

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

Work plan 2009

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 2009

The LAASER program is currently in its third year of implementation (program start: May 2006). As the program is now halfway the Steering Committee has given the assignment to execute a Midterm Review by an independent consultant. The consultant will present his findings in November 2008.

The results in 2008 already have been much more promising as they were in 2006 and 2007. This also means that more information becomes available. In 2009 more attention will go to processing these data and to the involvement of the Scientific Advisory Committee.

The main program management goals for the Aids Fonds in 2009 will therefore be

- to implement the recommendations in the Midterm Review
- to streamline and to intensify communications with the Scientific Advisory Committee
- to prepare cooperation with future partners and to prepare future applications
- to keep on strengthening communications within the program and strengthening the planning and steering procedures of the program.

This will be achieved by:

- Giving guidance on the discussions on the Midterm Review and monitoring the implementation of the recommendations;
- Doing more advanced planning for communications with the Scientific Advisory Committee;
- Giving more attention to the communication process between the Steering Committee, the partners and the Scientific Advisory Committee
- Making a strategy and a planning for internal and external communication on the scientific achievements of LAASER
- Making a network analysis and approaching the people that are seen as important
- Preparing a strategy for LAASER after the 5 year period
- Keeping up the current standard of project management skills by continuous monitoring, variance analysis, risk analysis and problem analysis.
- By further enhancing the standard of project management by synchronizing the monitoring procedures of each partner organisation, by fine-tuning the reporting requirements and by introducing change management procedures.
- Keeping attention to the importance of internal communication and facilitate further improvement

I.3 Work plan Description (DRAM)

Objective	Activity	Result
1. Strong program management	<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>Synchronize the monitoring procedures of each partner organisation, fine-tune the reporting requirements and introduce change management procedures.</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> <p>Enhanced standard of project management</p>
2. Program reporting to the Ministry of Foreign Affairs according to the guidelines and wishes of the Ministry	<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. Constructive and effective internal communication	<p>Make all the relevant documents available through the closed section of the website</p> <p>Maintain good relations with all the partners by phone calls, visits</p>	<p>Relevant information is available for everybody within the program</p> <p>Good relationship in which successes and problems can be shared</p>
4. Steering Committee adequately supported	<p>Facilitate monthly teleconferences</p> <p>Organise/facilitate bi-annual physical SC meetings</p> <p>Give guidance on the discussions on the Midterm Review and monitoring the implementation of the recommendations;</p> <p>Preparing a strategy for LAASER after the 5 year period</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> <p>The recommendations of the MTR are adequately implemented</p> <p>Steering Committee is prepared for decision-making with regard to the future of the program</p>
5. Scientific Advisory Committee adequately supported	<p>Facilitate communication between SAC and partners</p> <p>Fine-tune publication guidelines</p>	<p>The Scientific Advisory Committee is adequately informed about the scientific aspects of the programme</p>

	<p>Organise/facilitate annual physical SAC meetings together with the partners (more advanced planning and more personal attention)</p> <p>Making a strategy and a planning for internal and external communication on the scientific achievements of LAASER</p>	<p>The scientific quality of the programme is monitored continuously and the information that will be available in 2009 is discussed by the Scientific Advisory Committee</p> <p>Clear communication on the objectives and goals. Make it possible to make choices and coordinate efforts</p>
6. External communication	<p>Up-date website and information materials</p> <p>Actively participate in the WHO HIV Res Net</p> <p>Facilitate international communication at the policy level</p> <p>Make a network analysis and approaching the people that are seen as important</p>	<p>functional and updated website and information materials</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> <p>More stakeholders are involved in the program</p>

II. PharmAccess studies to evaluate resistance (PASER) work plan 2009

III. TREAT Asia Studies to Evaluate Resistance (TASER) Work Plan 2009

IV. International Civil Society Support – Roundtable Process Work Plan 2009

Activity/work plan 2009

I. 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 2009

- i. Maintain an up-to-date clinical protocol and related documents.
- ii. PASER-M: 550 baseline visits (completion of enrolment in all 13 clinics-240 patients per clinic)
- iii. PASER-M: 1391 patients with 12 months follow-up.
- iv. PASER-M: 367 patients with 24 months follow-up.
- v. PASER-M: conduct 2057 viral load tests and 1791 HIVDR tests.
- vi. PASER-S: complete 2 surveys (2x85 subjects)
- vii. PASER-S: conduct 170 viral load tests and 170 HIVDR tests.
- viii. PASER-M: capacity building: monitoring of the study primarily by local staff i.s.o. by PAI staff
- ix. PASER-M and PASER-S: continuous training of the local staff in order to conduct the program according to GCP and protocol.

Description of work

PASER-M

Background history:

By August 2008, a total of 13 clinics had been contracted and ethical clearance obtained. 11 clinics were enrolling patients, of which 6 clinics had completed the baseline cohort. It is expected that by the end of 2008 all 13 clinics will be enrolling patients and a total of

10 clinics will have completed the baseline cohort or the 18 months enrolment period.

Estimations for the number of baseline (BL), follow-up 12 months (FU12) and follow-up 24 months (FU24) visits per year:

2007

-667 BL visits completed

2008

-10 completed cohorts with a cumulative total of 2280 BL visits

-3 clinics still enrolling, estimation for 2008, a total of 170 BL visits

-total # of BL is $2280 + 170 - 667 = 1783$ BL visits

-520 FU12 visits (assumption of 10% lost-to follow-up (LTF) and 12% mortality after 24 months)

Expectations for 2009

2009

-completion of the enrolment of the 3 sites which were still enrolling in 2008, which means an additional 550 BL visits

-1391 FU12 visits (assuming 10% LTF and 12% mortality after 12 months)

-367 FU24 visits (assuming 20% LTF and 25% mortality after 12 months)

-Viral load tests on all samples received by the reference labs

-HIVDR on all baseline samples, and on 30% of the follow-up samples.

Patient enrolment will be closely monitored through e-mail and phone contacts. Up to 2008 the clinics have been supported and monitored through regular visits by PharmAccess staff (about 3 times per year after patient enrolment). Starting from end 2008 the monitoring approach will change. The current procedure is an intensive, time-consuming and expensive activity. In addition, the PASER program aims at building capacity for surveillance of resistance in Africa. To this end, PASER aims to gradually transfer specific responsibilities to competent African partners in the course of the program. This includes monitoring tasks, which can be delegated to selected individuals at some of the PASER-M sites. In addition to building local research capacity, this will reduce project expenses. Based on the quality of the data at each clinic, the clinics will be categorized as level 1 or level 2. Level 2 sites will get more intensive monitoring of data than level 1 sites. The new monitoring approach is described in a separate document.

Clinics will continue to send their blood specimen 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 60% of the specimen collected in 2009 will be received by the reference labs and tested for viral load and genotyping (2057 viral load tests and 1791 HIVDR tests).

