

The SAS System

11/2/2016

Site	SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal	% of promised
Maine	363	.	169	1	.	104	125	83.2
Tufts	497	2	249	.	1	146	112	130.4
MedStar	413	1	241	3	1	153	150	102.0
Duke	364	2	221	1	.	135	150	90.0
SouthCarolina	183	.	70	.	.	32	150	21.3
Florida	355	1	122	2	.	75	150	50.0
Atlanta	256	.	221	1	.	133	180	73.9
NewYork	190	.	73	.	.	37	100	37.0
Northwestern	307	1	220	2	2	116	125	92.8
Tennessee	82	.	38	.	.	29	150	19.3
Tulane	35	.	2	.	.	2	150	1.3
Pennington	253	.	84	1	.	47	190	24.7
HealthPartners	648	.	453	7	2	294	300	98.0
Kansas	390	2	182	2	2	110	150	73.3
Baylor	209	.	82	.	.	43	150	28.7
Nebraska	557	4	286	3	.	164	126	130.2
UTSouthwestern	117	.	77	1	.	42	120	35.0
LA	259	1	141	1	.	82	120	68.3
Stanford	331	.	155	3	.	88	150	58.7
Baltimore	206	.	120	1	.	78	100	78.0
Cleveland	185	1	93	1	3	51	100	51.0
Kaiser	468	.	390	2	3	247	130	190.0
Denver	326	.	129	1	.	76	65	116.9
Lenox	30	2	7	2	.	3	25	12.0
	7024	17	3825	35	14	2287	2382	96.0

7.1.a Detail on diabetes diagnosis

	Overall	M06	M12	M18	M24	M30	M36	M42	M48
Semi-annual visits	2893	1815	-	902 ¹	-	176	-	-	-
Diabetes, n (% visits)	70 (2.4)	52 (2.9)	-	16 (1.8)	-	2 (1.1)	-	-	-
Positive A1c and FPG	27	19	-	7	-	1	-	-	-
Positive A1c or FPG, pos. confirmatory	43	33	-	9	-	1	-	-	-
No diabetes, n	2823	1763	-	886	-	174	-	-	-
Negative A1c and FPG	2753	1710	-	871	-	172	-	-	-
Positive A1c or FPG, neg. confirmatory	70	53	-	15	-	2	-	-	-
Weight change (% from baseline)		-0.30%		-0.13%		-0.82%			
Annual visits	1866	-	1330 ¹	-	536	-	-	-	-
Diabetes, n (% visits)	83 (4.4)	-	63 (4.7)	-	20 (3.7)	-	-	-	-
Positive, met 2 criteria	27	-	21	-	6	-	-	-	-
Positive, met 1 criterion, pos. confirmatory	56	-	42	-	14	-	-	-	-
No diabetes, n	1783	-	1267	-	516	-	-	-	-
All 3 criteria negative	1683	-	1190	-	493	-	-	-	-
Met 1 criterion, neg. confirmatory	100	-	77	-	23	-	-	-	-
Weight change (% from baseline)			-0.13%		-0.22%				
Outside of study events by adjudication ²	19	3	7	5	2	2			
Total events	172	55	70	21	22	4			

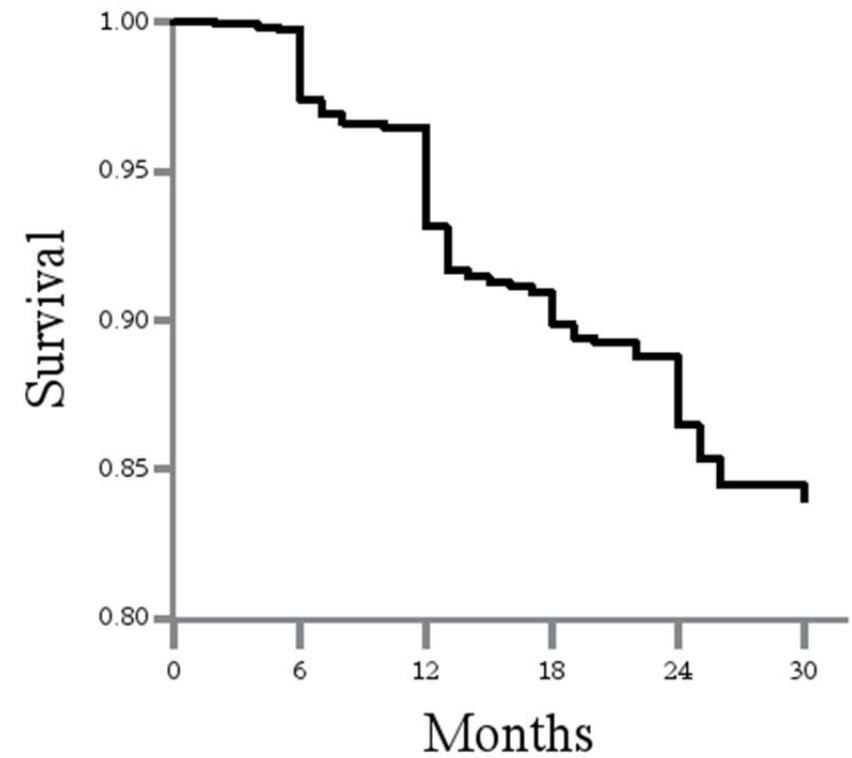
¹ Number excludes participants who have reached the *diabetes outcome* [by D2d criteria or adjudication].

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 = **6.94%**

Product-Limit Survival Estimates

Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	1826
6	0.9736	0.0264	0.00375	48	1420
12	0.9306	0.0694	0.00651	108	992
18	0.8976	0.1024	0.00839	142	614
24	0.8635	0.1365	0.0109	163	307
30	0.8386	0.1614	0.0143	170	61

