duration (C)	7		0
AEREFID	CHAR	5	5	Reference ID	8		0
AESTDTC	CHAR	16	16	Start Date/Time of Adverse Event	9		0
AEENDTC	CHAR	16	16	End Date/Time of Adverse Event	9		0
SUBJID	CHAR	8	8	Subject Identifier for the Study	8		0

```
AGE       NUM    8    8   Age                                        8   16.000    0
AAGE      NUM    8    8   Analysis Age                               8   16.000    0
AGEGR1    CHAR   4    7   Pooled Age Group 1                        12             0
SEX       CHAR   1    1   Sex                                        4             0
TRTSDT    NUM    8    8   Date of First Exposure to Treatment        7    3.000    0
TRTSTM    NUM    8    8   Time of First Exposure to Treatment        8   19440     0
TRTSDTM   NUM    8    8   Datetime of First Exposure to Treatment    8  239760     0
TRTEDT    NUM    8    8   Date of Last Exposure to Treatment         8    3.000    0
TRTETM    NUM    8    8   Time of Last Exposure to Treatment         8   82560     0
TRTEDTM   NUM    8    8   Datetime of Last Exposure to Treatment     8  239820     0
WEIGHTBL  NUM    8    8   Weight (kg) at Baseline                    8   41.100    0
HEIGHTBL  NUM    8    8   Height (cm) at Baseline                    8   20.000    0
BMIBL     NUM    8    8   BMI (kg/m^2) at Baseline                   8    8.257    0
trt01p    CHAR  26   26                                             12            12
trt01a    CHAR  26   26                                             12            12
tr01pg1   CHAR  10   10                                              4             0
tr01ag1   CHAR  10   10                                              4             0
tr01pg2   CHAR  21   21                                             12            12
tr01ag2   CHAR  21   21                                             12            12
trt01pn   NUM    8    8                                             12     0      12
trt01an   NUM    8    8                                             12     0      12
tr01pg1n  NUM    8    8                                              4   1.000     0
tr01pg2n  NUM    8    8                                             12     0      12
tr01ag1n  NUM    8    8                                              4   1.000     0
tr01ag2n  NUM    8    8                                             12     0      12
CQ02NAM   CHAR  53   53   Customized Query 02 Name                   2             2
```

**Compare of adae
from- STUDY1
to- ISS**

Value Comparison Results for Variables

```
        ||  Unique Subject Identifier
        ||  Base Value          Compare Value
    Obs ||  usubjid             usubjid
 _____||  _____    _____
        ||
      4 ||  10009               10005
      5 ||  10010               10005
      6 ||  10005               10006
      7 ||  10006               10009
      8 ||  10005               10009
      9 ||  10010               10009
     11 ||  10009               10010
     12 ||  10009               10010
```

```
        ||  Sequence Number
        ||     Base     Compare
    Obs ||    AESEQ       AESEQ      Diff.      % Diff
 _____||  _____    _____   _____    _____
        ||
      3 ||    3.0000      1.0000    -2.0000    -66.6667
      5 ||    1.0000      3.0000     2.0000    200.0000
      6 ||    2.0000      1.0000    -1.0000    -50.0000
      8 ||    1.0000      2.0000     1.0000    100.0000
      9 ||    2.0000      3.0000     1.0000     50.0000
     10 ||    1.0000      4.0000     3.0000    300.0000
     11 ||    3.0000      1.0000    -2.0000    -66.6667
     12 ||    4.0000      2.0000    -2.0000    -50.0000
```

```
        ||  Reported Term for the Adverse Event
        ||  Base Value          Compare Value
    Obs ||  AETERM              AETERM
 _____||  _____+  _____+
        ||
      3 ||  VOMITING            COUGHING
      4 ||  FEELING COLD        NAUSEA
      5 ||  FEELING COLD DURING VOMITING
      6 ||  NAUSEA              DIARRHEA
      8 ||  COUGHING            FEELING COLD
      9 ||  LACK OF APPETITE    NAUSEA
     10 ||  DIARRHEA            VOMITING
     11 ||  NAUSEA              FEELING COLD DURING
     12 ||  VOMITING            LACK OF APPETITE
```

```
        ||  Dictionary-Derived Term
        ||  Base Value          Compare Value
    Obs ||  AEDECOD             AEDECOD
 _____||  _____+  _____+
```

```
     ||
 3   ||  Vomiting              Cough
 4   ||  Feeling cold          Nausea
 5   ||  Infusion related rea  Vomiting
 6   ||  Nausea                Diarrhoea
 8   ||  Cough                 Feeling cold
 9   ||  Decreased appetite    Nausea
10   ||  Diarrhoea             Vomiting
11   ||  Nausea                Infusion related rea
12   ||  Vomiting              Decreased appetite
```

```
         ||  Body System or Organ Class
         ||  Base Value          Compare Value
  Obs    ||  AEBODSYS            AEBODSYS
_____  ||  _____ +   _____ +
         ||
 3       ||  Gastrointestinal dis  Respiratory, thoraci
 4       ||  General disorders an  Gastrointestinal dis
 5       ||  Injury, poisoning an  Gastrointestinal dis
 8       ||  Respiratory, thoraci  General disorders an
 9       ||  Metabolism and nutri  Gastrointestinal dis
11       ||  Gastrointestinal dis  Injury, poisoning an
12       ||  Gastrointestinal dis  Metabolism and nutri
```

```
         ||  Body System or Organ Class Code
         ||     Base      Compare
  Obs    ||   AEBDSYCD   AEBDSYCD      Diff.      % Diff
_____  ||   _____   _____   _____    _____
         ||
 3       ||   10017947   10038738      20791      0.2075
 4       ||   10018065   10017947   -118.0000   -0.001178
 5       ||   10022117   10017947      -4170     -0.0416
 8       ||   10038738   10018065     -20673     -0.2059
 9       ||   10027433   10017947      -9486     -0.0946
11       ||   10017947   10022117       4170      0.0416
12       ||   10017947   10027433       9486      0.0947
```

```
         ||  Lowest Level Term
         ||  Base Value          Compare Value
  Obs    ||  AELLT               AELLT
_____  ||  _____ +   _____ +
         ||
 3       ||  Vomiting             Cough
 4       ||  Feeling cold         Nausea
 5       ||  Infusion associated  Vomiting
 6       ||  Nausea               Diarrhea
 8       ||  Cough                Feeling cold
 9       ||  Appetite absent      Nausea
10       ||  Diarrhea             Vomiting
11       ||  Nausea               Infusion associated
12       ||  Vomiting             Appetite absent
```

```
              ||  Lowest Level Term Code
              ||     Base      Compare
      Obs     ||    AELLTCD    AELLTCD      Diff.      % Diff
   _____   ||   _____   _____    _____    _____
              ||
         3    ||   10047700   10011224      -36476     -0.3630
         4    ||   10016326   10028813       12487      0.1247
         5    ||   10059087   10047700      -11387     -0.1132
         6    ||   10028813   10012727      -16086     -0.1604
         8    ||   10011224   10016326        5102      0.0510
         9    ||   10003017   10028813       25796      0.2579
        10    ||   10012727   10047700       34973      0.3493
        11    ||   10028813   10059087       30274      0.3019
        12    ||   10047700   10003017      -44683     -0.4447
```

```
              ||  Preferred Term Code
              ||     Base      Compare
      Obs     ||    AEPTCD     AEPTCD       Diff.      % Diff
   _____   ||   _____   _____    _____    _____
              ||
         3    ||   10047700   10011224      -36476     -0.3630
         4    ||   10016326   10028813       12487      0.1247
         5    ||   10051792   10047700       -4092     -0.0407
         6    ||   10028813   10012735      -16078     -0.1603
         8    ||   10011224   10016326        5102      0.0510
         9    ||   10061428   10028813      -32615     -0.3242
        10    ||   10012735   10047700       34965      0.3492
        11    ||   10028813   10051792       22979      0.2291
        12    ||   10047700   10061428       13728      0.1366
```

```
              ||  High Level Term
              ||  Base Value           Compare Value
      Obs     ||  AEHLT                AEHLT
   _____   ||  _____+   _____+
              ||
         3    ||  Nausea and vomiting  Coughing and associa
         4    ||  Feelings and sensati Nausea and vomiting
         5    ||  Non-site specific pr Nausea and vomiting
         6    ||  Nausea and vomiting  Diarrhoea (excl infe
         8    ||  Coughing and associa Feelings and sensati
         9    ||  Appetite disorders   Nausea and vomiting
        10    ||  Diarrhoea (excl infe Nausea and vomiting
        11    ||  Nausea and vomiting  Non-site specific pr
        12    ||  Nausea and vomiting  Appetite disorders
```

```
              ||  High Level Term Code
              ||     Base      Compare
      Obs     ||    AEHLTCD    AEHLTCD      Diff.      % Diff
   _____   ||   _____   _____    _____    _____
              ||
```

```
      ||
  3   ||    10028817    10011233      -17584      -0.1753
  4   ||    10068759    10028817      -39942      -0.3967
  5   ||    10029559    10028817    -742.0000   -0.007398
  6   ||    10028817    10012736      -16081      -0.1603
  8   ||    10011233    10068759       57526       0.5746
  9   ||    10003022    10028817       25795       0.2579
 10   ||    10012736    10028817       16081       0.1606
 11   ||    10028817    10029559     742.0000     0.007399
 12   ||    10028817    10003022      -25795      -0.2572
```

