

## The SAS System

1/6/2015

| Site            | SCR visits | BAS potential | BAS visits | Awaiting BAS labs | Awaiting RAN | RAN visits | RAN goal | Time adjusted goal (%) | % of promised |
|-----------------|------------|---------------|------------|-------------------|--------------|------------|----------|------------------------|---------------|
| Maine           | 266        | 1             | 136        | .                 | .            | 79         | 125      | 57.3                   | 63.2          |
| Tufts           | 324        | .             | 178        | 2                 | .            | 101        | 112      | 81.1                   | 90.2          |
| MedStar         | 342        | 2             | 195        | .                 | 1            | 131        | 150      | 78.5                   | 87.3          |
| Duke            | 256        | 5             | 158        | .                 | .            | 89         | 150      | 53.3                   | 59.3          |
| South Carolina  | 164        | .             | 65         | .                 | .            | 31         | 150      | 18.6                   | 20.7          |
| Florida         | 235        | 4             | 77         | 1                 | 1            | 44         | 150      | 26.4                   | 29.3          |
| Atlanta         | 189        | .             | 157        | 2                 | 2            | 92         | 180      | 46.3                   | 51.1          |
| New York        | 190        | 4             | 73         | 1                 | .            | 36         | 100      | 32.3                   | 36            |
| Northwestern    | 235        | .             | 163        | .                 | .            | 87         | 125      | 63.1                   | 69.6          |
| Tennessee       | 82         | .             | 38         | .                 | .            | 29         | 150      | 17.4                   | 19.3          |
| Tulane          | 35         | .             | 2          | .                 | .            | 2          | 150      | 1.2                    | 1.3           |
| Pennington      | 185        | .             | 64         | .                 | .            | 38         | 190      | 18.2                   | 20            |
| HealthPartners  | 458        | .             | 287        | .                 | 2            | 189        | 300      | 57.1                   | 63            |
| Kansas          | 274        | 2             | 148        | 3                 | 2            | 87         | 150      | 52.1                   | 58            |
| Baylor          | 205        | 1             | 80         | .                 | .            | 41         | 150      | 24.6                   | 27.3          |
| Nebraska        | 320        | 6             | 176        | .                 | 3            | 84         | 126      | 59.8                   | 66.7          |
| UT Southwestern | 91         | 2             | 62         | 1                 | .            | 34         | 120      | 25.7                   | 28.3          |
| LA              | 223        | 2             | 112        | 1                 | .            | 66         | 120      | 49.8                   | 55            |
| Stanford        | 304        | .             | 117        | 4                 | 1            | 66         | 150      | 39.5                   | 44            |
| Baltimore       | 146        | 1             | 90         | 1                 | .            | 57         | 100      | 51.6                   | 57            |
| Cleveland       | 125        | 2             | 63         | .                 | 2            | 35         | 100      | 31.7                   | 35            |
| Kaiser          | 289        | .             | 250        | 1                 | .            | 147        | 130      | 102.6                  | 113.1         |
| Denver          | 182        | .             | 74         | 2                 | 2            | 33         | 65       | 65.7                   | 50.8          |
|                 | 5120       | 32            | 2765       | 19                | 16           | 1598       | 3243     | 40.2                   | 49.3          |

