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Info-GCP a platform for Indian CROs

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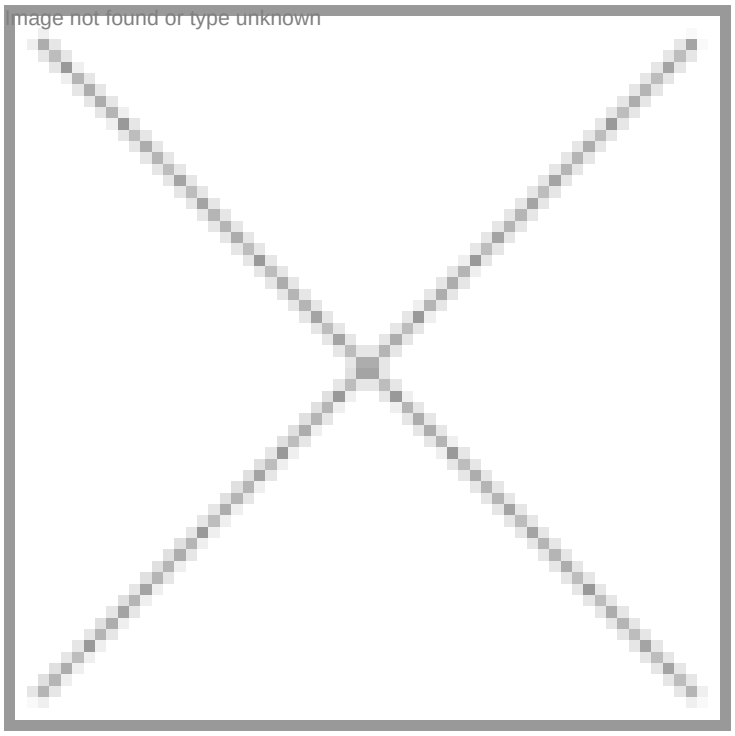

There are few areas of science that cross as many boundaries as does clinical research. "Therefore, expanding clinical research cannot succeed without the wholehearted support of academia, industry, regulators and civil society. It is vital to develop robust mechanisms for co-operation between these stakeholders," pointed out Dr Dhananjay Bakhle, head of Medical Research & Regulatory Affairs, Sanofi-aventis.

The India Forum for GCP (Info-GCP) was launched recently. Info-GCP would take a lead to develop such linkages to facilitate growth of clinical research in India.

The main objectives of this new initiative include:

- Facilitating a discussion of ethical and GCP related issues.
- Offer a platform to update guidelines and working practices for the purpose of improving clinical research standards.
- Create and spread awareness of ethical principles in research and promote efforts towards its integration in GCP while conducting such research.

- Stimulate a closer relationship and improve understanding between key stakeholders of clinical research field, and also individual members of the Forum while sharing best practices.

- Foster the development of clinical research professionals through various means including training and continuing education programs in biomedical research and related areas, promote the development of Indian guidelines/directives based on these discussions and interactions, and share updates on new legislations/guidelines to key stakeholders in clinical research.

- Provide a national platform for all key stakeholders in clinical research by dealing with matters brought to its attention by the members.

Why is it important? In 1996, the American Medical Association convened a major conference. The focus was on addressing the future of clinical research in the changing environment. The recommendation was to organize a national summit of key stakeholders in the domain of clinical research and as a result in 1998 a Clinical Research Summit was held at Graylyn, USA.

More than 175 representatives from key government agencies, the pharmaceutical industry, major purchasers of health care, health plans and insurance companies, patient and family advocates, ethicists, the broad research community, and leaders of academic health centers made it to the summit that identified some problems that confront the clinical research enterprises and also developed a set of goals that were fully described in the Report of the Graylyn Consensus Development Conference (1998).

The summit's final report, "Clinical Research: A National Call to Action (USA-November 1999)", identified the core problems and made recommendations to solve these problems. Nine core problem areas were identified. These being: lack of clear definition of clinical research; clinical research not being adequately understood or valued; lack of data on clinical research funding and productivity; insufficient funding for the conduct of some types of clinical research; insufficient numbers of clinical investigators; insufficient emphasis on incorporating research findings into clinical practice; inadequate coordination of clinical research among research entities and disciplines; and lack of comprehensive, dynamic and clinical research agenda. These core problems are not only relevant to the US but also to India, where clinical research is just making its entry. The Indian CROs have been facing these problems for some time but till now there have been no solutions in sight.

To tackle the problem of not adequately understanding or valuing clinical research, the summit has made the following recommendations:

â€¢ The ethical foundations of clinical research must be reinforced.

