REAGAN - UDALL FOUNDATION FOR THE Food and Drug Administration

Innovation in Medical Evidence Development and Surveillance (IMEDS)

CHARTER

First Draft Completed: April 2013
Proposed Revised Draft: August 2013

REAGAN - UDALL FOUNDATION FOR THE Food and Drug Administration

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1. Introduction

1.1 IMEDS Charter Scope

The Innovation in Medical Evidence Development and Surveillance (IMEDS) Charter was developed by the IMEDS-Methods Project Team[1] in collaboration with the IMEDS-Methods Organizing Committee[2] during the IMEDS-Methods Design Phase (October 2012-April 2013). The IMEDS-Methods Project Team leveraged and modified some of the applicable content from the *Observational Medical Outcomes Partnership (OMOP) Charter*[3] and *Mini-Sentinel Principles and Policies*[4] documents in order to streamline the creation of this Charter, and the design and implementation of IMEDS. As this document demonstrates, OMOP and Mini-Sentinel have made many foundational impacts upon IMEDS's policies and procedures.

The IMEDS Charter details the principles and policies governing all projects within the IMEDS program: IMEDS-Methods, IMEDS-Education, and IMEDS-Evaluation. The Charter documents the roles and responsibilities of the various IMEDS governing bodies and collaborators, which includes individuals and institutions that financially support or receive payment through IMEDS contracts, subcontracts or grants (this includes, but is not limited to, the IMEDS Program Team, data partners, funders, and research participants). These collaborators will have agreed to abide by all policies and procedures expressed herein and approved by the IMEDS Steering Committee[5] and Reagan-Udall Foundation (RUF) Board, as well as the requirements of their IMEDS grants, contracts or subcontracts (for the duration of those agreements and all applicable post-contract restriction periods).

IMEDS-Methods Design Phase version of Charter
Given that RUF has prioritized the design and implementation of IMEDS-Methods as the first IMEDS project, the bulk of this document outlines principles and policies specifically governing IMEDS-Methods. The IMEDS-Methods principles and policies include the process for creating the methods research agenda, the research participants, and data used to conduct research. Principles and policies governing IMEDS-Education and IMEDS-Evaluation will be completed after the design and implementation of IMEDS-Methods, and thus are not within the scope for the IMEDS Charter at this time. It is anticipated that many of the principles and policies developed for IMEDS-Methods will broadly apply to the full IMEDS program rather than be exclusive to IMEDS-Methods and, therefore, may be used in the design of IMEDS-Education and IMEDS-Evaluation.

1.2 IMEDS Background: Current Landscape of Safety Surveillance Methods Development

The safety of regulated pharmaceutical and biopharmaceutical products and medical devices is critical to the health of the American public. Thus, it is critical that all stakeholders within the healthcare

[1] The IMEDS-Methods Project Team consists of Jane Reese-Coulbourne and Troy McCall (Reagan-Udall Foundation), Greg Daniel (Brookings Institution), and Elizabeth Coulton, Tim Foley and Mike Brombach (Accenture).
[2] Membership of IMEDS-Methods Organizing Committee is listed in Section 7.
[3] *OMOP Charter* is available at: http://omop.fnih.org/sites/default/files/OMOP%20Charter%20June%202009.pdf
[4] *Mini-Sentinel Principles and Policies* is available at http://mini-sentinel.org/work_products/About_Us/Mini-Sentinel-Principles-and-Policies-August-2012.pdf
[5] More information on the IMEDS Steering Committee can be viewed in Section 2.3.6.1.

community continue to identify opportunities to improve the ability to learn about the performance of medical products once they are marketed and used broadly by the public. To protect the public health, The Food and Drug Administration (FDA), together with regulated industry and other stakeholders, supports continued post-market safety monitoring via multiple tools and the development of optimal practices in the appropriate use of observational data (e.g., administrative claims data, electronic healthcare records, registry data, etc.) to help assess medical outcomes.

In September 2007, the FDA Amendments Act of 2007 (FDAAA) was signed into law (P.L. 110-85), aiming to improve monitoring of FDA-regulated medical product safety. In response, FDA launched its Sentinel Initiative in 2008. Its main pilot, Mini-Sentinel, includes 26 Collaborating Institutions providing data, methods and expertise to conduct active medical product safety surveillance using a distributed data approach enabled through the use of a common data model. Mini-Sentinel consists of a coordinating center currently managed by Harvard Pilgrim Health Care Institute to support FDA in developing the scientific operations required to build an efficient, valid, and reliable Sentinel System[i].

In addition, in 2009, OMOP was launched to define leading methodological tools and processes to monitor medical product safety accurately and efficiently. To date, OMOP has conducted a series of experiments to generate empirical evidence about the performance of observational analysis methods in their ability to identify true risks of medical products and reliably discriminate between legitimate and false findings. In 2012, OMOP issued recommendations for building a risk identification and analysis system, as well as guidance for interpreting observational studies.[ii]

Over the past few years, Mini-Sentinel and OMOP have advanced the development of methods for the use and analysis of electronic healthcare data for safety evaluations. Their comprehensive methods-focused research 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 understanding of how an estimated effect from an observational study relates to the true relationship between medical product exposure and adverse events.[iii]

As the availability and form of electronic healthcare data evolve, ongoing research is needed both to better understand how these data should be used and which methods are most appropriate, and to develop new methods to generate valid and actionable information on the safety and use of medical products. Equally important are the need to create opportunities to train new scientists and equip them with the knowledge and expertise to conduct safety assessments with these data resources, as well as to create opportunities for the Sentinel tools and resources to be leveraged toward a national resource for evidence generation. Creating a mechanism for broader, sustainable collaboration and engagement from both the private and public sectors is critical. A new public-private partnership will allow for such collaborations to occur while building upon the tools and successes already generated by FDA and other organizations active in post-market surveillance.

1.3 IMEDS Charter Executive Summary[iv]

The IMEDS program is offered by the Reagan-Udall Foundation for the FDA (RUF), a 501(c)(3) organization authorized through 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. IMEDS serves to advance the science and tools necessary to support post-market evidence generation on regulated products, including safety surveillance[6] and evaluations, and to facilitate utilization of a robust secondary[7] electronic healthcare data platform for generating better evidence on regulated products in the post-market settings.

To accomplish these objectives, 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 first IMEDS project to be implemented is IMEDS-Methods. IMEDS-Methods coordinates methods research in support of FDA's safety surveillance needs, as well as the methods needs of a broader community of stakeholders, which will be conducted by a relatively small group of investigators through project workgroups and intramural research, as well as by a broader group of investigators through grants open for competition and unsolicited/independent research. In doing so, IMEDS will build an inclusive community of researchers from all stakeholder groups capable of collectively executing on the IMEDS-Methods Research Agenda.

IMEDS-Methods research leverages a data environment that includes an internal data laboratory (IMEDS Data Lab) as well as a distributed data network developed through partnerships with individual data partners. The latter is useful in developing and evaluating tools ultimately used within a distributed database context. The second and third IMEDS projects – IMEDS-Education and IMEDS-Evaluation, respectively – will be designed and implemented after the successful launch of IMEDS-Methods.

The IMEDS Program Team is responsible for managing the IMEDS Program and is comprised of dedicated RUF employees, contractors and detailed / seconded staff from other organizations. A number of governing bodies also provide strategic guidance to the IMEDS Program Team on the mission and vision, scientific guidance, and oversight of the various partnerships IMEDS forms. These governing bodies (the Reagan-Udall Foundation Board of Directors, IMEDS Steering Committee, and IMEDS Scientific Advisory Committee) are comprised of stakeholders from regulated industry, data partners, providers, academia, patient advocates, consumer advocates, FDA (as non-voting members), and other government entities to ensure IMEDS remains an effective and transparent public-private partnership.

[6] This document will assume the following definition for "safety surveillance", as defined previously by OMOP: *"a systematic and reproducible process to generate evidence efficiently to support the characterization of the potential effects of medical products from across a network of disparate observational healthcare data sources".*
[7] This document will assume the following definition for "secondary": *an additional use beyond the data's primary use (i.e., for tracking a patient's medical history).*

Funding from many of these diverse stakeholder groups enables IMEDS to be a long-term, sustainable solution for FDA's methodologic needs and enables collaboration among key stakeholders. Through transparency, research collaboration among stakeholders, alignment with FDA safety methods priorities, and communication with this diverse group of public and private stakeholders, IMEDS will increase overall expertise in both the research community and among practicing clinicians, and advance medical product safety surveillance efforts both in the US and globally.

2. IMEDS Program

2.1 IMEDS Mission Statement

IMEDS is a public-private collaboration in support of FDA's mission that promotes public health through advancing the science and tools necessary to further post-market evidence generation for FDA regulated medical products, and to facilitate utilization of a robust secondary electronic healthcare data platform for generating such evidence. In doing so, IMEDS will serve to enhance overall medical product safety methods and, in the long-term, could also enhance the science and opportunities for generating better post-market evidence beyond safety.

