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19 DATA ANALYSIS AND PUBLICATIONS PROCEDURES

19.1 Overview, Key Principles, and Definitions

Publications in peer-reviewed journals and presentations at scientific conferences represent the most significant products of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network’s research. The results of IMPAACT studies are to be published and shared in a timely manner in accordance with the [National Institutes of Health \(NIH\) Public Access Policy](#). This section describes the process and requirements for preparation and review of abstracts, manuscripts, and other documents through which study-related results are disseminated. These procedures are intended to ensure timely

development and dissemination of high-quality publications reporting the results of IMPAACT studies or otherwise using IMPAACT-related data.

All abstracts and manuscripts using IMPAACT data or reporting on IMPAACT studies must undergo an IMPAACT Network review before being submitted to a conference or journal (through submission to impaact.pubscoord@frontierscience.org, as described in detail below).

For each IMPAACT study, it is generally expected that the primary publication is submitted prior to secondary, exploratory, and ancillary study publications, unless otherwise specified in the study protocol or statistical analysis plan (SAP), or as agreed upon by the protocol team. For studies with multiple cohorts, groups, or other subsets, group-specific publications may be prepared prior to publication of any primary manuscripts. Publications reporting baseline findings, those reporting on the study design, or those presenting interim study results may also be prepared prior to the primary publication.

These procedures should be reflected in the terms of Clinical Trial Agreements (CTAs), Memoranda of Understanding (MOUs), or alternative agreements approved by the IMPAACT Manuscript Oversight Group (MOG), DAIDS or other study sponsor, for studies with co-sponsoring agencies, companies, or other clinical trials networks, and studies in which data are collected and analyzed by a network or group other than the IMPAACT Statistical and Data Management Center (SDMC).

All IMPAACT publications must meet the criteria for authorship, disclosure, scientific integrity, and other requirements of peer-reviewed scientific journals.

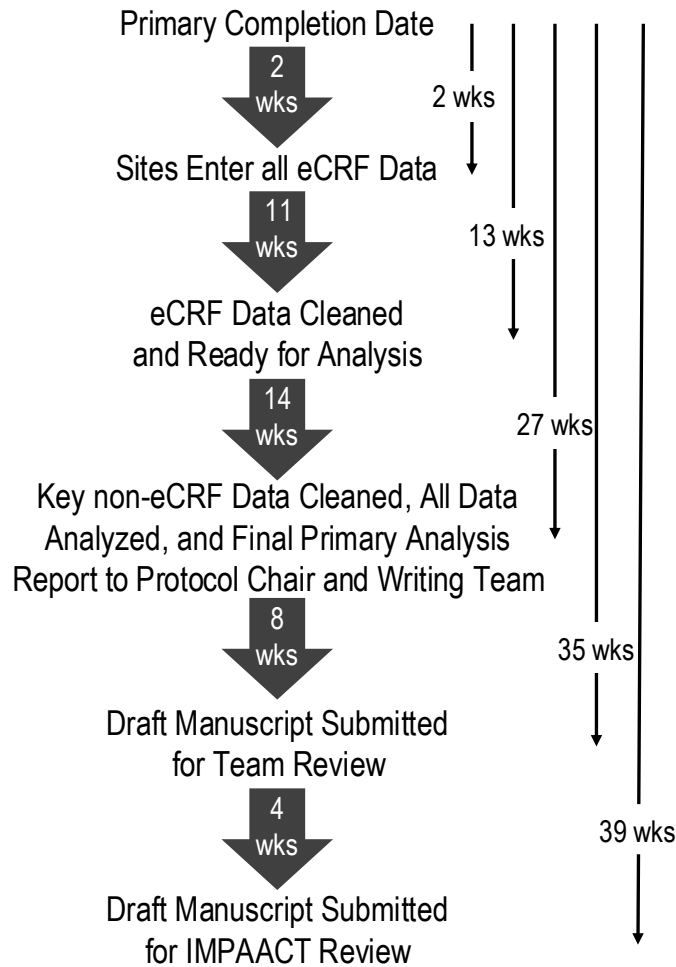
19.2 Key Groups and Responsibilities

19.2.1 Protocol Chair

The protocol chair assumes overall responsibility for ensuring publication of the study findings in a timely manner. The results of each study should be reported in at least one peer-reviewed publication addressing the primary objective(s) within the timeline outlined in Figure 19-1. The protocol chair may designate a writing team to draft manuscripts or abstracts; the lead author is then responsible for completion and submission for IMPAACT review within the timeline specified in Figure 19-1, with continued oversight by the protocol chair. The protocol chair ensures that analysis and publication of secondary, exploratory, or ancillary study results do not interfere with the analysis or publication of the primary study results and works closely with the Operations Center to track the manuscript development progress and to address any concerns that may arise.

For studies likely to generate multiple manuscripts, the protocol chair may elect to designate a subset of the protocol team to function as a study-specific publications committee to assist in performing the responsibilities described for the protocol chair. This committee may review and prioritize manuscript/abstract proposals from team members and others and, at minimum, includes the protocol chair, statistician, and CRM, with other protocol team members included as needed. It is critical for the protocol chair (or designated publications subset of the protocol team) to consult with the SDMC representatives on the planning and prioritization of the various publications for a study, ensuring that analyses for each can be completed as scheduled.

Figure 19-1. Timeline to Primary Manuscript



19.2.2 IMPAACT Publications Coordinator

Operations Center staff serve as the IMPAACT publications coordinator and facilitate and track development, submission, review, and outcomes of IMPAACT manuscripts and abstracts. When correspondence with the publications coordinator is required, it should be directed to impaact.pubscoord@frontierscience.org.

