

The SAS System

10/05/2016

Site	SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal	% of promised
Maine	359	1	167	.	.	104	125	83.2
Tufts	490	2	247	3	1	141	112	125.9
MedStar	408	2	237	1	.	152	150	101.3
Duke	361	2	219	2	.	132	150	88.0
SouthCarolina	183	.	70	.	.	32	150	21.3
Florida	345	1	119	1	.	73	150	48.7
Atlanta	252	.	217	1	1	128	180	71.1
NewYork	190	.	73	.	.	37	100	37.0
Northwestern	301	1	213	1	.	115	125	92.0
Tennessee	82	.	38	.	.	29	150	19.3
Tulane	35	.	2	.	.	2	150	1.3
Pennington	250	.	82	1	.	47	190	24.7
HealthPartners	621	.	434	3	1	283	300	94.3
Kansas	369	1	177	1	.	109	150	72.7
Baylor	209	.	82	.	.	43	150	28.7
Nebraska	548	6	281	1	1	161	126	127.8
UTSouthwestern	116	.	76	.	.	42	120	35.0
LA	251	.	134	.	.	80	120	66.7
Stanford	335	.	151	3	1	85	150	56.7
Baltimore	201	.	115	.	.	75	100	75.0
Cleveland	181	1	89	3	1	49	100	49.0
Kaiser	450	.	375	1	.	237	130	182.3
Denver	320	.	127	1	2	72	65	110.8
Lenox	19	3	.	.	.	.	25	.
	6876	20	3725	23	8	2228	2382	93.5

7.1.a Detail on diabetes diagnosis

	Overall	M06	M12	M18	M24	M30	M36	M42	M48
Semi-annual visits	2728	1760	-	846 ¹	-	122	-	-	-
Diabetes, n (% visits)	67 (2.5)	49 (2.8)	-	16 (1.9)	-	2 (1.6)	-	-	-
Positive A1c and FPG	27	19	-	7	-	1	-	-	-
Positive A1c or FPG, pos. confirmatory	40	30	-	9	-	1	-	-	-
No diabetes, n	2661	1711	-	830	-	120	-	-	-
Negative A1c and FPG	2595	1661	-	816	-	118	-	-	-
Positive A1c or FPG, neg. confirmatory	66	50	-	14	-	2	-	-	-
Weight change (% from baseline)		-0.27%		-0.09%		-0.61%			
Annual visits	1760	-	1283 ¹	-	477	-	-	-	-
Diabetes, n (% visits)	71 (4.0)	-	56 (4.4)	-	15 (3.1)	-	-	-	-
Positive, met 2 criteria	23	-	19	-	4	-	-	-	-
Positive, met 1 criterion, pos. confirmatory	48	-	37	-	11	-	-	-	-
No diabetes, n	1689	-	1227	-	462	-	-	-	-
All 3 criteria negative	1600	-	1157	-	443	-	-	-	-
Met 1 criterion, neg. confirmatory	89	-	70	-	19	-	-	-	-
Weight change (% from baseline)			-0.13%		-0.26%				
Outside of study events by adjudication ²	17	2	7	3	3	2			
Total events	155	51	63	19	18	4			

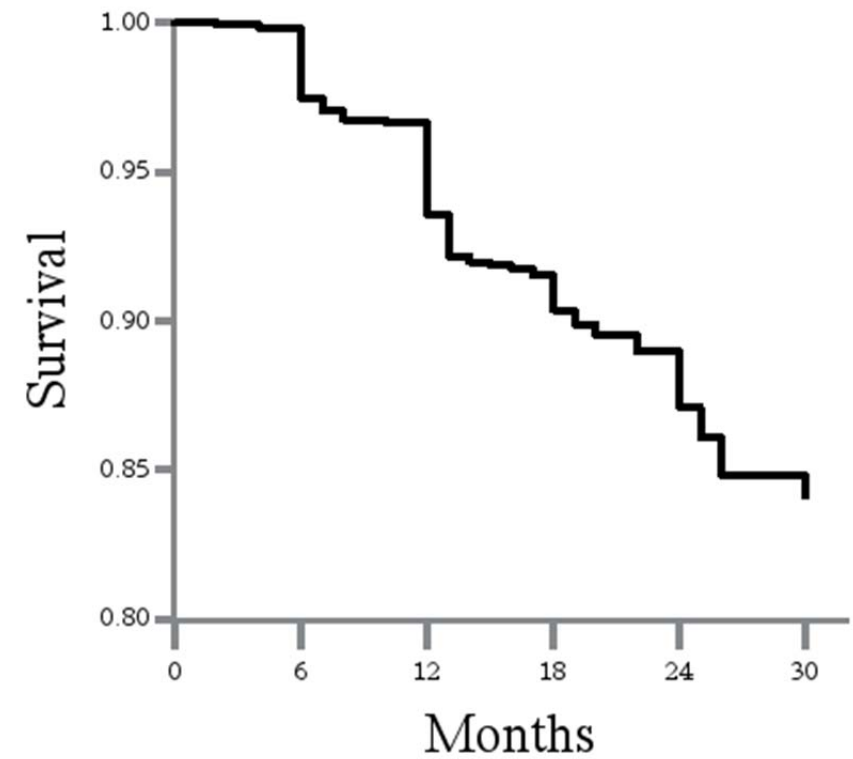
¹ Number excludes participants who have reached the *diabetes outcome* [by D2d criteria or adjudication].

² If diabetes outcome was adjudicated before stated interval, it is shown under stated interval. For example, adjudicated outcomes between the M06 and M12 visits are shown under M12. Longitudinal analyses (when conducted) will be based on “time-to-event.”

Annual Kaplan-Meier event rate = **6.49%**

Product-Limit Survival Estimates

Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	1770
6	0.9745	0.0255	0.00375	45	1372
12	0.9351	0.0649	0.00641	98	934
18	0.9028	0.0972	0.00841	129	563
24	0.87	0.13	0.0111	147	251
30	0.8401	0.1599	0.0165	153	44