Obs		High Level Group Term	
		Base Value AEHLGT	Compare Value AEHLGT
3	||	Gastrointestinal sig	Respiratory disorder
4	||	General system disor	Gastrointestinal sig
5	||	Procedural related i	Gastrointestinal sig
6	||	Gastrointestinal sig	Gastrointestinal mot
8	||	Respiratory disorder	General system disor
9	||	Appetite and general	Gastrointestinal sig
10	||	Gastrointestinal mot	Gastrointestinal sig
11	||	Gastrointestinal sig	Procedural related i
12	||	Gastrointestinal sig	Appetite and general

Obs		High Level Group Term Code			
		Base AEHLGTCD	Compare AEHLGTCD	Diff.	% Diff
3	||	10018012	10038716	20704	0.2067
4	||	10018073	10018012	-61.0000	-0.000609
5	||	10069888	10018012	-51876	-0.5152
6	||	10018012	10017977	-35.0000	-0.000349
8	||	10038716	10018073	-20643	-0.2056
9	||	10003018	10018012	14994	0.1499
10	||	10017977	10018012	35.0000	0.000349
11	||	10018012	10069888	51876	0.5178
12	||	10018012	10003018	-14994	-0.1497

Obs		Primary System Organ Class	
		Base Value AESOC	Compare Value AESOC
3	||	Gastrointestinal dis	Respiratory, thoraci
4	||	General disorders an	Gastrointestinal dis
5	||	Injury, poisoning an	Gastrointestinal dis
8	||	Respiratory, thoraci	General disorders an
9	||	Metabolism and nutri	Gastrointestinal dis
11	||	Gastrointestinal dis	Injury, poisoning an

```
         12  ||  Gastrointestinal dis  Metabolism and nutri
_____


_____
             ||  Primary System Organ Class Code
             ||     Base      Compare
         Obs ||    AESOCCD     AESOCCD      Diff.      % Diff
   _____  ||  _____   _____   _____   _____
             ||
          3  ||   10017947    10038738       20791      0.2075
          4  ||   10018065    10017947   -118.0000   -0.001178
          5  ||   10022117    10017947       -4170     -0.0416
          8  ||   10038738    10018065      -20673     -0.2059
          9  ||   10027433    10017947       -9486     -0.0946
         11  ||   10017947    10022117        4170      0.0416
         12  ||   10017947    10027433        9486      0.0947

_____


_____
             ||  Analysis Start Date
             ||     Base      Compare
         Obs ||     ASTDT       ASTDT       Diff.      % Diff
   _____  ||  _____   _____   _____   _____
             ||
          3  ||  01SEP2020   03SEP2020      2.0000    0.009026
          4  ||  02SEP2020   03SEP2020      1.0000    0.004513
          5  ||  03SEP2020   01SEP2020     -2.0000   -0.009025
          6  ||  03SEP2020   01SEP2020     -2.0000   -0.009025
          7  ||  01SEP2020   14SEP2020     13.0000      0.0587
          8  ||  03SEP2020   02SEP2020     -1.0000   -0.004512
          9  ||  03SEP2020   14SEP2020     11.0000      0.0496
         11  ||  14SEP2020   03SEP2020    -11.0000     -0.0496
         12  ||  14SEP2020   03SEP2020    -11.0000     -0.0496

_____


_____
             ||  Analysis Start Time
             ||     Base      Compare
         Obs ||     ASTTM       ASTTM       Diff.      % Diff
   _____  ||  _____   _____   _____   _____
             ||
          3  ||   10:15:00           .           .           .
          4  ||   18:48:00           .           .           .
          5  ||   16:52:00    10:15:00      -23820    -39.2292
          6  ||          .     6:00:00           .           .
          7  ||    6:00:00    12:00:00       21600    100.0000
          8  ||          .    18:48:00           .           .
          9  ||          .    12:00:00           .           .
         11  ||   12:00:00    16:52:00       17520     40.5556
         12  ||   12:00:00           .           .           .

_____


_____
             ||  Analysis Start Date/Time
             ||     Base      Compare
         Obs ||    ASTDTM      ASTDTM       Diff.      % Diff
   _____  ||  _____   _____   _____   _____
             ||
```

```
          ||
  3   ||   01SEP2020              .              .              .
  4   ||   02SEP2020              .              .              .
  5   ||   03SEP2020  01SEP2020        -196620        -0.0103
  6   ||        .      01SEP2020              .              .
  7   ||   01SEP2020  14SEP2020        1144800         0.0598
  8   ||        .      02SEP2020              .              .
  9   ||        .      14SEP2020              .              .
 11   ||   14SEP2020  03SEP2020        -932880        -0.0487
 12   ||   14SEP2020              .              .              .
```

Obs		Analysis Start Relative Day			
		Base ASTDY	Compare ASTDY	Diff.	% Diff
3	||	2.0000	4.0000	2.0000	100.0000
4	||	1.0000	4.0000	3.0000	300.0000
5	||	1.0000	2.0000	1.0000	100.0000
6	||	4.0000	2.0000	-2.0000	-50.0000
7	||	2.0000	13.0000	11.0000	550.0000
8	||	4.0000	1.0000	-3.0000	-75.0000
9	||	1.0000	13.0000	12.0000	1200
11	||	13.0000	1.0000	-12.0000	-92.3077
12	||	13.0000	1.0000	-12.0000	-92.3077

Obs		Analysis End Date			
		Base AENDT	Compare AENDT	Diff.	% Diff
3	||	01SEP2020	04SEP2020	3.0000	0.0135
4	||	02SEP2020	03SEP2020	1.0000	0.004513
5	||	03SEP2020	01SEP2020	-2.0000	-0.009025
6	||	03SEP2020	04SEP2020	1.0000	0.004512
7	||	04SEP2020	15SEP2020	11.0000	0.0496
8	||	04SEP2020	02SEP2020	-2.0000	-0.009024
9	||	04SEP2020	15SEP2020	11.0000	0.0496
11	||	15SEP2020	03SEP2020	-12.0000	-0.0541
12	||	15SEP2020	04SEP2020	-11.0000	-0.0496

Obs		Analysis End Time			
		Base AENTM	Compare AENTM	Diff.	% Diff
3	||	10:40:00	.	.	.
5	||	17:53:00	10:40:00	-25980	-40.3541
6	||	20:30:00	.	.	.
8	||	.	20:30:00	.	.
11	||	.	17:53:00	.	.

```
        ||  Analysis End Date/Time
        ||     Base      Compare
   Obs  ||    AENDTM      AENDTM      Diff.     % Diff
_____ ||  _____    _____    _____   _____
        ||
     3  ||  01SEP2020         .           .          .
     4  ||  02SEP2020   03SEP2020       86400   0.004512
     5  ||  03SEP2020   01SEP2020     -198780    -0.0104
     6  ||  03SEP2020         .           .          .
     8  ||        .     02SEP2020         .          .
    11  ||        .     03SEP2020         .          .
```

```
        ||  Analysis End Relative Day
        ||     Base      Compare
   Obs  ||    AENDY       AENDY       Diff.     % Diff
_____ ||  _____    _____    _____   _____
        ||
     3  ||    2.0000      5.0000      3.0000   150.0000
     4  ||    1.0000      4.0000      3.0000   300.0000
     5  ||    1.0000      2.0000      1.0000   100.0000
     6  ||    4.0000      5.0000      1.0000    25.0000
     7  ||    5.0000     14.0000      9.0000   180.0000
     8  ||    5.0000      1.0000     -4.0000   -80.0000
     9  ||    2.0000     14.0000     12.0000   600.0000
    11  ||   14.0000      1.0000    -13.0000   -92.8571
    12  ||   14.0000      2.0000    -12.0000   -85.7143
```

```
        ||  Analysis Duration (N)
        ||     Base      Compare
   Obs  ||    ADURN       ADURN       Diff.     % Diff
_____ ||  _____    _____    _____   _____
        ||
     3  ||   25.0000      2.0000    -23.0000   -92.0000
     4  ||  102.0000      1.0000   -101.0000   -99.0196
     5  ||   61.0000     25.0000    -36.0000   -59.0164
     6  ||    1.0000      4.0000      3.0000   300.0000
     7  ||    4.0000      2.0000     -2.0000   -50.0000
     8  ||    2.0000    102.0000    100.0000       5000
    11  ||    2.0000     61.0000     59.0000       2950
```

```
        ||  Analysis Duration (C)
        ||  Base Value        Compare Value
   Obs  ||  ADURC             ADURC
_____ ||  _____        _____
        ||
     3  ||  0d 0h 25m         2d
     4  ||  0d 1h 42m         1d
     5  ||  0d 1h 1m          0d 0h 25m
     6  ||  1d                4d
```

```
  7  ||  4d                  2d
  8  ||  2d                  0d 1h 42m
 11  ||  2d                  0d 1h 1m
```
───


```
        ||  Reference ID
        ||  Base Value          Compare Value
   Obs  ||  AEREFID              AEREFID
 ───────||  ─────                ─────
        ||
    3   ||  10001                10003
    4   ||  10001                10002
    6   ||  10002                10001
    7   ||  10001                10004
    8   ||  10003                10001
   10   ||  10004                10003
   11   ||  10002                10001
   12   ||  10003                10002
```
───


```
        ||  Start Date/Time of Adverse Event
        ||  Base Value           Compare Value
   Obs  ||  AESTDTC              AESTDTC
 ───────||  ──────────────       ──────────────
        ||
    3   ||  2020-09-01T10:15     2020-09-03
    4   ||  2020-09-02T18:48     2020-09-03
    5   ||  2020-09-03T16:52     2020-09-01T10:15
    6   ||  2020-09-03           2020-09-01T06:00
    7   ||  2020-09-01T06:00     2020-09-14T12:00
    8   ||  2020-09-03           2020-09-02T18:48
    9   ||  2020-09-03           2020-09-14T12:00
   11   ||  2020-09-14T12:00     2020-09-03T16:52
   12   ||  2020-09-14T12:00     2020-09-03
```
───


```
        ||  End Date/Time of Adverse Event
        ||  Base Value           Compare Value
   Obs  ||  AEENDTC              AEENDTC
 ───────||  ──────────────       ──────────────
        ||
    3   ||  2020-09-01T10:40     2020-09-04
    4   ||  2020-09-02T20:30     2020-09-03T20:30
    5   ||  2020-09-03T17:53     2020-09-01T10:40
    6   ||  2020-09-03T20:30     2020-09-04
    7   ||  2020-09-04           2020-09-15
    8   ||  2020-09-04           2020-09-02T20:30
    9   ||  2020-09-04           2020-09-15
   11   ||  2020-09-15           2020-09-03T17:53
   12   ||  2020-09-15           2020-09-04
```
───


```
        ||  Subject Identifier for the Study
```

