University of California
Center for Accelerated Innovation

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April 6, 2015
Outline

• CAI overview and introduction
• RFA and important dates
• Selection process
• Pre-application
• Finding help
CAI Overview

• Five UC medical campuses
  – Davis, Irvine, LA, San Diego, San Francisco

• One of three centers nationally
  – Harvard, Cleveland Clinic

• Overarching purpose:
  – Translate basic science advances and discoveries into commercially viable products for:
    • heart, lung and blood disease patients
    • treatment of Substance Use Disorders (SUDs)
UC Biomedical Research Acceleration Integration and Development (UC BRAID)

- IRB Harmonization
- Master Contracting
- Federated Research Data Repositories
  - Harmonizing Biobanking
- Discoveries-to-Products
  (UC Center for Accelerated Innovation)
  - 13 Million Patients
Governance

External Selection Committee

Executive Committee

Center Director

Associate Director

Business Review Panel

Skills Development Program

External Advisory Board

Domain/ Site Leaders

Domain Areas

Substance Use Disorders

Projects

Therapeutics

Diagnostics

Devices

Cardiovascular

Lung & Sleep Disorders

Blood Diseases

Domain/ Site Leaders

Program Resources

Administrative & Budgetary Support

Website & Data Management

Project Management

Industry Relations & IP

CTSA Infrastructure

Evaluation & Tracking

Executive Committee

Associate Director

Business Review Panel

Skills Development Program

External Advisory Board
Goals

Goal 1

- Engage University of California research innovators in entrepreneurship through a comprehensive education, training and mentorship program.
Goals

Goal 2

• Solicit and select technologies with high commercial potential that align with NHLBI or NIDA’s mission and address unmet medical needs or significant scientific opportunity.
Goals

Goal 3

• **Incubate** our most promising technologies in accordance with industry requirements to facilitate their translation to commercial products that improve patient care and enhance health.
Goals

Goal 4

• Create a high-performing, sustainable infrastructure that will serve as a model to academic research centers.
Technology Development Process

Technology Enters Center → Project Design → Project Plan → Product Development → Licensing → Exit Center

- Project Design Team
- Project Management Team
Exit Strategies

Development at the Center
- Continued evaluation by Center leadership
- Project aborted by PI
- Further management by Technology Transfer Office

Exit Processes
- Licensing
- Company formation
- Licensing not achieved

Development Outside the Center
- Review by Technology Transfer Office
- Low future interest
- Return IP
- High future interest
- Further incubation or marketing
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Eligibility

- Faculty in all series and ranks at UC Davis, UC Irvine, UCLA, UC San Diego, and UC San Francisco
- Postdoctoral scholars are eligible to submit applications as Co-PI with a faculty PI
- Projects within NIDA’s mission with clear potential for significant improvement over current treatments, diagnostics, devices, tools or services
- Therapeutic projects with existing or imminent target validation and a clear clinical indication
- Patents or patent applications are filed or potential for obtaining defensible intellectual property is strong
Solicitation Process

• Broad solicitation
  – Focus on NIDA priority areas
    • Discovery and development of medications for the treatment of SUDs stemming from tobacco, cannabis, cocaine, methamphetamine, heroin, or prescription opiate use. Multiple therapeutic approaches, ranging from small molecules to biologics (e.g., vaccines) are eligible.
    • Technologies or formulations to improve medication delivery and/or to deter drug abuse.
    • Tools to streamline drug design and preclinical development for SUD.
    • Novel patient adherence monitoring (systems and devices) at the point of care in clinical trials.
    • Technologies and tools with high potential of becoming commercially viable products designed to better inform the diagnosis and treatment of SUD.

• Centralized online RFP for all 5 campuses
RFA and Online Pre-App Submission

http://uccai.ctsi.ucla.edu

NEW UC CAI FUNDING OPPORTUNITY!! TECHNOLOGY DEVELOPMENT AWARD FOR SUBSTANCE USE DISORDERS

UC CAI Request for Applications Now Available
Pre-applications submission period is
April 6 - 13, 2015

Read the RFA

UC CAI anticipates awarding up to three Technology Development Grants worth up to $200K each in grant and local support for:

- Discovery and development of medications for the treatment of Substance Use Disorders (SUDs) stemming from tobacco, cannabis, cocaine, methamphetamine, heroin, or prescription opliate use. Multiple therapeutic approaches, ranging from small molecules to biologics (e.g., vaccines) are eligible.
- Technologies or formulations to improve medication delivery and/or to deter drug abuse.
- Tools to streamline drug design and preclinical development for SUD.
- Novel patient adherence monitoring (systems and devices) at the point of care in clinical trials.
- Technologies and tools with high potential of becoming commercially viable products designed to better inform the diagnosis and treatment of SUD.

Faculty in all series and ranks at UC Davis, Irvine, Los Angeles, San Diego and San Francisco are eligible. Postdoctoral scholars are eligible to submit as Co-PI with a faculty PI.

Pre-applications are required and must be submitted between Monday, Apr. 6 - Monday, Apr. 13. Successful applicants will be invited to submit full applications.

