Technical Workshops Series – 2016

Workshops on
Clinical Research and Medical Regulations

Learn	This workshop will give an overview about : - differences in the guidelines from CDSCO, ICH and WHO - various regulatory requirements, ethical considerations, roles and responsibilities of various stakeholders like Sponsor, Institution, Investigator, Monitor etc. - clinical trial documentation requirements like protocol, investigator's brochure, informed consent form, case record form, clinical study report etc. - record keeping and data handling requirements, - quality assurance and statistics in the conduct of a clinical trial or research, when done in compliance with GCP requirements - current rules and regulations for Ethics Committees and regulatory aspects for medical devices and IVD kits.
Organized by	• Venture Center • Indian Institute of Science Education and Research (IISER), Pune • Prashanti Cancer Care Mission (PCCM)
Knowledge Partners	• Clinical Development Services Agency (CDSA) • KEM Hospital, Pune
Supported by	• Biotechnology Industry Research and Assistance Council (BIRAC)
For whom	• Investigators, Ethics Committee Members, Clinical trial or research team members working in various aspects of Healthcare R&D. • Any one working in the area of clinical trial or research or aspires to work in this area including biomedical start-ups and healthcare entrepreuners.
When	**Tuesday – Thursday | 27 - 29 September 2016 | Time: 0900-1730 hrs**
Where	• 27 and 28 Sept 2016: Indian Institute of Science Education and Research, Dr. Homi Bhabha Road, Pashan, Pune-411008 • 29 Sept 2016: Lecture Theatre, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune-411008
Admin contact	Dr. Mugdha Lele/ Ms Lipika Biswas, Venture Center, Pune. Email us on : crmrworkshops@venturecenter.co.in | Phone: 020-25865877
Cost	The registration fees for the 3 workshops mention are as below: • **27 Sept 2016: Good Clinical Practice** • **28 Sept 2016: Current Regulatory Requirements for the Members of Institutional Ethics Committee Program** • **29 Sept 2016: Current Regulation on Medical Devices and *in vitro* Diagnostics (IVD) Kits**

Venture Center: http://www.venturecenter.co.in/
Contact No: 020 2586 5877; Email: eventsdesk@venturecenter.co.in
Facebook Page: https://www.facebook.com/venturecenterpune?ref=hl

Category	Fees
Students with valid ID card	Rs 1000/- per workshop
Academic Institutions, Non-profit Organizations, MSMEs, CDSA Alliances, BIRAC supported start –ups, Government Agencies, Individuals	Rs 2000/- per workshop
Industry like Pharmaceutical and Biomedical sectors	Rs 3000/- per workshop

Register online at: http://goo.gl/forms/On3SBgfp0jCJhcF63
More details on: http://www.venturecenter.co.in/workshops/
(All registrations will close on 20 Sept 2016, 5pm)

Note:-

- Fees paid are not refundable and transferable under any circumstances.
- Registration will not be confirmed until actual receipt of DD/Cheque/online transfer of registration fees.
- Registration will be confirmed only on cross checking of the ID documents, photocopy to be submitted along with the registration form.
- Accommodation is available on payment at IISER guest house for first 100 participants on first come first serve basis.

Introduction and Workshop Outline

27 Sept 2016: "Good Clinical Practice"

This program will give participants an overview about various aspects being covered starting from the differences in the guidelines from CDSCO, ICH to WHO, various regulatory requirements, ethical considerations, roles and responsibilities of various stakeholders like Sponsor, Institution, Investigator, Monitor etc. It will make participants aware of various clinical trial documentation requirements like protocol, investigator's brochure, informed consent form, case record form, clinical study report etc. This will make the participants understand and learn record keeping and data handling requirements and quality assurance in the conduct of a clinical trial or research, when done in compliance with GCP requirements.

Learning Objective: To understand the basics of Good Clinical Practice, so that the participants can imbibe them and ensure compliance, give public an assurance that the rights, safety and well-being of human subjects involved in research are well protected.

Expected Outcome: At the end of the program, the participants should be:

- Aware about the basic concepts of GCP.
- Understand Indian Regulations that govern human research.
- Know how to ensure protection of rights, safety and welfare of human participants.
- Be cognizant of quality, reliability and integrity of data. Know the 'Do's and 'Don'ts and be able to identify 'right' from 'wrong' approaches.
- Get acquainted with various standards and guidelines for the conduct of clinical research.
- Understand the simple formula, Good Clinical practice = Ethics + Quality Data.

28 Sept 2016: "Current Regulatory Requirement for the Members of Institutional Ethics Committee"

Learning Objective: To strengthen and empower the Institutional Ethics Committee (IEC) members to ensure that they understand scientific, regulatory norms, ethical design, conduct and reporting of clinical research that will be of uniform nature and meets national and international quality standards.

Expected Outcome: At the end of the program, the participants will be awareness about current guidelines and regulations for the conduct of clinical research in India so as to ensure that the right, safety and well-being of human participants involved in research are well protected.

