

# 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	03MAR23:14:42:44	03MAR23:14:42:44	106	12
COMPC.ADAE	03MAR23:14:42:44	03MAR23:14:42:44	103	12

## Variables Summary

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

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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)
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
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

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

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Number of Variables Compared with All Observations Equal: 43.
Number of Variables Compared with Some Observations Unequal: 54.
Number of Variables with Missing Value Differences: 5.
Total Number of Values which Compare Unequal: 379.
Maximum Difference: 1144800.
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Variable	Type	Len1	Len2	Label	Ndif	MaxDif	MissDif
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
AESOCOD	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
AENDOTC	CHAR	16	16	End Date/Time of Adverse Event	9		0

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SUBJID	CHAR	8	8	Subject Identifier for the Study	8		0
AGE	NUM	8	8	Age	8	16.000	0
AAGE	NUM	8	8	Analysis Age	8	16.000	0
SEX	CHAR	1	1	Sex	4		0
TRTSDT	NUM	8	8	Date of First Exposure to Treatment	7	3.000	0
TRTSTM	NUM	8	8	Time of First Exposure to Treatment	8	19440	0
TRTSDTM	NUM	8	8	Datetime of First Exposure to Treatment	8	239760	0
TRTEDT	NUM	8	8	Date of Last Exposure to Treatment	8	3.000	0
TRTETM	NUM	8	8	Time of Last Exposure to Treatment	8	82560	0
TRTEDTM	NUM	8	8	Datetime of Last Exposure to Treatment	8	239820	0
WEIGHTBL	NUM	8	8	Weight (kg) at Baseline	8	41.100	0
HEIGHTBL	NUM	8	8	Height (cm) at Baseline	8	20.000	0
BMIBL	NUM	8	8	BMI (kg/m^2) at Baseline	8	8.257	0
usubjid	CHAR	19	19	Unique Subject Identifier	8		0
trt01p	CHAR	26	26	Planned Treatment for Period 01	4		0
trt01pn	NUM	8	8	Planned Treatment for Period 01 (N)	4	1.000	0
trt01a	CHAR	26	26	Actual Treatment for Period 01	4		0
trt01an	NUM	8	8	Actual Treatment for Period 01 (N)	4	1.000	0
tr01pg1	CHAR	10	10	Planned Pooled Treatment 1 for Period 01	4		0
tr01pg1n	NUM	8	8	Planned Pooled Trt 1 for Period 01 (N)	4	1.000	0
tr01ag1	CHAR	10	10	Actual Pooled Treatment 1 for Period 01	4		0
tr01ag1n	NUM	8	8	Actual Pooled Trt 1 for Period 01 (N)	4	1.000	0
tr01pg2	CHAR	21	21	Planned Pooled Treatment 2 for Period 01	4		0
tr01pg2n	NUM	8	8	Planned Pooled Trt 2 for Period 01 (N)	4	1.000	0
tr01ag2	CHAR	21	21	Actual Pooled Treatment 2 for Period 01	4		0
tr01ag2n	NUM	8	8	Actual Pooled Trt 2 for Period 01 (N)	4	1.000	0
CQ02NAM	CHAR	53	53	Customized Query 02 Name	2		2

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Value Comparison Results for Variables

	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

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

Obs	Dictionary-Derived Term	
	Base Value	Compare Value
	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

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		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

		Lowest Level Term Code	
		Base	Compare
Obs		AELLTCD	AELLTCD
3		10047700	10011224
4		10016326	10028813
5		10059087	10047700
6		10028813	10012727
8		10011224	10016326

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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

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

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Obs	High Level Group Term	
	Base Value	Compare Value
	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

Obs	High Level Group Term Code			
	Base	Compare		
	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
3	Gastrointestinal dis	Respiratory, thoraci
4	General disorders an	Gastrointestinal dis
5	Injury, poisoning an	Gastrointestinal dis
8	Respiratory, thoraci	General disorders an
9	Metabolism and nutri	Gastrointestinal dis
11	Gastrointestinal dis	Injury, poisoning an
12	Gastrointestinal dis	Metabolism and nutri

Obs	Primary System Organ Class Code			
	Base	Compare		
	AESOC	AESOC	Diff.	% Diff



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3		10017947	10038738	20791	0.2075
4		10018065	10017947	-118.0000	-0.001178
5		10022117	10017947	-4170	-0.0416
8		10038738	10018065	-20673	-0.2059
9		10027433	10017947	-9486	-0.0946
11		10017947	10022117	4170	0.0416
12		10017947	10027433	9486	0.0947

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

Obs	Analysis Start Time		Diff.	% Diff
	Base	Compare		
	ASTTM	ASTTM		
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	.	.
11	12:00:00	16:52:00	17520	40.5556
12	12:00:00	.	.	.

