STDF Grants

Towards Development of National Pharmaceuticals Industries

Science and Technology Development Fund

www.stdf.org.eg

Call for Proposals

TARGETED CALL
I. Introduction

The Science and Technology Development Fund (STDF) was established by Presidential decree number 218/2007. Its mandate is to promote science and technology (S&T) through funding scientific research and technological development in a way that supports the complete cycle of innovation. STDF's specific objectives are to improve Egypt's research and development (R&D) environment, to fund S&T activities and to develop the innovation capacity in Egypt. STDF implements its objectives within the context of the national S&T development strategy. Since its establishment, STDF has disbursed tens of millions of pounds to researchers in universities and research institutions to improve the research and development capacity in these institutions. This targeted call is one of STDF series of targeted calls aiming at development and support of some national strategic industries such as pharmaceuticals, textiles and metallurgical.

The Egyptian pharmaceutical industry is the largest producer and consumer of pharmaceuticals in the Middle East and North Africa (MENA) region, where it provides 30% of the supply (Alexandria Bank-Economic Research Division, November 2010, Pharmaceutical Industry in Egypt). The growth of this sector is expected to continue at a rate of 11% through 2015 (Oxford Business Group, April 19, 2012, Egypt: Regulating pharmaceuticals production). According to the Ministry of Health, turnover from local consumption is expected to reach $7.8bn by 2015, and the government also hopes for exports to reach $1bn by that same year. By comparison, turnover from local consumption stood at $2.5bn in 2010 (Oxford Business Group, April 19, 2012, Egypt: Regulating pharmaceuticals production).

Currently, the Egyptian pharmaceutical sector consists of about 120 licensed pharmaceutical factories, including few of foreign multinationals, with 60 new factories under registration and around 100,000 employees working in the sector (Oxford Business Group, April 19, 2012, Egypt: Regulating pharmaceuticals production). The domestic pharmaceutical industry depends on production of the generic drugs rather than R&D, where 92.5% of pharmaceuticals are produced locally and 7.5% imported in the final form. This ability of the Egyptian market to stabilize prices is limited because the industry imports about 85% of the raw materials. There are some factors affect the competition in this industry; as economic, social, and regulatory factors (N. Al-Ali, 2002, The Egyptian Pharmaceutical Industry After TRIPS - A Practitioner’s View. Fordham International Law Journal, Volume 26, Issue 2, Article 4).
Egypt ranks 11th out of the 30 regional markets surveyed in one of the latest Pharmaceutical Risk/Reward Ratings (RRRs) for the Middle East and Africa (MEA). Egypt’s risks score remains below the regional average, in contrast to its more favorable rewards component. Globally, Egypt remains 56th out of 95 markets, between Kazakhstan above it and Morocco below (Espicom Business Intelligence-2010, April 22-The Pharmaceutical Market: Egypt-Opportunities and Challenges).

Pharma R&D environment is getting harsher, as more endemic diseases prevails, qualitatively and quantitatively, e.g. Cancer, HCV, Obesity, Diabetes and High Blood Pressure. The needs for innovative medicines to treat such ailments, and in particular those ones that International Pharma, have little interest and incentive to pursue. Such new therapies have to be clinically and economically better than the existing alternatives, together with hard, real-world outcomes data to back any claims about a medicine’s superiority.

The most novel and successful paradigm that adopted recently by Academia and International Industries is the Disruptive Innovation. It typically happens in industries that are broken (too expensive or inefficient), when assets and technologies (many of which are already in existence) are combined in new configuration (although they are at multiple sites) to deliver values more efficiently. And according to STDF records, funded research and capacities building projects and STDF initiative for center of scientific excellences, many of these technologies exist in today’s academia and research institutions. It is designed for drug development innovative thinkers who are determined to reinvent drug discovery that delves deeply into the key strategic factors impending discovery productivity and connects multi disciplines that can share current solutions, propose new solutions and commit to testing them and sharing the results.

STDF aims to and has the capacity to lead changes in R&D paradigm of Egypt. Such changes will require a monumental shift in thinking for conducting research. For examples:

- STDF have to be more selective about the diseases that to fund the research for cure of them.
- STDF foster the approach that every research center has to establish intra- and enter collaboration, with academia and other research organizations for more efficient involvement of talent and equipment utilization and work toward a common goal.
- STDF focus is on the secrets of sustainable collaborations to embrace new R&D model with a competitive edge.
• STDF’s new strategy is to increase our focus in research by promoting Team-work Collaboration and fostering Innovation for a Sustainable Future.

