

The SAS System

09/07/2016

Site	SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal	% of promised
Maine	357	2	165	1	.	102	125	81.6
Tufts	474	1	239	2	.	139	112	124.1
MedStar	406	5	235	1	2	150	150	100.0
Duke	356	5	211	2	1	126	150	84.0
SouthCarolina	183	.	70	.	.	32	150	21.3
Florida	337	.	118	2	1	71	150	47.3
Atlanta	244	.	211	2	2	124	180	68.9
NewYork	190	.	73	.	.	37	100	37.0
Northwestern	295	.	209	.	.	114	125	91.2
Tennessee	82	.	38	.	.	29	150	19.3
Tulane	35	.	2	.	.	2	150	1.3
Pennington	244	.	81	.	.	47	190	24.7
HealthPartners	621	.	418	2	3	272	300	90.7
Kansas	360	.	173	.	1	106	150	70.7
Baylor	209	.	82	.	.	43	150	28.7
Nebraska	533	7	272	2	7	146	126	115.9
UTSouthwestern	116	2	74	.	.	41	120	34.2
LA	248	.	133	.	.	79	120	65.8
Stanford	331	.	147	.	.	85	150	56.7
Baltimore	197	.	114	.	2	72	100	72.0
Cleveland	174	4	85	2	.	49	100	49.0
Kaiser	449	.	364	1	1	227	130	174.6
Denver	317	.	122	2	1	68	65	104.6
	6758	26	3636	19	21	2161	2382	90.7

7.1.a Detail on diabetes diagnosis

	Overall	M06	M12	M18	M24	M30	M36	M42	M48
Semi-annual visits	2528	1675	-	776 ¹	-	77	-	-	-
Diabetes, n (% visits)	58 (2.3)	45 (2.7)	-	13 (1.7)	-	0	-	-	-
Positive A1c and FPG	23	18	-	5	-	0	-	-	-
Positive A1c or FPG, pos. confirmatory	35	27	-	8	-	0	-	-	-
No diabetes, n	2470	1630	-	763	-	77	-	-	-
Negative A1c and FPG	2410	1585	-	750	-	75	-	-	-
Positive A1c or FPG, neg. confirmatory	60	45	-	13	-	2	-	-	-
Weight change (% from baseline)		-0.26%		-0.02%					
Annual visits	1624	-	1201 ¹	-	423	-	-	-	-
Diabetes, n (% visits)	59 (3.6)	-	46 (3.8)	-	13 (3.1)	-	-	-	-
Positive, met 2 criteria	20	-	16	-	4	-	-	-	-
Positive, met 1 criterion, pos. confirmatory	39	-	30	-	9	-	-	-	-
No diabetes, n	1565	-	1155	-	410	-	-	-	-
All 3 criteria negative	1488	-	1093	-	395	-	-	-	-
Met 1 criterion, neg. confirmatory	77	-	62	-	15	-	-	-	-
Weight change (% from baseline)			-0.14%		-0.25%				
Outside of study events by adjudication ²	16	3	6	2	3	2			
Total events	133	48	52	15	16	2			

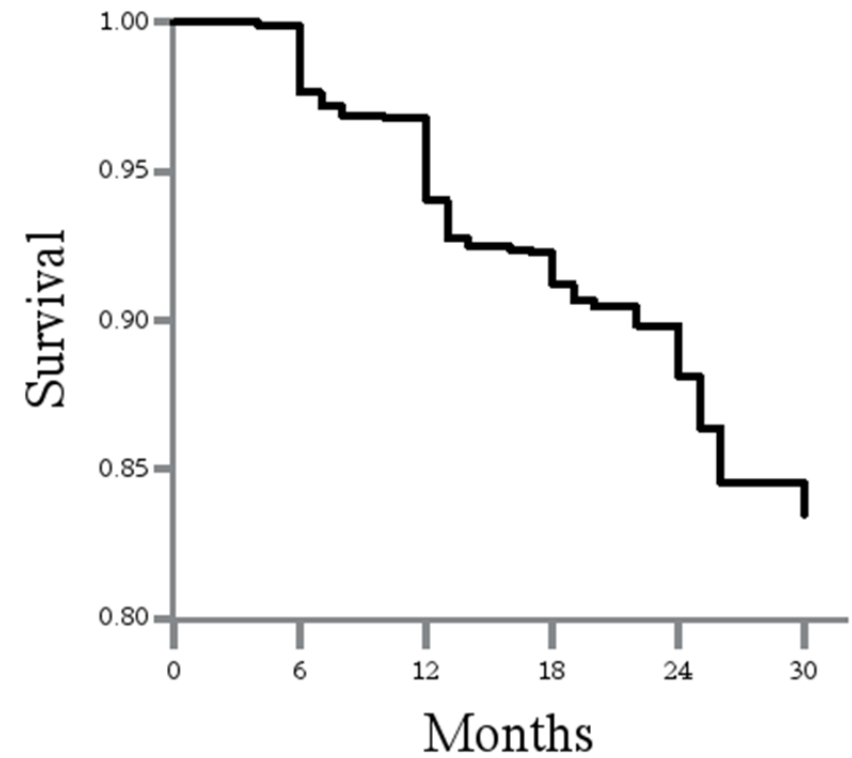
¹ Number excludes participants who have reached the *diabetes outcome* [by D2d criteria or adjudication].

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 = 6.03%

Product-Limit Survival Estimates

Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	1685
6	0.9762	0.0238	0.00372	40	1286
12	0.9397	0.0603	0.00638	86	860
18	0.9113	0.0887	0.00835	111	513
24	0.8804	0.1196	0.0113	126	202
30	0.8334	0.1666	0.0216	133	26