Compare of adae
from- STUDY1
to- ISS

Obs			Base Value SUBJID	Compare Value SUBJID
4	||		10009	10005
5	||		10010	10005
6	||		10005	10006
7	||		10006	10009
8	||		10005	10009
9	||		10010	10009
11	||		10009	10010
12	||		10009	10010

Obs		Age Base AGE	Compare AGE	Diff.	% Diff
4	||	45.0000	29.0000	-16.0000	-35.5556
5	||	42.0000	29.0000	-13.0000	-30.9524
6	||	29.0000	34.0000	5.0000	17.2414
7	||	34.0000	45.0000	11.0000	32.3529
8	||	29.0000	45.0000	16.0000	55.1724
9	||	42.0000	45.0000	3.0000	7.1429
11	||	45.0000	42.0000	-3.0000	-6.6667
12	||	45.0000	42.0000	-3.0000	-6.6667

Obs		Analysis Age Base AAGE	Compare AAGE	Diff.	% Diff
4	||	45.0000	29.0000	-16.0000	-35.5556
5	||	42.0000	29.0000	-13.0000	-30.9524
6	||	29.0000	34.0000	5.0000	17.2414
7	||	34.0000	45.0000	11.0000	32.3529
8	||	29.0000	45.0000	16.0000	55.1724
9	||	42.0000	45.0000	3.0000	7.1429
11	||	45.0000	42.0000	-3.0000	-6.6667
12	||	45.0000	42.0000	-3.0000	-6.6667

Obs		Pooled Age Group 1 Base Value AGEGR1	Compare Value AGEGR1
1	||	<=70	<55
2	||	<=70	<55
3	||	<=70	<55
4	||	<=70	<55
5	||	<=70	<55
6	||	<=70	<55

Compare of adae
from- STUDY1
to- ISS

```
 7  ||  <=70                 <55
 8  ||  <=70                 <55
 9  ||  <=70                 <55
10  ||  <=70                 <55
11  ||  <=70                 <55
12  ||  <=70                 <55
```

```
        ||  Sex
        ||  Base Value         Compare Value
   Obs  ||  SEX                 SEX
 _____ ||  _                   _
        ||
    4   ||  F                   M
    5   ||  F                   M
    6   ||  M                   F
    8   ||  M                   F
```

```
        ||  Date of First Exposure to Treatment
        ||      Base     Compare
   Obs  ||     TRTSDT     TRTSDT     Diff.      % Diff
 _____ ||  _____   _____   _____   _____
        ||
    4   ||  02SEP2020  31AUG2020   -2.0000   -0.009025
    5   ||  03SEP2020  31AUG2020   -3.0000    -0.0135
    7   ||  31AUG2020  02SEP2020    2.0000    0.009026
    8   ||  31AUG2020  02SEP2020    2.0000    0.009026
    9   ||  03SEP2020  02SEP2020   -1.0000   -0.004512
   11   ||  02SEP2020  03SEP2020    1.0000    0.004513
   12   ||  02SEP2020  03SEP2020    1.0000    0.004513
```

```
        ||  Time of First Exposure to Treatment
        ||      Base     Compare
   Obs  ||     TRTSTM     TRTSTM     Diff.      % Diff
 _____ ||  _____   _____   _____   _____
        ||
    4   ||  18:28:00   22:16:00     13680    20.5776
    5   ||  16:52:00   22:16:00     19440    32.0158
    6   ||  22:16:00   23:20:00      3840     4.7904
    7   ||  23:20:00   18:28:00    -17520   -20.8571
    8   ||  22:16:00   18:28:00    -13680   -17.0659
    9   ||  16:52:00   18:28:00      5760     9.4862
   11   ||  18:28:00   16:52:00     -5760    -8.6643
   12   ||  18:28:00   16:52:00     -5760    -8.6643
```

```
        ||  Datetime of First Exposure to Treatment
        ||      Base     Compare
   Obs  ||     TRTSDTM    TRTSDTM    Diff.      % Diff
 _____ ||  _____   _____   _____   _____
        ||
```

```
 4  ||  02SEP2020  31AUG2020   -159120  -0.008310
 5  ||  03SEP2020  31AUG2020   -239760    -0.0125
 6  ||  31AUG2020  31AUG2020      3840   0.000201
 7  ||  31AUG2020  02SEP2020    155280   0.008111
 8  ||  31AUG2020  02SEP2020    159120   0.008311
 9  ||  03SEP2020  02SEP2020    -80640  -0.004211
11  ||  02SEP2020  03SEP2020     80640   0.004212
12  ||  02SEP2020  03SEP2020     80640   0.004212
```

```
        ||  Date of Last Exposure to Treatment
        ||     Base      Compare
    Obs ||    TRTEDT     TRTEDT     Diff.      % Diff
 _____  ||  _____  _____  _____  _____
        ||
     4  ||  02SEP2020  31AUG2020   -2.0000  -0.009025
     5  ||  03SEP2020  31AUG2020   -3.0000    -0.0135
     6  ||  31AUG2020  01SEP2020    1.0000   0.004513
     7  ||  01SEP2020  02SEP2020    1.0000   0.004513
     8  ||  31AUG2020  02SEP2020    2.0000   0.009026
     9  ||  03SEP2020  02SEP2020   -1.0000  -0.004512
    11  ||  02SEP2020  03SEP2020    1.0000   0.004513
    12  ||  02SEP2020  03SEP2020    1.0000   0.004513
```

```
        ||  Time of Last Exposure to Treatment
        ||     Base      Compare
    Obs ||    TRTETM     TRTETM     Diff.      % Diff
 _____  ||  _____  _____  _____  _____
        ||
     4  ||  19:28:00  23:16:00    13680    19.5205
     5  ||  17:53:00  23:16:00    19380    30.1025
     6  ||  23:16:00   0:20:00   -82560   -98.5673
     7  ||   0:20:00  19:28:00    68880       5740
     8  ||  23:16:00  19:28:00   -13680   -16.3324
     9  ||  17:53:00  19:28:00     5700     8.8537
    11  ||  19:28:00  17:53:00    -5700    -8.1336
    12  ||  19:28:00  17:53:00    -5700    -8.1336
```

```
        ||  Datetime of Last Exposure to Treatment
        ||     Base      Compare
    Obs ||   TRTEDTM    TRTEDTM     Diff.      % Diff
 _____  ||  _____  _____  _____  _____
        ||
     4  ||  02SEP2020  31AUG2020   -159120  -0.008310
     5  ||  03SEP2020  31AUG2020   -239820    -0.0125
     6  ||  31AUG2020  01SEP2020      3840   0.000201
     7  ||  01SEP2020  02SEP2020    155280   0.008111
     8  ||  31AUG2020  02SEP2020    159120   0.008311
     9  ||  03SEP2020  02SEP2020    -80700  -0.004215
    11  ||  02SEP2020  03SEP2020     80700   0.004215
    12  ||  02SEP2020  03SEP2020     80700   0.004215
```

Obs	Weight (kg) at Baseline Base WEIGHTBL	Compare WEIGHTBL	Diff.	% Diff
4	56.2000	97.3000	41.1000	73.1317
5	68.9000	97.3000	28.4000	41.2192
6	97.3000	71.2000	-26.1000	-26.8243
7	71.2000	56.2000	-15.0000	-21.0674
8	97.3000	56.2000	-41.1000	-42.2405
9	68.9000	56.2000	-12.7000	-18.4325
11	56.2000	68.9000	12.7000	22.5979
12	56.2000	68.9000	12.7000	22.5979

Obs	Height (cm) at Baseline Base HEIGHTBL	Compare HEIGHTBL	Diff.	% Diff
4	157.0000	177.0000	20.0000	12.7389
5	168.0000	177.0000	9.0000	5.3571
6	177.0000	162.0000	-15.0000	-8.4746
7	162.0000	157.0000	-5.0000	-3.0864
8	177.0000	157.0000	-20.0000	-11.2994
9	168.0000	157.0000	-11.0000	-6.5476
11	157.0000	168.0000	11.0000	7.0064
12	157.0000	168.0000	11.0000	7.0064

Obs	BMI (kg/m^2) at Baseline Base BMIBL	Compare BMIBL	Diff.	% Diff
4	22.8001	31.0575	8.2574	36.2164
5	24.4118	31.0575	6.6456	27.2230
6	31.0575	27.1300	-3.9275	-12.6458
7	27.1300	22.8001	-4.3299	-15.9598
8	31.0575	22.8001	-8.2574	-26.5874
9	24.4118	22.8001	-1.6117	-6.6023
11	22.8001	24.4118	1.6117	7.0690
12	22.8001	24.4118	1.6117	7.0690