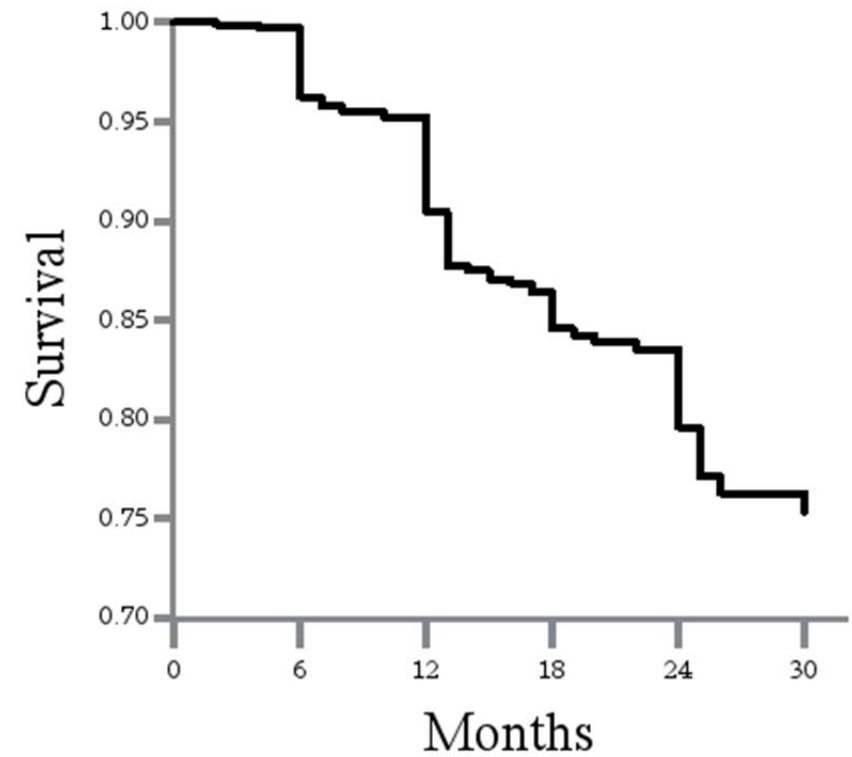


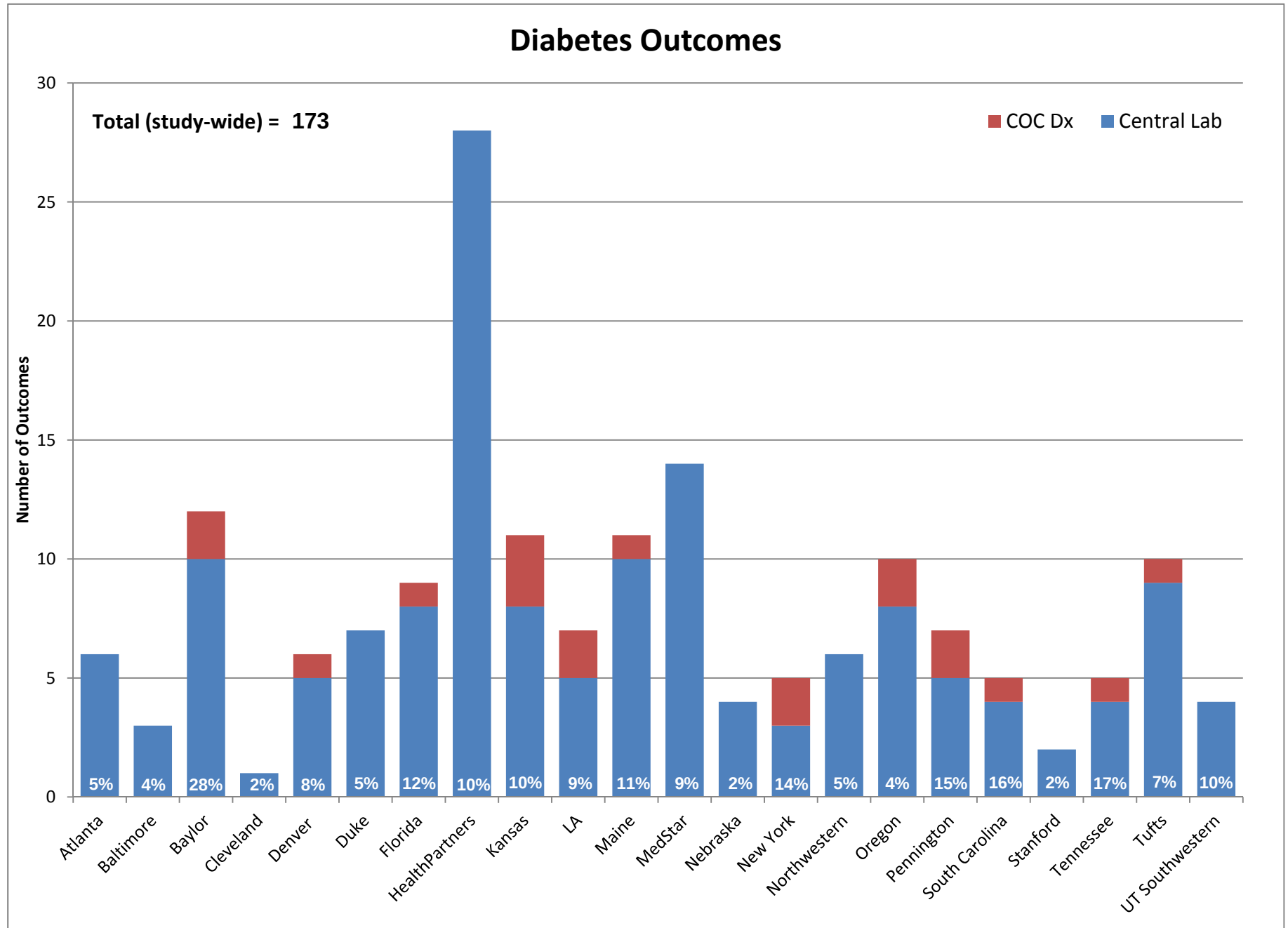
Among participants meeting DPP eligibility criteria (FPG 95-125 and 2hPG 140-199)

