

IMEDS Principles and Policies on Publications and External Communications

This Policy addresses three forms of Publications and External Communications, each defined below, relating to the Innovation in Medical Evidence Development and Surveillance (“IMEDS”) program, administered by the Reagan Udall Foundation for the Food and Drug Administration (“RUF”):

- 1) “IMEDS Official Results Communications.” These communications include, but are not limited to, detailed descriptions of the initiative and protocols, a common data model, data sets, formal reports describing the results of research performed, and recommendations for deployment of future systems or methods and tools for using observational data to study drug safety and benefit outcomes.
- 2) “IMEDS Sponsored Research Communications”. These are communications resulting from scientific research either funded by RUF as part of IMEDS (“Funded Research Communications”) or that result from research that is not funded by RUF, but that uses data specifically provided by RUF under IMEDS under a data use agreement (i.e., data that is not already in the public domain) (“Unfunded Research Communications”). They describe methods, tools, and approaches for conducting studies of drug safety and benefit outcomes. They are typically published in peer-reviewed scientific or technical publications or presented at scientific conferences.
- 3) Other external public communications regarding IMEDS, including but not limited to press conferences, press releases, other comments or statements to the press referring to or describing IMEDS, communications via social media, or other documents, presentations, and communications describing IMEDS (collectively, “IMEDS Publicity”).

All external communications will be undertaken consistent with IMEDS Policies, which may include Policies covering Confidentiality, Antitrust, Intellectual Property and/or Conflicts of Interest. In addition, the conduct of each of these three different types of communications will be governed by specific additional policies and procedures, as follows:

IMEDS Official Results Communications

- At the earliest possible time, RUF will describe publicly, via press release or notice on its website, its planned IMEDS Official Results Communications, their content, and an approximate timeline for their public release.
- The IMEDS Official Results Communications will be reviewed by the IMEDS Steering Committee, and consult with the IMEDS Scientific Advisory Board as needed for further scientific review or clarification. The IMEDS Steering Committee will then provide final review and approval before IMEDS Results are published or otherwise disseminated.

- All IMEDS Official Results Communications will be available to the public once analyses are complete and appropriate content and format are finalized via review by the IMEDS Steering Committee.
- No IMEDS Official Results Communications may be made public without the express permission of the IMEDS Steering Committee, unless the results contain findings that the FDA determines should be released under its regulatory authority in order to protect the public health. In such cases FDA may make public or otherwise release such findings without review or permission of the IMEDS Steering Committee.

IMEDS Sponsored Research Communications

- The RUF requires all Funded Research Communications to be communicated promptly in an appropriate scientific forum. The IMEDS Steering Committee may require that such Funded Research Communications be released or submitted for publication within six months after the completion of research. If six months have elapsed after the conclusion of any experiment and its results have still not been released, the IMEDS Steering Committee may release such results at its discretion.
- RUF also strongly encourages, but does not require, equally prompt communication of Unfunded Research Communications.
- For Funded and Unfunded Research Communications (collectively, “Communications”), the authors of the manuscript resulting from the research must submit the manuscript to IMEDS at least (30) days prior to journal submission, to allow the Scientific Advisory Committee (“SAC”) to review the manuscript. Within two weeks of the submission, the SAC Chair or IMEDS Scientific Officer (“IMEDS Representative”) shall notify the authors of any substantive points regarding the manuscript that have been identified by the SAC, and the authors shall work with the IMEDS Representative to resolve these points prior to journal submission.
- In the notification, the IMEDS Representative shall also identify any Confidential Information (as defined in the IMEDS Confidentiality Policy) in the Communication and may request that such Confidential Information be deleted from the research submitted for publication, upon which request such information shall be deleted from the Communication. Refusal to delete such Confidential Information shall be a basis for IMEDS to block publication of the manuscript through any means permitted by law.
- In the case of Funded Research Communications, IMEDS retains the right to deny publication of the manuscript if there are unresolved substantive disputes between IMEDS and the authors relating to the manuscript, but will not unreasonably exercise this right.
- In the case of Unfunded Research Communications, the authors retain the right to publish the manuscript regardless of unresolved substantive issues related to the publication, but will exercise reasonable efforts to resolve such disputes prior to publication.

- Once published, a reprint or copy of the manuscript or abstract should be sent to the IMEDS Chief Implementation Officer or other contact to whom he/she delegates authority.
- For conferences, the lead author or authors of IMEDS Sponsored Research Communications must notify the IMEDS Chief Implementation Officer and Scientific Officer when the abstract is submitted to a conference. All conference presentations will be publically posted after the conference on the IMEDS website.
- All IMEDS Sponsored Research Communications will appropriately reference IMEDS and describe the use of any IMEDS resources (data, methods, personnel) in the creation of manuscripts. However, in recognition of the fact that the RUF does not exercise editorial control over scientific communications, all IMEDS Sponsored Research Communications will also include a disclaimer stating that the communication represents only the opinions of the author(s) and not necessarily those of RUF.

Publicity

- All Publicity must be reviewed and approved by the IMEDS Chief Implementation Officer.
- Aside from the Chairperson of the IMEDS Steering Committee and the Executive Director, no Contributing Member, Participant, Supplier, Committee member or paid/volunteer employee will be authorized to:
 - Speak publicly regarding the IMEDS findings or activities; or
 - Speak on behalf of IMEDS without the prior approval of the Executive Director or Chairperson of the IMEDS Steering Committee.
- However, FDA may issue external public communications without review and approval by the RUF Executive Director or the Chairperson of the IMEDS Steering Committee if FDA determines such action should be taken in order to protect the public health.