PASER-S

Two geographical settings for PASER-S have been identified and selected in 2008. It is expected that in 2009 these 2 settings will complete 1 survey each. ICRH in Mombasa, Kenya and UVRI in Kampala, Uganda. Which means a total of 170 subjects will be

enrolled. The progress of the survey will be closely monitored through e-mail, phone contacts and regular visits by PharmAccess. The blood specimen for PASER-S will be shipped after completion of the survey to the reference laboratories for testing. ICRH will ship to JCRC in Kampala and UVRI will conduct the viral load and HIVDR testing themselves.

In contrast to the PASER-M database the PASER-S database will be developed by ICRH, including monitoring and data management. This is done in order to build local (research) capacity. See also WP B.

TRAINING

The local staff of the participating sites will continuously be trained, so they can conduct the program according to GCP-guidelines and the protocol. This is done by supporting training requests and by regular (monitoring) visits of PAI staff to the clinics/sites. During these visits all program-related issues are explained and if needed corrected. In addition, PAI organizes an annual network meeting to which all key-staff of each clinic is invited (physicians, nurse/counsellors, lab staff).

WP B: Database Monitoring System

Objectives for Database Monitoring System 2009

- i. Maintain the PASER-specific sections and modules of the HMS
- ii. HIVDR data from ABL sequence database linked to HMS
- iii. Data cleaning and validation (quality control) of PASER-M and PASER-S
- iv. Capacity building: Provide support to the locally developed database for PASER-S
- v. Disseminate the results to MOH of the participating countries
- vi. One scientific publication in peer-reviewed journals on resistance
- vii. Two abstracts submitted for presentation at international conferences
- viii. Two presentations at national/regional conferences
- ix. Two presentations at international conferences

Description of work

Background history:

A resistance-specific database (PASER-HMS) and a specimen track and trace system, was 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. In 2008 the HIVDR data was uploaded to the sequence database of ABL and downloaded to the HMS. A QC-procedure has been developed and implemented for the viral load and HIVDR results, before they are returned to the clinics. Finally a data quality control procedure has been developed, tested and implemented (double data entry system, data cleaning by comparing both databases and finally a query process to clarify discrepancies, inconsistencies, missing values etc.).

2009

The PASER-HMS will continuously be updated if needed. The sequence data will continue to be uploaded to the ABL sequence database and HIVDR results will be returned to the clinics after an internal QC procedure. As soon as sufficient data is available data of HMS and TAHOD may be linked for joint analyses.

The PASER-M data QC procedure which started in 2008, will be continued in 2009. Planning of the cleaning process will be according to upcoming congresses, in combination with the progress of each site.

The PASER-S database will be developed and maintained by ICRH in Kenya, including instalment and training at the PASER-S site in Uganda. PharmAccess staff will provide support to ICRH in the development of the PASER-S database and the QC-procedure.

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.

Data cleaning, analysis and publications will be according to a time table with upcoming congresses, as explained above.

WP C: Quality Assurance Scheme

Objectives for Quality Assurance Scheme 2009

- i. Participation of the reference labs in the TAQAS program for HIVDR QA.
- ii. Research and development of the use of dried fluid spots and sample tankers
- iii. Quality control of viral load and HIVDR data; including shipments from clinics to Master Clinics to reference lab, uploading of HIVDR data to ABL sequence database, and downloading to HMS and clinic.

Description of work

Background and history

Two reference labs (Wits in South Africa and JCRC in Uganda) have been selected for the PASER program to conduct viral load and HIVDR testing. Both of them participate in the TAQAS program, as well as in other QA programs for HIVDR. Wits started to conduct HIVDR-sequencing for the PASER-program in 2007, and JCRC fulfilled the requirements to start HIVDR-sequencing in August 2008. Research and development of the use of dried fluid spots is ongoing, in collaboration with the ART-A program, and will continue in 2009.

2009

Wits and JCRC will continue to participate in the QA-panels for HIVDR-testing from TAQAS. UVRI in Uganda will be a new site for PASER-S, and will conduct the HIVDR-testing of their own samples. In 2009 they will be linked to the TAQAS program.

As also described in WP-B, a QC procedure for viral load and HIVDR test results has been developed. It contains the QC of specimen shipments from the clinics to the Master Clinic, to reference labs, analysis by the reference lab and HIVDR uploading to the ABL sequence database, linking of the viral load and HIVDR results to the HMS, and return of the viral load and HIVDR results to the clinics.

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

Work package A

Objectives	Results	Key Activities	Start	End
(i) Maintain an up-to-date clinical protocol and related documents	A1. New editions of protocol and related documents	1. Update of protocol and related documents	01/01/09	31/12/09
(ii) PASER-M: 550 baseline visits (completion of enrolment in 13 clinics)	A2. PASER-M: 550 baseline visits entered in HMS including track and trace part for specimen	1. Purchase of computer, printers / IT investments	01/01/09	31/12/09
		2. Order and shipment of lab kits from CLS to Master Clinic	01/01/09	31/12/09
		3. Local staff executing the program according to protocol (PM, RN, PI, data entry, administration)	01/01/09	31/12/09
		4. Blood draw by clinic staff and tracking of specimen in HMS	01/01/09	31/12/09
		5. Shipment of PASER-M and PASER-S specimen from Master Clinics to Wits or JCRC (twice/year)	01/01/09	31/12/09
		6. Monitoring visits by local monitors and PAI monitors according to monitoring guidelines	01/01/09	31/12/09
(iii) PASER-M: 1391 patients with 12 months follow-up	A3. PASER-M: 1391 FU12 visits entered in HMS including track and trace part for specimen	1. Purchase of computer, printers / IT investments	01/01/09	31/12/09
		2. Order and shipment of lab kits from CLS to Master Clinic	01/01/09	31/12/09
		3. Local staff executing the program according to protocol (PM, RN, PI, data entry, administration)	01/01/09	31/12/09
		4. Blood draw by clinic staff and tracking of specimen	01/01/09	31/12/09

		in HMS		
		5. Shipment of <i>PASER-M</i> and <i>PASER-S</i> specimen from Master Clinics to Wits or JCRC (twice/year)	01/01/09	31/12/09
		6. Monitoring visits by local monitors and PAI monitors according to monitoring guidelines	01/01/09	31/12/09
(iv) PASER-M: 367 patients with 24 months follow-up	A4. PASER-M: 367 FU24 visits entered in HMS including track and trace part for specimen	1. Purchase of computer, printers / IT investments	01/01/09	31/12/09
		2. Order and shipment of lab kits from CLS to Master Clinic	01/01/09	31/12/09
		3. Local staff executing the program according to protocol (PM, RN, PI, data entry, administration)	01/01/09	31/12/09
		4. Blood draw by clinic staff and tracking of specimen in HMS	01/01/09	31/12/09
		5. Shipment of <i>PASER-M</i> and <i>PASER-S</i> specimen from Master Clinics to Wits or JCRC (twice/year)	01/01/09	31/12/09
		6. Monitoring visits by local monitors and PAI monitors according to monitoring guidelines	01/01/09	31/12/09
(v) PASER-M: conduct 2057 VL and 1791 HIVDR tests	A5. Result reports for VL and HIVDR of tested specimen	1. VL and HIVDR testing by Wits and JCRC	01/01/09	31/12/09
(vi) PASER-S: complete 2 surveys (2x85 subjects)	A6. PASER-S: 170 visits entered in HMS including track and trace part for specimen	1. Initiation visit to both PASER-S settings	01/01/09	31/12/09
		2. Order and shipment of lab kits from CLS to Master Clinic	01/01/09	31/12/09
		3. Local staff executing the program according to protocol (PM, RN, PI, data	01/01/09	31/12/09

