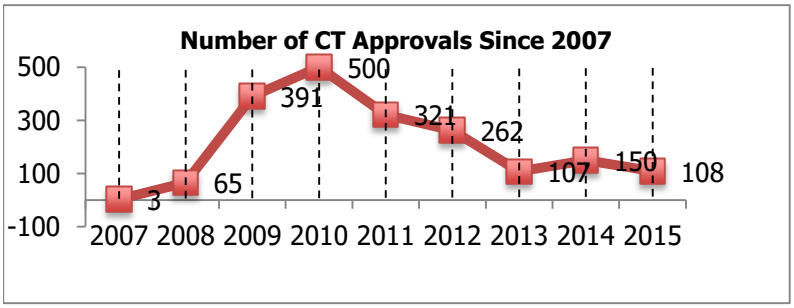
CDSA Newsletter

Issue 4.1 January 2016 Clinical Development Services Agency

Dear Reader,

Calendar year 2015 has seen additional amendments in Schedule Y from CDSCO and reductions in the number of approvals (n=108) compared to last calendar year (n=150). The fall in approvals has resulted in loss of new businesses in the CRO industry leading to closure of many CROs leading to loss of jobs and participation of India-based investigators in global trial programs.



However, CDSA is surging ahead increasing the human resource capacity and capability (4025 participants from 1141 institutions/ organisations) in the area of clinical development and translational research with 639 faculties across 35 cities. Towards the support of investigator and SME sponsored clinical studies, we are now actively coordinating the indigenously invented surfactant (GLSE) phase 2 clinical trial across 12 sites in India sponsored by AIIMS, New Delhi along with other studies. The guidance document for Institutional Ethics Committees (IEC) that review Clinical Trials on Human Participants is now available as a ready reckoner.

Due to unavoidable reasons, we would be able to continue the article/ part 2 of Gender Discrimination in the next quarter.

Happy reading !!

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Trainings and Programme Conducted by CDSA

Sucheta Banerjee Kurundkar & Neha Mishra

Keep Learning

On Diwali morning this year, a warm email from a participant, Dr. Soumya brightened my day. It lit upon many candles, a win over darkness by light. Our resources are limited but desire and efforts are magnanimous. A single ray of hope like this gives us immense impetus to give us assurance to keep working towards our goal of Keep Learning.

Awareness Program for IEC Members

Our awareness Series on Current Regulatory Requirements for members of Institutional Ethics Committee has completed a dozen recently covering 12 cities like Hyderabad, Ahmedabad, Pune, Delhi, Trivandrum, Jaipur, Kolkata, Dibrugarh, Bangalore, Mangalore, Chennai and Lucknow. This program till date touched 1462 participants from 394 Institutions steered by 158 Faculty.

Regulatory Requirements & Clinical Development for Innovators

Centre for Cellular and Molecular Platforms (C-CAMP) in collaboration with CDSA conducted a workshop on '*Regulatory Requirements & Clinical Development – A Workshop to Unlock the Potential of your Innovation*' on 16 October 2015 at C-CAMP, Bangalore. The objective of the workshop was to enable the participants understand various regulatory requirements in India in the field of new pharmaceuticals, medical devices, in vitro diagnostic kits, phytopharmaceuticals, cosmetics etc. This workshop provided a platform to interact with the regulators to know various steps necessary for taking an innovative technology or product from laboratory to market. The most unique session was '*Meet the Regulators'*. This was a rare opportunity provided to innovators, startups, SMEs etc. wherein they can interact directly with the current regulators [Shri Aseem Sahu, DDC(I), CDSCO, New Delhi & Shri Somnath Basu, ADC(I), CDSCO Hyderabad] and clarify doubts, seek guidance on one-one to basis.

Presentation & Communication Skills

An interactive training on Presentation & Communication Skills Training for Scientists and internal Staff was hosted recently by CDSA in collaboration with National Cancer Institute, National Institute of Health, US Department of Health & Human Services at NCR Biotech Science Cluster campus, Faridabad recently. Ms. Kellie Mullen, Senior VP-Global Media/Speaker Coach, Ogilvy Public Relations trained all participants on effective presentation skills.

