



REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION;
BAC 416404

REQUEST FOR SCIENTIFIC ADVISORY COMMITTEE NOMINATIONS

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

DATES: All nominations must be submitted to the Reagan-Udall Foundation for the FDA by May 24, 2015. IMEDS Scientific Advisory Committee members will be selected by the IMEDS Steering Committee before July 15, 2015; those selected will be notified by July 30, 2015 regarding the Steering Committee'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: Nicole Spear, Reagan-Udall Foundation for the FDA, 202-828-1210. Nominations should be sent to IMEDS@ReaganUdall.org. Email subject line: SAC Nomination.

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. 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 Innovation in Medical Evidence Development and Surveillance (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 and the Observational Medical Outcomes Partnership (OMOP).

IMEDS's primary objective is to advance the science and tools necessary to support post-market evidence generation on regulated products, including safety surveillance and evaluations, and to facilitate utilization of a robust electronic healthcare 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 Scientific Advisory Committee has oversight of all IMEDS projects.

II. IMEDS Scientific Advisory Committee Positions and Selection Criteria

RUF is seeking nominations for four (4) voting members of the IMEDS Scientific Advisory Committee listed below.

1. At Large (excluding Pharmaceutical representative): 2 members
2. Regulated Industry Representative: 2 members

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

1. Required Criteria for Each of 4 Positions
 - a. Currently employed by/volunteering for stakeholder field (e.g., 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 Scientific Advisory Committee (*It is not a requirement that all nominees meet all of these criteria, but collectively, the Scientific Advisory Committee members should meet them.*)
 - a. Ability to complete Scientific Advisory Committee responsibilities (which can be accessed via the IMEDS website: <http://imeds.reaganudall.org/governance>.)
 - b. Prior experience serving on a related or similar governance body.
 - c. Understanding of post-market surveillance landscape and impact upon stakeholder group represented by Scientific Advisory 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 US- and international-based institutions.

III. Terms of Service

- The IMEDS Scientific Advisory 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 two-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

- To apply, please submit the nominee's CV and the nomination form that can be found on the IMEDS website: imeds.reaganudall.org, to IMEDS@reaganudall.org with "SAC Nomination" in the subject line.
- Individuals may be nominated for one or more of the 4 voting positions, and those making nominations should specify for which of the 4 voting positions the nominee is being nominated.
- Individuals may nominate themselves.

Dated: May 4, 2015.

Jane Reese-Coulbourne

Executive Director

Reagan-Udall Foundation for the FDA

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