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"Ethics will be the gateway for clinical research in India"

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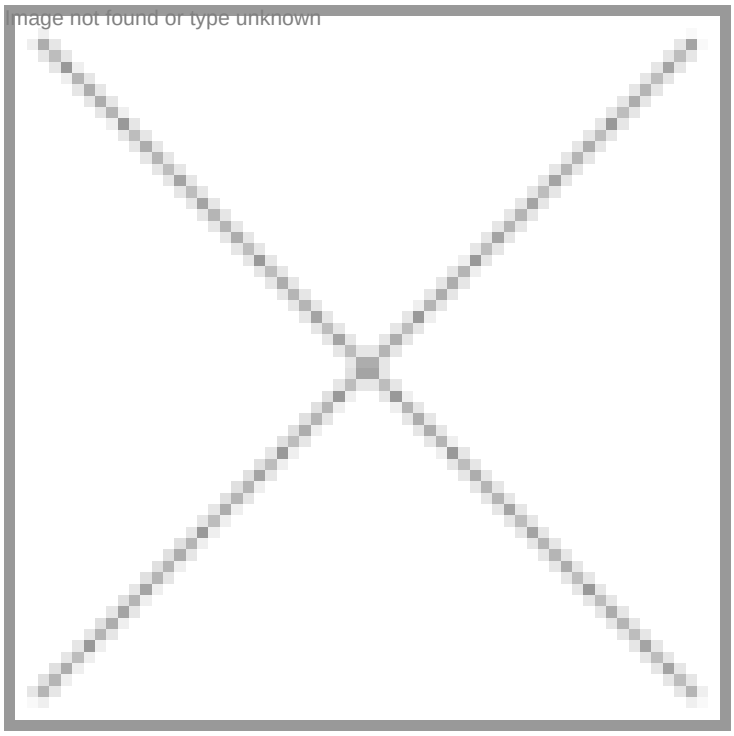

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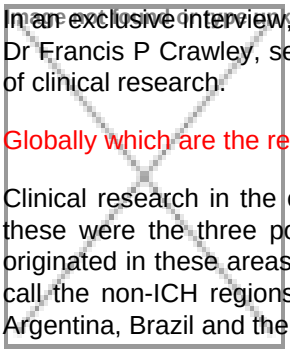

In an exclusive interview,
Dr Francis P Crawley, secretary general and ethics officer, European Forum for GCP, elaborates on the scenario in the area of clinical research.

Globally which are the regions where significant clinical research is happening today?

Clinical research in the early 1990s was really in terms of Europe, the US and Japan. That is where we had the ICH and these were the three powerful regions. All the financially significant research was carried out in these areas or at least originated in these areas. Towards the end of the 1990s, we saw an expansion of the work train in clinical trials into what we call the non-ICH regions. And in particular we saw clinical trials starting to develop a little bit in places like South Africa, Argentina, Brazil and then especially in Central and Eastern Europe.

Now there is a phenomenal research going on in places like Hungary, Czech Republic, Slovac Republic, Slovania, Bulgaria, Romania, Russia, Ukraine and even as far east as Kazakhstan and also in Turkey. But at the same time we see a lot of clinical studies going on in countries like Singapore now, which is fast becoming the Asian hub to a certain extent, Taiwan, Korea, Hong Kong. And now we see the developments in India
and China.

How do you view the global dynamics in clinical research in the future?

If we look into the future, maybe ten years from now, my guess is that we will see three major regions/countries in the world doing clinical research. These would be the US, India and China. And the great competition would be between Indian and China.

Today India may not be a developed nation but is poised to be one, while Europe is developed. Also, Singapore will continue to grow in this area but it has some inherent
limitations.

What are the significant differences between India and the rest of the developing nations in terms of clinical research?

The big difference between India and Eastern Europe like Russia, Ukraine, Bulgaria, Kazakhstan is that they do not have their own pharmaceutical industry although there are a lot of CROs there. They do not have a history of manufacturing as India does, for example, in generics. They do not have their own biotech companies like that in India. And now probably biotech is necessary to have a strong pharma industry. Many countries can generate studies but can they generate their own products and bring them to the market is the big question. India is already able to do that and will be doing it in a much larger way in the future. China will also be able to do so, its biotech industry is developing and its pharma industry will develop too. The big difference between India and China is really the market place. India has a much more open marketplace and a much greater sense of entrepreneurship. I think China is more hindered but there the government is a great facilitator. Now the Chinese government wants to stimulate clinical research and is planning to go the Singapore way.