Obs	Planned Treatment for Period 01 Base Value trt01p	Compare Value TRT01P
1		Study Drug Dose 1
2		Study Drug Dose 1
3		Placebo

```
   4  ||                        Placebo
   5  ||                        Placebo
   6  ||                        Placebo
   7  ||                        Study Drug Dose 1
   8  ||                        Study Drug Dose 1
   9  ||                        Study Drug Dose 1
  10  ||                        Study Drug Dose 1
  11  ||                        Study Drug Dose 1
  12  ||                        Study Drug Dose 1
 _____

 _____
        ||  Actual Treatment for Period 01
        ||  Base Value          Compare Value
  Obs   ||  trt01a              TRT01A
 _____ || _____+ _____+
        ||
    1   ||                        Study Drug Dose 1
    2   ||                        Study Drug Dose 1
    3   ||                        Placebo
    4   ||                        Placebo
    5   ||                        Placebo
    6   ||                        Placebo
    7   ||                        Study Drug Dose 1
    8   ||                        Study Drug Dose 1
    9   ||                        Study Drug Dose 1
   10   ||                        Study Drug Dose 1
   11   ||                        Study Drug Dose 1
   12   ||                        Study Drug Dose 1
 _____

 _____
        ||  Planned Pooled Treatment 1 for Period 01
        ||  Base Value          Compare Value
  Obs   ||  tr01pg1             TR01PG1
 _____ || _____           _____
        ||
    3   ||  Study Drug          Placebo
    4   ||  Study Drug          Placebo
    5   ||  Study Drug          Placebo
    6   ||  Study Drug          Placebo
 _____

 _____
        ||  Actual Pooled Treatment 1 for Period 01
        ||  Base Value          Compare Value
  Obs   ||  tr01ag1             TR01AG1
 _____ || _____           _____
        ||
    3   ||  Study Drug          Placebo
    4   ||  Study Drug          Placebo
    5   ||  Study Drug          Placebo
    6   ||  Study Drug          Placebo
 _____

 _____
        ||  Planned Pooled Treatment 2 for Period 01
```

Compare of adae
from- STUDY1
to- ISS

```
          ||  Base Value          Compare Value
     Obs  ||  tr01pg2              TR01PG2
 _____ ||  _____+   _____+
          ||
       1  ||                       Study Drug Dose 1 &
       2  ||                       Study Drug Dose 1 &
       3  ||                       Placebo
       4  ||                       Placebo
       5  ||                       Placebo
       6  ||                       Placebo
       7  ||                       Study Drug Dose 1 &
       8  ||                       Study Drug Dose 1 &
       9  ||                       Study Drug Dose 1 &
      10  ||                       Study Drug Dose 1 &
      11  ||                       Study Drug Dose 1 &
      12  ||                       Study Drug Dose 1 &
 _____
```

```
          ||  Actual Pooled Treatment 2 for Period 01
          ||  Base Value          Compare Value
     Obs  ||  tr01ag2              TR01AG2
 _____ ||  _____+   _____+
          ||
       1  ||                       Study Drug Dose 1 &
       2  ||                       Study Drug Dose 1 &
       3  ||                       Placebo
       4  ||                       Placebo
       5  ||                       Placebo
       6  ||                       Placebo
       7  ||                       Study Drug Dose 1 &
       8  ||                       Study Drug Dose 1 &
       9  ||                       Study Drug Dose 1 &
      10  ||                       Study Drug Dose 1 &
      11  ||                       Study Drug Dose 1 &
      12  ||                       Study Drug Dose 1 &
 _____
```

```
          ||  Planned Treatment for Period 01 (N)
          ||     Base    Compare
     Obs  ||    trt01pn   TRT01PN      Diff.      % Diff
 _____ ||  _____  _____   _____   _____
          ||
       1  ||       .     2.0000        .          .
       2  ||       .     2.0000        .          .
       3  ||       .     1.0000        .          .
       4  ||       .     1.0000        .          .
       5  ||       .     1.0000        .          .
       6  ||       .     1.0000        .          .
       7  ||       .     2.0000        .          .
       8  ||       .     2.0000        .          .
       9  ||       .     2.0000        .          .
      10  ||       .     2.0000        .          .
      11  ||       .     2.0000        .          .
      12  ||       .     2.0000        .          .
 _____
```

Compare of adae
from- STUDY1
to- ISS

Obs ||	Actual Treatment for Period 01 (N)		
	|| Base trt01an	Compare TRT01AN	Diff.	% Diff
1 ||	.	2.0000	.	.
2 ||	.	2.0000	.	.
3 ||	.	1.0000	.	.
4 ||	.	1.0000	.	.
5 ||	.	1.0000	.	.
6 ||	.	1.0000	.	.
7 ||	.	2.0000	.	.
8 ||	.	2.0000	.	.
9 ||	.	2.0000	.	.
10 ||	.	2.0000	.	.
11 ||	.	2.0000	.	.
12 ||	.	2.0000	.	.

Obs ||	Planned Pooled Trt 1 for Period 01 (N)		
	|| Base tr01pg1n	Compare TR01PG1N	Diff.	% Diff
3 ||	2.0000	1.0000	-1.0000	-50.0000
4 ||	2.0000	1.0000	-1.0000	-50.0000
5 ||	2.0000	1.0000	-1.0000	-50.0000
6 ||	2.0000	1.0000	-1.0000	-50.0000

Obs ||	Planned Pooled Trt 2 for Period 01 (N)		
	|| Base tr01pg2n	Compare TR01PG2N	Diff.	% Diff
1 ||	.	2.0000	.	.
2 ||	.	2.0000	.	.
3 ||	.	1.0000	.	.
4 ||	.	1.0000	.	.
5 ||	.	1.0000	.	.
6 ||	.	1.0000	.	.
7 ||	.	2.0000	.	.
8 ||	.	2.0000	.	.
9 ||	.	2.0000	.	.
10 ||	.	2.0000	.	.
11 ||	.	2.0000	.	.
12 ||	.	2.0000	.	.

Obs ||	Actual Pooled Trt 1 for Period 01 (N)		
	|| Base tr01ag1n	Compare TR01AG1N	Diff.	% Diff

```
        3  ||    2.0000    1.0000   -1.0000   -50.0000
        4  ||    2.0000    1.0000   -1.0000   -50.0000
        5  ||    2.0000    1.0000   -1.0000   -50.0000
        6  ||    2.0000    1.0000   -1.0000   -50.0000
```

```
            ||  Actual Pooled Trt 2 for Period 01 (N)
            ||     Base     Compare
       Obs  ||   tr01ag2n   TR01AG2N     Diff.      % Diff
_____     ||   _____   _____   _____   _____
            ||
        1   ||       .        2.0000       .          .
        2   ||       .        2.0000       .          .
        3   ||       .        1.0000       .          .
        4   ||       .        1.0000       .          .
        5   ||       .        1.0000       .          .
        6   ||       .        1.0000       .          .
        7   ||       .        2.0000       .          .
        8   ||       .        2.0000       .          .
        9   ||       .        2.0000       .          .
       10   ||       .        2.0000       .          .
       11   ||       .        2.0000       .          .
       12   ||       .        2.0000       .          .
```

```
            ||  Customized Query 02 Name
            ||  Base Value            Compare Value
       Obs  ||  CQ02NAM               CQ02NAM
_____     ||  _____+     _____+
            ||
        5   ||  Infusion-related rea
       11   ||                        Infusion-related rea
```

```
                          The COMPARE Procedure
                    Comparison of COMP.ADAE with COMPC.ADAE
                              (Method=EXACT)


                             Data Set Summary

      Dataset            Created         Modified   NVar    NObs

      COMP.ADAE    03MAR23:13:36:13  03MAR23:13:36:13   107       1
      COMPC.ADAE   03MAR23:13:36:13  03MAR23:13:36:13   103       1



                             Variables Summary

      Number of Variables in Common: 94.
      Number of Variables in COMP.ADAE but not in COMPC.ADAE: 13.
      Number of Variables in COMPC.ADAE but not in COMP.ADAE: 9.
      Number of Variables with Differing Attributes: 23.
```

```
                  Listing of Variables in COMP.ADAE but not in COMPC.ADAE


            Variable   Type   Length   Label

            CQO3NAM    Char        1   Customized Query O3 Name
            CQO4NAM    Char       16   Customized Query O4 Name
            CQO5NAM    Char        1   Customized Query O5 Name
            AGEGR3     Char       25   Pooled Age Group 3
            AGEGR3N    Num         8   Pooled Age Group 3 (N)
            AGEGR4     Char        4   Pooled Age Group 4
            AGEGR4N    Num         8   Pooled Age Group 4 (N)
            AGEGR5     Char        4   Pooled Age Group 5
            AGEGR5N    Num         8   Pooled Age Group 5 (N)
            AGEGR6     Char        5   Pooled Age Group 6
            AGEGR6N    Num         8   Pooled Age Group 6 (N)
            TRTDISFL   Char        1   Study Treatment Discontinuation Flag
            TRTMISFL   Char        1   Study Treatment Misallocation Flag


                  Listing of Variables in COMPC.ADAE but not in COMP.ADAE


            Variable   Type   Length   Label

            old_subj   Char       13   Unique Subject Identifier
            TRTP       Char       26   Planned Treatment
            TRTPN      Num         8   Planned Treatment (N)
            TRTA       Char       26   Actual Treatment
            TRTAN      Num         8   Actual Treatment (N)
            AEACNOTH   Char       20   Other Action Taken
            AEREFID    Char        5   Reference ID
            AESRECHA   Char        2   Event(s) Recur After Rechallenge
            AEDLT      Char        1   Is This Event a Dose Limiting Toxicity


                  Listing of Common Variables with Differing Attributes

Variable   Dataset        Type   Length   Label

usubjid    COMP.ADAE      Char       19
           COMPC.ADAE     Char       19   Unique Subject Identifier
AEDECOD    COMP.ADAE      Char       47   Dictionary-Derived Term
           COMPC.ADAE     Char       61   Dictionary-Derived Term
AELLT      COMP.ADAE      Char       47   Lowest Level Term
           COMPC.ADAE     Char       61   Lowest Level Term
AEHLT      COMP.ADAE      Char       60   High Level Term
           COMPC.ADAE     Char       79   High Level Term
AEHLGT     COMP.ADAE      Char       55   High Level Group Term
           COMPC.ADAE     Char       86   High Level Group Term
ADURC      COMP.ADAE      Char       11   Analysis Duration (C)
           COMPC.ADAE     Char       12   Analysis Duration (C)
AEOUT      COMP.ADAE      Char       26   Outcome of Adverse Event
           COMPC.ADAE     Char       32   Outcome of Adverse Event
CQO2NAM    COMP.ADAE      Char       63   Customized Query O2 Name
           COMPC.ADAE     Char       53   Customized Query O2 Name
ACOUNTRY   COMP.ADAE      Char       13   Analysis Country
           COMPC.ADAE     Char       18   Analysis Country
REGION1    COMP.ADAE      Char       13   Geographic Region 1
           COMPC.ADAE     Char       17   Geographic Region 1
AGEGR1     COMP.ADAE      Char        5   Pooled Age Group 1
```

```
           COMPC.ADAE  Char      7  Pooled Age Group 1
trt01p     COMP.ADAE   Char     26
           COMPC.ADAE  Char     26  Planned Treatment for Period 01
trt01a     COMP.ADAE   Char     26
           COMPC.ADAE  Char     26  Actual Treatment for Period 01
tr01pg1    COMP.ADAE   Char     10
           COMPC.ADAE  Char     10  Planned Pooled Treatment 1 for Period 01
tr01ag1    COMP.ADAE   Char     10
           COMPC.ADAE  Char     10  Actual Pooled Treatment 1 for Period 01
tr01pg2    COMP.ADAE   Char     21
           COMPC.ADAE  Char     21  Planned Pooled Treatment 2 for Period 01
tr01ag2    COMP.ADAE   Char     21
           COMPC.ADAE  Char     21  Actual Pooled Treatment 2 for Period 01
trt01pn    COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Planned Treatment for Period 01 (N)
trt01an    COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Actual Treatment for Period 01 (N)
tr01pg1n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Planned Pooled Trt 1 for Period 01 (N)
tr01pg2n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Planned Pooled Trt 2 for Period 01 (N)
tr01ag1n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Actual Pooled Trt 1 for Period 01 (N)
tr01ag2n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Actual Pooled Trt 2 for Period 01 (N)
```

```
                          Observation Summary

                    Observation      Base  Compare

                    First Obs           1        1
                    First Unequal       1        1
                    Last  Unequal       1        1
                    Last  Obs           1        1


         Number of Observations in Common: 1.
         Total Number of Observations Read from COMP.ADAE: 1.
         Total Number of Observations Read from COMPC.ADAE: 1.


         Number of Observations with Some Compared Variables Unequal: 1.
         Number of Observations with All Compared Variables Equal: 0.


                         Values Comparison Summary

         Number of Variables Compared with All Observations Equal: 83.
         Number of Variables Compared with Some Observations Unequal: 11.
         Number of Variables with Missing Value Differences: 8.
         Total Number of Values which Compare Unequal: 11.
         Maximum Difference: 1.


                       Variables with Unequal Values
```