The current program reflects STDF’s new paradigm and to build upon what has been achieved so far in a more focused and efficient manner, to maximize the benefits, and to better utilize and develop the available national research capabilities in certain priority areas, where Egyptian scientific schools have shown reputable scientific performance.

II. Grant Objectives

• Encourage Technology transfer (according to country needs) of novel drug targets or leads into commercial products in collaboration with international experts, especially, our Diaspora Experts.
• Assist Egyptian pharmaceutical industry in introducing new technology.
• Develop and introduce new technology plate form for the Production of potential pharmaceutical products.
• Collaboration between scientists from universities, research institutes and industry to transfer novel ideas from labs to the late-stage of drug development and production.
• Redirect research at Egyptian universities and research centers towards applied science according to industry and market needs.
• Provide researchers at Egyptian universities and research centers with practical experience with applied science.
• Benefit Egyptian pharmaceutical industry from the state of the art technologies and development for any component of drug industry at any phase.
• Development of Egyptian pharmaceutical technology for authentication of all drug products in harmony with international guidelines and with minimum added cost.
• Training and education in modern drug discovery techniques such as drug design, target validation, compound screening techniques, ADME (Absorption, Distribution, Metabolism, and Excretion) profiling (in vitro and in vivo).
III. Priority areas

1. Production of Pegylated α-interferon, and other therapeutic recombinant proteins and diagnostics (Pharmaceutical Biotechnology)
2. Extraction Technologies for Medicinal and Aromatic Plants
3. Advanced Pulmonary Delivery Systems
4. Local production of pharmaceutical raw materials (from natural or synthetic sources or patents in public domain)
5. Preclinical and clinical trials for promising drugs in pipeline
6. Development of biosensors
7. Products and delivery systems development
8. Discovery of novel pharmaceuticals to combat Hepatitis C, Cancer, Diabetes and others

IV. Eligibility Criteria

In order to be eligible for this grant, the following conditions should be met:

1. The PI must have valuable experience in the field of submission.
2. Any Egyptian citizen who is affiliated to an Egyptian institution may apply as a principal investigator (PI). For a non-Egyptian resident who is affiliated to an Egyptian institution, he/she may apply as a PI but the deputy-PI or co-PI must be an Egyptian citizen.
3. Adoption of new or improved production method, including methods of product packaging and delivery.
4. The projects should be novel, unique with prototype or pilot-scale demonstration.
5. Justifications for the need of each member of the research team must be provided. 
6. Industrial partner is a MUST for priority areas 1-7.
7. Industrial partner is requested to share with 10-20% of total budget; 10% for factories of Holding Company for Pharmaceutical Industries and 20% for other pharmaceutical companies. In kind support is accepted.
V. Proposal submittal process

All applications must be uploaded on the STDF website (www.stdf.org.eg) to which registration is required. The submittal will be a two-stage process, as follows:

The first stage: A pre-proposal is submitted (Please download the pre-proposal template by clicking the following link: Pre-proposal Template).

The second stage: The applicant principal investigators, whose pre-proposals are selected in the first stage, will be invited to present their full proposals.

VI. Evaluation Process

The evaluation process will be executed by independent experts and the STDF will assure that the process is transparent, impartial and researcher-supportive. Also, after full proposal submittal, the STDF officers may make field visits to assess the facility preparedness for the proposed research.

VII. Important dates

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Announcement of the call</td>
<td>16/4/2013</td>
</tr>
<tr>
<td>Deadline date for pre-proposal submittal</td>
<td>16/5/2013</td>
</tr>
<tr>
<td>Date of announcement of the accepted pre-proposals</td>
<td>30/5/2013</td>
</tr>
<tr>
<td>Deadline date for full proposal submittal</td>
<td>30/6/2013</td>
</tr>
<tr>
<td>Date of announcement of the accepted full proposals</td>
<td>15/7/2013</td>
</tr>
<tr>
<td>Date for grant contract agreement</td>
<td>01/8/2013</td>
</tr>
</tbody>
</table>

VIII. General Terms and Conditions

The following terms and conditions apply to the grant:

- All proposals will be evaluated on a competitive basis.
- The application must include a letter from the implementing institution’s legal representative stating the project title, the name, position and affiliation of the PI in charge of the proposal, that the project idea was not funded or submitted to
another agency (national or international), or otherwise declare, and that the institution approves the project. This letter must be signed and stamped by the institution.