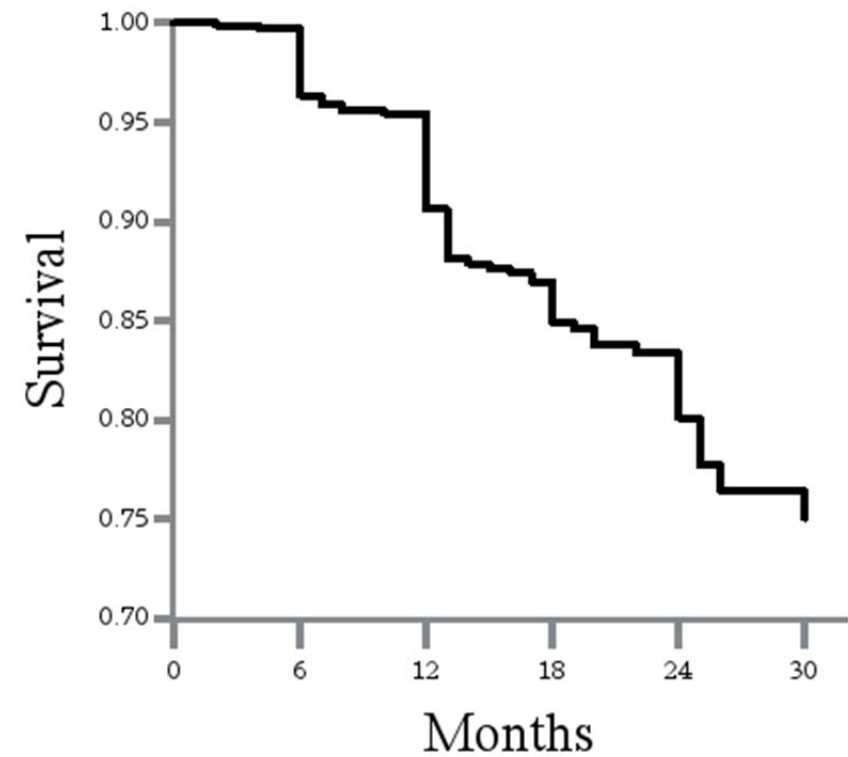


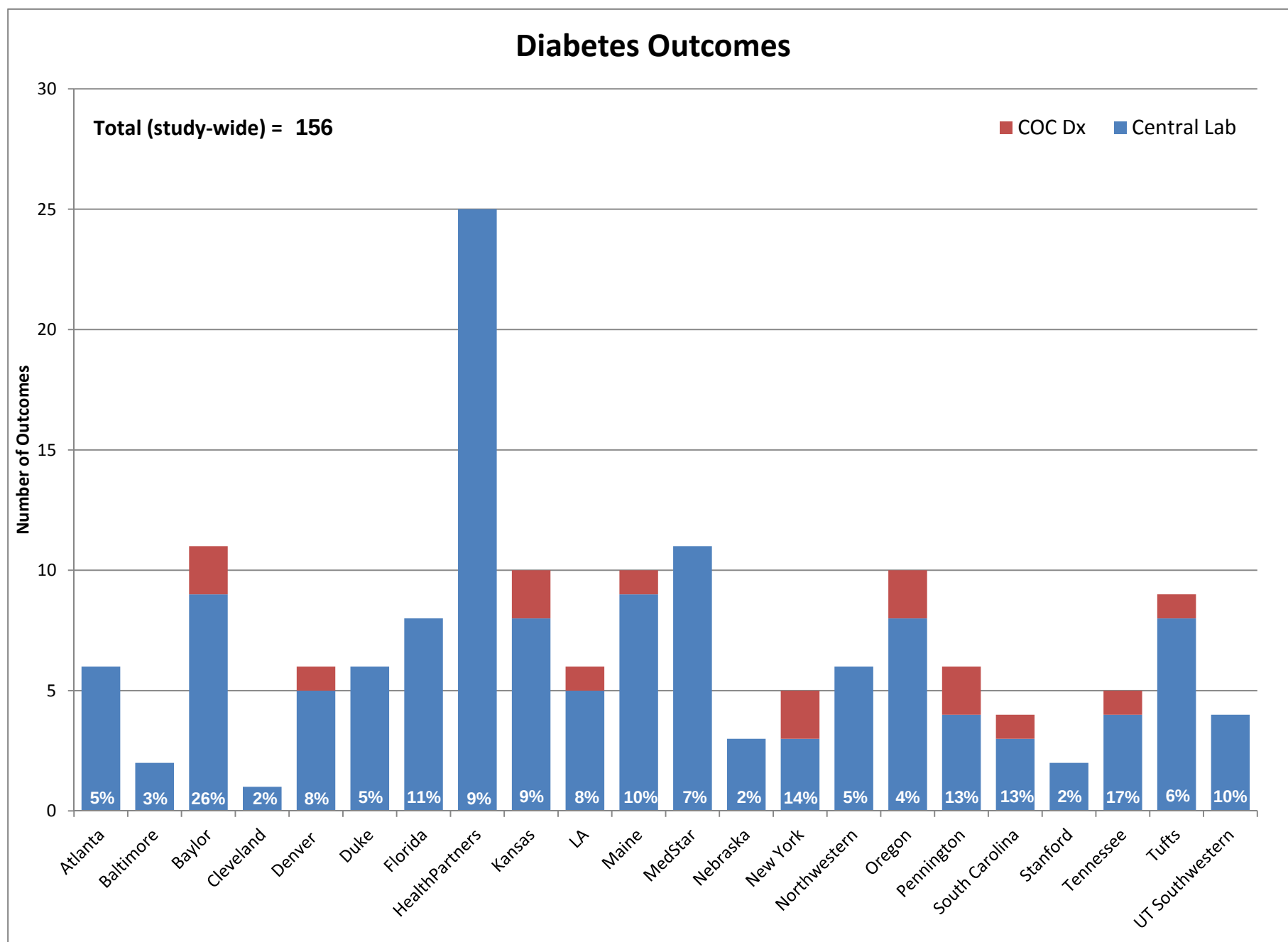
Among participants meeting DPP eligibility criteria (FPG 95-125 and 2hPG 140-199)

