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## **6 NETWORK MEETINGS AND COMMUNICATION**

Communication and information dissemination are critical to the successful management of a large, international, multicenter network such as the [International Maternal Pediatric Adolescent AIDS Clinical Trial Network \(IMPAACT\)](#). IMPAACT uses a variety of approaches to enhance communication within the Network about study-specific and network-wide research initiatives. The Operations Center supports and coordinates much of the communications within the IMPAACT through conference calls, in-person meetings, electronic and written materials, and announcements and postings through IMPAACT’s website. The website serves as a main driver of general and public communication, where study-specific information and postings about Network-wide activities can be found.

### **6.1 Meetings**

#### **6.1.1 Annual Network Meeting**

In collaboration with the IMPAACT leadership, the Operations Center organizes an annual Network meeting to bring together IMPAACT members and collaborators to discuss study designs and research goals, review data from ongoing trials, examine cross-cutting issues, and provide an overview of the IMPAACT scientific agenda. In addition, the meeting provides opportunities for training, identifying key issues, defining and discussing Network procedures, and clarifying roles and responsibilities of IMPAACT members. The meeting generally includes plenary sessions to update IMPAACT members on the latest scientific research related to the Network’s mission and agenda. The Network Scientific Leadership Group (SLG), Management Oversight Group (MOG), Scientific Committees (SCs), IMPAACT Community Advisory Board (ICAB), and protocol teams schedule meetings in conjunction with this yearly event.

The Operations Center is responsible for the overall logistics of the meeting; preparation of agendas and background materials; and subsequently, dissemination of any required materials for the SLG, MOG, SCs, protocol teams, and protocol-specific sessions in collaboration with the chair of the respective committee, team, or group. Additionally, the annual Network meeting may provide NIH training opportunities.

## **6.1.2 Leadership Retreats**

As described in Section 2, Network leadership groups (SLG, MOG, and SCs) may convene in-person meetings, which are generally held annually. The purpose of these meetings is to discuss the priorities and direction of the IMPAACT Network. The Operations Center is responsible for the overall logistics of the retreat including preparation of agendas and background materials.

## **6.1.3 Protocol Team Meetings**

In addition to routine conference calls, protocol teams may meet in-person during protocol development to facilitate the process, with the appropriate timing to be discussed and agreed upon by the team, as described in Section 9. The Clinical Trials Specialist (CTS) assigned to the protocol with assistance from other Operations Center staff will be responsible for the overall logistics of the meetings and conference calls including polling for call times and distribution of agendas, background materials and meeting summaries.

## **6.2 Communications**

### **6.2.1 Conference Calls**

Conference calls are used extensively to facilitate the Network's research activities. For each call, toll-free numbers are provided to all US participants and, when available, to non-US participants. Where a toll-free number is not available the Operations Center will make every effort to dial out to international participants.

Routine schedules of calls have been established for various IMPAACT groups and committees. As needed, Operations Center staff query IMPAACT members involved in protocol or committee work to schedule conference calls or meetings. Prompt response to these scheduling requests is required for efficient set-up of conference calls.

The Operations Center provides a broad range of administrative support for conference calls; preparation and/or distribution of call agendas and pre-meeting materials; sending email meeting reminder notices; and preparation, distribution, and archiving of conference call summaries. As part of their support of these groups, Operations Center staff generally document and distribute summaries of SLG, MOG, SC, protocol team, and other Network conference calls.

In addition, webinar support may be provided to allow for interactive slide presentations and other media rich methods for sharing of information and data.

### **6.2.2 Material Distribution**

Staff of the IMPAACT central resources (Leadership and Operations Center, Statistical and Data Management Center, and Laboratory Center) disseminate IMPAACT information and study materials using a variety of techniques including email, website postings, mail, and express mail services. To ensure information transfer, each Network organization must:

- Have the capacity to send, access, and receive materials distributed using the above techniques
- Ensure that IMPAACT communications and materials are distributed to all appropriate staff members
- Maintain all key study and IMPAACT communications in a well-organized filing system

Key IMPAACT information is posted on the public [IMPAACT website](#) for access by all Network members. Information from central resources and from National Institutes of Health (NIH) is included and maintained regularly to ensure timeliness of material availability and dissemination. Other websites with information relevant to the Network include:

- DAIDS Regulatory Support Center (RSC): <http://rsc.tech-res.com/>
- Office of Human Research Protections (OHRP): <https://www.hhs.gov/ohrp/>
- US Food and Drug Administration (FDA): <http://www.fda.gov/>
- National Institutes of Health (NIH): <https://www.nih.gov/>
  - National Institute of Allergy and Infectious Diseases (NIAID): <https://www.niaid.nih.gov/>
  - Eunice Kennedy Shriver National Institute of Child Health and Human Development: <https://www.nichd.nih.gov/>
  - National Institute of Mental Health (NIMH): <https://www.nimh.nih.gov/>
- Office of Clinical Site Oversight (OCSO): <https://www.niaid.nih.gov/about/division-aids-overview>
- US Centers for Disease Control and Prevention (CDC): <https://www.cdc.gov>

### 6.2.3 Network Website

The IMPAACT website (<http://impaactnetwork.org>) provides a wide range of materials.