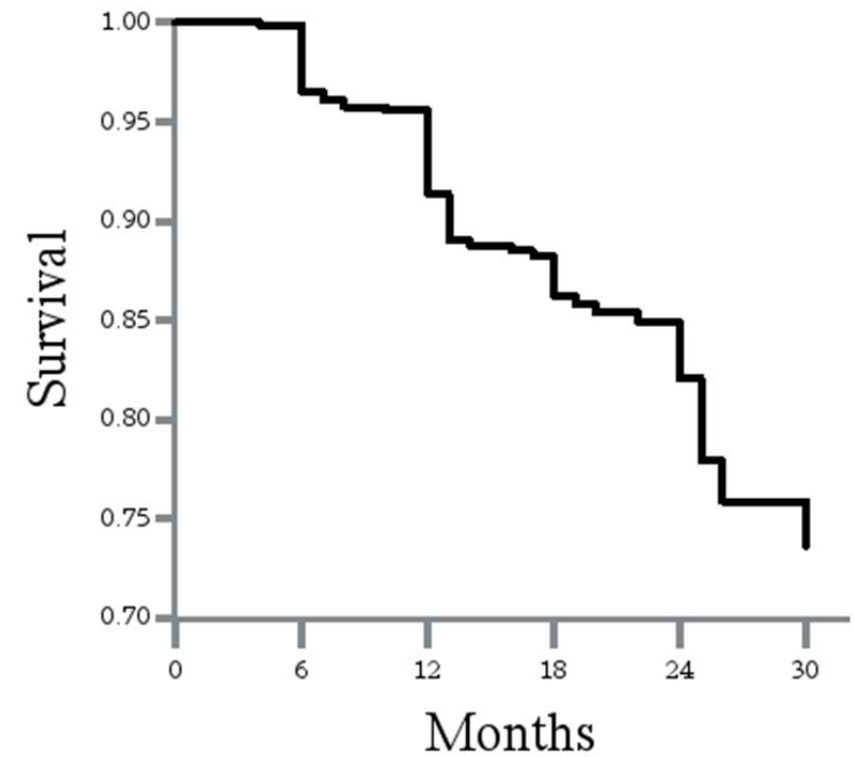


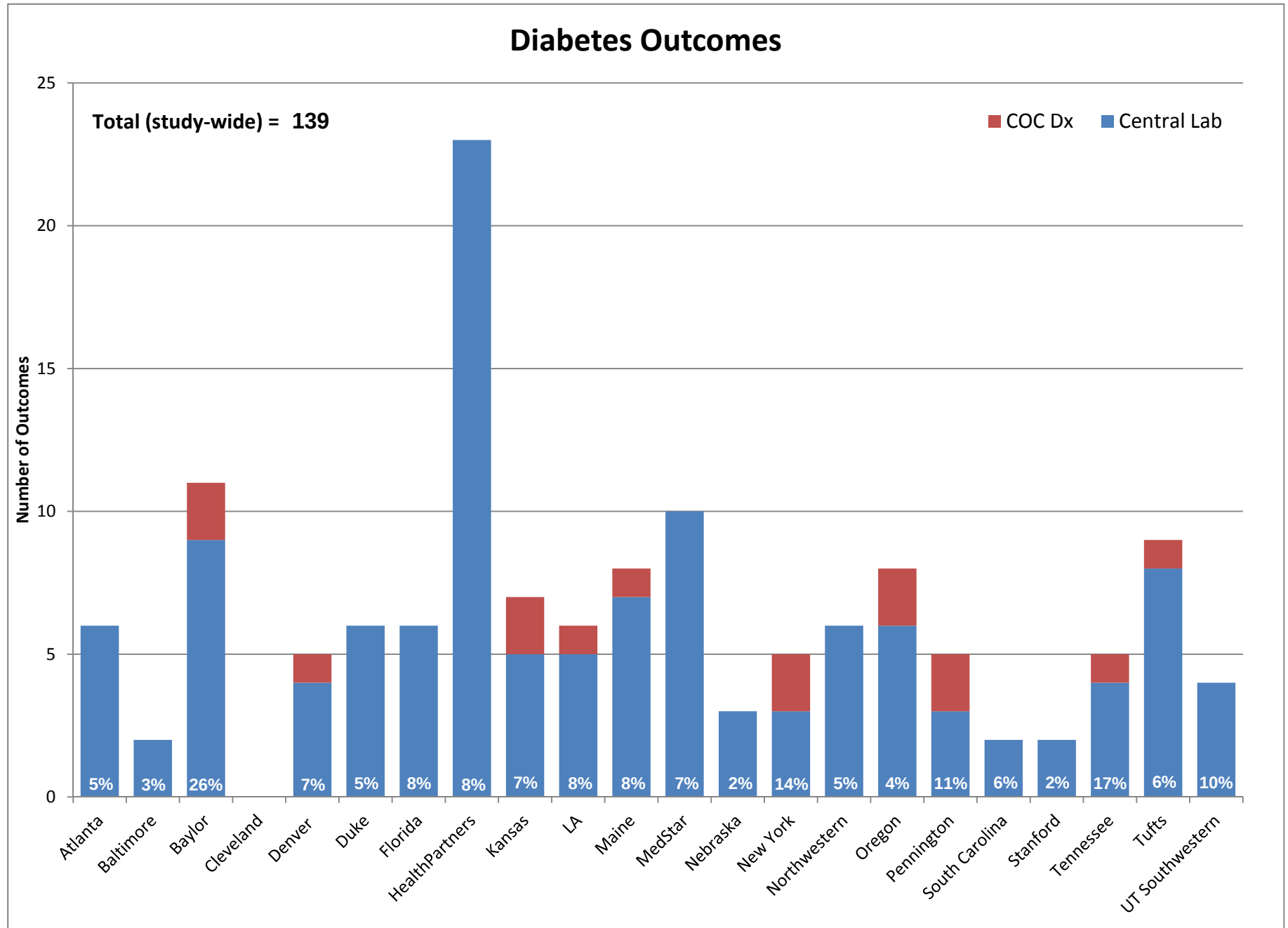
Among participants meeting DPP eligibility criteria (FPG 95-125 and 2hPG 140-199)

