

# Contracts & Grants Q316 Award Report

## The boom in corporate clinical trials

### Summary

One of the most significant award funding trends of the past few years has been the dramatic increase in UC's corporate-funded clinical trial research projects. They have grown in number and dollar volume, and in their contribution to the University's research enterprise. During the last fiscal year, there were over 3,000 clinical trials underway at UC's medical centers, and about 85% of them were sponsored by corporations. Up through FY 2011-12, corporate sponsorship for clinical trials represented about 3% of UC's total award funding. That percentage has increased over the last four years, and for the first three quarters of the current fiscal year, corporate-funded clinical trials make up about 8.3% of the award total.

The final section of this Report details these changes in the clinical trial research segment, and suggests some of the factors responsible for this trend.

Other aspects of UC's award funding for Q3 of FY 2015-16 and for the fiscal year to date remain on much the same course as last year — thanks to stable federal agency appropriations for academic research and related projects, along with a reasonably robust economy. Award funding for Q316 was just over \$1.1 billion, which is 0.6% above Q315. The year-to-date total is about \$4.17 billion — \$140 million (3.4 percent) higher than the total for Q1-3 last year.

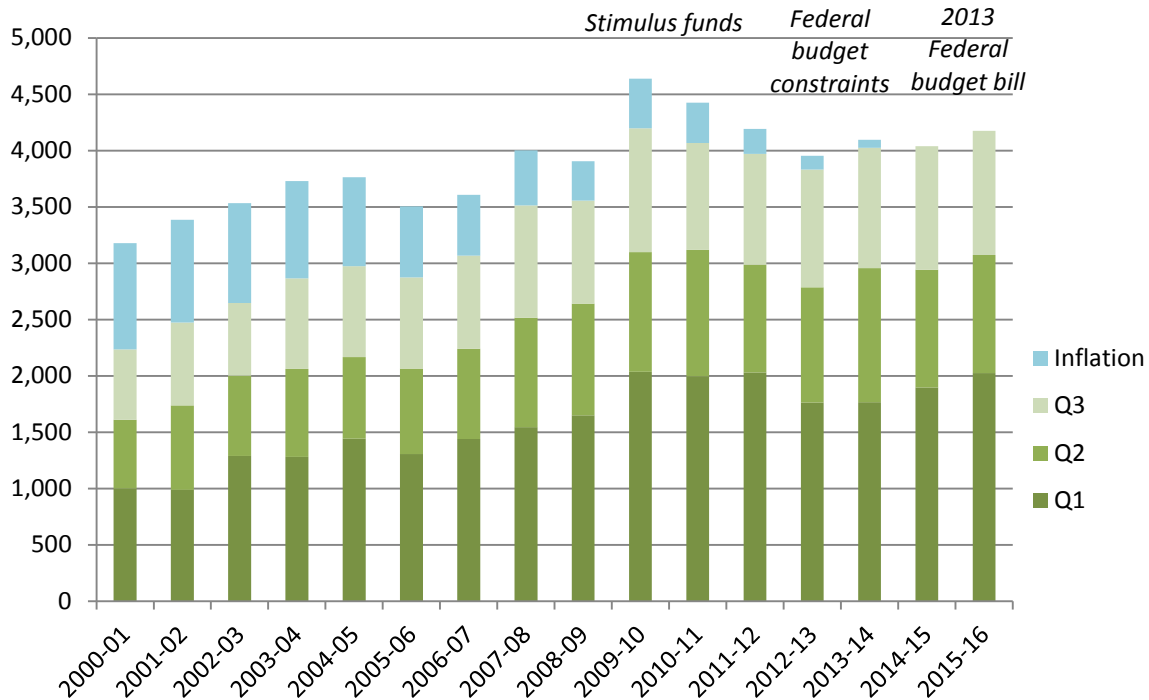
Atypically, this increase in funding over last year is not attributable to UC's federal agency sponsors. Generally, the pace of federal funding determines the progress for the year, because federal agencies are by far UC's largest source of sponsored projects. But this year, federal awards are actually about 1.6% below where they were last year. As this Report demonstrates, the increase in overall funding this year is due mainly to corporate funding, which at \$604 million so far this year is about 50% above 2014-15's year-to-date total, and already greater than the full-year total for last year. And clinical trials now represent a record 58% of corporate project funding.

