

RESEARCH ADVISORY BOARD (RAB)

June 6, 2017

8:30-10am

Medical Sciences Building, Chancellors Conference Room S-118

Attendees: Clarice Estrada, John Ellis, Jim Kiriakis, Jennifer Grandis, Sindy Mellon, Teresa Moeller, Suzanne Murphy, Michael Nordberg, Christine Razler, Matt Springer, Brian Smith, Eunice Stephens, Winona Ward

On the phone: Vanessa Jacoby, Jean Jones, Georgina Lopez, Theresa O'Lonegan

Not here: Jane Czech, Steven Lazarus, Wallace Marshall, Xiao Hu, Gretchen Kiser, Irene McGlynn, Thomas Neylan, Feroz Papa, Nirao Shah, Elizabeth Sinclair, James Sorensen, Paul Volberding

Guests: David Dobbs, Barry Selick

RAB Board Updates

- RAB meeting for July 4th is cancelled.

Clinical Research Data Request Online Update, David Dobbs

See PowerPoint presentation attached

- The purpose of this request system is to:
 - Provide requestors a simple and standardized online form to request clinical data
 - Create a central place to track all requests, improve compliance when releasing de-identified data, limited data sets, protected health information and personally identifiable information.
 - Standardize data use clauses and have them cover commercialization of UCSF data by external parties
- A streamlined Clinical Data Request Process was implemented on March 29th which allows an easy-to-use way for faculty, staff, and students to request clinical data for treatment, payment, operations, quality improvement and research purposes.
 - This process replaces two existing processes, APeX New/Modify Report Request Form and Clinical Data Research Consultations Request form.
 - More information can be found at data.ucsf.edu

Questions/Comments:

- In the past, there has not been a streamlined process so other departments have created their own processes, do you intend to harmonize all of the processes?
 - The goal is for all departments to use the same process; however, David's team will not force other departments to streamline to their process.

Vice Chancellor for Business Development, Innovation and Partnerships, Barry Selick

See PowerPoint presentation attached

- Barry Selick comes to UCSF from a former pharmaceutical company with broad biotech experience and industry knowledge. He was a postdoctoral scholar in the lab of one of the nation's foremost scientists, biochemist Bruce Alberts, PhD. Barry's goal is to help researchers turn their scientific findings into products.
- In 2016, research expenditures were \$1.3B
 - 80 filings of new patent applications
 - 72 licenses granted; 18 to UCSF start-ups
 - \$30-35M license revenues earned
 - 15% to "Research Share" to Dean of relevant school
 - 37.5% to "School Share" to Dean of relevant school
 - 12.5% to Chancellor (must go to UCOP assessments)
 - 35% to Inventors
- Barry plans to raise \$50M in commitments to fund this program.
- There are many NIH resources available and underutilized by UCSF faculty and staff, and Barry plans to redesign his programs webpage to create a centralized location for resources

Questions/Comments:

- What is the difference between "research share" and "school share"?
 - Research Share: Shared with the dean of the school the invention is from
 - School Share: Research explicitly
- If chairs are supporting faculty how will the return from operations be?

- The goal is to change the funding model to receive unrestricted philanthropy gifts only.
- Who will select and decide which scientists receive funding?
 - Barry will be part of an advisory board where applications will be reviewed and selected.

Mandatory Trainings Update, Brian Smith

- There are about 57 trainings with 45% of them housed under EH&S and 23% under IACUC.
- Campus trainings are focused for researchers and the number of trainings per individual vary depending on the type of their research.
- Brian is working with EH&S to update all trainings with a deadline of December 2017 to ensure the following:
 - Test out option is readily available
 - Regulations are updated
 - Broken links are fixed
 - Adding specifications for ADA requirements
- The original proposal to the RAB committee was to form a sub-committee, however, Brian would like to review the new proposed mandatory trainings then bring them to the RAB committee for final review. Other committees, such as the Chemical and Environmental Safety Committee will also be reviewing new trainings.

Questions/Comments:

- Is it possible for training notifications to be sent out in bulk as oppose to one at a time?
 - This is something Brian can look into for Phase 2 of the project for updating the trainings.
- What process will be put in place when a training is no longer required?
 - Brian will work with closely with the safety committees and updates to the trainings will occur on a more regular basis.

