

Linking African and Asian Societies for an enhanced response to HIV/AIDS (LAASER-HIV/AIDS program)

Work plan 2008

Therapeutics Research • Education • AIDS Training

TREATASIA

International Civil Society Support

PharmAccess
INTERNATIONAL



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I. LAASER-HIV/AIDS program - Aids Fonds work plan 2008

I.1 Introduction

The Aids Fonds received a 5-year grant (2006 – 2010) by the Ministry of Foreign Affairs to implement a multi-centre program titled "Linking African and Asian Societies for an enhanced response to HIV/AIDS (LAASER-HIV/AIDS)". The LAASER-HIV/AIDS program aims to build a clinical and laboratory network of HIV drug resistance monitoring and surveillance sites in Africa and Asia. Thus, capacity is built for an early warning system for the emergence of HAART resistance in a large number of resource-poor countries both in Asia and Africa. With the aim of linking this program to international groups and networks focused on scaling up access to quality HIV treatment and care, the program further includes a networking and learning forum for civil society organisations.

As the principal recipient of the grant of this program, the Aids Fonds has tasked TREAT Asia, PharmAccess and the International Civil Society Support (ICSS) unit with the implementation of the program.

PharmAccess is implementing the HIV drug resistance monitoring and surveillance study program in Africa. TREAT Asia, supported by the American Foundation for AIDS Research (AmFAR), is performing the work in parallel across Asia and the Pacific Region. The African patient cohort to monitor HIV drug resistance will comprise up to 3000 patients, while the Asian cohort aims to include up to 4000 patients over the five-year period. The surveillance component of the program is implemented by conducting a number of threshold surveys to assess first-line HAART resistance in selected treatment sites.

Bridging the gap to policy makers, ICSS is responsible for coordinating roundtable discussions that serve to provide opportunities for systematic learning and cooperation for civil society organisations that are active in the field of access to HIV/AIDS care and treatment.

The Aids Fonds is responsible for the coordination and monitoring of the LAASER program, with the following specific responsibilities:

1. Oversight of the appropriate implementation of the program,
2. Sound financial management and accountability to the Ministry of Foreign Affairs

I.2 Strategic aims for 2008

The LAASER program is currently entering its second year of implementation (program start: May 2006). While a lot has been achieved by all partners during the first year, all three implementing partners were unable to achieve the milestones and objectives as defined in their respective activity plans for 2006 and 2007. A significant part of the budget was not spent. One of the main program management goals for the Aids Fonds in 2008 will therefore be to further strengthen the planning and steering procedures of the program.

This will be achieved by:

- Enhancing project management skills among the partners (continuous monitoring, variance analysis, risk analysis, problem analysis)
- Synchronizing the monitoring procedures of each partner organisations
- Fine-tuning the reporting requirements
- Strengthening internal communication
- Introducing change management procedures

These procedures will support partners in more realistic planning, based on continuous monitoring linked to profound analyses. Furthermore, the procedures will enhance the ability to initiate adequate corrective measures in a timely manner and submit change requests accordingly.

The 2008 work plan describes the activities of the Aids Fonds program coordinator in 2007.

I.3 Work plan Description (DRAM)

Objective	Activity	Result
1. Program management improved/strengthened	<p>Facilitate program planning workshops including all partners 1-2 times per year</p> <p>Facilitate continuous monitoring of key indicators</p> <p>Facilitate change request management</p> <p>Conduct 2 site visits per year</p> <p>Review partner annual reports</p> <p>Review partner annual activity plans</p>	<p>All M&E indicators monitored, documented, and communicated continuously by all program partners as agreed upon</p> <p>Milestone plans monitored regularly by the SC</p> <p>Risk and problem analysis procedures implemented by all partners</p> <p>Procedure for change request implemented by all partners</p> <p>Comprehensive and informative reports available to the Aids Fonds according to an agreed schedule</p>
2. Program reporting to the Ministry of Foreign Affairs strengthened	<p>Prepare and submit LAASER annual report and activity plan</p> <p>Regular telephone calls to update BUZA and synchronize activities</p> <p>At least 2 physical meetings between the program coordinator and BUZA per year</p>	<p>Reporting and information requirements are met to the satisfaction of the Ministry of Foreign Affairs</p>
3. Internal program communication improved	<p>Develop binding communication plan</p> <p>Communicate meeting and phone memo's with key messages from BUZA to program partners</p>	<p>Partners communicate according to the agreed plan and schedule</p> <p>Program partners are informed and up-dated on BUZA standpoints and comments</p>
4. Steering Committee adequately supported	<p>Prepare bi-annual reports for SC</p> <p>Develop decision making procedure for SC</p> <p>Facilitate monthly teleconferences</p> <p>Organise/facilitate bi-annual physical SC meetings</p>	<p>The Steering Committee is adequately informed about the operational realization of the program</p> <p>Corrective measures are implemented in a timely manner</p>
5. Scientific Advisory Committee adequately supported	<p>Facilitate communication between SAC and partners</p> <p>Fine-tune publication guidelines</p> <p>Organise/facilitate annual physical SAC meetings together with the partners</p>	<p>The Scientific Advisory Committee is adequately informed about the scientific aspects of the programme</p> <p>The scientific quality of the programme is monitored continuously</p>
6. External communication	<p>Up-date and develop website</p> <p>Up-date and develop information material</p> <p>Actively participate in the WHO HIV Res Net</p> <p>Facilitate international communication at the policy level</p>	<p>Program website functional and updated</p> <p>Up-dated information material available</p> <p>Active membership in Steering Committee of WHO HIV Res Net</p> <p>Presentation of program results at min. 1 international meeting per year</p>

II. PharmAccess studies to evaluate resistance (PASER) work plan 2008

I.1 Work package descriptions (work package 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 HIVDR in up to 13 clinical centres and/or geographical settings in 5-8 African countries by:

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

Secondary Objectives

- To measure the success of the ART programs to prevent or minimize HIVDR in selected clinical sites
- To measure and categorize the prevalence of transmitted HIVDR in specific geographic settings.
- To identify specific HIVDR mutations and mutational patterns.
- To 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