Variable	Type	Len1	Len2	Label	Compare Label	Ndif	MaxDif	MissDif
REGION1N	NUM	8	8	Geographic Region 1 (N)	Geographic Region 1 (N)	1	1.000	0
AGEGR1	CHAR	5	7	Pooled Age Group 1	Pooled Age Group 1	1		0
AGEGR1N	NUM	8	8	Pooled Age Group 1 (N)	Pooled Age Group 1 (N)	1	1.000	0
trt01p	CHAR	26	26		Planned Treatment for Period 01	1		1
trt01a	CHAR	26	26		Actual Treatment for Period 01	1		1
tr01pg2	CHAR	21	21		Planned Pooled Treatment 2 for Period 01	1		1
tr01ag2	CHAR	21	21		Actual Pooled Treatment 2 for Period 01	1		1
trt01pn	NUM	8	8		Planned Treatment for Period 01 (N)	1	0	1
trt01an	NUM	8	8		Actual Treatment for Period 01 (N)	1	0	1
tr01pg2n	NUM	8	8		Planned Pooled Trt 2 for Period 01 (N)	1	0	1
tr01ag2n	NUM	8	8		Actual Pooled Trt 2 for Period 01 (N)	1	0	1

Value Comparison Results for Variables

```
               ||  Geographic Region 1 (N)
               ||       Base      Compare
       Obs     ||    REGION1N    REGION1N      Diff.      % Diff
_____         ||   _____    _____    _____    _____
               ||
         1     ||     1.0000      2.0000      1.0000    100.0000
```

```
               ||  Pooled Age Group 1
               ||  Base Value           Compare Value
       Obs     ||  AGEGR1               AGEGR1
_____         ||  ____                 _____
               ||
         1     ||  18-64                <55
```

```
               ||  Pooled Age Group 1 (N)
               ||       Base      Compare
       Obs     ||    AGEGR1N     AGEGR1N       Diff.      % Diff
_____         ||   _____    _____    _____    _____
               ||
         1     ||     2.0000      1.0000     -1.0000    -50.0000
```

```
               ||  Planned Treatment for Period 01
               ||  Base Value           Compare Value
       Obs     ||  trt01p               TRT01P
_____         ||  _____+    _____+
               ||
         1     ||                       Study Drug Dose 4
```

```
               ||  Actual Treatment for Period 01
               ||  Base Value           Compare Value
       Obs     ||  trt01a               TRT01A
_____         ||  _____+    _____+
               ||
         1     ||                       Study Drug Dose 4
```

```
               ||  Planned Pooled Treatment 2 for Period 01
               ||  Base Value           Compare Value
       Obs     ||  tr01pg2              TR01PG2
_____         ||  _____+    _____+
               ||
         1     ||                       Study Drug Dose 3 &
```

Compare of adae
from- STUDY2
to- ISS

```
         ||  Actual Pooled Treatment 2 for Period 01
         ||  Base Value         Compare Value
   Obs   ||  tr01ag2             TR01AG2
_____ ||  _____+   _____+
         ||
     1   ||                      Study Drug Dose 3 &
```

```
         ||  Planned Treatment for Period 01 (N)
         ||      Base      Compare
   Obs   ||    trt01pn     TRT01PN     Diff.      % Diff
_____ ||   _____    _____    _____   _____
         ||
     1   ||         .       5.0000          .          .
```

```
         ||  Actual Treatment for Period 01 (N)
         ||      Base      Compare
   Obs   ||    trt01an     TRT01AN     Diff.      % Diff
_____ ||   _____    _____    _____   _____
         ||
     1   ||         .       5.0000          .          .
```

```
         ||  Planned Pooled Trt 2 for Period 01 (N)
         ||      Base      Compare
   Obs   ||    tr01pg2n    TR01PG2N    Diff.      % Diff
_____ ||   _____    _____    _____   _____
         ||
     1   ||         .       3.0000          .          .
```

```
         ||  Actual Pooled Trt 2 for Period 01 (N)
         ||      Base      Compare
   Obs   ||    tr01ag2n    TR01AG2N    Diff.      % Diff
_____ ||   _____    _____    _____   _____
         ||
     1   ||         .       3.0000          .          .
```

The COMPARE Procedure
Comparison of COMP.ADAE with COMPC.ADAE
(Method=EXACT)

Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:13:36:14	03MAR23:13:36:14	100	3
COMPC.ADAE	03MAR23:13:36:13	03MAR23:13:36:13	103	9

