# FRANCE EXPERTISE INTERNATIONALE

**Bordereau de transmission**

**Objet :**

- [x] Accord bénéficiaire
- [ ] Convention de subvention
- [ ] CPS « Réseau Initiative 5% »
- [ ] CPS hors « Réseau Initiative 5% »
- [ ] CPS Expert Individuel
- [ ] CPS Expert Individuel
- [ ] Convention de délégation de gestion
- [ ] Avenant – préciser :
- [ ] Autre :

**Détails** :

**Code projet : 13INI134**

**Intitulé projet : Initiative 5%** - Mission de renforcement de capacités pour la prise en charge des co-infections / Thaïlande

*Dossier suivi par (chargé de projets) : Adeline Lautissier – 01.43.17.73.86*
*Date de transmission : 11/02/2014*

| | **DRAFT** (*pour envoi partenaire*) | **POUR SIGNATURE DU DIRECTEUR GENERAL FEI** |
|---|---|---|
| | **Date & Signature** | **Date & Signature** |
| **Responsable administratif et financier RAF** | | |
| **Directeur de missions DM** | | 21-02-14 |
| **Directeur des opérations DOD** | | 26 FEV. 2014 |

**Commentaire Chargé(s) projets:**
Signature scan en attente des originaux

**Commentaire Direction :**

INITIATIVE 5%
SIDA, TUBERCULOSE, PALUDISME

# AGREEMENT FOR THE IMPLEMENTATION OF AN EXPERTISE MISSION

## INITIATIVE 5%
## HIV/AIDS, Tuberculosis and Malaria

## No. ACC2013INI134

Between,

**France Expertise Internationale (FEI),**
Etablissement Public à caractère Industriel et Commercial,
45, rue Linois, 75015 Paris, France,
Represented by its Director General, Mr. Cyrille PIERRE,
*Hereafter referred to as "FEI"*

And

**Faculty of Associated Medical Sciences - Chiang Mai University**
**UMI 174 / PHPT**
110 Intawaroros Rd, T. Sripoom
Muang, Chiang Mai 50200, Thailand
Represented by the Dean Dr. Wasna SIRIRUNGSRI,
*Hereafter referred to as "the Beneficiary"or "PHPT"*

*Hereafter together referred to as the "Parties",*

**GIVEN:**

- The 5% Initiative, HIV/AIDS, Tuberculosis and Malaria, which is France's second means of contribution to the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria (GFATM), is dedicated to the sustainable improvement of health impacts of GFATM grants on populations affected by these diseases in priority countries for French development assistance. The Ministry of Foreign Affairs (MAE) supervises the 5% Initiative and France Expertise Internationale (FEI) is in charge of the operational implementation.

- The Beneficiary requested the support of the 5% Initiative, through Channel 1, for the implementation of an expertise mission to strengthen viral hepatitis B and C diagnosis, care, treatment and laboratory monitoring in HIV-infected patients.

- This request for an expertise mission was approved by the 5% Initiative Steering Committee on 5 December 2013.

**HAVE BEEN AGREED UPON:**

## ARTICLE 1 – PURPOSE OF THE AGREEMENT

1.1 The purpose of the Agreement is to establish the conditions of implementation of an expertise mission to support the Beneficiary and its partners to strengthen viral hepatitis B and C diagnosis, care, treatment and laboratory monitoring in HIV-infected patients

1.2 The mission is implemented by FEI, which can delegate its implementation to one of its accredited partners.

1.3 To execute the mission, FEI will provide the Beneficiary with 6 technical experts.

## ARTICLE 2 – EFFECTIVE PERIOD OF THE AGREEMENT AND OF THE IMPLEMENTATION OF THE MISSION

2.1 The agreement takes effect on January 1st, 2014. The implementation period is January 1st, 2014 – December 31st, 2014

2.2 The total duration of the missions is 46 working days maximum.

## ARTICLE 3 – BENEFICIARY'S RESPONSABILITIES

3.1 The Beneficiary agrees to implement all means at its disposal to ensure the proper execution of the mission. In particular, it will:

- Appoint Gonzague JOURDAIN as the focal point responsible for the implementation of the mission;
- Provide the experts with the means necessary for proper execution of the mission, as specified in the attached Terms of Reference, as well as any other means deemed necessary throughout the mission;
- Ensure the availability of staff to achieve the objectives of the mission;
- Facilitate the general execution of the mission;
- Sign the experts' timesheets within a reasonable timeframe.

