

MEMORANDUM OF UNDERSTANDING (MoU)

BETWEEN

THE Southern African Treatment and Resistance Network (SATuRN)

AND

**COLLABORATOR (ANTIRETROVIRAL PROVISION CENTRE, CLINICAL CENTRE,
DIAGNOSTIC OR RESEARCH LABORATORY)**

MEMORANDUM OF AGREEMENT (MoU)

BETWEEN

AND ON BEHALF OF

THE SOUTHERN AFRICAN TREATMENT AND RESISTANCE NETWORK (SATuRN)

AND

.....
(COLLABORATOR)

WHEREAS the Southern African Treatment and Resistance Network (www.bioafrica.net/saturn/) (hereafter called SATuRN), is a consortium of virologists, clinicians, epidemiologists, informaticians and social scientists working on HIV treatment and care in Southern Africa. The aims of the consortium, named the Southern African Treatment and Resistance Network (SATuRN) are 1) to develop a cross-national public health and virological research collaboration 2) to develop and implement innovative means of shared data collection, management, and analysis 3) to monitor and evaluate outcomes (behavioral, clinical, epidemiologic, virological-informatics) in response to ART in resource constrained public health settings in Southern Africa. SATuRN curates and maintains two relational online databases (REGADB and Stanford HIVdb) of anonymised patient clinical and laboratory data (including drug resistance information, CD4 counts and HIV-1 plasma viral loads) through the SATuRN db (www.bioafrica.net/regadb/ and www.bioafrica.mrc.ac.za/hivdb/).

WHEREAS is a (hereafter called Collaborator), involved in the clinical and/or laboratory management of HIV infected patients and interested in contributing anonymised clinical and laboratory data (including drug resistance information, CD4 counts and HIV-1 plasma viral loads) to the SATuRN Project.

WHEREAS the parties hereby wish to enter into collaborative engagement based on their mutual interest in the analysis of drug resistance, phylogenetic or phenotypic data from the region utilizing the bioinformatics resources at SATuRN's disposal.

THEREFORE SATuRN and the **COLLABORATOR** (hereafter jointly called the Parties), agree to the following.

ARTICLE I. SATuRN undertakes to:

1. Coordinate the:
 - i. Entry of published anonymised treatment and laboratory data into the SATuRN REGAdb;
 - ii. Curation of the data entered into the SATuRN REGAdb.
2. A steering committee of collaborators will be responsible for the review of proposals for secondary analysis of pooled SATuRN data (e.g. identification of new resistance mutations, molecular epidemiology, testing new resistance algorithms and bioinformatics programs)
3. Members of the steering committee will be elected annually at the HIV Drug resistance and Clinical Practice workshop

4. Members of the steering committee will meet bi-monthly(in person and/or by conference call)
5. Design of protocols for the analysis of the pooled drug resistance data through the steering committee.
6. Provide training for the collaborators to use the SATuRN REGAdb in the monitoring of their patients and also do their own data analysis.

ARTICLE II. The Collaborator undertakes to:

1. Contribute anonymised treatment and laboratory data for the SATuRN REGAdb.
2. Partner with SATuRN in the analysis of the pooled data.
3. Attend SATuRN meetings

ARTICLE III. SATuRN REGAdbDB data types

1. Clinical; treatment related side effects, opportunistic infections
2. Treatment history; ART regimens, start dates, stop dates, reasons for switching
3. Laboratory; T Cell Profiles (CD4 Counts), Viral load, drug resistance (nucleotide sequences)
4. Limited demographic data; country, province, sex, age

ARTICLE IV. SATuRN DB Access

1. All submitted unpublished data shall only be accessed by the Collaborator using his/her registered username and password in the SATuRN REGAdb. The SATuRN shall also have access to submitted unpublished data for the process of biocuration only.
2. The Collaborator shall be able to donate unpublished data to SATuRN and provide written consent that the data can be made public. Once data is donated it shall be accessible to all SATuRN members using their registered username and password in the SATuRN REGAdb.
3. All submitted published data shall be accessible to all SATuRN members using their registered username and password in the SATuRN REGAdb. The database of published data will be linked to the Stanford HIVDB, hence the published sequences and treatment history shall also be accessed to the general public through (<http://bioafrica.mrc.ac.za/hivdb/>)

ARTICLE V. Ownership of Data

1. The collaborator retains ownership of the all unpublished data.
2. All published data will be accessible to the general public through public databases such as the Stanford HIVDB

ARTICLE V. Publication of pooled SATuRN data

1. Individual researchers who analyse the data and write the papers are first, last and corresponding authors of the paper.
2. SATuRN members who generated the data will be listed as co-authors (with upto 2 members per laboratory that produces the data.
3. Annual reports on the analysis of the pooled drug resistance data for the region shall be produced.

