

### 14.3.14 Summary statistics and changes from baseline

#### 14.3.14.1 Summary statistics and changes from baseline of Systolic blood pressure [mmHg]

Visit	n	Mean	----- Result -----					Baseline					---- Change from baseline ----						
			95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max
Screening (-5 to D1)	3	136.7	117.7	155.6	135.0	7.64	130	145											
Baseline (D1)	3	139.3	119.1	159.6	143.0	8.14	130	145											
Day 2	3	120.7	72.9	168.4	124.0	19.22	100	138	139.3	119.1	159.6	143.0	-18.7	-75.3	38.0	-6.0	22.81	-45	-5
Day 3	3	138.3	100.4	176.3	135.0	15.28	125	155	139.3	119.1	159.6	143.0	-1.0	-42.8	40.8	5.0	16.82	-20	12
Day 4	3	139.0	134.7	143.3	140.0	1.73	137	140	139.3	119.1	159.6	143.0	-0.3	-23.4	22.7	-3.0	9.29	-8	10
Day 5	2	140.5	57.9	223.1	140.5	9.19	134	147	144.0	131.3	156.7	144.0	-3.5	-98.8	91.8	-3.5	10.61	-11	4
Day 6	2	137.5	42.2	232.8	137.5	10.61	130	145	144.0	131.3	156.7	144.0	-6.5	-114.5	101.5	-6.5	12.02	-15	2
Day 7	2	132.5	100.7	164.3	132.5	3.54	130	135	144.0	131.3	156.7	144.0	-11.5	-56.0	33.0	-11.5	4.95	-15	-8
Day 8	1	140.0			140.0		140	140	145.0			145.0	-5.0			-5.0		-5	-5
Day 9	1	134.0			134.0		134	134	145.0			145.0	-11.0			-11.0		-11	-11
Day 14	1	138.0			138.0		138	138	145.0			145.0	-7.0			-7.0		-7	-7
EoT	1	135.0			135.0		135	135	143.0			143.0	-8.0			-8.0		-8	-8
EoS (Day 21-28)	3	130.7	103.2	158.1	132.0	11.06	119	141	139.3	119.1	159.6	143.0	-8.7	-42.5	25.2	-4.0	13.61	-24	2

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

#### 14.3.14.2 Summary statistics and changes from baseline of Diastolic blood pressure [mmHg]

Visit	n	Mean	----- Result -----					Baseline					---- Change from baseline ----						
			95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max
Screening (-5 to D1)	3	83.7	56.4	110.9	80.0	10.97	75	96											
Baseline (D1)	3	82.3	60.6	104.0	80.0	8.74	75	92											
Day 2	3	71.7	57.3	86.0	75.0	5.77	65	75	82.3	60.6	104.0	80.0	-10.7	-25.6	4.3	-10.0	6.03	-17	-5
Day 3	3	76.7	50.8	102.5	80.0	10.41	65	85	82.3	60.6	104.0	80.0	-5.7	-30.7	19.3	-7.0	10.07	-15	5
Day 4	3	81.7	74.5	88.8	80.0	2.89	80	85	82.3	60.6	104.0	80.0	-0.7	-15.6	14.3	0.0	6.03	-7	5
Day 5	2	77.5	71.1	83.9	77.5	0.71	77	78	83.5	-24.5	191.5	83.5	-6.0	-107.6	95.6	-6.0	11.31	-14	2
Day 6	2	85.0	-42.1	212.1	85.0	14.14	75	95	83.5	-24.5	191.5	83.5	1.5	-17.6	20.6	1.5	2.12	0	3
Day 7	2	87.0	48.9	125.1	87.0	4.24	84	90	83.5	-24.5	191.5	83.5	3.5	-66.4	73.4	3.5	7.78	-2	9
Day 8	1	80.0			80.0		80	80	75.0			75.0	5.0			5.0		5	5
Day 9	1	86.0			86.0		86	86	75.0			75.0	11.0			11.0		11	11
Day 14	1	80.0			80.0		80	80	75.0			75.0	5.0			5.0		5	5
EoT	1	90.0			90.0		90	90	92.0			92.0	-2.0			-2.0		-2	-2
EoS (Day 21-28)	3	85.0	72.6	97.4	85.0	5.00	80	90	82.3	60.6	104.0	80.0	2.7	-31.2	36.6	5.0	13.65	-12	15

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

#### 14.3.14.3 Summary statistics and changes from baseline of Pulse [bpm]

Visit	n	Mean	----- Result -----					Baseline					---- Change from baseline ----						
			95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max
Screening (-5 to D1)	3	82.7	22.2	143.1	78.0	24.34	61	109											
Baseline (D1)	3	67.0	43.3	90.7	62.0	9.54	61	78											
Day 2	3	70.3	46.7	93.9	70.0	9.50	61	80	67.0	43.3	90.7	62.0	3.3	-31.5	38.1	-1.0	14.01	-8	19
Day 3	3	69.7	56.0	83.3	70.0	5.51	64	75	67.0	43.3	90.7	62.0	2.7	-12.3	17.6	2.0	6.03	-3	9
Day 4	3	60.3	43.4	77.2	58.0	6.81	55	68	67.0	43.3	90.7	62.0	-6.7	-14.3	0.9	-6.0	3.06	-10	-4
Day 5	2	82.0	-95.9	259.9	82.0	19.80	68	96	61.5	55.1	67.9	61.5	20.5	-151.0	192.0	20.5	19.09	7	34
Day 6	2	68.0			68.0	0.00	68	68	61.5	55.1	67.9	61.5	6.5	0.1	12.9	6.5	0.71	6	7
Day 7	2	63.0	50.3	75.7	63.0	1.41	62	64	61.5	55.1	67.9	61.5	1.5	-17.6	20.6	1.5	2.12	0	3
Day 8	1	60.0			60.0		60	60	61.0			61.0	-1.0			-1.0		-1	-1
Day 9	1	75.0			75.0		75	75	61.0			61.0	14.0			14.0		14	14
Day 14	1	85.0			85.0		85	85	61.0			61.0	24.0			24.0		24	24
EoT	1	62.0			62.0		62	62	62.0			62.0	0.0			0.0		0	0
EoS (Day 21-28)	3	90.7	72.4	109.0	88.0	7.37	85	99	67.0	43.3	90.7	62.0	23.7	-15.2	62.5	26.0	15.63	7	38