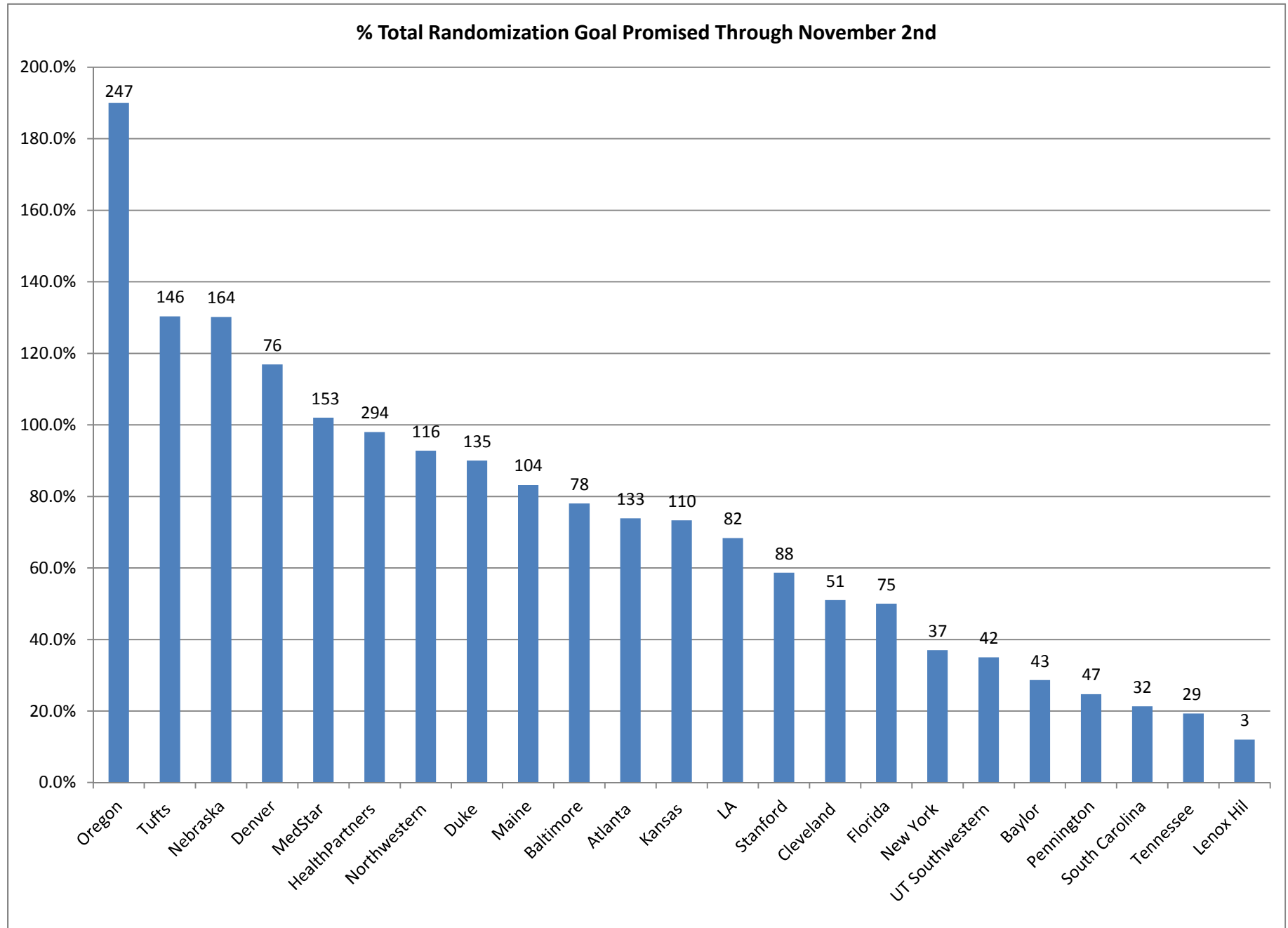
Annual Kaplan-Meier event rate = 9.74%

Product-Limit Survival Estimates

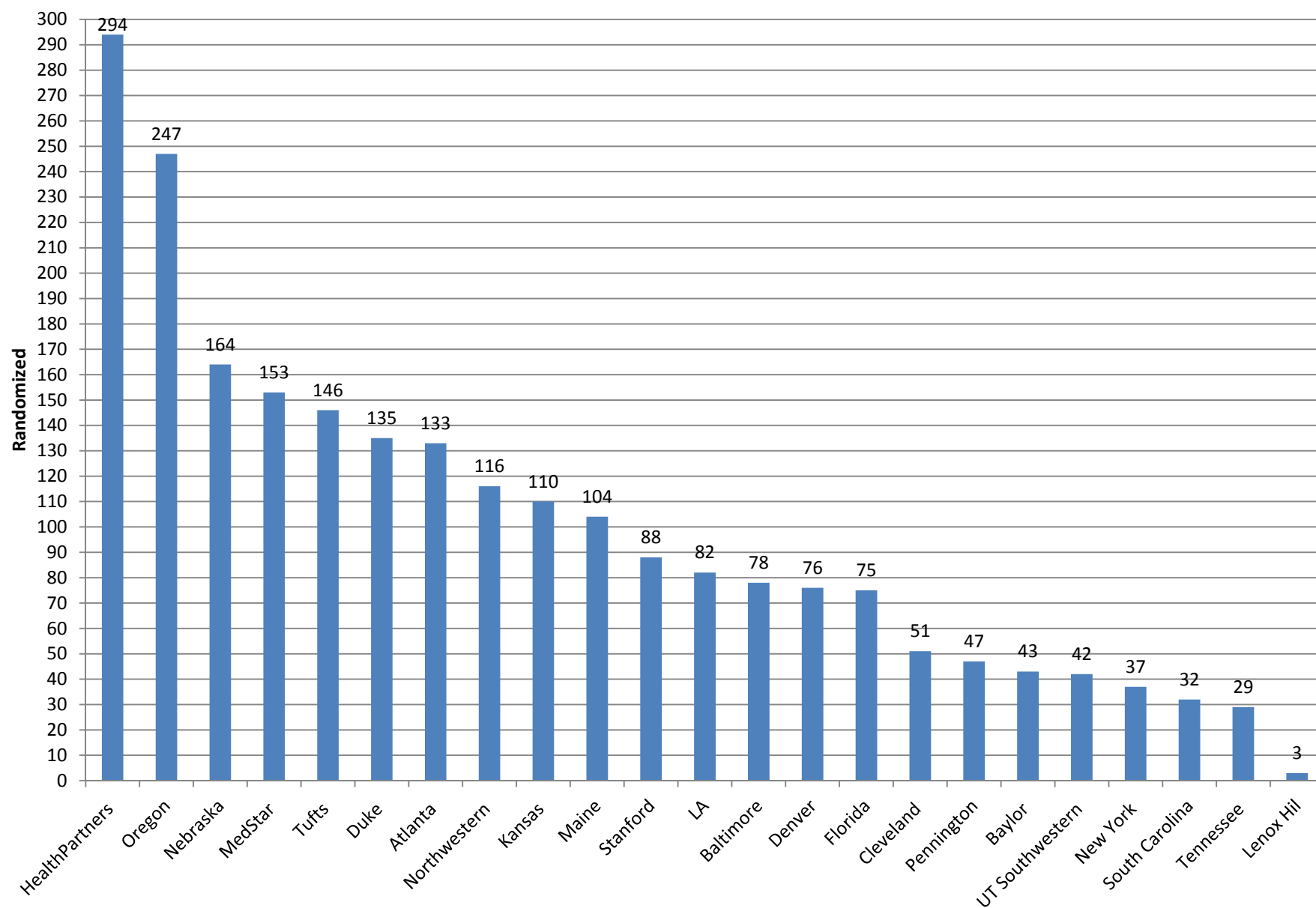
Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	869
6	0.9619	0.0381	0.0065	33	677
12	0.9026	0.0974	0.0109	73	455
18	0.8433	0.1567	0.0148	102	264
24	0.7929	0.2071	0.0191	116	128
30	0.7497	0.2503	0.0251	122	23







