



4164-04-P

REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

[BAC 416404]

Request for Steering Committee Nominations

ACTION: Request for nominations to the Steering Committee for the Foundation's Big Data for Patients (BD4P) Program.

SUMMARY: The Reagan-Udall Foundation (RUF) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Amendments of 2007, is requesting nominations for its Big Data for Patients (BD4P) Steering Committee. The Steering Committee will provide oversight and guidance for the BD4P program, and will report to the Reagan-Udall Foundation for the FDA's Board of Directors.

DATES: All nominations must be submitted to the Reagan-Udall Foundation for the FDA by Friday, September 4, 2015. The BD4P Steering Committee members will be selected by the Reagan-Udall Foundation for the FDA's Board of Directors; those selected will be notified by September 30 regarding the Board's decision. See the SUPPLEMENTARY INFORMATION section for Steering Committee responsibilities, selection criteria and nomination instructions.

ADDRESSES: The Reagan-Udall Foundation for the FDA is located at 1025 Connecticut Ave., NW, Suite 1000, Washington, DC. 20036.

FOR FURTHER INFORMATION CONTACT: Questions should be sent to The Reagan-Udall Foundation for the FDA, 202-828-1205, BD4P@ReaganUdall.org.

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) not-for-profit organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation; and enhance product safety. The Foundation acts as a neutral third party to establish novel, scientific collaborations. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research projects to advance regulatory science.

Big Data for Patients (BD4P), a new program led by the Foundation, will bring together multiple stakeholder groups to leverage collective knowledge, technical expertise, funding, and other resources, to create a state-of-the-art patient training program and online community focused on the opportunities and challenges posed by Big Data.

BD4P will empower patients and advocates with the language and concepts of data science, as well as critical appraisal skills, so they can effectively and actively participate in health research involving Big Data. Given the high profile of health research and initiatives using Big Data, combined with the growing efforts to make healthcare and medical research more patient-centered, it is critical that patients have a voice and active role in this work. It is still not completely understood how Big Data research will impact patient health care and medical decision making. BD4P presents an opportunity to ensure that patients are adequately informed and prepared to participate in this work, rather than being left out or left behind.

Development of the program will be a fully collaborative process, with patients and key stakeholders involved in shaping the program every step of the way—from prioritizing topics for program content and input on program design, to actually taking the training program and providing feedback to evaluate the program and make improvements. We will ensure that the focus is not only on the impact of Big Data on patients, but also the impact that patients can have on Big Data research. For additional information on the BD4P program, visit the Reagan-Udall Foundation website: <http://bit.ly/1HkhSOq>.

II. BD4P Steering Committee Roles and Responsibilities

The BD4P Steering Committee will provide guidance on the operation of the BD4P program, in conjunction with the RUF Board, project staff, and others. The Steering Committee will provide overall programmatic oversight to ensure a focus on the long-term vision of the program.

The BD4P Steering Committee will be charged with several responsibilities, including:

- Reviewing and approving the BD4P Program Charter
- Monitoring adherence to the BD4P Program mission and operational principles in the Charter
- Developing metrics and evaluating the project at various milestones
- Reviewing and approving the BD4P Program Development Plan, including program curriculum, stakeholder engagement plan, and long-term sustainability plan.
- Reviewing partnership and collaboration proposals submitted to the project team

The BD4P Steering Committee Chair must be able to complete additional responsibilities, including:

- Defining the BD4P Steering Committee's meeting agendas and facilitating those meetings
- Recommending for termination, as necessary, any BD4P Steering Committee members demonstrating dereliction of duties as specified in the BD4P Charter
- Other responsibilities as required upon implementation of BD4P program

A full list of BD4P Steering Committee responsibilities, as well as responsibilities of the Chair, may be found on the Reagan-Udall Foundation website: <http://bit.ly/1KEoNTN>

III. BD4P Steering Committee Positions and Selection Criteria

RUF is seeking nominations for 7 voting members of the BD4P Steering Committee, comprised of the following 5 categories:

- Patient Advocate: 3 members
- Pharmaceutical sector: 1 member
- Technology sector: 1 members
- Academia / Research Institute: 1 member
- At Large: 1 member

The BD4P Steering Committee will also have 1 member from the FDA (appointed by the FDA), 1 member from the National Institutes of Health (appointed by the National Institutes of Health), and 1 member from the Patient Centered Outcomes Research Institute (appointed by PCORI). These 3 individuals will be non-voting members.

Nominees for the voting positions will be evaluated by the RUF Board based on the following required criteria for each of the 7 positions:

- Ability to complete Steering Committee responsibilities, listed above
- Currently employed by/volunteering for stakeholder field (e.g., pharmaceutical, academia, patient advocate, etc.) with several years of relevant experience
- Leading expert in their relevant field (based on position, publications, or other experience)
- Working knowledge of at least one of the following areas: adult education, data sharing, data science, health informatics, learning health care systems, partnerships, patient advocacy, patient engagement, patient-centered/ patient-focused drug development, patient-centered outcomes research, patient reported outcomes, precision medicine, science/health communication.
- Prior experience serving on a related or similar governance body
- Understanding of the landscape and the impact on the stakeholder group they are representing with their seat

IV. Terms of Service

- The BD4P Steering Committee meets in-person at least twice per year, with teleconferences in between meetings as deemed necessary by the Chair
- Members will serve two or three year, staggered terms, as determined by the RUF Board
- Members do not receive compensation from RUF

- Members can be reimbursed by RUF for actual and reasonable expenses incurred in support of BD4P in accordance with applicable law and their specific institutional policies
- Members are subject to the BD4P Conflict of Interest policies (additional information can be accessed on the Reagan-Udall Foundation website at: <http://bit.ly/1KEoNTN>)

V. Nomination Instructions

- The nomination form can be accessed on the Reagan-Udall Foundation website: <http://bit.ly/1KEoNTN>
- Individuals may be nominated for 1 or more of the 5 stakeholder categories
- Individuals may nominate themselves or others
- The nomination deadline is September 4, 2015.

Dated: July 31, 2015.

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Executive Director,

Reagan-Udall Foundation for the FDA.

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