UCSF Medical Center

UCSF Benioff Children's Hospitals

Clinical Data Request Process

Presentation to RAB

June 6, 2016

David Dobbs, Kim Romero

Enterprise Information & Analytics

Clinical Data Request Intake Process

Main Objectives

- Provide requestors a simple and standardized online form to request clinical data
- Create a central place to track all requests
- Improve compliance with UCSF policies for controlling access to and releasing de-identified data, limited data sets, protected health information and personally identifiable information
- Standardize data use clauses and have them cover commercialization of UCSF data by external parties

High Level CDRP Flow

Research

- A systematic investigation to develop or contribute to generalized knowledge
- Typically grant or contract funded

Quality Improvement

- Activities to continuously evaluate and improve performance in a clinical area or department
- Typically hospital or department funded



LDS – Limited Data Set

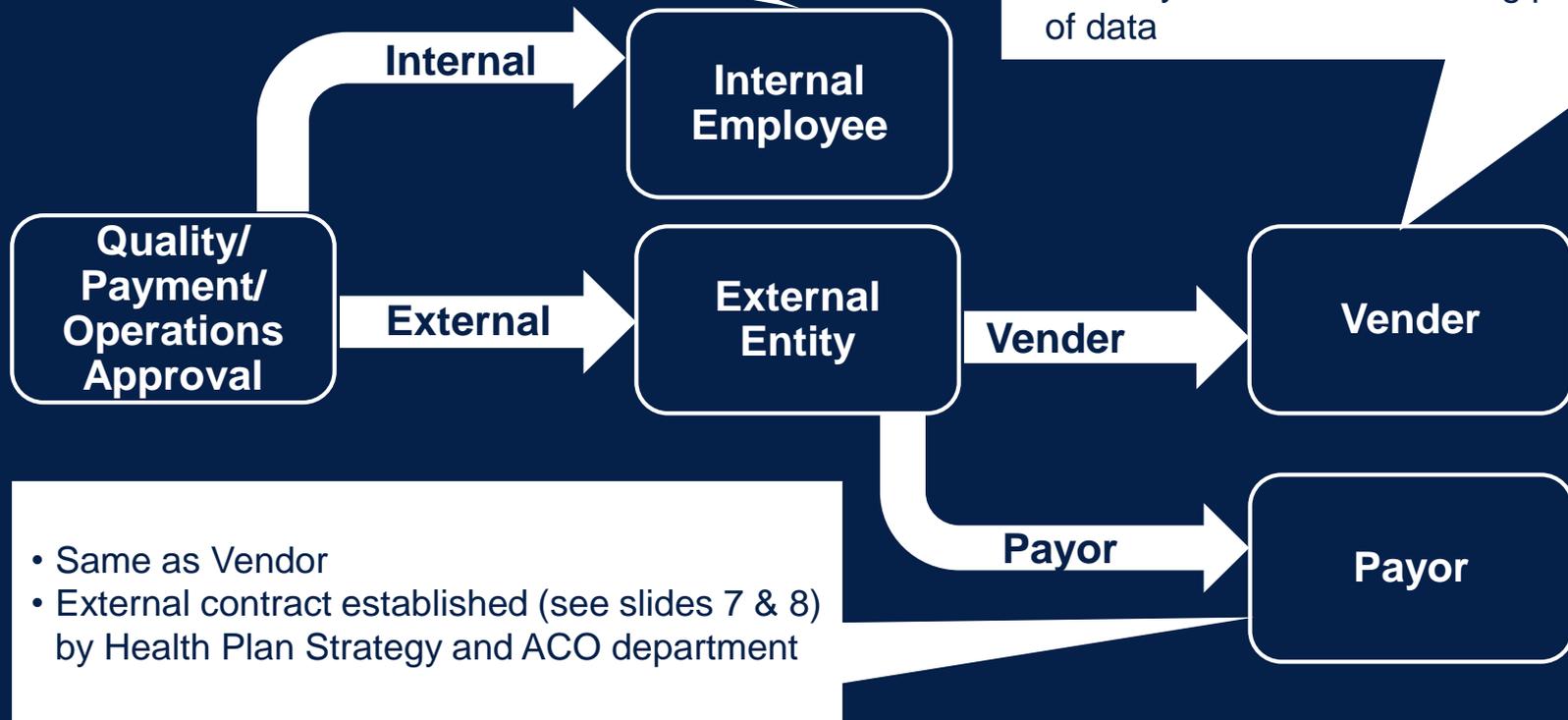
PHI – Protected Health information

PII – Personally Identifiable Information

Quality/Payment/Operations Approval

- Manager/Director Approval
- Attestation form sent to requestor via DocuSign

- Manager/Director Approval
- External contract established (see slides 7 & 8)
- Security assessment if taking possession of data

