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    O3MAR23:14:21:31  O3MAR23:14:21:31   108     12
    COMPC.ADAE   O3MAR23:14:21:30  O3MAR23:14:21:30   103     12


                        Variables Summary

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

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


                          Variable   Type   Length   Label


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



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


                          Variable   Type   Length   Label


                          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


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

```
tr01pg2   COMP.ADAE    Char      21
          COMPC.ADAE   Char      21   Planned Pooled Treatment 2 for Period 01
tr01ag2   COMP.ADAE    Char      21
          COMPC.ADAE   Char      21   Actual Pooled Treatment 2 for Period 01
trt01pn   COMP.ADAE    Num        8
          COMPC.ADAE   Num        8   Planned Treatment for Period 01 (N)
trt01an   COMP.ADAE    Num        8
          COMPC.ADAE   Num        8   Actual Treatment for Period 01 (N)
tr01pg1n  COMP.ADAE    Num        8
          COMPC.ADAE   Num        8   Planned Pooled Trt 1 for Period 01 (N)
tr01pg2n  COMP.ADAE    Num        8
          COMPC.ADAE   Num        8   Planned Pooled Trt 2 for Period 01 (N)
tr01ag1n  COMP.ADAE    Num        8
          COMPC.ADAE   Num        8   Actual Pooled Trt 1 for Period 01 (N)
tr01ag2n  COMP.ADAE    Num        8
          COMPC.ADAE   Num        8   Actual Pooled Trt 2 for Period 01 (N)
```

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```
                         Observation Summary

                 Observation      Base   Compare

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


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


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


                      Values Comparison Summary

      Number of Variables Compared with All Observations Equal: 42.
      Number of Variables Compared with Some Observations Unequal: 55.
      Number of Variables with Missing Value Differences: 5.
      Total Number of Values which Compare Unequal: 391.
      Maximum Difference: 1144800.


                    Variables with Unequal Values
```

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

```
AEENDTC    CHAR    16    16    End Date/Time of Adverse Event          9                    0
SUBJID     CHAR     8     8    Subject Identifier for the Study        8                    0
AGE        NUM      8     8    Age                                     8      16.000        0
AAGE       NUM      8     8    Analysis Age                            8      16.000        0
AGEGR1     CHAR     4     7    Pooled Age Group 1                     12                    0
SEX        CHAR     1     1    Sex                                     4                    0
TRTSDT     NUM      8     8    Date of First Exposure to Treatment     7       3.000        0
TRTSTM     NUM      8     8    Time of First Exposure to Treatment     8      19440         0
TRTSDTM    NUM      8     8    Datetime of First Exposure to Treatment 8     239760         0
TRTEDT     NUM      8     8    Date of Last Exposure to Treatment      8       3.000        0
TRTETM     NUM      8     8    Time of Last Exposure to Treatment      8      82560         0
TRTEDTM    NUM      8     8    Datetime of Last Exposure to Treatment  8     239820         0
WEIGHTBL   NUM      8     8    Weight (kg) at Baseline                 8      41.100        0
HEIGHTBL   NUM      8     8    Height (cm) at Baseline                 8      20.000        0
BMIBL      NUM      8     8    BMI (kg/m^2) at Baseline                8       8.257        0
trt01p     CHAR    26    26                                            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
CQO2NAM    CHAR    53    53    Customized Query O2 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
```

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

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

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

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

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

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

```
_____
        ||  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
```

```
_____  ||  _____+  _____+
          ||
       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
_____
```

Obs		Primary System Organ Class Code			
		Base	Compare		
		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

Obs		Analysis Start Date			
		Base	Compare		
		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

Obs		Analysis Start Time			
		Base	Compare		
		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        .          .         .
_____
```

```
_____
     ||  Analysis Start Date/Time
     ||      Base     Compare
Obs  ||    ASTDTM     ASTDTM     Diff.     % Diff
_____||  _____  _____  _____  _____
     ||
  3  ||  01SEP2020        .          .         .
  4  ||  02SEP2020        .          .         .
  5  ||  03SEP2020  01SEP2020   -196620   -0.0103
  6  ||        .    01SEP2020        .         .
  7  ||  01SEP2020  14SEP2020   1144800    0.0598
  8  ||        .    02SEP2020        .         .
  9  ||        .    14SEP2020        .         .
 11  ||  14SEP2020  03SEP2020   -932880   -0.0487
 12  ||  14SEP2020        .          .         .
_____
```

```
_____
     ||  Analysis Start Relative Day
     ||      Base     Compare
Obs  ||     ASTDY      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
_____
```

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

```
_____
        ||  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
```

Compare of adae
from- STUDY1
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
```

Compare of adae
from- STUDY1
to- ISS

```
 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
```
_____

```
_____
       ||  Pooled Age Group 1
       ||  Base Value        Compare Value
  Obs  ||  AGEGR1            AGEGR1
_____||  ____              _____
       ||
   1   ||  <=70              <55
   2   ||  <=70              <55
   3   ||  <=70              <55
   4   ||  <=70              <55
   5   ||  <=70              <55
   6   ||  <=70              <55
   7   ||  <=70              <55
   8   ||  <=70              <55
   9   ||  <=70              <55
  10   ||  <=70              <55
  11   ||  <=70              <55
  12   ||  <=70              <55
_____
```

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

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

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

Compare of adae
from- STUDY1
to- ISS

