



Center for Clinical Trials

Department of Biostatistics  
Department of Epidemiology  
Department of International Health

Department of Medicine  
Department of Ophthalmology  
Oncology Center

3 February 2016

**Memorandum**

To: Trialists

Fr: Curtis Meinert

Re: Trials by NIH agencies

The ACCT dataset (Aggregate Analysis of [ClinicalTrials.gov](http://www.clinicaltrials.gov); March 2015 dataset, downloaded from the Clinical Trials Transformation Initiative website; <http://www.ctti-clinicaltrials.org/>) identifies trials to sponsoring agencies. The NIH agencies represented are listed below. Trials identified simply to "NIH" (956 trials) have been eliminated from counts in Tables 2 and 3 because they cannot be associated with a specific NIH agency.

**NIH agencies represented in the ACCT database**

CC. . . . . National Inst of Health Clinical Center  
FIC. . . . . Fogarty International Center  
NCATS. . . . National Center for Advancing Translational Science  
NCCIH. . . . National Center for Complementary & Integrative Health  
NCI. . . . . National Cancer Inst  
NCMHD. . . . National Center on Minority Health & Health Disparities  
NCMRR. . . . National Center for Medical Rehabilitation Research  
NCRR. . . . . National Center for Research Resources  
NEI. . . . . National Eye Inst  
NHGRI. . . . National Human Genome Research Inst  
NHLBI. . . . National Heart, Lung, & Blood Inst  
NIA. . . . . National Inst on Aging  
NIAAA. . . . National Inst on Alcohol Abuse & Alcoholism  
NIAID. . . . . National Inst of Allergy & Infectious Diseases  
NIAMS. . . . National Inst of Arthritis & Musculoskeletal & Skin Diseases  
NIBIB. . . . National Inst for Biomedical Imaging & Bioengineering  
NICHD. . . . National Inst of Child Health & Human Development  
NIDA. . . . . National Inst on Drug Abuse  
NIDCD. . . . National Inst on Deafness & Other Communication Disorders  
NIDCR. . . . National Inst of Dental & Craniofacial Research  
NIDDK. . . . National Inst of Diabetes & Digestive & Kidney Diseases  
NIEHS. . . . National Inst of Environmental Health Sciences  
NIGMS. . . . National Inst of General Medical Sciences  
NIMH. . . . . National Inst of Mental Health  
NINDS. . . . National Inst of Neurological Disorders & Stroke  
NINR. . . . . National Inst of Nursing Research  
NLM. . . . . National Library of Medicine  
ODS. . . . . Office of Dietary Supplements

ORD..... Office of Rare Diseases  
ORWH..... Office of Research on Women's Health  
TRND..... Therapeutics for Rare & Neglected Diseases

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Counts in Table 1 (arranged in descending order by number of trials registered) are by recruitment status.

Open trials are trials that are recruiting, will be recruiting, or involve drugs that are available for expanded access.

A completed trial is one that has ended normally; one where participants are no longer being treated or examined.

The NCI accounts for 41% of all registered trials. The five NIH agencies with the most registrations account for two-thirds of all registered trials.

The lowest and highest percentages for the different recruitment categories are denoted by **italic bold** (lowest) and **bold** (highest) for the subset of agencies with  $\geq 100$  registered trials.

The National Cancer Institute (NCI) has the highest percentage of terminated, suspended, or withdrawn (T, S, or W) trials. The National Institute of Nursing Research (NINR) has the lowest percentage.

The mean and median times from start of enrollment to completion is given in Table 2. The median times range from two years for the National Institute of Allergy & Infectious Diseases (NIAID) to five years for the National Cancer Institute (NCI).

Table 3 gives sample sizes and publications by NIH agency for completed trials for agencies with  $>100$  registered trials. The median sample sizes range from 37 to 178 and the interquartile (IQ) ranges from 45 to 352.

A previous memo (7 January 2016) presented counts of publications by year of completion across all NIH agencies. Results in Table 3 give corresponding counts by NIH agency.

The supposition is that publications after trials are completed are of results. However, as noted in my 7 January 2016 memo, there is no way of being sure that is the case without looking at publications.

Percentages for publications after the year of completion (last column of Table 3) range from 5.6% (NCI: National Cancer Institute) to 18.8% (NICHD: National Institute of Child Health & Human Development).

