

Compare of adae from- STUDY1 to- ISS

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

Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:14:16:23	03MAR23:14:16:23	108	12
COMPC.ADAE	03MAR23:14:16:22	03MAR23:14:16:22	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
TRTP	Char	26	Planned Treatment
TRTPN	Num	8	Planned Treatment (N)
TRTA	Char	26	Actual Treatment
TRTAN	Num	8	Actual Treatment (N)
CQ01NAM	Char	1	Customized Query 01 Name
PART	Char	6	Part

Listing of Common Variables with Differing Attributes

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

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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

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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		4		0
trt01a	CHAR	26	26		4		0
tr01pg1	CHAR	10	10		4		0
tr01ag1	CHAR	10	10		4		0
tr01pg2	CHAR	21	21		4		0
tr01ag2	CHAR	21	21		4		0
trt01pn	NUM	8	8		4	1.000	0
trt01an	NUM	8	8		4	1.000	0
tr01pg1n	NUM	8	8		4	1.000	0
tr01pg2n	NUM	8	8		4	1.000	0
tr01ag1n	NUM	8	8		4	1.000	0
tr01ag2n	NUM	8	8		4	1.000	0
CQ02NAM	CHAR	53	53	Customized Query 02 Name	2		2

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Value Comparison Results for Variables

Obs	Unique Subject Identifier	
	Base Value	Compare Value
	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

Obs	Sequence Number		Diff.	% Diff
	Base	Compare		
	AESEQ	AESEQ		
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

Obs	Reported Term for the Adverse Event	
	Base Value	Compare Value
	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

Obs	Body System or Organ Class	Base Value	Compare Value
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	Body System or Organ Class Code	Base	Compare	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	Lowest Level Term	Base Value	Compare Value
3	Vomiting	Cough	
4	Feeling cold	Nausea	
5	Infusion associated	Vomiting	
6	Nausea	Diarrhea	
8	Cough	Feeling cold	
9	Appetite absent	Nausea	

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10		Diarrhea	Vomiting
11		Nausea	Infusion associated
12		Vomiting	Appetite absent

Obs	Lowest Level Term Code		Diff.	% Diff
	Base	Compare		
	AELLTCD	AELLTCD		
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		Diff.	% Diff
	Base	Compare		
	AEPTCD	AEPTCD		
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	Compare Value
	AEHLT	AEHLT
3		Nausea and vomiting Coughing and associa
4		Feelings and sensati Nausea and vomiting
5		Non-site specific pr Nausea and vomiting
6		Nausea and vomiting Diarrhoea (excl infe
8		Coughing and associa Feelings and sensati
9		Appetite disorders Nausea and vomiting
10		Diarrhoea (excl infe Nausea and vomiting
11		Nausea and vomiting Non-site specific pr
12		Nausea and vomiting Appetite disorders

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

Obs	High Level Group		Term	
	Base Value		Compare Value	
	AEHLGT	AEHLGT	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

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

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			+	+
3		Gastrointestinal dis	Respiratory, thoraci	
4		General disorders an	Gastrointestinal dis	
5		Injury, poisoning an	Gastrointestinal dis	
8		Respiratory, thoraci	General disorders an	
9		Metabolism and nutri	Gastrointestinal dis	
11		Gastrointestinal dis	Injury, poisoning an	
12		Gastrointestinal dis	Metabolism and nutri	

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

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

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

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11		12:00:00	16:52:00	17520	40.5556
12		12:00:00	.	.	.

		Analysis Start Date/Time			
		Base	Compare		
Obs		ASTDTM	ASTDTM	Diff.	% Diff
<hr/>					
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
<hr/>					
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
<hr/>					
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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Obs	Analysis End Time		Diff.	% Diff
	Base	Compare		
	AENTM	AENTM		
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	.	.

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

Obs	Analysis End Relative Day		Diff.	% Diff
	Base	Compare		
	AENDY	AENDY		
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

Obs	Analysis Duration (N)		Diff.	% Diff
	Base	Compare		
	ADURN	ADURN		
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

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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

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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		

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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

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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

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

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

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

|| BMI (kg/m^2) at Baseline

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Obs		Base BMIBL	Compare BMIBL	Diff.	% Diff
4		22.8001	31.0575	8.2574	36.2164
5		24.4118	31.0575	6.6456	27.2230
6		31.0575	27.1300	-3.9275	-12.6458
7		27.1300	22.8001	-4.3299	-15.9598
8		31.0575	22.8001	-8.2574	-26.5874
9		24.4118	22.8001	-1.6117	-6.6023
11		22.8001	24.4118	1.6117	7.0690
12		22.8001	24.4118	1.6117	7.0690

