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 products reporting the results of IMPAACT studies or otherwise using IMPAACT-related data.

All abstracts and manuscripts using IMPAACT data must undergo an IMPAACT Network review before being submitted to a conference or journal (through submission to impaact.pubscoord@fstrf.org, as

described in detail below). The results of the main study (primary manuscript) must be submitted – and ideally published – prior to those of sub-studies and secondary manuscripts, unless otherwise approved by the IMPAACT Management Oversight Group (MOG).

These procedures should be reflected in the terms of Clinical Trial Agreements (CTAs), Memoranda of Understanding (MOUs), or alternative agreements approved by the IMPAACT MOG 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.

Table 19-1. Definitions

Abstract	Brief report of IMPAACT study data prepared for submission to a conference; may be a regular abstract or a late-breaker abstract, as determined by conference submission requirements.
Closed to Follow-up ***[DAIDS study status]***	The study has permanently closed to accrual, all participants have completed study agents/products, and all follow-up visits have been completed. Last participant has completed the last study visit and all participants are "off study." Equivalent to "Study Completion" in ClinicalTrials.gov.
Data Analysis Concept Sheet (DACS)	A proposed investigation involving analysis of existing data from an IMPAACT (or Pediatric AIDS Clinical Trials Group [PACTG]) study to be undertaken by the Statistical and Data Analysis Center (SDAC) with IMPAACT funding. If the IMPAACT Network has not designated the study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT DACS or New Works Concept Sheet (NWCS) that is not yet completed.
Data Request (DR)	A proposed investigation for which existing data from an IMPAACT (or PACTG) study are being requested for analyses to be performed without IMPAACT funding. (Note that an SDAC statistician may be among the proposing investigators but would not be seeking IMPAACT support for the work). If the IMPAACT Network has not designated the IMPAACT study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT DACS or NWCS that is not yet completed. The statistical design of the research project and associated data analyses must be undertaken by the proposing investigators without IMPAACT funding.

Table 19-1. Definitions

IMPAACT Publications Review Group	Group responsible for reviewing IMPAACT manuscripts and abstracts on behalf of the Network prior to journal/conference submission. The group includes the IMPAACT Network chair and vice chair(s); the SDMC PI or designee; the Laboratory Center (LC) PI; representatives of NIAID, NICHD, and NIMH; and the relevant IMPAACT Scientific Committee (SC) chair. The protocol clinical research managers (CRMs) are also included in the distribution to the Publications Review Group. The Network chair serves as the chair of the IMPAACT Publications Review Group.
Masthead authors	Individuals listed as authors on a manuscript or abstract.
National Institutes of Health Manuscript Submission System (NIHMS)	An online system for submitting and managing final, peer-reviewed manuscripts in accordance with the NIH Public Access Policy.
New Works Concept Sheet (NWCS)	A proposed investigation involving use of existing biological specimens from an IMPAACT (or PACTG) study that may or may not require IMPAACT funding and may or may not involve analysis work by the SDAC. If the IMPAACT Network has not designated the study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report. The objectives should also not overlap with those specified in an approved IMPAACT NWCS that is not yet completed.
Participant Letter	A letter for study participants (or parents/legal guardians) summarizing or describing the study results and their implications or changes to an ongoing study necessitated by emergent findings from that study, another investigation, and/or other external factors such as a relevant change in treatment guidelines.
Primary Completion Date (PCD)	Date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome measure. May or may not be the same as the closed to follow-up date, depending on the study design.
Primary manuscript	Manuscript that reports findings related to the primary study objective(s) and outcome measures as described in the study protocol. Findings associated with secondary objectives may also be included. A protocol may have more than one primary publication. For example, a protocol may have more than one primary publication when a study is conducted in multiple stages and has a primary objective for each stage.
Protocol team	The team members whose names appear in the protocol roster, which usually includes pharmaceutical/industry representatives and other study sponsors/collaborators.
Publications Coordinator	Operations Center staff member who facilitates and tracks development, submission, review, and outcome of manuscripts and abstracts that use IMPAACT data, through the following address: impaact.pubscoord@fstrf.org.
Publication costs	Author fees associated with publishing peer-reviewed manuscripts.

