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 \(46+/-27\) days
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
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CONTRACTING Working Group 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
**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
## Top Industry Sponsors of Clinical Trials FY2008-2009

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### ADDITIONAL COMPANIES OF INTEREST

- **GILEAD SCIENCES, INC.**
  - # of Studies: 2
  - Funding Amount: $497,780
  - MTA Status: UCSF
  - Clinical Trials Agreement Status: negotiations terminated

- **BOEHRINGER INGLEHEIM**
  - # of Studies: 1
  - Funding Amount: $397,940
  - MTA Status: UCSF only
  - Clinical Trials Agreement Status: not interested in working on a master

- **TEVA**
  - # of Studies: 1
  - Funding Amount: $242,336
  - MTA Status: UC-Wide - Sponsor Initiated
  - Clinical Trials Agreement Status: UC-Wide - Sponsor Initiated

- **CELGENE CORPORATION**
  - # of Studies: 1
  - Funding Amount: $231,176
  - MTA Status: UCSF only
  - Clinical Trials Agreement Status: UC-Wide - Sponsor Initiated

- **GENZYME CORPORATION**
  - # of Studies: 1
  - Funding Amount: $99,498
  - MTA Status: UCSF only
  - Clinical Trials Agreement Status: UC-Wide - Sponsor Initiated

- **IMCLONE**
  - # of Studies: 1
  - Funding Amount: $1,537,564
  - MTA Status: UCSF only
  - Clinical Trials Agreement Status: Individual campuses - Sponsor Initiated

- **MILLENIUM**
  - # of Studies: 1
  - Funding Amount: $16,000
  - MTA Status: UCSF only
  - Clinical Trials Agreement Status: UC-Wide - Sponsor Initiated