		entry, administration)		
		4. Blood draw by clinic staff and tracking of specimen in HMS	01/01/09	31/12/09
		5. Shipment of <i>PASER-M</i> and <i>PASER-S</i> specimen from Master Clinics to Wits or JCRC (twice/year)	01/01/09	31/12/09
		6. Monitoring visits by PAI monitors according to monitoring guidelines	01/01/09	31/12/09
(vii) PASER-S: conduct 170 VL and 170 HIVDR tests	A7. Result reports for VL and HIVDR of tested specimen	1. VL and HIVDR testing by UVRI and JCRC	01/01/09	31/12/09
(viii) PASER-M: capacity building: monitoring of the study primarily by local staff i.s.o. by PAI staff	A8. Patients enrolled according to protocol and entered in HMS (see also A2, 3, 4)	1. Monitoring visits by local monitors and PAI monitors according to monitoring guidelines	01/01/09	31/12/09
(ix) PASER-M and PASER-S: continuous training of the local staff in order to conduct the program according to GCP and protocol	A9. List with participants from all trainings conducted	1. Incidental requests for training of local staff	01/01/09	31/12/09
		2. PASER Network meeting	01/01/09	31/12/09

Work package B

Objectives	Results	Key Activities	Start	End
(i) Maintain the PASER-specific sections and modules of the HMS	B1. An up-to-date HMS	1. Maintenance of HMS	01/01/09	31/12/09
(ii) HIVDR data from ABL sequence database linked to HMS	B2. HIVDR reports downloaded from Viroscore to HMS	1. Link data from Viroscore (ABL sequence database) to HMS	01/01/09	31/12/09
(iii) Data cleaning and validation (QC) of <i>PASER-M</i> and <i>PASER-S</i> data	B3. Validated data, ready for analysis, in the HMS for <i>PASER-M</i> and <i>PASER-S</i>	1. Double data entry, comparison of 1 st and 2 nd entry, correction of discrepancies	01/01/09	31/12/09
		2. Query run	01/01/09	31/12/09
		3. Solving queries by clinic staff and entering of answers in HMS	01/01/09	31/12/09
(iv) Capacity building: provide support to the locally developed database for <i>PASER-S</i>	B4. All <i>PASER-S</i> patient data available in HMS/database	1. Programming of <i>PASER-S</i> database by local staff	01/01/09	31/12/09
		2. Entering patient data in database, including QC procedure	01/01/09	31/12/09
(v) Disseminate the results to MOH of the participating countries	B5. Annual report to MOH of participating countries	1. Data analysis per country/clinic through automated reports from HMS	01/01/09	31/12/09
		2. Compile clinic/country data into a report (by Master Clinics)	01/01/09	31/12/09
(vi) One scientific publication in peer-reviewed journals on resistance	B6. One publication accepted	1. Data analysis on cleaned data (see objective iii), and write article. Possibly including TAHOD/TASER data.	01/01/09	31/12/09
(vii) Two abstracts submitted for presentation at international conferences	B7. Two abstracts submitted	1. Data analysis on cleaned data (see objective iii), and write abstract. Possibly including TAHOD/TASER data.	01/01/09	31/12/09

(viii) Two presentations at national/regional conferences	B8. Two presentations held	1. Data analysis on cleaned data (see objective iii), and prepare presentations. Possibly including TAHOD/TASER data.	01/01/09	31/12/09
(ix) Two presentations at international conferences	B9. Two presentations held	1. Data analysis on cleaned data (see objective iii), and prepare presentations. Possibly including TAHOD/TASER data.	01/01/09	31/12/09

Work package C

Objectives	Results	Key Activities	Start	End
(i) Participation of the reference labs in the TAQAS program for HIVDR QA	C1. Annual TAQAS QA report of genotyping specimen from reference lab Wits	1. QA panels of genotyping specimen of reference labs JCRC, Wits, UVRI	01/01/09	31/12/09
		2. Participation in TAQAS-workshop for staff from reference labs	01/01/09	31/12/09
(ii) Research and development of the use of dried fluid spots and sample tankers.	C2. Progress report from ART-A	1. Research will be carried out by the ART-A project	01/01/09	31/12/09
(iii) Quality control of viral load and HIVDR data	C3. VL and HIVDR data linked to HMS	1. Regular checks on quality of data in track and trace system of HMS	01/01/09	31/12/09
		2. Monthly QC on VL and HIVDR data, and returning of results to clinics	01/01/09	31/12/09

III. Risk assessment and contingency plan

Main risks

- Patient follow-up is below estimations
- Major staff changes in clinic, resulting in managerial discontinuity
- Local monitors not able to do the monitoring
- Data cleaning/analysis not according to time schedule
- Unforeseen political unstable situation in a specific country

Risk mitigation

- Improve patient counselling methods, adherence methods, lab monitoring methods
- Motivate clinics and monitors to conduct the program according to protocol and agreed on time lines

Contingency plan

- Put more manpower on monitoring and data cleaning

TREAT Asia Studies to Evaluate Resistance (TASER) Work Plan 2009

I. 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 centers 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 centers; 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 centers.

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 centers.

Jan – Dec 2009 Programmatic Objectives for TASER Project

TASER-Monitoring

- (i) Continue participant enrollment and follow-up in the TASER-Monitoring study;
- (ii) Achieve implementation and participation of thirteen TREAT Asia centers in the TASER-Monitoring study;
- (iii) Identify two additional TREAT Asia clinical centers to begin participation in the TASER-Monitoring study in 2010;

TASER-Surveillance

- (iv) Achieve implementation and participation of five TREAT Asia centers in the TASER-Surveillance study;
- (v) Implement BED assay to assist sites in identifying recently HIV-infected persons;
- (vi) Identify one additional TREAT Asia clinical center to begin participation in the TASER-Surveillance study in 2010;

Intra-Network and External Capacity Building

- (vii) Facilitate the linkage of clinical centers to laboratories with capabilities of performing HIV genotyping and participating in TAQAS and assist centers to build genotyping laboratory capacity;
- (viii) Identify technical capacity needs of TASER centers and facilitate capacity building from within and outside the TREAT Asia Network;

Data Management

- (ix) Ensure transfer of TASER data from clinical centers to NCHECR in March and September 2009;
- (x) Maintain TASER databases;
- (xi) Perform quality assurance assessments of TASER data;
- (xii) Transfer TASER data into ABL database.

