Compare of adae
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to- ISS

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

Data Set Summary

Dataset          Created          Modified   NVar    NObs

COMP.ADAE    03MAR23:14:31:01  03MAR23:14:31:01   106      12
COMPC.ADAE   03MAR23:14:31:01  03MAR23:14:31:01   103      12


Variables Summary

Number of Variables in Common: 97.
Number of Variables in COMP.ADAE but not in COMPC.ADAE: 9.
Number of Variables in COMPC.ADAE but not in COMP.ADAE: 6.
Number of Variables with Differing Attributes: 19.
```

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

```
     Variable  Type  Length  Label

     CQ03NAM   Char      35  Customized Query 03 Name
     AGEGR3    Char      25  Pooled Age Group 3
     AGEGR3N   Num        8  Pooled Age Group 3 (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

     TRTP      Char      26  Planned Treatment
     TRTPN     Num        8  Planned Treatment (N)
     TRTA      Char      26  Actual Treatment
     TRTAN     Num        8  Actual Treatment (N)
     CQ01NAM   Char       1  Customized Query 01 Name
     PART      Char       6  Part
```

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
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       3        3
                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: 10.
        Number of Observations with All Compared Variables Equal: 2.


                      Values Comparison Summary

        Number of Variables Compared with All Observations Equal: 43.
        Number of Variables Compared with Some Observations Unequal: 54.
        Number of Variables with Missing Value Differences: 5.
        Total Number of Values which Compare Unequal: 379.
        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
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                                           4                 0
trt01a     CHAR   26  26                                           4                 0
tr01pg1    CHAR   10  10                                           4                 0
tr01ag1    CHAR   10  10                                           4                 0
tr01pg2    CHAR   21  21                                           4                 0
tr01ag2    CHAR   21  21                                           4                 0
trt01pn    NUM     8   8                                           4      1.000      0
trt01an    NUM     8   8                                           4      1.000      0
tr01pg1n   NUM     8   8                                           4      1.000      0
tr01pg2n   NUM     8   8                                           4      1.000      0
tr01ag1n   NUM     8   8                                           4      1.000      0
tr01ag2n   NUM     8   8                                           4      1.000      0
CQ02NAM    CHAR   53  53   Customized Query 02 Name                2                 2
```

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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
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```
10  ||  Diarrhea           Vomiting
11  ||  Nausea             Infusion associated
12  ||  Vomiting           Appetite absent
```

| Obs | | Lowest Level Term Code | | | |
		Base AELLTCD	Compare 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

| Obs | | Preferred Term Code | | | |
		Base AEPTCD	Compare 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

Obs		High Level Term Base Value AEHLT	Compare Value 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

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```
_____
          ||  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
_____
```

```
_____
          ||  High Level Group Term
          ||  Base Value          Compare Value
     Obs  ||  AEHLGT              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
_____
```

```
_____
          ||  High Level Group Term Code
          ||     Base      Compare
     Obs  ||   AEHLGTCD    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
_____
```

```
_____
          ||  Primary System Organ Class
          ||  Base Value          Compare Value
     Obs  ||  AESOC               AESOC
```

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```
_____  ||  _____+  _____+
          ||
       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        .          .
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```
11 ||  12:00:00   16:52:00    17520   40.5556
12 ||  12:00:00       .          .        .
_____
```

Obs		Analysis Start Date/Time			
		Base ASTDTM	Compare 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

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```
_____
         ||  Analysis End Time
         ||      Base      Compare
    Obs  ||     AENTM       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
```

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to- ISS

```
   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
```

Compare of adae
from- STUDY1
to- ISS

```
_____   ||  _____      _____
           ||
      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
           ||  Base Value          Compare Value
     Obs   ||  SUBJID               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
_____
```

```
_____
           ||  Age
           ||      Base      Compare
     Obs   ||       AGE          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
_____
```

```
_____
           ||  Analysis Age
           ||      Base      Compare
     Obs   ||      AAGE         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
```
_____

_____

```
    ||  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
       _____
```

Compare of adae
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```
_____
            ||  Weight (kg) at Baseline
            ||     Base      Compare
    Obs     ||  WEIGHTBL    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
_____


_____
            ||  Height (cm) at Baseline
            ||     Base      Compare
    Obs     ||  HEIGHTBL    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
_____


_____
            ||  BMI (kg/m^2) at Baseline
            ||     Base      Compare
    Obs     ||    BMIBL       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
_____


_____
            ||  Planned Treatment for Period 01
            ||  Base Value          Compare Value
    Obs     ||  trt01p              TRT01P
_____   ||  _____+  _____+
            ||
```

```
    4  ||  Study Drug Dose 1      Placebo
    5  ||  Study Drug Dose 1      Placebo
    7  ||  Placebo                Study Drug Dose 1
    8  ||  Placebo                Study Drug Dose 1
_____


_____
       ||  Actual Treatment for Period 01
       ||  Base Value           Compare Value
  Obs  ||  trt01a               TRT01A
_____  ||  _____+  _____+
       ||
    4  ||  Study Drug Dose 1      Placebo
    5  ||  Study Drug Dose 1      Placebo
    7  ||  Placebo                Study Drug Dose 1
    8  ||  Placebo                Study Drug Dose 1
_____


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


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


_____
       ||  Planned Pooled Treatment 2 for Period 01
       ||  Base Value           Compare Value
  Obs  ||  tr01pg2              TR01PG2
_____  ||  _____+  _____+
       ||
    4  ||  Study Drug Dose 1 &    Placebo
    5  ||  Study Drug Dose 1 &    Placebo
    7  ||  Placebo                Study Drug Dose 1 &
    8  ||  Placebo                Study Drug Dose 1 &
_____
```

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```
_____
          || Actual Pooled Treatment 2 for Period 01
          || Base Value          Compare Value
   Obs    || tr01ag2             TRO1AG2
_____  || _____+  _____+
          ||
     4    || Study Drug Dose 1 &  Placebo
     5    || Study Drug Dose 1 &  Placebo
     7    || Placebo              Study Drug Dose 1 &
     8    || Placebo              Study Drug Dose 1 &
_____
```

```
_____
          || Planned Treatment for Period 01 (N)
          ||    Base    Compare
   Obs    ||   trt01pn   TRT01PN     Diff.     % Diff
_____  || _____  _____  _____  _____
          ||
     4    ||   2.0000    1.0000   -1.0000  -50.0000
     5    ||   2.0000    1.0000   -1.0000  -50.0000
     7    ||   1.0000    2.0000    1.0000  100.0000
     8    ||   1.0000    2.0000    1.0000  100.0000
_____
```

```
_____
          || Actual Treatment for Period 01 (N)
          ||    Base    Compare
   Obs    ||   trt01an   TRT01AN     Diff.     % Diff
_____  || _____  _____  _____  _____
          ||
     4    ||   2.0000    1.0000   -1.0000  -50.0000
     5    ||   2.0000    1.0000   -1.0000  -50.0000
     7    ||   1.0000    2.0000    1.0000  100.0000
     8    ||   1.0000    2.0000    1.0000  100.0000
_____
```

```
_____
          || Planned Pooled Trt 1 for Period 01 (N)
          ||    Base    Compare
   Obs    ||   tr01pg1n   TRO1PG1N    Diff.     % Diff
_____  || _____  _____  _____  _____
          ||
     4    ||   2.0000    1.0000   -1.0000  -50.0000
     5    ||   2.0000    1.0000   -1.0000  -50.0000
     7    ||   1.0000    2.0000    1.0000  100.0000
     8    ||   1.0000    2.0000    1.0000  100.0000
_____
```

```
_____
          || Planned Pooled Trt 2 for Period 01 (N)
          ||    Base    Compare
   Obs    ||   tr01pg2n   TRO1PG2N    Diff.     % Diff
_____  || _____  _____  _____  _____
          ||
     4    ||   2.0000    1.0000   -1.0000  -50.0000
```

```
     5  ||     2.0000      1.0000    -1.0000    -50.0000
     7  ||     1.0000      2.0000     1.0000    100.0000
     8  ||     1.0000      2.0000     1.0000    100.0000
_____
```