19.2.3 IMPAACT Publications Review Group

On behalf of the Network, the IMPAACT Publications Review Group is responsible for reviewing all manuscripts and abstracts reporting on Network studies and related investigations prior to submission to a conference or journal. The group's review ensures high quality publications, scientific rigor, and compliance with IMPAACT publications procedures, as outlined in this section. A Network chair serves as the chair of the IMPAACT Publications Review Group. Membership includes the IMPAACT Network chairs and vice chairs; the SDAC principal investigator (PI) or designee; the Laboratory Center (LC) PI or designee; Operations Center representatives; and representatives of the National Institute of Allergy and Infectious Diseases (NIAID), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), and National Institute of Mental Health (NIMH). The relevant scientific

committee (SC) chairs and clinical research managers (CRMs) are also included in distributions to the Publications Review Group.

19.3 Preparation, Review, and Completion of Analyses

19.3.1 Timeline Considerations

The timeline and process for preparation, review, and completion of primary analyses for publications are outlined in Table 19-2 and described in the remainder of this section. The timelines for secondary, exploratory, and ancillary study analyses may vary based on prioritization and data availability.

The primary analyses timeline is in relation to the primary completion date (PCD) and/or the closed to follow-up date. These dates may be the same or different depending on the study design, as outlined below:

- For studies in which the PCD and the closed to follow-up date are the same, data analyses for publications (and results entry into ClinicalTrials.gov; see Section 19.3.7, below) are typically completed after the closed to follow-up date to describe and report the final primary and secondary outcome measures.
- For studies in which the PCD precedes the closed to follow-up date, data analyses for publications (and results entry into ClinicalTrials.gov; see Section 19.3.7, below) are typically completed at two or more different times
 - First, related to data collected through the PCD
 - Subsequently, related to data collected through the final data collection date for each secondary outcome measure that requires longer follow-up

The protocol data manager (PDM) is responsible for notifying the protocol team of the anticipated and actual PCD and closed to follow-up date. Procedures for data entry and clean-up, resolution of data queries, and database lock, if applicable, for all data are initiated upon confirmation of the PCD and/or closed to follow-up date.

Timelines for studies with regulatory submissions may be adjusted, in consultation with the protocol team.

19.3.2 Updates to Statistical Analysis Plan(s)

For primary and secondary manuscripts, with input from the writing team, the statistical analysis plans (SAPs) and pharmacokinetic analysis plan are reviewed and, as needed, updated prior to the initiation of data analysis. Additional analyses may become important once the results become known; these may be completed and sent to the writing team for inclusion in the manuscript during the writing period. For manuscripts related to other and/or exploratory objectives, separate SAPs may be developed by the statistician in collaboration with the writing team(s).

The protocol statistician is responsible for updating the SAP, in close collaboration with the writing team. For pharmacokinetic (PK) studies, the protocol pharmacologist is responsible for updating the PK analysis plan.

19.3.3 Final Data Entry

Protocol teams determine appropriate timelines for completion of data entry, data cleaning, and data analysis, following the guidance provided in Figure 19-1 and adjusted for study-specific considerations (e.g., timelines may be extended for larger studies or may be modified to align with agreed-upon regulatory deadlines). The team must make sure their timelines include shipping, testing, and/or analysis after the PCD or closed to follow-up date. The PDM and laboratory data manager (LDM), in consultation with the protocol team, are responsible for communicating these study-specific timelines with sites and testing laboratories.

Refer to Section 14 for detailed instructions on site close-out communications and responsibilities.

19.3.4 Final Data Clean-Up

After all data have been entered by sites, the PDM continues to send out any additional queries to the sites to address delinquent or discrepant data.

In general, this data query period and subsequent completion of the database clean-up is expected to take approximately 14 weeks, although this time may be extended in some circumstances (e.g., studies with many sites, if data clean-up needs to be paused for preparation of a conference abstract or poster/presentation). Four weeks prior to the Study Database Closure/Database Complete Date, the PDM sends a notification to the sites that final Rave database lock will occur.

It is of the utmost importance that the protocol team agree that the study database is complete, that no more changes can be made to it, and that the final analysis will be based on the existing data in the database. The PDM informs the protocol team of the extent of any missing data throughout the conduct of the study. To confirm that Rave database freeze and lock can proceed as planned, the SDMC reviews data for completeness approximately two to four weeks prior to database freeze. If this review indicates that data necessary for any planned analyses are not being cleaned in a timely fashion, the SDMC sends a message to the site indicating that the site staff must rectify this situation.

19.3.5 Study Database Lock

Once review of data completeness and accuracy is conducted, study monitoring is complete, and the protocol team agrees, the protocol statistician indicates to the PDM that database freeze and lock should proceed as planned. After database lock has occurred, all routine completeness reports, queries, and discrepancy checks cease. The date of database lock is the Study Database Closure/Database Complete Date, upon which the database is considered complete to begin finalizing the analysis.

For studies in which the PCD precedes the closed to follow-up date, the database is not closed until all follow-up data are entered; however, data cleaning for the primary analysis is expected to follow a similar timeline as described in Section 19.3.4 and the study database snapshot date for the primary analysis is confirmed by the PDM.

Laboratory data not entered via eCRFs

Any non-eCRF laboratory data required for the final analysis report should be finalized by the Study Database Closure/Database Complete Date (e.g., virology outcome measures included as primary or secondary outcome measures). In some circumstances, due to the length of time required to conduct specialized assays, it might not be possible to complete last visit specimen testing, data entry, and

cleaning within the specified period after the study closes to follow-up; the planned Study Database Closure/Database Complete Date is updated to accommodate such special circumstances.

Additional, limited non-eCRF laboratory data not required for the final analysis report may be analyzed by the statistician for inclusion in the primary manuscript, during the manuscript writing period. These data are not required to be finalized by the Study Database Closure/Database Complete Date but must be finalized before the start of the manuscript writing period.

