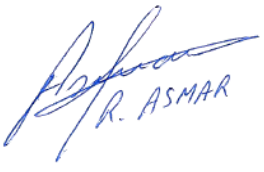
Foundation – Medical Research Institutes

Activities Report 2013

Pr. Roland Asmar
Chairman

Date: **March 10th, 2014**

Signature



CONTENTS

Summary

Research, especially in the Health area, represents a major issue with respect to the economic and social development of a country and. All actors in the field meet particular interest in that development: patients, universities, hospitals, practitioners, researchers and industries. In this regard, the medical research deserves much attention because of its direct consequences on the population.

The Foundation - Medical Research Institutes, established since 2009 as public utility non-for-profit organization in Geneva (Switzerland), has implemented officially in the Middle East in 2010 with a regional Head quarter in Lebanon. It designed its project entitled "Development of Academic Medical Research in the Middle East" with academic and interuniversity prospects to bring a significant contribution to the development of medical research and continuing medical education in the Middle-East region.

The first "Activities Reports" reported the essential activities undertaken by the Foundation in 2010-2012; they were classified according to the initial plan of the project described in the Foundation brochure, namely: administration, academic education, research units, research projects, public health and others.
The present "Activities Report" reports the main activities which have been continued and/or initiated by the F-MRI in 2013.

Overall, despite issues related to the political and security situation in the region, the activities undertaken during 2013 were significant. Particularly, it should be noted that the academic teaching of medical research undertaken by the Foundation in collaboration with the Lebanese University has met unlimited success. In addition, two clinical research units have been established in an academic hospital during 2013. Moreover, the other activities of the F-MRI have been considerably developed during 2013: Establishment of the Basic Science research unit and its related clinical studies; Development of the regional Continuous Medical Education program, and initiation of the public-health project with an important epidemiological study.
The future perspectives for 2013 are also described.

The Foundation-Medical Research Institutes

Main Issues

The Foundation - Medical Research Institutes (F-MRI): Governance*

The Foundation - Medical Research Institutes (F-MRI, Geneva Switzerland), is a public utility non-for-profit organization registered in Geneva, regulated by the Swiss law. This organization chaired by its President and founder, Prof Roland Asmar has been established in 2009 and officially recognised in 2010. It is registered with the trade and placed under the control of the supervisory authority of the Federal Department of Home Affairs in Bern, Switzerland.

Headquarter: The Foundation's headquarters location is: Place Saint Gervais 1, Po Box 2049, 1211 Geneva 1, Switzerland. Tel: +41 22 909 89 00. Fax: +41 22 909 89 39.
Email: contact@f-mri.org ; Web: www.f-mri.org

Duration: The duration of the Foundation is unlimited.

Resources: The main resources of the foundation are:

- Allowances, donation and bequests,
- Any other source authorized by law, including private donors and public institutions,
- Products of its shares as defined in the aims of the foundation.

Organs of the Foundation: The main bodies of the Foundation are:

- The Board of Trustees,
- The auditors,
- Scientific and other resource Committees.

** Details on the F-MRI governance are provided on the website: www.f-mri.org*

Main initial project*:

The initial project of the Foundation entitled:

« Development of Academic Medical Research in the Middle-East »

has been described in details in a specific brochure. Briefly, the main objective of the project is to develop the research activities in medical science in the Mediterranean / Middle-East region. This has been decided after permanent collaboration with various local and international entities: governments, institutions, and universities in order to fill a gap and meet the demand of the involved parties.

Structure of the project: The project has been planned as the progressive **creation in the participant country of a local F-MRI entity**. Each of the local entities is supervised by scientific council and a patronage committee which includes national and international personalities.

Functioning: All respective local F-MRI subsidiaries will develop following a single common design their proper activities according to the specific needs and progressively in four steps:

- Education on medical research
- Creation of clinical research units (CRU), initiation of medical research projects and a research network.
- Communication, Editorial and publishing
- Other issues: public health research projects

** Details of the project are described in specific downloadable brochure from the website*

Establishing of Lebanese local F-MRI Entity

In order to operate in the Middle-East, the Foundation has established a local independent legal office in Beirut, Lebanon as a public utility, non-for-profit organization registered in Beirut and regulated by the Lebanese law. This entity chaired by Prof Roland Asmar has been established in 2010 and officially recognised in 2011. It is registered under the control of the supervisory authority of the Ministry of Interior, Lebanon.

Headquarters: The Foundation's Lebanese headquarter is located at: Achrafieh, District Hôtel Dieu 64, street n°1, Olivetti Bldg. Beirut Lebanon. Tel: +961 1 424 027. Fax: +961 1 424 028.

An additional academic office of the Foundation has been also opened al the Faculty of Medicine of the Lebanese University, located at Hadath, Beirut Lebanon. Tel / fax: +961 5 470924. This office has been established after the signature of an agreement between the two entities to develop the university education of Medical research (see specific chapter hereafter).

Creating & Developing a Professional website

A professional website has been registered, created and developed both in English and French languages. It includes the followings:

- Report of the Foundation governance and objectives
- Description of the Foundation mission with the main project
- Education section
- Research section
- Publications with downloadable documents
- Specific restricted student's access pages with downloadable courses

EDUCATION IN MEDICAL RESEARCH

A physician interested in becoming researcher or study investigator must have been trained on medical research principles and methods. He or she will be assisted in this activity by persons belonging also to the medical sphere: the clinical research assistants (CRA) and clinical research technicians (CRT) the role of whom is to follow up a study, to ensure adequate application of good clinical practice, and to verify the quality of data collected in the study.

The Foundation decided to organize this specific education with two levels:

- A university (UD) diploma proposed to post-doctorate students, the objective of which is to introduce future investigators in research fundamentals and related regulatory and technical requirements.
- A professional education recognized by a university certificate, proposed to students having achieved their baccalaureate + three years of higher education, who are interested in becoming clinical research assistant (CRA) or clinical research technician (CRT).

These two university educational levels, initiated at the Lebanese University in 2010, welcome students from various Lebanese universities (see appendixes 1, 2).

The University Diploma "Principles of Medical Research"

The organization of this university diploma involves a collaborative participation of local and regional universities, with the participation of experts from Beirut (Lebanon) but also and principally from Toulouse, Nancy and Paris VI Universities (France) and as well as Cambridge university (United Kingdom). Details on the university diploma: objectives, required qualities, organisation, training, final exam, etc… can be obtained from the website.

Since its establishment in 2010, 4 academic years took place with 4 distinct classes; the first three classes were presented in the 2010-2012 activities reports. The fourth class is reported hereafter (see appendixes 1).