Over the next several quarters, we are likely to see higher levels of federal funding, a consequence of the Bipartisan Budget Act of 2015 passed by Congress late last year. UC's largest single source of sponsored project funding, the National Institutes of Health, will award 6.6% more in research funding than it did in 2015; overall, federal agencies will have an additional 4.7% in appropriations to support academic research. However, the budget's impact is not yet visible because there is generally a review period averaging nine months between when a proposal is submitted and when an award is issued. Given this time lag, the increase in federal funding should begin to show up in Q416, continuing through next fiscal year and hopefully beyond.

## I. Quarterly award totals

Extramural award totals for the quarter and for the year to date are nearly identical to last year's amounts. Awards for Q316 totaled about \$1.1 billion, \$7 million (0.6%) above the amount reported last year for Q315. For the year to date, the award total is about \$4.175 billion, \$36 million or about 3.3% more than last year.

### Q1-Q3 Extramural Awards \$ millions, inflation-adjusted



### Quarterly Extramural Awards \$ millions, inflation-adjusted

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Q1	1,420	1,351	1,722	1,667	1,824	1,592	1,693	1,759	1,812	2,250	2,173	2,143	1,819	1,796	1,896	2,025
Q2	869	1,026	952	1,014	916	927	943	1,107	1,088	1,174	1,218	1,012	1,056	1,211	1,047	1,048
Q3	888	1,008	860	1,047	1,023	985	971	1,135	1,004	1,214	1,032	1,037	1,078	1,086	1,095	1,102
Q4	1,067	1,222	1,337	1,243	1,489	1,492	1,529	1,588	1,518	1,519	1,440	1,445	1,416	1,712	1,693	
FY	4,245	4,607	4,871	4,971	5,252	4,996	5,136	5,589	5,422	6,157	5,864	5,637	5,370	5,805	5,731	4,175

Award totals for UC's third fiscal quarters are always well below the first-quarter amounts. This is a function of the federal funding cycle, which awards the largest amounts in the final quarter of the federal fiscal year (corresponding to UC's Q1). With direct federal sponsorship providing about two-thirds of all UC's awards, this produces sharp quarterly spikes in funding.

## II. Award trends by sponsor category

The most significant difference between Q316 award totals and Q315 is the sharp increase in corporate funding. The other major sponsor categories are all lower than they were last year.

**Q3 Awards by Sponsor Category, FY 2006-07 to 2015-16**  
(\$ millions, inflation-adjusted)

SPONSOR	Q307	Q308	Q309	Q310	Q311	Q312	Q313	Q314	Q315	Q316
<i>Federal</i>	514	594	514	714	558	580	455	568	561	523
<i>State</i>	59	67	106	73	105	66	153	53	79	54
<i>Other Gov't*</i>	18	33	46	34	39	28	23	43	22	25
<i>Corporate</i>	126	145	88	116	104	128	140	173	126	218
<i>Non-Profit</i>	136	182	142	139	125	108	187	131	177	157
<i>Academia**</i>	118	115	110	139	102	128	122	118	131	125
<b>TOTAL</b>	<b>972</b>	<b>1,135</b>	<b>1,005</b>	<b>1,215</b>	<b>1,033</b>	<b>1,037</b>	<b>1,079</b>	<b>1,086</b>	<b>1,095</b>	<b>1,102</b>