Obs		Actual Pooled Trt 1 for Period 01 (N)			
		Base	Compare		
		tr01ag1n	TR01AG1N	Diff.	% Diff
4	||	2.0000	1.0000	-1.0000	-50.0000
5	||	2.0000	1.0000	-1.0000	-50.0000
7	||	1.0000	2.0000	1.0000	100.0000
8	||	1.0000	2.0000	1.0000	100.0000

Obs		Actual Pooled Trt 2 for Period 01 (N)			
		Base	Compare		
		tr01ag2n	TR01AG2N	Diff.	% Diff
4	||	2.0000	1.0000	-1.0000	-50.0000
5	||	2.0000	1.0000	-1.0000	-50.0000
7	||	1.0000	2.0000	1.0000	100.0000
8	||	1.0000	2.0000	1.0000	100.0000

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

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


                         Data Set Summary

    Dataset           Created          Modified   NVar    NObs

    COMP.ADAE    03MAR23:14:31:02  03MAR23:14:31:02   107      12
    COMPC.ADAE   03MAR23:14:31:01  03MAR23:14:31:01   103       1


                        Variables Summary

     Number of Variables in Common: 98.
     Number of Variables in COMP.ADAE but not in COMPC.ADAE: 9.
     Number of Variables in COMPC.ADAE but not in COMP.ADAE: 5.
     Number of Variables with Differing Attributes: 20.
```

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


        Variable  Type  Length  Label


        CQ03NAM   Char     35   Customized Query 03 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)
        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


        TRTP      Char     26   Planned Treatment
        TRTPN     Num       8   Planned Treatment (N)
        TRTA      Char     26   Actual Treatment
        TRTAN     Num       8   Actual Treatment (N)
        PART      Char      6   Part



Listing of Common Variables with Differing Attributes


Variable  Dataset      Type  Length  Label


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)
CQ01NAM   COMP.ADAE    Char     53   Customized Query 01 Name
          COMPC.ADAE   Char      1   Customized Query 01 Name
CQ02NAM   COMP.ADAE    Char     14   Customized Query 02 Name
          COMPC.ADAE   Char     53   Customized Query 02 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
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
```

Compare of adae
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```
              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 2 in COMP.ADAE not found in COMPC.ADAE.

         Observation 3 in COMP.ADAE not found in COMPC.ADAE.

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

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

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

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

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

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

         Observation 10 in COMP.ADAE not found in COMPC.ADAE.

         Observation 11 in COMP.ADAE not found in COMPC.ADAE.

         Observation 12 in COMP.ADAE not found in COMPC.ADAE.
```

```
                              Observation Summary

                     Observation      Base  Compare

                     First Obs           1        1
                     First Unequal       1        1
                     Last  Unequal       1        1
                     Last  Match         1        1
                     Last  Obs          12        .


         Number of Observations in Common: 1.
         Number of Observations in COMP.ADAE but not in COMPC.ADAE: 11.
         Total Number of Observations Read from COMP.ADAE: 12.
         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: 38.
         Number of Variables Compared with Some Observations Unequal: 60.
         Number of Variables with Missing Value Differences: 14.
         Total Number of Values which Compare Unequal: 60.
         Maximum Difference: 31885740.


                          Variables with Unequal Values

     Variable  Type  Len1 Len2  Label                              Ndif    MaxDif  MissDif

     AETERM    CHAR    62  130  Reported Term for the Adverse Event   1               0
     AEDECOD   CHAR    47   61  Dictionary-Derived Term               1               0
     AEBODSYS  CHAR    67   67  Body System or Organ Class            1               0
     AEBDSYCD  NUM      8    8  Body System or Organ Class Code       1       774     0
     AELLT     CHAR    47   61  Lowest Level Term                     1               0
     AELLTCD   NUM      8    8  Lowest Level Term Code                1     12085     0
     AEPTCD    NUM      8    8  Preferred Term Code                   1     33367     0
     AEHLT     CHAR    79   79  High Level Term                       1               0
     AEHLTCD   NUM      8    8  High Level Term Code                  1      3643     0
     AEHLGT    CHAR    86   86  High Level Group Term                 1               0
     AEHLGTCD  NUM      8    8  High Level Group Term Code            1      1570     0
     AESOC     CHAR    67   67  Primary System Organ Class            1               0
     AESOCCD   NUM      8    8  Primary System Organ Class Code       1       774     0
     ASTDT     NUM      8    8  Analysis Start Date                   1       348     0
     ASTTM     NUM      8    8  Analysis Start Time                   1     78660     0
     ASTDTM    NUM      8    8  Analysis Start Date/Time              1   2.999E7     0
     ASTDY     NUM      8    8  Analysis Start Relative Day           1    65.000     0
     AENDT     NUM      8    8  Analysis End Date                     1       370     0
     AENTM     NUM      8    8  Analysis End Time                     1     82260     0
     AENDTM    NUM      8    8  Analysis End Date/Time                1   3.189E7     0
     AENDY     NUM      8    8  Analysis End Relative Day             1    87.000     0
     ADURN     NUM      8    8  Analysis Duration (N)                 1     31620     0
     ADURC     CHAR    11   12  Analysis Duration (C)                 1               0
     AEACN     CHAR    16   16  Action Taken with Study Treatment     1               0
     AEREFID   CHAR     5    5  Reference ID                          1               1
```

Variable	Type	Len1	Len2	Label	N	Value	Flag
AEDLT	CHAR	1	1	Is This Event a Dose Limiting Toxicity	1		1
AESTDTC	CHAR	16	16	Start Date/Time of Adverse Event	1		0
AEENDTC	CHAR	16	16	End Date/Time of Adverse Event	1		0
STUDYID	CHAR	6	6	Study Identifier	1		0
SUBJID	CHAR	8	8	Subject Identifier for the Study	1		0
AGE	NUM	8	8	Age	1	6.000	0
AAGE	NUM	8	8	Analysis Age	1	6.000	0
ETHNIC	CHAR	22	22	Ethnicity	1		0
RACE	CHAR	41	41	Race	1		0
RACEGR1	CHAR	22	22	Pooled Race Group 1	1		0
RACEGR1N	NUM	8	8	Pooled Race Group 1 (N)	1	1.000	0
ARACE	CHAR	41	41	Analysis Race	1		0
ARACEN	NUM	8	8	Analysis Race (N)	1	3.000	0
TRTSDT	NUM	8	8	Date of First Exposure to Treatment	1	283	0
TRTSTM	NUM	8	8	Time of First Exposure to Treatment	1	22800	0
TRTSDTM	NUM	8	8	Datetime of First Exposure to Treatment	1	2.443E7	0
TRTEDT	NUM	8	8	Date of Last Exposure to Treatment	1	283	0
TRTETM	NUM	8	8	Time of Last Exposure to Treatment	1	26340	0
TRTEDTM	NUM	8	8	Datetime of Last Exposure to Treatment	1	2.442E7	0
WEIGHTBL	NUM	8	8	Weight (kg) at Baseline	1	21.900	0
HEIGHTBL	NUM	8	8	Height (cm) at Baseline	1	1.000	0
BMIBL	NUM	8	8	BMI (kg/m^2) at Baseline	1	8.487	0
usubjid	CHAR	19	19	Unique Subject Identifier	1		0
trt01p	CHAR	26	26		1		1
trt01a	CHAR	26	26		1		1
tr01pg1	CHAR	10	10		1		1
tr01ag1	CHAR	10	10		1		1
tr01pg2	CHAR	21	21		1		1
tr01ag2	CHAR	21	21		1		1
trt01pn	NUM	8	8		1	0	1
trt01an	NUM	8	8		1	0	1
tr01pg1n	NUM	8	8		1	0	1
tr01pg2n	NUM	8	8		1	0	1
tr01ag1n	NUM	8	8		1	0	1
tr01ag2n	NUM	8	8		1	0	1

Compare of adae
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```
                    Value Comparison Results for Variables


_____
        ||  Reported Term for the Adverse Event
        ||  Base Value         Compare Value
   Obs  ||  AETERM             AETERM
_____||  _____+  _____+
        ||
    1   ||  BLOOD PRESSURE INCRE  CLOSED FRACTURE OF T
_____



_____
        ||  Dictionary-Derived Term
        ||  Base Value         Compare Value
   Obs  ||  AEDECOD            AEDECOD
_____||  _____+  _____+
        ||
    1   ||  Blood pressure incre  Rib fracture
_____



_____
        ||  Body System or Organ Class
        ||  Base Value         Compare Value
   Obs  ||  AEBODSYS           AEBODSYS
_____||  _____+  _____+
        ||
    1   ||  Investigations       Injury, poisoning an
_____



_____
        ||  Body System or Organ Class Code
        ||      Base     Compare
   Obs  ||   AEBDSYCD   AEBDSYCD      Diff.     % Diff
_____||  _____  _____  _____  _____
        ||
    1   ||   10022891   10022117  -774.0000  -0.007722
_____



_____
        ||  Lowest Level Term
        ||  Base Value         Compare Value
   Obs  ||  AELLT              AELLT
_____||  _____+  _____+
        ||
    1   ||  Increased blood pres  Closed fracture of o
_____



_____
        ||  Lowest Level Term Code
        ||      Base     Compare
   Obs  ||    AELLTCD    AELLTCD      Diff.     % Diff
_____||  _____  _____  _____  _____
```

```
       ||
   1   ||   10021655   10009570      -12085     -0.1206
_____


_____
       ||  Preferred Term Code
       ||      Base       Compare
  Obs  ||    AEPTCD       AEPTCD       Diff.      % Diff
_____ ||   _____    _____    _____    _____
       ||
   1   ||   10005750    10039117      33367      0.3335
_____


_____
       ||  High Level Term
       ||  Base Value           Compare Value
  Obs  ||  AEHLT                AEHLT
_____ ||  _____+   _____+
       ||
   1   ||  Vascular tests NEC (  Thoracic cage fractu
_____


_____
       ||  High Level Term Code
       ||      Base       Compare
  Obs  ||    AEHLTCD      AEHLTCD      Diff.      % Diff
_____ ||   _____    _____    _____    _____
       ||
   1   ||   10047110    10043467      -3643     -0.0363
_____


_____
       ||  High Level Group Term
       ||  Base Value           Compare Value
  Obs  ||  AEHLGT               AEHLGT
_____ ||  _____+   _____+
       ||
   1   ||  Cardiac and vascular  Bone and joint injur
_____


_____
       ||  High Level Group Term Code
       ||      Base       Compare
  Obs  ||    AEHLGTCD     AEHLGTCD     Diff.      % Diff
_____ ||   _____    _____    _____    _____
       ||
   1   ||   10007512    10005942      -1570     -0.0157
_____


_____
       ||  Primary System Organ Class
       ||  Base Value           Compare Value
  Obs  ||  AESOC                AESOC
```