Network Training and Capacity Building

- (xiii) Conduct three training workshops for TASER investigators
- (xiv) Conduct one TASER Steering Committee meeting
- (xv) Assess site training and resource needs

Description of work

Clinical Centers

TASER-M

Additional HIV clinical centers in the region will be assessed for capacity to participate in TASER-M in 2009 and 2010. In 2008, ten clinical centers were assessed and four were identified as having the capacity to implement the TASER-Monitoring study. One of these centers, Research Institute of Tropical Medicine in Philippines started enrolling patients. TREAT Asia staff will work with the other three sites that have capacity to participate to implement and begin enrolling TASER-M (Siriraj Hospital, Thailand; Chiang Rai Regional Hospital, Thailand; and Udayana University, Bali).

TREAT Asia staff will work with the six clinical centers that were assessed but still need to develop capacity before joining TASER. This will include assisting in developing and securing ethical clearance of protocol, identifying and collaborating with HIVDR testing laboratories, and setting up data management systems for collection and maintenance of research data. The centers included in this category include:

Sites

National Centre for HIV/AIDS, Dermatology and STDS
Beijing Ditan Hospital
Port Moresby General Hospital
Tropical Disease Hospital
Dong Da Hospital
Cipto Mangunkusumo General Hospital

Country

Cambodia
China
Papua New Guinea
Vietnam
Vietnam
Indonesia

TREAT Asia staff will assist TASER-M centers with identifying barriers to participant enrollment and developing systems to allow enrollment of 200 participants/site in 12-18 month period.

TASER-S

Three clinical centers started enrolling patients in TASER-S in 2008 (HIV-NAT, Thailand; Chiang Mai University, Thailand; and RITM, Philippines). Additional HIV testing centers in the region will be assessed for capacity to participate in TASER-S in 2009 and 2010.

TREAT Asia staff will assist TASER-S centers with identifying barriers to participant enrollment and developing systems to allow enrollment of 80 participants/site in 12 months or less.

Intra-Network and External Capacity Building

TREAT Asia will continue to facilitate collaboration between TREAT Asia centers and support the provision of technical assistance for TASER clinical centers and HIVDR laboratories. Specifically, TREAT Asia will:

- Facilitation of collaboration between Port Moresby General Hospital (Papua New Guinea) and National Yang-Ming University (Taiwan);
- Facilitation of collaboration between Udayana University (Bali) and National Yang-Ming University (Taiwan);
- Assist National Center for HIV/AIDS, STDs and Dermatology (Cambodia) in identifying a TREAT Asia HIVDR laboratory for genotype testing;
- Identify technical capacity needs of other TREAT Asia centers and facilitate capacity building from within and outside the TREAT Asia network.

Data Management

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. After the TASER workshop in April 2008, TASER Principle Investigators agreed that TASER participating centers will submit TASER-Monitoring and TASER-Surveillance data electronically to NCHECR quarterly. The first full data submission was in March 2008.

- 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 center.
- 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.

The TAHER Steering Committee will identify critical areas of research, develop research concepts, and present research results at international conferences and through manuscripts published in peer-reviewed medical journals. Specific TASER research analyses planned for 2009 include:

- TASER Cohort Profile
- TASER Review Resistance Testing in Asia Pacific
- HIV Drug Resistance Mutations among Antiretroviral-naïve HIV-infected Patients in Asia

TASER Network Training Workshops

Four workshops will be held for TASER principal investigators and research staff to develop research capacity and facilitate the collection of TASER data and dissemination of research results. Workshops will include:

- An amfAR-sponsored HIVDR workshop will be held during Bangkok International Symposium on HIV Medicine in January 2009. This workshop will include a presentation by TASER investigators of early TASER and TAQAS data analysis. This workshop will provide an opportunity for TASER investigators to learn new information about HIV and HIVDR in Asia. This workshop will be attended by many HIV clinicians and researchers from Asia and will provide the opportunity to identify potential new TASER sites.
- A training workshop about statistical manipulation and analysis of longitudinal clinical data training will be held in late summer 2009. Many

TASER sites are their country's national reference centers for advanced HIV clinical care and laboratory testing. However, a challenge for all of our sites is the lack of trained staff for conducting the research and monitoring that can help them to characterize their local ARV resistance patterns and inform treatment policy. Pilot training program objective is to improve resistance data management capacity in the TASER network to enhance national-level ARV resistance monitoring.

- TASER training workshop during the 2009 Annual TREAT Asia Network Meeting will inform investigators and research staff about TASER data collection and submission, operating procedures, data quality, provide an opportunity to discuss TASER data analyses, and strategies for the following year.
- Interim TASER training workshop (Spring 2009) will inform investigators and research staff about TASER data collection and submission, operating procedures, data quality, and provide an opportunity to discuss TASER data analyses.

TREAT Asia staff will determine the need, if any, for additional training and plan subsequent activities accordingly.

TASER Network coordination

- The TASER Steering Committee holds monthly teleconferences to update and discuss TASER-M and TASER-S study progress and address challenges.

TREAT Asia staff along with data management staff from NCHECR will make regular site visits to clinical centers and HIV genotyping laboratories throughout 2009 to ensure protocol compliance with participant enrollment and follow-up, data capture and submission, and ethical assurance.

TASER Work Plan B: TREAT Asia HIV Observational Database (TAHOD)

Five Year Primary Objectives of the 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 antiretroviral and prophylactic treatments as related to demographics and markers of HIV disease stage;
- (iv) To monitor toxicity to antiretroviral therapy; and
- (v) To examine HIV natural history, including relationship between access to antiretroviral therapy and disease progression.

Jan – Dec 2009 Programmatic Objectives for the TAHOD Project

- (i) Add three new clinical centers to participate in TAHOD;
- (ii) Increase participant enrollment and continue follow-up in TAHOD;
- (iii) Create linkages between TAHOD centers and local and national cancer registries to evaluate HIV-related malignancies and increase TAHOD enrollment;
- (iv) Maintain the high quality of HIV clinical data that is collected from each TREAT Asia clinical center and transferred to the TAHOD data management center at the National Centre in HIV Epidemiology and Clinical Research (NCHECR), University of New South Wales;
- (v) Conduct four training meetings for principle investigators and clinical research staff, and determine additional follow-up training needs, if any;
- (vi) Coordinate the TAHOD project by facilitating communication and work flow between principle investigators, clinical research staff, and the data management center.

Description of work

Clinical Centers:

TAHOD currently involves the participation of 17 clinical centers in twelve countries in the Asia-Pacific region. During 2008, TREAT Asia identified three additional clinical centers in Hanoi (Dong Da Hospital), Ho Chi Minh City (Hospital for Tropical Diseases), and Jakarta (Cipto Mangunkusumo General Hospital) interested in participating and enrolling participants into the TAHOD study. In 2009, TREAT Asia staff will assist these centers in preparing regulatory documents, obtaining ethics review and clearance of the protocols, executing award agreements, and implementing participant enrollment.