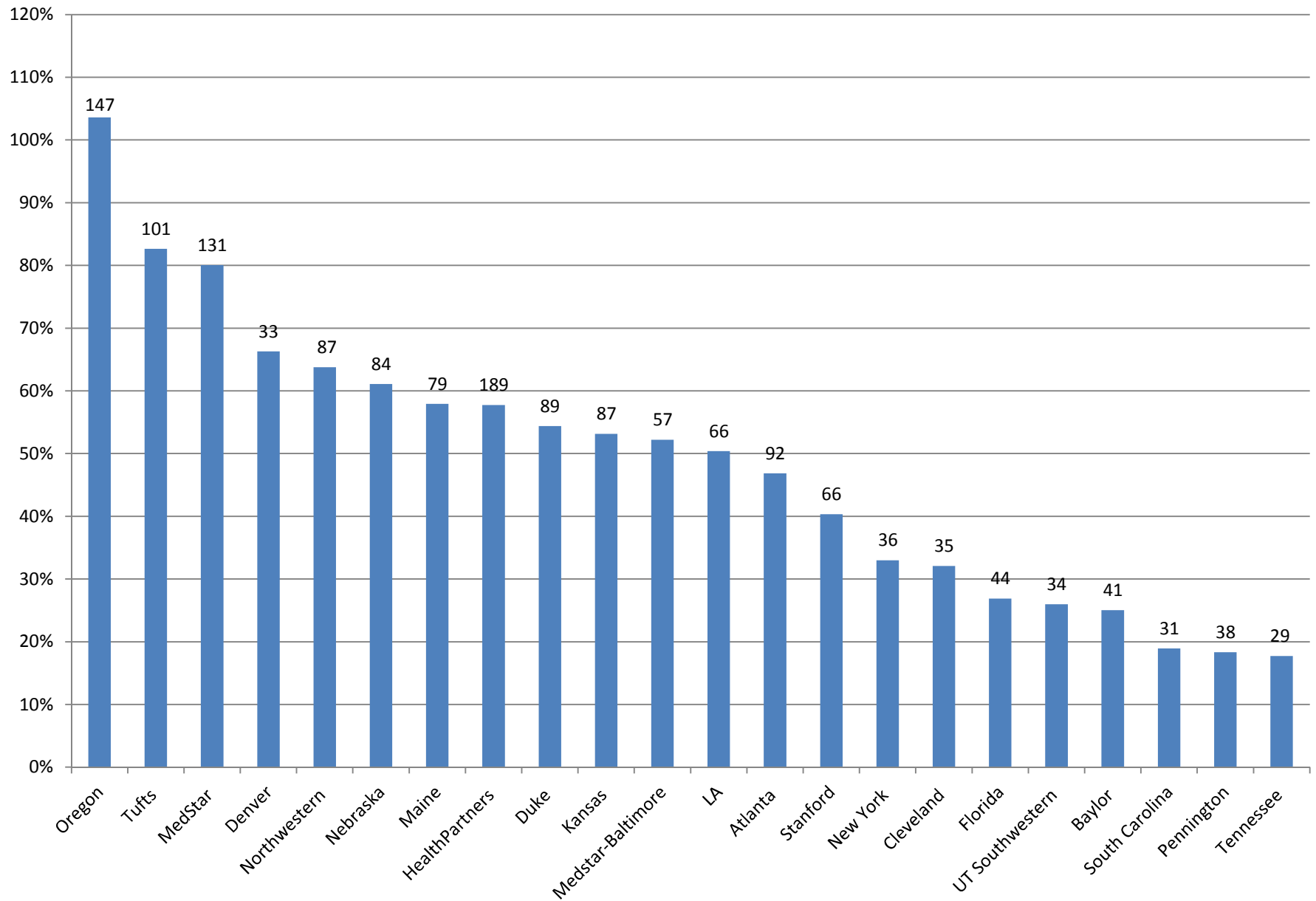
### 7.1.a Detail on diabetes diagnosis

|                                                      | M06      | M12              | M18              | M24 | M30 | M36 | M42 | M48 |
|------------------------------------------------------|----------|------------------|------------------|-----|-----|-----|-----|-----|
| Semi-annual visits                                   | 1132     | -                | 303 <sup>1</sup> | -   |     | -   |     | -   |
| Diabetes, n (% visits)                               | 24 (2.1) | -                | 6 (2.0)          | -   |     | -   |     | -   |
| Positive A1c and FPG                                 | 9        | -                | 4                | -   |     | -   |     | -   |
| Positive A1c or FPG, pos. confirmatory               | 15       | -                | 2                | -   |     | -   |     | -   |
| No diabetes, n                                       | 1108     | -                | 297              | -   |     | -   |     | -   |
| Negative A1c and FPG                                 | 1083     | -                | 294              | -   |     | -   |     | -   |
| Positive A1c or FPG, neg. confirmatory               | 24       | -                | 3                | -   |     | -   |     | -   |
| Annual visits                                        | -        | 689 <sup>1</sup> | -                | 28  | -   |     | -   |     |
