Activities Report
2012

Pr. Roland Asmar
Chairman

Date: 
Signature:

This document is confidential for your strict personal use.
CONTENTS

- Summary
- The F-MRI project: main issues
- Medical research education
  - University Diploma: “Principles of Medical Research”
  - Professional Certificate: “Clinical Research Assistant”
- Research
  - Clinical Research
  - Other Research
- Continuous Medical Education (CME)
- Future Perspectives
  - Education
  - Research
  - CME
- Appendixes
Summary

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

The Foundation - Medical Research Institutes established in 2009-2010 as public utility non-for-profit organization in Geneva (Switzerland), and implemented officially in the Middle East in 2010-2011. 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 Report” reported the essential activities undertaken by the Foundation in 2010-2011: 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.
This second “Activities Report” reports the main activities which have been continued and/or initiated by the F-MRI in 2012.

Overall, despite issues related to the political and security situation in the region, the activities undertaken during 2012 were satisfactory. 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, one clinical research unit has been established in an academic hospital during 2012. 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-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 Lebanon, the Foundation has established a local independent legal office 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 at 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
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 “clinical research assistant” (CRA) and “clinical research technician” (CRT) have been initiated at the Lebanese University in 2010. These education diploma and certificate welcomed 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, 3 academic years took place with 3 distinct classes; the first two classes were presented in the 2010-2011 activity report. The third class is reported hereafter (see appendixes 1).

- Academic year 2012-2013: Class “Pierre & Marie Curie ” included 16 participants

<table>
<thead>
<tr>
<th>NAME</th>
<th>DEGREE</th>
<th>UNIVERSITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abou Merhi Bassem</td>
<td>MD</td>
<td>Romania/AUB</td>
</tr>
<tr>
<td>Bassil Nadine</td>
<td>MD</td>
<td>UL</td>
</tr>
<tr>
<td>Benaicha Mohammed</td>
<td>Pharm D</td>
<td>USJ</td>
</tr>
<tr>
<td>Chamoun Kamal</td>
<td>MD</td>
<td>UL</td>
</tr>
<tr>
<td>Cherfan Michelle</td>
<td>Pharm D</td>
<td>AUB</td>
</tr>
<tr>
<td>Dbouk Rola</td>
<td>Pharm D</td>
<td>BAU</td>
</tr>
<tr>
<td>Drouby Fida</td>
<td>Pharm D</td>
<td>LAU</td>
</tr>
<tr>
<td>El Khoury Maya</td>
<td>Pharm D</td>
<td>UL</td>
</tr>
<tr>
<td>El Masri Sarah</td>
<td>Pharm D</td>
<td>BAU</td>
</tr>
<tr>
<td>El Youssef Khaled</td>
<td>MD</td>
<td>UOB</td>
</tr>
<tr>
<td>Hanna Philippe</td>
<td>MD</td>
<td>UL</td>
</tr>
<tr>
<td>Hassan Rahal</td>
<td>MD</td>
<td>UL</td>
</tr>
<tr>
<td>Rammal Ghina</td>
<td>Pharm D</td>
<td>UL</td>
</tr>
<tr>
<td>Tawil Samah</td>
<td>Pharm D</td>
<td>LAU</td>
</tr>
<tr>
<td>Yassine Hussein</td>
<td>MD</td>
<td>UL</td>
</tr>
<tr>
<td>Zaarour Rana</td>
<td>MD</td>
<td>UL</td>
</tr>
</tbody>
</table>

AUB = American University of Beirut; BAU = Beirut Arab University; UL = Lebanese University; UOB = University Of Balamand; 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, 3 academic years took place with 3 distinct classes; the first two classes were presented in the 2010-2011 activity report. The third class is reported hereafter (see appendixes 2).

