

Section 1: No PHI ACHIEVE Final Data Sets (V1.0)

Adverse Event Form: FORM CODE=AER_NP VERSION=01.00

Data set name: AER_NP

<i>ACHIEVE_VISIT</i>		<i>ACHIEVE Visit Recoded V7 / Ncs To Screen And Baseline</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	Adverse Events	

<i>AER0A_FOLLOWUPDAYS</i>		<i>Days Of Follow Up From Randomization Date To Completion Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	Range	-45 - 1568 (median=740 mean=690.3 std=473.9)

<i>AER0A_YEAR</i>		<i>Year Of Completion Date</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
18	2018	
17	2019	
12	2020	
26	2021	
24	2022	
2	2023	

<i>AER1</i>		<i>Description Of Adverse Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
11	A	
43	B	
41	C	
4	D	

<i>AER10</i>		<i>Was Adverse Event Unexpected According To Study Protocol</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
63	N	
36	Y	

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<i>AER2</i>		<i>Source Of Reporting</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
46	A	
4	B	
16	C	
1	D	
32	E	

<i>AER3_FOLLOWUPDAYS</i>		<i>Days Of Follow Up From Randomization Date To Start Date Of Adverse Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	Range	-45 - 1537 (median=687 mean=650.7 std=466.9)

<i>AER3_YEAR</i>		<i>Year Of Start Date Of Adverse Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
18	2018	
19	2019	
18	2020	
22	2021	
20	2022	
2	2023	

<i>AER4</i>		<i>Severity Of Adverse Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
45	A	
11	B	
43	C	

<i>AER5</i>		<i>Relationship Of Adverse Event To Study Procedures</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
61	A	
28	B	
10	C	

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<i>AER6</i>		<i>Participant Discontinued Study Due To The Adverse Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
60	N	
39	Y	

<i>AER7</i>		<i>Adverse Event Resolution Status</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
9	A	
48	B	
41	C	
1	D	

<i>AER8_FOLLOWUPDAYS</i>		<i>Days Of Follow Up From Randomization Date To Date Adverse Event Resolved</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
48	Range	-38 - 1568 (median=217.5 mean=548.38 std=545.44)
51		Missing

<i>AER8_YEAR</i>		<i>Year Of Date Adverse Event Resolved</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
1	2017	
11	2018	
16	2019	
1	2020	
5	2021	
14	2022	
51		Missing

<i>AER9</i>		<i>Did Adverse Event Meet Criteria For Serious Adverse Event</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
58	N	
41	Y	

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<i>AER9A</i>		<i>Did Adverse Event Cause Or Prolong Hospitalization</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
33	N	
3	Y	
63		Missing

<i>AER9B</i>		<i>Did Adverse Event Result In Persistent Or Significant Disability/Incapacity</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
28	N	
10	Y	
61		Missing

<i>AER9C</i>		<i>Did The Adverse Event Result In Congenital Anomaly Or Birth Defect</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
39	N	
60		Missing

<i>AER9D</i>		<i>Was Adverse Event Life Threatening</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
25	N	
16	Y	
58		Missing

<i>AER9E</i>		<i>Was Adverse Event Fatal</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
41	Y	
58		Missing

<i>AER9F</i>		<i>Was Adverse Event An Other Medically Important Condition</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
29	N	
7	Y	
63		Missing

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<i>FORM</i>		<i>FORM</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	AER	

<i>ID_C</i>		<i>Scrambled Cohort And De Novo Visit ID</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	Present	Text suppressed

<i>OCCURRENCE</i>		<i>OCCURRENCE</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
88	1	
9	2	
2	3	

<i>SUBJECTID</i>		<i>ACHIEVE SubjectID</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	Present	Text suppressed

<i>VERS</i>		<i>VERS</i>
<i>N</i>	<i>Value</i>	<i>Description</i>
99	0100	