Obs	Analysis Start Date/Time		Diff.	% Diff
	Base	Compare		
	ASTDTM	ASTDTM		
3	01SEP2020	.	.	.
4	02SEP2020	.	.	.
5	03SEP2020	01SEP2020	-196620	-0.0103
6	.	01SEP2020	.	.
7	01SEP2020	14SEP2020	1144800	0.0598
8	.	02SEP2020	.	.

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9		.	14SEP2020	.	.
11		14SEP2020	03SEP2020	-932880	-0.0487
12		14SEP2020	.	.	.

		Analysis Start Relative Day			
		Base	Compare		
Obs		ASTDY	ASTDY	Diff.	% Diff
3		2.0000	4.0000	2.0000	100.0000
4		1.0000	4.0000	3.0000	300.0000
5		1.0000	2.0000	1.0000	100.0000
6		4.0000	2.0000	-2.0000	-50.0000
7		2.0000	13.0000	11.0000	550.0000
8		4.0000	1.0000	-3.0000	-75.0000
9		1.0000	13.0000	12.0000	1200
11		13.0000	1.0000	-12.0000	-92.3077
12		13.0000	1.0000	-12.0000	-92.3077

		Analysis End Date			
		Base	Compare		
Obs		AENDT	AENDT	Diff.	% Diff
3		01SEP2020	04SEP2020	3.0000	0.0135
4		02SEP2020	03SEP2020	1.0000	0.004513
5		03SEP2020	01SEP2020	-2.0000	-0.009025
6		03SEP2020	04SEP2020	1.0000	0.004512
7		04SEP2020	15SEP2020	11.0000	0.0496
8		04SEP2020	02SEP2020	-2.0000	-0.009024
9		04SEP2020	15SEP2020	11.0000	0.0496
11		15SEP2020	03SEP2020	-12.0000	-0.0541
12		15SEP2020	04SEP2020	-11.0000	-0.0496

		Analysis End Time			
		Base	Compare		
Obs		AENTM	AENTM	Diff.	% Diff
3		10:40:00	.	.	.
5		17:53:00	10:40:00	-25980	-40.3541
6		20:30:00	.	.	.
8		.	20:30:00	.	.
11		.	17:53:00	.	.

		Analysis End Date/Time			
		Base	Compare		

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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
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		

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		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

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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			
Obs		Base	Compare	Diff.	% Diff
		AGE	AGE		
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			
Obs		Base	Compare	Diff.	% Diff
		AAGE	AAGE		
4		45.0000	29.0000	-16.0000	-35.5556
5		42.0000	29.0000	-13.0000	-30.9524
6		29.0000	34.0000	5.0000	17.2414
7		34.0000	45.0000	11.0000	32.3529
8		29.0000	45.0000	16.0000	55.1724
9		42.0000	45.0000	3.0000	7.1429
11		45.0000	42.0000	-3.0000	-6.6667
12		45.0000	42.0000	-3.0000	-6.6667

		Sex	
Obs		Base Value	Compare Value
		SEX	SEX
4		F	M
5		F	M
6		M	F
8		M	F

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		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

Obs	Time of First Exposure to Treatment					
	Base		Compare		Diff.	% Diff
	TRTSTM		TRTSTM			
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			
Obs		Base	Compare		
		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			
Obs		Base	Compare	Diff.	% Diff
		TRTEDT	TRTEDT		
4		02SEP2020	31AUG2020	-2.0000	-0.009025

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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

Obs	Time of Last Exposure to Treatment				
		Base	Compare	Diff.	% Diff
		TRTETM	TRTETM		
4		19:28:00	23:16:00	13680	19.5205
5		17:53:00	23:16:00	19380	30.1025
6		23:16:00	0:20:00	-82560	-98.5673
7		0:20:00	19:28:00	68880	5740
8		23:16:00	19:28:00	-13680	-16.3324
9		17:53:00	19:28:00	5700	8.8537
11		19:28:00	17:53:00	-5700	-8.1336
12		19:28:00	17:53:00	-5700	-8.1336

Obs	Datetime of Last Exposure to Treatment				
		Base	Compare	Diff.	% Diff
		TRTEDTM	TRTEDTM		
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	Compare	Diff.	% Diff
		WEIGHTBL	WEIGHTBL		
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

