

UNIVERSITY of CALIFORNIA

## Clinical Trial Contracting at UC

Achievements, Obstacles and Goals

UC BRAID Retreat  
September 14, 2012  
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## Agenda

- Achievements
  - Training
  - Communication across the system
  - Agreements
- Obstacles to Negotiation
  - UC policies vs. industry practices and policies
- Goals for 2012-2013
  - More master agreements
  - Improve relationships with certain companies
  - Improve communication across UC

## Achievements: Training

- Developed comprehensive, 11-module training program for clinical trial negotiators across UC
- Covers:
  - Overview of phases of clinical trials, classes of devices
  - Laws and regulations
  - UC's policies
  - Negotiation do's and don'ts of clinical trial agreements

## Achievements: Greater Communication and Collaboration

The screenshot displays a website dashboard with several key sections:

- Policy Guidance:** UC policies, federal and state regulatory updates to clinical trials, and a list of regulations at UC.
- Training Materials:** Training modules and a link to read more.
- Sponsors:** List of current sponsors of clinical trials at UC.
- Master Agreements and Templates:** Final, executed Master Agreements between UC and CT sponsors, with a link to read more.
- Current Ongoing Negotiations:** Commitment to fully complete track on pending negotiations with sponsors, with a link to please update regularly.
- Discussion Board:** Archive of current and past discussions on various issues related to CTAs, with a link to please participate.
- Calendar:** CT negotiator monthly calls to discuss meetings and other relevant events, including training, releases, and opportunities, with a link to submit.
- Fund-In-Person Meetings:** Meeting materials and presentations from the October 2011 meetings, with a link to submit slide meetings in 2011-2012.
- Recent Agreements:** Master Agreements currently in negotiation, with a link to view details. The table shows the following agreements are currently being negotiated by UCSP:
  - Health-care sponsor related CTA
  - Diagnostic Equipment related to CTAs related CTA
  - Non-Medicinal sponsor related CTA
  - Abbreviated substance master sponsor related CTA related CTA
- B2B Funds:** FDA Drug Info Resources, Communicating drug safety messages, Drug Shortages Index, Clinical Index, Protein Pump Inhibitors (PPI) Index, and Long-Acting Insulin Agreements (LAI) Index.
- News and Events:** The Pharmaceutical Exchange Index project, Right to Life issues, and an effort from LSI pharmaceuticals to educate Medicare beneficiaries about their benefits, with a link to read more.

## Achievements: Greater Communication and Collaboration

- Sharepoint site
  - Discussion board
  - Agreements in negotiation
  - Resources
- Working groups
  - Budgeting
  - Device Trials

## Achievements: Agreements (9/2011 - 9/2012)

- Abbott
- Allergan
- Bayer
- AstraZeneca
- Gilead
- Merck
- Novartis
- Pfizer
- Pharmacyclics\*

## Obstacles to Agreements

- Not negotiating directly with decision-makers
  - CROs: will often not honor terms of masters
- Negotiation of contract AND budget
- Study team completion of paperwork
- Demands of sponsors vs.:
  - Legal obligations (as a research site, public institution)
  - Principles and policies of the University
  - Realities of UC as a large, public institution

## Obstacles to Agreements: Sponsor Demands vs. UC Legal/Accreditation Requirements

Sponsor Demands	UC's Obligations
Keep terms of the agreement, budget, etc. confidential	UC must disclose public records, unless exempt under law
Access to protected health information	Access must comply with federal and state law
IP extending beyond performance of the study	Bayh-Dole, UC's obligations to other research funders
No notification of adverse events following study closure, no access to study records provided to Sponsor following study	Must have access to records post-study; accreditation requires notification of adverse events following study closure

## Obstacles to Agreements: Sponsor Demands vs. University Policies and Principles

- *The goals of our policies:*
  - To promote research
  - To make advances available to the public
  - To leave the subject in no worse position (physical or financial) for participating in the research

## Obstacles to Agreements: Sponsor Demands vs. University Policies and Principles

Sponsor Demands	UC Policies and Principles
No payment for subject injury	Policies require reimbursement for injuries that directly result from studies
Ownership of raw data	UC must own raw data
Right to edit publications	UC and its researchers must have control over publication
Everything related to the study must be kept confidential	Confidentiality terms cannot interfere with publication rights; principle of open academic environment
No "related" research	Research of one investigator cannot affect the research of another
Will only register study as required by federal law	ICMJE registration guidelines

## Obstacles to Agreements: UC is a large public research institution

Sponsor Demands	UC Constraints
Restricted use of biological samples	Lack of funds and mechanisms to restrict use
Present assignment of intellectual property	UC needs the paper trail, to record existence of invention and assign to proper party
No start up costs, no overhead for certain services	UC will incur a loss if these charges are not assessed
Withholding all payment until data queries are resolved to sponsor's satisfaction	UC needs payment for expenses properly incurred and work performed

## Goals

- More master agreements
  - Abbott device subsidiaries
  - Alvine
  - Biogen Idec
  - Boehringer Ingelheim
  - Celgene
  - Cook
  - Merck
  - Medtronic
  - Otsuka

## Goals

- More master agreements
- Improve relationships with key companies
  - Example: Johnson & Johnson
    - Address each party's concerns regarding:
      - Data and IP ownership
      - Research restrictions
      - Scope of confidential information
      - Subject injury and indemnification
  - External RPAC website

## Goals

- More master agreements
- Improve relationships with key companies
- Improve communication across UC
  - Campus to Campus:
    - More advanced training
    - SharePoint, work groups
    - Single system-wide database?

## Contract Repository

UC CONTRACT REPOSITORY

SEARCH | URLS | SUPPORT | ADMIN

Ref. ID:

Campus:

Negotiator:

Activity Type: 

- Confidential Disclosure Agreement
- Equipment Lease Agmt
- Equipment Loan Agmt
- Federal

(hold <Ctrl> to select multiple)

Sponsor/Funder:

(This field searches both Funder and Prime Funder)

Contract Status:  Executed  Abandoned

Date Executed: From:  To:

Keyword:

## Goals

- More master agreements
- Improve relationships with key companies
- Improve communication across UC
  - Negotiator to PI, PI to Negotiator:
    - Knowledge of PI's communications with sponsor
    - PI training?
    - Others?

## Thank You

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