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    03MAR23:13:38:56  03MAR23:13:38:56   108      12
COMPC.ADAE   03MAR23:13:38:56  03MAR23:13:38:56   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.
```

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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)
AGEGR6	Char	4	Pooled Age Group 6
AGEGR6N	Num	8	Pooled Age Group 6 (N)
AGEGR7	Char	7	Pooled Age Group 7
AGEGR7N	Num	8	Pooled Age Group 7 (N)

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

Variable	Type	Length	Label
old_subj	Char	13	Unique Subject Identifier
TRTP	Char	26	Planned Treatment
TRTPN	Num	8	Planned Treatment (N)
TRTA	Char	26	Actual Treatment
TRTAN	Num	8	Actual Treatment (N)
CQ01NAM	Char	1	Customized Query 01 Name

Listing of Common Variables with Differing Attributes

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

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

```
                               Observation Summary

                        Observation      Base  Compare

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


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


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


                             Values Comparison Summary

              Number of Variables Compared with All Observations Equal: 42.
              Number of Variables Compared with Some Observations Unequal: 55.
              Number of Variables with Missing Value Differences: 13.
              Total Number of Values which Compare Unequal: 443.
              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
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```
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                                               6                4
trt01a    CHAR   26   26                                               6                4
tr01pg1   CHAR   10   10                                               4                0
tr01ag1   CHAR   10   10                                               4                0
tr01pg2   CHAR   21   21                                              12               12
tr01ag2   CHAR   21   21                                              12               12
trt01pn   NUM     8    8                                              12     0          12
trt01an   NUM     8    8                                              12     0          12
tr01pg1n  NUM     8    8                                               4     1.000      0
tr01pg2n  NUM     8    8                                              12     0          12
tr01ag1n  NUM     8    8                                               4     1.000      0
tr01ag2n  NUM     8    8                                              12     0          12
CQ02NAM   CHAR   53   53   Customized Query 02 Name                    2                2
```

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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

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

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

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

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

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

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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 AESOCCD	Compare AESOCCD	Diff.	% Diff
Obs					
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 ASTDT	Compare ASTDT	Diff.	% Diff
Obs					
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 ASTTM	Compare ASTTM	Diff.	% Diff
Obs					
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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```
  11  ||      2.0000     61.0000     59.0000         2950
_____
```

```
_____
     ||  Analysis Duration (C)
     ||  Base Value          Compare Value
 Obs ||  ADURC               ADURC
_____||  _____          _____
     ||
   3 ||  0d 0h 25m           2d
   4 ||  0d 1h 42m           1d
   5 ||  0d 1h 1m            0d 0h 25m
   6 ||  1d                  4d
   7 ||  4d                  2d
   8 ||  2d                  0d 1h 42m
  11 ||  2d                  0d 1h 1m
_____
```

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

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

```
_____
     ||  End Date/Time of Adverse Event
     ||  Base Value          Compare Value
 Obs ||  AEENDTC             AEENDTC
```

```
_____  ||  _____      _____
          ||
       3  ||  2020-09-01T10:40    2020-09-04
       4  ||  2020-09-02T20:30    2020-09-03T20:30
       5  ||  2020-09-03T17:53    2020-09-01T10:40
       6  ||  2020-09-03T20:30    2020-09-04
       7  ||  2020-09-04          2020-09-15
       8  ||  2020-09-04          2020-09-02T20:30
       9  ||  2020-09-04          2020-09-15
      11  ||  2020-09-15          2020-09-03T17:53
      12  ||  2020-09-15          2020-09-04
_____
```

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

```
_____
    ||  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
```

