

Estratégias de Proteção e Comercialização de Tecnologias na Área de Saúde

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> Patrocínio VAMOCI

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Agenda

TRANSFERÊNCIA DE TECNOLOGIA TRADICIONAL

- "University of Southern California" e "USC Stevens Center for Innovation"
- Estratégias de Proteção de PI na Área da Saúde
- Marketing e licenciamento

MODELOS E ATIVIDADES NÃO-TRADICIONAIS DE TRANSFERÊNCIA DE TECNOLOGIAS

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MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES



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Academic Units

- USC Dana and David Dornsife College of Letters, Arts and Sciences
- 21 Schools and units

Student body

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Student enrollment statistics from the 2016-2017 academic year (rounded):

Faculty (full-time): 4,361

Staff: 15,235 **Student (2018):** 47,500

Undergraduates Graduate and professional students	19,000 25.000		Female Male	55% 45%
Total	44,000	13%	of freshmen generation c	were first- ollege students
16.6% of 54,2 applica admitte	82 freshman nts were d	3.75	5	
229 National Merit Scholars, 2016 freshman class		average un freshman c	weighted GPA lass	for entering

Regularly Enrolled International Students:

11,308





USC Facts

In 2018, USC ranked **number 17th** among more than 1000 public and private universities in the U.S. by the Wall Street Journal and Times Higher Education.

In student and faculty diversity, USC tied for second with Columbia among the top 25 nationally ranked universities (2016 ranking).

USC's distinguished faculty of 4,000 innovative scholars, researchers, teachers and mentors includes five Nobel laureates, and dozens of recipients of prestigious national honors including the MacArthur "Genius" Award, the National Medal of the Arts, the National Medal of Science, the National Medal of Technology and Innovation, and Pulitzer Prize.

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Vibrant Research Community

Largest graduate program in science, engineering and health of all private research universities

\$764 million in externally funded research in 2017-2018

Keck School of Medicine conducts research and clinical activities in a network of hospitals and clinics in more than 45 locations, serving more than 1 million patients annually.

Medical science accounts for more than 50 percent of the University's research expenditures





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USC campuses





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USC Stevens Center for Innovation



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Our Mission

Our **mission** is to maximize the translation of **USC research** into products for public benefit through **licenses**, **collaborations** and the promotion of **entrepreneurship** and **innovation**.



University-wide resource for USC innovators



Manages technology commercialization of inventions resulting from the university's nearly \$800 million research portfolio



Fosters innovation through startups, corporate collaborations, sponsored events & programs







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Our Functions and Services



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USC Stevens Metrics: Increasing Impact of University Research



Our Commercialization Process



Commercialization Process: Disclosure

- Critical first step in protecting intellectual property rights

http://stevens.usc.edu



After Invention is Disclosed

- Inventor meeting
- Detailed review of science
- Develop IP strategy to protect
- Explore leads for commercialization
- Stay current with the science & the market
- Periodic re-evaluation of OTT's plan
 - ✓ Be aware of patenting deadlines

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✓ Scientific Review Committee



IP Protection Strategies



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Generating Strong IP

Working closely with faculty

- Educate researchers
 - Disclose to OTT before disclosing to the public

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- Anticipate deadlines
- Fine-tuning of the invention
- Enabling an invention
- Strengthening the IP
- Establish relationships





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Publish or Patent ?





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Publish AND Patent



IP Protection: Initial Filing

 Provisional filing: factors to consider

Patent Landscape	Addressable Market	
Market Opportunity	Data Quality	
Support of Publications / High Impact Journals		

PÁTRIA AMADA BRASIL





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Market to Prospective Partners

Disclosure Review

Provisional Pendency & Beyond



Market to Prospective Partners



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USC Stevens Center for Innovation

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Monoclonal Antibody Inhibitors Targeting Cathepsin B protease

USC Case #2016-089

Market Opportunity:

The application of monoclonal antibodies to oncology in combination with standard chemotherapy regimes can significantly prolong the survival of patients with metastatic cancers of the lung, breast, colorectal and prostate. The cysteine protease <u>Cathepsin B</u> is frequently overexpressed in human lung, breast, colorectal and prostate cancers, and is correlated with poor prognosis. Specifically targeting <u>Cathepsin B</u> with a monoclonal antibody to inhibit its activity would be advantageous as opposed to traditional chemotherapeutic approaches.