```
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
_____
```


```
_____
         ||  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
```

Compare of adae
from- STUDY1
to- ISS

```
         ||      Base    Compare
         ||     BMIBL     BMIBL      Diff.     % Diff
  Obs    ||    _____    _____    _____    _____
_____  ||
         ||
    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
_____  ||  _____           _____
```

Compare of adae
from- STUDY1
to- ISS

```
        ||
   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 &
_____
```

```
_____
        ||  Actual Pooled Treatment 2 for Period 01
        ||  Base Value           Compare Value
  Obs   ||  tr01ag2               TR01AG2
_____ ||  _____+   _____+
        ||
   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
_____
```

Compare of adae
from- STUDY1
to- ISS

```
_____
        || Planned Pooled Trt 1 for Period 01 (N)
        ||   Base    Compare
   Obs ||  tr01pg1n   TR01PG1N     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   TR01PG2N     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 Pooled Trt 1 for Period 01 (N)
        ||   Base    Compare
   Obs ||  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
_____
```

```
_____
        || Actual Pooled Trt 2 for Period 01 (N)
        ||   Base    Compare
   Obs ||  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
_____
```

```
_____
        || Customized Query 02 Name
        || Base Value         Compare Value
   Obs || CQ02NAM             CQ02NAM
_____ || _____+  _____+
        ||
```

Compare of adae
from- STUDY1
to- ISS

```
  5  ||  Infusion-related rea
 11  ||                              Infusion-related rea
_____
```

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    03MAR23:14:21:31  03MAR23:14:21:31   107       1
   COMPC.ADAE   03MAR23:14:21:30  03MAR23:14:21:30   103       1



                      Variables Summary

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

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


          Variable  Type  Length  Label

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


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


          Variable  Type  Length  Label

          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

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

```
           COMPC.ADAE  Char     17  Geographic Region 1
AGEGR1     COMP.ADAE   Char      5  Pooled Age Group 1
           COMPC.ADAE  Char      7  Pooled Age Group 1
trt01p     COMP.ADAE   Char     26
           COMPC.ADAE  Char     26  Planned Treatment for Period 01
trt01a     COMP.ADAE   Char     26
           COMPC.ADAE  Char     26  Actual Treatment for Period 01
tr01pg1    COMP.ADAE   Char     10
           COMPC.ADAE  Char     10  Planned Pooled Treatment 1 for Period 01
tr01ag1    COMP.ADAE   Char     10
           COMPC.ADAE  Char     10  Actual Pooled Treatment 1 for Period 01
tr01pg2    COMP.ADAE   Char     21
           COMPC.ADAE  Char     21  Planned Pooled Treatment 2 for Period 01
tr01ag2    COMP.ADAE   Char     21
           COMPC.ADAE  Char     21  Actual Pooled Treatment 2 for Period 01
trt01pn    COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Planned Treatment for Period 01 (N)
trt01an    COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Actual Treatment for Period 01 (N)
tr01pg1n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Planned Pooled Trt 1 for Period 01 (N)
tr01pg2n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Planned Pooled Trt 2 for Period 01 (N)
tr01ag1n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Actual Pooled Trt 1 for Period 01 (N)
tr01ag2n   COMP.ADAE   Num       8
           COMPC.ADAE  Num       8  Actual Pooled Trt 2 for Period 01 (N)
```

```
                        Observation Summary

                 Observation      Base   Compare

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

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


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


                     Values Comparison Summary

      Number of Variables Compared with All Observations Equal: 91.
      Number of Variables Compared with Some Observations Unequal: 3.
      Total Number of Values which Compare Unequal: 3.
      Maximum Difference: 1.


                    Variables with Unequal Values

      Variable   Type  Len1 Len2   Label                 Ndif    MaxDif


      REGION1N   NUM      8    8    Geographic Region 1 (N)   1    1.000
      AGEGR1     CHAR     5    7    Pooled Age Group 1        1
      AGEGR1N    NUM      8    8    Pooled Age Group 1 (N)    1    1.000
```

Compare of adae
from- STUDY2
to- ISS

Value Comparison Results for Variables

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

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

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

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    03MAR23:14:21:31  03MAR23:14:21:31    100       9
     COMPC.ADAE   03MAR23:14:21:30  03MAR23:14:21:30    103       9



                           Variables Summary

      Number of Variables in Common: 97.
      Number of Variables in COMP.ADAE but not in COMPC.ADAE: 3.
      Number of Variables in COMPC.ADAE but not in COMP.ADAE: 6.
      Number of Variables with Differing Attributes: 37.
```

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
     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
```

Compare of adae
from- STUDY3
to- ISS

