

# FINAL REPORT (Core report)

<b>Grant agreement number</b>	FP7 INCO.2010-6-2 ERAWIDE
<b>Project acronym</b>	THEBERA
<b>Project title</b>	Theodor Bilharz into the European Research area
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## Table of contents

<b>List of Tables</b> .....	3
<b>List of Figures</b> .....	3
<b>Publishable Summary</b> .....	4
Executive Summary .....	4
Project Context and Objectives .....	5
<b>Core of the Report</b> .....	8
Project Objectives .....	8
Description of WP2 Results and Impact .....	9
Description of WP3 Results and Impact .....	16
Description of WP4 Results and Impact .....	21
Description of WP5 Results and Impact .....	28
Description of WP6 Results and Impact .....	33

## List of Tables

Table (1): Frequency distribution of international publications on hepatocellular carcinoma (HCC) over the period of 2005-2010	11
Table (2): Frequency distribution of international publications on liver transplantation in Egypt over the period of 2005-2010	11
Table (3): THEBERA WP3 main S&T Outputs in numbers	17
Table (4): Dimensions and Areas considered in the SWOT analysis	21
Table (5): Indicators considered in the SWOT analysis	22
Table (6): SWOT Results Overview	23
Table (7): Operational model and budgetary needs, for future research projects. The budget represents 52% of total budget	28
Table (8): Operational model and budgetary needs, for future research projects. The budget represents 52% of total budget (continued)	29

## List of Figures

Figure (1): Five years international liver publications by institute (A), field (B) and disease (C)	10
Figure (2): Frequency distribution of TBRI projects (2000- present) according to disease subject (A) and TBRI research program (B)	12
Fig (3): Overall evaluation of the participants for the study visit	24
Figure (4): Forecast of funding agencies profile over a period of five years	30

## **Publishable Summary**

### **Executive Summary**

THEBERA project aims at strengthening capacities of the Theodor Bilharz Research Institute (TBRI) in Egypt while realizing it as an international reference centre for liver disease management by defining liver research priorities to respond to socio-economic needs, facilitating participation in European liver research initiatives and inclusion in Euro-Mediterranean Research and Innovation Area.

To establish THEBERA center strategy/ the coordinating institute as an excellence center on liver research/management, the landscape of national liver disease state of the art was mapped to identify main policies, programs, funding needs, current cooperation patterns and relevant actors in liver disease. The most prominent findings were the inequity in viral hepatitis prevention plans and standard of care, the unavailability of training on liver care outside liver treatment centres. Gaps and needs on liver disease research/management for future planning that involved six pillars: Governance; finance; networking; training; policy; and research were presented to liver disease stakeholders. Salient research needs involved, innovative solutions for viral infection control, operational research on scale up of case detection and improvement of access to treatment, facilities for buildup of data base and networking liver disease institutes at national and EU level, also linking clinicians/researchers to policy makers. Studying the potential of the coordinating institute entailing a SWOT based methodology involved three main dimensions: Man power, infrastructure and organization. The skills and competence toolbox developed involved > 30 recommendations; the most noticeable were: more efforts towards internationalization with proper advocacy plan, buildup of strategic alliances with scientific and industry counterparts, a strategy to potentiate young researchers and better educational programs for supportive staff "technicians and nurses". To reinforce the cooperative capacities of TBRI to contribute to European international cooperation, four training and consortium building workshops were held raising the awareness regarding FP7 ( Health topics, People program and ERAfrica call) and Horizon 2020 programs clarifying rules for participation, funding opportunities, the guidelines for competitive proposal and concept note writing, the basic principles of ethics and IPR in medical research, preparation and buildup of a successful consortia. As an outcome, one cooperative (€7.8M) project funded under Health FP7 program (PDE4NPD) is just starting involving 9 EU partners. Five consortia were built including three successful submissions under the cooperative research projects and the mobility exchange of FP7 program and two consortia under H2020 Programs (RISE and Health Societal challenge), visibility of TBRI researchers was increased ( publishing profiles on CORDIS and Fit for Health) with generation of new research ideas (in progress). Stakeholders were reached including liver disease experts, policy makers, NGOs, media, EU representative at the closing event of THEBERA on the 5th of December 2013 in Cairo, Egypt with the aim of coordinating efforts and pin pointing of the role the EC funded research played and might still play.

THEBERA and TBRI visibility is ensured with the establishment of high traffic THEBERA website, (visitors exceeded 88000 to date) and video films clarifying TBRI potential and the impact of THEBERA. TBRI connection with other EU-Egypt Health initiatives e.g. Medspring, ShERACA , MIRA, EU-Egypt Year of Science, other ERAWIDES and the national network for liver disease were targeted as well as, the creation of competitive liver research actor data base to enhance contact between Egyptian and EU researchers.

## Project Context and Objectives

The FP7 ERA-WIDE call tackles the problem characteristic of health research across the Mediterranean Region, namely the lack of coherent, comprehensive policy. Although there were some efforts to foster transnational cooperation in the medical field, high barriers seemed to persist that hinder the deployment of international research schemes across the Mediterranean region resulting in a weakening effect of national programs and in scattered, patchy initiatives not allowing for a critical mass in terms of figures of data, trials or patients treated, which in medical science is a fundamental factor to demonstrate the validity of assumptions and the effectiveness of research results. Equally affected are research endeavors related to public health, such as the management of national healthcare systems, or the delivery of healthcare services in rapidly changing societies where epidemiological studies or other kinds of investigations across large segments of the population have a special importance in suggesting research directions to the scientific community. THEBERA project was planned to provide a response to the need of giving significant impulse to medical research, with particular emphasis on liver diseases in the Mediterranean region; a banging problem in one of the southern Mediterranean countries "Egypt; to allow for the integration of approaches and resources in this field of investigation.

Liver disease accounts for 1.6% of the global burden of the disease resulting in the loss of 4.2 million Disability-Adjusted Life Years (DALYs). In Egypt, hepatitis having the potential to proceed to chronic liver disease almost caused by viruses, particularly hepatitis B (HBV) and C (HCV) viruses are the most prevalent liver disease. HBV has been known since 1965 and the first vaccination was licensed in the early 1980's. HCV first known as non-A, non -B was not identified until 1989 and no vaccine is yet available. Infection by HBV and HCV occurs after exposure to infected blood or tissue fluids containing blood elements implying several possible modes of transmission, including parenteral, sexual and vertical transmission (from mother to child during pregnancy or birth). In Egypt, the National Control Strategy on viral hepatitis set 2008 reported estimates of HCV prevalence from 11% to 14%, with 8 to 10 million having anti-HCV and 5 to 7 million having active infections. The 1996/7 Egyptian household and workers national survey, a representative sample of 7,357 persons in 10 governorates, found an overall adjusted prevalence of 13.5% for HCV and 4.5% for HBV surface antigen (HBsAg). This implies chronic infection rates of 8.8% for HCV, with 1% having both infections. Both HBV and HCV exist in acute and chronic phases.

The percentage of total infections attributed to each mode of transmission varies by country, and between the HBV and HCV viruses. In the Western community, both viruses are principally found among high-risk populations, particularly injecting drug users (IDUs). Additionally, a significant number of HBV infections in these contexts are acquired during young adulthood via sexual activity, due to the virus' greater infectiousness. Nosocomial procedures are likely the leading source of HCV transmissions worldwide and are also responsible for a large percentage of HBV infections. Screening for HCV antibodies although it has been a routine practice yet still there are many developing nations who do not screen for viruses. Even in countries where the blood supply is screened for viral hepatitis, the risk of parenteral infection can be significant, as injections may be performed with inadequately sterilized equipment. The World Health Organization (WHO) estimates that unsafe injections accounted for million new HCV infections and 21 million new HBV infections worldwide in 2007. Exposures may be multiplied by the frequent practice of giving injections in non-medical settings: for example, injections may be given by family members, traditional healers, barbers, etc. Other medical procedures (dialysis, transplant procedures, obstetrical and dental procedures) and non-medical procedures (circumcision, tattoos, commercial barbering, body piercing) can also transmit the viruses if the equipment is not properly sterilized. In the context for accidental needle stick exposure and parenteral exposure via intravenous drug use, accidental needle stick accounts for a percentage transmission of 2-8% for HCV among health workers while the rate is significantly higher for HBV (~30%). The background of health education and post-exposure prophylaxis (PEP), although not endorsed by the American CDC, in the form of anti-viral medication for HCV and vaccination against HBV can reshape the condition. While parenteral exposure via intravenous drug users is a major risk factor resulting in high rates of HBV and HCV infections in Western nations, only a small percentage of viral hepatitis infections are due to injecting drug use in developing countries.

In Egypt, Viral hepatitis (particularly HCV) is currently and will remain for some time Egypt's most pressing public health issue. HBV accounts for 10-30% of chronic liver disease, and there is likewise a large occult reservoir of HCV-caused chronic liver disease. Current liver mortality, including liver cirrhosis and cancer, is over 40,000/year and is increasing annually. This represents more than 10% of total mortality. Liver disease is thus the second-

commonest cause of death in Egypt after heart disease. Deaths from liver disease are predicted to peak in 2010-2012: one model predicts 700,000 cases of cirrhosis and 140,000 cases of hepatocellular carcinoma (HCC) within the next 20-30 years. Similarly, sexual transmission of HBV is common in the West, but accounts for a much smaller proportion of infections in the developing world where most patients are infected as infants or children. Sexual transmission of HCV is much rarer as sero negative sexual partners of HCV-positive people rarely become infected even after years of cohabitation. This is likely due to the much lesser infectivity of HCV compared to HBV.

The burden of HCC is further demonstrative of the burden of disease linked to viral hepatitis in Egypt. HCC is one of the three most commonly diagnosed cancers in Egypt, and it is estimated that 51.5% of cases can be attributed to HCV infection and 21.3% to HBV infection, according to one study. Thus, some ¾ of HCC cases in Egypt are caused by these two viruses. Moreover, HCC rates appear to be on the rise, according to national and local cancer registries, as well as statistical models of the epidemic (one paper predicts a 2.4-fold increase of HCC over the next 20 years). Given the relatively high rates of vaccination against HBV in the country, HCV will continue to be the primary cause of HCC in coming years. Several specificities of the Egyptian epidemic are to be noted. First, nearly all Egyptian HCV infections (upwards of 95%) are genotype 4. While HCV genotype has no impact on the course of the disease, different genotypes do react differently to treatment - genotype 4 has an intermediate resistance to treatment. For this reason, Egyptian patients must undergo longer courses of treatment: 48 weeks instead of the 24 weeks recommended for patients infected with genotypes 2 and 3. Egyptian patients may also be co-infected with schistosomiasis, a pathogen that also harms the liver and accelerates the course of liver disease. Prevalence rates of HIV are extremely low (estimated at <1%) , which favorably affects the prognosis of individual patients. HIV can accelerate liver damage via the action of the virus itself. Finally, Egypt's Islamic culture, where the rates of alcoholism and average per capita alcohol consumption are much lower than in the West, may result in lower morbidity from viral hepatitis than would otherwise be the case

Recognizing the necessity for expanding cooperation and integration with the European Research Area, focusing on one of the binging health problems; liver disease; project aims for the Egyptian partner to increase their capacity for participation in European health research initiatives by defining health research priorities to respond to socio-economic needs, and facilitating development of strategy for research centre based on thorough analysis of current situation, cooperation patterns, relevant actors, needs and opportunities. This overall objective and underpinning rationale comprised:

- Monitoring and reviewing of state of the art in health sector in Egypt, with particular emphasis on liver research that entails (i) data collection of different health organizations in terms of innovativeness, research capacities / activities, metadata of basic and applied research and peer reviewed publications experience in international cooperation and EU projects participation,. After conduction of the complete analysis of liver disease state of art, analysis will be reviewed by independent external experts. Evaluation and comments by experts will be considered in an updated version. The updated version will be delivered by end of project so as to take stock of the evolutions of discussions generated out of the first document; include expert's comments and the most recent research publication on liver disease. This developed version will also include the priority needs retrieved from the analysis in view of current dynamic changes in research landscape and also a section on relevant European priorities to highlight foreseen future mutual cooperation based on the analysis. The summarized booklet that will be prepared in addition to presenting at diversified national scientific events will also be communicated to the widest range of liver disease stakeholders. Versions to nonscientists will be also prepared involving patients, NGO's and industry.
- Training activities: Collaboration in setting up joint workshop modules based on the existing expertise and ongoing collaboration of THEBERA with other project partners to increase the mobility of researchers, thereby enhancing its RTD potential in multidisciplinary subjects involved in the liver research topic.
- Increasing Capacity building for cooperation activities in conducting health research including Institutional Capacity Building for International Cooperation achieved through tutoring/coaching provided to the Egyptian beneficiary to facilitate their participation in future Calls for Proposals in order to support their integration into a competitive international consortium.

