

Frequency Percent Row Pct	Table 1 of Sex by pain						
	Controlling for screen=Fail						
	Sex	pain					Total
		0	1	2	3	4	
Female		3	0	0	0	0	3
		21.43	0.00	0.00	0.00	0.00	21.43
		100.00	0.00	0.00	0.00	0.00	
Male		11	0	0	0	0	11
		78.57	0.00	0.00	0.00	0.00	78.57
		100.00	0.00	0.00	0.00	0.00	
Total		14	0	0	0	0	14
		100.00	0.00	0.00	0.00	0.00	100.00
Frequency Missing = 37							

Frequency Percent Row Pct	Table 2 of Sex by pain						
	Controlling for screen=Pass						
	Sex	pain					Total
		0	1	2	3	4	
Female		0	5	10	10	10	35
		0.00	6.49	12.99	12.99	12.99	45.45
		0.00	14.29	28.57	28.57	28.57	
Male		0	7	7	12	16	42
		0.00	9.09	9.09	15.58	20.78	54.55
		0.00	16.67	16.67	28.57	38.10	
Total		0	12	17	22	26	77
		0.00	15.58	22.08	28.57	33.77	100.00

Frequency Row Pct	Table of Sex by sf_reason			
	Sex	sf_reason(Screen Failure Reason)		
		HIGH BLOOD PRESSURE	LOW BASELINE PAIN	Total
	Female	23 88.46	3 11.54	26
	Male	14 56.00	11 44.00	25
	Total	37	14	51
	Frequency Missing = 77			

Output 8.2.5: Diastolic Blood Pressure and Pulse Summary Statistics at Baseline Visit in Site 1

Sex	Systolic Blood Pressure	N Obs	Variable	Label	N	Mean	Std Dev	Minimum	Maximum
Female	Acceptable(120 or below)	37	dbp	Diastolic Blood Pressure	37	77.4	8.7	61.0	91.0
			pulse	Pulse	37	74.0	9.6	57.0	92.0
	High	24	dbp	Diastolic Blood Pressure	24	100.6	9.3	87.0	120.0
			pulse	Pulse	24	97.5	10.2	79.0	118.0
Male	Acceptable(120 or below)	55	dbp	Diastolic Blood Pressure	55	77.1	10.9	49.0	100.0
			pulse	Pulse	55	73.4	11.8	42.0	99.0
	High	12	dbp	Diastolic Blood Pressure	12	97.6	10.1	80.0	118.0
			pulse	Pulse	12	92.7	10.8	73.0	109.0

Output 8.2.6: Glucose and Hemoglobin Summary Statistics from Baseline Lab Results, Site 1

Sex	N Obs	Variable	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
Female	35	C_Gluc	96.0	101.0	105.0	109.0	116.0
		Hemoglob	11.5	12.7	13.6	14.6	16.5
Male	42	C_Gluc	98.0	101.0	106.0	109.0	118.0
		Hemoglob	11.2	13.0	13.4	14.3	15.8

Output 8.5.6: Visits for All Subjects with Days on Study, Site 1 (Partial Listing)

Subject Number	Vis1	Vis2	Vis3	Vis4	Vis5	Days
1	01/22/2018	04/24/2018	07/25/2018	10/25/2018	01/25/2019	368
2	01/23/2018	04/26/2018	07/28/2018	10/29/2018	01/30/2019	372
4	01/20/2018	04/19/2018	.	.	.	89
6	01/24/2018	04/26/2018	07/25/2018	10/22/2018	01/19/2019	360
8	01/21/2018	04/25/2018	07/25/2018	10/25/2018	01/25/2019	369
9	01/27/2018	04/30/2018	08/02/2018	11/04/2018	02/06/2019	375
10	01/24/2018	04/22/2018	07/22/2018	10/23/2018	01/24/2019	365
11	01/27/2018	04/27/2018	07/25/2018	10/21/2018	01/17/2019	355

Output 8.5.8: Baseline Lab Results for Subject 75, Site 1—Including Flag for Values Outside Normal Range

Subject	Laboratory Test	Collected Units	Value	Normal Range Lower Limit	Normal Range Upper Limit	RangeFlag
75	ALBUMIN	g/dL	4.5	3.4	5.4	0
75	ALK. PHOS.	IU/L	101	20	140	0
75	ALT (SGPT)	IU/L	12	5	35	0
75	AST (SGOT)	IU/L	22	10	34	0
75	DIRECT BILI	mg/dL	0.16	0	0.3	0
75	GGTP	IU/L	31	0	51	0
75	GLUCOSE	mg/dL	110	100	110	0
75	GLUCOSE		0	0	0	0
75	HEMATOCRIT	%	55	35	49	1
75	HEMOGLOBIN	g/dL	14.4	11.7	15.9	0
75	TOTAL BILI	mg/dL	1.2	0.3	1.9	0
75	TOTAL PROT	g/dL	5.7	6	8.3	0
75	PREG		0	.	.	0

Output 8.6.1: Rotated Data from Baseline Visit, Site 1 (Partial Listing)

Subject Number	Date of Visit	name	Value	units
1	01/22/2018	Systolic BP	110.0	mm-hg
1	01/22/2018	Diastolic BP	80.0	mm-hg
1	01/22/2018	Pulse	75.0	beats/min
1	01/22/2018	Temperature	98.4	F
1	01/22/2018	Weight	192.0	lb
2	01/23/2018	Systolic BP	99.0	mm-hg
2	01/23/2018	Diastolic BP	84.0	mm-hg
2	01/23/2018	Pulse	81.0	beats/min
2	01/23/2018	Temperature	98.5	F
2	01/23/2018	Weight	134.0	lb