3.2 The Beneficiary guarantees that the mission is executed in accordance with the Terms of Reference and will keep FEI informed of its smooth running. In particular, it will:

- Report any problems encountered during the implementation of the mission;
- Report any event or condition which may delay or prevent the successful completion of the mission;
- Send a completed assessment form at the end of the mission.

**ARTICLE 4 – SUBMISSION OF MISSION REPORTS**

4.1 The reports specified in the Terms of Reference will be presented to the Beneficiary by FEI.

4.2 The Beneficiary has a period of 30 days to comment or validate the report. In the absence of a written reply within this period, the report or summary will be deemed approved.

**ARTICLE 5 –OWNERSHIP AND VISIBILITY**

5.1 Ownership, title and intellectual property rights of the results of the mission and the reports and other related documents are granted to the Beneficiary.

5.2 The Beneficiary shall grant FEI, the Ministry of Foreign Affairs and the GFATM, the right to use free of charge, for non-profit purposes and as it sees fit all documents deriving from the expertise mission, whatever their form, provided it does not thereby breach existing intellectual property rights.

5.3 The Beneficiary shall ensure the visibility of the support for this mission by the 5% Initiative.

**ARTICLE 6 – TERMINATION OF THE AGREEMENT**

If a Party believes that the purposes of the Agreement can not longer be effectively or appropriately carried out, it shall consult the other Party. If no solution is found, either Party may terminate the Agreement with a written one month notice.

**ARTICLE 7 – CONTACT**

All official correspondence exchanged between the Parties under this Agreement must be sent to the addresses specified in this Article or any new address notified in writing by the Party to the other Party:

**FEI:**

**FRANCE EXPERTISE INTERNATIONALE**
5% Initiative HIV/AIDS, Tuberculosis and Malaria
45 rue Linois,
75015 Paris, France
Initiative5PC.FEI@diplomatie.gouv.fr

Representative responsible for the implementation of the present Agreement:
Audrey GIRET, Project Director,
Ph. : +33.1.43.17.68.83
E-mail : audrey.giret@diplomatie.gouv.fr

**Beneficiary:**

**Faculty of Associated Medical Sciences - Chiang Mai University**
**UMI 174 / PHPT**
110 Intawaroros Rd, T. Sripoom
Muang, Chiang Mai 50200, Thailand

Representative responsible for the implementation of the present Agreement:
Gonzague JOURDAIN, Director
Tel: + 66 8 1883 0065
Email: gonzague.jourdain@phpt.org

Signed in two original copies in English, one for each party's records:

**Faculty of Associated Medical Sciences of Chiang Mai University**
**UMI 174 / PHPT**
**Dr. Wasna SIRIRUNGSRI**
**Dean**