Compare of adae
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```
_____   ||  _____+ _____+
           ||
       1   ||  Investigations      Injury, poisoning an
_____
```

```
_____
           ||  Primary System Organ Class Code
           ||       Base     Compare
     Obs   ||     AESOCCD    AESOCCD      Diff.     % Diff
_____   ||  _____   _____   _____   _____
           ||
       1   ||   10022891   10022117  -774.0000  -0.007722
_____
```

```
_____
           ||  Analysis Start Date
           ||       Base     Compare
     Obs   ||      ASTDT      ASTDT       Diff.     % Diff
_____   ||  _____   _____   _____   _____
           ||
       1   ||  31AUG2020  14AUG2021   348.0000     1.5705
_____
```

```
_____
           ||  Analysis Start Time
           ||       Base     Compare
     Obs   ||      ASTTM      ASTTM       Diff.     % Diff
_____   ||  _____   _____   _____   _____
           ||
       1   ||   21:51:00    0:00:00     -78660  -100.0000
_____
```

```
_____
           ||  Analysis Start Date/Time
           ||       Base     Compare
     Obs   ||     ASTDTM     ASTDTM       Diff.     % Diff
_____   ||  _____   _____   _____   _____
           ||
       1   ||  31AUG2020  14AUG2021   29988540     1.5664
_____
```

```
_____
           ||  Analysis Start Relative Day
           ||       Base     Compare
     Obs   ||      ASTDY      ASTDY       Diff.     % Diff
_____   ||  _____   _____   _____   _____
           ||
       1   ||    1.0000    66.0000    65.0000       6500
_____
```

```
_____
           ||  Analysis End Date
           ||       Base     Compare
```

Compare of adae
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```
 Obs ||      AENDT      AENDT      Diff.     % Diff
_____ ||  _____  _____  _____  _____
        ||
   1 ||  31AUG2020  05SEP2021  370.0000    1.6698
_____
```

```
_____
        ||  Analysis End Time
        ||     Base    Compare
 Obs ||     AENTM      AENTM      Diff.     % Diff
_____ ||  _____  _____  _____  _____
        ||
   1 ||   22:51:00    0:00:00    -82260  -100.0000
_____
```

```
_____
        ||  Analysis End Date/Time
        ||     Base    Compare
 Obs ||     AENDTM     AENDTM     Diff.     % Diff
_____ ||  _____  _____  _____  _____
        ||
   1 ||  31AUG2020  05SEP2021  31885740    1.6655
_____
```

```
_____
        ||  Analysis End Relative Day
        ||     Base    Compare
 Obs ||     AENDY      AENDY      Diff.     % Diff
_____ ||  _____  _____  _____  _____
        ||
   1 ||    1.0000    88.0000    87.0000      8700
_____
```

```
_____
        ||  Analysis Duration (N)
        ||     Base    Compare
 Obs ||     ADURN      ADURN      Diff.     % Diff
_____ ||  _____  _____  _____  _____
        ||
   1 ||   60.0000     31680     31620     52700
_____
```

```
_____
        ||  Analysis Duration (C)
        ||  Base Value        Compare Value
 Obs ||  ADURC             ADURC
_____ ||  _____        _____
        ||
   1 ||  0d 1h 0m          22d 0h 0m
_____
```

```
_____
        ||  Action Taken with Study Treatment
```

Compare of adae
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```
         ||  Base Value          Compare Value
  Obs    ||  AEACN                AEACN
_____ ||  _____       _____
         ||
    1    ||  DOSE NOT CHANGED     NOT APPLICABLE
_____


_____
         ||  Reference ID
         ||  Base Value          Compare Value
  Obs    ||  AEREFID              AEREFID
_____ ||  _____                _____
         ||
    1    ||  10002
_____


_____
         ||  Is This Event a Dose Limiting Toxicity
         ||  Base Value          Compare Value
  Obs    ||  AEDLT                AEDLT
_____ ||  _                    _
         ||
    1    ||  N
_____


_____
         ||  Start Date/Time of Adverse Event
         ||  Base Value          Compare Value
  Obs    ||  AESTDTC              AESTDTC
_____ ||  _____       _____
         ||
    1    ||  2020-08-31T21:51     2021-08-14T00:00
_____


_____
         ||  End Date/Time of Adverse Event
         ||  Base Value          Compare Value
  Obs    ||  AEENDTC              AEENDTC
_____ ||  _____       _____
         ||
    1    ||  2020-08-31T22:51     2021-09-05T00:00
_____


_____
         ||  Study Identifier
         ||  Base Value          Compare Value
  Obs    ||  STUDYID              STUDYID
_____ ||  _____               _____
         ||
    1    ||  STUDY1               STUDY2
_____


_____
```

```
         ||  Subject Identifier for the Study
         ||  Base Value              Compare Value
  Obs    ||  SUBJID                  SUBJID
_____ ||  _____                _____
         ||
    1    ||  10004                   10001
_____
```