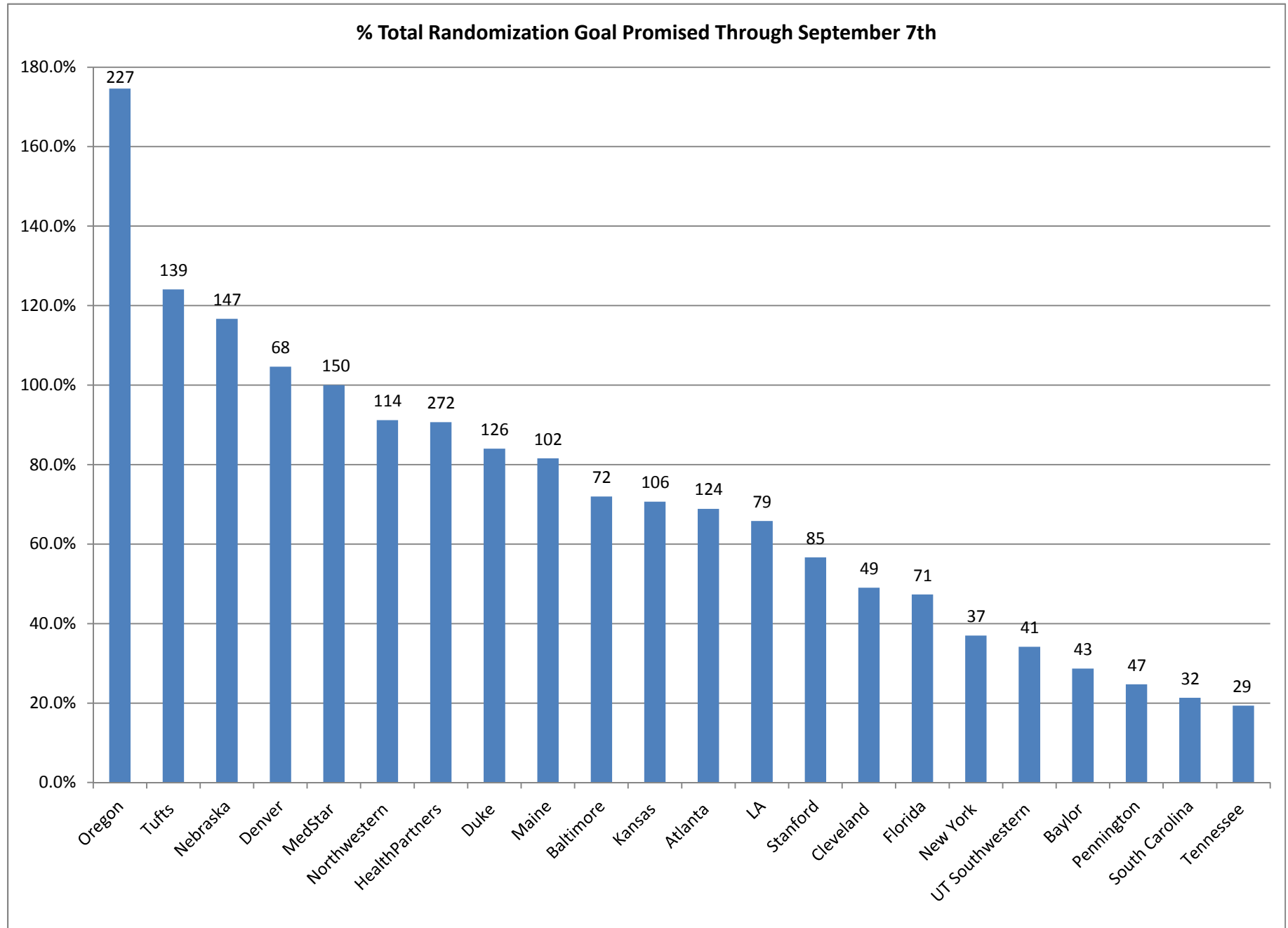
Annual Kaplan-Meier event rate = 8.79%

Product-Limit Survival Estimates

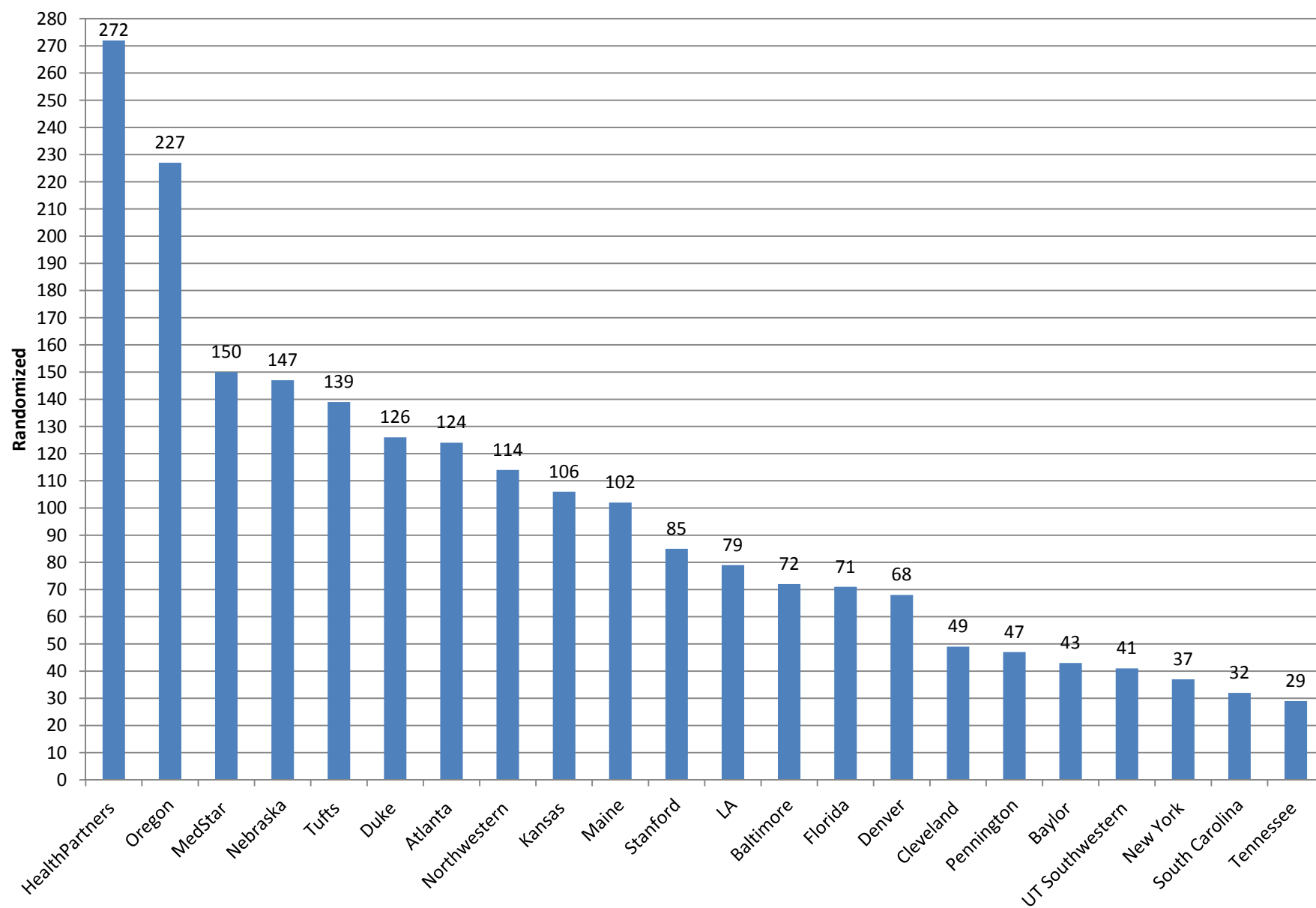
Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	800
6	0.9649	0.0351	0.00652	28	612
12	0.9121	0.0879	0.011	60	386
18	0.8603	0.1397	0.0151	81	219
24	0.8182	0.1818	0.0199	90	77
30	0.7324	0.2676	0.0398	96	10







