IMEDS Program Frequently Asked Questions (FAQs)
December 2013

1. **What is IMEDS?**
   The Innovation in Medical Evidence Development and Surveillance (IMEDS) program is offered by the Reagan-Udall Foundation for the FDA (RUF), a 501(c)(3) organization authorized through the 2007 FDA Amendments Act (FDAAA) to help advance the regulatory science needs of FDA. 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 OMOP. In mid-2013, the Observational Medical Outcomes Partnership (OMOP) was transitioned from the Foundation for the National Institutes of Health (FNIH) to the Reagan-Udall Foundation, and OMOP's tools, capabilities and resources became the foundation for IMEDS research and operations.

   IMEDS serves 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 secondary electronic healthcare data platform for generating better evidence on regulated products in the post-market settings. The IMEDS Program includes three components:

   a. **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.
   b. **IMEDS-Education:** Offers educational opportunities in areas related to medical product safety surveillance, and methods research and application for scientific professionals.
   c. **IMEDS-Evaluation:** Applies learnings from the Methods and Education program areas for medical product assessments to facilitate leveraging Sentinel tools and capabilities toward a national resource for evidence generation.

2. **Why is IMEDS necessary?**
   IMEDS is necessary to build on the work Mini-Sentinel and OMOP have completed over the last few years to advance the development of methods for the use and analysis of electronic healthcare data for safety evaluations. These pilot programs have served to inform the Sentinel Initiative and advance better methods for safety surveillance of regulated medical products using large-scale observational data. Mini-Sentinel has made significant progress in developing a system for conducting active medical product safety surveillance, which has proven to be a valuable tool for harnessing the potential of electronic healthcare data. Similarly, OMOP has strengthened the understanding of how an estimated effect from an observational study relates to the true relationship between medical product exposure and adverse events.

   As the availability and form of electronic healthcare data evolve, ongoing research is needed to better understand how these data should be used, and to refine existing methods or develop new methods to generate valid and actionable evidence on the safety and use of medical products. Continued methods development, performance measurement and data understanding will help ensure FDA, the pharmaceutical industry and all researchers have access to the most innovative tools.

3. **Why is the Reagan-Udall Foundation (RUF) the ideal home for IMEDS?**
   The RUF is positioned to convene public-private collaborations to advance regulatory science and research and collaborate across many sectors. Working with various sectors, including government and non-government, RUF can support methods development, training, and other needs of the FDA while incorporating the voice and guidance of all stakeholders, including patient and consumer advocates, the pharmaceutical industry, providers, data partners and academics.

4. **How did the IMEDS-Methods Research Agenda get developed and how is it implemented?**
   The IMEDS-Methods Research Agenda can be accessed http://imeds.reaganudall.org/Methods. The RUF, assembled a draft discussion document on the basis of conversations with the FDA, legacy OMOP investigators, and commercial and academic stakeholders, and which included feedback on the last full OMOP Research Agenda (drafted for OMOP Executive Board review in March 2013). The IMEDS SAC provided input on this draft discussion document in its kickoff meeting (September 6, 2013).

   Following the SAC kickoff meeting, RUF circulated a draft IMEDS-Methods Research Agenda among stakeholders, including the SAC itself, members of the FDA involved in Mini-Sentinel program, Mini-Sentinel investigators, legacy OMOP investigators, and representatives of organizations that had supported OMOP. This draft agenda was not confidential, and recipients were encouraged to share it and submit comments. Feedback from these organizations was consolidated and integrated into a revised draft, and the IMEDS-Methods Research Agenda (in accordance with the IMEDS Charter) was approved by the IMEDS Steering Committee on October 11, 2013.

   The RUF will be issuing Request for Proposals (RFPs) to accomplish projects within the agenda. Throughout the year, the agenda will be updated based on public feedback and results of work completed. There is also the opportunity to submit your own ideas and proposals ('unsolicited') outside of a formal RFP request initiated by RUF.

5. **Does the IMEDS-Methods Research Agenda address the needs and priorities of IMEDS-Evaluation and IMEDS-Education?**
   IMEDS Evaluation: The key components and governance of IMEDS-Evaluation are still in development by RUF with guidance provided by a small group of thought leaders from FDA, the pharmaceutical industry and data partners. However, one area that these stakeholders have aligned upon is that IMEDS-Evaluation aims to leverage the data maintained by the Mini-Sentinel Data Partners to complete non-FDA sponsored safety surveillance. IMEDS recognizes that this data will also be critical for implementing some aspects of the IMEDS-Methods Research Agenda. Such research will not be feasible until those data either become part of the IMEDS Lab or can be accessed through an IMEDS Distributed Database. Therefore, in the coming months, IMEDS will establish relationships with the Mini-Sentinel Data Partners to support both research within the IMEDS-Methods Research Agenda and safety assessments through IMEDS-Evaluation.

