MOU Control No. 225-13-0007

MEMORANDUM OF UNDERSTANDING BETWEEN THE

PHARMACEUTICAL USERS SOFTWARE EXCHANGE (PHUSE)

AND

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION (FDA)

I. Purpose:

This Memorandum of Understanding (MOU) defines the framework in which the United States Department of Health and Human Services Food and Drug Administration (FDA) and the Pharmaceutical Users Software Exchange (PhUSE) will bring FDA, industry, and academia together for work on collaborations established at symposiums and continued throughout the year. Collaborative projects will be created to address challenges related to access and review of data supporting product development. FDA and PhUSE will work on possible solutions and practical implementations with the goal of advancing computational science through broader community alignment and shared experiences.

II. Background:

The ability to acquire, store, analyze, use, and share information is critical to the successful development and expert regulatory oversight of new drugs. These capabilities enable sponsors, contract research organizations, and international regulatory agencies to make informed and timely decisions.

In 2008 FDA/CDER initiated the Computational Science Center (CSC), an infrastructure for Center for Drug Evaluation and Research (CDER)'s scientific community with the goal of supporting a number of ongoing efforts in pre-market development, modernization of drug review, post-market drug safety, and drug quality. The stated mission of the CSC is to provide CDER reviewers with a more aligned and automated method for completing reviews and more transparency in decision making and documentation. The CSC is focused on key projects which include the adoption and enhancement of submission and data standards and expanding the use of electronic review tools. CBER also has recognized many of the same challenges and has begun preparation and development of processes for receipt and review of standard submissions.

Pharmaceutical Users Software Exchange (PhUSE) is an independent and non-profit organization created by volunteers who work in the pharmaceutical industry. PhUSE has the support of most major pharmaceutical companies in both Europe and the United States. There is a Board of Directors supporting the organization and several sub

committees responsible for separate items. PhUSE offers information and events to all its members and allows its content to be open source.

The goal of this partnership is to review progress on topics such as data standards, best-practices-driven analytical tool development, business processes driving development of information systems, and experiences and evaluation of current tools by users.

III. Authority:

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the Act, FDA, among other activities, directs its efforts toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, and medical devices and the safety and security of foods, dietary supplements, cosmetics, and radiological products. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships with PhUSE will contribute to FDA's mission.

IV. Substance of Agreement:

The goals and expected results of this collaboration are to:

- Highlight both the need for a modern bioinformatics platform to support regulatory review and communication and the challenges of developing this platform.

- Share progress on data standards development and implementation between regulators and regulated industries.

- Discuss and share practices that will ensure effective and efficient regulatory review of data submissions.

- Discuss and develop needs and specifications for proposed new tools and solutions.

- Describe best practices (process, tools), implementation experiences, and the subsequent impact of computational technologies on organizational performance.

- Discuss and find solutions to common needs of FDA, industry and academia in the drug development and review lifecycle.

V. Responsibilities:

a. Food and Drug Administration agrees to:

- Provide representatives to the organizing and steering committees.
- Provide FDA working group co-leads to ensure the efforts of the working groups are aligned with the needs of the FDA.
- Identify and provide FDA speakers/presenters/moderators to participate in the annual conference program.
- Announce the collaboration via websites or other media deemed appropriate for the target audience.
- Share information concerning the program with the public upon request.

b. Pharmaceutical Users Software Exchange agrees to:

- Provide representation at all joint-planning meetings and program calls.
- Provide a system and framework to support the functionality of the working groups.
- Collaborate with the FDA to develop one or more interactive conferences that provide industry and FDA an opportunity to discuss issues and work towards solving them.
- Provide tools for facilitation of working groups, organize, and manage ongoing working group meetings.
- Maintain working group content that is openly available to the public. In addition, ensure contributions to the PhUSE Wiki, blogs, and forums are free of charge and not tied to any membership. Access to information requires username and password.
- Manage all annual conference logistics including registration, venue, audio/visual, food, printing of material, sharing of information, organizing post-conference e-workshops and exhibitors.

VI. General Provisions:

This is an MOU between FDA and PhUSE and does not confer any rights or benefits to any person or Parties.

VII. Resource Obligations:

This MOU represents the broad outline of the Parties present intent to enter specific agreements for collaborative efforts in areas of mutual interest to FDA and PhUSE. All activities undertaken through the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements with the Party.

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 PhUSE operate.

VIII. Liaison Officers:

1. For the Pharmaceutical Users Software Exchange (PhUSE):
   Chris Decker
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2. For the Food and Drug Administration:
   Crystal Allard
   Center for Drug Evaluation and Research (CDER)
   10903 New Hampshire Avenue
   Silver Spring, MD 20993
   (301) 796-2600
   (301) 796-9907 (FAX)
   crystal.allard@fda.hhs.gov

   And

   Center for Biologics Evaluation and Research (CBER)
   1401 Rockville Pike
   Suite 200N/HFM-47
   Rockville, MD 20852-1448
   (301) 827-1800

Each Party may designate new liaisons at any time by notifying the other Party's liaison in writing. If, at any time, an individual

designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Party for which that individual was the liaison will name a new liaison within 2 weeks and notify the other Party through that Party's designated liaison.

IX. Term, Termination, and Modification:

The terms of this agreement shall be effective for a period of three (3) years from the date of execution (date of last signature). This agreement may be modified or terminated by mutual written consent by both Partners or may be terminated by either Partner upon a 60 day advance written notice to the other."

APPROVED AND ACCEPTED FOR Pharmaceutical Users Software Exchange (PhUSE) By _____ Title _____	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION By _____ Title _____
_____ Date	_____ Date
_____	_____