- Facilitation and dissemination of Network integrating the Egyptian research centre with its European counterparts in view of the wider context of the Barcelona Strategy which sets forth recommendations for the strengthening of scientific research capacity and development, contribution to the training of researchers, and promotion of joint research projects based on scientific networks contributing in particular to EU-Med cooperative in order to improve the exchange of scientific knowledge and technology transfer, broker future scientific partnerships, and conduct joint scientific
- The project will present a well-developed action plan on liver disease research/management based on: liver disease needs retrieved out of the analysis of national liver disease state of the art and the SWOT analysis, recommendations. The scheduled activities within this supporting action include:
  - Developing THEBERA centre's strategy ( Internationalization unit) with the aim to increase the scope of its socioeconomic impact within its region in terms of expanding its regional coverage, enhancing its research profile, and diversifying activities
  - Developing links with industry to valorize research results, the project will set the needed tools to address the establishment of a research valorization system, in a trial to systemize industry connections and improve research capacity towards a good economic impact of science and technology
  - Establishment of a mobility plan ensuring the free movement of researchers, technology and ultimately knowledge across national boundaries is a key element in ensuring strong links with the European research area and also that Europe develops into a knowledge society.

## **Core of the Report**

### **Project Objectives**

- Development of 1<sup>st</sup> version on analysis of National liver disease state of the art involving main policies, programs, gaps, needs, current cooperation patterns and relevant actors in liver disease.
- Finalization of an updated summarized version of the analysis of national liver disease state of the art to scientists including THEBERA independent experts comments, most recent publications on liver disease and discussion evolves generated out of the first document.
- Development of liver disease state of the art analysis version tailored to nonscientists e.g. patients, NGO and industry.
- Organization of training and consortium building workshops involving coaching of scientists for enhanced participation into European research.
- Organization of research study visit to EU centers and feedback analysis of the visit.
- Development of first strategic action plan (SAP) document involving internationalization /industrialization plans and final updated document including THEBERA independent experts comments.
- Awareness raising and THEBERA closing event involving governmental bodies to present THEBERA findings and achievements, coordinate efforts and to inform about the role played by EC funded research, highlighting research areas of common EU and Egyptian interest.
- Further development of THEBERA web site and dissemination material involving booklets, catalogues and videos; also publications to communicate THEBERA research results.



## Description of WP2 Results and Impact

**WP2 title:** RESEARCH AND STATE OF ART IN LIVER RESEARCH

**Instrument:** COORDINATION AND SUPPORT ACTION

**WP leader:** TBRI

**WP 2 (T2.1/T2.2)**

### Main Significant Scientific and Technological Results

#### ANALYSIS OF NATIONAL STATE OF THE ART REGARDING LIVER DISEASE

To provide policy makers with coincided input regarding liver disease, build capacities of coordinating institute on a solid backbone to enhance participation in European health research and prioritize liver disease needs in the proper context, the first detailed document on analysis of national liver disease state of the art prepared involved an overview of liver disease context, tools and actors, analysis of strategies/policies, committees concerned with liver disease, strategic planning and coordination of research activities and actors in liver disease.

*(The full version is available from:*

*[http://www.thebera.eg.net/index.php?option=com\\_content&view=article&id=262:wp2&catid=67:wp2&Itemid=349](http://www.thebera.eg.net/index.php?option=com_content&view=article&id=262:wp2&catid=67:wp2&Itemid=349))*

##### ➤ Analysis of national strategies and policies

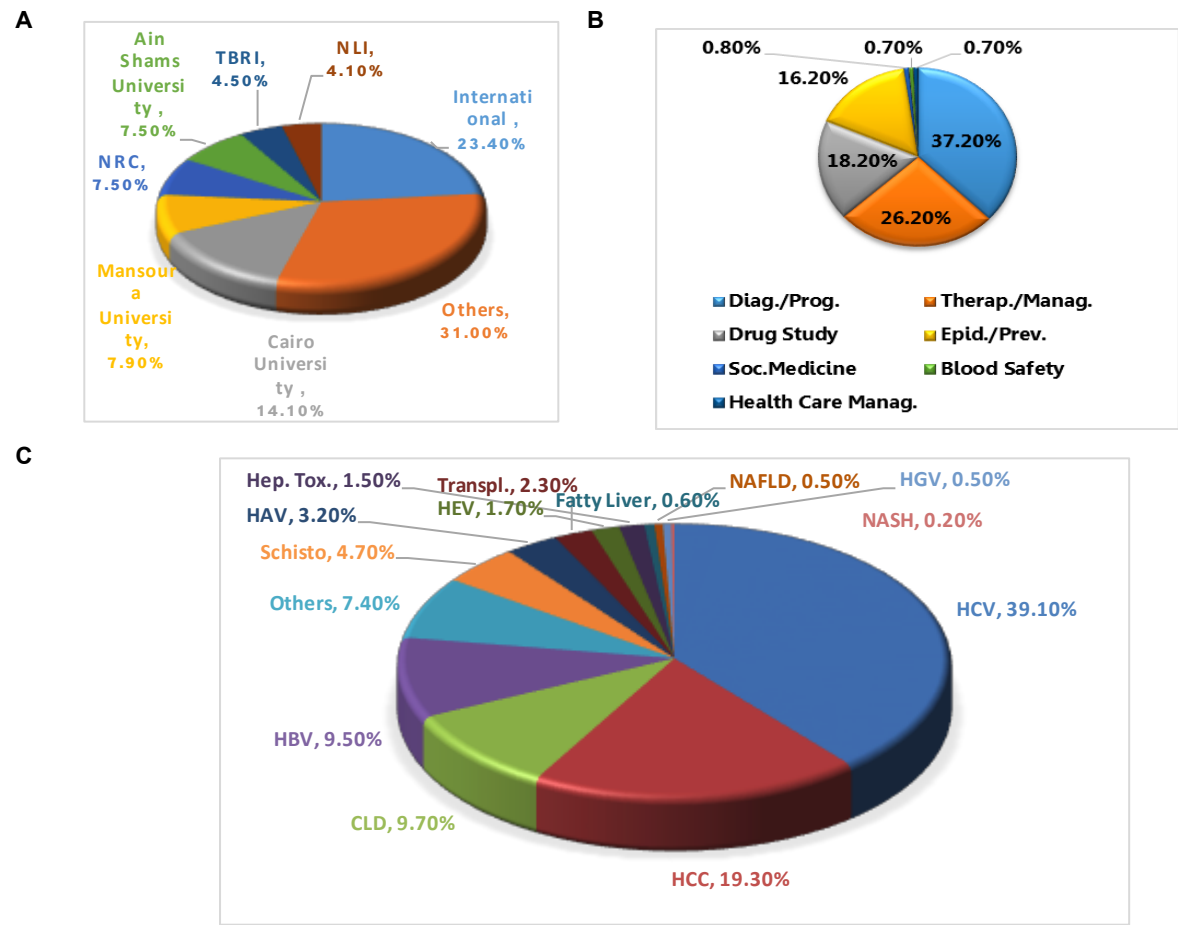
To find out how far national strategies served the national health policy and whether they were conducive to the needed development of appropriate platforms to protect against liver disease, mapping the landscape revealed limited strategies at national level, the only available was the National Control Strategy "NCS" on viral hepatitis. Criticising the strategy with respect to its objectives, whether it was evidence-based, action taken, the expected impact and the health research system tackling the problem of liver disease, the progress in priority areas and socioeconomic burden of HCV in Egypt including health services providers, funding sectors and limitation to treatment revealed a comprehensive, multi-sectoral review to "viral hepatitis", including situation and response analyses, a guide to the challenge of viral hepatitis management, a framework for ongoing monitoring and evaluation as well as a commitment to fund raising. The section of the Egyptian health system organization pointed out the defects and obstacles in the system and the limitations for proper management regarding proper quality of care. The strategy focused on viral hepatitis but neglected other viral and parasitic infections contributing to liver disease, the socioeconomic burden of the disease which is the backbone to forecast the needed budget. Not all the aspects of strategy could be efficiently controlled as the target of this strategy "viral hepatitis" is a multi-sectoral task that requires the coordination of several governmental ministries (MoH, MoHE, MoD, MoF etc...) yet with no overarching structure to link all health care service providers. The strategy also neglected some technical aspects, the most salient of which are: HBV vaccination focused only on children and neglected other high risk groups; infection control program is limited to MoH facilities with no extensions to small villages and private clinics; insufficient surveillance system for case finding or follow up and insufficient coverage of patients in need for treatment as the programme handled only 20% of the those eligible for interferon.

##### ➤ Potential of research institutes involved in liver disease:

Analysis of national research work on liver disease published internationally (2005-2010) revealed the potential of national institutes involved in liver disease research/management where a total number of 1904 organizations and institutes were encountered in international publications on liver disease, 295 of the institutes encountered were international organizations. Leading scientists in the international publications affiliated to national Institutes comprised 88%. The frequencies of international publications 2009/2010 revealed different institutions potential with respect to magnitude (Fig 1A), the targeted fields of research (Fig 1B) clarifying well investigated and under investigated fields, also the most frequent studied liver disease (HCV, HCC and CLD) and diseases to invest in

(Fig 1C) Well developed capacities (prognostic/diagnostic) and to leverage (epidemiology, prevention, infection control and social medicine) were also identified.

**Figure (1):** Five years international liver publications by institute (A), field (B) and disease (C)



Most of the international publications, relevant or indirectly relevant to the NCS on viral hepatitis, focused on optimal clinical management. TBRI publications on HCV, HCC and CLD followed big Universities and the NRC while for schistosomiasis TBRI led the publications. Tables 1 and 2 presents International publications on HCC and liver transplantation , revealing deficient metadata analysis to evaluate biomarkers ranking and publications on social medicine; epidemiology/prevention and health care with respect to transplantation. Most of the international publications were in journals with impact factor between 0 and 4 clarifying the need for more quality publications.

