

The SAS System

08/03/2016

Site	SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal	Time adjusted goal (%)	% of promised
Maine	348	.	164	2	.	101	125	58.0	80.8
Tufts	459	2	229	4	1	130	112	82.6	116.1
MedStar	402	6	229	2	.	149	150	70.6	99.3
Duke	344	3	202	.	1	120	150	56.9	80.0
SouthCarolina	183	.	70	.	.	32	150	15.2	21.3
Florida	321	2	109	.	1	65	150	30.8	43.3
Atlanta	235	.	202	1	1	119	180	47.4	66.1
NewYork	190	1	73	.	.	37	100	26.3	37.0
Northwestern	293	1	207	1	.	113	125	64.9	90.4
Tennessee	82	.	38	.	.	29	150	13.7	19.3
Tulane	35	.	2	.	.	2	150	.9	1.3
Pennington	240	.	80	.	.	47	190	17.8	24.7
HealthPartners	592	.	407	8	2	266	300	63.5	88.7
Kansas	345	.	169	.	.	105	150	49.8	70.0
Baylor	208	.	81	.	.	42	150	19.9	28.0
Nebraska	498	6	259	6	4	133	126	74.9	105.6
UTSouthwestern	113	.	74	.	.	41	120	24.5	34.2
LA	246	.	130	.	1	78	120	46.6	65.0
Stanford	325	.	146	1	.	85	150	40.3	56.7
Baltimore	193	.	112	.	.	71	100	43.2	71.0
Cleveland	166	.	84	2	.	48	100	29.2	48.0
Kaiser	417	.	354	1	3	218	130	102.2	167.7
Denver	303	.	118	1	3	64	65	72.7	98.5
	6538	21	3539	29	17	2095	3243	41.7	64.6

7.1.a Detail on diabetes diagnosis

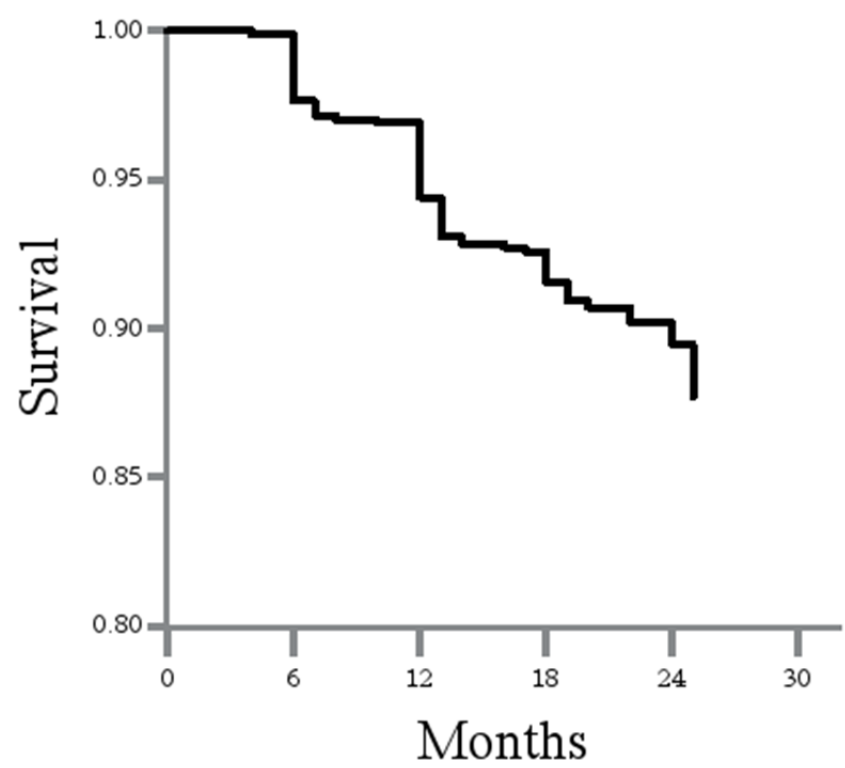
	Overall	M06	M12	M18	M24	M30	M36	M42	M48
Semi-annual visits	2344	1594	-	705 ¹	-	45	-	-	-
Diabetes, n (% visits)	55 (2.3)	43 (2.7)	-	12 (1.7)	-	0	-	-	-
Positive A1c and FPG	22	17	-	5	-	0	-	-	-
Positive A1c or FPG, pos. confirmatory	33	26	-	7	-	0	-	-	-
No diabetes, n	2289	1551	-	693	-	45	-	-	-
Negative A1c and FPG	2234	1508	-	682	-	44	-	-	-
Positive A1c or FPG, neg. confirmatory	55	43	-	11	-	1	-	-	-
Annual visits	1502	-	1137 ¹	-	365	-	-	-	-
Diabetes, n (% visits)	47 (3.1)	-	41 (3.6)	-	6 (1.6)	-	-	-	-
Positive, met 2 criteria	16	-	15	-	1	-	-	-	-
Positive, met 1 criterion, pos. confirmatory	31	-	26	-	5	-	-	-	-
No diabetes, n	1455	-	1096	-	395	-	-	-	-
All 3 criteria negative	1380	-	1036	-	344	-	-	-	-
Met 1 criterion, neg. confirmatory	75	-	60	-	15	-	-	-	-
Outside of study events by adjudication ²	10	2	4	2	2	0	-	-	-