Signature

Signed in Chiang Mai, date: 10 February 2014

**France Expertise Internationale**

Pour
**Cyrille PIERRE,**
**Directeur Général**

Signature

**Alexandre GRONIER**
*Directeur Délégué*
*Directeur des opérations et du Développement*

Signed in Paris, date: 24.02.2014

**ANNEX I, AN INTEGRAL PART OF THIS AGREEMENT: TERMS OF REFERENCE**

# TERMS OF REFERENCE

# Mission No. 13INI134

## I. General information

| | | | | |
|---|---|---|---|---|
| Title of the expertise mission | Support to improve viral hepatitis B and C diagnosis, care, treatment and laboratory monitoring in HIV-infected patients | | | |
| Component | HIV (co-infections) | | | |
| Issue(s) | Care | | | |
| Beneficiary | UMI 174 / PHPT – Faculty of Associated Medical Sciences of Chiang Mai University | | | |
| Country | Thailand | | | |
| Related Global Fund Grant(s) | Total Amount | Period | Grant Rating | Date of latest rating |
| THA-H-DDC-008/SSF | 1,339,194.74 | 01/10/2013 – 30/09/2014 | A2 | 16-Oct-2013 |
| Total number of working days | Up to a maximum of 46 working days | | | |
| Contact at FEI | Focal Point | | Contact Details | |
| | Adeline Lautissier | | Adeline.Lautissier@diplomatie.gouv.fr | |

## II. Background of the expertise mission

*HIV and viral hepatitis:*

There are an estimated 3.5 million people living with HIV in South-East Asia Region; of these, 37% are women. Five countries account for majority of the burden, namely India, Indonesia, Myanmar, Nepal and Thailand. Over 1 million people in Thailand have been infected with HIV and, up to 2003, approximately 551,000 HIV infected people died of AIDS.

Among HIV infected adults in Thailand, about 7% are chronically co-infected with Hepatitis B virus (HBV); and about 2.5% co-infected with Hepatitis C virus (HCV). While antiretroviral treatment has greatly improved the prognosis of HIV infected patients, patients with hepatitis co-infection remain at higher risk of morbidity and mortality, even when receiving HIV antiretroviral treatment.

*Thailand national HIV treatment program*

The use of potent antiretroviral drug combinations or Highly Active Antiretroviral Therapy (HAART) has been shown very effective in reducing HIV-related morbidity and mortality and improving quality of life. In 2012, 474,623 people were living with HIV in Thailand; 239,090 were on antiretroviral treatment while 341,752 had a CD4 cell count below 350 cells/mm3. While patients on antiretroviral treatments have a prolonged survival, they are still at risk for various long term complications, such as cancers, cardiovascular, kidney, bone, liver, neurocognitive and metabolic disorders. Those long term complications may result from different interacting factors: residual HIV replication, viral co-infections, immune activation and systemic inflammation, and side effects of antiretroviral drugs. In Thailand, HBV and HCV infections are responsible for liver diseases, cirrhosis and cancers in the general population. In HIV infected patients, these complications of viral hepatitis infections develop faster.

*IRD-PHPT (UMI 174)*

The international joint research unit "Prevention and treatment of HIV infections and virus-associated cancers in South East Asia" (UMI 174-PHPT) is a collaborative program between the Faculty of Associated Medical Sciences at Chiang Mai University, and the *Institut de Recherche pour le Développement* (IRD, France). The general objective of this collaboration is to contribute to the improvement of public health in Thailand, especially in the field of infectious diseases, involving a large network of scientists, academics, public health policy makers and clinicians affiliated with governmental and academic institutions in Thailand, in France and the USA. The PHPT clinical research group in Thailand includes a network of 50 public hospitals. Its coordination center in Chiang Mai is responsible for protocol development, training of health care workers and advanced students in health related sciences, monitoring of onsite activities, data processing and analysis, logistics, drug distribution and administration. A central Virology and Pharmacology Laboratory, linked to the Faculty of Associated Medial Sciences at Chiang Mai University, is supporting clinical research activities and conducting laboratory based research.

***Key issues:***

*Diagnosis of viral hepatitis*

In the PHPT cohort, HCV and HBV test is systematically performed before initiation of antiretroviral therapy. We have observed that the prevalence of these two co-infections is significant. However, in Thailand, most HIV infected people do not know whether they are also chronically co-infected with a hepatitis virus. Many HIV care providers would need some training to better understand testing for viral and other hepatitis, how and in which circumstances this should be done. As a consequence, patients may receive HIV antiretroviral drugs which are likely to cause hepatotoxicity, such as nevirapine, protease inhibitors or anti tuberculosis drugs. Materials for training should developed for HBV infection (past or active infection, tolerance phase, occult infection, immune protection, superinfection by HDV, value of rapid tests, etc.), HCV (serology, viral replication), etc.