| Diabetes, n (% visits)                               | -        | 24 (3.5)         | -                | 0   | -   |     | -   |     |
| Positive, met 2 criteria                             | -        | 8                | -                | 0   | -   |     | -   |     |
| Positive, met 1 criterion, pos. confirmatory         | -        | 16               | -                | 0   | -   |     | -   |     |
| No diabetes, n                                       | -        | 665              | -                | 28  | -   |     | -   |     |
| All 3 criteria negative                              | -        | 627              | -                | 28  | -   |     | -   |     |
| Met 1 criterion, neg. confirmatory                   | -        | 38               | -                | 0   | -   |     | -   |     |
| Outside of study events by adjudication <sup>2</sup> |          |                  |                  |     |     |     |     |     |

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

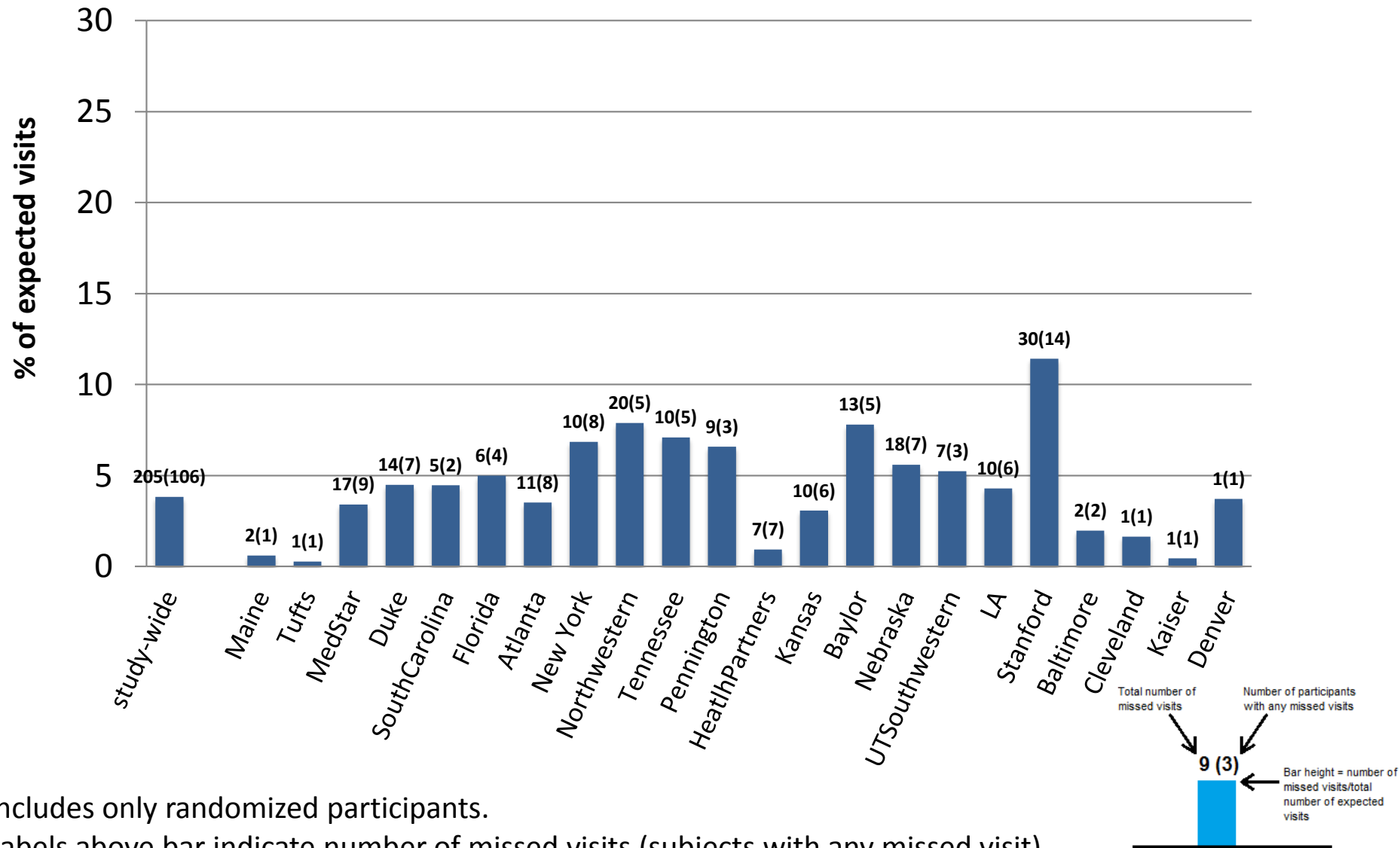
<sup>2</sup> If diabetes outcome was adjudicated before stated interval, it is shown under stated interval. For example, adjudicated outcomes between the M06 and M12 visits are shown under M12. Longitudinal analyses (when conducted) will be based on “time-to-event.”