ARTICLE VI. MECHANISM FOR IMPLEMENTATION OF COLLABORATION

1. Dr. Tulio de Oliveira, Dr. Chris Seebregts, Prof. David Katzenstein or Prof. Lynn Morris shall be the expert representative of SATuRN and shall be responsible for the successful implementation of this collaboration.
2. Prof./Dr./Mr./Mrs./Miss..... shall be the expert representative of Collaborator and shall be responsible for the successful implementation of this collaboration.

ARTICLE VII. ENTRY INTO FORCE AND TERMINATION

1. This MoU shall enter into force on the day of the last signature.
2. The MoU shall remain in force indefinitely unless terminated earlier by either party as the case may be; however the termination shall not affect data already made public in terms of this collaborative agreement.
3. In any event, this MoU shall automatically terminate and be superseded on execution of such superseding agreements as the parties may, in due course, execute in relation to this collaboration.
4. The Party seeking to terminate the MoU other than by its natural life cycle, shall give the other party a written notice of termination of one calendar month.
5. Termination of this MoU shall not necessarily interrupt or prematurely affect the continuity of existing projects run by either Party until their logical conclusion.
6. The MoU may be amended or extended by written agreement of the parties and any Party wishing to effect any amendment, change, alteration or deletion of any provision of this MoU shall make such a request in writing one (1) calendar month prior to the expected date of implementation of the said amendment, change, alteration or deletion.

ARTICLE VIII. GENERAL

1. Confidentiality

- i. The parties understand that the SATuRN db is an anonymised DB hence **NO INDIVIDUAL PATIENT IDENTIFICATION INFORMATION** (such as **Name, surname, ID number, hospital number**, etc) shall be used in all datasets entered into the REGA DB, only sequential identification numbers are to be used.
- ii. The parties agree that all data sets submitted by the Collaborator that have not yet been published shall have access restricted to the administrator (for curation process only) and the Collaborator only and will only be made public upon publication or donation by written consent.

2. Assignment

Neither of the parties shall assign or transfer or purport to assign or transfer any of its rights or obligations under this MoU without the prior written consent of the other party.

4. Successors and Assigns

This MoU shall operate for the benefit of and shall be binding on the successors in title and permitted assigns of each party.

5. Utmost Good Faith

Without limiting the generality of the aforesaid, the parties undertake in favor of one another to observe the utmost good faith in the implementation of the provisions of this MoU and each party hereby undertakes in favor of the other party that in their dealings, with each other, it shall neither do anything nor refrain from doing anything which might prejudice or detract from the rights, assets or interests of the other party.

6. Breach

- i. If either party shall be guilty of any breach or non-observance of any of the conditions of this MoU whatsoever or shall neglect or fail to carry out any of its obligations hereto, the innocent party shall be entitled to terminate this agreement after giving the other party fourteen (14) days to rectify the breach.
- ii. The guilty party shall in this event be liable to the innocent party in full for any damages arising from the breach and for legal charges at the legal practitioners to client scale including any administrative charges.

7. Notice

Any notice to be given hereunder shall be sufficiently served by hand delivery at either party's stated address or sent by registered post addressed to it at its usual or last known postal address.

8. Governing Law

This MoU shall be governed by and construed in accordance with South African laws.

9. Resolution of Disputes

- i. In the event that a dispute or difference arises between the parties relating to the rights and obligations of the Parties under this MoU and cannot be resolved within thirty (30) days from the time it arose, the parties shall refer the matter to arbitration to be conducted by an independent party in South Africa.
- ii. The head of the said centre shall choose the arbitrator whose decision shall be final.
- iii. The said arbitrator must make his decision within thirty (30) days of his appointment.

10. Address

The parties herein choose as their address for all purpose in connection with this agreement, whether in respect of court process, notices, requests, demand, processed or any other communication or whatsoever, the following addresses or such other address as each party may notify the other in writing:-

I. SATuRN provides the following address:
Africa Centre
Durban South Africa

II. Collaborator provides the following address:
XXXXXXXX; XXXXXXXXXXX; XXXXXXXXXXX
Durban, South Africa

Any notice dispatched by pre-paid registered post to such address of the party shall be deemed to have been delivered on the expiry of the seven (7) day period following the date of posting.

11. Entire Agreement

- i. This MoU constitutes the full understanding of the parties.
- ii. No addition to, variation, or agreed cancellation of this MoU shall be of any force or effect unless executed in writing and signed by or on behalf of the parties.

THUS DONE AND SIGNED at DURBAN this day of 2011

..... Date

Dr. Tulio de Oliveira
Dr. Chris Seebregts
Prof. David Katzenstein
Prof. Lynn Morris
Principal Investigators
(For and on behalf of SATuRN)

..... Date.....

Dr. XXXXXXX
Principal Investigator
(For and on behalf of Collaborator)