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CDSA promotes enhancement of clinical trial capacity

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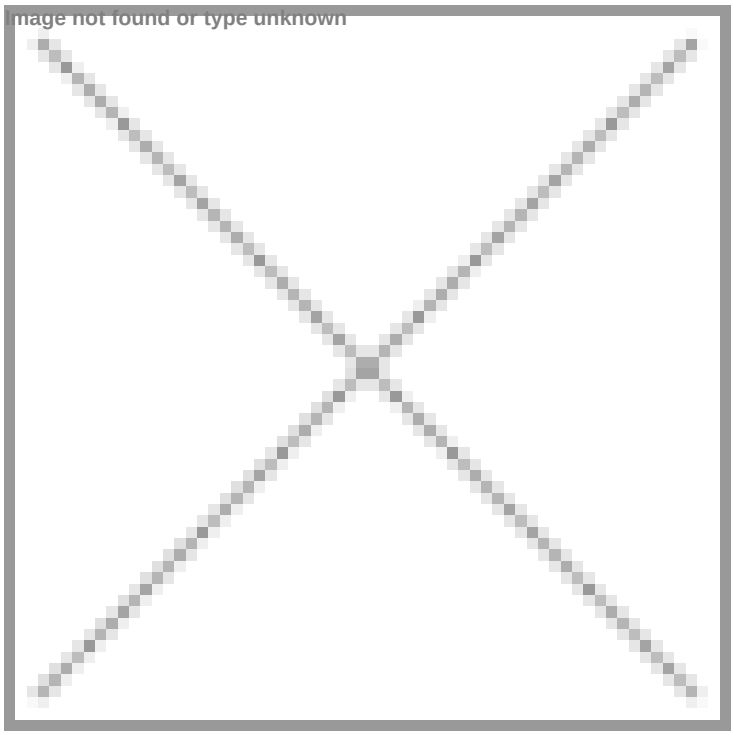
Role of CDSA: Create, develop and nurture clinical trial capacity in India



The first and foremost objective of Clinical Development Services Agency (CDSA) is to develop skilled work force of clinical researchers and support staff for development of technologies and products to impact public health in India. Apart from that, it aims to facilitate and accelerate public health related product development through clinical research centers of excellence (COEs) and provision of low-cost clinical research services.

Being an extramural unit of Gurgaon-based Translational Health Science and Technology Institute (THSTI), the agency has been established as a not-for-profit society to provide cost-effective, high quality, preclinical and clinical product development support services to meet the country's growing healthcare needs. It will tend enterprises; particularly small and medium enterprises (SMEs) involved in new technology innovation and facilitate translation of scientific know-how into viable products.

Two main streams of training that have been identified are the drug discovery and translational medicine to cover preclinical research from conceptual chemistry/molecular biology to early clinical development. For the first stream, partnerships are being envisaged to implement this program as a post-graduate diploma/degree course for students. The second one is the training in clinical trials for regulatory submissions. For this, at least five leading clinical research institutions are being identified across India to serve as potential partners for COE development.

In addition to that, the clinical investigator development program (CIDP) is aimed at developing an ecosystem of learning and knowledge management in clinical research. It also intends to develop a pool of clinical investigators and sustainable training

program. The strategy is to make use of existing clinical research training opportunities by leveraging on partnerships, alliances and collaborations with international agencies and universities. The program also aims to create opportunities for internships and exchange fellowship programs.

Funding is through a variety of resources like DBT training and workshop grants, CDSA training budget, joint funding applications with COEs to national and international agencies such as National Institutes of Health (NIH), the United States Agency for International Development (USAID), and PATH. At present the training advisory panel members include Dr JP Muliyil (chairman), Dr Nita Bhandari, Dr Rajat Goyal, Dr Shinjini Bhatnagar, Dr Shoibal Mukherjee, Dr Mouli Natchu and a nominee from each COE. The panel invites national and international experts as and when required. It establishes the overall strategy and goals of CIDP and decides on key focus areas of training. The agency evaluates progress and makes changes if deemed necessary.

Planned activities

The early focus of the CDSA mandate is to promote the enhancement of clinical trial capacity in India as per international standards. This would entail developing COE in clinical research through partnerships with leading institutions conducting clinical trials in India. Apart from that, it will be providing comprehensive and sustained training in clinical research through these COE in order to build a cadre of world class investigators capable of conducting clinical trials for regulatory submissions.

The initiatives proposed by CDSA include entering into long-term alliances and partnerships both for the purposes of establishment of centers of excellence and for training in clinical research. The agency would also assess clinical research and management training needs at research sites to implement a training curricula for principal investigators, research managers, administrators and others from the sites that will strengthen the capacity of investigators. The curriculum will encompass clinical research training and research management training. The agency intends to provide the services of data management and biostatistics from a central facility in National Capital Region (NCR) to support regulatory trials being carried out at the centers of excellence. It will also facilitate the formation of Institutional Review Board Services (IRBs) to ensure that the conduct of regulatory trials meets the requisite ethical standards. It will also facilitate the conduct of clinical trials with vaccines and/or diagnostic products for public health diseases.