Variables Summary

Number of Variables in Common: 97.
Number of Variables in COMP.ADAE but not in COMPC.ADAE: 3.
Number of Variables in COMPC.ADAE but not in COMP.ADAE: 6.
Number of Variables with Differing Attributes: 38.

```
               Listing of Variables in COMP.ADAE but not in COMPC.ADAE


               Variable  Type  Length  Label


                 CQO3NAM  Char       1  Customized Query O3 Name
                 CQO4NAM  Char       1  Customized Query O4 Name
                 TRTDVFL  Char       1  Treatment Deviation Flag



               Listing of Variables in COMPC.ADAE but not in COMP.ADAE


               Variable  Type  Length  Label


                 old_subj  Char      13  Unique Subject Identifier
                 TRTP     Char      26  Planned Treatment
                 TRTPN    Num        8  Planned Treatment (N)
                 TRTA     Char      26  Actual Treatment
                 TRTAN    Num        8  Actual Treatment (N)
                 AERELNST Char       1  Relationship to Non-Study Treatment



                   Listing of Common Variables with Differing Attributes


Variable  Dataset       Type  Length  Label


usubjid   COMP.ADAE     Char      19
          COMPC.ADAE    Char      19  Unique Subject Identifier
AESTDTC   COMP.ADAE     Char      10  Start Date/Time of Adverse Event
          COMPC.ADAE    Char      16  Start Date/Time of Adverse Event
AEENDTC   COMP.ADAE     Char      10  End Date/Time of Adverse Event
          COMPC.ADAE    Char      16  End Date/Time of Adverse Event
ADURC     COMP.ADAE     Char       3  Analysis Duration (C)
          COMPC.ADAE    Char      12  Analysis Duration (C)
AETERM    COMP.ADAE     Char      33  Reported Term for the Adverse Event
          COMPC.ADAE    Char     130  Reported Term for the Adverse Event
AEDECOD   COMP.ADAE     Char      23  Dictionary-Derived Term
          COMPC.ADAE    Char      61  Dictionary-Derived Term
AEBODSYS  COMP.ADAE     Char      36  Body System or Organ Class
          COMPC.ADAE    Char      67  Body System or Organ Class
AELLT     COMP.ADAE     Char      23  Lowest Level Term
          COMPC.ADAE    Char      61  Lowest Level Term
AEHLT     COMP.ADAE     Char      42  High Level Term
          COMPC.ADAE    Char      79  High Level Term
AEHLGT    COMP.ADAE     Char      44  High Level Group Term
          COMPC.ADAE    Char      86  High Level Group Term
AESOC     COMP.ADAE     Char      36  Primary System Organ Class
          COMPC.ADAE    Char      67  Primary System Organ Class
AEOUT     COMP.ADAE     Char      20  Outcome of Adverse Event
          COMPC.ADAE    Char      32  Outcome of Adverse Event
AEOUTN    COMP.ADAE     Num        8  Outcome of Adverse Event (N)
          COMPC.ADAE    Num        8  Outcome of AE (N)
AEACNOTH  COMP.ADAE     Char       1  Other Action Taken
          COMPC.ADAE    Char      20  Other Action Taken
AEWD      COMP.ADAE     Char       1  Subject Withdrawn as a Result of AE?
          COMPC.ADAE    Char       1  AE Leading to Withdrawal From Study
AEDLT     COMP.ADAE     Char       1  Dose-Limiting Toxicities
          COMPC.ADAE    Char       1  Is This Event a Dose Limiting Toxicity
AESRECHA  COMP.ADAE     Char       1  Event(s) Recur After Rechallenge
          COMPC.ADAE    Char       2  Event(s) Recur After Rechallenge
```

```
CQO2NAM   COMP.ADAE   Char        1   Customized Query 02 Name
          COMPC.ADAE  Char       53   Customized Query 02 Name
SUBJID    COMP.ADAE   Char        6   Subject Identifier for the Study
          COMPC.ADAE  Char        8   Subject Identifier for the Study
ACOUNTRY  COMP.ADAE   Char       13   Analysis Country
          COMPC.ADAE  Char       18   Analysis Country
REGION1   COMP.ADAE   Char       13   Geographic Region 1
          COMPC.ADAE  Char       17   Geographic Region 1
AGEGR1    COMP.ADAE   Char        5   Pooled Age Group 1
          COMPC.ADAE  Char        7   Pooled Age Group 1
AGEGR2    COMP.ADAE   Char       19   Pooled Age Group 2
          COMPC.ADAE  Char        7   Pooled Age Group 2
RACE      COMP.ADAE   Char       25   Race
          COMPC.ADAE  Char       41   Race
RACEGR1   COMP.ADAE   Char       25   Pooled Race Group 1
          COMPC.ADAE  Char       22   Pooled Race Group 1
SCRNFL    COMP.ADAE   Char        1   Screening Population Flag
          COMPC.ADAE  Char        1   Screened Population Flag
trt01p    COMP.ADAE   Char       26
          COMPC.ADAE  Char       26   Planned Treatment for Period 01
trt01a    COMP.ADAE   Char       26
          COMPC.ADAE  Char       26   Actual Treatment for Period 01
tr01pg1   COMP.ADAE   Char       10
          COMPC.ADAE  Char       10   Planned Pooled Treatment 1 for Period 01
tr01ag1   COMP.ADAE   Char       10
          COMPC.ADAE  Char       10   Actual Pooled Treatment 1 for Period 01
tr01pg2   COMP.ADAE   Char       21
          COMPC.ADAE  Char       21   Planned Pooled Treatment 2 for Period 01
tr01ag2   COMP.ADAE   Char       21
          COMPC.ADAE  Char       21   Actual Pooled Treatment 2 for Period 01
trt01pn   COMP.ADAE   Num         8
          COMPC.ADAE  Num         8   Planned Treatment for Period 01 (N)
trt01an   COMP.ADAE   Num         8
          COMPC.ADAE  Num         8   Actual Treatment for Period 01 (N)
tr01pg1n  COMP.ADAE   Num         8
          COMPC.ADAE  Num         8   Planned Pooled Trt 1 for Period 01 (N)
tr01pg2n  COMP.ADAE   Num         8
          COMPC.ADAE  Num         8   Planned Pooled Trt 2 for Period 01 (N)
tr01ag1n  COMP.ADAE   Num         8
          COMPC.ADAE  Num         8   Actual Pooled Trt 1 for Period 01 (N)
tr01ag2n  COMP.ADAE   Num         8
          COMPC.ADAE  Num         8   Actual Pooled Trt 2 for Period 01 (N)


                    Comparison Results for Observations

        Observation 4 in COMPC.ADAE not found in COMP.ADAE.

        Observation 5 in COMPC.ADAE not found in COMP.ADAE.

        Observation 6 in COMPC.ADAE not found in COMP.ADAE.

        Observation 7 in COMPC.ADAE not found in COMP.ADAE.

        Observation 8 in COMPC.ADAE not found in COMP.ADAE.

        Observation 9 in COMPC.ADAE not found in COMP.ADAE.
```

```
                                  Observation Summary

                          Observation      Base  Compare

                          First Obs           1        1
                          First Unequal       1        1
                          Last  Unequal       3        3
                          Last  Match         3        3
                          Last  Obs           .        9


                  Number of Observations in Common: 3.
                  Number of Observations in COMPC.ADAE but not in COMP.ADAE: 6.
                  Total Number of Observations Read from COMP.ADAE: 3.
                  Total Number of Observations Read from COMPC.ADAE: 9.


                  Number of Observations with Some Compared Variables Unequal: 3.
                  Number of Observations with All Compared Variables Equal: 0.


                               Values Comparison Summary

                  Number of Variables Compared with All Observations Equal: 40.
                  Number of Variables Compared with Some Observations Unequal: 57.
                  Number of Variables with Missing Value Differences: 15.
                  Total Number of Values which Compare Unequal: 129.
                  Maximum Difference: 3098520.


                              Variables with Unequal Values
```

Variable	Type	Len1	Len2	Label	Ndif	MaxDif	MissDif
usubjid	CHAR	19	19		2		0
AESEQ	NUM	8	8	Sequence Number	1	1.000	0
AEREFID	CHAR	5	5	Reference ID	2		0
AESTDTC	CHAR	10	16	Start Date/Time of Adverse Event	2		0
ASTDT	NUM	8	8	Analysis Start Date	2	100	0
ASTDTF	CHAR	1	1	Analysis Start Date Imputation Flag	1		1
ASTDY	NUM	8	8	Analysis Start Relative Day	2	98.000	0
AEENDTC	CHAR	10	16	End Date/Time of Adverse Event	3		1
AENDT	NUM	8	8	Analysis End Date	3	147	1
AENDTF	CHAR	1	1	Analysis End Date Imputation Flag	1		1
AENDY	NUM	8	8	Analysis End Relative Day	3	154	1
ADURN	NUM	8	8	Analysis Duration (N)	3	9.000	2
ADURC	CHAR	3	12	Analysis Duration (C)	3		2
AETERM	CHAR	33	130	Reported Term for the Adverse Event	2		0
AEDECOD	CHAR	23	61	Dictionary-Derived Term	2		0
AELLT	CHAR	23	61	Lowest Level Term	2		0
AELLTCD	NUM	8	8	Lowest Level Term Code	2	36990	0
AEPTCD	NUM	8	8	Preferred Term Code	2	29647	0
AEHLT	CHAR	42	79	High Level Term	2		0
AEHLTCD	NUM	8	8	High Level Term Code	2	27202	0
AEHLGT	CHAR	44	86	High Level Group Term	2		0
AEHLGTCD	NUM	8	8	High Level Group Term Code	2	17861	0
AEPATT	CHAR	14	14	Pattern of Adverse Event	2		0
AEOUT	CHAR	20	32	Outcome of Adverse Event	1		0
AEOUTN	NUM	8	8	Outcome of Adverse Event (N)	1	1.000	0
AEACN	CHAR	16	16	Action Taken with Study Treatment	1		0
AETOXGR	CHAR	1	1	Standard Toxicity Grade	2		0

```
AETOXGRN  NUM    8   8   Standard Toxicity Grade (N)              2    1.000      0
SUBJID    CHAR   6   8   Subject Identifier for the Study         2               0
AGE       NUM    8   8   Age                                      2    8.000      0
AAGE      NUM    8   8   Analysis Age                             2    8.000      0
AGEGR1    CHAR   5   7   Pooled Age Group 1                       3               0
AGEGR1N   NUM    8   8   Pooled Age Group 1 (N)                   3    1.000      0
AGEGR2    CHAR  19   7   Pooled Age Group 2                       3               0
AGEGR2N   NUM    8   8   Pooled Age Group 2 (N)                   3    1.000      0
SEX       CHAR   1   1   Sex                                      2               0
ETHNIC    CHAR  22  22   Ethnicity                                2               0
ARACE     CHAR  41  41   Analysis Race                            3               0
RACEGR1   CHAR  25  22   Pooled Race Group 1                      3               0
RACEGR1N  NUM    8   8   Pooled Race Group 1 (N)                  3    3.000      0
WEIGHTBL  NUM    8   8   Weight (kg) at Baseline                  2   29.800      0
HEIGHTBL  NUM    8   8   Height (cm) at Baseline                  2    7.000      0
BMIBL     NUM    8   8   BMI (kg/m^2) at Baseline                 3    7.389      0
TRTSDT    NUM    8   8   Date of First Exposure to Treatment      2   36.000      0
TRTSTM    NUM    8   8   Time of First Exposure to Treatment      2   11880       0
TRTSDTM   NUM    8   8   Datetime of First Exposure to Treatment  2  3098520      0
TRTEDT    NUM    8   8   Date of Last Exposure to Treatment       2   36.000      0
TRTEDTM   NUM    8   8   Datetime of Last Exposure to Treatment   2  3098520      0
TRTETM    NUM    8   8   Time of Last Exposure to Treatment       2   11880       0
trt01p    CHAR  26  26                                            3               3
trt01a    CHAR  26  26                                            3               3
tr01pg2   CHAR  21  21                                            3               3
tr01ag2   CHAR  21  21                                            3               3
trt01pn   NUM    8   8                                            3         0     3
trt01an   NUM    8   8                                            3         0     3
tr01pg2n  NUM    8   8                                            3         0     3
tr01ag2n  NUM    8   8                                            3         0     3
```

