

LAASER-HIV/AIDS

Activity plan 2007



Contents

	Page
Part I LAASER-HIV/AIDS Aids Fonds Activity Plan 2007	3
I.1 Workplan description	3
I.2 DRAM	4
Part II PharmAccess Studies to evaluate Resistance (PASER) Activity Plan 2007	5
II.1 Workpackage description	5
II.2 DRAM	10
II.3 Risk assessment	16
Part III Treat Asia Studies to evaluate Resistance (TASER) Activity Plan 2007	17
III.1 Workpackage description	17
III.2 DRAM	20
III.3 Risk assessment	24
Part IV International Civil Society Group (ICSS) Activity Plan 2007	25
VI.1 Workpackage description	25
VI.2 DRAM	27
VI.3 Risk assessment	30

Annexes

[PASER Activity Plan 2007 Gantt Chart](#)

[TASER Activity Plan 2007 Gantt Chart](#)

[ICSS Activity Plan 2007 Gantt Chart](#)

I. LAASER-HIV/AIDS (Aids Fonds) Activity Plan 2007

I.1. Workplan Description

Background

Expanding access to HIV treatment is critical to saving the lives of the 6.6 million people worldwide who are in immediate need of HIV treatment today. Great progress has been made since the reduction of the costs of HAART with substantial funding mechanisms now in place to provide this life-saving treatment to the poor. However, in many resource-poor countries health systems are over-burdened with the challenge of providing high-quality services that are fundamental to effective long-term HIV treatment. In the absence of a well-functioning health system, the risk of developing HIV drug resistance is imminent. Failing to limit HIV drug resistance in these settings will undermine the huge investments made in the development of medications and expansion of treatment programs, as well as potentially reverse the gains made in the fight against HIV. Countries in Africa and Asia that are now rapidly scaling-up HIV treatment programs illustrate the need for capacity building around HIV drug resistance monitoring and surveillance and other relevant issues.

To address this challenge the Aids Fonds received a 5-year grant (2006 – 2010) by the Ministry of Foreign Affairs to implement a multi-centre program titled “Building Civil Society’s Capacity to Improve Access to Treatment in Resource Poor Settings”. The Aids Fonds as the principal recipient of the grant of this program has tasked TREAT Asia, PharmAccess and the International Civil Society Support (ICSS) unit at the Aids Fonds with the implementation of the program. The program builds on the comparative advantages and strengths of these organizations that work in partnership.

Program overview

The overall aim of the program is to build capacity to strengthen and improve the quality and durability of HIV/AIDS treatment in Africa and Asia.

The ICSS unit will be responsible for developing and implementing a comprehensive Civil Society HIV/AIDS agenda that is owned and driven by Civil Society stakeholders and that supports Civil Society to strengthen their own response as well as the response of national governments and international institutions in the Global fight against HIV/AIDS.

PharmAccess and Treat Asia will implement a comprehensive program to evaluate HIV drug resistance in Asia and Africa and build capacity for HIV drug resistance testing including HIV drug-resistance surveillance of transmitted drug resistant HIV, drug resistance monitoring supported by a clinical observational database, and a laboratory quality assurance program.

The operational responsibility of the project lies with the three implementing partners, while the development and implementation of the program will be steered by a Steering Committee which is chaired by the director of the Aids Fonds and coordinated by a project manager at the Aids Fonds.

The workplan 2007 focuses on the specific tasks of the project manager at the Aids Fonds:

1. Administrative and financial management of the program
2. Reporting to the Ministry of Foreign Affairs
3. Coordinating and supporting the Steering Committee
4. Coordinating and supporting the Scientific Advisory Committee
5. Facilitating communication between all partners
6. Representing the program in external contacts and meetings
7. Supporting fund raising

I.2. DRAM

Objective	Activity	Result
Management and coordination of project implementation	<ul style="list-style-type: none"> • Develop monitoring framework, • Monitor implementation milestones, • Monitor budget • Facilitate communication between the partners and the ministry 	<p>Monitoring framework developed</p> <p>Milestones achieved or discrepancies accounted for</p> <p>Functioning work relationship between all partners and the ministry</p>
Coordination of the Steering Committee	<ul style="list-style-type: none"> • Communication • organisation • facilitation 	Bi-annual meetings and reports of the SC
Coordination of the Scientific Advisory Committee	<ul style="list-style-type: none"> • Communication, • organisation, • facilitation 	Bi-annual meetings and reports of the SAC
Preparation of the annual work plan	<ul style="list-style-type: none"> • Develop framework of work plan and • integrate individual plans 	Integrated work plan
Preparation of the annual budget	<ul style="list-style-type: none"> • Integrate individual budgets 	Integrated annual budget
Preparation of the annual report	<ul style="list-style-type: none"> • Develop framework • Integrate individual reports • 	Integrated annual report
External communication	<ul style="list-style-type: none"> • Develop and produce brochure • Develop website 	<p>Project brochure</p> <p>Project website (Aids Fonds)</p>
Project representation	<ul style="list-style-type: none"> • Develop and update presentation materials 	Participation and presentation at min. 1 international conference/meeting per year
Support for fund raising	<ul style="list-style-type: none"> • Identification and contact funding organisations 	Project presentation at one funding organisation

II. PharmAccess Studies to evaluate Resistance (PASER) Activity/work plan 2007

II.1. Work package descriptions (*workpackage A: Resistance monitoring and surveillance, B: Database monitoring system, C: Quality assurance scheme, D: ICSS roundtable*)

WP A: Resistance Monitoring and Surveillance

5 Year Objectives of the PASER Protocol

Primary Objectives

To build capacity on the monitoring and surveillance of genotypic HIVDR in African countries:

- Supporting the implementation of a monitoring program to assess the emergence of HIVDR in patients on HAART
- Conducting surveillance surveys to measure the prevalence of transmitted HIVDR in recently infected, treatment naïve HIV patients
- Establishing a quality assurance network of regional reference laboratories for HIVDR testing
- Providing training on HIVDR to medical and laboratory professionals

Secondary Objectives

- To measure the success of the ART programs to prevent or minimize HIVDR in selected geographic settings
- To measure and categorize the prevalence of transmitted HIVDR.
- To identify specific HIVDR mutations and mutational patterns.
- To study time trends.
- In contribution to the parallel public sector efforts the results will support policy makers in taking informed decisions on the first-line treatment protocols and optimal ART program practices.
- To create an international observational database on clinical factors and genotypic sequences, and to contribute to national observational databases.

