

The SAS System

1/4/2017

Site	SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal	% of promised
Maine	369	1	172	.	.	107	125	85.6
Tufts	510	1	262	1	.	153	112	136.6
MedStar	418	1	247	.	.	158	150	105.3
Duke	375	2	228	.	.	140	150	93.3
SouthCarolina	183	.	70	.	.	32	150	21.3
Florida	362	2	122	.	.	76	150	50.7
Atlanta	263	.	227	1	.	137	180	76.1
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	262	1	85	.	.	47	190	24.7
HealthPartners	639	.	474	.	2	316	300	105.3
Kansas	415	5	196	3	1	121	150	80.7
Baylor	209	.	82	.	.	43	150	28.7
Nebraska	559	.	296	.	.	175	126	138.9
UTSouthwestern	118	.	78	1	.	42	120	35.0
LA	260	.	143	.	.	84	120	70.0
Stanford	328	.	158	.	.	91	150	60.7
Baltimore	214	3	124	.	2	79	100	79.0
Cleveland	189	2	95	.	.	55	100	55.0
Kaiser	457	.	413	2	1	264	130	203.1
Denver	338	.	134	.	.	79	65	121.5
Lenox	50	2	16	.	1	12	25	48.0
	7132	21	3955	8	8	2398	3268	100.6

7.1.a Detail on diabetes diagnosis

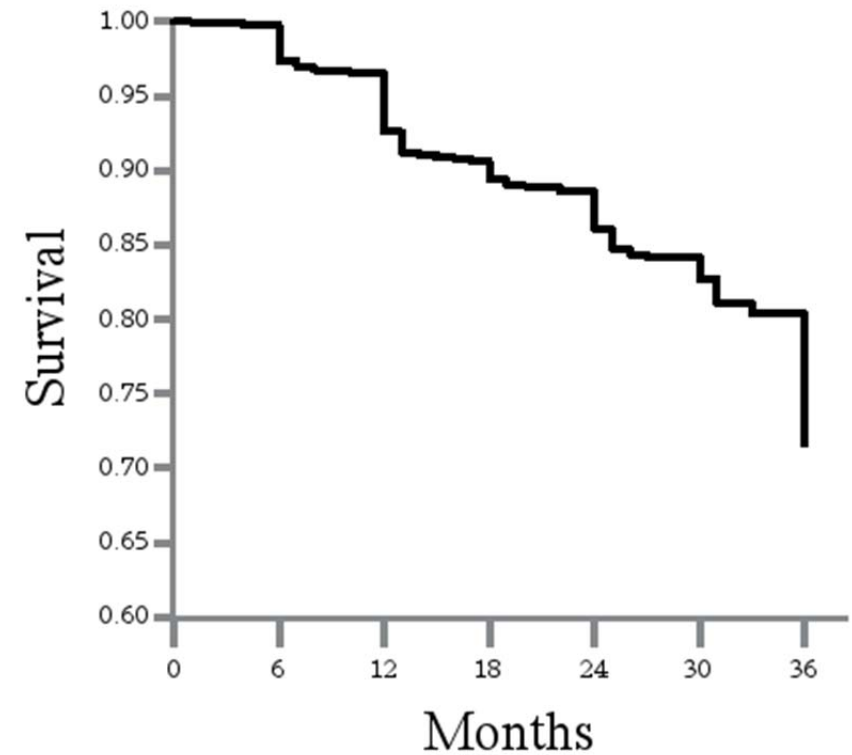
	Overall	M06	M12	M18	M24	M30	M36	M42	M48
Semi-annual visits	3209	1928	-	1004 ¹	-	277	-	-	-
Diabetes, n (% visits)	82 (2.6)	55 (2.9)	-	19 (1.9)	-	8 (2.9)	-	-	-
Positive A1c and FPG	28	19	-	7	-	2	-	-	-
Positive A1c or FPG, pos. confirmatory	54	36	-	12	-	6	-	-	-
No diabetes, n	3127	1873	-	985	-	269	-	-	-
Negative A1c and FPG	3044	1816	-	967	-	261	-	-	-
Positive A1c or FPG, neg. confirmatory	83	57	-	18	-	8	-	-	-
Weight change (% from baseline)		-0.21%		-0.17%		-0.48%			
Annual visits	2095	-	1437 ¹	-	631	-	27	-	-
Diabetes, n (% visits)	112 (5.3)	-	80 (5.6)	-	29 (4.6)	-	3 (11.1)	-	-
Positive, met 2 criteria	43	-	31	-	10	-	2	-	-
Positive, met 1 criterion, pos. confirmatory	69	-	49	-	19	-	1	-	-
No diabetes, n	1983	-	1357	-	602	-	24	-	-
All 3 criteria negative	1863	-	1272	-	571	-	20	-	-
Met 1 criterion, neg. confirmatory	120	-	85	-	31	-	4	-	-
Weight change (% from baseline)			-0.09%		-0.18%		0.24%		
Outside of study events by adjudication ²	22	4	8	6	2	1	1		
Total events	216	59	88	25	31	9	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 = 7.49%

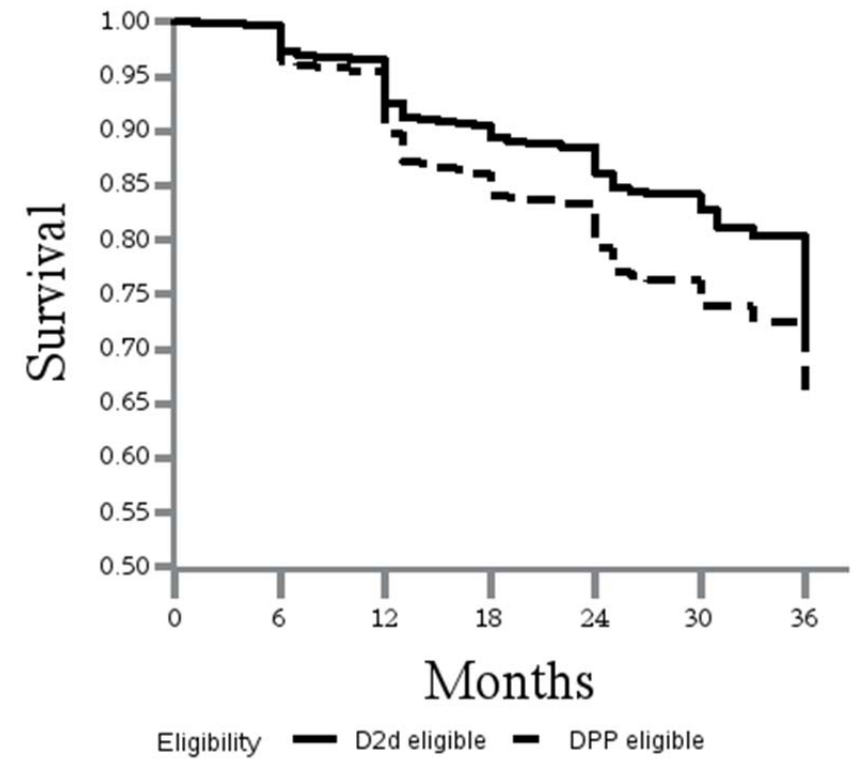
Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	2192
6	0.9736	0.0264	0.00362	52	1720
12	0.9251	0.0749	0.00645	127	1267
18	0.8924	0.1076	0.00801	168	861
24	0.8593	0.1407	0.0101	193	511
30	0.8253	0.1747	0.013	209	156
36	0.7094	0.2906	0.0525	216	0