Cumulative Percent of Randomization Goal Achieved Through January 6th

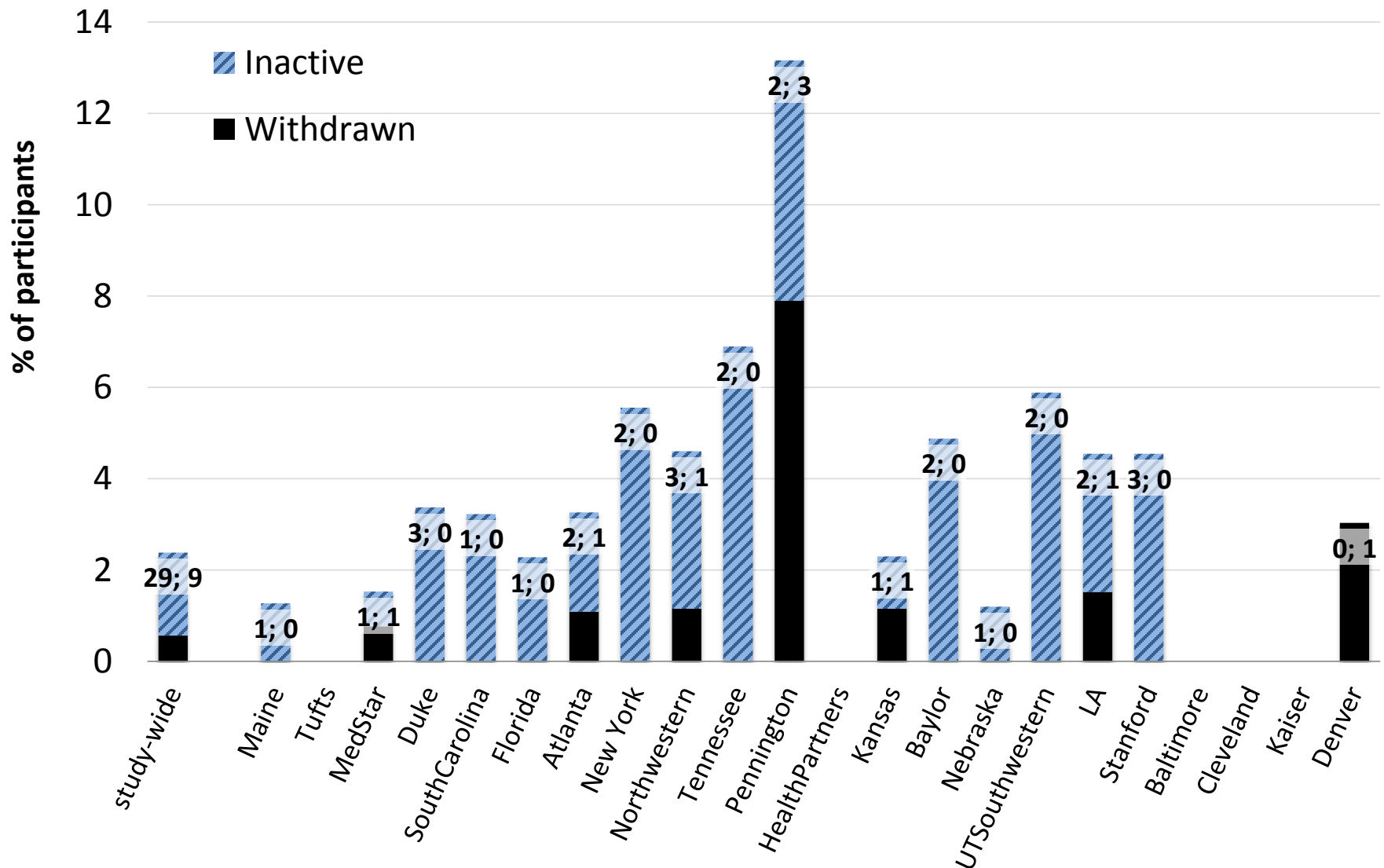


# Missed visits, (% of expected visits)

Study-wide = 3.8%

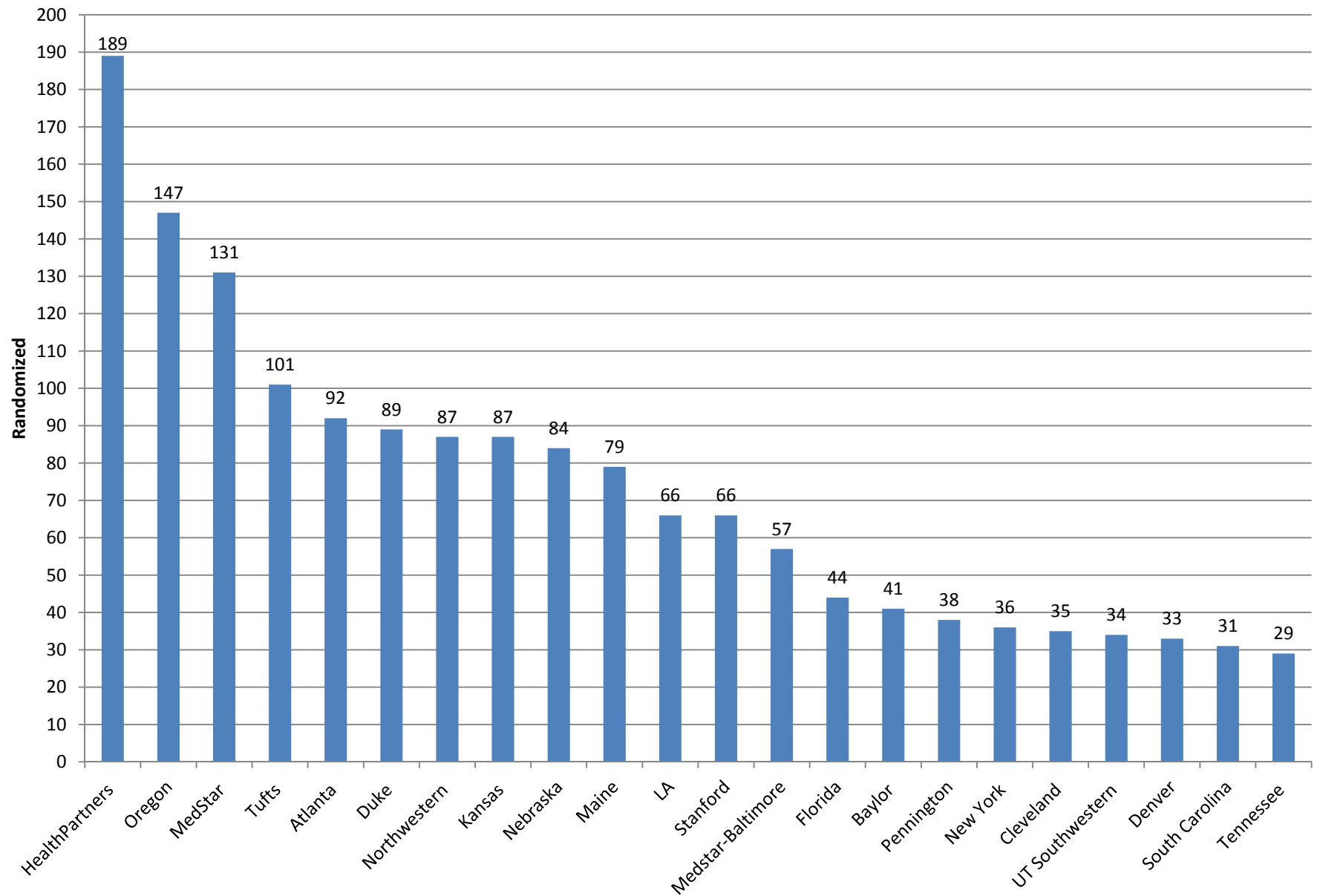