Output 8.6.2: Summary Report on Selected Vital Signs, All Visits, Site 1

Visit	Measurement	Units	Mean	Median	Std.Deviation	Minimum	Maximum
12 Month Visit	Diastolic BP	mm-hg	77.6	80.0	9.07	52.0	91.0
	Pulse	beats/min	74.4	75.0	9.78	45.0	89.0
	Systolic Bp	mm-hg	105.4	105.0	11.20	75.0	128.0
	Temperature	F	98.3	98.2	1.43	95.0	102.1
3 Month Visit	Diastolic BP	mm-hg	77.1	79.0	9.67	49.0	90.0
	Pulse	beats/min	73.5	75.0	10.46	44.0	89.0
	Systolic Bp	mm-hg	103.7	104.0	12.23	70.0	133.0
	Temperature	F	98.4	98.4	0.75	96.9	100.2
6 Month Visit	Diastolic BP	mm-hg	77.7	80.0	9.65	50.0	91.0
	Pulse	beats/min	74.3	76.0	10.71	43.0	90.0
	Systolic Bp	mm-hg	104.9	104.0	12.26	71.0	135.0
	Temperature	F	98.4	98.4	1.04	96.2	100.3
9 Month Visit	Diastolic BP	mm-hg	78.1	80.0	9.53	51.0	91.0
	Pulse	beats/min	74.8	75.5	10.18	45.0	93.0
	Systolic Bp	mm-hg	105.9	105.0	11.99	74.0	138.0
	Temperature	F	98.5	98.6	1.25	95.7	101.2
Baseline Visit	Diastolic BP	mm-hg	83.5	82.5	14.09	49.0	120.0
	Pulse	beats/min	79.9	79.0	14.70	42.0	118.0
	Systolic Bp	mm-hg	111.0	110.0	17.03	67.0	155.0
	Temperature	F	98.5	98.5	0.58	97.1	99.8

Output 8.6.3: BP Summaries, All Visits, Site

	Measurement					
	Diastolic BP			Systolic Bp		
Visit	Mean	Median	Std.Deviation	Mean	Median	Std.Deviation
12 Month Visit	77.6	80.0	9.07	105.4	105.0	11.20
3 Month Visit	77.1	79.0	9.67	103.7	104.0	12.23
6 Month Visit	77.7	80.0	9.65	104.9	104.0	12.26
9 Month Visit	78.1	80.0	9.53	105.9	105.0	11.99
Baseline Visit	83.5	82.5	14.09	111.0	110.0	17.03

Output 8.7.1: Adverse Events, Site 1 (Partial Listing)

SUBJECT	AETEXT	STDT	ENDT
25	TIA	11Jan2018	12Jan2018
25	CARPAL TUNNEL IN LEFT HAND	18Jan2018	19Jan2018
38	SUICIDAL	24Jan2018	24Jan2018
41	MOUTH PAIN	14Jan2018	15Jan2018
41	IRRITABLE BOWEL SYNDROME	28Jan2018	29Jan2018
41	LOOSE STOOL	30Jan2018	01Jan2018
46	RACING HEART BEAT	30Jan2018	01Jan2018
46	DELIRIOUS	26Jan2018	27Jan2018
50	HEART FLUTTERING	17Jan2018	17Jan2018
50	RINGING IN EAR	30Jan2018	01Jan2018

Visit	Test	Units	Mean	Median	Std.Dev.	Min.	Max.
12 Month Visit	Diastolic BP	mm-hg	77.6	80.0	9.07	52.0	91.0
	Pulse	beats/min	74.4	75.0	9.78	45.0	89.0
	Systolic Bp	mm-hg	105.4	105.0	11.20	75.0	128.0
	Temperature	F	98.3	98.2	1.43	95.0	102.
3 Month Visit	Diastolic BP	mm-hg	77.1	79.0	9.67	49.0	90.0
	Pulse	beats/min	73.5	75.0	10.46	44.0	89.0
	Systolic Bp	mm-hg	103.7	104.0	12.23	70.0	133.0
	Temperature	F	98.4	98.4	0.75	96.9	100.2
6 Month Visit	Diastolic BP	mm-hg	77.7	80.0	9.65	50.0	91.0
	Pulse	beats/min	74.3	76.0	10.71	43.0	90.0
	Systolic Bp	mm-hg	104.9	104.0	12.26	71.0	135.0
	Temperature	F	98.4	98.4	1.04	96.2	100.3
9 Month Visit	Diastolic BP	mm-hg	78.1	80.0	9.53	51.0	91.0
	Pulse	beats/min	74.8	75.5	10.18	45.0	93.0
	Systolic Bp	mm-hg	105.9	105.0	11.99	74.0	138.0
	Temperature	F	98.5	98.6	1.25	95.7	101.2
Baseline Visit	Diastolic BP	mm-hg	83.5	82.5	14.09	49.0	120.0
	Pulse	beats/min	79.9	79.0	14.70	42.0	118.0
	Systolic Bp	mm-hg	111.0	110.0	17.03	67.0	155.0
	Temperature	F	98.5	98.5	0.58	97.1	99.8