

Indo-Canada Nanotech Centre planned

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The recently concluded "Technology Summit" in New Delhi set the time table for the Indo-Canadian Science and Biotechnology agreement between the ministers of the two countries, which will happen in the third week of November this year. A joint Indo-Canadian Nanotechnology Centre has also been planned and an initial round of discussions took place at the summit.

Both India and Canada are high on three "Ts" namely Talent, Technology and Tolerance and thus have the potential of becoming world leaders, said Kapil Sibal, minister of state for science and technology, in his inaugural address at the Technology Summit, organized by CII. Canada was the partner country for this year's summit.

The minister added that technology has to ultimately reach the people and that is fundamental to any successful collaboration. The industry of both countries would benefit by shifting the manufacturing base to a low cost economy like India and then dual pricing could be worked out in area like healthcare devices for both the countries.

The Canadian Minister of International Trade, Jim Peterson, announced that collaborative research between Canadian and Indian scientists and entrepreneurs will be encouraged by the Canadian government. There will be funding to assist the development and commercialization of new technologies under the new international Science and Technology Partnership Program. Arthur J Carty, National Science Advisor to the Canadian Prime Minister, commented that great ideas were shared in the two-day summit. He believed this would lead to concrete ideas and strengthen an Indo-Canadian relationship on

"Canada keen on S&T ties with India"

Arthur J. Carty, National Science Advisor to the Canadian Prime Minister

You are looking at signing an S&T agreement with India. What does this agreement intend to do?

Both Canada and India are building knowledge societies. Both are committed to S&T, human resources and global positions. There are mutual needs in both countries that can be met through a comprehensive bilateral S&T linkage. We are committed to develop S&T relationships with India. The S&T Minister has visited India twice, while I have already made three visits to India. In 2004-2005, the total Canadian R&D expenditures are expected to reach \$24.5 billion. The total Canadian federal S&T expenditures in 04-05 are projected to be \$9.2 billion of which 63 percent (\$5.8B) will be for R&D. The federal government has committed \$13 billion in incremental funding for research from 1997-98 to 2003-04 and Budget 2005 added a further \$1.2 billion in direct S&T funding.

A policy statement was published in April and for the first time S&T has been included in the statement. The Prime Minister's challenge is to devote 5 percent of S&T investments to developing world issues and \$20 million has been allotted in Budget 2005 for new international S&T agreements with India, China and Israel.

The S&T Agreement has specified the priority areas for collaboration. The agreement will do the following:

Stimulate freer flow of students and professors; Attract human resources; Promote company-company collaborations; Boost private sector participation with the help of NRC-IRAP for Canadian SMEs; Explore research collaborations in areas like stem cell research; Facilitate joint venture companies; Set up networks of Centers of excellence; Leverage the Indian diaspora strengths of various academic, business and social organizations, including retired professionals, and make it integral to the S&T strategy.

What are the challenges in the Canadian Biotech sector?

Biotech is a very different proposition from IT. It takes about 10 years before a product hits the market. The challenges are different too. Canada has got a top class research base. A lot of ideas that have come from the labs and companies have got formed for commercialization of technology. Canada has done better on spin-offs. However, it is not the creation of companies that is important, but getting the investment and sustaining which is the challenge. In terms of venture capital amount available, Canada is the second largest. But there are several big differences in the way Venture Capitalists (VC) operate in Canada as opposed to the US. In the US, VCs are more entrepreneurial and willing to take the risk. But the case in Canada is not so. Though angel investors are not absent, there are relatively few organizations. With very few companies, one is looking at modest investment. Also big pension firms are absent.

So in a typical Canadian spin off, it is more difficult to get investment. And if you get, the investment is small. Within three years they have to go back to the market scouting for money. The original investor either exits or the company is sold off. This is an area of concern. There are a lot of products in the pipeline, close to 500. However, these will be influenced by the VC capital available.

Ch. Srinivas Rao

"We hope to make ISCR a top-of-mind reference source for information on clinical research"

Dr. Shoibal Mukherjee, president, Indian Society for Clinical Research (ISCR).

What are the objectives of ISCR?

It is a voluntary organization. The members are working in different companies. Getting people on a single platform is a challenging task. But we managed to put something together. Our focus is to bring all stakeholders of clinical research under one umbrella to discuss a number of issues related to training, regulatory, ethics etc. and try to collate the same for the mutual benefits of clinical research and the people involved. And also try to address and resolve a lot of issues that are of utmost importance in clinical research such as the health of the patients/volunteers.