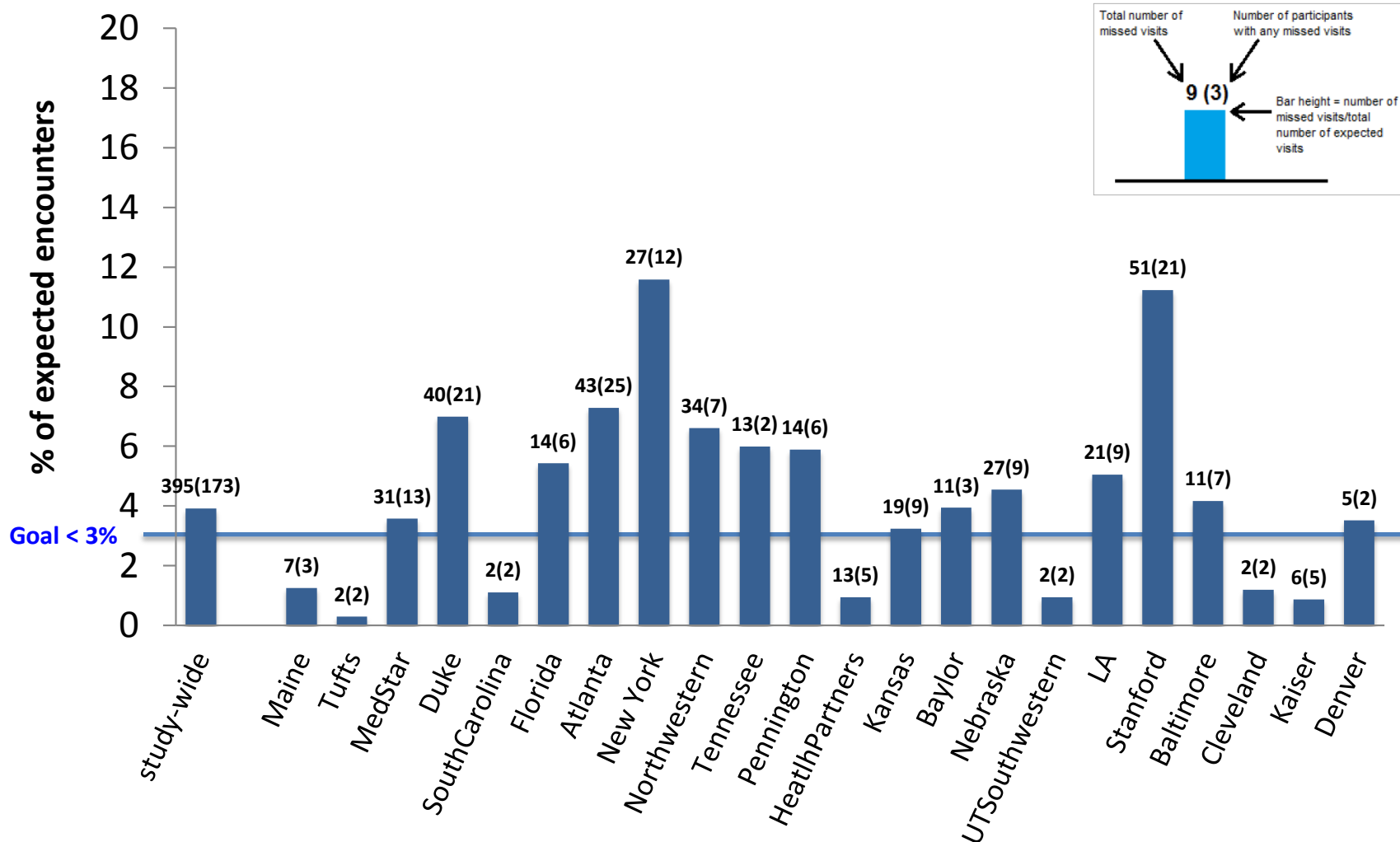
Randomizations by Site



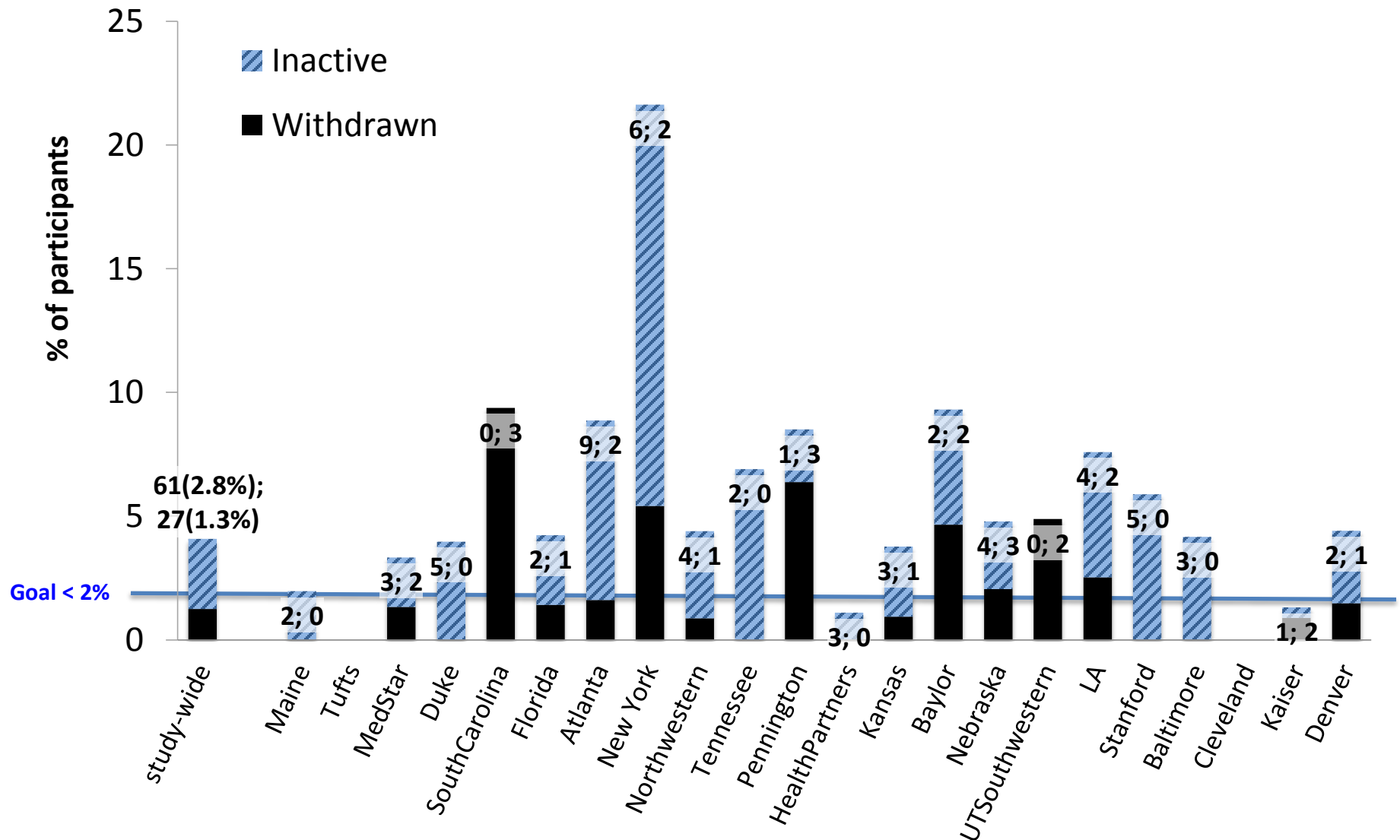
Missed encounters (visits and interim phone contact)