The general philosophy governing the design, maintenance, and content of the website is to provide a site that (1) contains useful and up-to-date information on the Network organization and studies; and (2) accommodates various internet connections and software and hardware limitations across this multinational Network.

Documents available on the IMPAACT website are to be in PDF unless otherwise noted. All documents open in new windows, thus providing browsers with easy access back to the main website. Information on the IMPAACT website is updated continuously. This may include posting IMPAACT protocols, letters of amendments, full protocol amendments, and study-specific procedure manuals. Study-specific pages are developed to suit the needs of each particular study. An updated list of site names and numbers and a list of protocols (numbers and titles) that includes participating sites and status of each study is also posted. The website also features a searchable IMPAACT publications database.

The design and maintenance of the IMPAACT website is the responsibility of the Operations Center. Questions and comments on the website may be sent to: [IMPAACT.webcontact@fstrf.org](mailto:IMPAACT.webcontact@fstrf.org).

## 6.3 Release of Information to the Public

### 6.3.1 Public Information Policy

Investigators and site staff may have access to proprietary and sensitive information as a result of their participation in IMPAACT protocols. The following guidelines relate to disclosure of product and study-related information to the public. These guidelines are in keeping with the policies and procedures of the DAIDS Office of Program Operations and Scientific Information, the NIAID Office of Communications and Government Relations (OCGR), and the NIAID News and Public Information Branch (NPIB).

Inquiries from the press, community representatives, and public officials concerning general study status may be addressed by the study investigators to whom questions are addressed; however, investigators may not independently provide public comments related to study outcomes or adverse events. Such activities are to be coordinated between the protocol team and the sponsor.

Press inquiries more specifically or generally about IMPAACT activities should be referred to the Network leadership and DAIDS.

Proprietary information about study products in development or used in a trial conducted under an Investigational New Drug (IND) application may not be discussed publicly by anyone without written permission of the product's manufacturer.

### **6.3.2 Disclosure of Study Results**

In general, results from multi-site studies are not released until completion of the study at all participating sites. Any exceptions to this policy require explicit approval of the Network chair, SDMC PI, Operations Center Director as well as the protocol chair and SLG.

The release of study results provides an opportunity to share findings that could influence the standard of care in the communities where IMPAACT studies are conducted or the design and/or conduct of ongoing or future trials. As outlined in Sections 14 and 19, the protocol team should create a study results communications plan well before the end of the study. The plan should identify key members of the communication team (i.e., protocol chair, protocol statistician, designated spokespeople, etc.) and their roles, specify the timeline and activities planned for release of the study results within the team and externally, and identify the key stakeholders (protocol team members/site staff, sponsors, community advisory boards, host country officials, collaborating institutions, other US government and non-US public health agencies, and investigators/sponsors of other studies that may be impacted by the study results) to be informed of the results. Disclosure of study results, particularly of Phase IIb/III trials, by the protocol statisticians to study investigators, other protocol team members, IMPAACT leadership, and sponsors should be part of the study communications plan.

Results are released to host country officials, study participants, community representatives, sponsoring industry collaborators, relevant non-governmental organizations, and other governments in an accurate, well-controlled and timely manner. Ideally this will happen before, or at the same time, as the results are released to the general public.

Particular care is to be taken to coordinate release of results with officials in host countries and in the communities where the study was conducted.

See the IMPAACT Publications Requirements and Procedures, Section 19, for additional details related to disclosure of study results.

### **6.3.3 Press Releases and Public Announcements**

All Network-related press releases and public statements will be developed or approved by NIAID, NICHD, and NIMH and, as appropriate, by its co-sponsors. When such materials are developed by the sponsor(s), the DAIDS Medical Officer and IMPAACT Operations Center will coordinate review by Network and/or study leaders as needed. When these materials are developed within the Network, the DAIDS Medical Officer and IMPAACT Operations Center will ensure that they are reviewed and approved by required groups. Before any materials undergo NIH review, the IMPAACT Operations Center ensures they have been reviewed and/or approved by relevant parties within the Network. Study-related press releases and materials must be approved by the protocol chair and the IMPAACT Network chair.

To ensure accuracy of information and proper identification of IMPAACT, NIH, and other funding sources, all press releases generated by the Network must be reviewed by the IMPAACT Operations Center, which will coordinate additional review by the appropriate funding institutes, as necessary. Investigators should allow sufficient time for this process.

When study results are to be published or presented at a scientific meeting, the IMPAACT Operations Center in collaboration with NIH and other relevant sponsors may coordinate press announcements with the authors and the publishing journal or scientific meeting organizer to comply with all required embargo guidelines. For studies conducted under a Clinical Trials Agreement (CTA) with a product manufacturer, the publication guidelines and procedures described in the CTA also must be followed. In cases of specific points of discordance between CTA requirements and this policy, the CTA requirements shall be followed.

All press releases, statements, and public announcements must properly acknowledge that the activities of the IMPAACT Network are performed cooperatively with NIAID, NICHD, and NIMH.

The IMPAACT Operations Center ensures that NIAID, NICHD, and NIMH program leadership and their respective communications offices are notified in advance of all IMPAACT news releases and statements before they are publicly disseminated.