## % inactive and withdrawn participants

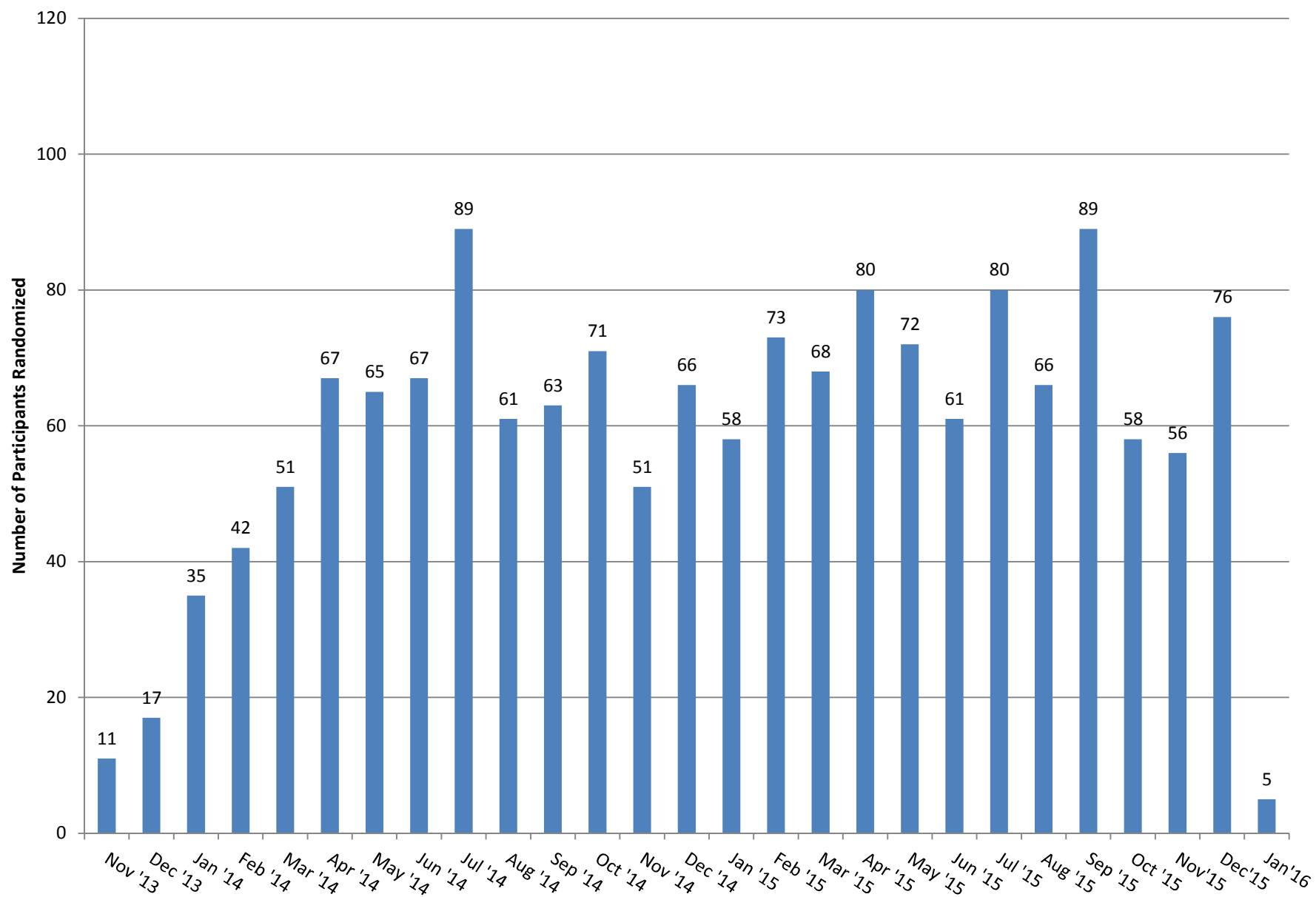


Includes only randomized participants. Labels are number of participants (inactive; withdrawn).