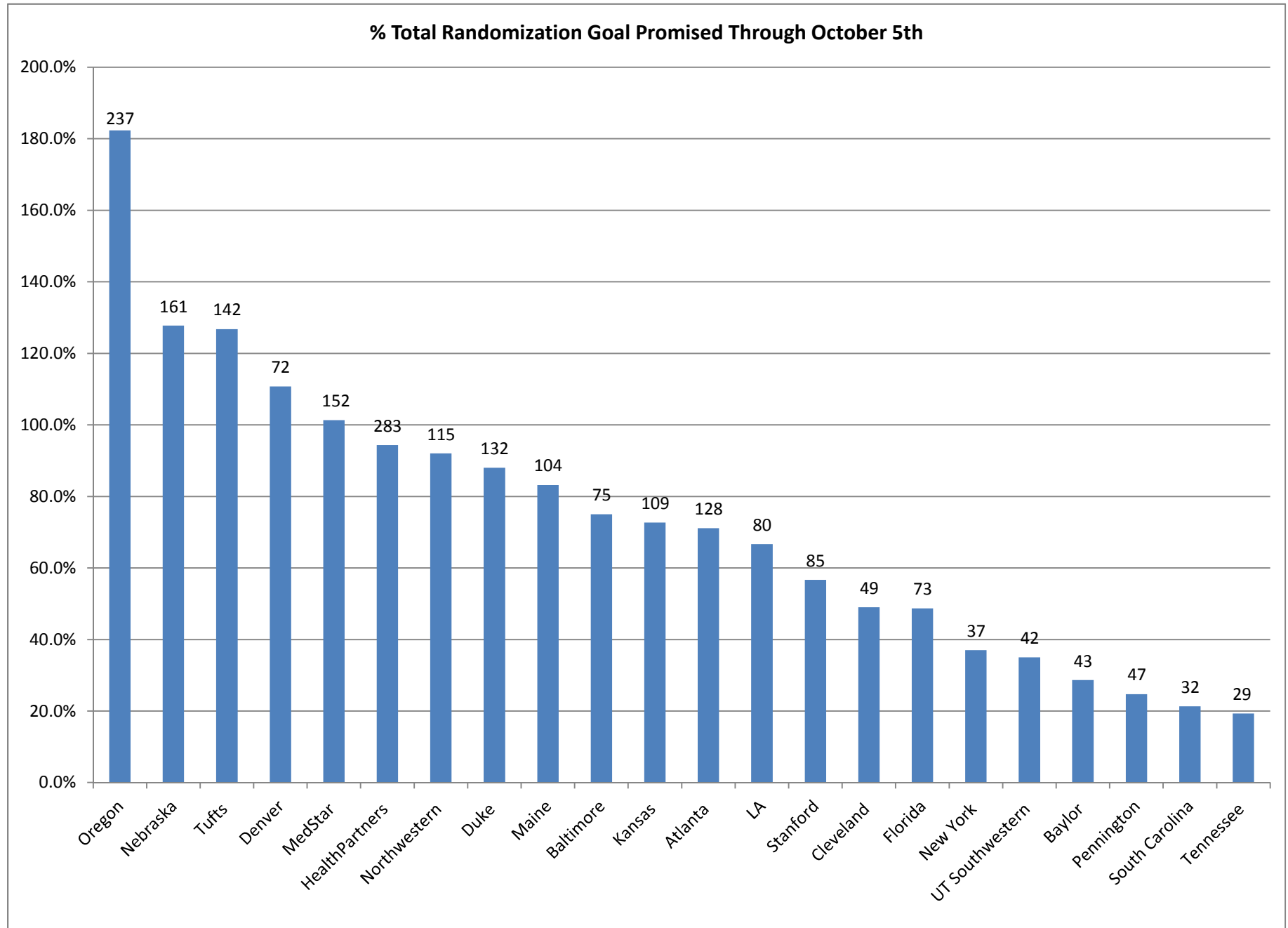
Annual Kaplan-Meier event rate = 9.57%

Product-Limit Survival Estimates

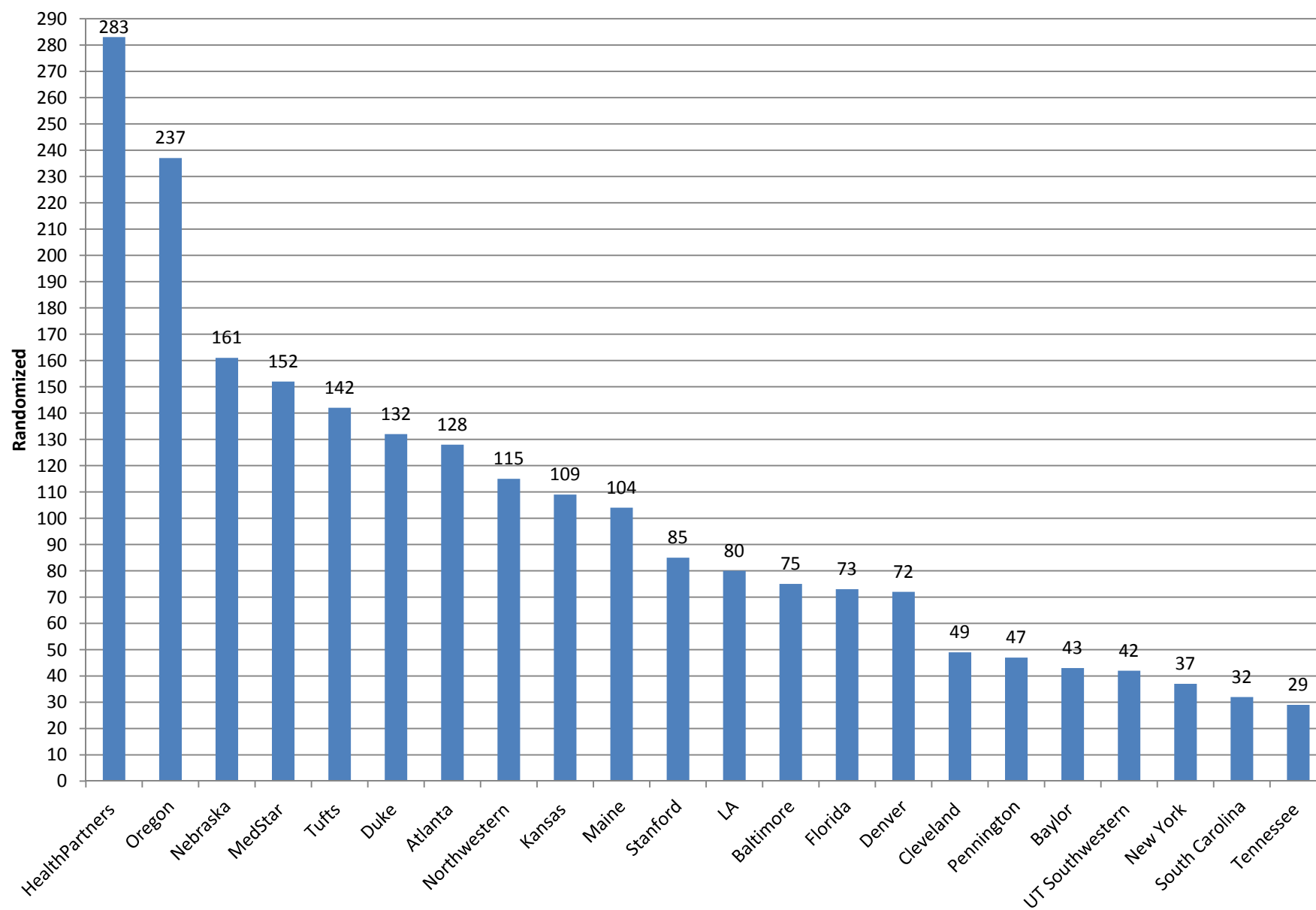
Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	839
6	0.9629	0.0371	0.00653	31	651
12	0.9043	0.0957	0.0111	69	426
18	0.8469	0.1531	0.015	95	241
24	0.7982	0.2018	0.0197	107	99
30	0.7473	0.2527	0.0294	112	16