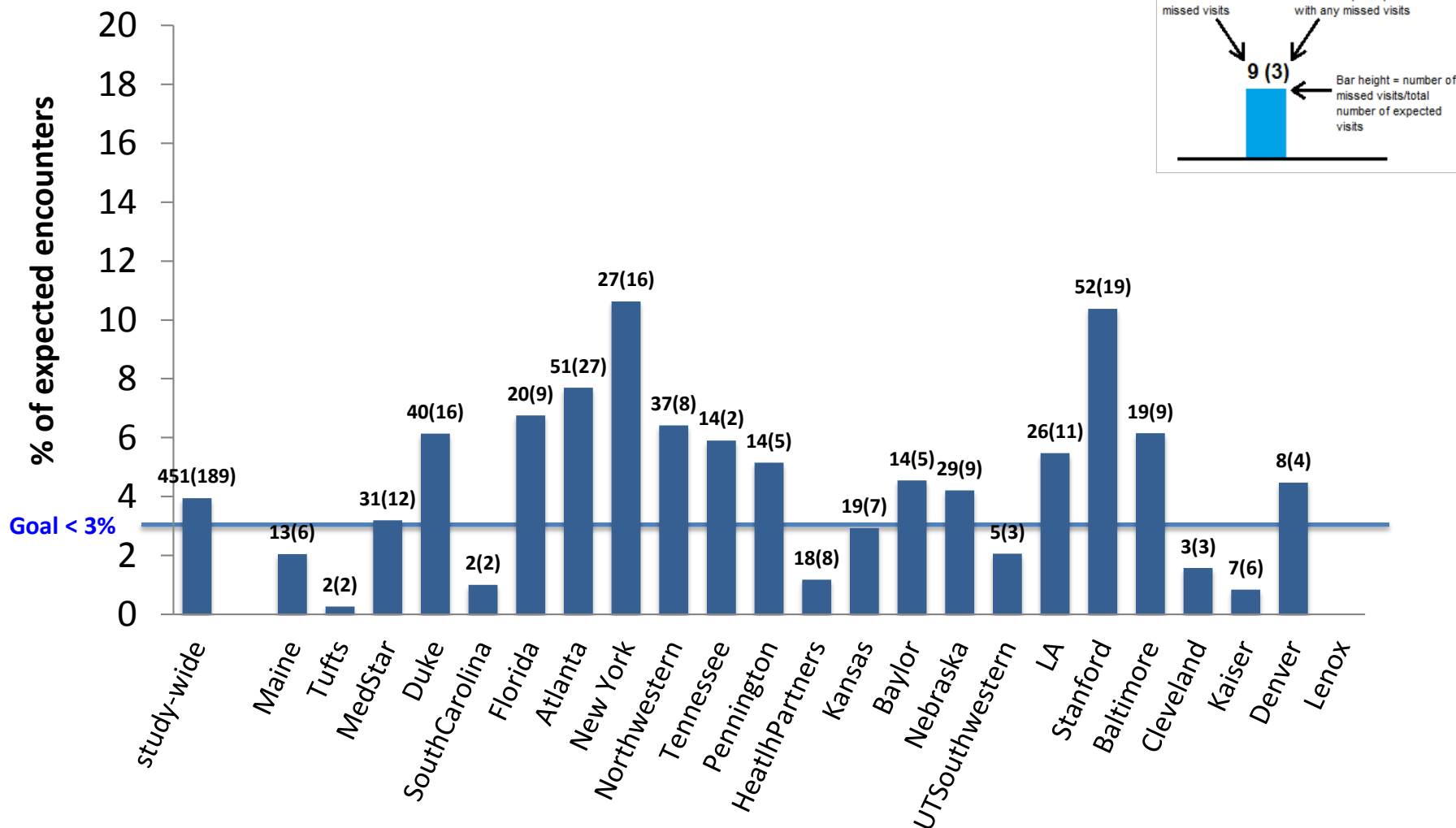
Randomizations by Site



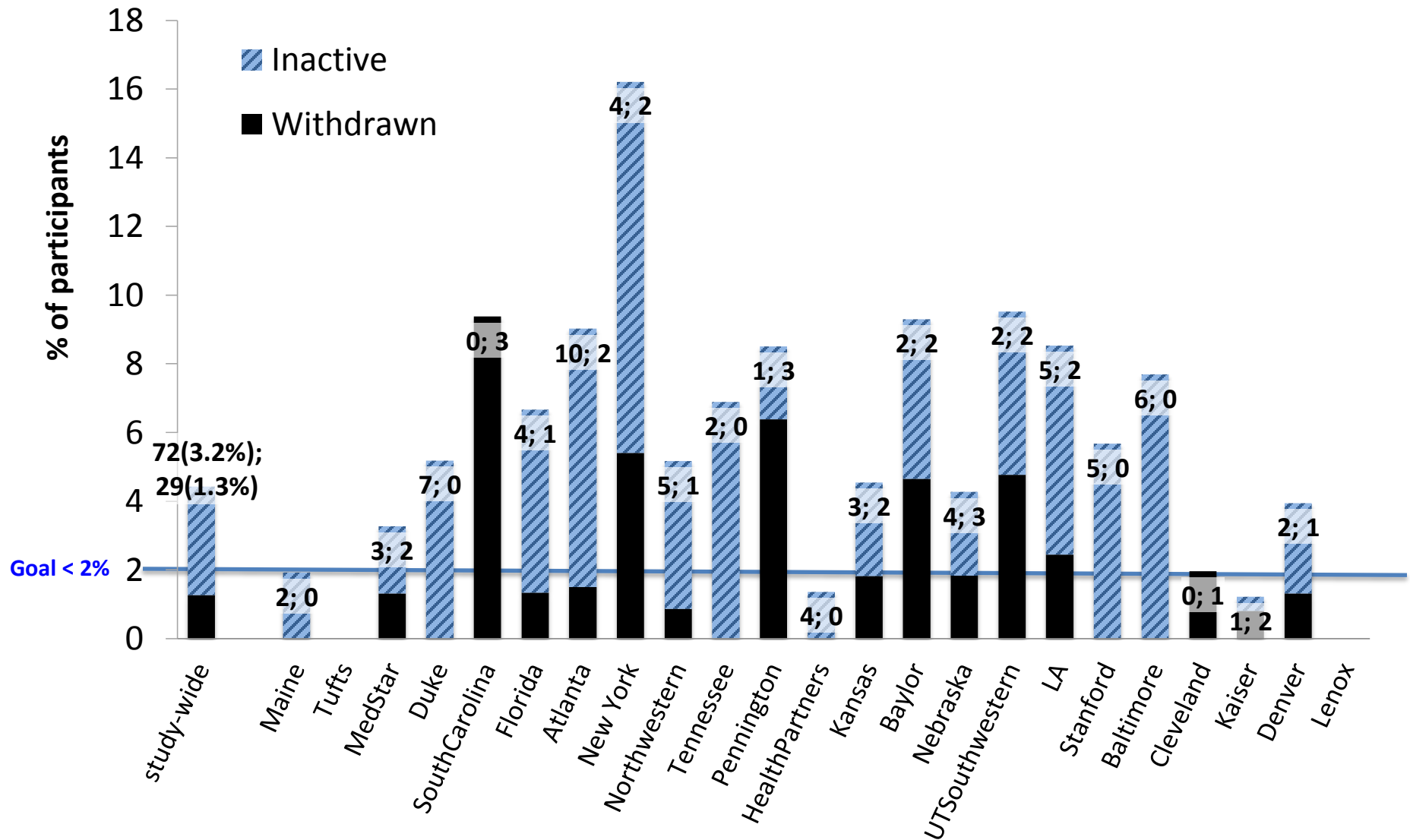
Missed encounters (visits and interim phone contact)