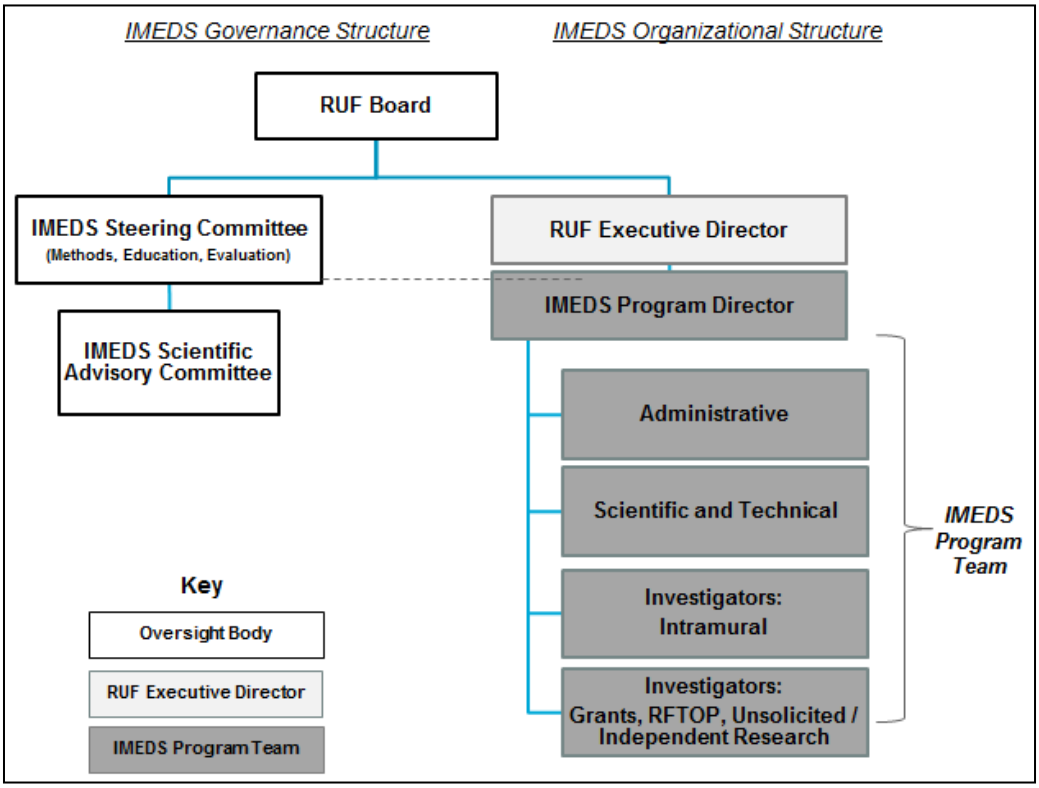
2.2 IMEDS Commitment to Transparency

To promote the engagement of the general public, IMEDS is committed to transparency in all aspects of its research and operations. IMEDS will demonstrate transparency in its operations by employing several tactics:

a. IMEDS will strive to make all work products, tools, and findings produced from IMEDS-Methods research available for use by the general public and accessible via the IMEDS website. Please refer to the section titled "Reporting and Publishing of IMEDS-Methods Research Work Products" for more information on this approach.
b. IMEDS will disseminate information about its operations through the IMEDS website and periodic IMEDS Symposiums (where IMEDS-Methods research will be presented to the general public). The scope of operations for which IMEDS will share information to the general public include, but are not limited to, the nomination and selection of IMEDS governing body members, creation of the IMEDS-Methods Research Agenda, disclosure of conflicts of interest among IMEDS governing body members and investigators, and evaluation of the IMEDS-Methods research work products.
c. The IMEDS Program Team will work with patient and consumer advocates to ensure IMEDS operations are communicated in a manner that is easily understood by the general public.
d. This IMEDS Charter will be posted on the IMEDS website for review by the general public.
e. The "conflict of interest" policy for this Charter will provide greater detail about the types of conflict of interest that IMEDS governing body members and research participants will be required to disclose (see "IMEDS Charter Legal Supplement" for more detail).

2.3 IMEDS Governance and Organizational Structures

IMEDS Governance and Organizational Structures



The structure outlined above describes the organizational approach governing the interaction between RUF/IMEDS Program Team and the IMEDS governing bodies overseeing all IMEDS Program projects: IMEDS-Methods, IMEDS-Education, and IMEDS-Evaluation. The roles and responsibilities of the RUF Executive Director, IMEDS Program Director, the IMEDS Program Team, and IMEDS governing bodies will be described within this document.

(Note: While this document provides preliminary details on the aforementioned groups' and individuals' roles and responsibilities, further details will be provided during the IMEDS-Methods Implementation Phase. Furthermore, this structure will be in effect for the duration of IMEDS pending any modifications recommended by the IMEDS Steering Committee and approved by the RUF Board.)

2.3.1 RUF Executive Director

The RUF Executive Director is appointed by the RUF Board and serves as supervisor to the IMEDS Program Director, who has oversight of the IMEDS Program Team.

2.3.1.1 RUF Executive Director Responsibilities

The RUF Executive Director's roles and responsibilities are detailed in the RUF's bylaws and governing statute, codified at 21 USC 379dd. The RUF Executive Director oversees all RUF projects approved by the RUF Board, including IMEDS. The RUF Executive Director's IMEDS-specific roles and responsibilities include, but are not limited to:

1. Recruit, interview, and hire the IMEDS Program Director.
2. Oversee the IMEDS Program Director's management of the IMEDS program.
3. Present periodic IMEDS updates, with the IMEDS Program Director, to the RUF Board.
4. Ensure alignment between RUF's mission and the missions of all IMEDS projects.
5. Collaborate with the IMEDS Program Director and RUF contractor(s) to create appropriate communication plans.
6. Review and approve the IMEDS operating budget (subject to review by IMEDS Steering Committee, and final review and approval by RUF Board).
7. Coordinate IMEDS fundraising efforts in collaboration with RUF Board and the IMEDS Program Director.

2.3.2 IMEDS Program Director

An IMEDS Program Director provides day-to-day management of IMEDS-Methods, IMEDS-Education and IMEDS-Evaluation. The IMEDS Program Director is an employee or contractor of RUF, reports to the RUF Executive Director, and oversees the IMEDS Program Team. As an RUF employee, the IMEDS Program Director is subject to the conflicts disclosure and transparency rules set forth in the bylaws for RUF employees. The IMEDS Program Director should have both business and scientific expertise, and should ensure that staff and contractors reporting to him/her will supplement that expertise as needed to manage IMEDS research and operations. Further detail on the credentials and expertise necessary for this position will be created in the position job description.

2.3.2.1 IMEDS Program Director Responsibilities[v]

The IMEDS Program Director's roles and responsibilities include, but are not limited to the following (the IMEDS Program Director may also assign completion of tasks associated with his/her responsibilities to the IMEDS Program Team, as necessary):

1. Ensure alignment between the missions and objectives of IMEDS-Methods, IMEDS-Education and IMEDS-Evaluation.
2. Serve as the key interface for IMEDS to the RUF Board, IMEDS Steering Committee, and FDA.
3. Provide day-to-day management of the IMEDS Program Team.
4. Oversee completion of all IMEDS-Methods research, and all external contractors hired to support IMEDS.
5. Recruit, interview, and hire IMEDS Program Team members (including administrative staff, technical staff, and intramural investigators), as necessary.
6. Nominate individuals to supplement the knowledge of the IMEDS Program Team in areas such as use of data, protocol design and infrastructure. These nominations must be approved by the IMEDS Steering Committee, and will serve as contractors to RUF.
7. Consult FDA and its associated contractors within the Sentinel Initiative, IMEDS investigators and the general public to create and refresh the IMEDS-Methods Research Agenda (subject to approval by the IMEDS Steering Committee), with support from the IMEDS scientific staff.

8. In consultation with the IMEDS Steering Committee, IMEDS Scientific Advisory Committee and the IMEDS Program Team, determine the appropriate approach to initiate each type of research commissioned within the IMEDS-Methods Research Agenda. The IMEDS Program Director will be required to report to the IMEDS Steering Committee periodically on the percentage of IMEDS-Methods research completed through each of the available research initiation approaches. The purpose of these reports is to ensure that a broad community of investigators is being used to complete IMEDS-Methods research, and that IMEDS is employing an appropriate distribution of research across the initiation approaches.
9. Oversee management of access to observational healthcare data for the IMEDS community. This includes establishing contracts for partners within the IMEDS distributed network.
10. Create and maintain the IMEDS operating budget (subject to review by the IMEDS Steering Committee, and final review and approval by the RUF Board).
11. Oversee the disbursal and tracking of funds used to execute the mission of IMEDS.
12. Assist in IMEDS fundraising efforts and communicate with IMEDS funders to share important program updates
13. Oversee external communications on behalf of IMEDS to FDA and other stakeholders, with oversight and guidance from the RUF Executive Director and IMEDS Steering Committee. Communications may be delivered through the RUF website, public symposia, teleconferences, and other means, and should be in alignment with any IMEDS communication plans. Communications will include the RUF annual report to Congress.
14. Ensure IMEDS's adherence to privacy and ethical standards, laws, and regulations.
15. Ensure the IMEDS Program Team and investigators accomplish metrics and goals established by RUF Board to measure effectiveness of IMEDS (please see section 2.3.5.1 for more details).
16. Ensure compliance among IMEDS participants with the policies outlined in this IMEDS Charter and developed at a later time by the IMEDS Steering Committee or the IMEDS Program Team.
17. Other responsibilities as required upon design of IMEDS-Education and IMEDS-Evaluation.

2.3.3 IMEDS Program Team

The IMEDS Program Team is comprised of RUF employees, contractors, or detailees/seconded staff from other organizations, and these individuals report to the IMEDS Program Director. The IMEDS Program Team provides administrative, scientific and technical support to the IMEDS investigators, Data Lab users, funders and other important stakeholders. IMEDS Program Team is subject to the conflicts disclosure and transparency rules set forth in the bylaws for RUF employees.

