

AIRIS PHARMA Private Limited.  
Protocol: 043-1810

## 16.2.1.9 Vital Signs

Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-001	Body Surface Area (m)	SCREENING	2.08	06MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	2.08	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	2.06	15MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	2.05	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	2.05	20MAY2019	AIRIS-101 1
	Diastolic Blood Pressure (mmHg)	SCREENING	79	06MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	75	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	76	15MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	79	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	72	20MAY2019	AIRIS-101 1
	Heart Rate (beats/min)	SCREENING	74	06MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	90	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	69	15MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	98	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	91	20MAY2019	AIRIS-101 1

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-001	Height (cm)	SCREENING	172.72	06MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	172.72	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	172.72	20MAY2019	AIRIS-101 1
	Systolic Blood Pressure (mmHg)	SCREENING	120	06MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	122	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	119	15MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	117	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	100	20MAY2019	AIRIS-101 1
	Temperature (C)	SCREENING	36.722222	06MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	37.055556	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	36.333333	15MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	37.222222	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	35.944444	20MAY2019	AIRIS-101 1
	Weight (kg)	SCREENING	94.347136	06MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	94.347136	08MAY2019	AIRIS-101 1

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043-18101-74001-001	Weight (kg)	CYCLE 1 DAY 8	92.895642	15MAY2019	AIRIS-101 1
		UNSCHEDULED 4.01	90.899837	17MAY2019	AIRIS-101 1
		UNSCHEDULED 4.03	91.171992	20MAY2019	AIRIS-101 1
043-18101-74001-002	Body Surface Area (m)	SCREENING	2.06	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	2.05	15MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	2.06	22MAY2019	AIRIS-101 1
		END OF TREATMENT	2.06	29MAY2019	AIRIS-101 1
		SAFETY FOLLOW-UP	2.02	24JUN2019	AIRIS-101 1
	Diastolic Blood Pressure (mmHg)	SCREENING	88	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	86	15MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	80	22MAY2019	AIRIS-101 1
		END OF TREATMENT	87	29MAY2019	AIRIS-101 1
		SAFETY FOLLOW-UP	90	24JUN2019	AIRIS-101 1
	Heart Rate (beats/min)	SCREENING	78	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	93	15MAY2019	AIRIS-101 1

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-002	Heart Rate (beats/min)	CYCLE 1 DAY 8	83	22MAY2019	AIRIS-101 1
		END OF TREATMENT	86	29MAY2019	AIRIS-101 1
		SAFETY FOLLOW-UP	78	24JUN2019	AIRIS-101 1
	Height (cm)	SCREENING	175.26	08MAY2019	AIRIS-101 1
	Systolic Blood Pressure (mmHg)	SCREENING	131	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	137	15MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	126	22MAY2019	AIRIS-101 1
		END OF TREATMENT	140	29MAY2019	AIRIS-101 1
		SAFETY FOLLOW-UP	132	24JUN2019	AIRIS-101 1
	Temperature (C)	SCREENING	36.722222	08MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	36.611111	15MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	36.777778	22MAY2019	AIRIS-101 1
		END OF TREATMENT	36.611111	29MAY2019	AIRIS-101 1
		SAFETY FOLLOW-UP	36.444444	24JUN2019	AIRIS-101 1
	Weight (kg)	SCREENING	90.264808	08MAY2019	AIRIS-101 1

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-002	Weight (kg)	CYCLE 1 DAY 1	89.539061	15MAY2019	AIRIS-101 1
		CYCLE 1 DAY 8	90.264808	22MAY2019	AIRIS-101 1
		END OF TREATMENT	89.901934	29MAY2019	AIRIS-101 1
		SAFETY FOLLOW-UP	86.001043	24JUN2019	AIRIS-101 1
043-18101-74001-003	Body Surface Area (m)	SCREENING	1.75	13MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	1.76	15MAY2019	AIRIS-101 1
		END OF TREATMENT	.	20MAY2019	AIRIS-101 1
	Diastolic Blood Pressure (mmHg)	SCREENING	60	13MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	56	15MAY2019	AIRIS-101 1
		END OF TREATMENT	56	20MAY2019	AIRIS-101 1
	Heart Rate (beats/min)	SCREENING	80	13MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	116	15MAY2019	AIRIS-101 1
		END OF TREATMENT	112	20MAY2019	AIRIS-101 1
	Height (cm)	SCREENING	167.64	13MAY2019	AIRIS-101 1
	Systolic Blood Pressure (mmHg)	SCREENING	96	13MAY2019	AIRIS-101 1