8

Study-wide = 3.9%

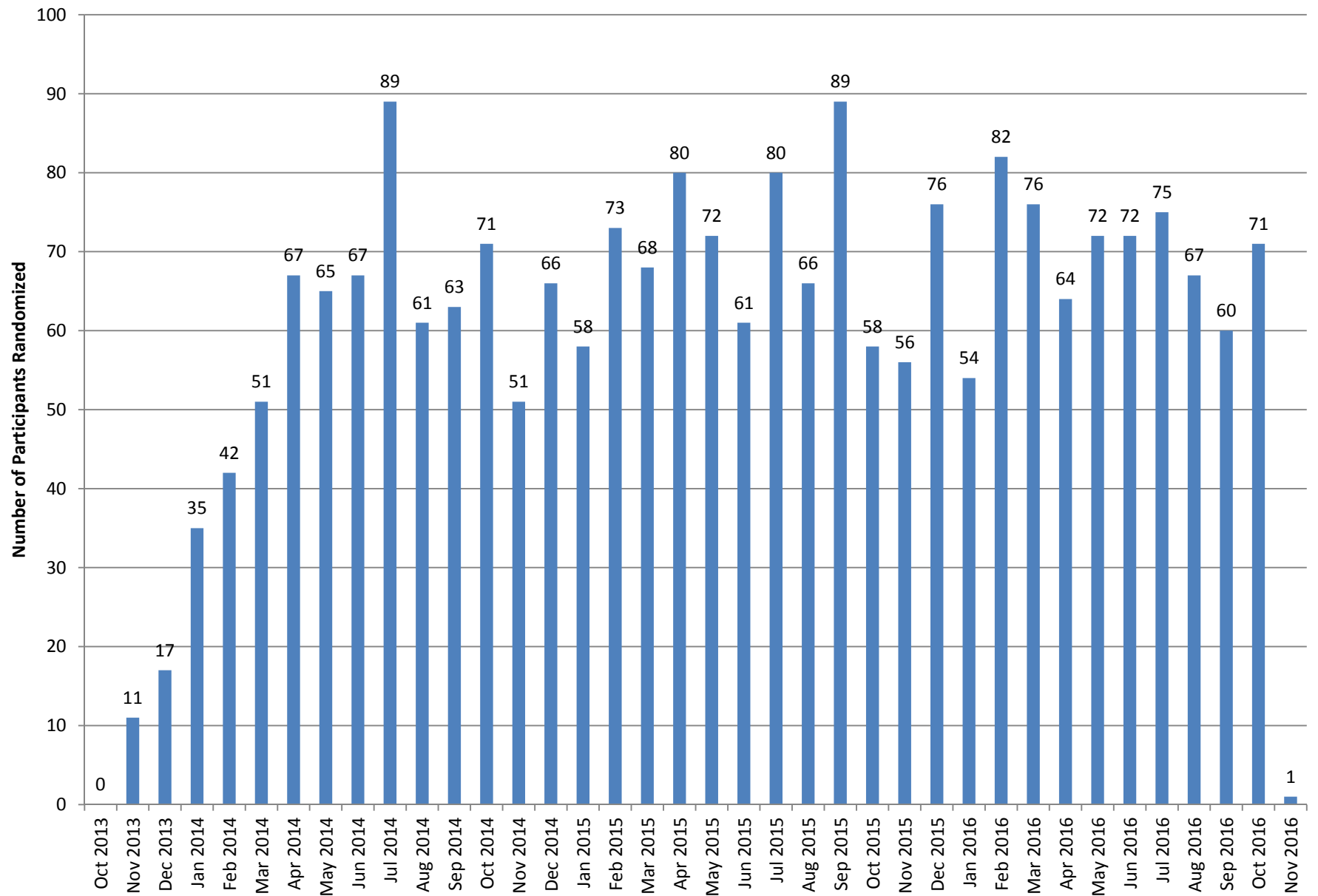


% inactive and withdrawn participants



Labels are number of participants (inactive; withdrawn).

