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16 TRAINING FOR SITE KEY PERSONNEL AND OTHER SITE AND LABORATORY STAFF

The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network is committed to developing qualified, trained staff to conduct IMPAACT studies. For each IMPAACT study, the site Investigator of Record (IoR) is responsible for ensuring that study-specific site staff are appropriately qualified and trained to carry out their delegated duties, and that all training is adequately documented. Clinical Trial Unit (CTU) leaders, Principal Investigators, and Clinical Research Site (CRS) leaders are responsible for ensuring that IoRs fulfill this responsibility. All sites must establish and follow standard operating procedures (SOPs) for personnel training and certification documentation; IoRs must maintain adequate training documentation, and make training documentation available to National Institute of Allergy and Infectious Diseases (NIAID) or National Institute of Child Health and Human Development (NICHD) Program Officers, site monitors, inspectors, and/or auditors acting on behalf of study sponsors, regulatory authorities, site institutional review boards/ethics committees (IRBs/ECs), and other applicable review bodies. Additional Division of AIDS (DAIDS) guidance can be found in the Site Clinical Operations and Research Essentials (SCORE) Manual, which is available at <https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations>.

Further training requirements related to Human Subjects Protection (HSP) and Good Clinical Practice (GCP) are presented in Section 16.1; related to laboratory specifications are presented in Section 16.2; related to data management specifications are presented in Section 16.3; and related to research ethics training for community representatives are presented in Section 16.4.

IMPAACT requires study-specific site training prior to study initiation (Section 16.5).

IMPAACT sites are also expected to provide training for new staff and continuing training for current staff. Sites are required to maintain up-to-date and accurate training records of all required Network and study-required trainings.

An overview of mandated training is found in Table 16-1 with further details in the following sections. When the term “key personnel” is referenced throughout the remainder of this section, it generally includes individuals named on the [Form FDA 1572](#) and/or DAIDS [Investigator of Record \(IoR\) Form](#); any CRS personnel who have more than minimal involvement with the conduct of research (e.g., performing study evaluations or procedures, or providing intervention); those who have more than

minimal study conduct-related contact with study participants, confidential study data records, or specimens; and any CRS personnel who are otherwise listed on the Delegation of Duties Log.

Table 16-1. IMPAACT Training Requirements

Training	Required Personnel	Timing/Frequency	Sources for Training
International Air Transportation Association (IATA) training	All staff who transport, ship, or receive infectious substances and diagnostic specimens	Prior to handling infectious substances and specimens as part of an IMPAACT study (certification of staff members required for study activation at the site); regulations reviewed annually and recertification required every two years thereafter	<ul style="list-style-type: none"> Resources listed in Section 16.2.2
Laboratory Data Management System (LDMS) training	IMPAACT laboratory staff	At time of installation of LDMS and then as needed	<ul style="list-style-type: none"> Frontier Science Foundation training at Network meetings and regional meetings, on-site, online, or at Frontier Science Resources can be found on the LDMS website at: https://www.ldms.org/training/
Good Clinical Laboratory Practice (GCLP)	Laboratory Director, Laboratory Manager/ Supervisor and/or quality assurance/quality control (QA/QC) technologists	Prior to involvement in an IMPAACT study and then as needed	<ul style="list-style-type: none"> GCLP courses provided by the DAIDS contractor (at annual and/or regional meetings) or online Courses available from private training companies <p>Note: these may not cover the appropriate DAIDS-related regulations</p>
Study-specific training	Site staff involved in the study, as delegated by the IoR	Prior to initiation of study (for new staff, prior to start dates on delegation of duties logs and performing study-specific tasks/duties without direct supervision) and then as needed	<ul style="list-style-type: none"> Clinical research managers (CRMs), data managers, Laboratory Center (LC) representative, and other protocol team members, as applicable and as described in Section 16.5 IoR or designee for new staff