19.3.6 Completion of Final Analysis

After the Study Database Closure/Database Complete Date, the protocol statistician conducts the data analysis and prepares a final analysis report in accordance with the SAP. For PK studies, generally, the protocol pharmacologist conducts the PK data analysis and prepares a final PK analysis report in accordance with the PK analysis plan. As described further in Section 19.4, text describing the background, study design, and other trial aspects are ideally drafted for primary and secondary manuscripts while data analyses are underway.

The draft final analysis report generated at SDAC is reviewed internally by SDAC before it is sent to the writing team. The protocol statistician(s) (or the non-SDAC statistician where applicable) and pharmacologist distribute their final analysis reports to the writing team(s) and notify the publications coordinator that the final analysis reports have been distributed, as outlined in Table 19-2. Additional analyses may become important once the results become known; these may be completed and sent to the writing team for inclusion in the manuscript during the writing period.

For protocols in which the PCD precedes the closed to follow-up date, a primary analysis report(s), separate from secondary and other analysis reports, is prepared and distributed to the writing team within approximately seven months, as per Figure 19-1, following the PCD.

Once all participants are off study and the primary analysis report(s) (includes all applicable primary analyses for a given study, such as primary safety and primary PK analyses) is completed and distributed to the writing team, the CRM notifies the protocol team and the DAIDS Regulatory Support Center Clinical Study Information Office (RSC CSIO) that the study status is “participants off study & primary analysis complete” (POS/PAC). This status also applies if it has been determined that no primary analysis can be done, and all participants are off study.

19.3.7 ClinicalTrials.gov Results Entry

The protocol statistician is responsible for preparing results for all non-PK primary and secondary outcome measures. For studies with PK data as part of the primary and secondary outcome measures, the protocol pharmacologist is responsible for preparing results for the relevant PK outcomes and providing this information to the statisticians for entry into ClinicalTrials.gov.

SDAC is responsible for collating and entering all results for study outcome measures in ClinicalTrials.gov. Results for all primary outcome measures must be entered into ClinicalTrials.gov within one year of the PCD. Results for secondary outcome measures with completion dates prior to or concurrent with the PCD must also be entered within one year of the PCD. These entries are required regardless of whether the results have been published.

To coordinate results submission for studies with PK data as part of the primary and/or secondary outcome measures, the protocol statistician distributes the *Plan for ClinicalTrials.gov Results Entry*, with updated deadlines for results submission, to the writing team, protocol chair, CRM, and protocol

pharmacologist (refer to Section 11 for details on initial development of the plan prior to opening to accrual). The statistician also provides a template to the protocol pharmacologist for submission of the PK results to SDAC for entry in ClinicalTrials.gov, as outlined in the *Plan for ClinicalTrials.gov Results Entry*.

Refer to Section 7 for detailed instructions on ClinicalTrials.gov management and timelines.

Table 19-2. Timeline for Primary Analysis Planning

Event	Timeline	Procedures	Responsibilities
Primary analysis planning	Six months prior to PCD for primary and secondary outcome measures with batched laboratory data	<ul style="list-style-type: none"> • Create timeline with planned dates • Start circulating the Status of Batched Laboratory Assays (SBLA) report • Check status of Material Transfer Agreements & laboratory contracts • Initiate data transfer agreements 	Statistician (with PDM/LDM) LDM LC/Westat LDM
Update analysis plans	Three months before anticipated PCD or closed to follow-up date (whichever comes first)	<ul style="list-style-type: none"> • Update the SAP and PK analysis plan (if applicable) prior to initiation of final analyses 	Protocol statistician, lead author, and other writing team members If primary analyses include pharmacology, pharmacologist
Primary completion date or closed to follow-up date (whichever comes first); final data entry period begins	Day 0	<ul style="list-style-type: none"> • Notify protocol team 	PDM
Receipt of primary analysis report by writing team	Seven months after Day 0	<ul style="list-style-type: none"> • Share final primary analysis report with writing team • Notify publications coordinator that the analysis report has been shared 	Protocol statistician

19.4 Development of Publications

The protocol chair ensures that analysis and publication of secondary, exploratory, and ancillary study results do not interfere with the analysis or publication of the primary study results and works closely with the CRM and statisticians to track publication development progress and to address any concerns that may arise.

19.4.1 Formation of Writing Teams

The writing team for the primary publication is typically designated in the primary SAP appendix; if a study is prematurely terminated such that advanced planning is not possible, the writing team is formed as soon as possible after study closure. Writing teams typically include the protocol chair(s), vice chair(s),

statisticians, CRMs, and other protocol team members, e.g., immunologist, virologist, pharmacologist, or other content expert(s), as appropriate. Site investigators should be considered when developing the writing team. It is understood that other protocol team members may contribute to the publication as needed; however, the writing team is responsible for developing a complete publication. Further detail on authorship guidelines is included in Section 19.9.

Lead author(s) and, if applicable, writing teams for secondary publications are typically designated by the protocol chair. The process of developing the list of proposed secondary analyses (new or specified in the protocol), potential publications, and writing teams is expected to begin when the primary analysis report is received by the protocol chair and to be completed within six months. As noted above (Section 19.1), the secondary analyses must be prioritized by the protocol team (or designated sub-group), with identification of any analyses to be performed without SDMC support.

Journal or conference choice is typically discussed and agreed upon within the designated writing team, with final decisions made by the lead author, in consultation with the protocol chair.

19.4.2 Primary Publications

The timeline and process for development and review of primary manuscripts is outlined in Table 19-3; these procedures and responsibilities are applicable for all primary publications, including manuscripts and abstracts. Manuscripts reporting the primary results of IMPAACT studies, including primary and applicable secondary outcome measures, are generally expected to be developed and submitted for internal IMPAACT review within nine months of the PCD or closed to follow-up date (whichever comes first).