2.3.3.1 IMEDS Program Team Responsibilities

The IMEDS Program Team's roles and responsibilities will be further developed in the IMEDS-Methods Implementation Phase. These roles and responsibilities will include, but are not limited to:

1. IMEDS Administrative staff: support the IMEDS Program Director in project and contract management for all IMEDS investigators and contractors. These individuals will also:
    a. Support IMEDS Program Director's presentations to and engagement with FDA, the RUF Board and IMEDS Steering Committee.
    b. Collaborate with RUF Board and IMEDS Steering Committee patient and consumer advocates to ensure IMEDS research and findings are communicated effectively to patients and consumers.

   c. Oversee disclosure of conflicts of interest from IMEDS governing body members, research participants and other relevant collaborators.
2. IMEDS Technical staff: provide support and expertise regarding the IMEDS Data Lab and its associated features to all collaborators for research related to the IMEDS-Methods Research Agenda. This includes establishing appropriate policies and licenses for de-identified data maintained in the IMEDS Data Lab.
   a. IMEDS also reserves the right to offer technical support to collaborators using the IMEDS Data Lab to complete research not related to the IMEDS-Methods Research Agenda, given sufficient resources, and will prioritize technical support needs based on criteria to be developed during the IMEDS-Methods Implementation Phase.
   b. Technical staff may also create the infrastructure/tools necessary for implementation and maintenance of the IMEDS distributed network.
3. IMEDS Scientific staff: provide support and expertise to the IMEDS Program Director in all scientific operations and activities. IMEDS may choose to hire a Scientific Director to fulfill these responsibilities and may supplement this individual with additional employees and/or contractors. The responsibilities of IMEDS scientific staff include:
   a. Shaping the IMEDS Research Agenda (including soliciting feedback from various stakeholder groups)
   b. Coordinating and facilitating the activities of the IMEDS Scientific Advisory Committee
   c. Collaborating with IMEDS Technical staff to ensure IMEDS data resources support IMEDS scientific research
4. IMEDS intramural investigators*: investigators who have committed some amount of time to IMEDS, and may be paid for this time by either RUF (either as an RUF employee, contractor, or detailee/seconded individual from another organization) or their employer. IMEDS is open to individuals from all organizations and groups to serve as intramural investigators. The intramural investigators' work will be overseen by the IMEDS Scientific Advisory Committee and will include the following:
   a. Complete IMEDS-Methods research as issued by the IMEDS Program Director.
   b. Review and provide written consensus and dissenting commentary on proposals for all IMEDS-Methods research including grant applications, Request for Task Order Proposal (RFTOP) project working team proposals, and unsolicited/independent research proposals. (More information on these research initiation approaches is available in Section 3.3.3).
   c. Review and provide written consensus and dissenting commentary on IMEDS-Methods research recommendations, methods and findings completed by the at-large research community (through grants or unsolicited/independent research), RFTOP project working teams, and IMEDS intramural investigators.

**Note: the IMEDS Organizing Committee did not agree unanimously upon the precise role of and reporting structure for the IMEDS intramural investigators. One proposed alternative was for RUF to contract with an IMEDS Methods Center (IMC) which would complete the work currently assigned to the IMEDS intramural investigators. The IMC would be competitively sourced through an open and transparent process (the details of which IMEDS would publish on its website) and would be selected using criteria developed by the IMEDS Program Team and pending approval of the IMEDS Steering Committee; these criteria could include expertise in this field, diversity of research perspectives of the proposed team, and cost. At the present time, IMEDS has decided not to contract with an IMEDS Methods Center.*

5. Investigators that complete IMEDS-Methods research through either RFTOP research, grants or unsolicited/independent research will also be accountable to the IMEDS Program Director. More information on research completed through these initiation approaches is available in section 3.3.3).

2.3.4 Role of FDA

IMEDS is a project of the Reagan-Udall Foundation. Federal government employees are permitted, pursuant to section 770(j) of the Federal Food, Drug, and Cosmetic Act, to "serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities." FDA participation in IMEDS activities is consistent with that statutory provision and thus no FDA employees will be involved in directing or controlling the activities of IMEDS pursuant to this Charter.[8] When FDA or other federal government employees are members of committees pursuant to this Charter, that participation will be solely as part of their official duties. While they will be involved in the deliberations of the committees and will express their views on behalf of FDA with respect to issues being considered by those committees, they will not be voting members of any such committee. It is understood that FDA representatives will not have any fiduciary duty to IMEDS and will not serve on a board of directors or trustees governing the property and business affairs of the organization, and will not serve as an officer of the organization who receives delegated powers to execute binding decisions with respect to the property and business affairs of the organization.

2.3.5 RUF Board[vi]

RUF is the legal entity which is responsible for the funding and administration of the IMEDS program. The RUF Board of Directors holds the ultimate oversight of RUF activities and appoints its Executive Director. The RUF Board will work with the RUF Executive Director, IMEDS Program Director, and IMEDS Steering Committee to ensure the successful conduct of IMEDS, and oversees the operations of IMEDS as an RUF-managed initiative.

The RUF Board members, terms of service, selection procedure and decision policies are all specified in the RUF's bylaws which are available on the RUF website.

2.3.5.1 RUF Board Responsibilities[vii]

In addition to its responsibilities described in its statute and bylaws, RUF Board responsibilities specific to IMEDS include, but are not limited to:

1. Appoint the RUF Executive Director.
2. Approve compensation for the IMEDS Program Director (who will be hired by the RUF Executive Director).
3. Select a Chair and Vice Chair for the IMEDS Steering Committee (following review of recommendation from IMEDS-Methods Organizing Committee).

[8] It is possible that IMEDS may at some point be selected to enter into some type of funding agreement with FDA. Should that occur, FDA participation under that agreement would be dictated by the terms of the agreement and applicable Federal law.

   a. Any non-FDA members of the IMEDS Steering Committee are eligible to serve as Chair and/or Vice Chair.
   b. The RUF Board's criteria for selecting the Chair and Vice Chair will be published on the IMEDS website for review by the general public.
4. Review and decide upon the membership nominations of the IMEDS Steering Committee
5. Review and decide upon any IMEDS Steering Committee members recommended by committee chairs for termination.
6. Review and decide upon IMEDS Steering Committee recommendations on partnerships, proposals and contracts.
7. Oversee IMEDS finances (including approving the IMEDS operating budget) to ensure viability and sustainability of the program.
8. Ensure IMEDS is operating in accordance with privacy and ethics standards, laws, and regulations.
9. Evaluate overall effectiveness of the IMEDS program.
   a. The RUF Executive Director and IMEDS Program Director will be expected to report on these criteria during periodic presentations on IMEDS to the RUF Board.
   b. The RUF Board criteria for evaluation of IMEDS will be posted on the IMEDS website for review by the general public. These criteria may evaluate the degree of collaboration between IMEDS and the Sentinel Initiative and/or FDA (which would be created in collaboration with, and agreed upon by, the Sentinel Initiative and/or FDA), the impact of IMEDS research, and IMEDS's financial performance These metrics would be tied to IMEDS' overall mission of generating medical evidence to support surveillance of marketed medical products, and will align with the objectives of the IMEDS Research Agenda.
10. Oversee and approve the transition of OMOP assets, personnel and responsibilities to IMEDS (to be completed and detailed further during the IMEDS-Methods Implementation Phase).
11. Support IMEDS through fundraising.
12. Review and decide upon, following review of IMEDS-Methods Organizing Committee and IMEDS Steering Committee recommendations, all principles and policies as outlined in the IMEDS Charter and any future necessary modifications.
13. Maintain visibility on IMEDS operations through its designated member on the IMEDS Steering Committee.
14. Other responsibilities as required upon design of IMEDS-Education and IMEDS-Evaluation.

2.3.6 IMEDS Steering Committee

A multi-stakeholder IMEDS Steering Committee will provide guidance on the operation of IMEDS, beginning at the launch of the IMEDS-Methods Implementation Stage (at which point the IMEDS-Methods Organizing Committee will be dissolved).

2.3.6.1 IMEDS Steering Committee Responsibilities

1. Nominate a Chair for the IMEDS Scientific Advisory Committee (subject to RUF Board approval).
2. Nominate IMEDS Steering Committee members to replace departing members (subject to RUF Board approval).
3. Review and decide upon the membership nominations of the IMEDS Scientific Advisory Committee.

4. Review and decide upon any IMEDS Scientific Advisory Committee members recommended by committee chairs for termination.
5. Work with and review recommendations of supporting governing bodies including the IMEDS Scientific Advisory Committee.
6. Review and decide upon the IMEDS-Methods Research Agenda (created by the IMEDS Program Team in collaboration with the IMEDS Scientific Advisory Committee and using feedback provided by the general public).
7. Oversee external communications regarding IMEDS activities and findings (with a goal of making IMEDS progress updates as transparent as possible).
8. Review and provide input to the IMEDS operating budget (subject to approval by the RUF Board).
9. Review and recommend whether RUF should accept IMEDS partnerships, proposals and contracts (subject to either RUF Executive Director and/or RUF Board approval based on the terms of the partnership in question). For research proposals, the IMEDS Scientific Advisory Committee will provide input into the scientific merit of the proposals, while the IMEDS Steering Committee will provide a programmatic review which takes into account both the scientific merit and financial implications of the proposals.
10. Complete a formal evaluation on the feasibility of RUF contracting with an IMEDS Methods Center (based on cost and available RUF funds) to complete methods research, and evaluate research proposals and work products. The IMEDS Steering Committee will issue a recommendation to the RUF Board, RUF Executive Director and IMEDS Program Director on this concept. (Please see the "IMEDS Program Team Responsibilities" section for more info on this responsibility).
11. Review and decide upon any conflict of interest issues escalated by the IMEDS Program Team.
12. Form temporary sub-committees as necessary to support its decision-making. These sub-committees may cover technical issues, data issues, privacy/legal and ethical issues,[9] policy issues, finance / audit, fundraising, vendor/supplier review, and/or communications. Membership on these sub-committees occurs through nomination and voting within the IMEDS Steering Committee itself.
13. Form an executive/rapid-response committee, as necessary, which could be convened expeditiously to make critical, time-sensitive decisions between formal IMEDS Steering Committee meetings.
14. Monitor adherence to the IMEDS mission and operational principles (including those defined in this IMEDS Charter).
15. Other responsibilities as required upon design of IMEDS-Education and IMEDS-Evaluation.