8

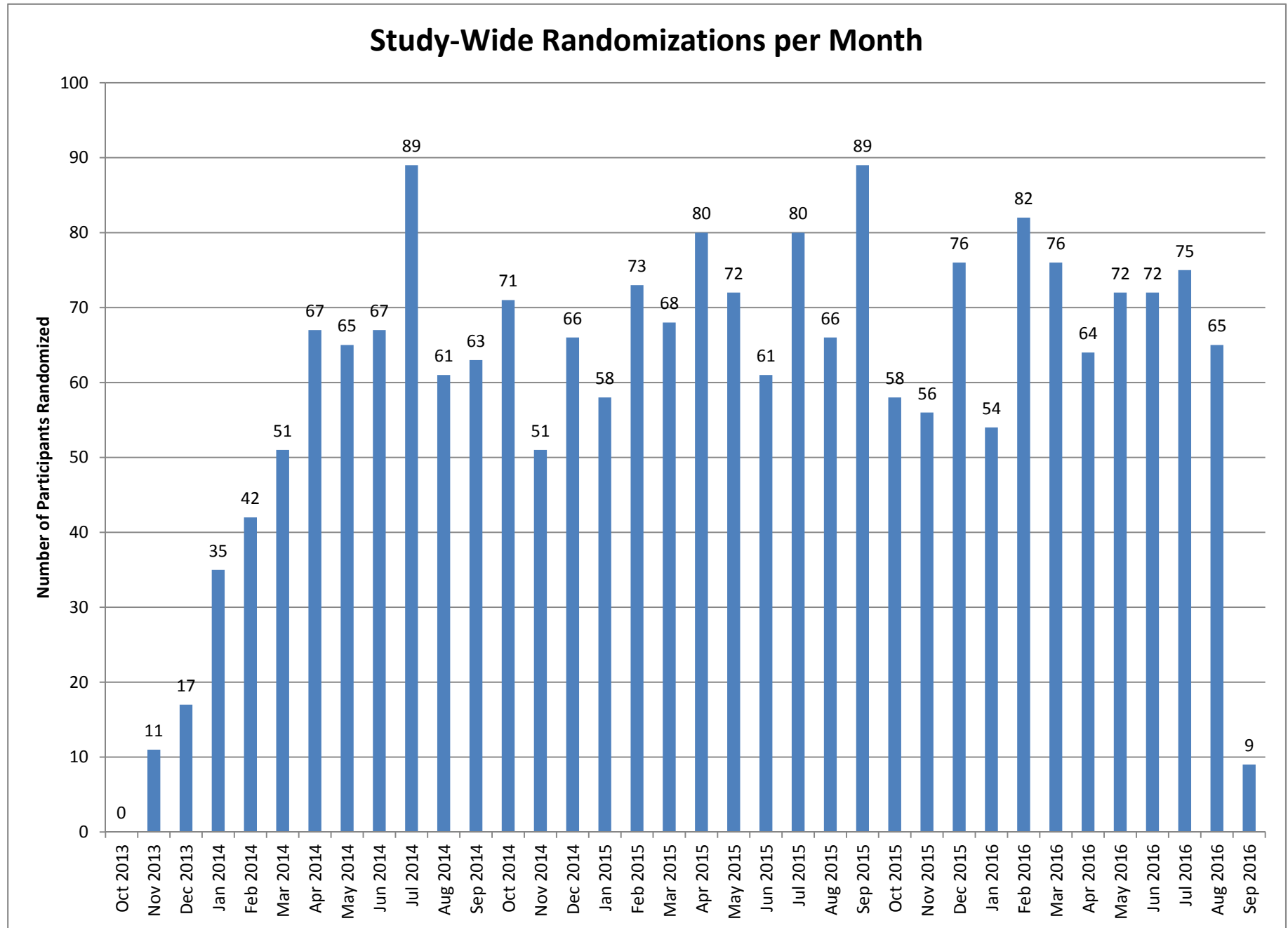
Study-wide = 3.9%



% inactive and withdrawn participants



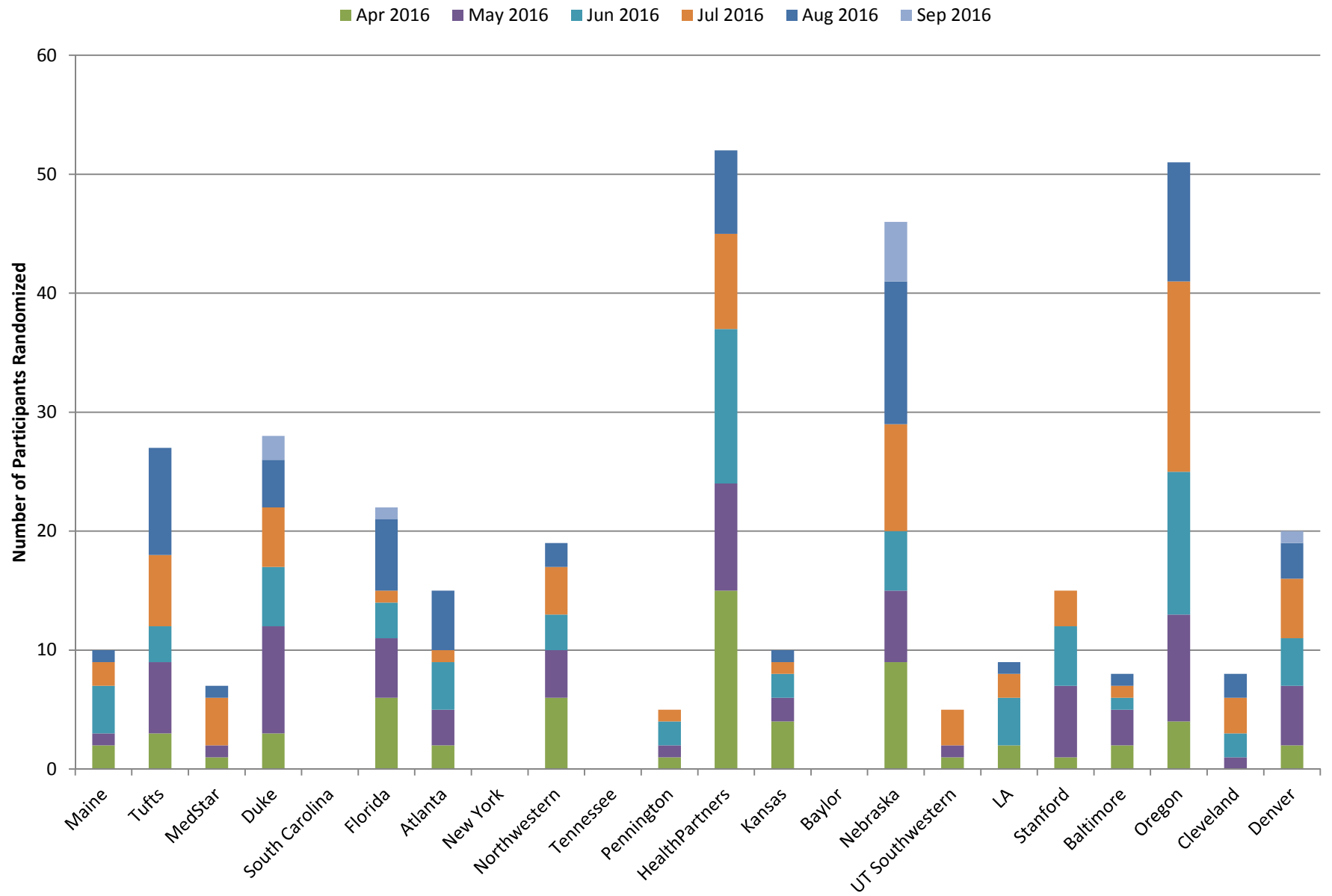
Labels are number of participants (inactive; withdrawn).