19.4.3 Other Protocol-Specified Publications: Secondary, Other, and Exploratory

The timeline for analysis of other protocol-specified (secondary, other, and exploratory) publications may vary based on prioritization and data availability (e.g., completion of laboratory assays). Responsibilities, timelines, and procedures for development and review of secondary manuscripts may vary but are generally expected to follow those for development of primary publications. Publications reporting on other or exploratory objectives should ideally be drafted within 12 weeks of receipt of all data.

To assist with prioritization, tracking, and publication of all study objectives, the protocol team (or designated subset) begins developing a list of potential additional publications, beyond the primary manuscript(s), which is maintained by the CRM with the protocol chair. The list includes the following for each additional publication:

- Proposed lead author (and writing team, if applicable) and brief title and description of each publication
- List and status of laboratory samples and assay results required for the publication, if applicable
- Expected timeline for analysis completion, considering the steps outlined above for primary publications

As all data analyses cannot proceed at the same time, preparation of additional, protocol-specified publications typically requires prioritization. The protocol chair consults with the SDMC on the planning and prioritization of various publications for a study, ensuring that analyses for each can be completed as scheduled. When necessary, IMPAACT Publications Review Group guidance may be sought on prioritization of additional publications. In some cases, analyses may have to be completed by a non-SDAC statistician.

The lead author for each additional publication reviews the applicable SAP and works with the protocol team or writing group on any updates; if some relevant analyses were completed as part of the primary analysis, the remaining analyses are to be completed within a specified time frame.

19.4.4 Publications from Ancillary Studies (DACS, NWCS, and DR)

Procedures for submission and review of ancillary studies are described in Section 15.

Any publications associated with an ancillary study should include the study number(s) (i.e., IMPAACT XXXX) associated with the project. Standard IMPAACT acknowledgements should be included for any publication supported by IMPAACT grants; if standard acknowledgements are not applicable, acknowledgement of provision of data by IMPAACT should be included. The timeline for preparation of the relevant analysis report may vary depending on a number of factors, including availability of data and assay completion. Publications should ideally be drafted within 12 weeks of receipt of all data.

For DACS and NWCS, the expectations and procedures for publication development and review are the same as for primary and secondary publications. For DR, draft publications need only be sent to the publications coordinator for review by the IMPAACT Publications Review Group and to confirm the appropriate acknowledgements, prior to submission.

19.4.5 Publications from Laboratory Projects

Any publications associated with an IMPAACT laboratory project should include the study number(s) (i.e., IMPAACT XXXX) associated with the project. Standard IMPAACT acknowledgements should be included for any publication supported by IMPAACT grants.

Manuscripts and abstracts from IMPAACT laboratory projects must undergo review by co-authors and by the IMPAACT Publications Review Group; however, for these manuscripts, it is not expected that study teams will review, unless data from the study were used. For these types of publications, the LC PI or designee serves as the primary reviewer.

Table 19-3. Timeline for Development and Review of Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Formation of writing team (see Section 19.4.1)	<p>For Primary Manuscript: Approximately four to six months before anticipated PCD or closed to follow-up date (whichever comes first)</p> <p>For Secondary Manuscripts: Within six months after primary analysis report is received by protocol chair</p> <p>For Exploratory and Ancillary Study Manuscripts: NA</p>	<ul style="list-style-type: none"> For Primary Manuscripts: Notify team that the study is nearing PCD or closed to follow-up status Remind protocol chair/lead author of timeline and need to designate a writing team Discuss writing team formation and agree on communications plan (e.g., materials to develop for participants, sites, and/or communities; how sites/participants are to be notified) 	<p>Protocol statistician</p> <p>CRM</p> <p>Protocol chair/lead author, CRM</p>
Manuscript preparation begins; 12-week clock starts	Writing period should take no more than eight weeks after the writing team's receipt of the final analysis report, leaving <u>at least</u> four weeks for review by co-authors and protocol team, with incorporation of comments/revisions	<ul style="list-style-type: none"> Remind protocol chair/lead author of manuscript submission deadline Oversee timely completion of manuscript and adherence to timelines Determine number and order of co-authors Develop full manuscript within eight weeks Distribute for review by: <ul style="list-style-type: none"> All co-authors (two weeks) Protocol team: minimally including protocol chair(s), protocol statistician(s), Medical Officers (MO), CRM(s) and, if applicable, pharmaceutical representatives (two weeks) Begin compilation of the appendix of contributors 	<p>CRM</p> <p>Protocol chair</p> <p>Protocol chair/ lead author and other members</p> <p>Protocol chair/ lead author and CRM</p>
Manuscript submission for IMPAACT review	12 weeks after analysis report provided to writing team	<ul style="list-style-type: none"> Submit manuscript to publications coordinator (impaact.pubscoord@frontierscience.org) indicating protocol number, primary/secondary manuscript, and to which journal the team will be submitting, if known: <ul style="list-style-type: none"> If submitting to an Open Access journal, notify the publications coordinator for determination of Open Access fee coverage (see Section 19.13 for more information) Forward manuscript to IMPAACT Publications Review Group and, if applicable, relevant SC chairs and CRMs, for review, with notification to the protocol chair/lead author Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements 	<p>Protocol chair/lead author</p> <p>Publications coordinator</p> <p>Publications coordinator</p>

