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

Adverse Event Form: FORM CODE=AER_NP VERSION=01.00

Data set name: AER_NP

AER0A_FOLLOWUPDAYS		*Days Of Follow Up From Randomization Date To Completion Date*
N	*Value*	*Description*
52	Range	1201 - 2464 (median=1781 mean=1784.9 std=292.7)

AER0A_YEAR		*Year Of Completion Date*
N	*Value*	*Description*
12	2022	
14	2023	
21	2024	
5	2025	

AER1		*Description Of Adverse Event*
N	*Value*	*Description*
12	A	
14	B	
20	C	
6	D	

AER10		*Was Adverse Event Unexpected According To Study Protocol*
N	*Value*	*Description*
31	N	
21	Y	

AER2		*Source Of Reporting*
N	*Value*	*Description*
18	A	
1	B	
11	C	
1	D	
21	E	

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AER3_FOLLOWUPDAYS		Days Of Follow Up From Randomization Date To Start Date Of Adverse Event
N	Value	Description
52	Range	1201 - 2373 (median=1749.5 mean=1749.27 std=271.32)

AER3_YEAR		Year Of Start Date Of Adverse Event
N	Value	Description
12	2022	
18	2023	
18	2024	
4	2025	

AER4		Severity Of Adverse Event
N	Value	Description
22	A	
5	B	
25	C	

AER5		Relationship Of Adverse Event To Study Procedures
N	Value	Description
30	A	
21	B	
1	C	

AER6		Participant Discontinued Study Due To The Adverse Event
N	Value	Description
34	N	
18	Y	

AER7		Adverse Event Resolution Status
N	Value	Description
3	A	
28	B	
20	C	
1	D	

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AER8_FOLLOWUPDAYS		*Days Of Follow Up From Randomization Date To Date Adverse Event Resolved*
N	*Value*	*Description*
28	Range	1201 - 2047 (median=1634 mean=1652.1 std=221.2)
24		Missing

AER8_YEAR		*Year Of Date Adverse Event Resolved*
N	*Value*	*Description*
8	2022	
14	2023	
5	2024	
1	2025	
24		Missing

AER9		*Did Adverse Event Meet Criteria For Serious Adverse Event*
N	*Value*	*Description*
29	N	
23	Y	

AER9A		*Did Adverse Event Cause Or Prolong Hospitalization*
N	*Value*	*Description*
18	N	
5	Y	
29		Missing

AER9B		*Did Adverse Event Result In Persistent Or Significant Disability/Incapacity*
N	*Value*	*Description*
20	N	
3	Y	
29		Missing

AER9C		*Did The Adverse Event Result In Congenital Anomaly Or Birth Defect*
N	*Value*	*Description*
22	N	
30		Missing

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AER9D		Was Adverse Event Life Threatening
N	Value	Description
16	N	
7	Y	
29		Missing

AER9E		Was Adverse Event Fatal
N	Value	Description
3	N	
20	Y	
29		Missing

AER9F		Was Adverse Event An Other Medically Important Condition
N	Value	Description
15	N	
8	Y	
29		Missing

EVENTNAME		EVENTNAME
N	Value	Description
52	ANX Adverse Events	

FORM		FORM
N	Value	Description
52	AER	

OCCURRENCE		OCCURRENCE
N	Value	Description
46	1	
4	2	
1	3	
1	4	

SUBJECTID		SubjectID
N	Value	Description
52	Present	Text suppressed

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VERS		*VERS*
N	*Value*	*Description*
52	0100	