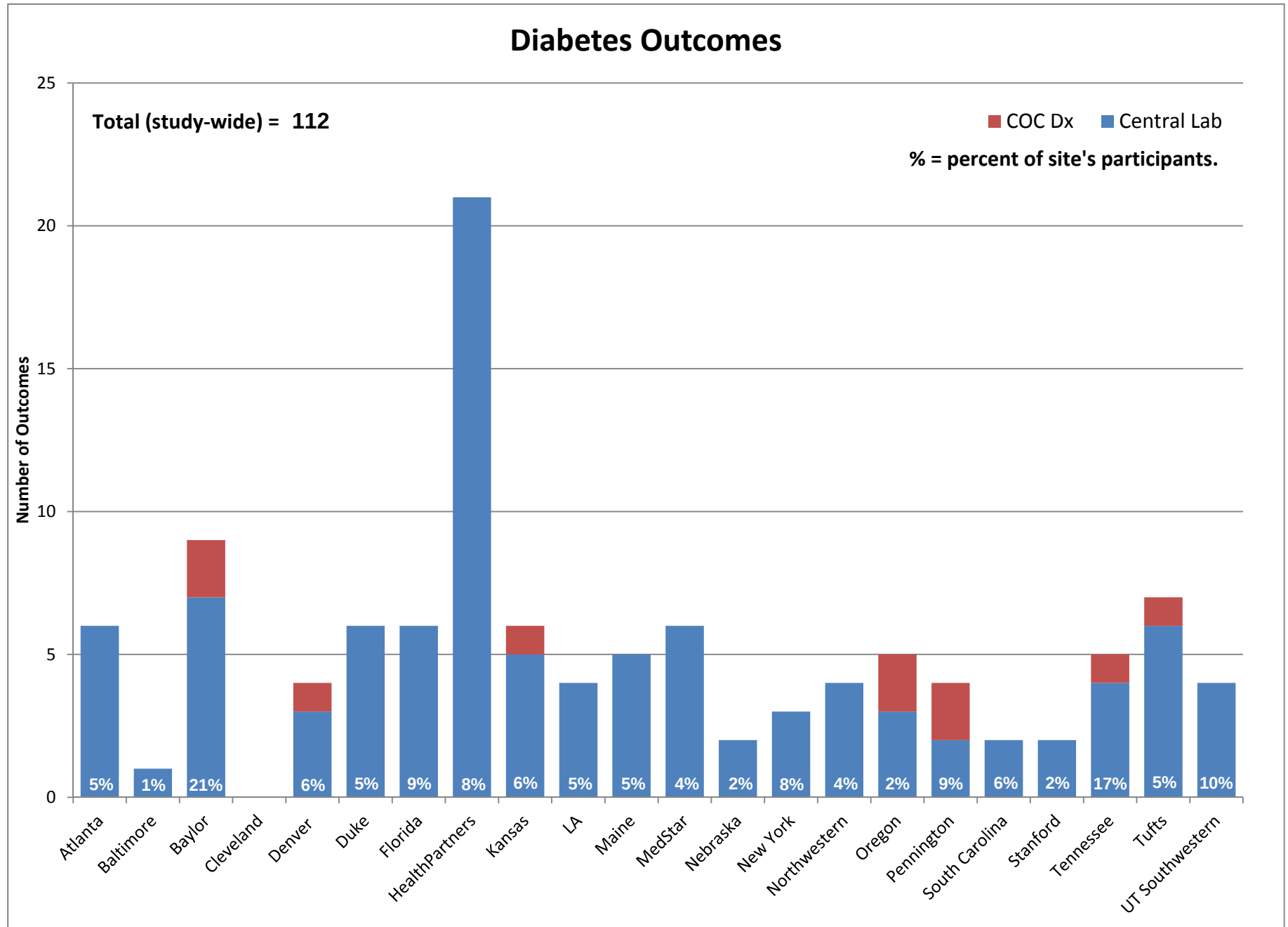
Total number of participants that met the diabetes outcome = 112

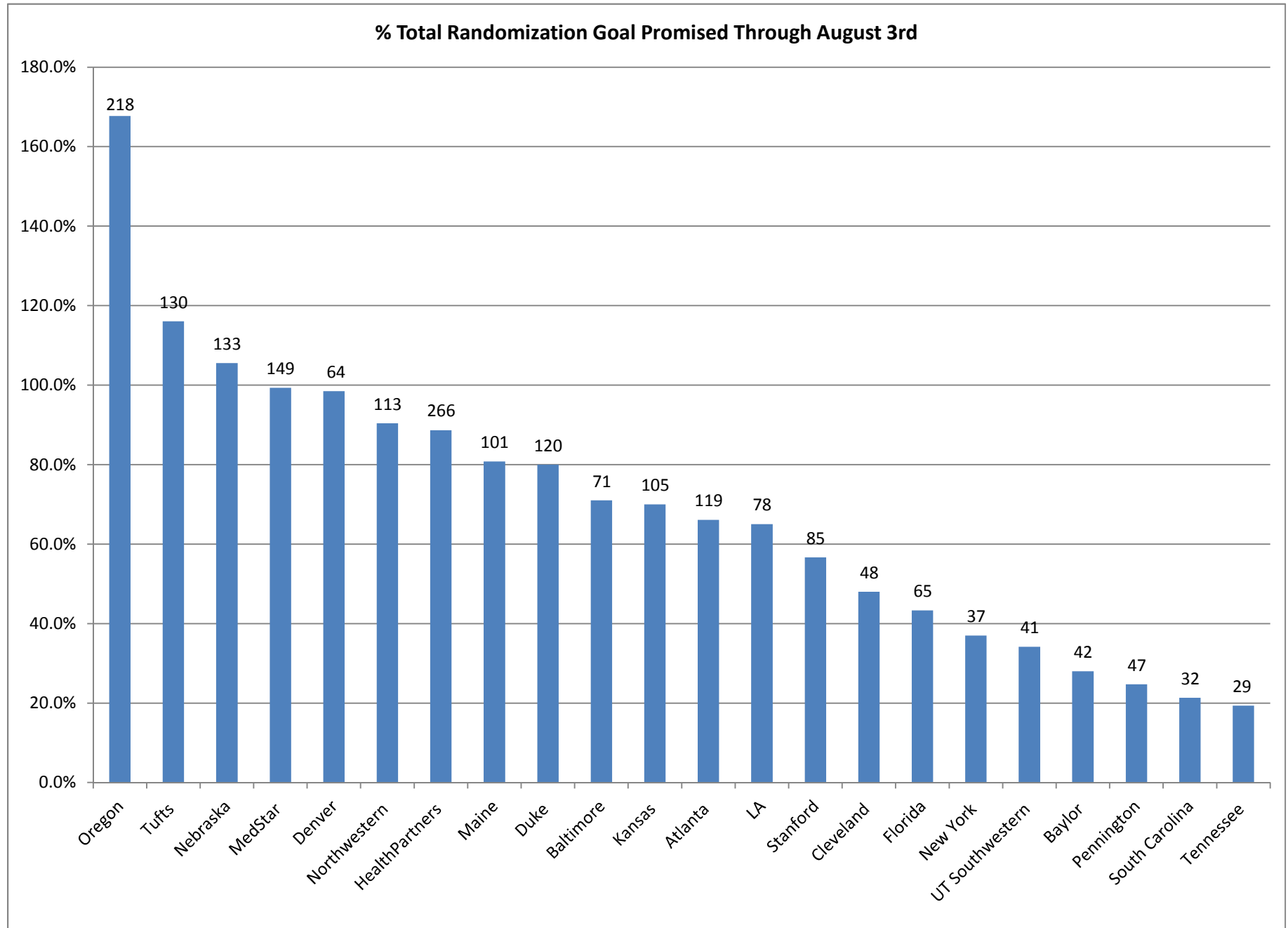
¹ Number excludes participants who have reached the *diabetes outcome* [by D2d criteria or adjudication].