Table 19-1. Definitions

PubMed Central (PMC)	The NIH digital archive of full-text, peer-reviewed journal articles; its content is publicly accessible and integrated with other databases (http://www.ncbi.nlm.nih.gov/pmc/).
Secondary manuscript	Manuscript that reports findings related to secondary study objectives and outcome measures as described in the study protocol, or scientific questions outside the primary objectives, e.g., baseline data reports, cross-protocol data, or analysis of specimens collected as part of a study but used for analyses not previously specified in the study protocol.
Site Investigator Letter	Limited scientific summary of the main trial results; disseminated to participating sites prior to public presentation or publication of the results or when changes to an ongoing study are necessitated by emergent findings from that study, another investigation, or other external factors such as a relevant change in treatment guidelines.
Writing team	A subgroup of the protocol team that collaborates to write an abstract or manuscript. Under certain circumstances, specialists who are not protocol team members may be included.

19.2 Key Responsibilities

Protocol Chair Responsibilities

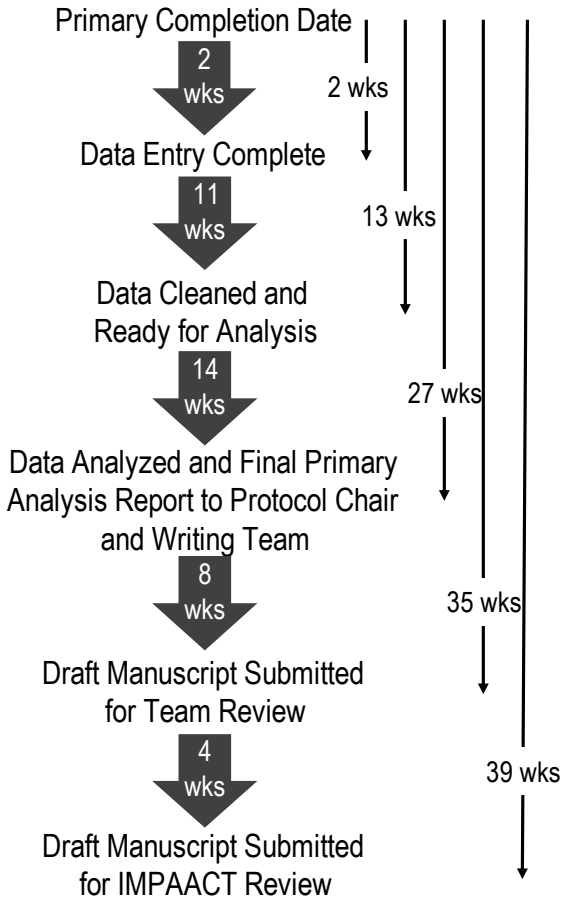
The protocol chair assumes overall responsibility for ensuring publication of the study findings in a timely manner. The results of each study should be reported in at least one peer-reviewed publication addressing the primary objective(s) within the timeline outlined in Figure 19-1. The protocol chair 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 or sub-study results do not interfere with the analysis or publication of the primary study results and works closely with the publications coordinator at the IMPAACT 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 should, at minimum, include the protocol chair and statistician(s), with other protocol team members included as needed. The SDMC contributes to the planning and prioritization of various manuscripts for a study, ensuring that analyses for each can be completed as scheduled. Prioritization is critical as all planned primary and secondary analyses cannot be expected to proceed at once. The list of secondary analyses will need to be carefully reviewed and prioritized, and in some cases, the analyses may have to be completed by someone outside of the SDMC.

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 products and publications, scientific rigor, and compliance with IMPAACT publications procedures, as outlined in this section. The Network chair serves as the chair of the IMPAACT Publications Review Group. Membership includes the IMPAACT Network chair and vice chairs; the SDAC principal investigator (PI) or designee; the Laboratory Center (LC) PI; Operations Center representatives; and representatives of the National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Child Health and Human Development (NICHD), and National Institute of Mental Health (NIMH); and the relevant scientific committee (SC) chair. The protocol clinical research managers (CRMs) are also included in the distribution to the Publications Review Group.