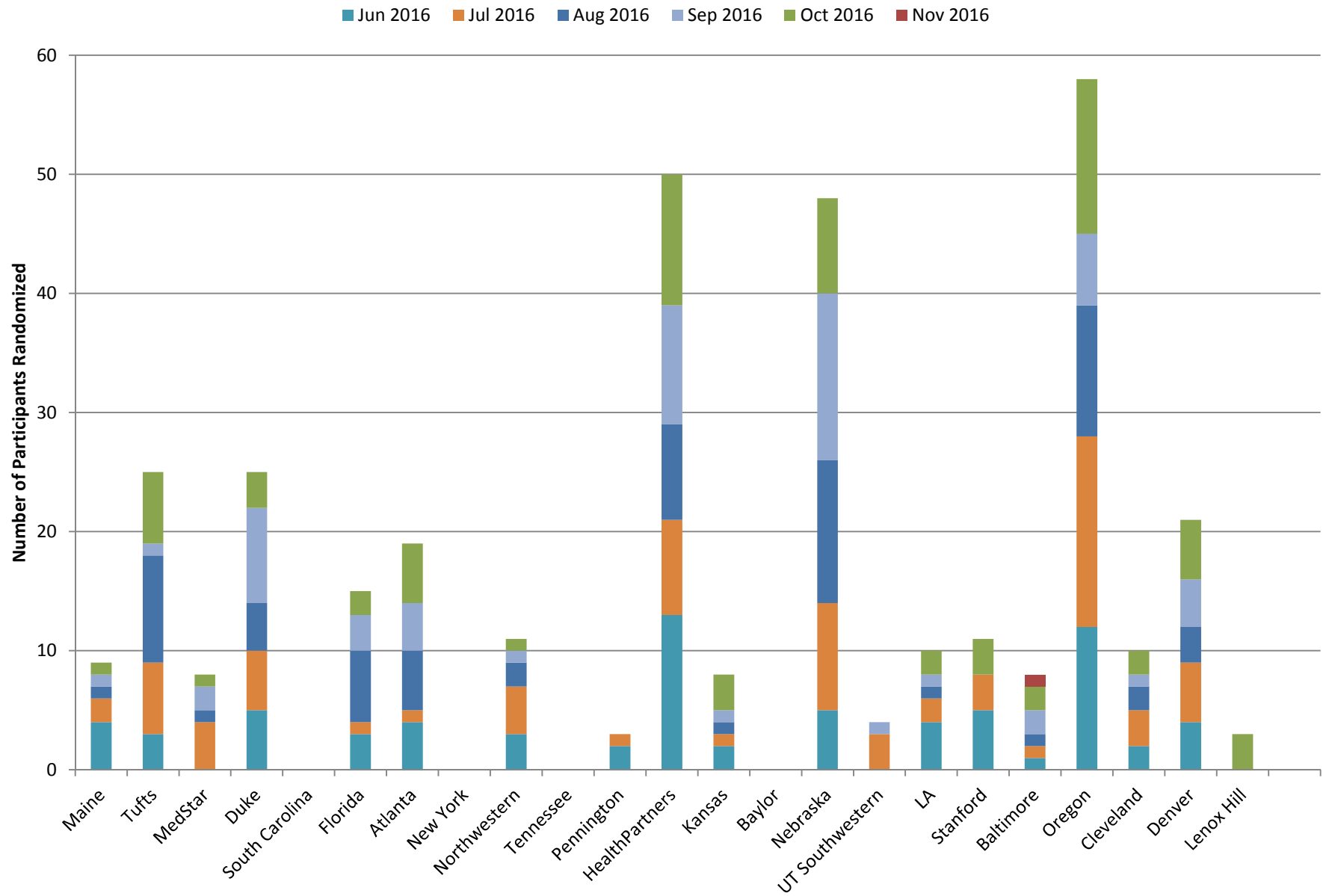
Study-Wide Randomizations per Month



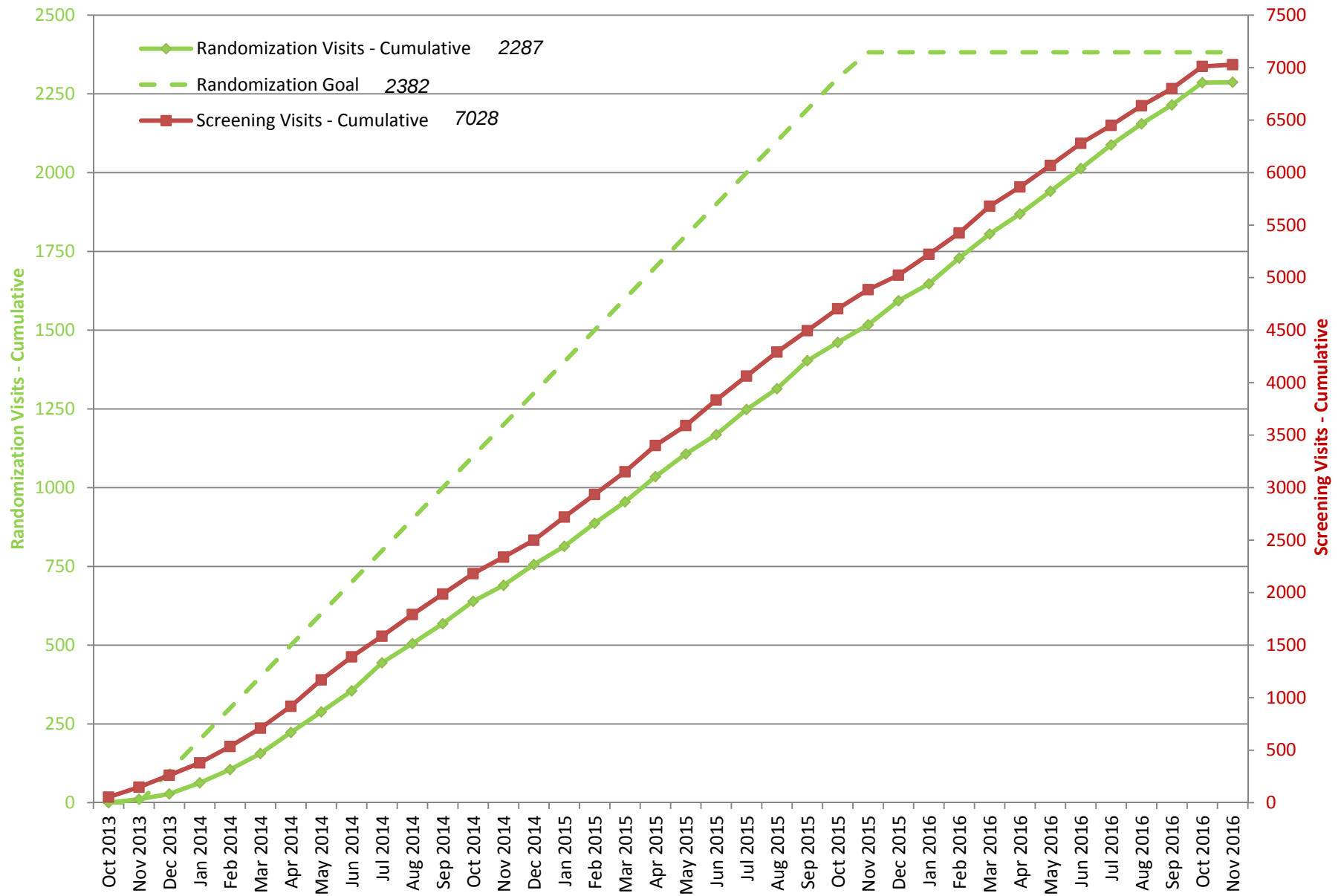
The SAS System

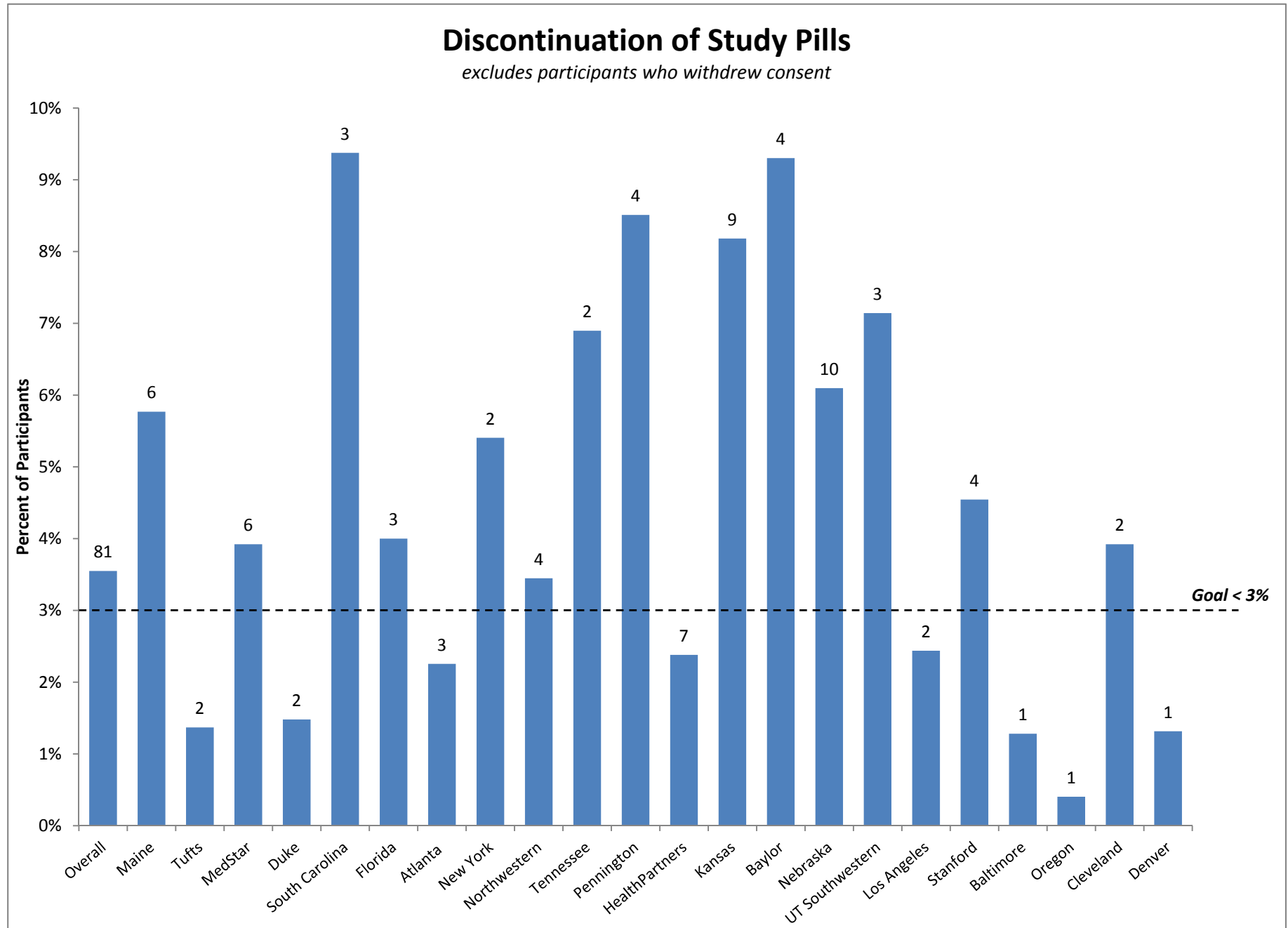
Site	Monthly RAN goal	RAN goal	SCR visits	BAS visits	RAN visits	SCR:RAN ratio	% of goal	11/2016 SCR visits	11/2016 BAS visits	11/2016 RAN visits	11/2016 SCR:RAN ratio	11/2016 RAN goal(%)	10/2016 SCR visits	10/2016 BAS visits	10/2016 RAN visits	10/2016 SCR:RAN ratio	10/2016 RAN goal(%)
Maine	5.2	125	363	169	104	3.5	83.2	.	.	.	.	.	4	2	1	4.0	19
Tufts	4.7	112	497	249	146	3.4	130.4	.	.	.	.	.	8	6	6	1.3	128
MedStar	6.3	150	413	241	153	2.7	102.0	.	1	.	.	.	5	4	1	5.0	16
Duke	6.3	150	364	221	135	2.7	90.0	.	1	.	.	.	3	1	3	1.0	48
SouthCarolina	6.3	150	183	70	32	5.7	21.3	.	.	.	.	.	.	.	.	.	.
Florida	6.3	150	355	122	75	4.7	50.0	1	.	.	.	.	11	6	2	5.5	32
Atlanta	7.5	180	256	221	133	1.9	73.9	.	.	.	.	.	5	4	5	1.0	67
NewYork	4.2	100	190	73	37	5.1	37.0	.	.	.	.	.	.	.	.	.	.