"This is to share a piece of good news that today I successfully completed the Bioethics Certificate Course conducted by Manipal University and CDSA, New Delhi an onsite and online program for 3 consecutive months after grueling 2 internal examinations with 2 written assignments, writing 4 questions, SAQ and a final 2 day examination both written with MCQs and SAQs and Practical session with Presentation followed by Discussion as Viva conducted on 5th and 6th November 2015. Finally declaration of result was today with distribution of qualifying and completed certificate. This course was undertaken following CDSA Introductory Workshop in Chennai.
Why I am writing to you is to share with you since you kindled the interest in Bioethics in Chennai workshop, which took me to Manipal and now I am planning to go through PG Diploma in PSG Coimbatore."
Thanking You for motivating.
Prof Dr Soumya Chakraborty HoD Anatomy & Member IRB, Med Ed unit, Member Secretary IEC, ESIC PGIMSR, Joka Kolkata

"I am Nachiket Deval, co-founder of Coeo Labs, I attended your workshop on Regulatory requirements and clinical development at C-CAMP Bangalore. The workshop was very useful with regards to the information we acquired on the regulatory pathway clarity it provided on conducting clinical studies"
Participant, C-CAMP CDSA Program (Oct 16, 2015), Bangalore

Down The Memory Lane

Sucheta Banerjee Kurundkar & Neha Mishra

Awareness Program for IEC Members at BBD University, Lucknow (Sept 15-16, 2015)

Meet the Regulators @ C-CAMP, Bangalore (Oct 16, 2015)

Regulatory Requirements & Clinical Development – A Workshop to Unlock the Potential of your Innovation' (Oct 16, 2015) at C-CAMP, Bangalore

BIRAC-CDSA Workshop Series in South India: "Regulatory Requirements for Biopharmaceuticals – From Science to Commercialization" at NCBS, Bangalore (Oct 15, 2015)

"Its really a nice opportunity and a very much useful Friday spent at C-CAMP during the workshop. It is to be really appreciated with respect to the arrangements and the opportunity not alone to meet the regulators but also the different entrepreneurs and their different ideas. Thanks for the opportunity and looking forward to much more interaction and help in future. Can we contact you in future for any assistance?"

Dr. K.G. Tirumurugaan, Programme Head (Diagnostics),
TRPVB, DCAHS, TANUVAS, Chennai,
[Participant, C-CAMP CDSA Program (Oct 16, 2015), Bangalore]

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Presentation & Communication Skills Training for Scientists and Program Staff at THSTI, Faridabad (Nov 30, 2015)

Essentials of Statistics and Clinical Data Analysis using R at ICGEB, New Delhi (Dec 01-04, 2015)

Good Clinical Practice (GCP) (An Awareness Program) at ESIC Dental College, Rohini (Dec 14, 2015)

Current Ethical & Regulatory Requirements (An Awareness Program) for Clinical Trials at ESIC Dental College, Rohini (Dec 15, 2015)

UPCOMING PROGRAMS			
No.	**Dates**	**Training Title**	**Venue**
1	Feb 16, 2016	Basics of Good Clinical Practice (Awareness Program)	Tata Memorial Hospital, Mumbai
2	Feb 17-18, 2016	Current Regulatory Requirements for Members of Institutional Ethics Committees (Awareness Program)	Tata Memorial Hospital, Mumbai
3	Feb 24, 2016	BIRAC CDSA Regulatory Workshop on Current Regulation on Medical Devices & *invitro* Diagnostic Kits	CDSCO Shastri Bhawan, Chennai
4	Mar 31 – Jun 04, 2016	Bioethics Certificate Course 2016 (Manipal University and CDSA Collaboration Program)	Online Course with 3 Contact Sessions at Manipal University, Manipal

Investigators' Meeting - GLSE Trial

Monika Bahl

CDSA is coordinating a phase 2 clinical trial of an indigenously developed Goat Lung Surfactant Extract (GLSE) for preterm neonates with Respiratory Distress Syndrome (RDS). The study is sponsored by AIIMS, New Delhi with funding from Wellcome Trust, UK. The Investigator's meeting for the study was held on 8th and 9th January 2016 at Heritage Village Manesar, Haryana.

Gayatri Vishwakarma

Department of Biostatistics at CDSA, has been continuously putting effort conducting training programs (awareness as well as hands-on) in addition to provide statistical services to investigators. Three training programs have been conducted in last year. Recently hands-on training program has been organized on "Essentials of Statistics and Clinical Data Analysis using R" from Dec 1 – 4, 2015 was held at ICGEB, Delhi where 45 participants took part from various part of the country including one international participant from ICDDR,B (International Center for Diarrheal Disease Research, Bangladesh).

Essentials of Statistics and Clinical Data Analysis using R" from Dec 1 – 4, 2015