Rolly Dureha

CANADA

Nova Scotia's Life Sciences Industry awaits ACOA funding

Members of the life sciences industry in Nova Scotia in Canada are anxious to catch the 'Second Wave' of funding that is coming out of the Atlantic Canada Opportunities Agency's (ACOA) Atlantic Investment Partnership (AIP). The announcement of the renewed program, which was made on July 11, 2005 by Joseph McGuire, minister of ACOA, appears to reaffirm the federal government's commitment to supporting innovation in the region.

Of the full $708-million announced under AIP, $300 million will go to the Atlantic Innovation Fund (AIF) over the next five years. This fund is designed to increase the region's capacity to carry out leading-edge research and development and commercialize more of the technologies developed in Atlantic Canada.

"This is fabulous news," said Marli MacNeil, CEO of BioNova - Nova Scotia's Biotechnology and Life Sciences Industry Association. "ACOA's continuing investment in the creation and commercialization of transformative technologies means researchers and innovative companies will be able to work together to contribute to the region's economic and social well-being."

As part of the AIP, the National Research Council (NRC), which is a significant partner in Nova Scotia's life sciences industry, will also get $110 million to develop technology-based clusters in Atlantic Canada. This funding will allow NRC to place increasing focus on assisting with the innovation needs of industries such as the life sciences.

Other proponents of AIP such as the Innovative Communities Fund (ICF), Entrepreneurship and Skills Development and Team Canada Atlantic trade missions, are also seen by the life sciences industry as necessary and worthwhile investments.

Source: www.bionova.ns.ca

CHINA

GM cotton: Expert team passes acceptance check

The Ministry of Science and Technology of the People's Republic of China (MOST) recently organized a meeting of experts to conduct acceptance check of the "State Base for Transgenic Cotton Pilot Test and Industrialization" in Anyang, Henan Province. The key people from MOST's Department of Rural and Social Development, China Rural Technology Development Center and the Department of Science and Technology of Henan Province and the acceptance expert team were present at the meeting.

After listening in earnest to the work report delivered by the leader of the project and field inspection, the expert team, on the basis of adequate discussion and review, believed that the project team had over fulfilled the contract assignment with overall high quality and agreed in consensus to accept the project.

The experts remarked that this project will not only set up the state platform for transgenic cotton technical study and industrialization, making major breakthrough in the scale and efficiency of the transgenic technology, but also provide the technological guarantee and facility support for the environmental release of transgenic cotton and pilot test popularization and greatly facilitate industrialization of domestic transgenic and pest-resistant cotton.

Source: www.most.gov.cn

GERMANY

Germany to fund 24 bio-agri projects

The German government is to support research into the safety of genetically modified (GM) plants with ten million euro over the next three years. Some 24 projects will receive the funding, all of which will investigate the effects that GM plants works have on the effectiveness of antibiotics and herbicides. Antibiotic resistance markers are important tools for the development of genetically modified crops. They are used to identify and isolate the gene or genes that have been moved from one plant to a plant that is to be genetically modified. Seven of the projects will address the replacement of antibiotics and herbicide resistance genes. The researchers will seek to develop methods to remove the marker gene after the creation of transgenic plants, or to ensure that it is only present in a specified area of the genome, in order to avoid unwanted side effects.

Nine projects will focus on transgenic varieties of maize. Other projects will look into the biological safety of transgenic cereal crops with resistance to fungus, and the impact of growing transgenic potatoes on the quality of the land.

Source: www.biotop.de

AMERICA

Colorado's bioscience industry evolving rapidly

Colorado is carrying out an aggressive plan to grow the state's bioscience industry into one of the country's premier bioscience clusters. A central organizing force and unifying voice for the industry is the Colorado BioScience Association (CBSA), a not-for-profit corporation providing services and support for Colorado's growing biosciences industry. CBSA currently enjoys the support of more than 300 member organizations representing both bioscience companies and companies providing key services to the bioscience industry and research institutions in Colorado.

The key to Colorado's emerging bioscience prominence is the $4.3-billion Fitzsimons Project on the front range of the Rockies. In the heart of Aurora, Colorado, an incredible development is taking place. The former Fitzsimons Army Medical Center is being transformed into a state-of-the-art, 578-acre integrated life sciences community. The concentration of exceptional talent, vision and extraordinary facilities at Fitzsimons will provide opportunities for collaboration and resource-sharing that will benefit global health care and improve people's lives.