Northwestern	5.2	125	307	220	116	2.6	92.8	.	.	.	.	.	8	7	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	253	84	47	5.4	24.7	1	.	.	.	.	3	3	.	.	.
HealthPartners	12.5	300	648	453	294	2.2	98.0	.	.	.	.	.	48	21	11	4.4	88
Kansas	6.3	150	390	182	110	3.5	73.3	2	.	.	.	.	21	6	3	7.0	48
Baylor	6.3	150	209	82	43	4.9	28.7	.	.	.	.	.	.	.	.	.	.
Nebraska	5.3	126	557	286	164	3.4	130.2	1	1	.	.	.	9	5	8	1.1	151
UTSouthwestern	5.0	120	117	77	42	2.8	35.0	.	.	.	.	.	1	1	.	.	.
LA	5.0	120	259	141	82	3.2	68.3	.	.	.	.	.	10	7	2	5.0	40
Stanford	6.3	150	331	155	88	3.8	58.7	1	1	.	.	.	10	5	3	3.3	48
Baltimore	7.7	100	206	120	78	2.6	78.0	.	.	1	.	13	5	5	2	2.5	26
Cleveland	7.7	100	185	93	51	3.6	51.0	1	.	.	.	.	4	5	2	2.0	26
Kaiser	10.0	130	468	390	247	1.9	190.0	1	.	.	.	.	42	16	13	3.2	130
Denver	5.4	65	326	129	76	4.3	116.9	1	1	.	.	.	5	1	5	1.0	93
Lenox	5.0	25	30	7	3	10.0	12.0	2	.	.	.	.	10	7	3	3.3	60
	.	.	7024	3825	2287	3.1	96.0	11	5	1	11	1	212	112	71	3.0	51