- Academic year 2013-2014: Class "Claude Bernard " included 23 participants

NAME	DEGREE	UNIVERSITY
Abboud Loubna	MD- Plastic surgery	UL
Atallah Sara	MD- Internal Medicine	UL
Baltagi Nour El Huda	MD- Pediatric Nephrologist	Universita Degli Studi Di Perugia, Italy
Berbari Christel	PharmD	UL
Berbari Sandra	PharmD	UL
El Hajj Haidar Zeinab	MD- Internal Medicine	UL
El Hajj Mariana	MD- Pediatrics and Neonatology	UL
El Hajj Weam	MD- Internal Medicine	UL
El Hayek Marylene	MD- Endocrinology and metabolism	UL
El Jabbour Tony	MD- Pathologist	UL
El Zein Ghenwa	MD- Internal Medicine	UL
Ghemrawi Nisrine	PharmD	UL
Hamdan Manal	MD- Internal Medicine	UL
Jabbour Elias	MD- Internal Medicine	UL
Khalifé Hassan	MD- Pediatrician	University of Brescia, Italy/ AUB
Matta Stephanie	PharmD	LAU
Mouannes Elias	Dentist	USJ
Moussallem Toufic	MD-General Surgeon	UL
Naous Amal	Pediatrician	BAU

Nasser Zeina	Pharm D	LIU
Tauk Alain	Dentist	USJ
Tauk Charbel	MD- Orthopedic surgery	USEK
Yared Georges	Obstetrics-Gynecology	UL

BAU = Beirut Arab University; LAU = Lebanese American University; LIU = Lebanese International University; UL = Lebanese University; USEK = Saint-Esprit Kaslik University; USJ = Saint-Joseph University;

The Professional Certificate of "Clinical Research Assistant"

Similar to the post Doc University diploma, the organisation of this certificate involves experts from local and regional universities: from Beirut (Lebanon), from Toulouse, Nancy and Paris VI Universities (France) as well as Cambridge university (United Kingdom).

Details on the university diploma: objectives, required qualities, organisation, training, final exam, etc can be obtained from the website.

Since its establishment in 2010, 4 academic years took place with 4 distinct classes; the first three classes were presented in the 2010-2012 activities reports. The fourth class is reported hereafter (see appendixes 2).

- Academic year 2013-2014: Class "Claude Bernard " included 24 participants

NAME	DIPLOMA	UNIVERSITY
Alayoubi Alamir Noureddine	BS- Biology	UOB
Al Harakeh Marwa	BS- Pharmacy	BAU
Arabi Sarah	MS- Biology	UL
Atab Fatima	BS- Pharmacy	BAU
Atwi Lina	Bachelor of Nursing Sciences	UL
Baddour Layal	MS- Biology	UL
Bader Sanaa	BS- Pharmacy	BAU
Dahboura Badria	BS- Pharmacy	BAU
El-Bekaai Manar	BS- Pharmacy	LIU
El-Helou Christine	MS- Biochemistry	UL
Haydar Ali	BS Biology- Med II	LAU
Jaafar Iman	BS- Pharmacy	BAU
Kanaan Sarah	BS- Pharmacy	LIU
Kandar Rana	MSc Biochemsitry/ BS- Pharmacy	UL/ LIU
Krayem Imtissal	MS- Biology	UOB
Labaki Lama	MS- Microbiology	UL
Labaki Nour	MS- Public health- Epidemio-Statistics	UL
Makhoul Khalil	BS Biology	UL
Mansour Farah	BS- Pharmacy	LIU
Mortada Lama	MS- Biochemistry	UL
Nasser Sarah	MS I- Biochemistry	UL
Noureldine Mohammad H.	BS Biology- Med II	LAU
Saad Layal	BS- Pharmacy	Damascus University –Syria
Sinno Maryam	BS- Pharmacy	Al-Zytounah University- Jordan

BAU = Beirut Arab University; LAU = Lebanese American University; LIU = Lebanese International University; UL = Lebanese University; UOB = University Of Balamand;

RESEARCH

1- Clinical Research

Clinical Research Units (CRUs) are units created within academic hospitals; they are meant to favour and promote the development of clinical research and improve the conditions of clinical study realization. CRUs are responsible for the concrete implementation of the studies, together with the participating investigators; they follow up the study within a monitoring process (quality insurance) with the collaboration of the CRAs. Details on the CRU: objectives, mission, organisation, etc, have been described in the Foundation brochure downloadable from the website. Briefly, the objective of the CRU is to provide logistical and technical support for the conception and realization of study projects within the medical and academic community.

The F-MRI project aims the implementation of distinct URCs within those academic hospitals or institutions having applied and declared their willingness to initiate a research activity. These structures must meet the participation criteria as described in specific documents. They have to apply and fulfil a specific affiliation form. According to the requested criteria, this can be accepted or not by the Foundation.

In 2011, the Foundation had received several demands from various hospitals and institution. After reviewing the corresponding affiliation forms, it has been decided to set-up 2 CRUs:

A- Mount Lebanon Hospital (MLH): This hospital is located in Beirut and affiliated to the Faculty of Medicine of the Lebanese University. It has been recently accredited by the Ministry of Health and the corresponding Institution. This multidisciplinary hospital has several excellence centres mainly in oncology, medical imaging, and endocrinology. The affiliation form has been accepted in July 2011 and the CRU established in October 2011. At the end of Q1 -2012, the CRU was fully operational with 4 trials being coordinated by the CRU under the direction of Dr Lena Massad; In 2013, the CRU was set-up further to the following initiation activities and contacts:

- Several meetings with MLH medical director, units staff and directors (laboratory, radiology ..), and medical affairs assistant, in order to evaluate the clinical research activities, and to present the new process of the CRU, aiming at applying the Good Clinical Practice and attracting a larger number of interventional clinical trials to MLH.

- Collaboration with MLH purchase and IT departments in order to complete the needed equipments to perform the clinical trials and their coordination

- Development of Standard Operating Procedures and initiation of a recruitment process for study coordinators: to date 2 study coordinators are permanently recruited: Dr M. Chami (MD) and Mrs N. Matar (nurse). Each Trial is assigned a principal coordinator and a back-up coordinator

- Several contacts with sponsors and CROs in order to present the CRU activities and the possibilities within MLH for interventional trials conduct

- **TRIALS COORDINATION ACTIVITIES PERFORMED BY THE CRU:**

For each clinical trial, the following activities are performed:

- Feasibility and set up meetings
- Administration and agreements between the multiple participants: Sponsor, Hospital, Investigator, The Foundation, etc.
- Training on study specific process
- Coordination of submission to Ethics Committee and regular reporting
- Patients logistic management

- Assistance to investigators in patient's medical management: schedule of the visits, data entry and queries handling, etc.
- Collaboration with the sponsor/CRO and facilitation of the monitoring process handling trial files and materials
- Preparation for study closure