Table 19-3. Timeline for Development and Review of Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
IMPAACT review complete (unless revision/resubmission required)	Ten business days after submission for IMPAACT review	<ul style="list-style-type: none"> • Forward review comments and approval (or resubmission request) to protocol chair/lead author <ul style="list-style-type: none"> – If manuscript is approved, address reviewer comments and proceed with next step – If approved with revision and resubmission requested, submit response and revised manuscript within four weeks to publications coordinator – If disapproved, submit a revised manuscript within eight weeks (substantial changes to be agreed upon by authors, protocol team [including pharmaceutical company representatives, if applicable], and IMPAACT Publications Review Group) 	Publications coordinator Protocol chair/ lead author
IMPAACT-approved primary manuscript submitted to journal	Within four weeks of IMPAACT approval	<ul style="list-style-type: none"> • Submit manuscript to journal and send copy to publications coordinator and cbar.pubs@sdac.harvard.edu • Ensure authors' disclosure of potential conflicts of interest as required by journal policy • See Section 19.7 for additional guidance related to journal submission and procedures for various outcomes 	Lead author
Acceptance for publication	Following journal submission	<ul style="list-style-type: none"> • Communicate outcome of submission to publications coordinator and cbar.pubs@sdac.harvard.edu • Ensure publishing agreement allows the paper to be posted to PubMed Central, in accordance with NIH policy, prior to signing the journal publication agreement (or similar copyright transfer agreement) • Ensure authors' disclosure of potential conflicts of interest as required by journal policy • If the manuscript is being published in a journal that does not deposit final published articles in PubMed Central: <ul style="list-style-type: none"> – Submit manuscript to PubMed Central via the National Institutes of Health Manuscript Submission System (NIHMS) – Confirm PubMed Central submission to the publications coordinator and cbar.pubs@sdac.harvard.edu – Approve the release and PubMed Central formatting of manuscript upon receipt of the email notification from NIHMS 	Lead author

19.5 Tracking Manuscript Preparation

The guidelines and procedures outlined in this section apply to primary and secondary manuscripts as well as manuscripts developed from DACSs or NWCSs. Timelines may vary for manuscripts from DRs.

Publication updates, including delays, are included in quarterly Study Operations Reports for MOG review and consultation. Upon identifying significant delays, the MOG communicates with the protocol chair(s) and/or lead author(s) to discuss concerns and request a detailed timeline for completion. Further delays without sufficient justification may result in replacement of the lead author (and/or writing team), as determined by the protocol chair (if different from the lead author) and the IMPAACT Publications Review Group chair in consultation with other members.

19.6 IMPAACT Publication Review Process

Publications based on IMPAACT data must be reviewed and endorsed internally prior to journal or conference submission. The lead author is responsible for ensuring that all applicable reviews are completed, and approvals are obtained prior to conference or journal submission.

19.6.1 Co-Author Review

Once the writing team has drafted a manuscript or abstract, the co-authors must have the opportunity to review. Determination of co-authors follows guidance as noted in Section 19.9. Co-authors are typically given at least one week to review abstracts and at least two weeks to review manuscripts. While neither review comments nor approval emails are required, at a minimum, each co-author should confirm their authorship and affiliation with the lead author.

19.6.2 Protocol Team Review

Once co-authors have reviewed the draft publication and confirmed their authorship, the applicable protocol team(s) must also have the opportunity to review the draft publication. At a minimum, this review includes the protocol chair(s), protocol statistician(s), MO(s), CRM(s) and, if applicable, pharmaceutical representatives. Any necessary reviews by industry or other sponsors/collaborators, as specified in the CTA or other third-party agreement, take place in parallel to the protocol team review. Internal organizational reviews may also be conducted (e.g., SDAC, NIH, and/or pharmaceutical company reviews) but must be coordinated in keeping within the overall timeline.

When United States (US) government (e.g., NIH) staff are co-authors, publications must be approved by their institute/agency. The US government staff person is responsible for obtaining the necessary approvals. Different government agencies have different review time requirements, so authors and the US government staff person should take those requirements into consideration during the publication review process.

Draft publications from ancillary studies do not require protocol team review if the applicable study(ies) is concluded or if the draft publication is a result of a data request.

Protocol teams are typically given at least one week to review abstracts and at least two weeks to review manuscripts. The CRM typically confirms with the lead author when protocol team review is complete.

19.6.3 IMPAACT Publications Review Group Review

Once the review steps above are completed, the lead author must submit a final draft manuscript or abstract, appendix of contributors (if applicable), Network and NIH acknowledgements, and the name of the journal or conference planned for submission to the publications coordinator to initiate the review process.

The publications coordinator reviews the submission to ensure that all applicable materials are included and distributes the draft to the IMPAACT Publications Review Group, with a copy to the relevant SC chairs and CRMs. A primary reviewer is assigned by the IMPAACT Publications Review Group chair to review the manuscript or abstract in detail and determine whether to endorse it for journal or conference submission. The primary reviewer may be a member of the IMPAACT Publications Review Group, an SC chair or vice chair, a member of the IMPAACT SLG, or another reviewer with specific expertise in the topic area.

The primary reviewer and IMPAACT Publications Review Group have ten working days from receipt of a manuscript in which to comment. Abstract review timelines may vary depending on the conference:

- For conferences with a large number of abstracts expected (e.g., AIDS, CROI), the draft abstract must be submitted to the publications coordinator at least ten working days prior to the deadline for the abstract to be submitted to the conference organizer.
- For other conferences, the draft abstract must be submitted at least five working days prior to the conference submission deadline.

If the data necessary to complete the abstract are not available within the designated time frame, an alternative review process may be determined by mutual agreement of the writing team and IMPAACT Publications Review Group chair.

Review outcomes and other comments are compiled by the publications coordinator and shared with the lead author (copying any others included in the submission) at the end of the comment period. All IMPAACT Publications Review Group members are not required to comment, and forfeit their right to do so at the conclusion of the comment period. The review will result in one of the following outcomes:

- Approve for submission
- Revise and re-submit
- Disapprove

IMPAACT endorsement for submission must be obtained before the publication may be submitted to a journal or conference. If the publication is approved for submission with reviewer comments, the writing team addresses comments as appropriate and then proceeds with preparation for submission.