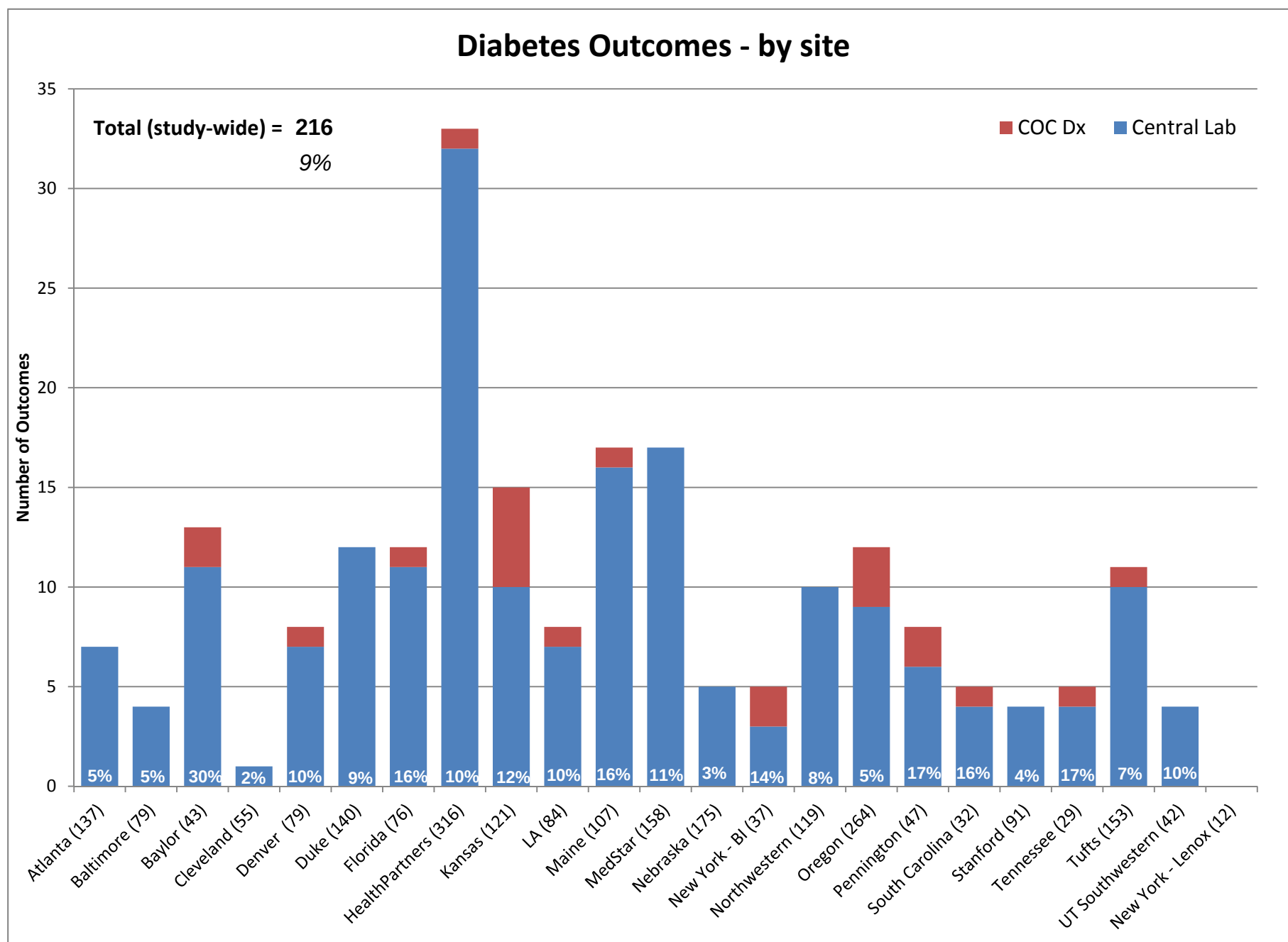


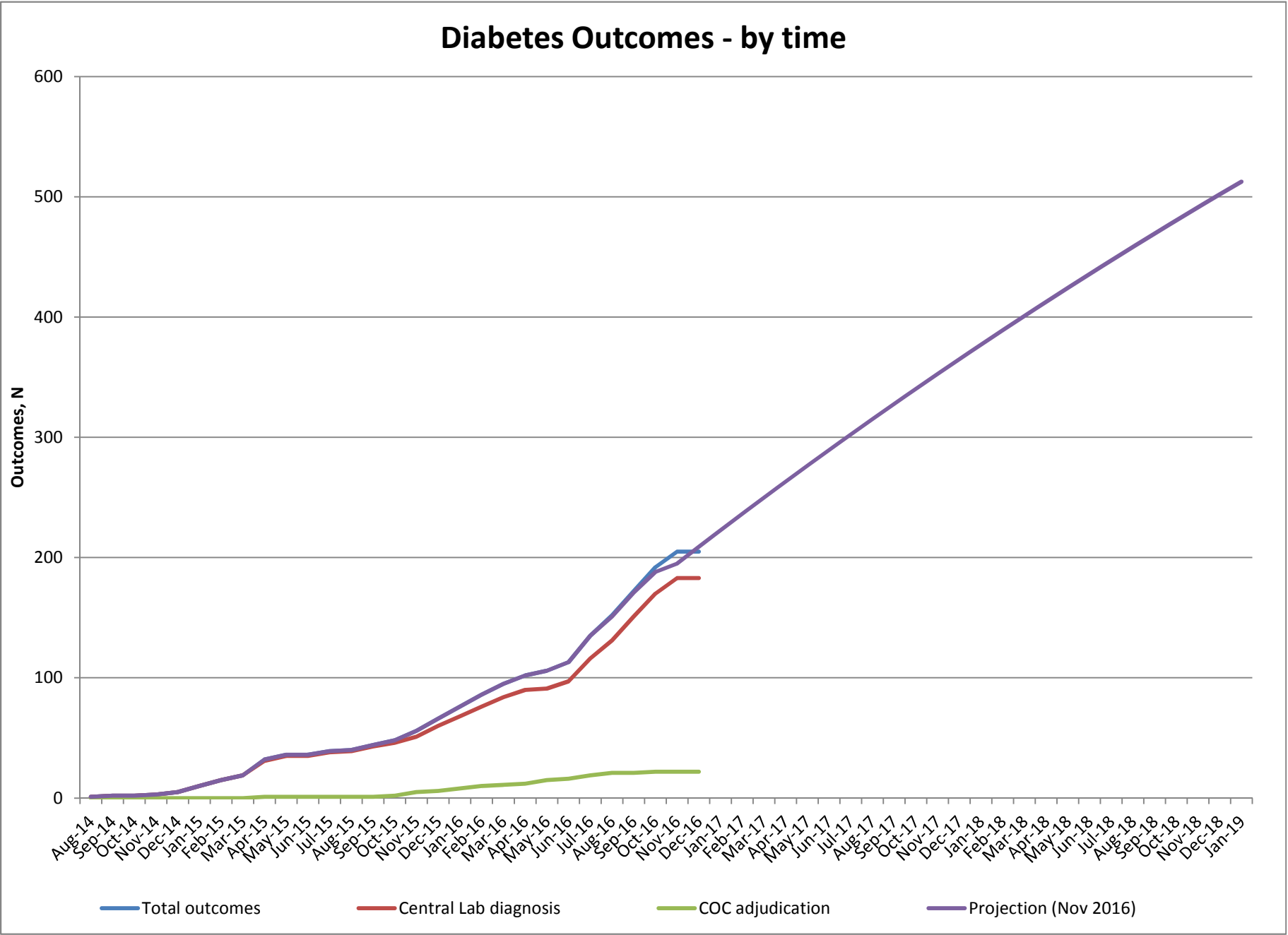
Among participants meeting DPP eligibility criteria (FPG 95-125 and 2hPG 140-199)

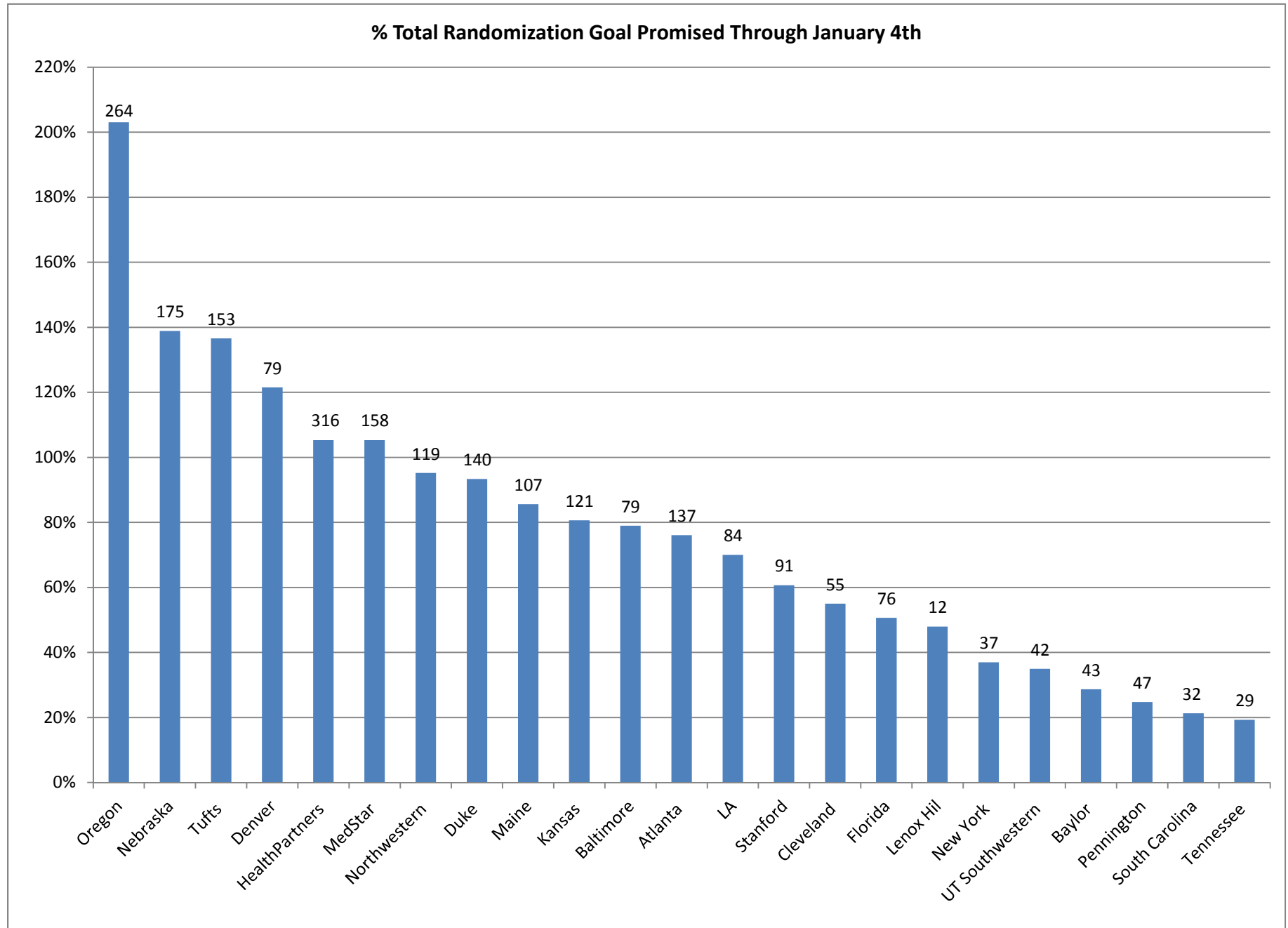
Annual Kaplan-Meier event rate = **10.38%**