In 2013, the CRU was fully operational, and to date **8 trials** have been or are being coordinated by the CRU; Three trials are completed and 5 others are still ongoing;

1- COMPLETED TRIALS:

- A phase III interventional, multinational, randomized, double-blind, double-dummy study in naive patients with type 2 diabetes

  - **Study status:** Closed
  - **Number of patients' status:** 4 patients completed the study
  - **Duration of study participation per patient:** 18 weeks

- A phase III interventional, multinational, double-blind, double-dummy, randomized study in fasting patients with type 2 diabetes

  - **Study status:** completed – under closure activities
  - **Number of patients' status:** 28 patients enrolled
  - **Duration of study participation per patient:** 12 to 26 weeks

- Efficacy and Safety phase II study in the Treatment of Acute Venous Thrombo-embolism in Cancer Patients

  - **Study status:** closed
  - **Number of patients' status:** 0 patients enrolled
  - **Duration of study participation per patient:** 7 months

2- **ONGOING TRIALS:**

- A phase III interventional, multinational, open label, non comparative study in patients with inadequately controlled type 2 diabetes

  - **Study status:** Ongoing
  - **Number of patients' status:** 46 patients enrolled
  - **Duration of study participation per patient:** 27 weeks

- A phase III interventional, multinational, randomised, double-blind study in naive patients with type 2 diabetes

  - **Study status:** ongoing
  - **Number of patients' status:** 3 patients enrolled
  - **Duration of study participation per patient:** 24 weeks

- A multinational, open label, randomized, active-controlled, 3-arm parallel group, 24-week study in patients with type 2 diabetes

  - **Study status:** Ongoing
  - **Number of patients' status:** 9 patients enrolled
  - **Duration of study participation per patient:** 24 weeks

- A phase III randomized, double-blind, placebo-controlled study in adults patients with active rheumatoid arthritis
  - **Study status:** Starting
  - **Number of patients' status:** 0 patients enrolled
  - **Duration of study participation per patient:** 6 months

- A three-arm, randomized, open label, phase II study in the treatment of postmenopausal women with estrogen receptor positive, locally advanced, recurrent, or metastatic breast cancer

  - **Study status:** Starting
  - **Number of patients' status:** 0 patients enrolled
  - **Duration of study participation per patient:** Unlimited (survival progression)

- **B- Lebanese Hospital Geitawi:** This hospital is located in Beirut and affiliated to the Faculty of Medicine of the Lebanese University. It has been recently accredited by the Ministry of Health and the corresponding Institution. The affiliation form has been accepted in December 2011.

  The set-up of the Clinical Research Unit (CRU) at Geitawi hospital started Q2 2013 further to the following initiation activities and contacts:

  - Several meetings with the medical director, in order to evaluate the clinical research activities, and to present the new process of the CRU, aiming at applying the Good Clinical Practice and attracting a larger number of clinical trials to Geitawi hospital. One presentation was made to the medical staff. A meeting was also held with the laboratory director in order to present the CRU.

  - Collaboration with Geitawi purchase and IT departments for provision of utilities and equipments needed for trials coordination

  - Communication to sponsors and CROs in order to present the CRU activities and the possibilities within Geitawi hospital for interventional trials conduct

  CRU staff remains the same as for Mount Lebanon Hospital, i.e 2 study coordinators that are permanently recruited: Dr M. Chami (MD) and Mrs N. Matar (nurse), managed by Dr L. Massad. Each Trial is assigned a principal coordinator and a back-up coordinator

  At the end of 2013, the CRU was fully operational.

2- Basic Science Research

The F-MRI has established its first basic science research unit within the Faculty of Medicine at the Lebanese University under the direction of Dr Mirna Chahine.

A first project, entitled "Tissue regulation of telomeres' length (TL)- Simultaneous study on telomeres' length in different tissue types", is in collaboration with the CHU de Nancy, France (Prof. Athanase Benetos) and the University of New Jersey, USA (Prof . Abraham Aviv).

- **Background:** The prevailing view in telomere epidemiology is that leukocyte telomere length (LTL) is associated with atherosclerosis and accelerated aging since it serves as a biomarker of the cumulative burden of inflammation and oxidative stress during adult life. It has been shown that TL is mainly determined at birth and childhood.

- **Hypothesis:** Since short telomeres antecede atherosclerosis, *we hypothesize that TL is not just a simple marker, but a real determinant of arterial aging.* That is because TL reflects cellular repair capacity and a short LTL denotes diminished repair reserves. This hypothesis cannot be tested by measurements of LTL alone, since this parameter reflects TL at birth and its age-dependent attrition thereafter. We propose, therefore, a model that makes it possible to examine different elements of TL dynamics in leukocytes and skeletal muscle in patients with or without atherosclerosis.

- **Aim :** The aim of this project is to examine different elements of TL dynamics in leukocytes and skeletal muscle in patients with or without atherosclerosis undergoing surgery or implantation of pacemaker/defibrillator.

- **Methodology:** So far 4 patients have been enrolled. Informed consents have been signed at the beginning of the hospitalization. DNA extraction has been performed from collected tissues (skeletal muscle and blood). More patients will soon be recruited in this study.

3- Epidemiological & Public Health research

During Q4, the F-MRI participated in the design of two Epidemiological projects about the "Prevalence" and the "Management" of Cardiovascular Diseases overall Lebanon.

- **The prevalence project :**

  - **Background:**

The incidence and the prevalence of cardiovascular diseases (CVD) have tremendously increased as they have become one of the main causes of death among adults.

According to the World Health Organization, CVD are the world's largest killers, claiming 17 million lives a year. In Lebanon, chronic diseases constitute an important public health problem.

  - **The objective of the prevalence study is :**

– to evaluate major CardioVascular (CV) risk factors such as Hypertension, Diabetes, Dyslipidemia, Smoking, Obesity ;
– to assess the prevalence of CardioVascular Diseases (CVD) in the adult Lebanese population.

  - **Methodology :**

A cross-sectional study will be carried out, using a multistage cluster sample all over Lebanon. Lebanese residents aged 20 years and above will be enrolled in the study, with no exclusion criteria.

  - **Procedure :**

From the list of circumscriptions in Lebanon (villages, towns and cities) (17), we will randomly select one hundred circumscriptions. Through a representative of local authorities, a list of dwellers would be provided to us. To select interviewees, randomization of dwelling residents aged 20 years and above from this list will be performed on a computerized software.

  - **Tools :**

For every individual, the following measurements will be performed: blood pressure, glycemia, height and weight, and waist circumference for abdominal obesity measurement. Moreover, standardized questionnaires will be used.

