4150-45

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology

Announcement of Requirements and Registration for "Market R&D Pilot Challenge"

Authority: 15 U.S.C. 3719

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

AWARD APPROVING OFFICIAL: Dr. Karen DeSalvo, National Coordinator for Health Information

Technology.

ACTION: Notice .

SUMMARY:

Developers and innovators have many great ideas and products that could improve the US health care

system and make life better for patients and care providers. However, effecting actual change is

extremely difficult due to the high barriers to entry in the health IT space. Once an innovative new

product has been developed, it needs to be tested in real-life care settings. But providers can be

hesitant to host this testing for a myriad of reasons – they may have had bad experiences in the past, be

anxious about deploying new tools that may disrupt their workflows, or be wary of encountering more problems than the solution solves. Without this testing, it cannot be determined how well the product actually works, making it difficult for the developers to identify the changes that need to be made to the product to make it more effective. Furthermore, without evidence of the uses a product can provide it is that much harder to acquire the venture funding that can fuel further advancement and lead to successful entry in the marketplace.

The Market R&D Pilot Challenge is intended to help bridge this gap by bringing together health care organizations ("Hosts") and innovative companies ("Innovators") through pilot funding awards and facilitated matchmaking. The Challenge seeks to award pilot proposals in three different domains: clinical environments (e.g., hospitals, ambulatory care, surgical centers), public health and community environments (community-based personnel such as public health departments, community health workers, mobile medical trucks, school- and jail-based clinics), and consumer health (e.g., self-insured employers, pharmacies, laboratories). Hosts and Innovators will submit joint pilot proposals, with the winners, as determined by an expert panel, proceeding to implement their pilots.

The Challenge's primary goals are to:

- Encourage early collaboration between entrepreneurs, medical and public health personnel, patients, and the research community to link innovation in health IT to innovation in care delivery;
- De-risk early stage health IT and digital health products for future clinical testing and investment;

- Encourage uptake of and ensure the market is aware of ONC standards and functions within certified electronic health record technologies; and

- Explore evidence collection methods and relevant metrics for early stage health IT products that may better match agile software development.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358).

DATES:

Applicants:

- Challenge launch: October 20, 2014

- Matchmaking events: early December, 2014 to mid-January, 2015

- Submissions due: March 2, 2015

- Winners announced: April 30, 2015

Winners:

- Pilot preparation and setup: May-July, 2015

- Pilots begin: August, 2015

- Pilots complete: January, 2015

FOR FURTHER INFORMATION CONTACT: Adam Wong, adam.wong@hhs.gov (preferred), 202-720-2866

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition:

The Market R&D Pilot Challenge will have up to six winners, preferably spread across each of the three Host domains: clinical environments, public health and community environments, and consumer health.

The Challenge is a multi-step process that builds on ONC's previous prize challenges.

1. Learn about the Challenge

   The challenge website will be the primary source for finding all information about the challenge, and will be updated regularly with the newest information. ONC will hold an informational webinar to provide details about the program and answer questions; the webinar will be recorded and made available for those who miss it.

2. Find a match

   The organizers will facilitate matchmaking to help Innovators and Hosts connect to discuss potential pilots through in-person and virtual events. Potential applicants are *not* required to participate in this process in order to submit a proposal. Interested Innovators and Hosts will submit an application form to be considered to participate in the facilitated matchmaking sessions. Hosts make the final selection about which Innovators they will meet with in person; Innovators will be officially notified of these meetings prior to the sessions. We encourage Innovators to reach out independently to health care service organizations and stakeholders for potential partnerships.

3. Submit joint proposal

   A Host and an Innovator will apply as a pair by submitting a joint pilot proposal. Applications without a Host or Innovator co-applicant will not be accepted. A panel of expert judges will review proposals and select up to 6 winning proposals to each receive a $50,000 award. Winners will be announced on a webinar where they'll present their pilot proposals.

   In addition to a description and budget of the pilot, the joint proposal will require general information about the Host and Innovator; description and demo video of the Innovator's technology; and letters of intent from the Host and Innovator.

4. Winners: Prepare and implement pilot project

   Pilot planning and implementation support services will be provided over a series of webinars. The selected winners will then implement and run their pilot projects over a period of 6-9 months.

5. Issue deliverable and promote results

   Upon completion of the pilot, the winners will be required to issue a deliverable that contributes to the public knowledge base, such as a white paper or open data set, or to open technology, such as an API or open source tool. Winners will also have the opportunity to present their pilot projects at a major health event or conference.

Applicants are strongly encouraged to address the following ONC priority areas:

- Standards/Data Formats

- Interoperability & Exchange

- Care Coordination/Transitions of Care

- Patient/PHR Portals

- Medication Management

- Blue Button

- Patient Generated Health Data

- Underserved Communities

Eligibility Rules for Participating in the Competition:

Host Eligibility: The Host must be a health care organization operating in a clinical environment, (e.g., hospital, ambulatory care, surgical center), public health and community environment (community-based personnel such as public health department, community health worker, mobile medical truck, school- and jail-based clinic), or consumer health (e.g., self-insured employer, pharmacy, laboratory) and must meet the following eligibility criteria:

- Ability to allocate time and resources to plan and implement the pilot project

- Allocate one business-minded internal lead to shepherd project from the initial application through the pilot's implementation

Innovator Eligibility: The Innovator, an early-stage health care technology company, must have a readily available tech-based product focused on improving health care that can be tested in the Host setting and meet the following criteria:

- Demonstration of financial stability, managerial capacity, and scalability

- Maximum number of 50 employees

- Less than $10,000,000 in venture capital funding raised

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

(1) Shall have registered to participate in the competition under the rules promulgated by the Office of the National Coordinator for Health Information Technology.

(2) Shall have complied with all the requirements under this section.

(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 IT.

(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.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Entrants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Entrants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities.

Submission Requirements

In order for an Innovator's application to be eligible to win this Challenge, it must meet the following requirements:

1. No HHS or ONC logo – The product must not use HHS' or ONC's logos or official seals and must not claim endorsement.

2. Functionality/Accuracy – A product may be disqualified if it fails to function as expressed in the description provided by the user, or if it provides inaccurate or incomplete information.

3. Security – Submissions must be free of malware. Contestant agrees that ONC may conduct testing on the product to determine whether malware or other security threats may be present. ONC may disqualify the product if, in ONC's judgment, the app may damage government or others' equipment or operating environment.

Registration Process for Participants:

To register for this Challenge, participants can access http://www.challenge.gov and search for "Market R&D Pilot Challenge."

Prize:

- Up to six Host/Innovator teams will each win $50,000 prizes (50% to be disbursed following award, 50% to be disbursed upon completion of pilot)
- Total: up to $300,000 in prizes

Payment of the Prize:

Prize will be paid by contractor.

Basis upon Which Winner Will Be Selected:

The review panel will make selections based upon the following criteria:

- Pilot proposal and design

- Pilot budget and scale

- Potential for health impact

- Relevance to ONC priorities

- Potential of Innovator's product

- Team experience and strength of match

- Proposed public deliverable

Additional Information:

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

Intellectual Property: Each entrant retains title and full ownership in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the challenge, each entrant hereby irrevocably grants to Sponsor and Administrator a limited, non-exclusive, royalty-free, 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.

Dated: October 9, 2014.

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Dr. Karen DeSalvo,

National Coordinator for Health Information Technology.

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