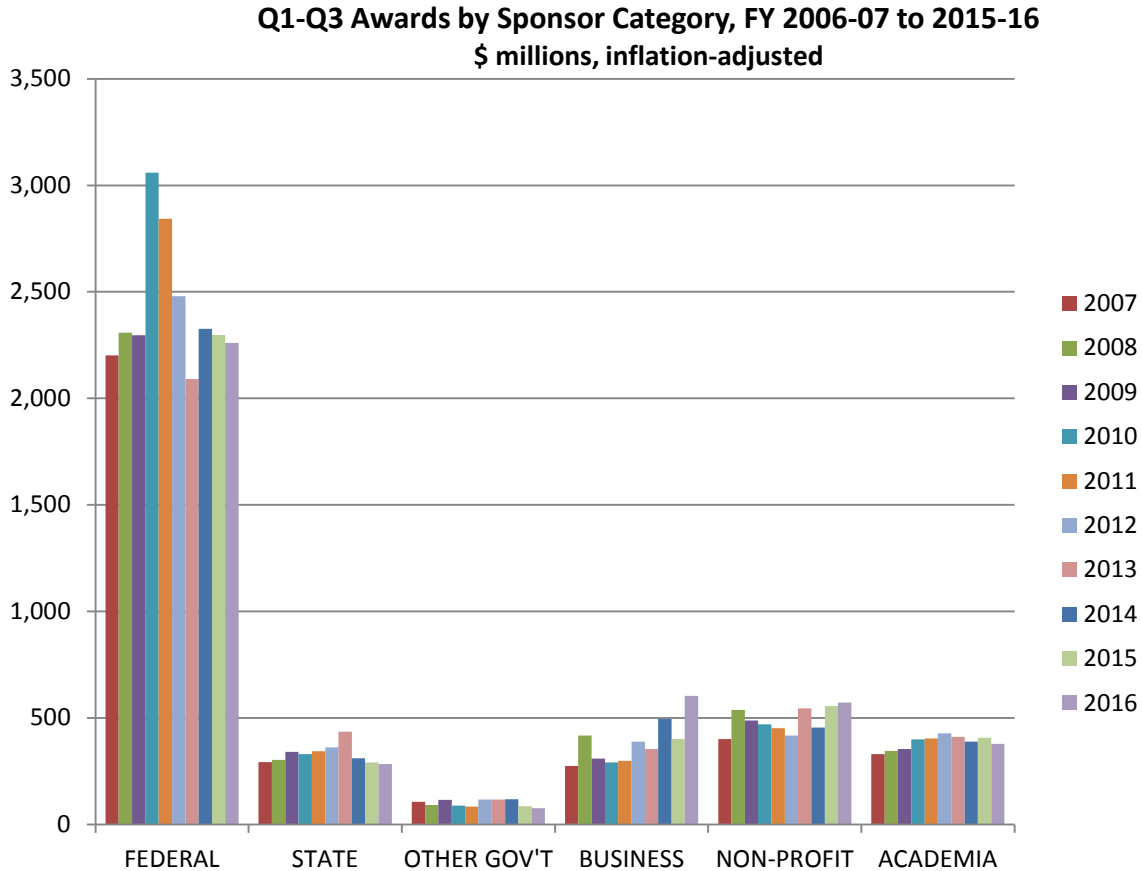
Fiscal-year-to-date comparisons provide a better sense of funding trends than just a single quarter part-way through the federal funding cycle. The table below shows the large increases in federal funding during 2010-11 and 2011-12 provided by the Recovery Act, which added about one billion dollars to UC's award total. This was followed in 2012-13 by a year of federal agency austerity, when federal and total funding dropped to pre-recessionary levels, after inflation is taken into account. Sponsorship by corporations and nonprofit organizations also show significant yearly variations, which are often driven by a small number of very large awards.

**Q1- Q3 Awards by Sponsor Category, FY 2006-07 to 2015-16**  
(\$ millions, inflation-adjusted)

SPONSOR	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
<i>Federal</i>	2,202	2,308	2,296	3,059	2,843	2,480	2,090	2,327	2,297	2,260
<i>State</i>	292	302	340	330	343	361	436	311	292	283
<i>Other Gov't*</i>	107	91	116	89	84	117	118	118	86	77
<i>Corporate</i>	275	418	309	291	298	389	354	495	401	604
<i>Non-Profit</i>	400	537	487	470	452	417	544	454	556	572
<i>Academia**</i>	331	344	355	399	403	427	412	388	407	378
<b>TOTAL</b>	<b>3,607</b>	<b>4,001</b>	<b>3,904</b>	<b>4,639</b>	<b>4,424</b>	<b>4,192</b>	<b>3,954</b>	<b>4,093</b>	<b>4,038</b>	<b>4,174</b>

\* Other Gov't includes Agricultural Market Order Boards.

\*\*Academia includes the categories of Higher Education, DOE Labs, Campuses and UCOP.



### III. Award trends by project type

Awards for research during Q316 amounted to \$812 million, plus \$137 million in clinical trial sponsorship, or \$949 million for all types of research. Research award totals during Q315 were quite similar, at \$926 million. Training, service and other awards came to about \$153 million.