29 Sept 2016: "Current Regulation on Medical Devices and in vitro Diagnostics (IVD) Kits"

Learning Objective: To provide direct, relevant and valuable information on key aspects of Medical Devices & in vitro Diagnostic Kits including its regulations in India.
Expected Outcome:

At the end of the program, the participants will be aware about the regulations that govern medical devices and in vitro diagnostic kits in India. Cognizance about design and development of medical devices, various standards, CE Certifications & ISO 13485. Understanding biocompatibility and clinical trial of medical device.

Regulations for import, manufacture and sale of medical devices. It will provide an opportunity to the participants to meet the regulators and clarify doubts.

Workshop includes

- Workshop includes tea and lunch at the workshop venue
- Course handout.
- Other resources available via restricted website
- Access to restricted website with online compilation of resources for 1 month
- One-on-one interactions with the experts
- Certificate of participation issued by organizers of the workshop
- Membership in mailing list to other workshops by Venture Center

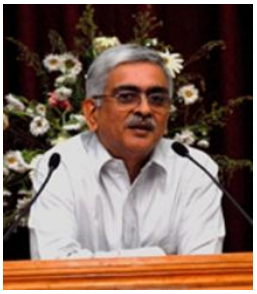
***Please note, the participants will have to arrange for their own travel/local transport and accommodation.**

- Accommodation is available on payment at IISER guest house for first 100 participants on first come first serve basis.
- For accommodation (standard and budgeted hotels) please visit: http://www.venturecenter.co.in/puneguide/standard.php
- For accommodation (deluxe and luxury hotels) please visit: http://www.venturecenter.co.in/puneguide/deluxe.php
- For local transport details visit: http://www.venturecenter.co.in/puneguide/taxi.php

Workshop Outline

Time (hrs)	Topic and Contents	Venue	Faculty
	Workshop 1: 27 Sept 2016		
0830-0900	Registration	Main Building, IISER	
0900-0915	Welcome and Introduction to the workshop	C V Raman Auditorium	C B Koppiker, L S Shashidhara
0915-1000	Overview of GCP • What is GCP; Why GCP? • Principles of GCP • Guidelines (CDSCO, ICH & WHO)	Auditorium	Pawandeep Kaur Dhawan
1000-1045	Current Regulations & Guidelines in India for Clinical Trials	Auditorium	A. B. Ramteke
1045-1115	Networking tea	Main Building	
1115-1200	Ethical Considerations • EC functioning • Informed Consent Process • Confidentiality and Privacy • Vulnerable Population	Auditorium	Nandini K. Kumar
1200-1230	Requirements of Clinical Trial Documentation: Protocol, IB, ICF, CRF, CSR	Auditorium	Pawandeep Kaur Dhawan
1230-1300	Record Keeping and Data Handling	Auditorium	Shilpi Sinha
1300-1400	Group photograph and Lunch	Cafeteria	
1400-1445	Roles and Responsibilities of Sponsor	Auditorium	Viraj Suvarna
1445-1515	Roles and Responsibilities of Monitor	Auditorium	Shilpi Sinha
1515-1600	Roles and Responsibilities of Investigator	Auditorium	Ashish Bavdekar
1600-1615	Tea/Coffee	Main Building	
1615-1645	Quality Assurance	Auditorium	Sucheta Banerjee Kurundkar
1645-1715	• Exit Assessment • Feedback	Auditorium	All faculty
1715-1730	Open Forum for Q & A and Distribution of Certificates	Auditorium	
	Workshop 2: 28 Sept 2016		
0830-0900	Registration	Main Building, IISER	
0900-0915	Welcome and Introduction to the workshop	Auditorium	M G Deo
0915-1015	ICMR Ethical Guidelines for Biomedical Research	Auditorium	Vasantha Muthuswamy
1015-1100	Regulations and Guidelines specific to Ethics in India: Schedule Y; Good Clinical Practice	Auditorium	A. B. Ramteke
1100-1115	Networking tea	Main Building	
1115-1200	ICMR-DBT National Guidelines for Stem Cell Research	Auditorium	Nandini K. Kumar
1200-1245	Ethics Committee • Composition	Auditorium	Ravindra Ghooi