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 = 5.65%



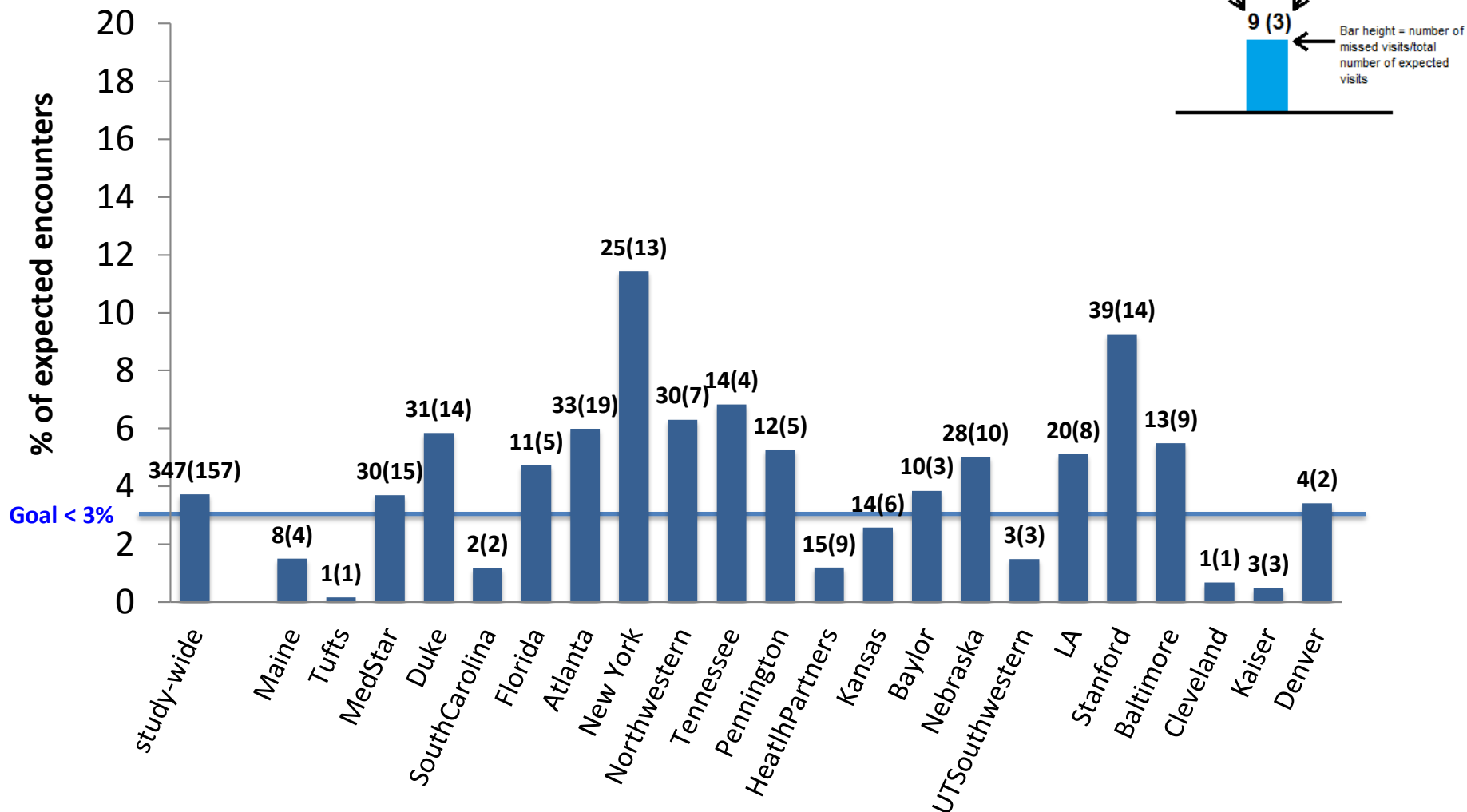




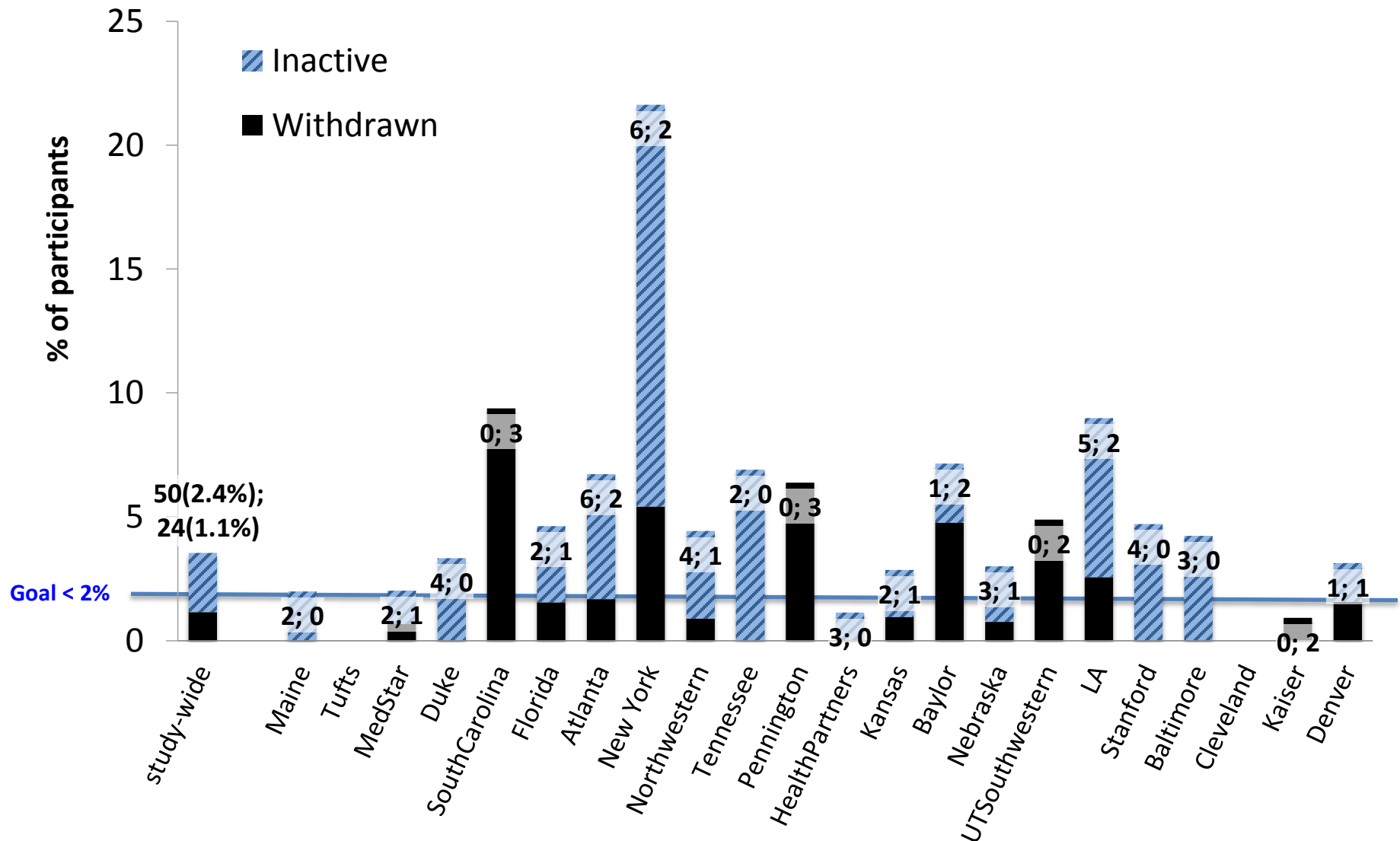
Missed encounters (visits and interim phone contact)