Visit Month	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0	1	0	0	0	1042
6	0.9638	0.0362	0.0061	34	810
12	0.8962	0.1038	0.0108	84	592
18	0.8388	0.1612	0.0139	119	381
24	0.7892	0.2108	0.0175	136	215
30	0.7349	0.2651	0.0226	148	68
36	0.6545	0.3455	0.0669	150	0

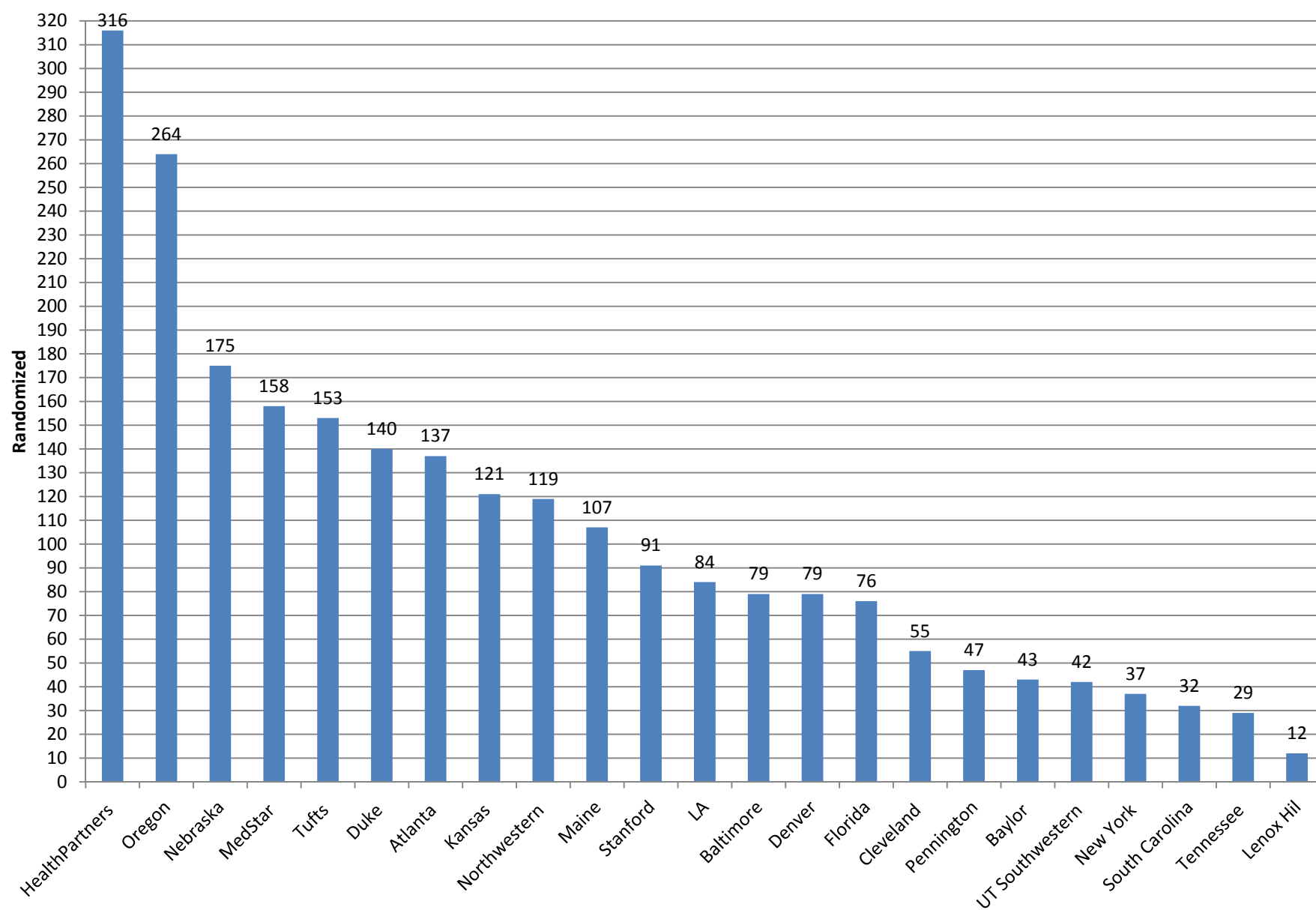








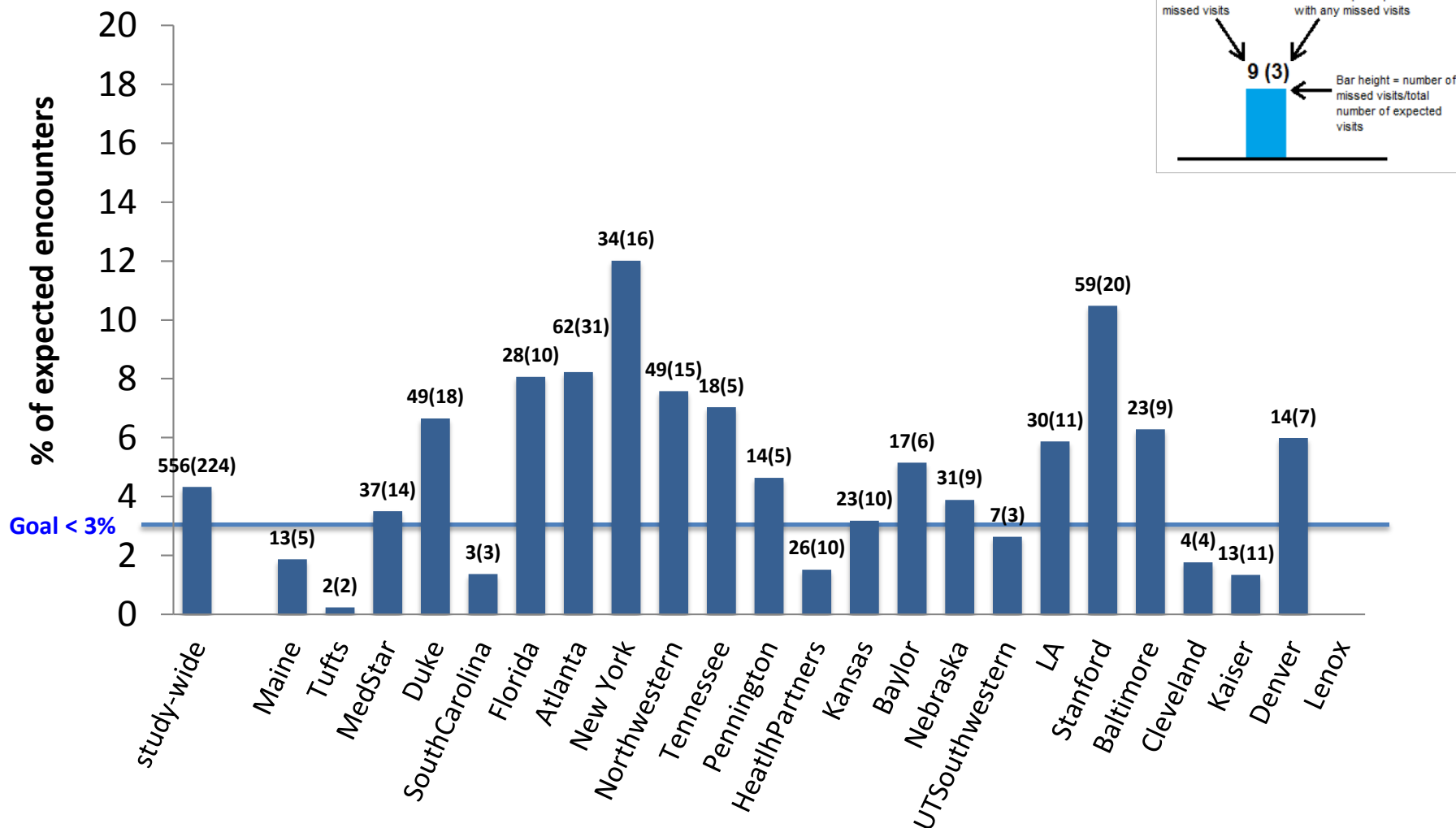
Randomizations by Site



Missed encounters (visits and interim phone contact)