Randomizations By Site - Last 6 Months



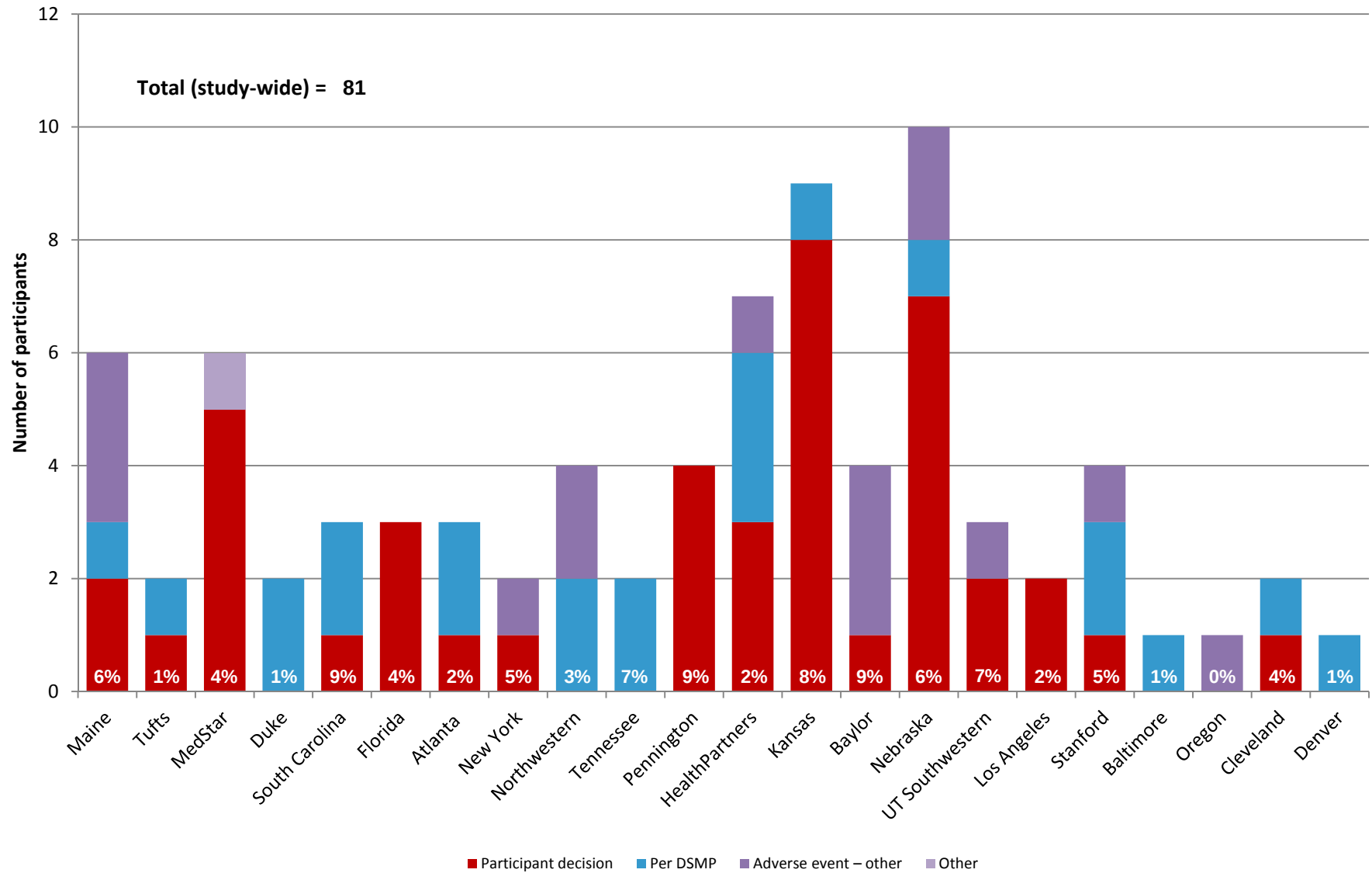
Cumulative Screening and Randomization Visits by Month





Discontinuation of Study Pills

excludes participants who withdrew consent



Biorepository Consent

Site	Total RAND	Biorepository Consent (%)	DNA Consent (%)
Atlanta	133	95%	94%
Baltimore	78	94%	91%
Baylor	43	93%	93%
Beth Israel Medical Center	37	86%	86%
Cleveland	51	96%	94%
Denver VA	60	100%	98%
Duke	135	81%	79%
Florida	75	96%	95%
HealthPartners	294	90%	89%
Kaiser	247	94%	91%
Lenox Hill	3	67%	67%
LA	82	88%	88%
Maine	104	89%	89%
South Carolina	32	75%	75%
MedStar	153	90%	86%
Northwestern	116	91%	87%
Omaha VA	116	91%	91%
Pennington	47	87%	85%
Stanford	88	93%	92%
Truman	13	85%	85%
Tufts	146	94%	93%
UC Denver	16	100%	100%
Kansas	97	82%	82%
Nebraska (UNMC)	48	85%	81%
Tennessee	29	62%	59%
UT Southwestern	42	100%	100%
Overall	2287	90%	89%

