

The SAS System

11/30/2016

Site	SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal	% of promised
Maine	367	2	170	1	.	105	125	84.0
Tufts	505	2	255	3	1	148	112	132.1
MedStar	418	2	246	2	1	155	150	103.3
Duke	372	1	228	3	1	136	150	90.7
SouthCarolina	183	.	70	.	.	32	150	21.3
Florida	359	2	123	2	.	75	150	50.0
Atlanta	258	.	223	2	1	133	180	73.9
NewYork	190	.	73	.	.	37	100	37.0
Northwestern	307	1	220	.	1	119	125	95.2
Tennessee	82	.	38	.	.	29	150	19.3
Tulane	35	.	2	.	.	2	150	1.3
Pennington	257	1	84	.	.	47	190	24.7
HealthPartners	663	.	466	2	3	306	300	102.0
Kansas	401	2	190	2	.	118	150	78.7
Baylor	209	.	82	.	.	43	150	28.7
Nebraska	559	2	294	3	1	170	126	134.9
UTSouthwestern	118	.	77	.	.	42	120	35.0
LA	260	1	143	.	.	84	120	70.0
Stanford	335	.	157	4	.	89	150	59.3
Baltimore	213	5	120	.	.	78	100	78.0
Cleveland	186	2	94	1	2	53	100	53.0
Kaiser	461	.	408	5	4	258	130	198.5
Denver	331	.	134	3	.	77	65	118.5
Lenox	43	3	10	.	.	8	25	32.0
	7112	26	3907	33	15	2344	2382	98.4

7.1.a Detail on diabetes diagnosis

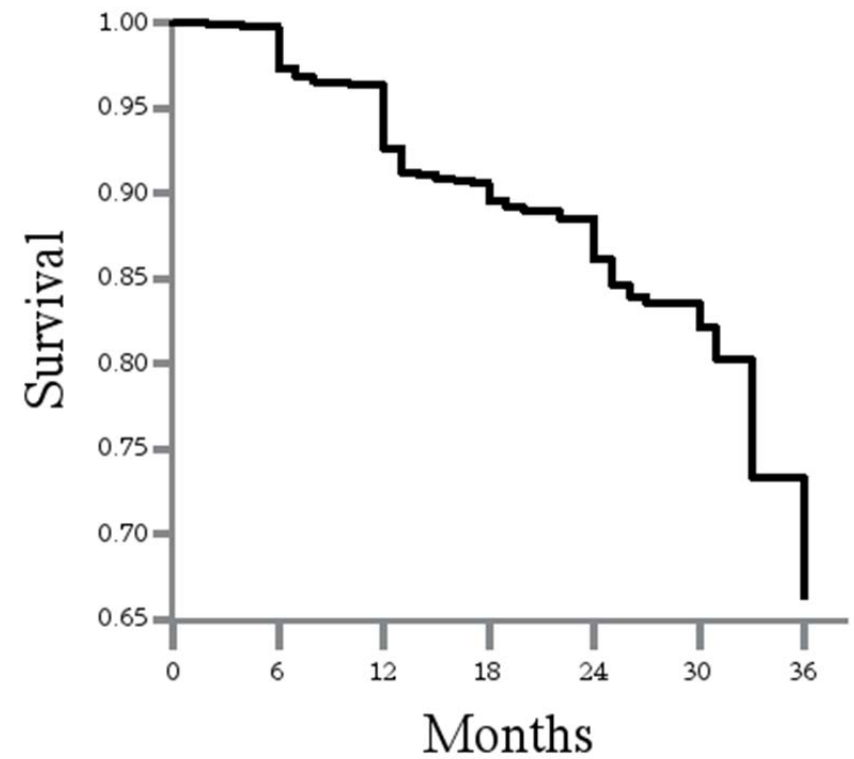
	Overall	M06	M12	M18	M24	M30	M36	M42	M48
Semi-annual visits	3033	1859	-	951 ¹	-	223	-	-	-
Diabetes, n (% visits)	77 (2.5)	55 (3.0)	-	16 (1.7)	-	6 (2.7)	-	-	-
Positive A1c and FPG	27	19	-	7	-	1	-	-	-
Positive A1c or FPG, pos. confirmatory	50	36	-	9	-	5	-	-	-
No diabetes, n	2956	1804	-	935	-	217	-	-	-
Negative A1c and FPG	2881	1753	-	916	-	212	-	-	-
Positive A1c or FPG, neg. confirmatory	75	51	-	19	-	5	-	-	-
Weight change (% from baseline)		-0.31%		-0.16		-0.87			
Annual visits	1950	-	1365 ¹	-	575	-	10	-	-
Diabetes, n (% visits)	95 (4.9)	-	69 (5.1)	-	25 (4.4)	-	1 (10)	-	-
Positive, met 2 criteria	34	-	25	-	8	-	1	-	-
Positive, met 1 criterion, pos. confirmatory	61	-	44	-	17	-	0	-	-
No diabetes, n	1855	-	1296	-	550	-	9	-	-
All 3 criteria negative	1747	-	1215	-	524	-	8	-	-
Met 1 criterion, neg. confirmatory	108	-	81	-	26	-	1	-	-
Weight change (% from baseline)			-0.11		-0.17		-0.17		
Outside of study events by adjudication ²	21	4	7	6	2	1	1		
Total events	193	59	76	22	27	7	2		

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 = 7.43%

Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	1887
6	0.9729	0.0271	0.00374	51	1464
12	0.9257	0.0743	0.00662	119	1048
18	0.8947	0.1053	0.00827	153	655
24	0.8598	0.1402	0.0107	176	353
30	0.8193	0.1807	0.0151	189	90
36	0.6555	0.3445	0.0945	193	0