*Fibrosis assessment*

The progression of the liver disease has to be assessed before any therapeutic decisions. Today in Thailand, patients whose liver disease has not yet significantly progressed, do not need to be treated immediately (it may be wise to postpone treatment until new promising interferon-free agents, currently in development, are available and affordable). Those with more advanced liver disease should be treated in priority before their health status has worsened to the point treatment is no longer possible. A limitation for the treatment of HBV and HCV infection in HIV infected patients is the lack of non-invasive tools to assess the progression of the liver disease. Liver fibrosis used to be assessed by liver biopsy but this cannot be widely implemented. It is considered today that noninvasive methods such as transient elastography (Fibroscan®) are essential to determine HCV or HBV treatment indications and therefore provide larger access to treatment. Transient elastography equipment is available in some University hospitals. PHPT will negotiate and organize the use of a transient elastography machine for the patients enrolled in the GFTAM program.

*HBV treatment*

HBV infection is highly prevalent in adults in South-East Asia (immunization programs have started to decrease the prevalence in children), and the most prevalent genotypes (C and B) are highly replicative, more likely to cause liver cancers. The situation of HDV super-infection in HIV infected patients is unclear in Asia. With regard to HBV specific treatment, as in many resource-limited countries, HIV-HBV co-infected patients often initiate their first-line HAART with a fixed dose combination that includes lamivudine. This treatment is suboptimal for HBV infection: it may lead to

rapid emergence of resistance mutations, compromising future HBV treatment options. The management of HIV-HBV co-infected patients is complicated due to interferences between the two diseases. Discontinuation of HBV infection treatment may trigger life-threatening disease exacerbations due to viral replication rebound. Although there are criteria to consider such discontinuation in mono-infected patients, this has not been evaluated in the context of HIV coinfection.

*Access to HCV treatment*

Peg-interferon + ribavirin treatment for Hepatitis C infection, currently recommended by the Asia Pacific Association for the Study of the Liver (APASL) can cure HCV infection, a major step to be achieved for co-infected patients to decrease the risk of cirrhosis and cancer. However this treatment is almost never administered to those who need it. Currently, gastro-enterologists provide hepatitis C treatment to a few mono-infected patients in Thailand. These specialists usually have little experience in managing HIV treatment. Conversely, HIV infection treatment is managed by internists and Infectious Disease specialists but they have no or little experience of managing HCV co-infection treatment and related side effects. HCV treatment costs are not covered by the Universal Coverage scheme for HIV-HCV co-infected patients. These are major barriers to access to state-of-the-art treatment for HCV-HIV co-infected patients. The recommended treatment of HCV is often associated with severe side effects (anemia, flu-like syndromes, psychiatric disorders) that require a team of well trained and supportive physicians and nurses.

Anemia is a major complication of treatment with ribavirin and it seems that therapeutic drug monitoring (TDM) could be useful in this setting to monitor dose reduction while maintaining efficacious concentration. Drug-drug interactions between HIV and HCV drugs also need to be considered. Increased toxicity in relation with alteration of exposure may occur with HIV-HCV cotreatment. For example, it is recommended to avoid the combination of didanosine (ddI) with ribavirin and/or pegylated interferon alfa-2b, which could cause or worsen mitochondrial toxicity. The PHPT pharmacology laboratory is currently establishing an assay to determine ribavirin levels and would need the support of an expert in this field to review and adapt our procedures for TDM.

*Evolution of the situation*

In conjunction with the GFATM portfolio manager and the CCM, the director of the Thailand MoPH-DDC GFATM-PR office has encouraged discussions between stakeholders in 2013 to improve the situation, in particular within the GFATM supported program. In particular, three sub-recipients (SR) of the MoPH-DDC grant, PSI Thailand, HIV-NAT and PHPT, have been requested to plan for HCV treatment in HIV co-infected patients in the context of their GFATM-supported program. This situation represents therefore a unique opportunity for many HIV co-infected patients to be cured of their HCV infection and, for Thailand, to embark on the treatment of HCV-HIV co-infection. Within the GFATM supported HIV treatment program conducted by PHPT, we will initiate in early 2014 a pilot program to treat co-infected patients in the setting where they receive HIV care (internal medicine departments).

