FormsSubmissionRequirements/ ElectronicSubmissions/ucm364432.htm.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–039
93.103

A. Background

CDER receives an enormous and growing amount of data in a variety of regulatory submissions from a multitude of sources and in a variety of formats. This wealth of data holds great potential to advance CDER's regulatory and scientific work, but the present lack of standardized data creates significant challenges to realizing that potential. The volume and complexity of drug-related information submitted to CDER for regulatory review is creating significant challenges to the Center's ability to efficiently and effectively perform its critical public health mission.

The lack of standardized data affects CDER's review processes by curtailing a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage, and reporting of regulatory data. Improved data quality, accessibility, and predictability will give reviewers more time to carry out complex analyses, ask in-depth questions, and address late-emerging issues. Standardized data will allow reviewers to increase review consistency and perform evaluations across the drug lifecycle. This will enhance the Center's performance across key drug regulatory functions and ongoing business operations, including premarket review, post-market safety, oversight of drug quality, and oversight of drug promotion.

Standardized data elements that are common to all clinical trials, such as age and gender, have been established through Clinical Data Interchange Standards Consortium standards. However, data elements that are unique for a particular disease or therapeutic area still need to be developed so that the data are consistent and consistently understood for efficacy analysis, and that data from multiple trials can be more easily grouped for reporting and meta-analysis.

In short, establishing common standards for data reporting will provide new opportunities to transform the massive amount of data from drug studies on specific diseases into useful information to potentially speed the delivery of new therapies to patients.

B. Research Objectives

The CFAST Initiative aims to accelerate clinical research and medical product development by establishing and maintaining data standards, tools, and methods for conducting research in therapeutic areas that are important to public health. It is established as a public-private partnership (PPP) involving multiple stakeholders. The Grantee funded through this announcement would be expected to accomplish activities such as, but not limited to:

• Maintenance of the scientific and administrative infrastructure of the PPP to support a series of projects under the CFAST Initiative.

• Coordination and management of therapeutic area standards development projects with key experts in the specific therapeutic areas, including stakeholders from industry, professional organizations, academia, and Government agencies.

• Identification and engagement with key experts in the therapeutic areas, including stakeholders from industry, professional organizations, academia, and Government agencies.

• Development of therapeutic area data standards, initially proposed for diabetes, QT studies, lipid lowering/ altering drugs, and hepatitis C. Additional or different areas can be considered as well.

• Identification and implementation of continuous quality improvements with respect to the data standards development process and product(s) to facilitate timely and sustainable standards.

C. Eligibility Information

The following organization is eligible to apply: The Critical Path Institute (C-Path).

Over the past 7 years, C-Path has become an international leader in forming and leading/managing collaborations globally. They currently lead 7 very active scientific consortia across multiple disease areas. C-Path consortia include more than 1,000 scientists from Government, academia, patient advocacy organizations, and 41 major pharmaceutical companies. C-Path has a proven process, capability, and institutional knowledge critical to successfully leading scientific consortia and rapid therapeutic area standards development projects through an open, transparent process as identified by the Prescription Drug User Fee Act V.

II. Award Information/Funds Available

A. Award Amount

Total amount of funding available is $2,000,000. Anticipate one award.

B. Length of Support

Scope of the proposed project should determine the project period. The maximum period is 3 years.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/Drugs/ DevelopmentApprovalProcess/ FormsSubmissionRequirements/ ElectronicSubmissions/ucm364432.htm.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Persons interested in applying for a grant may obtain an application at *http://www.fda.gov/ Drugs/DevelopmentApprovalProcess/ FormsSubmissionRequirements/ ElectronicSubmissions/ucm364432.htm.* For all the paper application submissions, the following steps are required:

• Step 1: Obtain a Dun and Bradstreet (DUNS) Number

• Step 2: Register With System for Award Management (SAM)

• Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/ organization_registration.jsp.* Step 3, in detail, can be found at *https:// commons.era.nih.gov/commons/ registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to: Kimberly Pendleton-Chew, 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, 301– 827–9363, email: *Kimberly.Pendleton@ fda.hhs.gov.*

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20823 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for

licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Monoclonal Antibodies That Recognize the Human Type I Interferon Receptor and Block Interferon Signaling

Description of Technology: Type I interferons play a critical role in both innate and adaptive immunity through the stimulation of the IFNAR1 which initiates interferon signaling in response to viral and bacterial infections. However, abnormal interferon signaling is associated with human diseases, such as lupus. The present invention discloses six hybridomas that produce mouse monoclonal antibodies specific for the extracellular domain of human IFNAR1. Two of the monoclonal antibodies are able to bind IFNAR1 and reduce interferon signaling. As such, they can be utilized as a research tool for studying the expression of IFNAR1 and the inhibition of IFNAR1 function in humans or possibly as therapeutic reagents for human diseases.