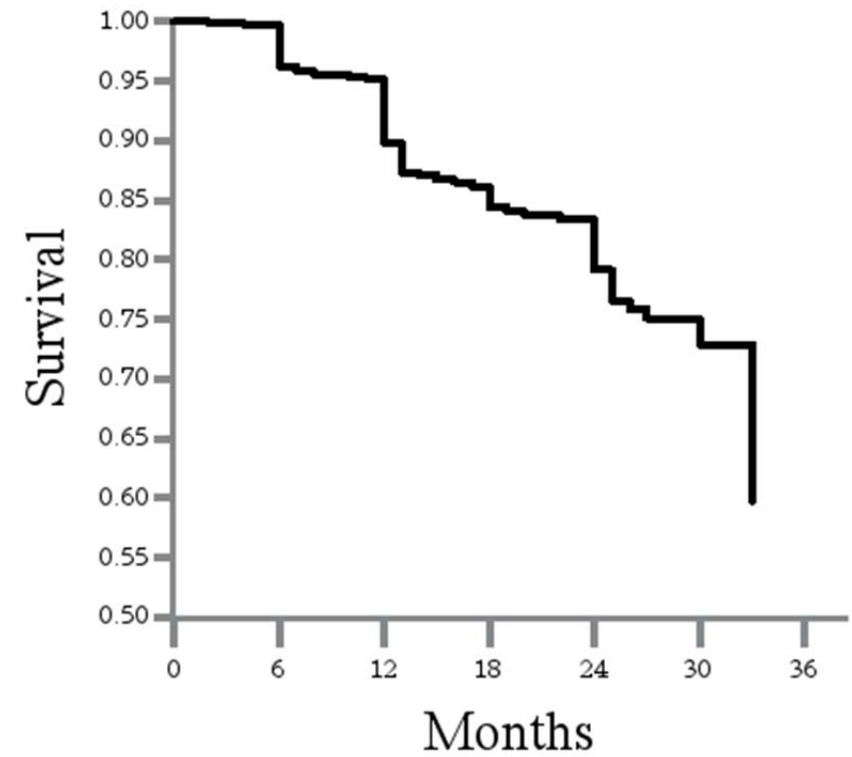


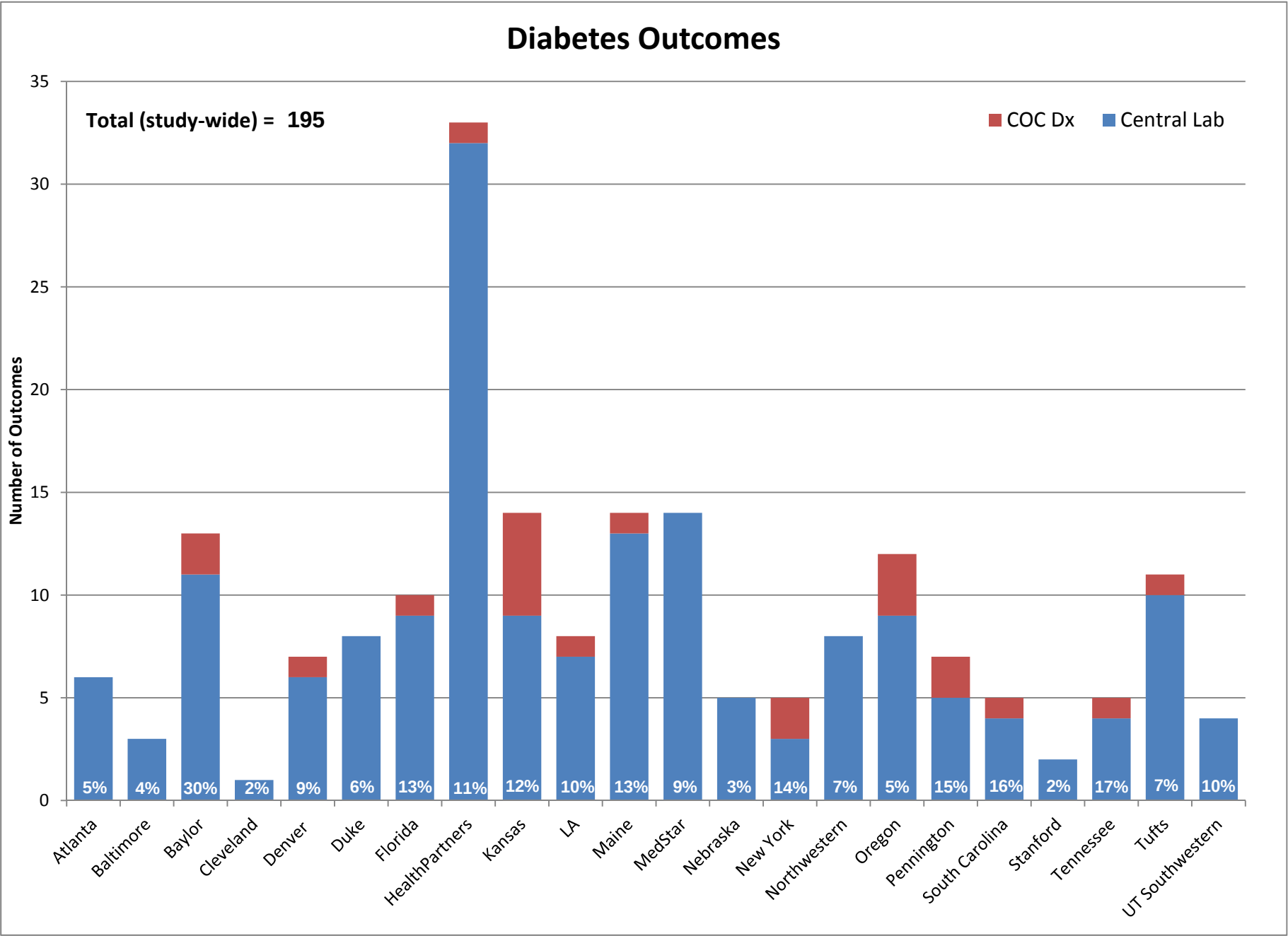
Among participants meeting DPP eligibility criteria (FPG 95-125 and 2hPG 140-199)

