



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 Innovation in Medical Evidence Development and Surveillance program.

SUMMARY: The Reagan-Udall Foundation 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 Innovation in Medical Evidence Development and Surveillance (IMEDS) Steering Committee. The IMEDS Steering Committee will provide oversight and guidance of the IMEDS Program, and will report to the Reagan-Udall Foundation for the FDA's Board of Directors. Instructions on making nominations are listed in the "Background" section.

DATES: All nominations must be submitted to the Reagan-Udall Foundation for the FDA by April 30, 2013. IMEDS Steering Committee members will be selected by the Reagan-Udall Foundation for the FDA's Board of Directors on May 23, 2013; those selected will be notified by May 30 regarding the Board's decision.

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

FOR FURTHER INFORMATION CONTACT: Jane Reese-Coulbourne, Reagan-Udall Foundation for the FDA, 202-828-1206. Nominations should be sent to IMEDS@ReaganUdall.org.

SUPPLEMENTARY INFORMATION:

I. Background

The Reagan-Udall Foundation for the FDA (the Foundation or RUF) 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. 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.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how Reagan-Udall Foundation projects can help the Agency to fulfill its mission.

The IMEDS program is offered by the Foundation. IMEDS is a public-private partnership created to build upon the significant progress made on research methodology by the Sentinel Initiative, including its Mini-Sentinel pilot and the Observational Medical Outcomes Partnership (OMOP).

IMEDS's primary objective is to advance the science and tools necessary to support postmarket evidence generation on regulated products, including safety surveillance and evaluations, and to facilitate utilization of a robust electronic health care data platform for generating better evidence on regulated products in the post-market settings. To accomplish this objective, the IMEDS program includes three projects:

1. IMEDS-Methods: Supports the development of a methods research agenda and coordination of methods research in support of using electronic health data for safety surveillance conducted by FDA as well as the broader community of researchers.

2. IMEDS-Education: Offers educational opportunities in areas related to medical product safety surveillance, and methods research and application for scientific professionals.
3. IMEDS-Evaluation: Applies Methods and Education lessons learned for medical product assessments to facilitate leveraging Sentinel tools and capabilities toward a national resource for evidence generation.

The IMEDS Steering Committee will have oversight of all IMEDS projects.

II. IMEDS Steering Committee Positions and Selection Criteria

RUF is seeking nominations for seven voting members of the IMEDS Steering Committee listed in this document. (The IMEDS Steering Committee will also have two members of FDA appointed by FDA, and a liaison from the Reagan-Udall Foundation Board of Directors who will be appointed by the Reagan-Udall Foundation Board of Directors; these three individuals will be nonvoting members).

1. Pharmaceutical Industry: Two members
2. Academia / Research Institute: One member
3. Provider (i.e., Clinician): One member
4. Data Partner: One member
5. Patient Advocate: One member
6. Consumer Advocate: One member

The following criteria will be used to evaluate nominees for the IMEDS Steering Committee.

1. Required Criteria for Each of Seven Positions

- a. Currently employed by/volunteering for stakeholder field (e.g., pharmaceutical, academia, patient advocate, provider, etc.) with several years of relevant experience.
 - b. Leading expert in their relevant field (based on position/title, publications, or other experience).
- 2. Criteria across Steering Committee (It is not a requirement that all nominees meet all of these criteria, but collectively, the Steering Committee members should meet them.)
 - a. Ability to complete Steering Committee responsibilities (which can be accessed via the Reagan-Udall Foundation Web site: <http://www.reaganudall.org/>.)
 - b. Prior experience serving on a related or similar governance body.
 - c. Understanding of postmarket surveillance landscape and impact upon stakeholder group represented by Steering Committee seat, or understanding of issues around use of electronic health data for observational purposes.
 - d. Individuals both with and without past experience in Mini-Sentinel, OMOP, and similar research/regulatory science initiatives to ensure a diversity of perspectives.
 - e. Individuals from both U.S.- and international-based institutions.
- 3. The IMEDS Steering Committee Chair must be able to complete the additional responsibilities listed for this position in the IMEDS Charter (section 2.3.6.2).

III. Terms of Service

- The IMEDS Steering Committee meets in-person at least twice per year, with bimonthly teleconferences in between meetings (or monthly teleconferences as deemed necessary by the Chair).

- Members serve 2-year terms, and a maximum of two terms (based on IMEDS fiscal calendar).
- Members do not receive compensation from RUF.
- Members can be reimbursed by RUF for actual and reasonable expenses incurred in support of IMEDS in accordance with applicable law and their specific institutional policies.
- Members are subject to the IMEDS Conflict of Interest policies.

IV. Nomination Instructions

- In 200 words or less, please describe the relevant expertise and experience the nominee would bring while serving as the IMEDS Steering Committee Chair and/or a Member and to what extent they would meet the criteria.
- Individuals may be nominated for one or more of the seven voting positions, and those making nominations should specify for which of the seven voting positions the nominee is being nominated.
- Individuals may nominate themselves.

Dated: April 17, 2013.

Jane Reese-Coulbourne,
Executive Director,
Reagan-Udall Foundation for the FDA.

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