6

Study-wide = 3.7%

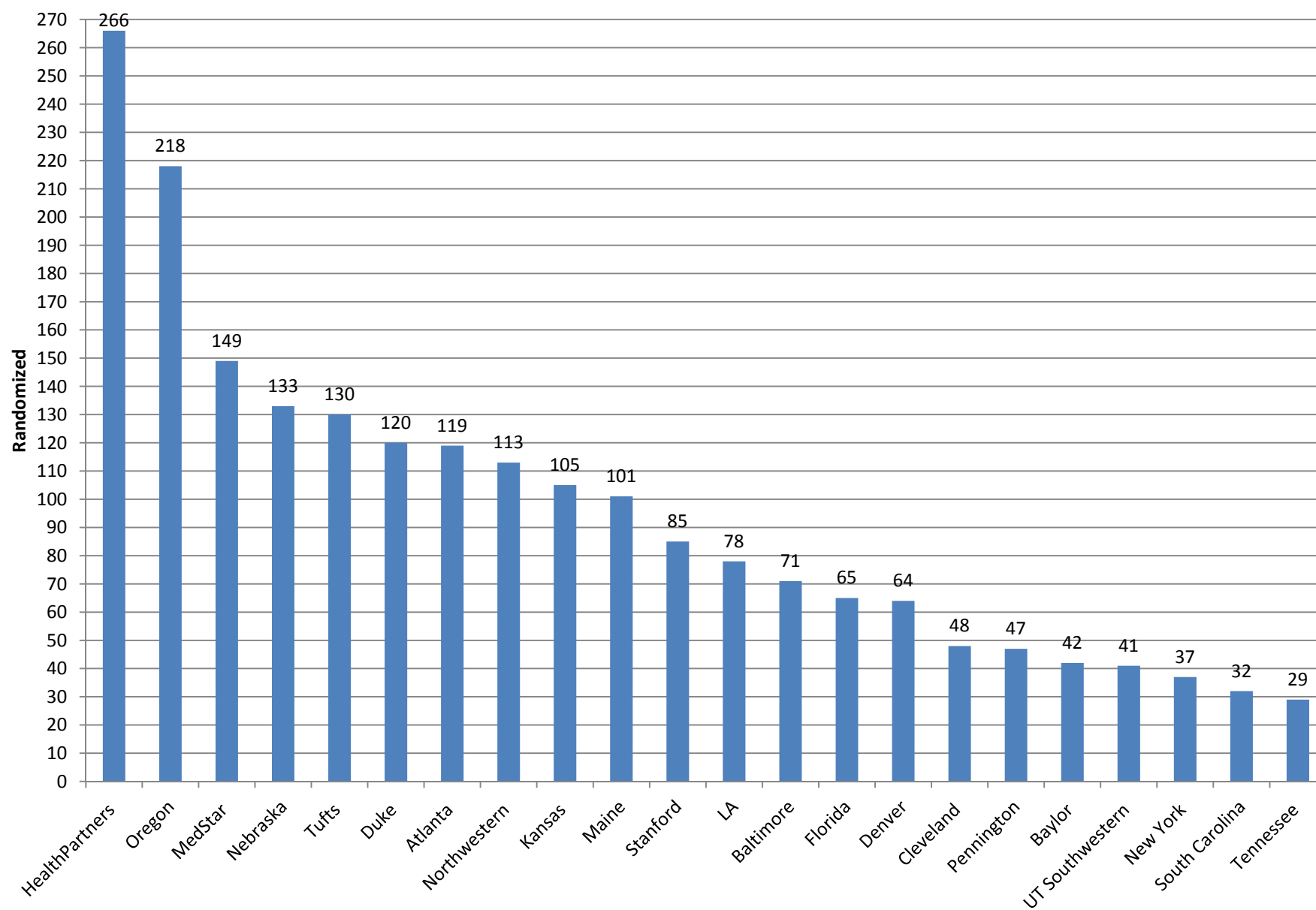


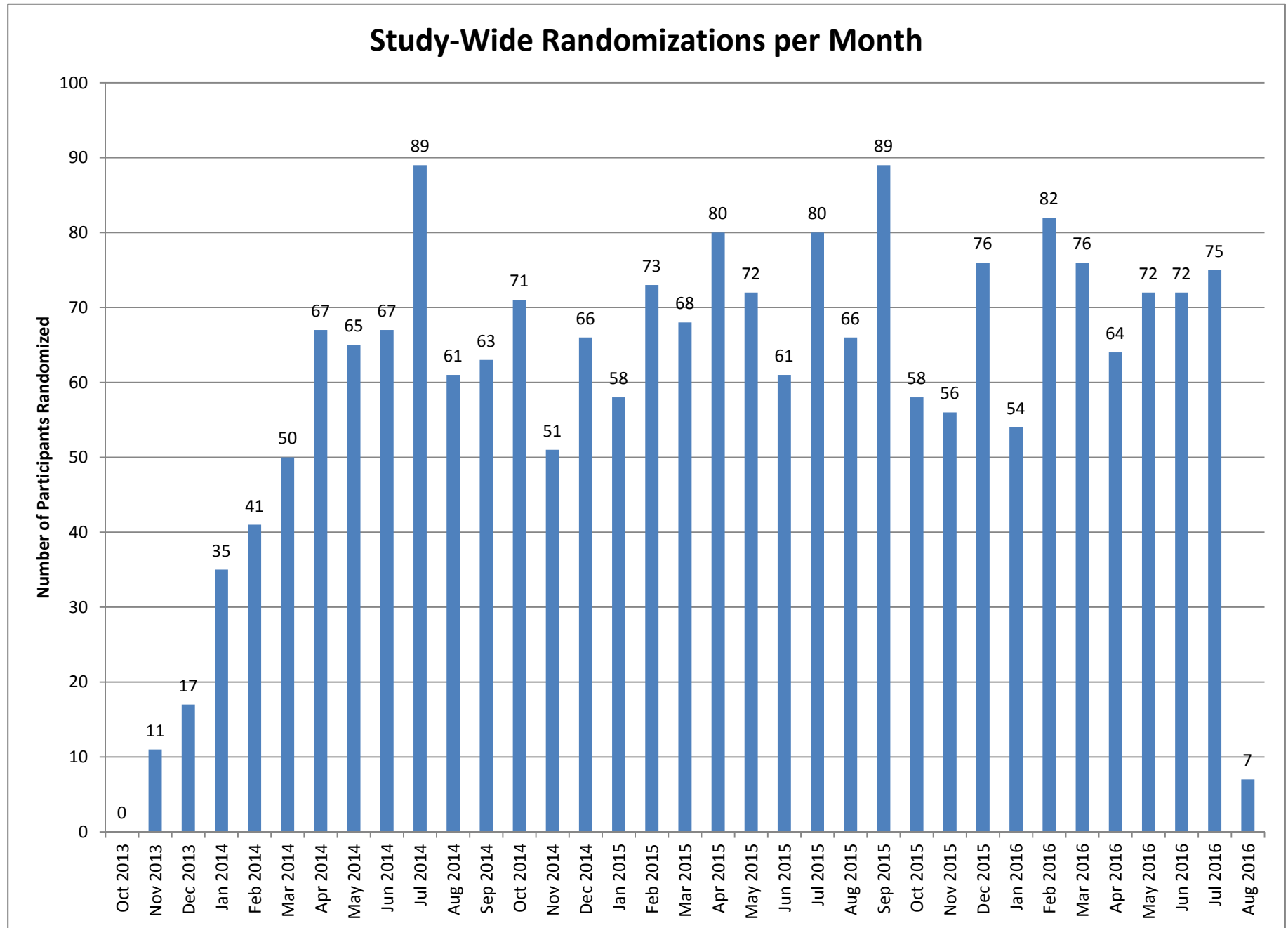
% inactive and withdrawn participants



Labels are number of participants (inactive; withdrawn).