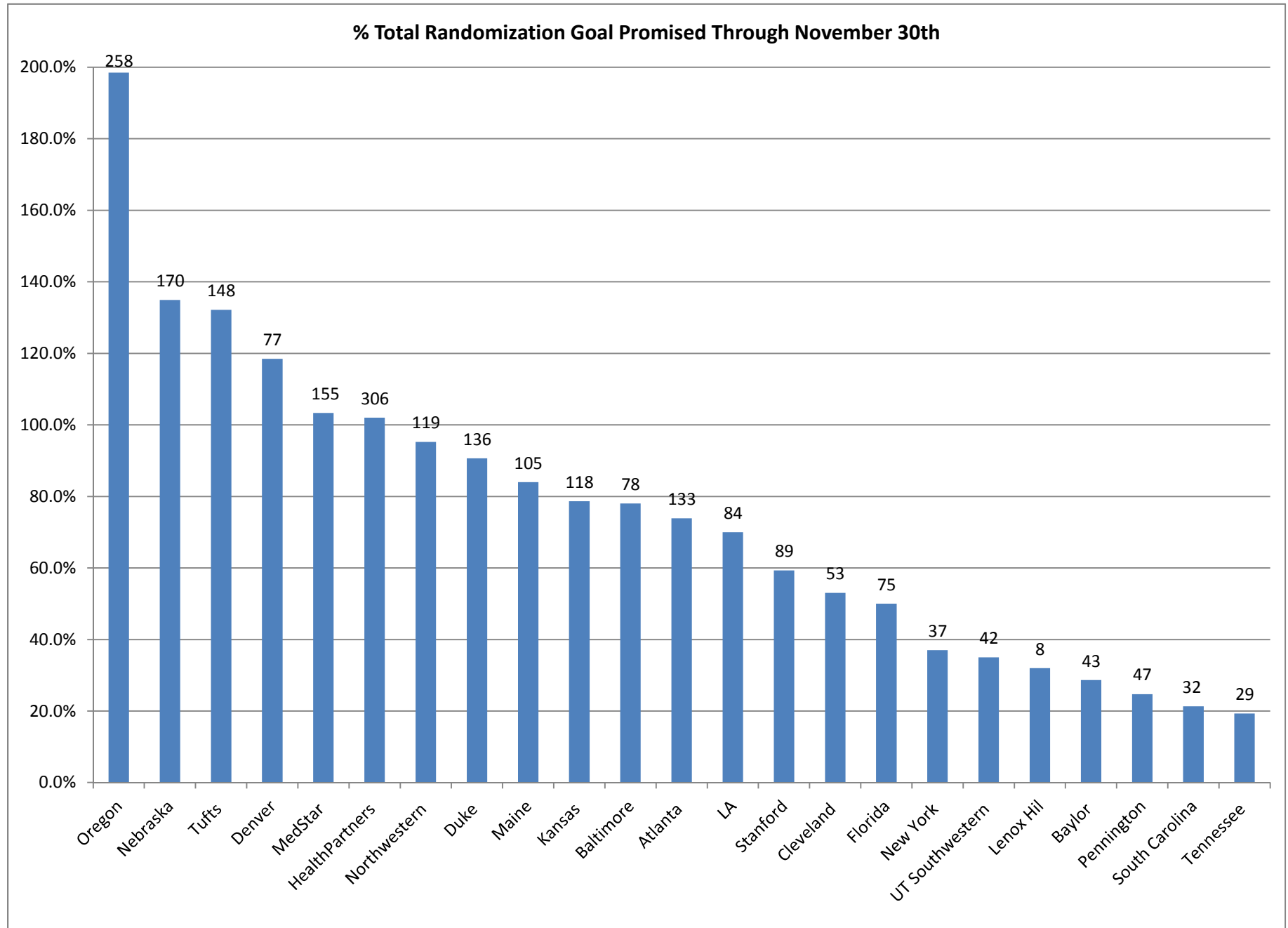
Annual Kaplan-Meier event rate = **10.36%**

Product-Limit Survival Estimates

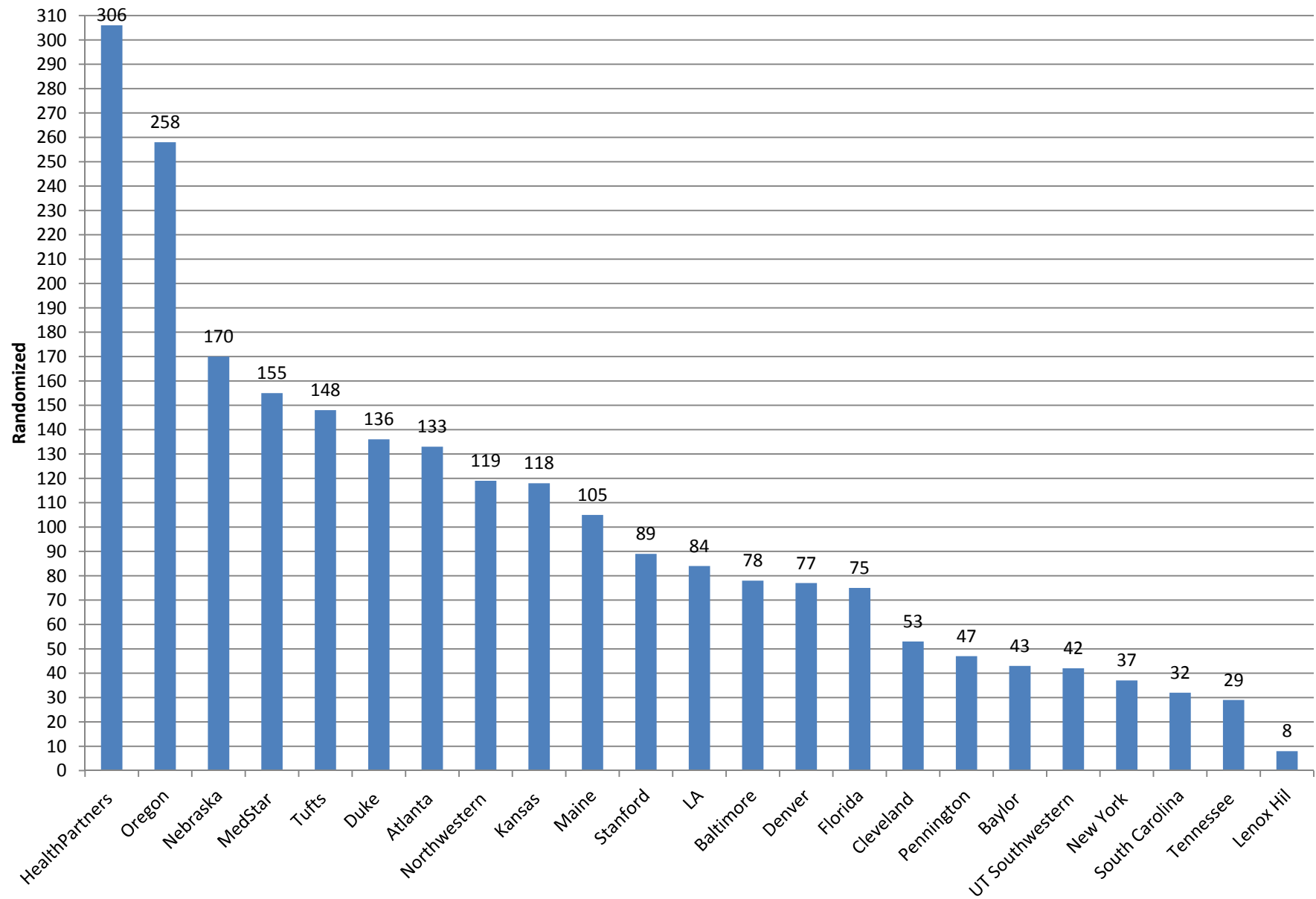
Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	903
6	0.9622	0.0378	0.00635	34	700
12	0.8964	0.1036	0.0111	80	488
18	0.8415	0.1585	0.0143	109	281
24	0.7879	0.2121	0.0187	125	150
30	0.7249	0.2751	0.0259	135	37
36	0.5799	0.4201	0.1313	136	0







