FOR FURTHER INFORMATION CONTACT: Edward Weinstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6382, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bacterial Vaginosis: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of BV. This draft guidance helps define enrollment criteria for BV trials and recommends that such trials be superiority trials. The draft guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of BV, including the characterization of the primary efficacy endpoint.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs. In 1998, FDA published a draft guidance entitled ''Bacterial Vaginosis—Developing Antimicrobial Drugs for Treatment'' (the 1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 7, 2013, **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16636 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for ''Blockchain and its Emerging Role in Health IT and Health-related Research''; Amendment

AGENCY: Office of the National Coordinator for Health Information Technology, HHS. *Award Approving Official:* Karen DeSalvo, National Coordinator for Health Information Technology.

ACTION: Notice; Amendment.

SUMMARY: This document amends the notice published in **Federal Register**, Friday July 8, 2016, volume 81, pages 44639–44640. This notice updates and extends the submission period to August 8, 2016, limits an investigator or co-investigator to one submission and adds prize details. The ''Use of Blockchain in Health IT and Health-related Research'' Ideation Challenge solicits white papers on the topic of Blockchain Technology and the potential use in Health IT to address privacy, security and scalability challenges of managing electronic health record and resources. Up to 15 winners will be awarded a cash prize and up to 8 winners may be invited to present their papers at an upcoming industry-wide workshop co-hosted with the National Institute of Standards and Technology (NIST). The statutory authority for this Challenge is section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES:

- Submission period begins: July 7, 2016.
- Submission period ends: August 8, 2016.
- Evaluation begins: August 9, 2016.
- Evaluation ends: August 19, 2016.
- Winners notified: August 22, 2016.
- Winners Announced: August 29, 2016.
- Winner Presentation: September 26–27, 2016.

FOR FURTHER INFORMATION CONTACT: Debbie Bucci, *debbie.bucci@hhs.gov* (preferred), (202) 690–0213.

SUPPLEMENTARY INFORMATION:

Subject of Challenge

A Blockchain is a data structure that can be timed-stamped and signed using a private key to prevent tampering. There are generally three types of Blockchain: Public, private and consortium. Potential uses include:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

This Ideation Challenge solicits White Papers on the topic of Blockchain Technology and the Potential for Its Use in Health IT and/or Healthcare Related Research Data. This nationwide call may be addressed by an individual investigator or an investigator team. Interested parties should submit a White Paper no longer than 10 pages describing the proposed subject. Investigators or co-investigators may only participate in one submission. Up to 15 of these submissions will be selected as winners. The selection of a White Paper may also result in an invitation to present at an upcoming industry-wide workshop on September 26th–27th, 2016, at NIST Headquarters in Gaithersburg, MD.

Objective

The goal of this Ideation Challenge is to solicit White Papers that investigate the relationship between Blockchain technology and its use in Health IT and/or Health Related research. The paper should discuss the cryptography and underlying fundamentals of Blockchain technology, examine how the use of Blockchain can advance industry interoperability needs expressed in the ONC's Shared Nationwide Interoperability Roadmap, as well as for Patient Centered Outcomes Research (PCOR), the Precision Medicine

Initiative (PMI), delivery system reform, and other health care delivery needs, as well as provide recommendations for Blockchain's implementation. In addition to a monetary award, winners may also have the opportunity to present their White Papers at an industry-wide ''Blockchain & Healthcare Workshop'' co-hosted by ONC and NIST.

Submission Requirements

The white paper must:

- Be no longer than ten (10) pages;
- Address whether there is a place in health IT and/or healthcare related research for the technology;
- Describe the value of Blockchain to the health-care system;
- Identify potential gaps in standards created and/or resolved by the use of Blockchain;
- Discuss the effectiveness of Blockchain to function in the ''real world.'' This discussion may include information regarding meeting privacy and security standards, implementation and potential performance issues, and cost implications. Risk analysis and mitigation would be appropriate to include here as well; and
- Discuss how Blockchain links to the stated objectives in the Nationwide Interoperability Roadmap, PCOR, PMI, delivery system reform, and other national health care delivery priorities.

How To Enter

Challenge participants will submit their submission on the challenge Web site [*http://www.cccinnovationcenter.com/challenges/block-chain-challenge*].

Eligibility Rules for Participating in the Challenge

To be eligible to win a prize under this Challenge, an individual or entity:

1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.
2. Shall have complied with all the stated requirements of the Blockchain and Its Emerging Role in Healthcare and Health-related Research Challenge.
3. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.
4. May not be a Federal entity or Federal employee acting within the scope of their employment.
5. Shall not be an HHS employee working on their applications or Submissions during assigned duty hours.
6. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.
8. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge Submission.
9. An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.
10. Submissions must not display HHS' or ONC's logos or official seals and must not claim endorsement.
11. Accuracy—A white paper submission may be disqualified if it provides inaccurate or incomplete information.

Registration Process for Participants

To register for this Challenge, participants can access *http://www.challenge.gov* and search for ''Blockchain and Its Emerging Role in Healthcare and Health-related Research.''

Prize

- 12–15 white papers will be awarded a cash prize in the range of $ 1,500–5,000,
- Up to 8 winners may be given the opportunity to present their paper at a Blockchain & Healthcare Workshop Hosted at NIST,
- Inclusion of the white papers in the Blockchain workshop proceedings.

Payment of the Prize

Prize will be paid by contractor.

Basis Upon Which Winner Will Be Selected

The judging panel will rate each submission based upon:

- Potential of the overall concept to help foster transformative change in the culture of health IT,
- Viability of the proposed recommendations,
- Innovativeness of the approach,
- Potential for achieving the objectives of ONC.

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Each participant retains title and full ownership in and to their Submission. Participants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the Challenge, each entrant hereby irrevocably grants to the Government a limited, non-exclusive, royalty-free, perpetual, worldwide license and right to reproduce, publically perform, publically display, and use the Submission to the extent necessary to administer the challenge, and to publically perform and publically display the Submission, including, without limitation, for advertising and promotional purposes relating to the Challenge. This may also include displaying the results of the Challenge on a public Web site or during a public presentation.

Representation, Warranties and Indemnification

By entering the Challenge, each applicant represents, warrants and covenants as follows:

(a) Participant is the sole author, creator, and owner of the Submission;

(b) The Submission is not the subject of any actual or threatened litigation or claim;

(c) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party.

Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of participant hereunder. The Federal sponsors reserve the right to disqualify any Submission that, in their discretion, deems to violate these Official Rules, Terms & Conditions.

Authority: 15 U.S.C. 3719.

Karen DeSalvo, MD., M.P.H., M.Sc.

National Coordinator for Health Information Technology.

[FR Doc. 2016–16607 Filed 7–13–16; 8:45 am]

BILLING CODE 4150–45–P