Primary Objectives

1. With respect to patients initiating first-line HAART in selected clinical centres in maximum 8 countries in sub-Saharan Africa:
 - a. To evaluate the prevalence of HIVDR at baseline
 - b. To evaluate the incidence of HIVDR at 12 and 24 months after initiation of first-line therapy in patients with VL > 1,000 copies/ml
2. With respect to patients switching to second-line HAART due to treatment failure in selected clinical centres in maximum 8 countries in sub-Saharan Africa:
 - a. To evaluate the prevalence of HIVDR at baseline
 - b. To evaluate the incidence of HIVDR at 12 and 24 months in patients with VL > 1,000 copies/ml

Secondary Objectives

1. To evaluate the proportion of patients with virologic suppression
 - a. On first-line HAART at baseline and at 12 and 24 months after initiation
 - b. On second-line HAART at switch (due to treatment failure) and at 12 and 24 months after switch (due to treatment failure).
2. To evaluate HIVDR mutational patterns:
 - a. On first-line HAART at baseline and at 12 and 24 months after initiation
 - b. On second-line HAART at switch (due to treatment failure) and at 12 and 24 months after switch (due to treatment failure)
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

Primary Objective

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

Secondary Objectives

1. To describe mutational patterns of transmitted HIVDR
2. To assess HIV-1 subtype distribution
3. To study time trends in the prevalence of transmitted HIVDR, patterns of HIVDR and subtype distribution
4. To contribute to the support of health policy makers to update national guidelines for first line

HAART regimens

Objectives for Monitoring and Surveillance 2008

- i. Maintain an up-to-date clinical protocol and related documents.
- ii. Identify and select 2 clinics to start PASER-M to complete the network of a total of 13 PASER-M sites and identify and select 1 geographical setting for PASER-S to complete the total of 3 geographical PASER-S settings.
- iii. Enrol a total of 2,000 patients in PASER-M
- iv. Follow-up of 450 patients in PASER-M started in 2007
- v. Enrol 150 patients in PASER-S in 3 geographical settings
- vi. Perform 1,838 viral load tests and 1,585 HIVDR tests for PASER-M and also 113 viral load tests and 113 HIVDR tests for PASER-S by reference labs

Clarification on Activity Plan 2008

Objective i: this is an ongoing process until all the selected clinics have started

Objective ii: the definition of geographical settings has been clarified in the protocol, and therefore PASER-M will be implemented in 13 clinics. PASER-S has been downscaled to 3 settings, as has been explained in the Annual Report 2006 and in the PAR 2007.

Objective iii-iv: is a combination, the number of patients that has been enrolled in 2007 has been downscaled to 450 and during 2008 a total of 2,000 new patients will be enrolled for PASER-M as new clinics will start enrolment.

Objective v: the number of geographical settings and the number of patients to be enrolled for PASER-S has been downscaled to 150 patients over a total of 3 geographical settings.

Objective vi: the number of HIVDR tests is estimated at 75% of the enrolment of new patients, so: $2,000 * 75\% = 1,500$. In addition, the already enrolled 450 patients are expected to have a 25% treatment failure and again a 75% test coverage, i.e.: $450 * 25\% * 75\% = 85$. Thus, the total is $1,500 + 85 = 1,585$. For viral load testing, 75% test coverage is estimated, explaining the figure of 1,838 ($= 75\% * (2,000 + 450)$). For PASER-S, according to the same logic, a 75% lab test coverage is expected, resulting in $75\% * 150 = 113$ tests for both disciplines respectively.

Description of work PASER-M

In 2007, the number of participating clinics has increased to encompass a total of 11 clinics, of which 8 clinics are expected to have started patient enrolment by the end of 2007. In 2008, 5 other clinics (of which 3 have been identified and selected) will start enrolment. All clinics have been selected from the network of clinics of PharmAccess based on a set of selection criteria for the resistance program. PharmAccess has conducted assessment visits to the clinics. Agreements between PharmAccess and the clinics need to be negotiated and signed for.

Ethical approval will be obtained in each participating country/clinic, before the 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 geographical setting, provided they do not possess one or do not have sufficient space in their freezer.

Medical doctors of clinics which will start in 2008 will be sent to the PharmAccess medical training. An initiation visit, detailing all program procedures, will be conducted by PharmAccess staff before the clinics start recruitment. It is anticipated that a total of 2,450 patients will be enrolled in PASER-M in 2008. Patient enrolment will be closely monitored through e-mail and phone contacts. The clinics will be supported and monitored through regular visits by PharmAccess (about 3 times per year after patient enrolment).

Clinics will send their specimen (PASER-M and PASER-S combined) for viral load and HIVDR genotyping on the day of blood draw directly to the Master Clinic in their respective countries. The Master Clinic will send the specimen to the reference labs (Wits in South Africa and JCRC in Uganda) twice per year after patient enrolment has started. Depending on the shipment dates it is expected that at least 75% of the specimen collected in 2008 will be received by Wits and tested for viral load and genotyping (1,838 viral load tests and 1,585 HIVDR tests).

PASER-S

Two geographical settings for PASER-S have been identified and selected. A last geographical setting will be selected in 2008. It is expected that in total 150 patients will be enrolled in 2008 in 3 geographical settings. Patient enrolment 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 (113 viral loads and 113 HIVDR tests).

WP B: Database Monitoring System

Objectives for Database Monitoring System 2008

- i. Maintain and further develop the HIVDR-specific sections and modules of the HMS, which were developed in 2006-2007 (patient visits, adherence tool and specimen tracking system).
- ii. Link data entered in HMS with TAHOD and the ABL sequence database
- iii. Manage the quality of data of PASER-M and PASER-S
- iv. Disseminate the results to MOH of countries which started enrolment.

Description of work

A resistance-specific database, a specimen track and trace system, and an adherence tool were developed in 2006 and incorporated into the already existing HMS. In 2007 the resistance-specific database has been maintained and improved by updating the entry screens. The specimen track and trace system will be reviewed and updated for use by the reference laboratories as soon as they are capable to perform genotyping. Specimen will be shipped to Wits and at a later stage to JCRC, Uganda, provided JCRC has passed 2 external quality control rounds for HIVDR testing.

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

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. In addition consistency checks will be performed and queries issued to the clinics if needed.

As of 2008 the MOH of each participating country which started patient enrolment will receive an annual report about the activities and results in their country.

