KALADRUG-R: management SOP II-b

BHU Sample database:

data management, database input & monitoring

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A. Data collection and management

1. The following information on cultures, collected samples and extracted DNA samples should be carefully recorded in the following sources by the persons handling the respective samples:

Source data	Info on cultures	Info on culture stabilates	Info on collected samples for PCR	Info on extracted DNA samples
Culture stabilate register in culture lab				
Register for samples for PCR?				
Register with information on DNA extraction?				

2. The collected data on cultures, samples and DNA will also be recorded in a central electronic database in Microsoft Access, called '**KDR_lab_BHU_db_*date*.mdb**'; in which '***date***' should be the date when the last modification of the database was entered.

3. The electronic database should be made available on only 1 computer at BHU.

B. Electronic database input

1. The electronic database will be updated on regularly basis by Vijay Kumar Prajapati using the source data described in point A. Vijay, could you appoint somebody that can help you entering data in the database, and can do some double entry checking? This person's name should be in this SOP.

2. If additional people are needed for data input, they will be trained by Vijay Kumar Prajapati on how to enter the source data in the electronic database.

C. Guidelines for entering and updating data in the sample database

1. Open database in Access.

2. A Kaladrug-R welcome screen appears, click 'click here to continue'.

3. A switchboard menu appears where you have to choose what type of sample data (VL, PKDL or asymptomatic) you want to enter <u>or</u> update.

4. **General user's guidelines to enter data**: All samples collected in 1 treatment course of a patient are registered together in 1 entry. One entry can consist of **3 yellow forms**:

- **patient and diagnosis form**: contains general patient information, diagnosis results and past/present treatments.
- **culture form**: contains all information on parasite isolation, culture and stabilates. This form is not available for asymptomatics.
- **sample from**: contains all information on samples taken for PCR analysis.

You can switch between the 3 forms by clicking the grey buttons indicating 'Go to ….. form' which you can find on each of the 3 forms to go to any other form. By switching yellow form, the information you entered is automatically saved as you exit that form.

When switching form, access will automatically filter out the 1 record you were looking at in the previous form. To remove this filter, and allow you to browse through the records, click the funnel-symbol in the tool-bar.

The fields in the yellow forms are either 'text fields' in which you freely can type information, or 'drop-down menus' which show you a list of entry options from which you have to choose. Common abbreviations used in these drop down menus are:

- **NA** = information is not available in the source data
- **NR** = information is not relevant, e.g. if patient has no VL history, than the field 'past treatment' is not relevant; or if the inoculated culture was sterile, than all fields regarding stabilates are not relevant.
- **to check** = information in source data is not clear, or not entered yet and should be checked again later.
- **'write other'** = if none of the options of the drop-down menu match your entry, you can type free text.

In general, all fields should be entered, blank fields will be assumed not to have been entered yet. If the information is simply not available (NA) or not relevant (NR), then use these short abbreviations to indicate as such. Blank fields cannot be used for data analysis!

5. To create a new entry, first fill in the ==research no.== in the yellow form titled '**patient and diagnosis form**'. The research no. is a unique KalaDrug-R number composed of '**KAM**' and a 3 digit number.

> *Examples*:

| KalaDrug-R Sample database BHU

- research numbers KAM012, KAM014, KAM57, etc....

If the patient starts a 2nd treatment during after re-admission later, then a new entry should be made for that patient with the same research number but followed by a abbreviation of the second treatment received since the date of first enrolment in Kaladrug-R.

Example:

- research number KAM476/AMB is used for patient KAM476 who starts a 2nd round of treatment with amphotericine B upon re-admission

This system allows us, in case of relapse, to trace the first sample as well as the consecutive samples of biological material collected in the same patient.

6. **Other crucial fields** in '**patient and diagnosis form**' are:

- 'Clinical information': use drop-down menus to record
  - o if patient has a VL history.
  - o which VL treatments the patient received in the past. If the type of past treatment is not in the drop-down menu or if the patient received several treatments in the past, then choose 'write other' and type in the respective past treatment(s) of that patient.
  - o chosen treatment at time of sampling, if chosen treatment is not in the drop-down list, choose 'write other' and type in the name of the treatment yourself.
  - o outcome of chosen treatment: choose option from drop-down menu.
- 'Diagnosis': use drop-down menus to record outcome diagnostic tests as reported in the Kaladrug-R laboratory register.
- 'Remarks': use this box to record any information you can't report in the given fields
- 'Subject to revision': this drop-down should be used by the people responsible for database monitoring (see point D) and be clicked on 'yes' if any field in any of the 3 forms contains unclear information. A short clarification on why the entry needs to be revised in the source data can be given in the text-box.

7. **Culture form**: ALL fields of this form are crucial here and should be filled in based on the lab records as soon as possible available, the field names of the forms match the field names of the source data registers present in the lab and specified in point A.

Carefully **register the strain names**, strain naming should be done as outlined in cSOP#E. Cultures at d0 of the treatment should have a matching numerical code as the research number; and the numerical code of the cultures started at the end of treatment should be adapted according to the time of sampling.

Example:

The culture isolated at d0 of treatment is KAM454/0 PI; then the culture isolated at end of treatment should be named KAM454/1 PI. If that patient is later re-admitted and treated with

amphotericine B, than the culture at the beginning of treatment should be labelled KAM454/AMB/0 and the culture at the end of treatment KAM454/AMB/1.

The same system should be used for the other samples (spleen, blood and filterpaper).

8. **Sample form:** ALL fields in this form are crucial and should be filled in based on the lab records as soon as possible available, the field names of the forms largely match the field names of the source data registers present in the lab and specified in point A.

Carefully **register the sample codes**, **only the common part of the sample code should be entered** at the top of the form once for each time of sampling (underneath 'At d0' and underneath 'At end of treatment').

NOTE: sample labels on sample tubes should include both the numerical code + abbr for sample type (BM, BL, FP) as per protocol cSOP#E.

9. To **update sample data** of a particular entry, you should choose 'Update….record' from the start switchboard. The first screen is again 'patient and diagnosis form'. You can search the record you wish to update by clicking the 'Find' button, this opens a classic Microsoft 'Find' window in which you can enter the research number you are looking for. Or alternatively, you use the arrow buttons always available at the bottom of each yellow form until you reach the entry you are looking for.

D. Data monitoring

1. WHO will check entered data for irregularities 1/month by randomly verifying 1/7 entries.

2. Mailing of clinical and sample access databases might proof difficult when using the standard ITM email-addresses. Hence please use the following instructions:

- Compress the database you wish to send to a zip-file, and mail it to the following gmail account:

kaladrugR@gmail.com

Usersname: kaladrugR

Password: limited use – request to sdecuypere@itg.be

- Also sent an email notifying a database has been mailed to the gmail account to Dr. Bart Ostyn, Dr. Saskia Decuypere and Manu Vanaerschot.

3. Each version of the electronic sample database received at KaladrugR@gmail.com will be saved on the ITMA server.

4. All sample entries will be revised by Saskia Decuypere or Manu Vanaerschot and if any irregularities are detected by the database monitors (FILL IN PERSON BHU/KAMRC, Saskia or Manu); then the 'revision box' of the respective irregular entiries will be ticked on 'yes' and these entries should be re-checked in the source data by Vijay.