5 Year Objectives for Monitoring (chapter 2 of PASER Protocol)

Primary Objectives

- I. To evaluate the prevalence of HIVDR in patients in selected clinical centers in specific geographic areas
 - a. on first-line HAART at baseline and at 12, 24, 36, 48 months after initiation
 - b. switching from first-line to second line HAART due to treatment failure, and at 12 and 24 months after initiation

Secondary Objectives

1. To evaluate the proportion of patients with virologic suppression
 - a. On first-line HAART at baseline and at 12, 24, 36 and 48 months after initiation
 - b. Switching from first-line to second-line HAART due to treatment failure, and at 12 and 24 months after initiation
2. To evaluate patterns of HIVDR mutations (in patients with HIV viral load > 1000 copies/ml)
 - a. On first-line HAART at baseline and at 12, 24, 36 and 48 months after initiation
 - b. Switching from first-line to second-line HAART due to treatment failure, and at 12 and 24 months after initiation
3. To evaluate predictors of virologic suppression and HIVDR
 - a. Individual patient predictors including history of previous exposure to ARV drugs and drug adherence
 - b. Programmatic predictors including prescribing practices, support for drug adherence, and continuity of drug supply
4. To evaluate the associations between HIV-1 subtype and patterns of HIVDR mutations

5 Year Objectives for Surveillance (chapter 3 of PASER Protocol)

Primary Objective

- I. To evaluate the prevalence of transmitted (or primary) HIVDR in treatment-naïve, recently HIV-infected individuals in selected clinical centers in specific geographic areas.

Secondary Objectives

- I. To describe mutational patterns of transmitted HIVDR
- II. To assess HIV-1 subtype distribution
- III. To study time trends in the prevalence of transmitted HIVDR, patterns of HIVDR and subtype distribution
- IV. To support health policy makers to update national guidelines for first line HAART regimens

Objectives for Monitoring and Surveillance in 2007

- i. Identify clinics to start program in 3 geographical settings in East Africa and 2 geographical settings in West Africa.
- ii. Enroll up to 400 patients (80 per geographical setting) in *PASER-M* in countries in East and West Africa.
- iii. Enroll up to 450 patients in *PASER-M* in 4 geographical settings in Southern Africa (clinics have been trained in 2006, and enrolled 250 patients).
- iv. Follow-up of 250 patients in Southern Africa in *PASER-M* of patients who have been enrolled in 2006.
- v. Genotyping and viral load testing of *PASER-M* specimen of 400 patients by Wits.
- vi. Enroll up to 270 patients in *PASER-S* in 9 geographical settings in Southern, East and West Africa.
- vii. Genotyping and viral load analysis of *PASER-S* specimen of up to 135 patients by Wits.
- viii. Continue outstanding activities from 2006 regarding *PASER-M* in Southern Africa.

Description of work**PASER-M**

In 2006 *PASER-M* started in 4 geographical settings in Southern Africa. In addition a couple of clinics in East and West Africa were identified and have been visited and selected to take part in the program. In 2007 the number of participating clinics in East and West Africa will be extended to a total of 9 geographical settings. The clinics will be selected from the network of clinics of PharmAccess based on a set of selection criteria for the resistance program. If a clinic has not yet been assessed by PharmAccess an assessment visit will be done and when found suitable an agreement between PharmAccess and the clinic will be signed.

Ethical approval will be obtained in each participating country, before start of the program. If necessary, documents will be translated into the local language.

Clinics will be upgraded with certain equipment in order to execute the protocol: Each clinic will be supplied with a computer and a bar code scanner for tracking of specimen. A -80°C freezer will be supplied to the Master Clinics in each country, provided they do not yet possess one.

A regional reference laboratory in East and West Africa will be identified and selected in collaboration with staff from the reference laboratory in South Africa (Wits). An agreement will be signed between PharmAccess and the reference labs. For each reference lab an upgrading plan will be written in collaboration with staff from Wits University.

A training for the new clinics in East and West Africa will be organised, before they start recruitment, one in English and one in French. The first group of clinics will start in the first half of 2007, and the second group in the second half of 2007. It is anticipated that the clinics in East and West Africa will enrol 400 patients in *PASER-M* in 2007. The clinics in Southern Africa started enrolment of 250 patients in 2006 and will continue enrolment of up to 450 patients. The clinics will be supported through phone contacts and regular visits by PharmAccess. The 250 patients who have been enrolled in 2006 will have their first follow-up visit in 2007.

Clinics will send their specimen for viral load and genotyping on the day of blood draw directly to the Master Clinic in their country. The Master Clinic will send the specimen to the reference lab (Wits) twice per year. In 2006 no specimen have been shipped yet. In 2007 each Master Clinic will send 2 shipments to Wits. Depending on the shipment dates it is expected that at least 50% of the specimen collected will be received by Wits and tested for viral load and genotyping.

In case the targets for 2006 were not reached, these activities will continue in the first half of 2007. Clinics which were not trained in 2006, will be invited to the training in East or West Africa, or possibly an additional training in Southern Africa will be organised.