**Table (1):** Frequency distribution of international publications on hepatocellular carcinoma (HCC) over the period of 2005-2010

Organization	Count	Field of Research				Total
		Diagnostic/ Prognostic	Drug Study	Epidemiology/ Prevention	Therapeutic/ Management	
National Hepatology and Tropical Medicine Research Institute.	Count	10	0	0	0	10
	% within Organization	100%	0%	0%	0%	100%
	% within field	4.2%	0%	0%	0%	2.5%
National Research Center	Count	8	14	1	2	25
	% within Organization	32%	56%	4%	8%	100%
	% within field	3.3%	23%	2%	4.3%	6.3%
<b>Theodor Bilharz Research Institute</b>	Count	17	0	1	3	21
	% within Organization	81%	0%	4.8%	14.3%	100%
	% within field	7.1%	0%	2%	6.4%	5.3%

**Table (2):** Frequency distribution of international publications on liver transplantation in Egypt over the period of 2005-2010

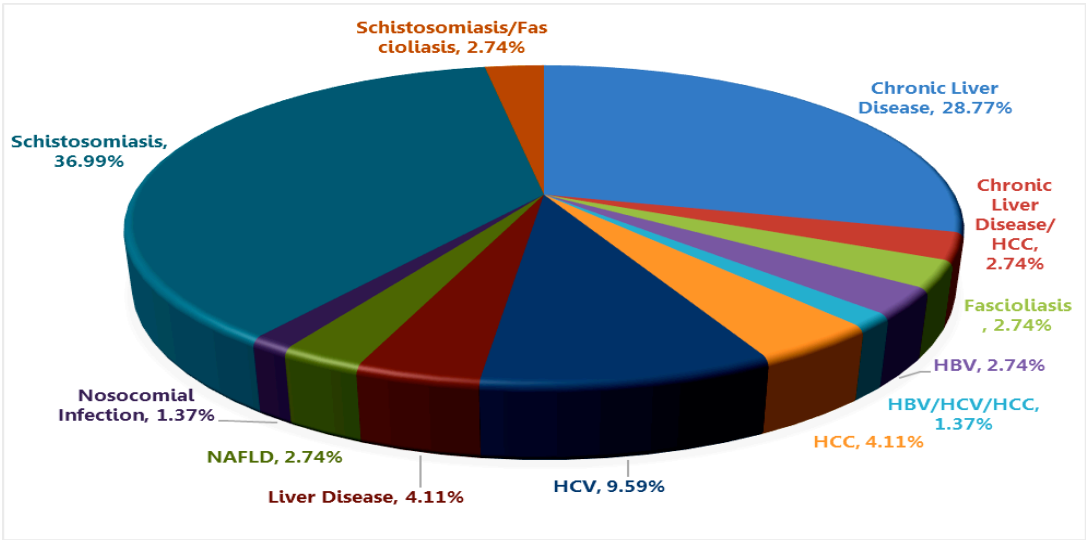
Organization	Count	Field of Research					Total
		Drug Study	Epidemiology/ Prevention	Healthcare Management	Social Medicine	Therapeutic/ Management	
<b>Ain Shams University</b>	Count	0	0	0	2	7	9
	% within Organization	0%	0%	0%	22.2%	77.8%	100.0%
	% within field	0%	0%	0%	50%	16.7%	17%
<b>Cairo University</b>	Count	0	0	0	1	12	13
	% within Organization	0%	0%	0%	7.7%	92.3%	100%
	% within field	0%	0%	0%	25%	28.6%	24.5%
<b>Dar Al-Fouad Hospital</b>	Count	0	0	0	0	3	3
	% within Organization	0%	0%	0%	0%	100%	100%
	% within field	0%	0%	0%	0%	7.1%	5.7%
<b>National Liver Institute</b>	Count	0	3	1	0	5	9
	% within Organization	0%	33.3%	11.1%	0%	55.6%	100%
	% within field	0%	100%	100%	0%	11.9%	17%

➤ **Coordinating Institute “TBRI” Potential:**

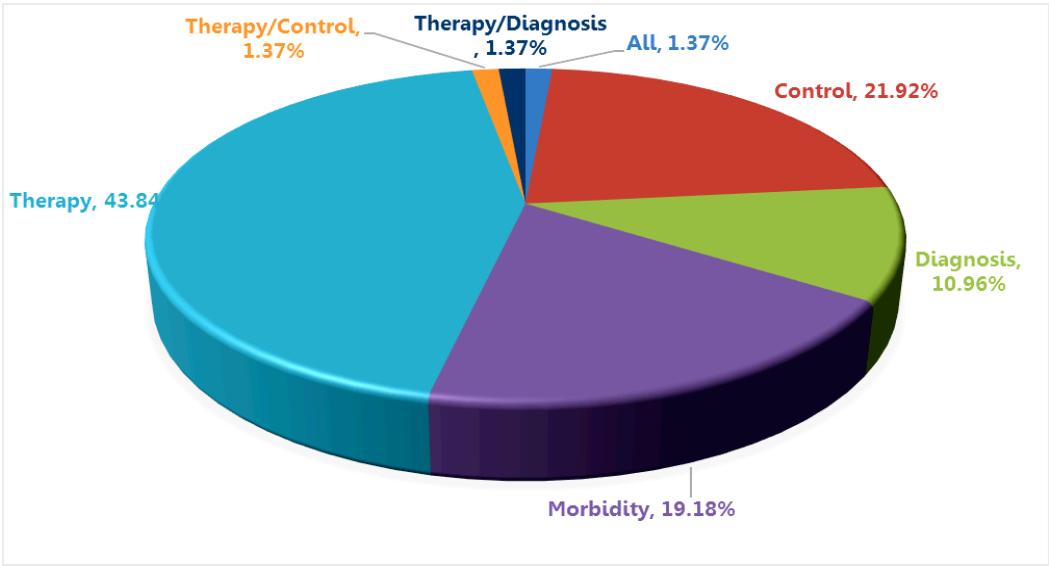
As a main player in the field of liver disease, TBRI potential was investigated to find out research production, funding resources, and how far the research implemented is responding to community needs. This was examined in view of institute human resources and infrastructure. Research projects and publications implemented by TBRI despite considerable yet 86% of it are funded by national organizations, clarifying the need for a fundraising plan. The main research subject was schistosomiasis followed by chronic liver diseases and hepatitis C virus (Figure 2A). The biggest number of projects implemented was responding to therapy and control programs of schistosomiasis, while CLD and HCV related projects responded to therapy and morbidity programs (Figure 2B).

**Figure (2):** Frequency distribution of TBRI projects (2000- present) according to disease subject (A) and TBRI research program (B)

A



B



TBRI profile of publications revealed clear responses to community needs, publications diverted from schistosomiasis to focus on the newly banging «viral hepatitis» problem. TBRI publications followed the same line of relevancy as the projects since the publications were covering not only viral hepatitis B and C but also other liver diseases e.g. trematodal infections affecting the liver. Publications responded to viral hepatitis NCS priority areas of research, followed by clinical trials priority areas. Researches relevant to population level survey and scale-up of case detection comprised only 1.4%, while the lowest publications (1.5%) fell into the priority area concerned with infection control and population surveys.

➤ **Development of Updated summarized version of national liver disease state of the art:**

The summarized updated version of national liver disease state of the art was planned to communicate to the widest audience of liver disease stakeholders. This version included the same sections included in the first document developed; the updates of programs implemented by the MoHP to control infection (ICP 2001), care and treat (NCS 2008) viral hepatitis infection focusing on the further developed Infection control program and new viral hepatitis care facilities that were presented in the report published in Morbidity and Mortality Weekly report (MMWR) in July 2012. The developed version included discussion evolves out of the several versions of National Liver Disease State of the Art prepared and presented at diversified events; the most recent publications on liver disease and the THEBERA independent experts remarks raised during the experts validation workshop at which core THEBERA deliverables were presented and discussed. Liver disease priority needs retrieved out of the analysis and discussed at Cairo THEBERA final stakeholder event were also included. Salient remarks raised by THEBERA independent experts included the need for sustained, standardized well controlled training program for the medical team, training of care givers to avoid iatrogenic spreading of infection for better control of nosocomial infections, strong central body with competent medical statistical analyst for proper collection, analysis and presentation of data and the importance of more inclusion of medical professionals active in liver disease in advisory board composition to raise efficiency

➤ **Research and Innovation Priorities**

The salient Liver research gaps and innovation priority needs were found to be under two main pillars of research and management

**A- For Liver Research**

These included the need for establishment of proper database systems at institutional and ministerial levels, enhancement of operational research concerning scaling up of case detection and improving access to medical care, innovative research e.g. adapting existing tools, modifying existing research and development (R&D) and new makeovers, research to focus on new directly acting antiviral drugs (DAAs), adequate consideration of metadata-analysis and mathematical modeling studies for morbidity and mortality assessment, announcement of the upcoming launch of a website on system analysis, linked to the EESA, a short term networking strategy at the governmental and non-governmental sectors for better coordination between existing bodies minding the currently unstable political situation, clustering entities of mutual interest based on flexibility and effectiveness to inform international funding agencies, improvement of information systems at organizational and inter-organizational level.

**B- For Liver Disease Management**

The needs revived under (i) governance: where the need is pressing for a supreme committee to co-ordinate between entities providing health research/ services for liver disease patients (ii) Finance involving the need for transparency regarding domestic funding with respect to disease management and prevention with establishment of a central body for alignment of budgetary plans (iii) Training involving sustained training for all levels of health care workers, tailored national training programs for the supportive staff with adoption of Training of Trainers (TOT), linking training with motivation and staff promotion with monitoring of the contribution of trainees to knowledge transfer (iv) Policy: the need for increasing the number of liver treatment centers with wider coverage of quality health services, Infection Control Program (ICP) to cover remote areas with increase of the Egyptian Ministry of Health and Population (MoHP) budget for ICP with development of innovative affordable interventions for infection control (IC) and pre-recruitment training on infection control policies and procedures with obligatory license, efficient notification system in private facilities, prohibition of infection transmission through legislation, activation of regulatory laws for Cadaveric and Living Donor Organ Transplantation as well as holding community discussions on necessary documents for organ donation, enhancing health promotion campaigns for raising awareness e.g. hepatitis transmission and organ donation and providing due care to sentinel/high risk groups through interim demographic health surveys for timely explanation of disease trend.

➤ **Key Competitive Parties and Funding Needs**

Liver research actors involving different universities, research institutes and scientists involved in liver disease management/research were presented in the first version developed of the analysis of national liver disease

state of the art (Annex II and IV). Research institutes were presented as affiliations encountered in national and international publications while scientists involved in liver disease research and management were presented with their affiliations to different universities and institutes. Detailed funding needs to forecast future budget for disease management was difficult to attain in view of the unavailability of documents focusing on budgetary needs, also domestic funding of research institutes involved in liver disease research/management; the only available documents was that on Socioeconomic disease burden in the expert opinion recommendations by Pharma ARC.

➤ **Identifying capacities to leverage and specific calls to support researchers and to address the needs of capacities recognized:**

For leveraging capacities, emphasis was given to young talented researchers. They were involved in the four THEBERA training workshops held at Theodor Bilharz Research Institute and the ASRT and were exposed to training regarding EU commission different programs.