USC Solution:

Through structure-guided rational design, USC researchers have synthesized a novel antibody that specifically targets <u>Cathepsin</u> B to inhibit its proteolytic activity. These novel antibody inhibitors provide potentially potent anti-metastasis therapeutics with excellent safety profiles.

Value Proposition

- Antibody-based protease inhibitors are ideal drug candidates
- Overexpression of Cathepsin B in human lung, breast, colorectal and prostate cancers is well characterized
- · Limited side effects

Keywords:

Monoclonal based oncology therapeutics, immunotherapy



Applications

 Arrest cancer metastasis by specifically targeting <u>Cathepsin B</u> protease

Stage of Development

- In Vitro activity data, Structure-Based design, Animal data in progress
- Available for exclusive license

Intellectual Property

Status: Provisional patent filed

Key Publication:

"Rational design of human anti-Cathepsin B antibodies." To be submitted, *Nature Structural & Molecular Biology.*

Contact information

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USC Stevens Center for Innovation Maximizing the translation of USC research into products for public benefit

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CIÊNCIA, TECNOLOGIA

Marketing Inventions: Non-Confidential Disclosure (NCD)

Example:

Covers the following:

- Market Opportunity
- USC Solution
- Value Proposition
- Keywords
- Applications
- Stage of Development

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 Intellectual Property (patent stage with link & key publications)







IP Protection: Conversions

- Main deciding factor: marketing feedback
- Research/Development continuity?
 - Enough funding?
 - Researcher's focus/interest?
- Licensing interest?
- Can we extend the patent life of an invention with an improvement technology?
- Can we combine patents to create a portfolio?





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Filing Strategies



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Typical Filing Strategy

Filing of a Provisional Patent

Filing an International Patent Application (PCT)

(PCT – Patent Cooperation Treaty)

Enter National/Regional Phase

Includes filing of non-provisional application in the USPTO

Validation or registration in additional countries

European Validation



One Size Does NOT Fit All



Strategy is tailored for every technology

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One Size does NOT fit All

Strategy is technology-dependent and licensing opportunity-dependent

- Cost of developing the technology
- Regulatory Burden
 - Immunotherapies China
 - Pelvic Organ Prolapse Mesh FDA approval difficult/expensive
- Epidemiology of disease
 - Stomach cancer technology (Japan)
 - Depression drugs (Scandinavian countries)

Manufacturing Capabilities

•Vaccines – consider filing in countries with strong manufacturing capabilities/ continental or regional hubs (Switzerland, Belgium, S. Africa, India, Brazil)

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Strength of Country's Patent System

• Licensee's presence in certain countries

- •India only if company can defend infringement law suit
- China increasing with our startups because of Chinese funding





When Best Filing Strategy is NOT to file

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Research Tools

- Some technologies may be commercialized through non-patent licensing.
- •Other technologies are transferred most expeditiously through publication.



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Non-Traditional Technology Transfer Approaches and Activities





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Technology Transfer in Biotechnology





Drug development is long, expensive, and uncertain



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Technology Transfer in Biotechnology



USC Stevens: Part of a Global Innovation Ecosystem



Connecting Across Greater Los Angeles and Beyond

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CIÊNCIA, TECNOLOGIA





From Bench to Bedside

a Long Journey



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CONFERÊNCIA INTERNACIONAL sobre PROCESSOS INOVATIVOS **DE BRASILI** Interfaces entre ICT- Empresários-Investidores

Obrigado pela Atenção!

Perguntas?

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PARA DISCUSSÃO
Commercialization Resources and Early Stage Funding

University System of Maryland



University of Maryland – UM Ventures





UM Ventures is a joint initiative of the University of Maryland, Baltimore and University of Maryland, College Park to commercialize technologies and expand industry collaboration.

