Dated: September 26, 2008.

Jeffrey Shuren,

Asssociate Commissioner for Policy and Planning.

[FR Doc. E8–23120 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]

[FDA No. 225–08–8004]

Memorandum of Agreement Between the Food and Drug Administration, the National Cancer Institute, a Part of the National Institutes of Health, and the CRIX International Association

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration FDA) is providing notice of a memorandum of agreement (MOA) between FDA, the National Cancer Institute (NCI) and CRIX International Association. The purpose of the MOA is to establish a public-private partnership to pilot the use of a nonprofit organization to manage the production instance of the Federal Investigator Registry of Biomedical Information Research Data (FIREBIRD) system as a vehicle for secure, rapid and efficient electronic exchange of clinical investigator credentialing information among clinical investigators at trial sites, sponsors (including NCI), and FDA; and to continue the development of FIREBIRD to fulfill the requirements of FDA and sponsors (including the NCI).

DATES: The agreement became effective August 28, 2008.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Director for Health and Regulatory Data Standards (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7784;

George Komatsoulis, Chief Operating Officer, Center for Bioinformatics, National Cancer Institute, 8800 Rockville Pike, Bethesda, MD 20892–8505, 301–451–2881; and

James L. Bland, Project Officer, CRIX International Association, 1195 Freedom Dr., Reston, VA 20190, 703–577–8788.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOA.

Dated: September 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

BILLING CODE 4160–01–S

FDA Record NO. 225-08-8004

MEMORANDUM OF AGREEMENT
between the
U. S. FOOD AND DRUG ADMINISTRATION
the
NATIONAL CANCER INSTITUTE,
a part of the
THE NATIONAL INSTITUTES OF HEALTH,
and
CRIX INTERNATIONAL

WHEREAS, the U.S. Department of Health and Human Services, Food and Drug Administration ("FDA"), an agency of the Federal Government, is charged by Congress with protecting the public health by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices, and is also responsible for advancing the public health by helping to speed innovations that lead to safer and more effective products under its jurisdiction;

WHEREAS, given its statutory obligations to regulate and monitor clinical investigators and the conduct of clinical trials in support of new medical product applications and unique perspectives on medical product research and development activities and in-depth understanding of clinical trial design, regulatory policy, and scientific expertise in evaluating new medical products, the FDA is interested in the development of a fully electronic submissions process for new medical product applications that enables rapid and efficient electronic exchange of regulatory data among the FDA, clinical investigators and sponsors from industry and government ("Sponsors");

WHEREAS, the U.S. Department of Health and Human Services, National Cancer Institute ("NCI"), a component of the National Institutes of Health and an agency of the Federal Government, is charged by Congress with leading the nation's efforts for cancer research and training and, in service of its mission, seeks to improve quality of care and outcomes by utilizing personalized medicine to drive the selection of medications, therapies or preventive measures that are particularly suited to individual patients at the time of administration;

WHEREAS, in recognition of the importance of using biomedical informatics and information technology to realize the promise of next generation developments in biomedicine, in 2003 the NCI launched the cancer Biomedical Informatics Grid™ ("caBIG™"), an electronic, standards-based infrastructure for sharing data, tools, and other resources among individuals, and organizations in an effort to speed the development of innovative approaches for the prevention and treatment of cancer;

WHEREAS, the NCI and the FDA are interested in exploring the use of an electronic infrastructure for the management of regulatory data submissions in order to help reduce the delays, errors, and costs associated with drug development and speed the discovery and delivery of new therapies, not just for cancer, but for all diseases;

WHEREAS, CRIX International Association (CRIX), a privately funded, not-for-profit corporation composed of board representation from public, private, and sponsor institutions, and located at 11951 Freedom Drive, 13th Floor, Reston, Virginia 20190, is dedicated to leveraging technology to provide and govern a collaborative electronic platform to share information and documents related to clinical research and medical product development between sponsors of new medical products, their business partners, research institutions, academia and health authorities involved in bringing new therapies to patients throughout the world.