- **The management project :**

  - **Background:**

The large numbers of epidemiological studies and clinical trials have documented the benefits of treating for example dyslipidemia, diabetes mellitus, hypertension, and obesity using behavioural and pharmacological means;

These epidemiological studies have led to clinical practice guidelines aimed at implementing these management *recommendations.*

  - **The objective of the management study is :**

– to assess the management of the major cardiovascular risk factors in the Lebanese adult population versus clinical practice guidelines.
– to evaluate the quality of the management of each of the major cardiovascular risk factors versus clinical practice guidelines, to evaluate the management of the multiple risk factors combination (patient at high cardiovascular risk) versus clinical practice guidelines, to

assess the management according to the physician phenotype and characteristics, because treatments can differ based on the sexe, the age and the location of the physician, and to compare risk factors management to the management as recommended by the guidelines

-

- **Methodology :**

A cross-sectional study will be carried out. Lebanese primary care physicians (GPs, Family Medicine, Internal Medicine) will be enrolled in the study to provide information on the management of CVD and risk factors of their adult patients aged 20 years and above.

- **Procedure :**

From the directory of the Lebanese Order of Physicians, we will select from different regions in Lebanon 100 Lebanese physicians among the 11 000 physicians that are members of the Order of Physicians. The selected 100 physicians will fill out a questionnaire regarding the first 10 adult patients (with CVD and/or diseases) aged 20 years and above who enter their clinics that day, and this will totalize 1000 patients.

- **Tools :**

Each physician will fill out:

- 1/only once a questionnaire capturing in-depth his own personal details because treatments can differ based on the different phenotypes of physicians (the sexe, the age, and the location of the physician)

- 2/ for each patient, a standardized questionnaire; notably, the subject's clinical characteristics (name, date of birth, gender, height, weight), if the subject is exposed to any CVD risk factors (diabetes, dyslipidemia, hypertension, smoking, physical activity, stress,…), if the subject suffers from any CVD (Heart, vessels including the brain, kidney, others…) and how much does he estimate the global risk score of this subject? Is it low, medium, high or very high? This will be compared with the information provided by the Lebanese residents in step 1 (prevalence) of this study, and questions about the treatment he is administering to his patients (anti-hypertensive, anti-dyslipidemic and anti-diabetic agents, others Cardiovascular medications, others…)

4- Other Research: Devices

Assessment of the accuracy of the blood pressure measurements using 3 various methods:

The aim of the study is to assess the accuracy of the blood pressure measurements performed with automatic electronic devices.

Mercury sphygmomanometer, brachial oscillometric device and wrist oscillometric device. Details of the study protocol have been described in specific document. Briefly, the study is performed in adult population according to the International protocol version 2 (2010) of the European Society of Hypertension. The statistical analysis is performed using specific software developed by the International Society of vascular Health and the Foundation.

Ambulatory patients from the Mount Lebanon Hospital and the Geitawi Hospital were included in the study.

This study has been possible thanks to collaboration among Asian and European Institutions and The Foundation.

It has been ended by 2013, its publication is in press;

CONTINUOUS MEDICAL EDUCATION

Continuous Medical Education (CME) activities were defined as one of the activities to be developed by the F-MRI. An efficient CME needs to be performed according to a well established methodology. After assessing the need of doctors and researchers, the adapted CME programs is defined and implemented. Moreover, CME activities need to be recognized and accredited by national or international scientific societies or institutions.

In order to develop recognised and accredited CME activities, the Foundation has entered in 2011 an agreement with the "International Society of Vascular Health".

During 2013, the F-MRI has organized many CME programs and seminars:

1- The Third Cardio-Metabolic Meeting in the Middle East (CME III) was fully organized by the F-MRI in collaboration with the ISVH in Istanbul, Turkey in April 2013 and accredited by the European Board for Accreditation in Cardiology (EBAC). Outstanding international speakers participated in this high scientific standard meeting **(See Program 1**). The attendance included 120 participants from Lebanon, Irak, KSA, and UAE; This has been possible thanks to an educational grant from Novartis Pharma and medical device manufacturers. Analysis of the evaluation forms fulfilled by the participants was very satisfactory, promising, and successful. **(See Evaluation form's results 1);**

2- The Fourth Cardio-Metabolic Meeting in the Middle East (CME IV) was fully organized by the F-MRI in collaboration with the ISVH in El Jadida, Morocco in May 2013. Outstanding international speakers participated in this high scientific standard meeting **(See Program 2**). The attendance included 180 participants from North Africa region; This has been possible thanks to an educational grant from Boehringer Ingelheim and medical device manufacturers. Analysis of the evaluation forms fulfilled by the participants was very satisfactory, promising, and successful. **(See Evaluation form's results 2);**

3- "Principles in Medical Research & GCP Training" was the first seminar of this type organised by the F-MRI in collaboration with ISVH in Beirut, Lebanon in August 2013 and accredited by the EBAC; International and national experts participated in this seminar **(See Program 3**). The attendance included participants (MD) from the Lebanese Military Hospital. This has been possible thanks to an educational grant from Novartis Pharma. Analysis of the evaluation forms fulfilled by the participants was very satisfactory, promising, and successful. **(See Evaluation form's results 3);**

Program 1:

"The 3rd Cardio - Metabolic Meeting in the Middle East"

Organised by: **ISVH**.
Course Director: **Dr. Jirar Topouchian**

Date: **26th April, 2013**
Venue (City/ Country): **Istanbul, Turkey**

"This programme is accredited by the European Board for Accreditation in Cardiology (EBAC) for 8 hour(s) of external CME credit(s). Each participant should claim only those hours of credit that have actually been spent in the educational activity. EBAC works according to the quality standards of the European Accreditation Council for Continuing Medical Education (EACCME), which is an institution of the European Union of Medical Specialists (UEMS)."

Agenda

9h-10h30: Session 1: Hypertension & other Risk Factors
Chairmen: Prof. Roland Asmar (FR) & Prof. Charles Saab (LB)

Guidelines for Hypertension Management Present & Future	**Prof. Giuseppe Mancia (IT)**	30'
Pharmacological treatment of hypertension & new perspectives	**Prof. Alejandro de la Sierra (ES)**	30'
New Modalities in type II Diabetes Management	**Prof. Wolfgang Schmidt (DE)**	30'

10h30 – 11h: Coffee Break

11h – 12h30: Session 2: Global Cardiovascular Risk
Chairmen: Prof. Bernard Waeber (CH) & Prof. Omar Hamoui (LB)
How to evaluate:

Arterial Remodeling	**Prof. Roland Asmar (FR)**	30'
Cardiac Remodeling	**Prof. Verdecchia Paolo (IT)**	30'
Kidney Abnormalities	**Prof. Ali Abu-Alfa (LB)**	30'

12h30 – 13h30: Lunch Break

13h30 – 15h: <u>Workshops parallel sessions*– (First Session)</u>

Workshop on Blood Pressure Measurement — **Prof. Roland Asmar (FR)**
Clinic – Home – Ambulatory

Workshop on Target Organ Damages — **Prof. Jirar Topouchian (FR)**
central BP and pulse wave

Workshop on Metabolic Assessment — **Prof. Charles Saab (LB)**
Umbilical & Waist circumference, Body composition
blood and urine dosage.