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-003	Systolic Blood Pressure (mmHg)	CYCLE 1 DAY 1	88	15MAY2019	AIRIS-101 1
		END OF TREATMENT	105	20MAY2019	AIRIS-101 1
	Temperature (C)	SCREENING	36.111111	13MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	36.111111	15MAY2019	AIRIS-101 1
		END OF TREATMENT	37	20MAY2019	AIRIS-101 1
	Weight (kg)	SCREENING	66.31515	13MAY2019	AIRIS-101 1
		CYCLE 1 DAY 1	67.313053	15MAY2019	AIRIS-101 1
		END OF TREATMENT	.	20MAY2019	AIRIS-101 1
	043-18101-74001-004 Body Surface Area (m)	SCREENING	2.03	10SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 1	2.04	13SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 8	2.06	20SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 15	2.02	27SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 22	2.02	04OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 1	2.03	11OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 8	2.01	18OCT2019	AIRIS-101 1A

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-004	Body Surface Area (m)	CYCLE 2 DAY 15	2	24OCT2019	AIRIS-101 1A
		CYCLE 3 DAY 1	1.98	07NOV2019	AIRIS-101 1A
		END OF TREATMENT	1.95	06DEC2019	AIRIS-101 1A
	Diastolic Blood Pressure (mmHg)	SCREENING	76	10SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 1	97	13SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 8	86	20SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 15	87	27SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 22	82	04OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 1	88	11OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 8	86	18OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 15	78	24OCT2019	AIRIS-101 1A
		CYCLE 3 DAY 1	76	07NOV2019	AIRIS-101 1A
		END OF TREATMENT	77	06DEC2019	AIRIS-101 1A
	Heart Rate (beats/min)	SCREENING	123	10SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 1	120	13SEP2019	AIRIS-101 1A

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-004	Heart Rate (beats/min)	CYCLE 1 DAY 8	106	20SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 15	119	27SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 22	115	04OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 1	115	11OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 8	114	18OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 15	102	24OCT2019	AIRIS-101 1A
		CYCLE 3 DAY 1	121	07NOV2019	AIRIS-101 1A
		END OF TREATMENT	120	06DEC2019	AIRIS-101 1A
	Height (cm)	SCREENING	162.56	10SEP2019	AIRIS-101 1A
	Systolic Blood Pressure (mmHg)	SCREENING	105	10SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 1	154	13SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 8	121	20SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 15	151	27SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 22	142	04OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 1	122	11OCT2019	AIRIS-101 1A



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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-004	Systolic Blood Pressure (mmHg)	CYCLE 2 DAY 8	122	18OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 15	110	24OCT2019	AIRIS-101 1A
		CYCLE 3 DAY 1	125	07NOV2019	AIRIS-101 1A
		END OF TREATMENT	117	06DEC2019	AIRIS-101 1A
	Temperature (C)	SCREENING	36.555556	10SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 1	36.333333	13SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 8	37.277778	20SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 15	37.111111	27SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 22	37.055556	04OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 1	37.055556	11OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 8	36.444444	18OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 15	36.388889	24OCT2019	AIRIS-101 1A
		CYCLE 3 DAY 1	37.277778	07NOV2019	AIRIS-101 1A
		END OF TREATMENT	36.555556	06DEC2019	AIRIS-101 1A
	Weight (kg)	SCREENING	98.883056	10SEP2019	AIRIS-101 1A

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-004	Weight (kg)	CYCLE 1 DAY 1	100.69742	13SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 8	102.42107	20SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 15	97.975872	27SEP2019	AIRIS-101 1A
		CYCLE 1 DAY 22	97.340843	04OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 1	99.336648	11OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 8	96.705814	18OCT2019	AIRIS-101 1A
		CYCLE 2 DAY 15	95.526475	24OCT2019	AIRIS-101 1A
		CYCLE 3 DAY 1	93.349234	07NOV2019	AIRIS-101 1A
		END OF TREATMENT	90.264808	06DEC2019	AIRIS-101 1A
043-18101-74001-005	Body Surface Area (m)	SCREENING	1.96	16DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 1	1.96	19DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 8	1.94	26DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 15	1.94	02JAN2020	AIRIS-101 2A
	Diastolic Blood Pressure (mmHg)	SCREENING	69	16DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 1	44	19DEC2019	AIRIS-101 2A

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-005	Diastolic Blood Pressure (mmHg)	CYCLE 1 DAY 8	63	26DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 15	70	02JAN2020	AIRIS-101 2A
	Heart Rate (beats/min)	SCREENING	49	16DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 1	50	19DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 8	45	26DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 15	50	02JAN2020	AIRIS-101 2A
	Height (cm)	SCREENING	165.1	16DEC2019	AIRIS-101 2A
	Systolic Blood Pressure (mmHg)	SCREENING	98	16DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 1	108	19DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 8	105	26DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 15	111	02JAN2020	AIRIS-101 2A
	Temperature (C)	SCREENING	36.444444	16DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 1	36.166667	19DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 8	36.277778	26DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 15	36.388889	02JAN2020	AIRIS-101 2A