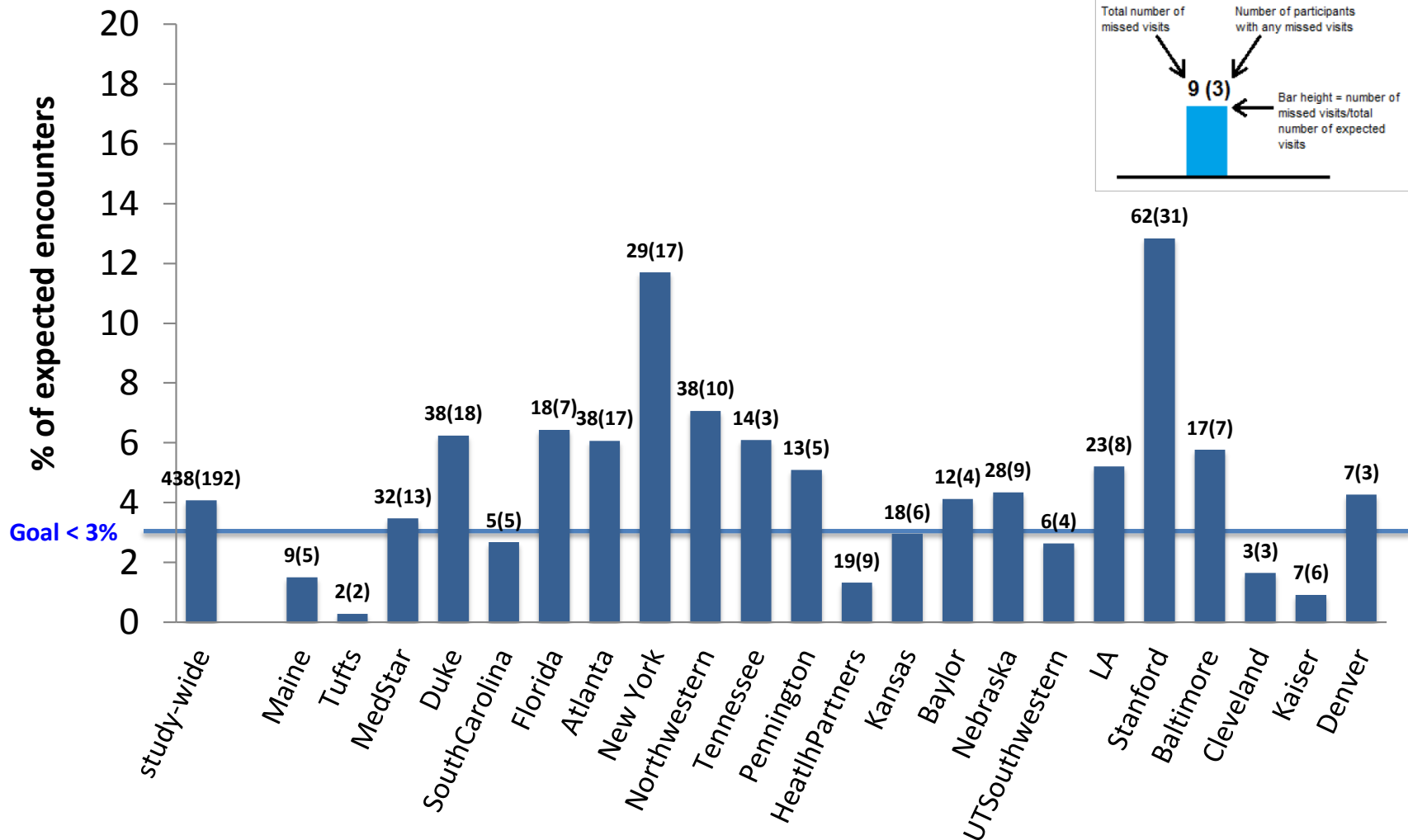
Randomizations by Site



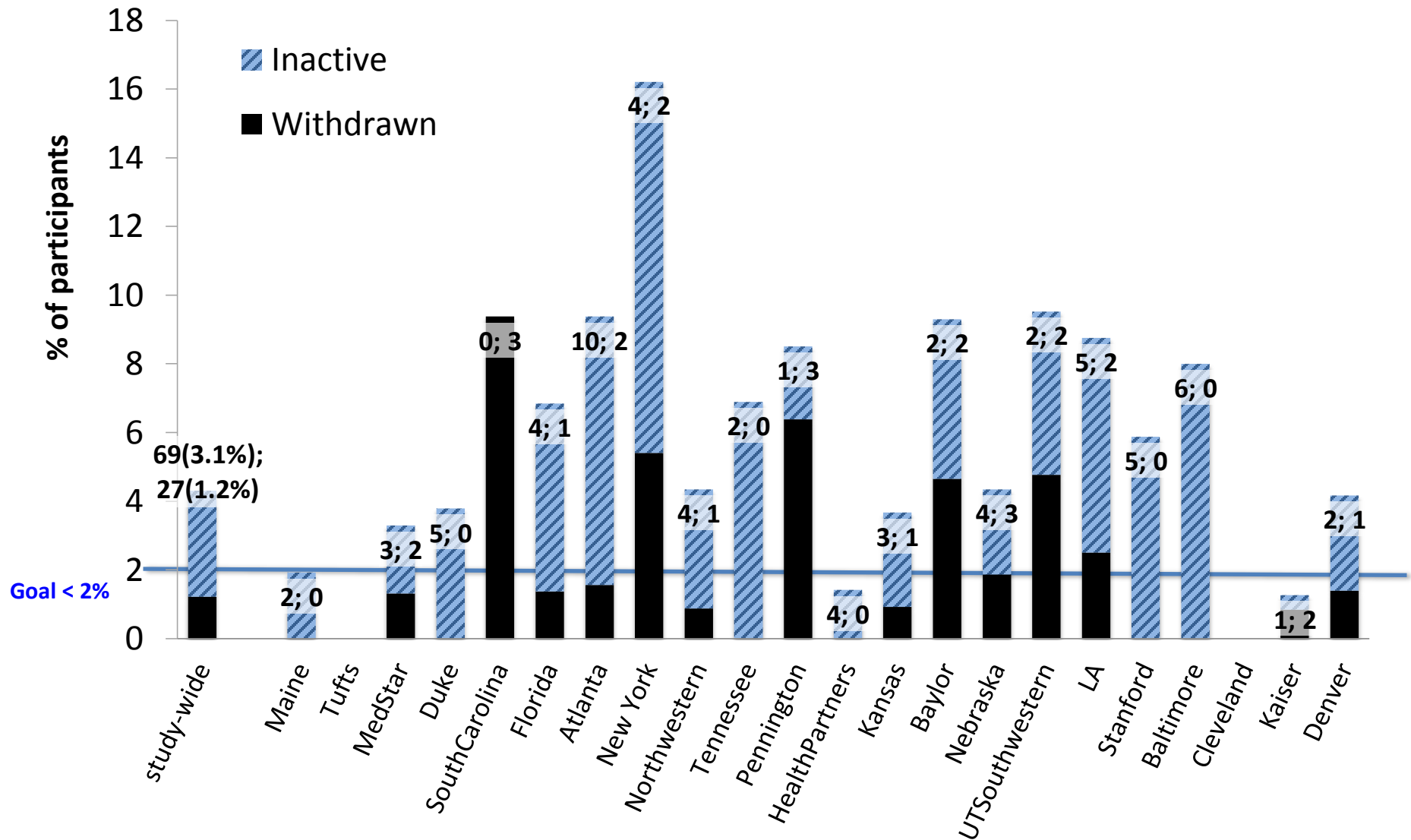
Missed encounters (visits and interim phone contact)