Colorado's bioscience industry is predominantly clustered within the Greater Denver region, Fort Collins, Boulder, and Colorado Springs. Three of the Colorado metro areas that make up the Denver Consolidated Metropolitan Statistical Area (CMSA) account for 80 percent of the state's bioscience employment and 73 percent of establishments.

Nearly three hundred and fifty bioscience companies have made their home under the gaze of the Rocky Mountains. These companies are conducting cutting-edge research to find cures to diseases such as cancer, heart disease; improve agricultural yields; and
develop cleaner, more efficient manufacturing methods.

Bioscience firms tend to geographically concentrate around academic health centers and research universities and Colorado's concentration provides a basis for further building a critical mass. Colorado has fostered a healthy partnership between academia and the private sector to speed basic science discoveries into novel treatments for patients. The University of Colorado system is home to significant research centers that support Colorado's biopharmaceutical industry. The Colorado Alliance for Bioengineering is responsible for the coordination of biotech activities among faculty in all universities throughout the state, while the Colorado Bioprocessing Center at the Colorado State University in Fort Collins develops therapeutic compounds and biologics for biotech companies.

Two additional factors in the vitality of the biosciences in Colorado are the federal awards to support both basic research activities, and basic innovation grants to small companies pursuing commercial viability of research conducted in both public and private laboratories in the state. Between 1999 and 2002, Colorado biotechnology companies received 984 Small Business Innovation Research Grants (SBIR), ranking 4th in the nation.

In 2003-2004, the biosciences industry sectors in the state employed 11,885 workers in four major sectors with an average salary of $61,414. In addition, more than 20,204 additional service sector jobs were generated to support this growing industry for a total employment impact of 32,089 jobs. The state's biosciences and service providers also contributed an estimated $415.7 million in local, state, and federal taxes.

Source: CBSA

Energy Policy Act to boost biofuels industry

The Energy Policy Act cleared on July 29, 2005 by the US Congress for President Bush's signature will improve domestic energy security by setting goals for production of renewable fuels obtained from US agricultural resources. "The measures that President Bush is about to sign into law are a big step towards enhancing our national security by providing incentives for energy produced from renewable agricultural feedstocks," said Jim Greenwood, president and CEO, BIO.

"The application of biotechnology in the industrial setting is affecting a paradigm shift in how we produce energy, and this legislation will provide incentives to hurry the future of biofuels. Soon, we could be producing up to 25 percent of our transportation fuel needs by using industrial biotechnology to produce bioethanol, while adding $5 billion to the farm economy," Greenwood observed.

In addition to requiring that the amount of renewable fuels â€“ such as ethanol â€“ blended with gasoline increase from 4 billion gallons in 2006 to 7.5 billion gallons in 2012, the Act provides credit for ethanol made from non-traditional feedstocks like wheat straw and corn stover. The Bill provides $200 million yearly until 2015 to update the Biomass Research and Development Act with the goal of rapidly boosting production of bio-based fuels at competitive prices and developing a broad range of bio-based products that replace petroleum-based products. In addition, the Act establishes a reverse auction to spur production of the first billion gallons of ethanol from cellulosic biomass and creation of a bioethanol industry. The Bill also expands the Federal Agency Biobased Procurement Program to all federal contractors and the US Capitol complex and provides loan guarantees for construction of biorefineries.

Source: www.bio.org

SINGAPORE

"Singapore â€“ a location for networking"

"The rapidly growing number of companies conducting drug discovery and basic research in Singapore will complement and reinforce our established biomedical sciences manufacturing and clinical research activities. In fact, Singapore is fast becoming the choice Asia Pacific location for scientists to meet and network," said Dr Balaji Sadasivan, Senior Minister of State for Health and Information, Communications and the Arts, Government of Singapore, at the opening ceremony of the Drug Discovery & Development Asia Pacific Congress 2005.

The three-day congress which was held in June 2005 featured over 40 internationally- renowned speakers, who gave updates on disease-specific drug discovery, and presented case studies of successful collaborations and lessons.

"Growth is the number one driver of partnering for pharma companies. Other key reasons for partnerships are to access critical capabilities, enter new markets, build up critical mass, accelerate R&D and reduce costs. There is a need for partnering worldwide due to globalization of markets, increasing financial pressures, decreasing R&D productivity and decreasing sales force effectiveness," said Dr Harvinder Popli, head-licensing, Ranbaxy Labs, who is based in India. "India is poised to play a major role in the biotech and pharma industries post 2005. We see that the future of the Indian pharmaceutical industry lies in co-marketing and co-promotion, a model that has already succeeded in the US and Europe," he added.