9

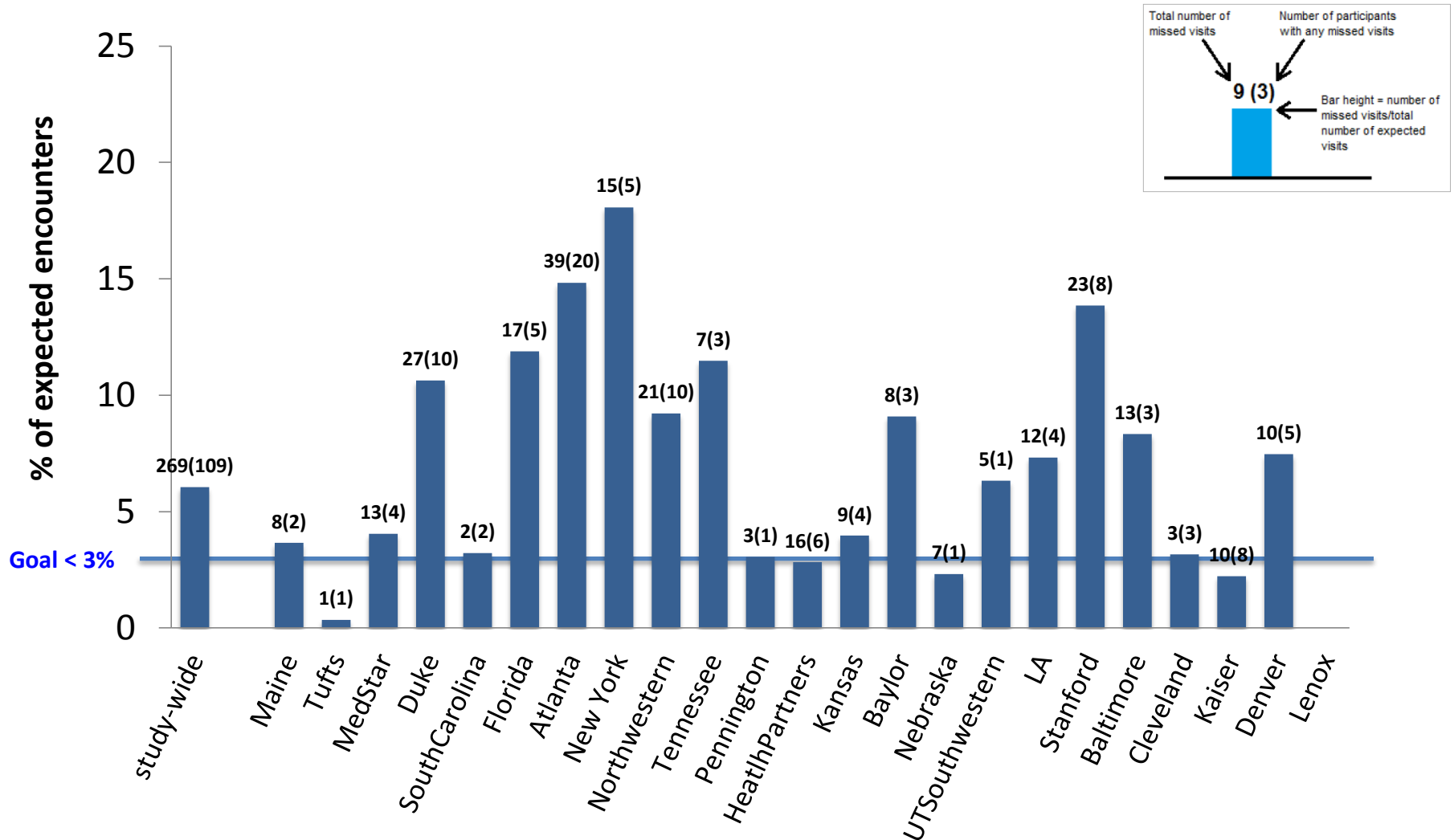
Study-wide = 4.3%



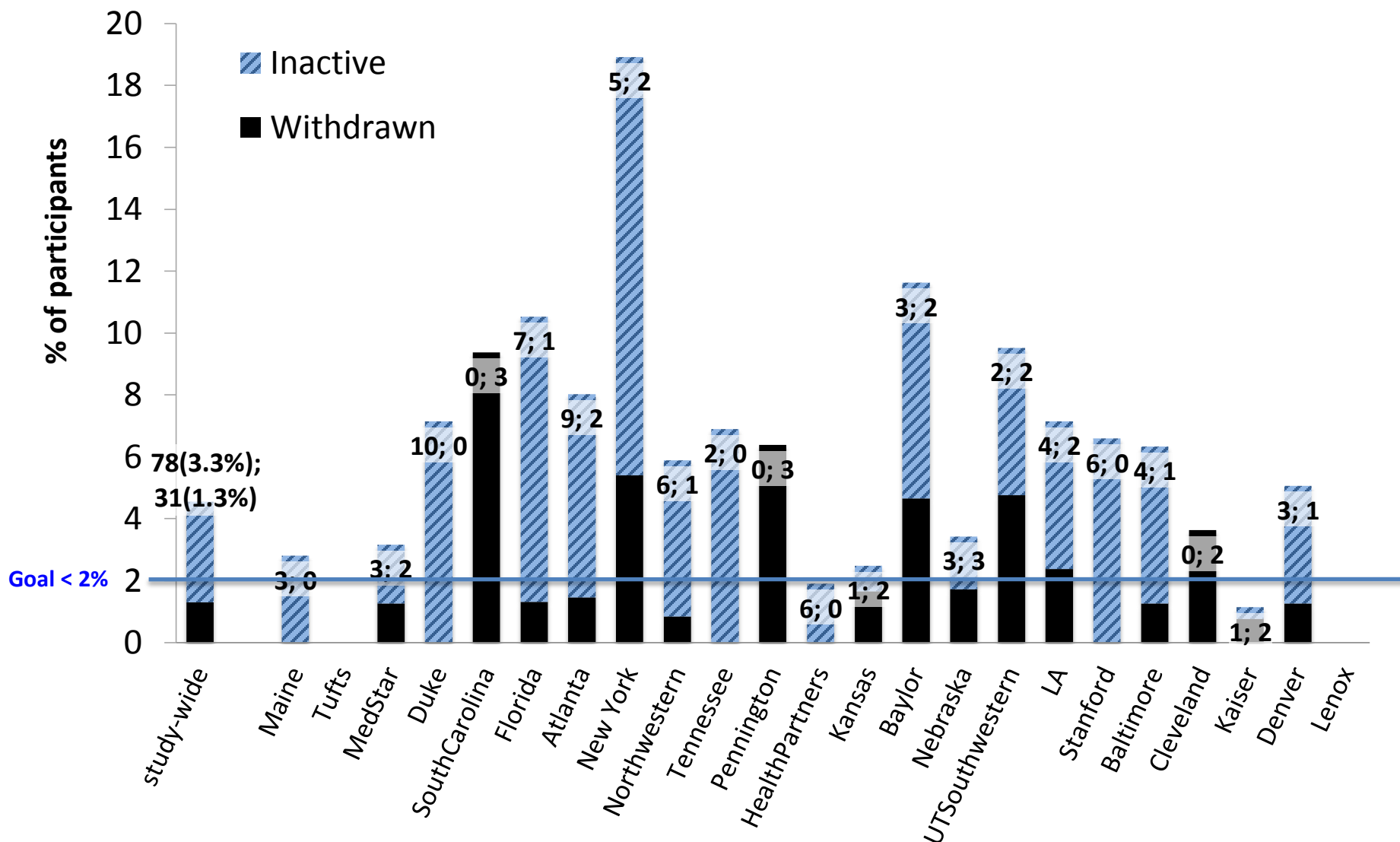
Missed encounters **within last 6 months** (visits and interim phone contact)