- All proposals must be drafted using the exact formatting requirements for the current call given in the attached Application Form. Failure to adhere to the exact format required will automatically deem the proposal ineligible.
- All proposals must be uploaded to the STDF website (www.stdf.org.eg); proposals submitted by e-mail or sent as hard copies will not be considered.
- All proposals must be in English.
- The project team must not include any foreign researchers. However, foreign consultants may be allowed, given that the relevant security approval has been obtained.
- Equipment purchased using STDF funds must be made available to all Egyptian researchers.
- A separate bank account for the project should be opened and managed by the host institution.

IX. Ethical Rules

Applicants to STDF are expected to maintain a high level of scientific honesty and integrity in all aspects of their work. Applicants are expected to refrain from plagiarism, i.e. "the act of taking credit, or attempting to take credit, for the work of another" (quoted from the publication ethics policies for medical journals, at www.wame.org). Applicants are also expected to avoid self-plagiarism or multiple submission of the same content in more than one document. Multiple reporting of the same data or results in various projects is also considered self-plagiarism and is strongly discouraged. Fabrication of data or results, or suppression of unexpected results is not accepted by STDF. STDF expects all research activities involving human subjects to strictly follow the bio-ethical guidelines.

Breaching the rules of research integrity will result in halting all research funding activities to the involved parties for a suitable period of time after thorough investigation and judgment by a specialized STDF committee.

Applicants are also expected to adhere to the highest standards of integrity within the domains of bioethical, bio-safety and animal protection considerations. The following
regulations are to be adopted, whenever needed, based on the field or topic of the proposed research:

- **Bioethical considerations:**

  Projects dealing with human subjects are required to satisfy the STDF requirements of bioethical aspects, and to comply with any other relevant laws. Such projects may include, but are not limited to, experiments on human subjects, testing of new therapeutic, preventive or diagnostic agents, handling human personal information, etc.

  In such cases, it is mandatory that the PI presents an ethical approval form approved from the ethical committee or institutional review board (IRB), before finalization of the project contracting process. In the case of absence of an IRB in the PI’s institution, obtaining an ethical approval from a national, regional or collaborating body will be subject to consideration and assessment by the STDF.

- **Bio-safety considerations:**

  Projects with bio-safety aspects, such as those dealing with genetically modified organisms (GMOs), should strictly adhere to the national bio-safety policies, which may require obtaining special permits and clearances from the relevant authorities.

- **Animal protection considerations:**

  STDF strongly rejects the unnecessary exposure of animals to pain, distress or fatality during scientific experimentation. It is the responsibility of the PI and his/her institute that these principles are adhered to. In the case of unacceptable acts of cruelty against animals, the STDF has the right to immediately terminate/suspend the project activities, and to hold the PI accountable for such acts.

- **Obtaining permits from relevant authorities:**

  STDF has the experience that the processing of research proposals involving activities which require special permits from the relevant governmental (or otherwise) authorities may be delayed. In order to speed up the process of handling the applications, the applicants are encouraged to obtain such permits before submitting their applications, and to include them in the project proposal. The following are examples of activities requiring approval from the authorities:
• Conducting surveys
• Collecting data, or conducting any other research activities near the country’s international borders, in the sea or on land
• Sending genetic and biological resources outside the country
• Ethical issues related to research on living matter (bio-safety, conservation of biodiversity, research ethics, ... etc.),
• Involvement of or collaboration with foreign researchers in the research activities
• Dealing with historical objects
• Development of patents that may violate the intellectual property rights of other (existing) patent holders.

X. Negotiation and Contract Signing

Negotiation and signing of the project’s funding agreement will take place shortly after the announcement of the evaluation results.

Since the processing and evaluation of the submitted proposals entail significant expenditure of financial and human resources, it is highly discouraged for the PI to decline from continuation of the project after proposal submission. Requests asking for project discontinuation by the PI after proposal submission, following contract signing, or during the project life-time will be thoroughly investigated by STDF. STDF has the right to have financial compensation and/or to impose a ban period on the PI from participating in STDF-related activities.

Moreover, the PI should clearly state in the proposal which of the following options he/she prefers in the unlikely event of his/her inability to complete the project:

a) Discontinuation of the project; however, the PI should be aware that, if he/she chooses this option, all funds and expenses paid by STDF must be refunded to STDF upon termination of the project.

b) Transferring all the PI responsibilities and rights to the Co-PI (if any).

XI. Intellectual Property Rights (IPR)

The applicant and the endorsing institution(s) shall conform to the STDF-IPR regulations, detailed as a separate document on the STDF website (www.stdf.org.eg).

9