Figure 19-1. Timeline to Primary



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 analyses, and for ancillary studies, 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 <u>are the same</u>, data analyses for publications and results entry into ClinicalTrials.gov will typically be 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 <u>precedes</u> the closed to follow-up date, data analyses for results entry into ClinicalTrials.gov will typically be completed at two or more different times (first, related to data collected through the PCD, and subsequently, related to data collected through the final data collection date for each secondary outcome measure that requires a longer follow-up). Publications may also, but are not required to, be completed at the time of results entry into ClinicalTrials.gov; protocol teams should discuss plans for publications and results dissemination, ensuring consistency with protocol specifications as well as with any Study Monitoring Committee (SMC) and/or Data and Safety Monitoring Board (DSMB) recommendations.

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 should be 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 Update Statistical Analysis Plan(s)

For primary and secondary manuscripts, with input from the writing team, the statistical analysis plans (SAPs) and pharmacokinetic (PK) SAP 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 SAP.

The preparation of analysis plans for DACSs, NWCSs, and DRs will vary but the process is generally as described in Table 19-4.

19.3.3 Final Data Entry

Protocol teams should 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). Additional exceptions may be considered for laboratory data that may require additional time for shipping, testing, and/or analysis after the PCD or close 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.

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

19.3.4 Final Data Clean-Up

After all remaining data have been entered by sites, the PDM will continue 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, such as for studies with many new sites or 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 will send 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 will inform 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 will review data for completeness approximately two to four weeks prior to database freeze. If this review indicates that data necessary for any planned analysis are not being cleaned in a timely fashion, the SDMC will send a message to the clinical research site (CRS) indicating that the site must rectify this situation.

Sub-studies involving eCRFs

The data clean-up timeline for a sub-study involving electronic case report forms (eCRFs) should be the same as that for the main study so final Rave database lock for the main study will not be delayed by the sub-study. By default, sub-study analysis will follow these guidelines. If, however, it is clear that there will be resource constraints involving analysis, they should be considered during the development of the sub-study and indicated in the analysis plan. It is acceptable that sub-study analysis might not begin until after the main study analysis has been completed. Clear communication between the main and sub-study teams is essential to ensure that the sub-study team can adhere to this timeline.

Sub-studies not involving eCRFs

Data clean-up for sub-studies not involving eCRFs should be done in accordance with good documentation practices and relevant institutional policies and procedures. Once the data clean-up has been completed, however, the analysis and manuscript preparation should proceed as described below. The assay and data clean-up timeline, except for any specimen eCRFs that are cleaned according to the main study timeline, should be determined by each sub-study team.

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 will indicate 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 will cease. The date of database lock is the Study Database Closure/Database Complete Date, upon which the database will be considered complete to begin finalizing analysis.

For protocols in which the PCD precedes the closed to follow-up date, the database will not be closed until all follow-up data are entered; however, the study database snapshot date for the primary analysis will be confirmed by the PDM.

Laboratory data not entered via eCRFs

Any non-eCRF laboratory data required for the final analysis report must 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.

Limited non-eCRF laboratory data to be included as secondary components of the primary manuscript could be analyzed by the statistician for inclusion during the manuscript writing period; these data would not need to be finalized by the Study Database Closure/Database Complete Date but would need to be finalized before the start of the manuscript writing period, which begins when the applicable final analysis report is received by the writing team.

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 SAP. As described further in Section 19.3, text describing the background, study design, and other trial aspects should ideally be 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 IMPAACT 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 final primary analysis report(s), separate from secondary and other analysis reports, should be 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 study status should be updated to "participants off study & primary analysis complete" (POS/PAC) by the CRM. 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 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 this, the protocol statistician will distribute 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 will also provide 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	• Create timeline with planned dates • Create specimen shipping and testing plan for laboratory data • Check status of Material Transfer Agreements & laboratory contracts • Initiate data transfer agreements	Statistician (with PDM/LDM) LDM LC LDM
Update statistical analysis plans	Three months before anticipated PCD or closed to follow-up date (whichever comes first)	• Update the statistical analysis plans prior to initiation of final analyses (SAPs are finalized prior to opening studies to accrual; for protocols opened before this policy was implemented, the SAPs should be finalized at this point)	Protocol statistician, lead author and other writing team members
Primary completion date or closed to follow-up date (whichever comes first); final data entry period begins	Day 0	• Notify protocol team	Protocol data manager
Receipt of final analysis report by writing team	Seven months after Day 0	• Submit final primary analysis report to writing team • Notify publications coordinator that the analysis report has been transmitted	Protocol statistician

19.4 Development and Review of Publications

19.4.1 Formation of Writing Team

For primary and secondary publications, including manuscripts and abstracts, the protocol chair is responsible for designating lead authors and members, which 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 others (e.g., protocol team members, etc.) 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 19.7.