An informational webinar for potential applicants will be held on Monday, Apr. 6 at 1PM. Please register for the webinar HERE.

UC CAI RFA and FAQs

About the UC CAI
The UC CAI is a collaboration of five UC medical campuses to accelerate the translation of UC discoveries to benefit patients with heart, lung and blood diseases, drug abuse and addiction. It is administrated from UCLA and supported by the National Heart, Lung, and Blood Institute and the National Institute on Drug Abuse (NIDA) through grant 1U54HL119893.
Important Dates

Mar 25  RFA is issued
Apr 6   Submission of pre-applications begins
Apr 13  Submission of pre-applications closes
Apr 24  Invitation to submit full proposals
May 22  Full application due
Aug 1   Earliest start date
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Technology Development Grants

- **Annual solicitation**
  - Therapeutics
  - Devices / digital health
  - Diagnostics
  - Tools
    - For monitoring, deterrence and treatment of SUDs

- **Up to three awards in yr−1 of up to $200K/2yrs**
Technology Selection Process

• **Solicit** 2–page pre–applications

• Review committee selects the best proposals for full application

• **1st Review**: Experts in drug abuse and addiction review and rank proposals based upon NIH review criteria

• **2nd Review**: BRAID Committee scores proposals and sends to NIDA

• **3rd Review**: NIH Technology Review Committee recommends proposals for funding
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Pre-application and Review

1. RFP Pre-application
2. Pre-application Review
3. Full Application
4. Committee Review
5. UC BRAID Review
6. NIDA Review
7. Technologies Selected for Entrance to Center
Two-page Pre-application

• **Two-page pre-application contains:**
  – Unmet need / significance
  – Innovation / competition / impact
  – Intellectual property
  – Commercialization milestones

• **Review committee** for pre-applications assess:
  – Scientific merit
  – Product development potential

• Highest potential projects **invited** to submit full proposals
Unmet Need/Clinical Impact

- **Treatment** where no treatment exists
- **Recovery** where only palliative therapy is available
- **Improve efficacy** over current therapy
- **Reduce toxicity** of current therapy
- **Improved diagnostics** that impacts how or to whom therapy is delivered
- **Lower costs and improve outcomes** of patient care
- **Tools** that provide an opportunity to better understand a given disease

*Treatment and therapy apply to therapeutics and devices*
Intellectual Property

• Patents
  – Composition of matter
  – Process patents
  – Use patents

• Do you have freedom to operate?
• Have you filed? What type of filing?
Commercialization Milestones

• Target validation
• Pilot toxicology
• Generation of clinical candidate

• Prototype generation
• Proof of principle

• Strengthening or creating new IP
Drug Development

- Target Discovery
- Early Drug Discovery
- Late Drug Discovery
- Pharmacodynamic Studies/ Early Preclinical Development
- Late Preclinical Development
- Phase I
- Phase II
- Phase III

- Bioinformatics
- Biochemistry and Enzymology
- Medicinal Chemistry
- Cellular Disease Models
- Informal Tox
- Stability/Formulation
- Patient Safety
- Patient Efficacy
- Double Blind Placebo Controlled Efficacy

- Genomics
- Assay Development
- Library Development
- Drug Mechanism of Action
- Animal Models of Disease - Efficacy
- Scaleup/Process Development
- Clinical Plan Animal Models
- Study Endpoints

- Target Identification
- High Throughput Screening
- Structure-Based Drug Design
- PK/ADME
- Dose and Schedule
- IND Enabling Studies
- Drug Synergy Studies (Cancer)

- Target Selection and Validation
- Hits Identification
- Lead Identification
- Biomarkers
- Clinical Candidate Selection
- Phase I Clinical Plan
- Patient Stratification
Device Development Profile

- Unmet Clinical Needs
  - Technology / Components
    - Cost Breakout
    - Good Laboratory Practices
- Testing / Validation
  - Hardware / Software Validation
  - Animal Model
  - Pilot Human Study
- IP/FDA
  - Intellectual Property
  - FDA Device Class Approval Path
  - Commercial Partner / FDA

Device Development Profile
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Resources

• Market size
  – Pubmed (disease, incidence, prevalence)
  – UCRex

• Competing Products
  – clinicaltrial.gov
  – Scifinder
  – USPTO
  – Google Scholar

• IP
  – Office of Intellectual Property
  – Freedom to Operate
  – File (Provisional or Non-provisional)
UC ReX

• Search 13 million de-identified patient records from the five UC medical centers with one query

• Provide **counts of eligible patients** by gender, race and ethnicity

• **Increase cohort identification** for the study of rare diseases

• Obtain coordinated data-provisioning support through UC ReX

[ucrex.org](http://ucrex.org)
Questions

About application requirements and process:
Elvira Liclican
Project Manager
eliclican@mednet.ucla.edu

About the website and online submission tool:
Maryam Ariannejad
Technical Support
uccai-support@ctsi.ucla.edu
Questions?

Webinar recording and slide deck will be available on the UC CAI website: http://uccai.ctsi.ucla.edu/pages/funding_opportunity