

ACRP Regulatory Affairs Committee (RAC) Review of FDA's Federal Register Notice and Request for Comments

Pilot Clinical Outcome Assessment Compendium (COA Compendium)

What is the notice?

The FDA issued a pilot clinical outcome assessment compendium as part of its efforts to foster patient-focused drug development. The FDA is seeking feedback from stakeholders on the utility of the COA Compendium and recommended improvements for future iterations.

Who does it impact & how?

Outcome assessments are used to define efficacy endpoints when developing a therapy for a disease or condition, and are generally based on specific clinical assessments of and by patients. They are called clinical outcome assessments (COAs) when used as clinical trial outcomes, and include any assessment that may be influenced by human choices, judgment, or motivation. The COA Compendium can impact and influence drug developers and researchers when and how to consider use of (COAs) in clinical trials.

What did ACRP RAC have to say about it?

ACRP's RAC recommended that future iterations of the COA Compendium include validated outcome tools with appropriate references.

When were the RAC's comments sent to the agency?

March 14, 2016

Where can I access this document?

<https://www.federalregister.gov/articles/2016/01/13/2016-00529/clinical-outcome-assessment-compendium>



MISSION:
ACRP promotes excellence
in clinical research.

99 Canal Center Plaza
Suite 200
Alexandria, VA 22314
USA

T | 703.254.8100
F | 703.254.8101

office@acrpnnet.org
www.acrpnnet.org

March 14, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

In reference to docket number: **FDA-2015-N-5106**

The Association of Clinical Research Professionals (ACRP) is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. ACRP was founded in 1976 to address the educational and networking needs of research nurses and others who supported the work of clinical investigations. Forty years later, ACRP is a global association comprised of individuals dedicated to clinical research and development. Our mission is "ACRP promotes excellence in clinical research."

ACRP appreciates the opportunity to provide the FDA with our comments on the Pilot Clinical Outcome Assessment Compendium as this issue has a significant impact on our membership. ACRP notices that the Clinical Outcome Assessment (COA) compendium focuses on current FDA guidance. Without validated outcomes tools, the probability that any COA provides meaningful, scientifically useful information is greatly diminished. Therefore, ACRP suggests that the COA compendium would be improved by including validated outcomes tools with appropriate references.

We applaud the FDA's efforts on this important issue and hope that our feedback helps improve the final version of the document. Please let me know if you have any questions regarding our comments, or if we may otherwise serve as a resource on issues related to clinical research.

Sincerely,

A handwritten signature in black ink, appearing to read "JP Kremidas".

Jim Kremidas
Executive Director

Board of Governors of the Federal Reserve System, January 7, 2016.

Robert deV. Frierson,
Secretary of the Board.

[FR Doc. 2016-00441 Filed 1-12-16; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 28, 2016.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Kristina Davidson, Greenwood Village, Colorado; and Zachary Davidson and Tiffany Davidson, both of Nine Mile Falls, Washington; Shauna Cumin and Macaulay Kerr, both of Billings, Montana; Robert Kerr, Spokane Washington; Scott Kerr, Satellite Beach, Florida; the Joshua K. Davidson Irrevocable Trust, Brighton, Colorado; and the Michelle M. Davidson Irrevocable Trust, Englewood, Colorado,* as members of the Davidson Family group and acting in concert; to retain voting shares of First American Bancorp, and thereby indirectly retain voting shares of First American State Bank, both in Greenwood Village, Colorado.

Board of Governors of the Federal Reserve System, January 8, 2016.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2016-00512 Filed 1-12-16; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-5106]

Clinical Outcome Assessment Compendium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (including academic institutions, regulated industry, and patient groups) on our pilot "Clinical Outcome Assessment Compendium" (COA Compendium). FDA has developed a Web site that describes the purpose of the pilot COA Compendium and provides background information. Comments received on the pilot COA Compendium during its pilot phase will help FDA determine its utility, and may assist FDA in developing future iterations of the COA Compendium and identifying best methods for conveying COA Compendium information on FDA's Web site.

DATES: Submit either electronic or written comments by March 14, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner

detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-N-5106 for "Clinical Outcome Assessment Compendium." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nikunj B. Patel, Clinical Outcome Assessments Staff (formerly Study Endpoints and Labeling Development (SEALD)), Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6369, Silver Spring, MD 20993-0002, 240-402-6502, email: COACompendium@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Capturing outcomes that are important to patients in clinical trials is a high priority for FDA. The pilot COA Compendium is part of FDA's efforts to foster patient-focused drug development.¹ The COA Compendium is intended to facilitate communication and to provide clarity and transparency to drug developers and the research community by collating and summarizing clinical outcome assessment information for many different diseases and conditions into a single resource. It can be used as a starting point when considering how certain clinical outcome assessments might be utilized in clinical trials and will likely be most informative in early drug development. The public is referred to the following FDA Web site for additional background information, along with the pilot COA Compendium: <http://www.fda.gov/COACompendium>.

II. Establishment of a Docket and Request for Comments

To help FDA determine the utility of the COA Compendium, develop future iterations of the COA Compendium, and identify best methods for conveying COA Compendium information on FDA's Web site, FDA is launching the pilot COA Compendium and soliciting public suggestions, recommendations, and comments for each aspect of the COA Compendium mentioned on the following FDA Web site: <http://www.fda.gov/COACompendium>.

¹ The term *drug*, as used in this notice, refers to human drugs including biological products.

www.fda.gov/COACompendium. Specifically, FDA welcomes your comments concerning: (1) The utility of the COA Compendium; (2) the best approach for developing future iterations of it, including any suggested expansions of its scope; and (3) COA Compendium-related questions you would like FDA to address in its future communications. FDA will consider all comments submitted but will generally not respond directly to the person or organization submitting the comment.

Dated: January 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-00529 Filed 1-12-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Cancer Genomics Cloud Pilots Survey (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; The quality, utility, and clarity of the information to be collected; and Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DATES: Comments regarding this information collection are best assured

of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Anthony Kerlavage, NCI CBIIT, Program Manager, 9609 Medical Center Drive, Room 1W-436, Rockville, MD 20850 or call non-toll-free number 240-276-5190 or email your request, including your address to: anthony.kerlavage@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

Proposed Collection: Cancer Genomics Cloud Pilots Survey, 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Center for Biomedical Informatics and Information Technology (CBIIT), in collaboration with the Center for Cancer Genomics at the National Cancer Institutes (NCI) in the National Institutes of Health (NIH), is coordinating a program to develop three Cancer Genomics Cloud Pilots to help meet the research community's needs to access and analyze high quality, large-scale cancer genomic data and associated clinical information. The goal of this effort is to develop an innovative, cost-effective model for computational analysis of biological data and provide broader yet secure access to genomic data that NCI generates. Cloud computing will be a valuable tool to support studies related to the mechanisms of cancer. This capability will be equally valuable to other NCI scientific areas, including clinical trials and other types of patient-focused research. In order to understand the utility and value of the tools being developed, the NCI has developed a survey instrument to capture feedback from the cancer research community. The information collected as part of this survey process will be used exclusively by the NCI to determine future funding of cloud technology projects.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 375.