- •UM Ventures internal Advisory Board was formed in August 2012
 - Deans of Business, Engineering, and Computer, Mathematical and Natural Sciences (UMCP)
 - •Deans of Law, Medicine, and Pharmacy (UMB)

•Unified licensing and patenting services and joint marketing to the business community to increase efficiency and productivity

- •UM Ventures is creating interdisciplinary teams (site-miners and EIRs) of clinicians, engineers, lawyers, and business experts to move the best technologies aggressively into the marketplace.
- •Seed Equity Investments in Startups

Resources

• UMB OTT

➢ IP Attorneys/Licensing Teams

- Venture Directors new
 - Experience: NewCo formation, management, SBIR, raising capital
- ► UMB E-I-Rs
 - > Former CEOs of Vapotherm, Novavax, Founder of Nora Therapeutics
 - Merck, DuPont Pharma, Pfizer, Wyeth, JHU,

UM Ventures

- ➢ Jim Hughes Director
- ➤ Site Miners
 - Dr. Reuben Mezrich (UMB)

Funding

UMVentures/UMB OTT (PI and/or Startup)

- LIFE Award (Annual UMB-Hopkins Alliance)
- Seed Grant Fund (Through UM Ventures/UMB OTT)
- Seed Equity/Loan Fund (UMB Startups)
- MedImmune Collaboration (5 projects/year)
 - > Looking to establish similar collaborations

➤ TedCo

- Maryland Innovation Initiative Awards (PI and/or Startup)
 - Phase I (PI Translational Research)
 - Phase II (Business Planning)
 - Phase III (Start-Up Company)
- > Maryland Industrial Partnerships (PI + Company)
- > Maryland Biotechnology Center (Company)
 - Biotechnology Development Awards
 - Other DBED Programs :
 - Biotechnology Investor Incentive Tax Credit,
 - Maryland Venture Fund

Maryland Innovation Initiative (MII)

The MII Program was created to foster the transition of promising technologies having significant commercial potential from Qualifying Universities, where they were discovered, to the commercial sector, where they can be developed into products and services that meet identified market needs.



Other Resources

- Partnerships with Prototyping Services Companies

 ✓ Design, engineer, prototype, and manufacture products
 ✓ Co-applicants in seed funding opportunities
- External Consultants ("middlemen")
 - \checkmark Potential to increase the deal flow
 - ✓ Addition to our marketing bandwidth
- Software services
 - ✓ Coding
 - ✓ Increase user-friendliness

Other Resources

INCUBADORAS

USC não possui uma incubadora de empresas de biotecnologia própria. Startups da USC utilizam outras incubadoras locais (ex.: Pasadena Bio, LA Biomed Incubator)

- ■Acesso à rede de pesquisadores, médicos, dentistas e outros potenciais colaboradores
- Acesso aos laboratórios, equipamentos e outras instalações das Universidades e Institutos de Pesquisa associadas às incubadoras.
- Instalações comuns na Incubadora: recepcionista, laboratórios e equipamentos comuns, auditórios, salas de reuniões, etc;
- Ambiente cooperativo com outros inquilinos: companias de biotecnologia, informática e CROs.
- Programa de Assistência à Negócios
- Aluguéis de curto prazo

Technology Accelerator

UMB Accelerator Program

Discovery Stage Company

NVT Activities

- Develop and execute business/project plan
- Prepare investor presentation
- Obtain non-dilutive and/or dilutive funding
- Coordinate NVAP
- Recruit management team and board

Development Stage Company

Directly increasing the success rate of startups founded on UMB technologies



UMB Accelerator Program



USC: Alfred E. Mann institute for Biomedical Engineering

AMI USC Alfred E. Mann Institute for Blomedical Engineerin USC University of Southern California

About US AMI Pull Model AMI Team Portfolio Outreach News Careers Contact US FAQs Q

Alfred E. Mann Institute for Biomedical Engineering



The Alfred E. Mann Institute for Biomedical Engineering (AMI-USC) was established at the University of Southern California in 1998. Its mission is to help bridge the gap between biomedical innovation and the creation of commercially successful medical products to improve and save lives. The University of Southern California was selected because it is one of a small number of premier research institutions on which the nation depends for a steady stream of new knowledge, art, and technology. USC has nearly \$700 million in annual research expenditures and has the largest graduate program in science, engineering, and health of all private research universities.