â€¢ Federal protections (or their equivalent) for human research subjects should be applied irrespective of funding or venue.

â€¢ Training for health professionals in the ethical framework of clinical research should be expanded.

â€¢ Public understanding of clinical research and confidence in clinical research ethics must be strengthened through dialogue that promotes mutual understanding

â€¢ The research community should develop separate and coordinated strategies to enhance public understanding of clinical research.

â€¢ Last but not least, all entities involved in clinical research should seek out means to restore trust between the scientific community and populations that have been subject to questionable or unethical research practices.

Similarly for lack of data on clinical research funding and productivity, the summit's recommendations include:

â€¢ Mechanisms to track and disseminate the aggregate levels of financial support for clinical research provided by public fundings, industry, foundations, voluntary organizations, health plans and insurers, academic health centers, hospitals, and other health care providers.

â€¢ A national strategy should be developed for a public-private sector partnership to fund the creation of broad-based clinical information systems.

â€¢ A substantial investment is needed to meet the requirements of health services and population-based research and the

advancement of evidence based medicine.

On the issue related to insufficient numbers of clinical investigators, the summit made the following recommendations.

â€¢ A process should be established to monitor and promote clinical research career development across the health professions, in order to meet the needs and promote the different categories of clinical research and foster the development of a cadre of well-trained clinical investigators across all health disciplines.

â€¢ An ongoing high-profile forum should be initiated to discuss strategies that could include: recruiting more trainees from underrepresented communities, building upon promising training models developed at academic health centers and the NIH and evaluating new clinical research development awards at NIH.

A visible, credible, and broadly representative entity should be established to focus on continuing needs, priorities, and future progress of clinical research. This, the summit noted, would help to overcome the problem of a lack of comprehensive, dynamic, clinical research agenda. To overcome the problem of ability of academic health centers to conduct clinical research, which is at risk, the summit suggested to support and strengthen the training required for investigators.

In addition to this, the summit maintained that support for efforts by industry and the NIH should be furnished to develop mixed academic/non-academic clinical trials sites. Incentives should be provided to managed-care organizations and other providers to participate directly in clinical research. Practice networks and managed-care organizations should expand their clinical trials capabilities, as well as their health services, prevention, and epidemiological research. These measures will try to bring down the insufficient emphasis on incorporating research findings into clinical practice.

Other models

For re-building clinical research program in the country of origin, one of the models that can be looked into is the British Model. It is Public-Charity-Academia partnership program. In 1997, the Wellcome Trust funded £20 million through Millennia Award Scheme to develop clinical research facilities at Birmingham, Cambridge, Edinburgh, Manchester and Southampton. Besides grants were also awarded to universities and trusts for infrastructure and the facilities run by National Health Service (NHS) from their R&D budgets. In addition to this, to strengthen the clinical research infrastructure in the UK, it has proposed a virtual national network for clinical research funded by Department of Health and managed through a Special Health Authority.

The European Parliament and Council have formed European & Developing Countries Clinical Trials Partnership (EDTCP) in response to the combined political will and health priorities of both the developing and developed world. Its objective was to contribute to the development of new and affordable therapeutics and prophylactics for HIV/AIDS, tuberculosis and malaria. Initially, EDTCP will focus on the countries most severely afflicted, primarily Sub-Saharan Africa. The EDCTP comprises 14 EU member states plus Norway and is funded by the European Union to promote a more integrated approach to health research amongst European countries.

At present, the EDCTP operates on a European Commission contribution of Euro 400 million distributed over five years. The EDCTP is about partnership, pursuing a common platform to optimise synergies. It is also forming strategic alliances with like-minded organizations in the public and private sector towards achieving common goals. It is poised to provide a platform for the conduct of large-scale clinical trials and the development of the required capacities in developing countries. Furthermore, it aims at improving synergies of, and collaboration amongst, national and international research programs.

Looking at these two initiatives, India still does not have one such forum. India has a good government medical infrastructure. But it is not sufficient to the growing population of India that has already crossed over a billion. The government hospitals were made for certain capability but are overused. This is what the union minister of state for tourism, Renuka Choudhary, who is keen on developing India as a destination for medical tourism, noted. The government needs some support from the private sector to develop the medical infrastructure so that more clinical trials could be carried out from these government hospitals.

The Info-GCP forum certainly can work not only for the industry but also act as a catalyst to build trust with the patients and changing public perceptions about clinical trials, which is the need of the hour. A beginning has been made.

Narayan Kulkarni