## Randomizations by Site



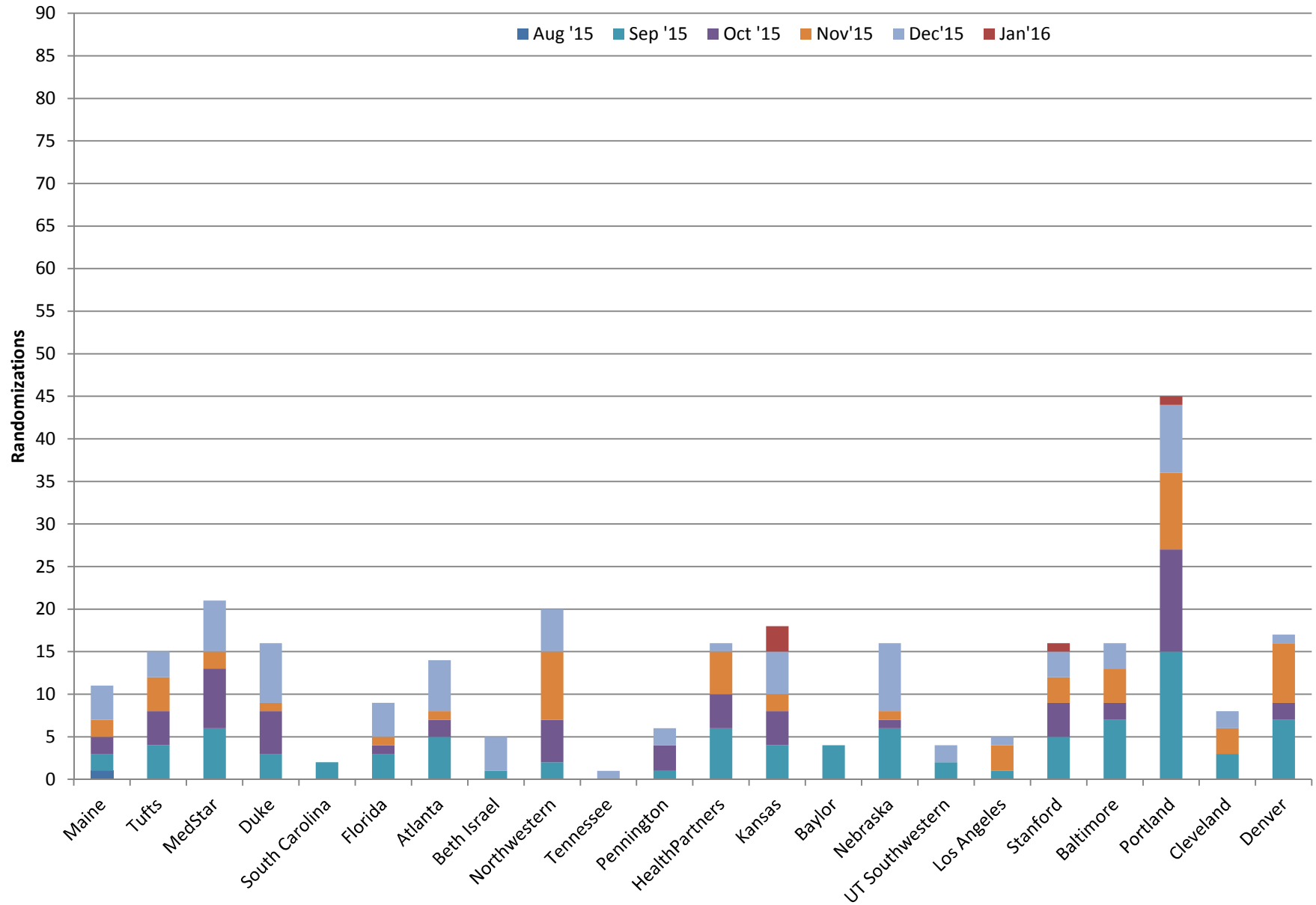
## Study-Wide Randomizations per Month



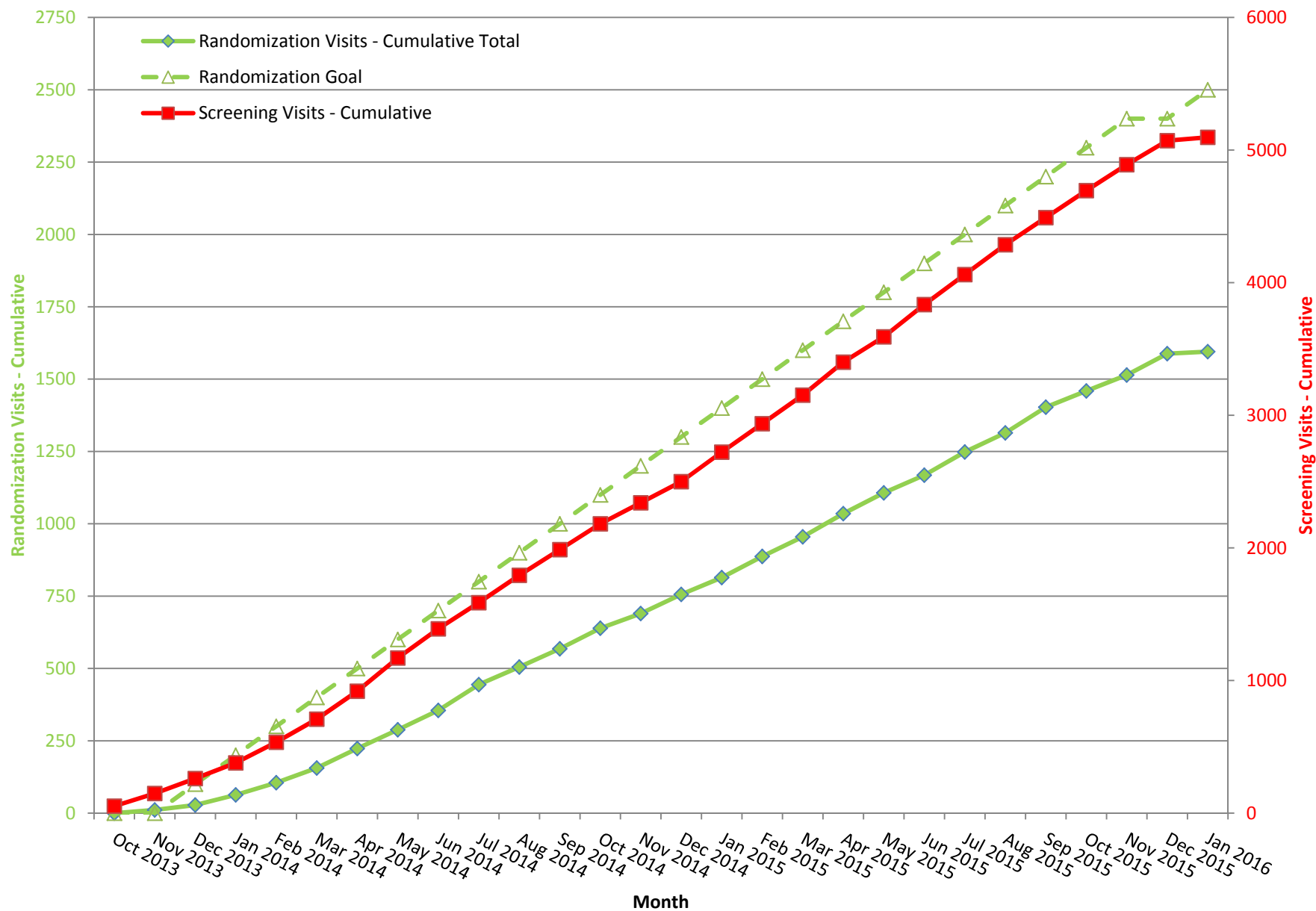
The SAS System

| Site            | Monthly<br>RAN goal | RAN<br>goal | SCR<br>visits | BAS<br>visits | RAN<br>visits | SCR:RAN<br>ratio | Time<br>adjusted<br>goal (%) | 1/2016<br>SCR<br>visits | 1/2016<br>BAS<br>visits | 1/2016<br>RAN<br>visits | 1/2016<br>SCR:RAN<br>ratio | 1/2016<br>RAN<br>goal(%) | 12/2015<br>SCR<br>visits | 12/2015<br>BAS<br>visits | 12/2015<br>RAN<br>visits | 12/2015<br>SCR:RAN<br>ratio | 12/2015<br>RAN<br>goal(%) |
|-----------------|---------------------|-------------|---------------|---------------|---------------|------------------|------------------------------|-------------------------|-------------------------|-------------------------|----------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-----------------------------|---------------------------|
| Maine           | 5.2                 | 125         | 266           | 136           | 79            | 3.4              | 57.3                         | 3                       | .                       | .                       | .                          | .                        | 2                        | 5                        | 4                        | 0.5                         | 77                        |
| Tufts           | 4.7                 | 112         | 324           | 178           | 101           | 3.2              | 81.1                         | 1                       | 1                       | .                       | .                          | .                        | 8                        | 4                        | 3                        | 2.7                         | 64                        |
| MedStar         | 6.3                 | 150         | 342           | 195           | 131           | 2.6              | 78.5                         | .                       | .                       | .                       | .                          | .                        | 7                        | 6                        | 6                        | 1.2                         | 95                        |
| Duke            | 6.3                 | 150         | 256           | 158           | 89            | 2.9              | 53.3                         | 2                       | .                       | .                       | .                          | .                        | 8                        | 6                        | 7                        | 1.1                         | 111                       |
| South Carolina  | 6.3                 | 150         | 164           | 65            | 31            | 5.3              | 18.6                         | .                       | .                       | .                       | .                          | .                        | 1                        | .                        | .                        | .                           | .                         |
| Florida         | 6.3                 | 150         | 235           | 77            | 44            | 5.3              | 26.4                         | 1                       | 1                       | .                       | .                          | .                        | 9                        | 6                        | 4                        | 2.3                         | 63                        |
| Atlanta         | 7.5                 | 180         | 189           | 157           | 92            | 2.1              | 46.3                         | 2                       | 2                       | .                       | .                          | .                        | 3                        | 3                        | 6                        | 0.5                         | 80                        |
| New York        | 4.2                 | 100         | 190           | 73            | 36            | 5.3              | 32.3                         | .                       | .                       | .                       | .                          | .                        | .                        | 1                        | 4                        | .                           | 95                        |
| Northwestern    | 5.2                 | 125         | 235           | 163           | 87            | 2.7              | 63.1                         | .                       | .                       | .                       | .                          | .                        | 7                        | 5                        | 5                        | 1.4                         | 96                        |
| Tennessee       | 6.3                 | 150         | 82            | 38            | 29            | 2.8              | 17.4                         | .                       | .                       | .                       | .                          | .                        | .                        | .                        | 1                        | .                           | 16                        |
| Tulane          | 6.3                 | 150         | 35            | 2             | 2             | 17.5             | 1.2                          | .                       | .                       | .                       | .                          | .                        | .                        | .                        | .                        | .                           | .                         |