PASER-S

In 2007 all selected clinics in 9 geographical settings will start recruitment of maximum 85 patients per geographical setting into PASER-S. Recruitment period will be 1,5 years, therefore it is expected that 30 patients per setting will be enrolled in 2007. Recruitment will be closely monitored through e-mail, phone contacts and regular visits by PharmAccess.

The specimen for PASER-S will be shipped together with those for PASER-M twice per year. Depending on the shipment dates it is expected that at least 50% of specimen will be received by Wits and tested for viral load and genotyping.

WP B: Database Monitoring System

Objectives for Database Monitoring System 2007

- i. Maintain/update the resistance-specific HMS which was developed in 2006 (patient visits, adherence tool, payment system, specimen tracking system).
- ii. Link data entered in HMS with TAHOD and international databases
- iii. Perform quality assurance assessments of PASER-M and PASER-S data
- iv. Dissemination of results to MOH of countries who started in 2006

Description of work

A resistance specific database, a specimen track and trace system, a payment system and an adherence tool were developed in 2006 and incorporated into the already existing HMS. In 2007 the resistance specific database will be maintained and improved if necessary by updating the entry screens. The specimen track and trace system will be reviewed and updated for use by the reference laboratories in East and West Africa as soon as they are capable to perform genotyping. Specimen will be shipped to Wits until the laboratories in East and West Africa are upgraded.

Data entered into HMS will be regularly linked to TAHOD and an international database.

A data management manual will be written on how to enter and clean data. Regular checks will be performed by PharmAccess on the quality of the data entry as specified in the data management manual. If relevant information is missing or data entry is incomplete the clinic will be contacted and visited if needed. These visits are part of the monitoring visits as described in Work Package A.

The MOH of each participating country will receive an annual report about the activities and results in their country. In 2007 this will be done for the countries which started in 2006. An analysis will be done on the data of the countries who started in 2006 and a report will be written and send to MOH of these countries.

WP C: Quality Assurance Scheme

Objectives for Quality Assurance Scheme 2007

- i. Set-up genotyping QC of reference lab East and West Africa with Australia (TAQAS)
- ii. Continue QC procedures Wits with TAQAS which was set up in 2006
- iii. Set-up viral load QC (IRC) of reference lab East and West Africa with UMCU
- iv. Continue viral load QC of specimen from Wits to UMCU which was set up in 2006
- v. Completion of research and development of the use of dried fluid spots and sample tankers
- vi. Quality control of specimen shipments from clinics to Master Clinic and reference lab

Description of work

The reference laboratories in East and West Africa will be supported through field visits by staff from PharmAccess and Wits. The reference laboratories will be linked to the TAQAS QC system. Staff of these laboratories will be invited to take part in the TAQAS-training and QC for genotyping specimen will be set up.

The genotyping QC system which was set up in 2006 between Wits and TAQAS will continue in 2007. Wits will continue to receive QC specimen and attend another TAQAS-training.

Viral load QC for the reference labs in East and West Africa will be set up with UMCU. UMCU will ship viral load specimen to these labs and IRC results will be collected weekly by UMCU. UMCU will produce an annual performance report. This viral load QC system was already set up in 2006 for Wits, and it will continue in 2007.

Quality control of specimen shipments from the clinics to the Master Clinic and Wits will be performed. PharmAccess will check data entered in the specimen track and trace system of the HMS. Checks will be done on whether the data has been entered correctly and whether quality of the biological samples is of sufficient standard (e.g. specimen have been shipped in time without thawing and refreezing, etc.). If needed clinics will be contacted and/or visited for correct data entry.

II.2. DRAM (Objectives, Results, Activities, Means)

Workpackage A

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Identify clinics to start program in 3 geographical settings in East Africa and 2 geographical settings in West Africa	A1. 3 geographical settings in East Africa and 2 in West Africa selected and contracted (minimum of 1 clinic per setting) (5 agreements between PharmAccess and clinics signed)	1. Select clinics in East and West Africa through visits	01/11/06	31/12/07
		2. Negotiate agreements between PharmAccess and clinics in East and West Africa	01/11/06	31/12/07
	A2. Ethical clearance in 3 geographical settings in East and 2 geographical settings in West Africa	1. Translation of EC-documents (protocol, informed consent etc.) if necessary	01/11/06	31/12/07
		2. Submission to ECs in each country	01/11/06	31/12/07
	A3. Upgrading of clinics by purchasing of necessary equipment	1. Purchase of computers and scanners for each clinic	01/04/07	31/12/07
		2. Purchase -80°C freezers for Master Clinics, if needed	01/04/07	31/12/07
	A4. Agreement between PharmAccess and reference laboratories in East and West Africa	1. Visit and select potential reference laboratories in East and West Africa	01/01/07	31/12/07
		2. Contract selected reference laboratories in East and West Africa.	01/04/07	31/12/07
	A5. Upgrading plan for regional reference laboratory in East and West Africa.	1. Visit reference labs in East and West Africa and prepare upgrading plan in collaboration with Wits.	01/01/07	31/12/07
(ii) Enroll up to 400 patients (80 per geographical setting)	A6. Key staff of clinics in East and West Africa trained	1. Organise training on resistance for key staff of clinics in East	01/01/07	31/12/07