```
_____
         ||  Age
         ||        Base     Compare
  Obs    ||         AGE         AGE      Diff.     % Diff
_____ ||  _____    _____    _____    _____
         ||
    1    ||   29.0000     35.0000      6.0000     20.6897
_____
```

```
_____
         ||  Analysis Age
         ||        Base     Compare
  Obs    ||        AAGE        AAGE      Diff.     % Diff
_____ ||  _____    _____    _____    _____
         ||
    1    ||   29.0000     35.0000      6.0000     20.6897
_____
```

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

```
_____
         ||  Race
         ||  Base Value              Compare Value
  Obs    ||  RACE                    RACE
_____ ||  _____+       _____+
         ||
    1    ||  BLACK OR AFRICAN AME  WHITE
_____
```

```
_____
         ||  Pooled Race Group 1
         ||  Base Value              Compare Value
  Obs    ||  RACEGR1                 RACEGR1
_____ ||  _____+       _____+
         ||
    1    ||  Black/African Americ  White
_____
```

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```
_____
        ||  Pooled Race Group 1 (N)
        ||       Base     Compare
  Obs   ||    RACEGR1N    RACEGR1N      Diff.     % Diff
_____ ||  _____   _____   _____   _____
        ||
    1   ||     1.0000      2.0000     1.0000   100.0000
_____
```

```
_____
        ||  Analysis Race
        ||  Base Value              Compare Value
  Obs   ||  ARACE                   ARACE
_____ ||  _____+   _____+
        ||
    1   ||  Black or African Ame  White - White/Caucas
_____
```

```
_____
        ||  Analysis Race (N)
        ||       Base     Compare
  Obs   ||     ARACEN      ARACEN       Diff.     % Diff
_____ ||  _____   _____   _____   _____
        ||
    1   ||     6.0000      9.0000     3.0000    50.0000
_____
```

```
_____
        ||  Date of First Exposure to Treatment
        ||       Base     Compare
  Obs   ||     TRTSDT      TRTSDT       Diff.     % Diff
_____ ||  _____   _____   _____   _____
        ||
    1   ||  31AUG2020  10JUN2021   283.0000     1.2772
_____
```

```
_____
        ||  Time of First Exposure to Treatment
        ||       Base     Compare
  Obs   ||     TRTSTM      TRTSTM       Diff.     % Diff
_____ ||  _____   _____   _____   _____
        ||
    1   ||   20:51:00    14:31:00     -22800   -30.3757
_____
```

```
_____
        ||  Datetime of First Exposure to Treatment
        ||       Base     Compare
  Obs   ||    TRTSDTM     TRTSDTM       Diff.     % Diff
_____ ||  _____   _____   _____   _____
        ||
    1   ||  31AUG2020  10JUN2021   24428400     1.2760
_____
```

Compare of adae
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```
_____
          ||  Date of Last Exposure to Treatment
          ||     Base     Compare
     Obs  ||    TRTEDT     TRTEDT      Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
      1   ||  31AUG2020  10JUN2021   283.0000    1.2772
_____
```

```
_____
          ||  Time of Last Exposure to Treatment
          ||     Base     Compare
     Obs  ||    TRTETM     TRTETM      Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
      1   ||  21:51:00   14:32:00   -26340    -33.4859
_____
```

```
_____
          ||  Datetime of Last Exposure to Treatment
          ||     Base     Compare
     Obs  ||    TRTEDTM    TRTEDTM     Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
      1   ||  31AUG2020  10JUN2021  24424860    1.2758
_____
```

```
_____
          ||  Weight (kg) at Baseline
          ||     Base     Compare
     Obs  ||   WEIGHTBL   WEIGHTBL     Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
      1   ||   75.3000    53.4000   -21.9000   -29.0837
_____
```

```
_____
          ||  Height (cm) at Baseline
          ||     Base     Compare
     Obs  ||   HEIGHTBL   HEIGHTBL     Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
      1   ||  163.0000   164.0000    1.0000     0.6135
_____
```

```
_____
          ||  BMI (kg/m^2) at Baseline
          ||     Base     Compare
     Obs  ||    BMIBL      BMIBL       Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
      1   ||   28.3413    19.8543   -8.4870    -29.9459
_____
```

```
_____
        || Unique Subject Identifier
        || Base Value       Compare Value
   Obs  || usubjid          usubjid
_____ || _____  _____
        ||
    1   || 10004            10001
_____
```

```
_____
        || 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 1 for Period 01
        || Base Value       Compare Value
   Obs  || tr01pg1          TR01PG1
_____ || _____        _____
        ||
    1   ||                  Study Drug
_____
```

```
_____
        || Actual Pooled Treatment 1 for Period 01
        || Base Value       Compare Value
   Obs  || tr01ag1          TR01AG1
_____ || _____        _____
        ||
    1   ||                  Study Drug
_____
```

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

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```
_____


_____
           ||  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 1 for Period 01 (N)
           ||       Base     Compare
     Obs   ||     tr01pg1n   TR01PG1N    Diff.     % Diff
_____  ||   _____  _____  _____  _____
           ||
       1   ||          .    2.0000         .         .
_____


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


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

Compare of adae
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```
        1  ||            .      2.0000          .         .
    _____
```

```
    _____
             ||  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    03MAR23:14:31:02  03MAR23:14:31:02    98      9
        COMPC.ADAE   03MAR23:14:31:01  03MAR23:14:31:01   103      9



                             Variables Summary

        Number of Variables in Common: 95.
        Number of Variables in COMP.ADAE but not in COMPC.ADAE: 3.
        Number of Variables in COMPC.ADAE but not in COMP.ADAE: 8.
        Number of Variables with Differing Attributes: 35.
```

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

   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
   AGEGR1    Char       7  Pooled Age Group 1
   AGEGR1N   Num        8  Pooled Age Group 1 (N)
   PART      Char       6  Part
```

Listing of Common Variables with Differing Attributes

```
Variable  Dataset      Type  Length  Label

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       4  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      25  Dictionary-Derived Term
          COMPC.ADAE   Char      61  Dictionary-Derived Term
AEBODSYS  COMP.ADAE    Char      47  Body System or Organ Class
          COMPC.ADAE   Char      67  Body System or Organ Class
AELLT     COMP.ADAE    Char      29  Lowest Level Term
          COMPC.ADAE   Char      61  Lowest Level Term
AEHLT     COMP.ADAE    Char      57  High Level Term
          COMPC.ADAE   Char      79  High Level Term
AEHLGT    COMP.ADAE    Char      51  High Level Group Term
          COMPC.ADAE   Char      86  High Level Group Term
AESOC     COMP.ADAE    Char      47  Primary System Organ Class
          COMPC.ADAE   Char      67  Primary System Organ Class
AEOUT     COMP.ADAE    Char      26  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 O2 Name
          COMPC.ADAE  Char       53  Customized Query O2 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
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)
```

```
                              Observation Summary

                       Observation      Base   Compare

                       First Obs           1         1
                       First Unequal       1         1
                       Last  Unequal       9         9
                       Last  Obs           9         9


          Number of Observations in Common: 9.
          Total Number of Observations Read from COMP.ADAE: 9.
          Total Number of Observations Read from COMPC.ADAE: 9.


          Number of Observations with Some Compared Variables Unequal: 9.
          Number of Observations with All Compared Variables Equal: 0.


                            Values Comparison Summary

          Number of Variables Compared with All Observations Equal: 45.
          Number of Variables Compared with Some Observations Unequal: 50.
          Number of Variables with Missing Value Differences: 7.
          Total Number of Values which Compare Unequal: 353.
          Maximum Difference: 5440080.