The writing team for the primary publication is typically designated when the study is approaching the PCD or closed to follow-up date (i.e., approximately four to six months before whichever date comes first); if a study is prematurely terminated such that advanced planning is not possible, the writing team will be formed as soon as possible after study closure.

The writing teams for secondary publications are typically designated within six months of receipt of the primary analysis report by the protocol chair. Specifically, 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 guidance from the IMPAACT Publications Review Group as needed, with identification of any analyses to be performed without SDMC support.

The formation of writing teams for DACSs and NWCSs will vary but the process is generally as described in Table 19-5.

19.4.2 Primary Publications

The timeline and process for development and review of primary manuscripts is outlined in Table 19-3 and described in the remainder of this section. 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). While timeline requirements are specified for primary manuscripts in Table 19-3, the procedures and responsibilities are applicable for all primary publications, including manuscripts and abstracts.

For each IMPAACT study, it is generally expected that the primary publication be submitted prior to secondary and sub-study publications, unless otherwise specified in the study protocol or otherwise approved by the IMPAACT MOG (e.g., based on the recommendation of a DSMB). However, for studies with multiple cohorts, groups, or other subsets, group-specific publications may be prepared prior to publication of any primary manuscripts. Also, publication reporting baseline findings or those reporting on the study design may also be prepared prior to the primary publications. The planned approach to publications may be described in the SAP. The protocol chair will ensure that analysis and publication of secondary or sub-study results do not interfere with the analysis or publication of the primary study results and will work closely with the CRMs to track the publication development progress and to address any concerns that may arise.

19.4.3 Secondary Publications

The timeline for analysis of secondary publications may vary based on prioritization and data availability (e.g., completion of laboratory assays). The timeline and process for development and review of secondary manuscripts are outlined in Table 19-4 and further described in this section. While timeline requirements are specified for secondary manuscripts in Table 19-4, the procedures and responsibilities are applicable for all secondary publications, including manuscripts and abstracts. Following receipt of the primary final analysis report by the protocol chair, the protocol team (or designated subset) begins developing a list of proposed secondary analyses, potential publications, and writing teams, if applicable, which is maintained by the protocol CRM with the protocol chair.

The list should include the following for each secondary publication:

- Proposed lead author and brief title and description of each publication,
- List and status of laboratory samples and assay results required for the publication, and
- Expected timeline for analysis completion, considering the steps outlined above for primary publications. As all secondary data analyses cannot proceed at the same time, preparation of secondary publications typically requires prioritization.

The lead author for each secondary publication will review the applicable SAP and work 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. Once the secondary analysis report is submitted to the writing team, the draft publication is expected to be submitted to the publications coordinator for IMPAACT review within 12 weeks of receipt of the analysis report, inclusive of eight weeks for publication development and four weeks for review by masthead authors, protocol team members, and sponsors/collaborators (unless otherwise specified in the CTA or other third-party agreement, as described for primary manuscripts). As described in Section 19.3.2, it is generally expected that secondary and sub-study publications be submitted after the results of the main study/project primary publication have been submitted. The IMPAACT review process for secondary publications is the same as for primary publications.

19.4.4 Publications from DACS and NWCS

Procedures for submission and review of DACSs and NWCSs are described in Section 15. Any publications associated with a DACS or NWCS should include standard IMPAACT acknowledgements and should include the study number(s) (e.g., IMPAACT 2010) associated with the project. The timeline and process for development and review of publications from DACSs and NWCSs are outlined in Table 19-5. The timeline for preparation of the relevant analysis report may vary depending on a number of factors, including availability of data and assay completion. However, once the analysis report is available, the expectations and procedures for publication development and review are the same as for primary and secondary publications.

