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Trends in National Institutes of Health Funding for Clinical Trials Registered in ClinicalTrials.gov

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Clinical trials inform evidence-based prevention and treatment recommendations. The National Institutes of Health (NIH) and the pharmaceutical industry have been major funders of trials. In general, the pharmaceutical industry funds trials that test their own products, whereas the NIH's funding strategies are not commercially motivated.

In 2005, registration of trials became required for publication in major journals. Registration is also required for trials that meet the definition of an “applicable clinical trial” from the US Food and Drug Administration Amendments Act 801 and that were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. There are legal repercussions if sponsors or principal investigators do not register accurately.

We hypothesized that the number of NIH-funded trials has decreased. We investigated trends in funding of trials using the NIH-built database, ClinicalTrials.gov, with a focus on NIH and industry funding.

Methods

We downloaded data from ClinicalTrials.gov, searched for “interventional study” and obtained counts of newly registered trials by funder type: “NIH,” “industry,” “other US federal agency,” or “all others (individuals, universities, organizations).” Funder type “NIH,” for example, retrieves records for which at least 1 NIH institute or center has been listed as

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the sponsor (generally indicating NIH intramural research) or collaborator (suggesting extramural NIH funding).

We searched for date “first received” and the self-reported “study start.” Counts are by year (“first received” and “study start” dates between 2006 and 2014), as of June 26, 2015.

We calculated differences, 95% confidence intervals, and *P* values (2-sided χ^2 test, α level < .05) using Stata version 12.1 (StataCorp).

Results

Examining data according to the first received date, the number of newly registered trials doubled from 9321 in 2006 to 18 400 in 2014 (Table 1). The number of industry-funded trials increased by 1965 (43%). Concurrently, the number of NIH-funded trials decreased by 328 (24%).

During this period of relatively few trials being funded by other US federal agencies, funding from the all others category increased by 7357 (227%). In a random sample of 500 trials in this category, a majority (353; 71%) did not have US-based funders.

Using the study start date instead of the first received date led to differences in counts per year but similar patterns (Table 2). From 2006 through 2014, the total number of newly registered trials increased by 5410 (59%) and that of industry-funded trials increased by 758 (17%). The number of NIH-funded trials declined by 316 (27%).

Discussion

From 2006 through 2014, there has been a decrease in newly registered NIH-funded trials, where as industry-funded trials increased substantially. The decrease in NIH-funded trials may have resulted from a decline in discretionary spending by the US federal government.

The 2014 NIH budget is 14% less than the 2006 budget (when adjusted for inflation).¹ An expanding portfolio of NIH research with a flat budget may also have contributed to the decline in NIH-funded trials.

Tracking patterns in trial funding using ClinicalTrials.gov has limitations. First, available data by registration date and study start date differ. A registration date is assigned for all trials, whereas the study start date may have missing values.

In addition, investigators may define study start differently. Registration of ongoing or finished trials during the earlier years may account for larger numbers of NIH-funded trials by registration date relative to study start date. However, trends did not differ.

Second, trend data are valid indicators only to the extent that registration behavior by funding sources is not differential over time. Because of federal regulations, registration of NIH-funded trials on ClinicalTrials.gov is likely to be relatively comprehensive.

If registration behavior has improved over time, we may have underestimated the observed reduction in NIH-funded trials. Also, we do not know if there have been changes in how other trials were registered.

Third, the all others funder category is heterogeneous. It comprises non-US governmental agencies, organizations, universities, and other funders, mainly from outside the United States.

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Trials Registered in ClinicalTrials.gov From 2006 Through 2014 by Year First Received^a

Table 1

Year of trial start	Funding Agency, No. (%) ^c			
	Total No. of Trials ^b	National Institutes of Health	Industry	Other US Federal Agency All Others
2006	9321	1376 (14.8)	4585 (49.2)	263 (2.8) 3240 (34.8)
2007	11122	1247 (11.2)	5462 (49.1)	275 (2.5) 4284 (38.5)
2008	13942	1333 (9.6)	7046 (50.5)	327 (2.3) 5385 (38.6)
2009	13712	1162 (8.5)	6390 (46.6)	327 (2.4) 5963 (43.5)
2010	13816	1113 (8.1)	5923 (42.9)	309 (2.2) 6595 (47.7)
2011	14202	1057 (7.4)	5839 (41.1)	320 (2.3) 7127 (50.2)
2012	15468	1015 (6.6)	5738 (37.1)	344 (2.2) 8507 (55.0)
2013	16217	1074 (6.6)	5355 (33.0)	363 (2.2) 9566 (59.0)
2014	18400	1048 (5.7)	6550 (35.6)	339 (1.8) 10 597 (57.6)
% Difference (95% CI) ^{d,e}		-9.1 (-9.9 to -8.3)	-13.6 (-14.8 to -12.3)	-1.0 (-1.4 to -0.6) 22.8 (21.6 to 24.0)
Absolute difference, No. (%) ^e	9079 (97.4)	-328 (-23.8)	1965 (42.9)	76 (28.9) 7357 (227.1)

^aData as of June 26, 2015.

^bOne trial may have more than 1 funding source.

^cUnless otherwise indicated.

^dAll comparisons yielded P values of <.001.

^eComparisons are between the year 2006 and 2014.

Trials Registered in ClinicalTrials.gov From 2006 Through 2014 by Year of Trial Start^a

Table 2

Year of trial start	Funding Agency, No. (%) ^f			
	Total No. of Trials ^b	National Institutes of Health	Industry	Other US Federal Agency All Others
2006	9208	1189 (12.9)	4516 (49.0)	229 (2.5) 3397 (36.9)
2007	10 275	1035 (10.1)	4950 (48.2)	265 (2.6) 4163 (40.5)
2008	11 650	1039 (8.9)	5359 (46.0)	278 (2.4) 5078 (43.6)
2009	12 507	1062 (8.5)	5469 (43.7)	300 (2.4) 5807 (46.4)
2010	12 903	1062 (8.2)	5325 (41.3)	311 (2.4) 6324 (49.0)
2011	13 514	949 (7.0)	5424 (40.1)	304 (2.2) 6955 (51.5)
2012	13 909	935 (6.7)	5135 (36.9)	290 (2.1) 7668 (55.1)
2013	14 221	951 (6.7)	5017 (35.3)	306 (2.2) 8084 (56.8)
2014	14 618	873 (6.0)	5274 (36.1)	292 (2.0) 8295 (56.7)
% Difference (95% CI) ^{d,e}		-6.9 (-7.7 to -6.2)	-13.0 (-14.2 to -11.7)	-0.5 (-0.1 to 0) ^f 19.9 (18.6 to 21.1)
Absolute difference, No. (%) ^e	5410 (58.8)	-316 (-26.6)	758 (16.8)	63 (27.5) 4898 (144.2)

^aData as of June 26, 2015.

^bOne trial may have more than 1 funding source.

^cUnless otherwise indicated.

^dComparisons yielded *P* values of <.001 unless otherwise indicated.

^eComparisons are between the year 2006 and 2014.

^f*P* = .01.