If revision and resubmission is requested, it is generally expected that a revised manuscript or abstract will be resubmitted within four weeks (for manuscripts) and as soon as possible (for abstracts).

If disapproved, the publications coordinator may arrange for a discussion of potential next steps by the primary reviewer, Publications Review Group chair, lead author, other writing team members, and other Publications Review Group reviewers, as needed. If agreement cannot be reached, the matter may be referred to the MOG. It is generally expected that a revised manuscript will be resubmitted within eight weeks.

Substantial changes to the publication made in response to either a request for revision and resubmission or a disapproval must be agreed upon by co-authors and the protocol team (if applicable) and may require re-review by the pharmaceutical company or other sponsors/collaborators prior to resubmission to the publications coordinator for IMPAACT Publications Review Group review.

19.7 Journal Submission

The lead author is responsible for the following:

- Reviewing journal embargo policies related to adherence to the 2024 NIH Public Access Policy, before submitting to the journal and ensuring adherence to these policies following acceptance (see Section 19.11)
- Submitting the final, IMPAACT-approved manuscript to the selected journal
- Ongoing correspondence with the journal (i.e., corresponding author), unless another co-author is delegated as such
- Ensuring that all required information is provided to the journal (e.g., co-author conflict of interest forms or statements, confirmation of co-authorship, provision of supplementary materials).
- If applicable, working with the protocol chair, CRM, and protocol team members on results dissemination (see Section 19.12)

If a journal requests a statement about access to data, use the following:

“The data cannot be made publicly available due to the ethical restrictions in the study’s informed consent documents and in the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network’s approved human subjects protection plan; public availability may compromise participant confidentiality. However, data are available to all interested researchers upon request to the IMPAACT Statistical and Data Management Center’s data access committee (email address: sdac.data@sdac.harvard.edu) with the agreement of the IMPAACT Network.”

Note: The previous email contact for the data access committee was sdac.data@fstrf.org.

The lead author is also responsible for informing the publications coordinator when the manuscript is submitted, when outcome(s) are received, and when the manuscript is accepted and published, as described further below.

Revisions Comments from the journal reviewers are handled at the writing team level. If significant changes are required, the lead author is responsible for notifying the publications coordinator, who works with the IMPAACT Publications Review Group chair to determine if additional IMPAACT review is required.

Rejections If the manuscript is rejected, the lead author must inform the publications coordinator of future plans for the manuscript. Generally, manuscripts should be resubmitted within eight weeks, unless additional major analyses are required. The lead author must circulate the revised manuscript to the protocol chair and co-authors prior to resubmission. In addition, if there are substantive changes (e.g., differences in the conclusions or findings described), re-review by the protocol team, pharmaceutical companies, and other sponsors/collaborators is required, and a copy of the reviewers’ critique and the revision are sent to the publications coordinator to share with the IMPAACT Publications Review Group, with re-review and approval by the primary reviewer required prior to resubmission.

Accepted manuscripts Upon acceptance of the manuscript for publication by the journal, the lead author is responsible for providing an electronic copy of the manuscript to the publications coordinator, co-authors, and the protocol team.

19.8 Conference Submission

The lead author is responsible for submitting the final, IMPAACT-approved abstract to the selected conference and for informing the publications coordinator of the conference's decision and, if known and accepted, the abstract's number and presentation type (e.g., poster or oral presentation) as soon as possible following notification by the conference organizer.

If applicable, the lead author is also responsible for working with the protocol chair, CRM, and protocol team members on results dissemination (see Section 19.12).

If an abstract is rejected by the conference organizer and substantive changes are made prior to submission to another conference, the revised abstract must be reviewed by co-authors, the protocol team, and the IMPAACT Publications Review Group prior to resubmission.

Preparation of Conference Presentation Materials

If an abstract is accepted, the lead author must circulate the draft slides and/or poster to co-authors and the protocol team (minimally including protocol chair(s), protocol statistician(s), MO(s), CRM(s), and, if applicable, pharmaceutical representatives), for review. Posters and slides do not need to be reviewed by the IMPAACT Publications Review Group. Use of the IMPAACT logo (available on the Network website, <https://www.impaactnetwork.org/resources/network-logos-templates>, or from the Operations Center) and appropriate contributors (Section 19.9.3) and acknowledgements (Section 19.10) are required on all abstract posters and presentations; use of IMPAACT templates is encouraged but not required.

Note: Encore or repeat presentations are allowed, with permission from the lead author. The presenter should inform the relevant protocol team(s) and the publications coordinator ahead of the presentation.

19.9 Authorship

The guidelines and procedures outlined in this section apply to primary and secondary publications, as well as publications developed from DACSs or NWCSs.

19.9.1 Guidelines for Authorship

The masthead should include those individuals who have made substantial intellectual contributions to the specific publication, as defined in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/icmje-recommendations.pdf>, updated January 2026):

“The ICMJE recommends that authorship be based on the following 4 criteria:

- *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
- *Drafting the work or reviewing it critically for important intellectual content; AND*
- *Final approval of the version to be published; AND*
- *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*

In addition to being accountable for the parts of the work done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged—see Section II. A.3 below. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.”

19.9.2 Decision for Authorship and Author Order

The lead author is responsible for identifying and confirming co-authors during the publication development process. The list and order of names on the masthead should be finalized by the time the draft publication is submitted to the publications coordinator. The number of co-authors of a publication may be limited by the journal or conference guidelines. When authorship must be limited, it is preferable for each organization/entity involved (e.g., protocol chair, Data Management Center (DMC), LC, Operations Center, SDAC, DAIDS, NICHD, NIMH, each participating site) to be represented by a single author. The first author of the manuscript is usually the lead author.