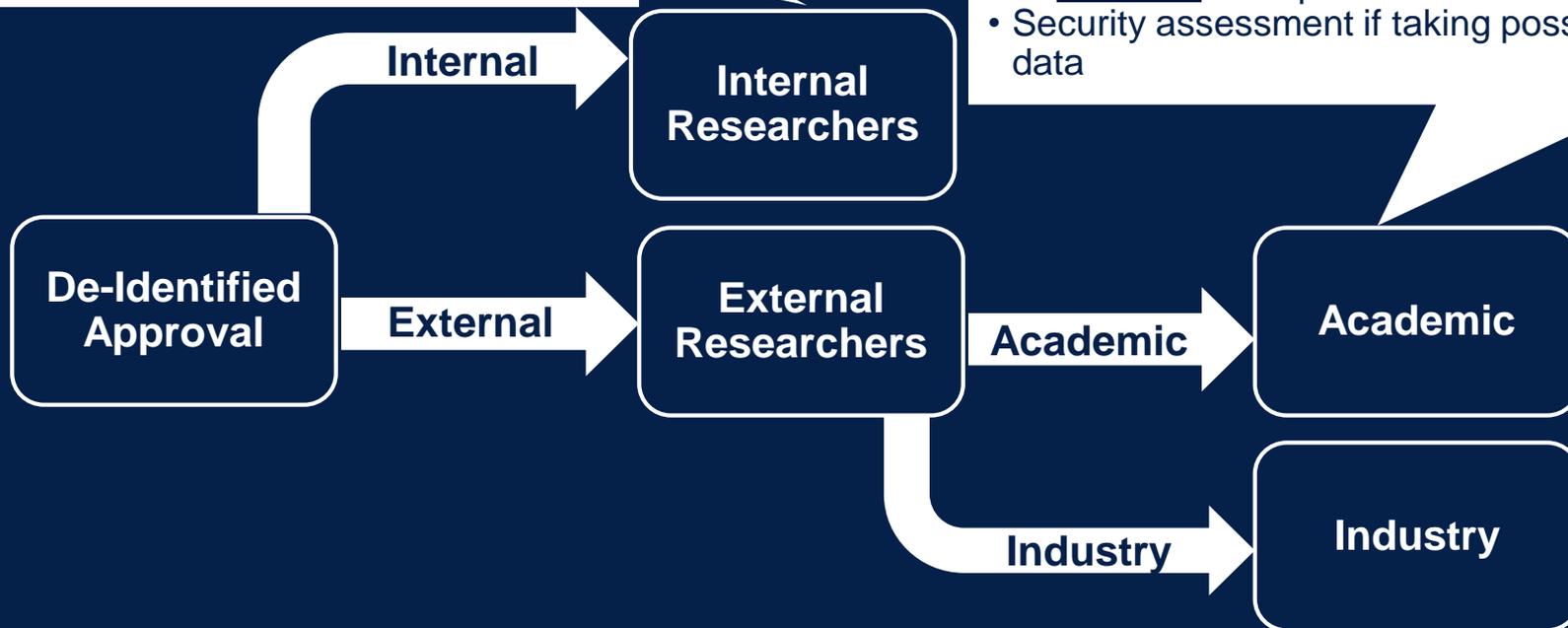


- Same as Vendor
- External contract established (see slides 7 & 8) by Health Plan Strategy and ACO department

Research De-identified Approval

- Attestation form sent to requestor via DocuSign
- PI informed of request via email
- No data use agreement required

- External research contract for de-identified data established (see slides 7 & 8) with DUA
- No Attestation form required because of contract
- PI informed of request via email
- Security assessment if taking possession of data



- Same as Academic approval
- Contract is different if industry is paying us for data and there is a higher due oversight required.

Research LDS/PHI/PII Approval

- LDS – Requestor and PI sign UCOP DUA via DocuSign
- PHI / PII - IRB approval. Requestor must be named on study team in iRIS
- Attestation form sent to requestor via DocuSign
- PI informed of request via email

- LDS / PHI / PII – IRB approval. External party must be named on study team in iRIS
- PI informed of request via email
- External research contract established (see slides 7 & 8) with DUA
- No attestation form require because of contract and standard data use language
- Security assessment if taking possession of data



- Same as Academic approval
- Contract is different if industry is paying us for data and there is a higher oversight required.

