

UC-wide Biomedical Research Acceleration Initiative
October 8, 2010

CONTRACTING

Working Group

Gary Firestein, UCSD

Clay Johnston, UCSF

CONTRACTING Working Group

- UC Davis
 - Rafael Gacel
 - Ahmad Hakim-Elahi
 - Erick Jenkins
- UC Irvine
 - Jacob Levin
 - Madeline Pahl
 - Bruce Morgan
- UCLA
 - Meghan Brennan
 - Mike Bunnapradist
 - Helene Orescan
 - Lillian Smith
- UCSD
 - *Gary Firestein*
 - Tony Perez
- UCSF
 - *Clay Johnston*
 - Erik Lium
 - Teri Melese
 - Melanie Funes

Laying the Groundwork

Current UC Contracting Landscape

- For industry:
 - Major barrier to partnerships
 - Particularly for multisite studies
- For investigators:
 - Cumbersome and time consuming
 - Process significantly delays the start of trials
- Major delays in contracting
 - Financial implications
 - Shortens participant recruitment time
 - UCSF study: From initiation of negotiation to full contract execution mean delay of **46+/-27days**

UC Coordination So Far

What has happened so far...

- Staff support
 - UCOP allocated a portion of 1 FTE to the following:
 - UC-wide MTAs
 - Industry contracts and grants for clinical trials
 - Master clinical trial agreements
 - Internal coordination of UCOP resources
 - Expansion of this role is critical
- Existing Master Agreements and MTAs
 - Master clinical trial agreements exist with several companies
 - Standard MTAs also established with some

Top Industry Sponsors of Clinical Trials FY2008-2009

	Sponsor	# of Studies	Funding Amount	MTA Status	Clinical Trials Agreement Status
1	ROCHE/GENENTECH	26	\$6,230,104	UCSF	Genentech - UC-Wide - Sponsor Initiated
				UCSF	Roche - UC-Wide - Sponsor Initiated
2	PFIZER	19	\$4,293,602		UC-Wide - Sponsor Initiated
3	NOVARTIS	10	\$2,683,266	UCSF only	UC-Wide - Sponsor Initiated
4	AMGEN	9	\$2,154,431	UC-Wide template	UC-Wide - Sponsor Initiated
5	SCHERING-PLOUGH CORPORATION	7	\$1,248,806		UC-Wide - Sponsor Initiated
6	ACTELION	6	\$1,537,564		UCSD (Template)
7	BAYER	6	\$1,040,361		UC-Wide - Sponsor Initiated (Template)
8	BIOGEN IDEC	6	\$790,114		UC-Wide - Sponsor Initiated
9	JOHNSON&JOHNSON	5	\$1,269,925		UC-Wide - Sponsor Initiated EXPIRED
10	WYETH	5	\$1,087,419		UC-Wide - Sponsor Initiated (Template)
11	MERCK	5	\$671,674	UC-Wide	UC-Wide - Sponsor Initiated
12	ASTRAZENECA	5	\$309,483		UC-Wide - Sponsor Initiated
13	ELI LILLY	4	\$901,818		UC-Wide (biomed) - Sponsor Initiated
14	ABBOTT LABORATORIES	4	\$633,631		UC-Wide - Sponsor Initiated
15	CHILTERN INTERNATIONAL LIMITED	4	\$451,135		
16	ASTELLAS PHARMA	4	\$335,295		UC-Wide - Sponsor Initiated
17	INTERMUNE PHARMACEUTICALS	3	\$1,057,938		UCSD (Template; UCSF (Template)
18	UNITED THERAPEUTICS CORP.	3	\$770,693		
19	LIFECYCLE PHARMA	3	\$628,482		
20	MEDTRONIC	3	\$564,828		UCSF (Template)
21	SHIRE	3	\$555,802		UCSD (Template)
22	SANOFI-AVENTIS GROUP	3	\$524,629		UC-Wide - Sponsor Initiated (Template)
23	GLAXOSMITHKLINE	3	\$516,360	UCSF	UC-Wide - Sponsor Initiated
24	VERTEX PHARMACEUTICALS	3	\$505,844		
25	RIGEL	3	\$356,902		
26	BIO-RAD LABORATORIES	3	\$68,092		

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Recommendations

Master Agreements for Industry-Sponsored Clinical Trials

- **Problem:** Several major industry sponsors of clinical trials must negotiate each time they engage with a campus for a new trial
- **Establish:** UC-wide Master Agreements for top companies (increase active by 5 new this year)
 - **Develop:** Goals and Timeline for this effort
 - Put resources (funding and staff) toward these goals
 - **Develop:** Information Gathering System

Clause Library

- **Problem:** Contracting in its current state is a handicraft as opposed to being a scalable endeavor
- **Develop:** UC-wide Clause Library
 - Develop a prototype clause library – UC Irvine
 - UC Irvine to convene the broader group and pilot in Spring 2011

Systemwide Training Program

- **Problem:** Staffing stability is a major factor in the success of a contract negotiation
 - Core consistent population of well trained staff is difficult to maintain
- **Develop:** Systemwide training program
 - Campuses are excited about collaboration
 - Partner as system on curriculum
 - SOPs
 - CTA negotiations
 - Language
 - Partner locally on delivery
 - Online training model with cadre of mentors

Developing Metrics

- **Problem:** Need data on contributors to delays in contract negotiations in order to improve business processes
- **Develop:** UC-wide Metrics
 - Create a Metrics working group
 - Develop process and organizational metrics that all institutions agree to track and report
 - Use CTSA metrics as a model and evolve them
 - Deploy a simplified system for tracking at two or more institutions
 - Learn from prototype dashboarding efforts at campuses

Material Transfer Agreements

- **Problem:** MTAs can be problematic, lacking process consistency from campus to campus
- **Establish:** Single MTA office
 - At each campus and for the University
- **Define:** Broader use of UBMTA
 - Campuses apply UBMTA differently
- **Develop:** MTA Standards and Rules
 - Systematizing MTAs across campuses

Information Sharing – Contracts Database

- **Problem:** Most contracts are re-worked from scratch
 - This is inefficient
 - Learning about what terms were negotiated previously could expedite new contracts with a sponsor
- **Develop:** UC-wide Contracts Database
 - Centralized repository of contracts
 - System must be easy to use and secure
 - Searchable to find companies, terms, types of studies
 - No recrimination between campuses and UCOP
- **Demo:** UCSF Contracts Database
 - Erik Lium, UCSF

In Summary....

SUMMARY

- Proactively establish UC-wide Agreements with Top Industry Sponsors of Clinical Trials
- Standardize UC-wide MTA process and procedures
- Establish a UC-wide clause library
- Establish a systemwide training program
- Develop Metrics
- Establish a UC-wide Contracts Database

THANK YOU

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	ADDITIONAL COMPANIES OF INTEREST				
	GILEAD SCIENCES, INC.	2	\$497,780		negotiations terminated
	BOEHRINGER INGLEHEIM	1	\$397,940		not interested in working on a master
	TEVA	1	\$242,336		UC-Wide - Sponsor Initiated
	CELGENE CORPORATION	1	\$231,176		UCSF only
	GENZYME CORPORATION	1	\$99,498		UC-Wide - Sponsor Initiated
	IMCLONE				Individual campuses - Sponsor Initiated
	MILLENIUUM				UC-Wide - Sponsor Initiated