*Needs*

Specific training for health care workers, laboratory specialists, patients, supportive groups and program managers is urgently needed. PHPT organized in Chiang Mai on 11 September 2013 a training on HCV treatment management. Participants were active in discussions, acknowledged that they learned about HCV treatment in HIV infected patients but still, after such a short training, did not feel that they were ready for managing HCV treatment. As for HIV-HBV co-infection management, PHPT has not had yet the possibility to organize specific trainings. In addition, there are scarce data on HCV infection and its treatment in South-East Asia, especially in the HIV

population. As part of its mission to improve public health in this field through clinical research, PHPT is implementing a cohort study of HIV-patients co-infected with hepatitis viruses. In that context, it is essential that data and blood samples from those patients are appropriately and accurately collected before and on specific treatment to allow reliable analyses and answer public health questions.

In summary, scientists and health care workers participating in the PHPT HIV program supported by the GFATM need expertise support to improve viral hepatitis monitoring, care and treatment.

## III. Objective and expected results

### 1) General objective of the expertise mission

Contribute to health system strengthening, through better knowledge and knowhow of hospital staffs in the field of HCV and HBV infection and their treatment.

### 2) Specific objectives

- To update the knowledge of health care workers, patients, groups of patients, and other representatives on the diagnosis of HCV and HBV (as well as HDV super-infection), their epidemiology, their natural history, acute and long term complications (fulminans hepatitis, fibrosis, cirrhosis, cancers), prevention and treatment, especially in the context of HIV infection.

- To build capacity for clinical management of hepatitis C and B treatment in HIV infected individuals: counseling and therapeutic education, management of complications and side effects, especially anemia and psychiatric effects.

- To build capacity for the interpretation of transient elastography (Fibroscan) for noninvasive assessment of liver fibrosis by clinical team members to help identify HIV co-infected patients in need of urgent treatment.

- To build capacity for laboratory diagnosis and monitoring of HBV and HCV infections in HIV infected individuals (children and adults): optimal use of diagnostic tests (including rapid and combined tests), assessment of liver disease using plasma fibrosis markers and virological evolution (HBeAg, HBV resistance tests, HCV and HBV viral loads, quantitative HBsAg, etc.).

- To build capacity for the use of clinical and laboratory data collected in patients co-infected with viral hepatitis.

### 3) Beneficiaries

The beneficiaries will be primarily program managers, health care workers, hospital staff, patients and community groups involved in the GFATM supported program and, ultimately, patients with HIV and viral hepatitis co-infections who receive care and prevention interventions today and in the future. The experts will mostly work with representatives of patients and health care professionals based in Chiang Mai to limit intra-country trip expenses and may need in some cases invite some of them from other PHPT sites to Chiang Mai or visit a site with an expert.

### 4) Expected results

Health care workers involved in the implementation of the Thai GFATM program improve their knowledge and knowhow regarding the management of HCV, HBV and HDV super-infection. They are able to diagnose, provide efficient counselling, monitor liver disease, deliver treatment and manage treatment side effects for the most frequent viral hepatitis in HIV co-infected patients.

## IV. Description of the expertise mission

### 1) Description of tasks

Item 1
- Identifying topics/concepts that are essential to communicate to patients, civil society members and patients representatives, to develop a basic understanding of viral hepatitis co-infection diagnosis, natural history, complications and treatment so they can, themselves, use this knowledge to support patients and their relatives and advocate access to appropriate care and treatment. This work will be performed with HCV-HIV treatment program managers, clinicians (physicians, nurses), patients representatives and Community advisory board members.
- Reviewing treatment protocols, manual of operations, presentations and other materials used by site clinicians to guide the management of HCV treatment in HIV co-infected patients. Work to be performed with HCV-HIV program managers and clinicians.