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Subject	Parameter (unit)	Analysis Visit	Observed value	Date/Time of Measurements	Planned treatment
043-18101-74001-005	Weight (kg)	SCREENING	88.541158	16DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 1	88.722595	19DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 8	87.180382	26DEC2019	AIRIS-101 2A
		CYCLE 1 DAY 15	86.363917	02JAN2020	AIRIS-101 2A
043-18101-74002-001	Body Surface Area (m)	SCREENING	1.32	24OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	1.34	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	1.34	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	1.33	21NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	1.31	05DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 8	1.31	12DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 15	1.3	19DEC2019	AIRIS-101 1A
	Diastolic Blood Pressure (mmHg)	SCREENING	64	24OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	79	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	81	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	91	21NOV2019	AIRIS-101 1A

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043-18101-74002-001	Diastolic Blood Pressure (mmHg)	CYCLE 2 DAY 1	82	05DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 8	85	12DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 15	86	19DEC2019	AIRIS-101 1A
	Heart Rate (beats/min)	SCREENING	88	24OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	75	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	93	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	102	21NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	109	05DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 8	112	12DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 15	112	19DEC2019	AIRIS-101 1A
	Height (cm)	SCREENING	152.4	24OCT2019	AIRIS-101 1A
	Systolic Blood Pressure (mmHg)	SCREENING	104	24OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	126	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	115	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	131	21NOV2019	AIRIS-101 1A

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043-18101-74002-001	Systolic Blood Pressure (mmHg)	CYCLE 2 DAY 1	113	05DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 8	124	12DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 15	120	19DEC2019	AIRIS-101 1A
	Temperature (C)	SCREENING	36.611111	24OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	36.555556	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	37	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	36.833333	21NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	37	05DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 8	37.111111	12DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 15	36.666667	19DEC2019	AIRIS-101 1A
	Weight (kg)	SCREENING	40.369688	24OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	41.549027	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	41.730464	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	40.913998	21NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	39.462504	05DEC2019	AIRIS-101 1A

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043-18101-74002-001	Weight (kg)	CYCLE 2 DAY 8	39.371786	12DEC2019	AIRIS-101 1A
		CYCLE 2 DAY 15	39.008912	19DEC2019	AIRIS-101 1A
043-18101-74003-004	Body Surface Area (m)	SCREENING	.	30OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	.	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	.	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	.	21NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 22	.	26NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	.	05DEC2019	AIRIS-101 1A
	Diastolic Blood Pressure (mmHg)	SCREENING	84	30OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	78	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	80	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	75	21NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 22	71	26NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	65	05DEC2019	AIRIS-101 1A
	Heart Rate (beats/min)	SCREENING	92	30OCT2019	AIRIS-101 1A

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043-18101-74003-004	Heart Rate (beats/min)	CYCLE 1 DAY 1	75	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	73	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	83	21NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 22	79	26NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	104	05DEC2019	AIRIS-101 1A
	Height (cm)	SCREENING	172.8	30OCT2019	AIRIS-101 1A
	Systolic Blood Pressure (mmHg)	SCREENING	110	30OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	149	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	118	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	121	21NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 22	122	26NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	112	05DEC2019	AIRIS-101 1A
	Temperature (C)	SCREENING	36.4	30OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	36.8	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	37.2	14NOV2019	AIRIS-101 1A



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043-18101-74003-004	Temperature (C)	CYCLE 1 DAY 15	36.9	21NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 22	36.8	26NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	37.6	05DEC2019	AIRIS-101 1A
	Weight (kg)	SCREENING	56.7	30OCT2019	AIRIS-101 1A
		CYCLE 1 DAY 1	57.2	07NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 8	57.8	14NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 15	57.2	21NOV2019	AIRIS-101 1A
		CYCLE 1 DAY 22	61.7	26NOV2019	AIRIS-101 1A
		CYCLE 2 DAY 1	56.6	05DEC2019	AIRIS-101 1A
043-18101-74004-002	Body Surface Area (m)	SCREENING	1.87	17DEC2019	
	Diastolic Blood Pressure (mmHg)	SCREENING	59	17DEC2019	
	Heart Rate (beats/min)	SCREENING	85	17DEC2019	
	Height (cm)	SCREENING	176	17DEC2019	
	Systolic Blood Pressure (mmHg)	SCREENING	111	17DEC2019	
	Temperature (C)	SCREENING	36.5	17DEC2019	

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043-18101-74004-002	Weight (kg)	SCREENING	71.6	17DEC2019	