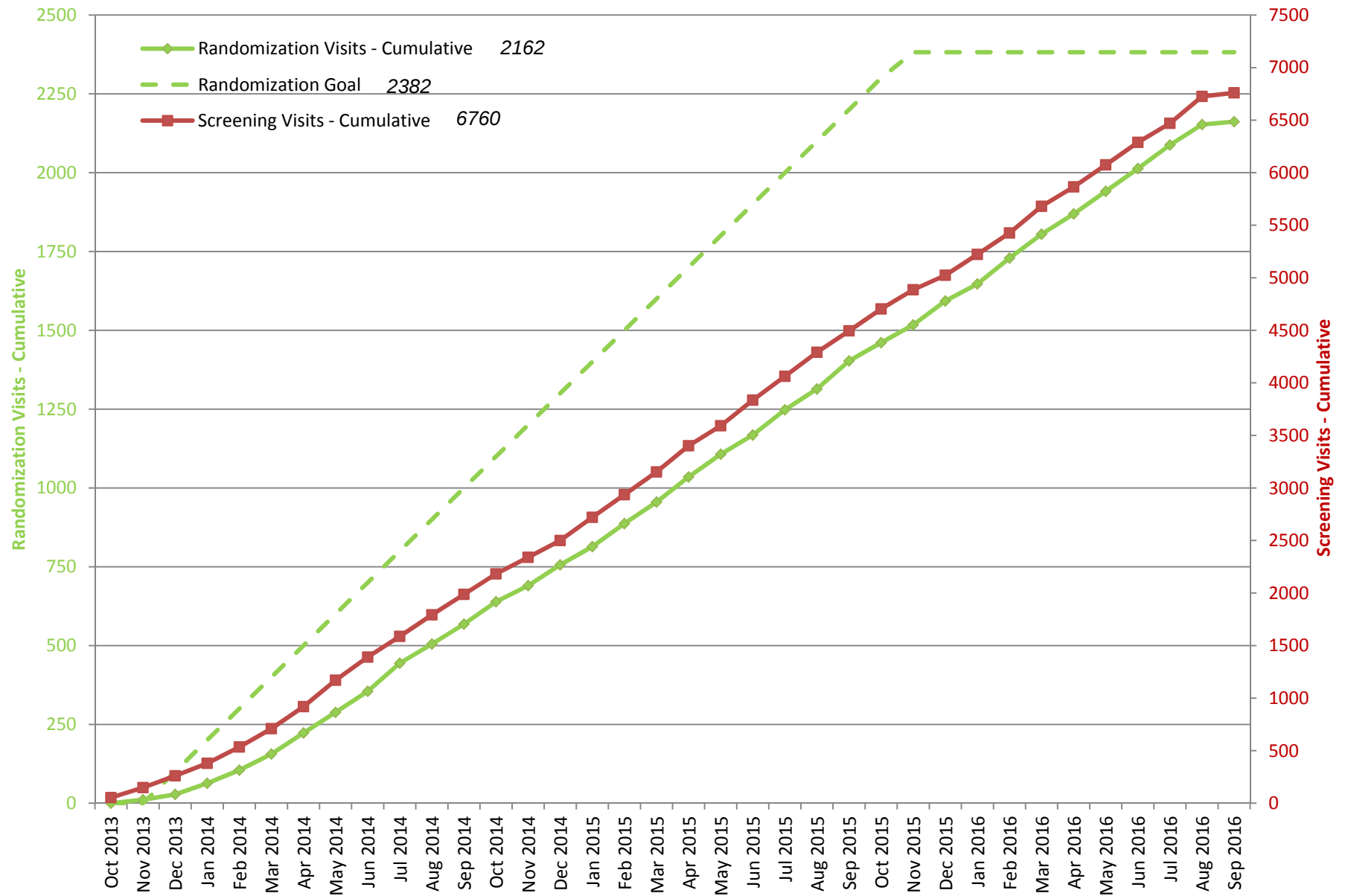
The SAS System

Site	Monthly RAN goal	RAN goal	SCR visits	BAS visits	RAN visits	SCR:RAN ratio	% of goal	9/2016 SCR visits	9/2016 BAS visits	9/2016 RAN visits	9/2016 SCR:RAN ratio	9/2016 RAN goal(%)	8/2016 SCR visits	8/2016 BAS visits	8/2016 RAN visits	8/2016 SCR:RAN ratio	8/2016 RAN goal(%)
Maine	5.2	125	357	165	102	3.5	81.6	.	1	.	.	.	11	1	1	11.0	19
Tufts	4.7	112	474	239	139	3.4	124.1	.	1	.	.	.	18	11	9	2.0	191
MedStar	6.3	150	406	235	150	2.7	100.0	.	1	.	.	.	6	6	1	6.0	16
Duke	6.3	150	356	211	126	2.8	84.0	1	2	2	.5	32	12	7	4	3.0	63
SouthCarolina	6.3	150	183	70	32	5.7	21.3	.	.	.	.	.	.	.	.	.	.
Florida	6.3	150	337	118	71	4.7	47.3	.	1	1	.	16	17	8	6	2.8	95
Atlanta	7.5	180	244	211	124	2.0	68.9	1	1	.	.	.	8	8	5	1.6	67
NewYork	4.2	100	190	73	37	5.1	37.0	.	.	.	.	.	.	.	.	.	.
Northwestern	5.2	125	295	209	114	2.6	91.2	.	.	.	.	.	3	3	2	1.5	38
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	244	81	47	5.2	24.7	2	.	.	.	.	2	1	.	.	.
HealthPartners	12.5	300	621	418	272	2.3	90.7	10	.	.	.	.	40	11	7	5.7	56
Kansas	6.3	150	360	173	106	3.4	70.7	4	.	.	.	.	11	4	1	11.0	16
Baylor	6.3	150	209	82	43	4.9	28.7	.	.	.	.	.	.	.	.	.	.
Nebraska	5.3	126	533	272	146	3.7	115.9	4	1	4	1.0	75	39	16	12	3.3	226
UTSouthwestern	5.0	120	116	74	41	2.8	34.2	.	.	.	.	.	4	.	.	.	.
LA	5.0	120	248	133	79	3.1	65.8	.	.	.	.	.	2	3	1	2.0	20
Stanford	6.3	150	331	147	85	3.9	56.7	4	.	.	.	.	3	1	.	.	.
Baltimore	7.7	100	197	114	72	2.7	72.0	.	.	.	.	.	5	2	1	5.0	13
Cleveland	7.7	100	174	85	49	3.6	49.0	.	1	.	.	.	8	.	2	4.0	26
Kaiser	10.0	130	449	364	227	2.0	174.6	5	.	.	.	.	53	11	10	5.3	100
Denver	5.4	65	317	122	68	4.7	104.6	1	1	1	1.0	19	14	4	3	4.7	56
	.	.	6758	3636	2161	3.1	90.7	32	10	8	4.0	6	256	97	65	3.9	47