Compare of adae
from- STUDY1
to- ISS

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

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

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

_____

Compare of adae
from- STUDY1
to- ISS

```
           ||  Actual Pooled Treatment 1 for Period 01
           ||  Base Value          Compare Value
      Obs  ||  tr01ag1             TRO1AG1
   _____ ||  _____           _____
           ||
       3   ||  Study Drug          Placebo
       4   ||  Study Drug          Placebo
       5   ||  Study Drug          Placebo
       6   ||  Study Drug          Placebo
   _____


   _____
           ||  Planned Pooled Treatment 2 for Period 01
           ||  Base Value          Compare Value
      Obs  ||  tr01pg2             TR01PG2
   _____ ||  _____+  _____+
           ||
       1   ||                      Study Drug Dose 1 &
       2   ||                      Study Drug Dose 1 &
       3   ||                      Placebo
       4   ||                      Placebo
       5   ||                      Placebo
       6   ||                      Placebo
       7   ||                      Study Drug Dose 1 &
       8   ||                      Study Drug Dose 1 &
       9   ||                      Study Drug Dose 1 &
      10   ||                      Study Drug Dose 1 &
      11   ||                      Study Drug Dose 1 &
      12   ||                      Study Drug Dose 1 &
   _____


   _____
           ||  Actual Pooled Treatment 2 for Period 01
           ||  Base Value          Compare Value
      Obs  ||  tr01ag2             TRO1AG2
   _____ ||  _____+  _____+
           ||
       1   ||                      Study Drug Dose 1 &
       2   ||                      Study Drug Dose 1 &
       3   ||                      Placebo
       4   ||                      Placebo
       5   ||                      Placebo
       6   ||                      Placebo
       7   ||                      Study Drug Dose 1 &
       8   ||                      Study Drug Dose 1 &
       9   ||                      Study Drug Dose 1 &
      10   ||                      Study Drug Dose 1 &
      11   ||                      Study Drug Dose 1 &
      12   ||                      Study Drug Dose 1 &
   _____


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

```
       ||
    1  ||            .     2.0000          .              .
    2  ||            .     2.0000          .              .
    3  ||            .     1.0000          .              .
    4  ||            .     1.0000          .              .
    5  ||            .     1.0000          .              .
    6  ||            .     1.0000          .              .
    7  ||            .     2.0000          .              .
    8  ||            .     2.0000          .              .
    9  ||            .     2.0000          .              .
   10  ||            .     2.0000          .              .
   11  ||            .     2.0000          .              .
   12  ||            .     2.0000          .              .
  _____
```

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

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

```
  _____
       ||  Planned Pooled Trt 2 for Period 01 (N)
       ||      Base      Compare
   Obs ||     tr01pg2n    TR01PG2N      Diff.        % Diff
  _____ || _____  _____   _____    _____
       ||
    1  ||            .     2.0000          .              .
    2  ||            .     2.0000          .              .
    3  ||            .     1.0000          .              .
```

```
          4  ||              .      1.0000          .              .
          5  ||              .      1.0000          .              .
          6  ||              .      1.0000          .              .
          7  ||              .      2.0000          .              .
          8  ||              .      2.0000          .              .
          9  ||              .      2.0000          .              .
         10  ||              .      2.0000          .              .
         11  ||              .      2.0000          .              .
         12  ||              .      2.0000          .              .
_____


_____
             ||  Actual Pooled Trt 1 for Period 01 (N)
             ||       Base     Compare
        Obs  ||     tr01ag1n   TR01AG1N      Diff.      % Diff
_____     ||     _____   _____    _____    _____
             ||
          3  ||       2.0000     1.0000     -1.0000    -50.0000
          4  ||       2.0000     1.0000     -1.0000    -50.0000
          5  ||       2.0000     1.0000     -1.0000    -50.0000
          6  ||       2.0000     1.0000     -1.0000    -50.0000
_____


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


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

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    03MAR23:13:38:57  03MAR23:13:38:57   107       1
COMPC.ADAE   03MAR23:13:38:56  03MAR23:13:38:56   103       1