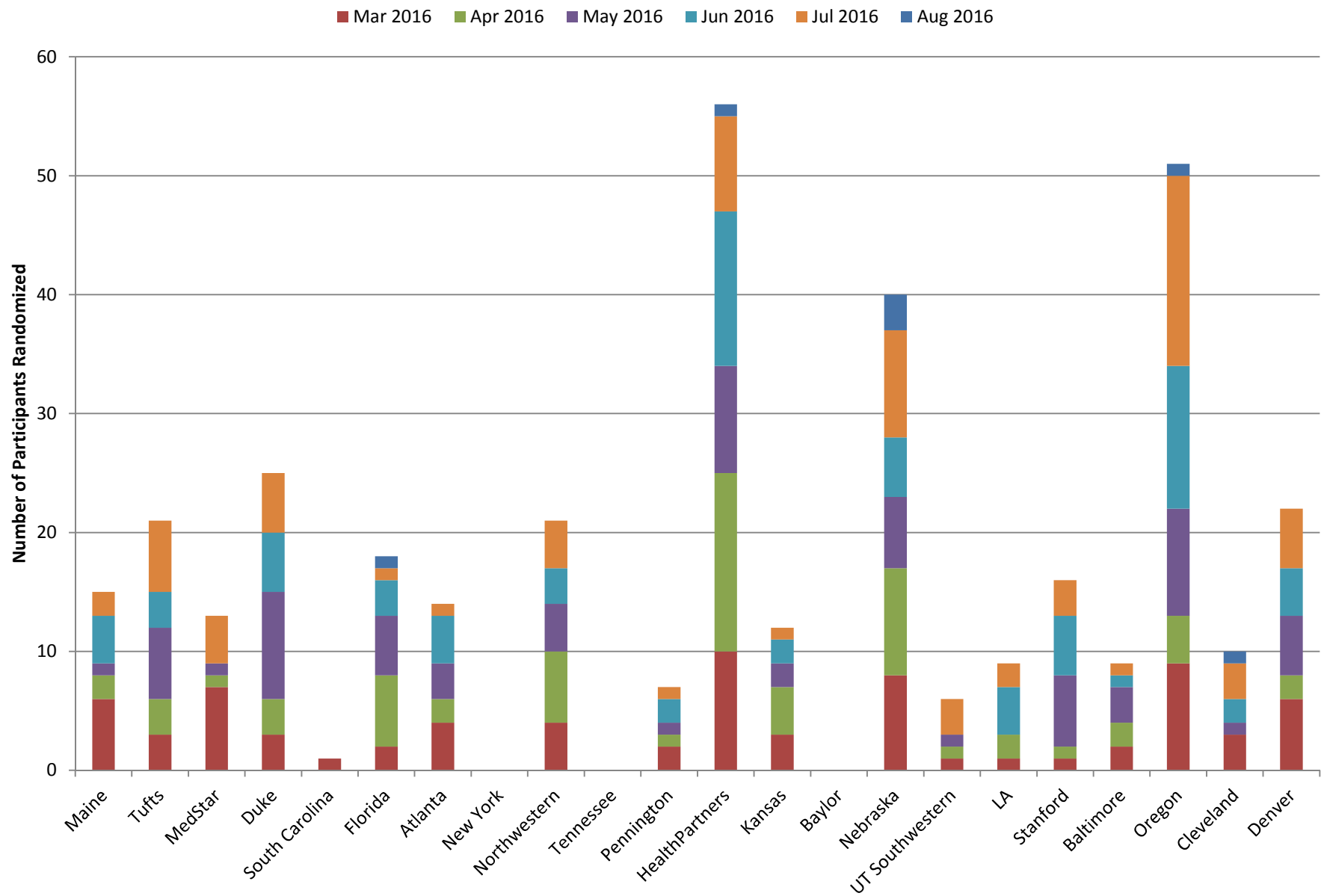
Randomizations by Site



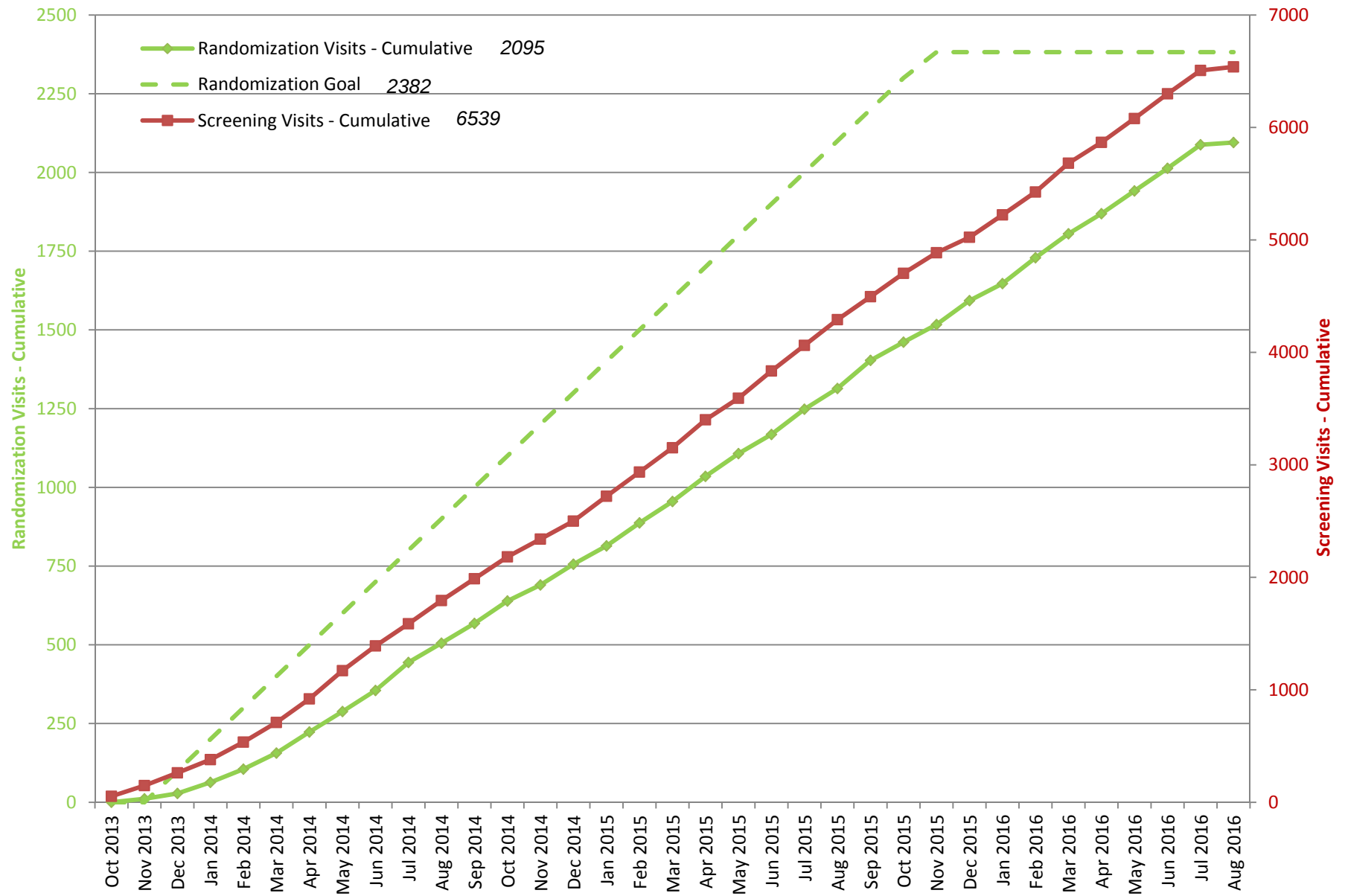


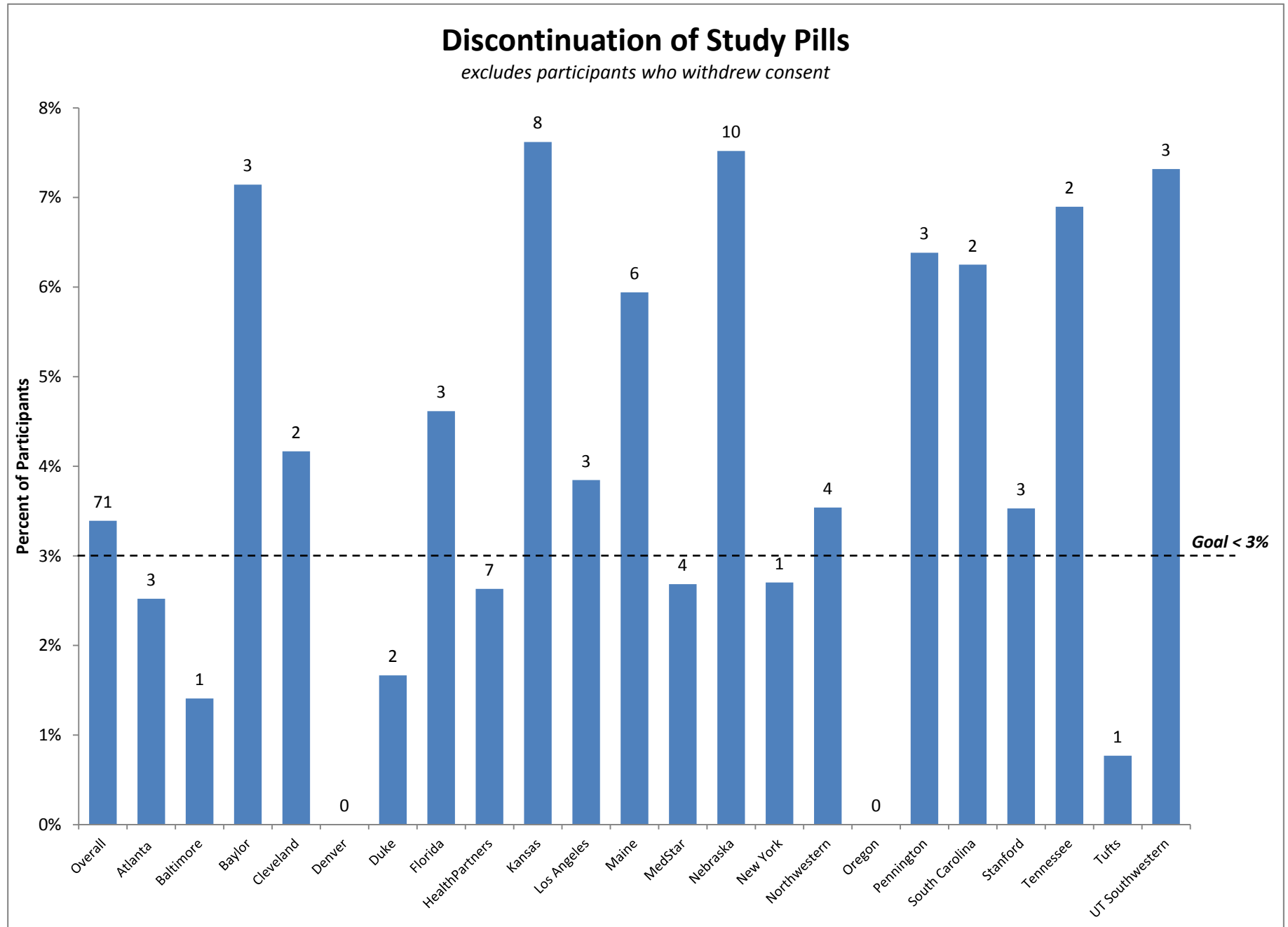
Site	Monthly RAN goal	RAN goal	SCR visits	BAS visits	RAN visits	SCR:RAN ratio	% of goal	8/2016 SCR visits	8/2016 BAS visits	8/2016 RAN visits	8/2016 SCR:RAN ratio	8/2016 RAN goal(%)	7/2016 SCR visits	7/2016 BAS visits	7/2016 RAN visits	7/2016 SCR:RAN ratio	7/2016 RAN goal(%)
Maine	5.2	125	348	164	101	3.4	80.8	2	.	.	.	.	8	3	2	4.0	38
Tufts	4.7	112	459	229	130	3.5	116.1	3	1	.	.	.	18	8	6	3.0	128
MedStar	6.3	150	402	229	149	2.7	99.3	2	1	.	.	.	8	3	4	2.0	63
Duke	6.3	150	344	202	120	2.9	80.0	1	.	.	.	.	15	5	5	3.0	79
SouthCarolina	6.3	150	183	70	32	5.7	21.3	.	.	.	.	.	.	.	.	.	.
Florida	6.3	150	321	109	65	4.9	43.3	1	.	1	1.0	16	14	3	1	14.0	16
Atlanta	7.5	180	235	202	119	2.0	66.1	.	.	.	.	.	4	4	1	4.0	13
NewYork	4.2	100	190	73	37	5.1	37.0	.	.	.	.	.	.	.	.	.	.