	• Roles & Responsibilities of Members • Functioning (SOPs, Checklists, Types of Reviews, Monitoring)		
1245-1330	Ethics Committee • Decision Making & Review Process • Risk Benefit Assessment, Communication (Reporting timelines, Communications to Investigator, DCGI, Response to Subject, etc.)	Auditorium	Nandini K. Kumar
1330-1430	Group photograph and Lunch	Cafeteria	
1430-1530	Informed Consent Process • Importance • Safeguarding: Volunteers & vulnerable groups • AV recording	Auditorium	Vasantha Muthuswamy
1530-1630	SAE Reporting Timelines, Causality Assessment and Compensation	Auditorium	Vikas Prakash Mathur
1630-1645	Tea/Coffee	Main Building	
1645-1715	• Exit Assessment • Feedback	Auditorium	Sucheta Banerjee Kurundkar
1715-1730	Open Forum for Q & A and Distribution of Certificates	Auditorium	
	Workshop 3: 29 Sept 2016		
0830-0915	Registration		
0915-0930	Welcome and Introduction to the workshop		V Premnath
0930-1000	Introduction to CDSCO, its structure with respect to Medical Devices.		A. B. Ramteke
1000-1100	Regulations for import, manufacture and sale of Medical Devices		Aseem Sahu
1100-1115	Group photograph and networking tea		
1115-1200	Classifications of Medical Devices – Comparative Analysis		Malay Mitra
1200-1245	Medical Device Clinical Evaluation & Investigation		Sumati Randeo
1245-1345	Lunch		
1345-1430	Design and Development of Medical Devices		G.Bhuvaneshwar
1430-1515	Regulations for IVD Kits & Role of NIB in Testing		R. K. Sharma
1515-1600	Medical Device Standards: CE Certifications & ISO 13485		Kalyan Verma
1600-1615	Tea/Coffee		
1615-1645	Industry perspective on current & future regulations		Ajay Pitre
1645-1745	Meet the Regulators		Moderator: A B Ramteke Panel: Malay Mitra, Aseem Sahu, All speakers
1745-1800	Open Forum for Q & A and Distribution of Certificates		

Speakers (in alphabetical order of last names)	
 Ashish Bavdekar	Dr. Bavdekar is Associate Professor and Consultant in Pediatric Research at KEM Hospital, Pune. He is also Consultant in Pediatric Research at Vadu HDSS, Vadu Rural Health Program of KEM Hospital. He completed his medical studies from B.J. Medical College and K.E.M. Hospital, Pune. He subsequently received training at Sheffield Children's Hospital, Sheffield, UK. He is a member of the WHO Product Development Vaccine Advisory Committee. He is the Past President of the Indian Academy of Pediatrics (IAP) – Gastroenterology Chapter. He has been on several IAP task force - Neonatal Cholestasis, Safe Injection Practices, Childhood Obesity and Acute Diarrhoea. He has special research interests in metabolic liver diseases, clinical nutrition, early life origins of adult disease, and human gut flora. Dr. Bavdekar is involved in many disease burden studies and Phase I-IV vaccine and drug trials as an investigator (The measles aerosol vaccine project, Meningoccal Vaccine Project, rotavirus vaccine efficacy studies, safety and immunogenicity studies on HPV, rotavirus, live attenuated hepatitis A, hepatitis B, H1N1, 13 valent pneumococcal, conjugate typhoid and other vaccines, probiotics in diarrhea, enzyme replacement therapy in Gaucher's disease, etc.). He is now actively involved with pneumococcal nasopharyngeal carriage and reduced dose pneumococcal vaccine studies.
 G Bhuvaneshwar	Dr. Bhuvaneshwar is presently an Independent Advisor and Technical Consultant in the area of Medical Device design, development, testing and Quality management systems. For the last 3 years, he was Director of Innovation at Trivitron Healthcare Pvt, Ltd., Chennai and earlier, he retired as Head of the Biomedical Technology Wing of Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum in 2012 after a long distinguished career of 36 years there. He was elected a "Fellow, Biomaterials Science & Engineering (FBSE) by International Union of Societies of BSE "– at the World Biomaterials Congress, Montreal (2016). Dr. Bhuvaneshwar graduated with B. Tech (Electronics) and M.S. (Bioengineering) from IIT Madras. He later obtained a PhD in Biomedical Technology (SCTIMST). He has been honored with several awards including the Distinguished Alumnus Award of IIT Madras in 1999, shared the FIE foundation award in 1994 for the development of Chitra Heart Valve and NRDC-Awards for meritorious invention for Chitra Heart Valve (1994) & Spictra Membrane Oxygenator (2006). For over 36 years, Dr. Bhuvaneshwar has been involved in the research in the development of cardiovascular devices and blood compatibility of materials at the SCTIMST, Trivandrum. His major contributions has been in the development the TTK-CHITRA HEART VALVE (TTK Health Care Ltd, Chennai), CEREDRAIN Hydrocephalus Shunt System (HLL Ltd., Trivandrum) and the SPICTRA Membrane Oxygenator (SIDD Life