➤ **Versions of national liver disease state of the art developed to non-scientists**

**Booklets addressed patients, NGO's and industry.**

**The booklet to patients was prepared** in a simple understandable language both in Arabic and English. The Arabic section was prepared and edited in collaboration with the journalist heading the scientific section at the first Arabic "El-Ahram" journal in Egypt and was validated by THEBERA independent expert. The booklet comprised focusing on liver organ, infection caused by viruses, disease prevention, liver cancer as end result of cirrhosis, symptoms, diagnosis, and treatment options. Several questions often raised by patients were addressed. The need to perform liver function tests, ultrasonography, in case of liver disease symptoms and other blood tests to diagnose the aetiology. Treatment of virus hepatitis B and C, serious complications of the disease e.g. esophageal varices, hepatic encephalopathy and ascites. The booklet included a list of governmental hospitals providing subsidized treatment for virus B and C all around. The booklet contained illustrative pictures (<http://www.shutterstock.com> website)

**Booklet addressed to NGOs and industry:** The booklet expressed the magnitude of the problem of liver disease, its impact on the socioeconomic status as well as the patients' quality of life before and after treatment, the type of societal support the patients need, financial support required to be extended to places offering treatment whether in cash or in kind, statements to point out how crucial liver disease health problem is, including the impact of the disease on socioeconomic burden and what contribution can be made on part of the civil society for the resolution of the problem. The booklet involved actions to be taken by the civil society and the NGOs and the institutes concerned with liver disease management.

➤ **Publication as Significant Result/Outcome:**

**Article I:** *"Analysis of National Liver Disease State of The Art in North African Country (Egypt): Identifying Gaps And Priority Needs To Reshape Liver Disease Problem And Promote Euro-Mediterranean Co-Operation"*, Authors: Hanan Ali Sayed, Howaida El -Dusoki, Noha El-Qareh, Moaz Abdel Wadoud, Effat El-Sherbini, Inas El-Defrawy, Nevine Fam, Moataz Siyam, Hesham El Khayat, Ola Lawrance\*, Amr Radwan\*, Yasmine Sabry\*, Alessandro Stefani\*\*, Paolo De Simone\*\*, Davide Ghinolfi\*\*, Franco Filipponi\*\*, Sanaa Botros, has been accepted for presentation at: International Conference on Emerging Trends for Sustainable Development and Human Capacity Building in the Third World Nations (ICETSDHCB 2014) May 28-31, 2014 at J.H.K. Nketia Conference Hall, The Institute of African Studies, University of Ghana. Also fast tracked publication as a Special Edition in Top United States journal based in Seattle, WA 98119-1950, United States of America (Emerging Academy Resources); Journal of engineering and life sciences.

**Article II:** *"Priority needs and Future Guidelines for Liver Research in Egypt And the European Commission Role in International Cooperation Panel discussion recommendations"* Authors: Emam Waked, Hesham El-Khayat, Mahmoud El-Meteini, Manal Hamdy El-Sayed, Sanaa Botros, Tomas Matraia, Wahid Doss, Yehia Zakaria Gad (panellists in alphabetical order). Submitted for publication to: liver International as Letter to the editor (under review).

## **WP 2 Results per Task (T2.1/T2.2)**

**Task 2.1: ANALYSIS OF NATIONAL STATE OF THE ART REGARDING LIVER DISEASE** aimed to analyze the current situation of liver disease at a national level by examining and analyzing main known policies and programs, funding needs and offers, current cooperation patterns and relevant actors in liver disease research / management. Analysis included strategies available at national level, universities and National institutes involved in liver disease management, available documents on liver disease socioeconomic burden, liver research actors, health institutes national and international publications on liver disease and the coordinating institute (TBRI) potential as one of the main players in the field of liver disease expressed as research projects implemented and publications. To achieve the goal, several collaborative meetings between ASRT and TBRI teams were held to develop the methodology for proper information gathering to create the database before conducting the analysis. Search for international publications was performed in Scopus database for liver diseases, impact factors were obtained. Database creation by Export from Scopus to excel files and Word files, files were then merged to one excel file and were imported to access with creation of forms and queries to display data. Plans for database formation on access were made and all data on access and Word files were matched by their code numbers and sorted to exclude irrelevant. On access files, data were sorted according to their subject. Tabulation included paper title, year, abstract, conclusion, field of study, relation and relevancy to National Control Strategy "NCS". These files were then transformed to excel files for statistical analysis using SPSS program. Local search was performed in Oracle local database. Several versions of the analysis of national liver disease state of the art were prepared, the final summarized updated version to communicate to the widest range of audience included in addition to the discussion evolves out of the first version prepared, the most recent publications on liver disease, the THEBERA independent experts comments raised during the expert validation working session attended by THEBERA experts and consortium.

Details of the task are included in D2.1

**Task 2.2: RESEARCH AND INNOVATION PRIORITIES, NEEDS and CAPACITIES** were concluded based on the analysis conducted. The report drafted included information regarding identification of TBRI liver research gaps to fill and innovation priority needs, key competitive parties working in the field of liver research, analysis of the funding needs and forecasting a financial framework to fund the development of liver research at the country level, identification of capacities to leverage, with special emphasis on young talented researchers, specific calls (Marie Curie Initial training networks, IRSES, ENPI CBC and TAIEX) to support researchers and to address the needs of capacities previously identified. A special attention is paid to EU-National S&T and Innovation programs and calls with encouragement to apply for FP7. International experts were involved in the analysis results of the national state of the art on liver disease and the first draft of conclusions r on gaps, needs and essential future funding to manage the problem. A version of liver disease priority needs and analysis to nonscientist stakeholders e.g. industry, users and patients were prepared and presented at THEBERA final conference.

Details of the task are included in D2.2 and D2.3

## Description of WP3 Results and Impact

**WP3 title: HORIZONTAL CAPACITY BUILDING INVOLVING FP7, IPR AND ETHICS**

**Instrument:** Coordination and Support Action

**WP leader:** ASRT

**Main Significant Scientific and Technological Results** to achieve WP3 objectives, the main emphasis was put to improve cooperation capacities and transferable skills of TBRI researchers. It has been accomplished through the following 3 outcomes:

➤ **Capacity Building:**

To achieve effective design of capacity building program, Needs assessment has been done through THEBERA prior to each training program and feedback analysis after the training was considered in designing the next training activity.

The training programs focused on Intellectual property rights, research ethics and EU funding programs.

Experts and trainers were selected carefully where they represented the most relevant authorities and agencies with enough experience to perform the training. They are mainly European Commission representatives, EU projects' coordinators, authorities at National patent agency, European universities and experts.

➤ **Identifying best partners**

Since capable Human Capital is the backbone of R&D , identifying and selecting the best partners, both at the local and European levels, has been a vital impact of THEBERA which has been comprehensively addressed in most work packages and specifically under WP3. Aligned with the priority needs identified under WP2 and capitalizing on the synergetic activities of existing competencies, THEBERA positively impacted EU-TBRI scientific cooperation by providing sustainable facilitation, coaching and assistance, identifying best partners and carefully assessing the cooperation capacities.

➤ **Providing access to information:**

Access to information on ERA activities and on the state and advancement of the European collaboration which was considered as a sustainable process, extending beyond the lifetime of THEBERA.



**Table (3): THEBERA WP3 main S&T Outputs in numbers**

	<b>Achievements</b>	<b>Description</b>	<b>Impact</b>	<b>Planned Objectives per (DoW)</b>
<b>Proposals</b>	3	Three proposals under H2020 Programmes (RISE and Health Societal challenge) by TBRI researchers with their counterparts in the MS/AC countries	Experiencing the practicality of proposal writing, negotiation and budgeting in addition to enhancing the proposal's management skills of TBRI researchers.	"Several Proposals to be submitted to EU Programs"
<b>Consortia built</b>	7	Seven consortia built included three successful submissions under the cooperative research projects and the mobility exchange programmes of the FP7	Networks and future clusters' enhancements	"Enhancing the EU-TBRI cooperation capacities"
<b>Projects</b>	1	The success of one project funded under Health FP7 programme-Cooperation Program-Health 2013 Innovation call	Securing the participation of Egypt for the first time in the innovation call of proposals under Health theme	"Enhancing the competitiveness of TBRI"
<b>Patents</b>	2	Two TBRI researchers prepared their patent application for commercialization of their research products	Promotion of Exploitation of research results at the institutional level.	"Encouraging Innovation related activities"
<b>Training</b>	4	96 Hours training were accomplished through capacity building program covering IPR, Research ethics and EU Funding.	125 participants from TBRI and researchers from Egypt have been professionally trained to get involved in European competitive programs	"3 Trainings"
<b>Coaching</b>	6	3 coaching sessions were performed in addition 3 e-coaching sessions.	The generation of new projects ideas by 43 TBRI researchers with their counterparts in Europe and Associated Countries for future proposal submissions under H2020 calls.	"3 Coaching sessions"

**Table (3): THEBERA WP3 main S&T Outputs in numbers (continued)**

	<b>Achievements</b>	<b>Description</b>	<b>Impact</b>	<b>Planned Objectives per (DoW)</b>
<b>Awareness Raising and Visibility</b>	1 Catalogue And Continuous awareness raising	Awareness raising about EU funding opportunities has been promoted and enhanced through all the project duration.  The visibility of TBRI researchers increased by publishing their profiles on Cordis, Fit-for-health websites.	Speeding up –On time-information and knowledge of EU programs including their rules for participation, the funding opportunities, the guidelines for writing competitive proposal and concept note with impact,the basic principles of ethics and IPR in medical research 1 catalogue of EU research organization	“General awareness raising”
<b>Consortium Building</b>	2	The awareness rose of TBRI researchers about the potential EU organizations having common research projects ideas.	Agreement between TBRI and Istanbul University to have a MoU in order to support their research cooperation	“2 consortium building workshops”

## **WP3 Results per Task**

### **T3.1 Organization and execution of training workshops**

TBRI has been responsible for organizing four training workshops:

THEBERA first training “How to increase TBRI participation in the 7th Framework Programme (FP7)”, 19-21 July 2011, Egypt

The training focused on FP7 health and people programmes funding opportunities and how to prepare competitive proposals. TBRI researchers presented topics relevant to FP7 2012 Health call. Additional distant e-presentations from UNIPi discussing transplantation organizational issues, brain death, donor network and liver transplantation techniques were discussed. The participants also participated in interactive exercises on how to use CORDIS website to find partners for consortium building, proposal writing and budget building in FP7 as well by practical quiz, testing their knowledge on FP7.

It was attended by 34 TBRI researchers.

THEBERA second training “Ethics - Intellectual Property Rights (IPR) - FP7 Programme”, 1-3 July 2012, Egypt

The training focused on the basic principles of ethics in medical research and the process of ethics review in international cooperation. The basics of IPR in different EU programs, IPR strategies and application for patents were presented.. The Egyptian patent system was reviewed and a success story for a patented new tool from a TBRI staff member was mentioned. A feedback on the brokerage event, held in Brussels on 30th May 2012, attended by THBERA coordinator, was presented. The FP7 programme with its funding schemes and rules of participation, future calls under people programme were also highlighted. The participants practiced exercises on ethics review process, IPR patent system, application procedure for patent, how to write a concept note with impact value for IRSES programme, and exercises on ethics individual report forms (IRFs) and ethics review reports (ERRs).

It was attended by 30 TBRI researchers.

THEBERA third training “European Opportunities for Collaborative Research, Project Management and Intellectual Property Rights “, 25-27 February 2013, Egypt

The training focused on future European opportunities for collaborative research (HORIZON 2020 and ERAfrica call), project management, research communication, dissemination and evaluation, IPR issues in FP7 and H2020 and protection of research results. Practical exercises comprised working groups for writing concept notes on collaborative research or building capacity topics for submission to the ERAfrica call.

It was attended by 32 TBRI researchers.