Planned Treatment for Period 01					
Obs		Base Value trt01p	Compare Value 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					
Obs		Base Value trt01a	Compare Value 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					
Obs		Base Value tr01pg1	Compare Value TR01PG1		
4		Study Drug	Placebo		
5		Study Drug	Placebo		
7		Placebo	Study Drug		
8		Placebo	Study Drug		

Actual Pooled Treatment 1 for Period 01					
Obs		Base Value tr01ag1	Compare Value TR01AG1		

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		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 &

		Planned Treatment for Period 01 (N)			
Obs		Base trt01pn	Compare 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)			
Obs		Base trt01an	Compare 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
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Planned Pooled Trt 1 for Period 01 (N)					
Obs		Base	Compare	Diff.	% Diff
		tr01pg1n	TR01PG1N		
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)					
Obs		Base	Compare	Diff.	% Diff
		tr01pg2n	TR01PG2N		
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)					
Obs		Base	Compare	Diff.	% Diff
		tr01ag1n	TR01AG1N		
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)					
Obs		Base	Compare	Diff.	% Diff
		tr01ag2n	TR01AG2N		
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					
Obs		Base Value	Compare Value		
		CQ02NAM	CQ02NAM		
			+		+

Compare of adae
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5		Infusion-related rea
11		Infusion-related rea

Compare of adae from- STUDY2 to- ISS

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

Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:14:16:23	03MAR23:14:16:23	107	1
COMPC.ADAE	03MAR23:14:16:22	03MAR23:14:16:22	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.

Compare of adae from- STUDY2 to- ISS

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

Variable	Type	Length	Label
CQ03NAM	Char	1	Customized Query 03 Name
CQ04NAM	Char	16	Customized Query 04 Name
CQ05NAM	Char	1	Customized Query 05 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
CQ02NAM	COMP.ADAE	Char	63	Customized Query 02 Name
	COMPC.ADAE	Char	53	Customized Query 02 Name
ACOUNTRY	COMP.ADAE	Char	13	Analysis Country
	COMPC.ADAE	Char	18	Analysis Country
REGION1	COMP.ADAE	Char	13	Geographic Region 1

Compare of adae from- STUDY2 to- ISS

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	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)

Compare of adae from- STUDY2 to- ISS

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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 ada from- STUDY2

Value Comparison Results for Variable

		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)			
Obs		Base AGEGR1N	Compare AGEGR1N	Diff.	% Diff
1		2.0000	1.0000	-1.0000	-50.0000

Compare of adae from- STUDY3 to- ISS

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

Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:14:16:23	03MAR23:14:16:23	100	9
COMPC.ADAE	03MAR23:14:16:22	03MAR23:14:16:22	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.

Compare of adae from- STUDY3 to- ISS

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

Variable	Type	Length	Label
CQ03NAM	Char	1	Customized Query 03 Name
CQ04NAM	Char	1	Customized Query 04 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
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CQ02NAM	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

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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: 62.
Number of Variables Compared with Some Observations Unequal: 35.
Number of Variables with Missing Value Differences: 4.
Total Number of Values which Compare Unequal: 145.
Maximum Difference: 52238.