in PASER-M in countries in East and West Africa	(list with training attendees)	Africa (3-5/clinic)		
		2. Organise training on resistance for key staff of clinics in West Africa (3-5/clinic)	01/01/07	31/12/07
	A7. 400 new patients entered in HMS	1. Monitor enrollment of 400 patients in PASER-M in East and West Africa through e-mail, phone contact and visits	01/05/07	31/12/07
(iii) Enroll up to 450 patients in PASER-M in 4 geographical settings in Southern Africa (clinics have been trained in 2006, and enrolled 250 patients).	A8. 450 new patients entered in HMS	1. Monitor enrollment of 450 patients in PASER-M in Southern Africa through e-mail, phone contact and visits.	01/01/07	31/12/07
(iv) 250 Follow-up visits in PASER-M in Southern Africa of patients who have been enrolled in 2006	A9. 250 follow-up patient visits entered in HMS	1. Monitor follow-up of 250 patients in PASER-M in Southern Africa through e-mail, phone contact and visits.	01/11/07	31/12/07
(v) Genotyping and viral load testing of PASER-M specimen of 400 patients by Wits.	A10. Track and trace report from HMS for all shipped specimen	1. Shipment of PASER-M specimen from Master Clinics to Wits.	01/05/07	31/12/07
	A11. Analysis report of 400 specimen tested for viral load and genotyping by Wits	1. Genotyping and viral load testing of 400 specimen by Wits.	01/05/07	31/12/07
(vi) Enroll up to 270 patients in PASER-S in 9 geographical settings in Southern, East and West Africa	A12. 270 patients entered in HMS	1. Monitor enrollment of 270 patients in PASER-S through e-mail, phone contact and visits.	01/01/07	31/12/07
(vii) Genotyping and viral load analysis of PASER-S specimen of up to 135 patients by Wits.	A13. Track and trace report from HMS for all shipped specimen	1. Shipment of PASER-S specimen from Master Clinics to Wits	01/05/07	31/12/07
	A14. Analysis report of 135 specimen tested for viral load and genotyping by Wits	1. Genotyping and viral load testing of 135 specimen by Wits	01/05/07	31/12/07

(viii) Continue outstanding activities regarding PASER-M in Southern Africa in 2006	A15. Key staff of clinics in Southern Africa trained	1. Organise training for staff of clinics in Southern Africa who were not trained yet in 2006	01/01/07	30/06/07
	A16. 250 new patients entered in HMS in PASER-M in Southern Africa, which were planned in 2006	1. Continue to monitor enrollment of 250 patients in PASER-M in Southern Africa in 2006 through e-mail, phone contact and visits.	01/01/07	31/12/07

Workpackage B

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Maintain/update the resistance-specific HMS which was developed in 2006 (patient visits, adherence tool, payment system, specimen tracking system)	B1. An up-to-date HMS	1. Check data-entry and improve screens if necessary.	01/01/07	31/12/07
		2. Adjust specimen track and trace system for use by reference laboratories in East and West Africa	01/01/07	31/12/07
(ii) Link data entered in HMS with TAHOD and an international database	B2. Report which shows data from HMS is linked to TAHOD and international database	1. Link data from HMS with TAHOD	01/08/07	31/12/07
		2. Link data from HMS with international database	01/08/07	31/12/07
(iii) Perform quality assurance assessments of PASER-M and PASER-S data	B3. Assure quality and consistency of data collected and stored in PASER-M and PASER-S	1. Data management manual on how to enter and clean data	01/01/07	31/12/07
		2. Regular checks on quality of data entry, if many missing / incomplete data liaise with clinic	01/01/07	31/12/07
(iv) Dissemination of 1 st year results to MOH of countries who started in 2006	B4. Annual report to MOH of participating countries who started in 2006	1. Analysis of results of 1 st year for countries who started in 2006	01/10/07	31/12/07
		2. Write report for each of the participating countries in 2006	01/10/07	31/12/07

Workpackage C

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Set-up genotyping QC of reference lab East and West Africa with Australia (TAQAS)	C1. Annual TAQAS QC report of specimen from reference labs in East and West Africa	1. Support visits by staff from Wits to reference labs in East and West Africa.	01/01/07	31/12/07
		2. Link reference labs in East and West Africa to TAQAS	01/01/07	31/07/07
		3. Participation in TAQAS-training for staff from reference labs in East and West Africa	01/01/07	31/12/07
		4. QC genotyping specimen from reference labs in East and West Africa to TAQAS	01/01/07	31/12/07
(ii) Continue QC procedures Wits with TAQAS which was set up in 2006	C2. Annual TAQAS QC report of specimen from Wits	1. Participation in TAQAS-training for staff from Wits	01/01/07	31/12/07
		2. QC genotyping specimen from Wits to TAQAS	01/01/07	31/12/07
(iii) Set-up viral load QC (IRC) of reference lab East and West Africa with UMCU	C3. Annual performance report of specimen from reference labs in East and West Africa	1. Shipment of viral load specimen UMCU to reference labs in East and West Africa	01/07/07	31/12/07
(iv) Continue viral load QC of specimen from Wits to UMCU which was set up in 2006	C4. Annual performance report of specimen from Wits	1. Shipment of viral load specimen UMCU to Wits	01/01/07	31/12/07
(v) Completion of research and development of the use of dried fluid spots and sample tankers	C5. Report on research activities dried fluid spots and sample tankers	1. Continue research activities on dried fluid spots with UMCU which started in 2006	01/01/07	31/12/07
		2. Continue research activities on sample tankers with Wits which started in 2006	01/01/07	31/12/07
(vi) Quality control of specimen shipments	C6. Report from track and trace	1. Regular checks by PharmAccess staff on	01/01/07	31/12/07

from clinics	system in HMS	specimen track and trace system in HMS		
		2. Follow-up on quality of specimen shipment data (data-entry as well as quality of data in track and trace system of HMS) with clinics through phone contacts, e-mail and visits.	01/01/07	31/12/07

II.3. Risk assessment and contingency plan

Main risks

Activities from 2006 not completed yet and therefore the patient numbers and number of participating clinics mentioned in Activity Plan 2007 is too ambitious. Possible reasons for delay in completion of activities:

- Not to be able to obtain ethical clearance
- Not to be able to enter a sufficient number of patients
- Not to be able to have a good follow up of the patients
- Unforeseen political unstable situation in a specific country
- Not to be able to raise 1/3 of the external funding

Risk mitigation

- Involving local partners to obtain ethical clearance
- To select extra clinics in a specific geographical setting to be able to increase numbers
- To improve counselling methods, adherence methods
- To motivate clinics to link up with VCT centers for referral to surveillance program

Contingency plan

- To involve different countries to participate in the project
- To involve a number of extra clinics
- If external funding not raised, number of participating clinics and number of patients need to be downscaled

III. TREAT Asia Studies to Evaluate Resistance (TASER) Work Plan 2007

III.1. Work plan descriptions (*A: Resistance Monitoring & Surveillance; B: Database monitoring system; C: Quality assurance scheme; D: ICSS roundtable*)

TASER Work Plan A: Resistance Monitoring and Surveillance

Five Year Objectives of TASER Project

(i) Primary Objectives

- (a) To build capacity for surveillance and monitoring of HIV drug resistance (HIVDR) in South, East, and Southeast Asia; and
- (b) To evaluate HIVDR in selected TREAT Asia centres in South, East, and Southeast Asia.

(ii) Secondary Objectives

- (a) To assess prevalence of HIVDR in recently-infected treatment-naïve individuals in selected TREAT Asia centres; and
- (b) To assess prevalence and incidence of HIVDR in individuals initiating first-line antiretroviral therapy (ART) or switching to second-line ART regimens in selected TREAT Asia centres.

Five Year Objectives of TASER-Monitoring Protocol

(i) Primary Objectives

- (a) To assess prevalence of HIVDR in individuals initiating first-line ART, and incidence of HIVDR at 12 months after ART initiation; and
- (b) To assess prevalence and incidence of HIVDR in individuals switching from first-line ART to second-line ART for lack of effectiveness.

(ii) Secondary Objectives

- (a) To assess prevalence and incidence of HIVDR in individuals initiating first-line ART at 24, 36, and 48 months after ART initiation and before stopping ART or switching to second-line ART;
- (b) To evaluate patterns of HIV mutations in individuals initiating first-line ART;
- (c) To evaluate patterns of HIV mutation in individuals switching from first-line ART to second-line ART due to lack of effectiveness;
- (d) To determine frequency of virologic suppression at 12 and 24 months after ART initiation among individuals taking first-line ART;
- (e) To determine frequency of virologic suppression at 12 and 24 months among individuals switching from first-line ART to second-line ART regimen due to lack of effectiveness; and
- (f) To evaluate individual predictors of virologic suppression.

Five Year Objectives of TASER-Surveillance Protocol

(i) Primary Objective

- (a) To assess the prevalence of transmitted HIVDR in treatment-naïve, recently HIV-infected individuals in selected TREAT Asia centres.

2007 Programmatic Objectives for TASER Project

- (i) Continue participant enrollment and follow-up in TASER-Monitoring study (target enrollment for 2007 is 400);
- (ii) Continue participant enrollment in TASER-Surveillance study (target enrolment for 2007 is 1040);
- (iii) Achieve ongoing participation of 13 TREAT Asia centres in TASER protocols by 2007 year end;
- (iv) Conduct TASER investigators' training meeting, and determine additional follow-up training needs, if any; and
- (v) Identify two additional TREAT Asia centres to participate in TASER studies in 2008.

Description of work

Participant enrollment will continue for TASER-M and TASER-S studies throughout the calendar year 2007. TREAT Asia centres participating in TASER-M and TASER-S protocols in 2006 will continue participation in 2007. Two additional centres will be added, bringing the total number of TREAT Asia centres participating in 2007 to 13.

A TASER investigator's training meeting will take place in conjunction with the 7th annual TREAT Asia Network meeting in 2007. TREAT Asia staff will determine the need, if any, for additional training and plan subsequent activities accordingly.

TREAT Asia staff will contact and visit additional clinical centres and HIV genotyping laboratories in order to identify two additional clinical centres to commence participation in TASER studies in 2008.

TASER Work Plan B: Database Monitoring System

2007 Programmatic Objectives for Database Monitoring System

- (i) Maintain TASER-Monitoring and TASER-Surveillance databases;
- (ii) Transfer TASER-Monitoring and TASER-Surveillance data to NCHECR;
- (iii) Perform quality assurance assessments of TASER-Monitoring and TASER-Surveillance data; and
- (iv) Transfer TASER-Monitoring and TASER-Surveillance data into SPREAD database.

Description of work

The National Centre in HIV Epidemiology and Clinical Research (NCHECR) at the University of New South Wales in Sydney, Australia will house and maintain the TASER-Monitoring and TASER-Surveillance databases. Data management for TASER, including data collection, submission and storage will utilize the same mechanisms that are already in place for the TREAT Asia Observational Database (TAHOD) housed at NCHECR. TASER participating centres will submit TASER-Monitoring and TASER-Surveillance data electronically to NCHECR no less than twice annually (March and September).

NCHECR will perform ongoing data quality assurance checks. Data quality will be assured through two mechanisms: (1) computer consistency checks after each data transfer will be used to identify internal data inconsistencies or suspect data values; and (2) annual random internal monitoring of submitted data against participant medical records for 10% of participants from each TREAT Asia centre.

As a component of the Linking Asian and African Societies to Evaluate Resistance (LAASER) project, TASER data will also be housed in the SPREAD database. NCHECR will transfer TASER-Monitoring and TASER-Surveillance data directly into the SPREAD database.