10

Study-wide = 6.1%

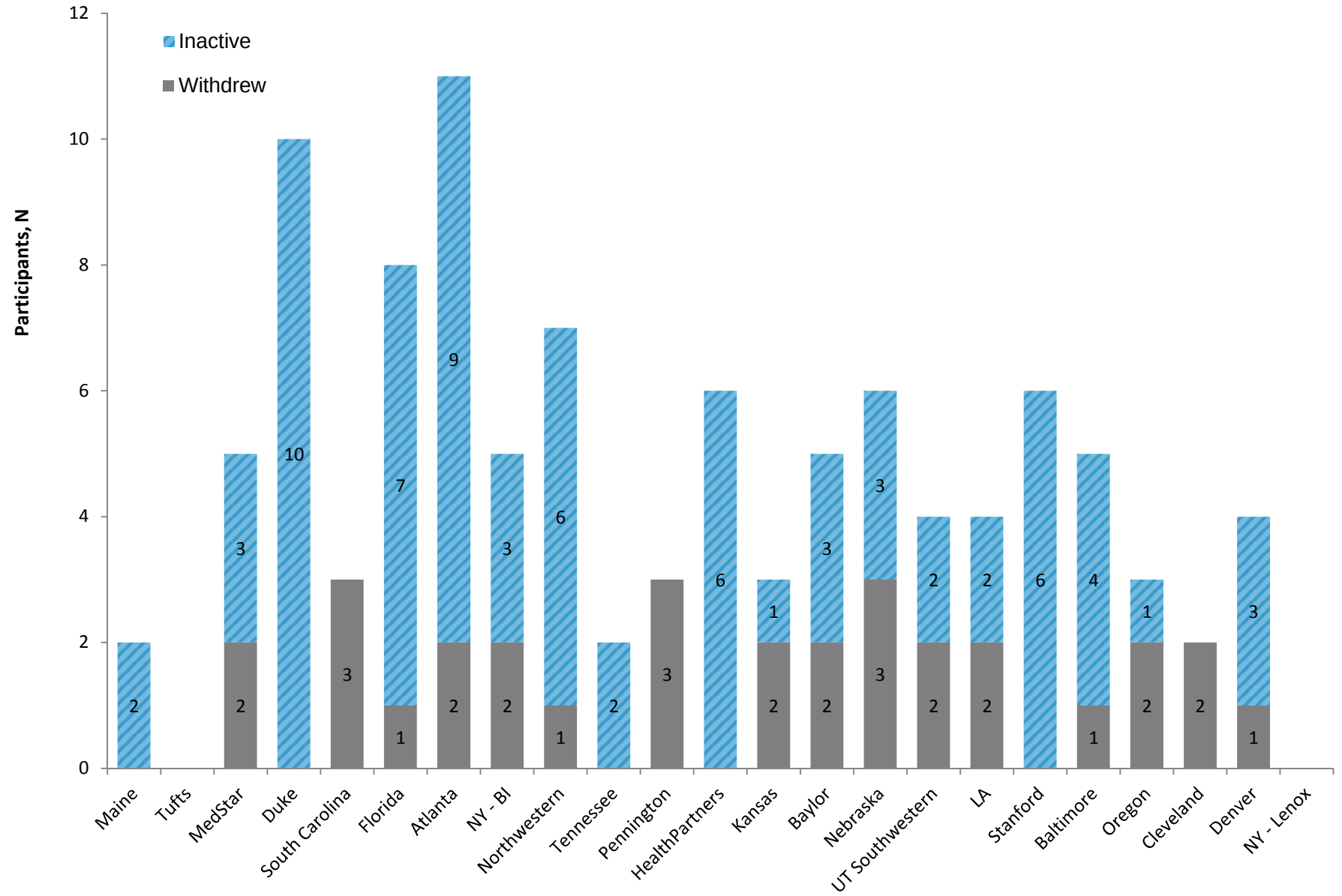


% inactive and withdrawn participants

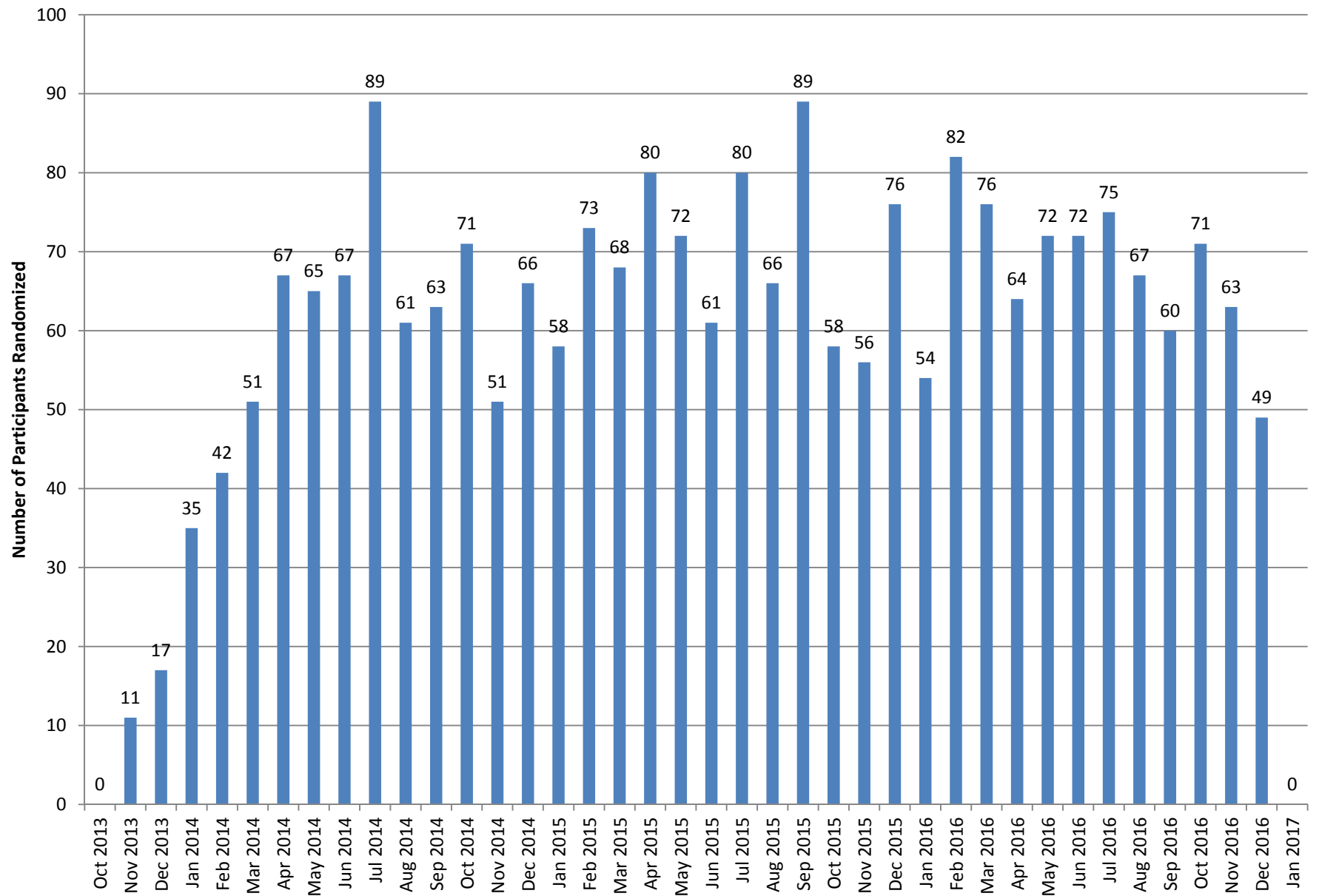


Labels are number of participants (inactive; withdrawn).