Randomizations By Site - Last 6 Months

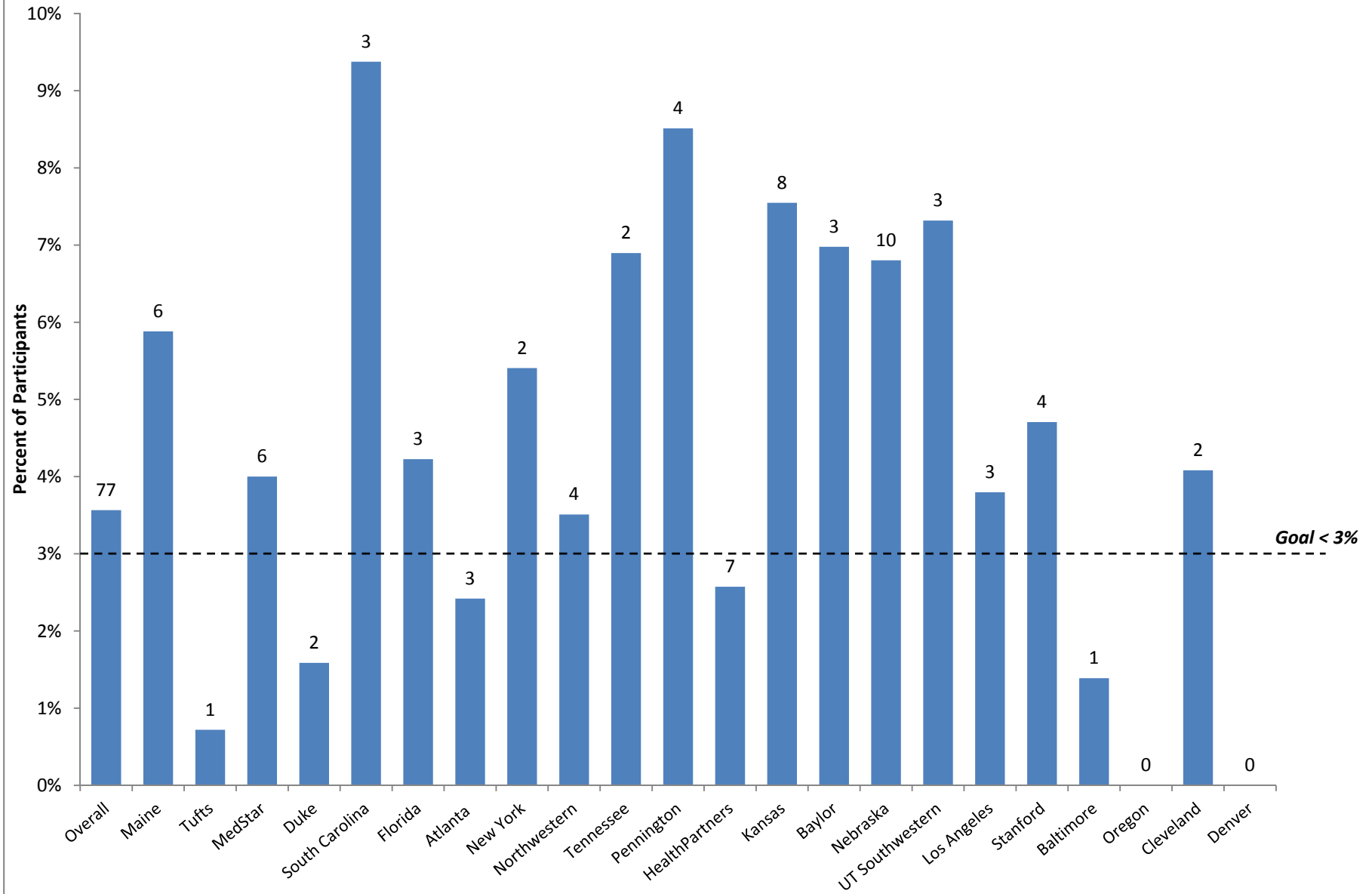


Cumulative Screening and Randomization Visits by Month



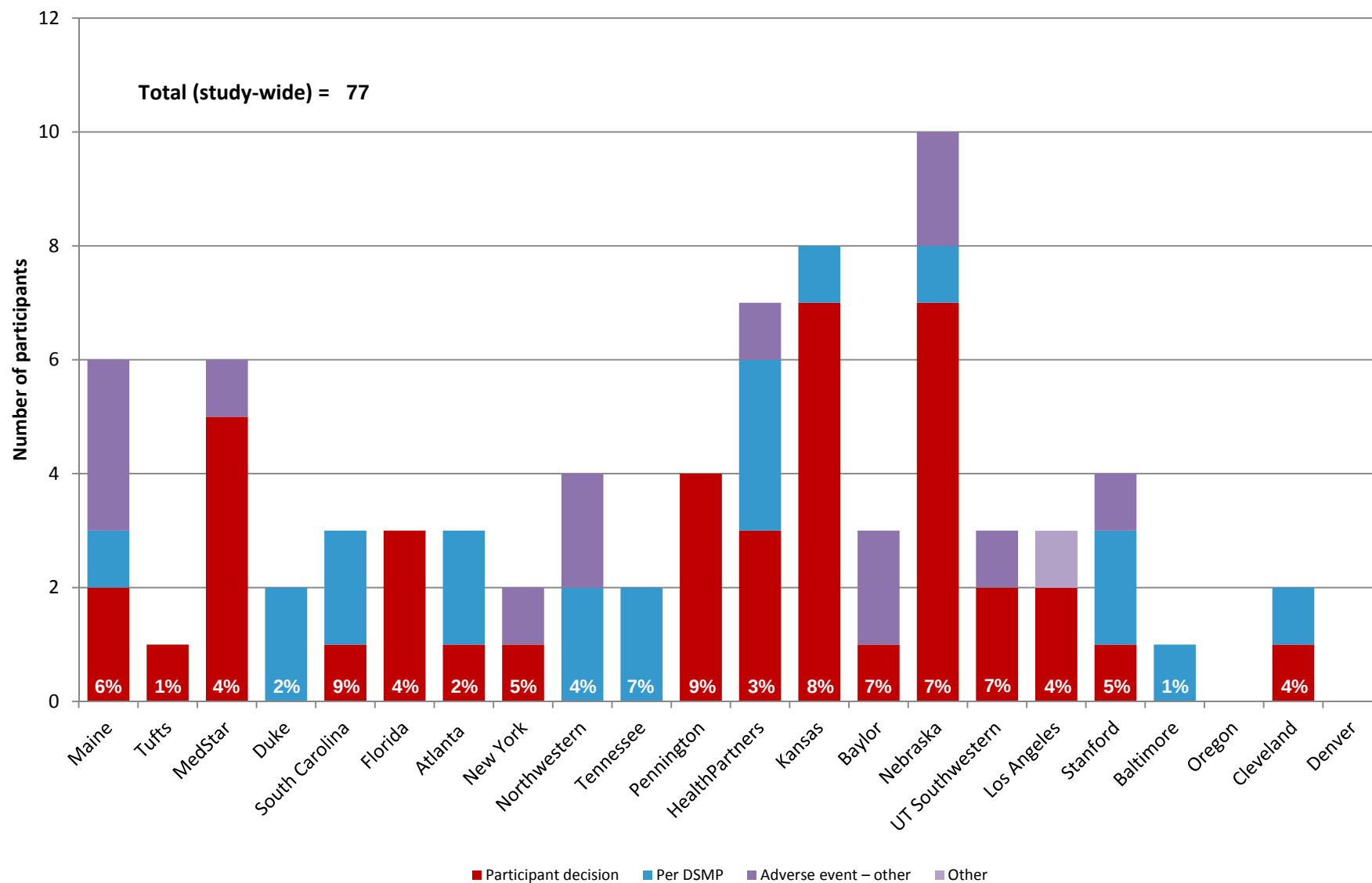
Discontinuation of Study Pills

excludes participants who withdrew consent



Discontinuation of Study Pills

excludes participants who withdrew consent



Biorepository Consent

Site	Biorepository Consent (%)	DNA Consent (%)
Atlanta	95%	94%
Baltimore	93%	90%
Baylor	93%	93%
Beth Israel Medical Center	86%	86%
Cleveland	96%	94%
Denver VA	100%	98%
Duke	80%	79%
Florida	97%	94%
HealthPartners	90%	89%
Kaiser	93%	91%
LA	90%	90%
Maine	89%	89%
South Carolina	75%	75%
MedStar	90%	86%
Northwestern	92%	88%
Omaha VA	91%	91%
Orlando VA	100%	100%
Pennington	87%	85%
Stanford	93%	92%
Truman	85%	85%
Tufts	95%	94%
UC Denver	100%	100%
Kansas	82%	82%
Nebraska (UNMC)	84%	79%
Tennessee	62%	59%
UT Southwestern	100%	100%