Variables with Unequal Values

Variable	Type	Len1	Len2	Label	Compare Label	Ndif	MaxDif	MissDif
AESEQ	NUM	8	8	Sequence Number	Sequence Number	4	1.000	0
AEREFID	CHAR	5	5	Reference ID	Reference ID	4		0
AESTDTC	CHAR	10	16	Start Date/Time of Adverse Event	Start Date/Time of Adverse Event	4		0
ASTDT	NUM	8	8	Analysis Start Date	Analysis Start Date	4	99.000	0
ASTDTF	CHAR	1	1	Analysis Start Date Imputation Flag	Analysis Start Date Imputation Flag	2		2
ASTDY	NUM	8	8	Analysis Start Relative Day	Analysis Start Relative Day	4	99.000	0
AEENDTC	CHAR	10	16	End Date/Time of Adverse Event	End Date/Time of Adverse Event	4		0
AENDT	NUM	8	8	Analysis End Date	Analysis End Date	4	107	0
AENDTF	CHAR	1	1	Analysis End Date Imputation Flag	Analysis End Date Imputation Flag	4		4
AENDY	NUM	8	8	Analysis End Relative Day	Analysis End Relative Day	4	107	0
ADURN	NUM	8	8	Analysis Duration (N)	Analysis Duration (N)	4	0	4
ADURC	CHAR	4	12	Analysis Duration (C)	Analysis Duration (C)	4		4
AETERM	CHAR	33	130	Reported Term for the Adverse Event	Reported Term for the Adverse Event	2		0
AEDECOD	CHAR	25	61	Dictionary-Derived Term	Dictionary-Derived Term	2		0
AEBODSYS	CHAR	47	67	Body System or Organ Class	Body System or Organ Class	2		0
AEBDSYCD	NUM	8	8	Body System or Organ Class Code	Body System or Organ Class Code	2	16552	0
AELLT	CHAR	29	61	Lowest Level Term	Lowest Level Term	2		0
AELLTCD	NUM	8	8	Lowest Level Term Code	Lowest Level Term Code	2	49518	0
AEPTCD	NUM	8	8	Preferred Term Code	Preferred Term Code	2	52238	0
AEHLT	CHAR	57	79	High Level Term	High Level Term	2		0
AEHLTCD	NUM	8	8	High Level Term Code	High Level Term Code	2	17308	0
AEHLGT	CHAR	51	86	High Level Group Term	High Level Group Term	2		0
AEHLGTCD	NUM	8	8	High Level Group Term Code	High Level Group Term Code	2	1932	0
AESOC	CHAR	47	67	Primary System Organ Class	Primary System Organ Class	2		0
AESOCOD	NUM	8	8	Primary System Organ Class Code	Primary System Organ Class Code	2	16552	0
AEPATT	CHAR	14	14	Pattern of Adverse Event	Pattern of Adverse Event	2		0
AEOUTN	NUM	8	8	Outcome of Adverse Event (N)	Outcome of AE (N)	1	1.000	0

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AGEGR1	CHAR	5	7	Pooled Age Group 1	Pooled Age Group 1	9		0
AGEGR1N	NUM	8	8	Pooled Age Group 1 (N)	Pooled Age Group 1 (N)	7	1.000	0
AGEGR2	CHAR	19	7	Pooled Age Group 2	Pooled Age Group 2	9		0
AGEGR2N	NUM	8	8	Pooled Age Group 2 (N)	Pooled Age Group 2 (N)	9	1.000	0
ARACE	CHAR	41	41	Analysis Race	Analysis Race	9		0
RACEGR1	CHAR	25	22	Pooled Race Group 1	Pooled Race Group 1	9		0
RACEGR1N	NUM	8	8	Pooled Race Group 1 (N)	Pooled Race Group 1 (N)	9	3.000	0
BMIBL	NUM	8	8	BMI (kg/m^2) at Baseline	BMI (kg/m^2) at Baseline	9	0.0042	0

Value Comparison Results for Variables

Obs	Sequence Number		Base AESEQ	Compare AESEQ	Diff.	% Diff
1			2.0000	1.0000	-1.0000	-50.0000
2			1.0000	2.0000	1.0000	100.0000
5			2.0000	1.0000	-1.0000	-50.0000
6			1.0000	2.0000	1.0000	100.0000

Obs	Reference ID		Base Value AEREFID	Compare Value AEREFID
1			10002	10001
2			10001	10002
5			10002	10001
6			10001	10002

Obs	Start Date/Time of Adverse Event		Base Value AESTDTC	Compare Value AESTDTC
1			2021-06	2021-02-22
2			2021-02-22	2021-06
5			2021-09-30	2021-07-06
6			2021-07-06	2021-09-30

Obs	Analysis Start Date		Base ASTDT	Compare ASTDT	Diff.	% Diff

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1		01JUN2021	22FEB2021	-99.0000	-0.4413
2		22FEB2021	01JUN2021	99.0000	0.4433
5		30SEP2021	06JUL2021	-86.0000	-0.3813
6		06JUL2021	30SEP2021	86.0000	0.3828

			Analysis Start Date	Imputation Flag
			Base Value	Compare Value
Obs		ASTDTF		ASTDTF
		—		—
1		D		
2			D	

		Analysis Start Relative Day			
		Base	Compare		
Obs		ASTDY	ASTDY	Diff.	% Diff
1		104.0000	5.0000	-99.0000	-95.1923
2		5.0000	104.0000	99.0000	1980
5		162.0000	76.0000	-86.0000	-53.0864
6		76.0000	162.0000	86.0000	113.1579

		End Date/Time of Adverse Event	
		Base Value	Compare Value
Obs		AEENDTC	AEENDTC
1		2021-07	2021-07-06
2		2021-07-06	2021-07
5		2021-10	2021-07-16
6		2021-07-16	2021-10

		Analysis End Date			
		Base	Compare		
Obs		AENDT	AENDT	Diff.	% Diff
1		31JUL2021	06JUL2021	-25.0000	-0.1112
2		06JUL2021	31JUL2021	25.0000	0.1113
5		31OCT2021	16JUL2021	-107.0000	-0.4738
6		16JUL2021	31OCT2021	107.0000	0.4760