Study Participants:

As of the latest data transfer, TAHOD clinical centers have enrolled 4,074 patients into prospective follow-up, an additional 558 from 2007. In 2009, participant enrollment is expected to increase with the addition of three new clinical centers. TREAT Asia staff will work to identify additional funding to support an increase in the number of participants enrolled to 300 participants per clinical center (from the current requirement of 200 per center).

HIV-Related Cancer Sub-Studies:

In beginning of 2008, a sub-study of retrospective HIV-related malignancies was initiated. However, the data collection is behind schedule at most sites due to delays in obtaining ethics approval. Sites currently are reviewing medical records and collecting cases of cancer diagnoses since 2000. An estimated 500 cases of cancer are expected to be identified. Data collection and submission is expected to be completed by March 2009.

One TAHOD clinical center, National Yang-Ming University in Taipei will implement a new HIV-related cancer sub-study in 2009. The center will link its TAHOD database with national cancer and medical insurance registries to identify patients with HIV-related malignancies. These patients will contribute to TAHOD.

Data Management:

To assure TAHOD data and analyses are of the highest quality, NCHECR staff will continue to perform ongoing data quality assurance checks. The next check will be performed after the completion of the second 2008 data transfer in September. Data quality will be assured through two mechanisms: (1) computer consistency checks 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 Center as guided by the TAHOD protocol. NCHECR will lead statistical analyses for all TAHOD research.

The TAHOD Steering Committee will identify critical areas of research, develop research concepts, and present research results at international conferences and through manuscripts published in peer-reviewed medical journals. Specific TAHOD research analyses planned for 2009 include:

- Patient characteristics and treatment outcomes associated with protease inhibitor use in the Asia-Pacific region;
- Prevalence and risk factors of metabolic complications and cardiovascular diseases among HIV-infected persons undergoing HAART in the Asia-Pacific region
- AIDS-related and other mortality rates in the TREAT Asia Observational Database and the Australian HIV Observational Database during the

HAART era;

- Deferred modification of antiretroviral regimen following treatment failure in Asia: results from The TREAT Asia HIV Observational Database;
- Anemia following AZT (IeDEA global analysis led by TAHOD)

TAHOD Network Training Workshops

Four workshops will be held for TAHOD principal investigators and research staff to develop research capacity and facilitate the collection of TAHOD data and dissemination of research results. Workshops will include:

An amfAR-sponsored scientific writing workshop for TAHOD/TASER principal and junior investigators will be held in Spring 2009. The goal of this workshop is to support and facilitate greater participation among investigators in the concept sheets and manuscript development process. It is expected that 30 investigators and experienced teaching faculty will attend.

An HIV-related cancers training workshop for investigators and research staff at participating TAHOD centers will be conducted to assess the feasibility of such linkage studies and to facilitate the implementation and conduct of such collaborations. This workshop will also include training participants about HIV-related cancer, diagnoses, and treatment, as well as linking HIV and cancer and data collection procedures.

TAHOD training workshop during the 2009 Annual TREAT Asia Network Meeting will inform investigators and research staff about TAHOD data collection and submission, operating procedures and data quality, provide an opportunity to discuss TAHOD data analyses, and strategies for the following year.

Interim TAHOD training workshop (Spring 2009) will inform investigators and research staff about TAHOD data collection and submission, operating procedures, data quality, and provide an opportunity to discuss TAHOD data analyses.

TREAT Asia staff will determine the need, if any, for additional training and plan subsequent activities accordingly.

Network coordination:

The TAHOD Steering Committee meets quarterly via teleconferences for continued TAHOD updates and discussions about data management challenges and new research ideas. TREAT Asia staff and NCHCR data managers will make regular site visits to the participating clinical centers throughout 2009 to strengthen relationships within the network and to troubleshoot data and study-related issues.

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 2009 Programmatic Objectives for Quality Assurance Scheme (TAQAS)

- (i) Conduct two rounds of quality assurance testing in participating laboratories;
- (ii) Provide results and feedback on quality assurance testing to participating laboratories;
- (iii) Conduct one training meeting for participating laboratory personnel;
- (iv) Implement TAQAS program in additional HIV genotyping laboratories linked with new TASER clinical centers; and
- (v) Investigate the use of dried blood spots for genotyping for possible future use as part of TAQAS and TASER.

Description of work

In 2009, the seventh and eighth rounds of TAQAS proficiency testing will be performed. It is expected that up to 20 laboratories from Asia (TREAT Asia) and Africa (PharmAccess) will participate in these QA panels.

The 4th TAQAS training workshop for laboratory personnel will take place Fall 2009. It is expected that more than 60 participants representing 20+ laboratories in Asia and Africa will attend. The agenda will include a review of the most recent testing results, a discussion of problems encountered, as well as induction of new laboratories into the program.

TREAT Asia staff will identify additional HIV genotypic resistance testing laboratories that are working with new TASER clinical centers to join TAQAS.

In 2008, the TAQAS Steering Committee initiated a working group aimed at incorporating a research component into the TAQAS program. In 2009, the working group will focus on the use of dried blood/plasma spots for HIV genotypic resistance testing. The use of dried blood spots will simplify and expedite sample processing and increase access for clinical centers that lack specimen processing and storage capacity.

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

Gantt Chart Planning and Monitoring Matrix 2009

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 the TASER-Monitoring study	HIV clinical data from six current participating clinical centers which are: 1. HIV-NAT, Thailand 2. Ramathibodi, Thailand 3. Chiang Mai University, Thailand 4. University of Malaya, Malaysia 5. Hospital Sungai Buloh, Malaysia 6. Research Institution of Tropical Medicine, Philippines	1. Renew grant contract 2. Renew ERC approval letter 3. Sites submit report of expenditure(ROE) biannually and payment is made upon the ROE submission	1. 01/01/09 2. 01/01/09 3.1 01/02/09 3.2 01/05/09 3.3 01/11/09	1. 31/01/09 2. 31/12/09 3.1 31/02/09 3.2 31/05/09 3.3 31/11/09
(ii) Achieve implementation and participation of thirteen TREAT Asia centers in TASER-Monitoring study	HIV clinical data from five clinical centers that have not yet started enrollment: 1. YRG Care, India 2. Institution of Infectious Disease, India 3. Udayana Hospital, Indonesia 4. Chiang Rai Hospital, Thailand 5. Siriraj Hospital, Thailand 2) Two additional TREAT Asia centers participating in TASER protocols by year 2009;	1. Assess performance of TASER participating centers based on participant enrollment and data quality. 2. Obtain Ethical Review Committee approval 3. Execute grant contracts 4. Sites submit report of expenditure(ROE) biannually and payment is made upon the ROE submission	1. 01/06/07 2. 01/01/08 3. 01/04/08 4.1 01/02/09 4.2 01/05/09 4.3 01/11/09	1. 31/12/09 2. 31/12/09 3. 31/12/09 4.1 31/02/09 4.2 31/05/09 4.3 31/11/09