            Variables Summary

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

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


          Variable   Type   Length   Label


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



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


          Variable   Type   Length   Label


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



               Listing of Common Variables with Differing Attributes


      Variable   Dataset      Type   Length   Label


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

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

```
                        Observation Summary

                  Observation      Base  Compare

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

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


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


                        Values Comparison Summary

       Number of Variables Compared with All Observations Equal: 88.
       Number of Variables Compared with Some Observations Unequal: 6.
       Number of Variables with Missing Value Differences: 3.
       Total Number of Values which Compare Unequal: 6.
       Maximum Difference: 1.


                        Variables with Unequal Values

   Variable   Type  Len1 Len2  Label                   Compare Label                            Ndif   MaxDif  MissDif

   REGION1N   NUM      8    8   Geographic Region 1 (N) Geographic Region 1 (N)                    1    1.000        0
   AGEGR1     CHAR     5    7   Pooled Age Group 1      Pooled Age Group 1                         1                 0
   AGEGR1N    NUM      8    8   Pooled Age Group 1 (N)  Pooled Age Group 1 (N)                     1    1.000        0
   tr01ag2    CHAR    21   21                           Actual Pooled Treatment 2 for Period 01    1                 1
   trt01an    NUM      8    8                           Actual Treatment for Period 01 (N)         1        0        1
   tr01ag2n   NUM      8    8                           Actual Pooled Trt 2 for Period 01 (N)      1        0        1
```

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
_____
```

```
_____
        ||  Actual Pooled Treatment 2 for Period 01
        ||  Base Value          Compare Value
  Obs   ||  tr01ag2             TRO1AG2
_____ ||  _____+   _____+
        ||
    1   ||                      Study Drug Dose 3 &
_____
```

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

```
_____
        ||  Actual Pooled Trt 2 for Period 01 (N)
        ||       Base     Compare
  Obs   ||   tr01ag2n    TRO1AG2N      Diff.     % Diff
_____ ||   _____    _____   _____   _____
```

Compare of adae
from- STUDY2
to- ISS

```
           ||
     1     ||          .       3.0000          .            .
_____
```

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    03MAR23:13:38:57  03MAR23:13:38:57   100      3
   COMPC.ADAE   03MAR23:13:38:56  03MAR23:13:38:56   103      9


                       Variables Summary

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

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


            Variable  Type  Length  Label


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



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


        Variable  Type  Length  Label


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



                Listing of Common Variables with Differing Attributes


Variable  Dataset      Type  Length  Label


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

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

Compare of adae
from- STUDY3
to- ISS

Comparison Results for Observations

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

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

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

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

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

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

Compare of adae
from- STUDY3
to- ISS

```
                           Observation Summary

                     Observation      Base   Compare

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


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


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


                        Values Comparison Summary

        Number of Variables Compared with All Observations Equal: 48.
        Number of Variables Compared with Some Observations Unequal: 49.
        Number of Variables with Missing Value Differences: 7.
        Total Number of Values which Compare Unequal: 105.
        Maximum Difference: 3098520.


                        Variables with Unequal Values

   Variable  Type  Len1 Len2  Label                              Ndif   MaxDif  MissDif