                          Variables with Unequal Values
```

Variable	Type	Len1	Len2	Label	Ndif	MaxDif	MissDif
AESEQ	NUM	8	8	Sequence Number	6	1.000	0
AEREFID	CHAR	5	5	Reference ID	6		0
AESTDTC	CHAR	10	16	Start Date/Time of Adverse Event	8		0
ASTDT	NUM	8	8	Analysis Start Date	8	220	0
ASTDTF	CHAR	1	1	Analysis Start Date Imputation Flag	2		2
ASTDY	NUM	8	8	Analysis Start Relative Day	8	157	0
AEENDTC	CHAR	10	16	End Date/Time of Adverse Event	8		2
AENDT	NUM	8	8	Analysis End Date	8	147	2
AENDTF	CHAR	1	1	Analysis End Date Imputation Flag	4		4
AENDY	NUM	8	8	Analysis End Relative Day	8	154	2
ADURN	NUM	8	8	Analysis Duration (N)	7	9.000	4
ADURC	CHAR	4	12	Analysis Duration (C)	7		4
AETERM	CHAR	33	130	Reported Term for the Adverse Event	9		0
AEDECOD	CHAR	25	61	Dictionary-Derived Term	9		0
AEBODSYS	CHAR	47	67	Body System or Organ Class	5		0
AEBDSYCD	NUM	8	8	Body System or Organ Class Code	5	23066	0
AELLT	CHAR	29	61	Lowest Level Term	9		0
AELLTCD	NUM	8	8	Lowest Level Term Code	9	50886	0
AEPTCD	NUM	8	8	Preferred Term Code	9	50886	0
AEHLT	CHAR	57	79	High Level Term	9		0
AEHLTCD	NUM	8	8	High Level Term Code	9	66690	0
AEHLGT	CHAR	51	86	High Level Group Term	8		0
AEHLGTCD	NUM	8	8	High Level Group Term Code	8	26995	0
AESOC	CHAR	47	67	Primary System Organ Class	5		0
AESOCCD	NUM	8	8	Primary System Organ Class Code	5	23066	0
AEPATT	CHAR	14	14	Pattern of Adverse Event	6		0
AEOUT	CHAR	26	32	Outcome of Adverse Event	2		0

```
AEOUTN     NUM     8    8   Outcome of Adverse Event (N)              2    3.000        0
AEACN      CHAR   16   16   Action Taken with Study Treatment         2                 0
AETOXGR    CHAR    1    1   Standard Toxicity Grade                   6                 0
AETOXGRN   NUM     8    8   Standard Toxicity Grade (N)               6    1.000        0
SUBJID     CHAR    6    8   Subject Identifier for the Study          8                 0
AGE        NUM     8    8   Age                                       8   25.000        0
AAGE       NUM     8    8   Analysis Age                              8   25.000        0
SEX        CHAR    1    1   Sex                                       6                 0
ETHNIC     CHAR   22   22   Ethnicity                                 4                 0
ARACE      CHAR   41   41   Analysis Race                             9                 0
RACEGR1    CHAR   25   22   Pooled Race Group 1                       9                 0
RACEGR1N   NUM     8    8   Pooled Race Group 1 (N)                   9    3.000        0
WEIGHTBL   NUM     8    8   Weight (kg) at Baseline                   8   37.900        0
HEIGHTBL   NUM     8    8   Height (cm) at Baseline                   7   17.000        0
BMIBL      NUM     8    8   BMI (kg/m^2) at Baseline                  9   13.118        0
TRTSDT     NUM     8    8   Date of First Exposure to Treatment       8   63.000        0
TRTSTM     NUM     8    8   Time of First Exposure to Treatment       8   11880         0
TRTSDTM    NUM     8    8   Datetime of First Exposure to Treatment   8   5439960       0
TRTEDT     NUM     8    8   Date of Last Exposure to Treatment        8   63.000        0
TRTEDTM    NUM     8    8   Datetime of Last Exposure to Treatment    8   5440080       0
TRTETM     NUM     8    8   Time of Last Exposure to Treatment        8   11880         0
usubjid    CHAR   19   19   Unique Subject Identifier                 8                 0
AGEGR2     CHAR    7    7   Pooled Age Group 2                        9                 0
```

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```
                        Value Comparison Results for Variables


_____
            ||  Sequence Number
            ||     Base     Compare
     Obs    ||     AESEQ      AESEQ       Diff.      % Diff
_____    ||  _____   _____    _____    _____
            ||
      2     ||    1.0000     2.0000      1.0000    100.0000
      4     ||    1.0000     2.0000      1.0000    100.0000
      5     ||    2.0000     1.0000     -1.0000    -50.0000
      6     ||    1.0000     2.0000      1.0000    100.0000
      8     ||    2.0000     1.0000     -1.0000    -50.0000
      9     ||    2.0000     1.0000     -1.0000    -50.0000
_____



_____
            ||  Reference ID
            ||  Base Value          Compare Value
     Obs    ||  AEREFID             AEREFID
_____    ||  _____               _____
            ||
      2     ||  10001               10002
      3     ||  10001               10002
      4     ||  10002               10001
      6     ||  10001               10002
      8     ||  10002               10001
      9     ||  10002               10001
_____



_____
            ||  Start Date/Time of Adverse Event
            ||  Base Value          Compare Value
     Obs    ||  AESTDTC             AESTDTC
_____    ||  _____          _____
            ||
      1     ||  2021-04-25          2021-02-22
      2     ||  2021-03-02          2021-06
      3     ||  2021-02-25          2021-06-05
      5     ||  2021-06-05          2021-07-06
      6     ||  2021-02-22          2021-09-30
      7     ||  2021-07-06          2021-03-02
      8     ||  2021-06             2021-02-25
      9     ||  2021-09-30          2021-04-25
_____



_____
            ||  Analysis Start Date
            ||     Base     Compare
     Obs    ||     ASTDT      ASTDT       Diff.      % Diff
_____    ||  _____   _____    _____    _____
            ||
      1     ||  25APR2021  22FEB2021   -62.0000     -0.2768
      2     ||  02MAR2021  01JUN2021    91.0000      0.4073
```

```
 3  ||  25FEB2021  05JUN2021   100.0000    0.4477
 5  ||  05JUN2021  06JUL2021    31.0000    0.1382
 6  ||  22FEB2021  30SEP2021   220.0000    0.9851
 7  ||  06JUL2021  02MAR2021  -126.0000   -0.5608
 8  ||  01JUN2021  25FEB2021   -96.0000   -0.4280
 9  ||  30SEP2021  25APR2021  -158.0000   -0.7006
_____


_____
        ||  Analysis Start Date Imputation Flag
        ||  Base Value         Compare Value
   Obs  ||  ASTDTF             ASTDTF
_____ ||  _                  _
        ||
    2   ||                     D
    8   ||  D
_____


_____
        ||  Analysis Start Relative Day
        ||     Base    Compare
   Obs  ||    ASTDY     ASTDY      Diff.     % Diff
_____ ||  _____  _____   _____   _____
        ||
    1   ||   27.0000    5.0000   -22.0000   -81.4815
    2   ||    6.0000  104.0000    98.0000       1633
    3   ||    1.0000   65.0000    64.0000       6400
    5   ||   65.0000   76.0000    11.0000    16.9231
    6   ||    5.0000  162.0000   157.0000       3140
    7   ||   76.0000    6.0000   -70.0000   -92.1053
    8   ||  104.0000    1.0000  -103.0000   -99.0385
    9   ||  162.0000   27.0000  -135.0000   -83.3333
_____


_____
        ||  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
    5   ||  2021-06-18         2021-07-16
    6   ||  2021-07-06         2021-10
    7   ||  2021-07-16         2021-03-06
    8   ||  2021-07            2021-03-19
    9   ||  2021-10
_____


_____
        ||  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
 5  ||  18JUN2021  16JUL2021      28.0000       0.1247
 6  ||  06JUL2021  31OCT2021     117.0000       0.5208
 7  ||  16JUL2021  06MAR2021    -132.0000      -0.5873
 8  ||  31JUL2021  19MAR2021    -134.0000      -0.5958
 9  ||  31OCT2021              .            .            .
```

```
           ||  Analysis End Date Imputation Flag
           ||  Base Value              Compare Value
    Obs    ||  AENDTF                  AENDTF
  _____  ||  _                       _
           ||
     2     ||                          D
     6     ||                          D
     8     ||  D
     9     ||  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
     5     ||   78.0000     86.0000      8.0000      10.2564
     6     ||  139.0000    193.0000     54.0000      38.8489
     7     ||   86.0000     10.0000    -76.0000     -88.3721
     8     ||  164.0000     23.0000   -141.0000     -85.9756
     9     ||  193.0000           .            .            .
```

```
           ||  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
     5     ||   14.0000     11.0000     -3.0000     -21.4286
     6     ||  135.0000           .            .            .
     7     ||   11.0000      5.0000     -6.0000     -54.5455
     8     ||         .     23.0000           .            .
```