WP C: Quality Assurance Scheme**Objectives for Quality Assurance Scheme 2008**

- i. Upgrade the JCRC reference lab in Uganda
- ii. Set-up genotyping QA of reference labs East Africa with Australia (TAQAS)
- iii. Continue the genotyping QA procedures of Wits using the TAQAS program
- iv. Set-up viral load QA (IRC) of reference labs East Africa with UMCU
- v. Set-up viral load QA (IRC) of reference lab Wits with UMCU
- vi. Complete research and development of the use of dried fluid spots and sample tankers
- vii. Control the quality of specimen shipments from clinics to Master Clinic and to reference labs

Description of work

A regional reference lab for East Africa has been identified (JCRC, Uganda) and selected in collaboration with staff of the University of Utrecht (UMCU) and of the reference lab in South Africa (Wits). An agreement has been signed between PharmAccess and the reference lab. An upgrading plan for equipment for the reference lab has been written in collaboration with staff from UMCU.

The reference lab will be linked to the TAQAS QA system. Staff will be invited to take part in the TAQAS-workshop and QA for genotyping specimen will be set up.

The genotyping QA system which was established between Wits and TAQAS will continue in 2008. Wits will continue to receive QA specimen and attend another TAQAS-workshop.

Viral load QA (Internal Run Control, IRC) for the reference labs will be set up with UMCU. UMCU will state their findings in an annual performance report.

The research and development of the use of dried fluid spots and sample tankers in collaboration with Wits and UMCU will continue in 2008.

Quality control of specimen shipments from the clinics to the Master Clinic and to reference labs 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 specimen handling and data entry.

11.2 DRAM (Objectives, Results, Activities, Means)

Work package A

Objectives	Results	Key Activities	Start	End
(i) An up-to-date clinical protocol and related documents	A1. New editions of protocol and related documents	1. Update of protocol and related documents	01/01/08	31/12/08
(ii) Identify and select the last 2 (of a total of 13) clinics to start <i>PASER-M</i> and identify and select 1 of 3 geographical settings for <i>PASER-S</i> .	A2. <i>PASER-M</i> : A total of 13 clinics contracted. <i>PASER-S</i> : A total of 3 settings selected and all participating clinics contracted	1. Identify and select clinics through assessment visits	01/01/08	31/06/08
		2. Negotiate agreements between PharmAccess and remaining clinics	01/01/08	31/06/08
		3. Recruitment of local project manager (0,5FTE per geographical setting), and one local research nurse (1FTE) per clinic	01/01/08	31/12/08
	A3. Ethical clearance for 13 clinics for <i>PASER-M</i> and for 3 geographical settings for <i>PASER-S</i>	1. Translation of EC-documents (protocol, informed consent etc.)	01/01/08	31/12/08
		2. Submission to EC's in each country	01/01/08	31/06/08
	A4. Upgrading of clinics by purchasing of necessary equipment	1. Purchase of computers and scanners for each clinic	01/01/08	31/12/08
		2. Purchase -80°C freezers for Master Clinics	01/01/08	31/12/08
(iii) Enrol and follow-up of 2,450 patients in <i>PASER-M</i>	A5. Medical doctors of clinics trained at PharmAccess training (list with training attendees)	1. Organise training on HAART and resistance for medical doctors of clinics participating in <i>PASER-M</i>	01/07/08	31/12/08
	A6. Initiation visit reports of the final 5 (of a total of 13) settings for <i>PASER-M</i> before enrolment starts.	1. Order and shipment of lab kits from CLS to Master Clinic	01/01/08	31/12/08
		2. Perform initiation visits to each clinic after ethical clearance for <i>PASER-M</i> has been obtained	01/01/08	31/12/08
	A7. 2,450 <i>PASER-M</i> patients entered in HMS	1. Monitor enrolment and follow-up of 2,450 patients in <i>PASER-M</i> through e-mail, phone and monitoring visits	01/01/08	31/12/08
(iv) Enrol 150 patients in <i>PASER-S</i> in 3 geographical settings (50 patients/ setting)	A8. Medical doctors of clinics trained at PharmAccess training (list with training attendees)	1. Organise training on HAART and resistance for medical doctors of clinics participating in <i>PASER-S</i> .	01/07/08	31/12/08
	A9. Initiation visit report <i>PASER-S</i> of each clinic before enrolment starts.	1. Order and shipment of lab kits from CLS to Master Clinic	01/01/08	31/12/08
		2. Perform initiation visit to each clinic after ethical clearance for <i>PASER-S</i> has been	01/01/08	31/12/08

		obtained		
	A10. 150 <i>PASER-S</i> patients entered in HMS	1. Monitor enrolment and follow-up of 150 patients in <i>PASER-S</i> through e-mail, phone and monitoring visits	01/01/08	31/12/08
(v) 1,951 viral load tests and 1,698 HIVDR tests for <i>PASER-M</i> and <i>PASER-S</i> performed by reference labs	A11. Track and trace report through HMS for all shipped specimen	1. Shipment of <i>PASER-M</i> and <i>PASER-S</i> specimen from Master Clinics to Wits or JCRC (twice/year)	01/01/08	31/12/08
	A12. Analysis report of tested specimen	1. 1,951 viral load tests and 1,698 HIVDR tests for <i>PASER-M</i> and <i>PASER-S</i> performed	01/01/08	31/12/08

Work package B

Objectives	Results	Key Activities	Start	End
(i) Maintain/update the resistance-specific HMS which was developed in 2006-2007 (patient visits, adherence tool, specimen tracking system)	B1. An up-to-date HMS	1. Check data-entry and improve screens	01/01/08	31/12/08
		2. Update HMS for use by new clinics and reference lab	01/01/08	31/12/08
(ii) Link data entered in HMS with TAHOD and international sequence database	B2. Report showing linkage HMS data to TAHOD and international sequence database	1. Link data from HMS with TAHOD	01/01/08	31/12/08
		2. Link data from HMS with international sequence database	01/01/08	31/12/08
(iii) Data management of <i>PASER-M</i> and <i>PASER-S</i> data	B3. Complete and consistent data in the HMS for <i>PASER-M</i> and <i>PASER-S</i>	1. Write a data Management Manual on how to enter and clean data	01/01/08	31/03/08
		2. Double data entry of data for <i>PASER-M</i> and <i>PASER-S</i>	01/01/08	31/12/08
		3. Regular checks on quality of data entry	01/01/08	31/12/08
(iv) Dissemination of results to MOH of countries which started enrolment.	B4. Annual report to MOH of participating countries	1. Database analysis of countries/clinics which started enrolment	01/10/08	31/12/08
		2. Write report for each of the participating clinics/countries which started enrolment	01/10/08	31/12/08