8

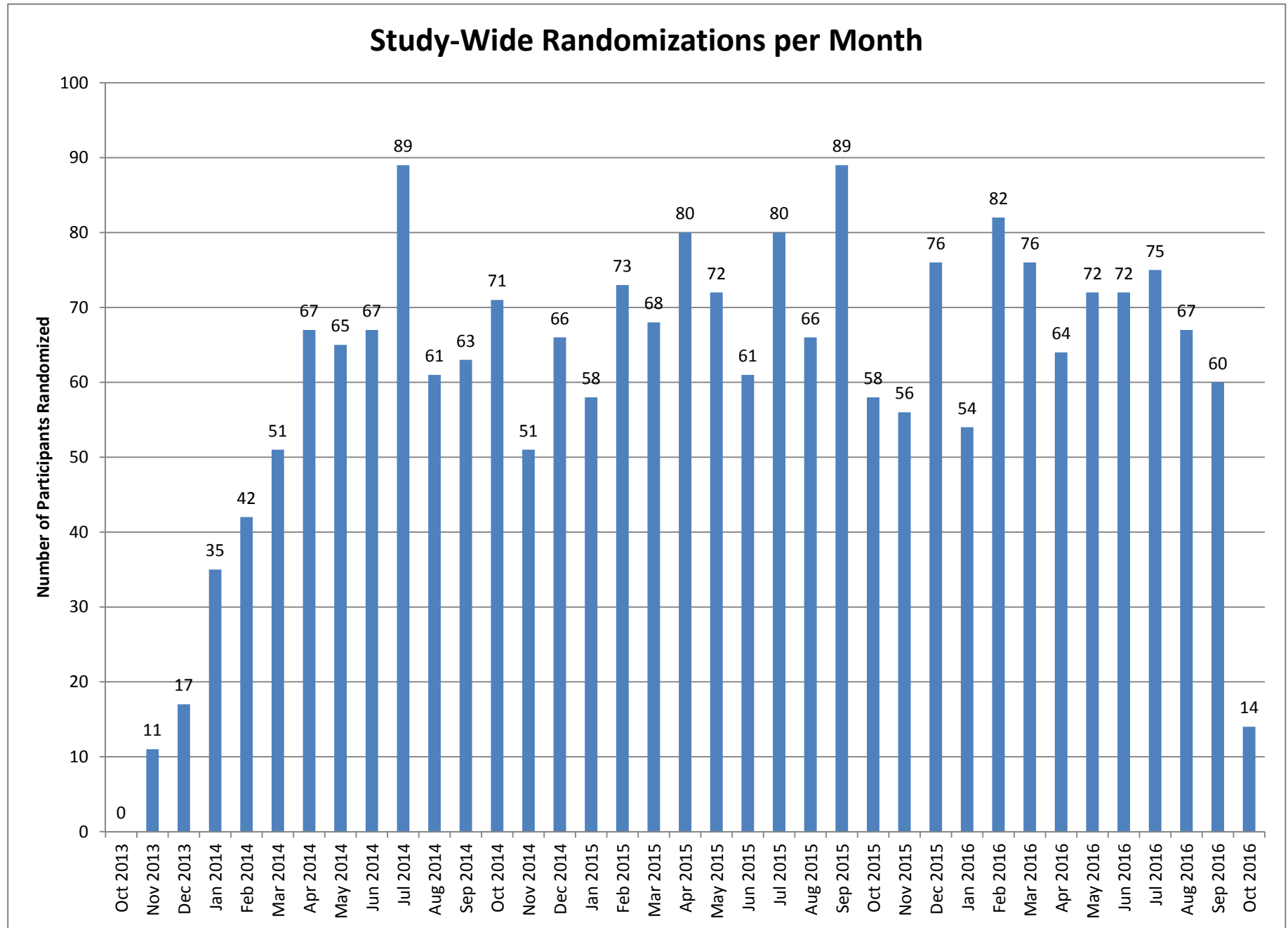
Study-wide = 4.1%



% inactive and withdrawn participants



Labels are number of participants (inactive; withdrawn).