... its mission is to help bridge the gap between biomedical innovation and the creation of commercially successful medical products to improve and save lives.

USC Stevens Center for Innovation Entrepreneurial Support Services



Online Resources: Incubate USC



GET STARTED

http://incubate.usc.edu

GET INVOLVED



6.8 Million suffer from Mitral Valve Regurgitation in U.S.

Challenge: Current treatment requires open heart surgery

- Large 6-8" incision
- Sternotomy
- Heart bypass
- Arrested heart
- 1-2% stroke risk
- 3-6 hour procedure
- 4-7 day hospital recovery
- Return to work > 1 month



- Over 100,000 MV operations per year
- Only 20% of patients who could benefit get open heart surgery



Harpoon Solution: Minimally invasive surgery device

- 1-2" incision
- No sternotomy. No bypass.
- Beating heart
- Negligible stroke risk
- 45-60 minute procedure
- 1-2 day hospital recovery
- Return to work in 5-7 days

2014: Raised \$3.6 Million* 2015: Clinical Trial

<u>UMB Inventor:</u> James Gammie, MD SOM, Surgery



USC Stevens Success Stories: Startups

A Recent USC Success Story



From a small academic laboratory to a potential therapy for a life- threatening human disease

Human rCollagen-7: Candidate treatment for Dystrophic Epidermolysis Bullosa (DEB)

- Rare Genetic Disease: fragile blistering skin, deformed limbs, widespread skin wounds, early death
- Young patients with DEB are often referred to as "butterfly children" because their skin is as frail as butterfly's wings
- Aberrant function /absence of C7 at dermal-epidermal junction affect attachment of epidermis to dermis



USC Stevens Success Stories: Startups

A Recent USC Success Story



From a small academic laboratory to a potential therapy for a life- threatening human disease

- No disease modifying treatment available; only recurrent, symptomatic treatments; painful and costly diseases
- Product being developed: IV recombinant C7 as a protein replacement therapy
- Mice treated with a single injection of recombinant Collagen 7 Lived Longer



DEB (Control) DEB (Shire Collagen 7)

USC Stevens Success Stories: Startups

A Recent USC Success Story

Drs. Woodley and Chen partnered with the USC Stevens Center for Innovation to seek companies interested in licensing various aspects of the C7 work.

USC Stevens helped connect the USC researchers to external entrepreneurs best suited to develop and commercialize a protein replacement therapy.



Drs. Woodley and Chen partnered with entrepreneurs to form Lotus Tissue Repair.

Lotus went on to secure a total of \$26 million in milestone-driven funding from Third Rock Ventures and was acquired by Shire Plc, a global specialty biopharmaceutical company.

Shire purchased Lotus Tissue Repair in 2013 for approximately \$50 million, with added potential success milestones totaling an additional \$275 million.

USC Stevens: How to Reach Us



Website: http://stevens.usc.edu/contact-us



E-mail and phone: communications@stevens.usc.edu 213.821.6063



Facebook: USC Stevens Center for Innovation



Twitter: @USCStevens



Instagram: <u>
@USCStevens</u>



Argus II Retinal Prosthesis

- First FDA-approved implanted device to re-establish sight in blind patients
- Dr. Mark Humayun and his teams from USC Neuroscience and the Doheny Eye Institute contributed to the development of the underlying hardware and software platform
- Manufactured by Second Sight Medical Products and is the result of a close collaboration by Keck School of Medicine of USC, the USC Eye Institute and the USC Viterbi School of Engineering
- USC Stevens completed exclusive patent license agreement for the technology with Second Sight

Photos courtesy of Second Sight Medical Products



Argus II The Technology



The Argus II device restores the sense of sight with advanced bioelectronic technology.