	sciences Ltd., Chennai) He has 7 patents 32 research papers and 3 book chapters. He has been closely involved in various national efforts to set up India's medical devices regulatory framework since 2003. During 2006-08, he led a small team, which drafted a Bill for the Medical devices regulation at the behest of the then Minister of S&T.
 M G Deo	Padmashree Dr. M G Deo is one of India's leading medical scientists whose work is widely recognized and cited internationally especially in the fields of protein energy malnutrition, endemic goiter, anti-leprosy vaccine, tobacco liked oral cancer and growth modulators. He has published more than 100 original papers. He obtained MBBS from Gajra Raja Medical College, Gwalior and MD, PhD from AIIMS, New Delhi. He was Professor of Pathology, AIIMS (1974-78), Director Cancer Research Institute (1978-95), Director Research & Chief of Laboratories Jaslok Hospital (1997 to 1998); Director, SSR Center for Medical Studies and Research, University of Mauritius (1998-2000). He has been an advisor to a number of national and international organizations. He is a member of all prestigious national Science and Medical Academies. He is perhaps the youngest medical scientists to have been elected as a fellow of INSA and was its Hon. Secretary (Biology) between1978-82. In recognition of his contributions to medical research, the Govt. of India decorated him with Padmashree in 1990. He has received several prestigious awards which include, Life Time Achievement Award, APINA, USA (2008), Emeritus Professor (Life time) National Academy of Medical Sciences (2002), Fogarty Scholar in Residence, National Institutes of Health, USA (1996-97), Visiting Professor, University of Paris VII (1990), Jawaharlal Nehru Birth Centenary Visiting Fellowship (INSA) (1993), Rameshwardas Birla National Award (Medical Sciences; 1992). Silver Jubilee Research Award, Medical Council of India (1989), Om Prakash Bhasin Award (988), Platinum Jubilee Lecture, Indian Science Congress (1988), Silver Jubilee Oration Award, All India Institute of Medical Sciences, (1987), Basanti Devi Amir Chand Oration, ICMR (Protein Calorie Malnutrition, 1980), B.C.Guha Lecture, Indian National Science Academy (Nutrition and Cancer; 1978), Shakuntala Amir Chand Prize, ICMR,(Intes Structure and Function in PCM; 1986), Amrut Mody Research Foundation award: For special branch of Medicine (1972), Khanolkar Prize, Ind. Assoc. of Path & Microbiologists (1966). He is credited with establishment of 'Moving Academy of Medicine and Biomedicine' in 2001 to meet these medical education challenges in India.

 Pawandeep Kaur Dhawan	Dr. Dhawan has joined CDSA as Associate Medical Director with 14 years of experience in professing clinical research, clinical practice and as clinical research scientist (Ranbaxy, u at Escorts Heart Institute and Research Centre, Delhi where she also played vital role for hospital accreditation. Before moving to Pharma Industry she worked as Assistant Professor in Institute of Clinical Research India and mentored students for various research projects of Cranfield University, UK. Dr. Pawandeep brings forth good amount of experience in the field of clinical research and development. She has played a crucial role in the development of new drug – through clinical phases and all the way to commercialization. In the process, her responsibilities have traversed from protocol designing, writing clinical study reports, new drug application and other regulatory documents as well as medical monitoring of clinical trials to ensure GCP compliance. She had been felicitated along with other scientists by Ex-President Dr. APJ Abdul Kalam for her outstanding contribution in development of new drug for malaria. She had presented and published research papers at national and international conferences and journals. A fellow of American College of Clinical Pharmacology, she is also a member of Cochrane Breast Cancer Group, Sydney & Cochrane Back Review Group (CBRG), Toronto.
 Ravindra Ghooi	Dr. Ghooi, a consultant in clinical research is a Pharmacologist with over 40 years' experience with the Pharmaceutical and Clinical Research Industry. After an M.Sc in Pharmacology from Karnataka University he obtained his Doctorate in Medicine from Bombay University. He has worked in pre-clinical drug research in Haffkine Institute Bombay and at Max Planck Institute for Experimental Medicine in Germany. He worked in the Medical Departments of Pharmaceutical Industry and rose to the position of Medical Advisor. Dr. Ghooi made a lateral shift to the Clinical Research Industry as the Vice President (Clinical Operations) of CliniRx Research Private Ltd. Since 2006, he has been in teaching holding the position of Principal of Institute of Clinical Research India at Delhi, and Dean Bilcare Research Academy, Pune. His last position before retirement was as the Professor of Drug Discovery and Clinical Research at Symbiosis School of Biomedical Sciences at Symbiosis International University, where he still guides students for Ph.D. Presently he runs a small consulting firm "Scientia Clinical Services" He works and lives in Pune. He has over 50 research papers in national and international journals; he has contributed chapters to three books and has published two books on clinical research. He is a reviewer for a number of national and international journals. His main interest is in the field of Ethics, and he is on the Ethics Committees of three organizations. He chairs the ethics committees of Jehangir Hospital and Sahyadri Hospitals in Pune and serves on two other ECs.
	Dr. Koppiker is the Director of Prashanti Cancer Care Mission, Pune. He is an internationally renowned Breast Oncosurgeon is the Medical Director of Orchids Breast Health Center, Pune. Dr. Koppiker has been a pioneer in