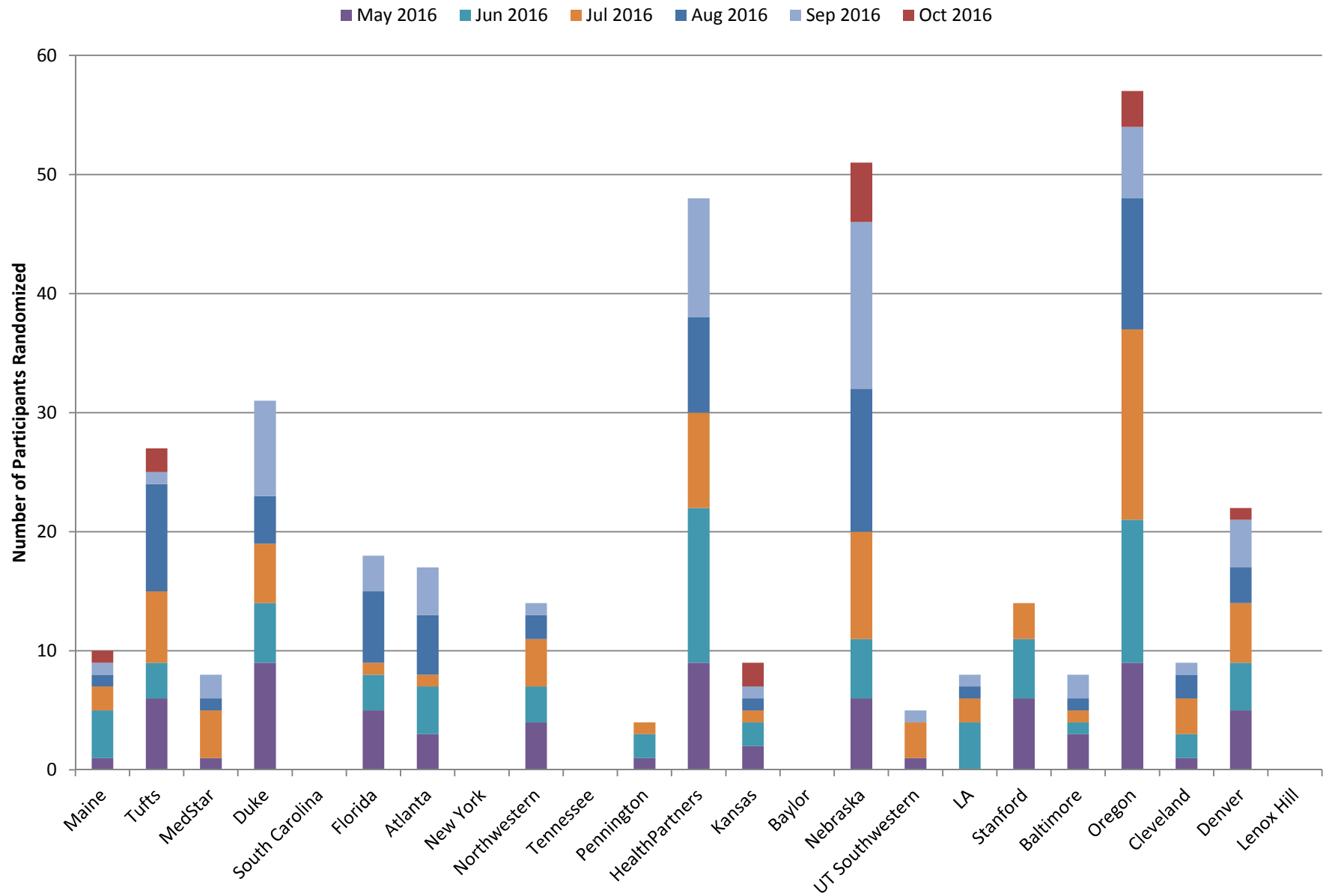


The SAS System

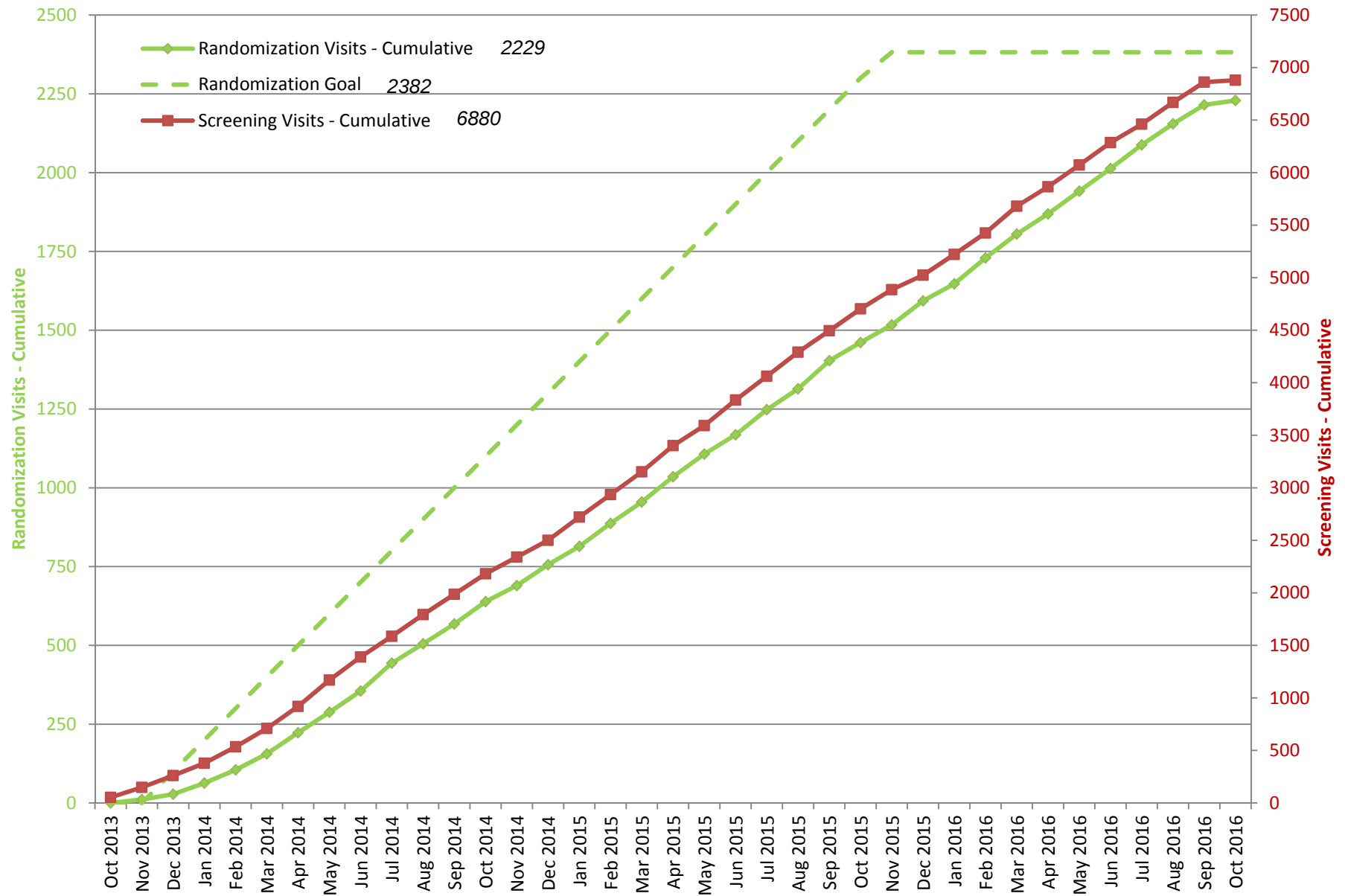
10/05/2016

Site	Monthly RAN goal	RAN goal	SCR visits	BAS visits	RAN visits	SCR:RAN ratio	% of goal	10/2016 SCR visits	10/2016 BAS visits	10/2016 RAN visits	10/2016 SCR:RAN ratio	10/2016 RAN goal(%)	9/2016 SCR visits	9/2016 BAS visits	9/2016 RAN visits	9/2016 SCR:RAN ratio	9/2016 RAN goal(%)
Maine	5.2	125	359	167	104	3.5	83.2	.	.	1	.	19	2	3	1	2.0	19
Tufts	4.7	112	490	247	141	3.5	125.9	1	1	2	1.0	21	16	9	1	16.0	21
MedStar	6.3	150	408	237	152	2.7	101.3	.	1	.	.	.	2	2	2	1.0	32
Duke	6.3	150	361	219	132	2.7	88.0	.	.	.	.	.	6	10	8	.8	127
SouthCarolina	6.3	150	183	70	32	5.7	21.3	.	.	.	.	.	.	.	.	.	.
Florida	6.3	150	345	119	73	4.7	48.7	2	1	.	.	.	6	1	3	2.0	48
Atlanta	7.5	180	252	217	128	2.0	71.1	1	.	.	.	.	8	7	4	2.0	53
NewYork	4.2	100	190	73	37	5.1	37.0	.	.	.	.	.	.	.	.	.	.
Northwestern	5.2	125	301	213	115	2.6	92.0	1	.	.	.	.	5	4	1	5.0	19