#### THEBERA fourth training "HORIZON 2020: Key elements", 10-11 February 2014, Egypt

The training focused on H2020 keys elements: programme structure and its differences from FP7, the calls for proposals under Health societal challenge and Marie SKŁODOWSKA-CURIE Actions and the legal and financial aspects. The participants practiced exercises in four working groups on drafting proposals focusing on the health collaborative projects and RISE programme. The proposals were evaluated by the trainers from EFB. In addition, the evaluation report of a previously submitted proposal by a TBRI researcher under the IRSES call 2013 was analyzed.

It was attended by 29 participants (20 from TBRI and 9 affiliated to different Egyptian, MPC, Associated Countries entities (Cairo University (EG), Suez Canal University (EG) Children Cancer Hospital in Cairo (EG), Istanbul University (TR) and Jordan SMES (JO)).

The trainers of the 4 training were mainly EFB in cooperation with ASRT and the support of UNIPi in specific presentations.

All the details of this task are presented in Deliverable 3.1

### **T3.2 Workshops building consortium**

ASRT was responsible for this task and performed the following activities:

Awareness, support and assistance to TBRI researchers during the different phases of the proposals preparation and submission.

ASRT, being also the PEOPLE and HEALTH NCP in Egypt built upon the results of the coaching sessions (virtual and one to one sessions) to actively support TBRI researchers to build consortia. The following were the sub activities undertaken:

Awareness: Dissemination of the opportunities that could be of interest of TBRI researchers by e-mail and on THEBERA website.

- Support and Assistance: ASRT encouraged to network and publish TBRI researchers ideas via the different websites - designed a guide for submission of proposals – disseminated 5 partner searches to the relevant network of NCPs - held 2 one to one assistance – met researchers via Skype conferences – answered questions from TBRI and their partners.

#### **Participation in brokerage events**

- Brokerage event, 30 May 2012, Brussels

A research profile of TBRI including the research points of interest was uploaded on the website of this brokerage event and was also distributed as hard copies during the event. In addition, 12 bilateral meetings were booked and attended by THEBERA coordinator.

The second brokerage event was the 1st Euro-Mediterranean Brokerage Event on Research and Innovation, 12-13 February 2014, Cairo at which TBRI researchers participated and had the opportunity to meet potential organizations and book meetings with selected researchers from research organizations and SMEs.

#### **Consortium building workshops**

- First consortium building event, 5 November 2012, Egypt

The consortium built under FP7 IRSES call by the TBRI researcher Dr. Eman El Ahwany, had several inquiries regarding the call. ASRT being also the NCP for People has invited the coordinator Dr. Aida Hajdarpasic (Bosnia and Herzegovina) and Dr. Eman to hold a meeting to clarify the different aspects of the call.

- Second consortium building event, 13 February 2014, Egypt

This event was a very practical event at which participants were classified into working groups according to their consortium and common interest and they were given the opportunity to discuss the challenges that faced them to submit their proposals under H2020 calls. A number of 3 moderators assisting the 3 groups in answering their inquiries were present: Yasmine Sabry (ASRT), Nicola Tucci (EFB) and Gamze Sart (Istanbul University).

A rapporteur for each group has been selected in order to present the outcomes of these fruitful discussions to the other groups, in view of the concrete results they have achieved and also the future steps to be taken.

The participation to this workshop went beyond THEBERA project expectations since not only 12 researchers from TBRI benefited from it but also one researcher from the AUC, another from Cairo University and a third representative from Jordan SMES. The two coordinators of the two consortia built (Dr. Iker Badiola from Spain and Dr. Otto Anderson from Norway) participated to the workshop. All the details of this task are presented in Deliverable 3.3.

### **T3.3 Coaching sessions**

EFB has been responsible for individual assistance and coaching, in one-to-one sessions to the TBRI researchers either to shape them for being attractive to competitive future project consortia or to be able to aggregate other partners around project ideas they could coordinate. The above activities entailed substantial cooperation with other complementary initiatives aimed at the creation of new consortia in the Health and Food programmes, People and Capacities (research infrastructure), TEMPUS and ENPI-CBC; that were more specifically devoted to support participation of TBRI researchers into FP7.

Researchers' inquiries have been answered within 48 hours in addition to providing them with the needed kits to efficiently prepare their research proposals.

During the last e-coaching session TBRI researchers had the possibility to deal with the new H2020 call for proposals.

Prior to coaching a great dissemination activity was performed by TBRI and EFB. The result of such efforts in dissemination has been reflected as an increase number of researchers who have been actually coached: it was possible to consistently overpass the number of 15 researchers originally foreseen, reaching a total number of 43 researchers affiliated to TBRI.

A total of 43 TBRI researchers have been coached during three training workshops held in Cairo on 16 July 2011, 3-4 July 2012 and 26-27 February 2013 and three e-coaching sessions held on 12 March 2012, 30 April 2012, and 14 November 2013.

The coaching sessions have been held at TBRI premises by two EU experts: Leonardo Piccinetti and Aneta Andrzejczyk. Coaching has been sustained till Month 40 of the project. Coaching continued in-between the virtual and physical coaching sessions as a technical helpdesk (coaching team) for answering and guiding researchers.

All the details of this task are presented in Deliverable 3.2

### **T3.4 Catalogue of projects' or research ideas**

The catalogue represented a tool to achieve the above mentioned objective. It included information on ten institutions representing different types of organizations in Europe having common interest with Theodor Bilharz Research Institute in terms of research activities.

All the details of this task are presented in Deliverable 3.4.

## Description of WP4 Results and Impact

**WP 4 title:** CAPACITY BUILDING FOR LIVER DISEASES RESEARCH

**Instrument:** COORDINATION AND SUPPORT ACTION

**WP leader:** UNIP

### Main Significant Scientific and Technological Results

WP4 main activities, namely the SWOT methodology conducted to analyze TBRI resources and the study visit held at Pisa University, aimed to update the coordinating institute researchers with the results of experimental research programmes carried out in liver research and to support the progress of TBRI as a leading competitive and multidisciplinary research centre for liver disease management in the Mediterranean region in order to transfer into clinical practice the achievements carried out in liver diseases research through;

➤ **Leveraging the institutional capabilities:**

In the context of THEBERA's contribution to capacity-building and restructuring processes of TBRI, a comprehensive **SWOT** (Strength/ Weakness/ Opportunities/ Threats) analysis methodology was conducted aiming to identify the gaps to fill, priorities including man power and infra-structure, the necessary competencies available and to leverage for the different research activities addressing liver disease problem.

This benchmarking exercise focused on assessing TBRI existing resources. The SWOT methodology was tailored towards the requirements of TBRI and the EU funded project. Two analytical factors were taken into account, namely; internal strengths and weakness under the control of TBRI and external opportunities and threats (not under the control of TBRI but ideally a comparative benchmarking with other Institutes/countries). Three dimensions have been decided for the analysis including man power, infrastructure/environment and organization. Each dimension has been divided into one or more topics (Table 4).

**Table (4):** Dimensions and Areas considered in the SWOT analysis

Dimension	Area
Organization	Operations
Man power	Human resources
Infrastructure/Environment	Infrastructures and technology Finance Innovations and marketing

**Table (5):** Indicators considered in the SWOT analysis

Areas	Dimensions		
	Man power	Infrastructure/environment	Organization
<b>Human resources</b>	<ul style="list-style-type: none"> <li>- Number of physicians/ researchers/ technicians/ nurses (p/r/t/n) (1)</li> <li>- Number of technicians/ nurses (2)</li> <li>- Number of early stage physicians/researchers (3)</li> <li>- Number of experienced physicians/researchers (4)</li> <li>- Personnel scientific background (5)</li> <li>- Personnel networking capacities (6)</li> <li>- Nurses and technicians level of training (10)</li> </ul>		<ul style="list-style-type: none"> <li>- Personnel commitment to continuing medical education (7)</li> <li>- Commitment to young personnel education (8)</li> <li>- TBRI commitment to its personnel continuing medical education (9)</li> </ul>
<b>Infrastructure and technology</b>		<ul style="list-style-type: none"> <li>- Technological level of clinical and research facilities(11)</li> <li>- Facilities and devices maintenance program(12)</li> <li>- Structural characteristics of TBRI facilities(14)</li> </ul>	<ul style="list-style-type: none"> <li>- Transparency in technological investments administration(13)</li> </ul>
<b>Finance</b>	<ul style="list-style-type: none"> <li>- Personnel salaries(15)</li> </ul>		<ul style="list-style-type: none"> <li>- Capacity to attract financial support(16)</li> <li>- Financial administration transparency (17)</li> </ul>
<b>Innovation and Marketing</b>	<ul style="list-style-type: none"> <li>- Scientific production (18)</li> <li>- International cooperation(19)</li> <li>- National cooperation (20)</li> </ul>		<ul style="list-style-type: none"> <li>- Administration commitment to innovation and personnel education (21)</li> <li>- Marketing plan (22)</li> </ul>
<b>Operations</b>			<ul style="list-style-type: none"> <li>- Administration strategic plan(23)</li> <li>- Inter-departments cooperation and coordination (24)</li> <li>- Bioethics and public relationships (25)</li> <li>- Risk management organization (26)</li> </ul>

The skills and competence toolbox developed out of the SWOT analysis involved 32 recommendations targeting the fields of man power, infrastructure and organization. The analysis revealed as well salient elements of strength and weakness, promising opportunities and threats to be considered (Table 6).

**Table (6):** SWOT Results Overview

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Sufficient number of researchers and physicians</li> <li>• Shared focus on liver diseases</li> <li>• Language skills and internationalization of staff</li> <li>• Engaged and self-governing management</li> <li>• Good team spirit</li> <li>• Responsibility towards young staff training</li> <li>• High publication output</li> <li>• High number of scientific projects</li> </ul>	<p><b>Weakness</b></p> <ul style="list-style-type: none"> <li>• No clear mission and strategy</li> <li>• No industrial support and connections</li> <li>• Low performing support staff</li> <li>• No systematic training organization and assessment</li> <li>• Low number of participations in international mobility and training networks</li> <li>• Not sufficiently equipped research lab</li> <li>• Not sufficiently equipped hospital</li> <li>• Lack of a maintenance program for TBRI technologies</li> <li>• Still limited management capacities</li> <li>• No commercialization culture for research and development</li> <li>• Lack of a marketing strategy</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• Increasing future demand for health care assistance in Egypt</li> <li>• Possibility of enlarging action space through European community</li> <li>• Possibility of enlarging action space through globalization opportunity</li> <li>• Good reputation</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Unstable political environment</li> <li>• Continuous low demand for innovation support from industries</li> <li>• Danger of technological decline in the next future without financial support</li> <li>• Absence of capital market for research and development</li> </ul>

To achieve sustainable capacity building as a priority for future buildup of a competence health care research institute in the field of liver diseases, recommendations were meant to guide the development of a business plan gathering the required critical mass (political, scientific, industrial, social) to select investment priorities, sacrifice non-strategic areas of research, promote national and international connections and industrial innovations, update diagnostics and research devices technologies and clinical management processes at European levels, implement fundraising activities, organize and properly assess training activities for young researchers, physicians, nursing and technicians.

### ➤ Publication as Significant Result/Outcome

**Article:** Understanding the needs for the establishment of competence research centres and capacity building in Southern Mediterranean medical Institutions for Liver research/management: a SWOT analysis based approach  
**Authors:** Ghinolfi D, El Baz HG, Borgonovi E, Radwan A, Laurence O, Sayed HA, Simone PD, Abdelwadoud M, Stefani A, Botros SS, Filippini F. (Under review in Arab Journal of Gastroenterology).

