

International Epidemiologic Databases to Evaluate AIDS (IeDEA)

PRINCIPLES AND PROCEDURES FOR MULTI-REGIONAL PROJECTS

Background

1. The International Epidemiologic Databases to Evaluate AIDS (IeDEA) is a National Institutes of Health (NIH) - funded global consortium, which was established in the year 2006 to develop seven regional data centres (four in sub-Saharan Africa) for compilation of data to address research questions in HIV/AIDS treatment and care that cannot be answered with individual cohorts (see www.iedea.org). The National Institute of Allergy and Infectious Diseases (NIAID) provides core funding supporting regional data centres and affiliated clinical sites through research cooperative agreements. The National Institute of Child Health and Development (NICHD) provides additional support to conduct paediatric research and the National Cancer Institute (NCI) to initiate cancer-related research in the IeDEA regional centres and affiliated sites.
2. In collaboration with participating sites, each regional centre is responsible for the development of a regional research agenda, the establishment of mechanisms for receiving and combining data from sites, verifying the quality of these data, harmonizing lists and definitions of variables captured, as well as for the implementation of methods for analyzing cohort data and training on data collection, processing and cleaning.
3. Multi-regional activities are an integral component of IeDEA, including the identification of research questions to be addressed in combined data sets from different regions, the definition of key information (“core data”) to be obtained across regions, the development of protocols for hypothesis testing, data collection, coding, merging and harmonization, and data analyses.

Proposing multi-regional analyses

4. Concept sheets describing multi-regional projects can be prepared by individuals and groups affiliated with one of the seven IeDEA regional centres or any clinical site, or by individuals and groups not affiliated with an IeDEA entity. A concept sheet must be proposed by a Project Primary Investigator (PI) to the Executive Committee (EC) of the IeDEA consortium (see article 8) with an EC member who will serve as IeDEA correspondent (see article 20). Multi-regional projects may involve some or all IeDEA regions, and within regions some or all sites. Multi-regional projects may require the submission of grant proposals to address specific research questions that require the gathering and use of multi-regional data, to build capacity and support networks.
5. Concept sheets (see page 7 for form) describing multi-regional projects are submitted to the IeDEA EC (see article 8) through the IeDEA Network Coordinating Center (INCC) at Vanderbilt. Individuals and groups wishing to submit grant proposals for multi-regional projects should contact the IeDEA EC in the early stages of the application.
6. Concept sheets are to include a concise description of the proposed research question, methodology and data required. Each concept sheet defines a focused research project which generally results in a single publication. Concept sheets submitted for preparing a grant application will also be reviewed by the EC. It is recognized that these proposals would be broader in scope. Within the concept sheet, the people responsible for the different steps of the project, in particular merging data and statistical analysis are identified. The concept sheet also provides a time plan and defined responsibilities for publication of results (Project PI, lead author if different, IeDEA correspondent).
7. If overlapping proposals are received and neither have been approved, the EC will discuss the overlapping issues and invite suggestions as to how they may be combined and re-submitted as one proposal, how they may be revised and re-submitted as two non-overlapping proposals, or to choose the proposal with the greatest overall merit. The authors of the overlapping concepts will be contacted and included in these discussions. If authors are developing a concept that overlaps with a previously approved concept proposal, then it is the responsibility of the authors of the new concept to contact the authors of the

previously approved concept in order to better define and delineate their study objectives (including the limits of their proposal to avoid redundancy) prior to submission to the EC. However to ensure that this issue is rarely encountered authors of concept proposals should try to submit focused concepts sheets as outlined in principle 6 above.

8. The use of leDEA data will remain restricted to the scope of the approved concept sheet and any expansion of the research would require an additional concept sheet.

Role of leDEA Executive Committee

9. The leDEA Executive Committee (EC) is composed of the PIs of the seven leDEA regional centres or their representatives and representatives of the NIH funding institutes and elects a Chair for a two-year mandate since March 2006. It oversees the overall agenda of the leDEA consortium including multi-regional projects.
10. The EC welcomes and facilitates multi-regional projects and analyses, proposed both by collaborative groups within leDEA and external investigators.
11. The EC reviews concept sheets for multi-regional projects and through consensus either approves or disapproves them.
12. The review process of multi-regional projects is co-ordinated by the Chair of the EC and supported by the INCC. Communication will be through electronic mail and conference calls. The review process of any concept sheet should not take longer than one month.