- Academic year 2012-2013: Class “Pierre & Marie Curie ” included 13 participants

<table>
<thead>
<tr>
<th>NOM</th>
<th>DEGREE</th>
<th>UNIVERSITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abou Khalil Diana</td>
<td>MSc Pharmacy</td>
<td>USJ</td>
</tr>
<tr>
<td>Anouty Zeinab</td>
<td>MSc Microbiology</td>
<td>USJ</td>
</tr>
<tr>
<td>Chalhoub Karen</td>
<td>BS Biology</td>
<td>UOB</td>
</tr>
<tr>
<td>Fakih Cherine</td>
<td>MSc Agronomy/ Biochemistry</td>
<td>UL</td>
</tr>
<tr>
<td>Farhat Soha</td>
<td>BS Pharmacy</td>
<td>BAU</td>
</tr>
<tr>
<td>Haddad Rana</td>
<td>BS Nursing</td>
<td>AUB</td>
</tr>
<tr>
<td>Haydar Ghina</td>
<td>MSc I Biochemistry</td>
<td>UL</td>
</tr>
<tr>
<td>Khalil Cynthia</td>
<td>BS Biology</td>
<td>UOB</td>
</tr>
<tr>
<td>Nasser Rania</td>
<td>BS Pharmacy</td>
<td>BAU</td>
</tr>
<tr>
<td>Rammal Farah</td>
<td>BSc Pharmacy</td>
<td>BAU</td>
</tr>
<tr>
<td>Shbaro Abeer</td>
<td>BS Pharmacy</td>
<td>BAU</td>
</tr>
<tr>
<td>Sleiman Hiba</td>
<td>MSc Biochemistry</td>
<td>UL</td>
</tr>
<tr>
<td>Slim Tala</td>
<td>BS Biochemistry</td>
<td>UL</td>
</tr>
</tbody>
</table>

AUB = American University of Beirut; BAU = Beirut Arab University; UL = Lebanese University; UOB = University Of Balamand ; USJ = Saint-Joseph University.
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:

- 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. During 2012, this unit has been involved both in term of initiation and/or management of several clinical studies (cf, hereafter). The CRU team has been confirmed and developed in 2012 and included: a unit director, his head assistant, and three CRAs.

The development of the CRU at MLH included the followings:
- Development of Standard Operating Procedures and initiation of a recruitment process for study coordinators.
- Several contacts and meetings with sponsors and CROs as well as with MLH medical director, units staff and directors in order to present the CRU activities and the possibilities within MLH for interventional trials conduct and to evaluate the clinical research activities.
- Collaboration with MLH purchase and IT departments for provision of utilities and equipments needed for trials coordination.

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:

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

- Study status: Completed
- Number of patients’ status: 4 patients completed the study
- Duration of study participation per patient: 18 weeks

F-MRI activities to date: Feasibility and set up meetings – discussion of agreement and budget – training on study specific process – coordination of the study and patients management – close collaboration with the CRO and facilitation of the monitoring process – handling trial files and materials - study closure
2- 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**: 6 patients currently enrolled
- **Duration of study participation per patient**: 27 weeks

F-MRI activities to date: Feasibility and set up meetings – discussion of agreement and budget – training on study specific process – coordination of the study and patients management – close collaboration with the sponsor and facilitation of the monitoring process – handling trial files and materials.

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

- **Study status**: starting
- **Number of patients’ status**: 1 patient pre-screened
- **Duration of study participation per patient**: 12 to 26 weeks

F-MRI activities to date: Feasibility and set up meetings – discussion of agreement and budget – training on study specific process – initiation of patients pre-screening - close collaboration with the sponsor - handling trial files and materials

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

- **Study status**: under set-up preparation
- **Number of patients’ status**: Not applicable yet
- **Duration of study participation per patient**: 24 weeks

F-MRI activities: Feasibility and set up meetings – discussion of agreement and budget

- **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 and the CRU is being established and will be operational during 2014.

---

2- Other Research

- **A- Technical Research**

Assessment of the accuracy of the blood pressure measurements using 3 various methods: 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 various outpatient clinics 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 2012, its publication is in press.

- **B- Epidemiological Studies**

The F-MRI participated in the design, realisation, and analysis of an MD thesis entitled: “Prevalence of Diabetes Mellitus among Patients with Essential Arterial Hypertension” during 2012. This thesis has been successfully defended and it has been submitted for publication.
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”.

A first experience of CME activity took place in 2011 at a regional level in Istanbul, Turkey. This has been possible thanks to the sponsoring of various pharmaceutical companies and medical device manufacturers. Analysis of the evaluation forms fulfilled by more than 150 participants was very satisfactory and promising.

In 2012, the F-MRI undertook two major CME activities:

1- A master class update on clinical research which has been held in collaboration with the Lebanese University in Q3.