| Pennington      | 7.9                 | 190         | 185           | 64            | 38            | 4.9              | 18.2                         | .                       | .                       | .                       | .                          | .                        | .                        | 2                        | 2                        | .                           | 25                        |
| HealthPartners  | 12.5                | 300         | 458           | 287           | 189           | 2.4              | 57.1                         | 5                       | .                       | .                       | .                          | .                        | 27                       | 6                        | 1                        | 27                          | 8                         |
| Kansas          | 6.3                 | 150         | 274           | 148           | 87            | 3.1              | 52.1                         | 2                       | .                       | 3                       | 0.7                        | 48                       | 8                        | 8                        | 5                        | 1.6                         | 79                        |
| Baylor          | 6.3                 | 150         | 205           | 80            | 41            | 5                | 24.6                         | .                       | .                       | .                       | .                          | .                        | 2                        | .                        | .                        | .                           | .                         |
| Nebraska        | 5.3                 | 126         | 320           | 176           | 84            | 3.8              | 59.8                         | 2                       | .                       | .                       | .                          | .                        | 19                       | 8                        | 8                        | 2.4                         | 151                       |
| UT Southwestern | 5                   | 120         | 91            | 62            | 34            | 2.7              | 25.7                         | .                       | .                       | .                       | .                          | .                        | 5                        | 4                        | 2                        | 2.5                         | 40                        |
| LA              | 5                   | 120         | 223           | 112           | 66            | 3.4              | 49.8                         | .                       | 1                       | .                       | .                          | .                        | 3                        | 1                        | 1                        | 3                           | 20                        |
| Stanford        | 6.3                 | 150         | 304           | 117           | 66            | 4.6              | 39.5                         | 3                       | 1                       | 1                       | 3                          | 16                       | 14                       | 7                        | 3                        | 4.7                         | 48                        |
| Baltimore       | 7.7                 | 100         | 146           | 90            | 57            | 2.6              | 51.6                         | .                       | 1                       | .                       | .                          | .                        | 7                        | 5                        | 3                        | 2.3                         | 39                        |
| Cleveland       | 7.7                 | 100         | 125           | 63            | 35            | 3.6              | 31.7                         | .                       | .                       | .                       | .                          | .                        | 7                        | 4                        | 2                        | 3.5                         | 26                        |
| Kaiser          | 10                  | 130         | 289           | 250           | 147           | 2                | 102.6                        | 1                       | .                       | 1                       | 1                          | 10                       | 27                       | 13                       | 8                        | 3.4                         | 80                        |
| Denver          | 5.4                 | 65          | 182           | 74            | 33            | 5.5              | 65.7                         | 1                       | 1                       | .                       | .                          | .                        | 19                       | 3                        | 1                        | 19                          | 19                        |
|                 | 138.3               | .           | 5120          | 2765          | 1598          | 3.2              | 40.2                         | 23                      | 8                       | 5                       | 4.6                        | 4                        | 183                      | 97                       | 76                       | 2.4                         | 55                        |