It is recommended that site investigators be invited to participate on the writing team early in the analysis plan development process so that they have the opportunity to meet the authorship criteria. Generally, for studies that enrolled participants from fewer than six sites, one investigator from each enrolling site may be considered for co-authorship. For studies involving more than six sites, site representation may be determined based on high overall enrollment, the number of participants included in a specific sub-analysis, investigator expertise in the topic of the publication, or an alternative plan for site investigator co-authorship, as developed by the team. The affiliation of co-authors should reflect their own site. If the protocol chair or vice chair is already an author, another investigator from that site may also be a co-author.

In instances where study work is completed or substantially conducted at one site and a co-author relocates to another site or institution prior to the publication being submitted to a journal or conference, both the author’s current and former institutions should be cited. It is the responsibility of the relocated author and the site leader of the former site to ensure that both institutions are cited in the publication.

Any disputes regarding study authorship or position on masthead are addressed first with the lead author and protocol chair. Decisions concerning authorship may be appealed, if necessary, to the IMPAACT Publications Review Group.

19.9.3 Appendix of Contributors

When allowed by the journal, primary and secondary manuscripts will include an appendix acknowledging contributors who were not listed on the masthead. The same listing may be used for exploratory manuscripts. Contributors not otherwise indicated as co-authors are listed in the appendix, including protocol team members and all participating site institutions enrolling participants. The listing may include up to four persons per participating institution, including participating sites, SDAC, DMC, LC, Operations Center, sponsoring NIH institutes, and industry or other collaborators. The listing is compiled by the lead author, protocol team chair, and CRM. The publications coordinator confirms that

there is an appropriate appendix of contributors upon submission for IMPAACT Publications Review Group review.

For NWCSs and DACSs, a statement acknowledging the participating sites of the parent studies is sufficient.

If no appendix of contributors is allowed by the journal, the acknowledgements should include those specified in this section, with the number of individuals cited per institution to conform to the journal's specifications.

In general, this policy to acknowledge contributors applies to any conference presentation materials.

19.10 Acknowledgements

19.10.1 Network and NIH Acknowledgements

The IMPAACT Network and the specific protocol number should be included in the title and body of the manuscript or abstract (e.g., IMPAACT XXXX).

The grant acknowledgment and disclaimer on behalf of NIH should be as follows:

“Overall support for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) was provided by the National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), all components of the National Institutes of Health (NIH), under Award Numbers UM1AI068632 (IMPAACT LOC), UM1AI068616 (IMPAACT SDMC) and UM1AI106716 (IMPAACT LC), and by NICHD contract number HHSN275201800001I. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.”

As applicable, any publications associated with an ancillary study should include the IMPAACT grant acknowledgement and NIH disclaimer, as described above in Section 19.4.4.

19.10.2 Other Acknowledgements

If the work represented by the publication was directly supported by sponsors other than those cited in Section 19.10.1, they should be acknowledged accordingly and in keeping with the terms of any applicable CTAs, MOUs, or other collaboration and sponsor agreements. For example, if study products were supplied by the manufacturer free of charge for use in the study, this should be acknowledged. It is the responsibility of the lead author and protocol team chair to ensure appropriate acknowledgement of contributors, sponsors, and collaborators.

19.11 Public Access Policy

The IMPAACT Network complies with the NIH Public Access Policy, available at: <https://publicaccess.nih.gov/policy.htm>. This policy was updated in December 2024, applicable for all IMPAACT manuscripts accepted for publication in a journal on or after 1 July 2025.

The policy requires all Author Accepted Manuscripts accepted for publication in a journal to be submitted to PubMed Central upon acceptance for publication, for public availability without embargo upon the Official Date of Publication.

- **Author Accepted Manuscripts** are defined as the author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material.
- The **Official Date of Publication** is defined as the date on which the Final Published Article is first made available in final, edited form, whether in print or electronic (i.e., online) format.

As noted in NIH guidance, compliance with the policy may be achieved through either:

- Submission of the electronic version of the Author Accepted Manuscript to PubMed Central upon its acceptance for publication, for public availability without embargo upon the Official Date of Publication
- Submission of the Final Published Article to PubMed Central from journals or publishers with formal agreements with NLM, upon the Official Date of Publication, for public availability without embargo

Further guidance is available here: <https://grants.nih.gov/policy-and-compliance/policy-topics/public-access/submitting-pubmed-central>.

PubMed Central maintains a list of journals indicating their policies for embargo, available at: <https://pmc.ncbi.nlm.nih.gov/journals/>. The lead author should access the searchable journal list to confirm the targeted journal's embargo policy prior to manuscript submission. Some journals submit manuscripts to PubMed Central automatically with no embargo (immediate release).

For journals that do not submit automatically with no embargo, the lead author must submit the manuscript to PubMed Central separately. Authors must inform the journal that the manuscript is subject to the Public Access Policy when submitting it for publication and make sure that any copyright transfer or other publication agreement allows the final peer-reviewed manuscript to be submitted to NIH in accordance with the policy. When the final peer-reviewed manuscript has been accepted for publication, the author must submit the manuscript to PubMed Central via the NIHMS, and confirm completion with the SDMC's publications tracking group (cbar.pubs@sdac.harvard.edu) and the IMPAACT publications coordinator. The lead author approves the release and PubMed Central formatting of the manuscript when receiving the email notification from NIHMS.

The publications coordinator follows up with authors on the status of manuscripts that have been approved for journal submission by the IMPAACT Publications Review Group and tracks the progress on journal submission, submission to PubMed Central, and assignment of ID numbers.

19.12 Dissemination of Study Results

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.