Value Comparison Results for Variables

```
_____
          || Unique Subject Identifier
          || Base Value          Compare Value
    Obs   || usubjid             usubjid
_____  || _____    _____
          ||
      2   || 10006               10001
      3   || 10007               10004
_____


_____
          || Sequence Number
          ||     Base    Compare
    Obs   ||    AESEQ     AESEQ      Diff.     % Diff
_____  || _____  _____  _____  _____
          ||
      2   ||   1.0000    2.0000    1.0000   100.0000
_____


_____
          || Reference ID
          || Base Value          Compare Value
    Obs   || AEREFID             AEREFID
_____  || ____                ____
          ||
      2   || 10001               10002
      3   || 10001               10002
_____


_____
          || Start Date/Time of Adverse Event
          || Base Value          Compare Value
    Obs   || AESTDTC             AESTDTC
_____  || _____           _____
          ||
      2   || 2021-03-02          2021-06
      3   || 2021-02-25          2021-06-05
_____


_____
          || Analysis Start Date
          ||     Base    Compare
    Obs   ||     ASTDT     ASTDT      Diff.     % Diff
_____  || _____  _____  _____  _____
          ||
      2   || 02MAR2021 01JUN2021   91.0000    0.4073
      3   || 25FEB2021 05JUN2021  100.0000    0.4477
_____


_____
          || Analysis Start Date Imputation Flag
          || Base Value          Compare Value
```

```
           Obs ||   ASTDTF                    ASTDTF
          _____  ||   _                        _
                  ||
             2  ||                           D
_____
```

```
                  ||  Analysis Start Relative Day
                  ||      Base     Compare
           Obs ||     ASTDY       ASTDY       Diff.     % Diff
          _____  ||  _____   _____   _____   _____
                  ||
             2  ||     6.0000    104.0000    98.0000       1633
             3  ||     1.0000     65.0000    64.0000       6400
_____
```

```
                  ||  End Date/Time of Adverse Event
                  ||  Base Value             Compare Value
           Obs ||  AEENDTC                AEENDTC
          _____  ||  _____              _____
                  ||
             1  ||                         2021-07-06
             2  ||  2021-03-06             2021-07
             3  ||  2021-03-19             2021-06-18
_____
```

```
                  ||  Analysis End Date
                  ||      Base     Compare
           Obs ||     AENDT       AENDT       Diff.     % Diff
          _____  ||  _____   _____   _____   _____
                  ||
             1  ||          .    06JUL2021        .          .
             2  ||  06MAR2021   31JUL2021   147.0000     0.6579
             3  ||  19MAR2021   18JUN2021    91.0000     0.4070
_____
```

```
                  ||  Analysis End Date Imputation Flag
                  ||  Base Value             Compare Value
           Obs ||  AENDTF                 AENDTF
          _____  ||  _                      _
                  ||
             2  ||                         D
_____
```

```
                  ||  Analysis End Relative Day
                  ||      Base     Compare
           Obs ||     AENDY       AENDY       Diff.     % Diff
          _____  ||  _____   _____   _____   _____
                  ||
             1  ||          .    139.0000        .          .
             2  ||   10.0000    164.0000   154.0000       1540
             3  ||   23.0000     78.0000    55.0000   239.1304
```

Compare of adae
from- STUDY3
to- ISS

```
          ||  Analysis Duration (N)
          ||     Base      Compare
   Obs    ||    ADURN       ADURN      Diff.      % Diff
_____||  _____    _____   _____    _____
          ||
    1     ||         .    135.0000          .           .
    2     ||    5.0000           .          .           .
    3     ||   23.0000     14.0000    -9.0000    -39.1304
```

```
          ||  Analysis Duration (C)
          ||  Base Value          Compare Value
   Obs    ||  ADURC               ADURC
_____||  ___                 _____
          ||
    1     ||                      135d
    2     ||  5d
    3     ||  23d                 14d
```

```
          ||  Reported Term for the Adverse Event
          ||  Base Value          Compare Value
   Obs    ||  AETERM              AETERM
_____||  _____+ _____+
          ||
    2     ||  URINARY TRACT INFECT  H PYLORI GASTRITIS
    3     ||  BLISTER OF BUTTOCK W  STREPTOCOCCAL PHARYN
```

```
          ||  Dictionary-Derived Term
          ||  Base Value          Compare Value
   Obs    ||  AEDECOD             AEDECOD
_____||  _____+ _____+
          ||
    2     ||  Urinary tract infect  Helicobacter gastrit
    3     ||  Blister infected      Pharyngitis streptoc
```

```
          ||  Lowest Level Term
          ||  Base Value          Compare Value
   Obs    ||  AELLT               AELLT
_____||  _____+ _____+
          ||
    2     ||  Urinary tract infect  Helicobacter pylori
    3     ||  Blister infected      Streptococcal pharyn
```

Compare of adae
from- STUDY3
to- ISS

```
           ||  Lowest Level Term Code
           ||     Base      Compare
      Obs  ||    AELLTCD    AELLTCD      Diff.     % Diff
  _____  ||   _____   _____   _____   _____
           ||
        2  ||   10046571   10051790       5219     0.0519
        3  ||   10005192   10042182      36990     0.3697
  _____
```

```
           ||  Preferred Term Code
           ||     Base      Compare
      Obs  ||    AEPTCD     AEPTCD       Diff.     % Diff
  _____  ||   _____   _____   _____   _____
           ||
        2  ||   10046571   10054272       7701     0.0767
        3  ||   10005192   10034839      29647     0.2963
  _____
```

```
           ||  High Level Term
           ||  Base Value         Compare Value
      Obs  ||  AEHLT              AEHLT
  _____  ||  _____+ _____+
           ||
        2  ||  Urinary tract infect  Helicobacter infecti
        3  ||  Skin structures and   Streptococcal infect
  _____
```

```
           ||  High Level Term Code
           ||     Base      Compare
      Obs  ||    AEHLTCD    AEHLTCD      Diff.     % Diff
  _____  ||   _____   _____   _____   _____
           ||
        2  ||   10046577   10019375     -27202    -0.2708
        3  ||   10040786   10042180       1394     0.0139
  _____
```

```
           ||  High Level Group Term
           ||  Base Value         Compare Value
      Obs  ||  AEHLGT             AEHLGT
  _____  ||  _____+ _____+
           ||
        2  ||  Infections - pathoge  Bacterial infectious
        3  ||  Infections - pathoge  Bacterial infectious
  _____
```

```
           ||  High Level Group Term Code
           ||     Base      Compare
      Obs  ||   AEHLGTCD   AEHLGTCD      Diff.     % Diff
  _____  ||   _____   _____   _____   _____
           ||
        2  ||   10021879   10004018     -17861    -0.1782
```

```
                     3  ||   10021879   10004018      -17861     -0.1782
_____


_____
                        ||  Pattern of Adverse Event
                        ||  Base Value          Compare Value
                  Obs   ||  AEPATT               AEPATT
_____         ||  _____        _____
                        ||
                     2  ||  SINGLE EPISODE       INTERMITTENT
                     3  ||  SINGLE EPISODE       INTERMITTENT
_____


_____
                        ||  Outcome of Adverse Event
                        ||  Base Value          Compare Value
                  Obs   ||  AEOUT                AEOUT
_____         ||  _____   _____+
                        ||
                     1  ||  RECOVERING/RESOLVING  RECOVERED/RESOLVED
_____


_____
                        ||  Outcome of Adverse Event (N)
                        ||  Outcome of AE (N)
                        ||      Base      Compare
                  Obs   ||     AEOUTN     AEOUTN      Diff.     % Diff
_____         ||  _____  _____  _____  _____
                        ||
                     1  ||    2.0000    1.0000    -1.0000   -50.0000
_____


_____
                        ||  Action Taken with Study Treatment
                        ||  Base Value          Compare Value
                  Obs   ||  AEACN                AEACN
_____         ||  _____      _____
                        ||
                     3  ||  DOSE NOT CHANGED     NOT APPLICABLE
_____


_____
                        ||  Standard Toxicity Grade
                        ||  Base Value          Compare Value
                  Obs   ||  AETOXGR              AETOXGR
_____         ||  _                    _
                        ||
                     2  ||  2                    1
                     3  ||  2                    1
_____


_____
                        ||  Standard Toxicity Grade (N)
                        ||      Base      Compare
                  Obs   ||   AETOXGRN   AETOXGRN      Diff.     % Diff
```

_____	||	_____	_____	_____	_____
	||				
2	||	2.0000	1.0000	-1.0000	-50.0000
3	||	2.0000	1.0000	-1.0000	-50.0000

Obs		Subject Identifier for the Study	
	||	Base Value	Compare Value
	||	SUBJID	SUBJID
_____	||	_____	_____
	||		
2	||	10006	10001
3	||	10007	10004

Obs		Age			
	||	Base AGE	Compare AGE	Diff.	% Diff
_____	||	_____	_____	_____	_____
	||				
2	||	40.0000	32.0000	-8.0000	-20.0000
3	||	53.0000	54.0000	1.0000	1.8868