Potential Commercial Applications:
• Research reagents for studying the expression and signaling of IFNAR1.
• A potential therapeutic reagent.
Competitive Advantages:
• Specific for the extracellular domain of human IFNAR1. Can therefore specifically recognize receptor expressed on the cell surface.
• Bind IFNAR1 and reduce interferon signaling
Development Stage:
• Pilot
• In vitro data available
Inventors: Sonja M. Best, Kirk Lubick, Shelly J. Robertson (NIAID)
Publications:
1. Goldman LA, et al. Characterization of antihuman IFNAR–1 monoclonal antibodies: epitope localization and functional analysis. J Interferon Cytokine Res. 1999 Jan;19(1):15–26. [PMID 10048764]

2. Benoit P, et al. A monoclonal antibody to recombinant human IFN-alpha receptor inhibits biologic activity of several species of human IFN-alpha, IFN-beta, and IFN-omega. Detection of heterogeneity of the cellular type I IFN receptor. J Immunol. 1993 Feb 1;150(3):707–16. [PMID 8423335]

Intellectual Property: HHS Reference No. E–527–2013/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Contact: Susan Ano, Ph.D.; 301–435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases (NIAID) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize human type I interferon receptor antibodies. For collaboration opportunities, please contact Alicia Evangelista at *alicia.evangelista@nih.gov* or 301–594–1673.

Anthrax Fusion Toxins With Improved Ability To Penetrate Cells

Description of Technology: Available for licensing are novel conjugated or fusion proteins comprised of anthrax toxin lethal factor cytolethal distending toxin subunit B. Several human tumor cell lines have been found to be highly sensitive to these toxins with LD50 values in the pM range. *In vivo* studies in mice have revealed that these toxins selectively treat tumors and have very low systemic toxicity.

Potential Commercial Applications:
• Pharmaceutical compositions to selectively treat cancer
• Applications to treat or prevent growth of undesirable cells
Competitive Advantages:
• Selective with low systemic toxicity
• Potent (pM LD50 values)
Development Stage:
• Early-stage
• In vitro data available
• In vivo data available (animal)
Inventors: Christopher Bachran and Stephen Leppla (NIAID)
Intellectual Property: HHS Reference No. E–120–2013/0—US Application No. 61/837,428 filed June 20, 2013

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Method and Platform for Selectively Labeling RNA

Description of Technology: The invention pertains to a three step initiation, elongation and termination method and platform for synthesizing selectively labeled RNA molecules by first polymerizing a first liquid phase RNA molecule from a solid phased DNA template fixed onto a solid phase. The method includes the steps of incubating the solid and liquid phases at appropriate elongation temperatures and then terminating elongation by a separation stage where the phases are incubated at near 0 degrees Celsius where it selectively terminates RNA elongation. The steps can be repeated by the number bases (rNTPs) in the final RNA molecule wherein in each iterative stage a new rNTP can be added that is selectively labeled. The DNA may have a density of 30–80% on the solid substrate, and the solid substrate may be a bead. The bead may comprise a gel, glass, or a synthetic polymer. The bead may have a diameter of 5–100 mm. The concentration of DNA may be 30 mm–1 nm. The concentration of rNTP may be 1–100 times the DNA concentration. The RNA polymerase may be a T7 RNA polymerase. The label may be $^{13}C/^5N$, ^2H, Cy3, Cy5, a fluorophore, a heavy atom, or a chemical modification.

Potential Commercial Applications: Differentially labeled diagnostics

Competitive Advantages: Multiple use detection method

Development Stage:
• Prototype
• In vitro data available

Inventors: Yun-Xing Wang (NCI), Liu Yu (NCI), Ping Yu (NCI), Rui Sousa (Univ. Texas Health Science Ctr)

Publications:

1. Guajardo R, Sousa R. A model for the mechanism of polymerase translocation. J Mol Biol. 1997 Jan 10;265(1):8–19. [PMID 8995520]

2. Guo Q, et al. (2005). Major conformational changes during T7RNAP transcription initiation coincide with, and are required for, promoter release. J Mol Biol. 2005 Oct 21;353(2):256–70. [PMID 16169559]

3. Mukherjee S, et al. Structural transitions mediating transcription initiation by T7 RNA polymerase. Cell. 2002 Jul 12;110(1):81–91. [PMID 12150999]