Northwestern	5.2	125	293	207	113	2.6	90.4	.	.	.	.	.	5	4	4	1.3	77
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	240	80	47	5.1	24.7	.	.	.	.	.	.	2	1	.	13
HealthPartners	12.5	300	592	407	266	2.2	88.7	3	.	1	3.0	8	38	17	8	4.8	64
Kansas	6.3	150	345	169	105	3.3	70.0	.	.	.	.	.	3	.	1	3.0	16
Baylor	6.3	150	208	81	42	5.0	28.0	.	.	.	.	.	.	.	.	.	.
Nebraska	5.3	126	498	259	133	3.7	105.6	5	1	3	1.7	57	26	22	9	2.9	170
UTSouthwestern	5.0	120	113	74	41	2.8	34.2	1	.	.	.	.	1	2	3	.3	60
LA	5.0	120	246	130	78	3.2	65.0	.	.	.	.	.	4	2	2	2.0	40
Stanford	6.3	150	325	146	85	3.8	56.7	.	.	.	.	.	6	3	3	2.0	48
Baltimore	7.7	100	193	112	71	2.7	71.0	1	.	.	.	.	4	1	1	4.0	13
Cleveland	7.7	100	166	84	48	3.5	48.0	.	.	1	.	13	8	2	3	2.7	39
Kaiser	10.0	130	417	354	218	1.9	167.7	11	.	1	11.0	10	31	15	16	1.9	160
Denver	5.4	65	303	118	64	4.7	98.5	1	1	.	.	.	15	7	5	3.0	93
	.	.	6538	3539	2095	3.1	87.9	31	4	7	4.4	5	208	103	75	2.8	54