With input from the NIH sponsors and other collaborators, the protocol team (minimally including the protocol chair(s), protocol statistician(s), MO(s), and CRM(s)) is responsible for determining the appropriate plans and timing for communication of study results depending on the nature and status of the study, whether the findings may impact study participants, or the standards of care. If results are to be

communicated prior to their publication or lifting of an embargo, the protocol team should ensure that recipients are aware of relevant embargoes and any applicable confidentiality requirements.

Pharmaceutical representatives should be informed of this planning when there is a CTA between DAIDS and the company for the study. The timing of development and implementation of the communications plan and materials may be dictated by a recommendation for early release of findings by the DSMB or SMC overseeing the study. At the discretion of IMPAACT leadership and/or as dictated by recommendations from the DSMB or SMC overseeing the study, select individuals or groups may be briefed about study results prior to public release. Signed confidentiality disclosure agreements may be required.

19.12.1 Communications Plan for Results Dissemination

A study-specific communications plan may be developed by the CRM in close collaboration with the protocol team (and lead author, if not part of the protocol team) to provide a framework around dissemination of key study results. Plans are generally developed ahead of results reporting in the following cases:

- Dissemination of primary analyses, particularly when results may impact guidelines/standards of care or when results are from Phase IIb/III/IV studies
- Dissemination of multiple analyses at one event, for example, when multiple abstracts presenting results from the same study are being presented at one conference

This plan includes the following information:

- Key members of the communications team (e.g., protocol chair, protocol statistician, designated spokespeople, etc.) and their roles
- Specified timelines and activities planned for release of the study results within the team and externally
- Key stakeholders (e.g., 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, as applicable

Results are released in an accurate, well-controlled, and timely manner to host country officials, study participants, community representatives, sponsoring industry collaborators, relevant non-governmental organizations, and other governments. Ideally this happens before, or at the same time as, the results are released to the general public. Particular care is to be taken to coordinate the release of results with officials in host countries and in the communities where the study was conducted.

Study results may be shared with participating sites, sponsors, and collaborators through a number of means, as described below.

19.12.2 Materials for Protocol Team, Participants, Community, and Other Key Stakeholders

Abstracts and manuscripts accepted for publication that report on primary and secondary objectives should be shared with the protocol team and site investigators; additional publications may also be shared. Manuscripts are shared with the protocol team and site investigators as soon as possible after their

publication date and sent to the publications coordinator for posting on the IMPAACT website. Accepted abstracts are typically sent by the CRM at least two days before conference presentation; however, the terms of any NIH or conference embargo take precedence. If NIH or Network leadership determines that a press release is to be issued, its development and release should follow the procedures outlined in Section 6. As soon as possible following conference presentation, the lead author should send a copy of the final materials presented to the publications coordinator for posting on the IMPAACT website.

The protocol team may determine that supplemental documents reflecting the same messages as the publication should be developed for different audiences. These materials are often developed for primary results but may also be developed for IMPAACT-related secondary abstracts or manuscripts that have clinical relevance (i.e., may impact clinical care) to study participants and communities. Common supplemental materials include:

- Results summary for participants and/or parents/guardians
- Results summary for community members
- Key talking points
- Question and answer documents intended primarily for use by participating study sites when sharing results with key stakeholders

Supplemental documents are generally developed by the CRM(s) and reviewed by members of the protocol team; consistency within and between these documents and the final publication is confirmed prior to distribution. The protocol team, minimally including the protocol chair(s), protocol statistician(s), MO(s), community program manager, and CRM(s), review the materials prior to distribution. Supplemental materials prepared in advance of a conference presentation are typically distributed to participating study sites at least two days in advance of the presentation date.

Any materials for dissemination to participants and communities are generally expected to meet the following guidelines:

- Written as concisely as possible (ideally no more than one to two pages in length)
- Language is clear and understandable:
 - Written in 6th to 8th grade level language and reading ease between 70 and 80
 - Avoids jargon; when not possible to avoid jargon, clearly explains terminology
- Includes the protocol number, title, and any study acronym
- Briefly describes the study purpose and includes the number and location of study participants
- Notes the current status of the study
- Includes the key findings of the publication and any implications for participants and/or communities

When the manuscript is published, or the abstract is presented, community- or external stakeholder-facing materials may also be posted on the study-specific webpage of the IMPAACT website.

19.13 Publication Costs

Through the Operations Center, IMPAACT may cover review fees and pages charges for primary and secondary manuscripts. Any additional author fees charged for approved manuscripts, including costs for publishing in an Open Access journal and charges for color figures, may be covered on a case-by-case basis as determined by the IMPAACT Leadership and Operations Center. All requests for publication costs are sent to the publications coordinator.

Once confirmation is received that the Operations Center will cover the publication costs, the publications coordinator provides the author with information for the invoice.

Costs associated with ordering reprints will not be covered by IMPAACT and remain the responsibility of the author. Publication costs for manuscripts resulting from ancillary studies will not be covered.

19.14 Concluding a Study

Per [DAIDS Study Statuses](#), a study is classified as concluded once it is ended and no further activity or resource expenditure on it is expected. The study must meet all of the following events prior to being classified as concluded:

- All protocol-required data analyses are finished, or it has been determined that no analysis can be done.
- Primary manuscript has been accepted for publication or determined to be “not publishable” in any journal.
- Primary manuscript is published if primary manuscript has been accepted for publication.
- Other manuscripts from study’s original plan have been accepted for publication or it has been determined that the analyses are “not publishable.”
- Final Report or Executive Summary is submitted to DAIDS.

Note that the requirement for a final report or executive summary is satisfied when SDAC sends the primary analysis report to the writing team, which includes a DAIDS MO.

Prior to indicating that a study is concluded, the team should consider specimen destruction requirements, as described further in Section 17.

The Operations Center notifies the RSC CSIO that the study status is “concluded”.