Item 2
- Interpretation of transient elastography exams (Fibroscan) before and after completion of specific treatment.
- Clinical management of HCV and HBV treatment side effects in the context of HIV-co-infection: guidelines for physicians and nurses at the clinics.
Work to be performed with HCV-HIV program managers, clinicians.

Item 3
- Review pharmacokinetic issues that may arise with the use of drugs for HCV treatment in HIV infected patients receiving antiretroviral treatment (drug to drug interactions)
- Develop practical guidelines for monitoring HCV/HIV treatment drug levels.
Work to be performed with PHPT pharmacologist, laboratory technicians, physicians, HCV-HIV program managers.

Item 4
- Developing materials for counseling before and throughout the treatment, monitoring and managing psychiatric side effects of peg-interferon, as well as addiction related issues.
Work to be performed with HCV-HIV treatment program managers, nurses, clinicians.

Item 5
- Reviewing procedures for virological evaluation of common viral hepatitis in HIV infected patients (diagnostic, resistance, laboratory procedures).
- Laboratory investigations in HBV-HIV co-infected children and adults.
Work to be performed with laboratory technicians in charge of tests for HBV, HCV, HIV, virologists involved in HCV, HBV treatment program for HIV infected patients.

Item 6
Developing easy-to-use materials to efficiently communicate in lay language specific HCV treatment information (expected benefits of treatment, principles, factors increasing the likelihood to achieve a cure, adherence, adverse effects ...) for HIV co-infected patients using what has been identified as essential in Item 1. Animation movies, flip charts, and presentations can be used as media.
Work to be performed with Patients representatives, Community advisory board (CAB) members, HCV-HIV program managers, clinician, nurses

Of note, Thailand will develop during the first months of 2014 a proposal to the GFATM through the New Funding Model mechanism. Each expert will be requested to discuss plans for PHPT's contribution to this proposal.

**2) Expected deliverables**

Item 1
- Training curriculum and materials, pre-and post-test evaluations, in lay language.
- Treatment protocol, manual of operations for HCV treatment in co-infected patients.

Item 2
- A presentation that explains the general principles of transient elastography, its indications for HCV and HBV treatment, fibrosis evolution on and after specific treatment.
- A presentation of the management of drug side effects of HCV treatment (especially peg-interferon + ribavirin) including anemia in a context where EPO is not available, based on national/regional recommendations (excluding psychiatric complications, which will be one of the focus of Dr. Laurent MICHEL's mission).

Item 3
Presentation/flow charts of Therapeutic Drug Monitoring guidelines for HCV treatment.

Item 4
A presentation of counseling guidelines; management of psychiatric side effects.

Item 5
Presentation, review of laboratory procedures.

Item 6
Animation movie, flip charts, presentations for patients and relatives counseling.

**3) Coordination**

The consultancy will be coordinated by Gonzague JOURDAIN and FEI.