Work package C

Objectives	Results	Key Activities	Start	End
(i) Upgrading of JCRC reference lab in Uganda	C1. Upgraded reference lab JCRC Uganda	1. Equipment upgrading for JCRC Uganda	01/01/08	31/06/08
		2. Support visits by staff from Wits/UMCU to reference labs in East Africa	01/01/08	31/06/08
(ii) Set-up genotyping QA of reference lab East Africa with Australia (TAQAS)	C2. TAQAS QA reports of genotyping specimen from reference lab East Africa	1. QA genotyping specimen of reference lab East Africa with TAQAS	01/01/08	31/12/08
		2. Participation in TAQAS-workshop for staff from reference lab in East Africa	01/01/08	31/12/08
(iii) Continue genotyping QA procedures Wits with TAQAS	C3. Annual TAQAS QA report of genotyping specimen from reference lab Wits	1. QA genotyping specimen of reference lab Wits with TAQAS	01/01/08	31/12/08
		2. Participation in TAQAS-workshop for staff from reference lab Wits	01/01/08	31/12/08
(iv) Set-up viral load QA (IRC) of reference lab East Africa with UMCU	C4. Annual QA performance report of viral load specimen from reference lab in East Africa	1. Shipment of viral load specimen (IRC) UMCU to reference labs in East Africa	01/07/08	31/12/08
		2. QA viral load specimen of reference lab JCRC with UMCU	01/07/08	31/12/08
(v) Set-up viral load QA (IRC) of reference lab Wits with UMCU	C5. Annual QA report of viral load specimen from reference lab Wits	1. Shipment of viral load specimen UMCU to reference lab Wits (IRC)	01/01/08	31/12/08
		2. QA viral load specimen of reference lab Wits with UMCU	01/01/08	31/12/08
(vi) Completion of research and development of the use of dried fluid spots and sample tankers	C6. Report on research activities dried fluid spots and sample tankers	1. Continue scientific support PASER program by UMCU	01/01/08	31/12/08
		2. Continue research activities on dried fluid spots with UMCU	01/01/08	31/12/08
		3. Continue research activities on sample tankers with Wits	01/01/08	31/12/08
(vii) Quality control of specimen shipments from clinics to Master Clinic and to reference lab	C7. Quality assured lab specimen shipments as monitored by HMS	1. Regular checks on quality of data in track and trace system of HMS	01/01/08	31/12/08
		2. Follow-up on any issues related to specimen shipments through e-mail, phone contact and monitoring visits	01/01/08	31/12/08

II.3 Risk assessment and contingency plan

Main risks

- Patient numbers per participating clinic may not be reached in time frames as defined by clinical protocol. Possible reasons for insufficient patient recruitment:
 - Not able to obtain ethical clearance
 - Not able to recruit sufficient numbers of patients
 - Not able to retain sufficient numbers of patients
 - Unforeseen political unstable situation in a specific country
 - Major staff changes in clinic, resulting in managerial discontinuity

Risk mitigation

- Involve local partners and possibly ICSS to obtain ethical clearance
- Select additional clinics in a specific geographical setting to increase numbers
- Improve patient counselling methods, adherence methods, lab monitoring methods
- Motivate clinics to link up with VCT centres for referral to surveillance programs (particularly for PASER-S)

Contingency plan

- Involve other countries to participate in the project
- Involve a number of additional clinics

III. TREAT Asia Studies to Evaluate Resistance (TASER) Work Plan 2008

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.

Jan – Dec 2008 Programmatic Objectives for TASER Project

- (i) Continue participant enrolment and follow-up in TASER-Monitoring study (target by the end of year 2008 from 10 clinical centres is enrolled additional 1,100 patients);
- (ii) Achieve implementation and participation of four TREAT Asia centres in TASER-Monitoring protocols;
- (iii) Achieve implementation and participation of four TREAT Asia centres in TASER-Surveillance protocols (target for 2008 is 320 patients from four clinical centres);
- (iv) Facilitate the linkage of clinical centres to laboratories with capabilities of performing HIV genotyping and participating in TAQAS and assist clinical centres to build in-house genotyping laboratory capacity;
- (v) Clinical centre transfer TASER-Monitoring and TASER-Surveillance data to NCHECR;
- (vi) Maintain TASER-Monitoring and TASER-Surveillance databases;
- (vii) Perform quality assurance assessments of TASER-Monitoring and TASER-Surveillance data;
- (viii) Transfer TASER-Monitoring and TASER-Surveillance data into ABL database.
- (ix) Conduct TASER investigators' training meeting, and determine additional follow-up training needs, if any;
- (x) Identify three additional TREAT Asia centres to begin participation in TASER-Monitoring study in 2009; and
- (xi) Identify one additional TREAT Asia clinical centres to implement and conduct new TASER-Surveillance study in 2009

	2007 <i>(Year 2)</i>	2008 <i>(Year 3)</i>	2009 <i>(Year 4)</i>	2010 <i>(Year 5)</i>	2011 <i>(Year 6)</i>
TASER-Monitoring					
- # of Clinical centers	6	10	13	15	15
- # of New enrolled participants	900	1100	600	400	-
- # of Follow up participants	-	900	2000	2600	3000
TASER-Surveillance					
- # of Clinical centers		4	5	6	6
- # of Enrolled participants		320	400	480	480

Description of work

Six TREAT Asia clinical centres with have been identified to implement and begin participant enrollment in 2007. All of them have received ethical clearance (HIV-NAT/Thai Red Cross, Bangkok; Ramathibodi Hospital, Bangkok; YRG CARE, Chennai; University of Malaya, Kuala Lumpur; Institute of Infectious Diseases, Pune; and Hospital Sungai Buloh, Kuala Lumpur). To date HIV-NAT/Thai Red Cross has enrolled 43 participants and Ramathibodi Hospital has enrolled six participants into the TASER-M study.

TREAT Asia staff is working to identify four clinical centres that will be capable of implementing and enrolling participants into the TASER-M study in 2008. To date, two sites have been identified that will likely be able to implement TASER-M enrollment in the beginning of 2008 (Chiang Mai University, Chiang Mai; and Research Institute for Tropical Medicine, Philippines). Both clinical centres have submitted documents for ethical clearance and their laboratory will participate in TAQAS round 4 which will occur in October 2007.