2- A major CME congress was fully organized by the F-MRI in collaboration with the ISVH in Istanbul in December 2012. Outstanding international speakers of a high calibre participated in this high scientific standard meeting (See Program hereafter). The attendance included 150 participants from several countries of the region. According to the evaluation forms, this CME was a real success (See Evaluation form’s results hereafter)
“The 2nd Cardio – Metabolic Meeting in the Middle East”

Final Program

December 1st, 2012 - Hilton Hotel - Istanbul, Turkey

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

A- Guidelines for Hypertension Management Present & Future
   Prof. Bernard Waerber (CH) 30’

B- Pharmacological treatment of hypertension
   The role of combination and new perspectives
   Prof. Atul Pathak (FR) 30’

C- 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:

A- Arterial Remodeling
   Prof. Roland Asmar (FR) 30’

B- Cardiac Remodeling
   Prof. Giuseppe Germano (IT) 30’

C- Kidney Abnormalities
   Prof. Ali Abu-Alfa (LB) 30’

12h30 – 13h30: Lunch Break

13h30 – 15h: Workshops parallel sessions – (First Session)

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

B- Workshop on Target Organ Damages Artery & central BP
   Prof. Jirar Topouchian (FR)
   Mr. Achim Schwarz (DE)

C- Workshop on Target Organ Damages Cardiac Assessment
   Prof. Elie Chammas (LB)

D- Workshop with Clinical Cases
   Prof. Samir Arnaout (LB)
   Prof. Omar Hamoui (LB)

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

15h – 15h30: Coffee Break

15h30 – 17h: Workshops – (Second Session)
Same program than First Session
Cardio-Metabolic Meeting in the Middle-East

Positive feedback on a mix between lectures and workshops
Publications

Several publications were performed in international peer-reviewed journals:


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:
  1- The Lebanese University and the University of Paris XIII.
  2- The Geitawi Hospital affiliated to the Lebanese University and the Hospital Créteil- Henri Mondor affiliated to University of Paris XIII.

- Seminars on medical research
  Considering that professional employments are also interested by the research education, the foundation is willing to develop specific modules and seminars. These seminars will take place during 2-3 days at the end of the week.

2- Research

- A- Clinical Research
  - 1- CRU: the Foundation is willing to develop one more CRU in the Geitawi academic hospital.
  - 2- Trial: A trial is pending, awaiting sponsor’s launching decision. It is a phase III interventional, randomized, phase III study in patients after heart valve replacement
    - Study status: pending (awaiting sponsor’s decision for launch)
    - Number of patients’ status: Not applicable yet
    - Duration of study participation per patient: 12 months

- B- Basic Science Research
  We are discussing with the Lebanese University for the opening of a Basic Research Unit with Dr Mirna Chahine as a head of this unit in 2013.

- C- Epidemiological Studies
  F-MRI is willing to develop in 2013 a large national epidemiological study entitled: “The Cardiovascular Prevalence Lebanese Project” in collaboration with the Faculty of Pharmacy of the Lebanese University. This study will help to estimate the prevalence of the major 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 “Pierre & Marie Curie” - Academic year 2012-2013.

2- Clinical Research Assistant/ Clinical Research Technician – Class “Pierre & Marie Curie” - Academic year 2012-2013.
University Diploma
« Principles of Medical Research »
Class “Pierre & Marie Curie”
Academic Year 2012 – 2013

Bassem Abou Merhi  Nadine Bassil  Mohammed Benaicha  Kamal Chamoun
Michelle Cherfan  Rola Dbouk  Fida Drouby  Maya El Khoury  Sarah El Masri  Khaled El Youssef
Philippe Hanna  Rahal Hassan  Ghina Rammal  Samah Tawil  Hussein Yassine  Rana Zaarour
Clinical Research Assistant / Clinical Research Technician
« Principles of Medical Research »
Class “Pierre & Marie Curie”
Academic Year 2012 – 2013

Diana Abou Khalil  Zeinab Anouty  Karen Chalhoub  Cherine Fakih  Soha Farhat

Rana Haddad  Ghina Haydar  Cynthia Khalil  Rania Nasser  Farah Rammal

Abeer Shbaro  Hiba Sleiman  Tala Slim