NOW THEREFORE, in consideration of the foregoing, and intending to be legally bound hereby, FDA, NCI, and CRIX (hereafter referred to as the Parties) covenant and agree as follows:

I. Purpose

The purpose of this MOA is to establish a public-private partnership between the Parties to pilot the use of a nonprofit organization to: (i) manage a production instance of the FIREBIRD system (described below in Article II) as a vehicle for secure, rapid and efficient electronic exchange of clinical investigator credentialing information among clinical investigators at trial sites, Sponsors (including the NCI) and the FDA; and (ii) continue development of FIREBIRD to fulfill the requirements of FDA and Sponsors (including the NCI).

Activities to be undertaken pursuant to this MOA will include:

1. Completion of the documentation of requirements for further development of FIREBIRD with respect to the submission of clinical investigator data
2. Further development and testing of FIREBIRD to fulfill the requirements of FDA and Sponsors
3. Deployment and migration of existing data to a production system for submission of clinical investigator data
4. Assessment of the ability of a nonprofit entity to manage a production system of FIREBIRD on a long-term basis in the context of a central system for investigator credentialing information

Responsibilities for performance of these activities are set forth below in Section IV.

II. Background

The NCI, in collaboration with the FDA, initiated development and implementation of the Federal Investigator Registry of Biomedical Information Research Data ("FIREBIRD"), a software application to manage and share clinical investigator credentialing information between Sponsors,

clinical investigators, and FDA via a secure electronic infrastructure, under MOA No. 225-06-8402 between the FDA and the NCI. FIREBIRD is one of several software modules under development as part of an NCI effort in its Center for Biomedical Informatics and Information Technology (CBIIT) to facilitate the exchange of clinical research information. Once implemented, FIREBIRD is designed to enable Sponsors (including the NCI) and the FDA to manage clinical investigator information, required by the FDA to be documented on FDA Form 1572, electronically in a fully secure manner. Although the NCI is currently using a production-grade instance of FIREBIRD in certain NCI-sponsored clinical trials, the development of FIREBIRD is ongoing, and several requirements have yet to be implemented.

Information in the production FIREBIRD system to be hosted and managed by CRIX (the "Production FIREBIRD System") falls into two categories, which, for the purposes of this MOA, are referred to as "FDA records" and "non-FDA records:"

"FDA records" refers to any information entered into the Production FIREBIRD System by or on behalf of FDA, as well as any information, regardless of who enters it into the Production FIREBIRD System, once it is electronically submitted to FDA. In order for any information entered into the Production FIREBIRD System by a Sponsor, including the NCI, or a clinical investigator to become an "FDA record," the system requires the submitter, whether the Sponsor or clinical investigator, to take an affirmative step to acknowledge the fact that the data are now accessible by the FDA. Such an acknowledgment is considered a submission to the FDA. Once submitted to the FDA, the information becomes available to the FDA and becomes an FDA record. Thereafter, only the FDA has access to "FDA records." Information entered into the Production FIREBIRD System by or on behalf of FDA resides only in the "FDA records" component of the system. The Production FIREBIRD System is designed to accommodate requests for access to data that are made available by the FDA to the public, in accordance with Section VI.A below.

"Non-FDA records" are any information not entered into the Production FIREBIRD System by or on behalf of FDA, as well as information entered into the Production FIREBIRD System by a sponsor or clinical investigator prior to taking the affirmative step that constitutes submission to FDA.

III. Adherence to caBIG Software Development Principles and Methodologies

FIREBIRD adheres to the caBIG™ principles of open source, open access, open development, and federation and is compatible with caBIG™ technical standards. The Parties agree that any further developments, enhancements, modifications or extensions ("Improvements") of FIREBIRD will adhere to caBIG™ software development principles and methodologies, including architecture specification, use of open, non-proprietary standards and an open, governed defined strategy for change management and evolution of the product, as follows:

A. Architecture Specification

Functionality must be defined as business-level services, vetted appropriately by stakeholders, and implemented in a Services-Oriented Architecture, in compliance with methodologies for

application and services specifications established by NCI CBIIT. Compliance with this specification will generate the ability to bind the FIREBIRD implementation to more than one technology, provide published interfaces for both human and automated interaction with FIREBIRD, and define quantitative conformance and compliance metrics for all implementations and instances.