Objectives	Results	Key Activities	Start	End
(iii) Identify two additional TREAT Asia clinical centers to begin participation in the TASER-Monitoring study in 2010	Number of TREAT Asia centers participating in the TASER- Monitoring study increased to fifteen in 2010.	<ol style="list-style-type: none"> 1. TREAT Asia staff identify, visit, and assess additional clinical centers 2. Identify two additional clinical centers with required capabilities to participate in the TASER study 	<ol style="list-style-type: none"> 1. 01/01/09 2. 01/01/09 	<ol style="list-style-type: none"> 1. 31/12/09 2. 31/12/09
(vi) Achieve implementation and participation of five TREAT Asia centers in TASER-Surveillance study	<p>Five clinical sites participate and enroll in the study are:</p> <ol style="list-style-type: none"> 1) HIV-NAT, Thailand 2) Chiang Mai University, Thailand 3) Research Institution of Tropical Medicine, Philippines 4) University of Malay, Malaysia 5) To be identified 	<ol style="list-style-type: none"> 1. Assess performance of TASER participating centers based on participant enrolment and data quality 2. Submit and obtain Ethical Review Committee approval 3. Execute grant contracts 4. Sites submit report of expenditure(ROE) biannually and payment is made upon the ROE submission 	<ol style="list-style-type: none"> 1 01/06/07 2 01/01/08 3 01/04/08 4.1 01/02/09 4.2 01/05/09 4.3 01/11/09 	<ol style="list-style-type: none"> 1 31/12/09 2 31/12/09 3 31/12/09 4.1 31/02/09 4.2 31/05/09 4.3 31/11/09
(v) Implement BED assay to assist sites in identifying recently HIV-infected persons for TASER-S study	Use BED Assay to more accurately identify qualified participants for study.	1. Obtain and distribute BED Assay kits	1. 01/10/08	1. 31/12/09

Objectives	Results	Key Activities	Start	End
(vi) Identify one additional TREAT Asia clinical center to begin participation in the TASER-Surveillance study by 2010	Number of TREAT Asia centers participating in the TASER-Surveillance study increased to six in 2010.	<ol style="list-style-type: none"> 1. TREAT Asia staff identify, visit, and assess additional clinical centers and HIV genotyping laboratories 2. Identify one additional clinical center with required capabilities to participate in the TASER study 	<ol style="list-style-type: none"> 1. 01/01/09 2. 01/01/09 	<ol style="list-style-type: none"> 1. 31/12/09 2. 31/12/09
(vii) Facilitate the linkage of clinical centers to laboratories with capabilities of performing HIV genotyping and participating in TAQAS and assist clinical centers to build genotyping laboratory capacity	Increase the number of clinical centers with capacity to perform HIVDR testing and participate in TASER studies.	<ol style="list-style-type: none"> 1. Assess TA network sites for HIVDR genotyping needs 2. Provide support for intra-network assistance 	<ol style="list-style-type: none"> 1. 01/01/09 2. 01/01/09 	<ol style="list-style-type: none"> 1. 31/12/09 2. 31/12/09
(i) Identify technical capacity needs of TASER centers and facilitate capacity building from within and outside the TREAT Asia Network	Increase the number of clinical centers with capacity to perform HIVDR testing and participate in TASER studies.	<p>Assess HIVDR capacity of TASER centers</p> <p>Provide external technical assistance</p>	<ol style="list-style-type: none"> 1. 01/01/09 2. 01/01/09 	<ol style="list-style-type: none"> 1. 31/12/09 2. 31/12/09
(ix) Ensure transfer of TASER data from clinical centers to NCHECR in March and September 2009	All TASER data housed in central database at NCHECR.	<ol style="list-style-type: none"> 1. Data transferred every 6 months from TASER centers to NCHECR. 	<ol style="list-style-type: none"> 1. 01/01/09 	<ol style="list-style-type: none"> 1. 31/12/09

Objectives	Results	Key Activities	Start	End
(x) Maintain TASER databases	Ongoing maintenance of functional databases for TASER studies.	1. NCHECR maintains TASER databases.	1. 01/01/09	1. 31/12/09
(xi) Perform quality assurance assessments of TASER data	Assure quality and consistency of data collected and stored in TASER databases.	1. NCHECR conducts computer consistency checks within TASER databases 2. NCHECR oversees conduct of random internal data monitoring by participating TASER centers 3. Bi-annual TASER Data Quality Assurance Reports	1. 01/01/09 2. 01/01/09 01/04/09 01/10/09	1. 31/12/09 2. 31/12/09 3.1 30/04/09 3.2 31/10/09
(xii) Transfer TASER data into ABL database	International database (linking TASER and PASER data) housed at ABL.	1. NCHECR electronically transfers TASER data into ABL database	1. 01/01/09	1. 31/12/09
(xiii) Conduct three training workshops for TASER investigators	Key research staff trained and/or provided in-depth update on implementing and conducting TASER protocols.	Organize meeting, including identifying curricula/content and presenters/trainers. Invite participants and arrange all logistics for transportation and lodging. Conduct training meeting.	01/04/09 01/04/09 01/09/09	30/09/09 30/09/09 31/12/09
(xiv) Conduct one TASER Steering Committee meeting	A review of the study progress, results of analyses performed in the last year, and a project's direction for next year.	1. Invite participants and arrange all logistics for transportation and lodging. 2. Conduct meeting.(One day meeting)	01/03/09 15/05/09	1. 30/04/09 2. 20/05/09
(xiii) Assess site training and resource needs	Additional training needs identified, if any.	1. Assess performance of TASER participating centers based on data quality and clinical center staff	01/06/09	3. 31/10/09

**Gantt Chart Planning and Monitoring Matrix 2009
TASER Work Plan B: TREAT Asia Observation Database (TAHOD)**

Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Add three new clinical centers to participate in TAHOD	Number of TREAT Asia centers participating in the TAHOD increased to twenty in 2010	1. TREAT Asia staff identify, visit, and assess additional clinical centers	a. 01/01/09	1. 31/12/09
		2. Identify three additional clinical centers with required capabilities to participate in the TAHOD	2. 01/01/09	2. 31/12/09
(ii) Increase participant enrollment and continue follow-up in TAHOD	HIV clinical data from seventeen current participating clinical centers which are: Cambodia National Institute of Public Health, Cambodia Beijing Ditan Hospital, China Queen Elizabeth Hospital, Hong Kong Institute of Infectious Disease, India YRG Centre for AIDS Research & Education, India Udayana University, Indonesia International Medical Centre of Japan, Japan Hospital Kuala Lumpur, Malaysia University of Malaya, Malaysia Port Moresby General Hospital, Papua New Guinea Research Institute for Tropical Medicine, Philippines Tan Tock Seng Hospital, Singapore Yonsei University, S. Korea National Yang-Ming University, Taiwan	a. Renew grant contract and make payment to clinical centers	1. 01/04/09	1. 31/08/09
		b. Renew ERC approval letter	2. 01/01/09	2. 31/12/09
		c. Sites submit report of expenditure(ROE) biannually	3.1 01/04/09 3.2 01/07/09	3.1 30/04/09 3.2 31/07/09