## Compare of adae from- STUDY1 to- ISS

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

		BMI (kg/m^2)	at Baseline		
		Base	Compare		
Obs		BMIBL	BMIBL	Diff.	% Diff
4		22.8001	31.0575	8.2574	36.2164
5		24.4118	31.0575	6.6456	27.2230
6		31.0575	27.1300	-3.9275	-12.6458
7		27.1300	22.8001	-4.3299	-15.9598
8		31.0575	22.8001	-8.2574	-26.5874
9		24.4118	22.8001	-1.6117	-6.6023
11		22.8001	24.4118	1.6117	7.0690
12		22.8001	24.4118	1.6117	7.0690

		Unique Subject Identifier	
		Base Value	Compare Value
Obs		usubjbid	usubjbid
4		10009	10005
5		10010	10005
6		10005	10006
7		10006	10009
8		10005	10009
9		10010	10009
11		10009	10010
12		10009	10010

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



# Compare of adae from- STUDY1 to- ISS

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4		Study Drug Dose 1	Placebo
5		Study Drug Dose 1	Placebo
7		Placebo	Study Drug Dose 1
8		Placebo	Study Drug Dose 1

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

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

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

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

Compare of adae  
from- STUDY1  
to- ISS

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Obs	Planned Pooled Trt 1 for Period 01 (N)				
	Base tr01pg1n	Compare TR01PG1N	Diff.	% Diff	
4	2.0000	1.0000	-1.0000	-50.0000	
5	2.0000	1.0000	-1.0000	-50.0000	
7	1.0000	2.0000	1.0000	100.0000	
8	1.0000	2.0000	1.0000	100.0000	

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

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

Obs	Planned Pooled Treatment 2 for Period 01	
	Base Value tr01pg2	Compare Value 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 &

Obs	Planned Pooled Trt 2 for Period 01 (N)				
	Base tr01pg2n	Compare TR01PG2N	Diff.	% Diff	
4	2.0000	1.0000	-1.0000	-50.0000	

Compare of adae  
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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 Treatment 2 for Period 01			
		Base Value		Compare Value	
Obs		tr01ag2		TR01AG2	
			+		+
4		Study Drug Dose 1 &		Placebo	
5		Study Drug Dose 1 &		Placebo	
7		Placebo		Study Drug Dose 1 &	
8		Placebo		Study Drug Dose 1 &	

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

		Customized Query 02 Name			
		Base Value		Compare Value	
Obs		CQ02NAM		CQ02NAM	
			+		+
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	03MAR23:14:42:45	03MAR23:14:42:45	105	1
COMPC.ADAE	03MAR23:14:42:44	03MAR23:14:42:44	103	1

## Variables Summary

Number of Variables in Common: 94.  
Number of Variables in COMP.ADAE but not in COMPC.ADAE: 11.  
Number of Variables in COMPC.ADAE but not in COMP.ADAE: 9.  
Number of Variables with Differing Attributes: 9.

# 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)
TRTDISFL	Char	1	Study Treatment Discontinuation Flag
TRTMISFL	Char	1	Study Treatment Misallocation Flag

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

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

## Listing of Common Variables with Differing Attributes

Variable	Dataset	Type	Length	Label
AEDECOD	COMP.ADAE	Char	47	Dictionary-Derived Term
	COMPC.ADAE	Char	61	Dictionary-Derived Term
AELLT	COMP.ADAE	Char	47	Lowest Level Term
	COMPC.ADAE	Char	61	Lowest Level Term
AEHLT	COMP.ADAE	Char	60	High Level Term
	COMPC.ADAE	Char	79	High Level Term
AEHLGT	COMP.ADAE	Char	55	High Level Group Term
	COMPC.ADAE	Char	86	High Level Group Term
ADURC	COMP.ADAE	Char	11	Analysis Duration (C)
	COMPC.ADAE	Char	12	Analysis Duration (C)
AEOUT	COMP.ADAE	Char	26	Outcome of Adverse Event
	COMPC.ADAE	Char	32	Outcome of Adverse Event
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
	COMPC.ADAE	Char	17	Geographic Region 1

Compare of adae  
from- STUDY2  
to- ISS

Observation Summary

Observation	Base	Compare
First Obs	1	1
First Unequal	1	1
Last Unequal	1	1
Last Obs	1	1

Number of Observations in Common: 1.  
Total Number of Observations Read from COMP.ADAE: 1.  
Total Number of Observations Read from COMPC.ADAE: 1.  
  