Table 16-1. IMPAACT Training Requirements

Training	Required Personnel	Timing/Frequency	Sources for Training
Data Management Center (DMC) Training	Site staff involved in the study, as delegated by the IoR	Prior to site activation and then as needed	<ul style="list-style-type: none"> • Frontier Science Portal Training: Complete new user training via Online Portal Training link • DMC Introductory Training and eLearnings: Complete self-guided courses for independent learning via DMC Virtual Learning Room • Medidata Rave: Required eLearning courses appear on iMedidata dashboard in the upper right-hand corner. Users must complete and pass these courses for further access to Medidata Rave. • Study Enrollment: Complete Study Enrollment System (SES)/Stars system new user training • Contact dmc.training@frontierscience.org for additional training options

16.1 Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training

HSP and GCP training of all IMPAACT site staff is encouraged. Requirements, sources, and options for HSP and GCP training are described in full in Section 8.

16.2 Laboratory-Related Training

To ensure quality research and to safeguard study participants, DAIDS requires that all IMPAACT studies be conducted in accordance with GCLP. The LC also requires that key laboratory personnel receive GCLP training prior to involvement in an IMPAACT study. Training of all IMPAACT key laboratory staff is facilitated through the provision of regional GCLP training as well as through an online training program. Refer to Section 17 for further details on IMPAACT Network Laboratory requirements.

All IMPAACT studies rely heavily on the capacity of IMPAACT laboratories to handle, process, and ship participant specimens. The work of qualified and trained laboratory staff at the research sites is essential. The IMPAACT Network requires the training described in the remainder of this section for laboratory personnel.

16.2.1 Laboratory Data Management System (LDMS)

The LDMS is the laboratory software provided to each of the sites/laboratories to assist with specimen management, labeling, storage, and shipping. LDMS training is provided by Frontier Science when the site/laboratory is provided access. If travel is required for training, this is a site/laboratory expense.

Opportunities for refresher training are provided as needed. At the request of the IMPAACT Laboratory Center (ILC), Frontier Science may provide refresher training on the LDMS at annual meetings, regional meetings, protocol-specific trainings, or through web-based trainings. The ILC staff members are typically available at protocol-specific training sessions to provide laboratory information related to IMPAACT, and to answer questions from site representatives. Site representatives are expected to share the information learned from training with other site staff.

In addition, there are numerous LDMS training resources available on the LDMS website (www.ldms.org), including training tutorial videos, workbooks, exercises, and quizzes.

As part of study monitoring and oversight, the protocol team and Network leadership routinely review specimen testing, availability, and data quality and completeness; if any issues or concerns are identified during these reviews, additional training or other corrective actions may be required (see Section 13).

Sites, at their expense, if applicable, may also request additional training if needed; for example, when new laboratory personnel are hired.

16.2.2 International Air Transport Association (IATA)

IATA regulates the safe transportation of dangerous goods by air in accordance with the legal requirements of the International Civil Aviation Organization (see Section 17 for further details). IMPAACT, in accordance with IATA requirements, requires training and certification for all IMPAACT laboratory staff involved with the handling, transporting (by air and ground), receiving, and shipping of infectious substances and diagnostic samples. Certification of all site staff members who transport and/or ship dangerous goods is required prior to study activation at a site.

Site personnel should review the IATA regulations annually as well as complete required training in hazardous materials (HAZMAT) regulations as they pertain to IATA shipping regulations.

Each site is responsible for training pertinent staff members on IATA shipping regulations and is required to have a current IATA manual on site. Sites are required to provide documentation of IATA certification of personnel upon request by the LC or a DAIDS contractor. The site's Primary Network Laboratory (PNL) is responsible for ensuring that the laboratory has a current IATA Dangerous Goods Manual and appropriate training materials. See Section 17 for a complete listing of additional laboratory-specific training resources.