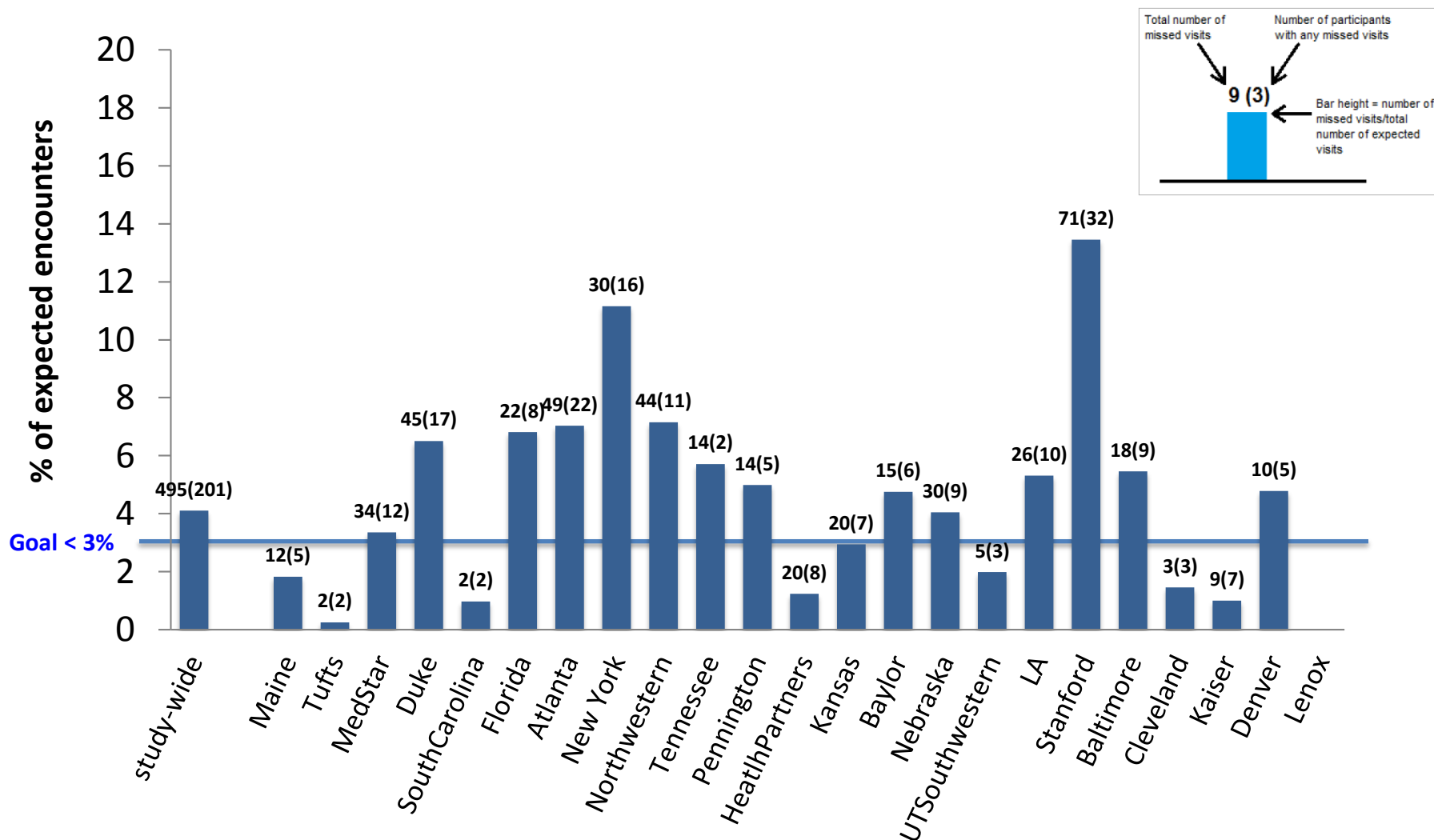
Randomizations by Site



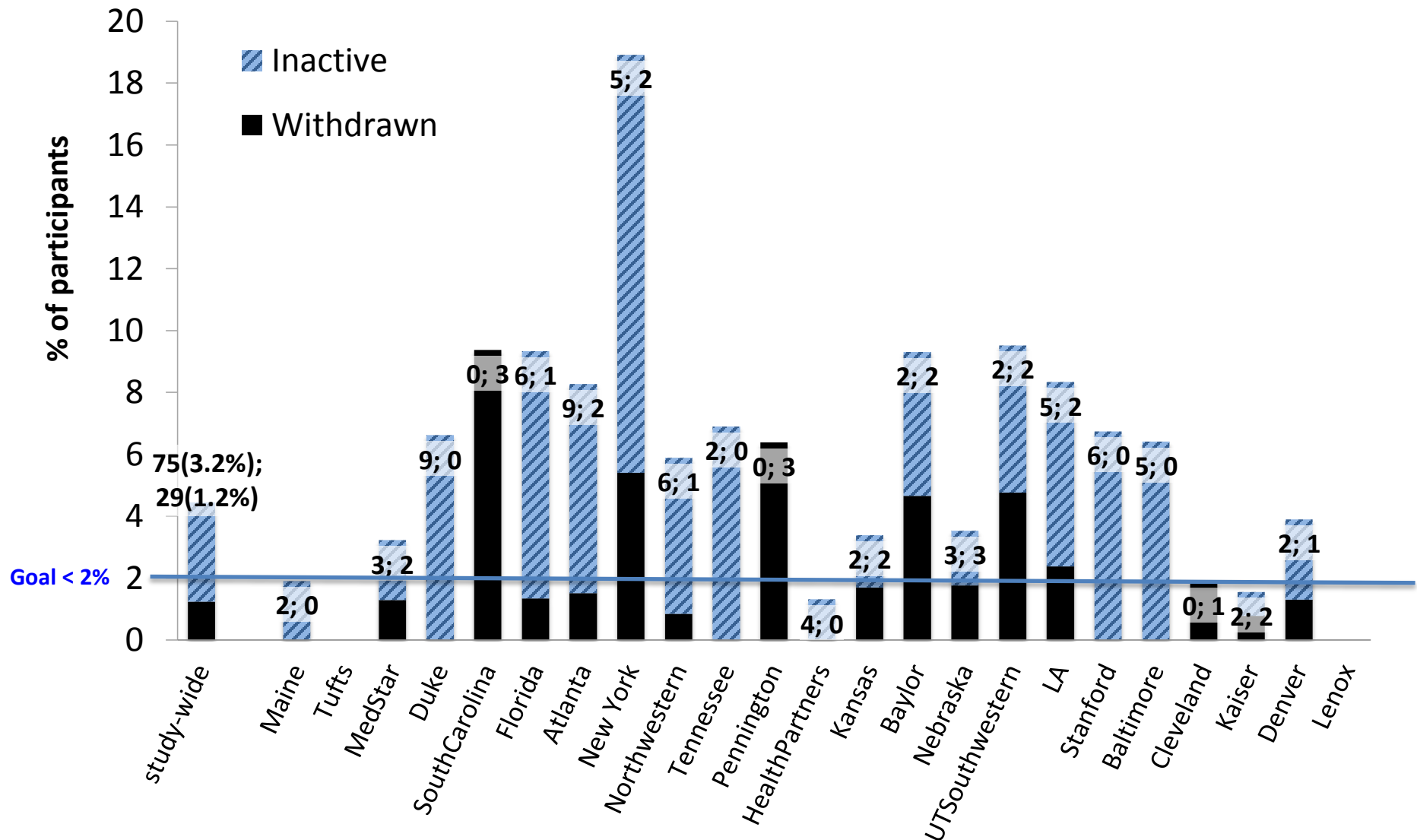
Missed encounters (visits and interim phone contact)