Overall	88%	89%

Demogrphics 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	Other
Atlanta	124	113	3	25	92	4	2	0	1
Baltimore	72	24	0	14	56	1	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	34	4	30	14	4	0	0	1
Denver VA	54	50	7	44	8	0	2	0	0
Duke	126	62	5	68	51	6	0	0	1
Florida	70	31	11	54	10	3	0	0	3
HealthPartners	272	165	9	246	13	8	2	0	3
Kaiser	227	124	18	187	10	16	1	0	13
LA	79	10	74	74	2	3	0	0	0
Maine	102	43	1	97	2	0	0	0	3
South Carolina	32	10	0	19	11	1	0	0	1
MedStar	150	73	7	44	98	4	0	2	2
Northwestern	114	71	7	79	29	6	0	0	0
Omaha VA	109	104	4	96	8	1	1	0	3
Orlando VA	1	1	1	1	0	0	0	0	0
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	139	70	8	91	35	11	0	0	2
UC Denver	14	9	0	9	5	0	0	0	0
Kansas	93	41	2	68	21	2	1	1	0
Nebraska (UNMC)	38	21	3	33	3	0	0	1	1
Tennessee	29	10	1	10	19	0	0	0	0
UT Southwestern	41	22	9	25	7	6	0	0	3
Overall	2162	1200	209	1438	550	113	11	5	43
			9.7%						