Inactive and Withdrawn Participants



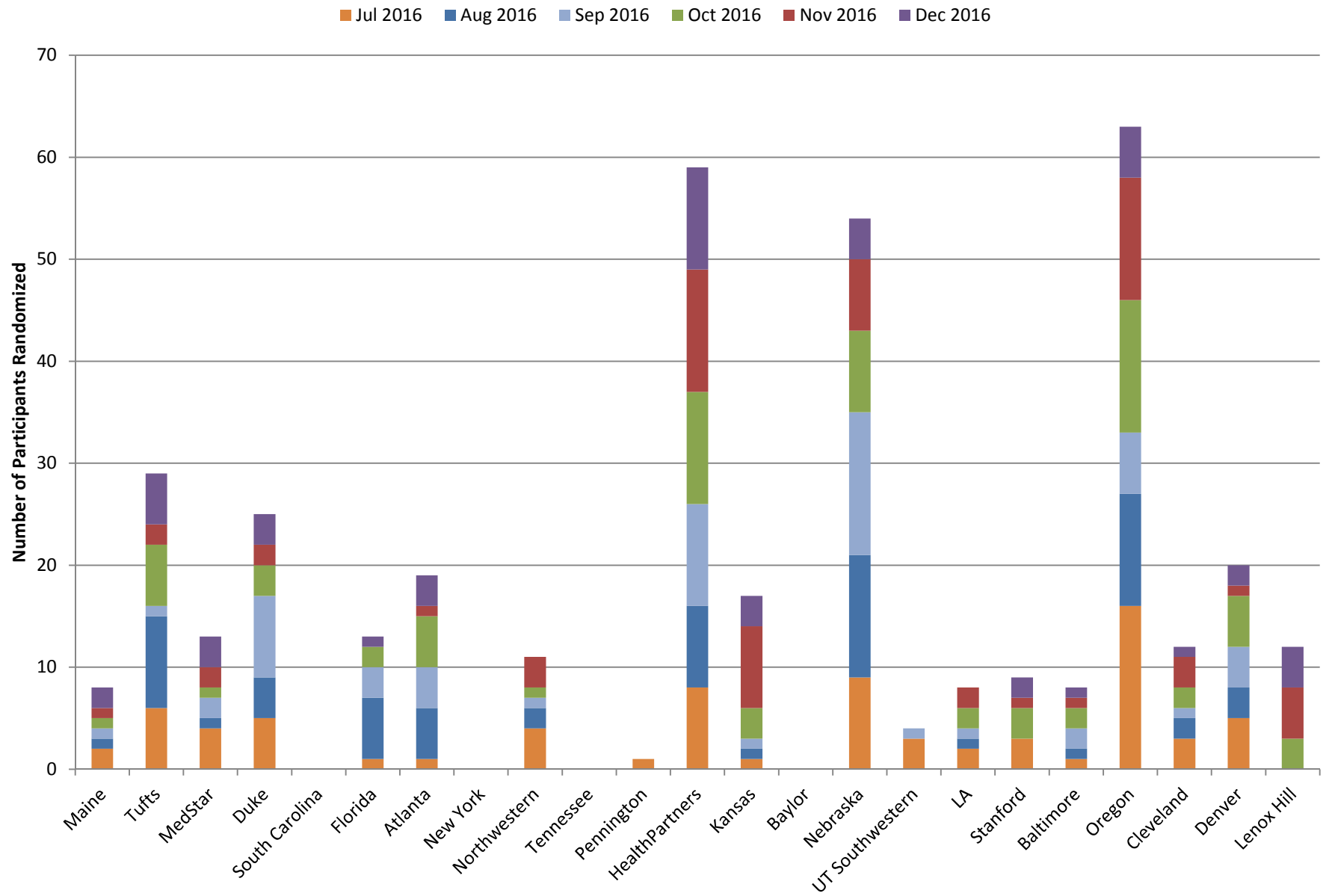
Study-Wide Randomizations per Month



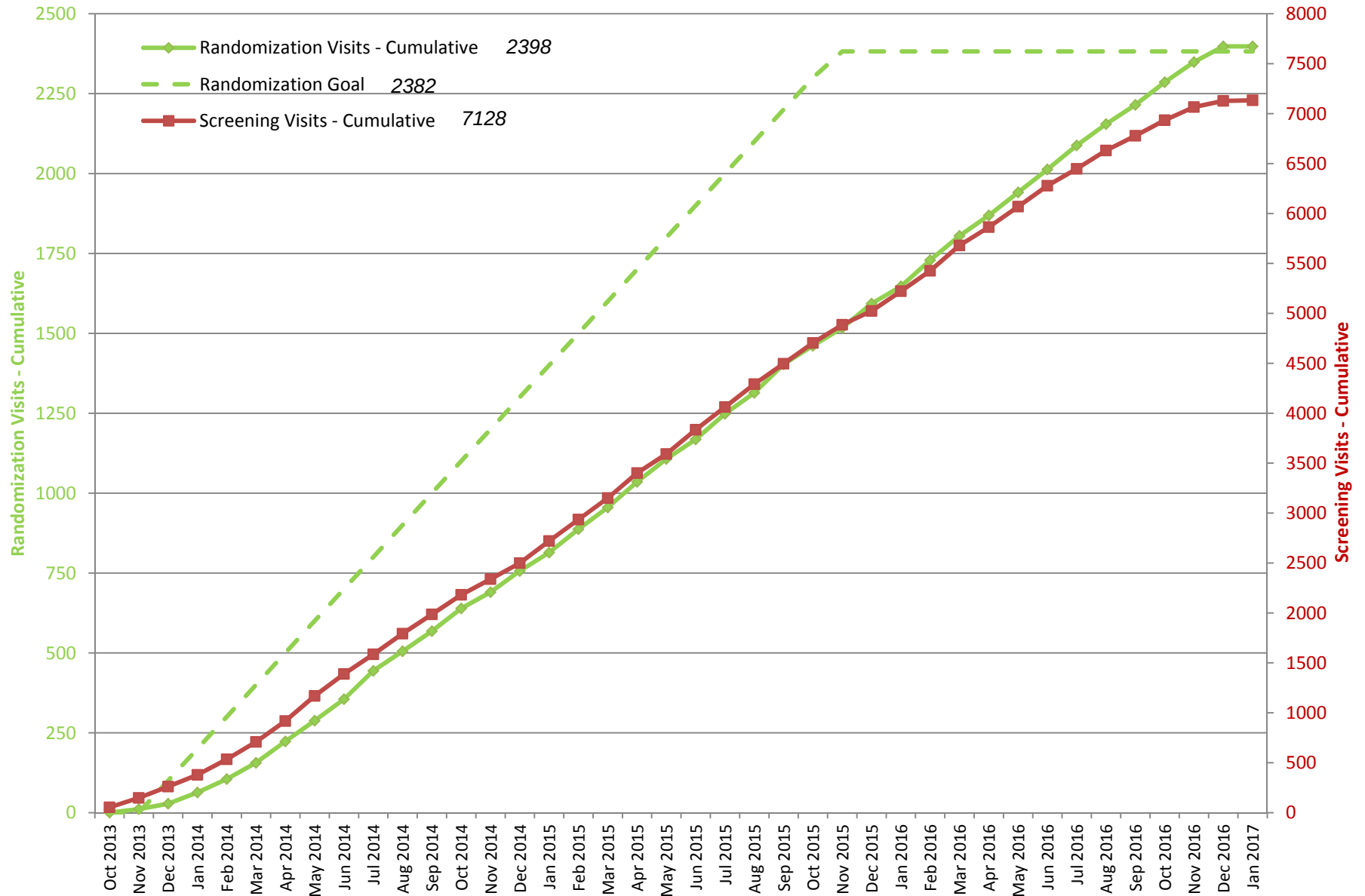
The SAS System

Site	Monthly RAN goal	RAN goal	SCR visits	BAS visits	RAN visits	SCR:RAN ratio	% of goal	1/2017 SCR visits	1/2017 BAS visits	1/2017 RAN visits	1/2017 SCR:RAN ratio	1/2017 RAN goal(%)	12/2016 SCR visits	12/2016 BAS visits	12/2016 RAN visits	12/2016 SCR:RAN ratio	12/2016 RAN goal(%)
Maine	5.2	125	369	172	107	3.4	85.6	.	.	.	.	.	2	2	2	1.0	38
Tufts	4.7	112	510	262	153	3.3	136.6	1	1	.	.	.	4	6	5	.8	106
MedStar	6.3	150	418	247	158	2.6	105.3	.	1	.	.	.	1	.	3	.3	48
Duke	6.3	150	375	228	140	2.7	93.3	.	.	.	.	.	3	.	3	1.0	48
SouthCarolina	6.3	150	183	70	32	5.7	21.3	.	.	.	.	.	.	.	.	.	.
Florida	6.3	150	362	122	76	4.8	50.7	.	.	.	.	.	3	.	1	3.0	16
Atlanta	7.5	180	263	227	137	1.9	76.1	.	.	.	.	.	5	4	3	1.7	40
NewYork	4.2	100	190	73	37	5.1	37.0	.	.	.	.	.	.	.	.	.	.
Northwestern	5.2	125	307	220	119	2.6	95.2	.	.	.	.	.	.	.	.	.	.
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	262	85	47	5.6	24.7	1	.	.	.	.	4	1	.	.	.
HealthPartners	12.5	300	639	474	316	2.0	105.3	.	.	.	.	.	6	5	10	.6	80
Kansas	6.3	150	415	196	121	3.4	80.7	1	1	.	.	.	14	6	3	4.7	48
Baylor	6.3	150	209	82	43	4.9	28.7	.	.	.	.	.	.	.	.	.	.
Nebraska	5.3	126	559	296	175	3.2	138.9	.	.	.	.	.	1	1	4	.3	75
UTSouthwestern	5.0	120	118	78	42	2.8	35.0	.	1	.	.	.	.	.	.	.	.
LA	5.0	120	260	143	84	3.1	70.0	.	.	.	.	.	.	.	.	.	.
Stanford	6.3	150	328	158	91	3.6	60.7	.	.	.	.	.	1	2	2	.5	32
Baltimore	7.7	100	214	124	79	2.7	79.0	.	.	.	.	.	.	4	1	.	13
Cleveland	7.7	100	189	95	55	3.4	55.0	.	.	.	.	.	3	1	1	3.0	13
Kaiser	10.0	130	457	413	264	1.7	203.1	.	1	.	.	.	4	1	5	.8	50
Denver	5.4	65	338	134	79	4.3	121.5	.	.	.	.	.	5	.	2	2.5	37
Lenox	5.0	25	50	16	12	4.2	48.0	.	.	.	.	.	7	6	4	1.8	80
	138.3	.	7132	3955	2398	3.0	73.4	3	5	.	.	.	63	39	49	1.3	35