## V. Place, duration and implementation details

1) **Implementation period :** January 2014 to December 2014

2) **Start date :** January 2014

3) **End date:** December 2014

4) **Effective duration :** up to 46 working days

## 5) Provisional timetable:

| Items | Expert | Tasks | Audience, primary recipients of the expertise | Deliverables | Implement ation Period | Place | Working Days |
|---|---|---|---|---|---|---|---|
| 1 | Christian TREPO | - Identifying topics/concepts that are essential to communicate to patients, civil society members and patients representatives, to develop a basic understanding of viral hepatitis co-infection diagnosis, natural history, complications and treatment so they can, themselves, use this knowledge to support patients and their relatives and advocate access to appropriate care and treatment.<br>- Reviewing treatment protocols, manual of operations, presentations and other materials used by site clinicians to guide the management of HCV treatment in HIV co-infected patients. | HCV-HIV treatment program managers, clinicians (physician + nurse), Community advisory board members, patients representatives (2 days)<br><br>HCV-HIV program managers, clinicians (3 days) | - Training curriculum and materials, pre-and post-test evaluations, in lay language.<br>- Treatment protocol, manual of operations for HCV treatment in co-infected patients. | Second semester 2014 | AMS-PHPT in Chiang Mai and an affiliated hospital in the Bangkok region | 5 days on site |
| 2 | Stanislas POL | - Fibrosis evolution on and after viral hepatitis treatment<br>- Fibrosis biological markers: AST-platelet ratio index (APRI), Forns index and FIB-4 for hepatitis<br>- Interpretation of transient elastography exams (Fibroscan) before and after completion of specific treatment.<br>- Clinical management of HCV and HBV treatment side effects in the context of HIV-co-infection: guidelines for physicians and nurses at the clinics. | HCV-HIV program managers, clinicians | - A presentation of fibrosis biological markers and transient elastography, their indications for HCV and HBV treatment.<br>- A presentation of the management of drug side effects of HCV treatment (especially peg-interferon + ribavirin) including anemia in a context where EPO is not available, based on national/regional recommendations. | Third quarter of 2014 | AMS-PHPT in Chiang Mai and in Bangkok region | 4 days on site |
| 3 | Anne- | - Review pharmacokinetic issues that may arise | Pharmacologist, | Presentation/flow charts | Second | AMS-PHPT | 5 days on site |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Marie TABURET | with the use of drugs for HCV treatment in HIV infected patients receiving antiretroviral treatment (drug to drug interactions)<br>- Develop practical guidelines for monitoring HCV/HIV treatment drug levels. | laboratory technicians, physicians, HCV-HIV program managers | of Therapeutic Drug Monitoring guidelines for HCV treatment. | quarter of 2014 | in Chiang Mai and an affiliated hospital in the Bangkok region | |
| 4 | Laurent MICHEL | - Developing materials for counseling before and throughout the treatment, monitoring and managing psychiatric side effects of peg-interferon, as well as addiction related issues. | HCV-HIV treatment program managers, nurses, clinicians | A presentation of counseling guidelines; management of psychiatric side effects. | June-July 2014 | AMS-PHPT in Chiang Mai and an affiliated hospital in the Bangkok region | 4 days on site in Thailand<br>+<br>3 days for preparation |
| 5 | Camille SUREAU | - Reviewing procedures for virological evaluation of common viral hepatitis in HIV infected patients (diagnostic, resistance, laboratory procedures).<br>- Laboratory investigations in HBV-HIV co-infected children and adults. | Laboratory technicians in charge of tests for HBV-HCVHIV. Virologists involved in HCV, HBV treatment program for HIV infected patients | Presentation, review of laboratory procedures. | First quarter 2014 | AMS-PHPT in Chiang Mai | 5 days on site in Thailand |
| 6 | Call for candidates to be launched | Developing easy-to-use materials to efficiently communicate in lay language specific HCV treatment information (expected benefits of treatment, principles, factors increasing the likelihood to achieve a cure, adherence, adverse effects ...) for HIV co-infected patients using what has been identified as essential in Item 1. Animation movies, flip charts, and presentations can be used as media. | Community advisory board (CAB) members, HCV-HIV program managers, clinician, nurses | Animation movie, flip charts, presentations for patient and relatives counseling. | Third quarter of 2014 | AMS-PHPT in Chiang Mai | 5 days on site + up to 15 days for preparation / finalization |
| | | | | ***TOTAL working days*** | | | **45** |

## VI. Expertise and profiles

1) **Number of experts :** up to 6 experts

2) **Experts Profiles :**

The proposed 5 experts are knowledgeable in hepatitis B and C, HIV infection and public health issues in South East Asia. All experts have teaching experience. Stanislas POL and Christian TREPO are hepatologists, internationally recognized for their contributions to the field of viral hepatitis. They have clinical experience in HCV and HIV co-infection treatment management, and extensive knowledge about these infections. S. POL has specifically worked on the impact of antiviral treatment on fibrosis and regression of cirrhosis. C. SUREAU, a virologist, is known for his expertise in HBV and HDV infections and will provide advice regarding laboratory aspects required for the virological assessment and follow up of patients, including assessment of resistance, laboratory security issues, etc. Laurent MICHEL, a psychiatrist, is specializing in addictology. He has extensive experience in the clinical psychiatric management of patients HIV-HCV co-infected and is involved in HCV/IVDU research in Vietnam. Anne-Marie TABURET is a pharmacologist with extensive therapy drug monitoring experience for HIV and viral hepatitis treatment management and has contributed to pharmacokinetic studies conducted in South East Asia (Vietnam, Cambodia).