Number of Observations with Some Compared Variables Unequal: 1.  
Number of Observations with All Compared Variables Equal: 0.

Values Comparison Summary

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

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

Compare of adae  
from- STUDY3  
to- ISS

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

Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:14:42:45	03MAR23:14:42:45	98	9
COMPC.ADAE	03MAR23:14:42:44	03MAR23:14:42:44	103	9

Variables Summary

Number of Variables in Common: 95.  
Number of Variables in COMP.ADAE but not in COMPC.ADAE: 3.  
Number of Variables in COMPC.ADAE but not in COMP.ADAE: 8.  
Number of Variables with Differing Attributes: 23.

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

Listing of Common Variables with Differing Attributes

Variable	Dataset	Type	Length	Label
AESTDTC	COMP.ADAE	Char	10	Start Date/Time of Adverse Event
	COMPC.ADAE	Char	16	Start Date/Time of Adverse Event
AEENDTC	COMP.ADAE	Char	10	End Date/Time of Adverse Event
	COMPC.ADAE	Char	16	End Date/Time of Adverse Event
ADURC	COMP.ADAE	Char	4	Analysis Duration (C)
	COMPC.ADAE	Char	12	Analysis Duration (C)
AETERM	COMP.ADAE	Char	33	Reported Term for the Adverse Event
	COMPC.ADAE	Char	130	Reported Term for the Adverse Event
AEDECOD	COMP.ADAE	Char	25	Dictionary-Derived Term
	COMPC.ADAE	Char	61	Dictionary-Derived Term
AEBODSYS	COMP.ADAE	Char	47	Body System or Organ Class
	COMPC.ADAE	Char	67	Body System or Organ Class
AELLT	COMP.ADAE	Char	29	Lowest Level Term
	COMPC.ADAE	Char	61	Lowest Level Term
AEHLT	COMP.ADAE	Char	57	High Level Term
	COMPC.ADAE	Char	79	High Level Term
AEHLGT	COMP.ADAE	Char	51	High Level Group Term
	COMPC.ADAE	Char	86	High Level Group Term
AESOC	COMP.ADAE	Char	47	Primary System Organ Class
	COMPC.ADAE	Char	67	Primary System Organ Class
AEOUT	COMP.ADAE	Char	26	Outcome of Adverse Event
	COMPC.ADAE	Char	32	Outcome of Adverse Event
AEOUTN	COMP.ADAE	Num	8	Outcome of Adverse Event (N)
	COMPC.ADAE	Num	8	Outcome of AE (N)
AEACNOTH	COMP.ADAE	Char	1	Other Action Taken
	COMPC.ADAE	Char	20	Other Action Taken
AEWD	COMP.ADAE	Char	1	Subject Withdrawn as a Result of AE?
	COMPC.ADAE	Char	1	AE Leading to Withdrawal From Study
AEDLT	COMP.ADAE	Char	1	Dose-Limiting Toxicities
	COMPC.ADAE	Char	1	Is This Event a Dose Limiting Toxicity



**Compare of adae  
from- STUDY3  
to- ISS**

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AESRECHA	COMP.ADAE	Char	1	Event(s) Recur After Rechallenge
	COMPC.ADAE	Char	2	Event(s) Recur After Rechallenge
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
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

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

## Variables with Unequal Values

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

**Compare of adae  
from- STUDY3  
to- ISS**

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

# Compare of adae from- STUDY3 to- ISS

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## Value Comparison Results for Variables

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

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

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

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

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

		End Date/Time of Adverse Event	
		Base Value	Compare Value
Obs		AEENDTC	AEENDTC
1			2021-07-06
2		2021-03-06	2021-07
3		2021-03-19	2021-06-18
5		2021-06-18	2021-07-16
6		2021-07-06	2021-10
7		2021-07-16	2021-03-06
8		2021-07	2021-03-19
9		2021-10	

	Analysis End Date				
	Base	Compare			
Obs	AENDT	AENDT	Diff.	% Diff	

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1			.	06JUL2021	.	.
2			06MAR2021	31JUL2021	147.0000	0.6579
3			19MAR2021	18JUN2021	91.0000	0.4070
5			18JUN2021	16JUL2021	28.0000	0.1247
6			06JUL2021	31OCT2021	117.0000	0.5208
7			16JUL2021	06MAR2021	-132.0000	-0.5873
8			31JUL2021	19MAR2021	-134.0000	-0.5958
9			31OCT2021	.	.	.