Randomizations By Site - Last 6 Months



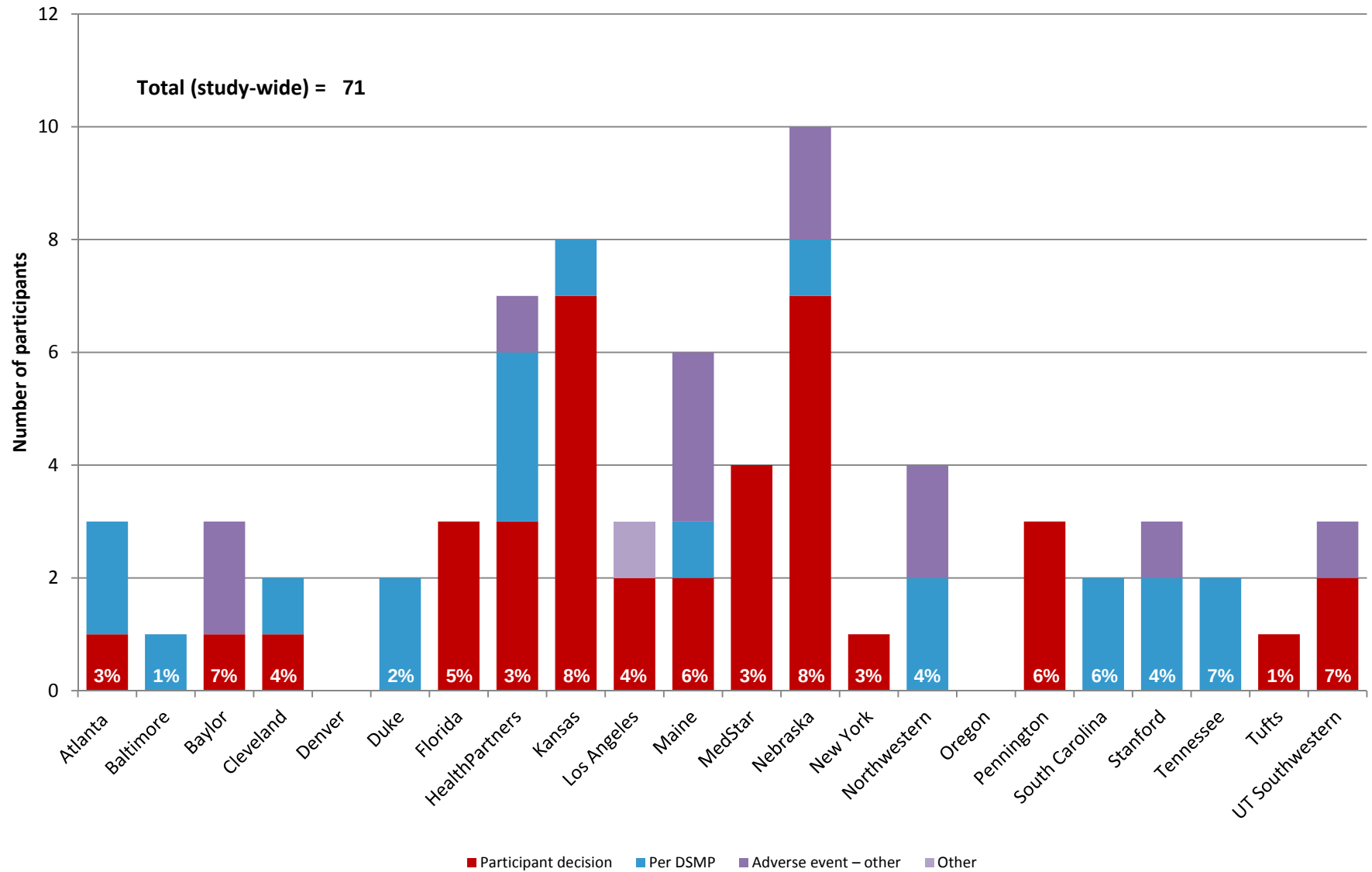
Cumulative Screening and Randomization Visits by Month