16.2.3 Biohazard and Containment Training

Clinical and laboratory personnel are expected to complete annual clinical safety training, including training on bloodborne pathogens and infection control. It is the responsibility of the site to provide this training to all clinical and laboratory staff using information and materials provided by their institutions as well as DAIDS contractors and cross-network training groups.

16.2.4 Other Requirements for Laboratory Personnel

Laboratory personnel are also expected to complete training as specified in this section; for key laboratory personnel, this includes HSP, GCP, GCLP, and study-specific training.

Sites are notified of relevant laboratory issues and developments which may affect multiple IMPAACT protocols or Network activities by the Operations Center, LC, and/or DMC. Such issues may also be discussed, with training opportunities, at the annual meeting or through other methods of communication.

16.3 Data Management Training

Site personnel are responsible for providing study data that are correct and of high quality to the DMC. Knowledge of data management systems, quality assurance tools, and reports is necessary to meet this requirement. Data management training is offered to site personnel through routine trainings at the DMC, at regional trainings, trainings offered at the Network annual meeting, web-based trainings, and study-specific trainings. Training resources, including historical presentations and recorded trainings, may be found on the training pages of the DMC portal website at: <http://www.frontierscience.org>.

16.4 Research Ethics Training for Community Representatives

The [Community Involvement in Research Training](#) is designed to train community representatives about the general principles of research ethics. It also reviews the purpose of IRBs, research history, informed consent, and other concepts. Community education staff, community advisors, and partners are encouraged to complete this training.

Additional details related to community participation and engagement in the IMPAACT Network is described in Section 5.

16.5 Study-Specific Training

Site IoRs are responsible for ensuring that study-specific site staff members are adequately trained to perform their delegated study-specific functions. In preparation for initiation of new IMPAACT studies, designated members of IMPAACT protocol teams — including but not limited to Operations Center, Statistical and Data Management Center (SDMC), and LC staff — collaborate with IoRs to fulfill this responsibility by conducting study-specific training. Self-study of study-specific documents and/or training materials alone is not typically considered adequate training for IMPAACT studies. However, study-specific training may be provided in various formats and for various durations depending on the training needs of the site and the study. The IMPAACT staff mentioned above work closely with the protocol chair(s) and site IoRs to determine the optimal format and length of each training.

Each site IoR is responsible for ensuring that all training is documented. Protocol team members may assist with this, for example, by providing copies of signature sheets from an in-person training or by providing participant logs from an online training. Presented training materials are also provided, typically by posting on the study-specific web page; if any materials are not suitable for public posting, copies are provided directly to site representatives via email or other delivery methods. When key site staff are not available to attend study-specific training for any reason, or if a staff member joins the study team after the study-specific training has already taken place, the site IoR is responsible for ensuring adequate and appropriate training of these staff, prior to their initiation of study activities. Documentation of all study-specific site staff training must be maintained in each site's Essential Records.

Blinded studies should include review of the Network Manual of Procedures (MOP) Appendix I, Unblinding Procedures, as part of study-specific training.

16.5.1 Development of Study-Specific Training Plan

For each IMPAACT study, the protocol team agrees on a study-specific training plan that is tailored to the needs of the study and participating study sites. Discussion of training plans is generally initiated within the protocol team around the time of protocol finalization and plans are further developed as sites work to complete site-specific study activation requirements, as described further in Section 11. Input on training plans is also obtained from site representatives to ensure that all perceived training needs are considered.

Once a study-specific training plan is finalized, the operational approach is communicated to the study sites, and training timelines and materials are developed. The Operations Center coordinates with the protocol chair, SDMC, and LC to lead these training efforts, with input from protocol pharmacists and medical officers, as needed. For studies involving specialized procedures and/or interventions, relevant content area experts are also consulted; these may be members of the protocol team or external to the team. Site input may be obtained in a variety of ways, including conference calls, email communications, and online surveys.