 C B Koppiker	introducing a novel alternative to conventional breast removal surgeries called as “Breast Oncoplastic Surgery” and has recently launched an International School of Breast Oncoplasty in collaboration with Senior faculty of the Association of Breast Surgeons, UK and University of East Anglia , UK. Dr. Koppiker is also a Distinguished Visiting Faculty Member to University of East Anglia, UK as well as to reputed cancer centers in India. Outside of Tata Memorial Hospital, Mumbai, Dr Koppiker was the first Oncosurgeon in Pune to lead the establishment of the 1st integrated cancer center namely the Budhrani Cancer Institute, Pune and Inlaks and Budhrani Hospital, Pune. He then helped set up 2 more reputed cancer centers first as the Director of the Ruby Hall Clinic Cancer Center and then at Cancer Clinic and Research Center at Jehangir Hospital, Pune. Dr. Koppiker has been an International Investigator in several important Breast Cancer clinical trials and has also collaborated on innovative research projects with academic groups. Koppiker is raying into translational Breast Cancer research by collaborating with biomedical start-ups working on proteomics and genomics platforms. Dr. Koppiker is the Founding Director and Managing Trustee of Prashanti Cancer Care Mission.
 Nandini K. Kumar	Dr. Nandini is MBBS and has done post graduate Diploma in Clinical Pathology from GMC, Trivandrum, and is a Fogarty Fellow graduate in Bioethics from University of Toronto. She worked as a researcher in the Gastroenterology Dept. of GMC, Trivandrum and in the Liver Clinic of Madras Medical College, Chennai. She retired as Deputy Director General, Senior Grade from ICMR, where she was Program Officer for bioethics, traditional medicine research and for some time for pharmacology and summer studentship for medical undergraduates. She was closely involved in formulation of several ethical guidelines in India under the aegis of ICMR, Dept. of AYUSH & NACO. She is national & international surveyor for ethics committee for SIDCER recognition program. She has pioneered Bioethics Education in India and has been instrumental in initiating the first online PG Diploma course in bioethics in India under ICMR-IGNOU joint initiative sponsored by the NIH, USA. She is a member of international panel of ‘President Obama's Commission for the Study of Bioethical Issues’, Advisory Council of Drug Information Association, India, and other nationally important committees. Presently, she is Dr. TMA Pai Endowment Chair and Adjunct Professor in Bioethics, KMC, Manipal University, and consultant for bioethical issues and traditional medicine research in India and abroad. She has publications in these areas and is also a reviewer for national and international journals for the same. She is an Adjunct Faculty at CDSA and PSG Institute of Medical Sciences and Research. She is the recipient of ISCR Lifetime Achievement Award 2015.

 Sucheta Banerjee Kurundkar	Dr. Sucheta has joined CDSA as Director Training in 2012. She has 18 years of experience in various capacities in research & CRO Industry. She was instrumental in setting up a pre-clinical & clinical research company to revenue generating level. In her last assignment, she was Chief Scientific Officer at a multinational Clinical Research Organization (CRO). Sucheta has worked for several years in the area of Quality Assurance in pre-clinical, clinical & medical laboratories. She is a GLP Trainer (WHO); Auditor for NABL (ISO 15189 & ISO 17025) & NABH. Sucheta has a Ph.D. in Biochemistry from the University of Pune and her doctoral work on a novel inhibitor received recognition at the World Congress on Insulin Resistance Diabetes & Cardiovascular Research, USA (2010). She has completed Advanced Quality Management Programme from IIM, Ahmedabad. Professionally trained in 'Management of Training' from ISTM, New Delhi, she has directed 70+ training programs across 40 cities covering around 5000 participants, 1380 institutions and 750 faculty members at CDSA. Sucheta is the reviewer to many International Journals of repute.
Vijay Prakash Mathur	Dr. Mathur is working as Additional Professor in the Centre for Dental Education and Research, All India Institute of Medical Sciences, New Delhi. He is also member secretary for Institute Ethics Subcommittee for Monitoring of Adverse Events in Clinical Trials for past 3 years. He has more than 50 publications and contributions in the books. He has presented more than 100 papers in the international and National prestigious conferences. He has been instrumental in development of several national guidelines and protocols with Ministry of Health and WHO. He has been awarded with prestigious Commonwealth Academic Fellowship in year 2014. He has been actively contributing for workshops and symposia for training of ethics committees and clinical trial professionals about the current legislation and handling of SAE in Clinical Trials. He is not affiliated to any commercial organization/ manufacturer / CRA.
Malay Mitra	Mr. Mitra is Former Deputy Drugs Controller (India), CDSCO, HQ, New Delhi. He is presently engaged in technical advisory capacities with various institutions. He joined CDSCO in 1982 and has audited about 1500 institutions till date. He participated in GMP programme (WHO) at USA & was an active member in developing the Schedule M, GMP part of the Drugs & Cosmetic Rules. He represented CDSCO at the Asian Harmonization Working Party conference (China) for medical device and was actively involved in the Medical Device and Cosmetic Import regulations, AYUSH, Ministry of Health regulations and gave valuable inputs in issues ranging from GMP, Regulations and Auditing. He prepared initial draft regulations for regulating Medical Devices under the Drugs & Cosmetic Rules. During his tenure heading the medical device division of CDSCO, he had made comprehensive strides in bringing about an understanding of medical device with constant interaction with the stake holders to get a comprehensive idea of the issues related to regulations of medical devices. He has assisted the DGDA of Bangladesh in