Role of regional data centers and sites

13. The leDEA regional centres PIs are responsible for consulting affiliated sites on whether or not they want to be included in multi-regional projects. Only sites that have agreed to participate are included in multi-regional projects.
14. The leDEA regional data centres are responsible for providing appropriate datasets from their region to the person responsible for the merging of the

multi-regional data in the team constituted by the project PI as specified in the concept sheet.

15. Clinical sites participating to a multi-regional project should comply with ethical requirements set by their respective leDEA regional centre.

The special case of existing collaborative groups

16. The work of the Adult and Pædiatric Antiretroviral Therapy in Lower Income Countries Collaborations (ART-LINC <http://www.art-linc.org>, KIDS-ART-LINC <http://www.rcqhc.org/kids-art-linc/>) and of the Treat Asia HIV Observational Database (TAHOD <http://www.amfar.org>) will continue within the framework of leDEA.

17. These collaborative groups will operate in close collaboration with leDEA regional centres and in accordance with the principles and procedures outlined in this document. Thus, the data for agreed analyses, based on approved concept sheets, will be provided by the leDEA regional data centres (rather than individual clinical sites).

Writing and submitting papers

18. It is expected that the results of multi-regional analyses will be published in peer-reviewed journals, with appropriate timelines.

19. The Project PI acts as the overall scientific leader and project manager. He/she is responsible from the development of the concept sheet and initial work plan to the circulation of the draft paper and its final submission to a peer-reviewed journal. The Project PI is responsible for adhering to agreed timelines, and usually acts as the first (or last) author and corresponding author on the paper, and will present accepted abstracts at conferences.

20. Each multi-regional project is assigned an leDEA correspondent. The leDEA correspondent is nominated by the leDEA EC. He/she is one the PIs of the seven leDEA regional centres or a representative. With the support of the INCC, he/she supports the process by keeping track of timelines and occasionally reminding the Project PI of relevant deadlines and milestones.

