225-07-4301

MEMORANDUM OF UNDERSTANDING

between the

NATIONAL CANCER INSTITUTE

and the

FOOD AND DRUG ADMINISTRATION

on

Janus Study Data Repository

I. Purpose

The purpose of this memorandum of understanding (MOU) is to establish a formal collaboration between the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute (NCI) to create a common standards-based data repository to facilitate the exchange and analysis of study data.

This MOU sets forth an agreement between FDA and NCI regarding roles, responsibilities, financial commitments, and information-sharing for the development and implementation of the Janus study data repository and integrated analysis tools environment. The ultimate goal for the Janus project is to provide an environment that will enable NCI, FDA, and entities sponsoring research studies of investigational drugs (*Sponsors of Drugs and Biologics* or *Sponsors*) to exchange and manage study data electronically in a fully secure manner.

Janus is one of several modules under development as part of an NCI effort in its Center for Bioinformatics (NCICB) to facilitate the exchange of clinical research information between sponsors, including NCI, and FDA. To accomplish this objective, NCICB will make use of the cancer Biomedical Informatics Grid (caBIG™), which is a common infrastructure for sharing data, tools, and other resources among all entities engaged in cancer research. Janus will adhere to the caBIG™ principles of open source, open access, open development and federation and will be compatible with caBIG™ technical standards. Upon the successful implementation of Janus, FDA intends to encourage Sponsors of both investigational and marketing applications to use the system to submit their study data to FDA using standards developed by the Clinical Data Interchange Standards Consortium (CDISC). For the purposes of this MOU, *study data* refers to data and information required to be submitted to FDA, including clinical and preclinical data in support of an investigational or marketing application.

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II. Background

The FDA/NCI Interagency Oncology Task Force (IOTF) was established in 2003 to enhance the efficiency of clinical research and the scientific evaluation of new cancer medications and diagnostics. The FDA and NCI both have interests in expediting the development of new drugs. One of the central goals of the IOTF is to implement an electronic drug application submission system that will help reduce the delays, errors, and costs associated with drug development. Such a system is expected to speed the discovery and delivery of new therapies.

Janus, a primary component of such a system, is envisioned as a common electronic infrastructure that will help accelerate and streamline interactions between sponsors (including NCI) and FDA by facilitating the exchange of CDISC-compatible study data. Once implemented, Janus is intended to enable sponsors (including NCI) and FDA to exchange and manage study data electronically in a fully secure manner. This MOU relates solely to Janus. NCI and FDA will work together to develop subsequent MOUs (or addenda to this MOU) related to other modules of an electronic product information exchange system.

III. Substance of Agreement; Responsibilities of NCI and FDA

This MOU addresses activities related to the development and implementation of Janus. Information in the Janus study data repository will fall into two categories, which, for the purposes of this MOU are referred to as *FDA records* and *non-FDA records*. *FDA records* refers to any information entered into the Janus repository by or on behalf of FDA, as well as any information, regardless of who enters it into Janus, once it is electronically submitted to FDA. For information entered into Janus by a sponsor (including NCI) to become an *FDA record*, the system will require the submitter to take an affirmative step acknowledging the fact that the data are now accessible by the FDA. This will be considered a submission to FDA. Once so submitted to FDA, the information becomes available to the FDA and becomes an FDA record. *Non-FDA records* are any information not entered into Janus by or on behalf of FDA, as well as information entered into Janus by a sponsor prior to taking the affirmative step that constitutes submission to FDA.

FDA and NCI will establish a Change Management Board, comprising representatives of both agencies, to discuss Janus's technical requirements and to discuss and decide on changes or enhancements to the technical capabilities of Janus.

Development of Janus will occur in four phases: (1) development and testing, (2) operational pilot testing, (3) production deployment, and (4) actual production. During phases 1, 2, and 3 of the project, FDA will transfer certain existing FDA information related to CDISC-compatible study data to NCI for the sole purpose of preparing such records for entry into the Janus repository. To get Janus established, during phases 1, 2, and 3, both FDA and NCI will have access to these FDA records and NCI's access to FDA records during this period is subject to the restrictions enumerated in III.A. of this agreement. After the conclusion of phase 3, NCI will not seek to access records in the FDA records component of Janus. During the first 6 months of phase 4, the system will limit access to FDA records solely to FDA and the contractor functioning as NCI's

database administrator for Janus, and the contractor will be bound by the same restrictions set forth in III.A. of this agreement. Thereafter, only FDA will have access to FDA records. Information entered into Janus by or on behalf of FDA will reside only in the FDA records component. Notwithstanding all of the foregoing, however, it is understood that NCI may be required to access records on its server if so required by law.