19.4.5 Publication from DR

Procedures for submission and review of DRs are described in Section 15. Any publications associated with a DR should include an acknowledgement of provision of data by IMPAACT; however, the timeline and process for development and review of publications from a DR need not follow the procedures outlined in Table 19-5. Any abstracts or manuscripts resulting from a DR should be sent to the IMPAACT publications coordinator prior to journal submission for review by the IMPAACT Publications Review Group and to confirm the appropriate acknowledgements.

Table 19-3. Timeline for Development and Review of Primary 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)	Approximately four-six months before anticipated PCD or closed to follow-up date (whichever comes first)	• 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)	Protocol statistician CRM Protocol chair/lead author, CRM
Manuscript preparation begins; three-month (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 at least four weeks for review by masthead authors, writing team, protocol team (including NIH, pharmaceutical company representatives, etc.) and incorporation of comments/revisions	• Remind protocol chair/lead author of manuscript submission deadline • Oversee timely completion of manuscript and adherence to timelines • Determine number and order of masthead authors • Develop full manuscript within eight weeks • Distribute for review by team/authors/sponsor/site Investigators of Record/pharmaceutical representatives and incorporate comments within four weeks • Begin compilation of the appendix of contributors	CRM and publications coordinator Protocol chair Protocol chair/lead author and other members Protocol chair/lead author and CRM
Manuscript submission for IMPAACT review	12 weeks after analysis report provided to writing team	• Submit manuscript to publications coordinator (impaact.pubscoord@fstrf.org) indicating protocol number, primary/secondary manuscript, and to which journal the team will be submitting, if known: – 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 relevant SC chair (if applicable) for review, with notification to the protocol chair/lead author • Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements	Protocol chair/lead author Publications coordinator Publications coordinator

Table 19-3. Timeline for Development and Review of Primary 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	• Forward review comments and approval (or resubmission request) to protocol chair/lead author • 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), primary reviewer, and IMPAACT Publications Review Group chair)	Publications coordinator Protocol chair/ lead author
IMPAACT-approved primary manuscript submitted to journal	Within four weeks of IMPAACT approval	• Submit manuscript to journal and send copy to publications coordinator • 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	Protocol chair/ lead author
Acceptance for publication	Following journal submission	• Communicate outcome of submission to publications coordinator • 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: – Submit a request with the final peer-reviewed version (e.g., Microsoft Word document), all tables, figures, and supplementary information, and a copy of the signed publication agreement (or similar copyright transfer agreement) to the publications coordinator – Submit manuscript to PubMed Central via the NIHMS on behalf of the corresponding author and supply the author with an NIHMS ID – Approve the release and PubMed Central formatting of manuscript upon receipt of the email notification from NIHMS	Protocol chair/ lead author Protocol chair/ lead author Publications coordinator Protocol chair/lead author

Table 19-4. Timeline for Development and Review of Secondary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Determination of secondary analyses, secondary writing teams, prioritization, and timelines	Within six months after final primary analysis report is received by the protocol chair	• Submit list of secondary analyses specified in the protocol, newly planned analyses, and potential secondary manuscripts to the publications coordinator List should include: • Proposed lead author and brief title and description of each manuscript • List and status of laboratory samples and assay results required • Expected timeline for analysis completion, considering the steps outlined above for primary manuscripts • Where necessary, IMPAACT Publications Review Group guidance will be sought on prioritization of secondary analyses/manuscripts and/or which analyses may need to be completed without SDMC support • Monitor adherence to timelines; update as necessary	Protocol chair Protocol chair and statistician Protocol chair and CRM
Writing team formation (see Section 19.4.1)	May vary	• Form writing team	Protocol chair/lead author
Manuscript preparation begins; three-month (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 at least four weeks for review by masthead authors, writing team (including NIH, pharmaceutical company representatives, etc.), and incorporation of comments/revisions	• Remind protocol chair/lead author of manuscript submission deadline • Oversee timely completion of manuscript and adherence to timelines • Determine number and order of masthead authors • Develop full manuscript within eight weeks • Distribute for review by team/authors/sponsor and incorporate comments within four weeks • Begin compilation of the appendix of contributors	CRM or publications coordinator Protocol chair Protocol chair/lead author and other members Protocol chair/lead author and CRM

