

**MOU 225-05-8000**

**MEMORANDUM OF UNDERSTANDING**

**BY AND BETWEEN**

**THE UNITED STATES FOOD AND DRUG  
ADMINISTRATION**

**AND CRITICAL PATH INSTITUTE**

## **MOU 225-05-8000**

This Memorandum of Understanding (MOU) between the U.S. Food and Drug Administration (FDA) and the Critical Path Institute (C-Path) (hereafter termed “the Parties”) formalizes an agreement between the two parties to develop collaborative activities in the areas of applied research, training and education to enhance safe and efficacious medical product development. The appropriate formal agreements will be executed as required by law for any activities that result from this collaboration.

### **I. Purpose**

The purpose of this MOU is to renew the overarching framework for collaboration between the United States Food and Drug Administration (“FDA”) and Critical Path Institute (“C-Path”). This MOU and the collaborative framework it provides will facilitate existing and new mutually agreed upon programs and activities, consortia and consensus development between the Parties. Data and outcomes of said programs may be used by stakeholders to inform medical product development. The Parties intend to leverage their expertise and resources across diverse disciplines including therapeutics, biological sciences, engineering and medical devices, and diagnostics through applied research and training/education programs.

### **II. Background**

The FDA is responsible for reviewing clinical research to ensure that marketed human medical products (drugs, biologics, and medical devices) are safe and effective. In a 2004 white paper now known as the Critical Path Initiative, the FDA called attention to an alarming 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 to develop improved testing methods and 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, and with offices in Phoenix, Arizona and Rockville, Maryland.

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In 2007, Congress 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. This legislation created an opportunity to expand FDA authority and resources to engage in collaborative research and regulatory science through public private partnerships.

Dedicated solely to implementing the FDA's Critical Path Initiative, C-Path has forged key partnerships and created collaborations that include FDA, European and Japanese regulatory agencies and private industry. These consortia create an environment where multiple stakeholders including scientists from academia, industry, government agencies, and non-profit organizations formally agree to share information, develop scientific consensus and make findings available for public use.

### **III. Substance of Agreement**

This MOU may facilitate joint collaboration through public private partnerships with the goal of developing new evaluative 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 the:

- 1) Preventive Safety Testing Consortium
- 2) Patient Reported Outcomes Consortium
- 3) Coalition Against Major Diseases Consortium
- 4) Tuberculosis Regimens Consortium

Training/Education programs: Parties will develop joint activities arising from complementary interests,

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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, and symposia.

### **IV. Resource Obligations**

This MOU describes in general terms the basis upon which the Parties intend to collaborate. It does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and appropriated funds. This MOU supersedes the MOU executed on October 17, 2005, but does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU.

### **V. Name and Address of Participating Parties and Liaisons**

#### **For the Critical Path Institute:**

Raymond L. Woosley, M.D., Ph.D.

President and CEO

Critical Path Institute

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### **For the Food and Drug Administration:**

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With copy to :

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### **VI. Period of Agreement**

This MOU becomes effective upon the date of the last Party to sign (“effective date”) and will continue in effect for five years. It may be modified by mutual written consent or terminated by either Party upon a 30-day advanced written notice to the other Party. The Parties agree to evaluate the MOU periodically during the effective period, but at least once annually, on or before the anniversary of the effective date. Upon evaluation, either Party shall have the option of continuing, proposing modifications or canceling this agreement as provided for in Article VI of this MOU.

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**SIGNATURES OF RESPONSIBLE PARTIES:**

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE  
UNITED STATES FOOD AND DRUG ADMINISTRATION

  
\_\_\_\_\_  
Janet Woodcock, M.D.  
Director, Center for Drug Evaluation and Research  
Food and Drug Administration

Date 5/19/10

APPROVED AND ACCEPTED FOR THE  
CRITICAL PATH INSTITUTE

  
\_\_\_\_\_  
Raymond L. Woosley, M.D., Ph.D.  
President and CEO  
Critical Path Institute

Date 5/6/2010