B. Use of Standards

Implementation must be based on non-proprietary standards including those defining static meta-data/information semantics (*e.g.*, the BRIDG Model, the HL7 Clinical Document Architecture (CDA R2)), standardized data semantics (*i.e.*, standardized terminologies such as MeDRA, LOINC, etc.), and standardized data types (*e.g.*, HL7 Version 3 Abstract Data Types (ADT R2)). In addition, the Services-Oriented Architecture implementation of FIREBIRD must use non-proprietary, open standards (*e.g.* those developed by OASIS, W3C, etc.) that are required. Closed and/or proprietary implementation technologies must not be used. All new releases of FIREBIRD must be determined by NCI, prior to distribution, to conform to the caBIG™- Compatibility Guidelines (https://cabig.nci.nih.gov/guidelines_documentation/) at the Silver or Gold level and reviewed annually thereafter by NCI for continued compliance.

C. Change Management/Evolution Strategy

A clearly defined, open, accountable, and version-managed change control process must be in place in order to enable timely bug fixes and relevant requirements changes, additions, or enhancements to be made, which process shall include logging and tracking of requests. This process must take place within an open, community-based framework that ensures that stakeholders have a voice in the direction of Improvements to FIREBIRD over time.

IV. Responsibilities of the Parties

The specific responsibilities of the Parties to this MOA are as follows:

A. NCI Responsibilities

- NCI will inform CRIX of all necessary interoperability and data standards requirements.
- Upon receipt from CRIX of all required documentation, NCI will conduct compatibility reviews of each new release of FIREBIRD prior to distribution to assess compliance with the caBIG Compatibility Guidelines and will supply mentors to work with CRIX to enable FIREBIRD to adhere to these guidelines.
- NCI will make recommendations to FDA and CRIX regarding security and NCI end-user requirements for FIREBIRD.

B. FDA Responsibilities

- FDA will make recommendations to NCI and CRIX regarding security and FDA end-user requirements.

- FDA will work with NCI and CRIX to enable FIREBIRD to fulfill all necessary security and FDA end-user requirements.
- FDA will develop a transition plan to migrate FDA's system of current clinical investigator data records to the Production FIREBIRD System, which is intended to become FDA's repository for storing and accessing clinical investigator data required under 21 CFR 312.
- FDA staff will enter into the Production FIREBIRD System relevant clinical investigator-related data submitted directly to FDA as well as other data generated by FDA (e.g., completed inspection dates and disqualification determinations).
- FDA will encourage sponsors and clinical investigators to use the Production FIREBIRD System to submit appropriate information to FDA, including data required to be submitted pursuant to 21 CFR 312.

C. CRIX Responsibilities

- CRIX will provide and manage the Production FIREBIRD System to enable electronic exchange of clinical investigator information, and will be responsible for defining all necessary security requirements.
- CRIX will gather and complete the requirements for Improvements to FIREBIRD with input and review from, but not limited to, Sponsors, medical professional communities, the FDA, and the NCI.
- CRIX will conduct a pilot for hosting and managing the Production FIREBIRD System.
- CRIX will make Improvements to FIREBIRD in compliance with caBIG interoperability and data standards requirements and will submit each new release of FIREBIRD to NCI, prior to distribution, for assessment of compliance with the caBIG™ Compatibility Guidelines. CRIX will be responsible for submitting current releases for review annually to facilitate continued compliance with caBIG™ standards.
- CRIX will offer the NCI and the FDA separate seats on the CRIX Board of Directors.

D. The Parties acknowledge and agree that the consideration for this agreement between the Government and CRIX is specified in Sections IV.A, IV.B, and IV.C of this agreement.