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

```
AEACN      CHAR   16   16   Action Taken with Study Treatment      1                  0
AETOXGR    CHAR    1    1   Standard Toxicity Grade                2                  0
AETOXGRN   NUM     8    8   Standard Toxicity Grade (N)            2      1.000       0
SUBJID     CHAR    6    8   Subject Identifier for the Study       2                  0
AGE        NUM     8    8   Age                                    2      8.000       0
AAGE       NUM     8    8   Analysis Age                           2      8.000       0
AGEGR1     CHAR    5    7   Pooled Age Group 1                     3                  0
AGEGR1N    NUM     8    8   Pooled Age Group 1 (N)                 3      1.000       0
AGEGR2     CHAR   19    7   Pooled Age Group 2                     3                  0
AGEGR2N    NUM     8    8   Pooled Age Group 2 (N)                 3      1.000       0
SEX        CHAR    1    1   Sex                                    2                  0
ETHNIC     CHAR   22   22   Ethnicity                              2                  0
ARACE      CHAR   41   41   Analysis Race                          3                  0
RACEGR1    CHAR   25   22   Pooled Race Group 1                    3                  0
RACEGR1N   NUM     8    8   Pooled Race Group 1 (N)                3      3.000       0
WEIGHTBL   NUM     8    8   Weight (kg) at Baseline                2     29.800       0
HEIGHTBL   NUM     8    8   Height (cm) at Baseline                2      7.000       0
BMIBL      NUM     8    8   BMI (kg/m^2) at Baseline               3      7.389       0
TRTSDT     NUM     8    8   Date of First Exposure to Treatment    2     36.000       0
TRTSTM     NUM     8    8   Time of First Exposure to Treatment    2     11880        0
TRTSDTM    NUM     8    8   Datetime of First Exposure to Treatment 2  3098520       0
TRTEDT     NUM     8    8   Date of Last Exposure to Treatment     2     36.000       0
TRTEDTM    NUM     8    8   Datetime of Last Exposure to Treatment 2   3098520       0
TRTETM     NUM     8    8   Time of Last Exposure to Treatment     2     11880        0
```

```
                          Value Comparison Results for Variables


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




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




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




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




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




_____
```

Compare of adae
from- STUDY3
to- ISS

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

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

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

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

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

```
_____
        ||  Analysis End Relative Day
        ||       Base    Compare
   Obs  ||      AENDY     AENDY      Diff.     % Diff
_____ ||  _____  _____  _____  _____
```

Compare of adae
from- STUDY3
to- ISS

```
           ||
     1     ||          .    139.0000          .             .
     2     ||   10.0000    164.0000    154.0000        1540
     3     ||   23.0000     78.0000     55.0000    239.1304
_____
```

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

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

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

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

```
_____
           ||  Lowest Level Term
           ||  Base Value        Compare Value
    Obs    ||  AELLT             AELLT
_____   ||  _____+  _____+
           ||
```

Compare of adae
from- STUDY3
to- ISS

```
2  ||  Urinary tract infect  Helicobacter pylori
3  ||  Blister infected      Streptococcal pharyn
_____


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


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


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


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


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

Compare of adae
from- STUDY3
to- ISS

```
_____
         ||  High Level Group Term Code
         ||     Base      Compare
  Obs    ||   AEHLGTCD   AEHLGTCD      Diff.     % Diff
_____ ||  _____   _____   _____   _____
         ||
    2    ||   10021879   10004018    -17861    -0.1782
    3    ||   10021879   10004018    -17861    -0.1782
_____


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


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


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


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


_____
         ||  Standard Toxicity Grade
         ||  Base Value           Compare Value
  Obs    ||  AETOXGR              AETOXGR
_____ ||  _                    _
```

```
         ||
    2    ||  2                      1
    3    ||  2                      1
_____
```

```
_____
         ||  Standard Toxicity Grade (N)
         ||       Base     Compare
   Obs   ||    AETOXGRN    AETOXGRN      Diff.     % Diff
_____ ||    _____    _____    _____   _____
         ||
    2    ||      2.0000      1.0000     -1.0000   -50.0000
    3    ||      2.0000      1.0000     -1.0000   -50.0000
_____
```

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

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

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

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

Compare of adae
from- STUDY3
to- ISS

_____

```
_____
          ||  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
_____


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


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


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


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

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

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

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

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

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

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

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

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

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

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

```
_____
        ||  Datetime of Last Exposure to Treatment
```

Compare of adae
from- STUDY3
to- ISS

```
         ||      Base    Compare
     Obs ||   TRTEDTM    TRTEDTM      Diff.     % Diff
 _____ ||  _____   _____   _____   _____
         ||
       2 ||  25FEB2021  18FEB2021    -609780    -0.0316
       3 ||  25FEB2021  02APR2021    3098520     0.1606
 _____
```

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