2.3.6.2 IMEDS Steering Committee Chair Responsibilities[viii]

The IMEDS Steering Committee Chair will be responsible for the items mentioned below. The Chair will be supported by a Vice Chair who will assist the Chair in completion of these responsibilities and/or assume the Chair's responsibilities should the Chair not be available to attend Steering Committee activities/meetings or complete the responsibilities.

[9] Should IMEDS need to address these issues, it may be appropriate to create an IMEDS privacy panel. This panel could provide expertise regarding federal patient privacy-related laws, regulations, and ethical standards pertaining to the conduct of IMEDS. Where possible, this panel should leverage documentation and principles already created by similar experts who currently support the Sentinel Initiative and/or who did support OMOP.

1. Define the IMEDS Steering Committee's meeting agendas and facilitate its meetings.
2. Call for special IMEDS Steering Committee meetings, as necessary.
3. Provide tie-breaking votes as needed.
4. Recommend for termination (as necessary) any IMEDS Steering Committee members demonstrating dereliction of duties as specified in this IMEDS Charter (subject to RUF Board approval).
    a. The policies used by the IMEDS Steering Committee Chair to recommend termination of an IMEDS Steering Committee member due to dereliction of duty are made publicly available on the IMEDS website.
5. Propose formation of IMEDS Steering Committee sub-committees, as necessary.
6. In collaboration with RUF Executive Director and IMEDS Program Director, report to RUF Board and other stakeholders as necessary on IMEDS.
7. Other responsibilities as required upon design of IMEDS-Education and IMEDS-Evaluation.

2.3.6.3 IMEDS Steering Committee Members

The IMEDS Steering Committee will have a total of 10 members, comprised as follows:

1. FDA: 2 members*
2. RUF: 1 *ex officio* member (serves as Liaison to RUF Board)*
3. Pharmaceutical Industry: 2 members
4. Academia / Research Institute: 1 member
5. Provider (i.e., Clinician): 1 member
6. Data Partner: 1 member
7. Patient Advocate: 1 member
8. Consumer Advocate: 1 member

(*non-voting member)

In order to meet the requirement of serving in any of the seats mentioned above (e.g., "Provider", "Data Partner" etc.), the member must either be employed by or volunteering for an organization that fits this description.

The federal participants on the IMEDS Steering Committee provide technical advice and regulatory expertise within the scope of their authority under federal law.

2.3.6.4 IMEDS Steering Committee Member Terms of Service[ix]

1. It is understood that FDA members serve in their official capacity as representatives of FDA, do not direct or control any activities of IMEDS, and do not have any fiduciary duty to IMEDS.
2. 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).
3. Members may be asked to serve on sub-committees (as created by the Chair) and review partnership agreements, findings, and recommendations outside of formal IMEDS Steering Committee meeting times, as necessary.
4. Members serve two-year terms, and a maximum of two terms (based on IMEDS fiscal calendar).

   a. The Reagan-Udall Board may choose to renew member terms for one- or two-years, or to not renew the terms of certain individuals.
   b. The IMEDS Steering Committee Chair and Vice Chair can each serve for a maximum of three years.
5. Member terms may be staggered upon formation of the Steering Committee to prevent full Committee turnover every two years.
6. Members do not receive compensation from RUF.
7. Given their role in approving the IMEDS Research Agenda, members are not permitted to participate in IMEDS research. Members are permitted to review research proposals assuming no conflicts of interest exist (e.g., a member is not permitted to review proposals submitted by an individual also employed by the member's employer).
8. 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.
9. Members are subject to the IMEDS Conflict of Interest policies (see "IMEDS Charter Legal Supplement").

2.3.6.5 IMEDS Steering Committee Member Selection Procedure[x]

1. FDA members will be appointed by FDA.
2. The RUF Board selects the RUF Board liaison.
3. The IMEDS-Methods Organizing Committee will identify and nominate non-FDA members for the IMEDS Steering Committee, and these nominations must be approved by majority vote of the RUF Board. The IMEDS Project team will create a mechanism by which IMEDS-Methods Organizing Committee members may submit nominations anonymously. The RUF Executive Director and IMEDS Program Director will incorporate these nominations with their own recommendations and present them for review and approval by the RUF Board.
4. Once the IMEDS Steering Committee has been formed, it assumes responsibility for nominating replacements for departing IMEDS Steering Committee members. The IMEDS Steering Committee will welcome suggestions for future replacements to the IMEDS Steering Committee from the general public. Individuals may suggest themselves or others for open positions.
5. The RUF Board will review SC membership for any SC member who changes employers to determine whether that individual qualifies to remain in his/her SC seat and/or another open Steering Committee seat, or whether he/she must be replaced.All criteria that the IMEDS-Methods Organizing Committee and IMEDS Steering Committee use to make nominations are made publicly available on the IMEDS website.

2.3.6.6 IMEDS Steering Committee Member Decision Policies[xi]

All appointments, nominations and approvals outlined in this IMEDS Charter which the IMEDS Steering Committee is responsible for requires a vote for approval.

1. 4+ voting members of the IMEDS Steering Committee must be present at the Committee meeting/call to vote. No proxies are allowed to vote.
2. A simple majority of the 4+ voting members will be needed for approval.
3. The FDA members serve ex officio and will not vote on any decisions made by the IMEDS Steering Committee, including proposed recommendations to the RUF Board. If one or both of the FDA members disagree with a proposed recommendation, that disagreement and the basis for it will be reported to the Board together with the recommendation.

4. Should there be significant disagreement on an issue among the Steering Committee members (even if a majority decides to approve the measure), this disagreement will be documented and presented to the RUF Board when it is required that the RUF Board must vote upon or oversee a decision made by the Steering Committee.
5. Voting may take place either in-person, over the phone or over email.

2.3.7 IMEDS Scientific Advisory Committee[xii]

The IMEDS Scientific Advisory Committee (SAC) provides independent review of and expert input into the scientific aspects of IMEDS's activities. The SAC advises the IMEDS Program Director and the IMEDS Program Team and reports to the IMEDS Steering Committee. IMEDS may also choose to create separate Scientific Advisory Committees for IMEDS-Education and IMEDS-Evaluation (to be determined during the design phases for those IMEDS projects).

2.3.7.1 IMEDS Scientific Advisory Committee Responsibilities

The SAC's roles and responsibilities are as follows:

1. Ensure that IMEDS materials, practices and protocols follow scientifically sound practices (which includes, but is not limited to, providing guidance on which data IMEDS should use within its Data Lab to support IMEDS methods research)
2. Provide input into the feasibility of proposed IMEDS-Methods Research Agenda items, and provide guidance to the IMEDS Program Director and IMEDS Scientific Director on the appropriate initiation approaches for each agenda item.
3. Provide input on scientific merit of proposals for all IMEDS-Methods research (the programmatic review of proposals will be completed by either the IMEDS Program Team with oversight from the IMEDS Steering Committee).
4. Provide input on research protocol as proposed by IMEDS intramural investigators.
5. (Pending availability) Provide input on IMEDS-Methods research recommendations, methods and findings completed by IMEDS-funded researchers or non-funded researchers (through grants or unsolicited/independent research), RFTOP project working teams, IMEDS intramural investigators. (The evaluation of work products will be completed by the IMEDS Program Team).

2.3.7.2 IMEDS Scientific Advisory Committee Members

SAC composition is intended to include individuals with expertise from a variety of scientific disciplines. The SAC will include a Chair which is nominated by the IMEDS Steering Committee (subject to RUF Board approval) and must be one of the nine at-large appointed members. Membership is determined based on the following guidelines:

1. Nine at-large members appointed by the IMEDS Steering Committee
    a. Of these nine members, the regulated industry may comprise no more than three members. (In order to meet the requirement of serving as a "regulated industry" member, the member must either be employed by or volunteering for a regulated industry organization).
    b. Of these nine members, one must be a patient advocate representative.
2. Three FDA representatives, including one from the Sentinel Initiative, one from the Center for Biologics Evaluation and Research (CBER), and one from the Center for Drug Evaluation and Research (CDER).

2.3.7.3 IMEDS Scientific Advisory Committee Terms of Service

1. SAC will meet in-person at least once per year, and on an as-needed basis as determined by the SAC Chair and the IMEDS Program Team (depending upon timing of research proposals, and completion of research).
2. Members serve two-year terms, and a maximum of two terms (based on IMEDS fiscal calendar).
3. Member terms may be staggered upon formation of the SAC to prevent full SAC turnover every two years.

a. The IMEDS Steering Committee may choose to renew SAC member terms for one- or two-years, or to not renew the terms of certain individuals.

b. The IMEDS SAC Chair can serve for a maximum of three years.