```
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
AGEGR1    COMP.ADAE   Char     5   Pooled Age Group 1
          COMPC.ADAE  Char     7   Pooled Age Group 1
AGEGR2    COMP.ADAE   Char    19   Pooled Age Group 2
          COMPC.ADAE  Char     7   Pooled Age Group 2
RACE      COMP.ADAE   Char    25   Race
          COMPC.ADAE  Char    41   Race
RACEGR1   COMP.ADAE   Char    25   Pooled Race Group 1
          COMPC.ADAE  Char    22   Pooled Race Group 1
SCRNFL    COMP.ADAE   Char     1   Screening Population Flag
          COMPC.ADAE  Char     1   Screened Population Flag
trt01p    COMP.ADAE   Char    26
          COMPC.ADAE  Char    26   Planned Treatment for Period 01
trt01a    COMP.ADAE   Char    26
          COMPC.ADAE  Char    26   Actual Treatment for Period 01
tr01pg1   COMP.ADAE   Char    10
          COMPC.ADAE  Char    10   Planned Pooled Treatment 1 for Period 01
tr01ag1   COMP.ADAE   Char    10
          COMPC.ADAE  Char    10   Actual Pooled Treatment 1 for Period 01
tr01pg2   COMP.ADAE   Char    21
          COMPC.ADAE  Char    21   Planned Pooled Treatment 2 for Period 01
tr01ag2   COMP.ADAE   Char    21
          COMPC.ADAE  Char    21   Actual Pooled Treatment 2 for Period 01
trt01pn   COMP.ADAE   Num      8
          COMPC.ADAE  Num      8   Planned Treatment for Period 01 (N)
trt01an   COMP.ADAE   Num      8
          COMPC.ADAE  Num      8   Actual Treatment for Period 01 (N)
tr01pg1n  COMP.ADAE   Num      8
          COMPC.ADAE  Num      8   Planned Pooled Trt 1 for Period 01 (N)
tr01pg2n  COMP.ADAE   Num      8
          COMPC.ADAE  Num      8   Planned Pooled Trt 2 for Period 01 (N)
tr01ag1n  COMP.ADAE   Num      8
          COMPC.ADAE  Num      8   Actual Pooled Trt 1 for Period 01 (N)
tr01ag2n  COMP.ADAE   Num      8
          COMPC.ADAE  Num      8   Actual Pooled Trt 2 for Period 01 (N)
```

Compare of adae
from- STUDY3
to- ISS

```
                            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: 88.
          Number of Variables Compared with Some Observations Unequal: 9.
          Total Number of Values which Compare Unequal: 71.
          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
      AGEGR1    CHAR    5    7    Pooled Age Group 1         Pooled Age Group 1        9
      AGEGR1N   NUM     8    8    Pooled Age Group 1 (N)     Pooled Age Group 1 (N)    7    1.000
      AGEGR2    CHAR   19    7    Pooled Age Group 2         Pooled Age Group 2        9
      AGEGR2N   NUM     8    8    Pooled Age Group 2 (N)     Pooled Age Group 2 (N)    9    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
```

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
_____
```

```
_____
         ||  Pooled Age Group 1
         ||  Base Value         Compare Value
   Obs   ||  AGEGR1             AGEGR1
_____  ||  _____             _____
         ||
    1    ||  19-64              <55
    2    ||  19-64              <55
    3    ||  19-64              <55
    4    ||  19-64              <55
    5    ||  19-64              55 - 64
    6    ||  19-64              55 - 64
    7    ||  19-64              <55
    8    ||  19-64              <55
    9    ||  19-64              <55
_____
```

```
_____
         ||  Pooled Age Group 1 (N)
         ||     Base      Compare
   Obs   ||   AGEGR1N     AGEGR1N      Diff.      % Diff
_____  ||  _____  _____  _____  _____
         ||
    1    ||    2.0000    1.0000   -1.0000   -50.0000
    2    ||    2.0000    1.0000   -1.0000   -50.0000
    3    ||    2.0000    1.0000   -1.0000   -50.0000
    4    ||    2.0000    1.0000   -1.0000   -50.0000
    7    ||    2.0000    1.0000   -1.0000   -50.0000
    8    ||    2.0000    1.0000   -1.0000   -50.0000
    9    ||    2.0000    1.0000   -1.0000   -50.0000
_____
```

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

Compare of adae
from- STUDY3
to- ISS

```
                5  ||  Adult (18-64 years)   19 - 64
                6  ||  Adult (18-64 years)   19 - 64
                7  ||  Adult (18-64 years)   19 - 64
                8  ||  Adult (18-64 years)   19 - 64
                9  ||  Adult (18-64 years)   19 - 64
_____
```

```
_____
          ||  Pooled Age Group 2 (N)
          ||      Base      Compare
   Obs    ||    AGEGR2N     AGEGR2N      Diff.     % Diff
_____  ||   _____    _____    _____   _____
          ||
     1    ||     1.0000      2.0000      1.0000   100.0000
     2    ||     1.0000      2.0000      1.0000   100.0000
     3    ||     1.0000      2.0000      1.0000   100.0000
     4    ||     1.0000      2.0000      1.0000   100.0000
     5    ||     1.0000      2.0000      1.0000   100.0000
     6    ||     1.0000      2.0000      1.0000   100.0000
     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
_____
```

```
_____
          ||  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
_____
```