Discontinuation of Study Pills

excludes participants who withdrew consent



Encounters and Adherence

Site	Site #	M03 No. visits (%expected)	M06 No. visits (%expected)	M06 No. adherent* (%encounters)	M12 No. visits (%expected)	M12 No. adherent* (%encounters)	M18 No. visits (%expected)	M18 No. adherent* (%encounters)	M24 No. visits (%expected)	M24 No. adherent* (%encounters)	M30 No. visits (%expected)	M30 No. adherent* (%encounters)
Maine	1	93 (98.9%)	79 (98.8%)	72 (91.1%)	67 (97.1%)	54 (81.8%)	53 (100%)	45 (86.5%)	36 (97.3%)	31 (88.6%)	4 (100%)	4 (100%)
Tufts	2	115 (99.1%)	105 (100%)	97 (92.4%)	85 (100%)	73 (85.9%)	57 (100%)	50 (87.7%)	30 (100%)	25 (83.3%)	5 (100%)	3 (75%)
MedStar	3	137 (95.8%)	129 (98.5%)	109 (84.5%)	101 (95.3%)	82 (82.8%)	71 (93.4%)	55 (80.9%)	41 (91.1%)	25 (69.4%)	9 (100%)	8 (88.9%)
Duke	4	102 (99%)	90 (97.8%)	77 (85.6%)	66 (94.3%)	63 (95.5%)	49 (94.2%)	44 (89.8%)	22 (84.6%)	21 (95.5%)	1 (100%)	1 (100%)
SouthCarolina	5	32 (100%)	28 (96.6%)	25 (89.3%)	25 (100%)	22 (88%)	15 (100%)	11 (73.3%)	10 (100%)	5 (50%)		
Florida	6	56 (100%)	46 (100%)	43 (95.6%)	33 (97.1%)	23 (79.3%)	15 (88.2%)	6 (46.2%)	3 (60%)	2 (66.7%)	1 (100%)	1 (100%)
Atlanta	7	108 (97.3%)	97 (98%)	75 (77.3%)	70 (92.1%)	54 (78.3%)	43 (87.8%)	26 (61.9%)	25 (96.2%)	19 (76%)	4 (100%)	2 (50%)
NewYork	8	35 (94.6%)	31 (86.1%)	22 (71%)	25 (92.6%)	16 (64%)	19 (86.4%)	14 (73.7%)	13 (92.9%)	8 (61.5%)		
Northwestern	9	100 (98%)	84 (95.5%)	77 (93.9%)	61 (93.8%)	53 (89.8%)	32 (88.9%)	27 (87.1%)	14 (77.8%)	12 (85.7%)	0 (0%)	
Tennessee	10	29 (100%)	28 (96.6%)	25 (89.3%)	26 (92.9%)	24 (92.3%)	26 (92.9%)	20 (76.9%)	12 (85.7%)	11 (91.7%)		
Pennington	12	39 (95.1%)	33 (94.3%)	27 (87.1%)	25 (89.3%)	19 (86.4%)	22 (95.7%)	13 (68.4%)	13 (100%)	9 (81.8%)	2 (100%)	1 (50%)
HealthPartners	13	236 (100%)	197 (100%)	184 (94.8%)	166 (98.8%)	150 (92%)	128 (97.7%)	116 (93.5%)	62 (98.4%)	57 (93.4%)	4 (100%)	3 (75%)
Kansas	14	98 (98%)	89 (96.7%)	74 (88.1%)	65 (97%)	48 (77.4%)	47 (97.9%)	34 (79.1%)	26 (96.3%)	19 (76%)	11 (100%)	10 (90.9%)
Baylor	15	40 (95.2%)	39 (97.5%)	33 (84.6%)	33 (97.1%)	28 (84.8%)	28 (96.6%)	27 (96.4%)	12 (92.3%)	10 (90.9%)		
Nebraska	16	108 (94.7%)	84 (95.5%)	80 (96.4%)	63 (94%)	54 (90%)	49 (92.5%)	40 (95.2%)	30 (90.9%)	25 (92.6%)		
UTSouthwestern	14	37 (100%)	33 (97.1%)	30 (90.9%)	25 (100%)	23 (92%)	18 (100%)	15 (83.3%)	10 (83.3%)	8 (88.9%)	4 (100%)	2 (66.7%)
LA	19	69 (97.2%)	63 (95.5%)	55 (88.7%)	53 (93%)	40 (75.5%)	29 (93.5%)	24 (82.8%)	18 (94.7%)	15 (83.3%)	2 (100%)	2 (100%)
Stanford	20	67 (94.4%)	64 (94.1%)	53 (85.5%)	43 (87.8%)	34 (79.1%)	37 (90.2%)	29 (82.9%)	27 (90%)	18 (66.7%)	5 (100%)	5 (100%)
Baltimore	22	63 (95.5%)	55 (94.8%)	46 (86.8%)	31 (91.2%)	22 (71%)	6 (75%)	6 (100%)				
Cleveland	24	41 (97.6%)	37 (100%)	32 (88.9%)	22 (100%)	16 (72.7%)	3 (100%)	2 (66.7%)				
Kaiser	23	182 (100%)	156 (99.4%)	146 (93.6%)	81 (97.6%)	73 (90.1%)	16 (100%)	14 (87.5%)				
Denver	25	48 (98%)	33 (94.3%)	30 (90.9%)	9 (100%)	9 (100%)						
Overall		1835 (97.9%)	1600 (97.4%)	1412 (89.4%)	1175 (95.7%)	980 (85%)	763 (94.7%)	618 (84.1%)	404 (92.9%)	320 (82.3%)	52 (98.1%)	42 (84%)

* Adherent = taking 80% or more of study pills (<80% in red font)

Biorespository Consent

Site	Total RAND	Biorepository Consent (%)	DNA Consent (%)
Atlanta	119	95%	94%
Baltimore	71	93%	90%
Baylor	42	93%	93%
Beth Israel Medical Center	37	86%	86%
Cleveland	48	96%	94%
Denver VA	51	100%	100%
Duke	120	81%	79%
Florida	64	97%	94%
HealthPartners	266	90%	89%
Kaiser	218	93%	91%
LA	78	90%	90%
Maine	101	89%	89%
South Carolina	32	75%	75%
MedStar	149	90%	86%
Northwestern	113	93%	88%
Omaha VA	97	90%	90%
Orlando VA	1	100%	100%
Pennington	47	87%	85%
Stanford	85	93%	92%
Truman	13	85%	85%
Tufts	130	95%	95%
UC Denver	13	100%	100%
Kansas	92	82%	82%
Nebraska (UNMC)	36	83%	78%
Tennessee	29	62%	59%
UT Southwestern	41	100%	100%
Overall	2095	90%	89%