Objectives	Results	Key Activities	Start	End
	Chiang Mai University, Thailand HIV-NAT/ Thai Red Cross, Thailand Ramathibodi Hospital, Thailand			
(iii) Create linkages between TAHOD centers and local and national cancer registries to evaluate HIV-related malignancies and increase TAHOD enrollment	Improved knowledge about HIV-related malignancies and HIV treatment outcomes	<ol style="list-style-type: none"> 1. Submit and obtain Ethical Review Committee approval 2. Execute grant contract 3. Implement linkage 	<ol style="list-style-type: none"> 1. 01/10/08 2. 01/10/08 3. 01/01/09 	<ol style="list-style-type: none"> 1. 31/12/08 2. 31/12/08 3. 31/12/09
(iv) Maintain the high quality of HIV clinical data that is collected from each TREAT Asia clinical center and transferred to the TAHOD data management center at the National Centre in HIV Epidemiology and Clinical Research (NCHECR), University of New South Wales	Assure quality and consistency of data collected and stored in TAHOD databases	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 1. 01/01/09 2. 01/01/09 3. 01/01/10 	<ol style="list-style-type: none"> 1. 31/12/09 2. 31/12/09 3. 31/03/10
(v) Conduct four training meetings for principle investigators and clinical research staff, and determine	Key research staff trained and/or provided in-depth update on implementing and conducting TAHOD protocols	<ol style="list-style-type: none"> 1. Organize meeting, including identifying curricula/content and presenters/trainers. 2. Invite participants and 	<ol style="list-style-type: none"> 01/01/09 01/01/09 	<ol style="list-style-type: none"> 30/09/09 30/09/09

Objectives	Results	Key Activities	Start	End
additional follow-up training needs, if any;		arrange all logistics for transportation and lodging. 3. Conduct training meeting. 4. Identify additional training, if any.	01/03/09 01/09/09	31/12/09 31/12/09
(vi) Coordinate the TAHOD project by facilitating communication and work flow between principle investigators, clinical research staff, and the data management center	Quarterly teleconferences for a review of the study progress and results of analyses performed in the that call period, and a discussion of new research ideas and data-related issues	1. Invite participants and arrange the call 2. Conduct teleconference meeting (Quarterly basis)	1. 01/01/09	1. 31/12/09

Gantt Chart Planning and Monitoring Matrix 2009
TASER Work Plan C: TREAT Asia Quality Assurance Scheme (TAQAS)
Please link activities to results and objectives

Objectives	Results	Key Activities	Start	End
(i) Conduct two rounds of quality assurance testing in participating laboratories	Continue HIV genotype resistance testing quality assurance measures for TASER studies	1. Ship five test samples from National Serology Reference Laboratory, Australia (NRL) to each participating laboratory	01/04/09 (QA#7) 01/10/09 (QA#8)	30/04/09 (QA#7) 31/10/09 (QA#8)
		2. Laboratories process test samples and report results to NCHECR	01/04/09 (QA#7) 01/10/09 (QA#8)	31/05/09 (QA#7) 30/11/09 (QA#8)
(ii) Provide results and feedback on quality assurance testing to participating laboratories	QA outcomes shared with TAQAS-participating laboratories	1. NRL and NCHECR to analyze results and compare to reference laboratory results (Stanford University)	01/06/09 (QA#7) 01/12/09 (QA#8)	30/06/09 (QA#7) 31/12/09 (QA#8)
		2. Results reported on the NRL website to all participating laboratories	01/07/09 (QA#7) 01/01/09 (QA#8)	31/07/09 (QA#7) 31/01/09 (QA#8)
		3. TAQAS laboratories to review results and identify problems and develop solutions to problems	3. 01/07/09	3. 31/12/09

Objectives	Results	Key Activities	Start	End
(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)	1. Organize meeting, including identifying curricula/content and presenters/trainers	1. 01/05/09	1. 30/09/09
		2. Invite participants and arrange all logistics for transportation and lodging	2. 01/05/09	2. 31/08/09
		3. Conduct training meeting	3. 01/09/09	3. 01/09/09
(iv) Implement TAQAS program in additional HIV genotyping laboratories linked with new TASER clinical centers	Provide TASER-participating centres access to quality assured HIV genotypic resistance testing laboratories	1. TREAT Asia staff identify, visit, and assess additional laboratories who has a link with new identified TASER clinical centers	1. 01/01/09	1. 31/12/09
		2. Reach agreement with laboratories to participate in TAQAS program.	2. 01/01/09	2. 31/12/09
(v) Investigate the use of dried blood spots for genotyping for possible future use as part of TAQAS and TASER	Expanding HIV-drug resistance capacity in TREAT Asia network sites	1. Establish a working group by inviting participants in TAQAS network and external experts 2. Brainstorm and receive input from the working group 3. Develop protocol 4. Provide technical and financial support and assistance	01/01/09	31/12/09

III. Risk assessment and contingency plan

Main risks

- (i) Inability of TASER clinical centers 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 centers to enroll sufficient numbers of participants;
- (v) Inability of TREAT Asia centers 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 centers.

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 centers and HIV genotyping laboratory;
- (iii) Encourage TREAT Asia centers to work with other local HIV/AIDS care and prevention centers to assist in identifying potential study participants;
- (iv) Provide TREAT Asia centers with frequent TASER data reports so that centers 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 centers located in areas with high concentrations of high-risk populations (i.e., IDU, MSM, commercial sex workers) and targeting those individuals

Activity Plan 2009

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.

Description of work

In 2008, it was decided to refocus of Roundtable Process (RTP) goal and objectives in such a way that they are fully aligned with and integrated in the FSP programme and will contribute to addressing the needs in the global HIV/AIDS civil society community in a more flexible and effective way.

The FSP aims to strengthen civil society's response to HIV/AIDS through enhanced collaboration at the global, regional and national/local level. It plans to do so primarily by facilitating improved coordination among existing HIV/AIDS networks, including the following: the Global Network of People living with HIV/AIDS (GNP+), the International Community of Women Living with HIV/AIDS (ICW), the International Council of AIDS Service Organisations (ICASO), the International Treatment Preparedness Coalition (ITPC), the International HIV/AIDS Alliance, the World AIDS Campaign and the Ecumenical Advocacy Alliance.

The goal is to support those networks to identify and review current gaps in civil society infrastructures and capacities and propose various strategies to overcome them. Equally important, the FSP will create a space for networks to discuss and build on current strengths and share resources more consistently. Taken together, these steps will increase the ability of civil society actors at all levels—national/local, regional and global—to provide extensive, appropriate, and sustainable services to their core constituents: people living with and affected by HIV/AIDS.