Trials by NIH agencies  
3 February 2016

**Table 1 NIH trials (interventional studies) registered on ClinicalTrials.gov by recruitment status**

| NIH agency                           | No.        |                    |           |                         |                    | %             |              |               |              |              | Trials registered |
|--------------------------------------|------------|--------------------|-----------|-------------------------|--------------------|---------------|--------------|---------------|--------------|--------------|-------------------|
|                                      | Open       |                    | Closed    |                         |                    | Open          |              | Closed        |              |              |                   |
|                                      | Recruiting | Other <sup>2</sup> | Completed | T, S, or W <sup>3</sup> | Other <sup>5</sup> | Recruiting    | Other        | Completed     | T, S, or W   | Other        |                   |
| <b>A: ≥ 100 trials registered</b>    |            |                    |           |                         |                    |               |              |               |              |              |                   |
| NCI                                  | 1,135      | 65                 | 3,380     | 969                     | 1,382              | 16.4          | 0.9          | <b>48.8</b>   | <b>14.0</b>  | <b>19.9</b>  | 6,931             |
| NIMH                                 | 205        | 27                 | 751       | 38                      | 174                | 17.2          | <b>2.3</b>   | 62.8          | 3.2          | 14.6         | 1,195             |
| NIAID                                | 145        | 14                 | 773       | 115                     | 124                | 12.4          | 1.2          | 66.0          | 9.8          | 10.6         | 1,171             |
| NHLBI                                | 256        | 19                 | 567       | 78                      | 164                | 23.6          | 1.8          | 52.3          | 7.2          | 15.1         | 1,084             |
| NIDA                                 | 193        | 22                 | 649       | 41                      | 133                | 18.6          | 2.1          | 62.5          | 3.9          | 12.8         | 1,038             |
| NIDDK                                | 149        | 6                  | 530       | 32                      | 130                | 17.6          | 0.7          | 62.6          | 3.8          | 15.3         | 847               |
| NICHHD                               | 181        | 10                 | 420       | 52                      | 106                | 23.5          | 1.3          | 54.6          | 6.8          | 13.8         | 769               |
| NCCIH                                | 61         | 6                  | 357       | 21                      | 39                 | 12.6          | 1.2          | 73.8          | 4.3          | 8.1          | 484               |
| NINDS                                | 74         | 4                  | 214       | 47                      | 46                 | 19.2          | 1.0          | 55.6          | 12.2         | 11.9         | 385               |
| NIA                                  | 88         | 4                  | 223       | 10                      | 52                 | 23.3          | 1.1          | 59.2          | 2.7          | 13.8         | 377               |
| NCRR                                 | 33         | 2                  | 223       | 20                      | 44                 | <b>10.2</b>   | 0.6          | 69.3          | 6.2          | 13.7         | 322               |
| NIAAA                                | 70         | 5                  | 164       | 8                       | 29                 | <b>25.4</b>   | 1.8          | 59.4          | 2.9          | 10.5         | 276               |
| NINR                                 | 36         | 4                  | 137       | 4                       | 25                 | 17.5          | 1.9          | 66.5          | <b>1.9</b>   | 12.1         | 206               |
| NIAMS                                | 25         | 1                  | 132       | 12                      | 28                 | 12.6          | 0.5          | 66.7          | 6.1          | 14.1         | 198               |
| NEI                                  | 29         | 0                  | 106       | 11                      | 26                 | 16.9          | <b>0.0</b>   | 61.6          | 6.4          | 15.1         | 172               |
| CC                                   | 19         | 0                  | 106       | 13                      | 3                  | 13.5          | 0.0          | <b>75.2</b>   | 9.2          | <b>2.1</b>   | 141               |
| NIDCR                                | 15         | 0                  | 66        | 3                       | 17                 | 14.9          | 0.0          | 65.3          | 3.0          | 16.8         | 101               |
| <b>No. trials</b>                    |            |                    |           |                         |                    |               |              |               |              |              | <b>15,697</b>     |
| <b>Range</b>                         |            |                    |           |                         |                    | <b>10.2 -</b> | <b>0.0 -</b> | <b>48.8 -</b> | <b>1.9 -</b> | <b>2.1 -</b> |                   |
|                                      |            |                    |           |                         |                    | <b>25.4</b>   | <b>2.3</b>   | <b>75.2</b>   | <b>14.0</b>  | <b>19.9</b>  |                   |
| <b>B: &lt; 100 trials registered</b> |            |                    |           |                         |                    |               |              |               |              |              |                   |
| NIDCD                                | 28         | 1                  | 21        | 7                       | 7                  | 43.8          | 1.6          | 32.8          | 10.9         | 10.9         | 64                |
| NIGMS                                | 22         | 1                  | 24        | 2                       | 8                  | 38.6          | 1.8          | 42.1          | 3.5          | 14.0         | 57                |
| NCMHD                                | 10         | 1                  | 31        | 0                       | 13                 | 18.2          | 1.8          | 56.4          | 0.0          | 23.6         | 55                |
| NIEHS                                | 6          | 2                  | 31        | 3                       | 4                  | 13.0          | 4.3          | 67.4          | 6.5          | 8.7          | 46                |
| ODS                                  | 3          | 0                  | 32        | 1                       | 5                  | 7.3           | 0.0          | 78.0          | 2.4          | 12.2         | 41                |
| NHGRI                                | 10         | 2                  | 18        | 1                       | 3                  | 29.4          | 5.9          | 52.9          | 2.9          | 8.8          | 34                |
| FIC                                  | 2          | 2                  | 22        | 0                       | 5                  | 6.5           | 6.5          | 71.0          | 0.0          | 16.1         | 31                |
| ORWH                                 | 3          | 0                  | 9         | 0                       | 4                  | 18.8          | 0.0          | 56.3          | 0.0          | 25.0         | 16                |
| NLM                                  | 4          | 0                  | 11        | 0                       | 1                  | 25.0          | 0.0          | 68.8          | 0.0          | 6.3          | 16                |
| NCATS                                | 8          | 0                  | 5         | 1                       | 1                  | 53.3          | 0.0          | 33.3          | 6.7          | 6.7          | 15                |