The specific responsibilities of the two parties to this MOU are as follows:

A. The National Cancer Institute (NCI)

- NCI will lead the development of Janus and provide for the maintenance of all hardware, software, and databases.
- NCI will design Janus to meet the requirements identified for the implementation of Janus. Changes or enhancements to the technical capabilities of Janus will only be made upon the approval of the Change Management Board.
- NCI will ensure that the data collected, stored, and exchanged through Janus meet applicable FDA requirements set forth in 21 CFR Part 11.
- NCI will not seek to access to any FDA record once the record has been submitted to FDA during phase 4, except as already permitted in accordance with any applicable FDA Privacy Act System Notice or the FDA disclosure regulations set forth in 21 CFR Part 20 or as otherwise required by law. However, the system may be designed to permit sponsors, including NCI, to create a mirror or duplicate of the record in the non-FDA records component of Janus. NCI will protect all FDA records from disclosure in accordance with applicable laws and regulations.
- For information transferred by FDA to NCI for preparation and entry into Janus during phases 1, 2 and 3, NCI agrees that, except as necessary for facilitating the information's entry into Janus, NCI will not use or disclose such information outside the Department of Health and Human Services without FDA's express written permission, except to the extent required by law. Furthermore, before giving its contractor access to any information transferred by FDA to NCI for preparation and entry into Janus, NCI will procure written agreement from its contractor not to further use or disclose such information, except to the extent required by law.
- If for any reason NCI plans to discontinue the maintenance of Janus, NCI will give FDA 60 days' advanced notice of this decision and transfer the system, software, and FDA records, as well as documentation, procedures and instructions concerning the normal and emergency operation of the Janus software, to FDA, or another party mutually agreed upon and in compliance with all applicable laws and regulations, in a timely fashion.

B. The Food and Drug Administration (FDA)

- FDA will inform NCI of all necessary server security requirements.
- FDA will work with NCI to ensure that Janus contains all necessary server security requirements.

- FDA will develop a transition plan to migrate FDA's current CDISC-compliant study data to the Janus repository, which is intended to eventually become FDA's repository for storing and obtaining access to study data required under 21 CFR 312.
- FDA staff will enter into the FDA records portion of Janus relevant CDISC-compatible study data submitted to FDA as part of new product applications as well as other data generated by FDA (e.g., metadata for the product applications associated with the CDISC-compatible study data).

IV. Funds

None of the activities outlined above currently requires the exchange of funds between NCI and FDA. In the event that the transfer of funds is deemed to be required in the future, the parties may enter into an interagency agreement pursuant to Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535).

V. Information-Sharing, Reports, and Notices

FDA shall determine, in compliance with applicable law, whether to disclose information in the FDA records component of Janus. Proprietary and/or nonpublic information submitted by sponsors, including NCI, to the Non FDA records component of Janus will not be publicly disclosed by NCI, unless such disclosure is governed by appropriate confidentially disclosure agreements, or to the extent such disclosure is required by law. If NCI receives a request, order, or demand for FDA records, including a request under the Freedom of Information Act, 5 U.S.C. 552, NCI will refer that request to FDA for response.

VI. Liaison Officers

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VII. Duration of MOU; Modifications; Termination

This MOU shall become effective on the date of signature by the parties and shall remain in effect for two (2) years unless modified by the mutual agreement of the parties upon sixty (60) days'

notice in writing, or until such time as the system and software have been transferred to the FDA or a mutually agreed upon third party. If either party wishes to terminate this MOU, it may do so by giving 60 days' advance notice of this decision to the other party and must ensure that records belonging to the other party are transferred to the other party in a timely fashion.

VIII. SIGNATURES OF RESPONSIBLE PARTIES

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

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

Date 1/31/07

Janet Woodcock, M.D.
Deputy Commissioner and Chief Medical Officer
U.S. Food and Drug Administration

APPROVED AND ACCEPTED FOR THE NATIONAL CANCER INSTITUTE

Date 3-2-07

John E. Niederhuber, M.D.
Director
National Cancer Institute