4. SAC members will not be permitted to review research proposals when the SAC member has also submitted a proposal for that research project or has another conflict of interest (e.g., a colleague from the SAC member's employer has submitted a research proposal).
5. Members do not receive compensation from RUF.
6. Members can be reimbursed by RUF for actual and reasonable expenses incurred in support of IMEDS in accordance with applicable law.
7. Meetings may take place either in-person, over the phone or over email.
8. Members are subject to the IMEDS Conflict of Interest policies (see "IMEDS Charter Legal Supplement").

2.3.7.4 IMEDS Scientific Advisory Committee Selection Procedure[xiii]

1. All non-FDA SAC members will be selected and approved by the IMEDS Steering Committee. The IMEDS Steering Committee nominates the SAC Chair from among the selected non-FDA SAC members (subject to approval by the RUF Board) using criteria made available to the general public.
2. FDA Representatives are chosen by FDA.
3. For all other non-FDA SAC positions, IMEDS will solicit nominations from the IMEDS Steering Committee and general public for the initial SAC members. When replacing SAC members, SAC Chair will solicit nominations from the remaining SAC members and the general public, and the IMEDS Steering Committee will review and decide upon these nominations. Individuals may nominate themselves or others for open positions.

2.4 IMEDS Communication Plan

IMEDS will use a proactive approach to communication for both the IMEDS-Methods Design Phase and IMEDS-Methods Implementation Phase. The IMEDS Program Director will be accountable for this Communication Plan during both phases and may be supported during the IMEDS-Methods Implementation Phase by contractors hired by RUF for either the design and/or implementation of this Communication Plan. The details of this approach include, but are not limited to:

1. IMEDS will send tailored updates regarding progress made on the IMEDS-Methods Design and Implementation Phases.
2. These updates are tailored to all impacted stakeholders including, but not limited to: FDA, RUF Board members, IMEDS-Methods Organizing Committee members, current members of the

FNIH Board and OMOP Executive Board, OMOP Investigators, OMOP Contributors, OMOP Staff, Sentinel Initiative Investigators and Collaborating Institutions, current and potential funders from regulated industry, foundations and other organizations, and the general public (through the IMEDS website).

2.5 IMEDS Funding Strategy

Given that other organizations solicit funding from many of the same institutions with whom IMEDS will interact through its research responsibilities (including regulated industry which currently fund academic institutions, payer research units, contract research organizations, and others), a clearly articulated funding strategy is necessary to ensure the long-term sustainability of IMEDS.

Guiding principles for this strategy include:

1. All IMEDS funding will be transparent and all funders will be disclosed on the RUF and IMEDS websites.
2. The RUF Board will approve all donations received by RUF for IMEDS.
3. IMEDS will be funded by a diverse stakeholder community (including government, regulated industry, payers, non-profit organizations, patient advocacy groups, and other vested stakeholders). This diverse funding is critical to ensure the sustainability of IMEDS, and will be obtained in a manner that is equitable and fair to all contributors. In addition, IMEDS will pursue appropriate scientific and technical expertise from all IMEDS funders to help shape IMEDS's design and implementation).
4. RUF will be able to allocate FDA funding for IMEDS for costs for which such funding may be appropriately used.
5. Non-medical product industry and non-FDA resources which IMEDS may engage for financial support include any and all institutions with an interest in improving overall drug safety.
6. IMEDS will not be restricted from accepting funds from any sources, so long as proper conflict of interest considerations are documented and these funding arrangements are in accordance with RUF principles and policies.
7. Funding should, at a minimum, meet IMEDS budget needs as specified by the IMEDS Program Director and approved by the IMEDS Steering Committee.
8. During the IMEDS-Methods Implementation Phase, IMEDS may create various fee-for-service programs to generate additional revenue for IMEDS. These programs must help advance IMEDS's overall mission and are subject to review by the IMEDS Steering Committee and RUF Board.

3. IMEDS Methods

3.1 IMEDS-Methods Mission Statement

As a core component of IMEDS, IMEDS-Methods supports FDA's mission by initiating and facilitating the execution of methodological research aimed at improving upon the tools for conducting post-marketing safety surveillance using automated healthcare data, and to foster the adoption of its findings as appropriate. In meeting this mission, IMEDS-Methods will also be able to add to the general body of knowledge for using automated health data for broader post-market evidence generation on regulated products.

3.2 IMEDS-Methods Objectives

IMEDS-Methods will create a long-term methods research agenda that can support FDA's activities, including its safety surveillance efforts within the Sentinel Initiative, and meets the methodological needs of the general public (which includes patients, consumers, regulated industry, payers, providers and academics). IMEDS-Methods will then coordinate the completion of that methods research, aligning the IMEDS-Methods mission with the work that is currently conducted within the Sentinel Initiative and OMOP (as a starting point).

3.3 IMEDS-Methods Research

3.3.1 Range of IMEDS-Methods Research Activities

All methods research that IMEDS coordinates is in alignment with FDA's mission (broadly defined). These research activities could span a range of needs in the areas of data knowledge and understanding, analytic tool development, and informatics issues - all of which are important in improving safety surveillance activities. Examples of research that could fall under these broad categories could include, but are not limited to:

Enhancing Data Knowledge

1. Better understanding of appropriate use of evolving electronic healthcare data for safety evaluations (e.g., projects aimed at better understanding data limitations and best uses).
2. Better understanding of attributes of safety questions for which secondary use of data is appropriate given current tools and capabilities.

Improving Analytic Tools/Techniques

1. Continued performance evaluation of analysis approaches within alternative study designs against disparate observational datasets.
2. Development and evaluation of the performance of new and/or refined analytic techniques that could be implemented into the distributed data environment.
3. Identification of novel methods for safety evaluations (e.g., development and/or refinement of techniques used outside traditional epidemiology and aimed at increasing Sentinel capabilities).

Informatics

1. Promoting and expanding the Mini-Sentinel Common Data Model to include more clinical data elements from EHRs and from other sources such as registries (state birth records, national death index, disease registries, etc.) as well as broader use and adoption by stakeholders.
2. Evaluating the strengths and limitations of leading common data models with the goal of determining how to harmonize different common data models.
3. Development of standardized procedures for defining and evaluating algorithms to identify exposures and outcomes.

In addition, IMEDS could consider including in its research agenda some methods research areas beyond safety surveillance should the research community indicate interest in and need for doing so. IMEDS-Methods may also coordinate with other national initiatives to facilitate development and/or refinement of methods, and to disseminate lessons learned from the work of IMEDS, should these initiatives help IMEDS accomplish its mission; these initiatives may include both public and private partners

3.3.2 Creating the IMEDS-Methods Research Agenda

IMEDS-Methods develops, manages and refreshes a methods research agenda with early and long-term goals that guide the research that IMEDS facilitates. The process for requesting recommendations for the research agenda, and the criteria for which recommendations will be prioritized over others, are made readily transparent to ensure substantial input from the public and fairness in decision making. Transparency will be achieved by publishing the research agenda and work products from methods research conducted on the IMEDS website (in a manner easily understood by the general public). IMEDS will strive to prioritize research which addresses the needs of all stakeholder groups.

As specified in the "OMOP Transition Plan" document created by the IMEDS Project Team[10], the OMOP 3-Year Research Agenda will be continued for 2013 and then. IMEDS will strive to create an IMEDS-Methods 3-Year Research Agenda by the end of 2013 which uses the OMOP 3-Year Research Agenda as a starting point.

The following process will be used to create the IMEDS-Methods 3-Year Research Agenda, and any subsequent iterations upon the IMEDS-Methods Research Agenda:

1. FDA states its methodologic needs as it relates to observational data
    a. The IMEDS Program Director will work with FDA to identify, articulate, and prioritize methodological needs that FDA views as important for conducting safety surveillance activities and potentially research areas beyond safety surveillance as necessary.
2. IMEDS drafts a 3-year research agenda based on those needs and requests input from its governing bodies and the general public
    a. The IMEDS Program Director and IMEDS Scientific Director, in consultation with the IMEDS Scientific Advisory Committee, create a draft 3-year research agenda that is intended fill the methodologic gaps identified by FDA. The IMEDS Program Director will also consult the RUF Executive Director to determine available RUF resources to support IMEDS research, and use this guidance to help prioritize IMEDS research.

[10] This OMOP Transition Plan will be posted on the IMEDS Website.

   b. IMEDS requests input on the draft research agenda from the general public through posting the draft agenda on the IMEDS website. IMEDS will also actively solicit input from key stakeholder groups including patient and consumer advocates, regulated industry, academics, payers, and providers.
3. IMEDS refines the draft agenda based on input received
   a. FDA confirms that the revised research agenda addresses FDA's methodological priorities (the agenda may also include other items that are targeted to meet non-FDA IMEDS stakeholder needs).
4. IMEDS secures approval for the revised agenda from the IMEDS Steering Committee
   a. The IMEDS Steering Committee should ensure that the needs of all stakeholders have been considered and integrated into this agenda.
   b. After approval, the research agenda is considered ready for implementation and the IMEDS Program Director will begin to determine how each research agenda item will be initiated with input from the IMEDS SAC (based on current IMEDS financial position, frequency of using each initiation approach, etc.) (described in Section 3.3.3).
5. IMEDS and FDA continue to refine research agenda to align with FDA stated needs, as necessary
   a. The IMEDS Program Director will meet with FDA no less than every 6 months to review the research agenda. During these meetings, FDA may modify or articulate new methodological gaps as those issues evolve.
   b. The IMEDS Program Director will then repeat steps #1-4 to create a revised IMEDS-Methods Research Agenda (which addresses FDA's methodological gaps) and seek the input of the aforementioned stakeholders, as necessary.