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		Analysis End Date Imputation Flag
		Base Value Compare Value
Obs		AENDTF AENDTF
		- -
1		D
2		D
5		D
6		D

		Analysis End Relative Day			
		Base Compare			
Obs		AENDY AENDY	Diff.	% Diff	
1		164.0000 139.0000	-25.0000	-15.2439	
2		139.0000 164.0000	25.0000	17.9856	
5		193.0000 86.0000	-107.0000	-55.4404	
6		86.0000 193.0000	107.0000	124.4186	

		Analysis Duration (N)			
		Base Compare			
Obs		ADURN ADURN	Diff.	% Diff	
1		. 135.0000	.	.	
2		135.0000 .	.	.	
5		. 11.0000	.	.	
6		11.0000 .	.	.	

		Analysis Duration (C)			
		Base Value Compare Value			
Obs		ADURC ADURC			
1			135d		
2		135d			
5			11d		
6		11d			

		Reported Term for the Adverse Event			
		Base Value Compare Value			
Obs		AETERM AETERM			
1		H PYLORI GASTRITIS	ANEMIA		
2		ANEMIA	H PYLORI GASTRITIS		

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		Dictionary-Derived Term	
		Base Value	Compare Value
Obs		AEDECOD	AEDECOD
		_____+	_____+
1		Helicobacter gastrit	Anaemia
2		Anaemia	Helicobacter gastrit

		Body System or Organ Class	
		Base Value	Compare Value
Obs		AEBODSYS	AEBODSYS
		_____+	_____+
1		Infections and infes	Blood and lymphatic
2		Blood and lymphatic	Infections and infes

		Body System or Organ Class Code			
		Base	Compare		
Obs		AEBDSYCD	AEBDSYCD	Diff.	% Diff
		_____	_____	_____	_____
1		10021881	10005329	-16552	-0.1652
2		10005329	10021881	16552	0.1654

		Lowest Level Term	
		Base Value	Compare Value
Obs		AELLT	AELLT
		_____+	_____+
1		Helicobacter pylori	Anemia
2		Anemia	Helicobacter pylori

		Lowest Level Term Code			
		Base	Compare		
Obs		AELLTCD	AELLTCD	Diff.	% Diff
		_____	_____	_____	_____
1		10051790	10002272	-49518	-0.4926
2		10002272	10051790	49518	0.4951

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Obs	Preferred Term Code		Diff.	% Diff
	Base	Compare		
	AEPTCD	AEPTCD		
1	10054272	10002034	-52238	-0.5196
2	10002034	10054272	52238	0.5223

Obs	High Level Term	
	Base Value	Compare Value
	AEHLT	AEHLT
1	Helicobacter infecti	Anaemias NEC
2	Anaemias NEC	Helicobacter infecti

Obs	High Level Term Code		Diff.	% Diff
	Base	Compare		
	AEHLTCD	AEHLTCD		
1	10019375	10002067	-17308	-0.1727
2	10002067	10019375	17308	0.1730

Obs	High Level Group Term	
	Base Value	Compare Value
	AEHLGT	AEHLGT
1	Bacterial infectious	Anaemias nonhaemolyt
2	Anaemias nonhaemolyt	Bacterial infectious

Obs	High Level Group Term Code		Diff.	% Diff
	Base	Compare		
	AEHLGTCD	AEHLGTCD		
1	10004018	10002086	-1932	-0.0193
2	10002086	10004018	1932	0.0193

Obs	Primary System Organ Class	
	Base Value	Compare Value
	AESOC	AESOC
1		
2		

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1		Infections and infes	Blood and lymphatic
2		Blood and lymphatic	Infections and infes

Obs		Primary System Organ Class Code			
		Base	Compare	Diff.	% Diff
		AESOCCD	AESOCCD		
1		10021881	10005329	-16552	-0.1652
2		10005329	10021881	16552	0.1654

Obs		Pattern of Adverse Event	
		Base Value	Compare Value
		AEPATT	AEPATT
5		SINGLE EPISODE	INTERMITTENT
6		INTERMITTENT	SINGLE EPISODE

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

Obs		Pooled Age Group 1	
		Base Value	Compare Value
		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)

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Obs		Base AGEGR1N	Compare AGEGR1N	Diff.	% Diff
1		2.0000	1.0000	-1.0000	-50.0000
2		2.0000	1.0000	-1.0000	-50.0000
3		2.0000	1.0000	-1.0000	-50.0000
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		
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

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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

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9		40.9800	40.9839	0.003900	0.009518
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