During the TASER workshop held in September 2007, TASER clinical investigators confirmed to move forward with the current TASER-Surveillance protocol as designed. Five TREAT Asia clinical centre has been identified to begin HIVDR surveillance in the beginning of 2008 (HIV-NAT/Thai Red Cross, Bangkok; YRG CARE, Chennai; University of Malaya, Kuala Lumpur; Institute of Infectious Diseases, Pune; and Hospital Sungai Buloh, Kuala Lumpur).

TREAT Asia is facilitating and supporting collaboration between and technical assistance for TASER clinical centres and HIVDR laboratories. Currently, TREAT Asia is facilitating collaborations between Chiang Mai University and HIV-NAT/Thai Rde Cross; Port Moreshby General Hospital (Papua New Guinea) and National Yang-Ming University (Taiwan); and National Center for HIV/AIDS, STDs and Dermatology (Cambodia) and University of New South Wales (Australia).

The National Centre in HIV Epidemiology and Clinical Research (NCHECR) at the University of New South Wales in Sydney, Australia houses and maintains 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 bi-annually after enrolment begins. The first data submission was from HIV/NAT in August 14th, 2007. The data collection specification template and data collection processes are complete.

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 HIVDR genotypic data will also be housed in the ABL database along with data from the PASER studies. NCHECR will transfer TASER-Monitoring and TASER-Surveillance data directly to the ABL database.

TASER investigators' training meetings will take place in April and September (in conjunction with TREAT Asia Network meeting in 2008). These trainings will include principal investigators and clinical staff from TREAT Asia clinical centres currently participating or expected to participate in the TASER studies. TREAT Asia staff will determine the need, if any, for additional training and plan subsequent activities accordingly.

Aside from training above, monthly TASER teleconferences will be held for TASER clinical centres to update and discuss on each site status and challenges.

Site visits to clinical centres and HIV genotyping laboratories will be conducted by TREAT Asia staffs throughout 2008 to ensure that the data capture capability of each clinical centre has met the standard. Also, TREAT Asia staff will contact and visit additional clinical centres and HIV genotyping laboratories in order to identify three additional clinical centres to commence participation in TASER-M studies and one additional for TASER-S in 2009

TASER Work Plan B: TREAT Asia HIV Observational Database (TAHOD)**Five Year Primary Objectives of TAHOD Project**

- (i) To develop capacity in HIV clinical data collection in countries of the Asia-Pacific region;
- (ii) To assist in evaluation of new HIV treatments for the Asia-Pacific region;
- (iii) To monitor anti-retroviral and prophylactic treatments as related to demographics and markers of HIV disease stage;
- (iv) To monitor toxicity to anti-retroviral therapy; and
- (v) To examine HIV natural history, including relationship between access to anti-retroviral therapy and disease progression.

Jan-Dec 2008 Programmatic Objectives for TAHOD Project

- (vi) Continue participant enrolment and follow-up in the existing TAHOD database;
- (vii) Maintain high quality of HIV clinical data that collected from each TREAT Asia centre and transferred to NCHECR (National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales);
- (viii) Identify three additional clinical centres to participate in TAHOD project;
- (ix) Implement HIV-related malignancies sub-study and recruit additional patients to TAHOD; and
- (x) Conduct one training meeting for principle investigators and clinical staff, and determine additional follow-up training needs, if any.

Description of work

TAHOD currently involves 17 participating clinical centers in twelve countries in the Asia and Pacific region. As of March 2007, TAHOD has enrolled 3,516 patients into prospective follow-up, and has published eight publications.

To assure the quality of data that is submitted bi-annually, NCHECR has performed an ongoing data quality assurance checks. For year 2007, data quality assurance check will be performed after the completion of the second annual data transfer in September. 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.

The annual TAHOD workshop took place on September 7, 2007 in Hanoi, Vietnam and was attended by 64 researchers. The agenda included a review of the study progress, results of analyses performed in the last year, and an introduction of the new HIV-related malignancies study.

In year 2008, TREAT Asia is working to identify three additional clinical centres to participate and enroll patients living with HIV in the TAHOD study. To date, clinical centres in Vietnam and Malaysia have been contacted and site assessment visits will be planned.

Beginning in 2008, TAHOD will add data variables to study HIV-related malignancies in the Asia Pacific region. This cancer study is supported under the NIH's International Epidemiologic Databases to Evaluate AIDS (IeDEA) project and is by the National Cancer Institute. It is expected that an additional 1,300 participants will be recruited and enrolled to TAHOD for the cancer study. By including the cancer study into the database, TAHOD will also be able to investigate cancer and its causes in people with HIV.

The TAHOD investigators' training meeting will take place in conjunction with 2008 TREAT Asia Network Meeting. This training will include principle investigators and clinical staff from TREAT Asia clinical centres currently participating and expected to participate in the TAHOD project. TREAT Asia staff will determine the need, if any, for additional training and plan subsequent activities accordingly.

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.

Jan – Dec 2008 Programmatic Objectives for Quality Assurance Scheme (TAQAS)

- (i) Continue TAQAS program by conducting two rounds of quality assurance testing in participating laboratories during 2008;
- (ii) Provide results and feedback on quality assurance testing to participating laboratories;
- (iii) Conduct one training meeting for participating laboratory personnel; and
- (iv) Identify no less than three additional HIV genotyping laboratories to participate in TAQAS program.

Description of work

Three rounds of TAQAS were completed in Apr06, Oct06 and Apr07 with twelve HIV genotyping laboratories successfully participating. These results were discussed and laboratory feedback was obtained. The fourth round of TAQAS will be conducted by 15 laboratories in October 2007 with results provided by December 2007. The fifth and the sixth round are scheduled for April 2008 and October 2008, respectively.

A second TAQAS training for laboratory personnel will be on September 5, 2007 in Bangkok with total of 35 participate from both clinical and laboratory staff. The third TAQAS training is tentatively will be on September 2008

TREAT Asia staff is working to identify three additional HIV genotypic resistance testing laboratories to join TAQAS in 2008. To date, laboratories in China, Vietnam, Cambodia, Indonesia, and Bangladesh have been contacted or visited.