ICSS will circulate a Concept Paper for the FSP that is intended to jumpstart its more formal development before the end of 2008. All participating networks are invited to provide comments and feedback which will play a key role in the development of an Action Plan that will be submitted to potential donors.

1.1 HIV/AIDS Strategy Caucus

1.1.1 Objectives

The Strategy Caucus meetings support the development of a long- and short-term CS vision and actions with regard to the response to HIV/AIDS, giving due consideration to how this relates to current developments in the global health arena, as well as national contexts.

Objective:

To facilitate and promote the HIV/AIDS Strategy Caucus; a systematic process of linking and learning that:

(a) enables civil society stakeholders to determine a collaborative vision (or visions) on the global response to HIV/AIDS; and

(b) provides guidance to the development and implementation of other FSP activity areas.

The FSP-Steering Group sets the long-term agenda of the HIV/AIDS Strategy Caucus, as well as the agenda, dates and composition of specific meetings, based on a consultative process that involves a wider range of members/partners of the networks/organizations.

ICSS functions as the HIV/AIDS Strategy Caucus Secretariat, preparing meetings, carrying out relevant consultations, supporting the FSP-SG in its steering role (preparing annual work plan, annual report and budgets etc) and is responsible for the transparent reporting on the Caucus meetings.

1.1.2 Results

Result	Measurable	Timeline
Key information is disseminated in a timely way and made readily available to those who need it	Questionnaire (7 participating networks; after 10 months)	December 2009
A comprehensive strategy and advocacy agenda is developed systematically over time in an open, accountable and inclusive way	Strategy in meeting report; Advocacy agenda in meeting report	July 2009
Alignment of messaging and (advocacy) efforts, appropriate follow up actions, division of tasks and removal of duplication between actors	Progress measured by questionnaire (all participants; after 10 months)	December 2009
CS stakeholders are better informed, more effective and proactive CS representatives in the global health arena; at the international, regional as well as country level	Progress measured by questionnaire (all participants; after 10 months)	December 2009

1.1.3 Activities

Organization of a three-day HIV/AIDS Strategy Caucus meeting and facilitation of appropriate communication and follow-up action.

Around 26 people will participate in each of the Caucus meetings, of whom at least 50% come from developing countries and 50% are women. Participant profiles:

- 9 senior representatives of the in the FSP participating networks/organizations (GNP+, ICW, ITPC, ICASO, IHAA, EAA, WAC, HDN, ICSS) that each can invite a CS leader from their network/organization; 16 in total;
- 9 representatives from networks representing key populations and the National Partnership Platforms (including Free Space Officers);
- 3 representatives from the Respresentatives Group;
- 2 external experts;
- 3 staff (including rapporteur).

1.2 Civil Society Representation in HIV/AIDS Responses

1.2.1 Objectives

To establish a systematic process of linking and learning that enables CS representatives in the international health institutions to:

- (a) Determine a collaborative vision (or visions) on the response to HIV/AIDS, TB and malaria in the context of the broader global health agenda; and
- (b) Support and establish more effective CS participation in the global health discourse and policy-making architectures.

Civil Society Representatives Group meetings will be organised (including appropriate information and consultation outreach) in order to:

- Share and discuss relevant policy and programmatic information and developments within and among the civil society delegations to the various institutions, international agencies and partnerships.
- Collation and analysis of information and civil society funding opportunities (as a cross-cutting issue for all civil society representatives).
- Strategic discussion and alignment on enhancing civil society participation in these agencies/partnerships and in global health discourses in general.
- Review and refinement of existing and future mechanisms to enhance and promote transparency and accountability of civil society participation in international bodies.

1.2.2 Results

Result	Measurable	Timeline
Key information is disseminated in a timely way and made readily available to those who need it	Success measured by questionnaire (score 5 out of 10)	December 2009
Enhanced quality of the civil society representation in international Institutions, benefiting from joint analyses and strategy development	Confirmed by CS delegation members (score 50%)	December 2009
	Confirmed in 360 degree evaluation(score 5 out of 10)	December 2009
Enhanced accountability of civil society's representation	Confirmed by CS representatives (score 5 out of 10);	December 2009
	confirmed by NNP members (score 6 out of 10)	December 2009
More effective feedback and consultation mechanisms within the CS HIV/AIDS communication environment.	Confirmed by CFPs of delegations (score 50%)	December 2009
	Confirmed by NNP members (score 5 out of 10)	December 2009

1.2.3 Activities

Organize a CS Representatives Group Meeting (36 people):

- GFATM CS delegations: 9 (Board member, Alternate and Communications Focal point from each of the three delegations).
- UNAIDS PCB NGO Delegation: 11 (Member and Alternate from each of the five regions plus the Communications Facility (one person)).
- UNITAID CS Board: 5 (2 Board Members, 2 Alternates, 1 Communications Focal Point).
- GAVI Alliance Board: 3 (2 CS Representatives, 1 Communications Focal Point).
- IHP+ SuRG: 3 (2 CS Representatives, 1 Communications Focal Point)
- External experts : 2

- Support staff: 3.

ICSS will provide secretarial support to the organisation of the Civil Society Representatives meetings.

1.3 Strengthening Civil Society at the Country Level

1.3.1 Objectives

- Establishing National Partnership Platforms (NPPs) that allow CS to strategize on the national agenda vis-à-vis national and international HIV/AIDS and Health policies and initiatives, and develop a shared advocacy agenda and appropriate follow up.
- Align and harmonize current information dissemination, communication and IT systems in order to improve timely access to appropriate information on all levels.

1.3.2 Results

- Follow up provided to the FSP Country Level Capacity meeting; NPPs in 2 countries initiated.
- Aligned and harmonized information dissemination and communication systems in place.

1.3.3 Activities

Further development and expanded implementation of National Partnership Platforms (NPP) strategy at the country level. The NPP strategy enhances civil society priority- and agenda-setting, strategic programming and planning, and provide an opportunity for identification of communication, policy advocacy and related organisation capacity needs. Next to this, NPPs provide an opportunity for connecting the national level to the regional and international level.

M&E

ICSS will continue to further develop a system for more rigorous and improved monitoring & evaluation of the FSP activities.

Budget

HIV/AIDS Strategy Caucus	TMF 2009
Steering Group Meeting 15 people, 2 days (travel, DSA, venue, support)	€ 10,000
Civil Society Representation in HIV/AIDS Responses	TMF 2009
Meeting cost 35 people, 3 days (travel, DSA, venue, support)	€ 70,000
National Partnerships Platforms (NPPs)	TMF 2009
Follow up to Country Level Meeting	€ 20,000
Total Activity Cost TMF 2009	€ 100,000
Total Personnel Cost TMF 2009	€ 156,961
Total project cost Free Space Process for TMF 2009	€ 256,961

Risk assessment and contingency plan

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.