Table 19-4. Timeline for Development and Review of Secondary Manuscripts, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
Manuscript submission for IMPAACT review	12 weeks after analysis report provided to writing team	• Submit manuscript to publications coordinator (impaact.pubscoord@fstrf.org) indicating protocol number, primary/secondary manuscript, and to which journal the team will be submitting, if known: – 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)	Lead author
		• Forward manuscript to IMPAACT Publications Review Group and relevant SC chair (if applicable) for review, with notification to the lead author	Publications coordinator
		• Confirm appropriate appendix of contributors and inclusion of Network and NIH acknowledgements	Publications coordinator
See Table 19-3 for all remaining procedures (including timelines, and responsibilities): IMPAACT review complete (unless revision/resubmission required), IMPAACT-approved secondary manuscript submitted to journal, and Acceptance for publication)			

Table 19-5. Timeline for Development and Review of Manuscripts from DACSs and NWCSs, including Timetable for Writing Team Formation and Manuscript Development and Review

Event	Timeline	Procedures	Responsibilities
DACS or NWCS submitted and approved (See Section 15)	Unless otherwise determined by the protocol team and MOG, one year after protocol team confirmation of secondary analyses to be completed and published by the team	• Once the study data are openly available for use by investigators outside of the protocol team, proposals for use of data and specimens are submitted via a DACS or NWCS and reviewed as described in Section 15	Proposing investigators (may be protocol team members or investigators outside of the team)
Writing team formation	May vary	• Form writing team • Notify publications coordinator of lead author	Lead author
Manuscript preparation begins; three-month (12-week) clock starts	Upon receipt of analysis report; timeline same as specified above for primary and secondary manuscripts	• See Table 19-3	See Table 19-3
See Table 19-3 for all remaining procedures (including timelines, and responsibilities): Manuscript submission for IMPAACT review, IMPAACT review complete (unless revision/resubmission required), IMPAACT-approved secondary manuscript submitted to journal, and Acceptance for publication)			

19.5 Tracking of 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.

If the publications coordinator does not receive a final draft manuscript within 12 weeks following distribution of the final analysis report for the primary analyses by the SDMC, they will query the protocol chair and writing team for an explanation and proposed new timeline in writing. Requests for extensions must be approved by the IMPAACT Publications Review Group chair.

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 and endorsed by the Scientific Leadership Group (SLG). The new lead author will be given a reasonable amount of time to complete the manuscript.

19.6 IMPAACT Publication Review Process

Publications based on IMPAACT data must be reviewed and endorsed internally prior to journal or conference submission. Prior to submission to the publications coordinator for IMPAACT Publications Review Group review, draft publications reporting study or study-related results must receive approval by the co-authors, be shared for review by the protocol team (at minimum, the protocol chair(s), protocol statistician(s), Medical Officers MO(s), CRM(s) and, if applicable, pharmaceutical representatives), and undergo any necessary review by industry or other sponsors/collaborators as specified in the CTA, other third-party agreement, or internal processes. 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. The lead author is responsible for ensuring that all applicable reviews are completed, and approvals are obtained prior to conference submission.

Once the review and approval steps above are completed, the lead author must submit a final draft, 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 will review the submission to ensure that all applicable materials are included. The publications coordinator will submit the draft to the IMPAACT Publications Review Group, with a copy to the relevant SC chair. 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.

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.

IMPAACT Publications Review Group Timelines and Outcomes

The primary reviewer and IMPAACT Publications Review Group have ten working days from receipt of the manuscript in which to comment. 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 corresponding 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 but forfeit their right to do so after ten working days. The review will result in one of the following outcomes:

- Endorsed for journal or conference submission with or without comments for author consideration; no further review required
- Revision and re-review required with comments to be addressed as appropriate
- Disapproval

IMPAACT endorsement for submission must be obtained before the publication may be submitted to a journal or conference. If the publication is endorsed for submission with reviewer comments, the writing team will address those comments as appropriate and then proceed with preparation for submission.

If revision and resubmission is requested, a response and revised publication must be submitted by the lead author to the publications coordinator within four weeks of receipt of the review comments.

If disapproved, the publications coordinator may arrange for a discussion of potential next steps by the primary reviewer, Publication 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, in response to either a revise and resubmit or disapproval, must be agreed upon by the writing team, masthead authors, and protocol chair 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.

