

Clinical Development Services Agency (CDSA): Create, develop and nurture world class clinical product development capacity in India

In year 2009, the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India launched CDSA as an extramural unit of Translational Health Science & Technology Institute (THSTI). The primary aim of establishing CDSA was to facilitate development of affordable healthcare products for public health solutions. It is a not-for profit research organization which aspires to develop an ecosystem for training and learning. It is engaged with public sector institutions and small & medium enterprises to translate innovative technologies into medical products for common good of public.

The CDSA capture reliable data quality and an audit trail with help of robust processes and data capture systems. The CDSA's clinical data management system provides customized data management services such as development of data management plan, e-CRF designing, data validation plan, edit checks programming, audit trail, customized reports, data backup and export etc.

The CDSA supports the sponsor, investigators, and researchers on initial and ongoing risk assessments, develop, implement or monitor project-specific safety management plans and the processes. The other services include clinical monitoring of systems according to international ethical and scientific quality standards. Other services provided by agency supports regulatory affairs, quality and compliance services, medical writing, biostatistics, prepares clinical study reports, etc.

Some of the recent events organized by CDSA include:

(i). CDSA supported the launch of ICMR TB vaccine trial for healthy household contacts of TB patients: On 15th July, 2019, agency provided study start-up support to all sites and oversaw the recruitment and vaccination of the first participant at National Institute of Tuberculosis and Respiratory Diseases (NITRD), New Delhi. This national workshop was first-ever government led vaccine trial after the Bacillus Calmette–Guérin vaccine launched in India in past. After a comprehensive landscape analysis of the available vaccine candidates, two potential vaccines were shortlisted for a ICMR led Phase III trial of 12000 healthy house hold

contacts of sputum smear positive TB patients. At trial launch, Dr. Balram Bhargava, Secretary, DHR & Director General, ICMR, emphasized the need of such vaccine in India where the disease is endemic for clinical trials to show the safety and effectiveness of the vaccine.

(ii). CDSA and C-CAMP co-hosted the National workshop on regulatory compliance for accelerating innovations: On 9th April 2019, the DBT, CDSCO, BIRAC, and CDSA with Centre Cellular and Molecular Platforms (C-CAMP), Bengaluru organized a day long interactive program entitled “National Workshop on Regulatory Compliance for Accelerating Innovations”. Senior representatives from different organizations, academia, medical device industry, *in vitro* diagnostics, biopharmacies, start-ups, hospitals, etc attend the workshop. The three major themes of the workshop were (a) medical devices, (b) new drugs & phytopharma, and (c) biopharma.

(iii). National workshop on Regulatory Compliance for Accelerating Innovations: On 13th June, 2019, CDSA in collaboration with DBT, BIRAC, and CDSCO conducted its fifth among the six national workshops on regulatory compliance for accelerating innovations with NIPER, Guwahati. The workshop was attended by all stakeholders. The workshop was attended by 149 participants from 52 institutions. This event provided participants an opportunity to interact and ask question about seeking clarity and better understanding to their questions, thus, making the ‘Make in India’ program successful.

(iv). CDSA organized GCP and GCLP programs at ICMR headquarters: From 11-12th April, 2019, the CDSA conducted programs on Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) at the ICMR Headquarters, New Delhi. Patients from ICMR headquarters, team members of ICMR’s POD-TB vaccine project and seven ICMR centres across India attend both programs. The participants were informed and educated about their roles and responsibilities for adapting good practices. Later on, all the participants submitted their exit assessment reports.

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