***NB:** Participants can attend successively two different workshops, one during each session.

15h – 15h30: <u>Coffee Break</u>

15h30 – 17h: <u>Workshops – (Second Session):</u>

Workshop on Blood Pressure Measurement — **Prof. Roland Asmar (FR)**
Clinic – Home – Ambulatory

Workshop on Target Organ Damages — **Prof. Jirar Topouchian (FR)**
central BP and pulse wave

Workshop on Metabolic Assessment — **Prof. Charles Saab (LB)**
Umbilical & Waist circumference, Body composition
blood and urine dosage,

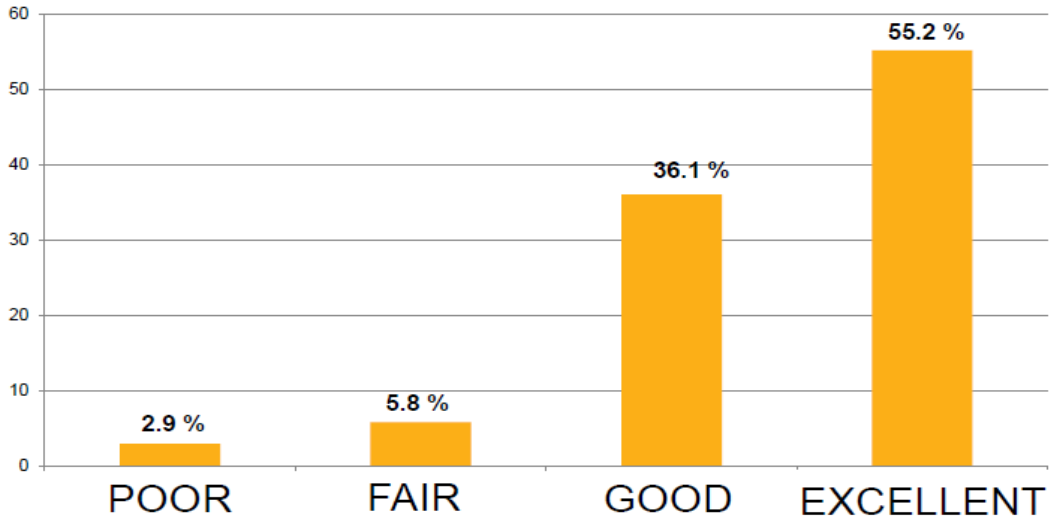
"In compliance with EBAC/ EACCME guidelines, all speakers/ chairpersons participating in this programme have disclosed or indicated potential conflicts of interest which might cause a bias in the presentations. The Organizing Committee/Course Director is responsible for ensuring that all potential conflicts of interest relevant to the event are declared to the audience prior to the CME activities."

Supported by an unrestricted educational grant from the "F-MRI®", "Novartis Pharma", "ISVH", "Foracare", and "IEM".

Evaluation form 1

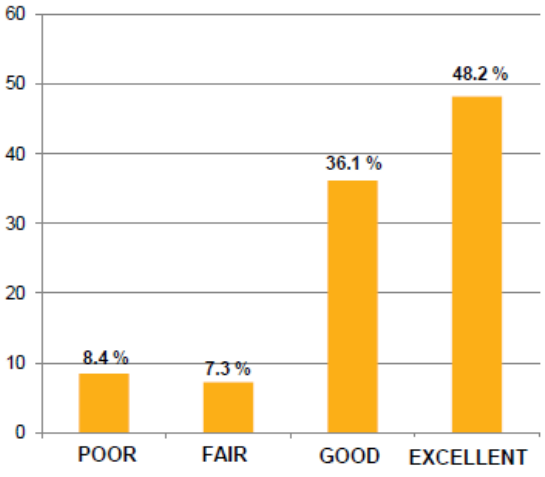
"The 3rd Cardio - Metabolic Meeting in the Middle East"

overall assessment



LECTURES (%)

WORKSHOPS (%)



Program 2:

ATELIERS
PRISE EN CHARGE
DU PATIENT A HAUT RISQUE
CARDIOVASCULAIRE
El-Jadida- 4 &5 Mai 2013

Programme Final

ISVH F-MRI

El-Jadida, Maroc, 4 et 5 Mai 2013

Jour 1

9h-10h30: Session 1: L'hypertension artérielle & Autres facteurs de risque

Présidents session: Prof Roland Asmar (FR) & Prof Jean Ribstein (FR)

A-	Prise en charge de l'Hypertension artérielle : Nouvelles recommandations & Perspectives	**Prof Bernard Vaïsse (FR)**	20' + 5'
B-	Traitement Pharmacologique de l'Hypertension : Actualités & Perspectives	**Prof Olivier Hanon (FR)**	20' + 5'
C-	Particularités dans le traitement de l'hypertendu diabétique	**Dr Magali Cocaul (FR)**	20' + 5'
D-	Discussion Générale		15'

10h30 – 11h: Pause café

11h – 12h30: Session 2: Risque Cardiovasculaire Global

Présidents session: Prof Bernard Vaisse (FR) & Prof Olivier Hanon (FR)

Comment évaluer:

A-	Remodelage Artériel	**Prof Roland Asmar (FR)**	20' + 5'
B-	Remodelage Cardiaque	**Prof Elie Chammas (FR)**	20' + 5'
C-	Anomalies Rénales	**Prof Jean Ribstein (FR)**	20' + 5'
D-	Discussion Générale		15'

12h30 – 13h30: Déjeuner

13h30 – 15h: Ateliers en sessions parallèles*– (Première Session)

A-	Atelier : La mesure de la pression artérielle Clinique – Maison – Ambulatoire	**Dr Jirar Topouchian (FR)**
B-	Atelier : les atteintes des Organes Cibles Pression Artérielle & Centrale	**Dr Sandrine Millasseau (FR)**
C-	Atelier : Cas cliniques	**Prof Bernard Vaïsse (FR)**
D-	Atelier : Evaluation du retentissement hémodynamique de l'HTA en échographie cardiaque- Nouveautés échographiques	**Prof Christophe Klimczak (FR)**

***NB:** Les participants ont la possibilité de participer à deux ateliers différents au cours de la demi-journée.

15h00 – 15h30: Pause café

15h30 – 17h: Ateliers (Seconde Session) : le même programme que la première session.