Clinical Data Request Process

- New, streamlined Clinical Data Request Process (CDRP) was implemented on March 29th
- An easy-to-use way for faculty, staff and students to request clinical data for treatment, payment, operations, quality improvement and research purposes; while ensuring all UCSF privacy and security policies are followed.
- Replaces 2 existing processes:
 - APeX New/Modify Report Request Form
 - Clinical Data Research Consultations Request Form
- Learn more about CDRP at data.ucsf.edu



University of California
San Francisco

Innovation Ventures

Current Status and Goals

Barry Selick
VC of Business Development, Innovation & Partnerships

6/5/2017

Innovation at UCSF

- 2016 Research Expenditures were \$1.3B
 - 80 filings of new patent applications
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Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
- Licensed to a start-up company
 - Founded and run by non-UCSF entrepreneurs
 - Founded and run by UCSF faculty/students/staff
- Retained by inventor for maturation within UCSF

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Ways in Which Inventions are Prosecuted

- Licensed to a pharma/existing company partner
 - + Let's inventor focus on their day job
 - + Is typically associated with an up-front payment (\$'s)
 - + Credible partner can invest meaningful resources (\$'s)
 - Inventor loses control of project
 - Up-fronts for early stage programs tend to be modest with modest milestones/royalties
 - Large companies tend to move at glacial speeds
 - Partner may have “different” vision for development of project
 - eg...“strategic decay”

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Ways in Which Inventions are Prosecuted

- Licensed to a start-up company
 - Founded and run by non-UCSF entrepreneurs
 - + Inventors are typically involved as advisors...more influence
 - + Start-up entrepreneurs tend to be more closely aligned with the needs of inventors/university
 - Not all start-up entrepreneurs are capable
 - Founded and run by UCSF faculty/students/staff
 - + Control/responsibility
 - +/- Running a start-up is a full-time job
 - You cannot be a FT CEO and UCSF faculty member simultaneously

Ways in Which Inventions are Prosecuted

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Ways in Which Inventions are Prosecuted

- Retained by inventor for maturation within UCSF
 - + Control
 - + Control
 - + Control
 - + Build greater value/generate greater upside before licensing (\$'s)
 - Most faculty/staff do not have the expertise/resources to mature programs to POC
 - Manufacturing, IND-enabling studies, FDA interactions can be distracting
 - \$'s required to prosecute programs internally

Potential Solution

- Raise \$'s from visionary donors to fund internal programs to POC before licensing
 - + Ongoing involvement of inventors
 - + Accelerated enablement by dedicated technology developers who work in partnership with inventors
 - + Utilize outside CROs with deep expertise in all aspects of technology development/POC demonstration
 - + Alignment of interests between inventors, developers, donors, UCSF
 - + Preserve greater upside for inventors and UCSF

Goal is to raise \$50M in commitments to fund this program

What Constitutes a “Great” Invention?

- While discoveries at UCSF are expected to be transformative, not all discoveries become inventions...

...and not all inventions are expected to be transformative

Patrick Soon-Shiong, UCLA: HSA-conjugated paclitaxel

sold to Celgene in 2010 for >\$3B

net worth in November 2016: ~\$9B

Queen & Selick: Humanized monoclonal antibody therapeutics

~15 approved drugs licensed technology

top 2 therapeutics (Herceptin & Avastin) had cumulative sales through 2016 of \$127B

What Constitutes a “Great” Invention? (cont.)

coflex®



Motion Preservation

Interlaminar Stabilization™

The 1st and only motion preserving, minimally invasive treatment approved for moderate to severe spinal stenosis post decompression.

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February 18, 2014

PDL BioPharma and Paradigm Spine Complete a \$75 Million Financing Transaction

[Paradigm Spine, LLC Announces Publication of 5 Year Long-Term Results of Level 1 Data for coflex® Interlaminar Stabilization® Compared to Fusion](#)

Wednesday, January 27, 2016



How to Invent at UCSF?



The Clinical & Translational Science Institute accelerates research to health. We do this by providing infrastructure to enable research to be conducted in new ways.

The Catalyst program accelerates translation of research into products with clinical impact through funding, mentorship, and identification of resources. Catalyst aims to foster academic and industry collaborations as well as enhance education in early translational research and entrepreneurship.