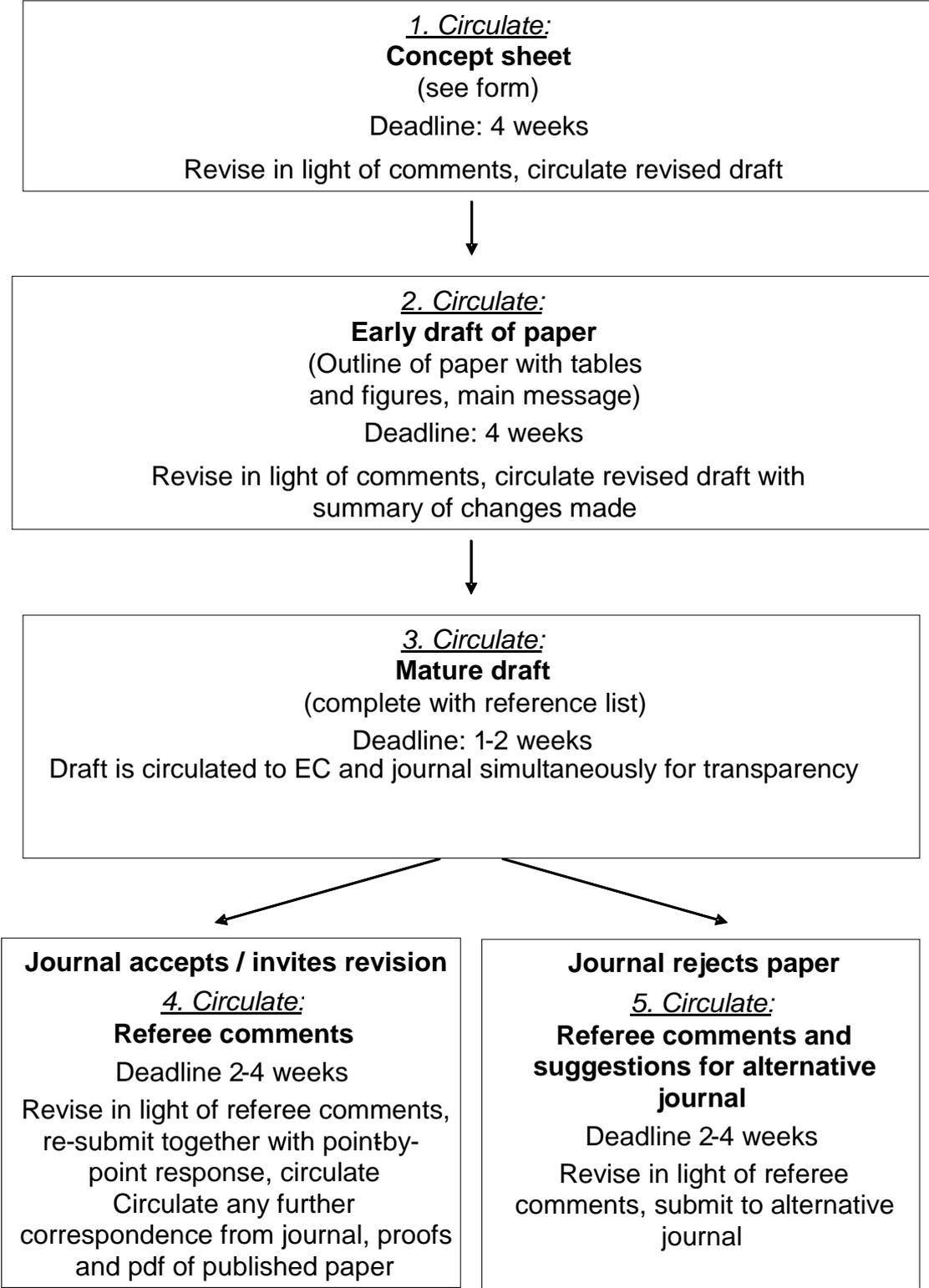
He/she supports the team in the choice of the target journal and mediates in the case of conflicts.

21. The inclusion of co-authors should be determined in line with the Uniform Requirements issued by the International Committee of Medical Journal Editors (see <http://www.icmje.org/>). The by-line should include “for the International Epidemiologic Databases to Evaluate AIDS (IeDEA)”.
22. Review and approval by the IeDEA EC is not required. The manuscript should be submitted to the EC and the journal for publication simultaneously. The intent is to keep the EC informed on the concept’s progress.
23. If the paper is published under a group authorship, the writing group should be listed in the appendix of the paper and include everyone who has made substantial contributions. The by-line should include “of the International Epidemiologic Databases to Evaluate AIDS (IeDEA)”.

Flow of information from concept sheet to publication

24. The flow of information from a multi-regional project group is summarized in the figure below. It will be assumed that participants on distribution lists who do not comment on circulated materials agree with the proposed project’s, analyses and manuscript.

Figure - Flow of information between IeDEA Executive Committee and multi-regional project: from concept sheet to publication.



International Epidemiologic Databases to Evaluate AIDS (IEDEA)

CONCEPT SHEET FOR MULTI-REGIONAL PROJECTS (to be written in English)

Title:	
Project PI:	
IeDEA correspondent:	
Collaborators:	
Data manager:	
Statistician:	
Where will data be merged?	
Where will statistical analyses be done?	
Abstract: (about 200 words)	Background and objectives Methods Anticipated results Anticipated conclusions
Outline of project (about 1000 words)	Background Objectives and hypotheses Study design Eligibility criteria Key variables and definitions Outcomes Statistical methods Sample size considerations Ethical considerations References
Funding	Requested: yes/no Possible sources of funding
Target journal:	Indicate journal and briefly explain your choice
Milestones:	Circulation of concept sheet to Executive Committee: <date> Approval of concept sheet by Executive Committee: <date> Time period for project implementation: <date> - <date> Circulation of early draft paper: <date> Circulation of mature draft paper: <date> Submission to target journal: <date>

Version date: _____