TASER Work Plan C: Quality Assurance Scheme

Five Year Objectives of TREAT Asia Quality Assurance Scheme (TAQAS)

To establish an external laboratory quality assurance scheme using samples derived from B and non-B clade isolates of HIV-1 to determine:

- (i) consistency of sequence data from plasma viral RNA, specifically nucleic acid, amino acids and subtype;
- (ii) detection of putative drug resistance mutations in plasma viral RNA consensus sequences from within B and non-B subtypes;
- (iii) identification of technical factors critical for obtaining optimal cDNA sequence results;
- (iv) participating laboratory performance;
- (v) ability of participating laboratories to detect evolving mixtures.

2007 Programmatic Objectives for Quality Assurance Scheme (TAQAS)

- (i) Continue TAQAS program by conducting two rounds of quality assurance testing in participating laboratories during 2007;
- (ii) Provide results and feedback on quality assurance testing to participating laboratories;
- (iii) Conduct one training meeting for participating laboratory personnel;
- (iv) Identify no less than two additional HIV genotyping laboratories to participate in TAQAS program.

Description of work

Two rounds of HIV genotypic resistance quality assurance (QA) testing are planned for 2007 (May and October). Results will be distributed to all participating laboratories in a blinded manner.

A second annual TAQAS training for participating laboratory personnel will be planned for July 2007.

Dried blood spot (DBS) samples may be integrated into the QA testing program during 2007 as laboratories develop the skills to extract DNA from DBS samples.

TREAT Asia staff will work to identify additional HIV genotypic resistance testing laboratories to join TAQAS in 2007 and 2008.

III.2. DRAM (*Objectives, Results, Activities, Means*)

Gantt Chart Planning and Monitoring Matrix 2007

TASER Work Plan A: Resistance Monitoring and Surveillance

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Continue participant enrollment and follow-up in TASER-M study	400 additional participants enrolled and baseline and follow-up data collected for TASER-M study.	1. Obtain initial ethical committee review and approval for each new participating centre. 2. Centres to identify and screen potential TASER-M participants.	1. 01/01/07 2. 01/01/07	1. 31/12/07 2. 31/12/07
(ii) Continue participant enrollment in TASER-S study	1040 additional participants enrolled for TASER-S study.	1. Obtain initial ethical committee review and approval for each new participating centre. 2. Centres identify and screen potential TASER-S participants.	1. 01/01/07 2. 01/01/07	1. 31/12/07 2. 31/12/07
(iii) Achieve ongoing participation of 13 TREAT Asia centres in TASER protocols by 2007 year end.	13 TREAT Asia centres participating in TASER protocols by year end; Participant enrollment, follow-up and data collection for TASER protocols underway at all sites.	1. Assess performance of TASER participating centres based on participant enrollment and data quality. 2. Execute grant contracts/renewals with participating centres. 3. Obtain ethical committee renewal for each existing center	1. 01/01/07 2. 01/08/07 3. 01/08/07	1. 31/12/07 2. 31/12/07 3. 31/12/07
(iv) Conduct TASER investigators' training meeting, and determine additional follow-up training needs, if any.	Key research staff trained and/or provided in-depth update on implementing and conducting TASER protocols. Additional training needs identified, if any.	1. Organize meeting, including identifying curricula/content and presenters/trainers. 2. Invite participants and arrange all logistics for transportation and lodging. 3. Conduct training meeting. 4. Identify additional training needs, if any.	1. 01/05/07 2. 01/05/07 3. 01/07/07 4. 01/07/07	1. 30/09/07 2. 30/09/07 3. 31/10/07 4. 31/10/07
(v) Identify two additional centres to commence participation in TASER studies in	Number of TREAT Asia centres participating in TASER studies increased to 15 in	1. TREAT Asia staff contact and visit additional clinical centres and HIV genotyping	1. 01/01/07 2. 01/08/07	1. 31/12/07 2. 31/12/07

Objectives	Results	Key Activities	Start	End
2008	2008.	laboratories. 2. Identify two additional clinical centres with required capabilities to participate in TASER protocols. 3. Negotiate grant contracts with participating centres. 4. Obtain ethical committee approvals for each new clinical center.	3. 01/08/07 4. 01/08/07	3. 31/12/07 4. 31/12/07

TASER Work Plan B: Database Monitoring System

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Maintain TASER-M and TASER-S databases	Ongoing maintenance of functional databases for TASER-M and TASER-S studies.	NCHECR maintains TASER-M and TASER-S databases.	01/01/07	31/12/07
(ii) Transfer TASER-M and TASER-S data to NCHECR	All TASER-M and TASER-S data housed in central database at NCHECR.	Data transferred every month from TASER centres to NCHECR.	01/01/07	31/12/07
(iii) Perform quality assurance assessments of TASER-M and TASER-S data	Assure quality and consistency of data collected and stored in TASER-M and TASER-S databases.	<ol style="list-style-type: none"> 1. NCHECR conducts computer consistency checks within TASER databases 2. NCHECR oversees conduct of random internal data monitoring by participating TASER centres 3. Annual TASER-M and TASER-S Data Quality Assurance Reports 	<ol style="list-style-type: none"> 1. 01/01/07 2. 01/04/07 3. 01/06/07 	<ol style="list-style-type: none"> 1. 31/12/07 2. 31/05/07 3. 31/07/07
(iv) Transfer TASER-M and TASER-S data into SPREAD database	LAASER database (linking TASER and PASER data) housed at SPEAD.	NCHECR electronically transfers TASER-M and TASER-S data into SPREAD	01/01/07	31/12/07

TASER Work Plan C: TREAT Asia Quality Assurance Scheme (TAQAS)

