

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
UNITED STATES FOOD AND DRUG ADMINISTRATION
AND THE
C-PATH INSTITUTE

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.

I. Purpose

The specific purpose of this MOU is to establish an overarching framework for collaboration between the Parties. This framework will be based on mutually agreed upon programs and activities in the areas of applied scientific research and training/education to foster the development of new evaluation tools to inform medical product development. The Parties shall each leverage its own expertise and resources to facilitate programs of shared interests across the diverse disciplines of therapeutics, biological sciences, engineering and medical devices in building applied research and training/education programs. The appropriate formal agreements will be executed as required by law for any activities that result from this collaboration.

II. Background

The FDA is responsible for reviewing clinical research to ensure that marketed human medical products (drugs, biologics, and medical devices) have been shown to be safe and effective.

The C-Path Institute is a non-profit research and education organization located in Tucson, Arizona. The Institute's purpose is to create innovative programs in education and research to enable safe acceleration of medical product development. It also serves as a 'neutral ground' for academia, industry and government to test ideas that will result in optimal (safe, effective, timely) drug development processes. C-Path brings together faculty from the UAZ Colleges of Pharmacy, Medicine, Agriculture and Life Sciences, and the School of Management as well as clinicians and researchers from the UAZ Comprehensive Cancer Center, the Sarver Heart Center, the Pima Community College, Arizona State University and the Translational Genomics Research Institute in programs related to pharmaceutical discovery and development, clinical research and good clinical practices (GCP) as well as scientific staff from SRI International (an independent, non-profit technology development organization), who have substantial experience in developing drugs for commercial manufacturing. SRI International is a contractor for NIH and has initiated a drug development consortium with other academic institutions, the purpose of which is to assist faculty investigators to translate research into clinical drug candidates.

III. Substance of Agreement

This MOU is intended as an overarching framework for joint collaboration between the Parties, toward the goal of developing new evaluative tools to inform medical product development. The areas of collaboration would include, but not be limited to:

Training/Education programs: Activities arising from complementary interests will be developed jointly by C-Path and FDA, and offered to academia, industry, and others as identified needs arise. The Parties will disseminate information through mutually agreed vehicles including training activities, meetings, and symposia.

Applied Research programs: Programs will be developed in areas of mutual complementary interest such as imaging, biomarkers and surrogate markers, proteomics and genomics, clinical trial design, and other areas that will enhance medical product development.

As specific topics for joint training/education and/or research are identified under this MOU they will be conducted under the appropriate formal agreements as required by law.

IV. Participation

It is anticipated that a wide range of faculty and graduate students, clinicians, and researchers from academic programs may participate in activities developed under this agreement, including, but not limited to, University of Arizona Comprehensive Cancer Care Center, the Sarver Heart Center, the Colleges of Pharmacy, Medicine, Management, and Agriculture and Life Sciences, Pima Community College, Arizona State University, Translational Genomics Research Institute, and SRI International. Other participants could include FDA staff, scientists from industry, field laboratories and others identified for joint training and outreach activities.

Each Party will appoint appropriate representatives to facilitate the planning, preparation, and implementation of the activities within the framework of this MOU. Meetings will be convened at a venue and time agreed between Parties, and each Party shall be responsible for its own expenses incurred in sending representatives to these meetings.

V. Resource Obligations

This MOU describes in general terms the basis upon which the Parties intend to cooperate. 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 does not affect or supersede any existing or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU.

VI. Name and Address of Participating Parties and Liaisons

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B. Food and Drug Administration
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VII. 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, modifying, or canceling this agreement as provided for in Article VII of this MOU.

APPROVED AND ACCEPTED FOR THE
C-PATH INSTITUTE

By Raymond L. Woosley
Title President

Date September 14, 2005

APPROVED AND ACCEPTED FOR THE
FOOD AND DRUG ADMINISTRATION

By [Signature]
Title Deputy Commissioner for Operations

Food and Drug Administration

Date 10/14/05

Cleared: R. Garwood, ORM 5/18/05
Reviewed and cleared: R. Springer, OM/OAGS 5/18/05
Reviewed and edited: L. Mahler, OCC 8/23/05
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