The objectives of study-specific training are to:

- Establish a common understanding of key aspects of the study, including the background and rationale, objectives and outcomes, design, intervention, and schedule of evaluations
- Ensure that study-specific site staff are informed and familiar with:
 - Day-to-day study implementation requirements, in accordance with the protocol, study-specific MOP, LPC, electronic case report forms (eCRF) completion guide, other relevant study implementation materials, and relevant regulations, guidelines, policies and procedures
 - Study-specific communication procedures and operational resources and utilities available to support day-to-day study implementation
- Ensure standardization of study implementation across sites so that data can be combined for analysis

Study-specific training plans may include, but are not limited to, the following:

- Self-study of training materials developed by the protocol team
- Remote participation in live or recorded conference call and/or webinar training sessions
- In-person participation in centralized, regional, or site-specific training sessions
 - When centralized or regional in-person trainings are planned, a train-the-trainer approach is typically taken, with study-specific site staff who attend the trainings being responsible for training other study-specific site staff members at their site.
 - When site-specific in-person trainings are planned, it is expected that most, if not all, key site staff attend the training.

Study-specific training plans should also:

- Identify members of the study-specific training team (i.e., protocol team members and others involved in providing training).
- Specify the extent to which translation into languages other than English may be required and indicate whether translation may need to be arranged centrally or performed locally at one or more study sites.
- Specify minimum requirements for sites to be considered adequately trained as a condition for site-specific study activation (generally, the IoR and Study Coordinator). Although it is generally expected that the same training is provided for all sites, when necessary, different approaches and requirements may be specified for different sites (e.g., less experienced sites may require additional training).

Initial draft training agendas are prepared as part of study-specific training plans. These include, at minimum, a listing of training topics to be covered and a designation of persons responsible for each topic; other details may be specified later, as agendas are further developed and finalized. Key considerations for training agendas include the following:

- Consider the audience, which site personnel are required, what they need to know, and what is the most effective method to present the material.
- Address community-related needs as well as scientific and operational training needs.
- Involve site staff and training team members when presenting/leading training topics.
- Allow adequate time for each topic, including time for questions and answers and discussion.
- Consider the overall training time as well as the amount of time scheduled for each topic (shorter sessions with breaks in between are usually advantageous for learning).
- Include interactive sessions when possible and applicable.
- Incorporate time for cross-site interaction and problem-solving when possible.

If a study design is straightforward and the participating sites have experience with similar studies, the training plan may specify web-based training. In contrast, if the study design is unique or complex, or if sites are less experienced, an in-person training may be required. In-person training may also be required when training on specialized study procedures is needed. A combined approach can also be taken. For example, a web-based training could be planned for experienced sites while in-person training would be offered to less experienced sites or for a targeted study-related purpose, such as reviewing specialized laboratory procedures. Cost-efficiency and training effectiveness are also key considerations when determining the best approach.

When in-person trainings are planned, options include regional trainings for study-specific site staff from multiple sites as well as individual on-site trainings. Study-specific trainings may include sessions for community educators and CAB members focused on topics such as community education and outreach, participant recruitment and retention, human subjects and participant safety protections, community perceptions, and potential misconceptions of the study.

16.5.2 Scheduling Study-Specific Site Training

The responsibility for scheduling study-specific training is shared among designated members of protocol teams in conjunction with site representatives.

Training is conducted as closely as possible to the time when one or more CRSs have met all other site-specific study activation requirements, such that activation and initiation of the study occur upon (or very soon after) completion of training. Generally, a study is open to accrual, or the majority of requirements needed to open a study to accrual have been met prior to training. In addition, one or more sites should have completed the DAIDS protocol registration process for the study and, if applicable, should have received supplies of the investigational study drug or product on-site. All other activation requirements should also be completed or nearly completed. For example, required site SOPs may be fully drafted prior to training with the expectation of finalization immediately following training (to incorporate information provided during the training). See Figure 16-1 for required and recommended study- and site-specific elements to be completed prior to training. Introductory overview sessions may be conducted prior to this timepoint, as webinars or at pre-convened meetings, such as the Network annual meeting.