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

Gantt Chart Planning and Monitoring Matrix 2008

TASER Work Plan A: Resistance Monitoring and Surveillance

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Continue participant enrolment and follow-up in TASER-Monitoring study	Six clinical centres are: 1. HIV/NAT, Thailand 2. Ramathibodi, Thailand 3. YRG Centre, India 4. Institute of Infectious Diseases, India 5. University of Malaya, Malaysia 6. Hospital Sungai Buloh, Malaysia	1. Sites submit report of expenditure(ROE) quarterly and payment is made upon the ROE submission 2. Renew ERC approval letter 3. Renew grant contract	1.1 01/01/08 1.2 01/03/08 1.3 01/07/08 1.4 01/10/08 2. 01/01/08 3. 01/11/07	1.1 31/01/08 1.2 31/03/08 1.3 31/07/08 1.4 31/10/08 2. 31/12/08 3. 31/01/08
(ii) Achieve implementation and participation of four TREAT Asia centres in TASER-Monitoring protocols	Four additional TREAT Asia centres participating in TASER protocols by year end; Participant enrolment, follow-up and data collection for TASER protocols underway at all sites	1. Assess performance of TASER participating centres based on participant enrolment and data quality. 2. Obtain Ethical Review Committee approval 3. Execute grant contracts	1. 01/06/07 2. 01/01/08 3. 01/04/08	1. 31/12/08 2. 30/06/08 3. 31/07/08
(iii) Achieve implementation and participation of two TREAT Asia centres in TASER-Surveillance protocols	1. Five clinical sites participate in the study which are: 1) HIV/NAT, Thailand 2) University of Malay, Malaysia 3) Sungai Buloh Hospital, Malaysia 4) YRG Care Hospital, India 5) Institute of Infectious Diseases, Pune	1. Submit and obtain Ethical Review Committee approval 2. Execute grant contracts	1. 01/07/07 2. 01/01/08	1. 31/03/08 2. 31/01/08
(iv) Facilitate the linkage of clinical centres to laboratories with capabilities of performing HIV genotyping and participatin	Four potential sites are <u>Building in-house laboratory</u> : 1.) Chiang Mai University, Thailand 2.) Research Institute for Tropical Medicine, Philippines <u>Joint laboratory</u> : 3.) Port Moresby General Hospital, Papua New	1. Identify, contact, and access clinical centres and HIVDR laboratories for participation in TASER 2. Prepare and participate in TAQAS workshop round 5 (For new in-house laboratory) 3. Prepare and	1. 01/01/08 2. 01/03/08 3. 01/09/08	1. 31/12/08 2. 31/04/08 3. 31/10/08

Objectives	Results	Key Activities	Start	End
g in TAQAS and assist clinical centres to build in-house genotyping laboratory capacity	Guinea using National Yang-Ming University, Taiwan 4.) National Center for HIV/AIDS(Cambodia) using UNSW (Australia)	participate in TAQAS workshop round 6 (<i>For new in-house laboratory</i>)		
(v) Maintain TASER-M and TASER-S databases	Ongoing maintenance of functional databases for TASER-M and TASER-S studies.	1. NCHECR maintains TASER-M and TASER-S databases.	1. 01/01/08	1. 31/12/08
(vi) Transfer TASER-M and TASER-S data to NCHECR	All TASER-M and TASER-S data housed in central database at NCHECR.	1. Data transferred every 6 months from TASER centres to NCHECR.	1. 01/01/08	1. 31/12/08
(vii) 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.	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	1. 01/01/08 2. 01/04/08 3. 01/06/08	1. 31/12/08 2. 31/05/08 3. 31/07/08
(viii) Transfer TASER-M and TASER-S data into ABL database	International database (linking TASER and PASER data) housed at ABL.	1. NCHECR electronically transfers TASER-M and TASER-S data into ABL database	1. 01/01/08	1. 31/12/08
(xi) Conduct TASER investigator s' training meeting, and determine additional follow-up training needs, if any	1. Key research staff trained and/or provided in-depth update on implementing and conducting TASER protocols. 2. A review of the study progress, results of analyses performed in the last year, and a project's direction for next year. 3. Additional training needs identified, if any. (<i>Tentatively Annual TASER networking meeting will be in September 2008</i>)	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. 01/05/08 2. 01/05/08 3. 15/09/08 4. 01/08//08	1. 31/08/08 2. 31/08/08 3. 15/09/08 4. 31/10/08
(x) Identify three additional TREAT Asia centres to begin participation in TASER-Monitoring study in 2009	Number of TREAT Asia centres participating in TASER studies increased to nine in 2008.	1. TREAT Asia staff contact and visit additional clinical centres and HIV genotyping laboratories. 2. Identify three additional clinical centres with required capabilities to participate in	1. 01/07/08 2. 01/10/08	1. 31/12/08 2. 31/12/08

Objectives	Results	Key Activities	Start	End
		TASER protocols.		
(xi) Identify one additional TREAT Asia clinical centre to implement and conduct new TASER-Surveillance study in 2009	One TREAT Asia clinical centre participate in new TASER-Surveillance	<ol style="list-style-type: none"> 1. TREAT Asia staff contact and visit additional clinical centres and HIV genotyping laboratories. 2. Identify one additional clinical centres with required capabilities to participate in TASER protocols. 	<ol style="list-style-type: none"> 1. 01/07/08 2. 01/10/08 	<ol style="list-style-type: none"> 1. 31/12/08 2. 31/12/08

TASER Work Plan B: TREAT Asia Observation Database (TAHOD)