Argus II is a retinal implant system (Images A & C) that consists of an eyeglass mounted camera and an implanted 60 electrode retinal stimulator.

The stimulator, implanted on the eye and interfacing directly to the retina, relays signals from the external camera to the retina via small electrical impulses, which triggers signals in the retina that are passed to the brain via the optic nerve. The brain is then able to process the signals into a visual picture (Image F).

Invention of the World's First FDA-Approved Artificial Retinal Prosthesis

After witnessing his grandmother slowly loosing vision due to complications from diabetes, Dr. Humayun devoted his scientific career to finding solutions for devastating conditions that cause blindness.

Dr. Humayun and Dr. James Weiland assembled a team of world experts to create a revolutionary retinal prosthesis system known as Argus II.

The Argus II 30-patient trial launched in 2007 at sites in the U.S. and Europe. It was approved by the U.S. Food and Drug Administration (FDA) in February 2013.

The project was funded by the National Institutes of Health (NIH), Office of Science at U.S. Department of Energy, National Science Foundation (NSF), W.M. Keck Foundation, Research to Prevent Blindness, and Second Sight Medical Products, Inc (SSMP).

SSMP launched Argus II worldwide and is available at more than 25 centers worldwide. 37 new units have been implanted during the first 2 quarters of 2018.

President Obama honors USC Eye Institute's Dr. Mark Humayun in White House ceremony



A Novel Stem Cell Therapy for Treatment of Dry Age-Related-Macular Degeneration

Dr. Mark Humayun, in collaboration with David Hinton, MD, received a \$19 million grant from the California Institute for Regenerative Medicine (CIRM) to lead a stem cell initiative. The research team has developed a unique procedure by which a scaffold of stem-cell derived retinal pigment epithelium cells may be surgically implanted into the back of the eye, replacing diseased tissue to treat those suffering from Age-Related Macular Degeneration (AMD).



A Novel Stem Cell Therapy for Treatment of Dry Age Related-Macular Degeneration

RPT was founded by Drs. Mark Humayun and David R. Hinton from the University of Southern California and Dr. Dennis O. Clegg from UC Santa Barbara. The technology to produce the CPCB-RPE1* implant is exclusively licensed to RPT from the University of Southern California, the California Institute of Technology and UC at Santa Barbara.



Santen Pharmaceuticals Announces Strategic Investment in Regenerative Patch Technologies LLC

* California Project to Cure Blindness - Retinal Pigment Epithelium 1

Polyethylene Technology for Artificial Human Joints

- High performing and long lasting polymer materials for artificial human joints
- Dr. Ronald Salovey of the USC Viterbi School of Engineering developed
- Improves hip reconstruction for patients, more wear resistant without compromising mechanical integrity over traditional hip replacement materials



Organic Light-Emitting Diodes (OLED)

- Most advanced TV technology to date over LCD & plasma TVs with thinner, lighter & more efficient flat panel displays
- Developed by Dr. Mark Thompson and researchers from USC Dornsife College of Letters, Arts & Sciences and Princeton University
- Clearer & brighter colors for smart phones, TVs and digital screens
- Used in screens for over 50 different phones, including the Samsung Galaxy
- USC Stevens completed patent license agreement for Universal Display Corporation for suite of technology (includes over 120 issued U.S. patents)



Photo courtesy of Universal Display Corporation

Light Stage

- Movie-making technology to create photoreal digital actors for film, TV, videogames and immersive simulations
- Paul Debevec and team at USC's Institute for Creative Technologies developed various forms and versions of the Light Stage technology
- Technology used in films such as Spider-Man 2 (2004 Academy Award for Visual Effects), Avatar, The Curious Case of Benjamin Button, Furious 7, The Jungle Book
- USC Stevens licenses all of the Light Stage technologies