If site activation is delayed following training, site IoRs are responsible for conducting retraining (see Section 16.5.5).

Figure 16-1. Guidelines for Scheduling IMPAACT Study-Specific Training

To be completed prior to scheduling study-specific training (as applicable to the study; see Section 11 for details related to study-specific pre-implementation activities):
<ul style="list-style-type: none">• Completion of US Food and Drug Administration (FDA) 30-day review period/safe to proceed notice• Signed Clinical Trials Agreement(s) (CTA)• Study product(s) available at the DAIDS Clinical Research Product Management Center (CRPMC)• Finalization of the study-specific MOP for use as a reference during training (Note: a draft version may be used for training purposes)• At least one site close to meeting all activation requirements, such that activation and initiation of the study occur upon (or very soon after) completion of training
Note: sites that have made significant progress towards meeting study-specific site activation requirements, as outlined in Section 11, are prioritized when scheduling study-specific training. However, other sites may be invited to participate in training sessions, as determined in the training plan.

16.5.3 Site Preparation for Training

In addition to completion of requirements for scheduling study training, study-specific site staff carry out other activities to prepare staff for study training and, ultimately, the conduct of the study. Under the supervision of the IoR, the following items are generally completed by sites as they prepare for study implementation:

- Hire staff (if needed)
- Designate study-specific site staff team and assess local training needs
- Provide orientation and background training locally, as needed, including:
 - Local staffing and organizational plan (including roles and responsibilities)
 - Local site operations
 - Local role-specific training and certification
 - Other local requirements
- Complete “mock visits” using study implementation materials, ideally in clinic and laboratory facilities that will be used for the study
- Discuss and develop SOPs (as needed) and other local study implementation materials
- Review and become thoroughly familiar with the study protocol, informed consent documents, CRFs, training materials, other study implementation materials, and site SOPs
- Review and become familiar with the study-specific specimen management plan and the “chain of custody” for study samples
- Identify questions, issues, and problems requiring training team input

Depending on the training plan, expectations of study-specific site staff prior to study-specific training may include:

- Work with training team to plan training and finalize agenda
- Work with training team to identify and meet translation and interpretation needs
- Arrange staff backup for staff attending the training sessions
- Arrange access to training rooms and any required equipment

16.5.4 Implementation of Study-Specific Training

Training team members are responsible for developing training agendas, developing training materials, and conducting training sessions. Topics to be covered for all IMPAACT studies are listed in Figure 16-2. Ideally, all site staff members who have been delegated duties or responsibilities for a study will take part in study-specific training; however, a train-the-trainer approach may also be considered for centralized or regional trainings, which all site staff may not be able to attend. The training plan should clearly identify required attendees.

During training sessions, study-specific site staff are expected to:

- Present training topics (if specified in the training agenda)
- Present site-specific operational plans and/or SOPs (if specified in the training agenda)
- Attend all required training sessions (by study-specific role if applicable) per the study training plan
- Fully engage in the training (ask questions; identify issues requiring additional clarification; describe site-specific study implementation plans, materials, and tools; etc.)

Failure of study-specific site staff to attend required training sessions typically delays site-specific study activation, as additional training is required before study activation can occur. Therefore, every effort should be made to avoid absences from required sessions.

Figure 16-2. Minimum Topics to be Covered for IMPAACT Study-Specific Trainings

- Study Overview including Rationale and Objectives
- Study-Related Communications
- Informed Consent Considerations
- Eligibility Criteria
- Screening and Enrollment Process
- Study Procedures (covering protocol Section 6 and the Schedules of Evaluation)
- Pharmacy and Study Drug Considerations
- Data Management Considerations
- Laboratory Considerations
- Toxicity/Participant Management
- Adverse Event and Expedited Adverse Event Reporting
- If needed, Network structure and procedures overview (including protocol deviation reporting)
- Other study- or site-specific topics may be added

16.5.5 Continuing Study-Specific Training

Site IoRs are responsible for ensuring that new study-specific site staff members are adequately trained to serve their delegated study-specific functions. Study-specific training teams typically do not provide training for newly hired site staff following the initial study training. However, team members make every effort to be available to answer questions and provide technical assistance to new key personnel, as needed. Conference call discussions and/or targeted webinar trainings can be provided, if requested by the site.