**Q3 Award Amounts by Project Type, FY 2006-07 to 2015-16**  
\$ millions, inflation-adjusted

PROJECT TYPE	Q307	Q308	Q309	Q310	Q311	Q312	Q313	Q314	Q315	Q316
Research	803	896	768	953	809	832	811	864	856	812
Clinical Trials	47	46	41	54	35	62	130	79	59	137
Training	31	62	38	55	68	50	37	43	42	44
Service	46	67	93	64	79	48	47	59	92	72
Other	43	64	64	89	42	45	53	41	46	38
<b>TOTAL</b>	<b>972</b>	<b>1,135</b>	<b>1,005</b>	<b>1,215</b>	<b>1,033</b>	<b>1,037</b>	<b>1,079</b>	<b>1,086</b>	<b>1,095</b>	<b>1,102</b>

#### IV. Significant awards to UC locations

During Q316, UC received about 6,750 contracts and grants from over 1,750 different sponsors (in addition to more than 1,300 Material Transfer Agreements). Listed below are the large or significant awards reported this quarter by campuses, Agriculture & Natural Resources, and Lawrence Berkeley National Lab.

LOCATION	SPONSOR CATEGORY	SPONSOR	PROJECT TITLE	AMOUNT
Agriculture and Natural Resources	Federal	United States Geological Survey	Identification of Seasonal and Decadal Drought Through Monitoring and Modeling	1,766,557
Berkeley	Corporate	Aduro Biotech	Master Collaborative Research Agreement	7,500,000
Davis	State	California Department of Food And Agriculture	Operation of the South Valley Health Laboratory in Tulare, California	16,048,589
Irvine	Corporate	Inc Research, LLC	Clinical Trial of Investigational Drug GDC-0032 in Patients with Locally Advanced or Metastatic Solid Tumors Or Non-Hodgkin's Lymphoma	6,356,700
Lawrence Berkeley Lab	Nonprofit	Howard Hughes Medical Institute	Operation of HHMI Biological Crystallography Beamline	1,392,526
Los Angeles	Federal	National Cancer Institute	Cancer Center Support Grant	4,295,192
Merced	Federal	U.S. Small Business Administration	UC Merced Small Business Development Center Regional Network Proposal	1,524,382
Office Of The President	Federal	Office of Postsecondary Education	California Gear Up III	5,000,000
Riverside	Federal	National Institute for Food and Agriculture	Effectormics of the Huanglongbing HLB-Associated Pathogen	3,990,772
San Diego	Federal	National Institute on Aging	Alzheimer's Disease Cooperative Study	10,006,406
San Francisco	Federal	Centers for Disease Control and Prevention	Supporting High Quality HIV Prevention, Care and Treatment Activities at Facility And Community Level in the Republic of Kenya Under the President's Emergency Plan for Aids Relief (PEPFAR)	9,973,601
Santa Barbara	Business	Simpson and Simpson Business and Personnel Services, Inc.	San Onofre Nuclear Generating Station Mitigation Project Monitoring Program, 2016-2017	5,362,124
Santa Cruz	Nonprofit	Heising-Simons Foundation	Paleo-Community Earth Systems Model (P-CESM): A Model for Exploring Deep Time Climates to Further Our Understanding of Earth's Future	1,264,273

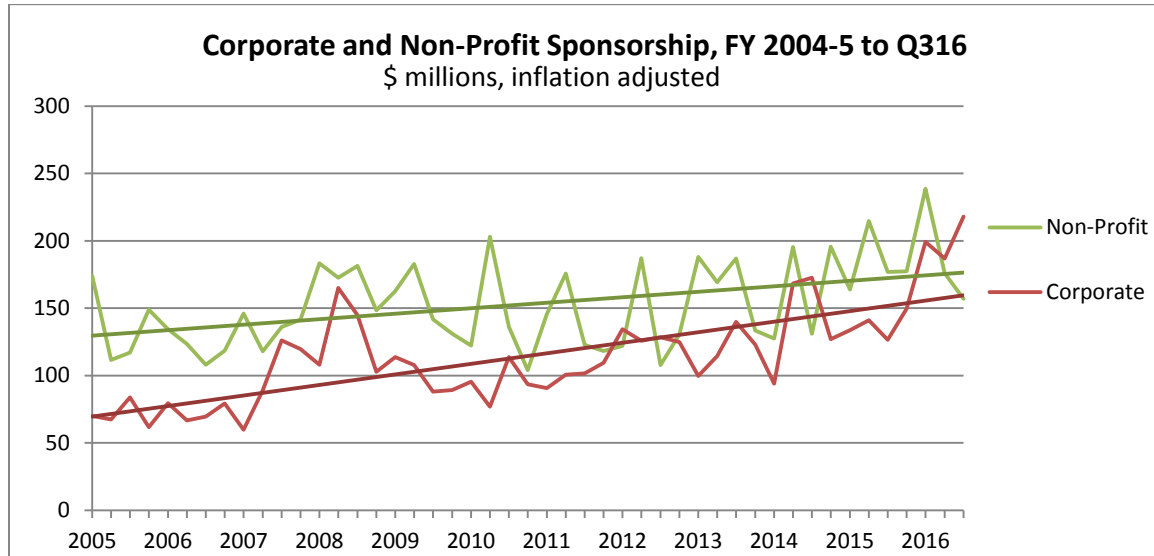
#### V. Award trends by recipient location

