

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0057]

Guidance for Industry and Food and Drug Administration Staff on Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled “Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data.” The guidance is intended to describe best practices pertaining to conducting and documenting pharmacoepidemiologic safety studies that use electronic healthcare data. The guidance includes recommendations for documenting the design, analysis, and results of such studies to optimize FDA’s review of protocols and final reports that are submitted to the Agency.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human drug products: Judy Staffa, Center for Drug Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 274, Silver Spring, MD 20993-0002.

Regarding human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM-17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled “Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data.” The primary goals of this guidance are to provide the following:

- Consistent guidance for industry and FDA to use when designing, conducting, and analyzing pharmacoepidemiologic safety studies;
- A framework for industry to use when submitting pharmacoepidemiologic safety study protocols and final reports to FDA; and
- A framework for FDA reviewers to use when reviewing and interpreting pharmacoepidemiologic safety study protocols and final reports.

This guidance does not address real-time active safety surveillance studies, as this field is still rapidly evolving, and it is not possible at this time to recommend sound best practices. The guidance is not intended to be prescriptive with regard to choice of study design or type of analysis and does not endorse any particular type of data resource or methodology. Finally, the guidance does not provide a framework for determining the appropriate weight of evidence to be given to studies from this data stream in the overall assessment of drug safety, as this appraisal represents a separate aspect of the regulatory decision-making process and is best accomplished in the context of the specific safety issue under investigation.

In the **Federal Register** of February 16, 2011 (76 FR 9027), FDA issued a draft version of this guidance entitled “Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets.” The comment period on the draft guidance ended on April 18, 2011. Most of the comments sought clarification and further illustrations of issues discussed in the guidance. FDA has carefully reviewed all comments received on the draft guidance (more than 400 comments were submitted to the public docket). As a result of the public comments, FDA

has clarified the following sections of the guidance: Interpretation of findings; study time frame; identification and handling of confounding and the use of statistical techniques to address confounding; exposure ascertainment; study design; outcome definition and validation; prespecified analysis plan; and the linkage and pooling of data from different data sources. Glossary definitions and references were added to different sections of the guidance to clarify terms and cite additional resources.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on best practices for conducting and reporting pharmacoepidemiologic safety studies using electronic healthcare data. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

This guidance provides best practices for reporting pharmacoepidemiologic safety studies using electronic healthcare data. The reports referenced in the guidance would be submitted under 21 CFR 314.81, 314.98, and 601.70. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) and are approved under OMB control numbers 0910-0001 and 0910-0338.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/>

Guidances/default.htm, or *http://www.regulations.gov*.

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-11361 Filed 5-13-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Device and System for Expression Microdissection (xMD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive commercial license agreement to practice the inventions embodied in International PCT Application S/N PCT/US03/23317 (HHS Ref. No. E-113-2003/0-PCT-02) filed July 23, 2003, which published as WO 2004/068104 on August 12, 2004, now expired; U.S. Patent No. 7,709,047 (HHS Ref. No. E-113-2003/0-US-03) issued May 4, 2010; U.S. Patent Application S/N 12/753,566 (HHS Ref. No. E-113-2003/0-US-07) filed April 2, 2010; U.S. Patent No. 7,695,752 (HHS Ref. No. E-113-2003/1-US-01) issued April 13, 2010; U.S. Patent Application S/N 12/713,105 (HHS Ref. No. E-113-2003/1-US-02) filed February 25, 2010; Australian Patent No. 2003256803 (HHS Ref. No. E-113-2003/0-AU-04) issued January 21, 2010; Australian Patent Application S/N 2009250964 (HHS Ref. No. E-113-2003/0-AU-06) filed July 23, 2009; and Canadian Patent Application S/N 2513646 (HHS Ref. No. E-113-2003/0-CA-05) filed July 23, 2003, all entitled; "Target Activated Microtransfer;" and all continuing applications and foreign counterparts to xMD Diagnostics, LLC, a company having a place of business in Maryland. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be "worldwide", and the field of use may be limited to the following below.

"Devices, systems, kits and related consumables, and methods using devices, systems, kits and related consumables, for micro-dissection of

biological specimens, as covered by the Licensed Patents Rights (the "Exclusive Field"). xMD Diagnostics, LLC (xMD) shall be the only entity granted rights in the Exclusive Field for commercial or other "for-profit purposes. Methods, kits, and related consumables that are used independent of the devices or systems by individual researchers employed at non-profit and academic institutions, if such kits were built by the researchers themselves from component parts and used for their own individual research purposes, shall not infringe xMD's rights. Diagnostic services performed using devices, systems, kits and related consumables purchased from xMD (or xMD's authorized distributor(s)) by those persons employed at non-profit and academic institutions that purchased the devices, systems, kits and related consumables used in the diagnostic services, shall not infringe xMD's rights."

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 29, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5018; Facsimile: (301) 402-0220; Email: *changke@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The subject technologies are methods, devices, and kits for target activated transfer of a target from a biological sample such as a tissue section, comprising: contacting the biological sample with a reagent that selectively acts on the target within the biological sample; placing a transfer surface adjacent the biological sample, wherein the reagent produces a change in the transfer surface by heating the target; heating the target to produce a change in the transfer surface and selectively adhere the target to the transfer surface, or to selectively increase permeability of the transfer surface to the target; and selectively removing the target from the biological sample by removing the transfer surface and the adhered target from the biological sample, or by moving the target through the transfer surface.

The prospective start-up exclusive commercial license will be royalty bearing and will comply with the terms

and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective start-up exclusive commercial license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 8, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-11357 Filed 5-13-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.