Tennessee	6.3	150	82	38	29	2.8	19.3	.	.	.	.	.	.	.	.	.	.
Tulane	6.3	150	35	2	2	17.5	1.3	.	.	.	.	.	.	.	.	.	.
Pennington	7.9	190	250	82	47	5.3	24.7	1	1	.	.	.	7	.	.	.	.
HealthPartners	12.5	300	621	434	283	2.2	94.3	3	1	.	.	.	32	16	10	3.2	80
Kansas	6.3	150	369	177	109	3.4	72.7	.	.	2	.	32	14	4	1	14.0	16
Baylor	6.3	150	209	82	43	4.9	28.7	.	.	.	.	.	.	.	.	.	.
Nebraska	5.3	126	548	281	161	3.4	127.8	1	.	5	.2	94	20	11	14	1.4	264
UTSouthwestern	5.0	120	116	76	42	2.8	35.0	.	.	.	.	.	.	2	1	.	20
LA	5.0	120	251	134	80	3.1	66.7	2	.	.	.	.	1	1	1	1.0	20
Stanford	6.3	150	335	151	85	3.9	56.7	2	2	.	.	.	6	2	.	.	.
Baltimore	7.7	100	201	115	75	2.7	75.0	.	.	.	.	.	3	.	2	1.5	26
Cleveland	7.7	100	181	89	49	3.7	49.0	1	1	.	.	.	7	5	1	7.0	13
Kaiser	10.0	130	450	375	237	1.9	182.3	3	.	3	1.0	30	31	12	6	5.2	60
Denver	5.4	65	320	127	72	4.4	110.8	.	.	1	.	19	4	6	4	1.0	74
Lenox	5.0	25	19	.	.	.	.	1	.	.	.	.	18	.	.	.	.
	.	.	6876	3725	2228	3.1	93.5	19	8	14	1.5	9	188	95	60	3.1	43

