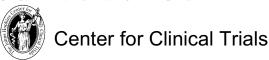
JOHNSHOPKINS



Department of Biostatistics Department of Epidemiology Department of International Health Department of Medicine Department of Ophthalmology Oncology Center

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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 <u>ClinicalTrials.gov</u>. 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 <u>ClinicalTrials.gov</u> 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 <u>ClinicalTrials.gov</u>.

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	x index		
All	1.06	1.05	1.02
NIH	1.06	1.08	1.08
Children in	dex		
All	0.20	0.17	0.16
NIH	0.22	0.21	0.17
Senior inde	X		
All	0.71	0.67	0.65
NIH	0.69	0.65	0.69
Drug trial i	ndex		
All	0.74	0.69	0.57
NIH	0.74	0.74	0.52
Phase 3, 4 i	ndex		
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.

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