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```
         ||  Analysis Duration (C)
         ||  Base Value          Compare Value
   Obs   ||  ADURC               ADURC
_____ ||  ____                _____
         ||
    1    ||                      135d
    2    ||  5d
    3    ||  23d                 14d
    5    ||  14d                 11d
    6    ||  135d
    7    ||  11d                 5d
    8    ||                      23d
_____
```

```
_____
         ||  Reported Term for the Adverse Event
         ||  Base Value          Compare Value
   Obs   ||  AETERM              AETERM
_____ ||  _____+  _____+
         ||
    1    ||  WORSENING BACK PAIN  ANEMIA
    2    ||  URINARY TRACT INFECT H PYLORI GASTRITIS
    3    ||  BLISTER OF BUTTOCK W STREPTOCOCCAL PHARYN
    4    ||  STREPTOCOCCAL PHARYN UVULITIS
    5    ||  UVULITIS             ACUTE SINUSITIS
    6    ||  ANEMIA               ACUTE SINUSITIS
    7    ||  ACUTE SINUSITIS      URINARY TRACT INFECT
    8    ||  H PYLORI GASTRITIS   BLISTER OF BUTTOCK W
    9    ||  ACUTE SINUSITIS      WORSENING BACK PAIN
_____
```

```
_____
         ||  Dictionary-Derived Term
         ||  Base Value          Compare Value
   Obs   ||  AEDECOD             AEDECOD
_____ ||  _____+  _____+
         ||
    1    ||  Back pain            Anaemia
    2    ||  Urinary tract infect Helicobacter gastrit
    3    ||  Blister infected     Pharyngitis streptoc
    4    ||  Pharyngitis streptoc Uvulitis
    5    ||  Uvulitis             Acute sinusitis
    6    ||  Anaemia              Acute sinusitis
    7    ||  Acute sinusitis      Urinary tract infect
    8    ||  Helicobacter gastrit Blister infected
    9    ||  Acute sinusitis      Back pain
_____
```

```
_____
         ||  Body System or Organ Class
         ||  Base Value          Compare Value
   Obs   ||  AEBODSYS            AEBODSYS
_____ ||  _____+  _____+
         ||
    1    ||  Musculoskeletal and  Blood and lymphatic
    4    ||  Infections and infes Gastrointestinal dis
```

```
        5 ||  Gastrointestinal dis  Infections and infes
        6 ||  Blood and lymphatic   Infections and infes
        9 ||  Infections and infes  Musculoskeletal and
_____
```

```
_____
          ||  Body System or Organ Class Code
          ||       Base       Compare
     Obs  ||    AEBDSYCD     AEBDSYCD      Diff.      % Diff
_____   ||    _____     _____    _____    _____
          ||
        1 ||    10028395     10005329     -23066     -0.2300
        4 ||    10021881     10017947      -3934     -0.0393
        5 ||    10017947     10021881       3934      0.0393
        6 ||    10005329     10021881      16552      0.1654
        9 ||    10021881     10028395       6514      0.0650
_____
```

```
_____
          ||  Lowest Level Term
          ||  Base Value            Compare Value
     Obs  ||  AELLT                 AELLT
_____   ||  _____+   _____+
          ||
        1 ||  Back pain aggravated  Anemia
        2 ||  Urinary tract infect  Helicobacter pylori
        3 ||  Blister infected      Streptococcal pharyn
        4 ||  Streptococcal pharyn  Uvulitis
        5 ||  Uvulitis              Acute sinusitis
        6 ||  Anemia                Acute sinusitis
        7 ||  Acute sinusitis       Urinary tract infect
        8 ||  Helicobacter pylori   Blister infected
        9 ||  Acute sinusitis       Back pain aggravated
_____
```

```
_____
          ||  Lowest Level Term Code
          ||       Base       Compare
     Obs  ||     AELLTCD      AELLTCD      Diff.      % Diff
_____   ||    _____     _____    _____    _____
          ||
        1 ||    10048412     10002272     -46140     -0.4592
        2 ||    10046571     10051790       5219      0.0519
        3 ||    10005192     10042182      36990      0.3697
        4 ||    10042182     10051962       9780      0.0974
        5 ||    10051962     10001076     -50886     -0.5062
        6 ||    10002272     10001076      -1196     -0.0120
        7 ||    10001076     10046571      45495      0.4549
        8 ||    10051790     10005192     -46598     -0.4636
        9 ||    10001076     10048412      47336      0.4733
_____
```

```
_____
          ||  Preferred Term Code
          ||       Base       Compare
```

```
Obs ||      AEPTCD     AEPTCD       Diff.      % Diff
_____ ||    _____   _____    _____   _____
        ||
    1  ||   10003988   10002034      -1954     -0.0195
    2  ||   10046571   10054272       7701      0.0767
    3  ||   10005192   10034839      29647      0.2963
    4  ||   10034839   10051962      17123      0.1706
    5  ||   10051962   10001076     -50886     -0.5062
    6  ||   10002034   10001076   -958.0000  -0.009578
    7  ||   10001076   10046571      45495      0.4549
    8  ||   10054272   10005192     -49080     -0.4882
    9  ||   10001076   10003988       2912      0.0291
_____
```

```
_____
        ||  High Level Term
        ||  Base Value            Compare Value
Obs ||  AEHLT                 AEHLT
_____ ||  _____+   _____+
        ||
    1  ||  Musculoskeletal and   Anaemias NEC
    2  ||  Urinary tract infect  Helicobacter infecti
    3  ||  Skin structures and   Streptococcal infect
    4  ||  Streptococcal infect  Oral soft tissue dis
    5  ||  Oral soft tissue dis  Upper respiratory tr
    6  ||  Anaemias NEC          Upper respiratory tr
    7  ||  Upper respiratory tr  Urinary tract infect
    8  ||  Helicobacter infecti  Skin structures and
    9  ||  Upper respiratory tr  Musculoskeletal and
_____
```

```
_____
        ||  High Level Term Code
        ||       Base     Compare
Obs ||     AEHLTCD    AEHLTCD       Diff.      % Diff
_____ ||    _____   _____    _____   _____
        ||
    1  ||   10068757   10002067     -66690     -0.6623
    2  ||   10046577   10019375     -27202     -0.2708
    3  ||   10040786   10042180       1394      0.0139
    4  ||   10042180   10031015     -11165     -0.1112
    5  ||   10031015   10046309      15294      0.1525
    6  ||   10002067   10046309      44242      0.4423
    7  ||   10046309   10046577    268.0000   0.002668
    8  ||   10019375   10040786      21411      0.2137
    9  ||   10046309   10068757      22448      0.2234
_____
```