V. Liaison Officers

Randy Levin
Director for Health and Regulatory Data Standards
Food and Drug Administration
Tel: 301-827-7784

George Komatsoulis
Chief Operating Officer
Center for Bioinformatics
National Cancer Institute
Tel: 301-451-2881

James L. Bland
Project Officer
CRIX International Association
Tel: 703-577-8788

VI. General Provisions

A. Information-Sharing and Records Retention

The FDA, the NCI and CRIX recognize that records in the Production FIREBIRD System will contain information that needs to be protected from unauthorized disclosure. Such information includes: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C. § 1905), the Privacy Act (5 U.S.C. 552a), the Freedom of Information Act (5 U.S.C. § 552), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.

The FDA and CRIX further recognize that, because FDA records will be stored in the Production FIREBIRD System and managed by CRIX, a separate legally binding agreement is necessary to ensure that CRIX adheres to FDA's records retention schedule and that FDA records are protected from unauthorized disclosure, pursuant to existing federal statutes as described above. FDA and CRIX agree to develop and finalize such an agreement before FDA records are stored in the Production FIREBIRD System.

B. Intellectual Property

CRIX shall ensure that all Improvements to FIREBIRD, which include source code, binary object code and related documentation, that are made in connection with activities carried out under the terms of this MOA by CRIX, or its grantees, contractors or subcontractors, will be made available under the following conditions:

1. CRIX hereby grants, and will ensure that its grantees contractors and subcontractors grant, to the Government and the public a nonexclusive, worldwide, perpetual, fully paid up, no-charge, irrevocable, transferable and royalty-free right and license in its rights in all Improvements to FIREBIRD, including any copyright or patent rights therein, to: (i) use, install, disclose, access, operate, execute, reproduce, copy, modify, translate, market, publicly display, publicly perform, and prepare derivative works of the

Improvements to FIREBIRD in any manner and for any purpose, and to have or permit others to do so; (ii) make, have made, use, practice, sell, offer for sale, import, and/or otherwise dispose of Improvements to FIREBIRD (or portions thereof); (iii) distribute and have distributed to and by third parties Improvements to FIREBIRD and any modifications and derivative works thereof; and (iv) sublicense the foregoing rights set out in (i), (ii) and (iii) to third parties, including the right to license such rights to further third parties.

2. End-user documentation included with the redistribution, if any, of Improvements to FIREBIRD must include the following acknowledgment: "This product includes software developed by _____." <Insert name of any organization conducting activities under this MOA, directly or indirectly.> If there is no end-user documentation, such acknowledgment shall appear in the Improvements to FIREBIRD itself, wherever such third-party acknowledgments normally appear.

3. The names "The National Cancer Institute", "NCI", "Cancer Bioinformatics Grid" or "caBIG™" "CRIX International", and "CRIX" shall not be used by CRIX, its grantees, contractors or subcontractors, or their end-users, to endorse or promote products derived from Improvements to FIREBIRD. CRIX, its grantees, contractors or subcontractors, and their end-users, are expressly not authorized by this MOA to use any trademarks, service marks, trade names, logos or product names of the FDA, the NCI, or CRIX. It is understood that such use may be permitted under separate license agreements granted by each of the Parties with respect to their trademarks.

4. For sake of clarity, and not by way of limitation, CRIX, its grantees, contractors and subcontractors may incorporate Improvements to FIREBIRD into their proprietary programs and into any third party proprietary programs. However, they must agree that, if they incorporate Improvements to FIREBIRD into third party proprietary programs, they are solely responsible for obtaining any permission from such third parties required to incorporate the Improvements to FIREBIRD into such third party proprietary programs and for informing their sublicensees, including without limitation their end-users, of their obligation to secure any required permissions from such third parties before incorporating the Improvements to FIREBIRD into such third party proprietary software programs.