## Randomizations By Site - Last 6 Months



## Cumulative Screening and Randomization Visits by Month



## Biorepository Consent

| Site                          | Total RAN   | Biorepository Consent (%) | DNA Consent (%) |
|-------------------------------|-------------|---------------------------|-----------------|
| Atlanta                       | 92          | 96%                       | 96%             |
| Baltimore-Medstar             | 57          | 96%                       | 96%             |
| Baylor                        | 41          | 95%                       | 95%             |
| Beth Israel                   | 36          | 86%                       | 86%             |
| Cleveland                     | 35          | 97%                       | 94%             |
| Denver VA                     | 26          | 100%                      | 100%            |
| Duke                          | 89          | 84%                       | 82%             |
| Florida                       | 45          | 98%                       | 93%             |
| HealthPartners                | 189         | 88%                       | 86%             |
| Kaiser                        | 147         | 94%                       | 92%             |
| LA                            | 66          | 89%                       | 89%             |
| Maine                         | 79          | 91%                       | 91%             |
| South Carolina                | 31          | 74%                       | 74%             |
| MedStar                       | 131         | 89%                       | 84%             |
| Northwestern                  | 87          | 93%                       | 87%             |
| Omaha VA                      | 58          | 90%                       | 90%             |
| Pennington                    | 38          | 89%                       | 87%             |
| Stanford                      | 66          | 94%                       | 92%             |
| Truman                        | 5           | 80%                       | 80%             |
| Tufts                         | 101         | 96%                       | 96%             |
| University of Colorado Denver | 7           | 100%                      | 100%            |
| Kansas                        | 83          | 81%                       | 81%             |
| Nebraska (UNMC)               | 26          | 92%                       | 85%             |
| Tennessee                     | 29          | 62%                       | 59%             |
| UT Southwestern               | 34          | 100%                      | 100%            |
| <b>Overall</b>                | <b>1600</b> | <b>91%</b>                | <b>89%</b>      |

## Demographics of Randomized Participants

| Site                          | Total       | Male       | Hispanic<br>or Latino | White       | Black or<br>African<br>American | Asian     | American<br>Indian or<br>Alaska Native | Native Hawaiian<br>or Other Pacific<br>Islander | Other     |
|-------------------------------|-------------|------------|-----------------------|-------------|---------------------------------|-----------|----------------------------------------|-------------------------------------------------|-----------|
| Atlanta                       | 92          | 87         | 3                     | 16          | 72                              | 2         | 1                                      | 0                                               | 1         |
| Baltimore-Medstar             | 57          | 20         | 0                     | 11          | 43                              | 2         | 0                                      | 0                                               | 1         |
| Baylor                        | 41          | 14         | 14                    | 23          | 14                              | 0         | 2                                      | 1                                               | 1         |
| Beth Israel                   | 36          | 17         | 13                    | 19          | 13                              | 3         | 0                                      | 0                                               | 1         |
| Cleveland                     | 36          | 25         | 4                     | 23          | 9                               | 3         | 0                                      | 0                                               | 1         |
| Denver VA                     | 26          | 24         | 6                     | 21          | 3                               | 0         | 2                                      | 0                                               | 0         |
| Duke                          | 89          | 40         | 2                     | 46          | 39                              | 4         | 0                                      | 0                                               | 0         |
| Florida                       | 45          | 16         | 8                     | 36          | 5                               | 1         | 0                                      | 0                                               | 3         |
| HealthPartners                | 189         | 109        | 5                     | 169         | 10                              | 7         | 1                                      | 0                                               | 2         |
| Kaiser                        | 147         | 81         | 13                    | 121         | 5                               | 10        | 1                                      | 0                                               | 10        |
| LA                            | 66          | 9          | 62                    | 62          | 2                               | 2         | 0                                      | 0                                               | 0         |
| Maine                         | 79          | 32         | 1                     | 76          | 0                               | 0         | 0                                      | 0                                               | 3         |
| South Carolina                | 31          | 10         | 0                     | 19          | 11                              | 1         | 0                                      | 0                                               | 0         |
| MedStar                       | 131         | 67         | 5                     | 34          | 92                              | 1         | 0                                      | 2                                               | 2         |
| Northwestern                  | 87          | 54         | 4                     | 61          | 21                              | 5         | 0                                      | 0                                               | 0         |
| Omaha VA                      | 58          | 56         | 2                     | 47          | 7                               | 1         | 1                                      | 0                                               | 2         |
| Pennington                    | 38          | 18         | 1                     | 22          | 14                              | 2         | 0                                      | 0                                               | 0         |
| Stanford                      | 66          | 43         | 3                     | 36          | 2                               | 26        | 0                                      | 0                                               | 2         |
| Truman                        | 5           | 3          | 0                     | 3           | 2                               | 0         | 0                                      | 0                                               | 0         |
| Tufts                         | 101         | 53         | 7                     | 65          | 28                              | 7         | 0                                      | 0                                               | 1         |
| University of Colorado Denver | 7           | 4          | 0                     | 4           | 3                               | 0         | 0                                      | 0                                               | 0         |
| Kansas                        | 83          | 39         | 2                     | 63          | 17                              | 2         | 0                                      | 1                                               | 0         |
| Nebraska (UNMC)               | 26          | 14         | 1                     | 21          | 3                               | 0         | 0                                      | 1                                               | 1         |
| Tennessee                     | 29          | 10         | 1                     | 10          | 19                              | 0         | 0                                      | 0                                               | 0         |
| UT Southwestern               | 34          | 16         | 9                     | 19          | 6                               | 6         | 0                                      | 0                                               | 3         |
| <b>Overall</b>                | <b>1601</b> | <b>862</b> | <b>166</b>            | <b>1027</b> | <b>442</b>                      | <b>85</b> | <b>8</b>                               | <b>5</b>                                        | <b>34</b> |
|                               |             |            | <b>10.4%</b>          |             |                                 |           |                                        |                                                 |           |