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Continue participant enrolment and follow-up in the existing TAHOD database	HIV clinical data from 17 TAHOD centres, which are 1. Cambodia National Institute of Public Health, Cambodia 2. Beijing Ditan Hospital, China 3. Queen Elizabeth Hospital, Hong Kong 4. Institute of Infectious Disease, India 5. YRG Centre for AIDS Research & Education, India 6. Udayana University, Indonesia 7. International Medical Centre of Japan, Japan 8. Hospital Kuala Lumpur, Malaysia 9. University of Malaya, Malaysia 10. Port Moresby General Hospital, Papua New Guinea 11. Research Institute for Tropical Medicine, Philippines 12. Tan Tock Seng Hospital, Singapore 13. Yonsei University, S.Korea 14. National Yang-Ming University, Taiwan 15. Chiang Mai University, Thailand 16. HIV/NAT, Thailand 17. Ramathibodi Hospital, Thailand	1. Clinical centres submit data in the standardized format to NCHECR every six month 2. Clinical centres submit report of expenditure (ROE) to TREAT Asia Grant Manager 3. Clinical centres renew protocol approval with local ethics committee (on an annual basis) 4. Clinical centres renew the status of FWA and IRB registration with OHRP (on 3-yr basis) 5. Clinical centres renew a legal agreement with TREAT Asia	1.1 01/03/08 1.2 01/09/08 2.1 01/04/08 2.2 01/07/08 3. 01/01/08 4. 01/01/08 5. 01/10/07	1.1 30/04/-08 1.2 31/10/08 2.1 30/04/08 2.2 31/08/08 3. 31/12/08 4. 01/12/08 5. 01/01/08
(ii) Maintain high quality of HIV clinical data that collected from each TREAT Asia center and transferred to NCHECR	Quality-assured and consistency data provided by each clinical centre and uploaded into the TAHOD database	1. NCHECR conducts computer consistency checks within TAHOD database 2. NCHECR oversees conduct of random internal data monitoring by participating TAHOD centres 3. Annual TAHOD Data Quality Assurance Report	1. 01/09/08 2. 01/09/08 3. 01/01/09	1. 31/12/08 2. 31/12/08 3. 31/03/09
(iii) Identify three additional clinical centres to participate in TAHOD project	Increasing in numbers of TAHOD-participating centres and expansion of TAHOD database	1. TREAT Asia staff identify HIV clinical centres who express interest in participating in TAHOD 2. TREAT Asia staff contact and visit additional clinical centres. 3. TREAT Asia identify three additional clinical centres with required capabilities to participate in TAHOD protocols. 4. TREAT Asia select new clinical centres who have ability to contribute data in a appropriate format 5. New clinical sites sign	01/01/08	31/12/08

Objectives	Results	Key Activities	Start	End
		agreement to participate in TAHOD		
(iv) Implement HIV-related malignancies sub-study and recruit additional patients to TAHOD	Be an information resource for the investigation of cancer and its causes in people with HIV, including <ol style="list-style-type: none"> a) Cancer rates and trends b) Cancer risk factors 	1. Establish and maintain a systematic cancer incidence and reporting system at each TAHOD clinical centres	01/01/08	31/12/08
(v) Conduct one training meeting for principle investigators and clinical staff, and determine additional follow-up training needs, if any	<ol style="list-style-type: none"> 1. Key research staff trained, and/or provided in-depth update on implementing and conducting TAHOD protocols. 2. A review of the study progress, results of analyses performed in the last year, and a project's direction for next year. 3. Additional training needs identified, if any. <p><i>(Tentatively Annual TAHOD Network Meeting will be in September 2008)</i></p>	<ol style="list-style-type: none"> 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, if any 	<ol style="list-style-type: none"> 1. 01/05/08 2. 01/05/08 3. 15/09/08 4. 01/08//08 	<ol style="list-style-type: none"> 1. 31/08/08 2. 31/08/08 3. 15/09/08 4. 31/10/08

TASER Work Plan C: TREAT Asia Quality Assurance Scheme (TAQAS)*Please link activities to results and objectives*

Objectives	Results	Key Activities	Start	End
(i) Continue TAQAS program by conducting two rounds of quality assurance testing in participating laboratories during 2008	Continue HIV genotype resistance testing quality assurance measures for TASER studies.	<ol style="list-style-type: none"> Ship five test samples from NSRL to each participating laboratory. Laboratories process test samples and report results to NCHECR. 	01/04/08 (QA#5) 01/10/08 (QA#6) 01/04/08 (QA#5) 01/10/08 (QA#6)	30/04/08 (QA#5) 31/10/08 (QA#6) 31/05/08 (QA#5) 30/11/08 (QA#6)
(ii) Provide results and feedback on quality assurance testing to participating laboratories	QA outcomes shared with TAQAS-participating laboratories.	<ol style="list-style-type: none"> NCHECR to analyze results and compare to reference laboratory results (Stanford University). Results reported to participating laboratories. TAQAS laboratories to review results and identify problems and develop solutions to problems. 	01/06/08 (QA#5) 01/12/08 (QA#6) 01/07/08 (QA#5) 01/01/08 (QA#6) 3. 01/07/08	30/06/08 (QA#5) 31/12/08 (QA#6) 31/07/08 (QA#5) 31/01/08 (QA#6) 3. 31/12/08
(iii) 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).	<ol style="list-style-type: none"> Organize meeting, including identifying curricula/content and presenters/trainers. Invite participants and arrange all logistics for transportation and lodging. Conduct training meeting. 	<ol style="list-style-type: none"> 01/05/08 01/05/08 01/09/08 	<ol style="list-style-type: none"> 30/09/08 31/08/08 01/09/08
(iv) Identify no less than three additional 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"> Identify laboratories with HIV genotypic resistance testing capabilities and ability to work with TREAT Asia centres. Reach agreement with laboratories to participate in TAQAS program. 	<ol style="list-style-type: none"> 01/01/08 01/01/08 	<ol style="list-style-type: none"> 31/12/08 31/12/08

III.3 Risk assessment and contingency plan

Main risks

- (i) Inability of TASER clinical centres to collect and submit study data in a timely manner;
- (ii) Delay on data submission for the first time data submission;
- (iii) Inability to identify new clinical centre with capabilities to implement TASER-M and new TASER-S;
- (iv) Inability of TASER clinical centres to enrol sufficient numbers of participants;
- (v) Inability of TREAT Asia centres to maintain adequate follow-up of TASER-M participants;
- (vi) TAQAS-participating laboratories reporting inaccurate HIV genotypic resistance results; and
- (vii) Inability of staff to identify new laboratories with HIV genotypic resistance testing capabilities and ability to work with TREAT Asia centres.

Risk mitigation

- (i) Set up a data collection process and mechanism for follow up data submission;
- (ii) Work with governments and other NGOs in South, East, and Southeast Asia region to build relationships and identify additional clinical centres and HIV genotyping laboratory;
- (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 enrolment and follow-up inadequacies; and
- (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. International Civil Society Support – Roundtable Process Work Plan 2008

IV.1 Work package descriptions (*Work package 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 2008

Primary objectives:

- a. Organize three follow up Roundtable Meetings.
- b. Develop follow-up activities according to outcomes of and other activities supporting the Roundtable meetings where necessary or relevant. (Measured by number of organizations to incorporate Roundtable Process (RTP) related activities in their work plans.)
- c. Mobilize resources in addition to the existing budget for activities as outcomes of the Roundtable meetings – when relevant. (Measured by number of funding proposals successfully submitted by December 2008.)
- d. Enhancing and improving involvement of LAASER partners in the three focus areas.