Review of Publications from Laboratory Projects

Manuscripts and abstracts from IMPAACT laboratory projects must undergo IMPAACT Network review as described above; 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 will serve as the primary reviewer.

19.7 Journal Submission

The final manuscript is submitted to the journal selected by the lead author in consultation with the protocol chair, and a copy is sent to the publications coordinator.

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@fstrf.org) with the agreement of the IMPAACT Network."*

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

Rejections If the manuscript is rejected, the writing team chair 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 masthead 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 should be sent to the publications coordinator for transmittal to 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, masthead authors, and the protocol team.

If the manuscript is being published in a journal that does not deposit final published articles in PubMed Central, the writing team chair should follow the Public Access Policy described in Section 19.11.

19.8 Conference Submission

The corresponding author will inform 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) within ten days of notification by the conference organizer and provide the final accepted version of the abstract.

If the abstract is accepted and the protocol team determines that a site investigator letter and/or a participant letter are needed, these will be prepared and typically distributed to participating study sites at least two days in advance of the conference presentation; however, the terms of any NIH or conference embargo will take precedence. If NIH or Network leadership determines that a press release should be issued, its development and release will follow the procedures outlined in Section 6.

If an abstract is rejected by the conference organizer and the authors decide to revise and resubmit it, it must undergo re-review by co-authors, the protocol team, and the IMPAACT Publications Review Group prior to resubmission, if substantive changes are made.

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 (at minimum the protocol chair(s), protocol statistician(s), MO(s), and CRM(s)), including NIH representatives and pharmaceutical industry and other collaborators, 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.

The accepted abstract will typically be sent by the CRM to the Investigators of Record of all participating sites at least two days before conference presentation; however, the terms of any NIH or conference embargo will take precedence.

Within two weeks of the conference presentation, the lead author should send a copy of the final materials presented to the publications coordinator for posting on the IMPAACT website.

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 2024):

"Authorship credit should be based only on:

- *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 the 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 it is ready for submission; the decision should be a reflection of individuals' intellectual contributions. The number of masthead 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 at sites that enrolled large numbers of participants or other IMPAACT investigators with specific expertise in the topic of the publication be invited to participate on the writing team early in the analysis plan development process so that they have the opportunity to meet these authorship criteria. Generally, for studies that enrolled participants from fewer than six institutions, one investigator from each institution contributing study participants may be considered for masthead authorship. For studies involving more than six institutions, institutions with high participant enrollment may have one investigator considered for masthead authorship. Site representation may also be determined based on the number of participants included in a specific sub-analysis. The address of each co-author should reflect their own site. If the protocol chair or vice chair is from a high enrolling institution and is already an author, they can place another investigator from that institution on the masthead. In cases where the large numbers of enrollees render the inclusion of a single representative from each site with high accrual infeasible, the team may consider developing an alternative plan for allowing masthead authorship by investigators from participating sites.

In instances where study work is completed or substantially conducted at one institution and a masthead author relocates to another 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 CRS to ensure that both institutions are cited in the publication.

The relative roles of each member of the writing team will be determined as soon as the writing team is formed. Any disputes regarding study authorship or position on masthead should be addressed first with the lead author and protocol chair. Decisions concerning authorship may be appealed, if necessary, to the IMPAACT Publications Review Group chair.

19.9.3 Appendix of Contributors

In addition to the authors listed on the masthead, study-related primary and secondary manuscripts must include an appendix acknowledging contributors who were not listed on the masthead. Other contributors (e.g., protocol team members who are not masthead authors, site investigators/staff) will be listed in the appendix. All participating site institutions enrolling participants will be acknowledged in the article and generally listed in order according to the number of participants enrolled. The listing will include up to four persons per participating institution, including SDAC, DMC, LC, Operations Center, sponsoring NIH institutes, and industry or other collaborators, as well as the participating sites. The listing will be compiled by the lead author, protocol team chair, and CRM. The publications coordinator will confirm that there is an appropriate appendix of contributors upon submission for IMPAACT review.

For NWCSs and DACSs, a statement acknowledging the participating CRSs 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 (i.e., 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."*

Any publications associated with a DACS, NWCS, or DR should include the IMPAACT grant acknowledgement and NIH disclaimer, as described above.