Trials by NIH agencies  
3 February 2016

| NIH agency                        | No.        |                    |           |                         |                    | %          |       |           |            |      | Total no. of trials |
|-----------------------------------|------------|--------------------|-----------|-------------------------|--------------------|------------|-------|-----------|------------|------|---------------------|
|                                   | Open       |                    | Closed    |                         |                    | Open       |       | Closed    |            |      |                     |
|                                   | Recruiting | Other <sup>*</sup> | Completed | T, S, or W <sup>#</sup> | Other <sup>§</sup> | Recruiting | Other | Completed | T, S, or W |      |                     |
| ORD                               | 4          | 0                  | 3         | 1                       | 2                  | 40.0       | 0.0   | 30.0      | 10.0       | 20.0 | 10                  |
| NIBIB                             | 5          | 0                  | 3         | 0                       | 2                  | 50.0       | 0.0   | 30.0      | 0.0        | 20.0 | 10                  |
| <b>No. trials</b>                 |            |                    |           |                         |                    |            |       |           |            |      | <b>395</b>          |
| <b>C: Other registered trials</b> |            |                    |           |                         |                    |            |       |           |            |      |                     |
| NIH                               | 260        | 33                 | 449       | 71                      | 143                | 27.2       | 3.5   | 47.0      | 7.4        | 15.0 | 956                 |
| NCMRR                             | 2          | 0                  | 1         | 0                       | 0                  | 66.7       | 0.0   | 33.3      | 0.0        | 0.0  | 3                   |
| TRND                              | 0          | 0                  | 2         | 0                       | 1                  | 0.0        | 0.0   | 66.7      | 0.0        | 33.3 | 3                   |
| <b>No. trials</b>                 |            |                    |           |                         |                    |            |       |           |            |      | <b>962</b>          |
| <b>Trials registered</b>          |            |                    |           |                         |                    |            |       |           |            |      | <b>17,054</b>       |

\* Not yet recruiting, available for expanded access, or listed as "open" but status is "unknown" (i.e., last status update greater than two years old)

# Terminated, withdrawn, or suspended

§ Active, not enrolling, enrolling by invitation, expanded access (temporarily not available, no longer available, or approved for marketing), or unknown recruitment status (i.e., where status has not been verified in the last two years)