5. For sake of clarity, and not by way of limitation, CRIX, its grantees, contractors and subcontractors may add their own copyright statement to portions of Improvements to FIREBIRD in which they have an interest, and they may provide additional or different license terms and conditions in their sublicenses of such interests, provided that their use, reproduction, and distribution of the Improvements to FIREBIRD otherwise complies with the conditions stated above.

6. Proprietary software shall not be used or delivered in the course of making Improvements to FIREBIRD under this MOA unless prior written permission is granted by the Parties to use or deliver such proprietary software and the terms of a license applicable to such proprietary software have been determined in advance. Any proprietary software that is delivered with such permission shall be segregated from all Improvements to FIREBIRD that modifies or extends such proprietary software and is delivered in performance of activities under this MOA or, if it is not, the entire product, consisting of both the proprietary software, including source code, binary object code and any related documentation, and the Improvements to FIREBIRD, shall be subject to the terms of this Section. CRIX shall be responsible for obtaining the rights set forth above to proprietary software owned or controlled by third parties that is used or delivered in performance of activities under this MOA. Modifications or extensions of proprietary software that are not funded, developed or used in connection with the activities conducted under this MOA are not subject to the provisions of this Section.

7. All Improvements to FIREBIRD shall be provided or made available by CRIX, its grantees, contractors and subcontractors in accordance with all applicable federal and state legal, regulatory and policy requirements.

8. THE GOVERNMENT MAKES NO EXPRESS OR IMPLIED WARRANTY REGARDING THE OWNERSHIP, MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE OF FIREBIRD OR IMPROVEMENTS TO FIREBIRD. IN NO EVENT SHALL THE GOVERNMENT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS FIREBIRD OR IMPROVEMENTS TO FIREBIRD, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH and the FDA, as agencies of the United States, assume liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

C. Resource Obligations

The Parties agree that this MOA creates binding, enforceable obligations on the Parties. This MOA and all associated agreements, including such agreements that obligate resources, *e.g.*, contracts, grants and other collaborative agreements, will be subject to applicable policies,

rules, regulations and statutes under which the FDA, the NCI, and CRIX operate. The Parties further recognize that participation in or activity pursued under this MOA does not preclude any Party from continuing to pursue similar or other related activities in its own interest.

D. Notices

All written notices required in connection with activities under this MOA should be delivered by hand, sent by pre-paid courier or registered mail or transmitted by digitally signed email to the Liaison Officers listed in Section VI below.

E. Duration and Modification

This MOA shall become effective on the date of signature of each Party 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 Production FIREBIRD System and Improvements to FIREBIRD have been transferred to the FDA or a mutually agreed upon third party.

F. Termination

If any Party wishes to terminate this MOA, it may do so by giving 60 days' advance notice of its decision to the other Parties. Following termination, CRIX must ensure that records belonging to the other Parties remain accessible to the other Parties in a usable form until the records are transferred in a timely fashion to the other Parties. CRIX's obligations under Section VI.B of the MOA shall survive termination. The Parties agree that no monies shall be due to any Party in the event of a termination.

G. Choice of Law

United States law will apply to resolve any claim of breach of this contract, as well as the construction, validity, performance and effect of this MOA.

H. Disputes

This contract is subject to the The Contract Disputes Act of 1978, as amended (41 U.S.C.601-613). 48 CFR 52.333-1 ("Disputes") is hereby incorporated by reference into this agreement.

I. Severability

If any provision or provisions of this MOA shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

FDA Record NO. 225-08-8004

VII. SIGNATURES OF RESPONSIBLE PARTIES

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

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

Date 8/28/08

Frank M. Torti, M.D., MPH
Principal Deputy Commissioner &
Chief Scientist
U.S. Food and Drug Administration

APPROVED AND ACCEPTED FOR THE NATIONAL CANCER INSTITUTE

Date 08/15/08

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

APPROVED AND ACCEPTED FOR CRIX INTERNATIONAL ASSOCIATION

Date: 8-4-2008

James L. Bland
Executive Director, CRIX

[FR Doc. E8–22992 Filed 9–30–08; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose