International epidemiologic Databases to Evaluate AIDS Southern Africa Collaboration (IeDEA-SA)

Principles of Collaboration

Version 3.0
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1 INTRODUCTION

The International epidemiologic Databases to Evaluate AIDS (IeDEA) Collaboration has been established to systematically review the effectiveness of antiretroviral therapy (ART) in various regions, and to compare the experience between these regions. The specific aims of the Southern African regional collaboration for the period 2011-2016 are:

1.1 To continue to provide the best available data related to the delivery of ART in children, adolescents and adults in Southern Africa, with a focus on long-term programme effectiveness and outcomes.

1.2 To describe the long-term and temporal trends in regimen durability and tolerability and to examine monitoring strategies.

1.3 To describe important co-morbidities and co-infections of HIV infection, with a focus on tuberculosis and cancer.

1.4 To explore the interface between ART and pregnancy, focussing on pregnant women on ART and cohorts of exposed non-infected infants.

This document describes the principles of the Southern Africa IeDEA collaboration. It is understood that these principles will be reviewed regularly and that this document can be modified by the Collaboration as experience accrues.

2 ROLE OF THE REGIONAL AND SUB-REGIONAL DATA CENTRES AND THE STATISTICAL SUPPORT CENTRE

There are two data centres in the IeDEA-SA collaboration: a regional data centre at the Institute of Social and Preventive Medicine (ISPM), University of Bern, Switzerland and a sub-regional data centre at the School of Public Health and Family Medicine, University of Cape Town, South Africa. The principal investigators of these data centres are Prof. Matthias Egger and Dr Mary-Ann Davies respectively. They lead the IeDEA-SA collaboration as joint principal investigators (PIs). The two PIs provide scientific oversight of the scientific agenda of the collaboration and, in the event of any conflict, both PIs are responsible for resolution.

The regional data centre at the University of Bern will be the primary administrative contact to the National Institutes of Health (NIH) for overall grant requirements and financial disbursements. Both data centres will jointly be responsible for the day-to-day data management, analyses, support of participating sites and co-ordination of scientific activities in accordance with the study protocol, with the University of Bern being the primary contact for sites outside of South Africa and UCT playing a similar role for South African sites. Key personnel in Bern and Cape Town will take the lead on different aspects of the projects. Data centre staff will communicate regularly through teleconference and email.

The statistical support centre is based at the University of California, Berkeley, USA and provides support for the development and implementation of statistical methods for the analysis of longitudinal data.

Both data centres and the statistical support centre commit to participate fully in activities of the collaboration.

3 COMMITMENT OF PARTICIPANTS

By agreeing to collaborate, participants commit themselves to supplying data of the quality and at the frequency agreed in the study protocol and to fully participate in all activities of the collaboration.

4 COMPOSITION AND ROLE OF STEERING GROUP

Collaborating sites included in the core consortium will be represented by a site investigator in the Steering Group. The Data Centres will maintain a current list of Steering Group members. The Steering Group will be responsible for providing scientific leadership to the collaboration. Concept sheets will be reviewed and approved by the Steering Group.

5 OWNERSHIP AND ANALYSIS OF DATA

Each site retains ownership of their original data and is able to analyze and submit publications on their own data. For the purposes of combined analyses as part of the collaboration, only projects that have been agreed on by the Steering Group will be presented outside of the collaboration. However, collaborators or groups of collaborators are encouraged to propose additional projects and analyses that have different aims and address new hypotheses. The process from submission of an analysis concept to publication is described in two documents, one for concepts based on Southern Africa data ('IeDEA-SA Publication Process: regional analyses') and one for multi-regional analyses ('IeDEA Multi-Regional Concepts SOP'). These documents include a standardized concept sheet template which must be used to submit data analysis proposals to the Steering Group.

6 UPDATE AND PROGRESS REPORTS

The Data Centres prepare an annual progress report for the NIH due 1 May; sites provide administrative and financial information to complete this report. The scientific section of the annual progress report to the NIH will be provided to sites by the data centres. There will be at least 2 meetings of the Steering Group during the 5-year project duration from 2011 to 2016. The two Principal Investigators co-chair these meetings.

7 ROLE OF THE SPONSORS

The sponsors of the IeDEA Collaboration are the National Institutes of Health (NIH) in the United States. A representative of the sponsoring organisation is invited to act in an ex officio capacity on the Steering Group.

8 CONFIDENTIALITY OF DATA

All data held in the IeDEA-SA database are to be kept confidential by the collaborators, members of their immediate scientific teams, and those involved directly in coordinating the collaboration. All data collected at the central level in the IeDEA-SA database will be coded first by sites. Sites will maintain the key and confirm that this key will not be shared with anyone conducting IeDEA-related analyses on the data. A Data Sharing Agreement must be signed whenever data are shared between the Data Centres and any third party. The data centres will maintain a log of datasets transmitted.

9 REMUNERATION AND FINANCIAL REPORTING

Cohorts that were included in the study protocol approved for funding by the NIH for the period July 2011 – June 2016 will receive funding as per protocol subject to annual revision of the entire study budget. This is contingent on these cohorts providing usable quality data in a timely fashion. The data centres expect to receive datasets at a minimum of every 2 years, and will provide a timetable to aid in planning data transfers.

Additional cohorts with data of usable quality wishing to participate in the collaboration will do so on an unfunded basis. Should funds become available to support the participation of unfunded cohorts, such cohorts may receive funds in one of two ways:

- through a protocol revision by agreement with the funders whereby additional funds have been secured for their participation.
- through ad hoc payment on data transfer as agreed between the Principal Investigators and the lead investigators at the site.

10 IRB APPROVAL AND REGULATORY COMPLIANCE

A condition of participating in the collaboration will be valid written approval by a local Institutional Review Board (IRB), and compliance with NIH human subjects protection and Federalwide Assurance (FWA) requirements. Participants are expected to comply with all other requirements as described in the current version of the NIH Grants Policy Statement.