3.3.3 Processes for Initiating IMEDS-Methods Research

In order to ensure broad participation among the research community, IMEDS initiates research in alignment with the IMEDS-Methods Research Agenda through several approaches. The IMEDS Program Director and IMEDS Scientific Director, in consultation with the IMEDS Scientific Advisory Committee, will create criteria to determine the appropriate research initiation approach to use based on the nature of the research agenda item and available IMEDS funds. These criteria will be subject to the review and approval of the IMEDS Steering Committee. IMEDS will also periodically evaluate the ability for each initiation approach to complete IMEDS-Methods research efficiently and effectively, and may create other initiation approaches, as necessary (pending approval of the IMEDS Steering Committee).

In deciding the most appropriate research initiation approach, IMEDS will strive to create and use a broad, inclusive range of individuals capable of collectively executing upon the IMEDS-Methods Research Agenda. This will likely include those investigators currently engaged in methods research activities that are a part of the Sentinel Initiative or OMOP given their background and experience in methods research.

These approaches include, but are not limited to, the Grants Open for Competition Approach, Requests for Task Order Proposals (RFTOPs) Approach, Intramural Research Approach, and Unsolicited/Independent Research Approach, which are described below in further detail.

3.3.3.1 Grants Open for Competition Approach

IMEDS may initiate research by issuing grants to the at-large research community for specific IMEDS-Methods Research Agenda items. Each grant opportunity would be established with a clear objective (e.g., maximizing predictive accuracy of a statistical method) and the community would be invited to develop proposals in response to publically stated grant needs.

As long as appropriate conflict of interest documentation is signed, all institutions and individuals (including individuals from both for-profit and non-profit institutions) will be eligible to participate in these competitions. The IMEDS Program Team will determine further eligibility criteria during the IMEDS-Methods Implementation Phase.

The IMEDS Program Team will create criteria to evaluate proposals for these grants and to ultimately select the institutions or individuals to receive these grants. The criteria will be developed in consultation with the IMEDS Scientific Advisory Committee (subject to review by the IMEDS Steering Committee). The IMEDS Scientific Advisory Committee will also provide guidance to the IMEDS Program Team in deciding which individuals will be awarded these grants.

The RUF Board must approve all grants made to research participants.

3.3.3.2 RFTOP Approach

IMEDS may issue Requests for Task Order Proposals (RFTOPs) to a defined group of investigators (detailed in section 3.3.3.1.3). This approach will likely be used when the research needed is very specific to evaluating, improving, or refining tools specific to Sentinel operations and where research is best completed by researchers currently involved in Sentinel activities. For RFTOP research, methods research is conducted through project workgroups.

Workgroups are created to develop and implement project-specific activities as part of the IMEDS-Methods Research Agenda. For each activity, the IMEDS Program Team, with input from the IMEDS Scientific Advisory Committee, issues a description of the project opportunity and coordinates the screening and selection of workgroup leaders and members.

The RUF Board must approve all contracts made with RFTOP research participants.

3.3.3.2.1 RFTOP Workgroup Responsibilities

1. Develop each project plan, including detailed specifications for its implementation.
2. Collaborate with the IMEDS Program Team and IMEDS Scientific Advisory Committee, where necessary, to ensure that workgroup activities fit expectations understood within the IMEDS-Methods Research Agenda.
3. Design and implement appropriate data collection strategies and analytic methods.
4. Prepare reports based on progress and findings of research, and other deliverables, for review by the IMEDS Program Director.
5. Meet deadlines and remain within budgetary guidelines established by the IMEDS Program Team.

3.3.3.2.2 RFTOP Workgroup Leadership

All institutions and individuals who are issued the RFTOP are invited to indicate their interest in leading the workgroup by submitting proposals. When more than one potential leader expresses interest, the IMEDS Program Director may confer with the interested individuals to determine a mutually acceptable leadership arrangement. If the interested individuals cannot agree, the IMEDS Program Director designates the leader in consultation with the IMEDS Steering Committee.

Potential workgroup leaders are responsible for preparing proposals describing their approach to the project opportunity. These proposals include:

1. Required Components
    a. Expertise relevant to the activity, which may include knowledge of appropriate methods, clinical subject area, and data characteristics.
    b. Demonstrated capacity to manage workgroups.
    c. Ability to meet deadlines and assurance the deadlines can be met.
    d. A feasible and valid approach to achieving the requested deliverables.
    e. A budget and timeline consistent with the available resources and time constraints.
    f. Demonstration of no conflicts of interest that should prevent participation in the research.

2. Preferred Components
    a. Representation on the proposed workgroup from multiple collaborators (especially when methods research requires access to data) to promote knowledge transfer and program development.
    b. Inclusion of mentoring opportunities to ensure continuity of expertise.

3.3.3.2.3 RFTOP Workgroup Membership

RFTOP workgroup membership is determined by using the following guiding principles:

1. With guidance from the IMEDS Steering Committee and IMEDS SAC, the IMEDS Program Team will issue RFTOPs to a limited number of institutions and individuals.
    a. Any interested institutions and individuals are expected to make their interest known to IMEDS leadership in receiving these RFTOPs. However, IMEDS reserves the right to determine which institutions and individuals will be issued each RFTOP.
    b. Upon implementation of IMEDS-Methods, all existing Sentinel Initiative collaborating institutions and investigators, and OMOP contributing members and investigators, are eligible for participation in RFTOP research.
    c. The number of institutions and individuals may be limited to ensure RUF has capacity to manage the RFTOP process (e.g., reviewing proposals).
2. Upon announcement of an RFTOP, individuals and institutions willing to participate in workgroups make their interest known to the IMEDS Program Team, which provides this information to interested potential workgroup leader(s) and provides a forum for communication among interested individuals.
3. Workgroup leaders are responsible for selecting members of their workgroup from the pool of collaborators.
    a. Individuals and institutions may participate in more than one proposed workgroup.
    b. When possible, workgroup members are selected by mutual agreement of interested investigators.

c. Effort will be made to distribute opportunities over time among interested, equally qualified collaborators with the ultimate goal of utilizing the investigators that are best capable of completing the particular research project. The highest priority is placed on identifying the most qualified workgroup members for specific activities.
d. Regulated industry scientists may participate in RFTOP research (as long as appropriate conflict of interest documentation is signed).
e. For workgroups that involve accessing data within the IMEDS distributed network, all data partners with suitable data for the specific activity are invited to participate. Workgroup leaders are responsible for selecting data partners if more are eligible and wish to participate than needed.
f. It is recommended that workgroup members commit a significant portion of their time to project tasks. This commitment will help expedite the completion of the research.

3.3.3.3 Intramural Research Approach

IMEDS may choose to designate specific research activities from the IMEDS-Methods Research Agenda to be completed by the IMEDS intramural investigators. IMEDS may limit the number of IMEDS intramural investigators, and interested individuals would be required to apply for these limited positions. Candidates would be evaluated based on criteria established by the IMEDS Program Director in consultation with IMEDS Steering Committee.

All intramural investigators will report to the IMEDS Program Director and be required to report periodically to the IMEDS Scientific Advisory Committee. Their IMEDS-Methods research responsibilities will include, but are not limited to:

1. Develop a research project plan, including detailed specifications for its implementation.
2. Collaborate with the IMEDS Program Director and IMEDS Scientific Advisory Committee, where necessary, to ensure that research activities fit expectations understood within the IMEDS-Methods Research Agenda.
3. Design and implement appropriate data collection strategies and analytic methods.
4. Prepare reports based on progress and findings of research, and other deliverables, as necessary.
5. Meet deadlines established by the IMEDS Program Director.

The RUF Board must approve all contracts made with IMEDS intramural investigators.

3.3.3.4 Unsolicited/Independent Research Approach

The at-large research community may also make unsolicited proposals to the IMEDS Program Team to complete methodological research in alignment with the IMEDS-Methods Research Agenda. These investigators would be subject to oversight by the IMEDS Program Team.

As long as appropriate conflict of interest documentation is signed, all institutions and individuals (including individuals from both for-profit and public/non-profit organizations) will be eligible to propose unsolicited research. The IMEDS Program Team will determine further eligibility criteria during the IMEDS-Methods Implementation Phase.

The IMEDS Program Team will create criteria to evaluate all unsolicited proposals in consultation with the IMEDS Scientific Advisory Committee (subject to review by the IMEDS Steering Committee).

The RUF Board must approve all grants made to independent research participants.

3.3.4 Review of IMEDS-Methods Research Proposals

The IMEDS Program Director holds ultimate contract authority for assigning responsibilities for executing IMEDS-facilitated research, and will use the guidance of the IMEDS Scientific Advisory Committee and the IMEDS Program Team to select winning proposals for grants open for competition, RFTOP workgroups, and unsolicited/independent research.

Individuals submitting proposals for consideration, or those from the same institution as an individual submitting a proposal, may not participate in the proposal review process. If the individual submitting the proposal in question is a regular member of the review process, the IMEDS Scientific Advisory Committee should nominate a reviewer in place of this individual.

If no proposed workgroup is considered satisfactory by the IMEDS Program Director, taking into account the recommendations of the IMEDS Scientific Advisory Committee and the IMEDS Program Team, the IMEDS Program Director may withdraw or reissue the project opportunity.

The IMEDS Program Director will strive to select the winning proposal to complete the given IMEDS-Methods research project within one month of the proposal submission deadline for the research project.