```
_____
        ||  High Level Group Term
        ||  Base Value            Compare Value
Obs ||  AEHLGT                AEHLGT
_____ ||  _____+   _____+
        ||
    1  ||  Musculoskeletal and   Anaemias nonhaemolyt
    2  ||  Infections - pathoge  Bacterial infectious
```

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```
3  ||  Infections - pathoge  Bacterial infectious
4  ||  Bacterial infectious  Oral soft tissue con
5  ||  Oral soft tissue con  Infections - pathoge
6  ||  Anaemias nonhaemolyt  Infections - pathoge
8  ||  Bacterial infectious  Infections - pathoge
9  ||  Infections - pathoge  Musculoskeletal and
```

```
          ||  High Level Group Term Code
          ||      Base      Compare
    Obs   ||    AEHLGTCD    AEHLGTCD     Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
     1    ||    10028393    10002086    -26307    -0.2623
     2    ||    10021879    10004018    -17861    -0.1782
     3    ||    10021879    10004018    -17861    -0.1782
     4    ||    10004018    10031013     26995     0.2698
     5    ||    10031013    10021879     -9134    -0.0911
     6    ||    10002086    10021879     19793     0.1979
     8    ||    10004018    10021879     17861     0.1785
     9    ||    10021879    10028393      6514     0.0650
```

```
          ||  Primary System Organ Class
          ||  Base Value          Compare Value
    Obs   ||  AESOC               AESOC
_____  ||  _____+   _____+
          ||
     1    ||  Musculoskeletal and  Blood and lymphatic
     4    ||  Infections and infes  Gastrointestinal dis
     5    ||  Gastrointestinal dis  Infections and infes
     6    ||  Blood and lymphatic   Infections and infes
     9    ||  Infections and infes  Musculoskeletal and
```

```
          ||  Primary System Organ Class Code
          ||      Base      Compare
    Obs   ||    AESOCCD     AESOCCD      Diff.     % Diff
_____  ||  _____  _____  _____  _____
          ||
     1    ||    10028395    10005329    -23066    -0.2300
     4    ||    10021881    10017947     -3934    -0.0393
     5    ||    10017947    10021881      3934     0.0393
     6    ||    10005329    10021881     16552     0.1654
     9    ||    10021881    10028395      6514     0.0650
```

```
          ||  Pattern of Adverse Event
          ||  Base Value          Compare Value
    Obs   ||  AEPATT              AEPATT
_____  ||  _____        _____
```

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```
      ||
   2  ||  SINGLE EPISODE        INTERMITTENT
   3  ||  SINGLE EPISODE        INTERMITTENT
   6  ||  INTERMITTENT          SINGLE EPISODE
   7  ||  INTERMITTENT          SINGLE EPISODE
   8  ||  INTERMITTENT          SINGLE EPISODE
   9  ||  SINGLE EPISODE        INTERMITTENT
```

_____

```
_____
        ||  Outcome of Adverse Event
        ||  Base Value          Compare Value
   Obs  ||  AEOUT               AEOUT
_____||  _____+  _____+
        ||
   1    ||  NOT RECOVERED/NOT RE  RECOVERED/RESOLVED
   9    ||  RECOVERED/RESOLVED    NOT RECOVERED/NOT RE
_____
```

```
_____
        ||  Outcome of Adverse Event (N)
        ||  Outcome of AE (N)
        ||      Base      Compare
   Obs  ||    AEOUTN      AEOUTN       Diff.     % Diff
_____||  _____    _____    _____   _____
        ||
   1    ||    3.0000      1.0000     -2.0000   -66.6667
   9    ||    1.0000      4.0000      3.0000   300.0000
_____
```

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

```
_____
        ||  Standard Toxicity Grade
        ||  Base Value          Compare Value
   Obs  ||  AETOXGR             AETOXGR
_____||  _                   _
        ||
   1    ||  2                   1
   2    ||  2                   1
   3    ||  2                   1
   7    ||  1                   2
   8    ||  1                   2
   9    ||  1                   2
_____
```

```
_____
        ||  Standard Toxicity Grade (N)
        ||     Base     Compare
   Obs  ||   AETOXGRN   AETOXGRN      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
     7  ||    1.0000     2.0000     1.0000   100.0000
     8  ||    1.0000     2.0000     1.0000   100.0000
     9  ||    1.0000     2.0000     1.0000   100.0000
_____
```

```
_____
        ||  Subject Identifier for the Study
        ||  Base Value        Compare Value
   Obs  ||  SUBJID            SUBJID
_____ ||  _____            _____
        ||
     1  ||  10008             10001
     2  ||  10006             10001
     3  ||  10007             10004
     5  ||  10004             10005
     6  ||  10001             10005
     7  ||  10005             10006
     8  ||  10001             10007
     9  ||  10005             10008
_____
```

```
_____
        ||  Age
        ||     Base     Compare
   Obs  ||      AGE        AGE       Diff.      % Diff
_____ ||  _____   _____   _____   _____
        ||
     1  ||   48.0000    32.0000   -16.0000   -33.3333
     2  ||   40.0000    32.0000    -8.0000   -20.0000
     3  ||   53.0000    54.0000     1.0000     1.8868
     5  ||   54.0000    57.0000     3.0000     5.5556
     6  ||   32.0000    57.0000    25.0000    78.1250
     7  ||   57.0000    40.0000   -17.0000   -29.8246
     8  ||   32.0000    53.0000    21.0000    65.6250
     9  ||   57.0000    48.0000    -9.0000   -15.7895
_____
```

```
_____
        ||  Analysis Age
        ||     Base     Compare
   Obs  ||     AAGE       AAGE       Diff.      % Diff
_____ ||  _____   _____   _____   _____
        ||
     1  ||   48.0000    32.0000   -16.0000   -33.3333
     2  ||   40.0000    32.0000    -8.0000   -20.0000
     3  ||   53.0000    54.0000     1.0000     1.8868
     5  ||   54.0000    57.0000     3.0000     5.5556
```

```
          6  ||    32.0000    57.0000    25.0000    78.1250
          7  ||    57.0000    40.0000   -17.0000   -29.8246
          8  ||    32.0000    53.0000    21.0000    65.6250
          9  ||    57.0000    48.0000    -9.0000   -15.7895
_____


_____
             ||  Sex
             ||  Base Value          Compare Value
       Obs   ||  SEX                 SEX
_____     ||  _                   _
             ||
          1  ||  F                   M
          2  ||  F                   M
          3  ||  F                   M
          5  ||  M                   F
          6  ||  M                   F
          8  ||  M                   F
_____


_____
             ||  Ethnicity
             ||  Base Value          Compare Value
       Obs   ||  ETHNIC              ETHNIC
_____     ||  _____+   _____+
             ||
          2  ||  HISPANIC OR LATINO  NOT HISPANIC OR LATI
          3  ||  NOT HISPANIC OR LATI  HISPANIC OR LATINO
          5  ||  HISPANIC OR LATINO  NOT HISPANIC OR LATI
          7  ||  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
          4  ||  WHITE - WHITE/CAUCAS  White - White/Caucas
          5  ||  WHITE - WHITE/CAUCAS  White - White/Caucas
          6  ||  WHITE - WHITE/CAUCAS  White - White/Caucas
          7  ||  WHITE - WHITE/CAUCAS  White - White/Caucas
          8  ||  WHITE - WHITE/CAUCAS  White - White/Caucas
          9  ||  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
4  ||   WHITE                White
5  ||   WHITE                White
6  ||   WHITE                White
7  ||   WHITE                White
8  ||   WHITE                White
9  ||   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
     4     ||    5.0000      2.0000     -3.0000    -60.0000
     5     ||    5.0000      2.0000     -3.0000    -60.0000
     6     ||    5.0000      2.0000     -3.0000    -60.0000
     7     ||    5.0000      2.0000     -3.0000    -60.0000
     8     ||    5.0000      2.0000     -3.0000    -60.0000
     9     ||    5.0000      2.0000     -3.0000    -60.0000
```

_____