8

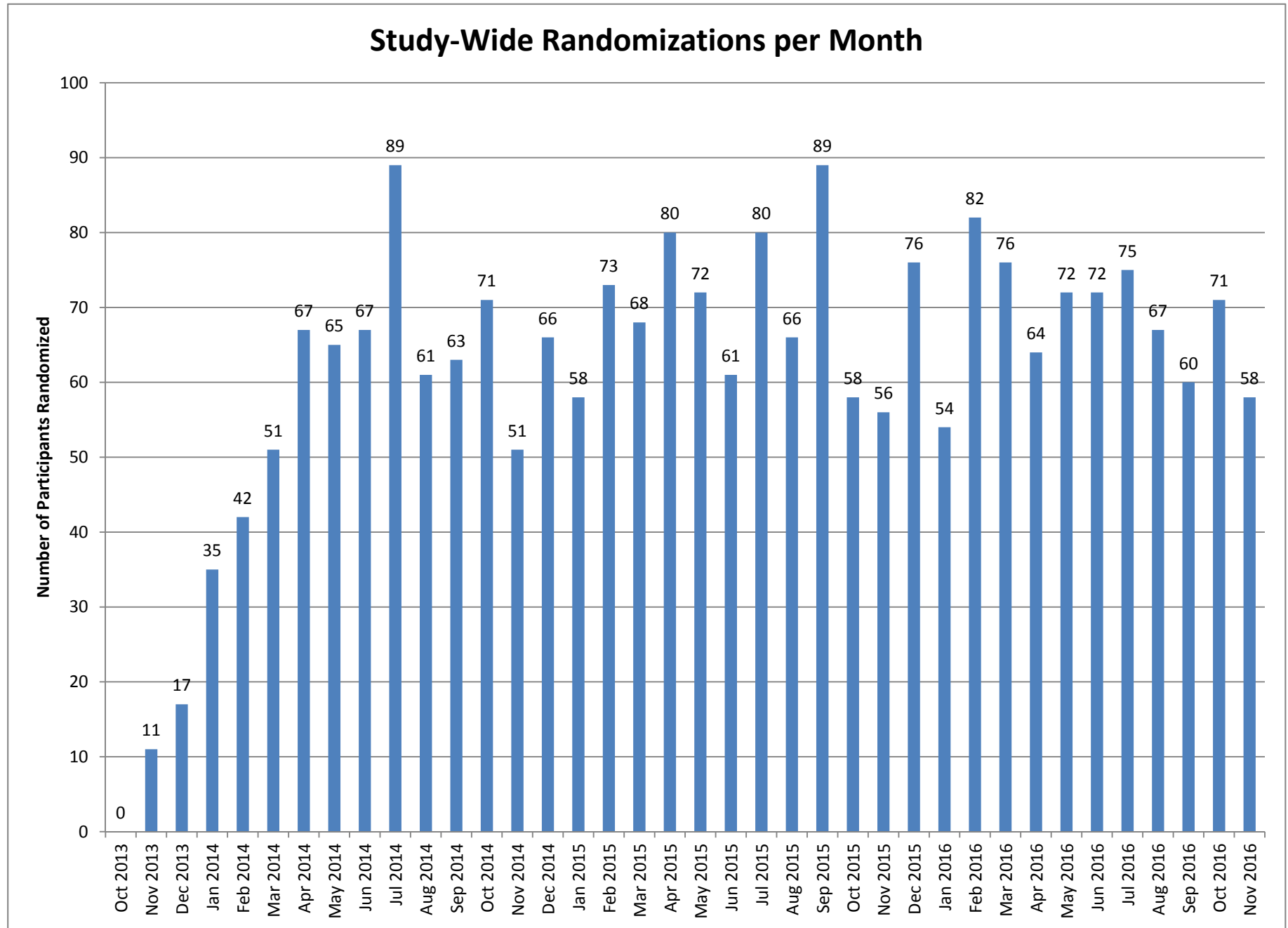
Study-wide = 4.1%



% inactive and withdrawn participants



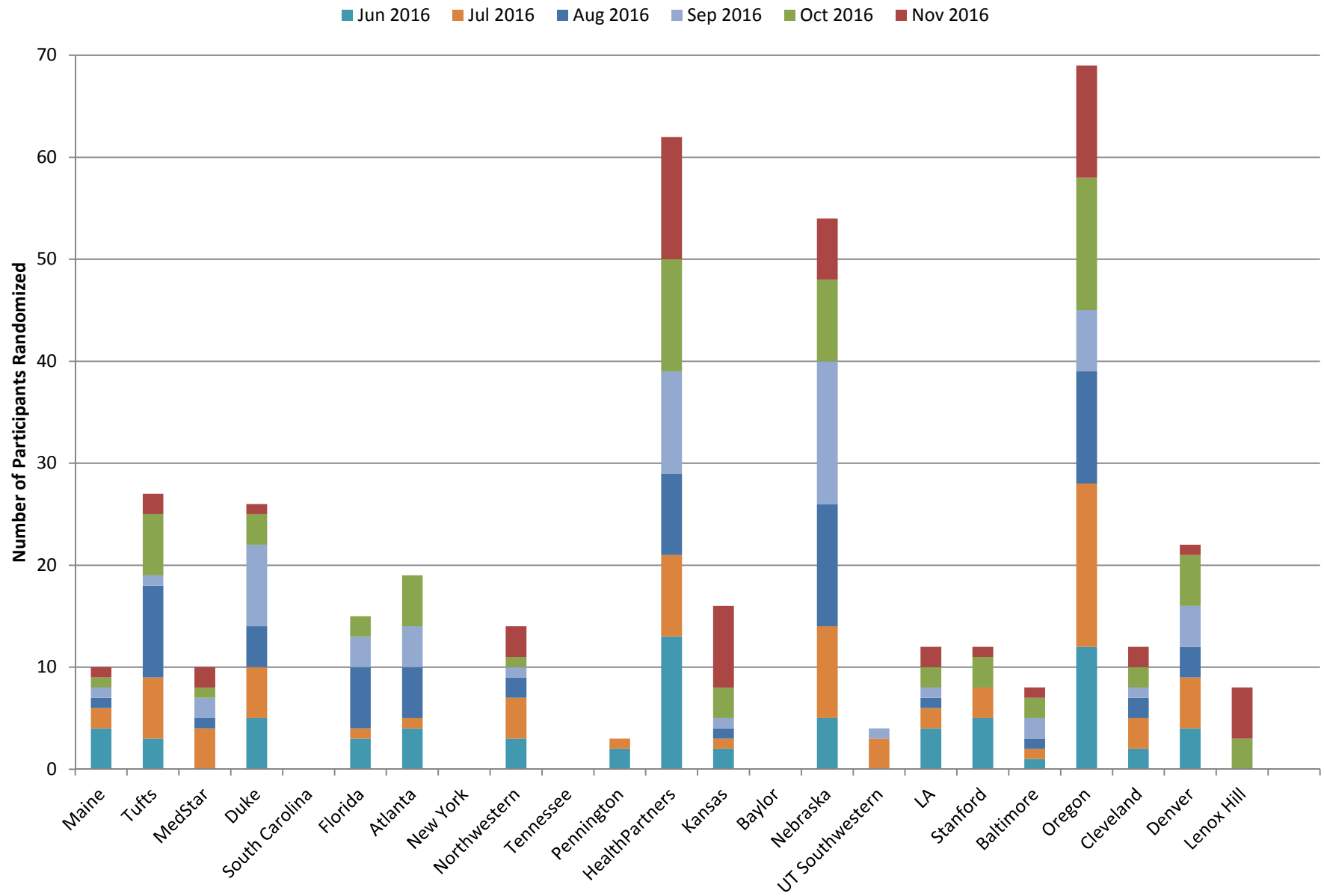
Labels are number of participants (inactive; withdrawn).