Contact Us

For general inquiries about Catalyst, please email CTSI@ucsf.edu or visit us at www.ctsi.ucsf.edu



Accelerating the Translation of Pioneering Medical Devices to Improve Patient Care

Surgical innovations is an initiative of the Department of Surgery in partnership with the Department of Biomedical Engineering & Therapeutic Sciences to identify, mentor, and facilitate the translation of novel medical technologies into transformative new devices and treatments to improve human health. Surgeons are natural innovators, consistently faced with opportunities to think creatively and devise new solutions in the operating room. [Read more >>](#)



Healthcare is notoriously technophobic. We're changing that.

Innovate

We provide UCSF faculty, researchers, and staff with the essential support and resources to create and commercialize transformative technologies.

Validate

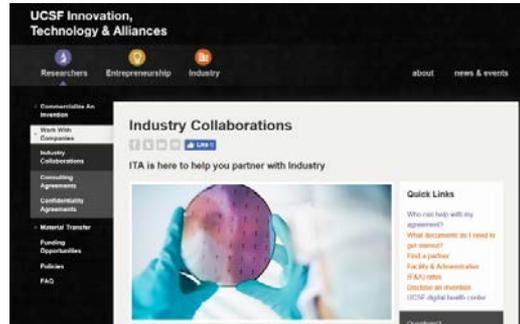
We leverage UCSF's clinical care resources to test and validate ideas as novel technologies, devices, and services.



Entrepreneurship Center

The Entrepreneurship Center at UCSF provides the knowledge, support and connections needed by our community of scientists and clinicians who want to commercialize their inventions through a startup. We empower our community by providing courses, programs and a network to expose them to the entrepreneurial mindset and the Silicon Valley ecosystem that is the world's standard. We support entrepreneurial interests in all areas of life science/healthcare, whether therapeutics, research tools, medical devices, diagnostics, digital health or Big Data.

Entrepreneurship events [View All](#)



Industry Collaborations

ITA is here to help you partner with industry

Quick Links

Who can help with my agreement?

What documents do I need to get started?

Find a partner

Faculty & Administrative (FAU) roles

Obtain an invention

UCSF Digital health center

Get started



WHERE STARTUPS GET STARTED

QB3 accelerates life science innovation and entrepreneurship. Learn how we can help your startup launch and grow.

[Learn More](#)



UCSF OTM

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At the UCSF Office of Technology Management, our mission is to commercialize UCSF's life science and medical technologies for public use & benefit.

Who to Talk to About Your Inventions at UCSF?

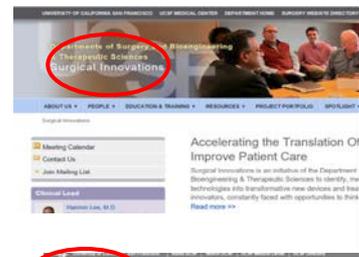


The Clinical & Translational Science Center (CTSC) accelerates translation of research into products with clinical impact through funding, mentorship, identification of resources. Catalyst aims to foster and promote industry collaborations as well as enhance educational and entrepreneurial opportunities.

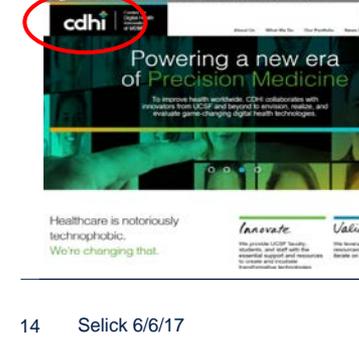
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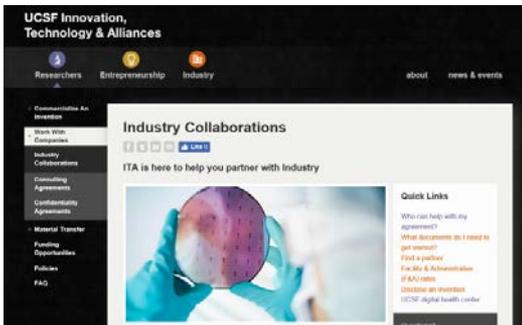
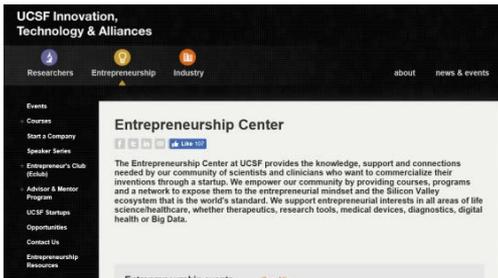
Cathy Tralau-Stewart