```
           ||  Weight (kg) at Baseline
           ||    Base      Compare
    Obs    ||  WEIGHTBL    WEIGHTBL      Diff.      % Diff
 _____  ||  _____    _____    _____    _____
           ||
     1     ||  114.3000    113.3000     -1.0000     -0.8749
     2     ||   83.5000    113.3000     29.8000     35.6886
     3     ||   84.4000     78.1000     -6.3000     -7.4645
     5     ||   78.1000    116.0000     37.9000     48.5275
     6     ||  113.3000    116.0000      2.7000      2.3831
     7     ||  116.0000     83.5000    -32.5000    -28.0172
     8     ||  113.3000     84.4000    -28.9000    -25.5075
     9     ||  116.0000    114.3000     -1.7000     -1.4655
```

_____

```
           ||  Height (cm) at Baseline
           ||    Base      Compare
    Obs    ||  HEIGHTBL    HEIGHTBL      Diff.      % Diff
 _____  ||  _____    _____    _____    _____
           ||
     1     ||  167.0000    180.0000     13.0000      7.7844
     2     ||  174.0000    180.0000      6.0000      3.4483
     3     ||  163.0000    170.0000      7.0000      4.2945
     6     ||  180.0000    170.0000    -10.0000     -5.5556
     7     ||  170.0000    174.0000      4.0000      2.3529
     8     ||  180.0000    163.0000    -17.0000     -9.4444
```

Compare of adae
from- STUDY3
to- ISS

```
    9  ||    170.0000   167.0000    -3.0000    -1.7647

_____
```

```
_____
       ||  BMI (kg/m^2) at Baseline
       ||     Base     Compare
  Obs  ||    BMIBL      BMIBL      Diff.      % Diff
_____ ||  _____   _____   _____   _____
       ||
    1  ||    40.9800    34.9691    -6.0109   -14.6678
    2  ||    27.5800    34.9691     7.3891    26.7916
    3  ||    31.7700    27.0242    -4.7458   -14.9379
    4  ||    27.0200    27.0242   0.004221     0.0156
    5  ||    27.0200    40.1384    13.1184    48.5507
    6  ||    34.9700    40.1384     5.1684    14.7795
    7  ||    40.1400    27.5796   -12.5604   -31.2915
    8  ||    34.9700    31.7663    -3.2037    -9.1612
    9  ||    40.1400    40.9839     0.8439     2.1024
_____
```

```
_____
       ||  Date of First Exposure to Treatment
       ||     Base     Compare
  Obs  ||    TRTSDT     TRTSDT     Diff.      % Diff
_____ ||  _____   _____   _____   _____
       ||
    1  ||  30MAR2021  18FEB2021   -40.0000    -0.1788
    2  ||  25FEB2021  18FEB2021    -7.0000    -0.0313
    3  ||  25FEB2021  02APR2021    36.0000     0.1612
    5  ||  02APR2021  22APR2021    20.0000     0.0894
    6  ||  18FEB2021  22APR2021    63.0000     0.2821
    7  ||  22APR2021  25FEB2021   -56.0000    -0.2501
    8  ||  18FEB2021  25FEB2021     7.0000     0.0313
    9  ||  22APR2021  30MAR2021   -23.0000    -0.1027
_____
```

```
_____
       ||  Time of First Exposure to Treatment
       ||     Base     Compare
  Obs  ||    TRTSTM     TRTSTM     Diff.      % Diff
_____ ||  _____   _____   _____   _____
       ||
    1  ||   11:20:00    9:08:00     -7920    -19.4118
    2  ||   10:31:00    9:08:00     -4980    -13.1537
    3  ||   11:38:00    8:20:00    -11880    -28.3668
    5  ||    8:20:00    8:14:00  -360.0000    -1.2000
    6  ||    9:08:00    8:14:00     -3240     -9.8540
    7  ||    8:14:00   10:31:00      8220     27.7328
    8  ||    9:08:00   11:38:00      9000     27.3723
    9  ||    8:14:00   11:20:00     11160     37.6518
_____
```

```
_____
       ||  Datetime of First Exposure to Treatment
       ||     Base     Compare
```

Compare of adae
from- STUDY3
to- ISS

```
           Obs ||   TRTSDTM    TRTSDTM     Diff.     % Diff
           _____ ||   _____   _____   _____   _____
                   ||
             1 ||   30MAR2021  18FEB2021  -3463920   -0.1792
             2 ||   25FEB2021  18FEB2021   -609780   -0.0316
             3 ||   25FEB2021  02APR2021   3098520    0.1606
             5 ||   02APR2021  22APR2021   1727640    0.0894
             6 ||   18FEB2021  22APR2021   5439960    0.2820
             7 ||   22APR2021  25FEB2021  -4830180   -0.2497
             8 ||   18FEB2021  25FEB2021    613800    0.0318
             9 ||   22APR2021  30MAR2021  -1976040   -0.1021
           _____


           _____
                   || Date of Last Exposure to Treatment
                   ||    Base     Compare
           Obs ||   TRTEDT     TRTEDT      Diff.     % Diff
           _____ ||   _____   _____   _____   _____
                   ||
             1 ||   30MAR2021  18FEB2021  -40.0000   -0.1788
             2 ||   25FEB2021  18FEB2021   -7.0000   -0.0313
             3 ||   25FEB2021  02APR2021   36.0000    0.1612
             5 ||   02APR2021  22APR2021   20.0000    0.0894
             6 ||   18FEB2021  22APR2021   63.0000    0.2821
             7 ||   22APR2021  25FEB2021  -56.0000   -0.2501
             8 ||   18FEB2021  25FEB2021    7.0000    0.0313
             9 ||   22APR2021  30MAR2021  -23.0000   -0.1027
           _____


           _____
                   || Datetime of Last Exposure to Treatment
                   ||    Base     Compare
           Obs ||   TRTEDTM    TRTEDTM     Diff.     % Diff
           _____ ||   _____   _____   _____   _____
                   ||
             1 ||   30MAR2021  18FEB2021  -3463920   -0.1792
             2 ||   25FEB2021  18FEB2021   -609780   -0.0316
             3 ||   25FEB2021  02APR2021   3098520    0.1606
             5 ||   02APR2021  22APR2021   1727760    0.0894
             6 ||   18FEB2021  22APR2021   5440080    0.2820
             7 ||   22APR2021  25FEB2021  -4830300   -0.2497
             8 ||   18FEB2021  25FEB2021    613800    0.0318
             9 ||   22APR2021  30MAR2021  -1976160   -0.1021
           _____


           _____
                   || Time of Last Exposure to Treatment
                   ||    Base     Compare
           Obs ||   TRTETM     TRTETM      Diff.     % Diff
           _____ ||   _____   _____   _____   _____
                   ||
             1 ||   12:20:00   10:08:00     -7920  -17.8378
             2 ||   11:31:00   10:08:00     -4980  -12.0116
             3 ||   12:38:00    9:20:00    -11880  -26.1214
             5 ||    9:20:00    9:16:00  -240.0000   -0.7143
             6 ||   10:08:00    9:16:00     -3120   -8.5526
```

Compare of adae
from- STUDY3
to- ISS

```
7  ||    9:16:00   11:31:00      8100    24.2806
8  ||   10:08:00   12:38:00      9000    24.6711
9  ||    9:16:00   12:20:00     11040    33.0935
```
_____


```
_____
       ||  Unique Subject Identifier
       ||  Base Value        Compare Value
  Obs  ||  usubjid           usubjid
_____||  _____  _____
       ||
   1   ||  10008             10001
   2   ||  10006             10001
   3   ||  10007             10004
   5   ||  10004             10005
   6   ||  10001             10005
   7   ||  10005             10006
   8   ||  10001             10007
   9   ||  10005             10008
_____
```


```
_____
       ||  Pooled Age Group 2
       ||  Base Value        Compare Value
  Obs  ||  AGEGR2            AGEGR2
_____||  _____            _____
       ||
   1   ||  19-64             19 - 64
   2   ||  19-64             19 - 64
   3   ||  19-64             19 - 64
   4   ||  19-64             19 - 64
   5   ||  19-64             19 - 64
   6   ||  19-64             19 - 64
   7   ||  19-64             19 - 64
   8   ||  19-64             19 - 64
   9   ||  19-64             19 - 64
_____
```