

Compare of adae  
from- STUDY1  
to- ISS

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

Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:16:02:54	03MAR23:16:02:54	107	12
COMPC.ADAE	03MAR23:16:02:51	03MAR23:16:02:51	104	12

Variables Summary

Number of Variables in Common: 98.  
Number of Variables in COMP.ADAE but not in COMPC.ADAE: 9.  
Number of Variables in COMPC.ADAE but not in COMP.ADAE: 6.  
Number of Variables with Differing Attributes: 6.

# Compare of adae from- STUDY1 to- ISS

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

# Compare of adae from- STUDY1 to- ISS

## Observation Summary

Observation	Base	Compare
First Obs	1	1
First Unequal	1	1
Last Unequal	11	11
Last Obs	12	12

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

Number of Observations with Some Compared Variables Unequal: 5.  
Number of Observations with All Compared Variables Equal: 7.

## Values Comparison Summary

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

## Variables with Unequal Values

Variable	Type	Len1	Len2	Label	Ndif	MaxDif
ADURC	CHAR	11	12	Analysis Duration (C)	5	

## Value Comparison Results for Variables

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

# Compare of adae from- STUDY2 to- ISS

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

## Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:16:02:54	03MAR23:16:02:54	107	1
COMPC.ADAE	03MAR23:16:02:51	03MAR23:16:02:51	104	1

## Variables Summary

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

# Compare of adae from- STUDY2 to- ISS

16:02 Friday, March 3, 2023 5

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

Variable	Type	Length	Label
ARELN	Num	8	Analysis Causality (N)
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: 2.  
Total Number of Values which Compare Unequal: 2.  
Maximum Difference: 1.

## Variables with Unequal Values

Variable	Type	Len1	Len2	Label	Ndif	MaxDif
AREL	CHAR	11	11	Analysis Causality	1	
REGION1N	NUM	8	8	Geographic Region 1 (N)	1	1.000

## Value Comparison Results for Variables

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

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

# Compare of adae from- STUDY3 to- ISS

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

## Data Set Summary

Dataset	Created	Modified	NVar	NObs
COMP.ADAE	03MAR23:16:02:54	03MAR23:16:02:54	98	9
COMPC.ADAE	03MAR23:16:02:51	03MAR23:16:02:51	104	9

## Variables Summary

Number of Variables in Common: 95.  
Number of Variables in COMP.ADAE but not in COMPC.ADAE: 3.  
Number of Variables in COMPC.ADAE but not in COMP.ADAE: 9.  
Number of Variables with Differing Attributes: 23.

# Compare of adae from- STUDY3 to- ISS

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)
AREL	Char	11	Analysis Causality
AERELNST	Char	1	Relationship to Non-Study Treatment
AGEGR1	Char	7	Pooled Age Group 1
AGEGR1N	Num	8	Pooled Age Group 1 (N)
PART	Char	6	Part

Listing of Common Variables with Differing Attributes

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



# Compare of adae from- STUDY3 to- ISS

16:02 Friday, March 3, 2023 9

	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

## Observation Summary

Observation	Base	Compare
First Obs	1	1
First Unequal	1	1
Last Unequal	9	9
Last Obs	9	9

Number of Observations in Common: 9.  
Total Number of Observations Read from COMP.ADAE: 9.  
Total Number of Observations Read from COMPC.ADAE: 9.

Number of Observations with Some Compared Variables Unequal: 9.  
Number of Observations with All Compared Variables Equal: 0.

## Values Comparison Summary

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

## Variables with Unequal Values

Variable	Type	Len1	Len2	Label	Compare Label	Ndif	MaxDif
AEOUTN	NUM	8	8	Outcome of Adverse Event (N)	Outcome of AE (N)	1	1.000
ARACE	CHAR	41	41	Analysis Race	Analysis Race	9	
RACEGR1	CHAR	25	22	Pooled Race Group 1	Pooled Race Group 1	9	
RACEGR1N	NUM	8	8	Pooled Race Group 1 (N)	Pooled Race Group 1 (N)	9	3.000
BMIBL	NUM	8	8	BMI (kg/m^2) at Baseline	BMI (kg/m^2) at Baseline	9	0.0042
AGEGR2	CHAR	7	7	Pooled Age Group 2	Pooled Age Group 2	9	

# Compare of adae from- STUDY3 to- ISS

Value Comparison Results for Variables

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

Obs	Analysis Race		Base Value		Compare Value	
	ARACE		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			

Obs	Pooled Race Group 1		Base Value		Compare Value	
	RACEGR1		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			

Obs	Pooled Race Group 1 (N)		Base		Compare	
	RACEGR1N		RACEGR1N		RACEGR1N	
					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

# Compare of adae from- STUDY3 to- ISS

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

Obs		Pooled Age Group 2	
		Base Value	Compare Value
		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