Who will be the actual beneficiaries of ISCR?

The organization has two types of members. One is the corporate member and other would be the individual member. To start with, we have five corporate members and about 35- 40 individual members. The process of enrollment is already in place. It is an online process that requires some streamlining. We are working with an IT company to ensure that the online enrollment process goes smoothly so as to enroll those people who wish to be part of the organization from a remote part of the country. That is why we are not pushing it aggressively. In the course of time we will try to enroll all the companies and individuals who are involved in clinical research to be part of the organization. By the end of the year, we will have good number of members.

How different is ISCR from ACRO?

The Association of Contract Research Organizations (ACRO) is an industry organization for CROs just like organizations for pharmaceutical industry such as OPPI, IDMA, and IPA. If you look at the investigators who are a very important part of the clinical research community, they have their own bodies such as the Association of Physicians of India, the Association of Pediatricians of India or Cardiological Society of India. They do participate in an organization which involves all of them. So they have to interact with one another and exchange ideas and views. Otherwise they will remain isolated.

Clinical research involves many people such as investigators, ethic committees, volunteers and sponsors. Sometimes even it involves academic research institutes, government agencies and CROs. All these people have to come together. ISCR is a platform for all these stakeholders to discuss and resolve a lot issues facing the sector.

How do you plan to address the issue of shortage of talents in the CRO space in the country?

In addition to the Academy for Clinical Excellence (ACE) and the Institute of Clinical Research India (ICRI), there are some academic institutes and universities that do offer courses related to clinical research. For example the Jamia Hamdard University in Delhi offers a three-year PhD course in pharmaceutical medicine. And clinical research is one of the major topics of the pharmaceutical medicine.

Similarly there are courses offered by the Nizam's Institute of Hyderabad. And there are individual universities like the University of Pune that provides training in bioinformatics and biotechnology. I am sure that it will grow. And we will have more people, as both private and public institutes will provide education and training to the student community in the coming days. What the ISCR will do is, it will discuss with its stakeholders and members and draw up curricula of what should be taught at the institutes/universities. This is our contribution to the CROs.

Discussing with all the members we wish to come out with specific and basic minimum curriculum addressing each stakeholders of the CRO sector such as CRAs, investigators, ethic committees, new people who are joining regulatory agencies, administrators/ managers of the CROs. This will not be the end. If the training institutes follow ISCR's curricula fully and provide courses that meet the industry standards, then it would be accredited by the society. There are some niche areas where training at the institutes is not available.

The society will aim to provide that kind of training by inviting experts both local and international to address the issues. The society will do this by organizing workshops and seminars as and when there is need from the sector.

What are your priority areas to pursue in the near future?

As we have already discussed, our first priority will be on education and training. Second area is ethics. There are many issues in ethics. For example; what are trial-related injuries? How should it be defined? What compensation should be available for that? What kind of cover the insurance companies are offering to the volunteers? Is that adequate? Which insurance companies are already covering the volunteers? And so on and so forth. There are many such issues that need to be discussed among all the stakeholders to take a holistic approach on what should be done. Then put out the same as

recommendations to our members and others who actually follow us.

The third one is creating a database of the Indian CROs. At present we don't have any clear picture about how many companies are involved in clinical research, how many trials they are working on and exactly how many volunteers have enrolled for these trials. If we are able to collate the data, we will be in a better position to say where the opportunities are available for Indian companies and also come out with projections for the next five years. We also want to bring a regulatory group which will discuss what are the topmost regulatory issues and how to overcome them.

One of ISCR's aims is to create awareness on clinical research among the patient community. How are you going to achieve this?

We are interested in creating that awareness among the patient community. But before moving ahead, we have to do a lot of homework. The homework involves the individual members who may be knowledgeable in one specific area of clinical research and not in other areas. There are some investigators who are working on clinical trials on CNS drugs. At the same time there are some companies who are developing drugs in that area. We try to bring together, discuss the kind of frontline research that is going on in specific areas, then begin to talk about the issue with support groups and come out with papers and articles which will enhance public awareness about clinical trials among the patient community. This is one root while the other one will be the website itself. The present website has some information about clinical research. This is only website probably in India that patients have access to and can have answers to certain specific questions on the website itself.

Going further we will also put up disease-specific information on the website. We hope to make it the top-of-mind reference source for those seeking information in connection with clinical research in India. This is a slow process but it will happen as the society grows.

Narayan Kulkarni