19.10.2 Other Acknowledgements

If the work represented by the publication was directly supported by other sponsors, 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 will comply with the NIH Public Access Policy. The complete information on this policy is available at the following website: https://publicaccess.nih.gov/policy.htm. The Public Access Policy requires that all manuscripts accepted for publication that are based on studies with NIH funding be submitted to the PubMed Central digital archive, where they will be available to the public. The final, peer-reviewed manuscript accepted for journal publication is the version to be submitted.

Some journals have made arrangements with the NIH to submit manuscripts accepted for publication without any further required action by the authors. The list of these journals can be reviewed at the following website: http://publicaccess.nih.gov/submit_process_journals.htm. For manuscripts submitted

to journals not on this list (not already complying with the Public Access Policy), 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 send a copy of this version of the manuscript and a copy of the signed publication agreement (or similar copyright transfer agreement) to the publications coordinator, who will submit the manuscript to PubMed Central via the NIHMS on behalf of the corresponding author and supply the author with an NIHMS ID, copying the SDMC's publications tracking group (cbar.pubs@sdac.harvard.edu). The lead author approves the release and PubMed Central formatting of the manuscript when receiving the email notification from NIHMS.

The publications coordinator will follow up with authors on the status of manuscripts that have been approved for journal submission by the IMPAACT Publications Committee and will track the progress on journal submission, submission to PubMed Central, and assignment of ID numbers.

19.12 Communications Plans and 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 (at minimum 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. Communicating interim results, prior to their publication, requires additional approval from IMPAACT leadership. Pharmaceutical representatives should be informed of this planning when there is a CTA between DAIDS and the company for the study. This determination should generally be made around the time that the final analysis report is provided to the writing team and protocol chair by SDAC or before. 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 is typically 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 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 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, including Site Investigator Summaries, Participant Letters, Lay Summaries, talking points, and question and answer documents.

19.12.2 Materials for Participant and Community Audiences

Typically, publications (e.g., manuscripts, abstracts) presenting results of a primary study analysis are accompanied by other documents reflecting the same messages as the publication in an appropriate format for participant and community audiences; these may include a Participant Letter, talking points, lay summary, or question and answer documents intended primarily for use by participating study sites to use when sharing results with key stakeholders. These documents are generally developed by the CRM(s) and reviewed by members of the protocol team; consistency within and between these supplementary documents and the final publication is confirmed prior to distribution. At minimum, the protocol chair(s), protocol statistician(s), MO(s), study community program manager, and CRM(s) should review the materials prior to distribution. These materials may also be developed for IMPAACT-related secondary abstracts or manuscripts that may have clinical relevance (i.e., may impact clinical care) to study participants and communities.

Dissemination of materials for participant and community audiences is generally expected to align with dissemination of conference abstracts to site investigators, i.e., at least one day before conference presentation. Dissemination of materials related to a manuscript publication is also expected to follow this timeline. The CRM is responsible for dissemination of the approved summary to participating study sites and team members.

Materials may be tailored to the study and sites participating in the study; however, all materials for dissemination to participants and communities should generally meet the following guidelines:

- Written as concise 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 will cover review fees and pages charges for primary and secondary manuscripts if they have been primarily funded by the Network and properly credited to the Network. 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 Publications Review Group chair.

IMPAACT will not cover Open Access costs for publishing in journals that do not require Open Access. Authors submitting a request for IMPAACT to cover Open Access costs in a journal that requires Open Access (e.g., PLOS ONE), must provide justification for submitting to this type of journal. If the publication cost is for a color figure(s), authors must provide justification for publishing in color.

Once confirmation is received that the IMPAACT Operations Center will cover the publication costs, the publications coordinator will provide 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 NWCSs and DACSs 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. In addition, the Operations Center and DMC will determine if the study qualifies for inclusion in the Specimen Repository website (https://www.specimenrepository.org). Studies meet requirements to be added to the website if the following conditions are met:

- The study informed consent forms allow for or specifically request consent for long-term storage and future testing, and
- Samples are available to be shipped or are stored at the IMPAACT specimen repositories (e.g., BRI for NIAID sites and Fisher for NICHD sites).

The Operations Center will update the DAIDS study status, as applicable.