MOU: 225-15-017

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE FOOD AND DRUG ADMINISTRATION

AND

THE CRITICAL PATH INSTITUTE

The United States Food and Drug Administration (FDA) and the Critical Path Institute (C-Path) (the Parties) share interests in promoting scientific progress through the exchange of scientific capital to develop innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety (Critical Path Public-Private Partnerships).

I. Purpose

The purpose of this Memorandum of Understanding (MOU) is to renew the overarching framework for Critical Path Public-Private Partnerships between FDA and C-Path. This MOU and the collaborative framework it provides will facilitate existing and new mutually agreed upon programs, activities, and consortia between the Parties. This MOU establishes the terms for collaboration to promote these shared interests, which can be pursued through a variety of programs including collaborative education, research, and outreach activities.

II. Background

FDA is charged with assuring the safety and effectiveness of medical products under the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.) and the Public Health Services Act, including sections 351 and 362 (42 USC 262, 264). In fulfilling these responsibilities, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of medical products, including drugs, biological products, veterinary products, medical devices and radiological products. FDA also advances the public health by supporting the development of innovative technologies which help to make medical products safer and more effective and available to more patients. As part of the goal of speeding innovation, FDA's Critical Path Initiative seeks to identify and address those scientific and technical obstacles to the optimum development of safe and therapeutically important medical products.

In a 2004 white paper now known as the Critical Path Challenges and Opportunities Report, the FDA called attention to a decline in the number of innovative medical products being submitted for FDA approval. To bridge the gap between basic scientific research and medical product development, the FDA created The Critical Path Initiative with a goal of developing improved processes to evaluate the safety and effectiveness of new medical products. In 2005, and with a planning grant from the State of Arizona, C-Path was founded as a 501(c) (3) corporation based in Tucson.

In 2007, Congress explicitly authorized the FDA to enter into Critical Path Public-Private Partnerships in Title VII, Section 603 of H.R. 3580, the Food and Drug Administration Amendments Act (codified at 21 USC 360bbb-5).

C-Path is an independent, non-profit institute created in 2005 by the University of Arizona and the FDA at which time an MOU was established with the agency. C-Path is dedicated to bringing scientists from the FDA and the European Medicines Agency, industry, and academia together in collaborative research endeavors to improve the path for innovative new product development to reach patients in need. Based in Tucson, AZ, C-Path's programs address scientific, safety, and educational aspects of medical product development in support of the FDA's Critical Path Initiative.

III. Substance of Agreement

This MOU may facilitate joint collaboration through public private partnerships with the goal of developing new tools to inform medical product development. The areas of collaboration would include but are not limited to:

Consortia: Parties will jointly create and participate in activities of complementary interest that are important to the public health, which may include but are not limited to: imaging, biomarkers and biosignatures, proteomics and genomics, quantitative disease progression models, clinical trial design, and other areas that will enhance medical product development.

This work may be executed through collaborations and consortium activities in public health priority areas such as, but not limited to, the:

1) Predictive Safety Testing Consortium (PSTC)
2) Patient-Reported Outcome Consortium (PRO)
3) Electronic Patient-Reported Outcome Consortium (ePRO)
4) Coalition Against Major Diseases Consortium (CAMD)
5) Critical Path to Tuberculosis Regimens Consortium (CPTR)
6) Polycystic Kidney Disease Outcomes Consortium (PKDOC)
7) Multiple Sclerosis Outcome Assessments Consortium (MSOAC)
8) Coalition For Accelerating Standards and Therapies (CFAST) Initiative
9) International Neonatal Consortium

Training/Education programs: Parties will develop joint activities arising from complementary interests, and offer these activities to academia, industry, and others as identified needs arise.

The Parties will disseminate information through mutually agreed vehicles including training activities, meetings, workshops, and symposia.

IV. General Provisions:

C-Path assures in this MOU with the FDA that the results of the Critical Path Public Private Partnership projects will not be influenced by any source of funding.

V. Resource Obligations:

This MOU represents the broad outline of the Parties' present intent to enter specific agreements for Critical Path Public-Private Partnership projects in areas of mutual interest to FDA and the participating Parties. All activities undertaken under this MOU are subject to available personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties. This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the participating Parties operate.

This MOU supersedes the MOUs executed on October 17, 2005 and May 19, 2010, but does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU.

VI. Liaison Officers:

For the Critical Path Institute:

Martha A. Brumfield, PhD
President & CEO
Critical Path Institute
1730 East River Road
Tucson, AZ 85718
Phone: 520-547-3440
Fax: 520-547-3456
Email: mbrumfield@c-path.org

For the Food and Drug Administration:

ShaAvhrée Buckman-Garner, M.D., Ph.D., F.A.A.P.
Director, Office of Translational Sciences
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg. 21, Room 4554
10903 New Hampshire Ave
Silver Spring, MD 20993

Tel: 301-796-2600
Email: shaAvhree.buckman@fda.hhs.gov

With copy to:

Susan McCune, M.D.
Deputy Director
Office of Translational Sciences
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg. 21, Room 4558
10903 New Hampshire Ave
Silver Spring, MD 20993
Tel: 301-796-1709
Email: susan.mccune@fda.hhs.gov

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

VII. Terms, Termination and Modification:

This agreement will be effective when accepted by all participating parties. This agreement may be modified or terminated by mutual written consent by the parties or may be terminated by either Parties upon a 30 day advance written notice to the other.

SIGNATURES OF RESPONSIBLE PARTIES:

APPROVED AND ACCEPTED
FOR THE CRITICAL PATH INSTITUTE

By: Martha A. Brumfield. Ph.D.
President & CEO
Critical Path Institute

Date: April 9, 2015

APPROVED AND ACCEPTED
FOR THE FOOD AND DRUG
ADMINISTRATION

By: Janet Woodcock, M.D.
Director,
Center for Drug Evaluation and Research

Date: April 9, 2015