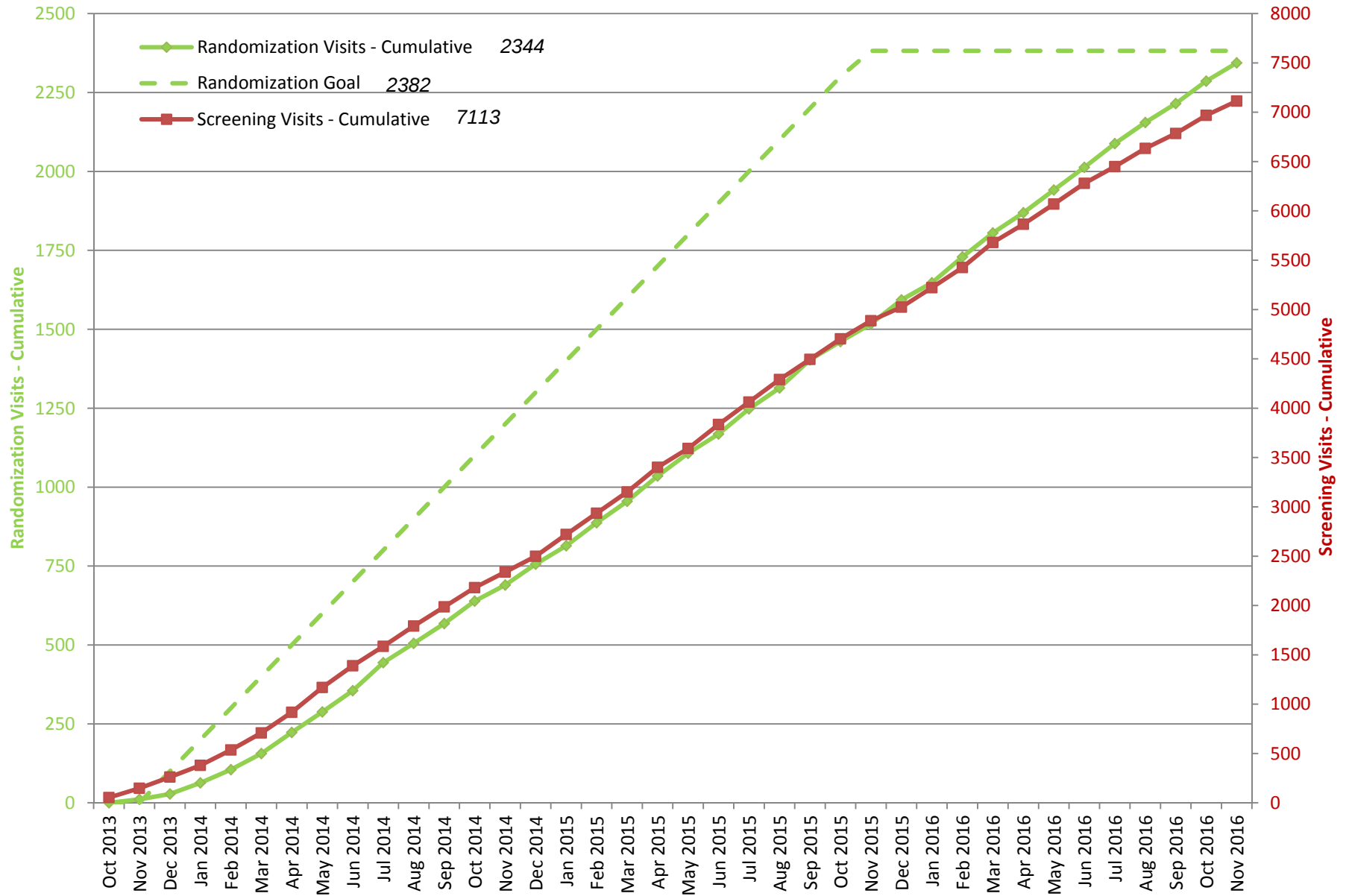
The SAS System

Site	Monthly RAN goal	RAN goal	SCR visits	BAS visits	RAN visits	SCR:RAN ratio	% of goal	11/2016 SCR visits	11/2016 BAS visits	11/2016 RAN visits	11/2016 SCR:RAN ratio	11/2016 RAN goal(%)	10/2016 SCR visits	10/2016 BAS visits	10/2016 RAN visits	10/2016 SCR:RAN ratio	10/2016 RAN goal(%)
Maine	5.2	125	367	170	105	3.5	84.0	4	1	1	4.0	19	4	2	1	4.0	19
Tufts	4.7	112	505	255	148	3.4	132.1	9	6	2	4.5	43	7	6	6	1.2	128
MedStar	6.3	150	418	246	155	2.7	103.3	5	6	2	2.5	32	5	4	1	5.0	16
Duke	6.3	150	372	228	136	2.7	90.7	8	8	1	8.0	16	3	1	3	1.0	48
SouthCarolina	6.3	150	183	70	32	5.7	21.3	.	.	.	.	.	.	.	.	.	.
Florida	6.3	150	359	123	75	4.8	50.0	4	1	.	.	.	12	6	2	6.0	32
Atlanta	7.5	180	258	223	133	1.9	73.9	2	2	.	.	.	5	4	5	1.0	67
NewYork	4.2	100	190	73	37	5.1	37.0	.	.	.	.	.	.	.	.	.	.
Northwestern	5.2	125	307	220	119	2.6	95.2	.	2	3	.	58	8	6	1	8.0	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	257	84	47	5.5	24.7	5	.	.	.	.	3	3	.	.	.
HealthPartners	12.5	300	663	466	306	2.2	102.0	28	13	12	2.3	96	38	21	11	3.5	88
Kansas	6.3	150	401	190	118	3.4	78.7	13	9	8	1.6	127	21	5	3	7.0	48
Baylor	6.3	150	209	82	43	4.9	28.7	.	.	.	.	.	.	.	.	.	.
Nebraska	5.3	126	559	294	170	3.3	134.9	5	10	6	.8	113	9	4	8	1.1	151
UTSouthwestern	5.0	120	118	77	42	2.8	35.0	1	.	.	.	.	1	1	.	.	.
LA	5.0	120	260	143	84	3.1	70.0	1	4	2	.5	40	10	5	2	5.0	40
Stanford	6.3	150	335	157	89	3.8	59.3	6	3	1	6.0	16	9	5	3	3.0	48
Baltimore	7.7	100	213	120	78	2.7	78.0	7	.	1	7.0	13	5	5	2	2.5	26
Cleveland	7.7	100	186	94	53	3.5	53.0	2	1	2	1.0	26	4	5	2	2.0	26
Kaiser	10.0	130	461	408	258	1.8	198.5	23	17	11	2.1	110	25	17	13	1.9	130
Denver	5.4	65	331	134	77	4.3	118.5	6	6	1	6.0	19	5	1	5	1.0	93
Lenox	5.0	25	43	10	8	5.4	32.0	15	4	5	3.0	100	10	6	3	3.3	60
	.	.	7112	3907	2344	3.0	98.4	144	93	58	2.5	42	184	107	71	2.6	51