Obs		Analysis Age			
	||	Base AAGE	Compare AAGE	Diff.	% Diff
_____	||	_____	_____	_____	_____
	||				
2	||	40.0000	32.0000	-8.0000	-20.0000
3	||	53.0000	54.0000	1.0000	1.8868

Obs		Pooled Age Group 1	
	||	Base Value	Compare Value
	||	AGEGR1	AGEGR1
_____	||	_____	_____
	||		
1	||	19-64	<55
2	||	19-64	<55
3	||	19-64	<55

Obs		Pooled Age Group 1 (N)			
	||	Base AGEGR1N	Compare AGEGR1N	Diff.	% Diff
_____	||	_____	_____	_____	_____
	||				
1	||	2.0000	1.0000	-1.0000	-50.0000
2	||	2.0000	1.0000	-1.0000	-50.0000
3	||	2.0000	1.0000	-1.0000	-50.0000

```
_____
```

```
_____
            ||  Pooled Age Group 2
            ||  Base Value          Compare Value
    Obs  ||  AGEGR2               AGEGR2
_____     ||  _____    _____
            ||
       1 ||  Adult (18-64 years)  19 - 64
       2 ||  Adult (18-64 years)  19 - 64
       3 ||  Adult (18-64 years)  19 - 64
_____
```

```
_____
            ||  Pooled Age Group 2 (N)
            ||      Base      Compare
    Obs  ||   AGEGR2N    AGEGR2N      Diff.      % Diff
_____     ||  _____   _____   _____   _____
            ||
       1 ||    1.0000     2.0000     1.0000   100.0000
       2 ||    1.0000     2.0000     1.0000   100.0000
       3 ||    1.0000     2.0000     1.0000   100.0000
_____
```

```
_____
            ||  Sex
            ||  Base Value          Compare Value
    Obs  ||  SEX                  SEX
_____     ||  _                    _
            ||
       2 ||  F                    M
       3 ||  F                    M
_____
```

```
_____
            ||  Ethnicity
            ||  Base Value          Compare Value
    Obs  ||  ETHNIC               ETHNIC
_____     ||  _____+    _____+
            ||
       2 ||  HISPANIC OR LATINO   NOT HISPANIC OR LATI
       3 ||  NOT HISPANIC OR LATI  HISPANIC OR LATINO
_____
```

```
_____
            ||  Analysis Race
            ||  Base Value          Compare Value
    Obs  ||  ARACE                ARACE
_____     ||  _____+    _____+
            ||
       1 ||  WHITE - WHITE/CAUCAS  White - White/Caucas
       2 ||  WHITE - WHITE/CAUCAS  White - White/Caucas
       3 ||  WHITE - WHITE/CAUCAS  White - White/Caucas
_____
```

```
                   || Pooled Race Group 1
                   || Base Value          Compare Value
          Obs      || RACEGR1             RACEGR1
_____           || _____+  _____+
                   ||
           1       || WHITE               White
           2       || WHITE               White
           3       || WHITE               White
```

```
                   || Pooled Race Group 1 (N)
                   ||    Base     Compare
          Obs      || RACEGR1N   RACEGR1N     Diff.     % Diff
_____           || _____   _____   _____   _____
                   ||
           1       ||   5.0000     2.0000    -3.0000   -60.0000
           2       ||   5.0000     2.0000    -3.0000   -60.0000
           3       ||   5.0000     2.0000    -3.0000   -60.0000
```

```
                   || Weight (kg) at Baseline
                   ||    Base     Compare
          Obs      || WEIGHTBL   WEIGHTBL     Diff.     % Diff
_____           || _____   _____   _____   _____
                   ||
           2       ||  83.5000   113.3000    29.8000    35.6886
           3       ||  84.4000    78.1000    -6.3000    -7.4645
```

```
                   || Height (cm) at Baseline
                   ||    Base     Compare
          Obs      || HEIGHTBL   HEIGHTBL     Diff.     % Diff
_____           || _____   _____   _____   _____
                   ||
           2       || 174.0000   180.0000     6.0000     3.4483
           3       || 163.0000   170.0000     7.0000     4.2945
```

```
                   || BMI (kg/m^2) at Baseline
                   ||    Base     Compare
          Obs      ||   BMIBL      BMIBL       Diff.     % Diff
_____           || _____   _____   _____   _____
                   ||
           1       ||  34.9700    34.9691   -0.000864   -0.002471
           2       ||  27.5800    34.9691    7.3891     26.7916
           3       ||  31.7700    27.0242   -4.7458    -14.9379
```

```
                   || Date of First Exposure to Treatment
                   ||      Base     Compare
```

Compare of adae
from- STUDY3
to- ISS

```
     Obs ||    TRTSDT      TRTSDT      Diff.      % Diff
 _____ ||   _____    _____    _____    _____
         ||
       2 ||  25FEB2021   18FEB2021    -7.0000    -0.0313
       3 ||  25FEB2021   02APR2021    36.0000     0.1612
```
_____

```
         ||  Time of First Exposure to Treatment
         ||       Base      Compare
     Obs ||    TRTSTM      TRTSTM      Diff.      % Diff
 _____ ||   _____    _____    _____    _____
         ||
       2 ||   10:31:00     9:08:00     -4980   -13.1537
       3 ||   11:38:00     8:20:00    -11880   -28.3668
```
_____

```
         ||  Datetime of First Exposure to Treatment
         ||       Base      Compare
     Obs ||   TRTSDTM     TRTSDTM      Diff.      % Diff
 _____ ||   _____    _____    _____    _____
         ||
       2 ||  25FEB2021   18FEB2021   -609780    -0.0316
       3 ||  25FEB2021   02APR2021   3098520     0.1606
```
_____

```
         ||  Date of Last Exposure to Treatment
         ||       Base      Compare
     Obs ||    TRTEDT      TRTEDT      Diff.      % Diff
 _____ ||   _____    _____    _____    _____
         ||
       2 ||  25FEB2021   18FEB2021    -7.0000    -0.0313
       3 ||  25FEB2021   02APR2021    36.0000     0.1612
```
_____

```
         ||  Datetime of Last Exposure to Treatment
         ||       Base      Compare
     Obs ||   TRTEDTM     TRTEDTM      Diff.      % Diff
 _____ ||   _____    _____    _____    _____
         ||
       2 ||  25FEB2021   18FEB2021   -609780    -0.0316
       3 ||  25FEB2021   02APR2021   3098520     0.1606
```
_____

```
         ||  Time of Last Exposure to Treatment
         ||       Base      Compare
     Obs ||    TRTETM      TRTETM      Diff.      % Diff
 _____ ||   _____    _____    _____    _____
         ||
       2 ||   11:31:00    10:08:00     -4980   -12.0116
       3 ||   12:38:00     9:20:00    -11880   -26.1214
```
_____

```
_____
            ||  Planned Treatment for Period 01
            ||  Base Value        Compare Value
       Obs  ||  trt01p            TRT01P
_____     ||  _____ +  _____ +
            ||
        1   ||                     Study Drug Dose 2
        2   ||                     Study Drug Dose 2
        3   ||                     Study Drug Dose 2
_____


_____
            ||  Actual Treatment for Period 01
            ||  Base Value        Compare Value
       Obs  ||  trt01a            TRT01A
_____     ||  _____ +  _____ +
            ||
        1   ||                     Study Drug Dose 2
        2   ||                     Study Drug Dose 2
        3   ||                     Study Drug Dose 2
_____


_____
            ||  Planned Pooled Treatment 2 for Period 01
            ||  Base Value        Compare Value
       Obs  ||  tr01pg2           TR01PG2
_____     ||  _____ +  _____ +
            ||
        1   ||                     Study Drug Dose 1 &
        2   ||                     Study Drug Dose 1 &
        3   ||                     Study Drug Dose 1 &
_____


_____
            ||  Actual Pooled Treatment 2 for Period 01
            ||  Base Value        Compare Value
       Obs  ||  tr01ag2           TR01AG2
_____     ||  _____ +  _____ +
            ||
        1   ||                     Study Drug Dose 1 &
        2   ||                     Study Drug Dose 1 &
        3   ||                     Study Drug Dose 1 &
_____


_____
            ||  Planned Treatment for Period 01 (N)
            ||       Base     Compare
       Obs  ||      trt01pn   TRT01PN    Diff.      % Diff
_____     ||     _____   _____   _____    _____
            ||
        1   ||        .       3.0000      .           .
        2   ||        .       3.0000      .           .
        3   ||        .       3.0000      .           .
_____
```

```
                 ||  Actual Treatment for Period 01 (N)
                 ||       Base     Compare
           Obs   ||    trt01an    TRT01AN      Diff.     % Diff
        _____  ||  _____   _____    _____   _____
                 ||
             1   ||        .       3.0000         .          .
             2   ||        .       3.0000         .          .
             3   ||        .       3.0000         .          .
```

```
                 ||  Planned Pooled Trt 2 for Period 01 (N)
                 ||       Base     Compare
           Obs   ||    tr01pg2n   TR01PG2N     Diff.     % Diff
        _____  ||  _____   _____    _____   _____
                 ||
             1   ||        .       2.0000         .          .
             2   ||        .       2.0000         .          .
             3   ||        .       2.0000         .          .
```

```
                 ||  Actual Pooled Trt 2 for Period 01 (N)
                 ||       Base     Compare
           Obs   ||    tr01ag2n   TR01AG2N     Diff.     % Diff
        _____  ||  _____   _____    _____   _____
                 ||
             1   ||        .       2.0000         .          .
             2   ||        .       2.0000         .          .
             3   ||        .       2.0000         .          .
```