Corporate Partnerships and Strategic Alliances

Corporate Collaborations

- Corporate Collaborations at USC is the proactive effort to build mutually beneficial research relationships between USC and industry that align with USC core values and industry strategic initiatives and areas of focus.
 - Assemble a portfolio of diverse opportunities to create strategic and enduring industry partnerships
 - Closely match high impact research to strategic business problems
 - Provide flexible collaboration models to craft the right partnership
 - Implement streamlined collaboration processes and governance

USC Stevens Center for Innovation: Corporate Collaboration Services

Navigate the USC environment to find the right experts and opportunities that are mutually aligned between USC and company

Coordinate in-person meetings between USC faculty and Industry; Pitch support for **faculty** presentations

Identify and align **mutual shared interests** and formulate partnering strategies to ensure real business value and produce impactful outcomes

Coordinate and support the development of multi-disciplinary and multidivisional collaborations across USC

Streamline collaboration processes to **maximize** agreement speed and transfer ideas into specific scope of work plans that translate into contractual agreements

Corporate Collaborations: Process



Types of Engagement

- Involvement with researchers
- Student-oriented engagement
- Access to resources
- Involvement with centers of expertise and schools
- Economic development

Types of Relationships

- Sponsored Research
- Licensing
- Incubator access
- New Co. creation
- Equity investment
- Flexible, multi-faceted

Growing Industry Partnerships at USC

Drug Discovery and Pharmaceuticals



Amgen

Amgen and USC have entered into a 3-year master research collaboration agreement

GPCR Institute

Public-private partnership for drug development bolsters USC's efforts to promote biomedical research in Los Angeles

Pfizer CTI

USC is part of this innovative Pharma program with leading university and academic research centers nationwide

Accelerating translation of novel targets to the clinic

Growing Industry Partnerships at USC

Liquid Biopsy - Precision Medical Diagnostics



Fluidigm

USC is the first academic partner to evaluate a novel imaging mass cytometer (IMC) for single cell analysis.

Trovagene

USC is part of this innovative Pharma program with leading university and academic research centers nationwide

Foundation for the National Institutes of Health (FNIH)

Public-Private Partnership to evaluate liquid biopsies as cancer biomarkers; *AbbVie, Amgen, Daiichi-Sankyo, and Eli Lilly*

Advance personalized medicine by investigating leading edge technologies
Program & Funding Announcements

NEW! CATALYST - Allied Minds and Bristol-Myers Squibb:

Applications accepted on a rolling basis.

http://www.ablifescience.com/catalyst

CATALYST is an exciting new program launched by Allied-Bristol Life Sciences (ABLS), a joint venture of global pharmaceutical company Bristol-Myers Squibb and venture builder Allied Minds, to identify and develop commercially-promising biopharmaceutical innovations from leading universities and research institutions.

Objectives: Through CATALYST, ABLS aims to:

- Identify therapeutic opportunities with strong translational potential and that are aligned with ABLS's strategic areas of interest.
- License and develop lead compounds, investing ~\$12M to \$16M per program to undertake pre-clinical development and position the program for further clinical development and commercialization by BMS.
- Priority will be given to those projects where initial lead molecules have already been identified and possess the potential to deliver first-in class drug candidates

Program & Funding Announcements

NEW! Pfizer Centers for Therapeutic Innovation (CTI)

Deadline to submit to USC Stevens: April 21, 2017

Pfizer CTI is looking to **fund early-stage large molecule projects** related to the following therapeutic areas of interest

- Oncology
- Inflammation and Immune Disorders
- Cardiovascular and Metabolic Diseases
- Neuroscience
- Rare Monogenic Genetic Diseases
- Large molecules include antibodies, proteins, peptides, ADCs, and fusion

Submit **non-confidential** 2-3 page overview of the target, mechanism (including evidence for disease linkage), and the proposed therapeutic drug. At a high level, the pre-proposal should suggest how the therapeutic hypothesis could be tested in the clinic.

Contact Mina Zion (<u>mzion@usc.edu</u>) for details