Randomizations By Site - Last 6 Months

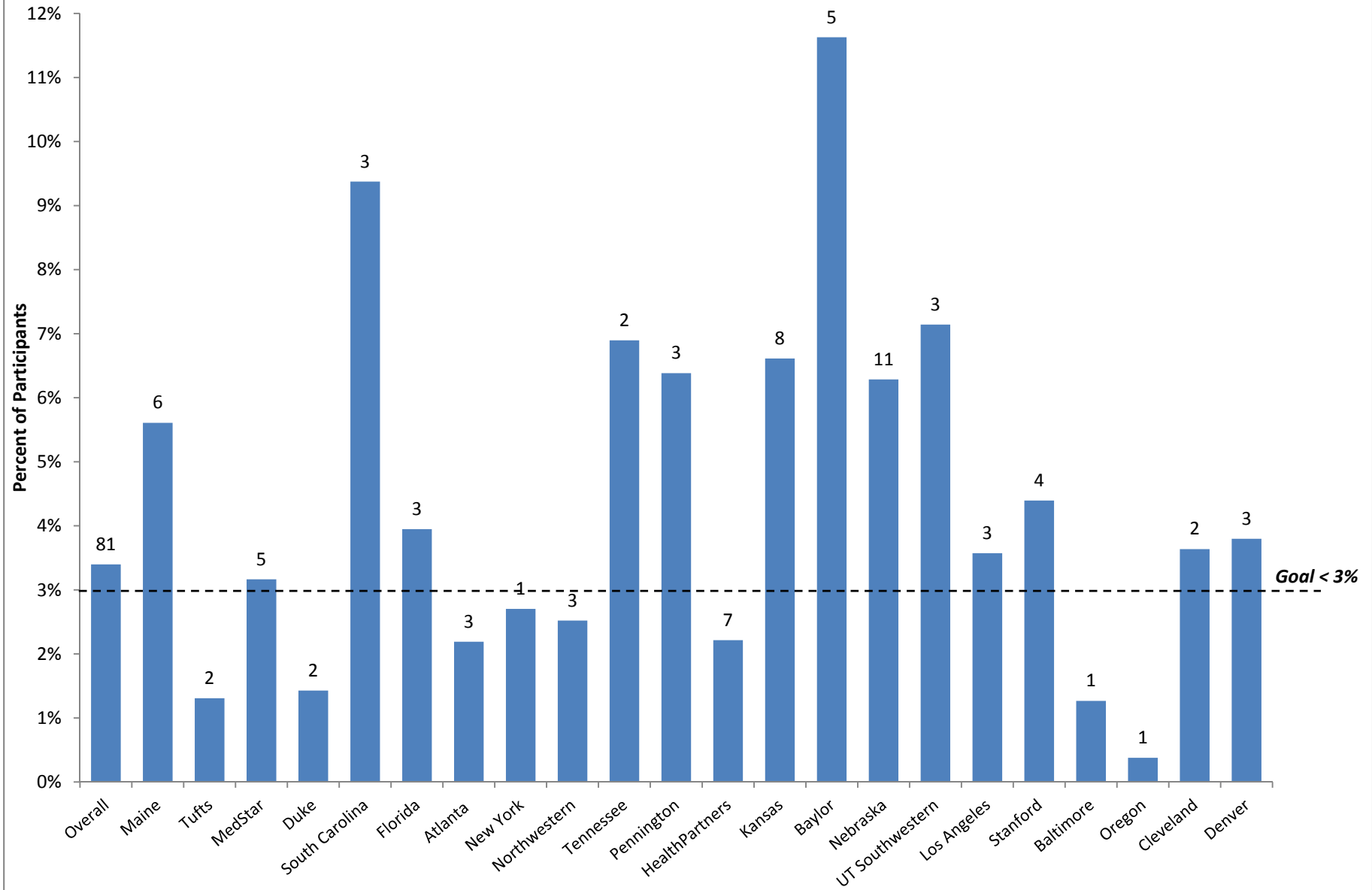


Cumulative Screening and Randomization Visits by Month



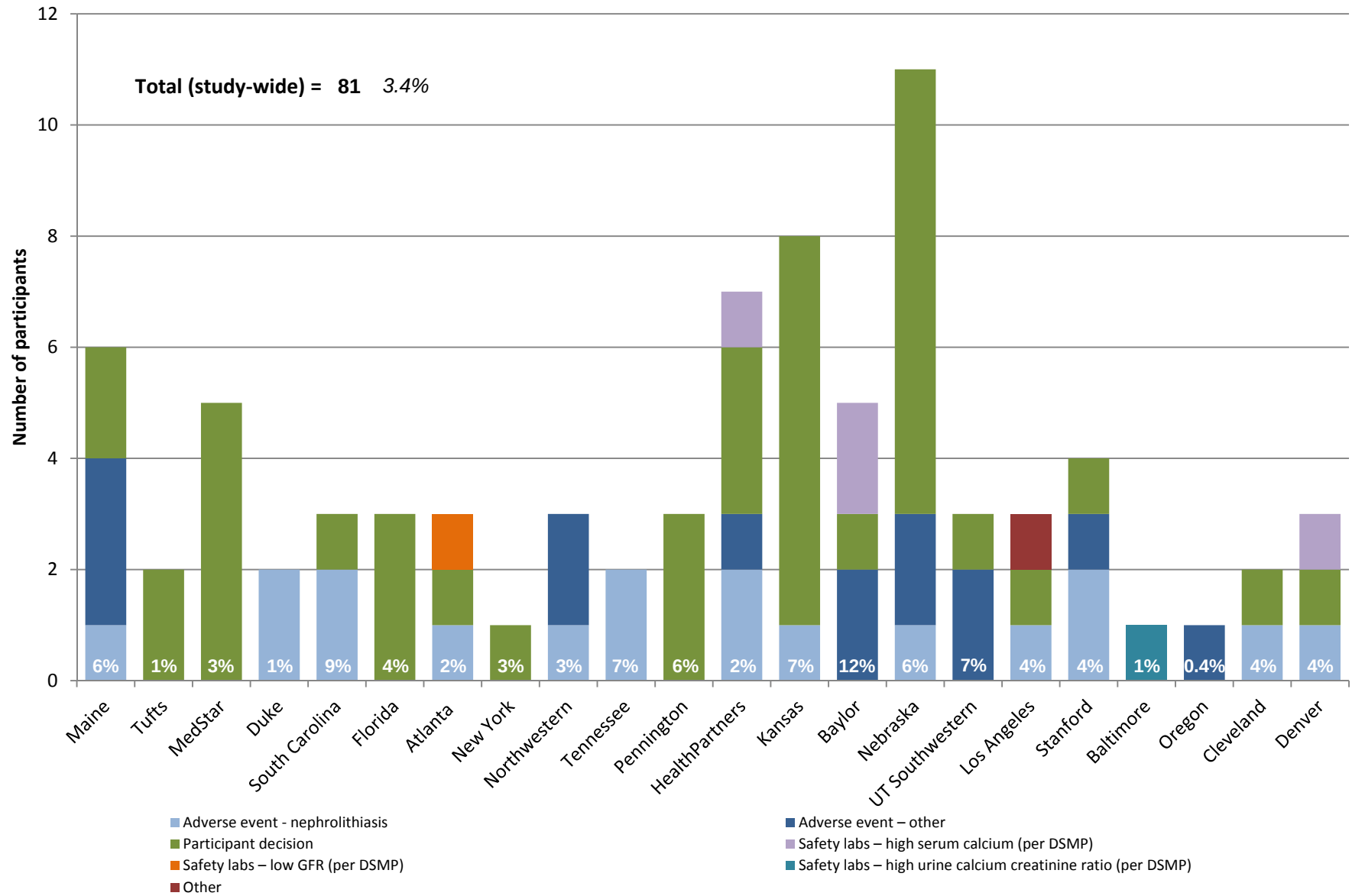
Discontinuation of Study Pills

excludes participants who withdrew consent



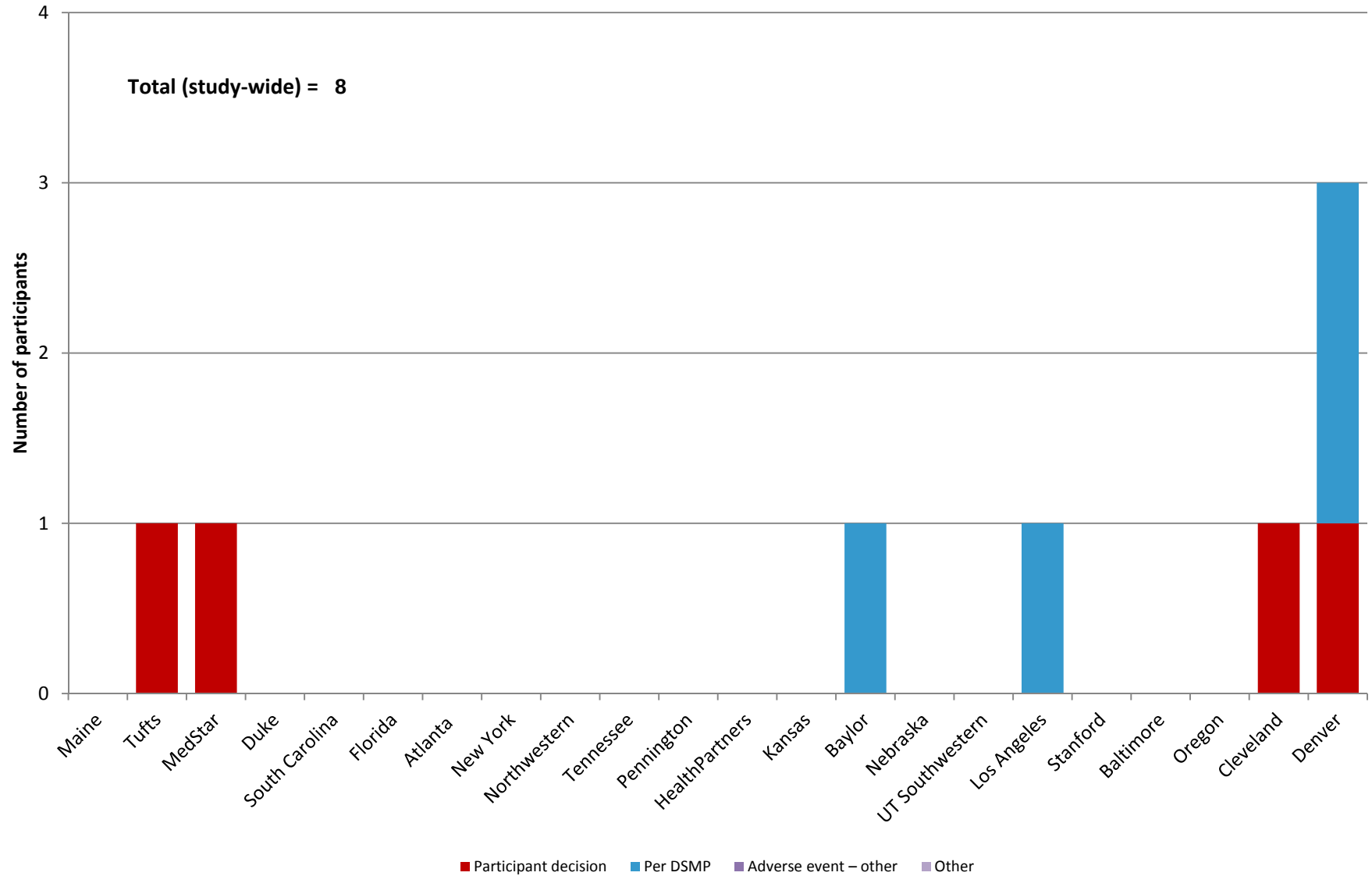
Discontinuation of Study Pills

excludes participants who withdrew consent



Discontinuation of Study Pills - Last 6 Months

excludes participants who withdrew consent



Metformin for Non-Diabetes Indications

Site	ID	Medication	Indication	Indication, other	Adjudication outcome
South Carolina	050123	Metformin	Other	pre-diabetes	Participant did not experience new-onset diabetes
Florida	060146	Metformin	Diabetes		Participant did not experience new-onset diabetes
Northwestern	090055	Metformin	Other	prediabetes	Participant did not experience new-onset diabetes
Northwestern	090153	Metformin	Other	prediabetes	Adjudication pending
Northwestern	090262	Metformin	Weight loss		Adjudication pending
HealthPartners	130289	Metformin	Diabetes		Participant did not experience new-onset diabetes
Kansas	140003	Metformin	Weight loss		Participant did not experience new-onset diabetes
Kansas	140168	Metformin	Diabetes		Participant did not experience new-onset diabetes
Baylor	150065	Insulin glargine	Other	gestational diabetes	Not being adjudicated - gestational diabetes
Baylor	150082	Metformin	Diabetes		Participant did not experience new-onset diabetes
UT Southwestern	170026	Metformin	Other	Diabetes prevention	Adjudication pending
LA	190023	Metformin	Diabetes		Participant did not experience new-onset diabetes
LA	190239	Metformin	Diabetes		Adjudication pending