**Table 2 Time from start of enrollment to completion of NIH trials (limited to agencies with > 100 trials registered)**

| NIH agency | Trials completed | Time to completion |             |          |
|------------|------------------|--------------------|-------------|----------|
|            |                  | Mean               | Mdn         | IQ range |
| NCI        | 3,380            | 5.09               | <b>5.00</b> | 4.00     |
| NIMH       | 751              | 4.14               | 4.00        | 2.00     |
| NIAID      | 773              | 2.96               | <b>2.00</b> | 3.00     |
| NHLBI      | 567              | 4.23               | 4.00        | 2.00     |
| NIDA       | 649              | 3.51               | 3.00        | 3.00     |
| NIDDK      | 530              | 3.90               | 4.00        | 3.00     |
| NICHD      | 420              | 3.68               | 3.00        | 3.00     |
| NCCIH      | 357              | 3.38               | 3.00        | 2.00     |
| NINDS      | 214              | 3.98               | 3.00        | 4.00     |
| NIA        | 223              | 3.92               | 4.00        | 3.00     |
| NCRR       | 223              | 3.14               | 3.00        | 2.00     |
| NIAAA      | 164              | 3.81               | 4.00        | 3.00     |
| NINR       | 137              | 4.17               | 4.00        | 2.00     |
| NIAMS      | 132              | 4.41               | 4.00        | 3.00     |
| NEI        | 106              | 3.26               | 3.00        | 2.00     |
| CC         | 106              | 4.00               | 4.00        | 3.00     |
| NIDCR      | 66               | 3.60               | 3.00        | 2.50     |

**Table 3 NIH completed trials: Sample sizes and number with one or more publications during or after the year of completion (limited to agencies with > 100 trials registered)**

| NIH agency                    | No. trials completed | Sample size       |                 |                 | ≥ 1 study publication |                |                   |                     |
|-------------------------------|----------------------|-------------------|-----------------|-----------------|-----------------------|----------------|-------------------|---------------------|
|                               |                      |                   |                 |                 | No.                   |                | % published       |                     |
|                               |                      |                   |                 |                 | Mean                  | Mdn            | IQ range          | During yr completed |
| NCI                           | <b>3,380</b>         | 215               | 42              | 54              | <b>131</b>            | <b>189</b>     | 3.9               | <b>5.6</b>          |
| NIMH                          | 751                  | 656               | 101             | 170             | 40                    | 99             | 5.3               | 13.2                |
| NIAID                         | 773                  | 455               | 70              | 198             | 38                    | 136            | 4.9               | 17.6                |
| NHLBI                         | 567                  | 431               | 139             | 332             | 58                    | 92             | 10.2              | 16.2                |
| NIDA                          | 649                  | 257               | 92              | 194             | 26                    | 77             | 4.0               | 11.9                |
| NIDDK                         | 530                  | 281               | 79              | 167             | 38                    | 73             | 7.2               | 13.8                |
| NICHD                         | 420                  | 737               | 127             | <b>352</b>      | 39                    | 79             | 9.3               | <b>18.8</b>         |
| NCCIH                         | 357                  | 354               | 67              | 106             | 7                     | 37             | 2.0               | 10.4                |
| NINDS                         | 214                  | 190               | 42              | 105             | 16                    | 19             | 7.5               | 8.9                 |
| NIA                           | 223                  | 544               | 125             | 236             | 20                    | 34             | 9.0               | 15.2                |
| NCRR                          | 223                  | 155               | 45              | 66              | 10                    | 26             | 4.5               | 11.7                |
| NIAAA                         | 164                  | 305               | 131             | 145             | 10                    | 16             | 6.1               | 9.8                 |
| NINR                          | 137                  | 385               | <b>178</b>      | 50              | 10                    | 16             | 7.3               | 11.7                |
| NIAMS                         | 132                  | 551               | 105             | 157             | 14                    | 24             | <b>10.6</b>       | 18.2                |
| NEI                           | 106                  | 252               | 66              | 183             | 11                    | 16             | 10.4              | 15.1                |
| CC                            | 106                  | <b>93</b>         | <b>37</b>       | <b>45</b>       | 8                     | 7              | 7.5               | 6.6                 |
| NIDCR                         | <b>66</b>            | <b>1,263</b>      | 154             | 345             | <b>1</b>              | <b>6</b>       | <b>1.5</b>        | 9.1                 |
| <b>Range</b>                  | <b>66 - 3,380</b>    | <b>93 - 1,263</b> | <b>37 - 178</b> | <b>45 - 352</b> | <b>1 - 131</b>        | <b>6 - 189</b> | <b>1.5 - 10.6</b> | <b>5.6 - 18.8</b>   |
| <b>Total completed trials</b> | <b>9,247</b>         |                   |                 |                 |                       |                |                   |                     |