4. Mentesana PE, et al. Characterization of halted T7 RNA polymerase elongation complexes reveals multiple factors that contribute to stability. J Mol Biol. 2000 Oct 6;302(5):1049–62. [PMID 11183774]

Intellectual Property: HHS Reference No. E–119–2013/0—US Provisional Patent Application No. 61/843,864 filed July 8, 2013

Licensing Contact: Michael Shmilovich, Esq., CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Blood-Based Assay for the Diagnosis and Monitoring of Hyposialylation Disorders

Description of Technology: Sialic acid, a monosaccharide widely distributed in glycoproteins and glycolipids, plays an important role in biological processes such as cellular adhesion, cellular communication and signal transduction. Reduced levels of sialic acid in tissues (also known as hyposialylation) affect the function of muscle, kidney, and other organ systems, and are found in a number of disorders, such as hereditary inclusion body myopathy (HIBM, also known as GNE myopathy), renal hyposialylation disorders, and congenital disorders of glycosylation.

The inventors have developed a sensitive, reliable assay for the diagnosis of hyposialylation disorders that detects a novel glycoprotein biomarker in a patient blood sample. This assay has been validated using samples from patients with GNE myopathy and other hyposialylation disorders. A distinct advantage of this assay is that it is minimally invasive, unlike many currently-available methods for diagnosing hyposialylation disorders, which typically require a tissue biopsy. In particular, this biomarker represents the first non-invasive method for diagnosis of renal hyposialylation.

Potential Commercial Applications:
• Diagnostic assay to detect hyposialylation
• Monitoring tool to track patient response to sialylation-increasing therapy

Competitive Advantages: A blood-based assay based on this technology would be less invasive, time-consuming, and costly than a tissue biopsy, which is the current diagnostic standard for hyposialylation disorders, particularly kidney disorders.

Development Stage:
• Early-stage
• In vitro data available

Inventors: Marjan Huizing (NHGRI), William Gahl (NHGRI), Nuria Carrillo-Carrasco (NCATS)

Intellectual Property: HHS Reference No. E–056–2013/0—U.S. Application No. 61/785,094 filed 14 Mar 2013

Related Technologies:
• HHS Reference No. E–217–2007/ 0—N-Acetyl Mannosamine as a Therapeutic Agent
• HHS Reference No. E–270–2011/ 0—Encapsulated N-Acetylmannosamine or N-Acetylneuraminic Acid to Increase Sialylation

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Vaccine Adjuvant for Inducing Th17 Focused Response

Description of Technology: Adjuvant selection can be critical to a vaccine's effectiveness. Ideally, an adjuvant will target and activate specific immune pathways to increase the magnitude of a response to the vaccine. A limited range of adjuvants are presently available for human clinical use; these primarily affect T helper cells 1 and 2 (Th1 and Th2). Currently, no adjuvants are approved for human use which primarily affect IL–17-producing T helper cells (Th17) cells. Th17 focused adjuvants may prove critical for developing operative vaccines against pathogens where Th17 activity is essential for protection. This technology relates to novel adjuvants activating either caspase-associated recruitment domain protein 9 (CARD9) or caspase 1 pathways, or a combination of the two; and methods for using these adjuvants for stimulating an immune response. These adjuvants induce Th17 focused stimulation, which may prove essential to development of effective vaccines against a range of pathogens including bacteria and fungi.

Potential Commercial Applications: Vaccine

Competitive Advantages: Th17 skewing adjuvant

Development Stage: Early-stage

Inventors: Alan Sher (NIAID), Kevin Shenderov (NIAID), Vincenzo Cerundolo (University of Oxford, U.K.), Gurdyal Besra (University of Birmingham, U.K.)

Publication: Shenderov K, et al. Cord factor and peptidoglycan recapitulate the Th17-promoting adjuvant activity of mycobacteria through mincle/CARD9 signaling and the inflammasome. J Immunol. 2013 Jun 1;190(11):5722–30. [PMID 23630357]

Intellectual Property: HHS Reference No. E–089–2012/0—U.S. Provisional Patent Application No. 61/709,713 filed October 4, 2012

Licensing Contact: Edward (Tedd) Fenn, J.D.; 424–500–2005; *Tedd.fenn@ nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Richard Kitei at 301–496–2644.

Dated: August 22, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–20888 Filed 8–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA: Oncological Sciences Grant Application.
Date: September 20, 2013.
Time: 10:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Denise R Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435– 0198, *shawdeni@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13– 008: Shared Instrumentation: Confocal Microscopy and Imaging.
Date: September 26, 2013.
Time: 8:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–435– 1236, *smirnove@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)