Randomizations By Site - Last 6 Months

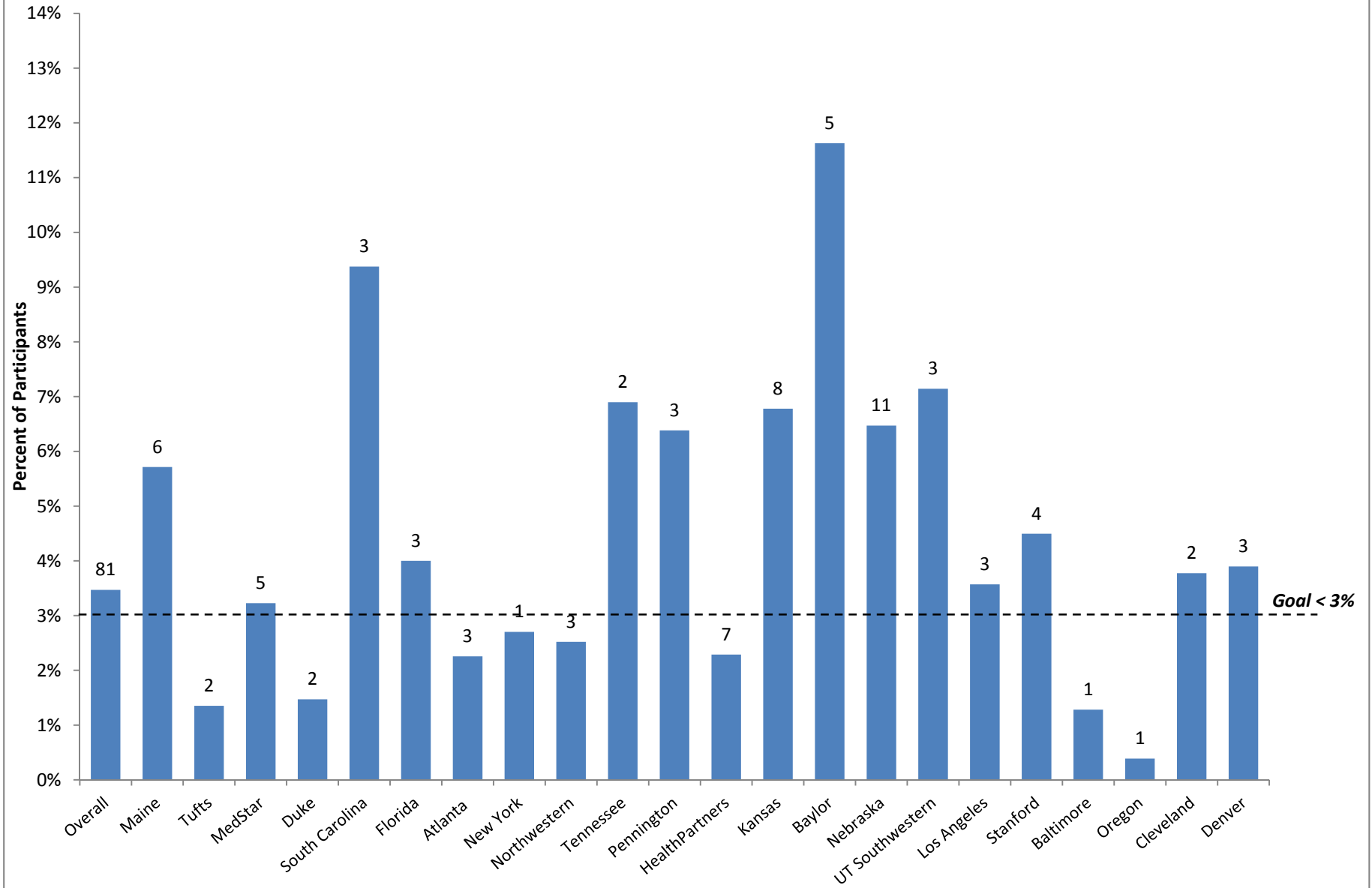


Cumulative Screening and Randomization Visits by Month



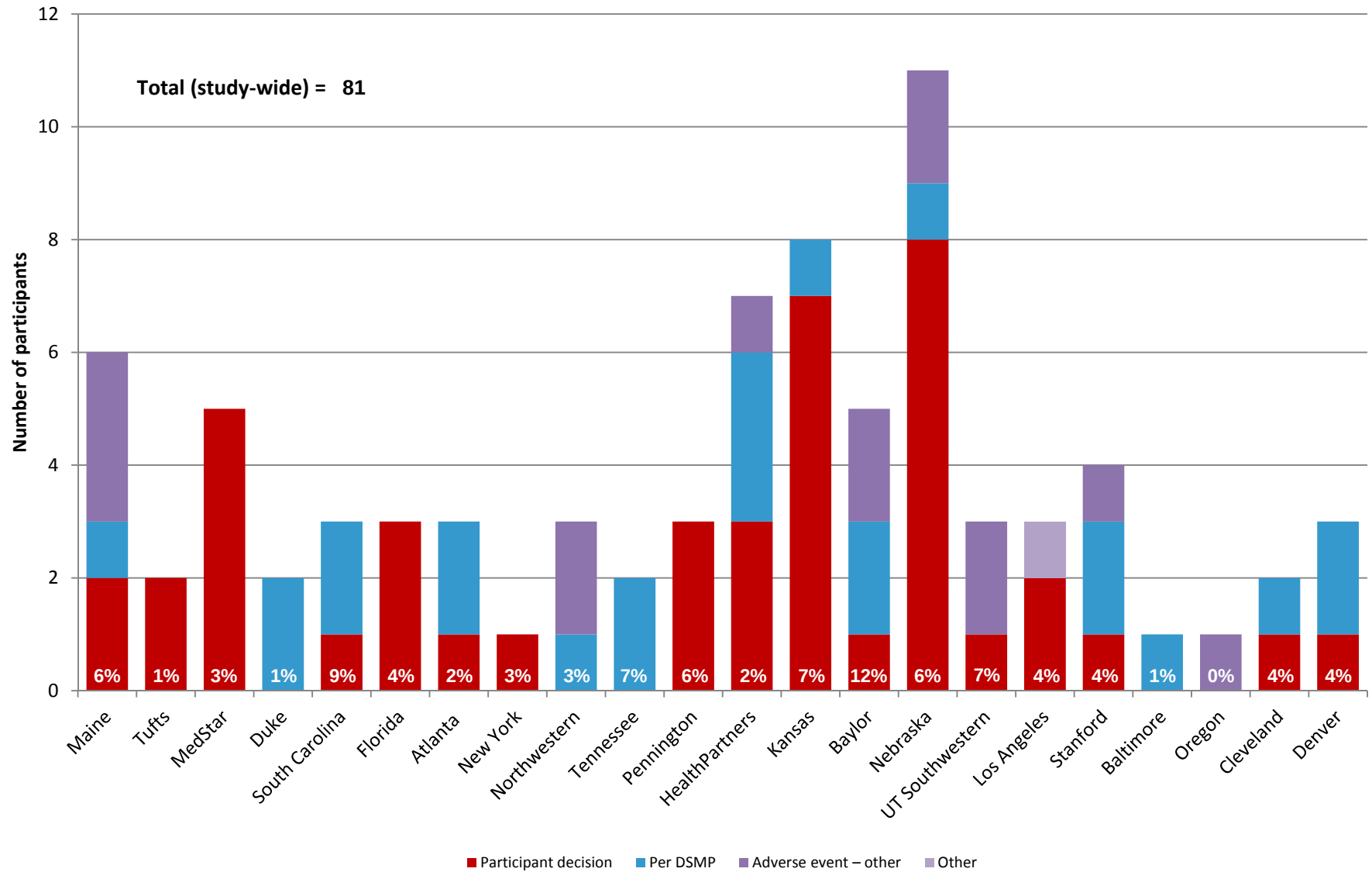
Discontinuation of Study Pills

excludes participants who withdrew consent



Discontinuation of Study Pills

excludes participants who withdrew consent



Site	Total RAND	Biorepository Consent (%)	DNA Consent (%)
Atlanta	134	95%	94%
Baltimore	78	94%	91%
Baylor	43	93%	93%
Beth Israel Medical Center	37	86%	86%
Cleveland	53	96%	94%
Denver VA	60	100%	98%
Duke	136	81%	79%
Florida	75	96%	95%
HealthPartners	306	91%	90%
Kaiser	258	94%	91%
Lenox Hill	8	88%	88%
LA	84	88%	88%
Maine	105	90%	90%
South Carolina	32	75%	75%
MedStar	155	90%	86%
Northwestern	119	92%	87%
Omaha VA	116	91%	91%
Pennington	47	87%	85%
Stanford	89	93%	92%
Truman	13	85%	85%
Tufts	148	94%	93%
UC Denver	17	100%	100%
Kansas	105	81%	81%
Nebraska (UNMC)	54	87%	83%
Tennessee	29	62%	59%
UT Southwestern	42	100%	100%
Overall	2344	91%	89%