Nebraska	210041	Metformin	Other	Diabetic Prevention	Participant did not experience new-onset diabetes
Oregon	230377	Metformin	Other	prediabetes	Adjudication pending

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	137	124	3	26	104	4	2	0	1
Baltimore	79	26	0	16	60	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	55	37	4	31	20	3	0	0	1
Denver VA	60	55	7	50	8	0	2	0	0
Duke	140	69	6	77	56	6	0	0	1
Florida	76	32	14	58	12	3	0	0	3
HealthPartners	316	193	9	287	14	10	2	0	3
Kaiser	264	143	22	218	14	18	1	0	13
Lenox Hill Hospital	12	7	1	7	2	3	0	0	0
LA	84	12	79	79	2	3	0	0	0
Maine	107	44	1	102	2	0	0	0	3
South Carolina	32	10	0	19	11	1	0	0	1
MedStar	158	76	7	48	99	6	1	2	2
Northwestern	119	74	7	81	31	7	0	0	0
Omaha VA	116	111	4	103	8	1	1	0	3
Pennington	47	19	1	29	16	2	0	0	0
Stanford	91	58	5	50	4	35	0	0	2
Truman	13	6	1	5	8	0	0	0	0
Tufts	153	74	8	95	41	15	0	0	2
UC Denver	19	12	1	12	7	0	0	0	0
Kansas	108	48	3	79	25	2	1	1	0
Nebraska (UNMC)	59	31	3	49	7	0	1	1	1
Tennessee	29	10	1	10	19	0	0	0	0
UT Southwestern	42	23	9	26	7	6	0	0	3
Overall	2398	1325	224	1600	605	130	13	5	43
9.3%									

Biorepository Consent Rates

Site	Total RAND	Biorepository Consent (%)	DNA Consent (%)
Atlanta	137	95%	94%
Baltimore	79	94%	91%
Baylor	43	93%	93%
Beth Israel	37	86%	86%
Cleveland	55	96%	95%
Denver VA	60	100%	98%
Duke	140	81%	79%
Florida	76	96%	95%
HealthPartners	316	91%	90%
Kaiser	264	94%	92%
Lenox Hill Hospital	12	83%	83%
LA	84	88%	88%
Maine	107	89%	89%
South Carolina	32	75%	75%
MedStar	158	91%	87%
Northwestern	119	92%	87%
Omaha VA	116	91%	91%
Pennington	47	87%	85%
Stanford	91	93%	92%
Truman	13	85%	85%
Tufts	153	94%	93%
UC Denver	19	100%	100%
Kansas	108	80%	80%
Nebraska (UNMC)	59	88%	85%
Tennessee	29	62%	59%
UT Southwestern	42	100%	100%
Overall	2398	91%	89%