Jour 2
Symposium Satellite

9h00-11h45 : Protection cardiovasculaire - Rôle du Telmisartan

Présidents session: Prof Elie Chammas (FR) & Prof Roland Asmar (FR)

A- Nouvelles recommandations dans l'HTA: Place du Telmisartan	**Prof Bernard Waeber (CH)**	25' + 5'
B- Prise en charge du patient à haut risque cardiovasculaire	**Prof Olivier Hanon (FR)**	25' + 5'

10h00 – 10h30: Pause café

C- Les nouvelles modalités de prise en charge du Diabète de type II	**Prof Paul Valensi (FR)**	25' + 5'
D- Place de la chronothérapie dans la prise en charge du patient hypertendu.	**Prof Roland Asmar (FR)**	25' + 5'
E- Discussion Générale		15'

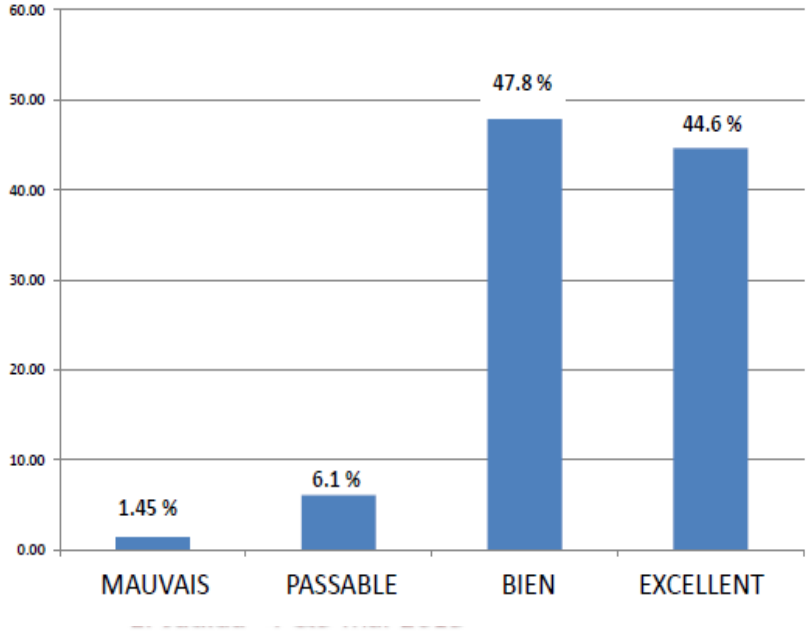
Supported by an unrestricted educational grant from the "F-MRI®", "Boehringer Ingelheim", "ISVH", "Foracare", and "IEM".

Evaluation form 2

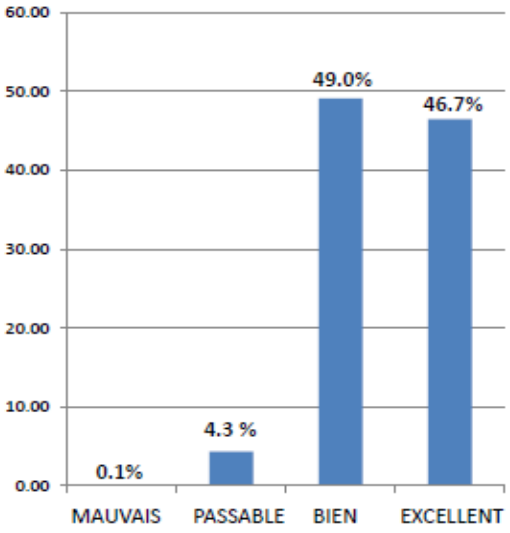
ATELIERS
PRISE EN CHARGE
DU PATIENT A HAUT RISQUE
CARDIOVASCULAIRE
El-Jadida- 4 &5 Mai 2013

ISVH FEMRI

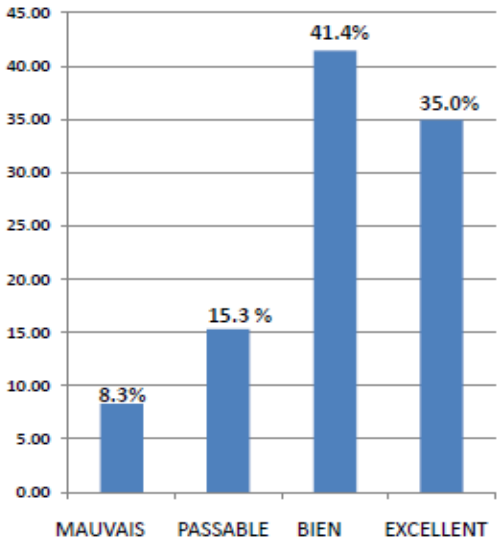
Overall assessment



LECTURES (%)



WORKSHOPS (%)



Program 3:

"Principles in Medical Research & GCP Training"

Organized by: **F-MRI**
Course Director: **Dr Lena Massad**

Date: **16th & 17th August, 2013**
Venue (City/ Country): **Hilton Beirut Metropolitan Palace, Beirut, Lebanon**

"This programme is accredited by the European Board for Accreditation in Cardiology (EBAC) for 11 hour(s) of external CME credit(s). Each participant should claim only those hours of credit that have actually been spent in the educational activity. EBAC works according to the quality standards of the European Accreditation Council for Continuing Medical Education (EACCME), which is an institution of the European Union of Medical Specialists (UEMS)."

Agenda: 16th August, 2013

13h00-15h40: Session 1:

A- Introduction	**Prof. Roland Asmar (FR/LB)**	10'
B- Application of Basic Research into Clinical Research	**Dr. Mirna N. Chahine (CAN/LB)**	45'
C- Basics of GCP, ethical considerations and patient protection	**Dr. Sheriff Odaranile (UK)**	60'
D- Quality in clinical trials: SOPs & Standard forms Audit and inspection - Trial Master File and investigator file	**Dr. Sheriff Odaranile (UK)**	45'

15h40 – 16h00: Coffee Break

16h00 – 18h30: Session 2:

A- Drug Development and prerequisites	**Dr. Lena Massad (FR/LB)**	45'
B- Clinical Development and trials characteristics.	**Dr. Lena Massad (FR/LB)**	45'
C- Trials major documents	**Dr. Lena Massad (FR/LB)**	60'

Agenda: 17th August, 2013

8h15-10h00: Session 1:

A- Bioethics	**Dr. Mirna N. Chahine (CAN/LB)**	45'
B- e-CRF and e-Core Lab	**Dr. Jirar Topouchian (FR)**	60'

10h00 – 10h30: Coffee Break

10h30 – 12h30: Session 2:

A- Statistics and data management for clinical research	**Dr. Nadine Saleh (LB)**	120'

12h30 – 13h30: Lunch Break

13h30 –15h45: Session 3:

A- Clinical Trials activities and milestones	**Dr. Lena Massad (FR/LB)**	45'
B- Clinical trial participants and Investigator's role	**Dr. Lena Massad (FR/LB)**	45'
C- Clinical trials monitoring	**Dr. Lena Massad (FR/LB)**	15'
D- Workshop: Quality - Protocol deviations.	**Dr. Lena Massad (FR/LB)**	30'

15h45 – 16h15: Coffee Break

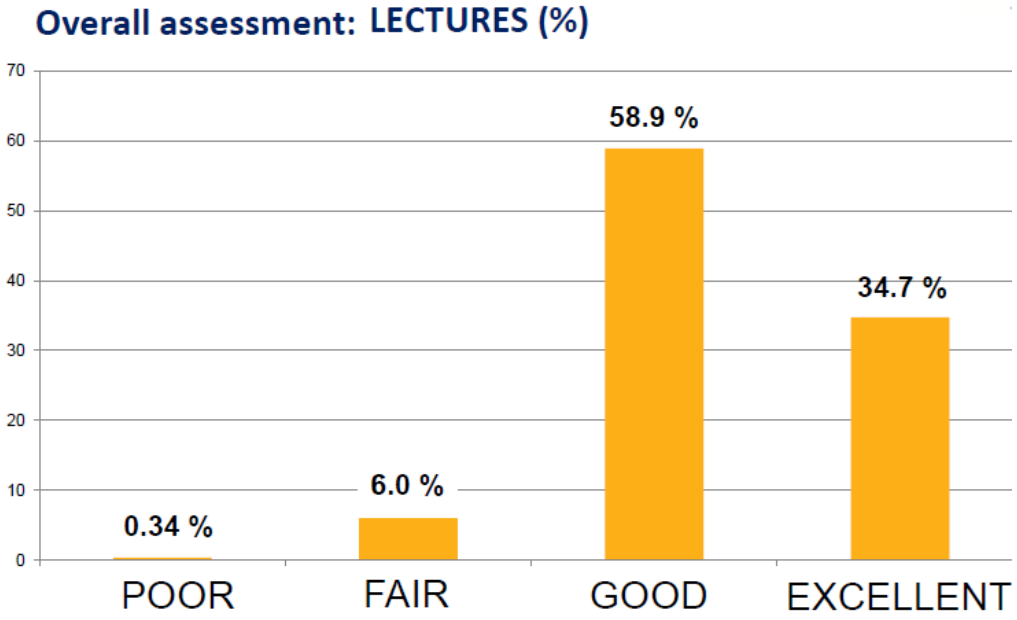
16h15 – 18h30: Session 4:

A- Trials treatments randomization and blinding – quiz	**Dr. Lena Massad (FR/LB)**	30'
B- Management of patients' safety: assessment and reporting.	**Dr. Lena Massad (FR/LB)**	45'
C- GCP: Understanding sponsor's obligations	**Dr. Lena Massad (FR/LB)**	15'
D- Workshop: GCP investigator's obligations - Safety reporting.	**Dr. Lena Massad (FR/LB)**	45'

"In compliance with EBAC/ EACCME guidelines, all speakers/ chairpersons participating in this programme have disclosed or indicated potential conflicts of interest which might cause a bias in the presentations. The Organizing Committee/Course Director is responsible for ensuring that all potential conflicts of interest relevant to the event are declared to the audience prior to the CME activities."

Supported by an unrestricted educational grant from the "F-MRI®" & "Novartis Pharma".

Evaluation form 3



Publications

Several publications were performed in international peer-reviewed journals:

1. Asmar R, Chahine MN, Assemaani N, Sayed-Hasan G, Chami-Chabbo M, Salameh P. Validation of the OMRON® M3500 blood pressure measuring device using the normal and high speed modes in **adult** population according to the Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO/ 81060-2:2009 Protocol. Publication process.

2. Asmar R, Chahine MN, Assemaani N, Sayed-Hasan G, Chami-Chabbo M, Salameh P. Validation of the OMRON® M3500 blood pressure measuring device using the normal and high speed modes in **children** population according to the Association for the Advancement of Medical Instrumentation – ANSI/AAMI/ISO/ 81060-2:2009 Protocol. Publication process.

3. Topouchian J, Agnoletti D, Blacher J, Youssef A, Chahine MN, Ibanez I, Assemaani N, Asmar R. Validation of four devices: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen KP-7670 for home blood pressure measurement according to the European Society of Hypertension International Protocol. Vasc Health Risk Manag. 2014 Jan 16;10:33-44.

4. O'Brien E, Parati G, Stergiou G, Asmar R, et al., European Society of Hypertension position paper on ambulatory blood pressure monitoring. J Hypertens. 2013 Sep;31(9):1731-68.

5. Cameron JD, Asmar R, Struijker-Boudier H, Shirai K, Sirenko Y, Kotovskaya Y, Topouchian J. Current and future initiatives for vascular health management in clinical practice. Vasc Health Risk Manag. 2013;9:255-64.

6. Cremer A, Butlin M, Codjo L, Coulon P, Ranouil X, Joret C, Coste P, Asmar R, et al. Determination of central blood pressure by a noninvasive method (brachial BP and QKD interval). J Hypertens. 30(8):1533-9, 2012.

7. Stergiou G, Parati G, Asmar A, O'Brien E. Requirements for professional office blood pressure monitors on behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring. Journal of Hypertension 2012, 30:537–542.

8. Asmar R. Telmisartan in High Cardiovascular Risk Patients. *European Cardiology*, 2012;8(1):10–6

9. Asmar R. L'hypertension au Coeur du cerveau. Editorial. Circulation, french version. 2011; 11: 371-2.

10. Topouchian J, Agnoletti D, Blacher J, Youssef A, Ibanez I, Khabouth J, Khawaja S, Beaino L, Asmar R. Validation of four automatic devices for self-measurement of blood pressure according to the international protocol of the European Society of Hypertension. Vascular Health and Risk Management 2011; 7:709–17.

11. Johnston A, Asmar R, Dahlöf B, Hill K, Jones DA, Jordan J, Livingston M, Macgregor G, Sobanja M, Stafylas P, Rosei EA, Zamorano J. Generic and therapeutic substitution: a viewpoint on achieving best practice in Europe. Br J Clin Pharmacol. 2011; 12;1365-2125.

12. Asmar R, Gosse P, Queré S, Achouba A. Efficacy of morning and evening dosing of Amlodipine/ Valsartan combination in hypertensive patients uncontrolled by 5 mg of amlodipine. Blood Press Monit. 2011; 16:80-6.

13. Asmar R, Oparil S. Comparison of the antihypertensive efficacy of irbesartan/HCTZ and valsartan/HCTZ combination therapy: impact of age and gender. Clin Exp Hypertens. 2010;32:499-503.