   IMEDS-Education: While the IMEDS-Methods Research Agenda will produce public tools and work products which will be of use for training scientists through IMEDS-Education, the curriculum and scope for IMEDS-Education will be created over the coming months as part of RUF's broader scientific capacity building efforts.

6. **How can I get involved in IMEDS research?**
   We welcome community involvement and ideas! A researcher can either respond to a formal RFP issued by RUF or if you have a research idea or experiment not outlined in the Research Agenda, it can be submitted to RUF as an "unsolicited" proposal. Both RFP submissions and unsolicited proposals will go thru a peer review process within RUF.

7. **What policies and procedures will govern IMEDS research and the publication of research findings/outcomes?**
   With the RUF By-laws, and IMEDS Charter, there are policies and procedures governing the IMEDS Research Laboratory, and RUF funded work and publication of findings through IMEDS research and other important components such as intellectual property of IMEDS research and operations can be accessed at: http://imeds.reaganudall.org.

8. **How can I get access to the IMEDS Research Laboratory?**
   The lab (5 datasets) and research tools are available for research purposes. If you are interested in access, you must submit a brief proposal which goes to the IMEDS Scientific Advisory Committee for review of your research purpose and the alignment with the IMEDS program. For more information on how to request access and a description of the proposal information go to: http://imeds.reaganudall.org/On-Boarding.

9. **What does the OMOP transition mean for the legacy OMOP Investigators and research community?**
   The legacy OMOP investigators have made important methodological and scientific contributions since the inception of OMOP, and these investigators have been critical in shaping the IMEDS-Methods Research Agenda. IMEDS will continue to leverage the contributions of these investigators, and strongly encourage them to participate in IMEDS research.

10. **Will the OMOP CDM and Standard Vocabulary model continue to be supported?**
    The legacy OMOP Laboratory is managed and operated by the Reagan-Udall Foundation for the FDA (and referred to as the "IMEDS Research Laboratory"). All OMOP tools and resources will remain available. Development will continue within IMEDS on common data models and vocabulary mappings and other tools to implement the IMEDS-Methods Research Agenda.

11. **How will IMEDS and the Sentinel Initiative partner together moving forward?**
    The IMEDS-Methods Research Agenda is intended to support FDA's activities, including its safety surveillance efforts within the Sentinel Initiative. IMEDS and the Sentinel Initiative will collaborate to apply and modify IMEDS-Methods research work products for use in the Sentinel system. Mini-Sentinel researchers are also encouraged to participate in the research areas and projects articulated within the IMEDS-Methods Research Agenda. In addition, through IMEDS-Evaluation, IMEDS and the Sentinel Initiative will partner together to determine how the Sentinel infrastructure can be leveraged to support non-FDA safety surveillance activities, and to launch an IMEDS Distributed Database and its supporting infrastructure.

12. **Can prospective funders sponsor specific projects in the IMEDS-Methods Research Agenda, or only the IMEDS-Methods Research Agenda as a whole?**
    The IMEDS-Methods Research Agenda has been constructed to complete research and develop infrastructure necessary to meet the methodological needs of its stakeholders. RUF recognizes that some research areas and projects within the IMEDS-Methods Research Agenda may align more closely than others with the near-term needs and priorities of prospective funders. While RUF would be open to discussions on how prospective funders can support specific projects, prospective funders are strongly encouraged to support the entire IMEDS-Methods Research Agenda. This support will enable RUF to allocate funding to each aspect of IMEDS research and operations based on the evolving short- and long-term needs of IMEDS and its stakeholders, and RUF will remain fully transparent on how these funds will be used to support these objectives.

13. **Will RUF ask prospective funders to support the three IMEDS program areas collectively, or will it make separate requests for IMEDS Methods, Education and Evaluation?**
    While Methods, Education and Evaluation are each critical components of the IMEDS mission, RUF recognizes that these distinct program areas are at different stages of development and some program areas may align more closely with the needs of prospective funders than others. Therefore, while RUF would welcome funding for the entire IMEDS program (for use by RUF as appropriate among the three program areas), it will make specific requests for support of each IMEDS program area separately.