



24 July 2015

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Clinical trials indexes

The world loves indexes. Economies rise and fall based on them.

Given the importance we attach to them, I invented a few of my own for clinical trials using ClinicalTrials.gov. The website opened in 2000 but registration did not become "standard" until the International Committee of Journal Editors (ICJME) made registration a requirement for publication of trials started after 1 July 2005.

The indices are based on registrations in ClinicalTrials.gov for "interventional studies" ("clinical trials"). Registrations for 2006, 2010, and 2014 were 9,321, 13,822, and 18,420, respectively. The corresponding numbers for NIH-funded trials were 1,374, 1,114, and 1,050, respectively.

Counts for the indices are, as generated, using the "advanced search" feature on ClinicalTrials.gov.

The Drug Trial Index is the number of trials that are Phase 1, Phase 2, Phase 3, or Phase 4 divided by the total number of registrations. For example, the index value of 0.57 for 2014 for all registrations is the number of trials registered from 1/1/2014 thru 12/31/2014 that are phase 1, 2, 3, or 4 divided by the total number of registrations for 2014, i.e., 10,469/18,420.

Gender index

Ratio of number of trials registered involving females to number involving males.

Children index

Ratio of number of trials registered involving children (age < 18 yrs) to total number of trials registered.

Senior index

Ratio of number of trials registered involving adults > age 65 to total number of trials registered.

Drug trial index

Ratio of number of trials that are phase 1, 2, 3, or 4 to total number of trials registered

Phase 3 or 4 index

Ratio of number of trials that are phase 3 or 4 to total number of trials registered

| | 2006 | 2010 | 2014 |
|-------------------------|-------------|-------------|-------------|
| Gender mix index | | | |
| All | 1.06 | 1.05 | 1.02 |
| NIH | 1.06 | 1.08 | 1.08 |
| Children index | | | |
| All | 0.20 | 0.17 | 0.16 |
| NIH | 0.22 | 0.21 | 0.17 |
| Senior index | | | |
| All | 0.71 | 0.67 | 0.65 |
| NIH | 0.69 | 0.65 | 0.69 |
| Drug trial index | | | |
| All | 0.74 | 0.69 | 0.57 |
| NIH | 0.74 | 0.74 | 0.52 |
| Phase 3, 4 index | | | |
| All | 0.38 | 0.29 | 0.23 |
| NIH | 0.18 | 0.16 | 0.09 |

The changes of note are for the drug trial and phase 3, 4 indexes. Both suggest declines in drug trials relative to totals.