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Identify no less than two HIV genotyping laboratories to participate in TAQAS program	Provide TASER-participating centres access to quality assured HIV genotypic resistance testing laboratories.	<ol style="list-style-type: none"> 1. Identify laboratories with HIV genotypic resistance testing capabilities and ability to work with TREAT Asia centres. 2. Reach agreement with laboratories to participate in TAQAS program. 	<ol style="list-style-type: none"> 1. 01/01/07 2. 01/01/07 	<ol style="list-style-type: none"> 1. 31/12/07 2. 31/12/07
(ii) Implement TAQAS program by conducting two	Initiate HIV genotype resistance testing	1. Ship five test samples from NSRL to each participating	01/04/07 (QA#1) 01/10/07	30/04/07 (QA#1) 31/10/07

Objectives	Results	Key Activities	Start	End
rounds of quality assurance testing in all participating laboratories	quality assurance measures for TASER studies.	laboratory. 2. Laboratories process test samples and report results to NCHECR.	(QA#2) 01/04/07 (QA#1) 01/10/07 (QA#2)	(QA#2) 31/05/07 (QA#1) 30/11/07 (QA#2)
(iii) Provide results and feedback on quality assurance testing to participating laboratories	QA outcomes shared with TAQAS-participating laboratories.	1. NCHECR to analyze results and compare to reference laboratory results (Stanford University). 2. Results reported to participating laboratories. 3. TAQAS laboratories to review results and identify problems and develop solutions to problems.	01/06/07 (QA#1) 01/12/07 (QA#2) 01/07/07 (QA#1) 01/01/08 (QA#2) 01/07/07	30/06/07 (QA#1) 31/12/07 (QA#2) 31/07/07 (QA#1) 31/01/08 (QA#2) 31/12/07
(iv) Conduct one training meeting for participating laboratory personnel	Improve laboratory performance for HIV genotypic resistance testing to acceptable level for participation in TASER (identify $\geq 90\%$ of resistance mutations).	1. Organize meeting, including identifying curricula/content and presenters/trainers. 2. Invite participants and arrange all logistics for transportation and lodging. 3. Conduct training meeting.	1. 01/05/07 2. 01/05/07 3. 01/07/07	1. 30/09/07 2. 30/09/07 3. 31/10/07

III.3. Risk assessment and contingency plan

Main risks

- (i) Inability of TREAT Asia staff to identify a sufficient number of new clinical centres with capabilities to conduct TASER studies;
- (ii) Inability of TASER clinical centres to enroll sufficient numbers of participants;
- (iii) Inability of TREAT Asia centres to maintain adequate follow-up of TASER-M participants;
- (iv) TAQAS-participating laboratories reporting inaccurate HIV genotypic resistance results;
- (v) Inability of staff to identify new laboratories with HIV genotypic resistance testing capabilities and ability to work with TREAT Asia centres;

Risk mitigation

- (i) Approximately 20% of the 3,150 participants currently enrolled in the TREAT Asia Observational Database (TAHOD) are treatment-naïve and will serve as a pool of potential TASER-M participants
- (ii) Work with governments and other NGOs in South, East, and Southeast Asia region to build relationships and identify additional clinical centres and (iii) Encourage TREAT Asia centres to work with other local HIV/AIDS care and prevention centres to assist in identifying potential study participants;
- (iv) Provide TREAT Asia centres with frequent TASER data reports so that centres can correct participant enrollment and follow-up inadequacies;
- (v) Provide an Internet-based forum for TAQAS-participating laboratory staff to interact, provide and receive advice, and continually improve quality of HIV genotypic resistance testing results.

Contingency plan

- (i) To identify and include additional clinical centres located in areas with high concentrations of high-risk populations (i.e., IDU, MSM, commercial sex workers) and targeting those individuals.

IV. ICSS Activity/Work Plan 2007

IV.I. Work package descriptions (D: ICSS Roundtable Process)

WP D: ICSS Roundtable Process

Five Year Objectives

Provide the opportunity for Civil Society (CS) stakeholders to enhance and improve their role as key actor in (global) efforts to scale up access to quality HIV treatment and care through facilitation of:

- a. In-depth exchange of knowledge and experience around issues linked to real needs (As (to be) identified by RTSC and stakeholders).
- b. Effective (and continued) collaboration among CS organizations and other stakeholders.
- c. Systematic efforts towards specific shared goals.

Objectives 2007

Primary objectives:

- a. Organize Roundtable meetings 4, 5 & 6.
- b. Develop governance structure(s) to involve (representatives of) stakeholders (of (international) CS organizations, including community representatives) to inform and advise the project process and support the project coordination (involving at least five partner organizations).
- c. Develop communications structure(s) to involve and inform partners in/of the process and support the over all project.
- d. Identify themes to be addressed during 2008 Roundtable meetings (at least three by Roundtable meeting 6).
- e. Mobilize resources in addition to the existing budget for activities as outcomes of the Roundtable meetings (Five funding proposals successfully submitted by December 2007).

Secondary objectives:

- a. Develop/Adapt governance and communication structures as the process evolves and as needs change.
- b. Develop/Adapt governance and communication structures as the process evolves and as needs change.
- c. Involve additional (to be identified) partners (e.g. networks of Men-who-have-Sex-with-Men (MSM), Commercial Sex Workers (CSW)) to ensure thematic linkages and association to national target settings (five to ten), who include the RTP in their work plans.
- d. Ensure capacity of networks to be participate in the project and assist in capacity building where relevant and possible. (Measured by additional funding being available at partner organizations)
- e. Develop follow-up activities to outcomes of and other activities supporting the Roundtable meetings (website, toolkits, pilot studies/projects, working sessions, etc.), where necessary or relevant. (Five organizations to incorporate RTP related activities in their work plans)

Description of work

Based on the input provided through the 2006 Survey and Inaugural meeting, the ICSS team will facilitate the process to organise thematic Roundtable Meetings and, where possible and relevant, will (assist to) coordinate follow-up activities.