	developing Rules for Medical devices.
 Vasantha Muthuswamy	Dr. Muthuswamy retired as Senior Deputy Director General (Scientist G) and Chief of Division of Basic Medical Sciences, Traditional medicine & Bioethics; Division of Reproductive Health & Nutrition, ICMR in 2008 after 30 years of service in different capacities. She has a MD (Obstet./Gynae.) from Madras. She joined ICMR (1975) and moved to its HQ, Delhi (1982). She was Director, Institute of Immunohaematology, Mumbai for 2 years. A WHO Fellow at Kennedy Institute for Ethics, USA, she is well recognised for bringing out the ICMR's "Ethical guidelines for biomedical research on human subjects"(2000) & its revised version "Ethical guidelines for research on human participants" (2006). She was instrumental in preparing various ICMR Guidelines (Guidance document for Animal experimentation; Guidelines for Stem cell research & Therapy; Guidelines for Safety evaluation of food derived from GE plants; Guidelines for Good Clinical Laboratory Practices). She is the Founder Secretary, FERCAP. She is a Faculty in Bioethics & GCP Workshops in more than 30 countries. She is the recipient of Lifetime achievement Award from ICSR, National Bioethics Conference (NBC), FERCAP & Yenopoya University. In 2013, she served as member of GOI Committee for Policy guidelines on Clinical trials approved by Drug Regulatory Authority, India. She is now President, FERCI; Advisor at Centre for Clinical Research and Ethics at PSGIMS&R, Coimbatore.
 Ajay Pitre	Mr. Pitre is the MD, Pitre Business Ventures Pvt. Ltd. (Sushrut Adler Group) which specialized in orthopaedic solutions for more than 25 years. He graduated in commerce with a course in 'Management for Small and Medium Enterprises' at The Indian Institute of Management. He is the Ex-Chairman of CII Medical Equipment Division. He is currently the Advisor of the Medical Device Forum of FICCI. He is one of the founder members of the Indian Medical Devices Association and a Co Opt Member of Committee of Administration of Pharmexcil and Governing Board CMTI (Central Manufacturing Technology Institute). In 2003, The Indian Orthopaedic Association honoured him with a 'Certificate of Excellence' in recognition for the contributions to the Orthopaedic fraternity in India. He is an invited speaker on various forums and workshops. He is also a member of various committees of professional organizations such as FICCI Healthcare Committee, CII Healthcare Committee, and Sub-Committee for standardization of Orthopaedic Implants of the Bureau of Indian Standards (BIS), Governing Council- Maharashtra Chamber of Commerce, Industry & Agriculture. Mr. Pitre is a member and the immediate past Chairman of CII Medical Technology Division. In 2003, The Indian Orthopaedic Association honoured him with a 'Certificate of Excellence' in recognition for the contributions to the Orthopaedic fraternity in India. Enabling the Sushrut-Adler Group to take larger steps by becoming part of Smith & Nephew, a global orthopaedic leader is Mr. Pitre's most recent achievement.

 A. B. Ramteke	Mr. Ramteke is presently working as a Consultant, Regulatory Affairs at CDSA. A Government of India Officer from Ministry of Health, CDSCO, New Delhi, he retired as a Joint Drugs Controller (India) with 35 years of experience in drug regulatory aspects. He possess in-depth knowledge of Indian Drugs & Cosmetics Act, Rules and Regulations of Global Drug Regulatory norms. He started his career as Deputy Assistant Director at Central Research Institute, Kasauli in biological-drug testing and Quality Control. He has extensive experience with new drugs, vaccines and biotech products/pharmaceuticals, medical devices approvals and development experience. He also has experience in review and evaluation of product dossier for pre-clinical, toxicological, pharmacological, CMC, Quality Control, clinical trial data of new drugs, biological and medical devices (INDs, ANDAs). He has contributed to the preparation and implementation of Good Clinical Practice (GCP), Schedule-Y amendment, Good Laboratory Practice (GLP) and Good Manufacturing Practice and part of many WHO, FDA, USP training workshops, nationally and internationally. He works as an Expert to the Pharmacovigilance Program, GCP Training and Inspections of CROs in India.
 Sumati Randeo	Ms. Randeo is the Director Global Strategy Regulatory Affairs & Advocacy at Abbott Laboratories. Sumati has been in the various Quality & Regulatory leadership roles with Abbott Laboratories for past 10 years. She has more than 20 years of industry experience with successful stints at leading pharmaceutical companies like Pfizer, Ranbaxy, and Dabur Research Foundation in addition to her current position at Abbott Laboratories. Sumati specializes in the fields of Clinical Research, Quality & Compliance and Regulatory operations, management, strategy and advocacy. Sumati is a Pharmacist, with B Pharm (JSS College of Pharmacy, Ooty). She is a certified Lead Auditor for ISO 13485:2003 & completed course in Good Clinical Practice Course by Thrombosis Research Institute, Kings College, London. She is recognized as a Subject Matter Expert in the field of Medical Device Regulations and Quality compliance. She has successfully held workshops for the training of the regulators from various regulatory authorities around the globe and has given discourses in international workshops held at London, Rome, Toronto, USA, China, Taiwan, Japan Korea and ASEAN countries. She is the faculty of the ASEAN Regulators Training Program sponsored and supported by USAID and US Department of Trade & Commerce. She is the industry chair of the AHWP (Asian Harmonization Working Party) “Clinical Safety & Performance” technical work group. She also represents AHWP in the ISO 14155 (Clinical Investigation Standard for Medical Devices) Standard Technical Committee. As a Subject Matter Expert on Medical Device Regulations, Sumati has been involved in drafting and presenting several recommendations and white papers to the Ministry of Health and Family Welfare India and regulatory authorities of ASEAN region.