Secondary objectives:

- a. Identify opportunities and structural ways to involve LAASER partners more formally and more intensively.
- b. Revise governance structure(s) to formally involve (representatives of) LAASER partners in the Roundtable Steering Committee, to inform and advise the project process and support the project coordination.
- 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. Further develop and implement M&E structure/system.
- f. Develop communications structure to involve and inform partners in/of the process and support the over all project.

Description of work

At the Roundtable Meeting I in March 2007, a large group of stakeholders confirmed that the ultimate goal of the Roundtable Process is to contribute to, complement, improve and enhance the drive to universal access. The meeting also reaffirmed the strategic choice to work with and through the networks involved, rather than individual organizations.

Based on the outcomes of Roundtable Meeting I, the following focus areas, each with proposed activities, have been identified:

I: Procurement; II: Stigma & Gender Dynamics; III: Financing.

In 2008, three follow up Roundtable Meetings will be organised to further discuss issues among these different areas.

Each (re-defined) focus area is being lead by two members of the RTP Core Group, to help guide the next steps, in particular regarding the content.

Procurement: IHAA & ITPC; Stigma & Gender Dynamics: GNP+ & ICW; Funding: ICASO & ICSS.

The ICSS team will support, coordinate and where necessary facilitate any next steps in close collaboration with the identified leading members. ICSS has the mandate and capacity to organize the Roundtable Meetings around the identified issues. Development or support of activities that go beyond this scope can be considered, but may not necessarily be suitable for implementation within the existing structure and means.

To enhance linkages, the various Roundtable Meetings for the three different focus areas could take place simultaneously. This may not be feasible, as it is also key to link the RTP activities to existing processes, to enhance efficiency, effectiveness and impact.

All Roundtable meetings taking place in 2008 will be organised, in close collaboration with the group of stakeholders (RTP Core Group), 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 people openly living with HIV and 50% women).

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.

Governance

The process and content of the RTP is driven and supervised by its governance structure, the Roundtable Steering Committee (RTSC), which consists of AIDS Fonds, ICASO, ICW, IHAA, ITPC and GNP+.

In 2008, the RTSC will be expanded to include again the other LAASER partners, PharmAccess Foundation and TREAT Asia. This, also to ensure easier and better linkages between the LAASER programme components, as well as to enable more effective input from the LAASER partners into the RTP and to facilitate exchange of knowledge and information between all partners involved.

Furthermore, terms of reference (TOR) for the RTSC will be made available in 2008, to allow for clear outlines for commitment and engagement in the RTP.

LAASER Linkages

In 2008, efforts will be made to ensure the RTP is meaningfully linked to the other two LAASER programme components. In addition to the revised governance structure, meetings will be organised between the LAASER partners and other RTP partners, to optimise opportunities for programmatic input and exchange of information. A similar effort will be developed. These meetings are in addition to the Roundtable meetings, but are ideally organised in conjunction with scheduled Roundtable meetings, for logistical and budgetary reasons.

M&E

ICSS will continue to further develop a system for more rigorous and improved monitoring & evaluation of the RTP activities. The RTP program manager will participate in activities initiated by the AIDS Fonds in this respect.

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

Primary Objectives (D.I)	Results	Key Activities	Start	End
a. Organize three follow up Roundtable Meetings	Roundtable Meetings V, VI, VII organized	D.I.a.1 Roundtable Meeting V D.I.a.2 Roundtable Meeting VI D.I.a.3 Roundtable Meeting VII	January 2008 May 2008 September 2008	April 2008 August 2008 December 2008
b. Develop follow-up activities to outcomes of and other activities supporting the Roundtable meetings	Follow-up activities developed, including activities by partner organizations (five organizations to incorporate RTP related activities in their work plans)	D.I.b. [Concrete activities depending on outcomes of RT meetings]	March 2008	January 2009
c. Mobilize resources for follow up activities	Funding in place for follow-up activities	D.I.c.1 Develop Resource mobilization strategy D.I.c.2 Identify potential donors D.I.c.3 Proposal writing & follow-up	April 2008 June 2008 September 2008	January 2009 January 2009 January 2009
d. Enhancing and improving involvement of LAASER partners in the three focus areas.	LAASER partners integral part of RTP; program components significantly linked	D.I.d.1 Organise joint meeting of LAASER SC and RTSC	January 2008	December 2008

Secondary Objectives (D.II)	Results	Key Activities	Start	End
a. Identify opportunities and structural ways to involve LAASER partners more formally and more intensively.	LAASER partners integral part of RTP; program components significantly linked	D.II.a.1 Consultation with LAASER partners on needs and opportunities D.II.a.2 Meetings and TRP activities aligned with other LAASER activities D.II.a.3 Systematic communication with LAASER partners	January 2008 January 2008 January 2008	December 2008 December 2008 December 2008
b. Revise governance structure to formally involve LAASER partners in RTP	RTP governance structure includes all LAASER partners	D.II.b Revised governance structure developed, implemented and TOR communicated	January 2008	March 2008
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 organizations	January 2008 March 2008	April 2008 December 2009
d. Ensure capacity of networks/ partner organizations to participate in the project and assist in capacity building	Sufficient capacity at participating partner organizations (measured by additional funding being available at partner organizations)	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	February 2008 February 2008	April 2008 April 2008
e. Develop & implement M&E system	M&E system developed & effectively being implemented	D.II.e.1 Attend M&E training D.II.e.2 Develop M&E system	January 2008 January 2008	December 2008 December 2008
f. 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.II.f.1 Develop interactive website D.II.f.2 Send out periodic communiqués to inform partners	January 2008 January 2008	March 2008 January 2009

IV.3 Risk assessment and contingency plan *(Work package 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 LAASER components.
3. Unable to provide desired follow-up activities as/for outcomes of Roundtable meetings.

Risk mitigation

1. Assuring RTP activities are included in respective partners activity plans.
2. Increased efforts to involve partners at all levels.
3. Develop resource mobilization strategies and involve donor community early on.

Contingency plan

1. Assist in increasing capacity at partner organizations to allow them to participate.
2. Work with directors of respective organisations to revitalise commitment to RTP and over all LAASER program.
3. Attach RTP to other, existing processes and initiatives, to ensure continuation and over all support.