			Analysis End Date Imputation Flag
			Base Value Compare Value
Obs			AENDTF AENDTF
			- -
2			D
6			D
8			D
9			D

			Analysis End Relative Day
			Base Compare
Obs			AENDY AENDY Diff. % Diff
1			. 139.0000 . .
2			10.0000 164.0000 154.0000 1540
3			23.0000 78.0000 55.0000 239.1304
5			78.0000 86.0000 8.0000 10.2564
6			139.0000 193.0000 54.0000 38.8489
7			86.0000 10.0000 -76.0000 -88.3721
8			164.0000 23.0000 -141.0000 -85.9756
9			193.0000 . . .

			Analysis Duration (N)
			Base Compare
Obs			ADURN ADURN Diff. % Diff
1			. 135.0000 . .
2			5.0000 . . .
3			23.0000 14.0000 -9.0000 -39.1304
5			14.0000 11.0000 -3.0000 -21.4286
6			135.0000 . . .
7			11.0000 5.0000 -6.0000 -54.5455
8			. 23.0000 . .

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

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

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

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

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5		Gastrointestinal dis	Infections and infes
6		Blood and lymphatic	Infections and infes
9		Infections and infes	Musculoskeletal and

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

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

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

	Preferred Term Code
	Base Compare



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

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

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

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

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

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

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

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

		Pattern of Adverse Event	
		Base Value	Compare Value
Obs		AEPATT	AEPATT

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

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

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

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

		Standard Toxicity Grade	
		Base Value	Compare Value
Obs		AETOXGR	AETOXGR
		_____	_____
		-	-
1		2	1
2		2	1
3		2	1
7		1	2
8		1	2
9		1	2

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		Standard Toxicity Grade (N)			
Obs		Base	Compare	Diff.	% Diff
		AETOXGRN	AETOXGRN		
1		2.0000	1.0000	-1.0000	-50.0000
2		2.0000	1.0000	-1.0000	-50.0000
3		2.0000	1.0000	-1.0000	-50.0000
7		1.0000	2.0000	1.0000	100.0000
8		1.0000	2.0000	1.0000	100.0000
9		1.0000	2.0000	1.0000	100.0000

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

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

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

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

		Sex	
		Base Value	Compare Value
Obs		SEX	SEX
		—	—
1		F	M
2		F	M
3		F	M
5		M	F
6		M	F
8		M	F

		Ethnicity	
		Base Value	Compare Value
Obs		ETHNIC	ETHNIC
		_____ +	_____ +
2		HISPANIC OR LATINO	NOT HISPANIC OR LATI
3		NOT HISPANIC OR LATI	HISPANIC OR LATINO
5		HISPANIC OR LATINO	NOT HISPANIC OR LATI
7		NOT HISPANIC OR LATI	HISPANIC OR LATINO

		Analysis Race	
		Base Value	Compare Value
Obs		ARACE	ARACE
		_____ +	_____ +
1		WHITE - WHITE/CAUCAS	White - White/Caucas
2		WHITE - WHITE/CAUCAS	White - White/Caucas
3		WHITE - WHITE/CAUCAS	White - White/Caucas
4		WHITE - WHITE/CAUCAS	White - White/Caucas
5		WHITE - WHITE/CAUCAS	White - White/Caucas
6		WHITE - WHITE/CAUCAS	White - White/Caucas
7		WHITE - WHITE/CAUCAS	White - White/Caucas
8		WHITE - WHITE/CAUCAS	White - White/Caucas
9		WHITE - WHITE/CAUCAS	White - White/Caucas

		Pooled Race Group 1	
		Base Value	Compare Value
Obs		RACEGR1	RACEGR1
		_____ +	_____ +

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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

Obs		Pooled Race Group 1 (N)		Diff.	% Diff
		Base RACEGR1N	Compare RACEGR1N		
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

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

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

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9		170.0000	167.0000	-3.0000	-1.7647
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Obs		BMI (kg/m^2) at Baseline			
		Base	Compare	Diff.	% Diff
		BMIBL	BMIBL		
1		40.9800	34.9691	-6.0109	-14.6678
2		27.5800	34.9691	7.3891	26.7916
3		31.7700	27.0242	-4.7458	-14.9379
4		27.0200	27.0242	0.004221	0.0156
5		27.0200	40.1384	13.1184	48.5507
6		34.9700	40.1384	5.1684	14.7795
7		40.1400	27.5796	-12.5604	-31.2915
8		34.9700	31.7663	-3.2037	-9.1612
9		40.1400	40.9839	0.8439	2.1024

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

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

		Datetime of First Exposure to Treatment	
		Base	Compare

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

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

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

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



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

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

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