

## **Central Africa leDEA**

### **Concept Proposal Standard Operating Procedures (SOP)**

**Version 5: July 2, 2024**

## 1. PURPOSE

CA-leDEA collects important data that can evaluate and inform national, regional and international HIV programs, practice, and policy, as well as future research. This document provides guidance for the development, review and approval of Concept Proposals for using CA-leDEA data.\*

## 2. SCOPE

Approval of a Concept Proposal is required for all analyses using data collected through the CA-leDEA infrastructure which are intended to result in abstracts, manuscripts, grant submissions or other research products.

## 3. PARTIES INVOLVED

- **Concept Lead:** Any CA-leDEA Investigator can lead a Concept Proposal.
- **CA-leDEA Leadership:** CA-leDEA is led by the three Multiple Principal Investigators (MPIs) (Drs. Kathryn Anastos, Denis Nash, and Marcel Yotebieng) and Country PIs or their designees (Drs. Anastase Dzudie, Cameroon; Patricia Lelo; DRC; Gad Murenzi, Rwanda; Christelle Twizere, Burundi; and Dominique Nsonde, ROC). This group votes on and approves Concept Proposals.
- **Methodological and Content Mentors:** Epidemiologists, statisticians, content experts and the data management team can support Investigators to prepare a Concept Proposal and complete the project.
- **Contextual Experts:** Investigators from each country whose data are included in the analysis will provide important contextual information.
- **Writing Team:** The writing team includes the Concept Lead, Mentors and Experts, and others who engage substantively in the project.
- **Concept Manager:** The Concept Manager moves Concept Proposals through the review and approval process, and tracks progress of approved Proposals.

## 4. DATA

Data available for analysis include:

- Patient-level data collected as part of routine service delivery at CA-leDEA sites (see [leDEA's data exchange standard](#)).
- Site-level data collected at CA-leDEA sites through the Global leDEA Site Surveys; and
- Data from "special studies" (e.g., SRN, AYANI) and linked research grants.

Investigators should review the variable lists carefully before proposing analyses.

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\* Note: Multiregional leDEA projects that use data from >2 leDEA regions have a separate approval process.

## 5. PROCEDURES

Concepts should be developed using the CA-leDEA [Concept Proposal Template](#) and following the steps below (see Figure 1).

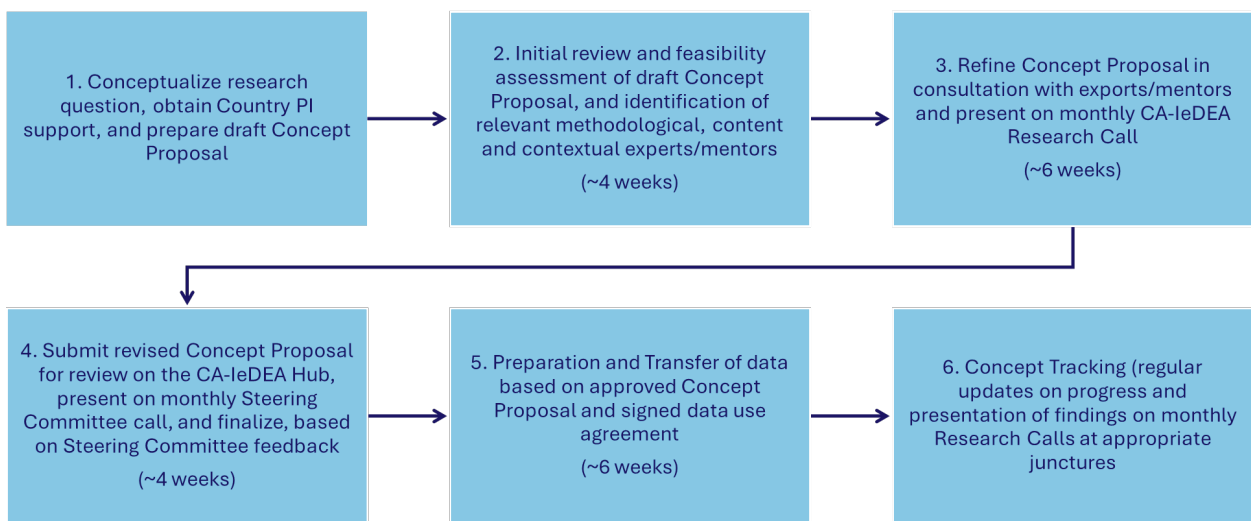
### Step 1: Investigator conceptualizes the research question, obtains PI support, and prepares draft Concept Proposal

- The Concept Lead discusses their idea with the Country PI (for in-country Investigators) or MPIs (for all other Investigators) and gets their approval of an initial draft Concept Proposal.
- The Concept Lead uploads the draft Concept Proposal to the [CA-leDEA Regional Hub](#). If support is needed to identify appropriate variables or develop the analysis plan, those sections can be left blank.

### Step 2: Initial review and feasibility assessment of Draft Concept Proposal

- Draft concepts uploaded on the CA-leDEA Hub are circulated to the MPIs and Data Management Team.
- The Data Management Team confirms that the requisite data are available and of sufficient quality for the proposed objectives. If the required data are not available or of poor quality, the Concept Proposal will be dropped.
  - *Timeframe: 2 weeks.*
- One or more MPIs will review the draft Concept Proposal and provide feedback to the Concept Lead and respective Country PI. This may include changes needed prior to circulation to the CA-leDEA Leadership Team. The MPIs will also identify methodological and content mentors, and, together with Country PIs, identify a contextual expert.
  - *Timeframe: 2 weeks.*

Figure 1. Concept Development Process



### Step 3: Concept Refinement

- The Concept Lead works with recommended mentors and experts to address the feedback provided by MPIs and Data Management Team.
- The Concept Lead presents the Concept Proposal on a Research Call to solicit input from the other CA-leDEA Investigators and to identify potential collaborators.
  - *Time frame: 4-8 weeks.*

### Step 4: Review by the CA-leDEA Leadership Team

- The Concept Lead uploads the revised Concept Proposal on the CA-leDEA Hub, with a description of changes made to address the feedback from the MPIs, the Data Management Team and the Research Call participants.
- If requested by the MPIs, the Concept Lead will present the Concept Proposal during a monthly Steering Committee call.
- Members of the Leadership Team vote<sup>†</sup> on the Concept Proposal on the CA-leDEA Hub.
  - *Timeframe: 2 weeks.*
- If approved by the Leadership Team, the Concept Lead will upload a final Concept Proposal to the CA-leDEA Hub. The final version should address any feedback received from the Leadership Team.
  - *Timeframe: 2 weeks.*

### Step 5: Data Preparation and Transfer

- The Data Management Team assigns a concept tracking number, prepares a data request and data use agreement (DUA) for signature by the Concept Lead.
- The Data Management Team prepares and transfers data to the Concept Lead or an analyst using encrypted, secure channels.
  - *Timeframe: 4-6 weeks.*

### Step 6: Concept Tracking

- The Concept Lead provides regular progress updates to the Concept Manager, including milestones to date, barriers hindering progress and timeline changes.
- If the Concept Proposal's scope changes or the writing team wants to prepare more than one abstract or manuscript, this will be discussed with the Leadership Team. An updated Concept Proposal may be requested.
- The Concept Lead shares updates and findings on CA-leDEA Research Calls at appropriate junctures (i.e., prior to presentation at conferences or while preparing manuscripts).

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<sup>†</sup> For concepts that involve data from a subset of CA-leDEA countries, only the MPIs and PIs from relevant countries will vote.