CONTRACTING

Fall 2011 UC BRAID Retreat

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Participants

- **UC Davis**
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- **UC Irvine**
  - Jacob Levin
  - Bruce Morgan
  - Madeline Pahl

- **UCLA**
  - Bishoy Anastasi
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  - Mike Bunnapradist
  - Helene Orescan
  - Brian Roe

- **UCSD**
  - Gary Firestein (CO-Chair)
  - Tony Perez

- **UCSF**
  - Clay Johnston (Chair)
  - Melanie Funes
  - Erik Lium
  - Teri Melese
  - Susan Shih
  - Irene Shin

- **UCOP**
  - Jeff Hall
  - Hillary Kalay
  - Dragana Nicolajevic
UC BRAID-Contracting within the UC Landscape

- Why are we here?
  - Forum that includes end-users
  - Strategic recommendations
  - Reinforce benefits of cooperation
  - Encourage new technologies/approaches
  - Focus on acceleration and innovation
Year 1

Goals and Objectives
GOAL: Accelerate Research Contracting at UC

1. Support efforts to increase Clinical Trial Master Agreements
2. Develop a Pilot Shared Database of Contract Terms
3. Support development of a Shared Clause Library
4. Plan a UC-wide Training Program for Contracting
5. Coordinate standardization of Material Transfer Agreements (MTAs)
6. Establish and Track Contracting Metrics
YR01 Work and YR02 Plans

Year 1: Accomplishments

Year 2: Goals
**Problem:** Industry sponsors of clinical trials must negotiate each time they engage with a campus for a new trial

**YR01 Goal:** Increase active CTAs (5 new)

**Accomplishment:**
- 5 New Master CTAs
- 2 in negotiation
Clinical Trials Agreements (CTAs)
LEADS: Jeff Hall, Hillary Kalay, Dragana Nicolajevic (UCOP)

YR02 Goals:
- Continue increasing Master CTAs (5/yr)
- Resolve issues, work through clauses, develop range of options for troublesome sponsor
  - Boehringer Ingelheim
  - Johnson & Johnson
  - Gilead
- Increase Master Confidentiality Agreements
UC-wide Contracts Database
LEAD: Erik Lium(UCSF)

**Problem:** Most contracts are re-worked from scratch, this is inefficient

**YR01 Goal:** Develop Pilot Contracts Database
- Easy to use centralized repository of contracts
- Searchable to find companies, terms, types of studies

**Accomplishment:** Pilot Database Created

**YR02 Goals:**
- Establish definitions
- Evaluate implementation at each campus
- Encourage deployment at each campus
Problem: Contracting in its current state is a handicraft as opposed to being a scalable endeavor.

YR01 Goal: Support development of a Clause Library

Accomplishment: Prototype Clause Library
- Prototype expected in December 2011

YR02 Goals:
- Prototype testing
- 2nd version created
Clinical Trial Negotiators Training
LEAD: Hillary Kalay (UCOP)

- **Problem:** Staffing stability is key in contract negotiation

- **YR01 Goal:** Plan a Training Program

- **Accomplishment:** Online Training Program
  - Interactive modules
  - Content includes:
    - Clinical Trials
      - Definition/types
      - components
      - distinction between phases
    - Regulating Bodies
    - Drugs and Devices
    - Contracting
      - UC principles
      - negotiating a CTA

- **YR02 Goal:** Online Training Program
  - Wide adoption of training program
Standardizing MTAs
LEAD: Gary Firestein (UCSD)

- **Problem:** MTAs can be problematic, lacking consistency from campus to campus

- **YR01 Goals:**
  - Establish a single MTA office at each campus
  - Define broader use of UBMTA
  - Develop MTA Standards systematizing across campuses

- **Accomplishment:** UC-wide agreement to use the UBMTA template as the default

- **YR02 Goals:** Mission Accomplished – Effort Retired
**Developing Metrics**

LEAD: Erik Lium (UC Davis)

- **Problem:** Need data on contributors to delays in contract negotiations in order to improve business processes

- **YR01 Goals:** Create Metrics Working Group
  - Develop UC-wide process and organizational metrics
  - Use CTSA metrics as a model

- **Accomplishment:** UC BRAID Metrics Working Group

- **YR02 Goal:**
  - Set goal for Contracting component of Metrics
Year 2

New Efforts
Faculty Research Consulting
LEAD: Clay Johnston (UCSF)

• **Problem:** Consulting for industry can lead to:
  ◦ FACULTY: conflict of interest and compliance issues
  ◦ UNIVERSITY: limits on future participation in clinical trials
  ◦ INDUSTRY: complicated process

• **YR02 Goals:** Faculty Research Consulting Program

• Create a Template and SOPs for implementation
  ◦ protect faculty from unknowingly conflicting themselves
  ◦ maximize University’s opportunity to participate in industry-sponsored clinical trials
  ◦ provide resources to the University research community and companies in support of consulting engagements
Thank You

Questions?