Aseem Sahu	Mr. Sahu is Deputy Drugs Controller (India) in Central Drugs Standard Control Organization (CDSCO), MOH&FW, DGHS, FDA Bhawan, New Delhi. Presently, he is engaged in all regulatory activities of Medical Device and Diagnostic in CDSCO. He has post-graduation qualification in Organic Chemistry from Deen Dayal Upadhyaya University, Gorakhpur, UP. He has a work experience of 16 years on drugs regulation in CDSCO and 8 years in the field of manufacturing and Quality Control of drugs, cosmetics and Medical Devices.
R K Sharma	Dr. Sharma is Scientist Grade III and Head of Immunodiagnostic kits laboratory at National Institute of Biologicals, Ministry of Health and Family Welfare, Government of India. He did his Ph. D. in Biotechnology from Dr. H. S. Gour University Sagar (MP) in the year 1994 and Post Graduate Diploma in Pharmaceutical Regulatory Affair from Jamia Hamdard University, New Delhi in the year 2013. He has several research publications in National & International Journals and has more than 21 years of work experience in Quality Evaluation of Biologicals at NIB.
 L S Shashidhara	Dr. Shashidhara is Professor and Chair of Biology at IISER, Pune. He completed his postgraduation from University of Agricultural Sciences, Dharwad and Doctorate and PDF from University of Cambridge, UK. He was scientist at Centre for Cellular and Molecular Biology, Hyderabad for 12 years, before joining IISER. He is JC Bose National Fellow, Associate Editor of Journal of Genetics since 2007, Member Editorial Board and MS handling Editor, Scientific Reports (Nature publication group) since 2011, Associate Editor of Current Science since 2013. He is Honorary Faculty Member, JNCASR, Bangalore, Vice-President (Science and Society), Indian National Science Academy and Secretary-General, International Union of Biological Sciences.
Shilpi Sinha	Dr. Shilpi is presently working as Sr. Site Manager & Quality Specialist at Bristol Myers Squibb India Private Limited at Mumbai. She has completed her post-graduation in Medical Biochemistry from KMC, Manipal. Presently, she is the Co-Chair Ethics Council of ISCR. She has over 12 years' experience, with 1.5 years as India lead in clinical operations with responsibilities of both functional and Line management, 6 years in Project & Quality Management and 4 years in clinical monitoring. Shilpi is a Certified Yellow Belt in Six Sigma Certification and is a Gold Medalist in Post Graduate examination conducted by Manipal Academy of Higher Education.
 Viraj Suvarna	Dr. Viraj is the Medical Director at Boehringer Ingelheim India Private Limited, where he is responsible for Clinical Operations, Regulatory Affairs, Pharmacovigilance, Quality Standards, and Medical Affairs. He has 18 years of experience in the Indian pharmaceutical industry, almost eleven years of which were in Pfizer (last position – Head, Medical Operations). Dr. Suvarna completed his MBBS from Topiwala National Medical College and BYL Nair Hospital, Mumbai (Recipient of Dr. Variyava & Dr. Sathe prizes in Anatomy & Pharmacology) and MD in Pharmacology from Grant Medical College and Sir JJ Group of Hospitals, Mumbai (First in University; Recipient of Dr. Bhalchandra Vad Prize). Additionally, he has a MSc in Pharmaceutical