Award totals for the first three quarters of FY 2015-16 are running 3.4% above last year. This increase was not evenly divided across reporting locations, with several of the smaller campuses showing declines from last year.



## VI. Private funding

While awards from both corporate and non-profit sponsors display much variation quarter by quarter, both sponsor categories show long-term increases.



Quarterly spikes in corporate and nonprofit funding are most often the result of a few extremely large research contracts, or even a single mega-award. For the fiscal year to date, however, the increase in corporate funding that began in the middle of last year appears to be a broadly based increase in the number and intensity of UC's corporate partnerships. If this trend continues, 2016 could be the first year that corporate sponsorship exceeds funding from non-profit organizations.

## VII. The boom in corporate clinical trials

Much of the increase in UC's corporate funding reflects the larger number and growing budgets of the corporate-sponsored clinical trial research projects conducted by UC Health. Corporations have historically played an important role in funding UC's research enterprise, and the last few years have seen an increase in both the dollar amount and relative share of corporate funding.

### Corporate sponsorship, % of UC award total

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016 Q1-3
\$ millions*	295	395	521	399	386	410	514	477	561	551	604
% UC Total	5.9%	7.7%	9.3%	7.4%	6.3%	7.0%	9.1%	8.9%	9.8%	9.6%	14.5%

\* All amounts are adjusted for inflation. For this analysis, totals include several recent deobligations of clinical trial awards, although for contractual reasons they will not be reported until FY 2017.

Corporate funding for just the first three quarters of 2015-16 already exceeds the amounts received in any previous full fiscal year, and much of the growth over the past few years has been fueled by the increase in corporate-funded clinical trials.

Corporations fund close to 85% of all the clinical trial projects conducted at UC, and funding for clinical trials represents a growing share of the University's corporate project sponsorship.

#### Clinical trial awards, % of corporate award total

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016 Q1-3
<b>\$ millions</b>	127	156	202	166	161	150	202	210	286	285	348
<b>Corporate %</b>	42.9%	39.5%	38.8%	41.5%	41.7%	36.7%	39.3%	43.9%	51.0%	51.7%	57.6%

Up until 2014, clinical trial awards represented roughly 40% of UC's corporate funding total. Over the past three years, this proportion has risen sharply and is now nearly 58% of the total for the first three quarters of the current fiscal year. The increase in corporate clinical trial award totals over the past three years is broadly based, rather than the product of a few very large awards. Compared to 2013 and previous years, not only has the number of awards increased, along with the average clinical trial award amount, but the number of sponsors providing these awards has grown larger as well.

#### Clinical trial awards: counts, average values and number of sponsors\*

Year	2013	2014	2015	2016, Q1-3
<b># of awards</b>	937	1,018	1,115	1,005
<b># of sponsors</b>	335	370	415	455
<b>Average award</b>	\$218,335	\$276,972	\$256,899	\$347,961

\* Award counts exclude deobligated awards, adjustment records and zero-dollar continuations. All amounts are adjusted for inflation.

Some portion of the increase in the number of different sponsors funding clinical trials each year is due to the rise of Clinical Research Organizations (CROs) — businesses that undertake the management and oversight of clinical trials for large pharmaceutical companies and medical equipment manufacturers. The great majority of the additional sponsors, however, are not management organizations but principals.

The economic forces behind this boom in UC's clinical trial research are not difficult to identify. Health care represents an ever larger component of virtually every national economy, and this drives innovation for the development of new therapies, diagnostics and medical equipment. These innovations can only come to market after they have been subjected to clinical trials demonstrating, to the satisfaction of regulatory agencies, that the new treatments and methods are both safe and effective. This requirement sets the stage for long-term partnerships between hospitals with strong research capabilities and pharmaceutical companies and medical device manufacturers with new products under development.

The recent expansion of UC Health, in terms of staffing, infrastructure, patient diversity and research capability, makes UC medical centers desirable partners in helping to bring new therapies and treatments to market.

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