Hanmin Lee



Mike Blum



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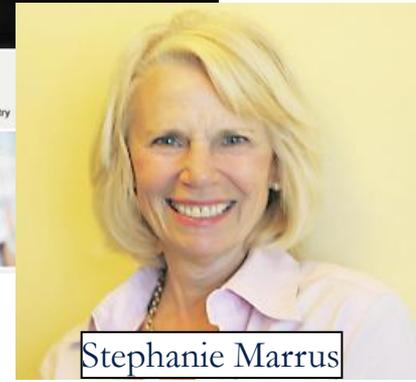
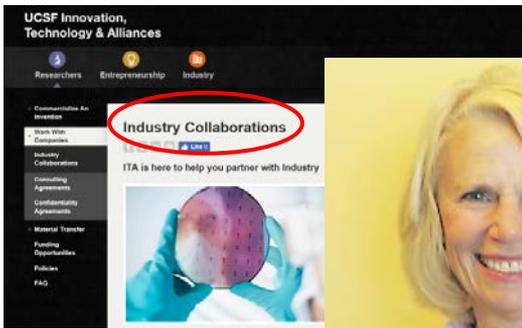
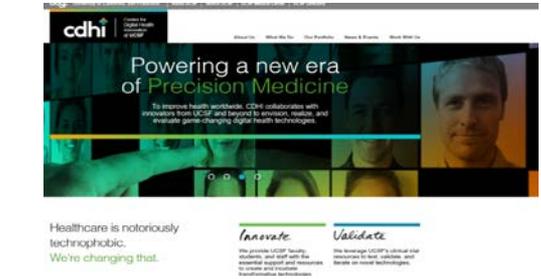


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Partner or DIY?



Reg and QB3 are Start-Up Gurus



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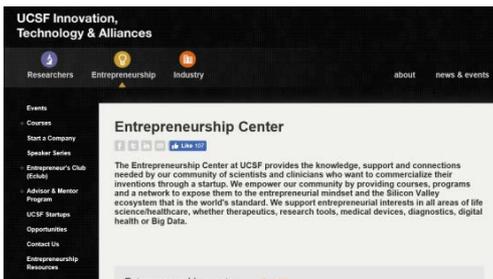
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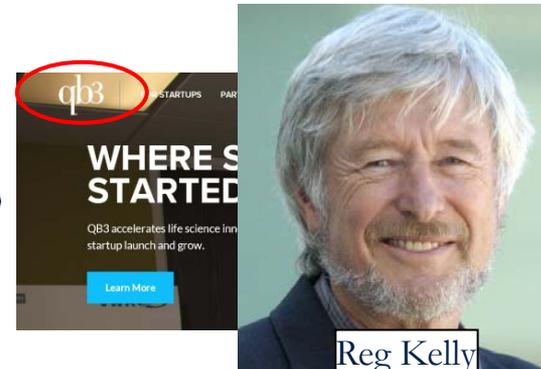


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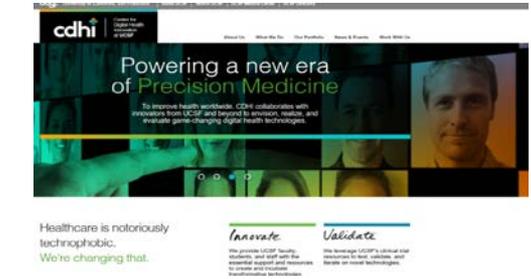
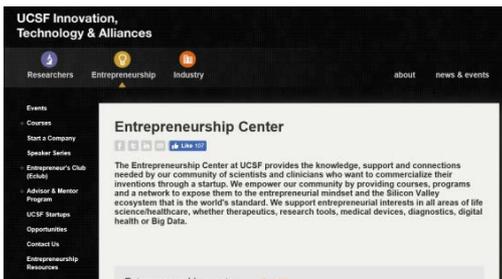


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But be Sure to Protect Your Ideas First...Talk to Karin



Innovation at ~~UCSF~~ Columbia...soon to be UCSF

Columbia University in the City of New York



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- Start a Company
- Request a Material Transfer or Confidentiality Agreement
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- Start the Licensing Process

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