**1 expert in: Communication for public health**

Qualifications and skills:

- Master degree in communication, public health, social sciences or a combination of university degree.
- Excellent interpersonal skills and ability to establish and maintain effective working relations with people in a multi-cultural, multi-ethnic environment with sensitivity and respect for diversity.
- Excellent planning, organisation and problem solving skills.
- Excellent command of the English language; verbal and oral.

Professional Experience:

*Essential:*

- At least 4 years of experience in the design and development of communication materials

*Preferred:*

- Prior working experience in Thailand.
- Experience working with international and national NGOs on health programs.
- Thai language skills are an advantage.

## VII. Mission Report

In addition to the deliverables, the experts will provide regular feedback to FEI, and:

- A final mission report due at the end of each on site mission, within 30 days of the return from the mission.

Language of the reports: English or French

Report terms: reports will be emailed to FEI.

## VIII. Monitoring and Evaluation

| Deliverable | Direct effects | Interim effects | Means of verification |
|---|---|---|---|
| HCV Training Curriculum and materials | 8 physicians, nurses and CAB members able to explain in lay language, and advocate access to, HCV diagnosis and treatment | Persons trained organize at least one meeting with at least 10 patients/relatives in the community to discuss HCV treatment issues | % of staff trained; meeting held |
| HCV treatment protocol and manual of operations | 3 program managers finalize expert-validated materials to guide HCV treatment in HIV infected patients | Materials are made available to at least 3 clinics within 6 months and used | Materials finalized and validated |
| Liver fibrosis evaluation | 12 program managers, nurses or physicians able to explain the indications and results of various way to assess fibrosis | 12 program managers, nurses or physicians implementing fibrosis assessment in their clinics | % of staff adequately trained (test |
| Clinical management of treatment side effects | 12 program managers and clinicians able to identify and manage treatment side effects | 12 nurse and physician clinicians monitoring HCV treatment side effects | % of staff adequately trained (test) |
| Therapeutic Drug Monitoring guidelines for HCV treatment | 2 program managers, 1 laboratory technician, 8 clinicians, understanding the indications for plasma anti-HCV/anti-HIV drug level determination | 11 pharmacologists, laboratory technicians, clinicians, and program managers monitoring drug levels and drug-drug interaction during HCV treatment for HIV-infected patients | % of staff adequately trained (test) |
| Guidelines and materials for counseling and management of psychiatric side effects | Materials for counseling and management of psychiatric side effects developed and validated by the expert | At least 3 clinics using these materials | Materials finalized and validated |
| Laboratory procedures for virological evaluation of viral hepatitis | A presentation explaining the principles and indications of virological tests for diagnosis and treatment monitoring of HBV and HCV infection, including resistance testing. | 13 clinics use the materials | Materials finalized and validated<br>% of staff trained |
| Animation movie, flip chart, presentation for HCV treatment information in HIV-infected individuals | HCV information materials to facilitate counseling and advocacy in the community developed, available and easy to use | 13 clinics and patients supportive groups use the materials | Materials finalized and validated<br>% of clinics using materials |

## IX. Practical Information

Experts will have access to all information regarding the GFATM supported PHPT cohort of HIV infected patients, laboratory results, previous analyses and reports. PHPT provides access to internet, meeting and conference rooms.
PHPT will invite local experts and clinicians, and organize the corresponding logistics.

Working meetings will take place at Chiang Mai University except one with participants from other locations, organized in Bangkok to minimize expenses.