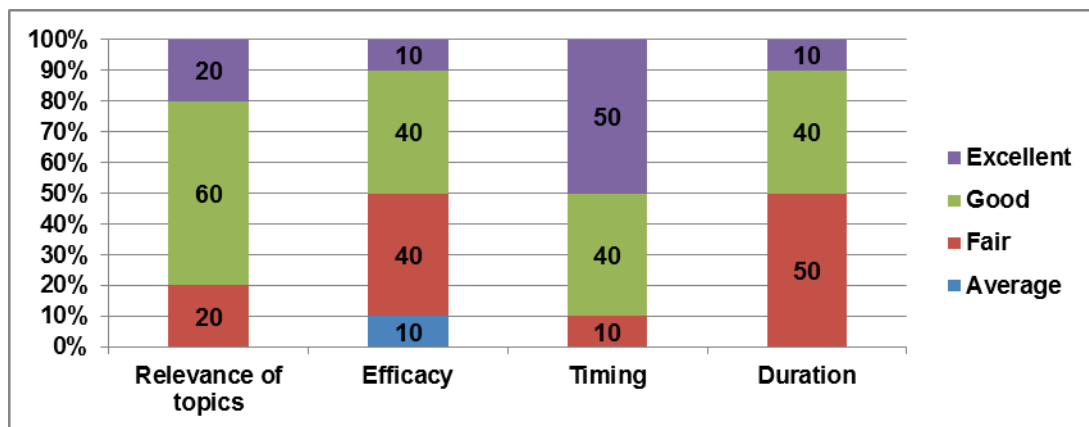
### ➤ Sharing experiences

Strengthening international cooperation of local health research actors was targeted by the study visit to respective EU research center (Pisa University) to achieve the utmost goals of the visit, special attention was dedicated to a fully exposition to research and clinical application facilities with an integration in an hands on activities at the Departments of Liver Transplantation, Hepatology and Infectious Disease at the University of Pisa.

The overall evaluation of the study visit based on the feedback reports of participants (Fig 3A, B &C) revealed points of strength including excellent schedule timing, friendly atmosphere, acquaintance with highly advanced infrastructure and last generation high-Tech of the Departments involved in Liver diseases and Transplantation with suggestions for stronger relation between the candidate and the tutor, planning of schedule following area of expertise interest to target the industrialization contacts and building of a MoU. The weak points were the short duration, heavy schedule and short time dedicated to floor experience

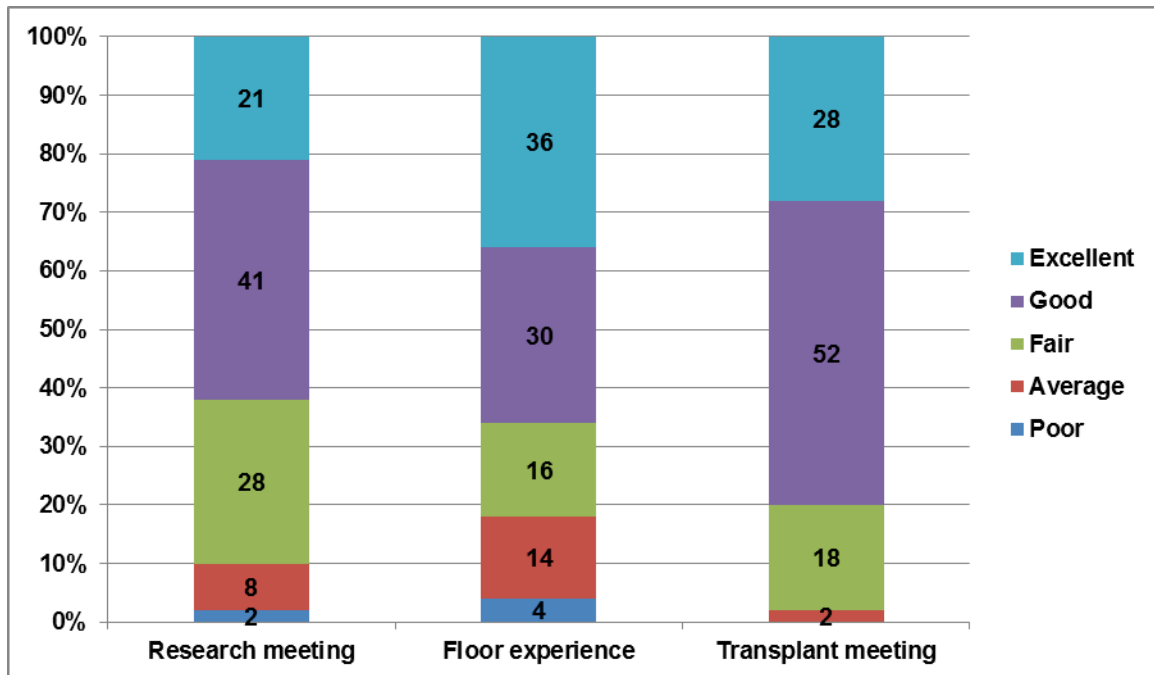
**Fig (3):** Overall evaluation of the participants for the study visit

**A**

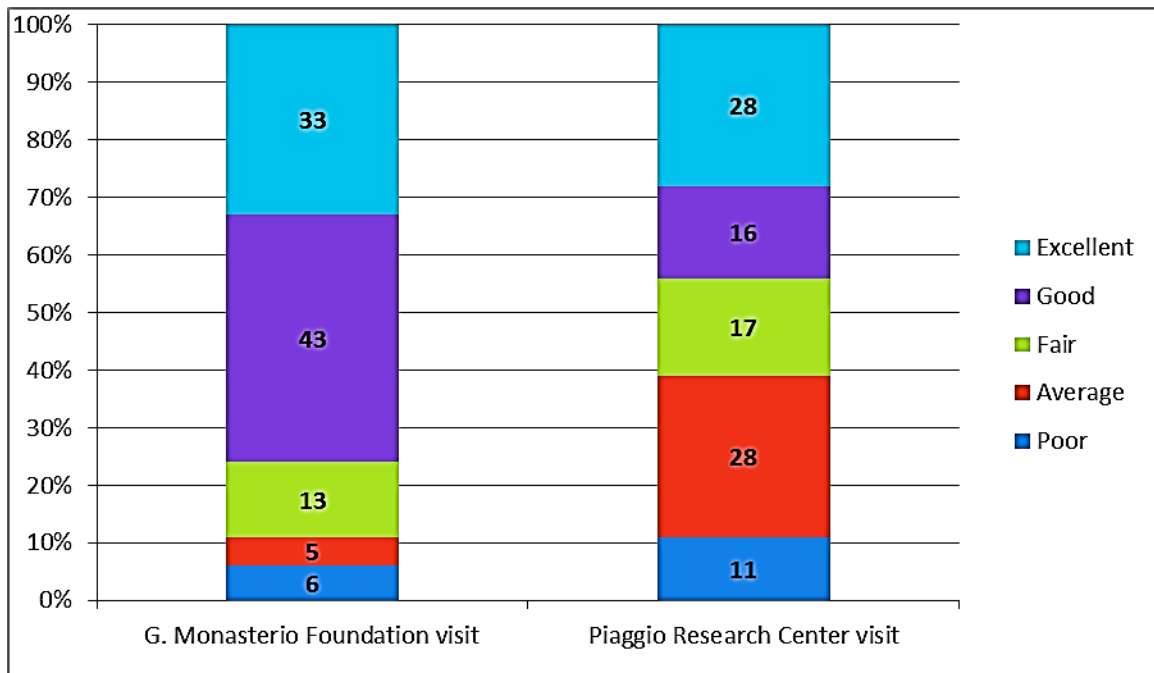




**B**



**C**



The feedback report on the study visit helped throwing light on targets, needs and future steps to be considered in the detailed strategic action plan consistent with TBRI long-term vision.

## **WP4 Results per Task**

### **T4.1 SWOT Analysis**

This task was led by UNIPI in collaboration with TBRI.

A comprehensive SWOT (Strength/ Weakness/ Opportunities/ Threats) analysis methodology was conducted based upon 3 main dimensions of Man power, Infrastructure/ Environment and Organization, as well as investigation of TBRI internal information with respect to human resources, finance, technology and administration. A preliminary brainstorming was performed among the actors for the selection of the dimensions to be investigated in the internal analysis. Indicators were analyzed with multiple questions through the distribution of a semi-quantitative or qualitative multi-answer template questionnaires. Templates were completed by 48 out of 54 participants selected among TBRI staff for the study, including medical/nursing (43) and managerial staff (11). Templates were filled according to participants' expertise, knowledge and involvement in TBRI activities. The information collected through the templates were crosschecked with specific information about TBRI human, financial, technological and administrative resources obtained from TBRI administration.

*Details of the task were presented in Deliverable 4.1 "Skills and Competences' Tool Box"*

### **T4.2 Study visit**

UNIPI has been responsible for organizing the study visit to Pisa University which was held during the period 14-17 November 2011.

The activities of the visit were tailored towards the needs and expectations of TBRI delegates. Eleven medical doctors participated in the study, representing different areas of expertise; surgery, hepatology, anesthesia, surgical ICU, radiology, pathology, immunology, microbiology, pharmacology and administration.

The schedule of the visit was focused on the following research topics: diagnosis of liver disease, timing of referral for liver transplantation and/or surgery, non-invasive liver disease staging (serology, transient elastography, radiology), serum prognostic factors of liver disease, with special focus to virus-related chronic diseases, histology of chronic and/or acute liver disease, immunosuppressive, strategies for liver transplant patients, with special focus onto novel therapeutics, post-surgical/post-transplant complications diagnosis, post-surgical/post-transplant complications management, diagnosis and management of recurrent native disease, with special focus on HCV, timing and indications to re-transplantation and expansion of Milan criteria as indication for OLT. A full integration in UNIPI activities has been achieved in areas of transplant management, coordination activities (transplant, hepato-biliary surgery, interventional radiology, imaging, pharmacology, and infectious diseases), surgical sessions and multidisciplinary meetings, round tables and clinical discussions on relevant cases. Invited speakers gave lectures on topics of special interest such as immunosuppression, transplant management, research activities and liver disease diagnosis. UNIPI has facilitated and settled up visits to other research centers e.g. National Research center- G. Monasterio Foundation visit which gave an overview of collaboration between the University Hospital and research societies, and visit to E. Piaggio Research Center where special attention was dedicated to tissue engineering and bioreactors and discussions on models to reproduce organ functions or characteristics to test drugs.

Meeting with Industries was designed at the end of the visit to provide a first contact with several local and international industries active in the field of transplant medicine which was considered a start point for addressing industrialization.

*Details of the task were presented in Deliverable 4.2 “Report-Feedback from the research visits”*

#### **Task 4.3: Developing synergy with EU centers**

Organization of strategic study visits to synergize with EU centers in view of TBRI needs aimed to empower the business plan developed under Workpackage 5, the study visits to well recognized EU centre were planned towards exchanging best practices and contacts with EU researchers for further enhancing the Euro-Mediterranean collaboration

The approach to synergize with EU centers included planning of visits to EU centers to initiate clusters, make agreements or MoUs. Synergy with EU institutions was initiated by TBRI, Suggestions for synergy addressed Tuscany Region aiming at continuation of cooperation between the Egyptian & Italian sides through educational programs and also contacting BIOCAT & Barcelona Center for International Health Research, CRESIB yet we were not successful to get a response from the European side to date.

Currently, EFB in collaboration with TBRI has successfully initiated fruitful communication with Istanbul University; an agreement MoU with Istanbul University is underway.