Source: www.biomed-singapore.com

AFRICA

AfricaBio project on training farmers a success

A project to determine the role of biotechnology in smallholder farming during the 2004 -05 maize season was highly successful. Some 636 small-scale farmers, 65 agricultural extension officers and 21 decision makers in six provinces received extensive training on biotechnology and
Bt maize.

AfricaBio, in collaboration with the National African Farmers' Union (NAFU), Buhle Farmers' Academy at Delmas in Mpumalanga, Cedara Agricultural College in KZN and the Provincial Departments of Agriculture, initiated this project during the 2004-planting season. Six demonstration sites were selected where Bt and conventional maize were planted side by side. The plots were planted with white Bt and conventional maize in November/December 2004 and harvested during June/July 2005. The average yield for the Bt maize was 42.5 percent higher than the conventional crop.

"Training farmers is an ongoing process. One training session is not enough and we will certainly repeat the project this coming season by adding more experimental sites in order to reach more farmers," said Prof Jocelyn Webster, executive director of
AfricaBio.

Source: www.africabio.com

Europe

EuropaBio sore over Commission's position on patenting

The European Association for Bioindustries, EuropaBio, has expressed its disappointment over the failure of the European Commission to take a position on the patenting of human DNA and human stem cells, which were not clarified in the EU Biotechnology
Patents Directive.

Directive 98/44 entered into force in July 2000 after ten years of debate between the EU institutions. In 2002, the Commission charged a group of experts with clarifying two topics within the Directive: the scope to be conferred to patents on sequences or partial sequences of genes isolated from the human body; and the patentability of human stem cells and of cell lines obtained from them.
It was expected that the Commission would propose new guidelines in its second report on the Directive, which was published on July 14. However, the report actually states that, with regard to DNA sequences, "The Commission will continue to monitor whether there are any economic consequences of possible divergences between Member States' legislation." On stem cells, the Commission makes a differentiation between totipotent stem cells, which can develop into a human being, and

pluripotent stem cells, which do not have this ability.

"In the light of the Commission's analysis, it appears that totipotent stem cells should not be patentable, on grounds of human dignity. There is no immediate answer to the question of the patentability of embryonic pluripotent stem cells and indeed at this stage it would appear premature to come to a definitive conclusion. The Commission will continue to monitor developments in this area," the report states.

Source: www.biotop.de

BIO hails Dr Crawford's confirmation as FDA chief

The Biotechnology Industry Organization (BIO) has welcomed the Senate confirmation of Dr Lester Crawford as Commissioner of the Food and Drug Administration (FDA). In a statement, James C Greenwood, president and CEO of BIO said, "Dr Crawford ably led the agency through a difficult period last year, and we welcome his confirmation as Commissioner. Dr Crawford recognizes that the FDA's role as a regulatory gatekeeper is pivotal to both fostering innovation and ensuring product safety."

He further noted, "The FDA must be prepared for innovations emerging from genomics, proteomics, nano technology and other biotechnology applications. We're entering an era of personalized medicine and a revolution with the potential to further tame disabling and deadly diseases. A well-funded, effectively managed FDA is essential to bringing those breakthroughs to patients. FDA is also a key reviewer of biotechnology applications for food and feed to safeguard all foods in the marketplace under the Federal Food Drug and Cosmetic Act. The agency's overview of these products helps to boost consumer confidence at home and abroad. "

Source: www.bio.org

Rice genome completed

The completion of the rice genome has been announced by an international consortium. The publicly available finished sequence is anchored to the genetic map, providing both the linear order of the 37,544 genes and their positions on the 12 rice chromosomes. The map-based characterization of the rice genome already has led to the identification of important genes, such as those which may increase yield and productivity.

The completed rice genome may enable agricultural breeders to also address other critical issues in rice cultivation. Messing noted that rice cultivation today creates an enormous environmental burden in terms of the quantities of water and fertilizer required to produce a successful crop.

The rice genome is the Rosetta Stone of all the bigger grass genomes. Knowing its sequence will provide instantaneous access to the same genes in the same relative physical position in other grasses and accelerate plant gene discovery in many important crops such as corn and wheat.

Source: Rutgers Media Statement