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

#### 14.3.14.4 Summary statistics and changes from baseline of Respiratory rate [bpm]

		----- Result -----							Baseline				---- Change from baseline ----						
Visit	n	Mean	95%	95%	Median	SD	Min	Max	95%	95%	Median	Mean	95%	95%	Median	SD	Min	Max	
			ICI	uCI					ICI	uCI			ICI	uCI					
Screening (-5 to D1)	3	13.3	7.6	19.1	12.0	2.31	12	16											
Baseline (D1)	3	14.7	8.9	20.4	16.0	2.31	12	16											
Day 2	3	14.7	8.9	20.4	16.0	2.31	12	16	14.7	8.9	20.4	16.0	0.0			0.0	0.00	0	0
Day 3	3	14.3	9.2	19.5	15.0	2.08	12	16	14.7	8.9	20.4	16.0	-0.3	-1.8	1.1	0.0	0.58	-1	0
Day 4	3	14.7	8.9	20.4	16.0	2.31	12	16	14.7	8.9	20.4	16.0	0.0			0.0	0.00	0	0
Day 5	2	15.5	9.1	21.9	15.5	0.71	15	16	16.0			16.0	-0.5	-6.9	5.9	-0.5	0.71	-1	0
Day 6	2	14.0			14.0	0.00	14	14	16.0			16.0	-2.0			-2.0	0.00	-2	-2
Day 7	2	14.0			14.0	0.00	14	14	16.0			16.0	-2.0			-2.0	0.00	-2	-2
Day 8	1	14.0			14.0		14	14	16.0			16.0	-2.0			-2.0		-2	-2
Day 9	1	12.0			12.0		12	12	16.0			16.0	-4.0			-4.0		-4	-4
Day 14	1	12.0			12.0		12	12	16.0			16.0	-4.0			-4.0		-4	-4
EoT	1	14.0			14.0		14	14	16.0			16.0	-2.0			-2.0		-2	-2
EoS (Day 21-28)	3	12.0			12.0	0.00	12	12	14.7	8.9	20.4	16.0	-2.7	-8.4	3.1	-4.0	2.31	-4	0

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

#### 14.3.14.5 Summary statistics and changes from baseline of Temperature [°C]

----- Result -----																			Baseline				---- Change from baseline ----						
Visit	n	Mean	95%	95%	Median	SD	Min	Max	Mean	95%	95%	Median	Mean	95%	95%	Median	SD	Min	Max										
			ICI	uCI						ICI	uCI			ICI	uCI														
Screening (-5 to D1)	3	36.50	36.07	36.93	36.40	0.173	36.4	36.7																					
Baseline (D1)	3	36.60	36.17	37.03	36.70	0.173	36.4	36.7																					
Day 2	3	36.60	36.10	37.10	36.60	0.200	36.4	36.8	36.60	36.17	37.03	36.70	-0.00	-0.25	0.25	0.00	0.100	-0.1	0.1										
Day 3	3	36.43	36.15	36.72	36.50	0.115	36.3	36.5	36.60	36.17	37.03	36.70	-0.17	-0.31	-0.02	-0.20	0.058	-0.2	-0.1										
Day 4	3	36.50	35.75	37.25	36.50	0.300	36.2	36.8	36.60	36.17	37.03	36.70	-0.10	-0.53	0.33	-0.20	0.173	-0.2	0.1										
Day 5	2	36.55	35.91	37.19	36.55	0.071	36.5	36.6	36.70			36.70	-0.15	-0.79	0.49	-0.15	0.071	-0.2	-0.1										
Day 6	2	36.50	35.23	37.77	36.50	0.141	36.4	36.6	36.70			36.70	-0.20	-1.47	1.07	-0.20	0.141	-0.3	-0.1										
Day 7	2	36.40			36.40	0.000	36.4	36.4	36.70			36.70	-0.30			-0.30	0.000	-0.3	-0.3										
Day 8	1	36.50			36.50		36.5	36.5	36.70			36.70	-0.20			-0.20		-0.2	-0.2										
Day 9	1	36.50			36.50		36.5	36.5	36.70			36.70	-0.20			-0.20		-0.2	-0.2										
Day 14	1	36.70			36.70		36.7	36.7	36.70			36.70	0.00			0.00		0.0	0.0										
EoT	1	36.40			36.40		36.4	36.4	36.70			36.70	-0.30			-0.30		-0.3	-0.3										
EoS (Day 21-28)	3	36.57	36.28	36.85	36.50	0.115	36.5	36.7	36.60	36.17	37.03	36.70	-0.03	-0.41	0.35	0.00	0.153	-0.2	0.1										

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.