## Description of WP5 Results and Impact

**WP5 title:** DEVELOPING THEBERA RESEARCH STRATEGY

**Instrument:** Coordination and Support Action

**WP leader:** UNIPi

### WP 5 Significant Scientific and Technological Results

This work package aimed to achieve TBRI long term vision to become an excellence reference Centre for liver disease research and management. To fulfill the goal a strategic action plan (SAP) was developed based on mapping the landscape of the National State of the Art on liver disease, SWOT analysis of the coordinating Institute (TBRI) defining liver disease gaps, priority needs and feedback from study visits to well-developed EU Institutes.

➤ **THEBERA SAP targeted three main pillars:**

**The first pillar** focused on optimizing the research governance. The Institute advisory board was planned to foster and support the long and short term objectives of the plan, where selection of the members of the advisory board are chosen by democratic election with presentation of a defined program that includes the center development activities, identification of new funding opportunities, specific ways to proceed with partnering chances, supporting communication between the centre, governmental bodies and industry. Membership of the board lapses is limited for 3 years and a member is elected for two lapses only, allocated chairs in the advisory board are planned for representatives from the academia, the government and industry to provide advice to the centre's executive board with respect to strategy, management policy developing activities and funding opportunities.

**The second pillar** aimed at continuous capacity leverage of the employees at different levels starting from the professional medical staff passing by paramedical staff (nurses and technicians), and administrators. Employees' category is targeted by tailored programs in the form of form a regular training (classrooms), self-study as e-learning, ICT, training courses besides targeting specific topics. It was planned to include also the basics of administration and finance with application of individual development plans. Mobility programs to health care professionals in countries with high standard in research and clinical management, international staff exchange programs and standardized continuous medical education are also planned.

**The Third pillar** addressed the unmet health needs on liver fibrosis by fostering strategic innovative bi-translational research for better prevention and management to the most morbid consequence of chronic liver disease; liver fibrosis. This bi-translational research is organized around three schemes, research and coordination, research infrastructure and applied basic research projects. Table (...) shows the planned portfolio of projects, the scheme under which the project will be implemented, the targeted topics which almost represents, the under investigated research areas, also the expected supporting/funding agency to target.

**Table (7):** Operational model and budgetary needs, for future research projects. The budget represents 52% of total budget

Scheme	Quantification: Number and Scale of Projects	Targeted Topics	Supporting and/or funding Agency.
Research Coordination and Support	Three small scale projects	<ul style="list-style-type: none"> <li>- HCV Supporting networks</li> <li>- Civil Society Hepatitis initiatives</li> <li>- Joining and consolidating with MoH Initiatives</li> </ul>	<ul style="list-style-type: none"> <li>- European Programs</li> <li>- United Nations' Programs</li> <li>- USAID</li> <li>- Civil Society</li> </ul>
Research Infrastructure	Two Large Scale Projects	<ul style="list-style-type: none"> <li>- Upgrading specific lab</li> <li>- Meeting an emergent need for establishing new lab</li> </ul>	<ul style="list-style-type: none"> <li>- Ministry of Scientific Research</li> <li>- Civil Societies</li> <li>- Pharmaceutical Industry</li> </ul>

**Table (8):** Operational model and budgetary needs, for future research projects. The budget represents 52% of total budget (continued)

<b>Scheme</b>	<b>Quantification: Number and Scale of Projects</b>	<b>Targeted Topics</b>	<b>Supporting and/or funding Agency.</b>
Applied Research Projects	Fifteen national projects Five International Projects	<ul style="list-style-type: none"> <li>- Testing of anti HCV new agents targeting genotype 4</li> <li>- Research on HCC</li> <li>- Prevention of HCV e.g. vaccination</li> <li>- Proteomic changes in liver in conjunction</li> <li>- Stem Cell therapy protocol</li> <li>- Noninvasive candidate markers</li> </ul>	<ul style="list-style-type: none"> <li>- European Programs</li> <li>- National Programs (STDF,.etc.)</li> <li>- Civil society and private donations</li> </ul>
Basic Research Projects	Three to five research projects	<ul style="list-style-type: none"> <li>- Pathogenesis of liver injury in CVH</li> <li>- Cell-based assay for validation of candidate antiviral</li> <li>- Immunological responses contributing to severity of extra-hepatic manifestations hepatocarcinogenesis in relation to HCV.</li> </ul>	<ul style="list-style-type: none"> <li>- European Programs</li> <li>- National Programs (STDF,.etc.)</li> <li>- Civil society and private donations</li> </ul>

These activities are supported by brokerage efforts, research and development networks with ICT supports.

➤ **Establishment of an internationalization and industrialization units**

These units are planned as tools needed to support innovative research and to ensure its sustainability and international visibility.

**Internationalization unit**

It aims for enhanced participation in the most competitive research programs with international partnerships ensuring the delivery of high profile good structured project proposals and strengthening of TBRI existence in the international competitive research society. The unit plans to keep record track and reports on the ongoing research helping better coordination of local research. Also designs of strategic protocols with international partners, identifying and screening large grant opportunities, to provide assistance in designing projects and accesses expertise from other institutions. More focus in this plan is directed to international research programs to lessen the dependence on national funding.

**The industrialization unit**

Because the bargaining power of any research institute depends mainly on its contractual government style and effective mechanism of industry relation, this unit aims to support conducting research with close industry involvement that further develops research outputs and manages their application and adoption by industry, expanding knowledge transfer, guiding commercialization and increasing institute financial resources. For the first instance and as a role model for further development towards commercialization existing coordinating institute projects that currently contain a prominently industry- applied component (low hanging fruits) will be first supported administratively and technically by the unit.

### Setting up a strategy for research fundraising at international, national and private levels

Participation in the most competitive research programs is considered. The fundraising strategy included measures to ensure adequacy of selecting appropriate national and international research programs, industry engagement, and project costs estimation with precise calculation using full cost recovery approach and also with cost cutting exercises as contingency plan, continuous reviewing and monitoring for update and exit strategies to further fund projects and for project sustainability.

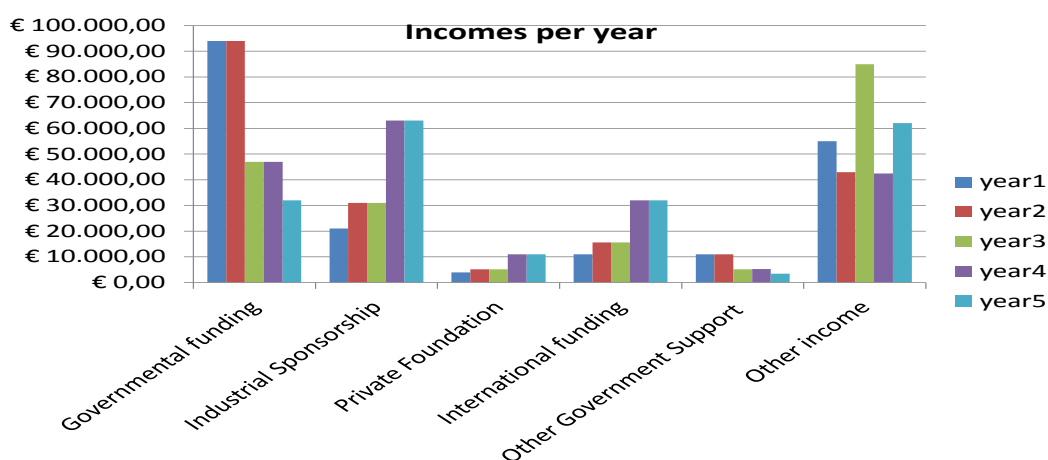
### Maintaining dialogue with policy makers and integration with international initiatives

Cooperation between scientific research and politics is fundamental; the establishment of the coordinating institute as a competence center in liver research is expected to impact Mediterranean, Middle East and African region politically. A dialogue to keep at the European level with Southern Mediterranean/North African countries is a main target. Considering liver research as a main priority at the EC-Egypt Science and Technology cooperation agreement in 2007, Egypt 2009 took a step forward where program level cooperation call targeting HCV was issued. Also both FP7 program and Science and Technology Development fund published similar calls targeting HCV.

### Budget plan

The SAP forecasted a five year budget which in the first two years will mainly be funded by the government and the institute with a gradual increase in the support from pharmaceutical companies and international agencies. (Figure 4)

**Figure (4):** Forecast of funding agencies profile over a period of five years



Financial self-support in the first two years of the forecasted budget is to help the newly established units to develop well and take their full role for fundraising and financial support by attracting pharmaceutical companies and international agencies to participate in the institute's research activities. The financial forecasting model applied in this strategic plan indicates a decrease in institutional funding, self-support, and government support gradually over the 5 years of the action plan with remarkable steady increase in the first 2 years. Soliciting financial support is planned mainly through pharmaceutical companies and research funding agencies.

Analysis showed that return of investment time will be realized on 2 years and 3 months which showing how long TBRI will take to recuperate its initial capital outlay on used assets.

### Validation of SAP by THEBERA independent experts

The SAP was validated by nominated experts with international reputation in liver disease. they were short listed out of 10 experts and using a scoring system set by UNIPi and TBRI. Two experts were European and the third was from an African country. THEBERA project independent experts were selected to evaluate and monitor the progress of the project, they were handled a hard copy of the SAP, analysis of National state of the art on liver disease and SWOT analysis of the coordinating institute one month before holding the expert validation working

session. A draft report was received and the salient suggested recommendations and comments were included in the final version of the SAP. Salient remarks were: setting an awareness program in relation to organ donation and transplantation, effective teaching especially electronic modes of teaching, screening and early diagnosis of liver diseases especially HCC. The report delivered by the experts including their comments and remarks were considered in the final version of the SAP.

### **Raising awareness among local governmental bodies for international cooperation**

In the context of coordinating efforts across the Mediterranean and to fully engage governmental bodies with activities related to TBRI and Egyptian participation in EU programs, a one day stake holder meeting was held in Cairo on the 5th of December 2013 under the patronage of the Minister of scientific Research to raise the awareness of governmental bodies for international cooperation. The event promoted THEBREA main achievements and results, which included the foundation of strategic action plan of Theodor Bilharz Research Institute for the next 5 years, national study analyzing the current status of liver disease management in Egypt in addition to TBRI SWOT analysis and visualization of the main competencies and weaknesses of liver disease research at the national level. Also, the local impact of THEBREA capacity building program and the possible mechanisms of synergy at the national level were discussed. The event embraced elite of dignitaries and eminent figures not only from academia but also, policy makers, representatives from NGOs, media and European commission. Priority needs and future guidelines for liver research in Egypt and the EC role in international cooperation were presented and discussed. The uncoordinated efforts at national level, networking at national and European levels, research priorities, capacity building and awareness raising and governance structures managing liver disease were the main subject of discussions. The Egyptian and European common points of interest and existing challenges were emphasized for further encouragement of Europe-Egypt collaboration in health research. The panel discussions, recommendations and comments were articulated and submitted to liver international journal to be published as a “letter to the editor”.