14. Parati G, Asmar R, Bilo G, Kandra A, Di Giovanni R, Mengden T. Effectiveness and safety of high-dose valsartan monotherapy in hypertension treatment: the ValTop study. Hypertens Res. 2010;33:986-94.

15. Mengden T, Asmar R, Kandra A, Di Giovanni R, Brudi P, Parati G Use of automated blood pressure measurements in clinical trials and registration studies: data from the VALTOP Study. Blood Press Monit. 2010;15:188-94

16. Parati G, Stergiou GS, Asmar R, & al. ESH Working Group on Blood Pressure Monitoring. European Society of Hypertension practice guidelines for home blood pressure monitoring. J Hum Hypertens. 2010; 24:779-85.

17. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; Working Group on Blood Pressure Monitoring of the European Society of Hypertension European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. Blood Press Monit. 2010;15:23-38. Erratum in: Blood Press Monit. 2010;15:171-2.

18. Asmar R, Khabouth J, Mattar J, Pecchioli V, Germano G. Validation of three professional devices measuring office blood pressure according to three different methods: the Omron BP10, the Omron HBP T105 and the Pic Indolor Professional.J Hypertens. 2010;28:452-8.

19. Asmar R, Khabouth J, Topouchian J, El Feghali R, Mattar J. Validation of three automatic devices for self-measurement of blood pressure according to the International Protocol: The Omron M3 Intellisense (HEM-7051-E), the Omron M2 Compact (HEM 7102-E), and the Omron R3-I Plus (HEM 6022-E). Blood Press Monit. 2010; 15:49-54.

20. Asmar R, Belghazi J, Khabouth J, Mattar J, Psimenos A, Germano G. Validation of three professional devices measuring office blood pressure according to three different methods: the Omron BP10, the Omron HBP T105 and the Pic Indolor Professional. J Hypertens 2010; 28(3): 452-458.

21. Asmar R, El Feghali R, Rejdych M, for the French Investigator Group. Antihypertensive effect of candesartan versus ramipril using ambulatory blood pressure monitoring in hypertensive patients. The Carapas study. Blood Press J 2010. (in press)

22. Codjo L, Coulon P, Cremer A, Litalien J, Lemetayer Ph, Coste P, Asmar R,Gosse Ph. Estimation of central blood pressure from the QKD interval. Validation by a non-invasive method. (*submitted and accepted in J. Hypertension*)

23. Germano G, Psimenos A, Sarullo F, Venditti A, Pecchioli V, Asmar R.Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol: the Pic Indolor Personal Check, Comfort Check, My Check and Travel Check.Blood Press Suppl. 2009;1:15-23.

24. Postel-Vinay N, Bobrie G, Asmar R. [Patient reporting of self-measurement results: survey Autoprov]. Rev Prat 2009;59(8 Suppl):8-12.

25. Sie MP, Yazdanpanah M, Mattace-Raso FU, Uitterlinden AG, Hofman A, Hoeks AP, Reneman RS, Asmar R, Van Duijn CM, Witteman JC. Genetic variation in the renin-angiotensin system and arterial stiffness. The Rotterdam Study. Clin Exp Hypertens. 2009;31:389-99.

26. Halimi JM, Asmar R, Ribstein J. Optimal nephroprotection: use, misuse and misconceptions about blockade of the renin-angiotensin system. Lessons from the ONTARGET and other recent trials. Diabetes Metab 2009;35(6):425-30.

27. Asmar R, Hosseini H. Endpoints in clinical trials: does evidence only originate from 'hard' or mortality endpoints? J Hypertens 2009;27 Suppl 2:S45-50.

28. Baguet JP, Asmar R, Valensi P, Nisse-Durgeat S, Mallion JM. Effects of candesartan cilexetil on carotid remodeling in hypertensive diabetic patients: the MITEC study. Vasc Health Risk Manag 2009;5(1):175-83.

FUTURE PERSPECTIVES

1- Education

- **Interuniversity collaboration**
  The F-MRI is contributing to a twinning or an association in order to initiate a close collaboration between universities and research centres.

- **Seminars on medical research**
  Considering that professional employments are also interested by the research education, the foundation is willing to develop specific modulus and seminars. These seminars will take place at the end of the week for 2 to 3 days, and will be organised as “Master classes”

2- Research

- **A- Clinical Research**
  The Foundation is willing to develop one more CRU outside Beirut.

- **B- Basic Science Research**
  The Basic Science Research Unit has been set up. Our perspectives for 2014 are to initiate studies and to establish collaboration with other national and internationals untis.

- **C- Epidemiological & Public Health Studies**
  F-MRI is willing to develop in 2014 a large national evaluation study entitled: *“The Cardiovascular Prevalence and Management Lebanese Project”*. This study will help to assess the epidemiological aspects in terms of prevalence and the management reality of the major cardiovascular risk factors in Lebanon.

3- CME

- **A- Accreditations:**
  In order to allow the participants of the CME activity to benefit from an European accreditation, the F-MRI will undertake actions to obtain accreditations from the European Board for Accreditation in Cardiology (EBAC).

- **B- Regional Development:**
  The F-MRI will continue to develop in collaboration with the ISVH an important regional CME activity.

4- Network

The Foundation will undertake actions to develop the regional and international network among the academic research institutions and persons.

APPENDIXES

1- University Diploma – Class “Claude Bernard” - Academic year 2013-2014.

2- Clinical Research Assistant/ Clinical Research Technician – Class “Claude Bernard” - Academic year 2013-2014.

University Diploma
« Principles of Medical Research »
Class “ Claude Bernard”
Academic Year 2013 – 2014

Abboud Loubna

Atallah Sara

Baltagi N. El Huda

Berbari Christel

Berbari Sandra

El Hajj H. Zeinab

El Hajj Mariana

El Hajj Weam

El Hayek Marylene

El Jabbour Tony

El Zein Ghenwa

Ghemrawi Nisrine

Hamdan Manal

Jabbour Elias

Khalifé Hassan

Matta Stephanie

Mouannes Elias

Moussallem Toufic

Naous Amal

Nasser Zeina

Tauk Alain

Tauk Charbel

Yared Georges

Clinical Research Assistant / Clinical Research Technician
« Principles of Medical Research »
Class “Claude Bernard”
Academic Year 2013 – 2014


Alayoubi A. Noureddine


Al Harakeh Marwa


Arabi Sarah


Atab Fatima


Atwi Lina


Baddour Layal


Bader Sanaa


Dahboura Badria


El-Bekaai Manar


El-Helou Christine


Haydar Ali


Jaafar Iman


Kanaan Sarah


Kandar Rana


Krayem Imtissal


Labaki Lama


Labaki Nour


Makhoul Khalil


Mansour Farah


Mortada Lama


Nasser Sarah


Noureldine Mohammad H.


Saad Layal


Sinno Maryam