Once a study is underway, designated protocol team members — typically the Operations Center, DMC, and LC staff — issue study-related communications, answers to frequently asked questions, and other similar documents to guide study implementation at each site (see Section 12). IoRs are responsible for ensuring that sites have SOPs in place for receipt and filing of these communications, and for ensuring

that all relevant study-specific site staff are informed of and trained on these materials, and incorporating the content into day-to-day study operations.

When necessary, designated protocol team members provide study-specific “refresher” training to site staff. This may be done via conference call or webinar, at in-person meetings (e.g., IMPAACT annual meeting) or during site visits. Recordings of prior training sessions may also be options for continuing training at sites.

16.6 Documenting Training

Site IoRs are responsible for ensuring that study-specific site staff are appropriately qualified and trained to carry out their delegated duties and that all training is adequately documented. Per the DAIDS SCORE Manual, all sites must establish and follow SOPs for personnel training and certification documentation. Site SOPs may specify the use of training logs, training certificates, meeting summaries with participant lists, and/or other documents as applicable. All training documentation must be maintained in on-site Essential Records.

The DAIDS SCORE Manual includes training log templates that are trainee-specific and topic-specific. Sites may use the template logs provided in the DAIDS SCORE Manual, or use their own institutional templates, but should ensure that the minimum information as described in the SCORE Manual is present.

For study-specific trainings, as described in Section 16.5, the CRMs may help document completed training; for example, by providing the sign-in log from an in-person training and by providing training materials as posted files on the study-specific web page or via email to site representatives. The lists of participants in webinar trainings are not comprehensive; as such, virtual attendees must document their attendance in on-site training files following site-specific SOPs for personnel training and documentation. See Figures 16-3 and 16-4 for examples of a training documentation message and of a training log documenting attendance for study-specific webinars.

Figure 16-3. Example of Training Memorandum from CRM Documenting a Study-Specific Webinar

TO: IMPAACT 2060 Sites
FROM: Sarah Adams, IMPAACT 2060 Clinical Research Managers
CC: IMPAACT 2060 Protocol Team
SUBJECT: Documentation of IMPAACT 2060 Cohort 2 Training

This memorandum serves to document the study-specific training webinar conducted for IMPAACT 2060, Phase I/II Study of Drug X in Children, on 18 January 2022 for approximately one and a half hours.

The training, entitled “IMPAACT 2060 Cohort 1 Overview,” was led by Emily Jones, Study Chair, and Sarah Adams, CRM. The training was intended primarily for Cohort 1 site staff; however, participation was not restricted, and other study-specific site staff were welcome to attend.

The objective of this training was to establish a common understanding of the following:

- Study design, rationale, and objectives
- Cohort 1 eligibility criteria and study-specific procedures for recruitment, screening, and enrollment
- Cohort 1 procedures and evaluations

The training also provided an opportunity to address questions and to share key information, operational tips, and reminders across sites.

The training materials presented as part of this webinar have been posted on the study-specific web page (<http://impaactnetwork.org/studies/IMPAACT2060>) and are available upon request from the IMPAACT Operations Center.

Study site Investigators of Record are responsible for ensuring that a copy of this message, the associated training materials, and site-specific attendance documentation are filed in on-site training files for IMPAACT 2060. As a reminder, per the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual, all sites must establish and follow a standard operation procedure (SOP) for personnel training and certification documentation. **Each site is responsible for preparing attendance documentation for this webinar in accordance with this SOP.**

Thank you for your participation in the webinar; please contact the protocol team with any questions.

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