### **➤ Results per task**

#### **Task 5.1: Strategic action plan**

The detailed strategic action plan organized was consistent with the TBRI long-term vision: to become an excellence and reference centre for liver disease research/management not only in Egypt but also for neighboring countries and for the Mediterranean area in general. The plan was built upon the analysis carried out in WP2 involving several versions of the analysis of National Liver Disease State of the Art, gaps and priority needs, the coordinating institute SWOT analysis and the feedback from visit to EU research institutions. The strategic action plan was planned to include an industrialization plan to help valorization of research results. At the institutional level, the plan targeted one of the most banging impactful problems of liver disease in Egypt “hepatic fibrosis” and its complications including liver surgery excellence where available capacities allow for high profile research work for better prevention and disease management to bring under control the major toll of liver disease on human health. Other activities included: assessment of the potential demand in the reference area and the potential funds investment in the next 3-5 years; detailed evaluation of the effort in terms of internal resources and related costs. TBRI potentials were planned to be assessed in terms of experience, expertise and facilities, including the capacity of designing, developing and managing transnational projects. The industrialization plan was planned to communicate to stakeholders, to help establishing the concept of sustainable R& D activities. It is prepared in view of promising coordinating institute innovative maneuvers, tools or health products. The plan included a template with essential information for any of these innovations, the necessary documents that should be available to support the suggested innovation and a road map on how to proceed for proper linking to industry.

Details of the task are included in D5.1

#### **Task 5.2: Identification and briefing external experts**

This task involved selection of internationally recognized experts in liver research. Selection criteria are set out to ensure that the selected experts have relevant technical competence, integrity and neutrality. It also ensures conduction of a fair and independent assessment by the experts. . Qualification criteria for selection of the experts are based on competence, training, qualifications and experience. Evidence of appropriate training was requested.

Details of the task are included in D5.2

### **Task 5.3: Working Session of External Experts**

After selection of the external experts, TBRI presented to experts the analysis of the national state of the art, the SWOT analysis of the coordinating institute and also the THEBERA SAP one month before the expert validation session to brief them with the landscape analysis for the current national situation regarding liver disease and to present TBRI vision for the coming five years. A draft report was prepared by external experts and discussed during the interactive working session held in Brussels in June 2013 and was attended by THEBERA experts and consortium. Experts raised several comments regarding all documents developed out of THEBERA. The experts' remarks helped to contribute to an updated versions of both THEBERA SAP.

Details of the task are included in D5.3 and D5.4

### **T5.4 Raising awareness among local governmental bodies for international Cooperation**

This task dealt with the need to fully involve governmental bodies with activities related to TBRI and Egyptian participation in the framework program. In particular this task tackled the issue of uncoordinated efforts by local governments and entities to which contacts with the EC are mandated. The idea is to raise awareness among government representatives about the role that EC funded research can play in their own countries and encourage them to share experiences and exchange successful practices.



## Description of WP6 Results and Impact

**WP6 title:** NETWORK FACILITATION AND DISSEMINATION

**Instrument:** Coordination and Support Action

**WP leader:** ASRT

### Main Significant Scientific and Technological Results

The results of the activities performed in WP6 represented an important impact on the visibility of THEBERA project, TBRI institute and the liver research in Egypt. The outcomes were as follows:

- THEBERA project succeeded in gathering the eminent national liver disease stakeholders involving policy makers, liver disease experts, NGOs, media representatives and all TBRI managing staff to set and deliver the priority needs and future guidelines for liver research in Egypt to provide timely input into future European-Egyptian collaboration; considering the European Commission (EC) role played and might still play in the further support of Southern Mediterranean countries. The role of THEBERA and TBRI in this important achievement has been well recognised at THEBERA closing conference.
- TBRI has been connected with the EU/Egypt health initiatives and the EU funded projects: (MEDSPRING – ShERACA – MIRA - EU- Egypt year of Science and Innovation 2012 - Health ERAWIDE projects cluster - National Network for Liver).
- The information on TBRI's health research and its achievements in liver research has been demonstrated and disseminated all over the world via the different communication channels: conferences, internet (website – online database - YouTube – online registrations), press releases, TV programme, and promotional material.
- The visibility and public awareness of THEBERA project progress and results to scientific organizations and researcher actors in health sector within EU have been maximized, not only via a total number of THEBERA website visitors exceeding 88332 but also via the different communication channels.

The contacts and relationships between TBRI researchers and their European counterparts have been facilitated. Description of significant results per task

### **T 6.1 Development of dissemination infrastructure and materials for dissemination of information**

ASRT was responsible for this task and developed a methodology for dissemination via different communications tools as follows:

#### ➤ **THEBERA website**

The initiated THEBERA website [www.thebera.eg.net](http://www.thebera.eg.net) was the main tool for THEBERA project dissemination. THEBERA website has been designed and structured to achieve the objectives of THEBERA project: it maximized the visibility and public awareness of the project objectives, activities and outcomes and provided information on TBRI's health research and its achievements.

THEBERA website has been developed by ASRT and the content of the website has been provided mainly by TBRI.

THEBERA project's partners, objectives, activities and deliverables have been published online: the material of the trainings workshops, press releases, THEBERA events, useful links, liver research articles, TBRI videos, dissemination activities, information about health research and FP7 calls for proposals have been provided by TBRI and uploaded by ASRT.

News and events were continuously updated during the lifetime of the project by TBRI in cooperation with the ASRT e.g.: the events of the Egyptian Society of Surgeons and Society of Paediatric Gastroenterology, Hepatology and Nutrition and the news about the European Association for the Study of the Liver "EASL", the

leading professional organization for clinical and scientific hepatologists in Europe - news about FP7 Health partnering event organized by "Fit for Health" and "Health-NCP-Net" ... etc.

Monitoring of the website was performed by TBRI during the whole projects period.

An important section on THEBERA website was dedicated to the database of competitive liver research actors in Egypt. The creation of a database of competitive liver research actors in Egypt constituted one of the main components of the project website. THEBERA's health research actors' database fulfilling the criteria of data integrated and data quality validated has been accomplished in a simple form. Access to information related to 110 liver research actors was available on THEBERA website through search technique. Sorting could be done using any item of liver research actor's profile. Collection of preliminary data from researchers to be inserted in the database was done via:

- Request e-mails to researchers
- A hard copy form has been created for data collection from the attendees of the Annual Scientific Meeting of Theodor Bilharz Research Institute.
- Direct registration on the website
- Internet

The database of liver research actors was designed by ASRT and fed by TBRI:  
[http://www.thebera.eg.net/index.php?option=com\\_wrapper&view=wrapper&Itemid=341](http://www.thebera.eg.net/index.php?option=com_wrapper&view=wrapper&Itemid=341)

#### ➤ **THEBERA presentations**

THEBERA partners have created presentations about THEBERA workpackages at the beginning of the project. These presentations have been updated and customized according to the date and target audience of the conferences attended by THEBERA representatives.

All the details of this task are presented in Deliverables 6.1, 6.2 and 6.6.

### **T6.2 Development of showcase brochures and video**

ASRT was the responsible of this task.

#### ➤ **THEBERA brochures**

##### **THEBERA first brochure**

The first brochure focused on the description of THEBERA project and TBRI institute as THEBERA coordinating institute. The following were presented:

- THEBERA project: (Objectives - Work packages description - Contact information)
- TBRI institution: (Mission – Vision)

##### **THEBERA second brochure**

The second brochure focused on the presentation of 33 research profiles of TBRI researchers, highlighting their research activities and strategies.

##### **THEBERA third brochure**

The third brochure focused on highlighting the most proactive liver research centres as well as the contact details of 10 universities working in the same field of research in Egypt.

##### **Dissemination**

The brochures were designed by ASRT and printed by TBRI and used for dissemination at the different events as follows:

- First brochure: 400 copies were printed
- Second brochure: 90 copies were printed
- Third brochure: 5 copies were printed

The brochures have been uploaded on THEBERA website.

#### ➤ **THEBERA interview**

Recorded interview with Professor Moataz Hassan the former president of Theodor Bilharz Research Institute concerning the international cooperation of the institute with other counterparts, has been produced by ASRT in cooperation with TBRI and was uploaded on THEBERA website homepage to increase the visibility of TBRI and open new prospects of cooperation.

➤ **THEBERA Videos**

**THEBERA first video**

The first video focused on presenting TBRI, the coordinating institute, in order to clarify its vision, mission and potential in health research, including its infrastructure and human capital to further market the institute.

**THEBERA second video**

The second video focused on the multidisciplinary objectives of THEBERA project which targeted the policymakers, stakeholders, liver researchers, the local community and the industry.

This video highlighted the impact of THEBERA project as follows:

- The results of reviewing and analysing the state of art regarding liver diseases and engagement of policy makers and stakeholders to work on a tailored strategy.
- TBRI's horizontal capacity building and the participation in FP7 and related programs
- Networking and creation of links between TBRI's researchers and their European counterparts
- Raising patient awareness to liver health problems
- The development of 5 years strategic action plan to establish Theodor Bilharz Research Institute as a competence center in liver research.
- The final video has been produced by Vision Films Company of Spain and posted to THEBERA website by the end of December 2013.

**Dissemination**

The videos have been uploaded on the website and used for dissemination at the different events.

All the details of this task are presented in Deliverable 6.3.

**T6.3 Networking activities and contacts with other relevant EU initiatives**

ASRT was the responsible of this task.

**Networking visits in Europe**

Eleven visits in Europe have been performed by TBRI researchers. Several activities have been undertaken:

- Presentation of THEBERA project's objectives, activities and outcomes.
- Presentation of the competitiveness of TBRI to participate in the European research funding opportunities.
- Distribution of TBRI liver research actors' brochure and THEBERA project brochure.
- Meeting EU researchers in the same fields of interest in view of opening new channels of research cooperation.
- Presentation of research posters.

**Networking activities with European projects/initiatives**

Six networking activities with other European projects and initiatives (MEDSPRING – ShERACA – MIRA - EU-Egypt year of Science and Innovation 2012 - Health ERAWIDE projects cluster - National Network for Liver).

**Press release and media**

Four press releases on THEBERA have been published at "Il Corriere della Sera" main Italian newspaper and ALAHRAM Egyptian governmental newspaper as well as a speech on THEBERA project was diffused at the Nile TV Egyptian Channel.

All the details of this task are presented in Deliverable 6.4

#### **T6.4 Final conference**

TBRI was the responsible of this task.

**The THEBERA Closing Event “*Priority Needs and Future Guidelines for Liver Research in Egypt and the EC role in International Cooperation*”, 05 December 2013, Egypt**

The final conference aimed at promoting the existing knowledge gained from ERAWIDE projects” THEBERA Project” and experiences of the consortium in dealing with strengthening the capacity of TBRI Excellence for better participation in European research initiatives by expanding cooperation and integration with the ERA while realizing it as a well-recognized center for liver disease research.

Additionally, the event presented THEBERA project analysis of the national liver disease state of the art with regard to the liver research capacity, main known policies and programs, funding needs and offers, current cooperation patterns and relevant actors in liver disease research. Besides, the closing event provided the participants with the final results of TBRI SWOT analysis and the integrated Strategic Action Plan (SAP) which included an industrialization plan to establish units that would help valorisation of research results.

This event tackled local challenges and the issue of uncoordinated efforts at the national level, more specifically it addressed liver research governance, networking at national and European levels, research priorities, capacity building and awareness raising. Another important objective was to highlight common points of interest and existing challenges, enabling possible mechanisms to invest in ERAWIDES outputs and to encourage Europe-Egypt collaboration in Health research in addition to exploring how different instruments under Horizon 2020 can enable an effective collaborative response to different challenges. In the context of the already established ERAWIDES, this event promoted tools to build new partnerships.

The meeting comprised researchers, officials and experts, government, academia and European Commission representatives. It contributed in defining solutions, set of recommendations and scenarios of effective management of liver disease.

All the details of this task are presented in Deliverable 6.5.