	Medicine from Hibernia University, Dublin (First Class). He is peer reviewer for Indian Journal of Pharmacology. He is the Member of Medical & Regulatory Committee, Compliance Governance group of Organization of Pharmaceutical Producers of India (OPPI); ex-Chair of the EFPIA India Regulatory Network. He is Faculty at Academy of Clinical Excellence and St. Xavier's college, Mumbai. Dr. Suvarna is a certified trainer in Leading Edge II.
Kalyan Verma	Mr. Verma has 20+ years of industrial experience at different roles, Mr. Varma is now leading Global Business Field Electrical and Business Stream Products IMEA region (India, Middle East & Africa) at TUV Rheinland Group. He is involved in testing and certification services in various positions for more than 16 years. Right from the inception of TUV Rheinland's testing and certification services, Mr. Varma has played a vital role in establishing these activities in India. Under the strong strategic leadership of Mr. Varma, various labs and services of TUV Rheinland India have been established successfully, starting with the electrical safety lab, EMC, wireless and photovoltaic lab across India. The labs have state-of-art technology of highest quality conforming to both national and international standards and carrying various prestigious accreditations such as FCC, CBTL, NABL, MNRE, BIS. Mr. Varma himself is a qualified auditor and technical certifier. He is an Electronics and Communication Engineer with a Management degree.
 Premnath Venugopalan	Dr. Premnath is Founding Director of Venture Center and Head, NCL Innovations. He holds a B.Tech from the Indian Institute of Technology - Bombay and a Ph.D. from the Massachusetts Institute of Technology, USA. He has also been a Chevening Technology Enterprise Fellow with the Centre for Scientific Enterprises, London Business School and Cambridge University, UK. He brings with him considerable experience in technology development and commercialization, working with start-up companies (in Cambridge-UK and India) and engaging with large corporations on research and consulting projects as project leader.

About the Organizers	
IISER PUNE	Indian Institute of Research, Pune is a premier Institute established in 2006 by the Ministry of Human Resource Development dedicated to research and teaching in basic sciences (Biology, Chemistry, Earth and Climate Sciences, Mathematics and Physics). In 2012, it was declared as an Institute of National Importance by an Act of Parliament. Faculty and students investigate questions in science that lie beyond the boundaries of conventional thinking. The whole ambience is very academic with high energy levels to pursue top quality research. For more information, visit: www.iiserpune.ac.in
Prashanti Cancer Care Mission Reaching out with excellence	Prashanti Cancer Care Mission (PCCM) is a registered, public charitable trust in Pune working with a goal of providing affordable medical treatment and rehabilitation to underprivileged cancer patients and their families. Since 2009, PCCM has also established Orchids Breast Health Center (OBHC)-a Center of Affordable Excellence for Breast Care with help from a team of Oncosurgeons, Radiologists, Medical & Radiation Oncologists, Clinical Scientists, Physicians, Nursing and Medical staff with patient counselors. OBHC is well-equipped with advanced cancer diagnostics and a chemotherapy day-care facility. This NGO has been conferred with a Scientific and Industrial Research Organisation (SIRO) status by the Department of Scientific and Industrial Research (DSIR), Government of India. For more information, visit: www.prashanticancercare.org
VENTURE CENTER	Entrepreneurship Development Center (Venture Center) – a CSIR initiative – is a Section 25 company hosted by the National Chemical Laboratory, Pune. Venture Center strives to nucleate and nurture technology and knowledge-based enterprises by leveraging the scientific and engineering competencies of the institutions in the Pune region in India. The Venture Center is a technology business incubator supported by the Department of Science & Technology's National Science & Technology Entrepreneurship Development Board (DST-NSTEDB). Venture Center's focuses on technology enterprises offering products and services exploiting scientific expertise in the areas of materials, chemicals and biological sciences & engineering. For more information, visit http://www.venturecenter.co.in/

About the Knowledge Partners	
	Clinical Development Services Agency (CDSA) is an extramural unit of Translational Health Science & Technology Institute (THSTI), an autonomous organisation of Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India. Registered as a not-for-profit research organization, it aims to develop an eco-system for learning, work with public sector institutions, small and medium enterprises (SME) to translate innovative technologies into medical products for public good. CDSA works on a national mandate to enhance the capacity and capability of translational research and clinical development in India. Till date, CDSA has completed 75 programs across India covering close to 5000 participants. For more information, visit: www.cdsaindia.in/
	The KEM Hospital, Pune, India, is the largest Non-Govt. Organization hospital in the Pune District of Maharashtra State. Run by the KEM Hospital Society, it is registered under the Societies' Registration Act 1860 and the Bombay Public Trusts Act 1950. The hospital is a 550-bedded, tertiary-level teaching institution, serving not only the people of the city itself, but also a large populace coming from the surrounding urban and rural areas. The KEM also runs a secondary level Rural Hospital at Vadu, which serves a rural population of about 68,000 people through a network of primary health centers. All the major clinical departments like Medicine, Surgery, Pediatrics, Obstetrics & Gynecology, Pathology and Radiology, are recognized for the Pune University MD and MS degrees and for the National Board DNB. For more information, visit: http://www.kemhospital.org

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