The follow-up activities will be developed depending on then outcomes of the Roundtable meetings and will make impact of the RTP process at the partner level more concrete.

As partner-level involvement becomes more clear after the initial Roundtable meetings and follow-up activities, more concrete and measurable indicators for partner-level involvement and impact will be developed.

The governance and communications structures will be developed as the project evolves and as concrete needs become more evident.

The three Roundtable meetings scheduled for 2007 will be organised, in close collaboration with the group of stakeholders (involving at least five partner organizations), i.e. taking into account involvement of (communities of) people living with HIV, regional balance and gender balance. (Ensuring involvement of 25% of participants of the Roundtable meetings to be PLHIV and 50% women). Exact timing of meetings will depend on needs of the partner organisations, other events, etc.

The ICSS team will also work on further development of the ideas to create “space for free thinking”, as assessed though the 2006 survey and discussions at inaugural meeting. For these activities, a separate activity plan, budget and resource mobilization strategy will be developed in 2007. 50% of this budget should be secured by the beginning of 2008.

Activities will be developed in connection with existing, ongoing processes, national target settings and (assist to) build the capacities of these existing structures where relevant and possible.

IV.2. DRAM (D: ICSS Roundtable Process)

WP D: ICSS Roundtable Process

Primary Objectives (D.I)	Results	Key Activities	Start	End
a. Organize Roundtable meetings 4, 5 & 6	Roundtable meetings 4, 5 & 6 organized	D.I.a.1 Roundtable meeting 4	February 2007	February 2007
		D.I.a.2 Roundtable meeting 5	June 2007	June 2007
		D.I.a.3 Roundtable meeting 6	November 2007	November 2007
b. Develop governance structure(s) to involve stakeholders to inform and advise the project process and support the project coordination	(In)formal governance structure established, composed of representatives from the larger group of stakeholders, committed to providing guidance and input to the project	D.I.b.1 Periodic teleconferences among 5 partners	January 2007	January 2008
		D.I.b.2 One physical meeting of partners in governance structure	June 2007	June 2007
c. Develop communications structure(s) to involve and inform partners in/of the process and support the over all project	Communications structure and/or strategy in place	D.I.c.1 Develop interactive website	January 2007	March 2007
		D.I.c.2 Send out periodic communiqués to inform partners	January 2007	January 2008
d. Identify themes to be addressed during 2008 Roundtable meetings	At least three themes identified for the three 2008 Roundtable meetings by November 2007	D.I.d.1 Extend 2006 survey and use other scheduled activities to inform objective	October 2007	November 2007

e. Mobilize resources in addition to the existing budget for activities as outcomes of the Roundtable meetings	Funding in place for follow-up activities	D.I.e.1 Develop Resource mobilization strategy D.I.e.2 Identify potential donors D.I.e.3 Proposal writing & follow-up	March 2007 March 2007 March 2007	January 2008 January 2008 January 2008
Secondary Objectives (D.II)	Results	Key Activities	Start	End
a. Develop/Adapt governance structure as the process evolves and as needs change	Effective governance structure in place, adapted to needs of partners	D.II.a.1 Consult five-ten partners on needs D.II.a.2 Propose & implement governance structure D.II.a.3 Evaluate governance structure	January 2007 February 2007 October 2007	February 2007 March 2007 November 2007
b. Develop/Adapt communication structures as the process evolves and as needs change	Effective communications structures in place, adapted to needs of partners	D.II.b.1 Consult five-ten partners on needs D.II.b.2 Propose & implement communications structure D.II.b.3 Evaluate communications structure	January 2007 February 2007 October 2007	February 2007 March 2007 November 2007
c. Involve additional partners to ensure thematic linkages and association to national target settings	Relevant partners involved (five to ten), who include the RTP in their work plans	D.II.c.1 Consult five-ten partners, per theme to identify other networks/organisations D.II.c.2 Involve relevant organisations	January 2007 March 2007	February 2007 January 2008

<p>d. Ensure capacity of networks/ partner organizations to participate in the project and assist in capacity building</p>	<p>Sufficient capacity at participating partner organizations (measured by additional funding being available at partner organizations)</p>	<p>D.II.d.1 Identify needs at partner organizations (min. five) D.II.d.2 Develop strategy to assist in capacity building; including development of resource mobilization strategy</p>	<p>February 2007 February 2007</p>	<p>April 2007 April 2007</p>
<p>e. Develop follow-up activities to outcomes of and other activities supporting the Roundtable meetings</p>	<p>Follow-up activities developed, including activities by partner organizations (five organizations to incorporate RTP related activities in their work plans)</p>	<p>D.II.e.1 [Concrete activities depending on outcomes of RT meetings]</p>	<p>March 2007</p>	<p>January 2008</p>

IV.3. Risk assessment and contingency plan (*D: ICSS Roundtable Process*)

WP D: ICSS Roundtable Process

Main risks

1. No effective participation by relevant partners, due to lack of capacity at partner organization's level.
2. Missing linkages with existing, ongoing processes.
3. Unable to provide desired follow-up activities as/for outcomes of Roundtable meetings.

Risk mitigation

1. Assist in capacity building at partner organizations.
2. Seek cooperation and coordination with all relevant initiatives, e.g. the Three Ones, GFATM, African CS Network, etc.
3. Develop resource mobilization strategies and involve donor community early on.

Contingency plan

1. To involve as many relevant partner organizations, including national, international and thematic networks, to ensure both inclusion of vulnerable/target populations.
2. Attach RTP to other, existing processes and initiatives, to ensure continuation and over all support.