Randomizations By Site - Last 6 Months

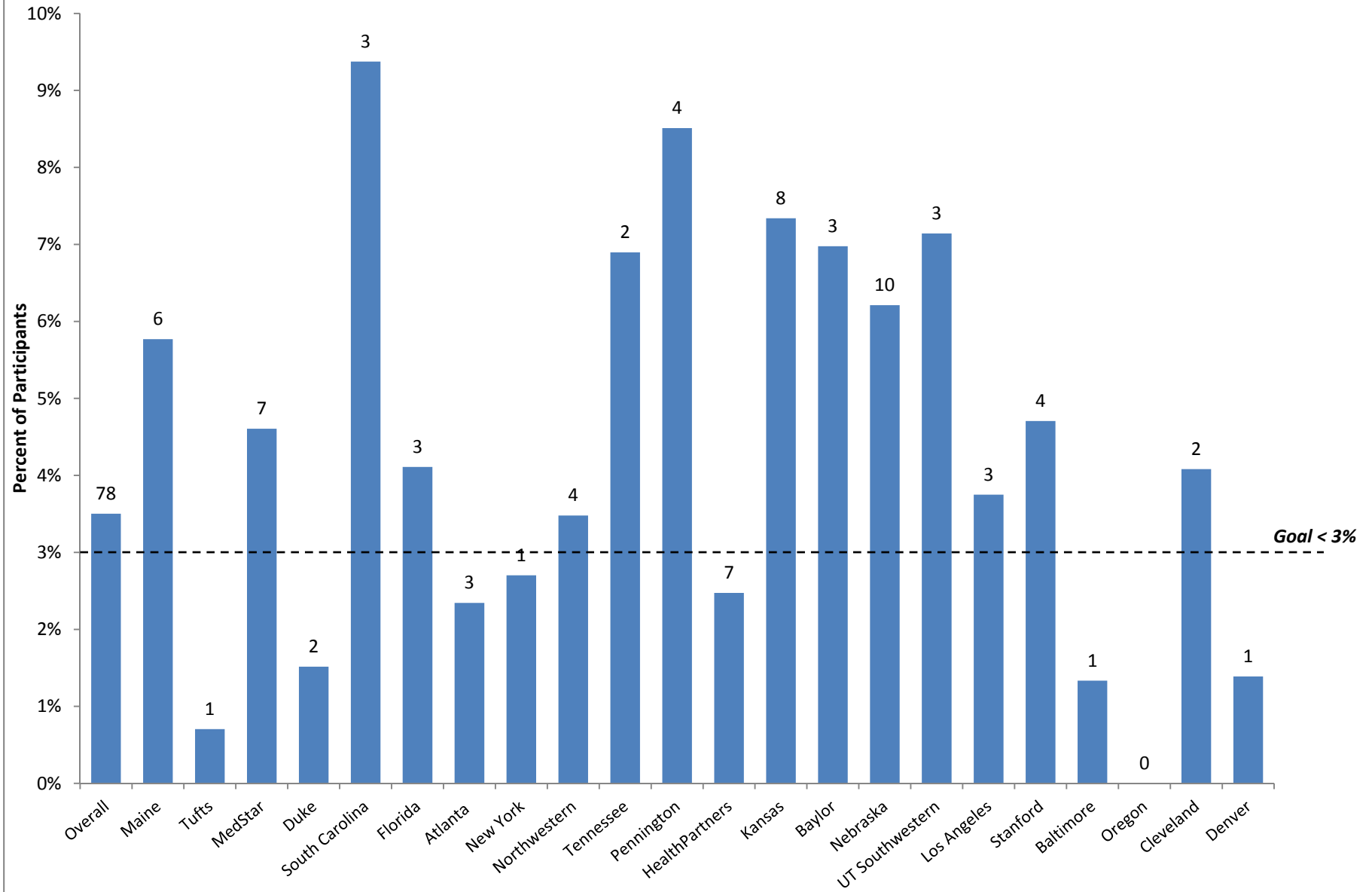


Cumulative Screening and Randomization Visits by Month



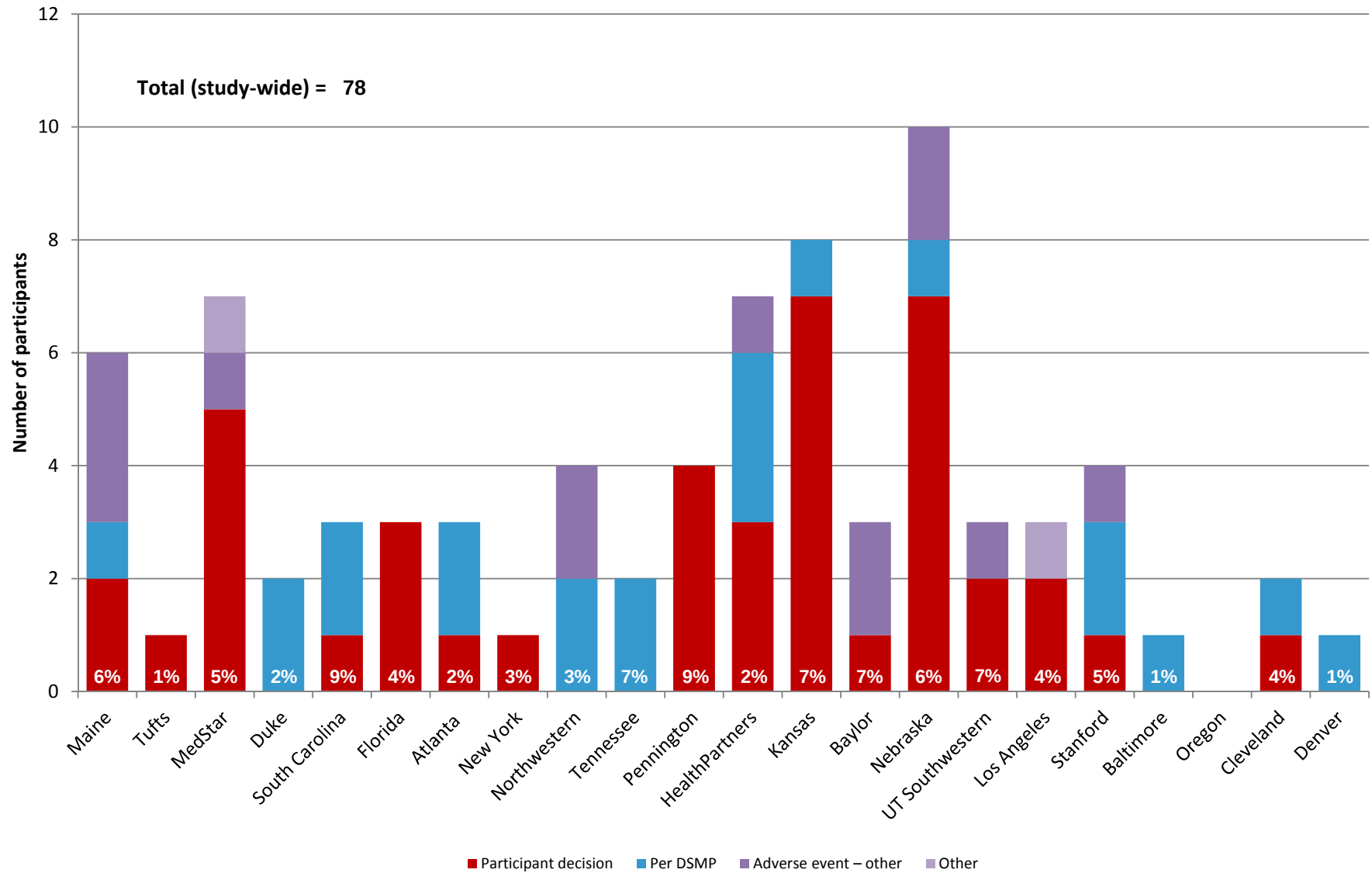
Discontinuation of Study Pills

excludes participants who withdrew consent



Discontinuation of Study Pills

excludes participants who withdrew consent



Biorepository Consent

Site	Total RAND	Biorepository Consent (%)	DNA Consent(%)
Atlanta	128	95%	95%
Baltimore	75	93%	91%
Baylor	43	93%	93%
Beth Israel Medical Center	37	86%	86%
Cleveland	49	96%	94%
Denver VA	56	100%	98%
Duke	132	80%	78%
Florida	73	96%	95%
HealthPartners	283	90%	89%
Kaiser	237	94%	91%
LA	80	90%	90%
Maine	104	89%	89%
South Carolina	32	75%	75%
MedStar	152	90%	86%
Northwestern	115	91%	87%
Omaha VA	115	91%	91%
Pennington	47	87%	85%
Stanford	85	93%	92%
Truman	13	85%	85%
Tufts	142	94%	94%
UC Denver	16	100%	100%
Kansas	96	82%	82%
Nebraska (UNMC)	46	85%	80%
Tennessee	29	62%	59%
UT Southwestern	42	100%	100%
Overall	2229	90%	89%

Demographics of Randomized Participants

Site	Total	Male	Hispanic or Latino	White	Black or African American	Asian	American Indian or Alaska Native	Native Hawaiian or Other Pacific Islander	Other
Atlanta	128	117	3	26	95	4	2	0	1
Baltimore	75	25	0	14	58	2	0	0	1
Baylor	43	14	14	24	15	0	2	1	1
Beth Israel Medical Center	37	17	14	19	13	3	0	0	2
Cleveland	49	33	4	30	15	3	0	0	1
Denver VA	56	52	7	46	8	0	2	0	0
Duke	132	65	6	73	52	6	0	0	1
Florida	73	32	13	57	10	3	0	0	3
HealthPartners	283	172	9	254	14	10	2	0	3
Kaiser	237	129	19	194	12	17	1	0	13
LA	80	11	75	75	2	3	0	0	0
Maine	104	43	1	99	2	0	0	0	3
South Carolina	32	10	0	19	11	1	0	0	1
MedStar	152	75	7	45	99	4	0	2	2
Northwestern	115	72	7	80	29	6	0	0	0
Omaha VA	115	110	4	102	8	1	1	0	3
Pennington	47	19	1	29	16	2	0	0	0
Stanford	85	56	5	47	4	32	0	0	2
Truman	13	6	1	5	8	0	0	0	0
Tufts	142	72	8	92	36	12	0	0	2
UC Denver	16	10	1	10	6	0	0	0	0
Kansas	96	42	2	70	22	2	1	1	0
Nebraska (UNMC)	46	25	3	38	6	0	0	1	1
Tennessee	29	10	1	10	19	0	0	0	0
UT Southwestern	42	23	9	26	7	6	0	0	3
Overall	2229	1240	214	1484	567	117	11	5	43
			9.6%						