3.3.5 Evaluation of IMEDS-Methods Research Work Products

All IMEDS investigators are required to submit their research for final review to the IMEDS Program Director to ensure adherence to the statements of work issued by the IMEDS Program Team to the investigators in accordance with the research they are contracted to complete.

3.3.6 Reporting and Publication of IMEDS-Methods Research Work Products

Investigators are encouraged to seek peer-reviewed publication for their research findings and projects. In order to ensure scientific accuracy of the research, the investigators are encouraged to consult the IMEDS Scientific Advisory Committee and the IMEDS Program Team prior to publication to evaluate the scientific quality of the research.

RUF reserves the right to post all IMEDS-Methods research and work products (e.g., programming code, protocol, analysis definitions, summary datasets, and final reports) on the IMEDS website, but can exercise judgment about the timing of posting in order not to unduly constrain publication opportunities. In the interest of transparency, efforts will be made to post research reports as soon as possible after completion of those reports. All IMEDS-Methods research projects will require a documented plan for target dates when appropriate work products will be posted, and the IMEDS Program Director will hold project leaders accountable for meeting these dates.

Other important legal policies governing the publication of these findings on the IMEDS website will be detailed in the "Confidentiality" section of the document (see "IMEDS Charter Legal Supplement").

3.4 IMEDS Data[xiv]

In general, with appropriate privacy and data use agreements executed among parties, IMEDS does not restrict itself from using any type of healthcare data that helps advance its research agenda. Potential data sources that could be considered for collaboration within the IMEDS community include, but are not limited to, outpatient and inpatient electronic health records (EHRs), publicly insured systems, administrative claims from private payers, hospital-based systems, registry data, lab data, data from regional health networks, and other data sets with specific population demographics. IMEDS may also pursue using both domestic (US) and international data to support its research.

IMEDS data resources will include data that already exist in the OMOP Research Lab (the ownership of which will transition to IMEDS with appropriate security measures in place, and will be called the "IMEDS Data Lab"), partnerships with new organizations which can license data for the IMEDS Data Lab, and data accessible through individual data partners provided through an IMEDS distributed network. All organizations reserve the right to determine whether they will contribute data to the IMEDS Data Lab or through an IMEDS distributed network on terms and conditions agreeable to that organization and IMEDS.

3.4.1 IMEDS Data Lab

The IMEDS Data Lab has the following features:

1. This cloud-based computing environment is capable of supporting secure access to both real and simulated de-identified data from multiple sources and across multiple formats, including both the OMOP and Mini-Sentinel data models. From 2009 through 2013, these assets included five real datasets in OMOP common data model format (Truven MarketScan Commercial Claims and Encounters (CCAE), MarketScan Medicare Supplemental Beneficiaries database (MDCR), MarketScan MultiState Medicaid Database (MDCD), MarketScan Lab Supplemental Database (MSLR), and GE Centricity EHR)[11], 16 simulated datasets in OMOP common data model format, additional datasets available in the Mini-Sentinel common data model format, and the OSIM2 program that generates datasets in the OMOP common data model format.
2. The IMEDS Data Lab will only include de-identified patient-level data which adheres to HIPAA standards unless there is a specific need for person-level information.[12] Such person-level information might include, for example, information (stripped of direct patient identifiers)

[11] More information on these data sources can be found at: http://omop.fnih.org/2012SymposiumPresentations.
[12] Direct identifiers are those excluded in the creation of Limited Data Sets, as specified by law. Specifically, this list includes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images (45 CFR Part 164.514(e)(2)).

regarding individuals who received specific vaccines on specific dates (e.g., August 2009) when such information is required for a specific project.

3. The IMEDS Data Lab can be readily used to "simulate" the behavior of a distributed environment, insofar as all programs can be developed in such a way that they can be executed against a source database without intervention and can generate aggregated output devoid of any patient identifiable information.
4. The IMEDS Data Lab will provide an opportunity to develop, explore, and improve upon common data model(s) for observational research.
5. The IMEDS Program Team is ultimately responsible for the IMEDS Data Lab's maintenance. The IMEDS Program Team is also responsible for refreshing and expanding the data available in the Data Lab through the negotiation of contracts with IMEDS data partners (once these partnerships are made) and/or creating new partnerships with additional IMEDS data partners.
6. Data transfer between organizations and the IMEDS Program Team to the IMEDS Data Lab is done by means of a secure web-based file sharing system. The IMEDS Program Team complies with standards established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Federal Information Security Management Act of 2002 (FISMA) and future legislation regarding privacy of health care data.

3.4.1.1 IMEDS Data Lab Access

1. The IMEDS Data Lab will be available to facilitate research by all investigators commissioned by IMEDS to complete research in alignment with the IMEDS-Methods Research Agenda (as long as proper data use agreements are signed).
2. The IMEDS Data Lab will also be accessible to anyone seeking to use the Lab for research that has not been specified in the IMEDS-Methods Research Agenda but is in alignment with IMEDS's mission.
    a. The IMEDS Program Director reserves the right to review work products from any users completing research that is independent from the IMEDS-Methods Research Agenda.
    b. IMEDS reserves the right to require those individuals using the Lab to complete research to reimburse IMEDS for any usage costs as necessary (e.g. server costs).
    c. Should the IMEDS Data Lab or the IMEDS Program Team have limited capacity to support multiple access requests for research, those individuals using the IMEDS Data Lab to complete IMEDS-Methods research will be given priority over those completing research not aligned to the IMEDS-Methods Research Agenda.
    d. IMEDS reserves the right to restrict technical support for these requests based on IMEDS Program Team availability.
3. All users of the IMEDS Data Lab will be subject to appropriate data use agreements and license restrictions.

3.4.1.2 IMEDS Distributed Data Network

IMEDS may also supplement the IMEDS Data Lab by creating an IMEDS distributed network of data partners.

Partnerships with these data partners may have the following features:

1. Distributed data partners maintain physical and operational control of their electronic healthcare data contributed to the IMEDS distributed network. These distributed data partners

execute standardized or custom data queries distributed by the IMEDS Program Team and then share the output of these queries, typically in summary form, with IMEDS and appropriate IMEDS investigators.

2. Distributed data partners should provide access to summary results from specific patient-level data which the research investigators deem is necessary to conduct research for a given project (based on certain data characteristics including number of lives or specific demographic needs). The research investigators are responsible for making these data needs known to IMEDS to enable IMEDS to negotiate engagement with the proper distributed data partners. These data partners will also provide input into what portions of their data will and will not be useful for methods research.
3. If transfer of data is necessary (e.g., for linking to electronic clinical data, registries) for the research to be undertaken, appropriate data use agreements will be in place prior to such activity.
4. IMEDS will not be restricted from forming partnerships with existing Sentinel Data Partners.
5. The IMEDS Program Team assumes responsibility for addressing the legal/privacy implications associated with access through its distributed data network. These implications include, but are not limited to, the possible need for Business Associate agreements to allow transfer of Limited Data Sets (if needed), and identification of IRB processes for applications for HIPAA waivers (if needed). Also, the transfer of results between IMEDS distributed data partners and IMEDS must comply with FISMA standards.

3.4.1.3 Common Data Model

Distributed data partners will conduct analyses within IMEDS by using a common data model that standardizes administrative and clinical information across data partners. The common data model allows data partners to execute standardized programs developed by the IMEDS Program Team in collaboration with the data partners. Several approaches to data modeling and standardization currently exist and are in active use within the broader research community. IMEDS will accommodate multiple perspectives into selecting, developing and/or improving the common data model used for the IMEDS distributed network.

Research that utilizes the IMEDS distributed network and that involves the development of tools intended to be used on data that are in accordance with Sentinel standards will utilize the common data model adopted by FDA. Currently, this is the Mini-Sentinel Common Data Model (MSCDM)[13]. This should not preclude other data partners who are not Mini-Sentinel Data Partners and whose data are not (or cannot) be formatted into the MSCDM from participating in IMEDS facilitated research, since IMEDS will continue to support the refinement and use of the OMOP CDM.
As part of its ongoing activities, IMEDS will support continued development and evaluation of data modeling and standardization strategies to support emerging data and expanding use cases of its stakeholders.

1. The IMEDS Program Team may form working groups as necessary to ensure that the common data model is designed to meet each stakeholder's needs.

[13] More information about the Mini-Sentinel Common Data Model can be found at http://mini-sentinel.org/data_activities/distributed_db_and_data/default.aspx

2. Data partners provide knowledge and expertise to inform design of common data models, and where possible, to ensure appropriate use and interpretation of data in the common data model format.

3.4.1.4 Original and External Source Distributed Data

3.4.1.4.1 Original Source Data

Distributed data partners possess several types of data acquired through their normal activities (referred to herein as "original source data"), including, but not limited to, administrative claims data, outpatient and inpatient electronic health records (EHRs), demographic information, and outpatient pharmacy dispensings. Distributed data partners retain stewardship and possession of both original source data and data transformed into common data model format. Distributed data partners manage and store the data in accordance with their own institutional policies.

Distributed data partners may use their own original source data transformed into common data model format for other purposes such as research.

3.4.1.4.2 External Source Data

As necessary, distributed data partners may be asked to collect information from sources other than their own institution (referred to as "external source data") for purposes such as identifying or confirming exposures or outcomes of interest. Healthcare data registries for particular diseases or medical procedures are one type of potential external sources. Data transfer from external sources to data partners is done in keeping with customary standards of secure file sharing.

The IMEDS Program Team, IMEDS investigators and IMEDS Data Lab users may use data obtained from external sources for IMEDS-Methods research if authorized by the external sources in keeping with all applicable data privacy regulations. Such data may not be reused, re-disclosed, altered, or sold for any purposes other than those defined in the base contracts and subsequent task order contracts without specific authorization.

