Compare of adae
from- STUDY1
to- ISS

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


                       Data Set Summary

      Dataset          Created          Modified   NVar    NObs

      COMP.ADAE    03MAR23:15:17:51  03MAR23:15:17:51   107      12
      COMPC.ADAE   03MAR23:15:17:48  03MAR23:15:17:48   104      12


                       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: 6.
      Number of Variables with Differing Attributes: 6.
```

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

        Variable  Type  Length  Label

        CQO3NAM   Char      35  Customized Query O3 Name
        AGEGR3    Char      25  Pooled Age Group 3
        AGEGR3N   Num        8  Pooled Age Group 3 (N)
        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)
        CQO1NAM   Char       1  Customized Query O1 Name
        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)
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
```

```
                       Observation Summary


                Observation      Base   Compare


                First Obs           1         1
                First Unequal       1         1
                Last  Unequal      11        11
                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: 5.
   Number of Observations with All Compared Variables Equal: 7.


                     Values Comparison Summary

   Number of Variables Compared with All Observations Equal: 97.
   Number of Variables Compared with Some Observations Unequal: 1.
   Total Number of Values which Compare Unequal: 5.
   Maximum Difference: 0.


                   Variables with Unequal Values


  Variable  Type  Len1 Len2   Label               Ndif   MaxDif


  ADURC     CHAR   11   12    Analysis Duration (C)   5




                 Value Comparison Results for Variables


    _____
              ||  Analysis Duration (C)
              ||  Base Value          Compare Value
         Obs  ||  ADURC                ADURC
    _____   ||  _____          _____
              ||
          1  ||  1h 0m                0d 1h 0m
          2  ||  5h 31m               0d 5h 31m
          5  ||  0h 25m               0d 0h 25m
          8  ||  1h 42m               0d 1h 42m
         11  ||  1h 1m                0d 1h 1m
    _____
```

Compare of adae
from- STUDY2
to- ISS

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


                               Data Set Summary

        Dataset            Created          Modified   NVar    NObs


        COMP.ADAE    03MAR23:15:17:51  03MAR23:15:17:51    107       1
        COMPC.ADAE   03MAR23:15:17:48  03MAR23:15:17:48    104       1



                               Variables Summary

        Number of Variables in Common: 95.
        Number of Variables in COMP.ADAE but not in COMPC.ADAE: 12.
        Number of Variables in COMPC.ADAE but not in COMP.ADAE: 9.
        Number of Variables with Differing Attributes: 9.
```

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

          Variable  Type  Length  Label

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


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

          Variable  Type  Length  Label

          TRTP      Char     26  Planned Treatment
          TRTPN     Num       8  Planned Treatment (N)
          TRTA      Char     26  Actual Treatment
          TRTAN     Num       8  Actual Treatment (N)
          AEACNOTH  Char     20  Other Action Taken
          AEREFID   Char      5  Reference ID
          AESRECHA  Char      2  Event(s) Recur After Rechallenge
          AEDLT     Char      1  Is This Event a Dose Limiting Toxicity
          PART      Char      6  Part


              Listing of Common Variables with Differing Attributes

          Variable  Dataset       Type  Length  Label

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

Compare of adae
from- STUDY2
to- ISS

```
                            Observation Summary


                    Observation      Base  Compare


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


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


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


                          Values Comparison Summary

       Number of Variables Compared with All Observations Equal: 93.
       Number of Variables Compared with Some Observations Unequal: 2.
       Total Number of Values which Compare Unequal: 2.
       Maximum Difference: 1.


                         Variables with Unequal Values


    Variable  Type  Len1 Len2  Label                     Ndif    MaxDif


    AREL      CHAR    11   11   Analysis Causality           1
    REGION1N  NUM      8    8   Geographic Region 1 (N)      1     1.000




                       Value Comparison Results for Variables


          _____
                    ||  Analysis Causality
                    ||  Base Value            Compare Value
            Obs ||  AREL                  AREL
          _____  ||  _____            _____
                    ||
              1  ||  Not Related           Not related
          _____




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

Compare of adae
from- STUDY3
to- ISS

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


                      Data Set Summary

   Dataset          Created          Modified   NVar    NObs

   COMP.ADAE    03MAR23:15:17:52  03MAR23:15:17:52    98       9
   COMPC.ADAE   03MAR23:15:17:48  03MAR23:15:17:48   104       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: 9.
 Number of Variables with Differing Attributes: 23.
```

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


            Variable  Type  Length  Label


            CQO3NAM   Char       1  Customized Query O3 Name
            CQO4NAM   Char       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)
          AREL      Char      11  Analysis Causality
          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



                              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: 89.
          Number of Variables Compared with Some Observations Unequal: 6.
          Total Number of Values which Compare Unequal: 46.
          Maximum Difference: 3.



                              Variables with Unequal Values


Variable  Type  Len1 Len2  Label                        Compare Label             Ndif   MaxDif


AEOUTN    NUM      8    8   Outcome of Adverse Event (N)  Outcome of AE (N)           1    1.000
ARACE     CHAR    41   41   Analysis Race                 Analysis Race               9
RACEGR1   CHAR    25   22   Pooled Race Group 1           Pooled Race Group 1         9
RACEGR1N  NUM      8    8   Pooled Race Group 1 (N)       Pooled Race Group 1 (N)     9    3.000
BMIBL     NUM      8    8   BMI (kg/m^2) at Baseline      BMI (kg/m^2) at Baseline    9    0.0042
AGEGR2    CHAR     7    7   Pooled Age Group 2            Pooled Age Group 2          9
```

Compare of adae
from- STUDY3
to- ISS

```
            Value Comparison Results for Variables


_____
          ||  Outcome of Adverse Event (N)
          ||  Outcome of AE (N)
          ||       Base      Compare
    Obs   ||     AEOUTN       AEOUTN      Diff.     % Diff
_____   ||   _____    _____   _____   _____
          ||
      9   ||     3.0000       4.0000     1.0000    33.3333
_____



_____
          ||  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
```
_____


```
_____
           ||  BMI (kg/m^2) at Baseline
           ||      Base     Compare
      Obs  ||     BMIBL      BMIBL      Diff.      % Diff
_____   ||  _____   _____   _____   _____
           ||
        1  ||    34.9700    34.9691  -0.000864  -0.002471
        2  ||    34.9700    34.9691  -0.000864  -0.002471
        3  ||    27.0200    27.0242   0.004221     0.0156
        4  ||    27.0200    27.0242   0.004221     0.0156
        5  ||    40.1400    40.1384  -0.001592  -0.003965
        6  ||    40.1400    40.1384  -0.001592  -0.003965
        7  ||    27.5800    27.5796  -0.000399  -0.001447
        8  ||    31.7700    31.7663  -0.003656    -0.0115
        9  ||    40.9800    40.9839   0.003900   0.009518
_____
```


```
_____
           ||  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
_____
```