Distributed data partners retain data obtained from external sources to meet the needs of specific projects, and data derived from these external sources, for no longer than three years after the project is deemed complete by IMEDS and the National Institute of Standards (NIST) in place at that time. The IMEDS Program Team and distributed data partners may review and revise this provision if it is determined that these data retention requirements do not adequately meet the scientific needs of IMEDS activities. Process requirements will be described in the IMEDS Standard Operating Procedures and posted on the IMEDS website.

4. IMEDS-Education

[Content for this section will be created upon commencement of the IMEDS-Education Design Phase]

4.1 IMEDS-Education Mission Statement

[Content for this section will be created upon commencement of the IMEDS-Education Design Phase]

4.2 IMEDS-Education Objectives

[Content for this section will be created upon commencement of the IMEDS-Education Design Phase]

5. IMEDS-Evaluation

[Content for this section will be created upon commencement of the IMEDS-Evaluation Design Phase]

5.1 IMEDS-Evaluation Mission Statement

[Content for this section will be created upon commencement of the IMEDS-Evaluation Design Phase]

5.2 IMEDS-Evaluation Objectives

[Content for this section will be created upon commencement of the IMEDS-Evaluation Design Phase]

6. IMEDS Operational Principles[xv]

1. Confidentiality
    a. Information and intellectual property (IP) disclosed by IMEDS participants (including IMEDS investigators, IMEDS governance body members, and the IMEDS Program Team) can be protected from further disclosure or use outside IMEDS to the extent permitted by applicable law.
    b. Participants are required to sign confidentiality agreements in order to protect the IP discussed in IMEDS working sessions, committee meetings, and internal working papers.
2. Intellectual Property (IP)
    a. IP created as a result of IMEDS is intended to be placed in the public domain (likely through publication in peer-reviewed journals, on the IMEDS website, IMEDS-generated emails, etc.). Exceptions to this policy may be possible, requiring approval of terms by the IMEDS Steering Committee.
    b. Existing IP offered for use in IMEDS are protected.
3. Data access rights
    a. In situations where data partners will maintain their data and provide summary results in a distributed network, the data partners retain ownership of that data.
    b. In all cases, IMEDS should retain rights to analysis results, and in keeping with its mission, should make all results publicly available to the general public.
4. Publication and other external communication of IMEDS findings
    a. IMEDS periodically publishes technical papers and assessment topics, with oversight and guidance from the IMEDS Steering Committee.
    b. In accordance with RUF bylaws, RUF also periodically publishes updates to Congress and the FDA which may include updates on progress made on IMEDS (including research conducted, published papers).
    c. The RUF Executive Director, with IMEDS Steering Committee oversight, coordinates official IMEDS public communications including release of research protocols once finalized.
5. Conflict of interest
    a. IMEDS governing body members and research participants are required to disclose potential conflicts to the extent permitted by applicable law to the IMEDS Program Team, and the disclosures are reviewed by the IMEDS Steering Committee.
    b. Should the IMEDS Steering Committee recommend remedial actions related to conflict of interest, such recommendations are subject to review and approval by the RUF Board.
    c. Conflict-of-interest disclosures should be reviewed and updated annually.
    d. Further details on the types of conflict of interest that IMEDS governing body members and research participants will be required to disclose will be articulated through the IMEDS conflict of interest policy (see “IMEDS Charter Legal Supplement”).
6. Ownership of Infrastructure
    a. All real assets built for or acquired by IMEDS become property of RUF.
    b. RUF Board, with consideration for recommendations from the IMEDS Steering Committee, determines disposition of IMEDS infrastructure as necessary should IMEDS cease to exist or management of IMEDS be transitioned to another organization.
7. Grants, Contracts and Supplier Relationships

   a. RUF negotiates and manages all agreements on behalf of IMEDS, employing a structured, transparent solicitation process that will be available for review by the IMEDS Steering Committee, IMEDS participants and interested suppliers.

8. Antitrust Policy
   a. IMEDS conducts all activities in strict compliance with the antitrust laws of the United States of America.
   b. IMEDS is not intended, in any way, to coordinate or restrict the commercial activities of its participants, particularly its private-sector participants, beyond the activities of IMEDS itself.
9. Federal Employees
   a. Federal employees who are involved in IMEDS may be subject to federal law or regulations regarding conflict of interest, confidentiality, and grants and contracts. In such cases federal law or regulations apply to their activities and supersede the policies of IMEDS.

7. IMEDS-Methods Design and Implementation Phases

IMEDS-Methods will be created and managed through two phases: a Design Phase, and an Implementation Phase.

IMEDS-Methods Design Phase[xvi]

The IMEDS-Methods Design Phase (October 2012-April 2013) involved the IMEDS-Methods Project Team which, in consultation with the IMEDS-Methods Organizing Committee, produced this IMEDS Charter.

In addition, the IMEDS-Methods Project Team produced a plan which details recommendations for the transition of OMOP to IMEDS and the sustainable implementation and management of IMEDS; the details of this plan are contained in an "OMOP Transition Plan" delivered to FNIH and RUF leadership.

The members of the IMEDS-Methods Organizing Committee who informed the design of the IMEDS Charter are as follows:

- Lesley Curtis (Duke University; Mini-Sentinel: Leader, Data Core)
- Garry Neil* (Apple Tree Partners, Apple Tree Pharmaceuticals, TransCelerate Biopharmaceuticals Inc., Reagan-Udall Foundation Board Liaison)
- Richard Platt (Harvard Pilgrim Health Care Institute; Mini-Sentinel: Principal Investigator; OMOP: Executive Board Member)
- Lee Rucker (AARP; OMOP: Executive Board Member)
- Patrick Ryan (Janssen R&D; OMOP: Principal Investigator)
- John Santa (Consumer Reports)
- Rachel Sherman** (Food and Drug Administration)
- Claire Spettell (Aetna)
- Alec Walker (World Health Information Science Consultants)

(*RUF Board liaison; non-voting member)
(**non-voting member)

This IMEDS Charter will be recommended by the IMEDS-Methods Organizing Committee (pending agreement through majority vote) and presented by the IMEDS Project Team for final approval to the RUF Board. The IMEDS Program Team may also make modifications to the IMEDS Charter upon completion of the IMEDS-Methods Design Phase.

IMEDS-Methods Implementation Phase[xvii]

Upon completion of the IMEDS-Methods Design Phase, the IMEDS-Methods Implementation Phase will begin. The main priorities that must be completed during this phase include, but are not limited to, the following:

1. Selection of the individuals to serve on the governance committees including the IMEDS Steering Committee and IMEDS Scientific Advisory Committee. The IMEDS-Methods Organizing Committee will dissolve upon the launch of the IMEDS Steering Committee.
2. Transfer of all OMOP methods-related assets (including intellectual property, data, tools, and personnel) to IMEDS as agreed upon by RUF and FNIH/OMOP leadership.

3. Hiring of remainder of the IMEDS Program Team members (should personnel gaps exist after acquisition of OMOP personnel/assets).
4. Development of the IMEDS-Methods 3-Year Research Agenda.
5. Assessment of existing infrastructure to house and manage data, and identification of necessary enhancements to support needs of users of IMEDS Data Lab.
6. Continuation of outreach efforts to prospective IMEDS collaborators that could provide either financial or in-kind support to IMEDS.
7. Continuation of communications effort to inform those stakeholders impacted by creation of IMEDS-Methods and interested in its work, including launch of a dedicated public website.
8. Start of design of IMEDS-Education and IMEDS-Evaluation.

8. Privacy

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

9. Confidentiality

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

10. Intellectual Property[xviii]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

11. Data Management and Access Policy[xix]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

12. Publications and External Communications[xx]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

13. Conflict of Interest Policy for IMEDS-Managed Initiatives[xxi]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

14. Policy Governing Ownership of Infrastructure[xxii]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

15. Selection and Award of Grants or Contracts Funded by RUF Under IMEDS[xxiii]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

16. Antitrust Policy and Guidelines[xxiv]

NOTE: RUF is working with Legal to finalize this section and these policies will be posted to the RUF website.

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[i] More information on the Sentinel Initiative can be found at http://www.fda.gov/safety/FDAsSentinelInitiative/ucm2007250.htm
[ii] http://omop.fnih.org/Research
[iii] http://omop.fnih.org/Research
[iv] Some content in this section was modified based on existing content within the Mini-Sentinel Principles & Policies document (2012)
[v] Some content in this section was modified based on existing content within the OMOP Charter (2009)
[vi] Some content in this section was modified based on existing content within OMOP Charter (2009).
[vii] Some content in this section was modified based on existing content within OMOP Charter (2009).
[viii] The responsibilities in this section were modified from existing content in the OMOP Charter (2009)
[ix] Some content in this section was modified based on existing content in the OMOP Charter (2009).
[x] Some content in this section was modified based on existing content in the OMOP Charter (2009).
[xi] Some content in this section was modified based on existing content in the OMOP Charter (2009).
[xii] Unless noted otherwise, this section was modified from existing content in the Mini-Sentinel Principles & Policies (2012).
[xiii] Some content in this section was modified based on existing content in the Mini-Sentinel Principles & Policies (2012).
[xiv] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xv] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xvi] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xvii] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xviii] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xix] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xx] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xxi] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xxii] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xxiii] Some content in this section was modified based on existing content within the OMOP Charter (2009).
[xxiv] Some content in this section was modified based on existing content within the OMOP Charter (2009).